Standards for Female and Male Sterilization Services

Research Studies & Standards Division
Ministry of Health and Family Welfare
Government of India
October 2006

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First published 1989
Second edition 1993
Third edition 1996
Fourth edition 1999
Fifth edition 2006

Printing of this edition for Government of India is supported by UNFPA, New Delhi

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Dated the 8th September 2006

Foreword

National Population Policy 2000 specifies unmet need for contraception as a priority area to be addressed urgently. The surveys conducted in India indicate that only 48% of the eligible couples adopt any contraceptive method to plan their family and sterilization is the most accepted method, contributing to nearly 75% of all the methods accepted. However, there is still a large unmet need of 7.5% in sterilization services.

Quality of services provided plays a major role in acceptance of any service. Poor quality of service in terms of technical inputs, processes, interpersonal communications, limited choice leads to unsatisfied clients with resulting under utilization of services. It is essential that standards are prescribed for the services which also facilitate in monitoring the quality of services provided. Quality Assurance is an ongoing cyclical process and revised Standards on Sterilizations is a part of this process to provide guidelines for ensuring quality care.

I appreciate the efforts of the Research Studies and Standards Division in revising this Manual after an exhaustive exercise with experts from various fields like Gynecology, Surgery, Anesthesia Programm Managers and International Agencies. It is hoped that the guidelines would serve the service providers and the program managers in providing quality care in sterilization services and evoke more confidence of the eligible couples in sterilization services for their better and larger utilization.

(PRASANNA HOTA)
Secretary to the Government of India

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Acknowledgement

Quality of care in sterilization services is a major thrust area in the Reproductive and Child Health Program of the Government of India for addressing the large unmet need in terminal methods. A revised 'Standards on Female and Male sterilization' has been prepared based on the latest guidelines available in this field, both in the national and international arena.

The updating of sterilisation standards has been made possible with the constant support and encouragement received from Shri P.K. Hota, Secretary (H&FW) and Smt. S. Jalaja, Addl. Secretary, Min. of Health & Family Welfare. I also thank Shri. Amarjeet Sinha, Joint Secretary , for his support in our undertaking and completion of this task.

I am thankful to all the experts and specialists who have contributed in bringing out this manual after extensive discussions and experience sharing. I am also thankful to all the invited State officials, whose experience in developing a system in quality care helped the expert group to prepare a need based manual. A special expression of appreciation is for Dr. Dinesh Agarwal from UNFPA who has been of immense support in preparing this document. My special thanks to WHO, especially Dr. Arvind Mathur and Ms. Antigoni for providing financial and technical support in developing the manual. The finalisation of the manual would have been very difficult without the constant help of Dr. Namshum, DC (Training), Dr Rajna, Consultant. I acknowledge the secret arial assistance rendered by Smt. Sampa Das, Shri. Sharma, Shri. Chauhan and Shri. Dhir from RSS division. A special word of appreciation for Dr. S.K. Sikdar, AC (RSS), whose tireless efforts has helped the division in finalizing the manual in time.

It is hoped that this manual serves the State Health System in strengthening their monitoring system for providing quality care in family planning.

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Contents

Introduction

The Development of Standards on Sterilization Services is an important step in ensuring the provision of quality services to the growing number of clients by programme managers and service providers providing permanent methods of contraception. This document sets out the criteria for eligibility, physical requirements, counselling, informed consent, preoperative, post-operative, and follow-up procedures, and procedures for management of complications and side effects. It also highlights the salient steps of the surgical procedures and the recommended practices for infection prevention.

The standards laid down in this document apply to both static and camp facilities. Programme managers and service providers are advised to refer to 'Standard Operating Procedures for Camps', being published separately by the Research Studies & Standards Division, Ministry of Health and Family Welfare (MOHFW).

Target audience

The document apprises doctors, other health personnel, and Reproductive and Child Health (RCH) programme managers throughout the country of the sterilization standards that are required to be maintained at their facilities.

1. Standards for female sterilization

INPUTS

1.1. Eligibility of Providers for Performing Female Sterilization

Service	Basic Qualification Requirement of Provider
Minilap services	Trained MBBS doctor
Laparoscopic sterilization	DGO, MD (Obst. & Gynae.), MS (Surgery) (trained in laparoscopic sterilization)

The state should constitute a district-wise panel of doctors for performing sterilization operations in government institutions and accredited private/NGO centres based on the above criteria. Only those doctors whose names appear on the panel should be entitled to carry out sterilization operations in the government and/or government-accredited institutions. The panel should be updated quarterly.

1.2. Physical Requirements

The infrastructural facilities required for performing female sterilization are placed in **Annexure 1**. This format is also applicable for accrediting a private facility providing services for female sterilization.

1.3. Case Selection

(*Self-declaration by the client will be the basis for compiling this information.*)

1.3.1. Clients should be married (including ever-married).

1.3.2. Female clients should be below the age of 49 years and above the age of 22 years.

1.3.3. The couple should have at least one child whose age is above one year unless the sterilization is medically indicated.

1.3.4. Clients or their spouses/partners must not have undergone sterilization in the past (not applicable in cases of failure of previous sterilization).

1.3.5. Clients must be in a sound state of mind so as to understand the full implications of sterilization.

1.3.6. Mentally ill clients must be certified by a psychiatrist, and a statement should be given by the legal guardian/spouse regarding the soundness of the client's state of mind.

PROCESSES

1.4. Clinical Processes

Preparation for surgery includes counselling, preoperative assessment, preoperative instructions, review of the surgical procedure, and post-operative care. It is essential to ensure that the consent for surgery is voluntary and well informed, and that the client is physically fit for the surgery. Preoperative assessments also provide an opportunity for overall health screening and treatment of RTIs/STIs.

1.4.1. Counselling

Counselling is the process of helping clients make informed and voluntary decisions about fertility. General counselling should be done whenever a client has a doubt or is unable to take a decision regarding the type of contraceptive method to be used. However, in all cases, method-specific counselling must be done.

The following steps must be taken before clients sign the consent form:

1.4.1.1. Clients must be informed of all the available methods of family planning and should be made aware that for all practical purposes this operation is a permanent one.

1.4.1.2. Clients must make an informed decision for sterilization voluntarily.

1.4.1.3. Clients must be counselled whenever required in the language that they understand.

1.4.1.4. Clients should be made to understand what will happen before, during, and after the surgery, its side effects, and potential complications.

1.4.1.5. The following features of the sterilization procedure must be explained to the client:

- It is a permanent procedure for preventing future pregnancies.
- It is a surgical procedure that has a possibility of complications, including failure, requiring further management.

- It does not affect sexual pleasure, ability, or performance.
- It will not affect the client's strength or her ability to perform normal day-to-day functions.
- Sterilization does not protect against RTIs, STIs, or HIV/AIDS.
- Clients must be told that a reversal of this surgery is possible, but that the reversal involves major surgery and that its success cannot be guaranteed.

1.4.1.6. Clients must be encouraged to ask questions to clarify their doubts, if any.

1.4.1.7. Clients must be told that they have the option of deciding against the procedure at any time without being denied their rights to other reproductive health services.

1.4.2. Clinical Assessment and Screening of Clients

Prior to the surgery, compilation of the client's medical history, physical examination, and laboratory investigations as specified below need to be done in order to ensure the eligibility of the client for surgery.

a) Demographic information: The following information is required: age, marital status, occupation, religion, educational status, number of living children, and age of the youngest child.

b) Medical history:

i) History of illness to screen for the diseases mentioned under the medical eligibility criteria

ii) Immunization status of women for tetanus

iii) Current medications

iv) Last contraceptive used and when

v) Menstrual history: Date of last menstrual period and current pregnancy status

vi) Obstetrics history

c) Physical examination: Pulse, blood pressure, respiratory rate, temperature, body weight, general condition and pallor, auscultation of heart and lungs, examination of abdomen, pelvic examination, and other examinations as indicated by the client's medical history or general physical examination.

d) Laboratory examinations: Blood test for haemoglobin, urine analysis for sugar and albumin, and other laboratory examinations as indicated.

There are no absolute medical contraindications for performing female sterilization. However, there are certain conditions that require doctors to be cautious, to delay the surgery, to refer the client to an especially equipped centre, or to counsel the client to go in for alternative contraception. The Medical Eligibility Criteria for Female Surgical Sterilization procedures outlined by WHO (2004) serve as guidelines for case selection based on the clinical findings of the client **(Annexure 2). However, the final selection of the case should be based on the case selection criteria outlined in 1.3 and guided by the medical eligibility criteria stated above.**

The operating surgeon must fill in the medical record and checklist placed at Annexure 3 before initiating the surgery.

1.4.3. Timing of the Surgical Procedure

a) **Interval sterilization** should be performed within 7 days of the menstrual period (in the follicular phase of the menstrual cycle).

b) **Post-partum sterilization** should be done after 24 hours up to 7 days of delivery.

c) **Sterilization with medical termination of pregnancy (MTP)** can be performed concurrently.

d) **Sterilization following spontaneous abortion** can be performed provided the client fulfils the medical eligibility criteria.

Laparoscopic tubal ligation should not be done concurrently with second-trimester abortion and in the post-partum period.

1.4.4. Informed Consent

1.4.4.1. Consent for sterilization operation should not be obtained under coercion or when the client is under sedation.

1.4.4.2. Client must sign the consent form for sterilization before the surgery (**Annexure 4**).

The consent of the spouse is not required for sterilization.

1.4.5. Preoperative Instructions

a) The client must bathe and wear clean and loose clothing.

b) The client must not consume anything (even water) by mouth 4 hours prior to surgery and no solids, milk or tea 6 hours prior to surgery.

c) On the morning of the surgery, she must empty her bowels. Before entering the OT, she must empty her bladder and also remove her glasses, contact lenses, dentures, jewellery, and lipstick, if she is wearing any of these items.

d) A responsible adult must be available to accompany the client back home after the surgery.

1.4.6. Part Preparation

i) The operative area should not be shaved. The hair can be trimmed, if necessary.

ii) The operative site should be prepared immediately preoperatively with an antiseptic solution, such as iodophor (Povidone iodine) or chlorhexidine gluconate (Cetavalone).

iii) Alcohol preparation should not be applied to the sensitive genitalia. Iodophor and chlorhexidine are safe to use on mucous membranes and can be used to cleanse the vagina and cervix.

iv) Iodophor requires 1 to 2 minutes to work because a certain amount of time is needed for the release of free iodine, which inactivates the micro-organisms.

v) Antiseptic solutions should be applied liberally at least two times on and around the operative site, which should be thoroughly cleansed by gentle scrubbing.

vi) The antiseptic solution should be applied in a circular motion, beginning at the site of incision and working out for several inches. This inhibits the immediate re-contamination of the site with local skin bacteria.

vii) The excess antiseptic solution should not be permitted to drip and gather beneath the client's body as this may cause irritation.

viii) After preparing the operative site, the area should be covered with a sterile drape.

1.4.7. Premedication/Anaesthesia/Analgesia

a) Premedication: Reassurance and proper explanation of the procedure go a long way in allaying the anxiety and apprehension of the client. However, if needed, Tablet Alprazolam (0.25 to 0.50 mg) or Tablet Diazepam (5 to 10 mg) can be given right before the operation.

b) Anaesthesia/Analgesia: Local anaesthesia is the preferred choice for a tubectomy operation. On the day of the operation, drugs for sedation and analgesia are to be given as shown in Table A.

Local Anaesthesia

Skin sensitivity testing for local anaesthetic agent (lignocaine) has no established predictive value for anaphylactic reaction. Therefore, it is not mandatory to perform a skin sensitivity test prior to infiltration of lignocaine.

The following are the requirements for the administration of local anaesthesia:

1) An IV line is to be secured before the start of the procedure.
2) Lignocaine without adrenaline is the local anaesthetic that is to be infiltrated on the OT table. The maximum dosage is 3 mg per kg body weight.

Table A: Drugs for preoperative and intra-operative sedation and analgesia

Approximate Weight/Build	Name of Drugs and Dose	Route and Time of Administration	Repeat Dose if Required on the Table**	
			Dose	Route
Thin (approx. < 40 kg)	Pethidine 25 mg+ Promethazine 12.5 mg OR Pentozocine 15 mg+ Promethazine 12.5 mg	IM: 30–45 min prior to surgery IM: 30–45 min prior to surgery	Pethidine 10 mg Pentozocine 5 mg	IV: 5 min prior to surgery IV: 5 min prior to surgery
Average (40–50 kg)	Pethidine 37.5 mg+ Promethazine 12.5 mg OR Pentozocine 22.5 mg+ Promethazine 12.5 mg	IM: 30–45 min prior to surgery IM: 30–45 min prior to surgery	Pethidine 10 mg Pentozocine 5 mg	IV: 5 min prior to surgery IV: 5 min prior to surgery
Well built (more than 50 kg)	Pethidine 50 mg+ Promethazine 25 mg OR Pentozocine 30 mg+ Promethazine 25 mg	IM: 30–45 min prior to surgery IM: 30–45 min prior to surgery	Pethidine 10 mg Pentozocine 5 mg	IV: 5 min prior to surgery IV: 5 min prior to surgery

(Dosage by body weight: Pethidine 0.5 to 1 mg/kg; Promethazine 0.3–0.5 mg/kg; Pentozocine 0.5 mg kg.)
** Only once, to be given after 45 minutes of the initial dose.

