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FEMALE AND MALE STERILIZATION

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## 1 Introduction

### 1.1 Definition

Voluntary female and male sterilization (also known as tubectomy, tubal occlusion, tubal ligation or surgical contraception and vasectomy) are among the most effective contraceptive methods available for men and women who desire no more children. Sterilization is also one of the safest methods, with low mortality and complication rates for both men and women. The sterilization procedure blocks either the sperm ducts (the vasa deferentia) or the oviducts (fallopian tubes) to prevent the sperm and ovum from uniting.

### 1.2 General indications

**Sterilization should be provided to any male or female client who has completed the desired family size and who requests it after receiving appropriate counselling and reaching an informed decision.**

Note: Some complex, irreversible psychiatric or neurological conditions are not compatible with parenthood and may lead to a request for sterilization when the client is unable to give consent. For these cases, the opinion of a knowledgeable consultant should be obtained in writing, and documentation must be kept including a discussion of alternatives to sterilization.

### 1.3 Pre-operative screening

The objectives of pre-operative client screening are:

- **To ensure, through counselling and the informed choice process, that:**
  - The client is making a voluntary and informed choice without coercion by relatives or service providers.
  - Any non-medical factors likely to cause regret are identified (for example, clients who are too young, have no or few children, are in an unstable relationship or are uncertain about the decision).
- To determine, through the medical assessment:
  - The client's fitness for sterilization.
  - Whether there are any conditions present that may increase the risks associated with the procedure.

- The most appropriate surgical approach, anaesthetic regimen and type of facility best suited to the client.

Where national laws and regulations permit, sterilization should be made available based on what is best for the individual. Programmes should avoid establishing arbitrary criteria based on age, parity or marital status, and should interpret guidelines based on the needs of each individual client.

For some clients it may be necessary to postpone the sterilization procedure (e.g., when there is a medical condition that needs to be evaluated or corrected). When this is the case, the reasons must be explained to the client and documented in writing. The client should be advised about the use of temporary methods and plans should be made to provide sterilization at a later date.

#### 1.4 Counselling and information

All sterilization clients must receive appropriate counselling for selecting the method.

- **Counsel both partners, if possible.**

- The question of which individual in a couple will be sterilized must be reviewed, and assistance given until the couple reach a firm and comfortable decision. If there are health risks for one partner to consider sterilization, this should be taken into account.
- One factor to take into account when discussing sterilization for either partner is a history of multiple caesarian section. If the woman is pregnant, sterilization can be performed at the time of the next caesarian section.
- Allow opportunity for individual counselling.

- **Encourage clients to ask all their questions and to express any concerns** so that misunderstandings and misinformation can be cleared up. For example, clients should be reassured that sterilization does not affect physical or mental health or normal sexual behaviour.

- **Clearly discuss the following points with each client, appropriately for his/her background and language:**

- *Alternative, temporary methods of family planning are available.* These methods must be available to the client, so that he or she may choose between temporary and permanent methods. Information on the temporary and permanent methods must include the

- effectiveness, benefits, risks and side-effects of each.
- *The procedure is surgical.* Review the details of the procedure. The client must understand: (a) the type of procedure to be performed, (b) where it will be performed, (c) the kind of anaesthesia to be used, (d) how he or she can expect to feel after the procedure, (e) the possibility of discomfort during the surgical procedure, and (f) if there will be any cost to the client for the procedure.
  - Although sterilization is a very safe procedure, there is a *small possibility of complications* related to the anaesthesia and to the surgery.
  - *The procedure has benefits*, including: an end to childbearing, no further pregnancy-associated risks, and no ongoing inconvenience or risks associated with temporary long-term contraceptive methods.
  - There is a *risk of failure*, even though sterilization is a very effective method of contraception.
  - *The results of the procedure are intended to be permanent*: after the surgical procedure, the client will no longer be able to have children. Notify the client that the procedure should be considered permanent (see also section 1.11).
  - Choosing the procedure must be *the voluntary, free choice of the client*, and it should not be forced in any way through coercion or inducements. Allow for any discussion and further exploration if there is any doubt that the client is choosing the operation of his or her own free will.
  - The client has *the right to change his/her opinion* at any time prior to surgery. The opportunity to review the decision and to change his/her mind before the procedure helps to ensure that the client's choice is voluntary and to prevent the possibility of coercion. A waiting interval of a few days is recommended when possible, although it should not be a strict requirement, especially if the client's decision is firm.
  - *Sterilization does not protect against HIV and other sexually transmitted infections (STIs). Couples who are at risk of these infections should be counselled about the use of condoms.*

### 1.5 Informed consent

*Informed consent for sterilization surgery* is an agreement by the individual based upon the exercise of free choice, with a full understanding of the nature and consequences of the surgical procedure. It must be obtained only after appropriate counselling as described above.

*The primary ethical responsibility* of the sterilization team is to ensure that the individual gives mature, informed, voluntary, unpressured consent to the operation, and that he or she is legally competent to give that consent.

