सत्यमेव जयते

Standards & Quality Assurance in Sterilization Services

November 2014

Family Planning Division
Ministry of Health and Family Welfare
Government of India

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

2014
Ministry of Health & Family Welfare
Government of India, Nirman Bhawan, New Delhi-110011

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First published 1989
Second edition 1993
Third edition 1996
Fourth edition 1999
Fifth edition 2006
Sixth edition 2014

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भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
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Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

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Dated : 3rd November, 2014

Message

With the introduction of RMNCH+A strategy, the horizon of Family Planning is widening in India. It is evident that Family Planning interventions hold one of the keys towards fulfilling India's commitment to MDGs for lowering maternal and child morbidity and mortality.

Sterilization has been the preferred contraceptive choice in India. Despite all efforts, the unmet need for limiting methods of contraception still remains high which is mainly due to the lack of availability of trained service providers at peripheral health facilities. The Government of India is committed to the provision of quality sterilization services in Family Planning which has been emphasized time and again.

This newly developed manual on 'Standards and Quality Assurance in sterilization services' will empower the State and district programme managers with the requisite knowledge to bridge the gap of provision of quality Family Planning Services.

The efforts of the Family Planning Division in developing this manual is appreciated. I hope this manual will help in improving the service quality and in turn will help in reducing the unmet need of Family Planning.

(Lov Verma)

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Dated: 7th November, 2014

FOREWORD

Quality of services forms the backbone of any health care delivery system. This is more so in the case of Family Planning services. 47% of the Eligible Couples in India are using some form of modern contraceptives. Currently sterilization is the most preferred method in India. In spite of its availability through a vast network of public health institutions in the country, there is still a large unmet need in the terminal methods for family planning.

The Government of India has been actively pursuing improvement in quality of sterilization services provided through fixed day as well camp modes in the states. Monitoring and constant assessment of services is very essential for providing quality services which also is a major thrust area under NHM.

The manual on 'Standards and Quality Assurance in sterilization services' is a comprehensive tool which addresses both the technical as well as the programmatic aspects and will ease the service provision as well as monitoring of the program. It has also been updated in the light of rapid advances in the field of medical sciences, dynamic changes in the programme and the rising expectations of a demanding and conscious society regarding reproductive health rights.

It will act as a ready reckoner for both program managers and service providers alike and will go a long way in improving and assuring quality of sterilization services in the public and accredited private/ NGO facilities in the country.

The efforts of the Family Planning Division in this endeavor are appreciated.

(C. K. Mishra)

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PREFACE

Providing quality contraception services to the clients is one of the cornerstones of achieving the MDG goals for improved maternal and child health. Family planning has therefore been anointed as on of the main pillars of the Government of India's RMNCH+A approach. It has also been observed that provision of quality services helps in addressing the high unmet need in the country. With the global commitment made under 'London Summit on Family Planning', it is now time to revise the current guidelines as per the new technological and programmatic development.

A large population of Eligible Couples in India prefers sterilization as the mode of contraception. In the last three years there has been a substantial decline in the failure, complication and death rates following sterilization and there are evidences that adhering to the quality guidelines and SOPs further decreases these rates. It thus becomes important to revise the existing SOPs and guidelines pertaining to the service provision.

This manual condenses the earlier manuals on quality, standards, fixed day approach and camp approach into one comprehensive one. It includes all the key aspects for ensuring sterilization service quality both in fixed day setting as well as the camp setting in public health and accredited private/ NGO facility.

The efforts of the Family Planning Division in developing this manual in a very short time, is commendable. I hope this manual helps in improving the service quality further and in turn will help in reducing the unmet need of Family Planning thereby accelerating the attainment of the MDG goals.

Rakesh

(Dr. Rakesh Kumar)

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ACKNOWLEDGEMENT

Quality of care in sterilization services is a major thrust area under the National Health Mission for addressing the large unmet need in terminal methods.

I'm thankful to Shri Lov Verma, Secretary (H&FW) for his guidance in this endeavor. I am also thankful to Shri. C. K. Mishra, Additional Secretary and Mission Director, for his unstinted support.

The updation and cumulation of sterilization standards, quality of sterilization services, fixed day approach and quality in the camp setting has been made possible with the constant support and encouragement received from Dr. Rakesh Kumar, Joint Secretary RMNCH+A.

I am thankful to all the experts of the 'National Technical Resource Group on Family Planning' who have contributed enormously in developing this manual after extensive discussions and experience sharing. I am also thankful to all the invited state and district programme officials whose experience from the field helped the expert group to prepare a need based manual.

A special expression of appreciation is reserved for, Dr.Alok Banerjee for providing constant support, and Dr. B.P Singh for preparing the working draft.

Appreciation is also extended to other members of Family Planning Division namely Dr. Teja Ram, DC; Dr. Pragati Singh, Ms. Renuka Patnaik. I am also thankful to all the National TSU team members especially Dr. Nidhi Bhatt for reviewing the technical content and helping in giving it it's final shape..

I hope this techno-managerial manual will empower the programme managers and service providers at the state and district level in all the states in strengthening their service delivery and monitoring systems for providing quality sterilization services in family planning.

(Dr. S. K. Sikdar)

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ABBREVIATIONS

DQAC	District Quality Assurance Committee
SQAC	State Quality Assurance committee
NGO	Non-Government Organization.
WHO	World Health Organization
RTI	Reproductive Tract Infections
STI	Sexually Transmitted Infections
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
LMP	Last Menstrual Period
MTP	Medical Termination of Pregnancy
ASHA	Accredited Social Health Activist
ANM	Auxillary Nurse Midwife
OCP	Oral Contraceptive Pills
IUCD	Intra Uterine Contraceptive Device
OT	Operation Theatre
QA	Quality Assurance
GA	General Anaesthesia
NSV	No Scalpel Vasectomy
FPIS	Family Planning Indemnity Scheme
Hb	Haemoglobin
MO	Medical Officer
AMC	Annual Maintenance Contract
IEC	Information Education Communication
FDS	Fixed Day Static
CHC	Community Health Centre
PHC	Primary Health Centre
ELA	Expected Level of Achievement
TFR	Total Fertility Rate
RCH	Reproductive and Child Health
SIHFW	State Institute of Health and Family Welfare
NRHM	National Rural Health Mission
RHFWTC	Regional Health and Family Welfare Training Centre

Background

India is the first country in the world that launched a National Family Planning Programme in 1952, emphasizing fertility regulation for reducing birth rates to the extent necessary to stabilize the population at a level consistent with the socio-economic development and environmental protection. Since then the demographic and health profile of India have steadily improved. The NHM provides a policy framework for advancing goals and prioritizing strategies during the next decade, to meet the reproductive and child health needs of the people and to achieve the replacement level total fertility rate (TFR) of 2.1 by 2017 (12th plan goal).

