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Male and Female Sterilisation

Clinical Effectiveness Unit

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GRADING OF RECOMMENDATIONS

A Evidence based on randomised controlled trials

B Evidence based on other robust experimental or observational studies

C Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

✓ Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the guideline group

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ABBREVIATIONS USED

ACOG	American College of Obstetricians and Gynecologists
AUA	American Urological Association
CBAVD	congenital bilateral absence of the vas deferens
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception
CI	confidence interval
CIS	contrast infusion sonography
COC	combined oral contraception
CPVP	chronic post-vasectomy pain
CREST	Collaborative Review of Sterilization
CUAVD	congenital unilateral absence of the vas deferens
Cu-IUD	copper intrauterine device
D&C	dilation and curettage
EUA	European Urological Association
FI	fascial interposition
FIGO	International Federation of Gynecology and Obstetrics
FSRH	Faculty of Sexual & Reproductive Healthcare
GMC	General Medical Council
GP	general practitioner
HR	hazard ratio
HRR	hazard rate ratio
HSG	hysterosalpingogram
HyCoSy	hysterosalpingo-contrast infusion sonography
IVF	*in vitro* fertilisation
LARC	long-acting reversible contraception
LIA	local infiltration anaesthesia
LNG-IUS	levonorgestrel intrauterine system
MIV	minimally invasive vasectomy
MRI	magnetic resonance imaging
NHS	National Health Service
NSAID	non-steroidal anti-inflammatory drug
NSV	no-scalpel vasectomy
OR	odds ratio
PET	polyethylene terephthalate
PFTC	primary fallopian tube carcinoma
PID	pelvic inflammatory disease
POP	progestogen-only pill
PVSA	post-vasectomy semen analysis
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	randomised controlled trial
RR	relative risk
STI	sexually transmitted infection
TVUSS	transvaginal ultrasound scan
UKMEC	*UK Medical Eligibility Criteria for Contraceptive Use*
UPSI	unprotected sexual intercourse
WHO	World Health Organization

Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit

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FSRH Guidance (September 2014)

Male and Female Sterilisation

(Revision due by September 2019)

1 Male and Female Sterilisation: General Information

1.1 Purpose, scope and methods

This document provides clinical guidance on elective male sterilisation (vasectomy) and female sterilisation (tubal occlusion). It is intended for any health professional or service that undertakes vasectomy and/or tubal occlusion in the UK as well as those who refer individuals for either procedure. The guidance does not include cost-effectiveness analysis of sterilisation in relation to other contraceptive methods. Recommendations made herein are intended to inform practice in the UK and therefore methods and practices not utilised in the UK are not included. Under an agreed arrangement with the Royal College of Obstetricians and Gynaecologists (RCOG) this document updates and replaces previous RCOG guidance on *Male and Female Sterilisation*[1] published in 2004.

An abridged version summarising the changes since 2004 and the main recommendations of the 2014 guidance is available in print and on the FSRH website (www.fsrh.org).

A supplementary document on consent and sterilisation will be published by the RCOG (www.rcog.org.uk).

A key to the Grading of Recommendations, derived from levels of evidence, is provided on the inside cover of this guideline. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this guidance are outlined in Appendix 1 and in the CEU section of the Faculty of Sexual & Reproductive Healthcare (FSRH) website. Recommendations within this document are based on the best available evidence and the consensus opinion of experts. They 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.

1.2 Prevalence

United Nations data for 2009 suggest that the prevalence of male sterilisation was higher in more developed regions whereas the prevalence of female sterilisation was higher in developing regions.[2] From an estimated world population of around 1179 million women aged 15–49 years, who were married or in a union, the worldwide prevalence of male sterilisation in 2009 was 2.4%[2] and the worldwide prevalence of female sterilisation in 2009 was 18.9%.[2]

Data from both England and Scotland show a downward trend in the number of vasectomies that were performed in a hospital setting between 2000 and 2010 with an increase in the number of procedures being carried out in other settings.[3,4] Data also show that there has been a decline in the cumulative total of vasectomies performed over the same period in both countries. In England the total number of vasectomies performed in all health care settings was 41 100 in 2000/2001 and 18 000 in 2010/2011,[4] a reduction of 56.2%. In Scotland a total of 5367 vasectomies were performed in 2010.[3] Since 2000 there has been a 55.5% decrease in the number of vasectomies performed in hospitals in Scotland.[3]

Both Scottish and English data show a progressive decline in the cumulative number of female sterilisation procedures undertaken between 2000 and 2010.[3,4] In England, 35 300 female sterilisation procedures were carried out in 2000/2001 and 9700 in 2010/11,[4] a reduction of 72.5%. In Scotland, 9.6/10 000 female sterilisation procedures were carried out in women aged 15–49 years in 2010.[3] Since 2000 there has been a 74.4% reduction in the number of female sterilisations carried out in Scotland.[3]

1.3 Sterilisation eligibility

Few medical conditions would absolutely restrict an individual's eligibility for sterilisation. Specific precautions may apply in certain circumstances. These precautions are highlighted in the relevant sections of this guidance (pages 4, 8, 17, 18, 24, 36, 41). Advice on precautions is also included in the *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC),[5] a set of guidelines adapted from the *World Health Organization Medical Eligibility Criteria* (WHOMEC).[6]

1.4 The moral, cultural and emotional dimensions of sterilisation

Sterilisation as a contraceptive method is acceptable to a majority of individuals in many well-resourced countries. However, there are certain communities and individuals with long-established religious, cultural and sometimes emotional objections to sterilisation and other forms of contraception. Psychosocial issues should not be overlooked or given less consideration than medical issues and should constitute part of comprehensive sterilisation counselling.

1.5 Health professionals' responsibilities

As a matter of good practice, health professionals should concentrate on factual information when counselling about contraception, and avoid persuasion or any act that may be deemed coercive, however clear the advantage of their recommended contraceptive method appears to be.[7–9] Health professionals who have an objection to sterilisation as a method of contraception are obliged to redirect individuals to a colleague/service that can support an individual's decision. Health professionals are not required to perform acts or operations against their own conscience or better judgement. All clinicians, including trainees, are responsible for their own actions. Health professionals should take reasonable steps to avoid being in a position that requires them to obstruct a reasonable expectation by a patient who has already been advised by another health professional. They should avoid putting another health professional in such a position when they have reason to believe that they may have objections in principle or lack the necessary competence.

If, for example, a clinician has a fundamental objection, for whatever reason, to sterilising childless women, they should take steps to ensure that such a case never appears on an operating list for which they have sole responsibility. The arrangements they make in this regard should precede admission to the place of operation and, if possible, any outpatient appointment. Such cases should be referred to a colleague who, to the best of their knowledge, does not share a similar objection.

1.6 Consent

Consent is defined as an individual's agreement for a health professional to administer/provide care.[7] 'Valid consent' is obtained by an individual being informed of the nature and purpose of any proposed treatment, as well as the likely outcome(s), including any significant potential adverse outcomes, and the likely result of not proceeding with the proposed treatment, in order to facilitate an individual making an informed decision.[7,8] The term 'valid consent' is now preferred as 'informed consent' infers that legally an individual has been informed of every conceivable outcome and risk, no matter how remote or unlikely.[7] Obtaining and giving consent should be regarded as a process, as opposed to a one-off event, and individuals can withdraw consent or change their minds at any time.[7] Health professionals should be aware that failure to respect the principle of valid consent may result in legal action by the individual, and action by their professional body.[7]

1.7 Mental capacity

General Medical Council (GMC) guidance[9] states that health professionals should presume that every adult patient has the capacity to make decisions regarding their treatment/care including whether to agree to or refuse an intervention. In England, Wales and Northern Ireland, adults are defined as being individuals aged 18 years and over. In Scotland, adults are defined as being individuals aged 16 years and over.[7]

GMC guidance[9] states that health professionals cannot assume that a patient lacks the capacity to consent solely on the basis of: disability, age, appearance, behaviour, medical condition (including mental illness), beliefs, or inability to communicate. GMC[9] and FSRH[7] guidance stipulate that individuals can be deemed unable to consent if it is clear (having been provided with appropriate help, support and information) that they cannot comprehend, retain, assess or use the information provided to make or communicate their decision.

The decisions and provision of treatment/care to individuals who are deemed to lack capacity is governed in the UK by the Adults with Incapacity (Scotland) Act 2000[10] and by the Mental Capacity Act 2005.[11] This legislation provides a statutory framework that should be adhered to when making decisions regarding the treatment of individuals deemed to lack the capacity to make decisions for themselves.[9] The legislation stipulates who can take decisions, in which situations, and how this should be carried out.[7] If there is doubt regarding an individual's capacity, health professionals should seek advice from experienced colleagues, and seek legal advice/input including referral to the courts.[12] If an application is made to court, health professionals should ensure that the individual is informed of the decision as soon as possible and of their right to be represented at the hearing.[12]

1.8 Documentation

Verbal and written consent are both considered equally valid in law.[7] Guidance by the GMC[9] and FSRH[7] both state that it is good practice to obtain written consent for procedures that involve significant risks, including sterilisation, and for procedures that involve general/regional anaesthesia or sedation.[7] Furthermore, both the GMC and FSRH state that an individual's medical records, or a consent form, should be used to record and document their agreement to the intervention, discussions which took place, any requests made by an individual, and details of any information provided (including the format).[7,9,13]

C Legal advice should be sought if there is any doubt as to whether a person has the mental capacity to consent to a procedure that will permanently remove their fertility.

✓ Written consent should be obtained from individuals wishing to undergo vasectomy or laparoscopic or hysteroscopic tubal occlusion.

✓ A consent form and clinical record should be used to document an individual's agreement to the procedure, discussion that took place, requests made by the individual, and any information provided.

1.9 Pre-sterilisation assessment

1.9.1 Pre-sterilisation counselling

Counselling is the process of enhancing a subject's ability to assess and understand the index situation, evaluate options and make an informed choice or decision. This entails sensitive provision of comprehensive information in a non-directive or non-judgemental manner. Inadequate counselling may underlie regret following sterilisation, and in extreme cases there may be psychological or psychosexual sequelae.[14]

Sterilisation should generally be one of a range of contraceptive options discussed by health professionals within the context of an individual's particular circumstances.[8]

A reasonable volume of evidence was identified that examined counselling, assessment, and sterilisation, in the form of non-systematic reviews[15–21]/expert opinion[22] and consensus statements.[23–25] The FSRH,[7] the RCOG,[26] and the International Federation of Gynecology and Obstetrics (FIGO)[8] have also produced documentation that outlines standards when counselling/assessing individuals. There is consensus in the literature that counselling should:

- include taking a medical history[18,21,22]
- include both verbal and written information[15,19,20]
- ideally be conducted with both partners together,[8,16,19,20,27] where acceptable and appropriate
- include information on sterilisation procedures[8,16–19,24]
- highlight the irreversibility/permanence of sterilisation[8,15,16,18–20,22,24,25] and that sterilisation reversal is not routinely available via the National Health Service (NHS)
- include information on risk and complications associated with sterilisation procedures[8,15,19–22,24,25,27]
- discuss myths and misconceptions associated with sterilisation[15,16,20,25]
- inform individuals that vasectomy is safer, quicker to perform and is associated with less morbidity than female sterilisation by laparotomy or laparoscopy[16–18]
- should include information on other methods of contraception, including long-acting reversible contraception (LARC)[8,16–20,25,27] (Appendix 2)
- assess individuals for known predictors of regret[18,19,22,27] and highlight the possibility of regret associated with sterilisation[8,16,18–20]
- ensure that individuals are aware that sterilisation does not confer protection against sexually transmitted infections (STIs)[8,18–20,22,27]
- highlight the need to use contraception until sterilisation has been carried out and the potential need to continue use beyond the procedure[16,17,22,24,25] (pages 7, 13, 30, 31, 37)
- enable individuals to make an informed decision and should include obtaining consent[15;18;20;21;24]
- be recorded/documented in clinical records[19,24]
- be carried out at a suitable interval prior to the procedure.[8,19,27]

1.9.2 Alternative contraceptive options

Vasectomy, tubal occlusion and other methods of contraception should be discussed with all men and women requesting sterilisation. Individuals should be made aware that some LARC methods are as effective as sterilisation (Appendix 2) and may confer non-contraceptive benefits. They should be advised that vasectomy is safer, quicker to perform and is associated with less morbidity than laparoscopic sterilisation. Hysteroscopic sterilisation, if available, should also be discussed as this approach/method has fewer contraindications than traditional methods, does not involve the use of general anaesthesia, and can be performed as an outpatient procedure. However, unlike laparoscopic tubal occlusion, vasectomy and hysteroscopic sterilisation require post-procedure confirmation before they can be relied upon for permanent contraception. Furthermore, hysteroscopic sterilisation is irreversible and micro-insert placement may not be successful.

Health professionals should bear in mind that the decision as to which partner is sterilised may not simply relate to efficacy and risks associated with a procedure.[28] Further information relating to other methods of contraception is outlined in method-specific guidance produced by the FSRH[29–32] and LARC guidance produced by the National Institute for Health and Care Excellence (NICE).[33]

1.9.3 Medical history and examination

The past history, present symptoms or abnormal examination findings may influence which partner goes forward to be sterilised: for example, if a past history of genital or scrotal surgery in the male partner makes vasectomy under general anaesthesia more likely, hysteroscopic sterilisation for the female partner may be preferable. Any contraindications to general anaesthesia in the woman may make hysteroscopic sterilisation or vasectomy a better alternative to be considered. Equally, an impending inguinal hernia repair may mean that vasectomy could be carried out under the same anaesthesia.

A gynaecological history from the female partner may reveal symptoms or known gynaecological pathology. An alternative form of contraception may be more suitable, such as the levonorgestrel intrauterine system (LNG-IUS), which is indicated for heavy menstrual bleeding, symptoms of endometriosis, and as a component of hormone replacement therapy. A hysterectomy may be an alternative if significant gynaecological pathology, such as symptomatic fibroids or a prolapse, is present. It is considered good practice for a bimanual pelvic examination to be performed before surgery so that the decision to proceed is made in

the light of all the available information and so that there are no unexpected findings under anaesthesia. Similarly, a scrotal examination of men is necessary to exclude potential problems (e.g. a large varicocele or hydrocele that may mean that the vas deferens is more difficult to palpate such that general anaesthesia is required).

The history and examination may reveal risk factors for laparoscopic tubal occlusion. Previous laparotomy,[34] previous abdominal or pelvic surgery,[35–37] previous pelvic inflammatory disease (PID),[37] and obesity[36,37] are all factors that increase the risk of a laparotomy with a laparoscopic approach.

1.9.4 Information and advice

FSRH standards[38] state that verbal advice should be supported by appropriate written/pictorial/audio-visual information that individuals can take away/download. Information, in whatever format, should be objective, evidence-guided, readily available and accessible to assist individuals in making informed choices about methods of contraception, and sexual and reproductive health. The FSRH standards and FIGO guidance stipulate that there should be a choice of languages/formats that are appropriate to patient groups served by specific providers, including those with sensory impairment.[38]

C All verbal advice must be supported by accurate, impartial, printed or recorded information (in translation, where appropriate and possible), which the individual requesting sterilisation may take away/download and review before the procedure.

C Counselling and advice on sterilisation procedures should be provided to women and men within the context of a service providing a full range of information about and access to other long-term reversible methods of contraception. This should include information on the advantages, disadvantages and relative failure rates of each method.

C Both vasectomy and tubal occlusion should be discussed with all men and women requesting sterilisation.

C A history should be taken from all men and women requesting vasectomy or tubal occlusion. Scrotal or bimanual pelvic examination should be carried out either at initial consultation or before commencing the procedure.

C Individuals should be informed that vasectomy carries a lower failure rate, in terms of post-procedural pregnancies, and that there is less risk associated with the procedure than sterilisation carried out by laparoscopy or laparotomy.

✓ Individuals should be informed of the method of access and tubal occlusion being recommended in their case, the reasons for preferring it over other methods, and the method to be used if the intended procedure cannot be performed.

✓ When a pregnancy occurs while an individual is on a waiting list for sterilisation they should be offered further counselling about future contraceptive choices due to the change in their circumstances.

The provision of sterilisation services varies across the UK. Individuals may approach their general practitioner (GP) or sexual and reproductive health services initially and may then be referred for outpatient consultation where, if agreed, their operation is booked or they are placed on a waiting list. Alternatively, such services may undertake outpatient procedures. Therefore individuals may have a consultation with one health professional but be operated on by another. Strict safeguards are required to ensure that adequate examination and counselling have taken place initially and that the health professional who eventually performs the procedure, and is ultimately responsible, is satisfied that this has been undertaken appropriately.

C The operating clinician must ensure that information exchange, history and examination have been completed and must be satisfied that the individual does not suffer from concurrent conditions that may require an additional or alternative procedure or precaution.

1.10 Pre-sterilisation assessment

1.10.1 Advice post-vasectomy

A small volume of literature was identified which stipulated what information men should be provided with following vasectomy. Men should be instructed to:

- contact their health care provider if they have any concerns following the procedure: for example, persistent bleeding, pain, possible infection,[22] or rapidly enlarging one-sided scrotal haematoma which would indicate being seen as a matter of urgency
- use non-steroidal anti-inflammatory drugs (NSAIDs) for pain/discomfort following the procedure,[22] unless contraindicated
- rest following the procedure and refrain from strenuous activity[22]
- abstain from sexual activity for between 2 to 7 days post-procedure[25]
- wear tight underpants/athletic support for the first few days following the procedure, including at night for the initial 48 hours or longer according to symptoms
- men should be provided with instructions regarding post-vasectomy semen analysis (PVSA) and provided with sample bottles if PVSA postal samples are used.

✓ Men who have undergone vasectomy should be provided with a post-procedural information leaflet that outlines appropriate self-care and instructions.

1.10.2 Advice post-tubal occlusion

Women should be informed of the method of occlusion used (for example, Filshie® clips or Falope® rings) before they are discharged, especially if it was not possible to use the intended method because of surgical difficulties or equipment failure. The implications for future reversibility or risk of ectopic pregnancy, should pregnancy occur, may vary depending upon the method used. Similarly, women should be informed if more than one clip or ring has been applied to either side because of doubt about the security of the first clip, or because of bleeding or transection of the fallopian tube.

Women should also be informed if technical difficulties arose during the operation that meant that tubal occlusion is in doubt. Advice should be given on how long to continue additional contraception (see pages 7, 30, 31, 37).

It should be regarded as good practice to ensure that a follow-up appointment with the health professional or their team is offered following any sterilisation procedure involving complications or a change in the intended method of tubal occlusion.