#### **Written informed consent must be obtained for all clients requesting sterilization:**

- To document informed and voluntary choice, *and*
- To serve as a legal authorization for surgery.

#### **Signatures:**

- The form must be signed by the person undergoing sterilization.
- For non-literate clients, the form must be read aloud and explained, and a thumb print or mark of the client may replace the signature. The signature of a literate witness is also recommended.
- The surgeon or designated assistant should also sign the consent form. This signature indicates that he/she has established that the individual choosing sterilization understands and willingly elects to undergo the operation.

#### **Language:**

- The terms and words used on the consent form and in the counselling process should be understood easily by the client. Avoid complicated medical and legal terms.
- In settings where more than one language is spoken, forms should be available in the common languages spoken. When possible, staff members who speak commonly used languages should be available. If this is not possible, interpreters should be used.

## 1.6 Health assessment

**An appropriate clinical record form should be used and completed for each client** to ensure that the essential elements of the history and the physical and laboratory examinations are collected and recorded.

- *Medical history:* in addition to personal and family data, including number of children and use of family planning methods, the following information should be obtained:
  - Past and present illnesses and other conditions which may present a risk for the operation, including diabetes mellitus, heart disease, hypertension, lung disease such as asthma or bronchitis, renal disease, genito-urinary infection, STIs, anaemia, bleeding/clotting problems, convulsions, psychiatric conditions, and any current illness or infection.
  - Previous relevant operations, previous problems with anaesthesia, limitations on activity, addictions, and history of tetanus immunization.
  - Allergies, including drug reactions.
  - Current medications.
- *Physical and laboratory examinations:* Physical examination as described in section 2.6 (male sterilization) and section 3.6 (female sterilization) should always be conducted before performing surgical procedures. Laboratory examinations are generally not required but should be performed if indicated by medical history and physical examination.

Routine screening for HIV is not needed. Appropriate infection prevention procedures must be carefully observed with all surgical procedures.

## 1.7 Anaesthesia

**Local anaesthesia is the preferred method for all types of sterilization procedure.** General, spinal or epidural anaesthesia is seldom justified.

## 1.8 Surgical principles for ensuring safety

- Surgeons and staff must be skilled and well trained in the techniques they are using, as well as in the early recognition and prompt management of complications.
- Approved medical and surgical guidelines and procedures must be strictly maintained.
- The surgeon should refrain from treating other pathological disorders

during routine sterilization, except if this has been planned in advance and is performed in an adequately equipped facility. One exception would be when emergency treatment is required.

- Infection prevention measures must be strictly followed (see chapter 15: Infection prevention control).
- All instruments and equipment must be in good working order before the start of the surgical procedure.
- The facility must be well equipped with drugs and equipment to handle life-threatening situations and other emergencies.

### 1.9 Post-operative instructions

Provide written post-operative instructions for literate and illiterate clients in language or diagrams that the client will easily understand.

Review each point orally with the client before he or she leaves the facility. Include discussion of:

- How to care for the wound.
- How to use any post-operative medications that are given.
- Instructions to rest at home for the rest of the day.
- What warnings signs to look for and what to do about each of them.
- When to resume normal activities, including sexual intercourse.
- Where to go and whom to contact in case of emergency.
- When and where to return for a follow-up visit.

### 1.10 Complications

- Major complications occur in fewer than 1% of all vasectomy and tubal occlusion cases. Early recognition and prompt appropriate management are essential.
- **All major or minor complications and documentation of their management should be recorded in the client's clinical record.**
- If a local sterilization programme has an unusually high level of complications (e.g., wound infections), an investigation should be carried out to identify the cause so that corrective action may be taken.
- See sections 2.12 and 3.13 of this chapter for more details of complications specific to male or female sterilization.

## 1.11 Reversal

- **Sterilization should be considered permanent.** Several factors affect the success of reversal cases, in some cases it is not feasible or advisable.
- Reversal surgery is more complex than sterilization. If there is a request for reversal the client should be referred to the appropriate level of health care.
- Because there is an increased risk of ectopic pregnancy following reversal, all women having a reversal operation must be followed up closely. A woman having a reversal operation should be advised that future pregnancy has an higher risk of being ectopic and that she should seek medical care if she becomes or suspects that she is pregnant.

## 1.12 Service management

### Facilities and equipment

- The following facilities are required for sterilization services:
  - A clean waiting room or reception area for new arrivals and follow-up clients. The environment should be consistent with local cultural background, and conducive to educational activities. Educational posters with information on all family planning methods should be displayed.
  - Space for counselling, preferably isolated or private.
  - An examining room for pre-operative and follow-up examinations.
  - A clean surgical area isolated from the outside and from clinic traffic.
  - Areas adjacent to the surgical area where surgical personnel scrub and change clothes.
  - Facilities for cleaning, sterilizing and disinfecting surgical instruments and materials, or access to them elsewhere.
  - Recovery room and rest area for clients after surgery.
  - Laboratory services or access to them elsewhere (e.g., blood, urine, semen analysis).
  - Arrangements for storage and retrieval of records.
  - Toilet and washing facilities for clients.
  - Laundry or access to a laundry.

