Royal College of Obstetricians and Gynaecologists
Setting standards to improve women's health

GUIDELINE

Male and Female Sterilisation

Evidence-based Clinical Guideline Number 4

January 2004

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Abbreviations

APTT	activated partial thromboplastin time
BPAS	British Pregnancy Advisory Service
CI	confidence interval
CPTP	chronic post-vasectomy testicular pain
CREST	Collaborative Review of Sterilization
CWS	categoric word score
D&C	dilatation and curettage
DoH	Department of Health
EV	epididymovasostomy
FFPRHC	Faculty of Family Planning and Reproductive Health Care
fpa	Family Planning Association
GP	general practitioner
hCG	human chorionic gonadotrophin
HDL	high-density lipoprotein
HSG	hysterosalpingogram
ICSI	intracytoplasmic sperm injection
IM	intramuscular
IP	intraperitoneal
IPPF	International Planned Parenthood Federation
IUCD	intrauterine contraceptive device
IV	intravenous
IVF	*in vitro* fertilisation
LDL	low-density lipoprotein
LMP	last menstrual period
LNG-IUS	levonorgestrel-releasing intrauterine system
MDU	Medical Defence Union
MESA	myoepithelial sialadenitis
OR	odds ratio
PID	pelvic inflammatory disease
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	randomised controlled trial
RR	relative risk
TESE	testicular sperm extraction
VAS	visual analogue scale
VV	vasovasostomy
VWFAg	von Willebrand factor antigen
WBC	white blood cell count
WHO	World Health Organization
WMD	weighted mean difference

Development of the guideline

This guideline is an updated version of that published in 1999 and was funded by the Department of Health. It was revised by Kirsten Duckitt MRCOG, who worked as a clinical research fellow on the original guideline.

The development of the original guideline was supported by a multidisciplinary group with representation of all parties interested in the provision of sterilisation services. In this document 'the guideline development group' and 'the guideline group' refers to this group.

The development of this revised guideline was supported by the RCOG Guidelines and Audit Committee. The members were:

Miss MC Davies MRCOG (Chair)
Dr R Anderson MRCOG
Ms T Belfield (Consumer representative), Family Planning Association
Mrs C Dhillon, Head of Clinical Governance and Standards, RCOG
Miss LMM Duley FRCOG
Professor NM Fisk FRCOG, Chairman of the RCOG Scientific Advisory Committee
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Dr D Rajasingam MRCOG (Trainees' representative)
Ms W Riches, National Institute for Clinical Excellence
Mr IV Scott FRCOG
Mr MI Shafi MRCOG
Miss JM Thomas MRCOG, Director, National Collaborating Centre for Women's and Children's Health

Peer reviewers

The document was sent out to 16 peer reviewers, nine of whom were the members of the original guideline development group. Responses were received from 12 of these peer reviewers: Mr VP Argent, Ms T Belfield, Mr P Bowen-Simpkins, Mr JM Emens, Mr GM Filshie, Mr MR Gazvani, Professor J Guillebaud, Dr GC Penney, Mr JP Pryor, Dr SC Rowlands, Dr L Spooner, Ms B Walters.

Comments on the draft guideline posted on the RCOG website were received from Dr M Kittel, Dr S Pringle, Dr D Sokal and Dr E Willis.

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Chapter 1
Executive summary

Introduction

This summary is based on the evidence-based and referenced guideline developed by a multidisciplinary guideline group and published by the Royal College of Obstetricians and Gynaecologists (RCOG) after extensive peer review. It replaces the previous version published in 1999.

Sterilisation procedures were one of the first clinical areas to be subject to detailed review, because large numbers are performed on mainly healthy individuals at their request and because they attract a relatively high level of medico-legal activity. A study of the General Practice Research Database data suggests that in 1999 an estimated 47 268 tubal occlusions and 64 422 vasectomies were performed in England in the National Health Service and charitable sectors.

The guideline synthesises available evidence and expert opinion on current tubal occlusion and vasectomy procedures in the UK. Its primary purpose is to inform healthcare providers and purchasers, so that patients receive a high-quality service based on the best evidence available.

Identified articles were assessed on their methodology and the best evidence was used to form and support the recommendations; for more information on methods see Chapter 3.

The guideline points towards best practice but does not preclude alternatives that can be justified on the basis of the individual needs of the case or special skills and innovations that are subject to ethically approved research. Particular attention should be paid to the estimate of average lifetime postoperative pregnancy rates and the specific consent issues that should be addressed in every case.

Indications for sterilisation

There are no absolute contraindications to sterilisation of men or women, provided that they make the request themselves, are of sound mind and are not acting under external duress. A history should be taken and an examination should be carried out on every person requesting sterilisation (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).

All verbal counselling must be supported by accurate, impartial printed or recorded information (in translation, where appropriate and possible), which the person requesting sterilisation may take away and read before the operation (C).

As a precaution against the risk of later regret, additional care must be taken when counselling people under the age of 30 years or people without children (C). Care should also be exercised in

discussions with people taking decisions during pregnancy, or in reaction to a loss of relationship, or who may be at risk of coercion by their partner or family or health or social welfare professionals. Counsellors and advisers should also be aware and take account of cultural, religious, psychosocial, psychosexual and other psychological issues, some of which may have implications beyond fertility.

If there is any question of a person not having the mental capacity to consent to a procedure that will permanently remove their fertility, guidelines from the Official Solicitor make it clear that the case should be referred to court for judgment (C).

The doctor who performs or supervises a trainee performing a sterilisation takes responsibility for the procedure even when discussion, examination and consent were undertaken by other healthcare professionals. The operating doctor will need to ensure that the counselling, information exchange, history and examination have been completed and be satisfied that the patient does not suffer from concurrent conditions which may require an additional or alternative procedure or precaution (C). They should also take steps to avoid finding themselves responsible for a procedure to which they may have objections in principle or for which they lack the necessary competence. Locally agreed protocols based upon these guidelines should be agreed for the management and referral from primary care of patients requesting sterilisation.

Sterilisation procedures

Tubal occlusion

Tubal occlusion can be performed at any time during the menstrual cycle provided that the clinician is confident that the woman has used effective contraception up until the day of the operation. Otherwise the operation should be deferred until the follicular phase of a subsequent cycle. The woman should be advised to use effective contraception until her next menstrual period (B).

Tubal occlusion should be performed after an appropriate interval following pregnancy, wherever possible. Women who request tubal occlusion postpartum or following abortion should be made aware of the increased regret rate and the possible increased failure rate (B). If tubal occlusion is to be performed at the same time as a caesarean section, counselling and agreement should have been given at least one week prior to the procedure (C).

A pregnancy test must be performed before the operation to exclude a pre-existing pregnancy. However, a negative test does not exclude the possibility of a luteal phase pregnancy. Routine curettage at the time of tubal occlusion, in order to prevent a luteal phase pregnancy, is not recommended (B).

Laparoscopic approach

Where equipment and trained staff are available, the laparoscopic approach to the fallopian tubes is quicker and results in less minor morbidity compared with mini-laparotomy (A). The procedure should be performed as a day case wherever possible (C).

Although general anaesthesia is usually used in the UK, local anaesthesia is an acceptable alternative (A). Topical application of local anaesthesia to the fallopian tubes should be used whenever mechanical occlusive devices are being applied, whether under a general or local anaesthetic (A).

Mechanical occlusion of the tubes by either Filshie clips or rings should be the method of choice for laparoscopic tubal occlusion (A). The routine use of more than one Filshie clip is not recommended (C). Diathermy should not be used as the primary method of tubal occlusion because it increases the risk of subsequent ectopic pregnancies and is less easy to reverse than mechanical occlusive methods (C).

All equipment involved in performing tubal occlusions should be properly maintained. Laparoscopic tubal occlusion should only be performed at a site where there are facilities to perform a laparotomy safely (✔). Trainees should perform at least 25 supervised laparoscopic tubal occlusions before operating without supervision (C).

Other approaches

When a mini-laparotomy is used as the method of approach for an interval sterilisation, any effective surgical or mechanical method of tubal occlusion can be used (B). A modified Pomeroy procedure rather than Filshie clip application may be preferable for postpartum sterilisation using mini-laparotomy or at the time of caesarean section, as it leads to lower failure rates (B).

Hysteroscopic methods for tubal occlusion are still under evaluation and should only be used within the present guidance system for new surgical interventions (C). Culdoscopy should not be used as a method of approach (A).

Vasectomy

Except when technical considerations dictate otherwise, a no-scalpel approach should be used to identify the vas, as this results in a lower rate of early complications (A). Division of the vas on its own is not an acceptable technique because of its failure rate. Division should be accompanied by fascial interposition or diathermy (A). Clips should not be used for occluding the vas, as failure rates are unacceptably high (B). Irrigation of the vas during vasectomy does not reduce failure rates or reduce time to clearance (A).

Vasectomy should be performed under local anaesthesia wherever possible (C). Excised portions of vas should only be sent for histological examination if there is any doubt about their identity (C).

Practitioners who are being trained to perform vasectomies should make sure that their training conforms to that advocated by the Faculty of Family Planning and Reproductive Health Care (FFPRHC). Doctors with no prior experience should be supervised for ten operating sessions or 40 procedures, while doctors with relevant prior surgical experience should perform eight supervised procedures (C).

Although there are no explicit standards for the facilities required for vasectomy at general practice or other sites away from hospital, there are general guidelines for minor surgery in these situations. Operators performing vasectomies in primary care settings should be able to demonstrate appropriate training or experience and planned appropriate access to secondary care advice and services when necessary.

Specific consent issues

Information should be given and specific consent sought from each patient regarding the following aspects of sterilisation.

Men and women requesting sterilisation should be given information about other long-term reversible methods of contraception. This should include information on the advantages, disadvantages and relative failure rates of each method. Both vasectomy and tubal occlusion should be discussed with all men and women requesting sterilisation (C). Women in particular should be informed that vasectomy carries a lower failure rate in terms of post-procedure pregnancy and there is less risk related to the procedure (B).

Although people requesting sterilisation should understand that the procedure is intended to be permanent, they should be given information about the success rates associated with reversal, should this procedure be necessary (B). They should be informed that reversal operations, *in vitro* fertilisation (IVF) and intracytoplasmic sperm injection (ICSI) are rarely provided by the NHS (✔).

People requesting sterilisation should be informed that tubal occlusion and vasectomy are associated with failure rates and that pregnancies can occur several years after the procedure. They should be told of the lifetime risk of failure in general for tubal occlusion, which is estimated at one in 200. They should also be made aware that the longest period of follow-up data available for the most common method used in the UK, Filshie clips, suggests a failure rate after ten years of two to three per 1000 procedures. The failure rate for vasectomy should be quoted as approximately one in 2000 after clearance has been given (B).

In a small minority of men, non-motile sperm persist after vasectomy. In such cases, 'special clearance' to stop contraception may be given when less than 10 000 non-motile sperm/ml are found in a fresh specimen examined at least seven months after vasectomy, as no pregnancies have yet been reported under these circumstances (C).

Women should be informed that if tubal occlusion fails the resulting pregnancy might be an ectopic pregnancy (B). After tubal occlusion, they should be advised to seek medical advice if they think that they might be pregnant or if they have abnormal abdominal pain or vaginal bleeding (✔).

Women should be informed of the method of access and, should tubal occlusion be recommended in their case, the reasons for preferring this method over others, and the method to be used if the intended method fails for any reason (✔). They should be informed of the risks of laparoscopy and the chances of laparotomy being necessary if there are problems with laparoscopy, particularly if they are at increased risk through conditions such as previous abdominal surgery or obesity (B).

No precautions can be guaranteed to avoid early pre-existing pregnancy, which may be undetectable. Women should be advised to use effective contraception until the day of the operation and to continue to use it until their next menstrual period (B). Men should be advised to use effective contraception until azoospermia has been confirmed. The way in which azoospermia is confirmed will depend upon local protocols (C).

Women should be reassured that tubal occlusion is not associated with an increased risk of heavier or irregular periods when performed after 30 years of age**.** There is an association with subsequent increased hysterectomy rates, although there is no evidence that tubal occlusion leads to problems that require a hysterectomy. Data are limited on the effect on menstruation when tubal occlusion is performed on women under 30 years of age (B).

Men requesting vasectomy can be reassured that there is no increase in testicular cancer or heart disease associated with vasectomy. The association, in some reports, of an increased risk of being diagnosed with prostate cancer is at present considered likely to be non-causative. They should be informed about the possibility of chronic testicular pain after vasectomy (B).

Women should be advised after the operation of the method of tubal occlusion actually used and of any complications that occurred during the procedure (✔).

Further research and audit

A national register and audit of failed sterilisations is needed. Hospital-based registers of sterilisation procedure failures would assist this (C). A national register would enable more accurate information to be given to women in the UK concerning short- and long-term failure rates. Like other Confidential Enquiries, it will also serve to inform clinicians about areas of substandard care.

It should be regarded as good practice to conduct a retrospective audit of an individual operator's procedure outcomes if more than one pregnancy is noted following sterilisation procedures with a short separation in either time or number of procedures. Hospital-based registers of sterilisation procedure failures would assist this.

The guideline also indicates areas that require further research. Most of the graded recommendations are suitable for use as audit measures and purchasers and providers are encouraged to undertake local audits based on an appropriate selection.

Revision and amendment of the guideline is due in 2006.

Chapter 2
Introduction

Introduction

Sterilisation has become increasingly popular since the late 1960s and it is now the principal method of contraception used worldwide.[1] Approximately 190 million couples use tubal occlusion while 42 million men have had a vasectomy.[2] In 2001, 44% of women aged 45–49 years in Great Britain were using sterilisation of themselves or their partner as their method of contraception. Of women aged 16–49 years, 10% had been sterilised, and of men aged 16–64 years, 15% had undergone vasectomy.[3] A study of the General Practice Research Database[4] data suggests that in 1999 an estimated 47 268 tubal occlusions and 64 422 vasectomies were performed in England in the NHS and charitable sectors.

Sterilisation can be an empowering decision for the right person at the right time in their lives. However, its role needs to be re-evaluated as other long-term yet reversible methods of contraception become available. Both male and female sterilisation require a surgical procedure and are therefore unusual in that the indication for surgery is a request by the patient for social reasons and not a treatment prescribed by a doctor for a medical condition. In addition, its intended permanency means that the onus is on the healthcare practitioners involved to ensure that the patient has all the information required in order to make an informed choice.

Sterilisation procedures, both male and female, are a frequent subject of litigation.[5–7] Sexual Health Direct, the national help line run by the Family Planning Association (fpa), receives many calls suggesting that practice surrounding sterilisation provision is less than perfect. It is partly for these reasons that a national guideline was thought necessary.

Aim of the guideline

The aim of this guideline is to ensure that patients receive a high-quality service based on the best evidence available. The document provides recommendations to help gynaecologists, urologists, family planning doctors, general practitioners, family planning nurses and practice nurses to achieve this standard. It is designed primarily for use in the UK. It is likely that the recommendations would have to be adapted for use in low resource situations. Where possible, recommendations are based upon and explicitly linked to the evidence that supports them. Guidelines are 'systematically developed statements to assist decisions about appropriate care for specific clinical circumstances'.[8] Practitioners are expected to use the recommendations in the light of each particular patient's circumstances and the resources available.

Patient preferences

The initial request for sterilisation comes from the patient. Throughout the guideline, emphasis has been placed on the importance of information provision to patients and the importance of choice with regard to long-term contraceptive methods, whether tubal occlusion, vasectomy or some other method. The guideline group acknowledges that people seeking such procedures are not ill, but the term 'patient' has nevertheless been used where necessary in this guideline to maintain consistency.

Likely costs and benefits

The cost implications of implementing this guideline have not been considered in detail. It is anticipated that there will be health benefits for men and women in the form of better information and service provision.

Local adaptation, dissemination and implementation

It has been shown that local adaptation enhances the implementation of and compliance with guidelines.[9,10] It is anticipated that this national guideline will be used as the basis for such local adaptation, based on local resources, community needs and patterns of service provision. Local adaptation should take place in a multidisciplinary group, with collaboration between all interested parties that would be affected by the guidelines. It is essential that commissioners of healthcare, as well as general practitioners and specialists, take part in such a process. A variety of approaches may be necessary to disseminate and implement the local protocols, e.g. distribution of printed protocols to all local general practitioners, specialists and trainees, PGEA (Postgraduate Education Allowance) sessions for general practitioners, postgraduate meetings in hospitals and audit sessions.

Clinical audit

The patient record standard in Appendix 2 could be used to form the basis for audit.

Chapter 3
Methods

Evidence identification, review and synthesis

Search strategy

The aim of the literature review was to identify and synthesise relevant evidence within the published literature to enable recommendations to be based upon evidence wherever possible.

Individual searches were carried out for each topic of interest. For each subject, including foreign language publications, the electronic database MEDLINE (CD Ovid version) was searched for the time period January 1966 to December 2002. The searches were performed using relevant MeSH (Medical Subject Headings) terms and relevant text words. In addition, the electronic database EMBASE was searched for the period between 1974 and December 1997 to identify those publications (usually European) not indexed on MEDLINE. The Cochrane Library was also searched up to Issue 4, 2002, to identify published systematic reviews, meta-analyses and controlled clinical trials. Reference lists of non-systematic review articles and studies obtained from the initial search were trawled and journals in the RCOG library were hand-searched to identify articles not yet indexed. Experts on the guideline development group were also asked to identify key references. There was no systematic attempt to search the 'grey literature' (conference abstracts, theses, unpublished trials).

Reviewing the literature

For all subject areas, published systematic reviews or meta-analyses were used. If these did not exist, randomised controlled trials (RCTs) were obtained. If there were no published RCTs, or if randomised controlled trials were not appropriate for a particular clinical question, other appropriate experimental or observational studies were sought. Articles were initially retained after reading their title and abstract. The full papers were then obtained and read. Articles not relevant to the subject in question were rejected, as were articles where desired outcomes were not reported.

Synthesising the evidence

Identified papers were assessed on their methodology and the best evidence was used to form and support the recommendations (Tables 3.1 and 3.2). If a question could be answered by a good systematic review, meta-analysis or RCT, studies of weaker design were ignored. The evidence was synthesised using qualitative methods. These involved summarising the content of identified papers into brief statements that accurately reflected the relevant evidence. Quantitative techniques (meta-analyses), apart from those published, were not performed owing to time constraints and the difficulty of combining studies of various designs.

Table 3.1 Levels of evidence

Level	Evidence
1a	Evidence obtained from systematic review of meta-analysis of randomised controlled trials
1b	Evidence obtained from at least one randomised controlled trial
2a	Evidence obtained from at least one well-designed controlled study without randomisation
2b	Evidence obtained from at least one other type of well-designed quasi-experimental study
3	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
4	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Table 3.2 Forming recommendations

Grade of Recommendation	Evidence Level
A	Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels 1a, 1b)
B	Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of the recommendation (evidence levels 2a, 2b, 3)
C	Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level 4)
Good practice points ✔	Recommended good practice based on the clinical experience of the Guideline Development Group

The views of the guideline group combined with comments from the peer review outlined below suggest that recommendations with C grading are acceptable to a wide body of expert opinion pending the results of future research.

Peer review

The 1999 guideline

After the initial draft of the guideline had been written and approved by the guideline group, a formal peer review process was undertaken. Each member of the guideline group put forward six to eight names of individuals or organisations from the area of practice that they represented. A copy of the draft guideline, together with a guideline appraisal document based on that used by the Scottish Intercollegiate Guidelines Network,[11] was sent out to 59 nominated people. Replies were received from 39 reviewers (37 completed the form; two others provided written comments only), a response rate of 66%.

All comments from this peer review were discussed by the guideline group and amendments agreed by informal consensus. There was little dissent among the peer reviewers with regard to the recommendations. Suggested amendments mainly concerned style, presentation and typography. There were also requests from peer reviewers for expansion on the evidence in certain areas. None of the recommendations was substantially changed as a result of the peer review.

The revised guideline

The members of the original guideline development group were invited to make comments on areas to be considered for this revision. Replies were received from eight of them, including a consumer representative and a representative of the Royal College of Nursing. A first draft of the revised guideline was circulated to members of the RCOG Guidelines and Audit Committee, who made comments on it and approved it for peer review. The guideline, together with guidance on appraisal, was sent out to the nine members of the original guideline development group and seven other nominated people. Replies were received from 12 of the peer reviewers, a response rate of 75%. Comments on the draft posted on the RCOG website were received from four people.

A list of these peer reviewers can be found on page v.

Review of the guideline

The guideline should be reviewed no later than the year 2006. This will be done by the RCOG using a similar methodology to that outlined above. The process will involve updating the literature searches and reviews for each topic, to take into account any new developments in the area.

Chapter 4
Summary of recommendations

General

Indications for or against sterilisation (Section 5.1)

Recommendation 1

C If there is any question of a person not having the mental capacity to consent to a procedure that will permanently remove their fertility, the case should be referred to the courts for judgment.

Recommendation 2

C Additional care must be taken when counselling people under 30 years of age or people without children who request sterilisation.

What is required before the procedure is performed? (Section 5.2)

Recommendation 3

C All verbal counselling advice must be supported by accurate, impartial printed or recorded information (in translation, where appropriate and possible), which the person requesting sterilisation may take away and read before the operation.

Recommendation 4

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.

Recommendation 5

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

Recommendation 6

B Women in particular should be informed that vasectomy carries a lower failure rate in terms of post-procedure pregnancies and that there is less risk related to the procedure.

Recommendation 7

C A history should be taken and an examination should be performed on all men and women requesting vasectomy or tubal occlusion.

Recommendation 8

C The operating doctor will need to ensure that the counselling, information exchange, history and examination have been completed and be satisfied that the patient does not suffer from concurrent conditions which may require an additional or alternative procedure or precaution.

Tubal occlusion

Methods (Section 6.1)

Recommendation 9

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

Recommendation 10

A Where equipment and trained staff are available, the laparoscopic approach to the fallopian tubes is quicker and results in less minor morbidity compared with mini-laparotomy.

Recommendation 11

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

Recommendation 12

B A modified Pomeroy procedure rather than Filshie clip application may be preferable for postpartum sterilisation performed by mini-laparotomy or at the time of caesarean section, as this leads to lower failure rates.

Recommendation 13

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

Recommendation 14

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

Recommendation 15

C Diathermy should not be used as the primary method of tubal occlusion because it increases the risk of subsequent ectopic pregnancy and is less easy to reverse than mechanical occlusive methods.