Sterilization is still the most popular Family Planning method adopted by our people to limit their family size. Sterilization as a component of family planning services are largely being provided through a network of public and private sector facilities. 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 and 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.

In the year 2006, the manual on 'Standards on Female and Male sterilization' as well as the 'Quality Assurance Manual' was updated based on the prevailing technical and programmatic update as well as the directions of the hon'ble Supreme court of India to lay down uniform guidelines for sterilization services in the country. Subsequently two more manuals namely the 'Standard Operating Procedures' for sterilization services in camps as well as the 'Fixed Day Static' manual were also brought out in 2008.

It has been 6-8 long years since the manuals have been revised and considering that a lot of advancements have happened in the field of medical sciences and the programme too has undergone a sea change under NHM with new policies and schemes in place, it was found to be an opportune time to update the manuals.

Another common problem faced in the field by the programme managers and service providers alike due to proliferation of so many manuals was the difficulty to consult so many manuals which also suffered from repetitiveness and duplication of various chapters, checklists, forms and formats. It was also a challenge to make all four manuals available simultaneously at one place.

With a view to streamline and sort out the above issues the Family Planning Division has under taken this endeavor to coalesce the above four manuals into one without diluting any of the contents and at the same time strengthening with new technical knowledge and current learning from the field so that the outcome is a comprehensive manual which touches all aspects of sterilization services in India and act as a **one stop reference for all issues concerning standards, quality assurance, skilled provision of services, logistics and supplies, indemnity coverage and robust monitoring protocols. The manual has also been made user friendly for all levels of the health system**.

Introduction

This new manual on 'Standards and Quality Assurance in Sterilization Services' is an important step to ensure 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, pre- & post-operative care, follow-up protocols and procedures for management of complications. It also highlights the salient pre-operative, operative and post-operative instructions of the surgical procedures and the recommended practices for infection prevention.

This manual will also serve as a guide for assessing service quality and enable programme managers and service providers both in the public sector and in accredited private/NGO facilities to provide quality sterilization services and to take remedial measures wherever deficient for ensuring adherence to standards in service delivery. In addition a framework for the process of payment of compensation for unforeseen situations such as complications /failures/ deaths, arising out of sterilization procedure for clients as well as service providers, has been specified in details.

The standards laid down in this manual apply to both 'Static' and 'Camp' modes.

Target Audience

This document is meant to be used universally all over the country by all stake holders comprising of policy makers at the national and state levels, programme managers at the national, state, district and block levels, faculty of medical colleges, trainers at the national and state level, service providers at all levels as well as by the clients too who want to get acquainted with the nuances of the programme and be aware of their rights and responsibilities.

It can also be used for monitoring and ensuring quality assurance in provision of sterilization services by outlining the steps and mechanisms for measuring the quality of services provided at both static facilities and camps.

This manual supersedes the existing manuals as below:

1. Standards for Female and Male Sterilization-2006.

2. Quality Assurance Manual for Sterilization Services-2006.

3. Standard Operating Procedures for Sterilization Services in Camps-2008.

4. Operational Guidelines on FDS(Fixed Day Static) approach for Sterilization Services-2008.

and can be quoted in a court of law as the standard guideline of the Government of India on all matters concerning sterilization services in India in public and accredited private/NGO facilities.

SECTION -I
STANDARDS IN STERILIZATION

Chapter 1.
General Aspects of Sterilization

1.1. Eligibility of Providers to Perform Sterilization procedure

	Sterilization	Service	Basic Qualification Requirement of Service Provider
Empanelled	Female	Minilap sterilization	i) DGO, MD/MS in ObGyn ii) Specialists in other surgical fields iii) MBBS } Trained in Minilap sterilization
		Laparoscopic sterilization	i) DGO, MD/MS in ObGyn ii) Specialists in other surgical fields iii) MBBS performing Minilap sterilization } Trained in laparoscopic sterilization
	Male	Conventional vasectomy	i) MBBS and above (trained in Conventional Vasectomy)
		No-scalpel vasectomy (NSV)	i) MBBS and above (trained in No Scalpel Vasectomy)

1. The state should maintain a district-wise list of doctors empanelled for performing sterilization operations in public and accredited private/NGO facilities based on the above criteria.
2. State should maintain a separate list for Minilap, Laparoscopic tubectomy, Conventional and No Scalpel Vasectomy providers.
3. Only those doctors whose names appear on the panel would be entitled to carry out sterilization operations in public and accredited private/NGO facilities. The panel should preferably be updated every three months or sooner if warranted. A doctor empanelled with one state/ district of India is eligible to perform sterilization operation in other states/ districts of India).
4. States can empanel doctors who are already performing sterilization operation in the public facilities for the last 3 years.

1.1.2 It is advisable that private facilities offering sterilization services get accredited with the SQAC/ DQAC if they wish to avail of the benefits of the compensation and the indemnity schemes as per guidelines of those schemes.

1.2. Physical Requirements

The infrastructural facilities required for performing female and male sterilization are placed in Annexures 5.

The format in Annexure 5 is also applicable for accrediting a private facility providing services for female and male sterilization.

1.3. Eligibility Criteria for Case Selection

(Self-declaration by the client will be the basis for compiling this information. No eligible client should be denied family planning services)

1.3.1. Clients should be ever married.

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

1.3.3. Male clients should be above the age of 22 years and below the age of 60 years.

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

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

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

1.3.7. Mentally challenged clients must be certified by a psychiatrist and a statement should be taken from the legal guardian /spouse regarding the soundness of the client's state of mind.

There are no absolute contraindications for performing Tubectomy/Vasectomy operation. There are certain conditions that require caution, delay or referral to a specially equipped centre. The Medical Eligibility Criteria for Female/Male Surgical Sterilization procedures outlined by WHO (2011) serves as guidelines for case selection based on the clinical findings of the client (refer to 'Reference Manual for Female and Male Sterilization' for details on eligibility criteria). **However, the final selection of the case should be based on the case selection criteria outlined in section 1.3 above and guided by the medical eligibility criteria stated above.**

1.4 Counselling

Counselling in family planning is the process of facilitating and enabling clients to make well informed, well considered and voluntary decisions about fertility and to choose a contraceptive method. Counselling is a client centered approach that involves communication between a service provider/counsellor and client. Counselling enables the service provider to understand client's perception, attitudes, values, beliefs, family planning needs and preferences and accordingly the counselor can guide her/him towards decision making. The provider/counselor should be non-judgmental. Privacy (auditory and visual) and confidentiality should be maintained during the process of counselling.

Clients may not have complete information about sterilization and its effect which is further compounded by misconceptions and concerns. These should be dispelled by providing correct information.