NOTE: Some of the above functions may share a common space.

The above requirements are most often met in a hospital or a permanent clinic. Other facilities may meet the above criteria in specific circumstances and according to local needs.

- *When the sterilization procedure is not performed in a hospital:*
  - The facility must have links with an institution which will be able to assure prompt emergency admission for the management of surgical complications.
  - The facility in which the surgery is performed must be able to promptly transport the patient to the referral institution.
- *Local anaesthetic:*
  - Lidocaine (lignocaine).
- *Emergency equipment required for each facility offering sterilization:*
  - *For both male and female sterilization:*
    - Suction machine with tubing and 2 traps.
    - Oral and nasal airways (2 sizes of each).
    - One manual resuscitator or breathing apparatus.
    - Emergency drugs, such as epinephrine (adrenaline) and antihistamines, for managing adverse reactions.
  - *Only for female sterilization:*
    - Anaesthesia mask and self-inflating bag with oxygen nipple.
    - Oxygen tank with reducing valve, flow meter, tubing and mask.
    - Intravenous fluids such as dextrose solutions, and administration sets with large-calibre needles.
    - Venesection instruments.
    - Sterile laparotomy kit for emergencies.
    - Laryngoscope and endotracheal tubes (appropriate only when trained personnel are available).
    - Additional emergency drugs, such as atropine, naloxone, physostigmine and calcium chloride, for managing adverse reactions to anaesthetic agents and other medications.

**The above equipment must be present and readily available for use during all sterilization procedures.** There should be one person at the clinic site responsible for ensuring that the emergency instruments are sterile, functional and ready for use before each operation.

**The surgical team must be sufficiently trained to be able to use the equipment effectively in case of emergencies.**

### **Policies and guidelines**

- Each programme offering sterilization services must maintain its policies and guidelines on the premises. Applicable references to sterilization-related local laws and regulations should also be available.
- Surgical and anaesthetic protocols, specific to the techniques used, should be available, as well as protocols for client monitoring and management of complications.
- Guidelines on infection prevention and control should be posted in the facility.
- The programme should have a mechanism to assure that all medical and paramedical staff understand and follow the practices set out in these guidelines.

### **Clinical records**

The programme should ensure that all aspects of pre-operative assessment, type of procedure, technique of occlusion, anaesthesia, operative findings, post-operative management, and reports of any complications and their treatment are recorded in an accessible clinical record for each client. The informed consent form should also be kept in the record.

### **Mobile teams**

Mobile teams consist of trained staff who periodically visit outreach areas to perform sterilization in existing permanent health facilities which do not have staff qualified to perform sterilization. If such facilities are not available, the team may operate in temporary medical settings such as schools or community buildings, taking great care to ensure that essential safety and medical standards are met in accordance with local regulations.

- Mobile teams should be staffed by the most highly trained, skilled and experienced personnel available for both counselling and surgical procedures.
- Appropriate infection prevention measures must be ensured.
- Measures to ensure follow-up care should be an integral part of any mobile-team system.

## Referrals

- A system must be in place for referrals in case of emergencies, complications and medical problems. If necessary, written agreements with the medical institutions accepting these referrals should be obtained.
- In programmes where sterilization is not offered, referral procedures for sterilization services must exist.

## Surgeons

The sterilization service should employ only those surgeons who have training, skill and experience in the standard sterilization techniques described in these guidelines. Job descriptions specifying these requirements should be used.

## Work load

The surgical team should limit the number of procedures performed to a number appropriate to the delivery of safe and quality services.

## Advocacy

Vasectomy is a much underutilized, safe and effective method. Programmes should implement strategies to clarify misconceptions that hinder acceptability of this method and to promote its use.

Female sterilization programmes should promote the availability of safe and convenient post-partum and post-abortion as well as interval sterilization services (see section 3.7 for definition). They should also encourage maternity services to offer antenatal counselling about sterilization and other contraceptive methods as well as immediate post-partum sterilization and other contraceptive services.

## Training

- A written curriculum for sterilization techniques, client care, management of complications, and counselling should be used for training new staff.
- Training needs of existing staff should be periodically assessed and necessary training provided.
- All members of the surgical team should be considered in the training programme (i.e., doctors, assistant doctors, nurses, auxiliary nurses, aides).

## 2 Male sterilization

### 2.1 Definition

Male sterilization, or vasectomy, is the interruption of the male reproductive capacity for the purpose of permanently ending fertility. This is accomplished by a simple, safe, inexpensive and well-accepted operation which can be performed as an outpatient procedure. In a vasectomy, each vas deferens is occluded or cut so that sperm are not released into the ejaculate.

Vasectomy is one of the most effective methods of contraception. When performed correctly, vasectomy has a failure rate of 0.1 pregnancies per 100 women partners in the first 12 months of use.

### 2.2 Indications

In addition to the general indications for sterilization (see section 1.2), vasectomy should be the method of choice where a medical risk exists for the female procedure.