Recommendation 16

C Hysteroscopic methods of tubal occlusion are still under evaluation and should only be used within the present guidance system for new surgical interventions.

Information (Section 6.2)

Recommendation 17

B Women, particularly those at increased risk from conditions such as previous abdominal surgery or obesity, should be informed of the risks of laparoscopy and the chances of laparotomy being necessary if there are problems with laparoscopy.

Recommendation 18

✔ Women 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 method fails for any reason.

Recommendation 19

✔ Women should be advised after the operation of the method of tubal occlusion actually used and of any complications that occurred during the procedure.

Anaesthesia (Section 6.3)

Recommendation 20

A While recognising that general anaesthesia is usually used in the UK for laparoscopic tubal occlusion, local anaesthesia is an acceptable alternative.

Recommendation 21

C Laparoscopic tubal occlusion should be performed as a day case wherever possible.

Recommendation 22

A Topical application of local anaesthesia to the fallopian tubes should be used whenever mechanical occlusive devices are being applied either under general or local anaesthesia.

Failure (Section 6.4)

Recommendation 23

B Women should be informed that tubal occlusion is associated with a failure rate and that pregnancy can occur several years after the procedure. The lifetime risk of failure in general is estimated to be one in 200. The longest period of follow-up data available for the most common method used in the UK, the Filshie clip, suggests a failure rate after ten years of two to three per 1000 procedures.

Recommendation 24

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

Recommendation 25

✔ After tubal occlusion, women should be advised to seek medical advice if they think they might be pregnant or if they have abnormal abdominal pain or vaginal bleeding.

Timing (Section 6.5)

Recommendation 26

B Tubal occlusion should be performed after an appropriate interval following pregnancy wherever possible. Should tubal occlusion be requested in association with pregnancy (either postpartum or post-abortion), the woman should be made aware of the increased regret rate and the possible increased failure rate.

Recommendation 27

C If tubal occlusion is to be performed at the same time as a caesarean section, counselling and agreement should have been given at least one week prior to the procedure.

Recommendation 28

B Tubal occlusion can be performed at any time during the menstrual cycle, provided that the clinician is confident that the woman has used effective contraception up to the day of the operation. If this is not the case, the operation should be deferred until the follicular phase of a subsequent cycle. The woman should be advised to continue to use effective contraception until her next menstrual period.

Recommendation 29

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

Recommendation 30

B Routine curettage at the time of tubal occlusion, in order to prevent a luteal-phase pregnancy, is not recommended.

Reversal (Section 6.6)

Recommendation 31

B Although women requesting sterilisation should understand that the procedure is intended to be permanent, they should be given information about the success rates associated with reversal, should this procedure be necessary.

Recommendation 32

✔ Women should be informed that reversal operations are rarely provided by the National Health Service.

Risks (Section 6.7)

Recommendation 33

B Women should be reassured that tubal occlusion is not associated with an increased risk of heavier or irregular periods when performed after 30 years of age**.** There is an association with subsequent increased hysterectomy rate, although there is no evidence that tubal occlusion leads to problems that require a hysterectomy. Data are limited on the effect on menstruation when tubal occlusion is performed on women under 30 years of age.

Equipment and facilities (Section 6.8)

Recommendation 34

✔ All equipment involved in performing tubal occlusions should be properly maintained.

Recommendation 35

✔ Laparoscopic tubal occlusion should only be performed at a site where there are facilities to perform a laparotomy safely.

Training (Section 6.9)

Recommendation 36

C Trainees should perform at least 25 supervised laparoscopic tubal occlusions before operating without supervision.

Vasectomy

Methods (Section 7.1)

Recommendation 37

A Except when technical considerations dictate otherwise, a no-scalpel approach should be used to identify the vas, as this results in a lower rate of early complications.

Recommendation 38

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

Recommendation 39

B Clips should not be used for occluding the vas, as failure rates are unacceptably high.

Anaesthesia (Section 7.2)

Recommendation 40

C Vasectomy should be performed under local anaesthetic wherever possible.

Histological examination (Section 7.3)

Recommendation 41

C Excised portions of vas should only be sent for histological examination if there is any doubt about their identity.

Post-vasectomy semen analysis (Section 7.4)

Recommendation 42

C Men should be advised to use effective contraception until azoospermia has been confirmed. The way in which azoospermia is confirmed will depend upon local protocols.

Recommendation 43

A Irrigation of the vas during vasectomy does not reduce failure rates or time to clearance.

Special clearance (Section 7.5)

Recommendation 44

C In a small minority of men, non-motile sperm persist after vasectomy. In such cases, 'special clearance' to stop contraception may be given when less than 10 000 non-motile sperm/ml are found in a fresh specimen examined at least seven months after vasectomy, as no pregnancies have yet been reported under these circumstances.

Failure (Section 7.6)

Recommendation 45

B Men should be informed that vasectomy has an associated failure rate and that pregnancies can occur several years after vasectomy. The rate should be quoted as approximately one in 2000 after clearance has been given.

Reversal (Section 7.7)

Recommendation 46

B Although men requesting vasectomy should understand that the procedure is intended to be permanent, they should be given information on the success rates associated with reversal, should this procedure be necessary.

Recommendation 47

✔ Men should be informed that reversal operations or intracytoplasmic sperm injections are rarely provided within the National Health Service.

Risks (Section 7.9)

Recommendation 48

B Men requesting vasectomy can be reassured that there is no increase in testicular cancer or heart disease associated with vasectomy. The association, in some reports, of an increased risk of being diagnosed with prostate cancer is at present considered likely to be non-causative.

Recommendation 49

B Men should be informed about the possibility of chronic testicular pain after vasectomy.

Training (Section 7.10)

Recommendation 50

C Practitioners who are being trained to perform vasectomies should ensure that their training conforms to that advocated by the Faculty of Family Planning and Reproductive Health Care. Doctors with no prior experience should be supervised for ten operating sessions or 40 procedures, while doctors with relevant prior surgical experience should perform eight supervised procedures.

Audit (Section 8.1)

Recommendation 51

C A national register and audit of failed sterilisations is needed. Hospital-based registers of sterilisation procedure failures would assist this.

Chapter 5
General evidence for recommendations

5.1 Indications for or against sterilisation

Sterilisation is indicated when a man or woman wishes to make permanent and irreversible their decision that they should never subsequently conceive any child of their own. It is a voluntary act, with the request coming from the person who wishes to be rendered infertile, and is irrespective of age or marital status. A recommendation to consider sterilisation by a professional should generally be part of a range of options offered for information or as a result of particular circumstances or opportunities.

The moral, cultural and emotional dimension to sterilisation

Approval of sterilisation as an option in contraceptive practice is acceptable to a majority of people in many well-resourced countries. However, there are communities and individuals with long-established religious, cultural and sometimes emotional objections to sterilisation and other forms of contraception. These will need to be taken into account when advising men and women with contraceptive needs that arise from medical conditions. As a matter of good practice, healthcare professionals should concentrate on factual information and avoid persuasion or any act that may be deemed coercive, however clear the advantage of their recommended option appears to be.

The doctor's responsibility

Doctors are not required to perform acts or operations against their own conscience or better judgement. All doctors, including trainees, are accountable for their own actions. Doctors 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 doctor or healthcare professional. They should also avoid putting another doctor or 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 doctor has a fundamental objection, for whatever reason, to sterilising childless women, then 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 for this should precede admission to the place of operation and, if possible, any outpatient appointment. Such cases should be diverted to a colleague who, to the best of their knowledge, does not share a similar objection.

Recommendation 1

C **If there is any question of a person not having the mental capacity to consent to a procedure that will permanently remove their fertility, the case should be referred to the courts for judgment.**

English law requires doctors to obtain the consent of an adult patient of sound mind before performing surgery or any other treatment involving physical force. If valid consent is not obtained, the application of force can be treated as an unlawful trespass to the person.[12]

Although a doctor or other responsible person may judge that sterilisation of a person with learning difficulties may be in his or her best interests, there is a risk that such decisions may be viewed as socially motivated on behalf of other carers.

Childs,[12] in her review of the legal position surrounding sterilisation of the mentally incompetent, describes the guidelines produced by the Official Solicitor in 1989; these guidelines were revised in 2001.[13] The guidance indicates that in virtually all cases such sterilisation will require the prior sanction of a High Court judge. The proceedings should normally be initiated by a parent or one of those responsible for the care of the person concerned or by those intending to carry out the proposed operations.

The purpose of the proceedings is to establish whether the proposed surgery is in the best interest of the person and not merely for the convenience of others. There should be a thorough investigation of all possible views and alternatives to sterilisation. The Official Solicitor must act as an independent guardian representing the best interests of the person. He or she will take whatever steps appear necessary in order to ensure that all relevant matters are canvassed thoroughly in court. In order to perform this duty, the Official Solicitor will meet the person in private in all cases where he or she is able to express any views, however limited, about the legal proceedings, sterilisation, parenthood, contraception or other relevant matters.

The judge determining the legality of the proposed sterilisation will normally be presented with the evidence of relevant experts. Expert evidence as to the person's capacity, the need for the surgery and possible reversible alternatives (see below) will be central to the Court's assessment of whether the operation is really in the person's best interests.

The Law Commission, in its comprehensive report on mental incapacity,[14] has advised that sterilisation for the purposes of contraception in these circumstances (which also apply to hysterectomy for menstrual disorders) should require the approval of a judicial forum, unless the operation has to be performed as a life saving procedure.

Recommendation 2

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

When patient selection for sterilisation is considered, psychosocial issues are often seen as less important than medical eligibility criteria because they are perceived as softer issues. Yet they are highly important if any decision made by the patient is to be made with confidence and be long-standing.

There are a number of studies which look at 'regret', satisfaction and effects of sterilisation, including helpful data generated by the Collaborative Review of Sterilisation (CREST) study.[15] Issues from these studies provide a basis for a common list of criteria that should be addressed with patients considering sterilisation:

- young age (under 30years)[16–19]
- few or no children (the number is not always defined but usually relates to two or fewer)[17]
- not in a relationship
- not in a mutually faithful relationship or in crisis in relationship [20–23]
- psychological issues (implications beyond fertility issues)[21]
- psychosexual issues[24]
- coercion by medical professional or partner[25,26]
- timing relating to abortion or childbirth[20,21,24,25]
- information requirements (of the procedure, its effectiveness/failure, alternative contraceptive choices).[27]

Although the 1996 World Health Organization eligibility criteria[28] mainly relate to medical fitness for operation, they acknowledge that "special care must be taken to assure a voluntary informed choice … particular attention must also be given in the case of young people, nulliparous women or men who have not yet been parents".

Anecdotal evidence to the fpa's Sexual Health Direct help line indicates that there are gender differences in decision making about sterilisation and reasons for regret afterwards. Specifically, this relates to men who have a vasectomy and then form a new relationship usually with (younger) women who have not had children. However, no published data are available to support this evidence.

5.2 What is required before the procedure is performed?

Recommendation 3

C **All verbal counselling advice must be supported by accurate, impartial printed or recorded information (in translation, where appropriate and possible), which the person requesting sterilisation may take away and read before the operation.**

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-judgmental manner. Inadequate counselling may underlie regret after sterilisation and in extreme cases there may be psychological or psychosexual sequelae.[22]

It is important that all information shared in the initial consultation is backed up by good quality, accurate, impartial written information that is easy to understand and well presented. It has generally been found that patients want to receive written information about medical and surgical interventions and that those given written information are more likely to express satisfaction with the patient–health professional relationship.[29–31]

However, in a 1998 report that interviewed women about their contraceptive choices and their access to contraceptive information, 65% of women who had chosen sterilisation as their form of contraception had not been given written information.[32] Similarly, a Scottish audit on laparoscopic sterilisation, published in 1997, found that 42% of consultants did not provide information leaflets.[33]

In agreement with this, a survey of patients performed in connection with the same audit[34] confirmed that 48% of women had been given 'no written information at all'. The RCOG report on communication standards in gynaecology: surgical procedures[35] endorses the use of information leaflets and recommends that 'it should become part of the culture that people are given the appropriate leaflets'. A randomised controlled trial has shown that providing leaflets improves knowledge of contraception, in relation to combined oral contraceptive pill use.[36]

Giving an explanatory leaflet to the patient is part of a risk management strategy advised by the Medical Defence Union[7] to try to reduce litigation surrounding sterilisation procedures. Poor counselling or consent featured in 37 (7%) of 500 medico-legal cases.[6]

The main problem with counselling was an inappropriate standard of communication and note keeping. In some cases, appropriate counselling and valid consent were not documented. In others, there was a clear difference between what verbal information was given to the patient compared with what she perceived or understood at the time of such communication, thus emphasising the need for written information as a backup.

In addition to providing written information, the needs of patients who cannot read such written information must be taken into account. The same information may need to be available on an audiotape for those who are blind or visually impaired or who have limited literacy skills. Consideration should also be given to providing the information in a range of languages to suit local ethnic representation.

The information given to the patient should be recorded in the notes and the provision of a supporting leaflet or tape to the patient should be documented. Appendix 2 gives an example of a patient record standard for tubal occlusion that could be used for audit and should help risk management.

Recommendation 4

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.**

Women should be informed of the variety of long-term reversible methods of contraception now available before they decide on tubal occlusion. These methods include: the levonorgestrel-releasing intrauterine system (LNG-IUS), subdermal implants and copper intrauterine contraceptive devices (IUCDs) that can remain *in situ* for three to eight years, depending upon the method. Copper IUCDs, if inserted after the age of 40 years, can be left *in situ* until the menopause. All have their associated risks and benefits. Some of these methods are as effective as tubal occlusion and yet preserve reversibility.[37] The cumulative pregnancy rate at 12 years with the TCu380A IUCD is 1.9/100 women[38] and for the LNG-IUS is 1.1/100 after five years of typical use.[37] These rates are comparable with the cumulative failure rates recorded for tubal occlusion in the CREST study[15] (see Recommendation 19 for a fuller discussion of failure rates). Although other newer methods have not yet been followed up for as long, medium term results are encouraging for the frameless IUCD, GyneFix® (Family Planning Sales Ltd),[39,40] and for parenteral progestogen-only contraceptives such as Implanon® (Organon Laboratories Ltd), a subdermal implant.[41]

Current contraceptive practice dictates that contraception should continue to be used until a woman has not had a period or any bleeding for two years, if aged under 50 years, or for one year,

if over 50 years.[42] Information about these methods must be provided so that women can choose the right method for themselves. Although a woman may have presented requesting sterilisation, she may not necessarily have considered and rejected all other options, as she may not previously have had sufficient information. A recent analysis of the General Practice Research Database[4] suggests that the popularity of tubal occlusion has declined in relation to vasectomy since 1996. This may reflect better information provision on alternative long-term reversible methods, as the incidence of vasectomy remained relatively static.

Recommendation 5

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

Recommendation 6

B **Women in particular should be informed that vasectomy carries a lower failure rate in terms of post-procedure pregnancies and that there is less risk related to the procedure.**

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

Women requesting sterilisation should be advised that vasectomy carries a lower failure rate in terms of post-procedure pregnancies and there is less risk related to the procedure. The failure rate for vasectomy is at least one order of magnitude lower than that of tubal occlusion (see Recommendations 23 and 45). There are fewer operation-related risks with vasectomy, as it avoids a laparoscopy and usually avoids a general anaesthetic (see Recommendations 17, 18, 19 and 40).

However, decisions as to which partner goes forward to have a procedure designed to irreversibly remove their fertility may not simply relate to efficacy and risks of that procedure.[43] Some men feel that vasectomy is an emotionally charged subject; more research is needed on what men feel about vasectomy and on the psychosexual aspects of vasectomy.

Many women who request tubal occlusion have not received sufficient information about vasectomy in order to make an informed choice. An interview study of women who had had interval sterilisation and of women married to men with vasectomies[44] found that all the men requesting vasectomy had been seen together with their partners and tubal occlusion had been discussed. Most women requesting sterilisation were seen on their own and vasectomy, as an alternative, was not discussed. In a patient survey conducted in connection with a Scottish audit,[34] 47% of women who responded reported that vasectomy was not discussed with them by either their GP or a doctor at their hospital visits.

Evidence level 3

Recommendation 7

C **A history should be taken and an examination should be performed on all men and women requesting vasectomy or tubal occlusion.**

The past history, present symptoms or abnormal examination findings may influence which partner

goes forward to have sterilisation. For example, if a past history of genital or scrotal surgery in the man makes vasectomy under general anaesthesia more likely, tubal occlusion for the woman may be preferable. Any contraindications to general anaesthesia in the woman may make a vasectomy under local anaesthesia for the man a better alternative. Equally, an impending inguinal hernia repair may mean that the vasectomy could be performed under the same anaesthetic.

A gynaecological history from the female partner may reveal menorrhagia. If this is the case, an alternative form of contraception such as an LNG-IUS may be suitable; it would reduce the menorrhagia and also provide long-term contraception. A hysterectomy may be an alternative if significant gynaecological pathology, such as large fibroids or a prolapse, is present. It is considered good practice for a bimanual pelvic examination to be performed on the woman before surgery so that the decision to proceed is made in the light of all the available information and there are no unexpected findings under anaesthesia. Similarly, a genital examination of the man is necessary to exclude potential problems (a large varicocele or hydrocele, for example, that may mean that the vas is more difficult to palpate and general anaesthesia is required).

The history and examination may also reveal risk factors for laparoscopic tubal occlusion. Previous laparotomy,[45] previous abdominal or pelvic surgery,[46–48] previous pelvic inflammatory disease[46] and obesity[46,47] are all factors that increase the risk of a laparotomy with a laparoscopic approach. Sometimes, the examination reveals previous surgery that the woman has omitted in the history. Detecting these factors prospectively allows for the woman to be warned of the risk of laparotomy and also allows for an experienced surgeon to be present and the possibility of opting for a mini-laparotomy or open laparoscopy[49] if tubal occlusion is still requested.

Recommendation 8

C	**The operating doctor will need to ensure that the counselling, information exchange, history and examination have been completed and be satisfied that the patient does not suffer from concurrent conditions which may require an additional or alternative procedure or precaution.**

The provision of sterilisation services varies across the UK. It is still traditional for women to approach their general practitioner or family planning clinic initially and for them to be referred to a gynaecologist for outpatient consultation where, if agreed, their operation is booked or they are put on a waiting list. However, direct referral to daycase lists from general practice and family planning clinics can occur.[50] Even if the traditional system is used, the woman may be counselled by one doctor in the outpatient clinic but be operated on by another. This probably cannot be avoided but strict safeguards are needed to ensure that adequate examination and counselling have taken place initially and that the surgeon who eventually performs the procedure, and is ultimately responsible, accepts that this has been done thoroughly. Local protocols, together with the patient record standard in Appendix 2, may help.

Chapter 6
Tubal occlusion

6.1 Methods

Recommendation 9

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

The approach to the fallopian tubes is usually made laparoscopically or through a mini-laparotomy incision. Culdoscopy has been used in the past as an alternative approach but has fallen into disuse after a World Health Organization randomised, prospective, multicentre study[51] showed that the incidence of technical failures and major complications from this approach was unacceptably high. A systematic review[52] has confirmed that major and minor morbidity was higher with culdoscopy than either mini-laparotomy or laparoscopy and that culdoscopy should therefore be abandoned.

Evidence level 1a

Recommendation 10

A **Where equipment and trained staff are available, the laparoscopic approach to the fallopian tubes is quicker and results in less minor morbidity compared with mini-laparotomy.**

If a mini-laparotomy is used for the approach, a partial salpingectomy can be performed and the tubes can be 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 or Hulka–Clemens clip). With laparoscopy, diathermy (either unipolar or bipolar) can be used to destroy a segment of the tube; the tube can be occluded (with a tubal ring or clip) or a modified Pomeroy technique can be performed using endoloop sutures.

In the UK, mini-laparotomy is rarely performed as a primary procedure. It may, however, be necessary if laparoscopic access has failed or has been rejected because of previous abdominal surgery or obesity.

A systematic review[52] comparing methods of access to the fallopian tubes has shown that there was no difference in major morbidity between the two approach methods, although there was significantly more minor morbidity with mini-laparotomy (OR 1.89, 95% CI 1.38–2.59). Laparoscopy took an average of five minutes less.

Evidence level 1a

Recommendation 11

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.**

There have been no well-controlled or randomised trials concerning different surgical techniques for ligating or 'tying' the tubes. Many of these techniques have been in use for many years and their use relies on tradition rather than reliable evidence. Two reviews of these procedures[53,54] highlight their advantages and disadvantages.

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

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

Other techniques involve burying the severed proximal end in either the muscle wall of the uterus (Irving technique), the round ligament (Cooke technique) or the broad ligament (Uchida technique). These techniques are technically more difficult to perform and are not designed to be reversible. The Wood technique uses a microsurgical technique to ligate, divide and bury the medial stump in a pocket cut in the mesosalpinx. As no tube is excised this method is potentially reversible. However, no large trials with long follow-up have been performed and the technique demands above average skill.

Two techniques that should not be used because of variable failure rates are the Madlener technique and fimbriectomy. The Madlener technique involves lifting up a loop of tube, crushing the base of the loop with a clamp or forceps and ligating the tube with non-absorbable suture material. Fimbriectomy involves complete removal of the fimbriae. It is very difficult to reverse.

There was no difference between pregnancy rates in studies[55] where the Filshie clip was used via mini-laparotomy, when compared with laparoscopy or with a tubal ring used either via mini-laparotomy or laparoscopy in interval sterilisations.

Evidence level 2

Recommendation 12

B **A modified Pomeroy procedure rather than Filshie clip application may be preferable for postpartum sterilisation performed by mini-laparotomy or at the time of caesarean section, as this leads to lower failure rates.**

Chi *et al.*[56] showed that, when mechanical methods were used for tubal occlusion with a mini-laparotomy approach for postpartum or post-abortion sterilisation, the failure rate over the 12 months of follow-up was significantly higher than when a modified Pomeroy technique was used. This difference was not shown in studies by Yan *et al.*[57] or Lee and Jones,[58] which compared the

Filshie and Hulka clips, respectively, with the Pomeroy technique in postpartum women. However, the length of follow-up did not exceed 24 months and was often shorter.

The CREST study,[15] with its ten-year follow-up, showed that the postpartum salpingectomy group (which mostly included modified Pomeroy-type ligation rather than other types of partial salpingectomy and total salpingectomy) performed by laparotomy had a low cumulative failure rate of 7.5/1000 procedures at ten years. This compares with an average of 18.5/1000 procedures for all methods of sterilisation and 20.5/1000 for interval partial salpingectomy. The authors pointed out, however, that the numbers in the interval group were small and were likely to be highly selected as, in this study, most interval sterilisations were carried out laparoscopically.