3) Client must be monitored and attended to after the parenteral administration.
4) Communication must be maintained with the client throughout the procedure.

General Anaesthesia

This is rarely necessary. However, it may be required in the following conditions:

i) In case of a non-cooperative patient

ii) In case of excessive obesity

iii) In case of a history of allergy to local anaesthetic drugs

In the above cases, the provision for general anaesthesia (including guidelines for personnel, facilities and equipment, and other) should be adhered to.

The following drugs may be made available for the GA cases in addition to the available drugs given in the emergency list:

- Injection Thiopentone Sodium
- Injection Propofol
- Injection Morphine, Injection Pethidine, Injection Fantanyl
- Injection Suxamethonium
- Injection Vecusonium Bromide
- Injection Neostigmine
- Injection Terbutaline
- Injection Ondansetron
- Salbutamol Solution for Nebulization
- Injection Nitroglycerin

c) Monitoring: Medical records are to be maintained relating to the vital signs (pulse, respiration, and blood pressure), level of consciousness, vomiting, and any other relevant information. If any drug is administered, its name, dosage route, and time must be recorded. Monitoring is to be done as described below:

i) Preoperatively: Pulse, respiration, and blood pressure should be taken prior to premedication and thereafter every 10 minutes.

ii) Intra-operatively: (a) Maintain verbal communication with client; and (b) check pulse, respiration, and blood pressure every 5 minutes, especially during the time of gas insuffulation and at the time of tubal ligation.

iii) Post-operatively: Pulse, respiration, and blood pressure should be monitored and recorded every 15 minutes for one hour following surgery or longer if the patient is unstable or not awake.

1.4.8. Surgical Techniques

a) General Requirements

i) The client's bladder must be empty. If there is a doubt, the client must be asked to void urine immediately before the procedure and should be catheterized, if indicated.

ii) The operating surgeon should identify each fallopian tube clearly, following it right up to the fimbria. The site of the occlusion of the fallopian tube must always be within 2–3 cm from the uterine cornu in the isthmal portion (this will improve the possibility of reversal if required in the future). Care must be taken to avoid damage to the blood vessels, ovaries, and surrounding tissues.

iii) Excision of 1 cm of the tube should be done. Use of cautery and crushing of the tube should be avoided.

iv) The skin incision is to be closed with an absorbable or non-absorbable suture, and a small dressing or bandage applied.

b) Minilaparotomy Requirements

i) An interval minilaparotomy procedure would benefit from the use of a uterine elevator to bring the fallopian tubes into the operative field.

ii) The incision for a minilaparotomy (interval, post-abortal, or post-partum) may be transverse or longitudinal.

iii) Modified Pomeroy's procedure should be followed for excision and ligation of tube, using a square knot with 1 '0 chromic catgut.

c) Laparoscopy Requirements

i) To avoid hypoventilation, the patient must not be placed in the Trendelenburg position in excess of 15 degrees.

ii) An uterine elevator should be used to visualize the fallopian tube.

iii) Pneumoperitoneum should be created with veres needle.

iv) Insufflation of abdomen with carbon dioxide is the preferred method. Intra-abdominal pressure must not exceed 15 mm of mercury. Slow insufflations with graded insufflator and gradual de-sufflation should be done.

v) The skin incision should not exceed the diameter of the trocar.

vi) The trocar is to be angled towards the hollow of the sacrum. The operator must lift the anterior abdominal wall before introducing the trocar.

vii) Tubal occlusion must always be done with Falope's rings (no cautery is to be used). The following precautions are to be followed in applying Falope's rings:

- ★ Draw the tube slowly and smoothly into the sleeve of the laparoscope after proper identification (include only the amount of tube necessary to provide adequate occlusion). Refer to para 1.4.8.a (ii) for appropriate site occlusion.
- ★ To prevent injury to the mesosalpinx/tube, avoid pulling up or back on the laparocator.
- ★ Do not apply the rings in case of thick, oedematous or fixed tubes. In such cases, tubal occlusion should be done with laparotomy under GA by conventional method.

viii) After applying the second ring, the operator should systematically inspect the pelvis to verify that both tubes are now occluded, that there is no unusual bleeding, and that there is no visceral injury.

ix) The surgeon should expel all the gas from the abdominal cavity slowly before removing the trocar.

1.5. Post-operative Care

a) The client is monitored as described in 1.4.7.c (iii).

b) The client may be discharged when the following conditions are met:

i) After at least 4 hours of procedure, when the vital signs are stable and the client is fully awake, has passed urine, and can walk, drink or talk.

ii) The client has been seen and evaluated by the doctor. Whenever necessary, the client should be kept overnight at the facility.

c) The client must be accompanied by a responsible adult while going home.

d) Analgesics, antibiotics, and other medicines may be provided and/or prescribed as required.

1.5.1. Post-operative and Follow-up Instructions

The client is to be provided with a discharge card indicating the name of the institution, the date and type of surgery, the method used, and the date and place of follow-up

(**Annexure 5**). Both written and verbal post-operative instructions must be provided in the local language.

The client must be advised to:

a) Return home and rest for the remainder of the day.

b) Resume only light work after 48 hours and gradually return to full activity by two weeks following surgery.

c) Use medicines as instructed.

d) Resume normal diet as soon as possible.

e) Keep the incision area clean and dry. Do not disturb or open the dressing.

f) Bathe after 24 hours following the surgery. If the dressing becomes wet, it should be changed so that the incision area is kept dry until the stitches are removed.

g) In the case of interval sterilization, the client may have intercourse one week after surgery, or whenever she feels comfortable. Sterilization procedures do not interfere with sexual pleasure, ability or performance.

h) The client must report to the doctor or the clinic if there is excessive pain, fainting, fever, bleeding or pus discharge from the incision, or if the client has not passed urine, not passed flatus, and feels bloating of the abdomen.

i) Follow-up contact with all tubectomy clients at home by the female health worker in a government health institution or reporting by the client to the clinic should be established within 48 hours of surgery.

j) The second follow-up should be done on the seventh post-operative day for the removal of stitches and post-operative check-up. A pelvic examination may be done, if indicated.

k) The third follow-up should be done after one month or after the client's first menstrual period, whichever is earlier.

l) The client must return to the clinic if there is a missed period/suspected pregnancy within two weeks of the missed period. If she has missed her period or is experiencing any menstrual abnormality, she must be examined to rule out pregnancy.

m) Instructions should be given on where to go for routine and emergency follow-up.

n) If the client has any questions, she should contact the health personnel or doctor at any time.

1.5.2. Certificate of Sterilization

A certificate of sterilization should be issued after one month of the surgery or after the first menstrual period by the Medical Officer of the facility.

1.6. Complications of Female Sterilization and Their Management

1.6.1. Intra-operative complications

a) **Nausea and vomiting:** Ondansetron (4 mg) or Metoclopramide (10 mg) may be given IM or IV.

b) **Vasovagal attack:** Raise the leg end and lower the head end and give oxygen. Administer Atropine (0.6 mg) IV if there is bradycardia. This can be repeated if the baseline pulse rate is not achieved within 1 to 2 minutes.

c) **Respiratory depression:** Keep the airway patent; assist breathing using manual resuscitation equipment with oxygen; assess the circulation by monitoring pulse, blood pressure, and respiration; give other supportive therapy as indicated.

d) **Cardiorespiratory arrest:** Details of the sequential management of cardiorespiratory arrest is placed at Annexure 11.

e) **Uterine perforation due to introduction of uterine elevator from below:** This needs to be repaired immediately if there is bleeding. Otherwise the patient needs to be placed under further hospital observation to ensure that she is stable.

f) **Bleeding from the mesosalpinx:** This can be treated through a laparoscope with a cautery or ring/clip application. Alternatively, the bleeding should be controlled immediately by laparotomy.

g) **Injury to the urinary bladder:** Enclose in two layers and put self-retaining catheter in bladder for 7 days or as long as necessary.

h) **Injury to intra-abdominal viscera (i.e. small or large bowel) and blood vessels:** This must be repaired immediately and the IV line maintained. If the operating surgeon is not confident of repairing, he/she must ask for help from a surgical colleague.

i) **Convulsions and toxic reactions to local anaesthesia:** The foremost priority is to maintain patency of airway and give 100% oxygen inhalation. If the convulsions persist, administer Injection Diazepam 5–10 mg IV. Administration of IV fluid is not generally required but may be given if necessary. Surgery should be stopped and the patient allowed to recover. Further, surgery should be performed at a centre with the full range of services.

1.6.2. Post-operative complications

a) **Wound sepsis:** Small stitch abscess is to be treated with drainage and dressings. However, severe sepsis needs opening of the incision and drainage of pus. Further, treatment should be done with dressings, antibiotics, and analgesics.

b) **Haematoma in the abdominal wall:** A small non-expanding, non-infected haematoma will resolve with no therapy. A large one, particularly if infected, may need drainage and treatment with antibiotics.

c) **Intestinal obstruction, paralytic ileus, and peritonitis:** The client should be hospitalized if she is not already in hospital. Keep the patient on nothing by mouth, put nasogastric suction, give IV fluids, antibiotics, and analgesics as indicated, and refer to a higher centre, if required.

d) **Tetanus:** If tetanus is diagnosed, the patient must be transferred immediately to a proper centre for treatment.

e) **Incisional hernia:** A rare complication that needs surgical treatment.

1.6.3. Failure of operation leading to pregnancy

This may be due to either technical deficiency in the surgical procedure or spontaneous re-canalization. To detect failure leading to pregnancy at the earliest, the client should be advised to report to the facility immediately after missed periods. The client should be offered MTP and repeat sterilization surgery or should be medically supported throughout the pregnancy if she so wishes. Ectopic pregnancy must be ruled out as tubectomy predisposes to this condition. Each case of sterilization failure should be reported to the District Quality Assurance Committee. The District Quality Assurance Committee will conduct a preliminary investigation and report to the State Quality Assurance Committee.

All cases of failure and complications, major or minor, arising during surgery or post-surgery must be documented. The complications that required hospitalization and all cases of failure must be reported to the district quality assurance committee. The district quality assurance committee will in turn be responsible for communicating such information to the concerned insurance service providers for compensation.

1.7. Conditions Not Related to Sterilization

a) **Menstrual irregularities (e.g. menorrhagia and scanty period):** These sometimes occur. But these are not complications of sterilization. Reassurance and treatment according to the cause are required in most cases.

b) **Chronic pelvic inflammatory disease:** This usually presents itself as lower abdominal pain and requires treatment with bed rest, antibiotics, and analgesics.

c) **Psychological problems (e.g. depression):** Discussing the problem, clarifying the role of sterilization, and answering questions are important steps.

2. Standards for male sterilization

INPUTS

2.1. Eligibility of Providers for Performing Male Sterilization

Service	Basic Qualification Requirement of Provider
Conventional vasectomy	Trained MBBS doctor
No-scalpel vasectomy (NSV)	Trained MBBS doctor

The state should prepare a district-wise panel of doctors for performing sterilization operations in government institutions and government-accredited private/NGO centres based on the above criteria. Only those doctors whose names appear in the panel should be entitled to carry out sterilization operations in government and/or government-accredited institutions. The panel should be updated quarterly.

2.2. Physical Requirements

The infrastructural facilities required for performing male sterilization are outlined in Annexure 6. This format is also applicable for accrediting a private facility providing services in male sterilization.

2.3. Case Selection

(Self-declaration by the client will be the basis for compiling this information).

2.3.1. Clients should be ever-married.

2.3.2. Male clients should ideally be below the age of 60 years.

2.3.3. The couple should have at least one child whose age is above one year unless the sterilization is medically indicated.

2.3.4. Clients or their spouses/partners must not have undergone sterilization in the past (not applicable in the cases of failure of previous sterilization).

2.3.5. Clients must be in a sound state of mind so as to understand the full implications of sterilization.

2.3.6. Mentally ill clients must be certified by a psychiatrist, and a statement should be given by the legal guardian/spouse regarding the soundness of the client's state of mind.

PROCESSES

2.4. Clinical Processes

Preparation for the surgery includes counselling, preoperative instructions, case selection, preoperative assessment, review of the surgical procedure, and post-operative care. It is essential to ensure that the consent for surgery is voluntary and well informed and that the client is physically fit for the surgery. Preoperative assessment can also provide an opportunity for overall health screening and treatment of RTIs/STIs.