### 2.3 Medical eligibility criteria

The World Health Organization (WHO) medical medical eligibility criteria use a specific classification for surgical sterilization, which differs from other methods of contraception because there is no condition that should permanently restrict the eligibility of the client from voluntarily obtaining this method. The medical considerations consist of weighing the respective risks of sterilization against those of an unintended pregnancy. However, some conditions represent an indication to take specific precautions or to delay the procedure.

*Conditions that require extra caution (category C of the WHO classification):* The procedure is normally conducted in a routine setting, but with extra preparation and precaution, in the presence of:

- Previous scrotal injury.
- Young age.
- Large varicocele.
- Large hydrocoele.
- Cryptorchidism.
- Diabetes mellitus.
- Depressive disorders.

*Conditions that require a delay in the sterilization procedure (category D of the WHO classification):* The procedure is delayed until the condition is evaluated and/or corrected, with alternative temporary methods of contraception provided in the presence of:

- Local infections:
  - Scrotal skin infection;
  - Active sexually transmitted infection (STI);
  - Balanitis;
  - Epididymitis or orchitis.
- Systemic infection or gastroenteritis.
- Filariasis/elephantiasis.
- Intrascrotal mass.

*Conditions that require special consideration (category S of the WHO classification):* The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support after considered decision upon the most appropriate procedure and anaesthesia regimen, with alternative temporary methods of contraception provided if referral is required or there is otherwise any delay, in the presence of:

- Inguinal hernia.
- Coagulation disorders.
- AIDS.

A further consideration is a history of impotence or other sexual disorders in which vasectomy could possibly intensify any underlying psychological problem.

## 2.4 Counselling, information and informed consent

Follow the general guidelines in chapter 2 (Counselling) and in sections 1.4 and 1.5 of this chapter.

- The client must also be informed that the procedure does not affect the male hormones or cause any change in sexual performance or sexual satisfaction.
- Another form of contraception must be used until it is demonstrated that sperm are not present in the ejaculate, or at least 12 weeks after the vasectomy (The counsellor should assess if the client or his partner needs a temporary contraceptive method).

**It is important to give clients an opportunity to express any concerns and to have all their questions answered before the procedure.**

## 2.5 Who can perform vasectomy?

All doctors, including general practitioners, can perform vasectomies if they have been properly trained. Under certain conditions, other health personnel can be trained to perform vasectomy procedures if the country's laws and regulations permit. When a non-doctor performs the procedure, a doctor should be available for consultation and in case of surgical difficulties or complications.

## 2.6 Health assessment

- In addition to the information in section 1.6, the medical history for a man requesting vasectomy should also include:
  - A history of scrotal or inguinal surgery or trauma/injury.
  - A history of pre-existing sexual impairment, such as impotence.
- The *physical examination* for vasectomy must include:
  - Scrotal examination, checking for skin thickness, scars or infection.
  - Examination for presence of undescended testes, hydrocoele, varicocoele, intrascrotal mass, or inguinal hernia.
  - Other examinations as indicated by the medical history.
- The following pre-operative *laboratory evaluations* are required only if suggested by the history or physical examination:

- Haemoglobin and/or haematocrit.
- Urinalysis to identify the presence of glucose or protein.

## 2.7 Pre-operative preparation

- Ensure that medical history, physical examination and any necessary laboratory tests are completed and documented in the clinical record.
- Review informed consent and ensure that the signed form is in the client's record.
- Pre-operative medication is not necessary in most situations. If the client appears nervous, sedation could be administered (e.g., 5 mg diazepam given by mouth 30 minutes before surgery).

## 2.8 Anaesthesia and operative procedure

### Local anaesthesia

Use the least possible quantity of local anaesthetic to ensure adequate comfort for the man. General anaesthesia is very rarely needed.

- Lidocaine (lignocaine) 1%, without epinephrine (adrenaline) is recommended (If only 2% lidocaine is available, dilute it to 1% by using saline solution).
- The maximum individual dose of lidocaine should not exceed 4.5 mg/kg (2 mg/lb) of body weight. In general, it is recommended that the maximum total dose should not exceed 300 mg (This equates to a maximum total volume of 30 ml 1% or 15 ml 2% lidocaine).

### Operative procedure

While there are many ways to occlude the vas (e.g., ligation, cautery, clips) there are two basic approaches for scrotal entry:

- Conventional or incisional vasectomy; or
- No-scalpel vasectomy (NSV).<sup>1</sup>

The NSV technique uses a vasal nerve block and two specialized instruments (a ringed clamp and dissecting forceps) (figures 8.1 and 8.2)

<sup>1</sup>For more details about no-scalpel vasectomy refer to: *No-scalpel Vasectomy: An Illustrated Guide for Surgeons*, 3rd edition. New York: EngenderHealth, 2003.

to isolate and deliver the vas. Because the scrotal skin puncture made with the dissecting forceps is so small, sutures are not needed. NSV offers several advantages over conventional vasectomy, including fewer haematomas and infections and less pain during the procedure. However, it should not be used unless the surgeon has received appropriate training, has experience in the procedure, and has the required instruments.