Evidence level 1a/2

Recommendation 13

A **Mechanical occlusion of the tubes by either Filshie clips or rings should be the method of choice for laparoscopic tubal occlusion.**

Mechanical occlusive methods are widely used in the UK and are preferable to bipolar diathermy because they destroy a smaller part of the tube and reversal of sterilisation is more likely to be successful.[59–62] If a pregnancy does occur, it is less likely to be ectopic if a mechanical method has been used.[63–66] For mechanical occlusive methods to be successful, however, they must be applied to the right part of the tube in the correct manner. In the case of the Filshie clip, for example, this means applying the clip at right angles to the isthmic portion of the tube, 1–2 cm from the cornu, making sure that the whole of the width of the tube is encased by the clip.[67] This should be explicitly checked by the operating surgeon at the conclusion of the operation and a note to this effect made in the operating notes.

The tubal ring has higher rates of technical difficulty and technical failure during the procedure, when compared with diathermy[63,68–70] or Filshie clips.[55,71] Short-term (two-year) failure rates are comparable with the Filshie clip.[71]

Spring-loaded clips, such as the Hulka clip, were found to be associated with the highest rate of failure in all age groups in the ten-year CREST study[15] and led to a higher cumulative probability of pregnancy after two years in a randomised trial comparing Hulka and Filshie clips.[72] Filshie clips should therefore be used in preference to Hulka clips.

Evidence level 1a/1b/2

Recommendation 14

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

Although a survey of practice[33] found that 16% of Scottish gynaecologists applied two clips to each tube routinely, multiple clips are not necessary for the procedure to be effective, as long as the single clip is applied in the correct manner. If there is any doubt about the security of the clip, a second clip may be placed immediately adjacent to the first on the uterine side.[67] Chi[73] looked at the use of multiple Filshie and Hulka clips in interval sterilisation. Multiple clips tended to be used

when surgical difficulties were encountered during the sterilisation or when the first clip was not optimally placed. There was no increase in immediate or short-term complications in women with multiple clips as opposed 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 the tube being damaged, which may potentially make any reversal operation more difficult and less successful.

Evidence level 3

Recommendation 15

B **Diathermy should not be used as the primary method of tubal occlusion because it increases the risk of subsequent ectopic pregnancy and is less easy to reverse than mechanical occlusive methods.**

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,[67,74–76] burns to the skin[74,77] and burns to the face and hands of the operator[78] were reported. Deaths following unipolar coagulation have also occurred.[68,79,80]

Instead of the electric current passing through the patient to a grounding plate on the patient's skin, bipolar diathermy uses both jaws of a pair of grasping forceps as the active and return electrodes, so that the current only passes between the two prongs, burning the tissue grasped. This technique should markedly reduce the risk of thermal bowel injury.[80] Doubt has been cast on some reports of bowel burns with unipolar diathermy,[81] with unrecognised trauma to the bowel being thought to be the main cause of bowel injury in laparoscopic sterilisation, even when unipolar diathermy is 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 and success rates for reversal are low.[82] It also increases the risk of any subsequent pregnancy being ectopic.[15,83–85] If diathermy is used, the tube should be occluded in the mid- to lateral portion of the isthmic part of the tube, at least 2 cm from the cornu.[86] Tubal 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.

Evidence level 2/3

The guideline group was not aware of any evidence that compared methods of tubal occlusion after a primary tubal occlusive method had failed. No recommendation can therefore be made in this area.

Recommendation 16

C **Hysteroscopic methods for tubal occlusion are still under evaluation and should only be used within the present guidance system for new surgical interventions.**

Only one form of hysteroscopic tubal occlusion method is licensed for use in the UK at present. This is a dynamically expanding metal micro-insert (Essure®, Conceptus Europe) that is inserted into the fallopian tube under hysteroscopic visualisation. Ensuing fibrosis helps to cause tubal occlusion, which is usually evaluated three months after the operation, with a hysterosalpingogram, so that

other contraception can be stopped. In the only clinical trial to look at this method,[87] only 111 women out of 130 could have bilateral placement of the device. It was well tolerated by most women. So far 114 women have accumulated 2400 months of wearing the device with no pregnancies reported. Other multicentre and comparative trials are awaited. Unlike other methods of tubal occlusion, this method is not even potentially reversible.

Evidence level 3

The National Institute for Clinical Excellence (NICE) has the responsibility for assessing whether new interventional procedures are safe enough and work well enough for routine NHS use. Practitioners are responsible for notifying NICE when they wish to use a new interventional procedure that they have not used before or have used only outside the National Health Service. Practitioners who wish to perform such a procedure during the period between notifying NICE and the issuing of NICE guidance are advised by NICE to inform their trust's chief executive or hospital of their intention. Women must be fully informed of the procedure's risks and uncertain efficacy, and this should be fully documented in the patient's notes.

Evidence level 4

Transcervical application of chemicals, such as quinacrine hydrochloride pellets,[88] adhesives (such as methylcyanoacrylate[89]) or synthetic plugs are not licensed for use in the UK and have therefore not been considered.

6.2 Information

Recommendation 17

B **Women, particularly those at increased risk from conditions such as previous abdominal surgery or obesity, should be informed of the risks of laparoscopy and the chances of requiring laparotomy if there are problems with laparoscopy.**

Morbidity and mortality can arise from most operations. Laparoscopic sterilisation is no exception. Most of the complications arise as a result of the development of the pneumoperitoneum and the blind insertion of the first trocar, rather than as a result of the actual procedure performed.[90]

Complications arising from laparoscopic surgery are often divided, fairly arbitrarily, into major and minor complications.

Major complications are injuries to bowel, bladder or blood vessels that require laparotomy or lead to death. The risk of laparotomy as a result of a severe complication in one large prospective study[45] was 1.9/1000 procedures with two other practice surveys[33,91] recording laparotomy rates of 1.4–3.1/1000 cases. The risk of death with a laparoscopy is one in 12 000.[45,68]

Minor complications are injuries or problems that can be dealt with during the laparoscopic procedure and do not prevent the intended procedure being completed. Previous abdominal or pelvic surgery, previous pelvic inflammatory disease and obesity significantly increase the relative risk of complications and need for laparotomy.[45,46] A laparotomy may mean that either a suprapubic or midline incision is made, depending upon the indication.

Recommendation 18

✔ **Women 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 method fails for any reason.**

Recommendation 19

✔ **Women should be advised after the operation of the method of tubal occlusion actually used and of any complications that occurred during the procedure.**

Although a woman should be told before the operation of the intended method of sterilisation (Filshie clips or Falope rings, for example), she should be informed of the method actually used before she is discharged, particularly if the method was changed during the operation 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, if more than one clip or ring has been applied to either side, because there was doubt about the security of the first clip or because bleeding or transection of the tube made it necessary, the woman should be informed.

Women should be informed afterwards if technical difficulties arose during the operation that meant complete tubal occlusion was in doubt and should be advised to continue with alternative contraception. A hysterosalpingogram should be arranged to assess tubal occlusion.

It would be good practice to ensure that a follow-up appointment with a specialist is offered following any sterilisation procedure involving complications or a change in the intended method of tubal occlusion.

Where diathermy has been used for the sterilisation procedure, women should be told and given supporting written information about the possibility of bowel injury and symptoms that would require medical consultation. Bowel perforation caused by diathermy burns can present late, often several days after the procedure.[74,92] Typically, patients with unrecognised bowel injuries present three to seven days after the procedure with complaints of fever and abdominal pain. They may sometimes present a couple of weeks later.[93] If left untreated, peritonitis and septicaemia can occur. Several deaths in women, from unrecognised bowel burns after unipolar cautery, have been reported.[68,79,80]

Bowel injuries can also occur from trocar perforation at laparoscopy, whatever method of tubal occlusion is used. Sometimes these may go unnoticed at the time of the operation and present in a similar way to perforation from bowel burns. When any woman has abdominal signs after laparoscopic sterilisation these uncommon but potentially life-threatening postoperative complications must be considered. The patient and her general practitioner should be made aware of the significance of any postoperative signs and symptoms, such as increasing abdominal pain and becoming generally unwell, that might indicate a bowel perforation that went undetected at the time of the procedure. One way of doing this is to include the information on the immediate discharge letter sent to the general practitioner, a copy of which is also given to the patient. New NHS requirements will require that any correspondence sent to the GP is also copied to the patient.

6.3 Anaesthesia

Recommendation 20

A **While recognising that general anaesthesia is usually used in the UK for laparoscopic tubal occlusion, local anaesthesia is an acceptable alternative.**

National studies in the UK,[68] USA[94] and France[95] have suggested that events related to general anaesthesia are the leading cause of deaths attributable to laparoscopy. These studies date from the 1970s and 1980s and it is possible that general anaesthetic techniques have since been refined. Although the use of local anaesthesia and intravenous sedation can eliminate deaths related to general anaesthesia, deaths are still possible due to overuse of sedation. In one study in Bangladesh,[96] 29% of deaths attributable to sterilisation were due to over-sedation, although mortality did drop dramatically after recommendations for lower doses of analgesics and larger doses of local anaesthetic drugs were introduced.[97] Local anaesthesia, with or without sedation, is not commonly used in either the UK or the USA. In the 1988 membership survey of the American Association of Gynecologic Laparoscopists,[66] only 8% used this method of anaesthesia for tubal sterilisation and in the UK 1978 survey of gynaecological laparoscopy[68] local anaesthesia was used in only 0.4% of sterilisations. There have been no other surveys on anaesthetic use in the UK since then.

Two studies[98,99] randomising women to either general anaesthesia or local anaesthesia with sedation and a UK cohort study[100] using local anaesthesia alone for laparoscopic sterilisation, have shown that either method is safe and acceptable.

The likelihood of success with local anaesthesia is enhanced by supportive operating room staff, maintaining communication with patients, gentle handling of patients and their tissues, use of nitrous oxide for insufflation (as carbon dioxide causes diaphragmatic irritation) and avoidance of overdistension. Selection of patients without obesity or previous abdominal or pelvic surgery is important. It is still vital that an anaesthetist is present in order to monitor the patient sufficiently and for the procedure to be carried out in an environment where an emergency laparotomy could be performed safely if necessary.[68]

Recommendation 21

C **Laparoscopic tubal occlusion should be performed as a day case wherever possible.**

It is government policy to encourage surgery to be performed on a daycase basis whenever possible. This is usually possible for laparoscopic sterilisation in the absence of medical, social or geographical contraindications. Eighty-four percent of Scottish gynaecologists[33] indicated that they routinely manage laparoscopic sterilisation as a daycase procedure, although in a casenote review presented in the same survey there were large inter-hospital variations in the use of daycase care, from 19% to 99%. Although it is commonly thought that women prefer a daycase service, one-third of women managed as day cases for laparoscopic sterilisation felt that their hospital stay was too short and would have preferred to have stayed overnight.[101]

Local protocols detailing the criteria for acceptance for daycase surgery should be available and should have been formulated in conjunction with the anaesthetists and the primary care team.

Recommendation 22

A **Topical application of local anaesthesia to the fallopian tubes should be used whenever mechanical occlusive devices are being applied either under general or local anaesthesia.**

Laparoscopic sterilisation is more painful than diagnostic laparoscopy,[102,103] probably because of local tissue necrosis and ischaemia at the site of tubal interruption.

Davis and Millar,[103] however, showed that pain after laparoscopic sterilisation was worse than diagnostic laparoscopy for the first four hours afterwards, although it was not significantly greater after hospital discharge on the same day as surgery. Pain varies with the method of sterilisation but is probably worst with tubal rings, least with diathermy and intermediate with clips.[104–106]

Several randomised controlled trials have shown that topical application of a local anaesthesia to the fallopian tube either prior to, or after, tubal occlusion significantly reduces postoperative pain scores and requirements for postoperative opioid analgesia after laparoscopic tubal occlusion performed under general anaesthesia.[107–112] Topical application of local anaesthesia to the fallopian tubes also reduces intraoperative[113–115] and postoperative pain[115] when laparoscopic tubal occlusion is being carried out under local anaesthesia.

Local anaesthesia applied to Filshie clips before application also reduced postoperative opioid analgesia and reduced recovery times compared with placebo in one randomised controlled trial.[116]

Intraperitoneal instillation with local anaesthesia at the end of the procedure may also be effective,[117–119] especially when a longer-acting local anaesthetic such as ropivacaine is used[120] or when meperidine/pethidine is instilled in addition to a local anaesthetic.[121]

A few studies have addressed infiltration of the mesosalpinx[118,119,122–124] or fallopian tube[125] with local anaesthetic and, although seemingly effective in these randomised controlled trials, this method is likely to be associated with risks of bleeding and haematoma formation if routinely used and is likely to increase operating time.

The beneficial effect, over and above normal postoperative analgesia, usually disappears by the time of discharge. Bupivacaine and etidocaine were used in most of the studies; as they are longer acting than lignocaine they should be used for preference. Etidocaine is not currently available in the UK.

The evidence for transcervical instillation of bupivacaine is conflicting.[126,127]

Evidence level 1b

6.4 Failure

Recommendation 23

Women should be informed that tubal occlusion is associated with a failure rate and that pregnancy can occur several years after the procedure. The lifetime risk of failure in general is estimated to be one in 200. The longest period of follow-up data available for the most common method used in the UK, the Filshie clip, suggests a failure rate after ten years of two to three per 1000 procedures.

The term sterilisation is really a misnomer, as the operation does not irreversibly deprive the woman of her reproductive potential. Tubal occlusion, being both factual and not implying permanent removal of fertility, is the preferred term. There is an associated failure rate, i.e. occurrence of a pregnancy subsequent to sterilisation, with all approaches and methods of tubal sterilisation:

- the ends of the fallopian tube can reconnect spontaneously (recanalisation)
- 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
- there may be a failure to maintain equipment (see Recommendations 34 and 35).

A luteal-phase pregnancy occurs when the woman has already conceived in the cycle in which the sterilisation is performed. As this is not related to the actual sterilisation method, these have usually been excluded from analysis in the studies looking at 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.

Obviously it is important to know how likely a subsequent pregnancy is, so that the woman can be fully informed about whether sterilisation is the right method of contraception for her. Most studies report the experience of a single medical centre or surgeon and different protocols are used among centres. Their data therefore cannot usually be pooled for study.[56] Method failure (technical failure), surgeon failure (operator failure), and luteal-phase pregnancies are not always distinguished from recanalisation. Some reports do not distinguish between postpartum, post-abortion and interval procedures. Incomplete follow-up and various lengths of follow-up also make interpretation and comparison difficult.[128] Pregnancy rate can be expressed as crude rate, Pearl rate, or cumulative failure rate by life-table analysis (see Appendix 3) and this adds to the difficulty of making comparisons between studies. Many studies have followed women for only one to two years and accepted failure rates have been based on these studies. In addition, many studies have not analysed their pregnancy rates as cumulative rates with life-table analysis (the preferred method, as this takes into account loss to follow-up and different follow-up times).

The CREST study[15] followed up 10 685 women and found that the ten-year cumulative life-table probability of failure after sterilisation was at least 16.6/1000 procedures (95% CI 13.5–19.7). Previous studies have shown:

- 12-month cumulative life-table pregnancy rates of 3–6/1000 procedures,[63,69,129–131]
- 24-month cumulative pregnancy rates of 8.6–10.0/1000 procedures[129,132]
- seven-year cumulative rates for all methods of 10/1000[131]
- eight-year cumulative rates of 11/1000 for procedures where a Hulka clip was used
- 26/1000 where diathermy (unspecified as to unipolar or bipolar) was used.[133]

Most studies have been unable to find a significant difference in pregnancy rates between methods but as numbers of subsequent pregnancies are low this may be due to insufficient numbers in each group. However, the CREST study[15] did show, after multivariate analysis, that the spring clip (equivalent to the Hulka clip) and bipolar diathermy were significant risk factors for failure.

The other significant finding from this study was the increased probability of failure in younger women. The probability of failure with all methods was greater if a woman was under 28 years of age; this also held for women under 34 years of age, except for the group having interval sterilisation with partial salpingectomy. This is not surprising, as younger women are more fertile and will have more fertile years remaining in which pregnancy can occur. However, this association

has not been so clearly demonstrated before. In 1999, in the UK, the mean age of women at the time of sterilisation was 34.6 years.[4]

In the UK, the Filshie clip is the most widely used method for tubal occlusion, being used by 82% of gynaecologists.[134] The best available data so far for the Filshie clip[135,136] (which was not available in the USA at the time of the CREST study) suggest a far lower failure rate than the laparoscopic methods used in the CREST study; it is a crude rate of 2–3/1000 women at ten years, although no cumulative rates have been presented. However, these series have depended upon experienced operators performing all the surgery. In the CREST study, where higher failure rates were reported, many of the operations were performed by residents (the US equivalent of specialist registrars) and may more accurately reflect common practice. At present, the longest period of follow-up data available is for ten years. 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 several 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 the peritoneum grows over the clip, which may then fall off. There are no reports of this leading to sterilisation failures.[137]

Recommendation 24

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

Recommendation 25

✔ **After tubal occlusion, women should be advised to seek medical advice if they think they might be pregnant or if they have abnormal abdominal pain or vaginal bleeding.**

Pregnancies after female sterilisation are rare but when they occur there is an increased risk of ectopic gestation. Ectopic pregnancies can be life threatening if they rupture. Early diagnosis and treatment are essential. Ectopic pregnancy is currently the greatest single cause of first-trimester maternal deaths and accounts for 6.25% of all direct maternal deaths in the UK.[138] The incidence of ectopic pregnancy following tubal sterilisation ranges from 4.3–76.0%, depending upon the method used to occlude or destroy the tube.[63–65,83–85,91,139–145] The wide variation of reported rates of ectopic pregnancy is difficult to reconcile or interpret.

Tubal occlusion with bipolar diathermy leads to a much higher rate of ectopic pregnancy, if pregnancy occurs. One study[139] showed the ectopic rate for this method to be 27 times higher than that seen with postpartum partial salpingectomy.

These studies show that when sterilisation failure occurs, ectopic pregnancy is more likely if tubal diathermy has been used and is less likely with either tubal ligation or mechanical occlusive methods. Although women who have been sterilised are at less risk of an ectopic pregnancy than non-sterilised fertile women (because they are protected from all pregnancies) the risk of an ectopic pregnancy is high in pregnant women who have been sterilised in the past.

6.5 Timing

Recommendation 26

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

Recommendation 27

C **If a tubal occlusion is to be performed at the same time as a caesarean section, counselling and agreement should have been given at least one week prior to the procedure.**

There will always be some women who regret their decision to be sterilised. The proportion of women expressing this regret varies between different studies and different countries but tends to range from 3% to 10% in the UK.[16,146] Good preoperative counselling about the intended permanence of the procedure can reduce the incidence of regret.[147] In developed countries, the most common reason for regret is the desire for a child with a new partner, whereas in less developed countries it is usually because of the death of a child, particularly a male child.[146]

Several studies[25,148,149] have shown that the incidence of regret and dissatisfaction is higher when a woman has been sterilised at the same time as a caesarean section, particularly when the woman has felt that the decision has been forced upon her by a doctor.[25] Data from the large prospective multicentre CREST study in the USA[149] suggest that the relative risk of regret after combined caesarean section and sterilisation compared with interval sterilisation is 5.8 after one year and 3.3 after two years. This difference persists for at least five years after sterilisation, when the incidence of regret in the caesarean section group is still twice that of the interval sterilisation group.[148] For this reason, sterilisation should not be performed at the same time as a caesarean section unless counselling has taken place and the decision is made at a time separate from the emotional upheaval of delivery coupled with a major operation. A reasonable time period would be at least one week prior to the caesarean section.

Evidence level 2a

Regret has also been shown to increase after postpartum sterilisation associated with a vaginal delivery[150] but this is no longer a common procedure in the UK. However, there are some countries, for example India, where the majority of female sterilisation procedures are carried out in association with delivery.

The situation is less clear when sterilisation is combined with induced abortion. No difference in regret rates was found between women undergoing sterilisation concurrent with termination of pregnancy (mostly first-trimester) and those undergoing interval sterilisation.[151–154] However, others have found an increased rate of regret when sterilisation is performed concurrently with termination of pregnancy.[155,156] In addition, a randomised controlled trial[157] of women requesting termination of pregnancy and sterilisation, where the women were randomised to either termination with sterilisation as a combined procedure or termination with sterilisation as an interval procedure at least six weeks later, found that 32.8% of women did not return for their interval sterilisation. This

suggests that at least some women changed their minds when they were able to reconsider their decision outside the stressful situation surrounding an unwanted pregnancy. This emphasises the need for careful counselling where sterilisation is requested in association with pregnancy. If any ambivalence is shown, the sterilisation procedure should be deferred. Women who become pregnant whilst on a waiting list for interval sterilisation should receive further counselling about their choices, as their situation has changed from when they were first counselled.

Evidence level 1b/2

Other reasons for performing sterilisation as an interval rather than a combined procedure concern the possibility that complication and failure rates increase when a sterilisation is performed in association with a pregnancy, rather than as an interval procedure. Although the addition of sterilisation to a procedure for termination of pregnancy does not seem to increase the complication rate already associated with termination of pregnancy,[158] it has been argued that the complication rate associated with a combined procedure is higher than that associated with interval sterilisation.[159] However, other studies[157,160–162] comparing termination combined with laparoscopic sterilisation against laparoscopic sterilisation alone found no significant differences in the complication rate between the two procedures.

There are conflicting results regarding failure rates when tubal occlusion is performed in association with a pregnancy. Data on laparoscopic procedures from the early days of laparoscopic tubal occlusions[163,164] suggest a higher failure rate (two to seven times higher) when the procedures were performed in association with termination of pregnancy or postpartum.

Evidence level 3/2a

A large case–control study[84] failed to find any association between timing of the procedure and failure rate. However, the follow-up time was short and there were less suitable controls for the post-termination and postpartum cases. The prospective CREST study,[15] with ten-year follow-up, found the lowest failure rate in the postpartum salpingectomy group (7.5/1000 procedures), which included mainly tubal occlusion using a modified Pomeroy method.

Evidence level 2b

Until further data are available, the evidence suggests that the regret rate is certainly higher and that failure rate from sterilisation associated with pregnancy may be higher than that from an interval procedure. Sterilisation should therefore be performed as an interval procedure wherever possible.