Where diathermy has been used as the occlusion method, women should be informed and given supporting information regarding the possibility of bowel injury and symptoms that would require medical consultation. Typically, individuals with bowel perforation caused by unrecognised bowel injuries present 3–7 days following the procedure with complaints of fever and abdominal pain but may present as much as 2 weeks later.[39–41] If left untreated, peritonitis and septicaemia can occur. Several deaths from unrecognised bowel burns after unipolar cautery have been reported.[42,43]

Bowel injuries can occur from Veress needle or trocar perforation at laparoscopy, irrespective of the method of tubal occlusion used. Sometimes these may go unnoticed at the time of the procedure and present in a similar way to perforation from bowel burns. When any woman has abdominal symptoms or signs following laparoscopic sterilisation these uncommon but potentially life-threatening postoperative complications must be considered. The woman and

their GP should be made aware of the significance of any postoperative signs and symptoms, such as increasing abdominal pain and becoming generally unwell, which might indicate a bowel perforation. This advice can be conveyed to the GP by including it in the immediate discharge letter, a copy of which is also given to the woman.

Women should also be advised about appropriate self-care, for example, information relating to wound care, sutures used, activity following the procedure and the use of analgesia for post-procedural pain/discomfort. They should also receive instructions about contacting their health care provider if they have specific concerns following the procedure. This information should be contained within a postoperative/self-care information leaflet, such as the RCOG's 'Recovering Well: Information for you after a laparoscopy' leaflet (http://www.rcog.org.uk/files/rcog-corp/LaparoscopyRecoveringWell.pdf).

✓ Women should be provided with information about the method of tubal occlusion undertaken and of any complications that occurred during the procedure.

✓ Women who have undergone tubal occlusion should be provided with a post-procedural information leaflet that outlines appropriate self-care and instructions.

1.10.3 Additional contraception

After vasectomy men should be informed of the need to use additional contraception until PVSA has been undertaken and clearance/special clearance given.[16,21,24,25] Similarly, women who have undergone hysteroscopic sterilisation should be informed of the need to use additional contraception until confirmatory testing has confirmed successful placement of the micro-inserts and/or tubal occlusion.[16,44]

✓ Individuals who have undergone vasectomy should be informed of the need to use additional contraception until sterility is confirmed.

✓ Individuals who have undergone hysteroscopic sterilisation with micro-inserts should be informed of the need to use additional contraception until sterility is confirmed.

1.11 Regret

A substantial body of evidence was identified in the literature that examined regret/remorse and satisfaction associated with sterilisation, including: a systematic review;[45] cohort studies;[46–52] cases series;[53,54] cross-sectional study;[55] non-systematic reviews;[16–18] and two consensus statements.[24,27] Many of these studies used cross-sectional methods to: ascertain the level of regret post-sterilisation at varying time intervals;[46,48,49,52,55] examine requests for information on sterilisation reversal;[47,50] examine requests for reversal;[14,18] and observe the number of reversals carried out.[14–16,20] Regret and remorse are subjective measures and therefore are difficult to quantify. Furthermore, a comparison between studies is also problematic due to differences in both the timing and measurement of regret. Additionally, there is more available evidence relating to tubal occlusion and regret than there is for vasectomy and regret. The American College of Obstetricians and Gynecologists (ACOG) suggests that the incidence of regret following tubal occlusion is between 0.9% and 26%.[27] The European Association of Urology (EAU) guideline on vasectomy states that approximately 2% of men who have undergone vasectomy will undergo a reversal within 10 years of the procedure.[24] There is broad consensus in the literature that regret following sterilisation is experienced by a minority of individuals and that a

number of risk factors may be useful predictors of regret, which should be assessed in individuals considering sterilisation:

- young age (<30 years at time of procedure)[16–18,24,27,45,47,48,55–57]
- nulliparous or low parity (the number is not always defined in the literature but usually refers to two or fewer children)[16,17,48,54]
- being in an unhappy relationship/in conflict with partner or spouse[14,16,17,46,54,55,57]
- not being in a relationship
- remarriage/change of partner/change in relationship status[17,18,49,51,53–55,57]
- death of a child[16–18,49,51]
- desire to have children/more children – including with a new partner[16,27,51,54]
- psychological problems/issues (implications beyond fertility issues)[16,17,54]
- psychosexual issues[58]
- coercion by health professional or partner/spouse[17,18,27,52,59]
- timing of procedure in relation to pregnancy – interval sterilisation results in a reduced risk of regret[16,52,54,57,58] (see next section on the timing of female sterilisation for more details)
- information requirements in terms of the procedure, its efficacy, and alternative contraceptive choices.[27,55,60]

B Additional care must be taken when counselling individuals under the age of 30 years or individuals without children who request sterilisation.

1.12 Regret associated with the timing of female sterilisation

A number of studies[52,61,62] have reported that the incidence of regret and dissatisfaction is increased when sterilisation has been performed concomitantly with caesarean section, particularly if women have felt pressured into the decision by a health professional.[52] Data from the large, prospective, multicentre, Collaborative Review of Sterilization (CREST) cohort study,[63] undertaken in the USA, reported that the relative risk (RR) of regret after combined caesarean section and sterilisation compared with interval sterilisation was 5.8 after 1 year and 3.3 after 2 years.[61] This difference persisted for at least 5 years following sterilisation, when the incidence of regret in the combined caesarean section and sterilisation cohort was still twice that of the interval sterilisation cohort. Consequently, sterilisation should not be performed concomitantly with caesarean section unless counselling has taken place and the decision is made at a time separate from caesarean section or labour. Where possible the decision should be documented at least 2 weeks in advance of the caesarean section.

Regret has also been shown to increase after postpartum sterilisation associated with vaginal delivery.[64] However, this is no longer a common procedure in the UK.

Available evidence is less clear when sterilisation was combined with induced abortion. No difference in regret rates was reported by some studies[65–68] between women undergoing sterilisation concurrently with abortion (predominately first-trimester) and those undergoing interval sterilisation. However, other studies[69,70] have reported an increased rate of regret when sterilisation was performed concomitantly with abortion. In addition, a randomised controlled trial (RCT),[71] in which women were randomised to either abortion with sterilisation as a combined procedure or abortion with sterilisation as an interval procedure at least 6 weeks later, reported that 32.8% of women did not return for interval sterilisation. This suggests that some women may have changed their minds when they were able to reconsider their decision outside the stressful situation surrounding an unintended pregnancy. This further emphasises the need for careful counselling where sterilisation is requested in association with pregnancy.

C If tubal occlusion is performed at the same time as a caesarean section, counselling and agreement should be given at least 2 weeks in advance of the procedure.

2 Vasectomy

2.1 Overview

Vasectomy is the technique of interruption of the vas deferens with an intention to provide permanent contraception. The procedure can be performed under local or general anaesthesia. The traditional method involves making one or two incisions in the scrotal skin to expose the vas deferens. The vas deferens is then occluded and divided using various techniques (Figure 1).

A relatively new technique to expose the vas, the no-scalpel vasectomy (NSV) developed by Li *et al*.,[72] involves a puncture wound in the scrotal skin to access and occlude the vas. This method was, developed to increase the acceptability of vasectomy by eliminating the fear of incision. Following anaesthesia, a specially designed fixation clamp encircles and firmly secures the vas without penetrating the skin. Sharp-tipped dissecting forceps are then used to puncture the skin and vas sheath and to stretch a small opening in the scrotum. The vas is lifted and occluded, as with other vasectomy techniques.[72] The same puncture hole can be used for the opposite vas or a separate puncture can be made.

A number of NSV techniques are reported in the literature. It has been suggested that these techniques should not be referred to as NSV but instead be referred to as minimally invasive vasectomy (MIV).[25] For the purposes of this guideline, the term MIV will be used to encompass NSV and any modified versions of this technique where the skin opening is ≤10 mm, and the dissection area surrounding the vas deferens is minimised and does not require the use of skin sutures.[25] MIV may include the use of a variety of surgical instruments, including a scalpel, to expose the vas.

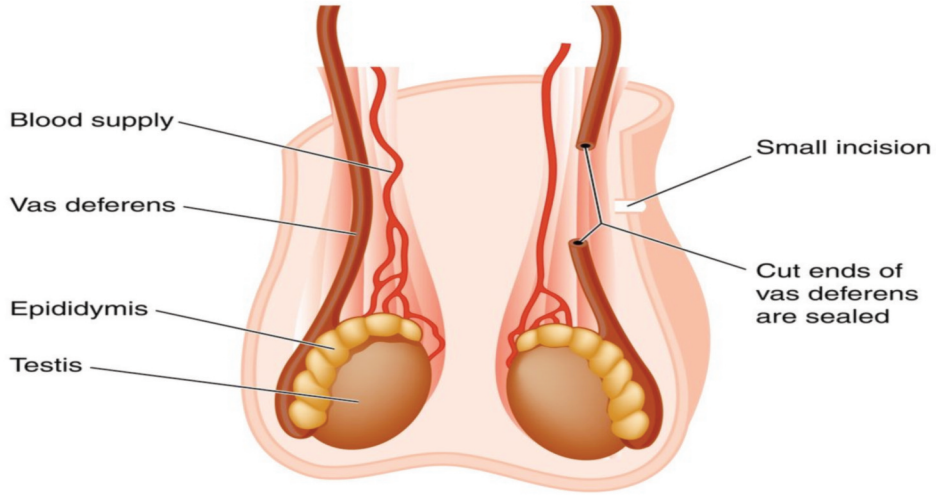

Figure 1: Vasectomy: sites of the skin incision and vas deferens interruption. © 123rf hfsimaging / 123RF Stock Photo.

2.2 Anaesthesia

A limited quantity of evidence was identified that examined the most appropriate anaesthesia for vasectomy. No RCTs were identified. A case series,[73] suggested that general anaesthetic may result in increased postoperative pain but concluded that full recovery time was the same for both local and general anaesthetics.

Local anaesthesia is contraindicated when there is a history of an allergy to local anaesthetic and/or the presence of a medical co-morbidity where it is clinically inappropriate to use a local anaesthetic.[73]

Four cohort studies[74–77] reported that local anaesthetic was effective in reducing pain during vasectomy. Furthermore, local anaesthesia is safer, less expensive, has a quicker recovery time and fewer anaesthetic complications than general anaesthesia.

The effect of heating local anaesthetic on pain at infiltration has been examined, albeit not specifically, in relation to vasectomy. The studies,[78–86] including a meta-analysis,[82] were consistent in recommending that warming anaesthetic to approximately body temperature before injection resulted in a clinically significant reduction in pain when compared to injecting local anaesthetic at room temperature.

No evidence was identified in the professional literature that compared the use of buffered and unbuffered local anaesthesia, or local anaesthesia with or without adrenaline (epinephrine), and pain at vasectomy.

Limited evidence was identified in the professional literature that examined the effect of needle size on pain at vasectomy.[77] There was consensus among the members of the multidisciplinary guideline development group that the use of fine-gauge needles resulted in less pain when compared to larger-gauge needles. Vasectomy guidance produced by the American Urological Association (AUA) also advocates the use of fine-gauge needles for anaesthesia at vasectomy.[25]

A limited volume of evidence was identified that examined the use of anaesthesia administered via no-needle jet injection (pneumatic injection), that utilises an instrument that produces a high-pressure spray of anaesthetic that is 'forced' through the skin, vas deferens and surrounding tissue. A cohort study,[75] which included 462 eligible participants, reported that the use of no-needle jet anaesthetic was effective before vasectomy, was well tolerated by participants, and resulted in no haematomas. The study also reported that the use of this method resulted in the use of less anaesthetic. Therefore the authors concluded that: the no-needle jet approach may decrease the fear associated with the use of needles for anaesthesia at vasectomy, may result in cost saving as less anaesthetic is required, and may reduce the risk of needlestick injury and waste generated.[75] Another small-scale cohort study[74] of 50 participants anaesthetised one vas deferens using the no-needle jet and the other using the traditional vasal block approach. The authors concluded that the no-needle jet approach reduced the pain associated with anaesthesia in advance of vasectomy but that further research was required.[74] Another comparative study[87] examined local infiltration anaesthesia (LIA), LIA and spermatic cord block, and no-needle jet anaesthesia before vasectomy. The study concluded that there was no difference in pain during anaesthesia but that use of LIA and spermatic cord block resulted in significantly less pain, both during vasectomy and postoperatively, when compared to LIA alone or no-needle jet anaesthesia.[87]

The addition of a vasoconstrictor, for example, adrenaline (epinephrine), to local anaesthetic reduces blood flow, which in turn slows the rate of absorption and thus results in an extended anaesthetic effect.[88,89] Vasoconstriction may also reduce bleeding in the operative field. Whilst this may be advantageous during vasectomy, there is a theoretical concern that the use of a vasoconstrictor may mask bleeding vessels and increase the risk of haematoma formation postoperatively. Caution is advised when using local anaesthetics in individuals with impaired cardiac function or cardiovascular disease, and use in combination with adrenaline is not advised in such patients.[88]

B Vasectomy should be performed under local anaesthesia wherever possible.

A Consideration may be given to warming local anaesthetic to approximately 37°C before infiltration to reduce pain associated with injection.

✓ Local anaesthetic with or without adrenaline (epinephrine) can be used during vasectomy (outside product licence for bupivicaine with adrenaline).

✓ Local anaesthetic should be administered via infiltration of the subcuticular tissue and by direct injection to the vas deferens.

✓ Local anaesthetic should be administered using a fine-gauge needle to reduce pain.

2.3 Exposing and identifying the vas deferens

Two well-conducted RCTs[90,91] and a systematic review [92] were identified that examined the effectiveness of a traditional approach using a scalpel, with a MIV approach. Two other systematic reviews examined alternative techniques in addition to the traditional and MIV methods, including: the use of an intra-vas device;[93] the use of two lateral incisions compared to a single incision;[94] the use of a 'pin-hole' approach using a special instrument,[94] and an electro-cautery approach.[94]

There is consensus in the literature that an MIV approach during vasectomy results in more favourable outcomes than other incision methods. Specifically, the evidence suggests that MIV is quicker to perform than other methods and results in less perioperative bleeding. MIV is also associated with reduced pain, both during and after vasectomy, less post-vasectomy infection and fewer haematomas.[91,95] The use of MIV is advocated by the EAU guidelines on vasectomy.[25]

A A minimally invasive approach should be used to expose and isolate the vas deferens during vasectomy, as this approach results in fewer early complications in comparison to other methods.

2.4 Interruption of the vas deferens in vasectomy

The basic steps aimed at interrupting the vas involve occlusion of the lumen followed by division of the vas deferens; some techniques also advocate the removal of a small portion of the vas deferens. The occlusion of the vas deferens during vasectomy is achieved by one of three procedures:

- coagulation/cauterisation (electrical, unipolar or bipolar diathermy)
- ligation with absorbable (for example, Vicryl®) or non-absorbable sutures (silk, cotton or linen) or metal clips (Hemoclip®)
- insertion of intra-vas devices or plugs.

A 1–3 cm segment of the vas can then be removed, although not all techniques advocate this.[96] An adjunct procedure, known as fascial interposition (FI), is often recommended and is intended to reduce the likelihood of recanalisation. One end of the vas, usually the prostatic or testicular end, is allowed to fall back into the wound in the internal spermatic fascia and the spermatic fascia is closed over the defect with either suture material or metal clip; thus separating the two ends into two different tissue planes making recanalisation of the ligated ends less likely.[97] Another procedure to separate the two ends of the cut vas consists of folding back one or both vas segments on themselves and suturing them in this position.

2.4.1 Ligation of the divided vas deferens

The risk of early failure associated with the use of ligation as an occlusion method has been reported in the professional literature as being between 8% and 13%[98–100] and the risk of early recanalisation as ranging between 13% and 25%.[101] (see the section on immediate and delayed postoperative complications section on pages 16 and 18). Pregnancy rates following occlusion by ligation have been reported in three cross-sectional studies as a cumulative pregnancy rate of 9.5%, at 5 years follow-up, in a cohort of men who underwent vasectomy by ligation and excision;[102] an estimated cumulative pregnancy rate of 4.2% at 3 years follow-up;[103] and a similar rate of 4.1% at 5 years follow-up.[104] A retrospective study[105] reported a pregnancy rate of

between 3% and 5% at 5 years follow-up. Whilst the studies identified may have been subject to systematic error, the balance of available evidence suggests that ligation and excision of the vas deferens is associated with a high failure rate.

The use of clips as an occlusion method is not routine and therefore evidence is scant.[94,106] A systematic review[106] identified a single RCT that examined the time to achieve azoospermia and complications when using clips or ligation and concluded that there was no difference in outcomes between the two techniques. However, the study was underpowered and subject to bias. Therefore, the review concluded that no recommendations could be made on the use of clips and that further research was required.[106] A retrospective cohort study[100] observed higher failure rates when clips and excision were used as the occlusion method, when compared to cautery, FI, and an open testicular end. Based on limited available evidence the use of clips is associated with a potentially higher failure rate than other occlusion methods.

A cohort study[107] examined the success rate of vasectomy following a change of suture material, from chromic catgut to Vicryl, and concluded that the choice of suture material can negatively affect vasectomy outcome. No additional studies were identified examining suture material; therefore, there is no evidence that any currently available suture material is superior.

2.4.2 Cauterisation or ligation

There is consensus in the literature that cauterisation is an effective vasectomy method.[24,25] Two cohort studies[108,109] that examined cauterisation as a vasectomy technique reported a failure rate of 0.8% and 0.38%, respectively, and an 85% probability of achieving azoospermia at 12 weeks.[109] A systematic review identified 11 studies of varying quality and a high degree of heterogeneity that compared ligation with different methods of cauterisation. The review concluded that whilst it was difficult to draw recommendations regarding complications, outcomes for cauterisation were associated with a lower risk of occlusive failure than ligation with suture material or metal clips.[94] The review was unable to assess outcomes for cauterisation with and without FI. This finding is consistent with the findings of two cohort studies[101,110] that compared ligation and cauterisation outcomes. The studies reported that the risk of early recanalisation was lowest when cauterisation was used.[101,110]

2.4.3 Fascial interposition

There is consensus in the literature that outcomes for vasectomy performed by ligation and excision are improved by the addition of FI. An RCT[111] that examined seven different occlusion techniques for MIV concluded that the highest rates of early failure (recanalisation) and complications were observed with an open-ended technique without FI. Another RCT[112] comparing ligation and excision with and without FI in MIV was halted after an interim analysis showed that the FI group had significantly higher success rates. A systematic review[106] concluded that ligation and excision with FI significantly reduced recanalisation and increased the likelihood of azoospermia. Another systematic review[94] examining ligation and excision and FI concluded that it was not possible to draw any recommendations regarding complications but that there was good evidence that FI reduced occlusive failure.