Figure 8.1



Extracutaneous ringed forceps

Figure 8.2



Dissecting forceps

Vasectomy should include division of each vas or removal of a short segment of each vas. If ligation and excision is used as the method of occlusion, fascial interposition is necessary. Thermal or electro-cautery may provide more effective vas occlusion than ligation and excision with fascial interposition, even when cautery is used without fascial interposition.

Some basic procedural principles, in addition to those listed in section 1.8, include:

- Proper asepsis, which requires a surgical scrub and the use of sterile gloves. Cap, mask and sterile gown are desirable but not necessary for vasectomy.
- An effective antiseptic (e.g., a water-based iodine or a 4% chlorhexidine solution) is required to prepare the scrotum, thighs and perineum. The operative area should be draped.
- Careful haemostasis and gentle tissue handling are important for patient's comfort and safety.

## 2.9 Post-operative care

- A man who has undergone vasectomy without sedation may leave the clinic after resting 30 minutes if the operative site shows no sign of bleeding. If sedation has been used, the client should be monitored until the sedation has worn off before he can leave the clinic.
- Simple oral analgesics may be given if needed for discomfort.

## 2.10 Instructions to men after the procedure

Before the client is discharged, provide the following instructions orally and in writing:

- He should rest at home for the remainder of the day. He should refrain from sexual intercourse, heavy work or strenuous exercise for 48 hours. This time of rest is important to decrease the risk of complications.
- He should keep the wound clean and dry. He may bathe on the day after surgery, but must avoid allowing the wound to become wet. Soap and water may be used to wash the wound after 3 days, making sure to dry the wound.
- He should contact the provider if there is any fever, bleeding or pus at the incision, or excessive pain or swelling.
- He is not immediately sterile: he must use condoms or another temporary method until at least 12 weeks after the vasectomy or until his semen is sperm-free (where semen analysis is available).
- If conventional vasectomy was performed he should come for a follow-up visit approximately 1 week after surgery.

The client should have the opportunity to ask questions and express concerns.

## 2.11 Follow-up care

### Post-operative follow-up examination

An appointment should be offered to the client for a follow-up visit approximately 1 week after surgery. Post-operative examination may be done by a trained, qualified health professional who is not a doctor, unless there are complications. During the follow-up visit:

- If conventional or incisional vasectomy was performed, examine the

scrotal area for proper healing.

- Review plans for semen analysis if available.
- Schedule another follow-up visit if further care is needed.

## Semen analysis

- If available, offer semen analysis after 12 weeks after the procedure.
- If the client requests semen analysis and the facility is not equipped to do it, refer him for this service.
- If motile sperm are still present after 12 weeks, the service provider must re-evaluate the case and take appropriate steps. A repeat semen analysis is indicated, and a second vasectomy procedure may be offered if failure has occurred.

## 2.12 Complications

Vasectomy complications may include intra-operative bleeding; reactions to local anaesthetic; post-operative scrotal swelling, bruising and pain; haematoma formation; infection; and later, congestive epididymitis and granuloma formation. Early recognition and prompt treatment of complications are essential, and **training for vasectomy services should include how to identify and manage complications.**

Any surgical difficulties encountered during the procedure should be recorded, for these difficulties may explain complications that arise during the post-operative period. Any surgical incident should be recorded in the client's record even if it was successfully corrected during the operation.

## 3 Female sterilization

### 3.1 Definition

Female sterilization is the interruption of the female reproductive capacity for the purpose of permanently ending fertility. This is accomplished by bilateral occlusion or section of the fallopian tubes.

Tubal occlusion is a safe and well-accepted procedure which can be accomplished by ligation, ligation with resection, or mechanically with clips or rings.

### 3.2 Indications

The indications for female sterilization are discussed in section 1.2.

### 3.3 Medical eligibility criteria

As noted in section 2.3, the WHO medical eligibility criteria use a specific classification for surgical sterilization, which differs from other methods of contraception because there is no condition that should permanently restrict the eligibility of the client from voluntarily obtaining this method. The medical considerations consist of weighing the respective risks of sterilization against those of an unintended pregnancy. However, some conditions represent an indication to take specific precautions or to delay the procedure.

*Conditions that require extra caution (category C of the WHO classification):*

The procedure is normally conducted in a routine setting, but with extra preparation and precaution, in the presence of:

- Young age.
- Obesity  $\geq 30$  kg/m<sup>2</sup> body mass index.
- Hypertension:
  - History of hypertension, where blood pressure cannot be evaluated (including hypertension during pregnancy).
  - Adequately controlled hypertension, where blood pressure can be evaluated.
  - Raised blood pressure (systolic 140-159 or diastolic 90-99 mmHg).
- History of ischaemic heart disease.
- History of cerebrovascular accident.
- Uncomplicated valvular heart disease.
- Epilepsy.
- Current breast cancer.
- Uterine fibroids (with or without distortion of uterine cavity).
- Past pelvic inflammatory disease (PID) without subsequent pregnancy.
- Schistosomiasis with fibrosis of liver.
- Diabetes mellitus without vascular disease (insulin and non-insulin dependent).
- Hypothyroidism.
- Mild compensated cirrhosis.