Recommendation 28

B **Tubal occlusion can be performed at any time during the menstrual cycle, provided that the clinician is confident that the woman has used effective contraception up to the day of the operation. If this is not the case, the operation should be deferred until the follicular phase of a subsequent cycle. The woman should be advised to use effective contraception until her next menstrual period.**

A certain percentage of sterilisation 'failures' are caused by luteal-phase pregnancies. These occur when women are sterilised after unknowingly conceiving in the same cycle as the sterilisation

procedure. Iatrogenic luteal-phase ectopic pregnancies can be caused by occluding the tube before the blastocyst has passed the site of occlusion.

Such pregnancies can be prevented by scheduling surgery in the follicular phase of the woman's cycle. However, this does not always fit in with operating times or with women who have unpredictable cycles. It is therefore crucial, in preoperative counselling, to emphasise the importance of continuing an effective method of contraception throughout the cycle in which the operation takes place. There is no evidence to support stopping the combined pill prior to surgery or to support the use of thromboprophylaxis (unless there are other risk factors) in women undergoing uncomplicated intermediate procedures such as laparoscopy.[165]

If the combined oral contraceptive pill is being used, the current packet should be finished. If the progestogen-only pill is being used, it should be continued until the end of the packet or the next period, whichever is the sooner. If a contraceptive patch is being used the current patch cycle should be completed.

If the woman has a copper IUCD or LNG-IUS *in situ*, this should be removed at the next period. Removing the IUCD or LNG-IUS during the sterilisation procedure means that the woman may be left unprotected if she has ovulated prior to the procedure and a fertilised ovum has already passed the site of tubal occlusion. In the absence of evidence regarding the timing of removal of an LNG-IUS after sterilisation, the consensus view of the Guideline Group is to leave it in for at least seven days before removal.

Luteal-phase pregnancies are estimated to occur in about 2–3/1000 interval procedures.[166,167] Grubb and Peterson,[168] using data from the CREST study, found a similar rate of 17 in 5772 women sterilised. Other reports from single institutions suggest local rates may be even higher.[169,170] Grubb and Peterson[168] found that women who used more effective contraception, such as the combined oral contraceptive pill or IUCD, prior to sterilisation had a significantly lower luteal-phase pregnancy rate than women using barrier, fertility awareness or withdrawal methods.

Evidence level 2

Recommendation 29

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

Preoperative same-day pregnancy testing on all women undergoing sterilisation can identify pre-existing pregnancies and at least some luteal-phase pregnancies.[169–171] In one study, 21 of 802 women (2.6%) had a positive pregnancy test on the day of their planned interval laparoscopic sterilisation.[171] Not all of these would have been revealed by history alone. It would still be important to take a thorough history on admission to include the last menstrual period and any acts of unprotected intercourse since then. Women at risk include those who have had any unprotected sexual intercourse in the same cycle as the sterilisation procedure. Even the sensitive beta human chorionic gonadotrophin tests in routine use will not be positive until seven to eight days after the date of ovulation at the earliest, so a negative test could provide false reassurance.

Evidence level 3

Recommendation 30

B **Routine curettage at the time of tubal occlusion, in order to prevent a luteal-phase pregnancy, is not recommended.**

Evidence level 2/3

Concurrent dilatation and curettage (D&C) has often been performed in an attempt to reduce the incidence of luteal phase pregnancies. Grubb and Peterson[168] found that concurrent D&C did not significantly reduce the luteal pregnancy rate. Lichter *et al.*[172] also studied the value of routine D&C at the time of interval sterilisation. After detecting two luteal-phase pregnancies in 265 women at risk, they calculated that over 130 unnecessary procedures would have to be performed for every one that would be abortifacient. They therefore doubted the value of D&C, especially when unsuccessful pregnancy termination increases as gestational age falls.[173] Another study[174] showed that this practice was associated with five uterine perforations and one readmission for bleeding when performed at the same time as sterilisation in 222 women, showing that morbidity is present even with a relatively quick and simple procedure. There is also doubt regarding the legality of a concurrent D&C in UK law.[175] The procedure could be interpreted as an attempt to procure an abortion. This may then constitute a criminal offence unless the conditions of the 1967 Abortion Act are complied with.

6.6 Reversal

Recommendation 31

B **Although women requesting sterilisation should understand that the procedure is intended to be permanent, they should be given information about the success rates associated with reversal, should this procedure be necessary.**

Recommendation 32

✔ **Women should be informed that reversal operations are rarely provided by the National Health Service.**

Careful preoperative counselling can reduce the number of requests for reversal of sterilisation but can never eliminate them. Approximately 3–10% of women who have been sterilised express regret[16,146] and a proportion of these request reversal of sterilisation.[148,176] The most common reason for this request is a new relationship.[20,151]

Tubal reanastomosis gives a good chance of an intrauterine pregnancy. Literature reviews[59,77] have established that the overall intrauterine pregnancy rates following reversal of sterilisation range between 31% and 92%. In selected patient groups, particularly those who were sterilised with clips or rings, successful reversal may be at the top end of this range.[60–62] Most studies have shown that success rates are improved by using microsurgical techniques.[59,61] Case series of laparoscopic reversal of sterilisation report pregnancy rates of 31–73% with an associated ectopic pregnancy rate of 0–7%.[177]

Evidence level 3

In vitro fertilisation (IVF) was originally developed for tubal infertility and it has been questioned whether this might not be the most effective therapy for women who have been sterilised and who want to conceive again. The success rates discussed above[59] compare favourably with the average success rate of 21.8% per IVF cycle.[178] However, no randomised controlled trials have been performed comparing these two methods of conception following tubal occlusion. Miscarriage and multiple pregnancy rates are also lower after surgical reversal than with IVF. Ectopic pregnancy rates, as might be expected, are higher after surgical reversal but are not unacceptable. Repeated cycles of IVF may achieve a higher success rate but, on average, only one to two cycles of IVF are performed per woman in the UK.[178] Even in women over 40 years of age, reversal of sterilisation achieves a good intrauterine pregnancy rate of 42–52%,[179–181] whereas success with IVF diminishes after this age to a livebirth rate per treatment cycle of 5.4%.[178] No pregnancies have been reported in women over 43 years of age after reversal operations.[177]

While health authorities are obliged to provide male and female sterilisation services free of charge,[182] reversal operations are rarely funded on the National Health Service, although this may depend upon the particular health authority and individual circumstances. Women should be informed of the local availability or otherwise of NHS-funded sterilisation reversal operations and of IVF.

6.7 Risks

Recommendation 33

B **Women should be reassured that tubal occlusion is not associated with an increased risk of heavier or irregular periods when performed after 30 years of age. There is an association with subsequent increased hysterectomy rate, although there is no evidence that tubal occlusion leads to problems that require a hysterectomy. Data are limited on the effect on menstruation when tubal occlusion is performed on women under 30 years of age.**

In 1951, Williams *et al.*[183] reported 'significant abnormal bleeding' among women who had received tubal sterilisation compared with a non-sterilised control group. Today, researchers still debate whether the 'post-tubal sterilisation syndrome' exists. A review of earlier literature indicates that many of these studies have serious methodological problems, e.g. recall bias, inappropriate control groups, failure to elicit prior history of gynaecological or psychological problems and failure to account for the use of oral contraceptives or IUCDs.[183,184] When interpreting data, consideration should also be given to the natural changes in menstrual function as women grow older, regardless of whether they have been sterilised: women's menstrual cycles gradually shorten in duration and decrease in variability of duration until just before menopause.[185,186] If tubal occlusion were to cause an increase in menstrual disturbances, the public health impact in terms of morbidity and subsequent major surgery (i.e. hysterectomy) could be substantial.[187]

A systematic review[188] has reviewed the literature on menstrual and hormonal changes in women who have undergone tubal occlusion. This review, and a subsequent five-year follow-up of a sub-cohort of women recruited to the CREST study,[189] found the risk of hysterectomy to be higher among women who underwent tubal occlusion when compared with women partners of men with vasectomies or the general population There is no evidence, however, to suggest that tubal occlusion leads to the problems that necessitate hysterectomy. Women who seek a surgical solution

to contraception may also seek such a solution for their gynaecological complaints. Three studies indicated that women who had undergone tubal occlusion at a younger age were at significantly greater risk of hysterectomy than women who had undergone this procedure later on in life, although the CREST study found an elevated risk for all ages.[189]

Evidence level 2a

This review found that, at least for women over 30 years of age, tubal occlusion did not cause significant changes to either the heaviness of their periods or the duration of their menstrual cycle. Data on women under 30 years are limited due to the small numbers of women who have tubal occlusion at this age. Further information is required on menstrual changes following mechanical methods of tubal occlusion, especially the Filshie clip, as it is possible that any effect on menstrual function caused by alteration in ovarian blood supply will be minimised, as these methods cause the least tubal and mesosalpingeal damage.

Women should be reminded that if they are changing from using oral contraceptives to tubal occlusion their periods are likely to return to their previous state. This may involve heavier and more uncomfortable periods.

6.8 Equipment and facilities

Recommendation 34

✔ **All equipment involved in performing tubal occlusions should be properly maintained.**

Recommendation 35

✔ **Laparoscopic tubal occlusion should only be performed at a site where there are facilities to perform a laparotomy safely.**

Properly maintained diathermy equipment is essential for sterilisation, even though it may only be used as a backup when tubal occlusion with clips or rings fails. It is also important that theatre staff are trained in its correct use.

When bipolar diathermy is used, it is important to ensure that the correct settings are used and that the forceps and generator are matched, otherwise there is a risk that the tube will only be partially destroyed, leading to sterilisation failure and pregnancy.

Good practice dictates that all equipment should be maintained and serviced regularly. This is particularly true for ring and clip applicators as, like all mechanical equipment, they can deteriorate with use and age. The Filshie clip manual,[67] for example, gives clear instructions (which should be followed carefully) for assembly, cleaning and maintenance.

Laparotomy may be necessary as a result of intraoperative complications during sterilisation, such as bowel perforation, blood vessel damage with the laparoscope trochar or bowel burns (if diathermy is used). It is therefore vital that laparoscopic sterilisation is only performed in a place where there are facilities to perform a laparotomy immediately and safely. This was a recommendation in the RCOG report on gynaecological laparoscopy in 1978.[68] Women with

preoperative risk factors for operative difficulty (e.g. previous abdominal or pelvic surgery or obesity)[46] should be specifically advised that laparotomy may be required and that occasionally this may mean a midline incision.

6.9 Training

Recommendation 36

C **Trainees should perform at least 25 supervised laparoscopic tubal occlusions before operating without supervision.**

Failure of sterilisation and complications arising from sterilisation are a common cause of litigation among gynaecologists. Failed sterilisation accounted for 25% of 100 consecutive gynaecological claims notified to the Medical Defence Union, and for 17.4% of 100 gynaecological claims settled.[7] Failed sterilisation also accounted for 19% of 275 gynaecological cases that were notified to lawyers over the period 1984–94.[6] While failures can occur even when tubal occlusion is performed correctly, laparoscopic sterilisation performed by inexperienced operators is, not surprisingly, associated with a higher rate of failure.[84,190,191]

The Guideline Group suggests that a trainee should not perform laparoscopic sterilisation unsupervised until he or she has performed at least 25 supervised procedures and can perform a laparotomy unsupervised. Supervision means the presence of a senior gynaecologist (consultant or SpR year 4/5) in the operating theatre.

Evidence level 4

A structured learning package has also been shown to enhance trainees' knowledge about laparoscopic sterilisation.[192] The RCOG has three levels of training for laparoscopic surgery. Level 1 training includes laparoscopic sterilisation and should be achieved by all specialist registrars during their structured training. The RCOG report on training in gynaecological endoscopic surgery[193] recommends that 'all registrars should attend one of the fundamental training courses; this should occur at an early stage in each registrar's training'.

Evidence level 4

Laparoscopic sterilisation associated with a termination of pregnancy[163] or previous abdominal or pelvic surgery[46] may be associated with higher complications and failure rates, particularly when performed during the learning curve. It is thus particularly important that these procedures are performed by a senior, trained member of staff.

Chapter 7
Vasectomy

7.1 Methods of vasectomy

Recommendation 37

A **Except when technical considerations dictate otherwise, a no-scalpel approach should be used to identify the vas, as this results in a lower rate of early complications.**

Recommendation 38

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

Recommendation 39

B **Clips should not be used for occluding the vas, as failure rates are unacceptably high.**

Vasectomy is performed in two separate steps. First, the vas deferens has to be exposed out of the scrotum and then the vas must be occluded or interrupted. Conventionally, one or two incisions are made with a scalpel and the fascial layers divided until the vas is exposed.

A newer technique is the no-scalpel vasectomy developed by Li Shun Quiang *et al.*[194] This method was developed to increase the acceptability of vasectomy by eliminating the fear of the incision. The technique employs two unique instruments. After anaesthesia is injected, a specially designed fixation clamp encircles and firmly secures the vas without penetrating the skin. The second instrument, a sharp-tipped dissecting forceps, is then used to puncture the skin and vas sheath and stretch a small opening in the scrotum. The vas is lifted and occluded, as with other vasectomy techniques. The same puncture site can be used for the opposite vas or a separate puncture can be made.

Two randomised controlled trials have evaluated these two methods of approach to the vas.[195,196] The larger trial involved 1429 men and found that the Li method took less time and significantly reduced short-term complications of bleeding, haematoma formation, infection and pain. Long-term complications were similar in both groups, as were early failure rates.[195] The smaller trial only involved 99 men and, as it found no significant differences between complication rates, may have been underpowered.[196]

Evidence level 1

Vas occlusion during the vasectomy can be performed by one of three procedures:

- ligation with absorbable or non-absorbable sutures (silk, cotton or linen)
- coagulation (electrical, monopolar or bipolar, or thermic)
- application of clips.

Once the scrotal incision has been made and the vas identified, the vas is occluded or interrupted using one of the methods described above. A 1–3-cm piece of vas can be removed, although not all techniques advocate this.[197] An additional procedure needs to be performed to reduce the likelihood of recanalisation, otherwise failure rates may be unacceptably high.[198] One end, usually the distal, is allowed to fall back into the wound and the spermatic fascia is closed over the defect. This technique, known as fascial interposition, separates the ends into two different tissue planes, making recanalisation between the two ligated ends less likely.[199]

Alternatively, intraluminal diathermy can be used.[200] This technique may make reversal more difficult, however, as it damages more of the vas.

Very few trials have assessed these different techniques for occluding the vas. One randomised controlled trial found that the highest rates of early recanalisation and complications were seen with the open-ended method without fascial interposition.[201] Preliminary results from a randomised controlled trial comparing ligation and excision with and without fascial interposition in no-scalpel vasectomies was stopped after an interim analysis showed that the facial interposition group had a significantly higher vasectomy success rate as determined by time to two consecutive azoospermic semen samples.[202]

Evidence level 1

Another comparative study found higher failure rates with clipping and excision when compared with cautery, fascial interposition and an open testicular end.[203] Randomised controlled trials of different occlusion methods with longer follow up are needed to find the best method, both in terms of failure rates and complication rates.

Evidence level 2a

7.2 Anaesthesia

Recommendation 40

C **Vasectomy should be performed under local anaesthetic wherever possible.**

Most men will tolerate vasectomy under local anaesthesia. As local anaesthesia is both safer and less expensive than general anaesthesia, vasectomy should be performed under local anaesthesia wherever possible. Recovery from local anaesthesia is quick and anaesthetic complications are rare. There are no controlled studies comparing vasectomy under general anaesthesia with local anaesthesia, although a retrospective questionnaire survey of 115 men suggested that postoperative pain was higher after general anaesthesia. This may be because the more difficult cases were performed under general anaesthesia. The number of days to full recovery was the same in both groups.[204]

Evidence level 3

There are contraindications to vasectomy under local anaesthesia. A general anaesthetic is necessary if there is:

- a history of an allergy to local anaesthetic
- a history of fainting easily
- patient refusal of local anaesthesia.

Vasectomy should be delayed when the following conditions are present:[28]

- scrotal skin infection, active sexually transmitted disease, balanitis, epididymitis or orchitis; there is an increased risk of postoperative infection
- systemic infection or gastroenteritis; there is an increased risk of postoperative infection
- intrascrotal mass; this may indicate underlying disease.

Caution is needed when the following conditions are present and specialist referral may be necessary:[28]

- previous scrotal injury
- large varicocele or large hydrocele; the vas may be difficult or impossible to locate.

Specialist referral with availability of general anaesthesia may be necessary with the following conditions:[28]

- cryptorchidism
- inguinal hernia
- coagulation disorders.

7.3 Histological examination

Recommendation 41

C	**Excised portions of vas should only be sent for histological examination if there is any doubt about their identity.**

Although it is usually accepted practice to send anything excised from the body for histological examination, it is not now customary to send the excised sections of the vasa deferentia for histological examination unless there is doubt about their nature.[205] Routine histology on vasectomy specimens represents an unacceptable burden both on laboratory staff and time and is expensive. Storage of excised vas specimens is inconvenient and requires meticulous labelling, organisation and storage resources. Operative error or early recanalisation should be picked up on the post-vasectomy semen analysis.

7.4 Post-vasectomy semen analysis

Recommendation 42

C	**Men should be advised to use effective contraception until azoospermia has been confirmed. The way in which azoospermia is confirmed will depend upon local protocols.**

The rationale for post-vasectomy semen analysis is to confirm clearance of stored spermatozoa downstream of the vasectomy site and to confirm, as quickly as possible, men who fail to become sterile through either technical failure or early recanalisation. The timing of post-vasectomy semen analysis and the number of specimens required to confirm clearance remain controversial.

By convention, in the UK, two post-vasectomy samples are usually examined before clearance to stop contraception is given, although the timing varies.[206] There is little evidence to support the need for two samples and only one study has compared a regimen with two tests against one with just one test.[207] In this study, men either had one test 16 weeks after vasectomy or two tests at 12 and 16 weeks after vasectomy. The proportion of men declared azoospermic after one sample was the same in both groups but compliance for the second test was lower than the first test in the two-test group.

Evidence level 2

The main rationale for testing two samples, however, is to help detect cases of early recanalisation, when the first test shows azoospermia but the second and subsequent tests are positive. This occurred in three out of 574 (0.5%) men who had a vasectomy during one year of observation.[208]

Evidence level 3

Testing should not start until at least eight weeks after the vasectomy because the time necessary for complete expulsion of stored sperm may vary, depending in part upon the frequency of ejaculation and on age.[198,208–211] All vasectomy patients should be clearly warned of this problem and advised to use other contraceptive measures until azoospermia has been confirmed. If testing is started too early most men will not yet be azoospermic and will have to endure several repeat tests. Compliance with post-vasectomy testing is often poor,[206,212–215] so a regimen is needed that ensures as many men as possible will need the minimum number of tests.

Evidence level 2a/3

Local considerations may influence the most convenient time to start testing. Any pattern of testing, as long as it starts after eight weeks, is acceptable. In some countries where semen analysis is not widely available, a defined number of ejaculations are advised before contraception can be stopped.

These two policies, of clearance after a defined number of ejaculations and semen analysis at a defined interval after vasectomy, have never been directly compared. In 1980, the recommendation of the International Planned Parenthood Federation (IPPF) was that, if semen cannot be checked, men should use other birth control methods for at least 20 ejaculations, while the Association for Voluntary Sterilization recommended at least 15 ejaculations or six weeks after the procedure.[216] Using a defined number of post-vasectomy ejaculations to time the post-vasectomy semen analysis is used successfully in some places in the UK.[217,218]

Recommendation 43

A **Irrigation of the vas during vasectomy does not reduce failure rates or time to clearance.**

Irrigating the vas during vasectomy may decrease the postoperative count but does not reduce failure rates or time to clearance .[219–223]

Evidence level 1b/2a

7.5 Special clearance

Recommendation 44

C **In a small minority of men, non-motile sperm persist after vasectomy. In such cases, 'special clearance' to stop contraception may be given when less than 10 000 non-motile sperm/ml are found in a fresh specimen examined at least seven months after vasectomy, as no pregnancies have yet been reported under these circumstances.**

Evidence level 2

Men who have operative failure or early recanalisation will need to have the vasectomy repeated. Late recanalisation is not usually discovered until a pregnancy is reported. What is more uncertain is what to do with the small percentage of men who have persisting non-motile sperm in their samples. 'Special clearance' is the term given to the advice to stop contraception despite a very low concentration of non-motile sperm being present and may affect 2.0–2.5% of men undergoing vasectomy.[224,225] No pregnancies were reported for over 600 men followed up for one to three years when contraception was discontinued after less than 10 000 non-motile sperm/ml had been found in a fresh specimen examined at least seven months after vasectomy.[224–226]

The issue of whether special clearance should be granted to men with small numbers of non-motile sperm remains controversial, especially from a medico-legal point of view, although it seems, from the studies presented above, that these men have no greater risk of late recanalisation and failure than all men with vasectomies. Smith,[205] however, is at pains to emphasise that, in this case, the decision to discontinue contraception should lie with the patient rather than with the doctor.

7.6 Failure

Recommendation 45

B **Men should be informed that vasectomy has an associated failure rate and that pregnancies can occur several years after vasectomy. The rate should be quoted as approximately one in 2000 after clearance has been given.**

Vasectomy failure can be defined as lack of azoospermia on semen analysis or presence of a pregnancy. Although pregnancy is obviously the most important adverse outcome, such an outcome is difficult to measure when it is not occurring in the subject being studied and azoospermia is widely used as a surrogate outcome instead.

Vasectomy failure can result from:

- operative failure
- unprotected intercourse shortly after vasectomy while there are still residual sperm stored in the male reproductive tract on the urethral side of the obstruction
- spontaneous recanalisation of the vas.

Failure rates from all these causes range from 0–2%,[216] with most studies reporting less than 1%.

Operative failures can occur because the wrong structure is occluded (leaving one or both vasa intact) or because the vas is inadequately occluded (if ligatures or clips are applied too loosely). When operative failures occur, sperm are present in the post-vasectomy semen analyses. Rarely, failure is caused by congenital duplication of one or both vas.[224] Although the vasa may have been occluded bilaterally, if there are any more vasa, spermatozoa can still be released.

The most important cause of failure is unprotected intercourse before the seminal reservoirs are cleared of sperm.

Recanalisation of the vas can occur at an early or late stage. Early recanalisation was first described in 1969,[227] and is recognised by post-vasectomy sperm counts which may at first be azoospermic or reduced but then rapidly increase again.