An RCT[98] that examined ligation with and without FI concluded that FI reduced the failure rate by approximately 50%. This conclusion is consistent with two further analyses[101,110] of the results of this RCT[98] and with a well-conducted observational study[109] that compared ligation and cauterisation with and without FI. The RCT[98] suggested that more favourable outcomes were achieved with cauterisation (i.e. a lower risk of failure) but that the addition of FI improved outcomes if ligation and excision were used. However, analysis concluded that FI may be less important if cautery was used for occlusion but it was unable to draw any definite conclusions regarding outcomes for cautery with or without FI.[101,110]

2.4.4 Other occlusion methods

A limited body of evidence was identified that examined other vasectomy techniques or adjunct procedures. A systematic review[106] examined the use of an intra-vas device for occlusion and concluded that there was limited evidence of the effectiveness of this technique

but that it may result in higher satisfaction and lower risk of granuloma. An RCT[113] was also identified that compared the use of intra-vas device, an intra-vas device with a tail used for fixing the device to the vas deferens, and NSV. The study reported no significant differences in pregnancy or short-term complication rates between the three study arms but reported a higher rate of complications at 12 months for the NSV cohort.[113] There was, however, insufficient evidence to allow any recommendation to be made regarding the use of an intra-vas device as a vasectomy technique.

A case-control study[114] sought to assess whether the length of vas deferens segment excised affected vasectomy success. The study concluded that there was no significant association between the length of vas segment excised (2 cm or shorter) and vasectomy failure/success.[114]

The adjunct technique of folding back was examined by a systematic review.[94] The available evidence did not demonstrate any advantage in folding back the vas deferens following occlusion in terms of either efficacy or complications. The same review[94] also assessed the impact of leaving the testicular end of the vas open following occlusion. The open-end technique was not associated with increased occlusive failure, when the prostatic end was closed by FI and cauterisation, but no conclusion could be drawn regarding post-vasectomy complications.[94]

Fulguration of the lumen following ligation and excision accompanied by FI was assessed in a cohort study,[115] which concluded that this intervention did not improve post-vasectomy outcomes.

A Cauterisation followed by division of the vas deferens, with or without excision, is associated with the lowest likelihood of early recanalisation (failure) when compared to other occlusion techniques.

A Division of the vas on its own is not an acceptable technique because of the associated failure rate. It should be accompanied by diathermy or ligation and fascial interposition.

A Clips are not recommended for occluding the vas deferens as their use is associated with a potentially high failure rate when compared to other occlusion methods.

2.5 Histological examination

Operative error or early recanalisation should be identified during PVSA.[24,116–118] Routine histology on vasectomy specimens represents an unacceptable burden on both laboratory staff and time and is expensive. Storage of excised vas specimens is inconvenient and requires meticulous labelling, organisation and storage resources. No evidence was identified in the professional literature that supported routine histology of vasectomy specimens to assist medico-legal claims.

C Routine histological examination of the excised portions of vas deferens is no longer recommended.

2.6 Post-vasectomy semen analysis

The rationale for PVSA is to confirm clearance of stored spermatozoa downstream of the vasectomy site and to identify early failure or early recanalisation. The literature is consistent in highlighting the need for PVSA to confirm the success of vasectomy and consequently to give clearance to stop using contraception.[24,99,109,116–125] However, there is no consistency regarding the number or frequency of PVSA tests.

The debate surrounding PVSA testing frequency and number focuses on how long it takes before the use of other contraceptive methods can stop and vasectomy be relied on for contraception. The time necessary for complete expulsion of stored sperm may vary, depending in part upon the frequency of ejaculation and age.[109,118,126–129] Guidelines published by the EAU[24] state that PVSA should take place 12 weeks after vasectomy whereas the British Andrology Society[124] recommends PVSA at 16 weeks with a follow-up test 2 or 4 weeks later. Guidelines published by the Association of Biomedical Andrologists[130] recommend 16 weeks, while the AUA[25] state that PVSA can be carried out between 8 and 16 weeks post-vasectomy. A number of studies have assessed compliance and outcomes with different frequencies and numbers of PVSA tests,[90,99,116,117,119,121,123,125,126,131,132] with most studies advocating PVSA at 12 weeks post-vasectomy,[116,117,125,126,131] others at 16 weeks.[119]

The rationale for PVSA at 12 weeks is based on an estimate that suggested that 80% of men will have no spermatozoa at this interval.[24,25,109,118,125] There is consensus that a second PVSA should be undertaken in cases where azoospermia has not been achieved but that most authorities and services do not require a routine second test in the event of azoospermia.[24,116,118,119,124,125,133] Compliance with PVSA testing is generally poor,[116,117,119,120,122,125,131,133] with attrition rates ranging from 14.0% to 46.2%.[116,117,119,120,122,123,131,133] Several studies have demonstrated that attrition increases with the number of PVSA requests made.[116,117,122,123,125,131,133] It has also been suggested that compliance is affected by the time taken until PVSA is carried out, with a long interval being associated with decreased compliance.[117,119,123,125] Age, educational status and number of children have also been identified as potential predictors of compliance; with having more than four children, smoking and not having a college education being predictive of non-compliance.[120] Guidance produced by the British Andrology Society[124] and by the Association of Biomedical Andrologists[130] both state that postal samples can be used for PVSA in order to maximise compliance. If postal samples are used, local labelling and packaging requirements must be followed and these must also comply with Royal Mail standards for posting biological specimens (http://www.royalmail.com/business/help-and-support/tell-me-about-restricted-goods). If any sperm are observed in a postal sample then sperm motility must be assessed using a fresh sample[130] (processed within hours of production in accordance with local protocols).

There is good evidence that centrifugation is not required routinely. The literature is consistent in recommending that clearance should be given following microscopy of non-centrifuged semen.[24,119,121,124] Some studies have recommended centrifugation of samples prior to microscopy. However, other studies have suggested that the examination of a centrifugate is not routinely required.[119,121] The World Health Organization (WHO) has produced guidance that outlines recommendations for the laboratory examination of semen.[134] This guidance suggests that centrifugation should not be used to confirm the motility of low concentrations of sperm identified at PVSA as a precursor to giving 'special clearance'.[134] The AUA[25] and EAU[24] state that PVSA should be conducted in accordance with recommendations set out in the WHO guidance.[134]

Some of the literature suggests that in addition to a fixed period of time having elapsed between vasectomy and PVSA that a minimum number of ejaculates are also required.[24,90,99,109,118,124] A systematic review[118] calculated that between 11 and 20 ejaculates are estimated to be required before 80% of men achieve azoospermia. There is insufficient evidence to enable any recommendation to be made, although it is plausible that the number and frequency of ejaculates will influence post-vasectomy clearance.

2.6.1 Special clearance

The available literature suggests that some men who have undergone vasectomy will have low concentrations of persistent non-motile sperm in their first PVSA sample. This proportion varies from approximately 1.4–2.5%[108,118,135] to 15–21%,[100] depending on the timing of the initial PVSA, definition of rare non-motile sperm, and the semen analysis method performed. Most of these men will eventually achieve azoospermia, although the timing can vary between individuals. There is consensus that special clearance to cease using additional contraception can be given when sufficiently low numbers of non-motile sperm are observed in a fresh semen sample[117,119,123,124,136] at PVSA. Different levels of sperm concentrations have been examined in different studies, specifically <10 000 sperm/ml,[108,135] <62 000 sperm/ml[119] and <100 000

sperm/ml.[24,118,124,136] No pregnancies were reported in the literature when using any of these sperm concentrations following initial PVSA and follow-up.

Limited quantity suggests that a vasectomy should be considered a failure if motile sperm are present at PVSA 6[24,25] or 7 months[117] following the procedure. No evidence was identified that examined PVSA samples with >100 000 sperm/ml non-motile sperm and vasectomy failure. Guidance by the AUA[25] states that if >100 000 non-motile sperm/ml are observed in a sample 6 months following the procedure, clinical judgement and individual PVSA results should be used to determine whether or not the procedure should be classified as a failure (page 19).

2.6.2 *Interventions to accelerate time to clearance*

A limited quantity of good-quality evidence was identified examining interventions intended to accelerate the time to clearance of sperm, or azoospermia, after vasectomy. Five RCTs examined whether irrigation of the vas deferens during vasectomy with either saline[137–139] or sterile water[141] was more effective in accelerating time to azoospermia compared to non-irrigation. There is consensus that irrigation of the vas deferens during vasectomy may reduce postoperative sperm counts but that it does not reduce the time to reach azoospermia when compared to non-irrigation.

B Post-vasectomy semen analysis (PVSA) should be carried out to identify early failure. Additional contraception should be used until azoospermia is confirmed or special clearance given.

B Evidence suggests that 12 weeks post-vasectomy is the optimal timing to schedule the first PVSA. Earlier or later testing is acceptable taking into account that earlier testing increases the probability of additional tests and later testing prolongs the need for additional contraception.

✓ Postal semen samples can be used for PVSA; however, such samples will not be suitable for the assessment of sperm motility.

✓ Packaging and labelling of postal samples should conform to local laboratory policy/requirements and must comply with Royal Mail standards for the posting of biological specimens.

B A routine second PVSA is not required if azoospermia is found in the first sample.

B In a small proportion of men non-motile sperm will persist following vasectomy. In such cases special clearance can be given to cease using additional contraception when less than 100 000 non-motile sperm/ml are observed in a fresh semen sample post-vasectomy.

C If motile sperm are observed in a fresh sample 7 months post-procedure, the vasectomy should be considered a failure.

✓ If more than 100 000 non-motile sperm/ml are observed in a fresh sample 7 months after vasectomy, clinical judgement and/or local protocols may be used to determine whether or not the procedure should be deemed a failure.

A Routine irrigation of the vas deferens does not reduce time to achieve azoospermia and is not recommended.

C Centrifugation is not recommended for establishing the absence of sperm post-vasectomy and may interfere with evaluation of sperm motility.

2.7 Intraoperative complications

A limited volume of evidence was identified in the literature that reported intraoperative complications during vasectomy. This evidence was principally in the form of case reports and expert opinion, including from members of the multidisciplinary guideline development group.

2.7.1 Identification of the vas deferens

A number of case reports were identified that reported vas deferens anomalies as a potential intraoperative complication of vasectomy. Reports of a 'missing vas deferens', congenital unilateral absence of the vas deferens(CUAVD), or congenital bilateral absence of the vas deferens (CBAVD) have been published in the literature.[142–145] It has been calculated that CUAVD is uncommon, affecting <1% of the male population[144,146] and occurring more frequently on the left side than the right.[145] The absence of a vas deferens is associated with ipsilateral renal malformations in addition to genetic mutations linked to cystic fibrosis.[145,146] No evidence was identified that examined CBAVD and vasectomy, presumably because this is a rare occurrence.

If CUAVD or CBAVD is suspected, health professionals should seek the opinion of a urology specialist. If CUAVD is confirmed, unilateral vasectomy can be performed on the other side and PVSA undertaken at the appropriate time following the procedure.[142,144] It has been suggested that men with CUAVD should be referred for renal ultrasound,[142,145,146] particularly if they have symptoms suggestive of kidney disease. The need for further investigation should be guided by specialist advice. Testing for cystic fibrosis transmembrane conductor regulatory (CFTR) gene mutation is not routinely required in men with CUAVD or CBAVD undergoing vasectomy.[144]

A limited volume of evidence was also identified that reported cases of duplication of the vas deferens or of a 'double vas deferens'. Duplication of the vas deferens is characterised by a second vas deferens within the spermatic cord,[147] whereas a double vas deferens can be described as ipsilateral renal agenesis where the additional structure is actually an ectopic ureter that ends in the ejaculatory system.[147] There is consensus that duplication of the vas deferens is rare, with only a limited number of cases having been published in the literature.[118,147,148] It has been calculated that this congenital anomaly affects approximately <0.05% of the male population and that unilateral duplication of the vas is more prevalent than bilateral duplication.[147] As evidence is scant there is no consensus regarding the management of these men at vasectomy. However, there is consensus that failure to identify a duplicate vas deferens can result in failure of vasectomy.[147,148] Therefore it is prudent to consider using Doppler ultrasound to determine whether it is in fact a 'true' duplicate as opposed to an ectopic ureter; consideration may also be given to renal and bladder ultrasound.

✓ If a vas deferens cannot be palpated or located, unilateral vasectomy can be carried out following appropriate counselling, and the man advised to comply with additional contraception until sterility is confirmed. These men should be informed of the probability of ipsilateral renal agenesis and may be referred for renal ultrasound.

✓ Where apparent bilateral absence of the vas deferens is encountered, men should be referred to a urology specialist.

✓ If a double or duplicate vas deferens is encountered or suspected, a Doppler ultrasound should be used to determine whether it is a 'true' double vas or an ectopic ureter.

✓ Where an anomaly of the vas deferens is suspected, the need for further investigation should be individually assessed by a urology specialist.

2.7.2 *Anatomical factors that may complicate vasectomy*

Pathology or scrotal anatomy can serve to make vasectomy more complicated; such factors include:

- retractile/ascending testes
- scarring as a consequence of previous scrotal surgery
- a small and tight scrotum[91] or a brisk cremasteric reflex
- obesity which may make access more difficult as a consequence of adipose tissue and may also result in thickened spermatic cords[91]
- individual variability in vas deferens thickness/palpability[91]
- large hydrocele
- large spermatocele
- extreme scrotal hypersensitivity
- inguinoscrotal hernia
- infectious conditions/signs of scrotal infection.

It is therefore considered essential to carry out a thorough scrotal examination at the initial assessment or immediately before carrying out the procedure, thereby enabling health professionals to identify any factors that might complicate vasectomy and to discuss with the man potential risks and management.

2.7.3 *Bleeding*

Administration of local anaesthesia and scrotal skin puncture may damage small vessels, which can potentially result in the formation of a haematoma. Excessive bleeding may also occur as an intraoperative complication of vasectomy. MIV techniques have been shown to reduce the level of such bleeding in comparison to other methods of exposing the vas deferens.[92] Health professionals should avoid any obvious vessels when puncturing the scrotal skin and should ensure that haemostasis is achieved by sealing any small perivasal and subdermal blood vessels that are bleeding.

✓ Health professionals should cauterise or suture any bleeding perivasal and subdermal blood vessels to ensure haemostasis.

2.7.4 *Pain*

The incidence of intraoperative pain has been shown to be reduced by the adoption of a MIV approach to exposing the vas deferens.[91,92,95] The speed and adequacy of response to local analgesia will be subject to individual variation. If a man complains of pain during the procedure, health professionals should consider the administration of additional anaesthesia/analgesia. Health professionals should be aware that a man can withdraw consent at any time during vasectomy and ask them to stop the procedure.

✓ If pain is experienced during vasectomy, health professionals should consider the administration of additional anaesthesia/analgesia.

2.7.5 *Vasovagal response*

During vasectomy or in the immediate postoperative period some men can experience a vasovagal response that may manifest as syncope, apnoea or convulsions. It has been suggested that health professionals can mitigate against this risk by ensuring that the clinical room is well ventilated and not too warm or cold. Furthermore, if a man is cold or anxious this may elicit contraction of the cremaster muscle causing the scrotum to shrink, making the procedure more difficult.[149] Health professional dialogue with men has also been identified as important in reducing patient anxiety and it has been suggested that health professionals should provide reassurance to men throughout the procedure.[149] A recently published Cochrane

systematic review[150] reported that listening to music has a significant beneficial effect on preoperative anxiety. None of the studies examined the outcome in relation to vasectomy; however, consideration should be given to playing music or the radio in the clinical room during vasectomy.

✓ Health professionals should ensure that the clinical room is well ventilated and a comfortable temperature.

C Health professionals can consider playing music in the clinical room if the patient wishes, as listening to music has been shown to reduce patient anxiety.

✓ Health professionals should engage men undergoing vasectomy in conversation and provide reassurance over the course of the procedure.

2.8 Immediate and delayed postoperative complications

2.8.1 Bleeding and haematoma

The frequency of postoperative bleeding and haematoma is low. The EAU[24] guidelines observed variations in defining the risk of haematomas with resulting reports of 4–22%. The AUA[25] guidance on vasectomy states that the risk of haematoma and wound infection following vasectomy is approximately 1–2%. Bleeding disorders lead to an elevated risk of postoperative haematoma formation which, in turn, leads to an increased risk of infection.[119,121]

UKMEC[5] includes a section on male surgical sterilisation. UKMEC states that when vasectomy has to be performed in men with coagulation disorders or who are anticoagulated, that the procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support (UKMEC Category S).[5]

A systematic review[92] of the method of exposing the vas deferens, which relied principally on a single large multicentre RCT of 1429 men, concluded that the use of MIV techniques resulted in less perioperative bleeding, haematoma and infection compared to a conventional technique.

2.8.2 Infection

It has been estimated that the frequency of infection following vasectomy is 0.2–1.5%.[24] UKMEC[5] includes categories related to infection and male sterilisation. UKMEC[5] states that vasectomy should be delayed until the condition is evaluated and a Category D is assigned for the following infectious conditions: scrotal skin infections; active STIs; balanitis; epididymitis or orchitis; systemic infections or gastroenteritis. A limited number of case reports were identified in the literature that reported cases of severe infection following vasectomy, leading to Fournier's gangrene.[151–155] This rare but serious complication is most often associated with infection of the scrotal incision or the presence of infective lesions/pustules of the scrotal skin. Anecdotal evidence has also suggested that in a limited number of cases, vasectomy is associated with septicaemia. No evidence was identified in the literature that recommended the administration of routine prophylactic antibiotics prior to vasectomy.

✓ The routine use of prophylactic antibiotics is not recommended prior to vasectomy.

✓ Skin cleansing in advance of vasectomy should be undertaken in accordance with local infection control protocols.

✓ The decision to shave the scrotum prior to vasectomy should be based on local infection control/preoperative policies.