- Benign and malignant liver tumours.
- Thalassaemia.
- Sickle cell disease.
- Iron deficiency anaemia (Hb 7-10 g/dl).
- Diaphragmatic hernia.
- Kidney disease.
- Severe nutritional deficiencies.
- Elective sterilization concurrent with abdominal surgery.
- Depressive disorders.
- Previous abdominal or pelvic surgery.

*Conditions that require a delay in the sterilization procedure (category D of the WHO classification):* The procedure is delayed until the condition is evaluated and/or corrected, with alternative temporary methods of contraception provided in the presence of:

- Pregnancy.
- Postpartum (7 to <42 days).
- Severe pre-eclampsia/eclampsia.
- Prolonged rupture of membranes (24 hours or more).
- Puerperal sepsis or intrapartum/puerperal fever.
- Severe antepartum or postpartum haemorrhage.
- Severe trauma to the genital tract at the time of delivery (cervical or vaginal tear).
- Post-abortion sepsis.
- Severe post-abortion haemorrhage.
- Severe trauma to the genital tract at the time of abortion (cervical or vaginal tear).
- Acute haematometra.
- Current deep vein thrombosis (DVT)/pulmonary embolism (PE).
- Major surgery with prolonged immobilization.
- Current ischaemic heart disease.
- Unexplained vaginal bleeding before evaluation.
- Malignant gestational trophoblastic disease.
- Cervical cancer awaiting treatment, or endometrial or ovarian cancers.

- Pelvic inflammatory disease (PID) current or within the last 3 months.
- Sexually transmitted infection (STI) including purulent cervicitis.
- Current gallbladder disease.
- Active viral hepatitis.
- Iron deficiency anaemia (Hb < 7g/dl).
- Local abdominal skin infection.
- Acute bronchitis or pneumonia.
- Systemic infection or gastroenteritis.
- Sterilization concurrent with abdominal surgery (emergency without previous counselling) or infectious condition.

*Conditions that require special precautions (category S of the WHO classification):* The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support after considered decision upon the most appropriate procedure and anaesthesia regimen, with alternative temporary methods of contraception provided if referral is required or there is otherwise any delay, in the presence of:

- Postpartum uterine rupture or perforation.
- Post-abortion uterine perforation.
- Multiple risk-factors for arterial cardiovascular disease (e.g., older age, smoking, diabetes mellitus and hypertension).
- Raised blood pressure (systolic  $\geq 160$  or diastolic  $\geq 100$  mmHg).
- Hypertension with vascular disease.
- Complicated valvular heart disease.
- Endometriosis.
- AIDS.
- Known pelvic tuberculosis.
- Diabetes mellitus with nephropathy/retinopathy/neuropathy.
- Diabetes mellitus with other vascular disease or of > 20 years' duration.
- Hyperthyroidism.
- Severe decompensated cirrhosis.
- Coagulation disorders.
- Chronic asthma, bronchitis, emphysema or lung infection.

- Fixed uterus due to previous surgery or infection.
- Abdominal wall or umbilical hernia.

### 3.4 Counselling, information and informed consent

Follow general guidelines in chapter 2 (Counselling) and sections 1.4 and 1.5 of this chapter. Explain to the client that:

- Female hormones are not affected, and there will be neither loss of femininity nor any change in sexual functioning or satisfaction.
- Menstrual cycles will continue as usual. (If she is discontinuing an IUD or hormonal method, she may experience a temporary change in menstrual pattern).
- There is a small risk of failure, and the resulting pregnancy could be ectopic.

**The decision to be sterilized should generally not be made at a time of stress**, such as immediately before, during, or after delivery or abortion.

- However, by the time of delivery, some clients may already have made a decision to choose sterilization without having yet made a formal request. Thus, sterilization should not be denied to a woman who voluntarily and spontaneously requests it after delivery or abortion, who has received counselling and who has made a well-considered decision.
- In some circumstances, a woman may learn about sterilization for the first time during the puerperal or post-abortion period and be able to make a voluntary and informed decision after careful counselling.

**It is important to give clients an opportunity to express any concerns and to have all their questions answered before the procedure.**

### 3.5 Who can perform female sterilization?

- Specialized or non-specialized doctors can perform minilaparotomy, provided they have been properly trained both in operative technique and in the technique of local anaesthesia.
- Under certain conditions, such as when demand for the operation exceeds the supply of trained doctors, nurses and midwives with surgical experience can be trained to perform the procedure if the country's laws and regulations permit.

- When a non-doctor performs the procedure, a doctor should be available for consultation and in case of surgical difficulties or complications. Protocols for exclusions should be clearly defined.
- All operators should be certified for competence in performing sterilization procedures by **an accredited training authority and should have done at least 10 solo cases in his/her training.**
- The minimum medical team for a female sterilization service is three people: a doctor, or nurse trained to do the surgery; a surgical assistant; and an auxiliary nurse or aide to give support to the operator and the assistant and to monitor the condition of the client.
- Only doctors with experience in abdominal and pelvic surgery should be trained to perform laparoscopic sterilization.