Late recanalisation became recognised after six such failures were reported in 1984.[228] It usually presents with a pregnancy several months or years after two consecutive azoospermic samples. When the semen analysis is repeated at the time of the pregnancy, motile sperm are present. However, pregnancies have been reported after vasectomy where semen analysis showed a small number of non-motile sperm despite two initial azoospermic samples.[205,229] Paternity was proved with DNA testing. The pregnancy rate due to late recanalisation is approximately 1 in 2000.[228] This is at least ten times lower than that for tubal occlusion in women.

Evidence level 3

7.7 Reversal of vasectomy

Recommendation 46

B **Although men requesting vasectomy should understand that the procedure is intended to be permanent, they should be given information on the success rates associated with reversal, should this procedure be necessary.**

Recommendation 47

✔ **Men should be informed that reversal operations or intracytoplasmic sperm injections are rarely provided within the National Health Service.**

Men who are considering vasectomy reversal need an accurate understanding of the likelihood of subsequent pregnancy.

There are at present no standardised and uniform criteria in reporting the results of vasectomy reversal. A wide range of success rates have been reported, from 52%[230] to over 82%.[231] This wide range of success rates may to some extent reflect variations in:

- time since vasectomy
- type of vasectomy being reversed (e.g. open-ended, sealed with suture, sealed with heat)
- type of reversal (vasovasostomy or vasoepididymostomy, unilateral or bilateral)
- technique used (macrosurgical or microsurgical, one-layer or two-layer anastomosis)

- surgeon skill and experience
- presence or absence of other pathology (e.g. varicocele)
- presence or absence of sperm antibodies.

The follow-up time at which failure to achieve pregnancy is declared may affect reported pregnancy rates. This follow-up period must be long enough to allow for most pregnancies to occur, yet short enough to include most patients before they become lost to follow-up. A large proportion of male infertility patients are lost to follow-up after surgical treatment (defined for these purposes as failure to obtain or report a semen analysis or pregnancy for 12 consecutive months). Fazeli-Matin *et al.*[232] found this proportion to be 53% for vasovasostomy. When finally contacted, the pregnancy rate in lost-to-follow-up patients was virtually identical to the pregnancy rate in those regularly followed up after vasovasostomy procedures.

When case series are reported over a long period of time, there may be an improvement of anatomical or functional success due to better technical skill of the surgeons, magnification and smaller suture materials used. Personal experience with a particular technique is an important factor in success, especially for microsurgical techniques.[233–235]

To minimise the effect of surgical technique and intraoperative findings, either favourable or unfavourable, on the outcome of vasectomy reversal, the pregnancy rate achieved in the partners of a group of men with postoperative patency can be studied. Usually, this implies the presence of sperm in the ejaculate and does not necessarily mean that there is bilateral patency or normal fertility potential. Unilateral obstruction may also exist in the normally fertile population.[236] There is a discrepancy between patency rates and pregnancy rates, with patency rates superior to pregnancy rates. The reasons for this discrepancy remain unclear, although the formation of antisperm antibodies is thought to be a contributory factor.

The longer the time from vasectomy to a reversal operation, the lower the pregnancy rates. Up to ten years, the rates vary between 32% and 80%;[231,237–240] over ten years the rates vary between 9% and 35%.[234,238,240]

Evidence level 3

Confounding factors, however, may be the duration of follow-up of men after reversal and the age and potential fertility of the female partner.[241]

Extraction procedures from either the testicle or epididymis combined with intracytoplasmic sperm injection (ICSI) is an alternative way to achieve pregnancy after vasectomy. In a non-randomised study, pregnancy rates were higher with vasovasotomy when compared with ICSI and there was a much lower multiple pregnancy rate of 0.7% compared with 15.8% in the ICSI group.[242]

Evidence level 2a

7.9 Risks

Recommendation 48

B **Men requesting vasectomy can be reassured that there is no increase in testicular cancer or heart disease associated with vasectomy. The association, in some reports, of an increased risk of being diagnosed with prostate cancer is at present considered likely to be non-causative.**

Vasectomy and prostate cancer risk

A systematic review of five cohort studies and nine case–control studies[243] found that the age-adjusted relative risk for prostate cancer with vasectomy was 1.2 (95% CI 1.0–1.5). However, both clinical and statistical heterogeneity was present. When this was investigated, it seemed that study design, study base and selection bias might have accounted for the heterogeneity and an overestimate of the association between prostate cancer and vasectomy. There was no significant association when cohort studies or population based studies or studies with adequate selection of controls were looked at alone. Although a case–control study[244] published after this systematic review found a significant association between the rates of vasectomy in men with prostate cancer when compared with vasectomy rates in men with lung cancer or the male population of Quebec (OR for the 1925–39 birth cohort 2.6, 95% CI 1.7–4.3), this association could still be influenced by ascertainment or detection bias which is a feature of case–control studies rather than population or cohort studies. A population-based study published after the systematic review similarly found no association between vasectomy and prostate cancer.[245]

Evidence level 2

Vasectomy and testicular cancer risk

Studies from Ireland and Scotland suggest that the risk of testicular cancer may increase after vasectomy.[246,247] However, cohort studies and case–control studies with a longer interval between vasectomy and follow-up do not show any increased risk of testicular cancer after vasectomy, suggesting that the positive association in the other studies could have been due to detection bias.[248–253]

Evidence level 2

Vasectomy and cardiovascular disease

Vasectomy has been reported to accelerate atherosclerosis in monkeys.[254,255] Numerous studies have been carried out to determine whether this is the case in men. In two comprehensive literature reviews, Liskin *et al.*[216,256] found no significant difference between men with and without vasectomies in the rates of cardiovascular disease, atherosclerotic diseases generally or specifically of hypertension, acute myocardial infarction or coronary heart disease. There is no association between vasectomy and any coronary disease risk factors and no relationship between vasectomy and degree of occlusion of the coronary vessels. There is also no significant difference in mean

systolic or diastolic blood pressure after vasectomy. Later studies[257–259] substantiate these findings. The incidence of cardiovascular disease or coronary heart disease does not rise with time after vasectomy in excess of the normal increase with ageing, even when men are followed up long-term after the procedure for ten or 15 years. Morbidity and mortality from cardiovascular disease does not increase after vasectomy and may even be reduced, as healthier men seem to choose vasectomy.

Evidence level 2

Vasectomy and other diseases

Hospitalisation rates for diseases of the genitourinary system were higher in men with vasectomies compared with those without, during the early post-vasectomy period. A significantly higher percentage of men with vasectomies had kidney or bladder infection and there was also a significant increase in the incidence of epididymitis and orchitis. This amounts to a 1.5–2.5 times greater risk of genitourinary tract infection or inflammation up to two years after the procedure.[216,256] A significant association between vasectomy and urolithiasis was also shown for all age ranges, although there are no recognised risk factors for urolithiasis that can be attributed to vasectomy.[260]

With the exception of the conditions described above, there is no significant difference in the incidence of or hospitalisation for any other disease group: neurological, pulmonary, endocrine, autoimmune or mental disorders. There is no significant change in activity of blood clotting factors, no clinical evidence of thrombosis at a mean of 1.3 years after vasectomy and no significant difference in blood chemistry measurements, white blood cell count or haematocrit. The largest cohort study to date,[261] involving nearly 22 000 men, found that men who had undergone vasectomy had similar or lower rates of 98 diseases (including various cancers, autoimmune diseases and heart disease) as controls who had not had vasectomies. Sivanesaratnam,[262] in his review of long-term effects of vasectomy, noted that, while at least 50% of men permanently had sperm agglutinating or immobilising autoantibodies in their serum after vasectomy, numerous studies failed to show any immunological or other adverse effects upon general health. These antisperm antibodies are therefore important only to those men seeking a return of fertility and even then the correlation is poor.

Recommendation 49

B **Men should be informed about the possibility of chronic testicular pain after vasectomy.**

Chronic pain, which can be described as testicular or scrotal and may develop months or years after the vasectomy, is an important complication of a procedure that is done for essentially social rather than medical reasons. The incidence of chronic post-vasectomy pain ranges from 12% to 52%, depending upon the study population. This is likely to represent an overestimate, as most of the studies involved questionnaire surveys, to which men with complications may be more likely to respond. The proportion of men who sought help or whose quality of life was adversely affected was between 0.9% and 5.2%.[197,263–267]

The only study that tried to assess testicular pain in a control group of men without vasectomy found a prevalence of pain of any type to be present in 26%.[267] However, while vasectomy was associated with a doubling of the rate of occasional testicular pain (47% versus 23%, 95% CI for a difference

10–35%), severe testicular pain was reported in only 6% of cases and 2% of controls. None of the vasectomised men expressed regret.

Evidence level 2

Epididymectomy, vasovasostomy and denervation of the spermatic cord have been described in case series as effective treatments for this condition[266,268–271] but no randomised controlled trials were found.

Evidence level 2

Two randomised controlled trials have shown that the injection of a local anaesthetic into the vas at the time of vasectomy may prevent chronic pain; further studies with longer follow up are warranted.[272,273]

Evidence level 1b

7.10 Training

Recommendation 50

C **Practitioners who are being trained to perform vasectomies should ensure that their training conforms to that advocated by the Faculty of Family Planning and Reproductive Health Care. Doctors with no prior experience should be supervised for ten operating sessions or 40 procedures, while doctors with relevant prior surgical experience should perform eight supervised procedures.**

Vasectomy has become one of the main causes of claims against GPs for medical negligence related to minor surgery.[5] The Medical Defence Union examined 26 settled claims involving minor surgery over a five-year period. These cases represented 2.5% of all settled medical negligence claims against GPs in the UK. Of these, 8% were in connection with vasectomy. When 53 notified cases (on average 70% of notified claims do not proceed beyond disclosure of records) were analysed, vasectomies accounted for 38%. The most common reason for complaint about vasectomy was failure of the procedure, when patients had not been told that sometimes the operation might be unsuccessful. This problem accounted for more than one in four vasectomy-related claims. Lack of preoperative information, such as failure to warn patients to expect postoperative pain, also prompted other claims.

Since the first version of this guideline, which advocated the development of a national training standard for vasectomy, was published in 1999, a special skills training module has been developed by the Faculty of Family Planning and Reproductive Health Care in conjunction with the Urological Specialist Advisory Committee of the Royal College of Surgeons. The training syllabus and logbook are now available (see the Faculty's website at http://www.ffprhc.org). The minimum number of supervised operating sessions is ten, or 40 vasectomy procedures for doctors with no prior special surgical experience, and a minimum of eight supervised procedures for those with prior experience of performing vasectomies.

Evidence level 4

Chapter 8
Audit and further research

8.1 Audit

Recommendation 51

C **A national register and audit of failed sterilisations is needed. Hospital-based registers of sterilisation procedure failures would assist this.**

By keeping a national register of failed sterilisations, a data set will gradually be generated that looks at failure rates in UK practice. This will mean, in the long term, that more accurate information can be given to women in the UK concerning short- and long-term failure rates. Like other Confidential Enquiries, it will also serve to inform clinicians about areas of substandard care.

In at least two unpublished reports that were known to members of the steering group and were initiated following medico-legal activity, a cluster of female sterilisation failures was related to recurrent human error by an individual consultant. In the absence of medico-legal interest, these occurrences can be hard to detect without some system of recording pregnancies following sterilisation. It should be regarded as good practice to conduct a retrospective audit of an individual operator's procedure outcomes if more than one pregnancy is noted following sterilisation procedures with a short separation in either time or number of procedures. Hospital-based registers of sterilisation procedure failures would assist this.

8.2 Areas needing more research

When reviewing the evidence that forms the basis for the preceding recommendations, it became obvious that there were several areas which need more research. These areas are:

- controlled comparisons between different methods of vasectomy
- long-term studies on failure rates related to the method used for vasectomy
- long-term failure rates of the 'no scalpel' method in particular
- the long-term significance of persistent non-motile sperm post-vasectomy
- the prevention of chronic testicular pain after vasectomy
- the psychosexual sequelae of vasectomy
- long-term follow-up studies on the Filshie clip with regard to failure rate, ectopic pregnancy and effect on menstrual cycle
- effect on menstrual cycle and hysterectomy rates in women having tubal occlusions under 30 years of age
- long-term studies on failure rates of all female sterilisation techniques in the UK.

Appendix 1
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Evidence table 1

Decisions around vasectomy and tubal occlusion (Recommendation 6)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Shain *et al.* 1985[43]	248 married women scheduled for tubal occlusion and 165 wives of men scheduled for vasectomy	Interviews	Factors surrounding choice of sterilisation procedure	Both groups chose sterilisation in general because of its certainty, safety, permanence, ease and opposition to other birth control methods. 39% of women who chose tubal occlusion were against vasectomy because their partner refused surgery. 7% of vasectomy wives chose vasectomy because they refused surgery. 17% of tubal occlusion and 26 % of vasectomy wives fearful of surgical complications or side effects with non-chosen method.	Women for tubal occlusion approximately one year older than vasectomy wives and of higher parity. More sterilisations associated with pregnancy than vasectomies. Otherwise groups were similar.	Comparative study	3

Evidence table 2

Method of referral (Recommendation 8)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
McKessock *et al.* 2001[50]	232 women referred for tubal occlusion June 1996 to March 1997	Referral from GP practices that had received criteria for direct referral (n = 75) or normal referral from control practices (n = 157)	Patient waiting times, satisfaction, short-term regret, operative complications and costs, patient preferences, adherence to criteria referral, GP and gynaecologist satisfaction, NHS costs	No inappropriate direct referrals. Lower waiting time in intervention group but more GP visits. No difference in patient or doctor satisfaction, operative complication rate, total cost to patient or NHS. Women preferred routine referral. Only 31% of all referred during study period were suitable for direct referral.		RCT	1b

Evidence table 3

Methods of approach to the fallopian tubes (Recommendations 9 and 10)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Kulier *et al.* 2003[52]	2601 women having interval sterilisation	All RCTs involving laparoscopy, mini-laparotomy, culdoscopy as an approach to the fallopian tubes for tubal occlusion 1: Mini-laparotomy versus laparoscopy (n = 1911) 2: Mini-laparotomy versus culdoscopy (n = 395) 3: Mini-laparotomy versus laparoscopy versus culdoscopy (n = 295)	Operative morbidity and mortality	1. No difference in major morbidity. Minor morbidity significantly more with mini-laparotomy (OR 1.89, 95%CI 1.38–2.59). Laparoscopy on average five minutes shorter operating time (WMD 5.34, 95% CI 4.52–6.16). 2. Mini-laparotomy had less major morbidity (OR 0.14, 95% CI 0.02–0.98). Culdoscopy five minutes shorter (WMD 4.91, 95% CI 3.82–6.01). 3. Laparoscopy versus culdoscopy: no difference in major morbidity. Significantly less minor morbidity in laparoscopy group (OR 0.20, 95% CI 0.05–0.77).	Data on long term outcomes are better obtained from cohort studies rather than RCTs.	Systematic review (Cochrane)	1a

Evidence table 4

Operative risks of laparoscopy (Recommendation 7)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Jansen *et al.* 1997[45]	All laparoscopic procedures from the participating centres during 1994 were registered and complications documented	Laparoscopic procedures were divided into three categories: diagnostic, sterilisation and operative laparoscopy	Recorded complications were also divided into two categories: the laparoscopic approach and the laparoscopic technique	In the sterilisation group 39 complications (4.5/1000) occurred. The laparotomy rate as a result of a severe complication was 1.9/1000 procedures. Most complications occurred as a result of haemorrhage of the epigastric vein, gastrointestinal lesions and mesosalpinx injury. Complications were divided according to method of sterilisation (bipolar coagulation, clip or rings) but there was no statistical difference between the groups. Risk factors were also examined. The majority of women with complications (58%) had no risk factors. However, the most frequently encountered association with complications of laparoscopy was a previous laparotomy (OR 3.73, 95% CI 1.39–9.99). This rate of complications (0.45%) associated with laparoscopic sterilisations is similar to rates reported in retrospective studies,[43,45,46,129,130] which varied from 0.37% to 1.8%. Two deaths occurred in the 25 764 laparoscopic procedures analysed in the Dutch study, both related to the laparoscopic approach. This is similar to the mortality rate of eight per 100 000 procedures found in a UK survey[131] of laparoscopy in 1977. Both these results equate to a risk of death with laparoscopy of one in 12 000.		Multicentre prospective cohort study from 72 hospitals in the Netherlands	2a

Evidence table 5

Methods of tubal occlusion (Recommendations 9–15)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Bhiwandiwala *et al.* 1982[69]	24 439 women undergoing tubal occlusion	Diathermy, tubal ring via conventional and open laparoscopy, Rocket clip and prototype spring loaded clip	Surgical difficulty, surgical complications, technical failures, pregnancy rates up to one year, menstrual cycles	No difference between any of the methods. Menstrual cycles did not change overall.		Prospective cohort study	2a
Nardin *et al.* 2003[70]	9 RCTs, 4553 women	Different methods of tubal occlusion: 1. Ring versus spring-loaded clip (3 trials, 1327 women). 2. Pomeroy versus diathermy (2 trials, 1910 women). 3. Ring versus diathermy (2 trials, 599 women). 4. Pomeroy versus Filshie clip (1 trial, 200 women). 5. Hulka versus Filshie clip (1 trial, 200 women). Different approaches and different anaesthesia used	Major and minor morbidity Failure rates	1. Minor morbidity more common in ring group (OR2.15, 95% CI 1.22–3.78). Failure of technical approach more often with ring (OR 3.87, 95% CI 1.9–7.89). No difference in pregnancy rates, technical difficulties, women's complaints or menstrual irregularities. 2. Major morbidity higher with Pomeroy (OR 2.87, 95% CI 1.13–7.25) and more postoperative abdominal pain (OR 3.85, 95% CI 2.91–5.10). 3. More postoperative abdominal pain in ring group (OR 3.28, 95% CI 2.31–4.66). No differences in minor morbidity, technical failures, technical difficulties, operating time, menstrual irregularities. No failures in either group. 4. No differences in minor morbidity or menstrual irregularities. One pregnancy in Pomeroy group. 5. No differences between the groups.	Small sample size and relatively short period of follow up limited the power to show clinical or statistical differences for rare outcomes such as failure rates.	Systematic review (Cochrane)	1a

Evidence table 5 (continued)

Methods of tubal occlusion (Recommendations 9–15)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Dominik *et al.* 2000[72]	2126 women (878 mini-laparotomy and 1248 laparoscopy) having interval tubal occlusion	Filshie or Hulka clips	Failure rates and complications, one-year follow up apart from 24/12 follow-up in subset of 599 women in laparoscopy group	11 intrauterine pregnancies occurred: 9 Hulka, 2 Filshie. 12-month life table pregnancy probability 1.1/1000 Filshie clip and 6.9/1000 Hulka clip. In extended follow-up group, 12+24-month cumulative pregnancy probabilities were 3.9/1000 and 9.7/1000 for Filshie and 11.7/1000 and 28.1/1000 for the Hulka clip. Not significantly different. No difference between groups for early complications. No clip expulsions.	Not mentioned in Cochrane review above. Evaluated by blinded physician other than operator. More experienced operators than those in CREST.	RCT	1b
Sokal *et al.* 2000[71]	2746 women (915 mini-laparotomy, 1831 laparoscopy) having interval tubal occlusion	Filshe clips or tubal rings	Failure rates and complications One year follow up	2 in each group became pregnant, all intrauterine and all in laparoscopy groups. In the subset being studied for 24 months 1 more pregnancy in the Filshie group between 12 and 24 months. 12-month life-table pregnancy probability of 1.7/1000 in each group. 12- and 24-month cumulative pregnancy probabilities were 3.0–6.8 and 3.0–3.0 per 1000 for Filshie and ring respectively. 2 more pregnancies after 12 months but not in the subset being studied for longer. 1 in each group with Filshie being intrauterine and ring being ectopic. The tubal ring was more difficult to apply and had higher rates of tubal or mesosalpingeal injuries at surgery. Filshie clip had 3 cases of spontaneous clip expulsion during the follow-up period.	Excluded from Cochrane review above as said not to be intention to treat analysis. Evaluated by blinded physician other than operator. More experienced operators than those in CREST.	RCT	1b

Evidence table 6

Hysteroscopic methods of tubal occlusion (Recommendation 16)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Kerin *et al.* 2001[87]	130 women aged 21–43 years seeking permanent contraception	Dynamically expanding metal micro-insert (Essure pbc) inserted into the fallopian tube under hysteroscopic visualisation under IV sedation or paracervical block, followed by HSG at 3 months. All at one centre	Safety and effectiveness	111/130 had bilateral placements, 3/130 had unilateral placement, failure to position either 16/130. Total failures = 15%. 4 in wrong position on HSG. 105/107 had bilateral tubal occlusion at 3 months; the remaining 2 had tubal occlusion at 6 months. Well tolerated by most. 114 women had accumulated 2400 months wearing the device; no pregnancies reported so far. Mean time 21 months, median 20 months.	Multicentre trials will be available soon. Advanced hysteroscopic skills required.	Prospective phase 2 study; single arm, non-randomised	3

Evidence table 7

General anaesthesia versus local anaesthesia for tubal occlusion (Recommendation 20)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Peterson *et al.* 1987[98]	100 women	Standard general or local anaesthesia with sedation where chlorprocaine was used for periumbilical anaesthesia, bupivacaine was sprayed on to the peritoneal surfaces of the fallopian tubes and intravenous diazepam, fentanyl and glycopyrrolate were given	Completion of planned procedure, complications, anaesthesia time, recovery room stay, immediate postoperative events, physician visits or postoperative medication	4 women in the local anaesthesia group did not have their procedures completed due to technical difficulties associated with obesity, although 13 women > 80 kg, including 4 women over 100 kg, were sterilised satisfactorily. There were no major complications in either group and no difference between the groups in any of the other outcomes. Women in the local anaesthesia group returned to normal activities quicker than those in the general anaesthesia group but no test of significance was reported. 80% of women in both groups would choose the same method of anaesthesia again.		RCT	1b
MacKenzie *et al.* 1987[100]	200 consecutive women out of a possible 220 initial requests	Lignocaine with adrenaline was used to infiltrate the sub-umbilical and suprapubic regions ensuring the peritoneal layer was reached. Filshie clips were used for tubal occlusion while nitrous oxide was used to create the pneumoperitoneum. Lignocaine was also dropped on to the tube at the site of the proposed clip application	Completion of procedure and patient satisfaction	The procedure was successfully completed in all but 2 women, due to dense pelvic adhesions in one and marked obesity in the other. The former was sterilised successfully under general anaesthesia at a later date and a vasectomy was arranged for the husband of the other. 194 (97%) completed questionnaires were returned after women had experienced their first menstrual period after the procedure. Of these respondents, 177 (91%) stated they would recommend the operation to a friend. Of the 17 women that would not have recommended it, 2 failed to say why, 6 thought they would have preferred general anaesthesia and 3 would have liked more time before discharge.		Large case series	3