2.4.1. Counselling

Counselling is the process of helping clients make informed and voluntary decisions about fertility. General counselling should be done whenever a beneficiary has a doubt or is unable to take a decision regarding the type of contraceptive method to be used. However, in all cases method-specific counselling must be done.

The following steps must be taken before the client signs the consent form:

2.4.1.1. Clients must be informed of all the available methods of family planning and made aware that for all practical purposes this operation is a permanent one.

2.4.1.2. Clients must make an informed decision for sterilization voluntarily.

2.4.1.3. Clients must be counselled whenever necessary in the language they understand.

2.4.1.4. Clients should be made to understand what will happen before, during, and after the surgery, its side effects, and potential complications.

2.4.1.5. The following features of the sterilization procedure should be explained to the client:

a) It is a permanent procedure for preventing future pregnancies.

b) It is a surgical procedure that has a possibility of complications, including failure, requiring further management.

c) It does not affect sexual pleasure, ability or performance.

d) It does not affect the client's strength or his ability to perform normal day-to-day functions.

e) After vasectomy, it is necessary to use a back-up contraceptive method until azoospermia is achieved (usually this takes three months).

f) Sterilization does not protect against RTIs, STIs, and HIV/AIDS.

g) A reversal of this surgery is possible but the reversal involves major surgery and its success cannot be guaranteed.

2.4.1.6. Clients must be encouraged to ask questions to clarify their doubts, if any.

2.4.1.7. Clients must be told that they have the option of deciding against the procedure at any time without being denied their rights to other reproductive health services.

2.4.2. Clinical Assessment and Screening of Clients

a) Demographic information: The following information is required: age, marital status, occupation, religion, educational status, number of living children, and age of youngest child.

b) Medical history:

i) History of illness to screen out the diseases mentioned under the medical eligibility criteria and also to screen out severe anaemia, acute febrile illness, jaundice, chronic systemic disease, bronchial asthma, heart disease, uncontrolled diabetes, hypertension, thyrotoxicosis, severe nutritional deficiencies, and sexual impairments or sexual problems;

ii) Immunization status of men for tetanus;

iii) Current medications, if any;

iv) Current use of contraception by the couple;

v) Last menstrual period (LMP) of the wife.

c) Physical examination: Pulse and blood pressure, temperature, general condition and nutritional status, and examination of penis, testicles, and scrotum. Further examinations as indicated by the client's medical history.

d) Laboratory examinations: Urine analysis for sugar and other laboratory examinations as indicated.

There are no absolute contraindications for performing male sterilization. There are certain conditions that require caution, delay or referral to a specially equipped centre. The Medical

Eligibility Criteria for Male Surgical Sterilization procedures outlined by WHO (2004) serves as guidelines for case selection based on the clinical findings of the client **(Annexure 7). However, the final selection of the case should be based on the case selection criteria outlined in 2.3 and guided by the medical eligibility criteria stated above**.

The operating surgeon must fill in the Medical Record and Checklist for Sterilization placed at Annexure 3 before initiating the surgery.

2.4.3. Timing of Surgical Procedure

Male sterilization can be done at any convenient time on healthy clients.

2.4.4. Informed Consent

2.4.4.1. Consent for the sterilization operation should not be obtained under coercion or when the client is under sedation.

2.4.4.2. Client must sign the consent form for sterilization before the surgery (**Annexure 4**).

The consent of the spouse is not required for sterilization.

2.4.5. Preoperative Instructions

a) The client should trim the pubic, scrotal, and perineal hair.

b) The client should bathe and wear clean and loose clothes to the OT.

c) The client should have a light meal on the morning of the surgery.

d) The client should empty his bladder before entering the OT.

2.4.6. Skin Preparation and Surgical Draping

i) The operative site should not be shaved. The hair can be trimmed, if not done earlier.

ii) The operative site should be prepared immediately preoperatively with an antiseptic solution such as iodophor (Povidone iodine) or chlorhexidine gluconate (Cetavalone).

iii) Iodophors require 1 to 2 minutes to work because there must be time for the release of free iodine, which inactivates the micro-organisms.

iv) Antiseptic solutions should be applied liberally at least two times on and around the operative site, which should be thoroughly cleansed by gentle scrubbing.

v) The antiseptic solution should be applied in a circular motion, beginning at the site of incision and working out for several inches. This inhibits immediate recontamination of the site with local skin bacteria.

vi) Excess antiseptic solution should not be permitted to drip and gather beneath the client's body as this may cause irritation.

vii) After preparing the operative site, the area should be covered with a sterile drape.

2.4.7. Premedication/Anaesthesia/Analgesia

a) **Premedication** is optional. It should be administered only in the case of an anxious client in order to allay anxiety and to relax the scrotum. The drug of choice is tablet diazepam 10 mg, which should be given one hour prior to surgery with a sip of water.

b) **Local anaesthesia** is recommended for vasectomy procedures. The local anaesthetic to be used is 1% lignocaine without adrenaline. The maximum dosage is 200 mg or 20 ml of 1% lignocaine or 10 ml of 2% lignocaine (10 ml solution of 2%, to be diluted with an equal amount of distilled water).

i) Adequate time must be allowed for the medication to be effective.

ii) Communication must be maintained with the client throughout the operation.

c) **Monitoring**: Vasectomy involves brief surgery. Constant communication with the client will alert the surgeon to any adverse event. The staff should monitor the pulse, respiration, and blood pressure, and should respond to any emergency. A full record of any adverse event must be kept.

2.4.8. Surgical Techniques

I. Conventional Vasectomy

a) **Incision:** The vasectomy operation is to be performed either with two incisions located at the root of the scrotum on either side, or with one incision on the midline. The length of each incision should not be more than 2 cm. Smaller incisions will minimize the chances of complication.

b) **Site of vasectomy:** The mid-scrotal part of the vas should be removed. It must not be cut close to the epididymis, over the convoluted part of the vas deferens.

c) **Excision of vas:** The vas must be separated from the tissues and excised in all cases. The portion excised should not be more than 1 cm in length. Removal of

the excess length of the vas may make a re-canalization operation difficult, if it is required in the future.

d) **Tying of cut ends of vas:** The cut ends of the vas must be tied with 2'0' silk, and the sheath of the vas (Spermatic fascia) should be interposed between the two cut ends.

e) **Closing Skin incision:** The skin incision should be closed with non-absorbable sutures and covered with a piece of sterile gauze. Before closing the wound, all bleeding points must be tied so as to ensure compete haemostasis and to prevent bleeding or haematoma formation. Use of tincture of benzoin causes excoriation of the scrotal skin and should therefore be avoided for dressing.

f) **Scrotal support:** The patient should wear a suspensory bandage for one week, until the stitches are removed.

II. No-Scalpel Vasectomy (NSV)

The basic difference between the NSV procedure and the conventional technique is in the surgical approach to the vas, which is through a small puncture in the scrotum rather than by a cut with a scalpel. The surgical procedure of vas ligation is the same as in the conventional method. Long-term clinical reports have shown that NSV is less invasive than the conventional technique, causes fewer complications, and takes much less time.

a) **Preoperative instructions:** Same as given in 2.4.5.

b) **Skin preparation and surgical draping:** Same as given in 2.4.6.

c) **Anaesthesia:** NSV is performed using local anaesthesia. The preferred anaesthesia is 1% lignocaine without adrenaline. The administration of anaesthesia is done strictly perivasally about 5 ml on either side, and this is adequate for the analgesia during the NSV procedure.

d) **Fixation, puncture, and delivery of vas:** The site of fixation and puncture of the vas will be at the junction of the upper and the middle third of the scrotum on the midline. The vas is fixed in the midline at the junction of its upper one-third and lower two-third by a vas fixation forceps. This is done by the three-finger technique. The skin is then punctured with a vas dissection forceps, the vas is dissected out, the bare vas is delivered out of the puncture hole, and is ligated and excised.

e) **Excision of vas:** About 1 cm length of the bare vas should be ligated and excised. The removal of the excessive length of vas may make the re-canalization operation difficult, if it is required by the client in the future.

f) Ligature of vas: The cut ends of the vas should be tied with non-absorbable suture material (2 '0 ' black silk), and the sheath of the vas should preferably be interposed between the two cut ends.

g) Delivery of the opposite vas: The opposite vas must be fixed exactly in the same manner using the three-finger technique at the lower end of the previously made puncture hole. It should be punctured and delivered in the same way through the earlier hole without increasing its size.

h) Skin wounds: After the excision and ligature of both the vas, inspect the puncture site for any bleeding. If there is none, the puncture site should be dressed with a small piece of gauze. This should be retained for 48 hours. No stitch is applied since the puncture contracts and is nearly invisible after the removal of the instruments.

i) Scrotal support: The client should wear his normal snugly fitting underwear, or use scrotal support with suspensory bandage.

2.5. Post-operative Care

a) The client should be discharged when the following conditions are met:
   i) Thirty minutes have passed after the surgery.
   ii) The client is alert and ambulatory.
   iii) The client's vital signs are stable and normal.
   iv) The client has been seen and evaluated by a doctor.

b) Analgesic and other medicines if needed must be provided/prescribed prior to sending the client home.

c) Following vasectomy, the client should wear tight underpants or a loincloth to keep the scrotum from moving and the subsequent possibility of bleeding and haematoma formation.

2.5.1. Post-operative Instructions

The client should be provided with a discharge card indicating the name of the institution, the date and type of surgery, and the date and place of follow-up (**Annexure 8**). Both verbal and written post-operative instructions should be given in the local language.

The client should be told to do the following after he is discharged:

a) Return home and take adequate rest.

b) Resume normal work after 48 hours and return to full activity, including cycling, after one week following surgery.

c) Take analgesics and other medicines as advised by the doctor.

d) Resume a normal diet as soon as possible.

e) Keep the operated area clean and dry, and not disturb or open the dressing.

f) The client may bathe after 24 hours, while keeping the operated part of the body protected. If the dressing becomes wet, it should be changed. After 48 hours, the dressing may be taken off.

g) The client may have intercourse whenever it is comfortable after the surgery. He must be told that he does not become sterile immediately after the operation and that he or his wife/partner will have to use another method of contraception or for three months following vasectomy or until the semen analysis shows no sperms. The client must use condoms if his wife/partner is not using contraception.

h) The client should report to the doctor or the clinic if there is excessive pain, fainting, fever, bleeding, increase in scrotal size, or pus discharge from the operated site.

i) The client should return to the clinic (in case of conventional vasectomy) for removal of stitches and post-operative check-up in seven days.

j) The client should report to the clinic for semen analysis after three months.

k) If the client has any questions, he should contact the health personnel or doctor at any time.

l) The client must be provided with instructions about where to go in case of complications (such as infection, swelling of the scrotum, fever, increase in pain, and bleeding from the wound).

2.5.2. *Follow-up Instructions*

a) All clients who undergo vasectomy (both conventional and NSV) should report to the clinic within 48 hours.

b) In case of conventional vasectomy, the client should come after one week for removal of stitches.

c) In both conventional vasectomy and NSV, the client should come for follow-up for undergoing semen analysis after three months.

2.5.3. *Certificate of Sterilization*

A certificate of sterilization should be issued only after the semen analysis shows no sperm.

2.6. Complications of Male Sterilization and Their Management

2.6.1. *Intra-operative complications*

Although the incidence is rare, the following may be encountered:

a) **Transient drop in blood pressure or dizziness due to vasovagal attack:** In such cases, the procedure should be delayed and the patient allowed to rest. The head end of the bed should be lowered and the leg end raised. An intravenous injection of atropine (0.6 mg) may be given if there is bradycardia. It can be repeated if the baseline pulse rate is not achieved within 1 to 2 minutes. Oxygen should also be administered simultaneously.

b) **Convulsions and reactions to local anaesthesia:** In such cases, first and foremost, maintain the patency of airway and give 100% oxygen inhalation. If convulsions still persist, injection diazepam 5–10 mg IV may be given. Administration of IV fluids is generally not needed, but may be done depending on the case. In such an event, surgery should be stopped and the patient allowed to recover. Further surgery should be performed only at a centre with a full range of services.

c) **Injury to testicular artery:** This complication is very rare, but if it does occur, first pressure should be used to tamponade both ends of the vessel. Subsequently, both ends of the artery must be ligated.

2.6.2. *Immediate complications*

a) **Swelling of the scrotal tissue, bruising, and pain:** These minor complications often disappear without treatment within 24 to 48 hours. Ice packs, scrotal support, and simple analgesics may provide relief.

b) **Haematoma:** If small, it can be treated by scrotal support, analgesics, and antibiotics. A large haematoma may need evacuation, antibiotics, and further treatment. If a haematoma is detected early, it is desirable to cut the stitches, remove the clots, and look for the bleeding or oozing points, which should be tied. Referral should be considered.

c) **Infection**

i) **Stitch abscess:** To be treated with removal of stitch, drainage, dressings and antibiotics.

ii) **Wound sepsis:** In case of severe sepsis, the wound should be opened and the pus drained. Further treatment should include application of dressings and administration of antibiotics and analgesics.

iii) **Orchitis:** Cases must be treated with antibiotics, analgesics, scrotal support, and bed rest. Severe orchitis may need hospitalization.

d) **Tetanus:** A rare complication. If tetanus is detected, the patient must be transferred immediately to a proper centre for treatment.