2.8.3 *Early failure*

Despite the low level of adverse outcomes associated with confirmation of azoospermia and special clearance, neither is a guarantee of sterility. Vasectomy failure can be classified as either early (i.e. before PVSA) or late failure that is defined in the literature as being either pregnancy or the reappearance of motile spermatozoa following confirmation of sterility at PVSA. Although pregnancy is the most obvious and significant adverse outcome associated with vasectomy failure (contraceptive failure), it is problematic to measure as it occurs in a subject not being studied and thus azoospermia is widely used as a surrogate outcome instead (occlusion failure). The literature reports variable failure rates for vasectomy with an optimal failure rate being less than 1%.[24,25,117,124,156–158]

Recanalisation of the vas deferens can occur at an early or late stage following vasectomy. Early recanalisation was first described in 1969[159] and is recognised at PVSA by sperm counts that may at first be azoospermic or reduced but subsequently show a rapid increase.[118] Literature has suggested that non-compliance with the use of additional contraception and PVSA protocols accounts for at least 50% of vasectomy contraceptive failures.[17,157–159]

Early vasectomy occlusion failure can be due to early recanalization, or in some rare instances due to technical failure. Technical failure occurs when the vas deferens has not been completely occluded or has been incorrectly occluded[117–119,124] or when the wrong structure has been occluded. The majority of vasectomy occlusion failures are due to early recanalisation.[101] The early occlusive failure attributed to recanalisation has been reported to vary widely with the vasectomy occlusion technique performed.[24,124,160] Occlusion failure rate should be less than 1% when an appropriate vasectomy occlusion technique is performed (see the section on the interruption of the vas deferens on page 11).

B Clinicians should modify their technique if overall failure attributable to technical failure, recanalisation and non-compliance with additional contraception is more than 1%.

C The incidence of bleeding, haematoma formation and infection is low and can be further reduced by the adoption of minimally invasive vasectomy techniques.

2.9 Long-term complications

2.9.1 *Late failure*

Late failure is defined as the presence of sperm after confirmation of sterility (azoospermia or special clearance at PVSA). The rate of late failure due to recanalisation is reported to be between 0.03% and 1.2%.[24,124,156] In normal clinical practice instances of late recanalisation are only identified in men whose partners conceive after initial PVSA confirming sterility. When PVSA is repeated at the time of pregnancy, motile sperm are nearly always observed.[24,118,124,156] However, some studies have reported a small number of non-motile sperm[131,161–165] and, most importantly, motile sperm[127,163,164,166–168] despite previous evidence of azoospermia at PVSA. In 1995, six cases of true vasectomy failure (confirmed by DNA testing) were reported in men who did not have any sperm demonstrated in repeat samples.[161,169] The first report to assess the frequency of late contraceptive failure (i.e. true pregnancies) was reported in 1984, with six pregnancies from a denominator of 14 047 procedures, giving an estimated failure rate of 1:2300.[156]

B Individuals should be informed that vasectomy has an associated failure rate and that pregnancy can occur several years after vasectomy. The contraceptive failure rate should be quoted as approximately 1 in 2000 (0.05%) after clearance has been given.

2.9.2 *Chronic post-vasectomy pain*

Chronic post-vasectomy pain (CPVP) refers to persistent pain more than 3 months after the procedure. Although commonly testicular in origin, this pain may present as scrotal, penile, pelvic or lower abdominal discomfort. A variety of hypotheses have been proposed as causal factors including nerve entrapment and the development of sperm granulomas. A reasonable volume of evidence was identified with regard to CPVP in the form of cross sectional,[170–173] case series[96,174,175] and cohort studies.[176,177] There is consensus in the literature that there is an association between vasectomy and postoperative scrotal pain or discomfort. It is difficult to ascertain or quantify the likelihood, onset, extent or magnitude of pain experienced as it is a subjective measure, although it has been estimated that the frequency of CPVP is 1–14%.[24,177] Furthermore, the methodologies used may mean that the results are subject to possible confounding or bias. Despite these limitations, there is conclusive evidence that CPVP is a possible adverse outcome of vasectomy and that in some men this can be severe. An unpublished cohort study[177] reported that 1/300 (0.3%) previously asymptomatic men experienced pain, following vasectomy, which was severe enough to warrant medical attention and/or to affect the man's quality of life. The study[177] also reported that 270/300 participants reported zero (new) pain at 5.1 years follow-up and that the remaining 29 participants had lesser pain, of varying degrees, which was not severe enough to affect their quality of life. Available evidence suggested that this may be in some part dependent on the technique used to expose the vas deferens, as use of MIV resulted in more favourable outcomes in terms of postoperative pain when compared to other methods of incision.[91,176] However, an RCT[91] did not find any difference in long-term pain (follow-up ranged from 16 to 511 days for the MIV group and 16 to 498 days for the standard incision group) between MIV and the traditional method.

B Vasectomy is associated with a risk of postoperative testicular, scrotal, penile or lower abdominal pain that is rarely severe and chronic in some men.

2.9.3 *Interventions for chronic post-vasectomy pain*

It is acknowledged that the mechanism of CPVP is not well understood and there is limited evidence that suggests it may be neuropathic pain. Other possible causes of scrotal pain, such as STI, should be excluded. NSAIDs, tricyclic antidepressants (such as amitriptyline) and gabapentin have been tried in clinical practice but there is a paucity of evidence relating to the medical management of CPVP in the existing literature.

The majority of the evidence identified on CPVP relief relates to surgical interventions and is available in the form of case series[170,178–184] although one cohort study[185] was also identified. These studies support microsurgical vasovasostomy or vasoepididymostomy, as broadly effective procedures in alleviating CPVP. One study[170] examined denervation of the spermatic cord as a treatment for CPVP, but there was insufficient evidence to allow any recommendation on the use of this procedure. More details on vasovasostomy and vasoepididymostomy are outlined in the vasectomy reversal section (page 22).

✓ Non-steroidal anti-inflammatory drugs (NSAIDs) and treatment to alleviate neuropathic pain are common first-line treatment options for chronic post-vasectomy pain (CPVP) and are preferable to surgical treatment, which involves the reversal of vasectomy.

C Surgical interventions can be effective in alleviating CPVP, however permanent relief is not achieved in every case.

2.9.4 *Prostate and testicular cancer*

Case-control[186,189] and cohort studies[190–193] examining vasectomy and the risk of prostate cancer have produced conflicting results. The majority of these studies have not found any association between vasectomy, age at vasectomy, obstruction interval and prostate cancer.[186,189,191,192] Although two cohort studies,[190,193] a systematic review[194] and a meta-analysis[195] suggested a small, statistically significant risk of prostate cancer, the association can readily be explained by bias or confounding factors such as age.[194,195] A recently conducted meta-analysis[25] undertaken by the AUA showed no association between prostate cancer and vasectomy.

There is a paucity of available evidence examining the association between vasectomy and testicular cancer. Of the identified cohort[191,196–198] and case-control[173,199–202] studies, two papers[198,199] concluded that there was evidence of a statistically significant increase in testicular cancer following vasectomy, but these studies were limited by a short follow-up period and possible ascertainment bias. Studies that included a longer follow-up after vasectomy are consistent in their conclusion that there is no evidence of an increased risk of testicular cancer.[173,191,196,197,200–202]

As the pathogenesis of prostate and testicular cancer is incompletely understood, it is possible that other, as yet unknown, confounding factors are involved. There is broad consistency in the literature that any association between vasectomy and prostate or testicular cancer is not strong and that there is no evidence of causation.

B There is no evidence of an increase in testicular cancers associated with vasectomy. The weak association observed in some studies between vasectomy and prostatic cancer is unlikely to be causal.

2.9.5 *Cardiovascular disease*

In the 1970s and 1980s, a limited body of evidence suggested that vasectomy accelerated atherosclerosis in primates and concluded that therefore there may be a similar risk in humans.[203–205] Subsequently further studies by the same authors concluded that these initial reports were flawed and that further research did not support their initial conclusions.[206,207]

Two cohort studies[191,208] were identified that examined the relationship between vasectomy and cerebrovascular accident (stroke). Neither of these studies reported a higher incidence of stroke in men who had undergone vasectomy. Furthermore, no association was observed in relation to the risk of stroke and obstruction interval.

No association between vasectomy and cardiovascular disease was identified in three cohort studies[191,208,209] and a case-control study.[210]

B There is no evidence to support an association between vasectomy and cardiovascular disease.

2.9.6 *Psychological and sexual function*

No evidence was identified in the literature that examined the relationship between vasectomy and psychological outcomes following the procedure. Guidelines produced by the AUA[25] identified a number of articles published between the 1960s and 1980s that examined psychosocial outcomes post-vasectomy. The guidance states that heterogeneity between studies was too great to enable any conclusions to be drawn regarding psychological function and vasectomy.[25]

A cross-sectional study[211] was identified that examined sexual problems in men who had undergone vasectomy. The study reported that having a vasectomy was not associated with specific sexual problems, for example, lack of interest in sex or taking too long to achieve orgasm. Following vasectomy, men were slightly more likely to report problems in maintaining an erection, but this difference was attributed to confounding factors such as age and sociodemographic variables. The study also observed that men who had undergone vasectomy were more likely to be extremely satisfied with their relationship overall, when compared to men who had not undergone vasectomy.[211] Guidance by the AUA[25] states that there is no evidence to suggest that vasectomy is associated with erectile dysfunction; reduced or missing orgasmic sensation; reduced ejaculate volume; reduced sexual interest; or decreased sensation or sexual satisfaction.

2.9.7 Other diseases/conditions

Literature was identified that examined vasectomy and its relationship with various other diseases, however the volume of evidence was insufficient to allow any recommendations to be drawn.

A large cohort study involving almost 22 000 men found that men who had undergone vasectomy had similar or lower rates of 98 diseases (including a number of cancers, autoimmune and heart disease) as controls.[212] A more recent study concurred with this assessment, and concluded that among a cohort of men who had had a vasectomy there was no increased long-term risk of immune-related diseases.[213] A non-systematic review of long-term effects of vasectomy noted that while at least 50% of men permanently had sperm agglutinating or immobilising auto-antibodies in their serum after vasectomy, numerous studies have failed to show any immunological or other adverse effect upon health. [214]

A single, small-scale, case-control study[215] was identified which reported that vasectomy may be associated with primary progressive aphasia, a form of dementia, due to autoimmune reactions (i.e. anti-sperm antibodies). However, a recently published study did not observe such an association.[216]

While there are no recognised risk factors for urolithiasis (renal stones) attributable to vasectomy,[217] two studies suggest that there is a higher incidence of urolithiasis in men who had a vasectomy.[217,218]

2.10 Vasectomy reversal

Vasectomy involves occlusion of the vas deferens and thus transport of sperm is prevented. Vasovasostomy is a surgical procedure that endeavours to reconnect the occluded sections of the vas deferens and thus can be used to reverse vasectomy. Vasoepididymostomy (also known as epididymovasostomy) is a more complex technique that can also be undertaken to reverse vasectomy. Typically, vasoepididymostomy is performed when epididymal obstruction is present or when vasovasostomy has been unsuccessful. The procedure involves the anastomosis of a single epididymal tubule to the lumen of the vas deferens.

The cohort studies[219–231] and a systematic review[232] identified on the effectiveness of vasectomy reversal typically involved the retrospective review of vasovasostomy and/or vasoepididymostomy outcomes. In the literature, patency was used as a proxy for pregnancy rates, where patency was defined as the presence of motile sperm in a postoperative semen sample. Many of the studies identified may have been subject to confounding and/or bias, with many being potentially underpowered, lacking adequate follow-up, and failing to control for individual characteristics. Moreover, it is important to recognise that high postoperative patency does not necessarily equate to high pregnancy rates, and many of the studies were subject to high attrition rates.

Table 1: Success of vasectomy reversal linked to obstruction interval.[233] Table reproduced with the kind permission of the British Association of Urological Surgeons.

Interval (years)	Patency rate (%)	Pregnancy rate (%)
<3	97	75
3–8	88	50–55
9–14	79	40–45
15–19	70	30
>19	40	<10

On the balance of available evidence, a longer obstruction interval is associated with lower patency/pregnancy rates, [219,227,228,230,231] although this association has not been observed in other studies.[220,221,223,225,229] A longer obstruction interval may potentially allow the formation of more scar tissue, meaning that the technically more challenging vasoepididymostomy is more likely to be performed. Furthermore, fertility naturally decreases with age therefore obstruction interval may be a confounder for the age of a man or his partner. The type of vasectomy performed may also determine whether vasovasostomy or vasoepididymostomy is appropriate.[230]

There is no consensus regarding success rates for specific obstruction intervals, however the rates of success linked to obstruction interval according to the British Association of Urological Surgeons are given in Table 1.

There is consensus that having a female partner ≥40 years of age is associated with lower pregnancy rates following reversal of vasectomy.[220,221,223,225,228,230]

The majority of the studies identified utilised a microsurgical approach for vasectomy reversal with only three comparing macro- versus microsurgery outcomes. Two studies reported better outcomes for microsurgical as opposed to macrosurgical vasectomy reversal[229,230] and one reported that outcomes for both were equal.[232] A consensus statement by the Practice Committee of the American Society for Reproductive Medicine recommends a microsurgical approach.[234] There is consensus that surgical experience is also a significant factor that affects postoperative patency, with more experienced surgeons achieving better outcomes especially for vasoepidiymostomy.[220,225,226,232]

It is important to note that the NHS does not currently offer vasectomy reversal routinely. Additionally, developments in assisted reproductive technology may offer a potentially more efficacious intervention, however there is scant available evidence comparing outcomes of assisted reproduction and surgical interventions.

B Vasectomy reversal involves complex surgery that can result in high postoperative patency rates, but may not result in pregnancy or a return to fertility.

3 Tubal occlusion

3.1 Overview

Elective female sterilisation may be achieved by the occlusion or interruption of the fallopian tubes, preventing fertilisation and providing permanent contraception. This can be achieved by accessing the fallopian tubes via laparoscopy (keyhole abdominal surgery); transcervical route (usually hysteroscopic techniques); mini-laparotomy (a small transverse lower abdominal incision); and during caesarean section operation. Transvaginal methods (culdoscopy and colpotomy) have been used but are obsolete in the UK.[235,236]

Methods that occlude/interrupt the fallopian tubes include: application of a mechanical device on the tubes (occlusion by Falope ring or Filshie or Hulka-Clemens® clip); ligation (occlusion of the tube using absorbable or endoscopic sutures); salpingectomy (excision of a small portion of the tube); the use of micro-inserts (occlusion of the tubal isthmus by hysteroscopically applied Essure® device); and diathermy (occlusion of the tubal isthmus by unipolar or bipolar diathermy).

3.2 Approach to the fallopian tubes

3.2.1 Transcervical

Tubal occlusion can be achieved by a transcervical approach aided by a hysteroscope. Flexible Essure micro-inserts are then passed through the hysteroscope and inserted into the proximal section of each fallopian tube. More information on hysteroscopic sterilisation is given on page 33.

3.2.2 Laparoscopy

During laparoscopy, the fallopian tube can be occluded (with a tubal ring or clip); a modified Pomeroy technique (page 25) can be performed using endoscopic sutures; or diathermy (either unipolar or bipolar) can be used to destroy a segment of the fallopian tube.

Laparoscopic sterilisation is associated with morbidity and occasional mortality. Most of the complications arise as a result of the blind insertion of the Veress needle or first trocar, rather than as a consequence of the actual procedure performed.[237]

Minor complications are injuries or problems that can be addressed during the laparoscopic procedure and do not prevent the intended procedure from being completed. Previous abdominal or pelvic surgery, previous PID, endometriosis and obesity significantly increase the relative risk of complications and the need for laparotomy.[238,239]

Major complications associated with laparoscopic surgery are injuries to the bowel, bladder and blood vessels that require laparotomy. The risk of laparotomy as a consequence of a severe complication reported in a large prospective study[240] was 1.9/1000 procedures. Two other practice surveys[241,242] reported laparotomy rates of 1.4–3.1/1000 cases. The risk of death associated with laparoscopy is reported as being 1/12000.[238,241]

3.2.3 Mini-laparotomy

If mini-laparotomy is used for the approach to the fallopian tubes, a partial salpingectomy can be performed and the tubes ligated (usually by a modified Pomeroy technique) or occluded (with a mechanical device such as a tubal ring or clip such as a Filshie clip, Falope ring or Hulka-Clemens clip). In the UK, mini-laparotomy is rarely performed as a primary procedure but may be performed if laparoscopic access has failed or is contraindicated.

A systematic review[235] comparing methods of access to the fallopian tubes reported that there was no difference in major morbidity between mini-laparotomy and laparoscopy. However, there was significantly more minor morbidity associated with mini-laparotomy [odds ratio (OR) 1.89; 95% confidence interval (CI) 1.38–2.59]. The review also reported that laparoscopy took an average of 5 minutes less to perform than mini-laparotomy.[235]

There is a paucity of evidence directly comparing hysteroscopic, laparoscopic or mini-laparotomy approaches to the fallopian tubes. A comparison of hysteroscopic sterilisation in comparison to other techniques is outlined on page 40.

A Culdoscopy should not be used as a method of approach for sterilisation.

A The laparoscopic approach to the fallopian tubes is quicker to perform and results in less minor morbidity compared to mini-laparotomy.

B All women should be informed of the risks associated with laparoscopy and when this may proceed to laparotomy.

✓ In some cases laparoscopy/laparotomy may be contraindicated and consideration should be given to other methods.

3.3 Occlusion methods

3.3.1 Ligation

No RCTs examining different surgical techniques for ligating the fallopian tubes were identified. Many surgical techniques have been in use for many years and their use relies on tradition rather than reliable evidence. Two non-systematic reviews[243,244] highlight the advantages and disadvantages of ligation procedures.

The Pomeroy technique is the most widely used ligation technique because it is simple and effective. It involves using absorbable suture material to tie the base of a loop of fallopian tube near the mid-portion (ampulla) and excising the top of the loop. The suture material is absorbed rapidly, reducing the chances of inflammation and the formation of fistulae in the tubes. After the sutures are absorbed, the ends of the tube pull apart. This procedure destroys 3–4 cm of the fallopian tube, making reversal of the procedure more difficult.

The modified Pomeroy technique, often used in the USA (also known as the Parkland or Pritchard technique) involves separating a small segment of the fallopian tube from the mesosalpinx. Each end of the tube is ligated and the portion of the tube between the sutures excised.

Other more complex and surgically demanding ligation techniques can be used but are largely obsolete.

No difference in pregnancy rates was reported by studies[245] that examined Filshie clips used via mini-laparotomy compared with laparoscopy or with a tubal ring used either via mini-laparotomy or laparoscopy in interval sterilisations (i.e. sterilisation that is performed at a time interval after pregnancy rather than intrapartum at the time of caesarean section or immediately postpartum).

B Any effective surgical or mechanical method of tubal occlusion can be used when a mini-laparotomy is the method of approach for an interval sterilisation.

The CREST study,[246] which had a 10-year follow up, demonstrated that a postpartum salpingectomy group (which predominately included modified Pomeroy-type ligation as opposed to other forms of partial salpingectomy and total salpingectomy) performed via laparotomy had a low cumulative failure rate of 7.5/1000 procedures at 10 years.