1.4.1 General Counseling: Should be done for all the clients seeking family planning services. The main aim of general counselling is to provide informed choice to enable them to take a decision regarding the type of contraceptive method to be used. However, in all cases method-specific counselling on the chosen method must be done.

1.4.2 Method Specific Counseling: During counselling for sterilization, use of simplified schematic diagrams can be helpful (refer to diagrams in 'Reference Manual for Female Sterilization (2014)').

The following steps should be ensured before the client signs the consent form:

A. Clients have been counselled wherever required in the language they understand.

B. Clients have been informed of all the available methods of family planning and procedures.

C. Clients have been made to understand what may happen before, during and after the surgery, its side effects and potential complications.

D. Clients have made an informed decision for sterilization voluntarily.

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

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

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

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

iv) It will not affect the client's strength or ability to perform normal day-to-day functions.

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

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

vii) A reversal of the surgery is possible but the reversal involves a major surgery the success of which cannot be guaranteed.

viii) In the unlikely event of any complication/ failure/death there is a redressal mechanism available in the form of an indemnity coverage.

1.4.3 Follow-up Counselling: The information provided after the procedure is reinforced. Service providers need to listen attentively and be prepared to answer questions the client may have and address problems she/ he has experienced after undergoing the procedure. This helps the client cope with common problems or side effects.

Female Sterilization	: Advise client to return to the facility if there is any missed period/no periods, with in 2 weeks to rule out pregnancy.
Male Sterilization	: Advise client to return to the facility after three months for semen examination to see if azoospermia has been achieved. If semen still shows sperm return to facility every month till 6 months.

1.5 Informed Choice and Informed Consent

The concepts of informed choice and informed consent are related but quite different in their intent. The purpose of informed choice is to ensure that all clients choose the best option/s for their health care needs after getting full information about all available options. Informed consent means that a client understands the surgical procedure and other options and then decides to receive the care. However, informed consent alone does not constitute informed choice (Annexure 1).

The consent of the partner is not required for sterilization.
However the partner should be encouraged to come for counseling.

1.5.1 Documentation of Informed Consent

The client's signature or putting her thumb impression on an informed consent form is the legal authorization for the sterilization procedure to be performed. The client must always sign or put her/ his thumb impression on the consent form. In case of thumb impression a signature of a witness (any person not associated with the service facility and chosen by the client) is a must (Annexure1).

Consent for sterilization should not be obtained when physical or emotional factors may compromise a client's ability to make a carefully considered decision about contraception.

1.5.2 Documenting Denial of Sterilization

When a client evaluation indicates sterilization to be unsuitable for her/him either on medical or non-medical reasons, the client record should specify the reasons (e.g. the client has a condition that precludes surgery, client is uncertain about her/ his choice, etc).The action taken by the provider should also be described (e.g. referral, treatment, etc). These records should be kept at the service facility where the client was evaluated and the sterilization found unsuitable for her/ him.

All cases of failures and complications, major or minor and deaths arising out of surgery or post-surgery must be documented. The major complications that required hospitalization, deaths and all cases of failures must be reported to the District Quality Assurance Committee (DQAC). The District Quality Assurance Committee (DQAC) will in turn be responsible for processing the claims as per the guidelines of the Family Planning Indemnity Scheme.

Chapter 2.
Standards for Female Sterilization

2.1. 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 needs to be done in order to ensure the eligibility of the client for surgery. The details are specified in the 'Reference Manual for Female Sterilization (2014)'.

2.1.1 Demographic Information

The ensuing information is required: Name of the client, spouse's name, age, address, marital status, occupation, religion, educational status, number of living children and age of the youngest child. If possible, contact telephone number of client, ASHA/ANM (if available).

2.1.2 History

Specific information which should be obtained as part of the history includes:

- **Menstrual History** - date of last menstrual period (LMP), cycle details including length of cycle, duration and amount of flow, dysmenorrhea, regularity of periods.
- **Obstetric history -** number of pregnancies and living children and mode of delivery, date of last childbirth, number and date of abortion/MTP, current pregnancy status.
- **Contraceptive History -** when and what was the last contraceptive used. If discontinued, when and why.
- **Medical History**
  - History of illness and other medical conditions in the past or at present to screen out the diseases as mentioned under the medical eligibility criteria. Refer to 'Reference Manual for Female Sterilization (2014)' for details on eligibility criteria. Rule out any febrile illness, coagulation disorder or diabetes.
  - Immunization status for tetanus.
  - Any known drug allergies especially to analgesics and other medications.
  - Current medications and reason.

2.1.3 When to perform Female Sterilization:

Woman's Situation	When to Perform
Having Menstrual Cycles	• Any time within 7 days after the start of her menstrual bleeding. • Any time of menstrual cycle, provided it is reasonably certain that she is not pregnant.
Switching from another method	• OCP: To be done any time, but she can continue the pill until the pack is finished to maintain her regular cycle. • IUCD: To be done anytime, concurrently with removal of IUCD.
No monthly menstrual bleeding	• Any time provided it is reasonably certain she is not pregnant.

Woman's Situation	When to Perform
After childbirth	• Within 7 days after giving birth (only Post-Partum Minilap tubectomy can be performed). • Any time 6 weeks or more after childbirth if it is reasonably certain she is not pregnant. (Interval Sterilization).
After MTP	• Concurrently with surgical MTP or within 7 days post MTP. • In case of Medical Abortion the tubectomy should be done after next menstrual cycle. • Laparoscopic tubal occlusion procedure can be performed only in MTPs up to 12 weeks of gestation.
After miscarriage or abortion	• Within 7 days, if no complications.
After using emergency contraceptive pills (ECPs)	• Within 7 days after the start of her next monthly bleeding or any other time if it is reasonably certain she is not pregnant.

Laparoscopic tubal occlusion should not be done concurrently with second-trimester abortion and in the early post-partum period up to 42 days.

2.1.4 Physical Examination:

- General Examination–Check and record pulse, blood pressure, respiratory rate, temperature, body weight, general condition and nutritional status and signs of anaemia (such as pale skin or conjunctiva, rapid pulse (>100/min), systolic murmurs)
- Abdominal Examination – for any tenderness, mass etc.
- Pelvic Examination - Inspect external genitalia for abnormalities and lesions, enlarged groin nodes.

  Ensure that the client has passed urine before performing a pelvic examination

- Speculum Examination - check for abnormal vaginal discharge, cervix for purulent cervicitis. If indicated by history, physical findings and microscope is available, obtain specimens of vaginal and cervical discharge for diagnostic studies. Rule out RTI/STI.
- Bimanual Pelvic Examination–Rule out PID, Uterus–size, position, mobility, adenexa, pouch of Douglas etc.
- Any other examination, as indicated by the client's medical history or general physical examination.