### 3.6 Health assessment

- *Medical history:* Refer to section 1.6 of this chapter. In addition, history for the female client should include:
  - Current contraceptive status.
  - Last menstrual period (LMP).
  - History of pelvic disease.
  - Obstetric history.
  - Previous abdominal or pelvic surgery.
- *The physical examination should include:*
  - Weight.
  - Temperature.
  - Blood pressure.
  - Pulse.
  - Auscultation of heart and lungs.
  - Abdominal examination.
  - Evaluation of nutritional status.
  - Examination of the skin of the operative area.
  - Other examinations as indicated by the medical history.

*In addition, before an interval procedure, the surgeon must perform a careful bi-manual pelvic examination, noting in particular uterine size, position and mobility as well as signs of pelvic infection or masses which may require delay to a standard surgical approach.*

*Before a postpartum or post-abortion procedure, the surgeon must carefully check for complications of delivery or abortion to identify any temporary contra-indications. If the required medical history and physical examination are not documented in the clinical record, these must be carried out.*

- *Laboratory investigations should include:*
  - Haemoglobin and/or haematocrit.
  - Other laboratory tests as indicated by the medical history and physical examination.
  - A cervical smear if possible and due. However, not obtaining the cervical smear or its result should not be a reason for postponing or denying the procedure.

**All findings of the medical assessment must be documented in the client's record.**

NOTE: If an IUD or an implant is used it may be removed immediately after surgery. In this way the client continues to be protected in the event that the tubal occlusion is not completed.

### 3.7 Timing of female sterilization procedures

**Female sterilization may be safely performed at the following times:**

- *Interval sterilization:* Not associated with a pregnancy.
- *Post-partum sterilization:* Within 1 week of delivery or concurrently with caesarean section. The optimal time for the post-partum procedure is within 48 hours of delivery. If surgery is performed on the 3rd to 7th day post-partum, the tubes may be difficult to reach from a subumbilical incision due to involution of the uterus. Careful palpation of the fundus must be performed to assess its position.
- *Post-abortion sterilization:* within 1 week after abortion.

Do not perform post-partum or post-second-trimester abortion procedures any later than the end of the 7th day following delivery or abortion. After the 7th day, the procedure should be postponed until after 28 days in order to avoid additional surgical difficulties and risks.

### 3.8 Pre-operative preparation

- Ensure that the medical history, physical examination and laboratory tests are completed and documented in the clinical record.
- Review the informed consent form and ensure that the signed form is in the client's record.
- Give pre-operative medications.

### 3.9 Anaesthesia and operative procedure

#### Anaesthesia

Use local anaesthesia with light sedation for female sterilization procedures. With proper training, local anaesthesia can be used for minilaparotomy and laparoscopy. The purpose of light sedation is to ensure a calm, relaxed client **while maintaining wakefulness**.

- Use only doses of analgesics (such as 25-50 mg meperidine) and sedatives (such as 5-10 mg diazepam) which allow the woman to stay awake. Doses which put the woman into a semi-conscious or unconscious state compromise ventilation and result in respiratory depression.

*Technique for local anaesthesia:*

- Infiltrate the skin, fascia and peritoneum with 1% lidocaine (lignocaine) without epinephrine (adrenaline) through a single puncture at the operative site. If only 2% lidocaine is available, dilute it to 1% by using saline solution.
- Wait 1-3 minutes for the local field block to take effect before making the incision.
- *The maximum safe dose of 1% lidocaine is 4.5 mg per kg of body weight. For a woman of 50 kg, that equates to 25 ml of 1% lidocaine.*

All staff need to be trained and aware of correct doses for all drugs in the anaesthetic protocol, understanding the need to decrease doses for the underweight client. If a new drug is introduced, clear instructions should be developed and added to the anaesthesia guidelines.

NOTE: General anaesthesia may be required in cases of extreme obesity, expected abdominal adhesions or some cases of mental illness. Spinal or

epidural anaesthesia is seldom justified for the short sterilization procedure.

## Operative procedure

Some basic procedural principles, in addition to those listed in section 1.8, include:

- Proper asepsis with a surgical scrub and the use of cap, mask, sterile gown, and sterile gloves.
- Use of an effective antiseptic (for example, a water-based iodine or a 4% chlorhexidine solution) to prepare the operative area.
- Proper use of the uterine elevator for interval procedures.
- Careful haemostasis and gentle tissue handling are important for patient comfort and safety. Incisions should be as small as possible while allowing good access to the fallopian tubes.