A systematic review,[247] RCT[248] and cohort study[249] consistently recommended that the use of the Pomeroy technique was more efficacious than Filshie or Hulka-Clemens clips for postpartum sterilisation and resulted in lower failure rates. The systematic review[247] reported that the

cumulative pregnancy rate was 1.7/1000 procedures for Filshie clips and 0.4/1000[250] for a modified Pomeroy method at 24 months. Evidence[251,252] from the early 1990s that compared Filshie and Hulka-Clemens clips, respectively, with the Pomeroy technique in postpartum women did not observe the same effect. A systematic review[253] conducted a pooled analysis of data from studies that compared the modified Pomeroy method and Filshie clip for immediate postpartum sterilisation. The study reported that, following analysis, there was no difference between the failure rates of the two methods (OR 0.76; 95% CI 0.30–1.95) and that complication rates were similar. Therefore, the review recommended that Filshie clips could be used as an alternative to the modified Pomeroy technique for postpartum sterilisation.[253] A small RCT,[254] which compared Filshie clips with the Pomeroy technique for postpartum sterilisations, concluded that the use of Filshie clips was quicker to perform and was the preferred occlusion method of surgeons.

A For postpartum sterilisation, both Filshie clips and modified Pomeroy technique are effective. Filshie clip application is quicker to perform.

3.3.2 Mechanical methods

Mechanical occlusive methods are widely used in the UK. For mechanical occlusive methods to be successful the manufacturer's instructions should be followed. The correct placement of mechanical occlusive devices should be explicitly checked by the operating surgeon at the conclusion of the operation. A note to this effect should be made in the operating notes and where possible photographic evidence logged in the clinical record.

The tubal ring (Falope ring) has higher rates of technical difficulty and technical failure during the procedure when compared to diathermy[238,255–257] or Filshie clips.[245,258] Short-term (2-year) failure rates are comparable with Filshie clips.[258]

Spring-loaded clips, such as the Hulka-Clemens clip, were found to be associated with the highest rate of failure in all age groups during the 10-year follow-up of the CREST study.[246] This in turn led to a higher cumulative probability of pregnancy after 2 years in an RCT comparing Hulka-Clemens and Filshie clips.[259] Therefore, Filshie clips should be used in preference to Hulka-Clemens clips.

Multiple Filshie clips are not necessary for tubal occlusion to be effective, providing that the single clip is applied in the correct manner (Figure 2).[239] If there is any doubt regarding the security of a clip, a second clip may be placed immediately adjacent to the first on the uterine side.[260] The use of multiple Filshie and Hulka-Clemens clips has been examined in the literature.[261] Multiple clips tended to be used when surgical difficulties were encountered during sterilisation or when the first clip was not placed optimally. There was no increase in immediate or short-term complications in women with multiple clips when compared to women with single clips. However, the routine use of multiple clips should not be encouraged, as this will lead to a greater length of fallopian tube being damaged, which may potentially make any reversal operation more difficult and less successful.

A Mechanical occlusion of the fallopian tubes by Filshie clips should be the method of choice for laparoscopic tubal occlusion.

C The routine use of more than one Filshie clip is not recommended.

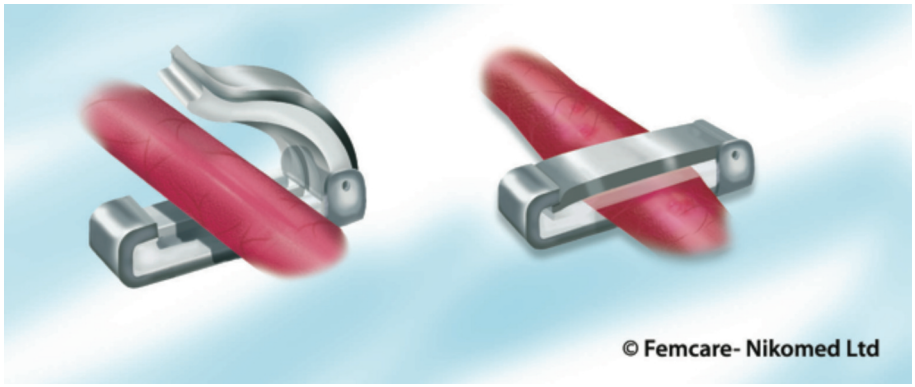

Figure 2: Filshie clip before and after application to the fallopian tube. © Femcare-Nikomed.

3.3.3 Diathermy

Unipolar diathermy has been largely replaced by bipolar diathermy, owing to the severity of complications that occurred with the use of unipolar diathermy. Thermal injury to the bowel[39,262,263] and burns to the skin[39,264] have been reported, with some injuries resulting in death.[42,43,238] Burns to the face and hands of the operator have also been reported.[265]

Instead of the electric current passing through the patient to a grounding plate attached to their skin, bipolar diathermy uses both jaws of the grasping forceps as the active and return electrodes, so that the electric current only passes between the two prongs, burning the tissue grasped.

This technique was adopted to reduce the risk of thermal bowel injury.[43] The risk of bowel injury has been reduced but it has not be eliminated,[266] with unrecognised trauma to the bowel being thought to be the main cause of bowel injury in laparoscopic sterilisation, even when bipolar diathermy was used.

Bipolar diathermy may still have a place as a second-line method when mechanical occlusive devices have failed. However, it causes more tubal destruction, success rates for reversal are low[57] and there is an increased risk of subsequent pregnancy being ectopic[246,263,267,268] compared with mechanical occlusive methods. If diathermy is used the fallopian tube should be occluded at the mid- to lateral portion of the isthmus. Tubes should be occluded at least 2 cm from the cornu[269] because coagulation close to the cornu can cause activation of the tubal epithelium, which in turn can cause uteroperitoneal fistula formation. Such fistulae allow sperm access to the peritoneal cavity and the possibility of fertilisation leading to ectopic pregnancy. Information on failure and ectopic pregnancy is on pages 31 and 32.

3.4 Anaesthesia and analgesia

Two studies[239,270] that randomised participants to either general or local anaesthesia with sedation, and two UK cohort studies[271,272] using local anaesthesia alone for laparoscopic sterilisation, demonstrated that either method was safe and acceptable. However, the majority of the identified UK literature reported utilising general anaesthesia. No evidence was identified that compared local and general anaesthesia for hysteroscopic sterilisation.

Two recently published RCTs[273,274] and a cohort study[275] examined the use of regional anaesthesia for tubal occlusion (i.e. spinal anaesthesia). Heterogeneity between the studies was too great to enable any specific recommendations to be drawn, however the studies all report no major adverse events and high patient satisfaction associated with the use of regional anaesthesia at the time of tubal occlusion.

B Laparoscopic tubal occlusion can be performed using general, regional or local anaesthesia but general anaesthesia is routinely used in the UK for laparoscopic tubal occlusion.

Laparoscopic sterilisation is more painful than diagnostic laparoscopy,[276,277] possibly because of local tissue necrosis and ischaemia at the site of tubal interruption. It has been demonstrated that pain following laparoscopic sterilisation was worse than diagnostic laparoscopy for the first 4 hours post-procedure, however pain was not significantly greater after hospital discharge on the same day as surgery.[278] Evidence has also shown that pain varies with the method of sterilisation and is probably most severe with tubal rings and least severe with diathermy and intermediate with clips.[279,280]

Available evidence suggested that the topical application of a local anaesthetic to the fallopian tubes either prior to, or after, tubal occlusion significantly reduced postoperative pain scores and the requirement for postoperative opioid analgesia following laparoscopic tubal occlusion carried out under either local or general anaesthesia.[276,277,280–288] A single RCT[289] showed that local anaesthesia (lignocaine gel) applied to Filshie clips before application also reduced postoperative opioid analgesia and reduced recovery time, after general anaesthesia, when compared to a placebo. There is limited high-quality evidence to suggest that intraperitoneal instillation with local anaesthesia at the end of the procedure may be effective,[290–292] especially when a long-lasting anaesthetic is used[293] or when meperidine/pethidine is instilled in addition to abdominal wall local anaesthetic.[294 294] Some RCTs have also studied infiltration by needle of the mesosalpinx[290,291,295–297] or fallopian tubes[298] in addition to topical local anaesthesia. Whilst these latter studies have generally shown these interventions to be effective at reducing pain, there is likely to be increased risk of bleeding and haematoma formation associated with the routine use of this intervention, as well as increased operating time.

A recently published meta-analysis[280] reported that the use of local anaesthesia (applied topically to the fallopian tubes or to clips or rings, via injection, or intraperitoneal injection) reduced postoperative pain in women undergoing laparoscopic tubal occlusion under general anaesthesia, and was effective for up to 8 hours post-procedure.

The beneficial effect conferred by these interventions, over and above that of normal postoperative analgesia, may disappear by the time of patient discharge. Bupivacaine and etidocaine were used in the majority of studies; as they are longer acting than lidocaine, they should be used preferentially. However etidocaine is not currently available in the UK.

There is conflicting evidence for transcervical instillation of bupivacaine.[299,300]

A Topical application of local anaesthesia to the fallopian tubes may be used whenever mechanical occlusive devices are being applied as short-term postoperative pain is reduced.

3.5 Postpartum and post-abortion sterilisation

Complication rates, failure rates and rates of regret increase when sterilisation is performed in association with pregnancy, as opposed to a so-called interval procedure performed at an interval after pregnancy. More detail on regret and the timing of tubal occlusion is outlined in the corresponding section of this guideline (page 8). The available evidence regarding risks associated with postpartum or post-abortion sterilisation is conflicting. A large retrospective cohort study,[301] which compared interval sterilisation with laparoscopic and mini-laparotomy postpartum sterilisation, reported that the risks associated with sterilisation were not significantly different between the groups. However, the study[301] reported fewer minor complications when sterilisation was carried out as an interval procedure, although the difference in overall risk was not statistically significant.

Whilst the addition of sterilisation to a procedure for induced abortion does not appear to increase the complication rate already associated with abortion,[302] it has been argued that the complication rate associated with the combined procedure is higher than that associated with interval sterilisation.[303] However, studies[71,304–306] that compared abortion combined with laparoscopic sterilisation against laparoscopic sterilisation alone report no significant differences in the complication rate between the two procedures.

There is conflicting evidence regarding failure rates when tubal occlusion is performed in association with pregnancy. Data on laparoscopic procedures from the early days of laparoscopic tubal occlusion[307,308] suggest a higher failure rate (two to seven times higher) when the procedures were performed in association with abortion or postpartum. A large case-control study[267] failed to find any association between timing of the procedure and failure rate. However, the study had a short follow-up and included less suitable controls for post-abortion and postpartum cases. The CREST study,[246] which had a 10-year follow-up, reported the lowest failure rate in the postpartum salpingectomy group (7.5/1000 procedures), which predominately included tubal occlusion carried out using a modified Pomeroy method.

B Tubal occlusion should be performed at an appropriate interval after pregnancy wherever possible. Should tubal occlusion be requested either postpartum or post-abortion, women should be made aware of the increased rate of regret and the possible increased failure rate.

3.6 Excluding pregnancy prior to surgery

3.6.1 Luteal-phase pregnancy

A proportion of sterilisation 'failures' are attributable to luteal-phase pregnancies, which occur when patients are sterilised after unknowingly conceiving in the same cycle as the sterilisation procedure is performed. Iatrogenic luteal-phase ectopic pregnancies can be caused by occluding the fallopian tubes before the blastocyst has passed the site of occlusion.

Luteal-phase pregnancies are estimated to occur in about 2–3/1000 interval procedures.[309,310] A study[311] that extrapolated data from the CREST study reported a similar rate of 18/4941 sterilisations, approximately 3.6/1000. The study[311] also reported that women who used more effective methods of contraception, such as combined oral contraception (COC) or a copper intrauterine device (Cu-IUD), prior to sterilisation had a significantly lower luteal-phase pregnancy rate than women using barrier, fertility awareness or withdrawal methods. Other reports from single institutions have reported higher local rates.[312,313]

Such pregnancies can be prevented by scheduling procedures during the proliferative phase of the menstrual cycle. However, this may be difficult to arrange, particularly in women who have unpredictable menstrual cycles. It is therefore crucial, in preoperative assessment, to emphasise the importance of continuing an effective method of contraception until the procedure. Some methods must be continued for a period of time following sterilisation. The FSRH consider that hormonal, intrauterine and barrier methods can be deemed reliable providing they have been used consistently and correctly on every incidence of intercourse. This should be assessed on an individual basis. More detailed criteria for pregnancy exclusion are outlined in Appendix 3.

3.6.2 Pregnancy testing

All women should have a preoperative same-day pregnancy test before undergoing sterilisation. This will identify existing pregnancies and a small proportion of luteal-phase pregnancies.[312–314] In one study,[314] 21/802 (2.6%) women had a positive pregnancy test on the day of their planned laparoscopic sterilisation. However, a negative urinary pregnancy test does not rule out pregnancy, as the sensitive beta human chorionic gonadotrophin tests may not correctly identify pregnancy until 3 weeks after unprotected sexual intercourse (UPSI).

B A pregnancy test must be performed before sterilisation to exclude the possibility of a pre-existing pregnancy. However, a negative test result does not exclude the possibility of a luteal-phase pregnancy.

B Tubal occlusion can be performed at any time during the menstrual cycle, providing that the woman has a negative pregnancy test and is not at risk of luteal-phase pregnancy [no unprotected sexual intercourse (UPSI) in the past 3 weeks]. If this is not the case, the procedure should be deferred and contraception used until at least 3 weeks from the last instance of UPSI.

3.6.3 *Dilatation and curettage*

Concurrent dilatation and curettage (D&C) was often performed in an attempt to reduce the incidence of luteal-phase pregnancies. Evidence from the 1980s[311,315] and 1990s[316] suggested that D&C did not significantly reduce luteal-phase pregnancies and was associated with unnecessary morbidity. Its value was questioned, especially as unsuccessful induced abortion increases with earlier gestational age[317] and there is also doubt regarding the legality of a concurrent D&C in UK law.[318] The procedure could be interpreted as an attempt to procure an abortion, which may constitute a criminal offence unless the conditions of the 1967 Abortion Act are met.

B During tubal occlusion curettage should not be performed for the purpose of preventing luteal-phase pregnancy.

3.6.4 *Stopping contraception after laparoscopic tubal occlusion*

There is no evidence to support stopping combined hormonal contraception (CHC) prior to surgery or the use of thromboprophylaxis (unless there are other risk factors) in women undergoing uncomplicated procedures such as laparoscopy.[5,319]

Theoretically CHC could be stopped at the time of laparoscopic tubal occlusion if it has been consistently and correctly used in the previous 7 days. However, the multidisciplinary guideline development group considered it a safe and simple approach to advise that CHC (i.e. COC, vaginal ring, transdermal patch) should be continued for at least 7 days. If sterilisation is scheduled for the hormone-free interval or Day 1 of a cycle of CHC following the hormone-free interval, CHC should be restarted. Alternatively, the hormone-free interval can be omitted and CHC continued for a minimum of 7 days after sterilisation.

If the progestogen-only pill (POP) is being used, it should be continued for at least 7 days after sterilisation. If the progestogen-only injectable or implant is being used, sterilisation can be carried out at any time during the period of licensed use without the need for additional contraception. The progestogen-only implant can be removed at the time or any time following sterilisation.

Removing a Cu-IUD or LNG-IUS during the sterilisation procedure may result in an unintended pregnancy if ovulation has occurred prior to the procedure and a blastocyst has already passed the site of tubal occlusion. Therefore, if a Cu-IUD or LNG-IUS is *in situ*, this should not be removed until at least 1 week after sterilisation.

C There is no evidence to support stopping CHC use prior to sterilisation or to support the routine use of thromboprophylaxis.

C Women using CHC, the POP or non-hormonal contraception should be advised to continue their contraceptive method for at least 7 days after laparoscopic sterilisation.

C If laparoscopic sterilisation is scheduled for the hormone-free interval or Day 1 of a cycle of CHC, the hormone-free interval should be omitted or CHC should be restarted, and CHC should be continued for at least 7 days after sterilisation.

C If the progestogen-only injectable or implant is being used, laparoscopic tubal occlusion can be carried out at any time during the period of licensed use without the need for additional contraception.

C The progestogen-only implant can be removed at the time of the procedure or any time following laparoscopic tubal occlusion.

C If a Cu-IUD or LNG-IUS is *in situ* prior to sterilisation, this should be retained and removed at least 1 week after laparoscopic tubal occlusion.

3.7 Failure of tubal occlusion

There is an associated failure rate (i.e. occurrence of a pregnancy subsequent to sterilisation) following tubal occlusion with all approaches and methods. The reasons postulated include:

- the ends of a fallopian tube can recanalise
- a fistula can develop at the occluded portion of the tube
- there may be incomplete occlusion of the tube
- there may be slippage of the occlusive device
- the occlusive device can be placed on the wrong anatomical structure.

As luteal-phase pregnancy is unrelated to the sterilisation method employed, these are usually excluded from analysis in studies examining sterilisation failures. Subsequent pregnancies can be intrauterine or tubal. The proportion of tubal pregnancies is an important outcome, as ectopic pregnancies can be life- threatening if undiagnosed. More detail on ectopic pregnancy is given on page 32.

Available evidence is subject to a number of limitations; for example: the classification of failure, type of procedure, and follow-up period are not always clearly outlined nor standardised across different studies. The majority of studies report the experience of a single centre/surgeon with different protocols being used across different centres, meaning that it is not possible to pool the data for analysis.[300,320] Pregnancy rate can be expressed as a crude rate, Pearl index or cumulative failure rate by life-table analysis, which that further adds to the difficulty of comparing outcomes across studies.

Previous studies have shown:

- 12-month cumulative life-table pregnancy rates of 3–6/1000 procedures[255,256,321–323]
- 24-month cumulative pregnancy rates of 8.6–10/1000 procedures[322,324]
- 7-year cumulative pregnancy rates for all methods of 10/1000[323]
- 8-year cumulative pregnancy rates of 11/1000 for procedures where a Hulka-Clemens clip was used and 26/1000 where diathermy (unspecified as to unipolar or bipolar) was used.[325]

The CREST study[246] followed up 10 685 women and found that the 10-year cumulative life-table probability of failure following sterilisation was at least 18.5/1000 procedures (95% CI 15.1–21.8).