2.1.5 Laboratory Examination

Blood test for haemoglobin, urine examination for sugar and albumin and pregnancy test, if needed.

Caution: Clients with Haemoglobin <7 gm/ dl should not be accepted for sterilization and referred to higher centres for management.

2.2 Written Informed Consent

Client must sign the consent form for sterilization before the surgery. The importance and details of consent procedure have been detailed under section 1.5 or Annexure 1.

The operating surgeon must fill in the medical record and checklist placed at Annexure-2 before initiating the surgery.

2.3. Preoperative Instructions (For Clients)

- Bathe and wear clean and loose clothes to the OT.
- Not to take anything orally (not even water) at least 4 hours prior to surgery and any solids, milk or tea at least 6 hours prior to surgery.
- Empty her bowels on the morning of the surgery and pass urine before entering the OT. She should remove her glasses, contact lens, dentures, jewellery and lip stick if she is wearing any of these items.
- A responsible adult must be available to accompany the client back home after the surgery.

2.4 Part Preparation

- The operative area should not be shaved. The hair can be trimmed if necessary, since shaving the operative site on the eve of the surgery increases colonization of micro-organisms. However, shaving done just prior to surgery is acceptable.
- The operative site should be prepared immediately preoperatively with an antiseptic solution, such as iodophor (Povidone iodine) or chlorhexidine gluconate (Cetavalone).
- The antiseptic solution should be applied twice 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.
- After preparing the operative site, the area should be covered with a sterile drape.

2.5 Premedication/Anaesthesia/Analgesia

Local anaesthesia is recommended both for Minilap tubectomy and Laparoscopic tubal occlusion which has enabled health institutions to provide sterilization services safely even in settings with limited resources.

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, preferably Tablet Alprazolam (0.25 to 0.50 mg) or Tablet Diazepam (5 to 10 mg) can be given one hour before the operation.

b) Sedation/Analgesia

The anxiolytic, sedative, light muscle relaxant and amnesic effect produced in the client following administration of sedation allow sterilization procedure to be performed smoothly under local anesthesia. On the day of the operation, drugs for sedation and analgesia are to be given as shown in Table A

Approximate Weight/Build of client	Name of the Drugs (Dose)	Route and time of administration	Repeat Dose if required on the table**	Route and time of administration**
Thin (< 40 kg)	Pethidine 25 mg + Promethazine 12.5 mg	IM: 30-45 min prior to surgery	Pethidine 10 mg	IV: 5 min prior to surgery
	OR			
	Pentazocine 15 mg + Promethazine 12.5 mg	IM: 30-45 min prior to surgery	Pentazocine 15 mg	IV: 5 min prior to surgery
Average (40-50 kg)	Pethidine 37.5 mg + Promethazine 12.5 mg	IM: 30-45 min prior to surgery	Pethidine 10 mg	IV: 5 min prior to surgery
	OR			
	Pentazocine 22.5 mg + Promethazine 12.5 mg	IM: 30-45 min prior to surgery	Pentazocine 15 mg	IV: 5 min prior to surgery

Approximate Weight/Build of client	Name of the Drugs (Dose)	Route and time of administration	Repeat Dose if required on the table**	Route and time of administration**
Well built (>50 kg)	Pethidine 50 mg + Promethazine 25 mg	IM: 30-45 min prior to surgery	Pethidine 10 mg	IV: 5 min prior to surgery
	OR			
	Pentazocine 30 mg + Promethazine 25 mg	IM: 30-45 min prior to surgery	Pentazocine15 mg	IV: 5 min prior to surgery

Dosage by body weight: Pethidine 0.5 to 1 mg/kg; Promethazine 0.3-0.5 mg/kg; Pentazocine 0.5 mg/ kg.
*** Repeat dose to be given after 45 minutes of the initial dose, by slow intravenous injection.*

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

The drugs should be diluted with equal quantity of normal saline or distilled water before IV administration.

Client must be monitored and attended to after the parenteral administration.

c) Local Anaesthesia

Following are the requirements for the administration of local anaesthesia:

- Lignocaine is the recommended local anaesthetic and the recommended concentration is 1% lignocaine without adrenaline. 2% lignocaine solution must be diluted to 1% using normal saline or sterile water for injection.
- To minimize the risk of major complications, local anaesthetic should be used in the smallest effective doses with careful attention to proper technique. In most cases, 10 ml of 1% lignocaine is adequate. In no case should the total dose exceed 3 mg per kg body weight of the client (i.e. about 20 ml) with maximum limit of 200mg.
- Onset of action is typically within three to five minutes with the anaesthetic effect lasting up to 45 minutes.
- Confirm the effect of anaesthesia before surgery.
- If required an intravenous line may be secured before the start of the procedure

Local anaesthesia is safer than general anaesthesia

The key to safe use of a local anaesthetic is to be sure that it is not injected directly into a vein and to use the lowest effective dose

Skin sensitivity test 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.

General Anaesthesia

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

- non-cooperative patient.
- obesity.
- history of allergy to local anaesthetic drugs.
- anticipated difficult surgery.

Sterilization under GA and regional anaesthesia should be done in centres where all routine and emergency back-up facilities are present for providing such anaesthesia and to be administered by a qualified/competent anesthetist.

2.6 Monitoring

Client monitoring must be a routine practice in performing sterilization procedure. It is of special importance during the use of local anesthesia, especially if sedatives and analgesics are also used, as the drugs may cause respiratory and cardiovascular depression, hypersensitivity reactions or central nervous system toxicity.

Steps

I) **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. The name of the drug(s), dosage, route and time of administration must be recorded (Annexure 3).

ii) **Monitoring** is to be done as described below:

- Preoperatively: Pulse, respiration and blood pressure should be taken prior to premedication and thereafter every 10 minutes.
- 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 insufflation and at the time of tubal ligation.
- Post-operatively: Pulse, respiration, blood pressure and also skin color (nail bed) should be monitored and recorded every 15 minutes for one hour following surgery or longer, if the patient is unstable or not awake.

2.7. Surgical Techniques

a) General Requirements

i) Ensure client's bladder is 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 / Occlusion of 1 cm of the tube should be done. Use of cautery and crushing of the tube should be avoided.

iv) Check that ligatures on the cut ends are secured.

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

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

iii) In Interval minilaparotomy procedure the use of a uterine elevator to bring the fallopian tubes into the operative field would help in visualization of tubes.