Evidence table 8

Intraoperative interventions to reduce postoperative pain; interventions for analgesia with tubal occlusion; topical anaesthetics to fallopian tubes plus local anaesthesia (Recommendation 22)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Pelland 1976 [114]	100 women undergoing laparoscopic tubal fulguration under sedation	5 ml 4% lidocaine to both, right, left tubes or normal saline to both prior to fulguration	Nurse observation of intraoperative pain	Lower pain scores at all times with lidocaine in both compared with placebo.		Double blind RCT	1b
Koetsawang *et al*. 1984[113]	300 women undergoing day case standard or open laparoscopy with tubal rings under IV sedation	10 ml 1% xylocaine or none	Intraoperative pain	Significantly more women in the treated groups reported no pain during surgery and less pain in the recovery period (open group but not standard group). Intensity of intraoperative pain much more likely to be moderate or severe in untreated groups.		RCT	1b
Garwood *et al*. 2002[115]	24 women undergoing day case laparoscopic tubal occlusion with Filshie clips under local anaesthesia	5 ml 1% lidocaine with 1:200 000 epinephrine or saline to each tube before tubal occlusion	Pain as assessed by VAS and CWS after clip application, 15 minutes and 1 hour after operation and at discharge	No women in treated group required extra intraoperative analgesia whereas 7 did in the placebo group. Significantly lower VAS and CWS scores at time of clip application and at 15 minutes postoperatively, despite more rescue analgesia being given to the placebo group. No difference at 1 hour after or on discharge. More women with severe pain reported in the placebo group.		RCT	1b

Evidence table 9

Topical anaesthetics to fallopian tubes plus general anaesthesia (Recommendation 22)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
McKenzie *et al.* 1986[109]	102 women undergoing day case laparoscopic tubal occlusion under general anaesthesia with Silastic bands	5 ml 1% etidocaine to each tube before bands applied or nothing to tube.	Postoperative pain assessed with VAS at 1, 2and 4 hours	Significantly more women did not require any further analgesia in etidocaine group (45% versus 10%). Significantly more women in etidocaine group did not require opioid analgesia (35% versus 78%). Significantly lower pain scores at 2 hours and total mean scores in etidocaine group compared with placebo. Significantly fewer women admitted overnight in etidocaine group (5 versus 12).		RCT	1b
Baram *et al.* 1990[107]	Laparoscopic tubal occlusion with Falope rings	5 ml 1% etidocaine to banded portion of fallopian tube or normal saline	Self-reported postoperative pain	Significantly reduced self-reported postoperative pain in etidocaine group.		RCT	1b
Kaplan *et al.* 1990[108]	64 women undergoing day case laparoscopic tubal occlusion under general anaesthesia with Falope rings	4 groups with either 3 ml 0.5% topical bupivacaine to both tubes, right tube, left tube or neither before rings applied via spinal needle	Postoperative pain as assessed by modified McGills pain intensity scale at approximately 15 minutes, 1 hour, 3–5 hours and next day	Significantly lower scores between treated and untreated women at 15 minutes and 1 hour but no difference at discharge or next day. Significantly lower proportions of women in fully treated group requiring analgesia at 1st and 2nd assessment compared with placebo. Single treated sides all reported less pain on treated side at discharge. No significantly differences in time of stay between groups or in operating time.		RCT	1b
Wheatley *et al.* 1994[111]	60 women undergoing day case laparoscopic tubal occlusion under general anaesthesia with Filshie clips	10 ml 0.5% bupivacaine or 10 ml physiological saline dripped on to tubes through Verres needle after clips applied	Postoperative pain as assessed by VAS at time of first analgesia and time to first analgesia	Significantly fewer women in treated group required escape analgesia before in the 1st hour. Pain intensity scores significantly lower in treated group at first assessment (1 hour) but not at discharge. Time to first analgesia significantly longer in treated group (pain scores similar in both groups at time of first request for analgesia).	Wounds also infiltrated with bupivacaine. Double-blind.	RCT	1b

Evidence table 9 (continued)

Topical anaesthetics to fallopian tubes plus general anaesthesia (Recommendation 22)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Tool *et al.* 1997[110]	105 women undergoing day-case laparoscopic tubal occlusion under general anaesthesia with Silastic bands	1. IM ketorolac and topical placebo applied to fallopian tubes 2. IM placebo and topical bupivacaine 3. IM placebo and topical placebo	Postoperative pain perception as assessed by modified McGills pain intensity scale at 30 minutes postoperatively, discharge from recovery room and following morning by telephone interview	Topical bupivacaine significantly reduced pain scores at 30 minutes postoperatively and at discharge from recovery room, compared with placebo. Ketorolac and placebo similar. No differences the next morning. No difference in analgesia requirement or in nausea and vomiting.		RCT	1b
Wrigley *et al.* 2000[112]	61 women undergoing day case laparoscopic tubal occlusion under general anaesthesia with Yoon rings or Filshie clips	1. 15 ml 0.5% bupivacaine transcervically through Rubens cannula used for uterine manipulation 2.15 ml physiological saline through Rubens cannula and 15 ml 0.5% bupivacaine topically applied to fallopian tubes	Postoperative pain as assessed with VAS	No differences in any of the pain ratings at any of the times evaluated or time to any of the analgesia dosages or amount of analgesia received.	All women had 15 ml 0.5% bupivacaine to incision sites. Similar proportions in each group with clips and rings.	RCT	1b

Evidence table 10

Local anaesthesia applied to occlusive device plus general anaesthesia (Recommendation 22)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Ezeh *et al.* 1995[116]	80 women undergoing day case laparoscopic tubal occlusion under general anaesthesia	10 ml 2% lignocaine gel on inner surfaces of Filshie clips or 10 ml KY® jelly (Johnson & Johnson)	Postoperative pain as assessed by VAS one hour after eye opening, at discharge and at any other times of request for analgesia	Time to first analgesia significantly longer in lignocaine group. Pain scores significantly lower in lignocaine group at 1 hour but not at time of first analgesia, time of requested analgesia or at discharge. Number of women receiving escape analgesia, opioid analgesia and the mean opioid requirements lower in the lignocaine group. Median recovery time shorter in lignocaine group 5 hours versus 5.99 hours.		RCT	1b

Evidence table 11

Intraperitoneal local anaesthesia and mesosalpinx infiltration with local plus general anaesthesia (Recommendation 22)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Benhamou *et al.* 1994[118]	50 women undergoing day case laparoscopic tubal occlusion under general anaesthesia with Yoon rings	1.80 ml saline IP plus 10ml saline to mesosalpinx 2.80 ml 0.5% lidocaine with 1:320 000 epinephrine and 10 ml 2% lidocaine with 1:80 000 epinephrine in each mesosalpinx	Postoperative pelvic and subscapular pain as assessed with VAS 1, 2 and 8 hours after surgery and via questionnaire at 12, 24, 36 and 48 hours after surgery	Postoperative pain scores significantly lower in lidocaine group at 12, 24 and 36 hours after surgery. Pelvic pain scores lower at all times in lidocaine group except at 12 hours. Analgesia requirements significantly lower in lidocaine group. Number of days to resume normal activities significantly lower in lidocaine group (4.2 ± 1.9 days versus 6 ± 1.9 days).	IP instillation at beginning of procedure specifically to subdiaphragmatic area with mesosalpinx infiltration with spinal needle at end. No toxic concentrations of lidocaine were found in any of the women. Double-blind placebo-controlled.	RCT	1b
Callesen *et al.* 1999[119]	Women undergoing day case laparoscopic tubal occlusion	Ropivacaine to port site, mesosalpinx and intraperitoneally. Total dose 285 mg or saline	Abdominal pain scores, use of morphine, nausea and vomiting	Ropivacaine group had significantly lower abdominal pain scores, required less additional morphine and had less nausea and vomiting in first 72 hours.	Not clear if placebo group also had port site infiltration. If not, effect may be due to this difference alone and not the mesosalpinx infiltration or IP instillation.	RCT	1b

Evidence table 12

Intraperitoneal local plus general anaesthesia (Recommendation 22)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Kelly 1996[117]	58 women undergoing day case laparoscopic tubal occlusion with Filshie clips	0.75 ml/kg 0.125% bupivacaine (n = 28) or 0.75 ml of physiological saline (n = 30) instilled through umbilical port at end of procedure	Postoperative pain as assessed with VAS at 1, 2 and 4 hours postoperatively and on discharge Time to and type of first analgesia Total analgesia requirement	Significantly lower VAS at 2 hours, significantly fewer women requiring postoperative morphine and significantly less oral analgesia in bupivacaine group.	Mean dose 61 mg bupivacaine. No wound infiltration.	Double-blind, placebo-controlled RCT	1b
Colbert *et al.* 2000[121]	100 women undergoing day case laparoscopic tubal occlusion with Filshie clips	1. IP bupivacaine (80 ml 0.125% with 1:200 000 epinephrine), IP saline (10 ml) and IM meperidine (50 mg) 2. IP bupivacaine, IP meperidine (50 mg mixed up to 10 ml) and IM saline (1 ml). Instillation via umbilical port	Postoperative pain assessed at 30 minutes, 2, 4 and 6 hours postoperatively using VAS	At all time periods, the pain scores were lower in group 2; greatest difference at 2 hours. No difference in time to first analgesia, need for further analgesia, nausea scores, number of women who vomited.	No wound infiltration but all had per rectum diclofenac.	RCT	1b
Dreher *et al.* 2000[120]	19 women undergoing day case laparoscopic tubal occlusion using Filshie clips	20 ml (200 mg) ropivacaine (n = 10) or 20 ml physiological saline diluted to 40 ml with physiological saline (n = 9) through the umbilical port following clip application	Postoperative pain score using VAS	Significantly lower 2-hour postoperative pain scores, total postoperative fentanyl usage, in ropivacaine group.	All wounds infiltrated with 5 ml 2% lignocaine.	Double-blind RCT	1b

Evidence table 13

Mesosalpinx block plus general anaesthesia (Recommendation 22)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Alexander *et al.* 1987[122]	100 women undergoing laparoscopic tubal occlusion with Yoon rings	Mesosalpinx infiltration with: i) lidocaine 1% ii) bupivacaine 0.5% iii) physiological saline iv) no infiltration	Pain intensity as assessed by self-assessment on pain intensity scale and amount of supplementary fentanyl given	Significant reduction in pain intensity in groups (i) and (ii). Significantly less fentanyl given in bupivacaine group.		RCT	1b
Smith *et al.* 1991[123]	30 women undergoing day case laparoscopic tubal occlusion	Rectus sheath block or rectus sheath block plus mesosalpinx block	Postoperative pain as assessed by VAS, analgesic requirements	Significantly less postoperative pain and analgesia requirement in mesosalpinx block group. All ready for discharge at 8 hours while only 7/15 without mesosalpinx block ready for discharge at this time ($P < 0.05$).		RCT	1b

Evidence table 14

Mesosalpinx infiltration with preoperative ketoprofen plus general anaesthesia (Recommendation 22)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Van Ee *et al.* 1996[124]	60 women undergoing day-case laparoscopic tubal occlusion with Falope rings	20–100 mg ketoprofen orally preoperatively and each mesosalpinx infiltrated with 5 ml saline plus epinephrine 20–100 mg ketoprofen orally preoperatively and each mesosalpinx infiltrated with 5 ml 0.5% bupivacaine plus epinephrine 20 placebo capsule preoperatively and each mesosalpinx infiltrated with 5 ml 0.5% bupivacaine plus epinephrine	Postoperative pain as assessed by VAS and the self-assessment 11-point scale	No-infiltration group required opioid analgesia. VAS scores significantly higher in ketoprofen-only group from other 2 groups. Significantly longer extubation to transfer to day unit time, extubation to discharge time and days to recovery in ketoprofen group compared with both infiltration groups.	Double-blind. Infiltration done with aortography needle and 5 minutes allowed to elapse before rings applied. Infiltration took about 5 minutes.	RCT	1b

Evidence table 15

Fallopian tube infiltration with local plus general anaesthesia (Recommendation 22)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Fiddes *et al.* 1996[125]	59 women undergoing day-case laparoscopic tubal occlusion with Filshie clips	2 ml 1% lignocaine or physiological saline infiltrated into the subserosal aspect of the corneal end of the fallopian tubes	Postoperative pain by VAS and modified McGill present pain score 1 hour after operation, 2 hours after operation and by self-administration 24 hours after operation	Significant reduction in pethidine usage in first hour, analgesic-free time, present pain scores 2 hours postoperative and 2 hours after discharge and pain relief scores in lignocaine group. No difference 24 hours later but very little pain in both groups at this time and no difference in time to discharge.	Double blind. Added approximately 4 minutes to procedure. All wounds infiltrated with lignocaine as well as PR diclofenac. Standardised analgesia with pethidine to both groups.	RCT	1b

Evidence table 16

Transcervical local anaesthesia (Recommendation 22)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Ng *et al.* 2002[127]	66 women undergoing day-case laparoscopic tubal occlusion with Filshie clips	Transcervical 30 mg papaverine (muscle relaxant) or 30 ml bupivacaine 0.375% or saline before application of clips	Need for analgesia in first 60 minutes, time to first analgesia, rescue analgesia need, VAS pain scores	No significant differences between groups.		RCT	1b

Evidence table 17

Failure rates (Recommendation 23)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
US Collaborative Review of Sterilization (CREST)[15]	10 685 women.	Tubal occlusion	Failure after tubal occlusion	10-year cumulative life-table probability of failure after sterilisation was at least 16.6/1000 procedures (95% CI 13.5–19.7) and could be as high as 18.5/1000 procedures (95% CI 15.1–21.8) if undocumented spontaneous abortions reported by the women in the study are included. Multivariate analysis showed that the spring clip (equivalent to the Hulka clip) and bipolar coagulation were significant risk factors for failure. Probability of failure with all methods was greater if the woman was < 28 years and this also held for women < 34 years except for group having interval sterilisation with partial salpingectomy.		Prospective, cohort multicentre study	2a
Vessey *et al.* [131]	2243 women.	Tubal occlusion, mostly laparoscopic tubal diathermy	Failure rates	Cumulative rates at 7 years for all methods as 10/1000.		Prospective cohort	2a
Koetsawang *et al.*[133]	449 women in Thailand	Laparoscopic tubal occlusion with either Hulka clip, unipolar diathermy or tubal rings	Failure rates	Cumulative pregnancy rates at eight years of 11/1000 for procedures where a Hulka clip was used and 26/1000 where electrocoagulation (unspecified as to unipolar or bipolar) was used.		Prospective cohort	2a
Filshie *et al.* 1998[135]	First 202 responders from a series of 434 women; March 1982 to June 1992	Laparoscopic tubal occlusion wth Filshie clips under local anaesthesia	Complications, failure rate and regret	1 small bowel perforation requiring laparotomy. 1 failed insufflation. 3 transfers form local to general anaesthesia for pain. 1 clip failed to close properly. 1 pregnancy 6 months after procedure in 42-year-old: clip appeared to have been misapplied. 10 women (5%) expressed regret and 3 women had undergone reversal with 2 additional women requesting reversal.	67.8% surgery 10 years previously. 32.2% 5–9 years since surgery.	Case series	3
Rioux 1997[280]	497 women having Filshie clip for tubal occlusion.	10-year follow up	Pregnancy rates	No failures.		Case series	3

Evidence table 17 (continued)

Failure rates (Recommendation 23)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Kovacs and Krins 2002[136]	All specialist gynaecologists practising in the state of Victoria, Australia	Questionnaires (up to 3) followed up by phone calls if necessary	Pregnancies after tubal occlusion using Filshie clips	276/277 responses 73 failures from an estimated 30 000 procedures. Equivalent to 2–3/1000. 29 properly applied; 14 misapplication of clip; 30-unknown. No ectopic pregnancies reported.	223/276 no personal experience of failure. The 73 failures came from 53 respondents.	Retrospective study	3
Peterson *et al.* 1999[281]	2267 women followed up for 8–14 years as part of CREST study. 1662 enrolled 1978–82. 605 enrolled 1985–87.	Bipolar electro-coagulation	Failure rate and risk factors for failure	37/2267 women became pregnant: 30 within the 5-year period for analysis; 18 ectopic, and 12 intrauterine. 5-year cumulative probability of pregnancy: 1978–82, 19.5/1000; 1985–87, 6.3/1000 but if >3 sites coagulated probability 3.2/1000; <3 sites 12.9/1000. Only significant feature was a history of PID increasing risk of pregnancy.	Analysis limited to five years for both cohorts as later cohort could only be followed up for that time.	Prospective cohort study	2a
Peterson *et al.* 2001[274]	Women undergoing tubal occlusion	3329 women with silicone rubber bands (Yoon rings) 1595 women having spring-loaded clip	Failure rate and risk factors for failure	Silicone rubber band: 10-year cumulative probability of pregnancy varied from 0/1000 at one site to 42.5/1000 at the four combined sites in which fewer than 100 procedures were performed. Spring clip: varied from 7.1/1000 procedures at 10 years to 78/1000 at 5 years at another site. Also varied with site of clip application, study site, race and ethnicity, tubal disease and history of abdominal/pelvic surgery. Proper placement of either device was the key to success.		Prospective cohort study	2a

Evidence table 18

Ectopic pregnancies (Recommendation 24)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Peterson *et al.* 1997[139]	10 685 women undergoing sterilisation	Followed up for 8–14 years after sterilisation	Cumulative probability of ectopic pregnancy	47 ectopic pregnancies. 10-year cumulative probability for all methods was 7.3/1000 procedures. If bipolar diathermy used in a woman under 30 years and compared with postpartum salpingectomy, risk of ectopic pregnancy increased by 27 times. Ectopic rate 4–10 years just as high as first three years.		Multicentre, prospective cohort study	2a
Chi *et al.* 1980[84]	14 700 female sterilisation patients 1972–78	66.8% laparoscopic 27.1% mini-laparotomy 6.1% culdoscopy 69.1% interval 12.3% post-abortion 18.6% postpartum	Risk factors associated with pregnancy failure following tubal occlusion	222 women pregnant at follow-up and 62 women determined to be in the luteal phase of the cycle and excluded from the analysis. 160 pregnancies conceived following sterilisation and 8 of these ectopic. After pregnancies due to technical errors were excluded, 6 of the 119 pregnancies were tubal, a rate of 5/100 pregnancies. Comparisons between women with tubal pregnancy and those with intrauterine pregnancy revealed no significant differences in age, parity, previous contraceptive method, pre-existing pelvic infection, incidence of surgical difficulties, or operative route. In the single ectopic pregnancy that followed culdoscopy, the tantalum clip had been used. There were 34 pregnancies following an interval laparoscopic sterilisation and 5 of these were ectopic: 4 followed electrocoagulation and 1 occurred after the prototype spring clip. Only 3 of the 29 intrauterine pregnancies followed electrocoagulation. Thus, the risk of an ectopic pregnancy was significantly higher for those sterilised with electrocoagulation.		Case–control	2b

Evidence table 18 (continued)

Ectopic pregnancies (Recommendation 24)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Chi *et al.* 1984[140]	23 640 female sterilisations for which at least 6 months of follow-up were available were compared with 30 non-pregnant control women who had also undergone female sterilisation	Ectopic pregnancy cases and controls were individually matched for clinic, study type, surgeon, surgical approach, tubal occlusion technique, age (within 5 years) and parity. Controls had been followed up for at least as long as the case they matched	Ectopic pregnancy rate	A history of induced abortion, any pelvic surgery, abdominal surgery or pelvic infection were looked for. The only significant difference was the greater proportion of women with ectopic pregnancies reporting a history of termination of pregnancy (OR 9, 95 % CI 1.39–58.26). Women with ectopic pregnancies were further compared with 78 women with post-sterilisation intrauterine pregnancies (unmatched). Results again showed a significantly greater risk of conceiving an ectopic pregnancy following previous termination (OR 5.8, 95 % CI 1.78–18.60). Women with previous abdominal surgery also ran a significantly higher risk of post-sterilisation ectopic (OR 10, 95% CI 2.45–40.83).		Case–control study	2b
McCausland 1980[85]	Studies reporting ectopic pregnancy rate in women following tubal occlusion	Non-laparoscopic tubal ligations and laparoscopic tubal occlusion	Ectopic pregnancy rate	In 13 studies published between 1940 and 1978 a total of 13 909 non-laparoscopic tubal ligations had been performed. There were 106 failures, of which 93 were intrauterine pregnancies (93/106 = 87.7%) and 13 were ectopic pregnancies (13/106 = 12.3%). In 17 other studies published between 1971 and 1977, a total of 23 238 laparoscopic tubal coagulations had been performed. There were 45 failures, of which 22 were intrauterine pregnancies (22/45 = 49%) and 23 were ectopic pregnancies (23/45 = 51%). All failures mentioned here were method failures. Those secondary to technique (e.g. round ligament coagulation) were excluded.		Systematic review of observational studies	2b

Evidence table 18 (continued)

Ectopic pregnancies (Recommendation 24)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Tatum and Schmidt 1977[141]	5724 women from case series reporting ectopic rates after sterilisation	Laparoscopic tubal occlusion with diathermy	Ectopic pregnancy rate	70% of the failures were ectopic pregnancies. Of the 5724 coagulations without transection, 42.9% of the failures were ectopic pregnancies.		Non-systematic review of the literature	3
McCann and Kessel 1978[142]	8500 women undergoing laparoscopic sterilisation		Ectopic pregnancy rate	16 failures in 5097 women with tubal occlusion by diathermy; 50% of these failures were ectopic pregnancies.		Case series	3
Phillips *et al.* 1977[83]	Members of The American Association of Gynecologic Laparoscopists in 1975		Ectopic pregnancy rate	The incidence of ectopic pregnancy among the failures subsequent to tubal diathermy sterilisation was 24.7% but only 9.2% among failures after tubal ligation procedures.		Survey	3
Peterson *et al.* 1993[91]	1314 members of The American Association of Gynecologic Laparoscopists in 1991	40 337 laparoscopic sterilisations, 15 414 postpartum Pomeroy procedures	Ectopic pregnancy rate	The relative likelihood of ectopic pregnancy was also greater after coagulation procedures than after mechanical ones. In 1988, the proportions of ectopic pregnancies after sterilisation failures were: 49% after the Pomeroy technique, 66% after bipolar coagulation, 68% after unipolar coagulation, 52% after bands and 30% after clips.		Survey	3
Chick *et al.* 1985[64]	Female sterilisation using tubal occlusive methods		Ectopic pregnancy rate	11 000 Falope ring sterilisations, of which only 4.3% of failures were ectopic pregnancies. Their review of interval laparoscopic sterilisations where clips were employed found no cases of tubal pregnancy.	Not systematic	Literature review	3
Chi *et al.* 1986[63]	Family Health International data set, 1973–79	Interval, post-abortion and postpartum tubal occlusion via laparoscopy, laparotomy, mini-laparotomy, culdoscopy, colpotomy	Rare events: luteal phase pregnancy, intraoperative complications, deaths, pregnancy, hysterectomy, early readmission	Two-year life-table ectopic pregnancy rates per 1000 are significantly higher after sterilisation via laparoscopic electrocoagulation (n = 5845) than after the tubal ring (n = 3633).		Prospective cohort	2a