2.6.3. Delayed complications

a) **Sperm granuloma:** This can occur either at the site of the vas occlusion or over the epididymis. The majority of these are symptomless, and respond to analgesics and anti-inflammatory drugs. Very occasionally a persistent and painful granuloma may necessitate surgical intervention.

b) **Psychological problem:** Uncommon. However, discussion of the problem, clarification of the role of sterilization, and answering questions are important steps. Appropriate referral should be given to the patient.

c) **Failure of vasectomy:** Incidences of failure are quite low, but may occur because of technical deficiencies in the surgical procedure or as a result of spontaneous re-canalization. The client's wife should be offered MTP or should be medically supported throughout pregnancy. The client should be offered a repeat surgery, as indicated.

There is no association of prostatic or testicular cancer and cardiovascular disorder with vasectomy.

All cases of failure and complications, major or minor, arising during surgery or post-surgery must be documented. The major complications that required hospitalization and all cases of failure must be reported to the district quality assurance committee. The district quality assurance committee will in turn be responsible for communicating such information to the concerned insurance service providers for compensation.

3. Prevention of infection: asepsis and antisepsis

It is mandatory to practise appropriate infection-prevention procedures at all times with all clients to decrease the risk of transmission of infection, including the Human Immunodeficiency Virus (HIV), Hepatitis C (HCV), and Hepatitis B (HBV). Standard universal precautions of infection prevention include:

1. Washing hands
2. Ensuring self-protection by wearing gloves and employing other physical barriers
3. Adopting safe work practices (to prevent injuries from sharps instruments)
4. Maintaining proper methods of environmental cleanliness
5. Ensuring the proper processing of instruments and other items
6. Following proper waste-disposal practices and handling, transporting, and processing used and/or soiled linens in the recommended and prescribed manner.

3.1. Hand Washing

3.1.1. Routine Hand Washing

a) Routine hand washing should be done before wearing gloves, after examining or after having any direct contact with a client, and after removing gloves.

b) Plain or antiseptic soap should be used for routine hand washing. Hands should be rinsed in a stream of running water and dried with a clean personal towel or air-dried. Towels should not be shared.

Practices such as using a common basin where a number of people or even one person washes or dips his/her hand(s) repeatedly is dangerous and must be abandoned.

3.1.2. Surgical Scrub

a) The surgeon and his/her assistant must scrub both their hands and forearms up to the elbows thoroughly with soap and water or antiseptic agents. The entire

procedure should be repeated several times so that the scrub lasts for 3 to 5 minutes. The hands and forearms should be dried with a sterile towel only.

b) When plain soap is used, it is best to rinse the hands with alcohol or rub 3 to 5 ml of an alcohol–glycerine mixture (2 ml glycerine in 100 ml alcohol) on the hands until dry.

c) A small stick or brush should be used for cleaning fingernails.

Ideally, the surgeon and the assistant should scrub thoroughly between each procedure. In *high caseload settings*, in order to prevent re-colonization of the skin by micro-organisms, the surgical staff should do a three-minute surgical scrub every hour or after every five cases (whichever is earliest), or if the surgeon (and/or the surgical stuff) goes out of the OT, or touches any infected item, or if the glove is torn. An alcohol scrub should be done after every procedure.

3.2. *Self-protection of Health Care Providers*

1. All doctors, nurses, and other health providers must wear proper gloves during all procedures involving contact with any patients and biological fluids.
2. Cleaners and other staff working in sluice rooms and laundries should wear protective heavy-duty gloves and gumboots while cleaning and handling other soiled materials and linen.
3. The staff should wear utility gloves when handling and transporting waste, and should wash the gloves as well as their hands when finished.
4. For female sterilizations, all medical personnel working in the OT must change their shoes, wear theatre gowns/short-sleeved shirts, pyjamas, caps, masks, and surgical gloves.
5. For vasectomy procedures that are not done in the OT, all medical personnel must at least wear caps, masks, and surgical gloves.
6. Operating surgeons should have short and clean fingernails and should remove all jewellery. The surgical mask should cover the bridge of the nose at all times.

3.3. Safe Work Practices

a) Safe handling of sharp instruments during the operation requires using the 'no touch technique' by placing them on a small kidney tray.

b) Accidental needle-stick injuries occur mostly during the removal of the needle

from the syringe or during cap replacement. Therefore, used needles should not be bent, broken, recapped, or removed from the syringe before disposal. Instead, the assembled needle and syringe should be discarded in a puncture-resistant container. If recapping is absolutely necessary, the cap should be held with a clamp while lacing it back over the needle or a one-handed technique should be used (while holding the syringe in one hand, scoop the cap off the flat surface with the needle, and then secure the cap on the needle with the other hand).

c) Immediately after use, sharp objects (such as needles, scalpel blades, suture needles, glass ampoules, etc.) should be disposed of in a puncture-resistant container with a lid made of either metal or heavy rigid plastic or cardboard. The container should be sealed and disposed of once three-fourths is filled, either by burying or incinerating.

3.4. Maintenance of Asepsis in OT

3.4.1. Before Surgery

- Clean the floor with a mop soaked in 0.5% chlorine solution.
- Clean the table/counter top with a cloth soaked in 0.5% chlorine solution

3.4.2. After Surgery

- Decontaminate all operating room surfaces that come into contact with the patient (such as table) between procedures by scrubbing and wiping them with 0.5% chlorine solution.
- The operating table, counters/table tops, and light handles should be wiped with a detergent and 0.5% chlorine solution.

3.4.3. When Not in Use

- The OT should be locked when not in use.
- Weekly cleaning: Scrub the room with the recommended disinfectant. Washing should be performed from top to bottom.

3.4.4. Movement In and Around the OT

- The entry of people and their movement inside the OT should be minimal as the introduction of a number of micro-organisms is related directly to the number of people and their movement.

- During surgery, the door of the OT should be kept closed.
- Only the personnel performing or assisting should enter the OT.
- Personnel who have any infection should not enter the OT at all.

3.5. Processing of Equipment, Instruments, and Other Reusable Items

Decontamination and cleaning of equipment, instruments, and other reusable items, followed by sterilization or high-level disinfection (HLD), minimizes the risk of transmission of infection. HLD does not reliably destroy all bacterial endospores. Hence instruments and other items used during surgery should be sterilized. When that is not possible, HLD is the only acceptable alternative for processing instruments and other items for reuse.

3.5.1. Decontamination

- Surgical instruments, reusable gloves, and other items that have been in contact with blood or other body fluids should be decontaminated prior to cleaning.
- Immediately after use, these items should be placed in a plastic bucket containing a solution of 0.5% chlorine for 10 minutes.
- After 10 minutes, the items should be removed from the chlorine solution and rinsed with water or cleaned immediately. Utility gloves and clothes should be worn during this and subsequent steps.
- A new chlorine solution should be prepared at the beginning of each day.

Preparation of 0.5% Chlorine Solution

Mix 15 gm of commercially available bleaching powder (about 1 tablespoonful/3 teaspoonful) in one litre of tap water.

3.5.2. Cleaning

Cleaning reduces the number of micro-organisms and endospores on instruments and equipment.

- The instruments and other items should be scrubbed vigorously with a brush in lukewarm water with detergent to remove all blood, tissue, and other residue.

Detergent should be used as water alone will not remove proteins or oil. Soap is not recommended as it can leave a residue.

- Hot water should not be used because it can coagulate protein such as blood, making it harder to remove.
- The items should then be rinsed thoroughly with water and allowed to air-dry. Items that require HLD by boiling can be placed directly in a pot of water after cleaning.

3.5.3. High-level Disinfection (HLD)

HLD is effective in eliminating all micro-organisms (viruses, bacteria, Protozoa, and fungi). It is the only acceptable alternative for processing instruments and other items for reuse if sterilization is not possible. HLD can be achieved either by boiling or by soaking in a high-level disinfectant depending on the heat-resistant properties of the objects that are to be disinfected.

a) HLD by Boiling

- Instruments for HLD must be decontaminated and cleaned with detergent and water prior to boiling.
- Once the water starts boiling, boil for 20 minutes in a pot with a lid.
- Articles must be completely immersed in the water.
- Do not add anything to the pot after boiling begins.
- After boiling, remove objects with a sterile or previously HLD forceps.
- Use objects immediately or store them in a covered, airtight, dry HLD container for up to seven days. If stored in an ordinary covered container, the objects can be used for up to 24 hours.

b) Sterilization by Chemical Method

- After decontaminating, cleaning, and drying the used objects, soak for 20 minutes in a solution containing 2% glutaraldehyde.
- Thoroughly rinse the objects with water boiled for 20 minutes before use.
- Use objects immediately or place them in a covered, dry HLD container.

Items should never be kept soaked in water or solutions such as Cetavalone, spirit, carbolic acid, glutareldehyde, etc. Always store HLD items dry.

3.5.4. Sterilization

Sterilization eliminates all micro-organisms (bacteria, viruses, fungi, and Protozoa), including bacterial endospores, from instruments and other items.

Sterilization is recommended for items such as reusable needles, syringes, and surgical instruments. For sterilization to be effective, decontamination, careful cleaning, and thorough rinsing must precede sterilization. Sterilization can be done by using steam (autoclaving) or soaking in a chemical solution.

a) Steam Sterilization (Autoclaving)

- Always consult the specific operating instructions supplied by the manufacturer.
- Decontaminate, clean, and dry all instruments that are allowed to be autoclaved.
- Wrap cleaned instruments in cloth or newspaper, or place unwrapped instruments in a metal container.
- Arrange wrapped packs in the chamber or drum to allow free circulation of heat or steam among the surfaces of all items.
- Items such as scissors and forceps should be sterilized in an open position.
- Sterilize instruments for the recommended time as shown below:

Steam Sterilization Standards

Time: 20 minutes for unwrapped and 30 minutes for wrapped instruments and linen. Gloves should always be sterilized for 30 minutes by wrapping in paper or newspaper, and should be used within 24 to 48 hours after sterilization so that they regain their elasticity.

Temperature: 121°C
Pressure: 15 lb/sq inch. Often a temperature gauze has not been fitted in the autoclave. In that case, observe pressure only.

Sterilized packs can be used for up to one week if kept dry and intact and if the drum is not opened. Once the drum is opened, use within 24 hours.

b) Sterilization by Chemical Method

- Decontaminated, cleaned, and dried items are put in 2% glutaraldehyde solution for at least 8 to 10 hours.
- Items such as scissors and forceps should be put into the solution in an open position.
- Do not add or remove any items once the timer starts.
- Items should be rinsed well with sterile water (not boiled water), air-dried, and stored in a covered sterile container for up to 7 days. Sterile water can be prepared by autoclaving water for 20 minutes at 15 lb/sq inch in an autoclave.
- This method is most suitable for endoscopes and plastic cannulae.

3.5.5. Processing Laparoscopes

Laparoscopes and accessories should be sterilized or should undergo HLD using the chemical method by soaking in 2% glutaraldehyde solution. All steps of the decontamination and cleaning process must be followed before the laparoscopes and accessories are put in the chemical solution.

a) Decontamination: Immediately after use, gently wipe the laparoscope, fibre-optic light source, and cable and plastic tubing with luer lock using a cloth soaked in 60–90% ethyl or isopropyl alcohol to remove all blood and organic material.

b) Cleaning: Place the dissembled parts of the laparoscope in a basin of clean water. Wash all outer surfaces using a soft cloth. Clean the inner channels with a clean brush supplied with the laparoscopic kit.

c) High-level disinfection: Put clean and dried dissembled equipment in a basin containing 2% glutaraldehyde solution for 20 minutes. For the disinfection to be effective, all parts of the laparoscope must be fully immersed and the disinfectant must touch all the surfaces of the instrument. Rinse twice with HLD water (water boiled for 20 minutes and cooled) to remove all traces of the disinfectant.

d) Sterilization: To sterilize, soak the clean and dried dissembled laparoscope in 2% glutaraldehyde solution for 8 to 10 hours. Rinse twice with sterile water to completely remove all traces of the disinfectant and store in a sterile covered container.