The equipment required for Minilap sterilization are detailed in Annexure 8.

c) Laparoscopy Requirements

I) To avoid hypoventilation, the client must not be placed in the Trendelenburg position in excess of 20 degrees.

ii) Pneumoperitoneum should be created with veress needle. Alternatively pneumoperitoneum can be created by directly introducing the trocar, if the surgeon is experienced and confident.

iii) Insufflation of abdomen should be done preferably with carbon dioxide. Slow insufflations with graded insufflator and gradual de-sufflation should be done. Use the high flow switch to introduce carbon dioxide at the rate of 1 litre per minute. Intra-abdominal pressure should not exceed 15 mm of mercury. (in field situations where availability of carbon dioxide is an issue, air may be used)

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

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

vi) A uterine elevator should be used to visualize the fallopian tube (optional).

vii) Tubal occlusion must always be done with Falope rings (no cautery is to be used).

viii) The following precautions are to be taken while applying Falope 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).
- 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, tubectomy should be done with laparotomy under GA by conventional method.

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

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

The equipment required for Laparoscopic sterilization are detailed in Annexure 9.

2.8 Post-operative Care

In the post-operative period, the client should be kept under observation by a nurse/doctor. Following are the tasks to be carried out in the post-operative period:

- Receive the client from the operating theatre; review the client record.
- Make the client as comfortable as possible (handle the woman gently when moving her).
- Make sure that an over sedated client is never left unattended.

- Monitor the client's vital signs - check blood pressure, respiration and pulse every 15 minutes for one hour following surgery or till the patient is stable and awake. Thereafter, check vitals every one hour until four hours after surgery. Record vital signs in the client record each time they are checked.
- Check the surgical dressing for oozing or bleeding.
- For interval cases, check for vaginal bleeding other than menstruation. If the client is bleeding, the doctor should check for possible injury to the cervix that may have been caused by the vulsellum.
- Administer drugs or treatment for symptoms according to the doctor's orders.
- Provide water, tea and fruit juices when the client feels comfortable.
- Fill in the client record form.

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

- After at least 4 hours of procedure, when the vital signs are stable and the client is fully awake, has passed urine and can talk, drink and walk.
- The client has been seen and evaluated by the health care provider. Whenever necessary, the client should be kept overnight at the facility.
- The client must be accompanied by a responsible adult, while returning home.
- Analgesics, antibiotics and other medicines may be provided and/or prescribed as required.
- After sedation has worn off and before discharge, a trained staff member should repeat the postoperative instructions to the client or designated accompanying person. A written copy of the postoperative instructions should also be provided.

2.9. 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 3). Both written and verbal post-operative instructions must be provided in the local language.

- In the case of interval sterilization (Minilap and Laparoscopic), the client may have intercourse one week after surgery or whenever she feels comfortable thereafter.
- In case of post partum sterilization (after caesarian or normal delivery) client may have intercourse 2 weeks after sterilzation or whenever she feels comfortable.

2.10. Certificate of Sterilization

A certificate of sterilization should be issued one month after the surgery or after the first menstrual period, whichever is earlier, by the Medical Officer of the facility. If the client does not resume her period even after one month of surgery, rule out pregnancy before issuing sterilization certificate (Annexure 4).

For payment of compensation for undergoing sterilization operation, discharge slip/card will be considered a valid proof of under going Sterilization

In case the surgeon was unable to identify the tube on one side and thereby could not occlude/ligate it, he/she should document it on the case sheet and inform the client accordingly that the sterilization procedure has not been successful. This documentation on the case sheet should also be countersigned by the client or their thumb impression taken (if illiterate). In such cases sterilization certificate should not be issued even if she resumes her menstrual cycle.

Such cases where sterilization certificate has not been issued are not eligible for compensation for 'failure' under FPIS.

2.11. Complications and Management of Female Sterilization

Overall, Female Sterilizations (minilap tubectomy and laparoscopic tubal occlusion) are safe procedures and few women experience complications. It occurs in less than 2 % of all cases and serious complications are rare. If complications are immediately and accurately diagnosed and effectively treated, the morbidityis low and mortality is rare. Details of various complications and their management are given in 'Reference Manual for Female Sterilization (2014)'.

2.11.1. Intra-operative Side effects/complications

- Nausea and vomiting
- Vasovagal attack
- Respiratory depression
- Cardio-respiratory arrest
- Convulsions and toxic reactions to local anaesthesia
- Gas / Air Embolism
- Uterine perforation due to introduction of uterine elevator from below
- Bleeding from the meso-salpinx
- Injury to the urinary bladder
- Injury to intra-abdominal viscera (i.e. small or large bowel) and blood vessels
- Subcutaneous emphysema

2.11.2. Post-operative Complications

- Wound sepsis
- Haematoma in the abdominal wall
- Intestinal obstruction, paralytic ileus and peritonitis
- Tetanus
- Incisional hernia

2.12. Failure of Operation Leading to Pregnancy

Female Sterilization is one of the most effective methods but carries a small risk of failure. The incidence of failure is less than one pregnancy per 100 women over the first year after having the sterilization procedure (5 per 1000). This means that 995 of every 1000 women relying on female sterilization will not become pregnant. However, a small risk of pregnancy remains beyond the first year until women reach menopause. The failure over 10 years of use is about two pregnancies per 100 women (18 to 19 per 1000 women). Ectopic pregnancy must be ruled out as female sterilization predisposes to this condition.

In case of missed menstrual period, the clients are advised to report to the health care facility within two weeks for confirmation about the failure of her sterilization procedure. She should be offered MTP and repeat sterilization procedure free of cost or be medically supported throughout the pregnancy if she wishes to continue.

2.13. Conditions not Related to Sterilization

Refer to the 'Reference Manual for Female Sterilization (2014)' for the details on the conditions mentioned below.

- Menstrual irregularities (e.g. menorrhagia and scanty period)
- Chronic pelvic inflammatory disease
- Psychological problems (e.g. depression)

2.14. Reversal of Sterilization

The wide spread prevalence of female sterilization particularly those opting for it at a younger age has led to an increasing number of requests for reversal procedures. Most women and their partners are satisfied with the procedure but life's circumstances and outlook can change which may need reversal of female sterilization. Women considering female sterilization should not think it is reversible. The female sterilization reversal is a major surgical procedure involving end to end anastomosis of the ligated/occluded fallopian tube(s) i.e. Tuboplasty. Hence, the success of this procedure can not be guaranteed.

Chapter 3.
Standards for Male Sterilization

3.1. Clinical Assessment and Screening of Clients

3.1.1 Demographic Information

The ensuing information is required: Name of the client, spouse's name, age, address, marital status, occupation, religion, educational status, number of living children and age of the youngest child.

3.1.2 History

Specific information which should be obtained as part of the history includes:

- **Medical History**
  - History of illness or other medical conditions in the past or present to screen out the diseases mentioned under the medical eligibility criteria and also to rule out acute febrile illness, uncontrolled diabetes, bleeding disorders, sexual problems and mental illness.
  - Immunization status of men for tetanus.
  - Current medications, if any.
  - Current use of contraception by the couple.
  - Last menstrual period (LMP) of the wife.