Evidence table 18 (continued)

Ectopic pregnancies (Recommendation 24)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Khandwala 1988[143]	9 studies reporting pregnancy rates following tubal occlusion	Bipolar electrocoagulation, endocoagulation, silicone ring, Hulka clip and Filshie clip	Ectopic pregnancy rate	Incidence of ectopic pregnancy ranged from 35% to 67 % with bipolar electrocoagulation and was 27% with endocoagulation.		Review of cohort and case–control studies	2
Kjer and Knudsen 1989[144]		Analysed ectopic pregnancy after laparoscopic sterilisation and compared with the occurrence of ectopic pregnancy in a fertile female population of Denmark		41 ectopic pregnancies were reported between 1978 and 1980. Of these, 39 followed bipolar electrocoagulation, one followed a Filshie clip and 1 followed a silicone rubber band. When a post-sterilisation pregnancy occurred, ectopic pregnancy occurred 76% of the time, and the incidence of ruptured ectopic pregnancy was significantly increased after previous laparoscopic sterilisation. The incidence of ectopic pregnancy in laparoscopically sterilised women was found to be significantly decreased compared with the non-sterilised fertile female population.		Case–control	2b
Mol *et al.* 1995[145]	Cohort or case control studies reporting on ectopic pregnancy rate in relation to contraception method.		Ectopic pregnancy rates.	OR for tubal sterilisation was 0.48 (95% CI: 0.40–0.59) when compared with non-pregnant controls and 9.3 (95% CI: 4.9–18.0) when compared with pregnant controls. This means that the risk of having an ectopic pregnancy for women who have been sterilised is approximately half that of the general population but if a woman who has been sterilised becomes pregnant, then the risk of it being an ectopic pregnancy increases nine-fold.		Meta-analysis of cohort and case–control studies	2a
Hendrix *et al.* 1998[278]	All women with ectopic pregnancy admitted over 5 years at 2 hospitals	Women with prior tubal occlusion and ectopic pregnancy compared with next non-sterilised woman admitted within 30 days	Compared presentation, diagnostic findings, intraoperative management, postoperative complications	38/208 (18%) women with ectopic pregnancies had had prior tubal occlusion (55% Pomeroy, 45% tubal fulgaration). Compared with 38 from women without tubal occlusion. Women with prior tubal occlusion were less likely than controls to have serial βhCGs and their mean duration of symptoms was shorter. Similar distribution of management, but trend towards higher ectopic rupture and haemoperitoneum in sterilised group.	Exclusions include those whose sterilisations had been reversed and if no operating notes for original operation were available.	Case–control	2b

Evidence table 19

Failure rate when tubal occlusion combined with pregnancy (Recommendation 26)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Hughes 1997[163]	All women sterilised in Aberdeen 1969–76	55% laparoscopic.; 29% postpartum tubal ligation	Failure rate	Incidence of failure of sterilisation was doubled if the sterilisation had been performed laparoscopically in association with a first trimester termination of pregnancy, as opposed to as an interval procedure	It is possible that some of the increased failure rate may have been attributable to the learning curve after introduction of laparoscopy as a method for sterilisation in the unit where the analysis took place.	Retrospective case note review	3
Chi *et al.* 1981[164]	9399 women undergoing laparoscopic tubal occlusion.	Diathermy, tubal ring or prototype spring loaded clip	Failure rate	12-month life table rates for pregnancies following sterilisation were 6.0/1000, 26.4/1000, 43.5/1000 procedures for interval, post-abortion and postpartum procedures respectively. The same differences in failure rates between non-pregnant and pregnant women persisted for different methods of tubal occlusion. There were more surgical difficulties in the pregnancy-associated procedures than in the interval procedures, which is not surprising in view of the larger uterus and increased vascularity associated with the pregnant state.	Even if the pregnancies due to technical error were excluded from the analysis, the failure rate was still significantly higher in the pregnancy-associated sterilisations, possibly due to the women being a more fecund group.	Large prospective multicentre study	2a
Chi *et al.*1980[84]	14700 women undergoing tubal occlusion	66.8% laparoscopic; 27.1% mini-laparotomy; 6.1% culdoscopy; 69.1% interval; 12.3% post-abortion; 18.6% postpartum	To ascertain risk factors for sterilisation failure	No association between timing of the procedure and failure rate was found.	This could have been due to the short follow-up (6 months) and the fact that more of the post-abortion and postpartum cases were excluded because of lack of suitable controls.	Case–control study	2b
Peterson *et al.* 1996[15]	10685 women.	Analysis of the long-term follow-up data from the CREST study	Failure rate	Postpartum sterilisation using partial salpingectomy had one of the lowest method failure rates of all methods used: 7.5/1000.		Prospective cohort study	2a

Evidence table 20

Incidence/risk factors of regret (Recommendations 2 and 26)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Winston 1977[20]	103 women requesting reversal between 1975 and 1976	Patient interview	Patient characteristics and reason for request for reversal	Average age 26.7 years. 75.7% had been unhappily married at time of sterilisation and remarriage was the main reason for request for reversal. 63.1% had been sterilised straight after a pregnancy. 37.8% sterilised by irreversible methods. Only half those with tubal ligation had tubes suitable for reversal.		Case series	3
Howard 1982[23]	76 men requesting vasectomy reversal between 1978–81 Historical control group of 100 men requesting vasectomy 1975–78	Patient interview	Patient characteristics and reason for request for reversal	31 still married, 45 divorced or separated. 80% of the new partners were childless. Reversal group significantly younger than control group. < 29-year-olds over-represented in the reversal request group. No difference in family size between groups. Some did not want more children but wanted to be put back to normal. Pregnancy or financial stress a major reason for initial request for vasectomy in the reversal group.		Case series	3
Emens and Olive 1978[25]	185 women sterilised at caesarean section or postpartum and 151 women with interval sterilisation	Followed up for 2–7 years after sterilisations	Satisfaction/regret	1/3 of all operations recommended by doctors. Split into satisfied, relatively dissatisfied and dissatisfied. Significantly increased dissatisfaction rate in the sterilisations carried out in relation to pregnancy.		Prospective cohort study	2a
Hillis *et al.* 1999[17]	11 232 women recruited for CREST study followed up for 14 years after sterilisation	Follow-up interview	Cumulative probability of regret and risk factors for regret	Overall regret 12.7% (95% CI 11.2,14.3). Cumulative probability of regret was 20.3% for women < 30 years and 5.9% for women > 30 years. (adjusted RR 1.9, 95% CI 1.6–2.3). For women under 30 years the lowest level of regret was for women who had no previous births 6.3% (95% CI 3.1–9.4). Women sterilised within a year of their youngest child being born were just as likely to regret it as if sterilised postpartum.		Prospective cohort study	2a

Evidence table 20 (continued)

Incidence/risk factors of regret (Recommendations 2 and 26)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Schmidt *et al.* 2000[18]	11 232 women recruited for CREST study followed up for 14 years after sterilisation	Follow up interview	Cumulative probabilities of requesting information on reversal and undergoing reversal	Overall 14-year cumulative probability of requesting information on reversal 14.3% (95% CI 12.4–16.3). Among women aged 18–24 years at time of operation this was 40.4% (95% CI 31.6–49.2). Women aged 18–24 years were almost 4 times as likely to request information on reversal as women > 30 years old (adjusted RR 3.5 95% CI 2.8–4.4). Number of living children was not associated with requesting reversal information. Overall cumulative probability of obtaining reversal was 1.1% (95% CI 0.5–1.6). Women < 30 years were more likely to obtain reversal (RR 7.6, 95% CI 3.2–18.3).		Prospective cohort study	2a
Nervo *et al.* 2000[19]	100 women requesting reversal of sterilisation	Questionnaire	Characteristics of women requesting reversal of sterilisation	56% were < 30 years at time of operation, 53% were associated with a pregnancy. Changed marital status was the main reason for request (74%). 31 went on to have either microsurgery (17) or IVF (14) and 12/37 (38.7%) have had at least one child.	No control group of women not requesting reversal.	Case series	3
Jamieson *et al.* 2002[275]	525 women with husbands having vasectomy and 3672 women having tubal occlusion (subcohort of CREST study)		5-year cumulative probability of woman expressing regret	No difference between groups in terms of regret. Vasectomy: 6.1% (95% CI 3.6–8.6); tubal occlusion: 7.0% (95% CI 5.8–8.1). Risk factors for regret in both groups was a report of substantial conflict with partners before the procedure.	May change with longer follow up, small numbers in vasectomy group but still bigger than most other similar studies.	Prospective cohort study	2a

Evidence table 21

Methods and prognostic factor for success of reversal of tubal occlusion (Recommendation 31)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Boeckx *et al.* 1986[60]	78 women requesting reversal 1977–82	Reversal of sterilisation using microsurgical methods	Pregnancy rate	92% pregnancy rate when Falope rings and isthmo-isthmic anastomosis done. No pregnancy when final tubal length after anastomosis less than 4 cm. 5% ectopic pregnancy rate.		Case series	3
Gomel 1980[61]	118 women undergoing reversal of sterilisation	Patient characteristics and reason for request for reversal	Pregnancy rate, time to pregnancy	64.4% pregnancy rate. Mean time to pregnancy after reversal 10.2 months. Longest time 40 months. Inverse relationship between length of fallopian tubes and pregnancy rate.		Case series	3
Cohen *et al.* 1999[276]	153 women undergoing reversal of tubal occlusion	Standard microsurgical reversal 1988–95	Pregnancy rates stratified for age	22 women lost to follow up. < 30 years: 78%; 30–34 years: 69%; 35–39 years: 55%; > 40 years: 24% significantly different from other groups.	Length of follow up ranged 1–9 years.	Retrospective cohort	2b
Van Voorhis 2000[177]	Publications concerning women requesting reversal	Microsurgical reversal with laparotomy Reversal with laparoscopy. Prognostic factors	Pregnancy rates Ectopic rates	Laparotomy: pregnancy rate range 55–90%; ectopic rate range 1–6%. Laparoscopy: pregnancy rate range 31–73%; ectopic rate range 0–7%. No trials found comparing IVF with microsurgical reversal or cost analysis. No pregnancies reported with reversals over the age of 43 years.	No systematic searching described.	Literature review of case series	3
Mettler *et al.* 2001[277]	35 women requesting reversal of tubal occlusion	Laparoscopic reversal	Pregnancy rates and ectopic pregnancy rates	Only 28 suitable for reversal at laparoscopy. 17/28(61%) pregnancy rate; 2/17 (7%) ectopic.		Case series	3

Evidence table 22

Long-term outcomes after tubal occlusion (Recommendation 33)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Gentile *et al.* 1998[188]	51 relevant studies		Hysterectomy after tubal occlusion (11 studies) Change in menstrual symptoms after tubal occlusion not controlled for prior contraceptive use (5 studies) Change in menstrual symptoms after tubal occlusion controlled for prior contraceptive use (15 studies) Non-hormonal objective measures of menstrual changes (4 studies) Hormonal measures in women after tubal occlusion (16 studies)	10 of these studies showed no significant change in menstrual symptoms. 3 of the remaining studies found significant changes only in women who had had diathermy or a Pomeroy procedure. The 2 remaining studies, which had follow-up periods of 60 and 84 months, found, respectively, significantly more cycle abnormalities > 2 years after the procedure and increased menstrual pain and bleeding five years after tubal occlusion. However, the study with the longest follow-up, to 96 months, found no significant changes. All these studies reported subjective outcomes and none measured menstrual blood loss (MBL) objectively. 3 of these studies looked at the results of endometrial biopsy in women who had had tubal occlusion compared with women who had not. However, the histological state of the endometrium does not necessarily correlate with menstrual abnormalities. The remaining study[165] assessed objectively the menstrual blood loss in 25 women for up to 3 months before sterilisation and for 6 consecutive periods after the operation. In 10 women alternate periods were measured until the twelfth postoperative period. The procedures used were: tubal ligation (in 22), laparoscopic sterilisation by diathermy (in 2) and Pomeroy tubal ligation (in 1). No significant change of menstrual blood loss was detected subsequent to the sterilisation operation. In those studies in which the women served as their own controls (this obviates the need for other confounders to be taken into account) and had preoperative hormone levels assessed, no significant or persistent changes in hormone levels were demonstrated.		Systematic review of cohort and case–control studies	2a

Evidence table 22 (continued)

Long-term outcomes after tubal occlusion (Recommendation 33)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Peterson *et al.* 2000[279]	9514 women who had tubal occlusion and 573 women whose partners had a vasectomy	Pre- and post-procedure interviews assessing characteristics of their menstrual cycles	Menstrual cycle changes	No difference in intermenstrual bleeding or length of cycle. Women having tubal occlusion more likely to have decreased number of days of bleeding, amount of bleeding, menstrual pain, but more irregular cycles.		Multicentre prospective cohort study with appropriate control group	2a
Hillis *et al.* 1998[189]	7718 women (subset of CREST study) and 544 women whose husbands had vasectomy		Relative risk of hysterectomy after five years	8% hysterectomy rate in sterilised women versus 2% in wives of vasectomised men. RR 4.6 (95% CI 2.4–9.0) No difference for women aged under or over 34 years.		Multicentre prospective cohort with control group	2a

Evidence table 23

Method of approach to exposing the vas (Recommendation 37)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Christensen *et al.* 2002[196]	99 men	Conventional bilateral incision (n = 51), Li method (n = 48)	Effectiveness, time of operation, pain and discomfort, preoperative and postoperative complications	No significant differences between any of the outcomes. 87% returned questionnaires. 26 men returned semen samples at three months. 2 in conventional group and 3 in Li group had positive semen analysis. This was not significantly different but in the context of only 26 returned samples could mean the failure rate is underestimated.	Li method taught to young trainee surgeons. Only supervised once after training video before being included in study. Paper translated from Danish.	RCT	1b
Sokal *et al.* 1999[195]	1429 men seeking vasectomy between 1988 and 1991 in good health and with normal physical examination	No-scalpel (n = 705) and standard approach (n = 723) to vasectomy. Surgeons (urologists 79%, general 21%) already familiar with standard method and trained in no-scalpel method. After different approaches, both groups had a small segment of vas excised and both ends of the cut vas ligated	Operating time, postoperative complications assessed 3–15 days post-operatively. 10 weeks semen analysis: <15 days early; >15 days late	Operating time significantly shorter for no-scalpel method. Only 2% of no-scalpel method had skin sutures as opposed to 29% in standard group. Early vasectomy failure same in both groups (1.8% versus.1.6%). Surgical difficulties similar in both groups (11.4% versus 11.2%). Significantly less bleeding (2.1% versus 4.3%) and surgical equipment difficulties (0.4% versus 1.7%) reported with no-scalpel method. Significantly less pain in no-scalpel group. In early complications, standard group more likely to have a haematoma (1.8% versus 12.2%), mild or moderate pain (44.6% versus 55.1%) at early follow-up and incision infection 0.2% versus 1.5%). No-scalpel group resumed intercourse sooner. Long-term pain or tenderness reported in 4.0% versus 5.1%. No long-term complications, significant difference between groups nor satisfaction with 90% in both groups satisfied or very satisfied.	Evaluators (responsible for care from the time of discharge from the operating room to last follow-up contact) blinded to method.	Multicentre, randomised, partially blinded, controlled trial	1b

Evidence table 24

Methods of vas occlusion (Recommendation 39)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Li *et al*. 1994[201]	2713 men undergoing no scalpel vasectomy	7 different occlusion techniques	Recanalisation rates, complication rates	Highest rates of recanalisation (7.53%) and complications (2.17%) seen with open ended method without fascial interposition.	Authors recommend ligation of vas ends with fascial interposition.	Multicentre RCT	1b
Labreque *et al*. 2002[203]	3761 men undergoing vasectomy	Clipping and excision of a small vas segment (n = 2040, July 1996 to October 1999) or thermal cautery with fascial interposition and an open testicular end (n = 1721, July 1996-November 2000). All performed by same surgeon with scalpel free technique to expose vas	Failure to occlude vas and complication rate	29% in the clipping and 32% in the cautery group did not provide any semen analyses. In men with at least 1 semen analysis, the risk of confirmed or possible failure was higher in clipping than cautery group 8.7% versus 0.3% (OR 37 95% CI 12–116). Even using confirmed failure only similar results 7.6% versus 0.1% (OR 93 95% CI 13–669). Haematoma and infection more common in cautery group 1.6% versus 0.5% (OR 3.4, 95% CI 1.6–6.9) but no difference in painful granuloma, non-specific pain.		Retrospective cohort study with prospective data collection	2a

Evidence table 25

General versus local anaesthesia for vasectomy (Recommendation 40)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Canter and Goldthorpe 1995[204]	115 men in two general practices in Liverpool	68 men responded and of these 31 (45.%) vasectomised under general and 37 (54.4%) under local anaesthesia		Postoperative pain and discomfort was higher in the general anaesthesia group. However, the number of days to full recovery was the same in both groups with a median of 7 days.		Comparative case series	3

Evidence table 26

Timing of post-vasectomy semen analysis (Recommendation 42)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Chan *et al.* 1997 [208]	574 vasectomies in the UK with 510 men that submitted post-vasectomy samples	Post-vasectomy semen analysis	Time to 2 azoospermic samples	87% only needed to submit 2 samples when testing started 12 weeks after vasectomy and was repeated at 16 weeks.		Case series	3
Smith *et al.* 1998 [215]	345 men with vasectomies at 2 hospitals with differing post-vasectomy semen analysis practices	Semen analyses at 3 months post-vasectomy (n = 245) versus semen analyses at 6 months post-vasectomy (n = 100)	Positive semen analyses and compliance	3 months: 58/245 (24%) failed to return any samples. 36 first sample positive; further 10 second sample positive despite negative first. 24% in total had positive sample at 3 months, only 4 (2%) had sperm at 6 months with only 1 man requiring re-exploration. 6 months: 24/100 (24%) failed to provide samples. 13% positive sample at 6 months, although eventually all became negative and no explorations required. Men in first group asked views on timing. 27% preferred 3 months, 35% 6 months and 38% had no preference.		Prospective cohort study	2a
Bradshaw 2001 [206]	Practice of 15 surgeons in one hospital with regard to post-vasectomy semen analysis	Questionnaire and analysis of all post-vasectomy semen analysis results between April 1995 and April 1996	How vasectomy success established, success rates, compliance	240 vasectomies performed during study period; all 15 surgeons required 2 consecutive semen analyses to confirm success. If either of these showed sperm continue until 2 consecutive samples negative. 14% returned no samples; 206/240 86% of men returned one specimen; 184/240 77% returned two specimens; 168/240 70% achieved criteria for success. Remaining 72–18 azoospermic on first sample but never did second. 16/184 9% did not have 2 negative samples but only deemed to have failed in 2/16 men, 1 of whom did not require repeat vasectomy. 4 others given special clearance. Remaining 10 did not respond to letters. 15/184 (8%) had re-appearance of sperm at some stage after one negative test 8 went on to have 2 consecutive negative tests, 4 given special clearance and 3 defaulted to follow up.		Case series	3

Evidence table 27

Interventions to accelerate time to clearance (Recommendation 43)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Pearce *et al.* 2002[220]	72 men having vasectomy	Perioperative distal vasal lavage with 50 ml physiological saline or no lavage	Sterility rates at 8,10 and 12 weeks Patient compliance	No difference in sterility rates at 8,10 or 12 weeks between lavage and no lavage groups. No difference between general and local anaesthesia groups.		RCT	1b
Mason 2002[221]	200 men having vasectomy	Standard vasectomy or vasectomy plus irrigation of each distal vas deferens with sterile water. Both groups provided semen analyses at 6 and 12 weeks postoperative and every 4 weeks thereafter if necessary	Time to 2 clear semen analyses	22/200 11% sent none or insufficient samples; 15/200 sent samples in after too long a time. 163 remained (76 irrigation, 87 standard). No significant difference between groups in mean time to clearance, number who achieved clearance at 16 weeks, or number with persistent sperm present at more than 40 weeks. 13 failed to achieve clearance (6 flush, 7 control), 5 had repeat vasectomy (2 flush, 3 control).		RCT	1b
Berthelsen 1976[222]	59 men having vasectomy	No irrigation versus irrigation of distal vas with sterile water	Time to azoospermia	No difference between groups.		RCT	1b
Leungwattanakij *et al.* 2001[223]	62 men having vasectomy	Irrigation with normal saline (n = 37) versus no irrigation (n = 41) in no-scalpel vasectomies	Number of postoperative ejaculations, sperm concentration and numbers of men given clearance (no motile sperm in the ejaculate)	No significant differences in any of these outcomes between the groups.	Hospital number used to choose treatment group.	Prospective, non-randomised, partially blinded, controlled trial	2a

Evidence table 28

Special clearance (Recommendation 44)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Philp *et al. et al.*[224]	310 (2.2%) men	Special clearance with non-motile sperm (< 10 000/ml) after vasectomy	Pregnancy rates	No pregnancies	? length of follow up.	Case series	3
Davies *et al.*[225]	151 (2.5%) men	non-motile sperm (< 10 000/ml) who were given special clearance as long as seven months had elapsed since the vasectomy	Pregnancy rates	No pregnancies	Slightly overlapping series from the same clinic as above. They were followed up for a minimum of 3 years after vasectomy.	Case series	3
Edwards and Farlow[226]	200 men with non-motile sperm	Special clearance	Pregnancy rates	No pregnancies	190 that were followed up for 12–15 months after vasectomy.	Case series	3