Summary of Methods of Sterilization and High-level Disinfection for Various Materials

Material	Method	Duration of Treatment
Linen (drapes, sponges, scrub suits, operating packs, etc.)	Autoclave	121°C at 15 lb/sq inch pressure for 30 minutes. Should be used within one week. If drum is opened, then use only within 24 hours.
Rubber goods (gloves, catheters, and rubber tubing)	Autoclave	121°C at 15 lb/sq inch pressure for 30 minutes. Always wrap items in paper/newspaper before autoclaving. Gloves should always be sterilized for 30 minutes at 15 lb/sq inch pressure by wrapping in paper/newspaper, and should be used 24–48 hours after sterilization so that they regain their elasticity.
	HLD boiling	20 minutes
	Immersing in chemical solution: Sterilization time Dilution Disinfection (HLD) time Dilution	Paracetic acid 10 minutes 10 minutes Glutareldehyde 2% 10 hours None 20 minutes None
Surgical instruments*	Autoclave	121°C at 15 lb/sq inch pressure, 30 minutes for wrapped and 20 minutes for unwrapped items
	HLD boiling	20 minutes
	Immersing in chemical solution: Sterilization time Dilution Disinfection (HLD) time Dilution	Paracetic acid 10 minutes 10 minutes Glutareldehyde 2% 10 hours None 20 minutes None

* Unwrapped surgical instruments are meant for immediate use. If wrapped, instruments can be used for up to one week if the drum is not opened.

3.6. Disposal of Waste, Needles, and Other Materials

3.6.1. Contaminated waste is a potential source of infection for the staff as well as the local community. Therefore, waste should be disposed of properly.

3.6.2. Waste should be buried or burnt. Burning should preferably be done in an incinerator or steel drum as opposed to open burning.

3.6.3. If burning is not possible, then the waste should be put in a pit and buried, but it should never be thrown outside or left in open pits.

3.6.4. For waste that is to be picked by the municipal authorities, these should be placed in closed dumpsters prior to removal.

3.6.5. Solid waste, including dressings and other items contaminated with blood and organic material, should be disposed of in leak-proof washable containers conveniently located in the OT/procedure house.

3.6.6. Liquid waste should be poured down a utility drain or into a toilet or latrine with a flush; or else it should be buried. Avoid splashing when disposing of liquid waste.

3.6.7. Sharp objects (hypodermic needles, scalpel blades, suture needles) should be disposed of in a puncture-resistant container with a lid made of either metal or heavy rigid plastic or cardboard.

3.6.8. Containers with needles and sharp objects should be disposed of by burning or burying on site.

Summary of Waste Disposal and Decontamination Procedures

Step I
While still wearing gloves and apron, dispose of contaminated waste items (gauze, cotton, etc.) by placing these in a leak-proof container (e.g. a plastic bag). Put sharp objects into a plastic bucket containing 0.5% chlorine solution and other metal instruments into a second plastic bucket.
Step II
Make sure that all objects are completely immersed. Soak for 10 minutes in plastic buckets containing 0.5% chlorine solution.
Step III
Remove the used sheet from the operating table and decontaminate by soaking it for 10 minutes in 0.5% chlorine solution.
Step IV
Decontaminate all operating room surfaces that have come into contact with the patient (such as the table) between procedures by wiping them with 0.5% chlorine solution followed by scrubbing and mopping.
Step V
Before removing gloves, immerse gloved hands in a bucket containing 0.5% chlorine solution to clean bloodstains. Remove gloves carefully by turning them inside out and discard disposable gloves in a waste container, or place reusable gloves in 0.5% chlorine solution and soak for 10 minutes.

Annexures

Annexure 1

Physical Requirements for Female Sterilization

Sr. No	Item	Requirements
1	Facilities	♦ Well-ventilated, fly-proof room with concrete/tiled floor, which can be cleaned thoroughly ♦ Running water supply through tap or bucket with tap ♦ Electricity supply with a standby generator and other light source
2	Space Required	♦ Area for reception ♦ Waiting area ♦ Counselling area which offers privacy and ensures avoidance of any interruptions ♦ Laboratory with facilities for blood & urine examination ♦ Clinical examination room for initial assessment and follow up ♦ Preoperative preparation room for trimming of hair, washing, changing of clothes and premedication ♦ Hand washing area near the OT for scrubbing ♦ Sterilization room, near the OT, for autoclaving, washing and cleaning equipment, preparation of sterile packs ♦ Operation theatre: should be isolated and away from the general thoroughfare of the clinic, it should be large enough to allow operating staff to move freely and to accommodate all the necessary equipment. Lighting should be adequate. ♦ Recovery room: must be spacious and well ventilated, number of beds will be determined by the available space, should be adjacent to the OT. ♦ Adequate number of toilets: sufficient number of sanitary type toilets with running water for the clients and the staff. ♦ Storage area ♦ Office area for keeping records
3 Equipment and Supplies		
3A	Examination Room Requirements	♦ Examination table ♦ Foot stool ♦ Blood pressure apparatus ♦ Thermometer ♦ Stethoscope ♦ Examination light ♦ Weighing scale ♦ Instrument for pelvic examination
3B	Laboratory	♦ Haemoglobinometer and accessories ♦ Apparatus to estimate albumin and sugar in urine ♦ Reagents

Sr. No	Item	Requirements
3C	Sterilization Room	♦ Autoclave ♦ Boiler ♦ Surgical drums ♦ SS Tray ♦ Glutaraldehyde solution 2%
3D	Cleaning Room	♦ Hand brushes ♦ Utility gloves ♦ Basins ♦ Detergents ♦ Chlorine solution 0.5%
3E	Operation Theatre	♦ Operating table capable of Trendelenburg position ♦ Step-up stool ♦ Spot light in OT ♦ Instrument trolley ♦ Minilaparotomy kit ♦ Laparoscopy kit ♦ Blood pressure instrument ♦ Stethoscope ♦ Syringe with needles ♦ Emergency equipment and drugs ♦ Room heater ♦ IV stand ♦ Waste basket, storage cabinet, buckets, basins for decontamination ♦ Box for used linen ♦ Puncture-proof box for needles
3F	Recovery Room	♦ Patient's cot with mattress, sheet, pillow, pillow cover, and blankets ♦ Blood pressure instrument ♦ Stethoscope ♦ Thermometers ♦ IV stand ♦ Emergency equipment and drugs as per list
4	Emergency Equipment and Supplies	♦ Stethoscope ♦ Blood pressure instrument ♦ Oral airways guedel size 3, 4, 5 ♦ Nasopharyngeal airways size 6, 6.5 , 7.0 ♦ Suction machine with tubing and two straps ♦ Ambu bag with mask size 3, 4, 5 ♦ Tubing and oxygen nipple ♦ Oxygen cylinder with reducing valve and flow metre ♦ Blanket ♦ Gauze pieces ♦ Kidney tray ♦ Torch ♦ Syringes and needles, including butterfly sets, IV cannula

Sr. No	Item	Requirements
		♦ Intravenous infusion sets and fluids ♦ Sterile laparotomy instruments ♦ Endotrachael tube size 6, 6.5 , 7, 7.5, 8.0 ♦ Laryngeal mask airway size 3, 4, 5 ♦ Combitube ♦ Cricothyroidectomy set
5	Essential Drugs	♦ Injection Adrenaline ♦ Injection Atropine ♦ Injection Diazepam ♦ Injection Deriphylline ♦ Injection Physostigmine ♦ Injection Xylocard ♦ Injection Hydrocortisone (Dexamethasone) ♦ Injection Pheniramine Maleate ♦ Injection Promethazine ♦ Injection Pentazocine ♦ Injection Ranitidine ♦ Injection Metoclopramide ♦ Injection Calcium Gluconate/Calcium Chloride ♦ Injection Sodium Bicarbonate (7.5%) ♦ Injection Dopamine ♦ Injection Mephenteramine ♦ Injection Frusemide ♦ Injection Methergine ♦ Injection Oxytocin ♦ Water-soluble jelly ♦ Electrode jelly **IV fluids** ♦ Ringer lactate ♦ 0.9% sodium chloride (normal saline) ♦ 5% Dextrose ♦ Heta Starch (HES 6%) ♦ Glucose 25%

Annexure 2

Medical Eligibility Criteria for Female Surgical Sterilization

(*Source: Medical Eligibility Criteria for Contraceptive Use, Third Edition, WHO, 2004*)

There are no absolute contraindications for performing a sterilization operation. However, there are certain relative contraindications where one needs to apply the criteria of "C", "D", and "S" as stated below.

A	Accept	There is no medical reason to deny sterilization to a person with this condition.
C	Caution	The procedure is normally conducted in a routine setting, but with extra preparation and precautions.
D	Delay	The procedure is delayed until the condition is evaluated and/or corrected. Alternative temporary methods of contraception should be provided.
S	Special	The procedure should be undertaken in a setting with an experienced surgeon and staff, the equipment needed for providing general anaesthesia, and other back-up medical support. To meet these conditions, the capacity to decide on the most appropriate anaesthesia regimen is also needed. Alternative temporary methods of contraception should be provided if referral is required or if there is otherwise any delay.

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
Pregnancy	D	
Young age*	C	**Clarification:** Young women, like all women, should be counselled about the permanency of sterilization and the availability of alternative, long-term, highly effective methods. **Evidence:** Studies show that up to 20% of women sterilized at a young age later regret this decision, and that young age is one of the strongest predictors of regret (including requests for reversal information and obtaining reversal) that can be identified before sterilization.
Parity*		
a) Nulliparous	A	
b) Parous	A	
Breastfeeding	A	

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
Post-partum*		
a) < 7 days	A	
7 to < 42 days	D	
≥ 42 days	A	
b) Pre-eclampsia/ eclampsia		
i) mild pre-eclampsia	A	
ii) severe pre-eclampsia/ eclampsia	D	
c) Prolonged rupture of membranes: 24 hours or more	D	
d) Puerperal sepsis, intrapartum or puerperal fever	D	
e) Severe antepartum or post-partum haemorrhage	D	
f) Severe trauma to the genital tract: cervical or vaginal tear at time of delivery	D	
g) Uterine rupture or perforation	S	**Clarification:** If exploratory surgery or laparoscopy is conducted and the patient is stable, repair and tubal sterilization may be performed concurrently if no additional risk is involved.
Post-abortion*		
a) Uncomplicated	A	
b) Post-abortal sepsis or fever	D	
c) Severe post abortal haemorrhage	D	
d) Severe trauma to the genital tract: cervical or vaginal tear at time of abortion	D	
e) Uterine perforation	S	**Clarification:** If exploratory surgery or laparoscopy is conducted and the patient is stable, repair and tubal sterilization may be performed concurrently if no additional risk is involved.
f) Acute haematometra	D	

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
Past ectopic pregnancy	A	
Smoking a) Age < 35 years b) Age ≥ 35 years i) < 15 cigarettes/day ii) ≥ 15 cigarettes/day	 A A A	
Obesity ≥ 30 kg/m2 body mass index (BMI)	C	**Clarification:** The procedure may be more difficult. There is an increased risk of wound infection and disruption. Obese women may have limited respiratory function and may be more likely to require general anaesthesia. **Evidence:** Women who are obese are more likely to have complications when undergoing sterilization.
Cardiovascular disease		
Multiple risk factors for arterial cardiovascular disease* (Such as older age, smoking, diabetes, and hypertension)	S	
Hypertension		
For all categories of hypertension, classifications are based on the assumption that no risk factors for cardiovascular diseases exist. When multiple risk factors do exist, risk of cardiovascular disease may increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.		
a) Hypertension, adequately controlled b) Elevated blood pressure levels (properly taken measurements) i) Systolic 140–159 or diastolic 90–99 ii) Systolic ≥ 160 or diastolic ≥ 100 c) Vascular disease	C C S S	**Clarification:** Elevated blood pressure should be controlled before surgery. There are increased anaesthesia-related risks and an increased risk of cardiac arrhythmia with uncontrolled hypertension. Careful monitoring of blood pressure intra-operatively is particularly necessary in this situation.

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
History of high blood pressure during pregnancy (where current blood pressure is measurable and normal)	A	
Deep venous thrombosis (DVT)/ Pulmonary embolism (PE)		
a) History of DVT/PE	A	
b) Current DVT/PE	D	**Clarification:** To reduce the risk of DVT/PE, early ambulation is recommended.
c) Family history of DVT/PE (first-degree relatives)	A	
d) Major surgery	D	
i) with prolonged immobilization		
ii) without prolonged immobilization	A	
e) Minor surgery without immobilization	A	
Known thrombogenic mutations (e.g. Factor V Leiden; Prothrombin mutation; Protein S, Protein C, and Antithrombin deficiencies)	A	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
Superficial venous thrombosis		
a) Varicose veins	A	
b) Superficial thrombophlebitis	A	
Current and history of ischaemic heart disease*	D	
a) Current ischaemic heart disease	C	
b) History of ischaemic heart disease		

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
Stroke (history of cerebrovascular accident)	C	
Known hyperlipidaemias	A	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of the procedure.
Valvular heart disease a) Uncomplicated b) Complicated (pulmonary hypertension, atrial fibrillation, history of subacute bacterial endocarditis)	 C S	 **Clarification:** The woman requires prophylactic antibiotics. Clarification: The woman is at high risk for complications associated with anaesthesia and surgery. If the woman has atrial fibrillation that has not been successfully managed or current subacute bacterial endocarditis, the procedure should be delayed.
Neurologic conditions		
Headaches a) Non-migrainous (mild or severe) b) Migraine i) without aura Age < 35 Age ≥ 35 ii) with aura (at any age)	 A A A A	
Epilepsy	C	
Depressive disorders		
Depressive disorders	C	
Reproductive tract infections and disorders		
Vaginal bleeding patterns a) Irregular pattern without heavy bleeding b) Heavy or prolonged bleeding (includes regular and irregular patterns)	 A A	
Unexplained vaginal bleeding (suspicion for serious condition) Before evaluation	 D	 **Clarification:** The condition must be evaluated before the procedure is performed.