3.1.3 Physical Examination

Pulse and blood pressure, temperature, general condition and local examination of penis, testicles and scrotum. Further examinations as indicated by the client's medical history.

3.1.4 Laboratory Examinations

Urine analysis for sugar and other laboratory examinations as indicated.

3.2 Timing of the Surgical Procedure

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

3.3 Written Informed Consent

Client must sign the consent form for sterilization before the surgery .

The Importance and details of consent procedure have been detailed under section 1.5 and Annexure 1.

The operating surgeon must fill in the medical record and checklist placed at Annexure-2 before initiating the surgery.

3.4 Preoperative Instructions (For Clients)

- Preferably trim the pubic, scrotal and perineal hair. Shaving of pubic hair, if warranted, should be done just prior to surgery.
- Bathe and wear clean and loose clothes to the OT.

- Have a light meal on the morning of the surgery.
- Empty his bladder before entering the OT.

3.5. Skin Preparation and Surgical Draping

- The pubic hair can preferably be trimmed, if not done earlier, since shaving the operative site on the eve of the surgery increases colonization of micro-organisms. However, shaving done just prior to surgery is acceptable.
- The operative site should be prepared immediately pre-operatively with an antiseptic solution such as iodophore (Povidone iodine).
- The antiseptic solution should be applied twice 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.
- Entire scrotum should be painted beginning at the site of incision/puncture.
- After preparing the operative site, the area should be covered with a sterile drape.

3.6. Premedication/Anaesthesia/Analgesia

a) **Premedication** is not necessary in vasectomy. However if the client is very anxious and to assist in relaxing the scrotum, tablet preferably Alprazolam 0.25-0.5 mg or Diazepam 5-10 mg may be given one hour prior to surgery with a sip of water.

b) **Local anaesthesia** is recommended for vasectomy procedures. Good local anaesthetic technique is essential for a pain-free vasectomy. The local anaesthetic to be used is **1% lignocaine without adrenaline.** The maximum individual dose of lignocaine without adrenaline should not exceed 3 mg/kg of body weight. In general, it is recommended that the maximum total dose does not exceed 200 mg or 20 ml of 1% lignocaine or 10 ml of 2% lignocaine (2% lignocaine, 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.

3.7. Surgical Techniques

3.7.1 Conventional Vasectomy

Conventional vasectomy has been used for half a century and has proved to be a method that is simple, inexpensive and effective. The surgical incision, however, accounts for most of the operation-related complications, in particular bleeding, haematoma and infection. Incisional vasectomy requires the same client counselling, pre-vasectomy assessment, vas occlusion, post vasectomy care and complications management as in NSV techniques. The equipments required for conventional vasectomy are given in Annexure 10.

a) Incision:

- Two or with one incision on the midline.
- The length of each incision should not be more than 2 cm.

b) Site of Vasectomy:

- The mid-scrotal part of the vas should be removed.

c) Excision of Vas:

- Not more than 1.0 cm in length of vas is removed.
- Removal of the excess vas may make a subsequent re-canalization operation difficult.

d) Tying of Cut Ends of Vas:

- Ligate at two points about 1.5 cm apart using 2-0 silk.
- Fascial interposition is recommended (optional).

e) Closing Skin Incision:

- The skin incision should be closed with non-absorbable sutures after ensuring complete haemostasis.

3.7.2 No-Scalpel Vasectomy (NSV)

NSV is a refined surgical procedure requiring unique surgical skills. 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. The equipment required for vasectomy are given in Annexure 11.

a) Preoperative instructions: Same as given in 3.4.

b) Skin preparation and surgical draping: Same as given in 3.5.

c) Anaesthesia: NSV is to be performed under local anaesthesia. Bilateral vasal block is achieved using 2% lignocaine without adrenaline. The administration of local anaesthesia is also unique. The anaesthetic is administered strictly perivasally which makes the procedure completely painless.

d) Fixation, Puncture and Delivery of Vas:

- The vas is fixed in the midline at the junction of its upper one-third and lower two-third by a vas fixation forceps.
- The skin of the scrotum, is then punctured at this site and vas is then delivered out of wound in one motion.

e) Excision and Ligation of Vas:

- About 1 cm length of the bare vas should be excised and ligated with 2-0 black silk.

f) Delivery of the Opposite Vas:

- The opposite vas must be fixed, delivered, excised and ligated through the same puncture hole.

g) Fascial Interposition: (Optional)

- Places a tissue barrier between the two cut ends of the vas
- It should be performed on both the sides.

This step may reduce the failure rates.

h) Dressing the Wounds:

- After ensuring haemostasis apply a swab with antiseptic solution. A sterile gauze dressing can be held in place with a scrotal supporter or an adhesive tape. This should be retained for 48 hours.

i) Scrotal Support:

- The client should wear his normal snugly fitting underwear, or use scrotal support with suspensory bandage.

3.8. 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) Analgesics 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.

d) Explain to the client in simple language how to care for the wound, what side effects to expect, what to do if complications occur, where to go for emergency care and when and where to return for a follow-up visit. Tell him that minor pain and bruising are to be expected, which do not require medical attention. The man should seek medical attention if he has fever, if blood or pus oozes from the puncture site or if he experiences excessive pain or swelling. Give the client a brief, simply written summary of the instructions.

3.9. Post-operative and Follow-up Instructions

The client is to be provided with a discharge slip indicating the name of the institution, the date and type of surgery, the method used and the date and place of follow-up (Annexure 3). Both written and verbal post-operative instructions must be provided in the local language.

- Tell client that he should report to the clinic for semen examination three months after the surgery.
- If sperms are still present then semen is tested every month till six months.
- Failure of vasectomy should not be declared till six months.
- If sperms are still present after six months re-vasectomy should be considered

After Surgery(both conventional and No-scalpel vasectomy)client should:

a) Wear Scrotal support: for one week, until the stitches are removed.

b) Limit activities after surgery for 24 hours. Light activities can be resumed after two or three days but should avoid heavy work for a week or so after removal of stitches.

c) Refrain from bathing for at least 24 hours after surgery.

The client may resume sexual activity as and when he feels comfortable but should use either condom or another method of family planning until it is confirmed that sperms are no longer present in the semen. A slight pain may be felt or blood may be noticed in semen which is normal.

3.10. Certificate of Sterilization

A certificate of sterilization should be issued only after three months once the semen examination shows no sperm. (Annexure 4).

For payment of compensation for undergoing sterilization operation, discharge slip/card will be considered a valid proof of undergoing Sterilization.

In case the surgeon was unable to identify the vas on one side and thereby could not occlude/ligate it, he/she should document it on the case sheet and inform the client accordingly that the sterilization procedure has not been successful. This documentation on the case sheet should also be countersigned by the client or their thumb impression taken (if illiterate). In such cases sterilization certificate should not be issued .