### *Type of surgical approach*

- **Minilaparotomy:** Minilaparotomy is a simplified laparotomy approach using an incision of 5 cm or less. A transverse or longitudinal incision is made under the umbilicus for post-partum cases (usually no more than 2 cm) and a transverse suprapubic incision is used for interval or post-abortion procedures.
  - Minilaparotomy may be difficult if the woman is obese, if the uterus is immobile, or if the tubes have adhesions from infection or previous surgery. In these cases, referral to another facility may be appropriate.
- **Laparoscopy:** The operator uses endoscopic equipment inserted through a 1.0-1.5 cm incision under the umbilicus.
  - Laparoscopy must *not* be performed immediately post-partum nor immediately after a second-trimester abortion.
- **Other surgical approaches:** Laparotomy uses an incision over 5 cm in length. It should not be used in routine sterilization procedures. It may be used when sterilization is performed in conjunction with caesarean section or another gynaecological operation. If a laparotomy is required, regional or general anaesthesia should be used.

Vaginal approaches (e.g., colpotomy, culdoscopy) are not recommended for routine use in sterilization programmes due to the increased infection

rates associated with these approaches.

**Recommendation: Minilaparotomy is the preferred method for settings with basic resources and should be offered extensively in most facilities; laparoscopy should usually be reserved for referral centres** where trained surgeons, properly maintained instruments, and immediate back-up for complications are available.

#### *Method of occlusion*

- Several methods exist for occluding the tubes. Procedures which cause the least damage to the tubes should be used routinely. These methods include *modified Pomeroy ligation, the ring and the clip*. The Parkland technique of double ligation of the tube, with resection of the portion between, is also appropriate.
- *Not* recommended for routine use in tubal occlusion are electrocoagulation, fimbriectomy, and salpingectomy.
- Hysterectomy should not be used for sterilization purposes alone. It should be reserved for women who have gynaecological conditions that require removal of the uterus.

**Recommendation: Ligation or mechanical occlusion with clips or rings are the preferred methods of tubal occlusion.**

#### *Monitoring of the client during the procedure*

- Take and record vital signs (pulse, respiration, blood pressure) in normal, uncomplicated procedures immediately before the operation, and monitor them as needed during the operation and just before the client is removed from the surgical table.
- If the procedure takes longer than usual or in the event of complications or prolonged general anaesthesia, then closer monitoring of vital signs is required.
- Members of the surgical team should talk to the woman during the procedure to give empathetic support and reassurance as well as to monitor the depth of analgesia and sedation.

### 3.10 Post-operative care

- Monitor pulse, respiration, blood pressure and general status every 15 minutes for at least 1 hour until signs are stable at pre-operative rates, then every hour until recovery and discharge. Vital signs must be recorded in the clinical record.
- Offer liquids such as fruit juice.
- The client may be discharged home the same day surgery is performed, after she has recovered from the procedure, the anaesthetic and the sedation.
  - The Romberg sign (client standing steadily with eyes closed) may be used as a sign of recovery.
  - Usually the woman can go home once she is fully ambulant, able to dress herself and converse coherently.
- As a general rule, do not use prophylactic antibiotics.
- Use simple oral analgesics for pain. Give the woman a 2 day supply on discharge.

### 3.11 Instructions to women after the procedure

Before the client is discharged, repeat all instructions related to post-operative care, and give the client written instructions.

Explain to the post-operative female client the following:

- That she should rest at home for 1 or 2 days. This rest is important to decrease the risk of complications.
- That she may resume light activities after 2 to 3 days and all normal activities, including intercourse, after 1 week.
- That she should keep the wound clean and dry. She may bathe after 24 hours, making sure that the dressing is kept dry.
- How to use any medications that are given.
- What warnings signs to look for and what to do about each of them (e.g., fever, pain, bleeding).
- Where to go and whom to contact in case of emergency, or for any other problem or questions.
- When and where to return for a follow-up visit.

In addition, inform the client that:

- She is sterile from the time the operation is completed.
- Her monthly periods will continue until menopause.
- If she misses a menstrual period, has any other signs suggestive of pregnancy or has abdominal or pelvic pain, she should contact the clinic.

The client should have the opportunity to ask questions and express concerns.

### **3.12 Follow-up care**

The follow-up visit should take place within 7-10 days. It is desirable that the operating surgeon conducts the follow-up examination. However, another qualified health professional can conduct the examination and manage minor complications. During the follow-up visit:

- Discuss with the client any concern or question she may have.
- Examine the operative site, and remove sutures if required. Perform any other examination needed for that individual.
- Schedule another follow-up visit if continued care is needed.

Special efforts, including the use of community-based follow-up, should be made to contact any client who does not return for the follow-up examination.

Innovative ideas for follow-up should be encouraged; for example, some programmes give clients postcards to send if problems or questions arise.

### **3.13 Complications**

Complications of tubal occlusion include intraperitoneal haemorrhage (seen primarily with laparoscopy), pelvic infection or peritonitis, haematoma formation, and bleeding or infection at the incision site. Rarely, surgical emergencies, such as injury to the uterus, bowel or bladder, or emboli or surgical emphysema (laparoscopy), may occur. Early recognition and prompt treatment are essential. In the event of method failure, the possibility of ectopic pregnancy should be excluded.

**Training for tubal occlusion should include how to identify and manage complications.**

Any surgical difficulties encountered during the procedure should be recorded, for these difficulties may explain complications that arise during the post-operative period. Any surgical accident should be recorded in the client's record even if it was successfully corrected during the operation.