Evidence table 29

Failure of vasectomy (Recommendation 45)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Philp *et al.* 1984 [228]	2900 men	Vasectomy	Pregnancy rate	1/2900 (0.03%)	Same clinic population as above study.	Case series	3
Nielsen *et al.* 2002 [282]	2563 men with vasectomies at one Danish Hospital, January 1997 to January 2001	Postoperative semen analysis initially at 3 months and then thereafter until negative test obtained	Positive semen analysis with sperm still present, reoperation rate	79% submitted a semen sample for analysis; 15% initially had sperm and samples were repeated until azoospermia; 1.4% needed reoperation for early recanalisation. Rate of recanalisation not related to experience of surgeon.	Paper translated from Danish.	Case series	3
Haldar *et al.* 2000 [283]	Men given clearance after 2 azoospermic samples after vasectomy	Vasectomy performed by several operators with division of vas deferens and intraluminal cautery each end of vas	Semen analysis at 1, 2 and 3 years post-vasectomy and any pregnancies	15/2250 men had positive semen analysis at 1 year, 4/1400 men at 2 years and 1/1000 at 3 years. Those positive at years 2 and 3 had negative test at 1 year. 17/20 had counts under 10 000/ml and 14 were negative 1 month later. No pregnancies reported. 2/20 >100 000 at 1 year and in 1 subsequent test still positive with count >600 000. Advised to have repeat vasectomy.	No distinction between motile and non-motile sperm.	Observational study	3

Evidence table 30

Vasectomy reversal: influence of time since vasectomy on patency and pregnancy rates (Recommendation 46)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Belker *et al.* 1991[240]	1469 men	Microsurgical vasectomy reversal at 5 different institutions in a 9-year period	Patency and pregnancy rates as related to time of reversal after original vasectomy	< 3 years: 97%, 76% 3–8 years: 88%, 53% 9–14 years: 79%, 44% > 15 years: 71%, 30%		Retrospective cohort study	2b
Schoor *et al.* 2002[284]	34 men undergoing unilateral (n = 4) or bilateral (n = 28) EV between May 1995 and September 2000	< or > 15 years since vasectomy	Patency, with azoospermia at 12 months being defined as failure	Short period: patency 58% (7/12); long period: 15% (3/12). No patency in men having unilateral EV.	EV more technically difficuly than vasovasostomy. All 3 successes in the long group were in men with congenital obstruction.	Retrospective cohort study	2b

Evidence table 31

Reversal: comparison with intracytoplasmic sperm injection (Recommendation 46)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Heidenreich *et al.* 2000[242]	Men with vasectomies wanting to re-establish fertility	157 men had VV between Jan 93 and June 98 111 couples having MESA/TESE with ICSI Mean interval from operation 7.6 years (range 0.5–18.0 years)	Pregnancy rates	Pregnancy rate 52% after VV, 22.5% with MESA/ICSI and 19.5% after TESE/ICSI. Multiple births 15.8% in ICSI versus 0.7% after reversal.	Cost comparison presented in DM/euros.	Prospective cohort study	2a
Fuchs and Burt 2002[241]	173 men with vasectomy reversals >15 years after vasectomy	VV ± EV by single surgeon in one centre	Pregnancy rates	48 men lost to follow up, 9 excluded as had not tried for a pregnancy with their partner. Mean obstructive interval 18 years. Mean female partner age 34.3 years. Overall patency rate 85%, pregnancy rate 43%, birth rate 36%. Trend but not significant difference between men with interval from operation 15–19 years and those 20–25 years. Pregnancy and birth rates directly proportional to age of female partner. When compared with published rates for ICSI in men with obstructive azoospermia, no significantly difference (43% versus 40% and 36% versus 27%).		Retrospective cohort study with historical controls	2b

Evidence table 32

Characteristics of men undergoing reversal operations (Recommendation 46)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Holman *et al.* 2000[285]	28 246 men undergoing vasectomy between 1980 and 1996	Vasectomy	VV rate as compared with age at vasectomy	Overall, 1902 men had VV (2.4%). Age 20–24 years 11.1%. Age 25–29 years 6.2%.		Prospective cohort study	2a

Evidence table 33

Vasectomy and prostate cancer (Recommendation 48)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Bernal-Delgado *et al.* 1998[243]	Men with prostate cancer compared with men with other cancers (case–control) or vasectomised men compared with non-vasectomised men (cohort)	Vasectomy	Incidence of prostate cancer as confirmed by histological diagnosis	9 case–control studies (14 334 men) and 5 cohort studies (206 904 men). Age-adjusted RR 1.23 (95% CI 1.01–1.49). Study design: cohort RR 1.13 (95% CI 0.84–1.52); case–control RR 1.3 (95% CI 1.04–1.79). Study base: population-based RR 1.12 (95% CI 0.96–1.32) and hospital-based RR 1.98 (95% CI 1.37–2.86). Selection bias: RR 1.11 (95% CI 0.94–1.31) and 2.24 (95% CI 1.42–3.54) for adequate and inadequate selection of controls, respectively.	MEDLINE, EMBASE and IME searched 1985–96. Manual retrieval from primary sources.	Systematic review of observational studies	? 2a (not 1a as not RCTs)
Emard *et al.* 2001[244]		Men with prostate cancer or lung cancer in Quebec from population database and male population of Quebec	Incidence of vasectomy in these groups	For all birth cohorts, vasectomy rates in prostate cancer group significantly higher than in lung cancer or male population groups: 8.8 versus 3.8 versus 3.2; 17.0 versus 5.3 versus 6.8; 36.8 versus 12.7 versus 12.3.	Middle birth cohort existed at the time when vasectomy most commonly used and followed up long enough for them to get into age group where prostate cancer most likely to occur.	Retrospective case–control study	1a
Cox *et al.* 2002[245]	National population-based case–control study of 923 new cases of prostate cancer in men aged 40–74 years in New Zealand and 1224 randomly selected controls		Relative risk of vasectomy in these groups	No association between vasectomy and prostate cancer RR 0.92 (95% CI 0.75–1.14) nor with time since vasectomy (RR 0.92 (95 % CI 0.68–1.23) for ≥25 years since vasectomy).		Population case-based control study	2a

Evidence table 34

Vasectomy and testicular cancer (Recommendation 48)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Thornhill *et al.* 1987[246]	240 consecutive testicular cancer patients	Vasectomy		Three men had a history of recent vasectomy (1.3%). By using census information the expected prevalence of vasectomy was only 0.2%.	Short interval between vasectomy and testicular cancer: < 2 months.	Case–control	2b
Cale *et al.* 1990[247]	3079 men	Vasectomy	Incidence of testicular cancer	8 cases of testicular cancer as against 1.9 expected, giving a standardised morbidity ratio (ratio of observed to expected numbers) of 4.2 (95% CI 1.8–8.2).	3 months to 4 years in the Scottish study.	Cohort	2a
Moller *et al.* 1994[248]	73 917 men	Identified in hospital discharge and pathology registers as having had a vasectomy for any reason during 1977–89	Incidence of testicular cancer	Overall pattern of cancer incidence in study cohort was similar to that expected nationally in Denmark. No increased incidence in testicular cancer observed: 70 cases; standardised morbidity ratio 1.01 (95% CI 0.79–1.28). Incidence during first year of follow-up was also close to that expected: 9 cases; standardised morbidity ratio 0.80 (95% CI 0.36–1.51).		Cohort	2a
Strader *et al.* 1988[249]	333 men from western Washington State who had testicular cancer diagnosed between 1977 and 1983 and 729 men selected from the same population by dialling telephone numbers at random	Interviewed regarding history of genital tract conditions including vasectomy	Vasectomy rate in each group	More cases than controls reported having had a vasectomy. OR for vasectomy of 1.5 (95% CI 1.0–2.2).	Association was present only in Catholic men and was attributed to bias arising from under-reporting of vasectomy by Catholic men without testicular cancer. OR in Catholics was 8.7 (95% CI 2.8–27.1), in Protestants 1.0 (95% CI 0.6–1.7) and in people with other religions 1.3 (95% CI 0.6–3.0).	Case–control	2b

Evidence table 34 (continued)

Vasectomy and testicular cancer (Recommendation 48)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Moss *et al.* 1986[250]	273 men from Northern California aged under 40 years with testicular cancer diagnosed 1976–81 compared with matched peer controls	Interview		OR for vasectomy 0.6 (95% CI 0.3–1.2).		Case–control	2b
Swerdlow *et al.* 1987[251]	259 men with testicular cancer 238 men with other diagnoses but attending the same radiotherapy departments 251 men who were hospital inpatients not attending radiotherapy	Interview and case-note review		OR for vasectomy 1.3 (95% CI 0.63–2.04).		Case–control	2b
Nienhuis *et al.* 1992[252]	13 246 men in Oxford who had vasectomy between 1970 and 1986 and 22 196 controls admitted during same period for operations, appendicitis or injuries		Hospital admission or death	RR of testicular cancer of 0.46 (95% CI 0.1-1.4). RR prostate cancer 0.44 (95% CI 0.1–4.0). RR myocardial infarction 1.00 (95% CI 0.8–1.3).	Linked medical record abstracts used.	Retrospective cohort study	2b
UK Testicular Cancer Study Group 1994[253]	794 men aged 15–49 years and a similar number of controls matched within 1 year of age		Risk of testicular cancer	No overall association between testicular cancer and vasectomy (OR 1.09 95% CI 0.77–1.52).		Case–control	2b

Evidence table 35

Vasectomy and cardiovascular disease (Recommendation 48)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Chi *et al.* 1990[257]	Men from 4 cities in South Korea	Vasectomy	Incidence of cardiovascular death	No increased incidence of cardiovascular death.	Length of follow up?	Community-based case–control study	2b
Giovannucci *et al.* 1992[258]	14 607 men in each group	Vasectomy by 1976 or no vasectomy	All cause mortality by 1989	Overall age-adjusted mortality slightly lower in the men with vasectomy (RR 0.85, 95 % CI 0.76–0.96). Reduction in mortality from all causes was due to lower mortality from cardiovascular disease (RR 0.76; 95 % CI 0.63–0.92) and vasectomy was unrelated to overall mortality from cancer (RR 1.01, 95 % CI 0.82–1.25).		Prospective cohort study with reference population	2a
Coady *et al.* 2002[259]	Men in USA from North Carolina, Mississippi, Minnesota and Maryland	1050 with vasectomy and 2907 without vasectomy	Inflammation and coagulation factors, carotid intimal–medial thickness, carotid plaque, prevalent peripheral arterial disease, incident coronary heart disease and stroke	Men with vasectomy had significantly lower systolic blood pressure, thinner carotid arterial wall and were less likely to be diabetic or on antihyperensives. No difference in total cholesterol, LDL, HDL, cholesterol or triglycerides, WBC, factor V3, fibrinogen, APTT, protein C or factor V2. Significantly lower antithrombin 3 and VWFAg. No relation to prevalent peripheral arterial disease, incident myocardial infarction, coronary heart disease or stroke.	Mean time from vasectomy 16 years (range 1–38 years). 20% had vasectomy > 20 years ago and even these men not at elevated risk.	Prospective cohort study	2a

Evidence table 36

Incidence of chronic post-vasectomy scrotal pain (Recommendation 49)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Glavind and Lauritsen 1990[263]	42 men for 4 years after surgery	Vasectomy	Postoperative pain	86% 10 days post-operatively; 27% at 3 months; 12% >3 months.		Case series	3
McMahon *et al.* 1992[264]	253 men	Vasectomy 4 years previously. All operative procedures included ligation of proximal and distal ends of the vas deferens	Incidence of chronic testicular pain as assessed by postal questionnaire and telephone interview	6 of 172 men (3.5%) recalled significant early postoperative complications (taking more than 1 week to resolve) and 3 of them developed chronic testicular discomfort, which was troublesome in 2 cases. Chronic testicular discomfort was present in 56 men overall (33%). It was considered troublesome by 26 of them but not by the other 30. In 9 cases (5%) there was testicular discomfort related to sexual intercourse; 7 of them had it at other times as well. 9 men had sought further medical help for chronic testicular pain or swelling and 2 of them had had further surgery (one epididymectomy and one excision of a hydrocele). Only 3 men regretted or had reservations about the vasectomy because of chronic pain.	Response rate of 68% (172 men).	Questionnaire	3
Schmidt 1995[197]	6248 men	Consecutive vasectomies he had performed over a period of 38 years with a section–fulguration–fascial interposition technique. Procedure performed under local anaesthesia with no resection of a vasal segment	Incidence of complications	Spermatic granuloma of the epididymis was diagnosed in 56 men (0.9%), of whom 6 (10%) required epididymectomy because of pain. Spermatic granulomas of the vas were diagnosed in 1.36% (90) of the men and corrective surgery was carried out in half. Several were bilateral (not concurrently), several recurred and 1 developed into a vasocutaneous fistula. The time of occurrence varied, from a few months to 5 years after vasectomy.	Author does not report on the incidence of pain, apart from that in the context of spermatic granuloma. No post-vasectomy pregnancies were reported and no patient showed a persistence of sperm. However, the length and range of follow-up is not stated which would be important for both failure rate and incidence of chronic pain.	Case series	3

Evidence table 36 (continued)

Incidence of chronic post-vasectomy scrotal pain (Recommendation 49)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Choe and Kirkemo 1996[265]	470 men	Vasectomy	Post-vasectomy complications, incidence of post-vasectomy scrotal pain and quality-of-life issues as assessed by postal questionnaire with 154 questions and telephone follow-up surveys	Postoperative skin bleeding and scrotal haematoma in 23 men (26.7%). Most common late complication was post-vasectomy scrotal pain in 34 men (18.7%), which adversely affected quality of life in 4 (2.2%). In retrospect, 71.4 % of men were satisfied with decision for vasectomy, 19.3 % had equivocal feelings and 9.3 % were dissatisfied. Of the 13 men who were dissatisfied, 10 cited chronic scrotal pain as the reason for regretting decision to undergo vasectomy, while three voiced concerns about the potential association between vasectomy and prostate cancer.	Mean follow up 4.8 years. 182 men responded (42.3%).	Case series	3
Ahmed *et al.* 2002[266]	560 men	Vasectomy; mean time since vasectomy 19 months (range 8–39 months)	Incidence of chronic post-vasectomy testicular pain	Of 396 replies (70% response rate), 108 (27.2%) men complained of some testicular pain following operation. In 88 (82%) of these 108 men, pain was brief and was not defined as chronic post-vasectomy testicular pain, while 20 (19%) men had pain for > 3 months. Development of pain occurred less than 1 month after vasectomy in 17 men (15.7%), between 1 and 3 months in 49 (45.4%), at 3–6 months in 35 (32.4%), at 6–12 months in 5 (4.6%) and after 1 year in 2 (1.9%). Among the 108 patients who reported pain, 21 (19%) had mild pain that did not interfere with their daily activities; 33 (31%) men required analgesics to control the pain. 14 (13%) took time off work because of pain. Discomfort during sexual intercourse was experienced by 40 (37%).		Retrospective postal survey	3

Evidence table 36 (continued)

Incidence of chronic post-vasectomy scrotal pain (Recommendation 49)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Morris *et al.* 2002[267]	198 men with a vasectomy more than 3 years previously and 102 men from the same area for a control group	Questionnaire	Incidence of chronic post-vasectomy testicular pain	Mean time from vasectomy 46.5 months. 101/198 (51%) replied. No demographic differences in responders from non-responders. Non-troublesome discomfort 37/101 versus 21/102; occasional discomfort 10/101 versus 3/102; severe pain requiring medical advice 6/101 versus 2/102 (3/6 said that the pain interfered with intercourse); none of the vasectomy group expressed regret about procedure.		Postal survey with appropriate controls	2a

Evidence table 37

Interventions for chronic post-vasectomy scrotal pain (Recommendation 49)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Ahmed *et al.* 1997[266]	17 men who had chronic post-vasectomy testicular pain for at least 1 year, mean time since vasectomy, 6 years (range 1–26 years)	Denervation of the spermatic cord	Resolution of pain	13 reported complete relief of pain at 3 months. The other 4 had significant improvement in symptom score and were satisfied with the result.		Case series	3
Selikowitz and Schned 1985[268]	Over a 2-year period from 18 men with unremitting epididymal pain and induration 5–7 years after vasectomy unresponsive to conservative measures including empirical antibiotics	Total unilateral or bilateral epididymectomy and partial vasectomy	Resolution of pain	Complete relief of symptoms, usually within 24 hours, in all men.	Pathological examination of specimens revealed features consistent with sequelae of long-standing obstruction.	Case series	3
Chen and Ball 1991[269]	10 men with post-vasectomy pain	Epididymectomy performed between 6 months and 20 years (mean 7 years 7 months) after vasectomy	Resolution of pain and histopathological examination of specimens.12 specimens from eight men in post-vasectomy group compared with epididymectomy performed for chronic epididymo-orchitis despite antibiotic treatment (n = 7) and epididymal cysts (n = 7).	50% of post-vasectomy group had resolution of pain. Pathological findings revealed features of long-standing obstruction and interstitial and perineural fibrosis which may have accounted for the pain.		Case series	3

Evidence table 37 (continued)

Interventions for chronic post-vasectomy scrotal pain (Recommendation 49)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
West *et al.* 2000[270]	16 men (19 epididymectomies: 3 bilateral, 13 unilateral) over 10-year period	Epididymectomy for pain after vasectomy (mean time since vasectomy 3 years (range 0–11 years)	Resolution of pain at 3 months (outpatient clinic) and 3–8 years (telephone interview)	3 months: 14/16 symptomatic benefit; 3–8 years: 9/10 sustained improvement.		Case series	3
Nangia *et al.* 2000[271]	13 men with chronic post-vasectomy pain; mean onset of pain 2 years (range 9 days to 9 years)	VV (3 unilateral, 10 bilateral) performed at a mean of 4.8 years (range 0.8–014 years)	Resolution of pain and histological features	9/13 (69%) became completely pain free. No differences in histology between those who became pain-free and those still with pain or compared with another group of 32 men matched for time since vasectomy having VV for reestablishment of fertility who never had pain.	Mean follow up 1.5 years.	Retrospective review	3

Evidence table 38

Prevention of chronic post-vasectomy scrotal pain (Recommendation 49)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
McConaghy *et al.* 1998[273]	42 men having vasectomy under general anaesthesia	5 ml bupivacaine 0.5% along incision line and into lumen of vas either before (1st side) or after vas transacted and ligated (2nd side)	VAS for pain on D1 and D7 and after 1 month if still pain on D7	VAS scores for pain significantly lower on the first operated side than the second on D1 and D7. No difference in pain scores, depending on which side operated on first.	Men acting as own controls. Randomisation concerned which side to start first.	RCT	1b
Paxton *et al.* 1995[272]	70 men undergoing vasectomy as day case	Intra-vas deferens 0.5% bupivacaine 1 ml and 0.9% saline 1 ml was injected into the lumen of the right or left vas deferens or no injection	Postoperative pain at day 1, day 7 and post-vasectomy scrotal pain 1 year postoperative as assessed by visual analogue scores	No difference between control group and saline side of the treatment group in VAS scores on both days 1 and 7 after operation or in incidence and duration of chronic testicular discomfort. VAS scores for pain on days 1 and 7 were significantly lower on the side of the bupivacaine infiltration in the treatment group. Prolonged testicular discomfort was present on the saline-treated side in the treatment group for a mean of 34 days in 45% men and for 30 days in 38% of men in the control group. No surgical intervention was required although 3 men (2 in control group, 1 in treatment group) needed a prolonged course of simple analgesic drugs for their discomfort. No one experienced prolonged testicular discomfort on the bupivacaine treated side.		RCT with patient-blinding to side of active intervention	1b

Appendix 2
Patient record standard for tubal occlusion procedures in women

A feature of many medico-legal cases concerning sterilisation procedures is poor note keeping. In order to aid risk management and facilitate clinical audit, the following criteria have been chosen as essential information that needs to be documented in the medical record. The criteria should be present in 100% of cases.

Preoperative notes

Outpatient consultation and counselling

- Parity and any complex obstetric history.
- Gynaecological history and current symptoms.
- Current medical conditions and previous abdominal surgery.
- Pelvic examination.
- Addressing of age and relationship issues as appropriate.
- Discussion of long-term contraception alternatives to tubal occlusion.
- Expected method of access to tubes and method of occlusion (and reason for method of occlusion if not mechanical).
- Risk of extended procedure if planned method of access fails and the nature of that procedure (laparotomy or mini-laparotomy).
- Extent of consent to extended procedure, if non-life-threatening problems occur.
- Extent of consent to alternative methods of tubal occlusion if first intended method not possible.
- General lifetime failure rate of one in 200.
- With Filshie clips, failure rate after ten years of two to three in 1000 procedures.
- Risk of ectopic pregnancy.
- Irreversibility, potential for reversibility with expected method and availability of reversal locally within the NHS.
- Written information given.

Immediate pre-procedure

- Date of last menstrual period.

- Pregnancy test result.
- Confirming of outpatient details and other preoperative discussions or counselling.
- Confirming of valid signed consent form with patient's name, name of doctor obtaining consent; to be countersigned by surgeon performing procedure.
- Fitness for anaesthesia and daycase care, according to local guidelines or protocols.
- Operation notes.
- Name of operating surgeon(s) including surgeon present in the operating theatre taking overall responsibility.
- Ease of access to tubes.
- Clarity of identification of tubes.
- Accurate placement of occlusive method.
- Additional procedures or unexpected events.

Post-procedure

- Method actually used.
- Discharge letter to GP.
- Patient informed of method used and any intraoperative findings or events.
- Whether further contraception advised, e.g. up to next period, or pending result of tubal patency test.
- Contact point for postoperative questions as per patient information.

Appendix 3
Pregnancy rates

Crude rate

Number of failures (pregnancies)/number of sterilisations (e.g. per 1000 procedures).

There is no attempt to take into consideration the length of follow-up after sterilisation; i.e., it discounts the influence of time and favours short follow-up studies.

Pearl rate

Number of failures (pregnancies)/100 woman-years at risk of failure.

Using a woman-year denominator requires that the risk be constant over time. This is not the case for the risk of pregnancy following tubal sterilisation; while most pregnancies occur during the first year after sterilisation, a substantial number also occur subsequently. Since it assumes an equal monthly risk factor it favours the longer follow-up study.

Life-table analysis

- Takes into account variation in observation time after sterilisation (time period during which a pregnancy could possibly be identified).
- Takes into account changing levels of risk of pregnancy with time.
- Preferred method of reporting failure rates following tubal sterilisation; the best data for comparison.
- Cannot usually be calculated for earlier data because of inadequate information about sterilisation-failure intervals.

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