Such cases where sterilization certificate has not been issued are not eligible for compensation for 'failure' under FPIS.

Certificate can be delayed till 6 months if the semen shows sperm after 3 months of semen examination but even if after 6 months semen shows sperms then the certificate should not be issued.

3.11. Complications of Male Sterilization and Their Management

Details of various complications and their management are given in 'Reference Manual for Male Sterilization'.

3.11.1 Intra-operative Complications

Although the probability is low, the following complications may be encountered:

- Transient drop in blood pressure or dizziness due to vaso-vagal attack.
- Convulsions and reactions to local anaesthesia.
- Injury to testicular artery.

3.11.2 Postoperative Complications

3.11.2.1 Early Complications

- Swelling of the scrotal tissue, bruising and pain
- Haematoma
- Infection
- Stitch abscess
- Wound sepsis
- Orchitis

3.11.2.2 Delayed complications

- Sperm granuloma
- Psychological problem

3.12 Failure of Vasectomy

Male Sterilization (both NSV & Conventional method) is not effective till the seminal fluid is completely sperm free, which takes almost about a period of three months or more, after the procedure. The reason for this is that the sperms are stored in distal reproductive system located

'upstream' from the sites of vasal occlusion and it takes 3 months or more to make the reproductive passage empty. Pregnancy may occur after vasectomy, if the couple does not use condoms or another effective contraceptive method consistently and correctly before the seminal fluid is devoid of all sperms and semen examination proves no sperm. This is sometimes presumed to be a vasectomy failure, which is not correct. This is the most common reason for pregnancy after a male sterilization (vasectomy). Rarely spontaneous recanalization may occur

If failure occurs, the client's partner should be offered MTP or should be medically supported throughout pregnancy. The client should be offered a repeat surgery, as indicated.

3.13 Vasectomy Reversal

Most men and their partners are satisfied with the procedure but life's circumstances and outlook can change which may need reversal of vasectomy. Men considering vasectomy should not think it is reversible. Reversal of vasectomy or vaso-vasotomy is a microsurgical procedure requiring considerable skills. Vaso-vasostomy is effective at achieving pregnancy in a variable percentage of cases but its success rate cannot be guaranteed. After reversal, sperm counts and motility are usually much lower than pre-vasectomy levels.

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

Chapter 4.
Sterilization Services in Camp Mode

4.1 Background

Traditionally the country has been adopting the camp approach in sterilization since the early 70's to address the issue of large need versus low service availability. There is a need to continue with the camp approach for some more years until adequate institutionalized services are made available as per the needs of the people at the most peripheral level. Though this approach has the advantage and flexibility of reaching the needy at their doorsteps, quality of care becomes an area of concern in such settings. This chapter addresses these barriers by spelling out operating procedures and thus empowers service providers and camp managers to deliver quality services under all circumstances.

4.2 What is a "Camp"?

A sterilization camp is defined as an alternate service delivery mechanism, where an "operating team located at one facility (usually higher level) conducts sterilization operations at another facility (usually lower level), where these services are not routinely available."

Camps may be utilized for purposes of training at facilities equipped with adequate infrastructure.

The In-Charge of the facility where the camp is being organized may be designated as the 'Camp Manager', who would have the overall responsibility for the effective organization of the camp.

4.3 Services Offered in Camp Settings

a Permanent Methods

- **Vasectomy and/or Tubectomy**
  - Screening and clinical assessment
  - Pre-procedure instructions/preparation
  - Procedure
  - Post-operative care & instructions
  - Follow-up

Additional Services

Depending upon the availability of human resources and service availability at the camp sites, Camp managers may decide the type of additional services to be offered in Sterilization Camps.

b Spacing Methods

- **IUCD**
  - Counselling
  - Screening and clinical assessment
  - Insertion
  - Follow-up
  - Management of complications
  - Removal
- **Combined Oral Pills**
  - Counselling
  - Eligibility assessment
  - Provision
- **Condoms**
  - Counselling
  - Provision
  - Instructions for proper use

c	**Emergency contraception**	♦ Counselling ♦ Eligibility assessment ♦ Provision
d	**Screening and management of RTIs/STIs**	♦ Diagnosis and management as per National guidelines
e	**Lab Tests**	♦ Hb ♦ Urine for sugar and albumin ♦ Urine for Pregnancy Test (as indicated in manual) ♦ In case of RTI/STI as per GOI Guidelines

4.4 Pre-requisites for Camps

4.4.1. Site

- **All Sterilization Camps must be organized only at established health care facilities with functional operation theatres**
- **For IUCD insertion, a clean separate room with adequate lighting** arrangement and privacy is sufficient.
- Oral Pills, Emergency Contraceptive Pills and Condoms can be dispensed at the counselling area.

Under no circumstances should camps be organized in a school building / Panchayat Bhavan or any other such set up other than an established health facility

The Government of India emphasizes continued supervision and monitoring of 'camp mode' till static services are universalized

4.4.2 Probable Client Load

Estimation of likely number of clients to turn up for accessing services will help in determining the number of teams. For maintaining quality services, each surgeon should restrict to conducting a maximum of

- 30 Laparoscopic tubal occlusion (for 1 team with 2 laparoscopes)

  or

- 30 Minilap tubectomy cases

  or

- 30 Vasectomy (NSV or conventional)

  or

  a combination of the above with the total not exceeding 30 procedures in a single day

  With additional surgeons, support staff, adequate operation theatre space, instruments, equipment and supplies, the number of procedures per camp may increase proportionately. Depending upon the expected client load, requisite number of teams should be mobilized.

4.4.3. Camp Timings

Camp timings should preferably be between 9 a.m. and 5 p.m.

4.4.4 Staff

(a) Local Team

S. No.	Camp Service Site/ Counter	Female Sterilization		Male Sterilization	
		No. of Staff	Category and No. of Staff	No. of Staff	Category and No. of Staff
1	Registration	1	Male worker/clerk – 1	1	Male worker/clerk – 1
2	History & Clinical Assessment	2	MO – 1 Staff Nurse/LHV/ANM – 1	2	MO – 1, Male worker – 1
3	Counselling Area	1	Counselor/ Health supervisor/ANM – 1	1	Male Supervisor/Male worker – 1
4	Laboratory Examination	2	Lab Technician – 1 Cleaner – 1	2	Lab Technician – 1 Cleaner – 1
5	Pre-operative / Premedication preparation room	1	Staff Nurse/LHV/ANM – 1	1	Health worker-male – 1
6	Instrument & reusable items processing / IP Room	2	OT Attendant – 1 Ward Boy/Aya – 1	2	OT Attendant – 1 Ward Boy/Aya – 1
7	Operation theatre	3	Staff Nurse/ANM – 1 (either from the site area or with the visiting team) OT Attendant – 1 Cleaner – 1	2	Staff Nurse/ANM – 1 (either from the site area or with the visiting team) Cleaner – 1
8	Post-operative room	2	MO – 1 Staff Nurse/ANM – 1	2	MO – 1 Staff Nurse/ANM – 1
9	Office-cum-store	2	Clerk – 1 Compounder/ Pharmacist – 1	2	Clerk – 1 Pharmacist – 1
10	IUCD/Other procedure room	2	ANM– 2		