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
Endometriosis	S	
Benign ovarian tumours (including cysts)	A	
Severe dysmenorrhoea	A	
Trophoblastic disease a) Benign gestational trophoblastic disease b) Malignant gestational trophoblastic disease	 A D	
Cervical ectropion	A	
Cervical intraepithelial neoplasia (CIN)	A	
Cervical cancer* (awaiting treatment)	D	
Breast disease a) Undiagnosed mass b) Benign breast disease c) Family history of cancer d) Breast cancer i) current ii) past and no evidence of current disease for 5 years	 A A A C A	
Endometrial cancer*	D	
Ovarian cancer*	D	
Uterine fibroids* a) without distortion of the uterine cavity b) with distortion of the uterine cavity	 C C	

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
Pelvic inflammatory disease (PID)*		
a) Past PID (assuming no current risk factors for STIs)		
i) with subsequent pregnancy	A	
ii) without subsequent pregnancy	C	
b) PID – current	D	**Clarification:** A careful pelvic examination must be performed to rule out recurrent or persistent infection and to determine the mobility of the uterus.
STIs*		
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	D	**Clarification:** If no symptoms persist following treatment, sterilization may be performed.
b) Other STIs (excluding HIV and hepatitis)	A	
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	A	
d) Increased risk of STIs	A	
HIV/AIDS		
High risk of HIV	A	**Clarification:** No routine screening is needed. Appropriate infection-prevention procedures, including universal precautions, must be observed carefully with all surgical procedures. The use of condoms is recommended following sterilization.
HIV-infected	A	
AIDS	S	**Clarification:** The presence of an AIDS-related illness may require that the procedure be delayed.
Other infections		
Tuberculosis		
a) Non-pelvic	A	
b) Known pelvic	S	
Malaria	A	

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
Endocrine conditions		
Diabetes*		
a) History of gestational disease	A	
b) Non-vascular disease:		
i) non-insulin dependent	C	
ii) insulin dependent	C	**Clarification:** If blood glucose is not well controlled, referral to a higher-level facility is recommended.
c) Nephropathy/ retinopathy/ neuropathy	S	**Clarification:** There is a possible decrease in healing and an increased risk of wound infection. Use of prophylactic antibiotics is recommended.
d) Other vascular disease or diabetes lasting >20 years	S	**Evidence:** Diabetic women are more likely to have complications when undergoing sterilization.
Thyroid disorders		
a) Simple goitre	A	
b) Hyperthyroid	S	
c) Hypothyroid	C	
Gastrointestinal conditions		
Gall bladder disease		
a) Symptomatic		
i) treated by cholecystectomy	A	
ii) medically treated	A	
iii) current	D	
a) Asymptomatic	A	
History of cholestasis		
a) Pregnancy related	A	
b) Past COC related	A	
Viral hepatitis*		**Clarification:** Appropriate infection- prevention procedures, including universal precautions, must be observed carefully with all surgical procedures.
a) Active	D	
b) Carrier	A	
Cirrhosis		
a) Mild (compensated)	C	
b) Severe (decompensated)	S	**Clarification:** Liver function and clotting might be altered. Liver function must be evaluated.

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
Liver tumours a) Benign (adenoma) b) Malignant (hepatoma)	 C C	 **Clarification:** Liver function and clotting might be altered. Liver function must be evaluated.
Anaemias		
Thalassaemia	C	
Sickle-cell disease*	C	
Iron-deficiency anaemia a) Hb < 7 g/dl b) Hb ≥ 7 g/dl to < 10 g/dl	 D C	 **Clarification:** The underlying disease should be identified. Both preoperative Hb level and operative blood loss are important factors in women with anaemia. If peripheral perfusion is inadequate, this may decrease wound healing.
Other conditions relevant only for female surgical sterilization		
Local infection Abdominal skin infection	 D	 **Clarification:** There is an increased risk of post-operative infection.
Coagulation disorders*	S	
Respiratory diseases* a) Acute (bronchitis, pneumonia) b) Chronic i) asthma ii) bronchitis iii) emphysema iv) lung infection	 D S S S S	 **Clarification:** The procedure should be delayed until the condition has been corrected. There are increases in anaesthesia-related and other perioperative risks.
Systemic infection or gastroenteritis*	D	
Fixed uterus due to previous surgery or infection*	S	
Abdominal wall or umbilical hernia	S	**Clarification:** Hernia repair and tubal sterilization should be performed concurrently, if possible.
Diaphragmatic hernia*	C	
Kidney disease*	C	
Severe nutritional deficiencies*	C	
Previous abdominal or pelvic surgery	C	**Evidence:** Women with previous abdominal or pelvic surgery are more likely to have complications when undergoing sterilization.

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
Sterilization concurrent with abdominal surgery a) Elective b) Emergency (without previous counselling) c) Infectious condition	 C D D	
Sterilization concurrent with caesarean section*	A	

** See additional comments*

Additional comments

Parity

Nulliparous: Nulliparous women, like all women, should be counselled about the permanency of sterilization and the availability of alternative, long-term, highly effective methods.

Post-partum

< 7 days post-partum: Sterilization can be performed safely immediately post-partum.

7 to 42 days: There is an increased risk of complications when the uterus has not fully involuted.

Pre-eclampsia/eclampsia: There are increased anaesthesia-related risks.

Prolonged rupture of membranes, 24 hours or more: There is an increased risk of post-operative infection.

Puerperal sepsis, intrapartum or puerperal fever: There is an increased risk of post-operative infection.

Severe antepartum or post-partum haemorrhage: The woman may be anaemic and unable to tolerate further blood loss.

Severe trauma to the genital tract: cervical or vaginal tear at time of delivery: There may be significant blood loss and anaemia. The procedure may be more painful.

Uterine rupture or perforation: There may have been significant blood loss or damage to abdominal contents.

Post-abortion

Post-abortion sepsis or fever: There is an increased risk of post-operative infection.

Severe post-abortal haemorrhage: The woman may be anaemic and unable to tolerate further blood loss.

Severe trauma to the genital tract: cervical or vaginal tear at time of abortion: The woman may be anaemic and unable to tolerate further blood loss. The procedure may be more painful.

Uterine perforation: There may have been significant blood loss or damage to abdominal contents.

Acute haematoma: The woman may be anaemic and unable to tolerate further blood loss.

Multiple risk factors for arterial cardiovascular disease

When multiple risk factors are present concurrently, the woman may be at high risk for complications associated with anaesthesia and surgery.

Current and history of ischaemic heart disease

The woman is at high risk for complications associated with anaesthesia and surgery.

Cervical cancer (awaiting treatment)

In general, the treatment renders a woman sterile.

Endometrial cancer

In general, the treatment renders a woman sterile.

Ovarian cancer

In general, the treatment renders a woman sterile.

Uterine fibroids

Depending on the size and location of the fibroids, it might be difficult to localize the tubes and mobilize the uterus.

Pelvic inflammatory disease (PID)

PID can lead to an increased risk of post-sterilization infection or adhesions.

STIs

There is an increased risk of post-operative infection.

Diabetes

There is a risk of hypoglycaemia or ketoacidosis.

Thyroid disorders

The woman is at high risk for complications associated with anaesthesia and surgery.

Viral hepatitis

The woman is at high risk for complications associated with anaesthesia and surgery.

Sickle-cell disease

There is an increased risk of pulmonary, cardiac or neurological complications, and possible increased risk of wound infection.

Coagulation disorders

Women with coagulation disorders are at increased risk of haematological complications of surgery.

Respiratory disease

For laparoscopy, the woman may experience acute cardiorespiratory complications induced by pneumoperitoneum or the Trendelenburg position.

Systemic infection or gastroenteritis

There are increased risks of post-operative infection, complications from dehydration, and anaesthesia-related complications.

Fixed uterus due to previous surgery or infection

Decreased mobility of the uterus, fallopian tubes, and bowel may make laparoscopy and minilaparotomy difficult and increase the risk of complications.

Diaphragmatic hernia

For laparoscopy, the woman may experience acute cardiorespiratory complications induced by pneumoperitoneum or the Trendelenburg position.

Kidney disease

Blood clotting may be impaired. There may be an increased risk of infection and hypovolemic shock. The condition may cause baseline anaemia, electrolyte disturbances, and abnormalities in drug metabolism and excretion.

Severe nutritional deficiencies

There may be an increased risk of wound infection and impaired healing.

Sterilization concurrent with caesarean section

Concurrent sterilization does not increase the risk of complications in a surgically stable client.

Annexure 3

Medical Record and Checklist for Female/ Male Sterilization

Reg. No ..... Date ..... / ..... / ..... (D/M/Y)	OT No ..... Date of operation Date ..... / ..... / ..... (D/M/Y)
Name of the state	.....
Name of the district	.....
Name and type of the hospital/facility	..... Camp ..... PP centre ..... PHC/CHC ..... District hospital ..... Medical college hospital ..... Other (specify .....
Name of the acceptor	.....
Name of father	.....
Name of husband/wife	.....
Address Contact number (if available)	....

1. Socio-demographic information

Age of client	..... (in completed years)
Age of spouse	..... (in completed years)
Education	Illiterate ..... Primary school ..... Middle school ..... High school ..... Higher secondary ..... Graduation and above .....
Religion	Hindu ..... Muslim ..... Christian ..... Other (specify .....
Caste	SC ..... ST ..... OBC ..... Other .....
Occupation	.....
Marital status	Married ..... Divorced/Widowed/Separated .....
Number of children born	..... (Total) ..... (Sons) ..... (Daughters)
Number of children currently living	..... (Total) ..... (Sons) ..... (Daughters)
Age of the youngest child	.....

2. A. Menstrual history (for female acceptors)

Cycle days	.....
Length	.....
Regularity	Regular ..... Irregular .....
Date of LMP	.....

B. Obstetrics history (for female acceptors)

No. of spontaneous abortions	.....
No. of induced abortions	.....
Currently lactating	Yes ..... No.....
Amenorrhoeic	Yes ..... No.....
Whether pregnant	Yes ..... No..... If yes (no. of weeks of pregnancy).....

C. Contraceptive history

Have you or your spouse ever used any contraception?	Yes ..... No.....
Are you or your spouse currently using any contraception, or have you or your spouse used any contraception during the last 6 months?	None ..... IUCD ..... Condoms ..... Oral pills ..... Any other (specify).....

D. Medical history

Recent medical illness	Yes	No .....
Previous surgery	Yes	No .....
Allergies to medication	Yes	No .....
Bleeding disorder	Yes	No .....
Anaemia	Yes	No .....
Diabetes	Yes	No .....
Jaundice or liver disorder	Yes	No .....
RTI/STI/PID	Yes	No .....
Convulsive disorder	Yes	No .....
Tuberculosis	Yes	No .....
Malaria	Yes	No .....
Asthma	Yes	No .....
Heart disease	Yes	No .....

Hypertension	Yes ..... No .....
Mental illness	Yes ..... No .....
Sexual problems	Yes ..... No .....
Prostatitis	Yes ..... No .....
Epididymitis	Yes ..... No .....
H/O blood transfusion	Yes ..... No .....
Gynaecological problems	Yes ..... No .....
Currently on medication (if yes, specify)	Yes ..... No .....

Comments .....

.....

.....

Physical Examination

BP ..... Pulse ..... Temperature.....

Lungs	Normal..... Abnormal .....
Heart	Normal..... Abnormal .....
Abdomen	Normal..... Abnormal .....

3. Local examination

Male sterilization

Skin of scrotum	Normal..... Abnormal .....
Testis	Normal..... Abnormal .....
Epididymis	Normal..... Abnormal .....
Hydrocele	Yes ..... No.....
Varicocele	Yes ..... No.....
Hernia	Yes ..... No.....
Vas deferens	Normal..... Abnormal .....
Both vas palpable	Yes ..... No.....

Female sterilization

External genitalia	Normal.....	Abnormal.....
PV examination	Normal.....	Abnormal.....
PS examination	Normal.....	Abnormal.....
Uterus position	A/V.....	R/V.....
	Mid position.....	Not determined.....
Uterus size	Normal.....	Abnormal.....
Uterus mobility	Yes	No .....
Cervical erosion	Yes	No .....
Adnexa	Normal.....	Abnormal.....