Most studies have been unable to demonstrate a significant difference in pregnancy rates between sterilisation methods, but this may be because the number of pregnancies is low and such studies are underpowered to detect a relatively rare event. The CREST study[246] did show, following multivariate analysis, that the spring clip (equivalent to the Hulka-Clemens clip) and bipolar diathermy were significant risk factors for failure. However, the CREST study[246] included data collected when bipolar diathermy was a relative new procedure, meaning that there may have been an associated learning curve.[326] Another cohort study,[326] that utilised data from the CREST study,[246] reported that the number of sites of bipolar diathermy was associated with failure. The study[326] reported that participants who had fewer than three sites coagulated on each fallopian tube had a cumulative 5-year probability of failure of 12.9/1000 (95% CI 0.0–38.0), whereas women with three or more sites coagulated had a cumulative 5-year probability of failure of 3.2/1000 (95% CI 0.0–9.6). The authors also highlight that the extent of fallopian tube desiccation achieved via bipolar diathermy is, in large part, determined by the amount of energy utilised, the duration of the current, and the wattage delivered to the fallopian tube.[326]

The CREST study[246] also demonstrated the increased probability of failure in younger women. The probability of failure with all methods was greater for women aged ≤28 years; this also held for women aged <34 years except in a cohort undergoing interval sterilisation with partial salpingectomy.[246] This finding is not surprising, as younger women are more fertile and have more fertile years remaining during which time pregnancy could occur.

A survey of UK gynaecologists in the year 2000 showed that the Filshie clip was the most widely used method for tubal occlusion, being used by 82% of gynaecologists.[327] Available data for the Filshie clip[272,328,329] (which was not available in the USA at the time of the CREST study[246]) suggest a far lower failure rate than reported for laparoscopic methods in the CREST study. The Filshie clip gives a crude failure rate of 2–3/1000 women at 10 years, although no cumulative rates were presented. However, these series have depended on experienced operators performing all surgery. In the CREST study,[246] where higher failure rates were reported, many of the procedures were carried out by residents (the USA equivalent of speciality trainees) and may more accurately reflect common practice. Currently, the longest period of follow-up data available is between 10 and 15 years.[272] The failure rate after this time is not expected to change substantially, but any woman's lifetime risk will probably depend upon her age at sterilisation and the subsequent number of fertile years during which she is at risk of pregnancy.

Although there are a number of case reports of Filshie clip migration and expulsion, at times remote from the operation, occurrences are rare with no reported serious sequelae. After the crushed tissue under the clip necroses, the tube may eventually divide but the healed stumps remain closed. As peritonealisation of the clip varies individually, the tube may weaken before peritoneum grows over the clip, which may then fall off. There are no reports of this leading to sterilisation failure.[330]

B Late failures resulting in a pregnancy can occur any time after tubal occlusion.

B The lifetime risk of laparoscopic tubal occlusion failure, using a mix of occlusion methods, is estimated to be 1 in 200.

B The longest period of available follow-up data for the most commonly used method in the UK, the Filshie clip, suggests a failure rate of 2–3 per 1000 procedures at 10 years.

3.8 Ectopic pregnancy

Pregnancies following female sterilisation are rare but when they do occur, there is an increased risk of ectopic gestation. The incidence of ectopic pregnancy post-female sterilisation varies depending on the method used to occlude the fallopian tubes.[242,246,256,267,268,272,331–339] The CREST study[246] estimated the 10-year cumulative probability of ectopic pregnancy as being 7.3/1000 procedures (95% CI 5.0–9.6). A more recent cohort study,[340] with a population of 44 829, estimated the 10-year cumulative probability to be 2.4/1000 procedures (95% CI 1.9–3.0).

The CREST study[341] reported a 10-year cumulative probability of ectopic pregnancy associated with bipolar diathermy of 17.1/1000 procedures (95% CI 9.8–24.4) and 7.3/1000 procedures (95% CI 1.6–12.9) associated with the spring-loaded clip. The study[341] did not report statistically significant associations for any other method of tubal occlusion. A cohort study[340] reported an adjusted hazard ratio (HR) of 5.65 (95% CI 2.38–13.40; $p<0.001$) for ectopic pregnancy associated with diathermy and HR 14.57 (95% CI 3.50–60.60; $p<0.001$) partial salpingectomy performed via laparoscopy, when compared to unspecified destruction or occlusion of the fallopian tubes. The CREST study[341] reported a relative risk (RR) of 10.0 (95% CI 2.2–45.1; $p<0.001$) of ectopic pregnancy associated with bipolar diathermy and an RR of 7.4 (95% CI 1.2–44.7; $p<0.001$) for interval partial salpingectomy, when compared to postpartum partial salpingectomy. Neither study reported any statistically significant risks associated with any other methods of tubal occlusion.

Although women who have been sterilised are at a lower risk of ectopic pregnancy when compared to non-sterilised women (because they are protected from all pregnancies), the proportion of ectopic to intrauterine pregnancies is high when female sterilisation fails. Therefore, women should be advised of the symptoms of ectopic pregnancy (e.g. shoulder-tip pain, diarrhoea or painful defecation). As the overall risk is low, a previous history of ectopic pregnancy is not a contraindication to sterilisation in UKMEC.[5]

B Women should be informed that if tubal occlusion fails, the resulting pregnancy may be ectopic.

✓ Women should be informed about symptoms of ectopic pregnancy, and the possibility of ectopic pregnancy should be considered in women who have undergone sterilisation and present with abdominal pain, especially in connection with missed periods.

4 Hysteroscopic sterilisation

4.1 Overview

Transcervical sterilisation is usually performed without the need for anaesthesia and involves a hysteroscope being inserted into the vagina and cervix vaginoscopically or by using a speculum. Flexible micro-inserts (Essure) are then passed through the hysteroscope and inserted into the proximal section of each fallopian tube. The micro-inserts elicit a benign tissue response (fibrosis) resulting in the permanent occlusion of each tube after approximately 3 months. Additional contraception is required until successful placement of the micro-inserts and tubal occlusion is confirmed by X-ray, ultrasound scan or HSG at least 3 months after the procedure. More detail on confirmatory imaging post-hysteroscopic sterilisation is outlined in the corresponding section of this guideline (page 37). In addition to Essure, other micro-inserts have been used/developed.

Two main types of micro-insert are examined in the literature: the Essure device (Bayer) and the Adiana® device (Hologic Inc.) The Adiana device was licensed for use in the USA by the Food and Drug Administration (FDA) in 2009. However, following concerns regarding sales/market share, as well as a legal dispute between the manufacturer of Essure and Hologic Inc., the Adiana micro-insert was withdrawn from sale and is no longer manufactured.

The Essure device (ESS205) (Figure 3) was licensed for use in the USA by the FDA in 2002[342] and is comprised of the micro-insert and a delivery catheter. The Essure micro-insert is 40 mm in length with a diameter of 0.8 mm and has a stainless steel inner coil, a nickel titanium (nitinol) elastic outer coil and polyethylene (PET) fibres.[343] Once inserted the outer coil expands to lock the micro-insert in place and the PET fibres elicit fibrosis (Figures 4 and 5).[343] A modified Essure micro-insert (ESS305) was introduced in 2007.[344]

Figure 3: The Essure ESS305 micro-insert. © Bayer. Figure reproduced with the kind permission of Bayer.

Figure 4: The Essure ESS305 micro-insert *in situ* before fibrosis. © Bayer. Figure reproduced with the kind permission of Bayer.

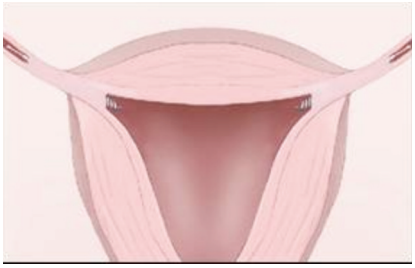

Figure 5: The Essure ESS305 micro-insert *in situ* after fibrosis. © Bayer. Figure reproduced with the kind permission of Bayer

4.2 Anaesthesia and analgesia for hysteroscopic sterilisation

A limited quantity of high-quality evidence, including a systematic review,[345] two RCTs,[346,347] a case-control study[348] and case series,[349] was identified which examined anaesthesia and analgesia for hysteroscopic sterilisation. The systematic review[345] and RCTs[346,347] concluded that the use of a cervical block with lidocaine, as opposed to saline, resulted in some reduction in pain during hysteroscopic sterilisation but that there was insufficient evidence to recommend its routine use. These studies highlighted that a cervical block was ineffective in reducing pain associated with the placement of micro-inserts in the tubal ostia and that participants frequently identified the injection and micro-insert placement as the most painful aspects of the procedure.[345–347] A case-control study[348] and case series[349] also concluded that the procedure can be carried out without the need for local anaesthesia and was well tolerated by participants. However, the use of cervical block may be effective if dilatation of the cervix is required during hysteroscopy.

The systematic review[345] also examined the use of intravenous (IV) sedation and oral analgesia. It concluded that when compared with oral analgesia, IV sedation reduced the pain associated with the insertion of the second micro-insert but there was insufficient evidence to recommend one intervention over another. IV sedation also has associated risks (e.g. inadvertent anaesthesia) and anecdotal evidence suggests that its use during hysteroscopic sterilisation is not common practice in the UK. A cohort[350] and case-control study[351] both reported conflicting outcomes regarding the use of NSAIDs, which may reduce tubal spasms. The cohort study[350] reported that the use of NSAIDs was associated with increased micro-insert placement success (OR 2.6; 95% CI 1.1–5.8), whereas the case-control study[351] reported a non-statistically significant result (OR 1.71; 95% CI 0.22–68.8). None of the studies identified on any aspect of hysteroscopic sterilisation advocated the use of general anaesthesia, and all studies reported using either oral analgesia or IV sedation prior to the insertion of micro-inserts. The micro-insert manufacturer's instructions for use recommend the administration of NSAIDs, either orally or via suppository, 1–2 hours before the procedure.[44]

A systematic review[352] was identified that examined pain associated with the use of a vaginal speculum in comparison to vaginoscopy for outpatient hysteroscopy. Following meta-analysis, vaginoscopy was associated with reduced pain when compared to the use of a speculum [standard mean difference (SMD) –0.44; 95% CI –0.65 to –0.22; I^2 = 58%], and that there was no significant difference in the number of failed procedures (p=0.38).[352]

A There is insufficient evidence to recommend the routine use of oral NSAIDs or intravenous sedation for hysteroscopic sterilisation. The use of such pharmacological agents should be based on clinical judgement.

A Local anaesthesia is not routinely required prior to hysteroscopic sterilisation as it does not alleviate pain associated with the placement of micro-inserts into the fallopian tubes. However, local anaesthesia should be used when dilatation of the cervix is necessary to aid passage of the hysteroscope into the uterine cavity.

4.3 Insertion of the micro-inserts

A significant volume of evidence was identified that examined successful placement of intra-fallopian micro-inserts/implants (Essure). The systematic review,[343] cohort studies,[342,350,351,353–363] case-control studies[348,364] and case series[365–372] identified were broadly consistent, reporting successful micro-implant insertion rates of between 81% and 100% following a maximum of two insertion attempts typically in an outpatient setting. There is broad consensus that insertion of the micro-inserts should be scheduled during the proliferative phase of the menstrual cycle where possible.[350,351,359–361,365,367,368,371] Advantages of insertion during the proliferative phase are that a negative pregnancy test would rule out pregnancy, and the endometrium would not be thickened, which may facilitate visualisation of the tubal ostia. The likelihood of successful micro-insert placement is increased in theory if the procedure is scheduled during the

proliferative phase of the menstrual cycle.[354,355] Many of the studies identified had small sample sizes and were based at a single site, meaning that they may have been underpowered, subject to bias, and are non-generalisable. Additionally, some of the research identified was commissioned by the micro-insert manufacturer.

Caution must be applied when attempting to compare the successful insertion rates reported by individual studies as it is not always clear which version of the Essure implant was used (i.e. ESS205 or ESS305). Many of the studies identified may have been subject to methodological flaws. Available evidence is mixed regarding the level of operator skill and experience required to competently perform Essure insertion.[342,350,356,358,366,373] Most studies suggest that there is a learning curve associated with the successful placement of micro-inserts but that clinicians experienced in hysteroscopy can quickly acquire the necessary skills.

Pregnancy should be excluded before hysteroscopic sterilisation. The same criteria for excluding pregnancy for other methods of tubal occlusion apply to hysteroscopic sterilisation and are outlined in Appendix 3. The manufacturer of Essure states that until tubal occlusion is confirmed, typically 3 months after the procedure, additional contraception must be used.[374]

The manufacturer does not recommend the continued use of intrauterine contraception as a contraceptive method following insertion of the Essure micro-insert until successful bilateral placement has been confirmed.[44] However, a limited volume of evidence was identified which examined Essure insertion in women with a Cu-IUD *in situ*. A case series[375] that examined micro-insert insertion in women with a Cu-IUD *in situ* reported that successful bilateral insertion was achieved in 71.4% (20/28) of participants without the need for the Cu-IUD to be removed. A total of eight (28.6%) women had the Cu-IUD removed in order to facilitate successful Essure insertion because the Cu-IUD either restricted visualisation or access to the fallopian tubes, and were advised to use additional contraception. The authors stated that there were no major complications observed during the procedures and that that there was no relationship between the type of Cu-IUD and insertion difficulties. At 3 months post-procedure, 92.8% (26/28) of the participants had correct bilateral placement and occlusion and no pregnancies were reported.[375] These conclusions were consistent with those of a small-scale case series[376] that examined Essure insertion in six women with a Cu-IUD in place.

A small-scale case-control study[377] that examined Essure insertion in women with a LNG-IUS *in situ* was also identified. The study examined micro-insert insertion in 12 women with an LNG-IUS in place compared with 36 women without. The authors concluded that the Essure micro-insert could be safely inserted with an LNG-IUS *in situ*.[377]

B The incidence of unsuccessful placement of intra-fallopian implants is reported as ranging between 0% and 19%, following up to two attempts in an outpatient setting.

B The likelihood of successful micro-insert placement is increased if the procedure is scheduled during the proliferative phase of the menstrual cycle.

C Clinicians should undergo a period of supervised training to become proficient in the hysteroscopic insertion of micro-inserts.

B Following sterilisation via hysteroscopy and the insertion of intra-fallopian micro-inserts, additional contraception must be used until either successful insert placement and/or tubal occlusion are confirmed, depending upon the confirmatory test employed.

✓ Hysteroscopic sterilisation may be safely and effectively undertaken when intrauterine contraception is already *in situ* (outside the terms of the manufacturer's instructions for use). Women should be advised to use additional contraception or abstain from intercourse for 7 days before the procedure in case the intrauterine device needs to be removed to gain access to the fallopian tubes.

4.4 Intraoperative complications with tubal micro-inserts

Studies that examined the placement of the Essure micro-insert have reported a low level of intraoperative complications, such as vasovagal response[350,353,354,356,359,360,365,371] and pain during the procedure.[350,353,354,359,363] Such complications were self-limiting and generally resolved on the day of the procedure. Difficulties such as tubal spasm,[351,354,356,358,365,371] uterine pathology[348,350,351,354,357,358,360,365,371] and obstructed view[348,350,351,356–358,365] are also reported in the literature. Obstructed view of the tubal ostium was the only factor that was identified as being significantly associated with failure (OR 7.5; 95% CI 7.23–41.21; $p<0.001$).[351] Another study suggested that a previous history of an STI was associated with failure to insert the micro-insert (OR 2.64; 95% CI 1.01–6.90; $p=0.048$).[357] In some instances, intraoperative complications meant that the procedure was not attempted or was unsuccessful on the first attempt; however, this was encountered in a minority of women.[348,350,351,354,356,358,360,365,367,371] A small number of intraoperative implant failures are also reported,[354,356,371] although these failures predominately relate to the previous version of the Essure micro-insert (i.e. ESS205).

B Hysteroscopic sterilisation via the placement of intra-fallopian micro-inserts is associated with a low level of intraoperative complications in a minority of patients.

4.5 Postoperative complications of hysteroscopic sterilisation

There is a paucity of available long-term follow-up data for Essure and many studies only followed participants until the tubal occlusion confirmation test carried out 3 months post-procedure. Some studies have reported no postoperative complications.[348,358,361,369] However, other studies[343,350,353,354,356,359,360,365,367] have reported postoperative complications in a minority of participants; with postoperative pain being the most frequently reported complication.[343,353,354,359,360,367] There is consensus that postoperative pain generally resolved, for most women, within 1–2 days following the procedure. However, a systematic review reported that in three cases the pain was deemed to be so severe that the insert was subsequently removed.[343] A limited number of case reports[378–382] were also identified that are consistent with this finding, and detail the removal of the Essure micro-insert in eight patients due to persistent pain following the procedure.

Post-procedural bleeding, characterised as either spotting or light bleeding, is also reported in three cohort studies[350,354,360] and the systematic review.[343] The literature is consistent in stating that postoperative bleeding resolved after approximately 3 days[359,360] and by a maximum of 15–26 days[354,356] post-procedure. Changes to menstrual pattern/bleeding were also reported; however, there is no consensus regarding a clear pattern of change.[354,360,365] These results may be subject to confounding as many of the participants observed utilised hormonal methods of contraception, such as the LNG-IUS, which alter menstrual pattern. Therefore, upon cessation of such methods some participants may have experienced a return to their unaltered, 'natural' menstrual pattern.

Other postoperative complications are also reported as affecting a minority of participants, specifically: nausea,[343,365] stomach cramps,[343] dyspareunia,[354,360] urinary tract infection,[360] nickel allergy,[353,359,383–385] vaginal discharge[360] and PID.[359] A small number of micro-insert expulsions,[350,353,358,359,364] micro-insert migration,[353,358,359] and a low number of perforations,[343,359,364,386–388] as well as the incorrect/unsatisfactory placement of the Essure device,[343,353,359,366] are also reported. A case report was also identified that reported the expulsion of a single micro-insert during menses 14 days after successful bilateral insertion/occlusion was confirmed by HSG 3 months post-procedure.[389] Additionally, case reports[390–392] were identified that reported two cases of small bowel obstruction 4 weeks after the insertion of the micro-inserts.

B Hysteroscopic sterilisation via the placement of intra-fallopian micro-inserts is associated with a low level of postoperative complications. The majority of post-procedural adverse events are self-limiting, with most women able to return to daily activities 1–2 days following the procedure.

✓ Hysteroscopic sterilisation with micro-inserts is contraindicated if there is documented proven patch test for nickel allergy.