Comments .....

.....

.....

4. Laboratory investigations

Haemoglobin level	.....	gm %
Urine: Albumin	Yes 1	No..... 2
Urine: Sugar	Present 1	Absent..... 2
Any other (specify)	.....	
	.....	

Name and signature of the examining doctor

To be filled by the operating surgeon

5. Checklist before conducting surgery

Client is within eligible age	Yes ..... No .....
Client is ever married	Yes ..... No .....
Client has at least one child more than one year old	Yes ..... No .....
Lab investigations (Hb, urine) undertaken are within normal limits	Yes ..... No .....
Medical status as per clinical observation is within normal limits	Yes ..... No .....
Mental status as per clinical observation is normal	Yes ..... No.....
Local examination done is normal	Yes ..... No .....
Informed consent is given by the client	Yes ..... No .....
Explained to the client that consent form has authority as legal document	Yes ..... No .....
Abdominal/pelvic examination has been done in the female and the findings are within normal limits (WNL)	Yes ..... No .....
Infection-prevention practices followed as per laid down standards	Yes ..... No .....

6. Preoperative preparation

Fasting	Yes ..... No .....
Passed urine	Yes ..... No .....
Any other (specify)	....

7. Anaesthesia/analgesia

Type of anaesthesia given	Local only ..... Local and analgesia ..... *General, no intubation ..... *General, intubation ..... *Any other (specify).....
Time	.....
Drug name	.....
Dosage	.....
Route	.....

*Signature of anaesthetist in case of regional or general anaesthesia

8. Surgical approach

Male sterilization

Local anaesthesia	Lignocaine 2%.....cc Other.....
Technique	Conventional..... NSV .....
Type of incision Conventional NSV	 Single vertical..... Double vertical..... Single puncture.....
Material for occlusion of vas	2–0 Silk ..... 20 Catgut .....
Fascial interposition	Yes ..... No ..... If no, give reasons..... ....
Length of vas resected	.....cm
Suture of silk for conventional vasectomy	Silk ..... Other .....
Surgical notes	....
Any other surgery done at time of sterilization?	Yes ..... No..... If yes, give details..... .....
Specify details of complications and management	....

Name and signature of the operating surgeon

Date

Female sterilization

Local anaesthesia	Lignocaine .....%
	Other.....
Timing of procedure	24 hours–7 days post-partum.....
	Interval (42 days or more after delivery or abortion).....
	With abortion, induced or spontaneous
	Less than 12 weeks.....
	More than 12 weeks .....
	Any other (specify.....
Technique	Minilap.....
	With C section.....
	With other surgery.....
	Laparoscopy
	SPL/DPL .....
Method of occlusion of fallopian tubes	Modified Pomeroy
	Laparoscopy:
	Ring.....
	Clip.....
Details of gas insufflation pneumoperitoneum created (CO_2/Air)	Yes ..... No.....
Insufflator used	Yes ..... No.....
Specify details of complications and management	.....
	.....
	.....

Name and signature of the operating surgeon

Date

9. Vital signs: monitoring chart (for female sterilization)

Event	Time	Sedation*	Pulse	Blood Pressure	Respiratory Rate	Bleeding	Comments (Treatment)
Preoperative (every 15 in after premedication)							
Intra-operative (continuous)							
Post-operative 1. Every 15 min for first hour and longer if the patient is not stable/awake	15 min 30 min 45 min						
2. Every 1 hour until 4 hours after surgery	1 hr 2 hrs 3 hrs 4 hrs						

*Sedation: 0–Alert 1–Drowsy 2–Sleeping/arousable 3–Not arousable

Name and signature of the attending staff nurse

10. Post-operative information

Passed urine	Yes ..... No .....
Abdominal distension	Yes ..... No .....
Patient feeling well	Yes ..... No .....
If no, please specify	....

11. Instructions for discharge

Male sterilization client observed for half an hour after surgery	Yes ..... No .....
Female sterilization client observed for four hours after surgery	Yes ..... No .....
Post-operative instructions given verbally	Yes ..... No .....
Post-operative instructions given in writing	Yes ..... No.....
Patient counselled for post-operative instructions	Yes ..... No .....
Comments	....

Name and signature of the discharging doctor

Annexure 4

Informed Consent Form for Sterilization Operation/Re-sterilization

1. Name of client: Shri/Smt .....

2. Name of spouse: Shri/Smt .....

Address .....

.....

3. Name of father: Shri.....

Address .....

4. Religion .....

5. Educational qualifications.....

6. Business/occupation.....

7. Operating centre .....

I, Smt/Shri ....., hereby give consent for my sterilization operation. I am married and my husband/wife is alive. My age is ..... years and my husband's/wife's age is ..... years. We have ..... male and ..... female living children. The age of my youngest living child is ..... years.

I am aware that I have the option of deciding against the sterilization procedure at any time without sacrificing my rights to other reproductive health services.

a) I have decided to undergo the sterilization/re-sterilization operation on my own without any outside pressure, inducement or force. I declare that I/my spouse has not been sterilized previously (may not be applicable in case of re-sterilization).

b) I am aware that other methods of contraception are available to me. I know that for all practical purposes this operation is permanent. I also know that there are still

some chances of failure of the operation for which the operating doctor and the health facility will not be held responsible by me or by my relatives or by any other person whomsoever.

c) I am aware that I am undergoing an operation that carries an element of risk.

d) The eligibility criteria for the operation have been explained to me, and I affirm that I am eligible to undergo the operation according to the criteria.

e) I agree to undergo the operation under any type of anaesthesia that the doctor/ health facility thinks suitable for me and to be given other medicines as considered appropriate by the doctor/health facility concerned.

f) If, after the sterilization operation, I/my spouse experience (s) a missed menstrual cycle, then I/my spouse shall report within two weeks of the missed menstrual cycle to the doctor/health facility and may avail of the facility to get an MTP done free of cost.

g) In case of complications following the sterilization operation, including failure, I will accept the compensation as per the existing provisions of the Government of India Family Planning Insurance Scheme as full and final settlement.

h) If I/my wife get (s) pregnant after the failure of the sterilization operation and if I am not able to get the foetus aborted within two weeks, then I will not be entitled to claim any compensation over and above the compensation offered under the Family Planning Insurance Scheme from any court of law in this regard or any other compensation for the upbringing of the child.

i) I agree to come for follow-up visits to the hospital/institution/doctor/health facility as instructed, failing which I shall be responsible for the consequences, if any.

j) I understand that vasectomy does not result in immediate sterilization. *I agree to come for semen analysis three months after the operation to confirm the success of the sterilization surgery (azoospermia), failing which I shall be responsible for the consequences, if any.

(*Applicable in cases of male sterilization)

I have read the above information.

 # The above information has been read out and explained to me in my own language, and it has been explained to me that this form has the authority of a legal document.

Name and signature/thumb impression of the acceptor

.....

Signature of witness:

.....

Full name.....

Full address .....

 # (Only for those beneficiaries who cannot read and write)

Applicable in cases where the client cannot read and where the above information has been read out.

Shri/Smt ..... has been fully informed about the contents of the Informed Consent Form in his/her own/local language.

Signature of counsellor**

Full name .....

Full address .....

I certify that I have satisfied myself that:

1) Shri/Smt ..... is within the eligible age group and is medically fit for the sterilization operation.
2) I have explained all clauses to the client and also explained that this form has the authority of a legal document.
3) I have filled out the medical record-cum-checklist and followed the standards for sterilization procedures as laid down by the Government of India.

....

Signature of operating doctor Signature of medical officer in-charge of the facility

(Name and address) Seal (Name and address) Seal

Denial of sterilization

I certify that Shri/Smt ..... is not a suitable client for re-sterilization/sterilization for the following reasons:

1.

2.

He/she has been advised the following alternative methods of contraception:

1.

2.

Signature of the counsellor** or
doctor making the decision
(Name and full address)

(** The counsellor can be any health personnel, including a doctor).

Annexure 5

Post-operative Instruction Card following Female Sterilization

Name and type of hospital/facility	.....
Acceptor's name	.....
Father's name	.....
Husband's name	.....
Address Contact number (if available)	....
Date of operation	...../...../..... (D/M/Y)
Type of operation	Minilap/Post-partum/Laparoscopic (SP/DP).....

Post-operative Instructions

1. Please come for follow-up:
   a) After 48 hours for a check-up
   b) On the 7th day for stitch removal
   c) After one month or after first menstrual period, whichever is earlier
   d) In an emergency as and when required
2. Medication as prescribed:
3. Return home and rest for the remainder of the day.
4. Resume only light work after 48 hours and gradually return to full activity in two weeks following surgery.
5. Resume a normal diet as soon as possible.
6. Keep the incision area clean and dry. Do not disturb or open the dressing.
7. Bathe after 24 hours following the surgery. If the dressing becomes wet, it should be changed so that the incision area is kept dry until the stitches are removed.
8. In the case of interval sterilization, the client may have intercourse one week after surgery, or whenever she feels comfortable.
9. Report to the doctor or clinic if there is excessive pain, fainting, fever, bleeding or pus discharge from the incision, or if the client has not passed urine, not passed flatus, and experiences bloating of the abdomen.
10. Contact health personnel or a doctor in case of any doubt.
11. Return to the clinic if there is any missed period/suspected pregnancy.

Follow-up report

Follow-up	Time after surgery	Date of follow-up	Complications if any	Action taken
1st	48 hours			
2nd	7th day			
3rd	1 month after surgery or after the first menstrual period, whichever is earlier			
Emergency				

Comment.....

Name, designation, and signature of the person filling out the report

Annexure 6

Physical Requirements for Male Sterilization

Sr. No	Item	Requirements
1	Facilities	♦ Well-ventilated, fly-proof room with concrete/tiled floor, which can be cleaned thoroughly ♦ Running water supply through tap or bucket with tap ♦ Electricity supply with a standby generator and other light source
2	Space Required	♦ Reception area ♦ Waiting area ♦ Counselling area that offers privacy and ensures avoidance of any interruptions ♦ Laboratory for urine and semen analysis ♦ Clinical examination room for initial assessment and follow-up ♦ Preoperative preparation room for trimming of hair, washing, changing of clothes, and premedication ♦ Hand-washing area near the OT for scrubbing ♦ Sterilization room, near the OT, for autoclaving, washing, and cleaning of equipment and for preparation of sterile packs ♦ OT should be isolated, being located away from the general thoroughfare of the clinic. It should be large enough to allow the operating staff to move about freely and to accommodate all the necessary equipment. Lighting should be adequate. ♦ Recovery room must be spacious and well ventilated. The number of beds will be determined by the space available. It should be adjacent to the OT. ♦ Sufficient number of sanitary-type toilets with running water for clients and staff ♦ Storage area ♦ Office area for keeping records
3 Equipment and Supplies		
3A	Examination Room Requirements	♦ Examination table ♦ Foot stool ♦ Blood pressure apparatus ♦ Thermometer ♦ Stethoscope
3B	Laboratory	♦ Haemoglobinometer and accessories ♦ Apparatus to estimate albumin and sugar in urine ♦ Reagents
3C	Sterilization Room	♦ Autoclave ♦ Boiler ♦ Autoclave drums ♦ Glutaraldehyde solution

Sr. No	Item	Requirements
3D	Cleaning Room	♦ Hand brushes ♦ Utility gloves ♦ Basins ♦ Detergents ♦ Chlorine solution 0.5%
3E	Operation Theatre	♦ Operating table ♦ Step-up stool ♦ Spotlight in OT ♦ Instrument trolley ♦ Conventional vasectomy kit ♦ Non-scalpel vasectomy kit ♦ Blood pressure instruments ♦ Stethoscope ♦ Syringe with needles ♦ Emergency equipment and drugs as per list ♦ Room heater ♦ IV stand ♦ Waste basket, storage cabinet, buckets and basins for decontamination ♦ Used linen box ♦ Puncture-proof box
3F	Recovery Room	♦ Patient's cot with mattress, sheet, pillow, pillow cover, and blankets ♦ Blood pressure instruments ♦ Stethoscope ♦ Thermometers ♦ IV stand ♦ Emergency equipment and drugs as per list
4	Emergency Equipment and Supplies	♦ Stethoscope ♦ Blood pressure instruments ♦ Oral airways guedel, sizes 3, 4, 5 ♦ Nasopharyngeal airways, sizes 6, 6.5, 7.0 ♦ Suction machine with tubing and two straps ♦ Ambu bag with mask, sizes 3, 4, 5 ♦ Tubing and oxygen nipple ♦ Oxygen cylinder with reducing valve and flow metre ♦ Blanket ♦ Gauze pieces ♦ Kidney tray ♦ Torch ♦ Syringes and needles, including butterfly sets, IV cannula ♦ IV stand ♦ Intravenous infusion sets and fluids ♦ Endotrachael tube, sizes 6, 6.5, 7, 7.5, 8.0 ♦ Laryngeal mask airways, sizes 3, 4, 5 ♦ Combitube ♦ Cricothyroidectomy set

Sr. No	Item	Requirements
5	Emergency Drugs	♦ Injection Adrenaline ♦ Injection Atropine ♦ Injection Diazepam ♦ Injection Deriphylline ♦ Injection Xylocard ♦ Injection Hydrocortisone (Dexamethasone) ♦ Injection Physostigmine ♦ Injection Pheniramine Maleate ♦ Injection Promethazine ♦ Injection Pentazocine ♦ Injection Ranitidine ♦ Injection Metoclopramide ♦ Injection Calcium Gluconate/Calcium Chloride ♦ Injection Sodium Bicarbonate (7.5%) ♦ Injection Dopamine ♦ Injection Mephentermine ♦ Injection Frusemide ♦ Water-soluble jelly ♦ Electrode jelly **IV fluids** ♦ Ringer lactate ♦ 0.9% sodium chloride (normal saline) ♦ 5% Dextrose ♦ Glucose 25% ♦ Heta starch (HES 6%)

Annexure 7

Medical Eligibility Criteria for Male Surgical Sterilization

(*Source: Medical Eligibility Criteria for Contraceptive Use, Third Edition, WHO, 2004*)

There are no absolute contraindications for performing a sterilization operation. However, there are certain relative contraindications where one needs to apply the criteria of 'A', 'C', 'D', and 'S' as stated below.