4.6 Post-procedure imaging following micro-insert placement

A limited volume of evidence was identified that examined confirmatory tests to confirm successful micro-insert placement and tubal occlusion. Pelvic X-ray, transvaginal ultrasound scanning (TVUSS), hysterosalpingo-contrast sonography (HyCoSy), CIS and HSG have been assessed.[362,366,370,372,393–401] The evidence was consistent in recommending the necessity of image testing to confirm tubal occlusion; however, different studies have different outcome measures, thus making it difficult to form a specific recommendation based on the available evidence.

The licence for use of Essure in the USA currently stipulates that image testing must be conducted via HSG.[44,402] Some of the literature[370,396,400] states that HSG should be used as other imaging methods may be able to confirm successful micro-insert placement but cannot confirm tubal patency.

In Europe, Essure received a CE mark in 2001 and the licence for use states that TVUSS, pelvic X-ray or HSG can be used to confirm placement of micro-inserts.[44] Studies have suggested that micro-insert placement be assessed initially via TVUSS[362,398] or X-ray,[362] and if the results of these assessments is unclear then HSG can be performed,[362,398] thus reducing the costs, inconvenience and discomfort associated with HSG examination. A large-scale Dutch cohort study[403] assessed confirmatory imaging testing based on the difficulty of micro-insert insertion and developed a protocol. The study reported that TVUSS could be safely employed in cases where insertion was deemed to be straightforward/uncomplicated but that HSG should be used in patients where there was a difficult micro-insert insertion. The study stated that TVUSS when compared to HSG had sensitivity of 50%, specificity of 95% and a positive predictive value of 99%.[403] The authors concluded that the adoption of TVUSS was less invasive than HSG and X-ray.[404] Bayer[44] state that pelvic X-ray or TVUSS may be used as the first-line confirmatory test in Europe but that HSG should be used in the following circumstances:

- there was concern regarding possible perforation due to either excessive force and /or a sudden loss of resistance at insertion
- there was difficulty identifying the tubal ostia due to anatomical variation or technical factors (e.g. example, poor distension, suboptimal lighting or endometrial debris
- health professional uncertainty regarding micro-insert placement at insertion
- procedure time >15 minutes (from insertion to removal of hysteroscope)
- micro-insert placement with 0 (zero) or >8 trailing coils (i.e. inside the uterine cavity)
- unusual post-procedural pain, either transient or persistent, or onset at some later point post-procedure, without any identifiable cause
- if X-ray or TVUSS is equivocal or unsatisfactory.[44]

Further information regarding the satisfactory placement and confirmatory imaging is available via the manufacturer's Essure Instructions for Use documentation.[44]

There is a paucity of evidence examining compliance with post-procedural testing. ACOG guidance states that compliance rates vary between 12.7% and 86.4%.[402] A retrospective case series[404] examined a number of variables and their association with compliance with first HSG confirmatory test in a cohort of women attending a hospital in the USA. The study reported that sociodemographic variables associated with adherence with HSG were: lower education level (p=0.01); not working outside the home (p=0.04); being married (p<0.0001); lower gravidity (p=0.03); fewer lifetime sexual partners (p<0.0001); no history of STI (p<0.01); Hispanic ethnicity (p<0.0001); Spanish as primary language (p<0.0001); living further from the clinic (p<0.01).[404] However, it should be noted that HSG confirmatory testing in the USA has an associated cost that may adversely affect compliance reported in some studies. Anecdotal evidence for the UK suggests an approximate confirmatory testing attrition rate of 10%. A Dutch cohort study that assessed correct placement using TVUSS had a compliance rate of 98%.[403]

B A confirmatory imaging test should be undertaken 3 months after the insertion of intra-fallopian micro-inserts. This may be via X-ray or transvaginal ultrasound scanning (TVUSS) in the first instance, followed by hysterosalpingogram (HSG) in selected patients where X-ray/TVUSS cannot confirm satisfactory placement.

B HSG should be used as a first-line test where the hysteroscopic procedure was considered suboptimal, according to local protocols.

B HSG can be used as a routine test to confirm tubal occlusion following insertion of intra-fallopian micro-inserts.

✓ Women who do not attend for confirmatory testing should be informed that they need to continue using additional contraception until tubal occlusion is confirmed.

4.7 Training issues in post-procedure imaging of micro-inserts

Confirmatory image testing to confirm successful placement and/or tubal occlusion following insertion of the Essure micro-insert requires health professionals to be adequately trained in the confirmatory imaging technique being employed (i.e. X-ray, TVUSS or HSG). Furthermore, health professionals should be adequately trained in recognising micro-inserts using confirmatory imaging techniques that are used locally. Depending on the technique that is used, health professionals must also be able to confirm satisfactory micro-insert placement and/or tubal occlusion. A number of pregnancies[342,359,396,403,405] (i.e. failures) were reported in the professional literature that were attributed to misinterpretation of confirmatory testing and erroneous advice that the micro-insert could be relied upon for contraception.

✓ Training in interpretation and performance of confirmatory imaging techniques specifically for sterilisation using Essure is essential, as a number of pregnancies have been attributed to the misinterpretation of images.

4.8 Efficacy of micro-inserts

The majority of the literature identified that examined hysteroscopic sterilisation via insertion of the Essure micro-insert does not report any pregnancies during the study period.[348,350,354,358,360,364,370,371] However, because it is a relatively novel procedure there is a paucity of longitudinal data available, and many studies cease follow-up once confirmatory testing has taken place.

The majority of reported pregnancies in the literature occurred in women who had either no follow-up confirmatory testing or inadequate confirmation of tubal occlusion or micro-insert placement.[405] Bayer state that the Essure micro-insert has an effectiveness rate of 99.83% at 5 years post-insertion (1.7 pregnancies per 1000 women).[374] A high-quality cohort study[359] calculated that Essure had a pregnancy rate of 0.09% after successful insertion. Another cohort study[342] reported three pregnancies from a cohort of 884 at confirmatory test. A case series[368] with a 5-year follow-up period reported three pregnancies following insertion of Essure in a cohort of 1200 women, which equates to a 5-year effectiveness rate of 99.75%. Pregnancies are also reported in a number of case reports following insertion of the Essure micro-insert.[406–408] A systematic review[343] stated that a total of 64 pregnancies from a total of 50 000 procedures were reported by the manufacturer between 1997 and 2005. A cohort study[354] with a 3-year follow-up period states that the Essure micro-insert had a 1-year effectiveness rate of 100% (95% CI 98.47–100) and a 2-year effectiveness rate of 100% (95% CI 98.45–100). Another systematic review[405] concluded that pregnancy following insertion of the Essure micro-insert is rare among women who complied with 3-month confirmatory testing.

B Available evidence suggests that tubal occlusion by intra-fallopian micro-insert has a low associated failure rate of approximately 1 in 500 at 5 years of follow-up; this includes cases where luteal-phase pregnancy or non-adherence with post-procedural instructions was documented.

4.9 Patient satisfaction with hysteroscopic sterilisation

A number of the cohort studies[350,353,354,358,360,361,363,366,409] and case studies[365,371] were identified which examined patient satisfaction with the Essure procedure and tolerance/comfort of wearing the micro-insert. The literature is consistent in reporting high levels of satisfaction with the procedure[350,353,358,360,361,366,409] and comfort of wearing the micro-insert.[350,354] Furthermore, the majority of the participants who took part in the reported studies would recommend the procedure to a friend or relative.[360,361,363,365,371,409]

B Available evidence suggests that the use of intra-fallopian micro-inserts for tubal occlusion is a procedure that is well tolerated by the majority of women and results in good long-term satisfaction in terms of comfort and tolerance of the insert.

4.10 Hysteroscopic sterilisation and other procedures

4.10.1 Magnetic resonance imaging

The manufacturer reports that the Essure micro-insert was determined as being magnetic resonance (MR)-conditional[410] and that the micro-insert is MR safe and radiopaque but may cause artefacts in pelvic imaging.[44] Bayer state that women wearing the Essure micro-insert can safely have a magnetic resonance imaging (MRI) scan immediately after placement of the insert providing there is a static field of 3 Tesla or less and there is a maximum spatial gradient of the magnetic field of 720 Gauss/cm or less.[44] Robust *ex vivo* testing of the Essure micro-insert was carried out using standardised methods to assess movement and heating. Two laboratory studies[410,411] were identified which reported that results from standardised testing methods indicated that there were no magnetic field interactions,[410,411] that induced electrical currents were low,[410] that the highest temperature changes observed was ≤0.6°C,[410] and that artefact occurrence was relatively low.[410] The author concluded that diagnostic MRI should therefore not be impaired by the Essure micro-insert unless the area of interest was the exact same position as, or in close proximity to, the location of the micro-insert.

4.10.2 Intrauterine procedures

The Essure manufacturer states that women who have had micro-inserts fitted may, at a later date, be offered intrauterine procedures that utilise electrical energy.[44] They state that electrocautery should be avoided in surgical procedures that are carried out on the uterine cornua and fallopian tubes. Furthermore, they state that other pelvic procedures should avoid electrocautery within 4 cm of the Essure micro-insert, as there may be risks associated with such procedures that are as yet unidentified.[44]

The Essure micro-insert manufacturer also states that any uterine procedure, such as endometrial biopsy, D&C, hysteroscopy (either operative or diagnostic), including endometrial ablation, may potentially interrupt the ability of the micro-insert to prevent pregnancy.[44] Furthermore, the manufacturer states that there may also be as yet unidentified risks associated with such procedures.[44]

4.10.3 Endometrial ablation

Women undergoing endometrial ablation may wish to be sterilised as subsequent pregnancies may be complicated and thus are not recommended. The manufacturer of the Essure micro-insert states that endometrial ablation can be carried out immediately following the insertion/placement of micro-inserts using the Gynecare Thermachoice® uterine balloon system, Novasure® endometrial ablation system, and the Hydro Thermablator®.[44] There is consensus in the cohort study[412] and case series[413–416] identified in the literature that both procedures can be carried out in combination. However, there is no consistency between the studies relating to whether micro-insert placement should precede or follow endometrial ablation and the subsequent impact this may have on visualisation of the tubal ostia. Furthermore, the studies all

utilised a retrospective design, different ablation procedures, and sample populations drawn from single health care centres therefore they may potentially have been subject to systematic error. Moreover, there is a paucity of longitudinal follow-up data that assesses efficacy and complications. A case report[388] was identified that outlined a case of bilateral cornual abscess in a woman who had endometrial ablation with Essure micro-inserts *in situ*.

C Limited available evidence suggests that intra-fallopian micro-insert insertion can be carried out in combination with endometrial ablation.

4.11 Hysteroscopic sterilisation compared to other approaches

Evidence comparing hysteroscopic sterilisation with laparoscopy or laparotomy is scant. A cohort study[417] comparing hysteroscopic and laparoscopic sterilisation concluded that the majority of participants expressed satisfaction with both procedures. However, fewer hysteroscopic procedures were completed than laparoscopic procedures (81% vs 100%). Tolerance of the procedure was rated as good or excellent by 82% of the Essure group compared to 41% of the laparoscopy group (p=0.0002). Thirty-one percent of the hysteroscopic group reported moderate or severe pain compared to 63% of the laparoscopy group (p=0.08). Eleven percent of participants in the Essure group experienced problems immediately following the procedure compared to 27% of participants in the laparoscopy group.[417]

Satisfaction regarding the decision to go ahead with the procedure was higher post-procedure for the Essure group than the laparoscopy group (94% vs 80%).[417] The mean time spent in hospital was shorter for the Essure group than the laparoscopy group (188.7 vs 396.1 minutes; p<0.005). At 90 days post-procedure satisfaction in terms of speed of recovery in the Essure group was 100% compared to 80% in the laparoscopy group, and 21% of the hysteroscopic group experienced adverse events compared to 50% of the laparoscopy group.[417]

Another study[418] examined the reliability of laparoscopic compared with hysteroscopic sterilisation at 1 year, using a decision analysis, and suggested that laparoscopic sterilisation was more reliable. However, the study was subject to selection and sample bias, and the authors highlight the limitations of the model due to the uncertainty of the data used (i.e. the data were drawn from observational studies and the analysis also excluded the most recent 5 years of follow-up data for Essure).[418]

A more recent study,[419] by the same authors, utilised a Markov model and simulated cohort to compare the probability of pregnancy associated with laparoscopic and hysteroscopic sterilisation over a 10-year period. The study utilised data from the CREST study on laparoscopic sterilisation by bipolar diathermy or Falope rings and compared it with data extrapolated from published studies of hysteroscopic sterilisation with the Essure micro-insert. The authors concluded that at all time points, over the 10-year period, the initial and cumulative risk of pregnancy was higher for hysteroscopic sterilisation (96 per 1000 women) when compared to laparoscopic Falope ring (24 per 1000 women) or bipolar diathermy (30 per 1000 women).[419] Furthermore, the authors concluded that pregnancy risk associated with hysteroscopic sterilisation was accrued, predominately, over the course of the first year following the procedure. One-way sensitivity analysis identified that the risk of pregnancy was associated with the probability of a number of events (including non-compliance with HSG testing and use of additional contraception following the insertion of the Essure micro-inserts). Two-way sensitivity analysis suggested that higher bilateral micro-insert insertion rates (>98%) and maximum compliance with HSG (100%) and a drop in the efficacy of laparoscopic methods would result in an equivalent pregnancy risk of approximately 80 per 1000 women at 10 years.[419]

This recent study[419] was subject to a number of limitations: data from studies where Essure placement was not assessed by HSG were excluded, meaning the no European data were included, no adjustment was made for studies using the ESS205 and ESS305 micro-inserts, Filshie

clips were not included in the analysis because data for laparoscopic sterilisation was drawn from CREST which was undertaken over 10 years ago, and the potential for systematic error, especially selection and sample bias, was not clearly addressed. Moreover, the study[419] utilises a decision analysis/modelling approach that may mean that there were issues in the management of data (i.e. missing data, the assumptions made in order to construct the model, and residual confounding). Collectively, these limitations restrict the generalisability of the results reported.

It has also been suggested that hysteroscopic sterilisation may have advantages over laparoscopic sterilisation because it can be performed in an outpatient setting, thus avoiding the need for preoperative assessment, general anaesthesia, theatre time, and day surgery unit or ward and theatre staff.[420] A single cohort study[417] was identified that compared a hysteroscopic and laparoscopic approach. The study reported that procedural time was significantly longer for hysteroscopic sterilisation compared to laparoscopy (mean 13.2 vs 9.7 minutes; p=0.045). However, the authors concluded that if the time required for insertion of the Veress needle and insufflation during laparoscopy was included, total operative times would be similar for both approaches. The disadvantages of hysteroscopic techniques include the irreversibility and the need for additional contraception and confirmatory testing. There are also fewer long-term data on safety and efficacy compared with the longer-established laparoscopic methods of tubal occlusion.[420] As yet no RCTs have been published; therefore, there is insufficient evidence to recommend one technique over another.

4.11.1 Eligibility

The Essure micro-insert manufacturer[44] lists the following contraindications for use:

- uncertainty about ending fertility
- pregnancy or suspected pregnancy
- delivery or abortion of a second-trimester pregnancy <6 weeks before micro-insert insertion
- active or recent pelvic infection
- untreated acute cervicitis
- unexplained or severe vaginal bleeding
- known or suspected gynaecological malignancy
- known abnormal uterine cavity or fallopian tubes that impairs visualisation of the tubal ostia or that makes cannulation of the proximal fallopian tube difficult/impossible
- allergy to contrast media used for HSG
- women taking corticosteroids.[44]

While obesity and previous pelvic or abdominal surgery can affect the safety and success of laparoscopic sterilisation, the limited available evidence reported that hysteroscopic sterilisation is unaffected by weight/body mass index[342,350,360,365,421] or previous surgery.[350,365] A small-scale case series[365] reported that 60% (n=36) of study participants had a contraindication for laparoscopy, including diabetes mellitus or medical disease. The study reported that 95% (n=58) of the total cohort had the micro-insert successfully inserted and that 57 women had correct placement and tubal occlusion confirmed at the 3-month post-procedure imaging.[365]

A small cohort study[422] and case series[423] reported successful Essure insertion in women with severe cardiac disease for whom laparoscopy and pregnancy posed an elevated risk.

4.11.2 Cost effectiveness

A limited volume of evidence was identified that sought to examine the cost effectiveness of hysteroscopic compared to laparoscopic sterilisation.[343,421,424–427] The majority of this evidence utilised data from the USA health care system, meaning that no direct comparison with the UK was possible. However, there was consensus that the cost of the micro-inserts is the largest cost associated with the procedure; the retail price of the Essure micro-inserts in the USA is reported to be US$1299.[344] The prices for the micro-insert in the UK as quoted by the manufacturer are given in Table 2.

Table 2: Costs of the Essure® micro-insert supplied by the manufacturer.[428]

Quantity (units)	Price each*
1–4	£805
5–30	£680
31–50	£650
51–99	£640
100+	£630

*Exclusive of VAT, charged at 5%.

The current cost of a Filshie system (i.e. a pair of clips and an applicator) to the NHS is £137.[429]

The identified studies calculated costs associated with both laparoscopy and hysteroscopy using different criteria (e.g. confirmatory testing costs were not always included in the analysis). Some studies undertook a cost comparison of both approaches in the operating theatre, meaning that a comparison between the outcomes reported across studies could not be undertaken. However, on the basis of the available evidence there is consensus that hysteroscopic sterilisation using the Essure micro-insert was more cost effective than laparoscopic sterilisation.[343,421,424–427] The literature reported lower health professional staffing costs,[421,427] lower pharmacy costs[421] and less post-procedure recovery time and associated costs[421,424,427] for hysteroscopic sterilisation. It is possible that hysteroscopic sterilisation would be more cost effective than laparoscopic sterilisation in the UK, as hysteroscopic procedures could be carried out in an outpatient setting and laparoscopic procedures in a hospital setting under general anaesthesia. However, further research is required to further test this hypothesis in the UK health care system.

4.12 Long-term complications of female sterilisation

Hysteroscopic sterilisation, using the Essure micro-insert, is a relatively novel health care intervention and thus there is a paucity of longitudinal data available on adverse outcomes. The following sections are drawn from evidence relating to other conventional approaches/methods.

4.12.1 Ovarian cancer

Two meta-analyses,[430,431] cohort studies[432–434] and case-control studies[435,436] that examined the risk of ovarian cancer and tubal occlusion were consistent in their conclusions that there is not a positive association between tubal occlusion and the risk of developing ovarian cancer. Moreover, all of these studies[430–436] reported a decrease in the risk of ovarian cancer associated with tubal occlusion (i.e. a negative/inverse association), although the strength of this association was not found to be statistically significant in all studies.[432] One of the meta-analyses[430] and one of the cohort studies[433] also found that the negative association between tubal occlusion and ovarian cancer persisted for >10 years following the procedure, therefore suggesting that tubal occlusion is protective against ovarian cancer and that protection persists over time. The pathogenesis of ovarian cancer is incompletely understood and it is possible that other, as yet unknown, confounding factors are involved in the relationship

between tubal occlusion and ovarian cancer. Furthermore, the biological mechanism whereby protection is conferred via tubal occlusion is also unclear, meaning that analysis of the sequelae of tubal occlusion is inhibited.