A	Accept	There is no medical reason to deny sterilization to a person with this condition.
C	Caution	The procedure is normally conducted in a routine setting, but with extra preparation and precautions.
D	Delay	The procedure is delayed until the condition is evaluated and/or corrected. Alternative temporary methods of contraception should be provided.
S	Special	The procedure should be performed by an experienced surgeon and staff, in a setting where equipment for providing general anaesthesia and other back-up medical support is available. To meet these conditions, the capacity to decide on the most appropriate anaesthesia regimen is also needed. Alternative temporary methods of contraception should be provided, if referral is required or if there is otherwise any delay.

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
Young age	C	**Clarification:** Young men, like all men, should be counselled about the permanency of sterilization and the availability of alternative, long-term, and highly effective methods. **Evidence:** Men who underwent vasectomy at young ages were more likely to have the procedure reversed than those who underwent vasectomy at older ages.
Depressive disorders		
Depressive disorders	C	
HIV/AIDS		
High risk of HIV **HIV infected**	A A	**Clarification:** No routine screening is needed. Appropriate infection-prevention procedures, including universal precautions, must be observed carefully with all surgical procedures. The use of condoms is recommended following sterilization.

Condition	Category	Clarification/Evidence
Personal characteristics and reproductive history		
AIDS	S	**Clarification:** The presence of an AIDS-related illness may require a delay in the procedure.
Endocrine conditions		
Diabetes*	C	
Anaemias		
Sickle-cell disease	A	
Other conditions relevant only for male surgical sterilization		
Local infections*		
a) scrotal skin infection	D	
b) active STI	D	
c) balanitis	D	
d) epididymitis or orchitis	D	
Coagulation disorders*	S	
Previous scrotal injury	C	
Systemic infection or gastroenteritis*	D	
Large varicocele*	C	
Large hydrocele*	C	
Filariasis; Elephantiasis*	D	
Intrascrotal mass*	D	
Cryptorchidism	C	**Clarification:** If the cryptorchidism is bilateral and fertility has been demonstrated, it will require extensive surgery to locate the vas, and this becomes category 'S'. If the cryptorchidism is unilateral and fertility has been demonstrated, vasectomy may be performed on the normal side and semen analysis performed as per the routine. If the man continues to have a persistent presence of sperm, more extensive surgery may be required to locate the other vas, and this becomes category 'S'.
Inguinal hernia*	S	

** See Additional Comments*

Additional comments

Coagulation disorders

Bleeding disorders lead to an increased risk of post-operative haematoma formation, which, in turn, leads to an increased risk of infection.

Diabetes

Diabetics are more likely to get post-operative wound infections. If signs of infection appear, treatment with antibiotics needs to be given.

Local infections

There is an increased risk of post-operative infection.

Systemic infection or gastroenteritis

There is an increased risk of post-operative infection.

Large varicocele

The vas may be difficult or impossible to locate; a single procedure to repair varicocele and perform a vasectomy decreases the risk of complications.

Large hydrocele

The vas may be difficult or impossible to locate; a single procedure to repair hydrocele and perform a vasectomy decreases the risk of complications.

Filariasis; elephantiasis

If elephantiasis involves the scrotum, it may be impossible to palpate the spermatic cord and the testes.

Intrascrotal mass

This may indicate an underlying disease.

Inguinal hernia

Vasectomy can be performed concurrently with hernia repair.

Annexure 8

Post-operative Instruction Card following Male Sterilization

Name and type of hospital/facility	..... Camp ..... PP centre ..... PHC/CHC ..... District hospital ..... Medical college hospital ..... Any other (specify) .....
Acceptor's name	.....
Father's name	.....
Wife's name	.....
Address Contact number (if available)	....
Date of operation Type of operation	...../...../..... (D/M/Y) Conventional vasectomy / NSV .....

Post-operative Instructions

1. Please come for follow-up:
   a) After 48 hours for check-up
   b) On the 7th day for stitch removal (for conventional vasectomy)
   c) After 3 months for semen analysis
   d) In an emergency as and when required
2. Medication as prescribed.
3. Scrotal support or snug undergarment for 48 hours.
4. Return home and take adequate rest.
5. Resume normal work after 48 hours and return to full activity, including cycling, within one week following surgery.
6. Resume a normal diet as soon as possible.
7. Keep the operated area clean and dry, and do not disturb or open the dressing.
8. The client may bathe after 24 hours, with the operated part of the body protected. If the dressing becomes wet, it should be changed. After 48 hours, the dressing can be taken off.
9. The client may have intercourse whenever it is comfortable after the surgery but must ensure use of condom if his wife/partner is not using contraception. Vasectomy does not interfere with sexual pleasure, ability, or performance.
10. The client should use another method of contraception for at least 3 months following vasectomy or until the semen analysis shows no sperms. Should use condom if his wife/partner is not using contraception.
11. Report to the doctor or clinic if there is excessive pain, fainting, fever, bleeding, increase in scrotal size, or pus discharge from the operated site.
12. If there are any questions, contact the health personnel or doctor at any time.

Signature of the discharging doctor

Follow-up report

Follow-up	Time after surgery	Date of follow-up	Complications if any	Action taken
1st	48 hours			
2nd	7th day			
3rd	3 months after vasectomy			
Emergency				

Comment.....

Result of semen analysis .....

Name, designation, and signature of the person filling out the report

Annexure 9

Minilaparotomy Set

Item	Quantity
Sponge-holding forceps	2
Surgical drape (towel with central hole)	1
Syringe, 10 cc	2
Needle, 22-G, 1½"	2
Scalpel	1
Scalpel blade, size 15	2
Allis forceps	2
Medium artery forceps straight	3
Medium artery forceps curved	3
Needle holder	1
Straight scissors	1
Curved scissors	1
Babcock clamp (medium size)	2
Small Langenbeck (right-angle abdominal)	2
Retractor	1
Dissecting forceps, toothed	1
Dissecting forceps, non-toothed	1
Uterine elevator (for interval procedures)	1
Speculum, vaginal, Sim's medium	2
Small stainless-steel bowl	1
Volsellum	1
Tubal hook, Ramathibodi	1
'O' chromic catgut	1
Small round-bodied curved needle	1
Small cutting needle	1
Non-absorbable suture material	1
Dressing material	1
SS kidney tray	1

Annexure 10

Laparoscopy Kit

Item	Quantity
Veress needle (both sizes)	2
Light source for laparoscope with spare bulb	1
Emergency light source	1
Fiber-optic cable	1
Trocar with cannula	2
Operating laparoscope or laparocator	1
Carbon dioxide gas cylinder	2
Pneumoperitoneum insufflation apparatus	1
Falope-Ring loader	2
Falope-Ring	2
Dissecting forceps, toothed	1
Scalpel with # 11 blade	1
Sim's vaginal speculum	1
Uterine sound	1
Uterine elevator	1
Volsellum	1
Straight scissors	1
Needle holder	1
Sponge-holding forceps	2
Catgut suture, 0 or 00	1
Small curved cutting needle	1
Dressing material	1
Iodophor solution	1 Q.S.
Syringe, 10 cc	1
Needle, 22-G, 1½"	1
Gauze	4
Glutaraldehyde container (plastic with cover)	1
SS tray (to rinse the laparoscope)	2
SS small bowls	2
SS kidney tray	1

Q.S.: Quantity Sufficient

Annexure 11

Vasectomy Kit

Item	Quantity
Gauze pieces	8
Towel with central hole	1
Mosquito artery forceps, curved	2
Mosquito artery forceps, straight	2
Allis forceps	2
Needle holder	1
Thumb forceps, toothed	1
Metzenbaum scissors	1
Scalpel handle	1
Scalpel blade, size 15	2
Stainless-steel bowl, small	1
Sponge holder	1
Surgical tray with cover	1
Gloves, sizes 6½ , 7, and 7½	2 pairs each
Silk suture, 2–0/non-absorbable suture	1
Small round-bodied curved cutting needle	1
Syringe, 5 cc	2
Needle, 22-G, 24-G	1
Suspensory bandage	1
Iodophor solution	1 Q.S.

Q.S.: Quantity Sufficient

Annexure 12

No-scalpel Vasectomy Kit

Item	Quantity
Gauze pieces	6
Towel with central hole	1
Stainless-steel bowl, small	1
Sponge holder	1
Surgical tray with cover (small)	1
Mayo scissors	1
Extra-cutaneous vas fixation ring forceps	1
Vas dissecting forceps	1
Non-absorbable suture (2–0 silk)	1
Gloves, sizes 6½ , 7, and 7½	2 pairs each
Syringe, 5 ml	2
Needle, 22-G, 1.5 inch length, 24-G	2
Iodophor solution	Q.S.
Suspensory bandage	1
Dressing material	2

Q.S.: Quantity Sufficient

Annexure 13

Training in Permanent Family Planning Methods

Details	Laparoscopic training	Minilap	NSV
Nature of Trainees	Team comprising Gynaecologist/Surgeon (of 3 years' standing) who is already performing or who is trained in Minilap, and OT Nurse and OT Technician	Medical Officers, Nurses, and OT Technician (if needed)	Medical Officers
Duration	**12 working days**	**12 working days**	**5 working days**
Content of Training	♦ Pre- and post-sterilization counselling ♦ Selection of cases ♦ Clinical procedures, including post-operative management ♦ Recognition and management of complications ♦ Infection-prevention measures ♦ Management/ maintenance of equipment	♦ Pre- and post-sterilization counselling ♦ Selection of cases ♦ Clinical procedures, including post-operative management ♦ Recognition and management of complications ♦ Infection-prevention measures ♦ Management/maintenance of equipment	♦ Conducting NSV procedures ♦ Pre- and post-procedure counselling ♦ Clinical procedures ♦ Recognition and management of complications
Reference Material for Training	**Standards for Female and Male Sterilization**, published by MOHFW, GOI. In addition, trainers may recommend other texts.	**Standards for Female and Male Sterilization**, published by MOHFW, GOI. In addition, trainers may recommend other texts.	**NSV Surgeons Manual**, published by AVSC. In addition, trainers may recommend other standard texts for reference.
Training Centres	State-identified centres	State-identified centres	State-identified centres
Number Trained per Course	One team consisting of 1 Surgeon, 1 Staff Nurse, 1 OT Technician	2–3	2–4

Details	Laparoscopic training	Minilap	NSV
Number of Cases to be Performed	Assist at least 10 Perform at least 10 under supervision Perform at least 5 independently	Assist at least 10 Perform at least 10 under supervision Perform at least 5 independently	Assist at least 5 Perform at least 5 independently
Evaluation and Certification	Trainer must evaluate the trainee using a checklist and by inspecting the diary maintained by the trainee. Proficiency certificate to be awarded by the Training Institute after assessing the trainee.	Trainer must evaluate the trainee using a checklist and by inspecting the diary maintained by the trainee. Proficiency certificate to be awarded by the Training Institute after assessing the trainee.	Trainer must evaluate the trainee using a checklist and by inspecting the diary maintained by the trainee. Proficiency certificate to be awarded by the State/District Trainer after assessing the trainee.

References

1. *Standards for Female and Male Sterilization* (1999), Ministry of Health and Family Welfare, Government of India, New Delhi.
2. *Medical Eligibility Criteria for Contraceptive Use* (2004), World Health Organization, Geneva.

List of Experts

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Notes