A Tubal occlusion is not associated with an increased risk of ovarian cancer. Evidence suggests that the procedure may have a protective effect against developing ovarian cancer that persists over time.

4.12.2 Breast cancer

A limited volume of evidence that examined the association between tubal occlusion and breast cancer was identified. A high-quality meta-analysis,[437] case-control[438] and cohort studies[432,433,439] were consistent in concluding that there was no association between tubal occlusion and breast cancer. Furthermore, one of the cohort studies suggested that tubal occlusion may actually be associated with a statistically non-significant reduction in breast cancer risk.[432]

The mechanism by which tubal occlusion may confer protection against breast cancer is not fully understood. Furthermore, the studies identified may have been subject to bias and confounding and the method of tubal occlusion employed is seldom included in analysis.

A There is no available evidence of an association between tubal occlusion and breast cancer risk.

4.12.3 Cervical and endometrial cancer

There is scant available evidence examining the association between tubal occlusion and cervical and endometrial cancer. Two well-conducted cohort studies[432,433] were identified and there was consensus between these studies that tubal occlusion was not associated with an increased risk of cervical or endometrial cancer; in fact both studies reported a non-statistically significant decrease in risk.

Both of the identified studies may have been subject to bias, specifically a screening effect, especially the study[433] that reported an increased risk of cervical intraepithelial neoplasia (CIN3), which is generally asymptomatic, in tandem with a decrease in cervical cancer risk. The method of tubal occlusion was not included in analysis but it is probable that during sterilisation procedures, endometrial cancer would be more readily identified. Furthermore, a high proportion of women included in these studies would also have undergone cytology testing.

B Available evidence suggests that there is no association between tubal occlusion and cervical or endometrial cancer risk.

4.12.4 Other gynaecological cancers

Literature was identified that examined tubal occlusion, undertaken by non-hysteroscopic methods, and its relationship with other diseases and conditions, however existing evidence was insufficient to allow any recommendations to be drawn. A cohort study[440] examining the association between tubal occlusion and primary fallopian tube carcinoma (PFTC) reported that tubal occlusion appeared to confer some protection against PFTC but that the significance of this protection was not statistically significant. Furthermore, the authors stated that mechanism of this protective effect was unclear.

4.12.5 Sexual function

A cross-sectional study[441] of sexual problems in women following tubal occlusion reported that having a tubal occlusion was not associated with any specific sexual problems. Moreover, the authors stated that after controlling for potential confounders, tubal occlusion may be associated with some benefits in terms of sexual outcomes. Specifically, sterilised women were less likely than non-sterilised women to experience a lack of interest in sex, to 'take too long' to reach orgasm, to suffer from vaginal dryness, and to find sex unpleasurable. Sterilised women were more likely than non-sterilised women to experience high levels of sexual and relationship satisfaction as well as sexual pleasure.[441]

4.12.6 Menstrual and gynaecological symptoms

There is consensus in the findings of a systematic review,[442] case-control[443] and cohort studies[444,445] identified on tubal occlusion, not carried out by hysteroscopy, and changes in sex hormone levels when controlling for age. These studies consistently reported no significant changes in hormone level from baseline to follow-up following tubal occlusion.[442–445] The literature also suggests that there was no significant difference in hormone levels between sterilised and non-sterilised women.[443]

A systematic review[442] and cohort study[446] both reported that there is an elevated risk of hysterectomy in women who have undergone tubal occlusion in comparison to women whose partner has had a vasectomy or the fertile female population. However, there is no evidence to suggest that tubal occlusion *per se* leads to problems that necessitate hysterectomy. Furthermore, women who seek a surgical solution to contraception may also seek such a solution for their gynaecological complaints. It has been suggested in the literature that having tubal occlusion at a younger age is associated with a significantly increased risk of hysterectomy; however, a well-conducted cohort study observed an elevated risk for all ages.[446]

No evidence was identified in the literature that suggested that tubal occlusion, not carried out by hysteroscopy, is effective at improving menstrual symptoms. Early literature reported 'abnormal bleeding' in women following tubal occlusion,[447] and there was debate as to whether 'post-tubal sterilisation syndrome' existed. However, much of this early literature was methodologically flawed and subject to bias/confounding, inappropriate control, and a failure to account for prior history of gynaecological/psychological problems and contraceptive use.[447,448] A case series,[449] conducted in the 1970s, objectively measured menstrual blood loss before and after sterilisation. This was the only study identified in the literature that had the primary outcome measure of observing menstrual blood loss before and after sterilisation. The study observed a wide variation and distribution of results and concluded that menstrual blood loss was not associated with sterilisation. The majority of recent studies identified suggested that tubal occlusion did not result in the exacerbation of menstrual symptoms.[442,444,450] A cohort study reported that menstrual symptoms following tubal occlusion by Filshie clip were broadly similar to those reported by other occlusion methods.[451]

Women who have changed from hormonal methods of contraception to tubal occlusion will experience a return to 'natural' cycle/symptoms prior to the procedure. This may involve heavier and more uncomfortable menses among women with a history of unacceptable periods, currently, or prior to using hormonal contraception. The LNG-IUS, with similar contraceptive efficacy and reversibility but with proven relief of menstrual symptoms, should be considered before sterilisation.

B There is no evidence that tubal occlusion results in significant changes to hormone levels.

B Evidence suggests that there is an association between tubal occlusion and an increased risk of subsequent hysterectomy but there is no evidence of causation.

B Women may report worsening menstrual symptoms following tubal occlusion but there is no evidence to suggest a causal effect.

4.13 Female sterilisation reversal

Available evidence suggests that tubal re-anastomosis following sterilisation can result in an intrauterine pregnancy, however many of the studies identified were underpowered, lacked adequate follow-up, and were subject to bias. Furthermore, the generalisability of the findings may be limited as tubal re-anastomosis is a complex surgical procedure, carried out by a limited number of experts. Literature reviews[264,452] have reported that the overall intrauterine pregnancy rates following reversal of sterilisation range between 31% and 92%. Cohort studies,[51,453] a case series[454] and meta-analysis[455] that examined the reversal of sterilisation are consistent with this finding and the meta-analysis reported a mean pregnancy rate of 74.4%.[455] Available evidence suggests that the risk of ectopic pregnancy is increased following reversal of tubal occlusion.[453,454,456,457]

Studies[456,458,459] have reported that sterilisation method is associated with pregnancy rate following sterilisation reversal, with individuals sterilised with either clips or rings achieving high pregnancy rates. However, a cohort study reported that the method of sterilisation used (i.e. Pomeroy, Falope rings, Filshie clips) and the relationship with pregnancy rate was not statistically significant [hazard rate ratio (HRR) 1.2; 95% CI 0.44–3.5].[51] It has also been reported that higher success rates are achieved using microsurgical techniques.[452,458] The length of fallopian tube following re-anastomosis has also been identified by some case series[456,458] as being associated with successful pregnancy; this association was not observed in a cohort study[51] that concluded that fallopian tube length did not have a statistically significant effect on fertility. However, it should be noted that the estimates surrounding the effect size in these studies is wide, suggesting that they lack precision.

Conflicting outcomes are also reported in the literature in relation to age at reversal. It has been suggested by some studies[460–462] that a pregnancy rate of between 42% and 52% can be achieved in women aged <40 years. However, a cohort study reported a positive pregnancy test (HRR 0.32; 95% CI 0.12–0.88) for women aged ≥40 years when compared to women aged <40 years.[51] A case series[454] reported no pregnancies in women aged >40 years following sterilisation reversal; another study[457] reported no pregnancies in women aged >43 years. It has been suggested that *in vitro* fertilisation (IVF) may be the most efficacious intervention for women who wish to conceive following sterilisation; however, a systematic review[463] that sought to compare tubal re-anastomosis with IVF was unable to identify any evidence to assess.

The average rates of successful IVF treatment by age according to Human Fertilisation and Embryology Authority data are given in Table 3

Table 3: Success of *in vitro* fertilisation by patient age.[464] Adapted from data published by the Human Fertilisation and Embryology Authority.

Woman's age (years)	***In vitro* fertilisation average success rate (%)**	
	2009	**2010**
<35	32.3	32.2
35–37	27.2	27.7
38–39	19.1	20.8
40–42	12.7	13.6
43–44	5.1	5.0
≥45	1.5	1.9

Due to the mechanism of action of micro-inserts/implants the use of these devices for female sterilisation may render reversal impossible, meaning that IVF may be the only available option for women who wish a return to fertility. A case series[465] reported that the Essure micro-insert was successfully used for tubal occlusion in women with unilateral or bilateral hydrosalpinx. Following IVF a live birth rate of 63% per patient and 27% per transfer/cycle was observed.[465] An earlier case series[466] by the same author, which examined the same intervention, reported an ongoing pregnancy rate of 40% with 20% live births following one cycle of IVF. The studies identified were underpowered and subject to bias, however they suggest that IVF can be successful following tubal occlusion with micro-inserts.

A limited volume of evidence[378,380,382,467] was identified that reported the successful removal of the Essure micro-inserts due to suboptimal placement or pain. No studies were identified that examined the removal of micro-inserts in order to restore fertility.

It is important to note that at present female sterilisation reversal is not routinely offered by the NHS.

B Fallopian tube re-anastomosis following sterilisation can result in high postoperative patency rates, but may not result in pregnancy or a return to fertility.

✓ To date, reversal of sterilisation with micro-inserts cannot be achieved via fallopian re-anastomosis, therefore consideration should be given to *in vitro* fertilisation.

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APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

GUIDELINE DEVELOPMENT GROUP

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Mr John Scott – Researcher, Clinical Effectiveness Unit

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Declared Interests

Professor John Guillebaud receives consultancy and lecture fees from pharmaceutical companies, including Bayer, Consilient, Glaxo, HRA Pharma, Janssen and MSD.

Professor Michael Labrecque accepted stock options for Contravac Inc. in return for conducting a study of SpermCheck. Part of his income is obtained by performing vasectomies.

Ms Pauline Bagnall has received exhibition sponsorship from Lilly and Pfizer.

Dr Kay McAllister has received payment from pharmaceutical companies for educational meetings.

Dr Stephen Searle has received sponsorship from pharmaceutical companies for educational events.

FEMALE STERILISATION

Dr Soe Nyunt Aung – FSRH Clinical Standards/Education Committee representative; Specialty Trainee Community Sexual and Reproductive Healthcare, CASH Services, Beeston Village Surgery, Leeds

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Mr T Justin Clark – Consultant Obstetrician and Gynaecologist/Honorary Reader, Birmingham Women's Hospital, Birmingham

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APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

FEMALE STERILISATION (continued)

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Declared Interests

Professor John Guillebaud receives consultancy and lecture fees from pharmaceutical companies, including Bayer, Consilient, Glaxo, HRA Pharma, Janssen and MSD.

Dr Sebastiaan Veersema, Mr Andrew Baxter and Mr T Justin Clark have been consultants and Essure trainers for Bayer.

Dr Sue Milne's department receives endowment funds from Bayer for acting as a training centre for Essure.

Dr Farah Chaudhry has acted as a speaker at events sponsored by Bayer and MSD and was a member of an advisory board for Bayer.

Mr T Justin Clark is a scientific editor for *BJOG* and receives an honoraria for each article edited.

Patient Consultation

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

Clinical Effectiveness Unit (CEU) guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). The CEU guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialities, and user representation. In addition, the aim is to include a representative from the FSRH CEC, the FSRH Meetings Committee and FSRH Council in the multidisciplinary guideline development group.

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (Ovid version) (1996–2014); EMBASE (1996–2014); PubMed (1996–2014); The Cochrane Library (to 2014) and the US National Guideline Clearing House. The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for relevant systematic reviews, meta-analyses and controlled trials relevant to sterilisation. Previously existing guidelines from the FSRH (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Care Excellence (NICE). All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded as in the table on the inside front cover of this document using a scheme similar to that adopted by the RCOG and other guideline development organisations. The clinical recommendations within this guidance are based on evidence whenever possible. Summary evidence tables are available on request from the CEU. The process for the development of CEU guidance is detailed on the FSRH website (www.fsrh.org). The methods used in the development of this guidance (CEU Process Manual version 2.0) have been accredited by NHS Evidence.

APPENDIX 2: TYPICAL AND PERFECT USE FAILURE RATES OF CONTRACEPTIVE METHODS

The table below shows the percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception (USA data)[468]

Contraceptive method	Percentage of women experiencing an unintended pregnancy within the first year of use (%)	
	Typical use	Perfect use
No method*	85	85
Withdrawal	29	18
Diaphragm†	16	6
Condoms‡		
Female	21	5
Male	15	2
Combined pill and progestogen-only pill	8	0.3
Evra® patch	8	0.3
NuvaRing®	8	0.3
Depo-Provera®	3	0.3
Copper-bearing intrauterine device	0.8	0.6
Levonorgestrel-releasing intrauterine system	0.2	0.2
Implanon®	0.05	0.05
Female sterilisation (laparoscopic tubal occlusion)	0.5	0.5
Male sterilisation	0.15	0.10

*The percentages becoming pregnant in typical and perfect use are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.
†With spermicide.
‡No spermicide.

APPENDIX 3: CRITERIA FOR EXCLUDING PREGNANCY*

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

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

A pregnancy test, if available, adds weight to the exclusion of pregnancy, ***but only if performed at least 3 weeks since the last episode of unprotected sexual intercourse.***

NB. Health professionals should also consider if a woman ***is at risk of becoming pregnant*** as a result of unprotected sexual intercourse within the last 7 days.

*Adapted from *UK Selected Practice Recommendations for Contraceptive Use*.[469]

Questions for Continuing Professional Development

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

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

1 When undertaking a vasectomy, which of the following best reflects advice in relation to anaesthesia?

a. General anaesthesia is the preferred option for most men
b. Local anaesthesia warmed to 27°C should be used
c. Local anaesthesia with adrenaline should not be used
d. Local anaesthesia should be administered via a fine-gauge needle

2 Following vasectomy, the optimal time to undertake a post-vasectomy semen analysis is:

a. 8 weeks post-procedure
b. 12 weeks post-procedure
c. 16 weeks post-procedure
d. 24 weeks post-procedure

3 Which of the following best describes when special clearance to cease contraception can be given:

a. Less than 100 000 non-motile sperm/ml are observed in a fresh sample
b. Less than 100 000 non-motile sperm/ml are observed in a fresh or postal sample
c. Less than 1000 non-motile sperm/ml are observed in a fresh sample
d. Less than 1000 non-motile sperm/ml are observed in a fresh or postal sample

4 Which of the following methods for occluding the vasa deferentia is associated with the highest failure rate?

a. Division, cautery and excision
b. Division, ligation and excision
c. Division, ligation, excision and facial interposition
d. Division of the vas deferens

5 In a woman undergoing sterilisation, which of the following approaches is not recommended for tubal occlusion?

a. Culdoscopy
b. Laparoscopy
c. Mini-laparotomy
d. Transcervical

6 A woman calls for advice. She is due to undergo laparoscopic sterilisation in 7 days' time. She is on Day 5 of her hormone-free interval and had sex yesterday. What is the most appropriate advice to give her based on current guidance?

a. Advise emergency contraception and that the procedure should be delayed
b. Advise restarting combined oral contraception (COC) and continuing for at least 3 months post-procedure
c. Advise restarting COC and continuing until 7 days post-procedure
d. Advise using condoms from now until the procedure

7 A woman enquires if she needs to use her combined hormonal contraception following hysteroscopic sterilisation. Which of the following is the most appropriate advice to give?

a. No, it is effective immediately
b. Yes, but only for 7 days
c. Yes, for at least one more cycle
d. Yes, for at least 3 months

8 A woman presents with a history of heavy menstrual bleeding. She wants to know if it will be helped by sterilisation. What is the single most appropriate response?

a. Sterilisation has been shown to alleviate heavy menstrual bleeding
b. Sterilisation has been shown to be as effective as a levonorgestrel intrauterine system (LNG-IUS)
c. Sterilisation has been shown to be associated with a worsening of bleeding
d. There is no evidence to show it will improve bleeding patterns

9 A couple present enquiring about the risks associated with female sterilisation versus vasectomy. What is the most appropriate response?

a. Laparoscopy is associated with a lower failure rate than vasectomy
b. Laparoscopy is associated with a higher risk to the individual than vasectomy
c. Vasectomy carries a higher failure rate than laparoscopy
d. Vasectomy is associated with a higher risk of failure than hysteroscopic sterilisation

10 A couple attend the clinic for contraceptive advice. The woman is currently using the LNG-IUS for contraception but it is due to be replaced and they are considering sterilisation as an alternative option. She has a body mass index of 42 kg/m^2 and a history of heavy menstrual bleeding. Both partners are willing to be sterilised. What is the single most appropriate advice to offer this couple?

a. Due to her body mass index, she is not a candidate for sterilisation; therefore vasectomy is the best option.
b. Either partner could be sterilised but female sterilisation increases bleeding, therefore vasectomy is the best option.
c. Either partner could be sterilised but female sterilisation would be best as most women become amenorrhoeic.
d. Either partner could be sterilised but the LNG-IUS is also highly effective and would help with heavy menstrual bleeding.

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

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

Auditable Outcomes for Male and Female Sterilisation

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

Auditable Outcomes

1 There should be a recorded discussion of long-acting reversible contraception (LARC) methods of contraception with men and women requesting sterilisation. [Auditable standard 97%]

2 A valid written consent form should be obtained. [Auditable standard 97%]

3 Mechanical occlusion of the fallopian tubes by Filshie clips should be the method of choice for laparoscopic tubal occlusion. [Auditable standard 97%]

4 Following vasectomy or hysteroscopic sterilisation, there should be a record of the ongoing contraception advised until confirmation of sterility. [Auditable standard 97%]

5 Men who have undergone vasectomy or women who have undergone tubal occlusion should be provided with a post-procedural information leaflet that outlines appropriate self-care and instructions. [Auditable standard 97%]

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

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

The FSRH are unable to respond individually to all feedback. However, the FSRH will review all comments and provide an anonymised summary of comments and responses, which are reviewed by the Clinical Effectiveness Committee and any necessary amendments made.