(b) Visiting Team

S. No.	Staff Category	No. of staff for Female Sterilization		No. of staff for Vasectomy
		Laparoscopic Tubal Ligation	Minilap Tubectomy	
1	Empanelled Surgeon	1	1	1
2	Staff Nurse (if not available at site)	1	1	1
3	OT Attendant (if not available at site)	1	1	1

4.4.5 Equipment/Instruments and Supplies

The Equipment/Instruments and supplies needed for ensuring quality services in sterilization camps is given in Annexure 7. In camps where other services are offered, additional supplies for those services also need to be made available.

4.5. Roles and responsibilities of Program Managers and Service Providers

All functionaries in a camp must work together as a team towards successful and smooth conduction of the camp. The roles and responsibilities given here are only suggestive and can be interchanged as per requirement of a particular situation.

a. Surgeon/gynaecologist

- To ensure that each client has been adequately counselled and screened as per laid down Standards in the prescribed format including ensuring/confirming pre-procedure fitness and informed consent of client for the procedure.
- To fill the checklist before conducting the procedure.
- To ensure requisite equipment/instruments and supplies for the procedure as well as those needed for emergency preparedness are as per the Standards.
- To perform sterilizations of screened clients as per the laid down procedures.
- To ensure emergency and surgical procedure preparedness.
- To practice and ensure adherence to universal IP practices in all procedures.
- To document procedural details and post-operative instructions on the records of all operated cases as given in the Standards.
- To do post-operative check-up wherever required as per Standards.
- To deal with emergencies and ensure appropriate referral to higher centre in case of complications.

b. Anaesthetist (if available)

- To verify the availability and functionality of anaesthetic instruments and drugs at the camp site.
- To ensure pre-operative check-up and fitness for anaesthesia whenever required.
- To supervise local and administer regional or general anaesthesia according to the situation.
- To deal with any emergency/complication related to procedures.
- To document anaesthesia notes in the chart of each client.
- To do immediate post-operative follow-up of cases operated under anesthesia.

c. Staff Nurse/ANM

She will be overall in-charge of preparation and maintenance of Operation Theatre (OT) complex and infection prevention measures.

- To provide counselling for all the clients coming for sterilization.
- To assist MO in performing pre-procedure clinical assessment.
- To ensure documentation of written informed consent.
- To ensure sufficient material including sterilized linen, instruments and other supplies.
- To ensure proper IP practices at all levels before and during all procedures.
- To ensure that all the emergency equipment is in functional order and available.

- To confirm the pre-procedure check-up of clients by empanelled surgeon/gynaecologist and anaesthetist and ensure completion of records before the procedure.
- To assist empanelled surgeon/gynaecologist and anaesthetist during procedures.
- To monitor the clients during the procedure and assist in post-operative care.

d. Operation Theatre Assistant (OTA)

- To work in coordination with staff nurse/ANM/LHV.
- To verify the availability of all the equipment and instruments and ensure that they are in functional condition in the Operation Theatre.
- To ensure HLD/sterilization of equipment, instruments, linen, etc.
- To ensure cleanliness and disinfection of OT.
- In case of female sterilization, to make sure that the laparoscopes are processed after each procedure and at the end of the camp session, as laid down in the Standards.
- To assist the empanelled surgeon and anaesthetist during procedures.
- To perform any other job assigned by the visiting team.

e. Laboratory Technician

- To ensure availability of all the laboratory equipment and reagents for the camp.
- To perform pre-procedure investigations like Hb, urine, etc.
- To document the findings of investigations on the client's chart.
- To maintain the record of all investigations done.
- To ensure quality of all laboratory investigations.

f. Pharmacist

- To ensure sufficient medicines and other supplies for all the clients.
- To distribute medicines to the clients as per guidance of medical officers/surgical team.

g. Class IV (OT Attendant/Ward boy/Ayah, etc.)

- To prepare facility for the camp under guidance of supervisors.
- To shift clients to and from OT.
- To carry equipment/articles from and to the vehicle.
- To assist OT Assistant and staff nurse in OT.
- To decontaminate articles.
- To clean instruments and linen.
- To perform any other job assigned by the camp manager.

h. Safai Karmchari (Cleaner)

- To clean the premises including lab, procedure room and OT.
- To trim hair in vasectomy clients.
- To disinfect procedure room and OT under guidance of OT Staff.
- To help the other Class IV workers to shift equipments and linen from one place to another and also to shift the clients, if necessary.
- To perform any other job assigned by the camp manager.

4.5.1. Pre-camp Activities

4.5.1.1 At District Level (Beginning of the Year)

- To update the list of empanelled surgeons and circulate.
- To ensure availability of funds.
- To constitute teams for camps and develop block-wise quarterly camp calendar
- To keep a stock of equipment/instrument such as Laparoscopes/ Minilap/Conventional vasectomy/NSV sets ready and also arrange for AMC/repairs.
- To ensure availability of equipment, instruments and other supplies for each camp.
- To ensure intense IEC activities regarding the camps.

4.5.1.2 At Facility Level (Before the camp is held)

- Ensuring availability of funds for camps including compensation for clients.
- Orientating site staff, reviewing infrastructure and availability of equipment and supplies including case sheets, consent forms, follow up cards, etc.
- Mobilizing staff from periphery, preparing of duty list etc.
- Ensuring electricity and running water supplies.
- Making adequate arrangements for drinking water, sanitation and toilet facilities and adequate sitting and waiting arrangements.
- Oversee safety and security arrangements in coordination with the local police authorities.
- Display clear signages for the different service areas as specified below to facilitate the smooth flow of clients.

GENERAL AREAS	PROCEDURE AREAS
♦ Waiting area ♦ Registration area ♦ Counselling Area ♦ Clinical Examination ♦ Laboratory ♦ Examination ♦ Office-cum-store	♦ Pre-procedure preparation area ♦ Instrument processing area ♦ Scrub area ♦ Operation theatre - if both tubectomy and vasectomy services are provided, there should be separate operation theatres ♦ Post-operative or recovery room/ward

4.5.2. Communication Activities

Publicize in advance about the camp dates and venue through posters, pamphlets, audio and video material and by putting up of banners at important busy sites as also advertising through local cable network if available.

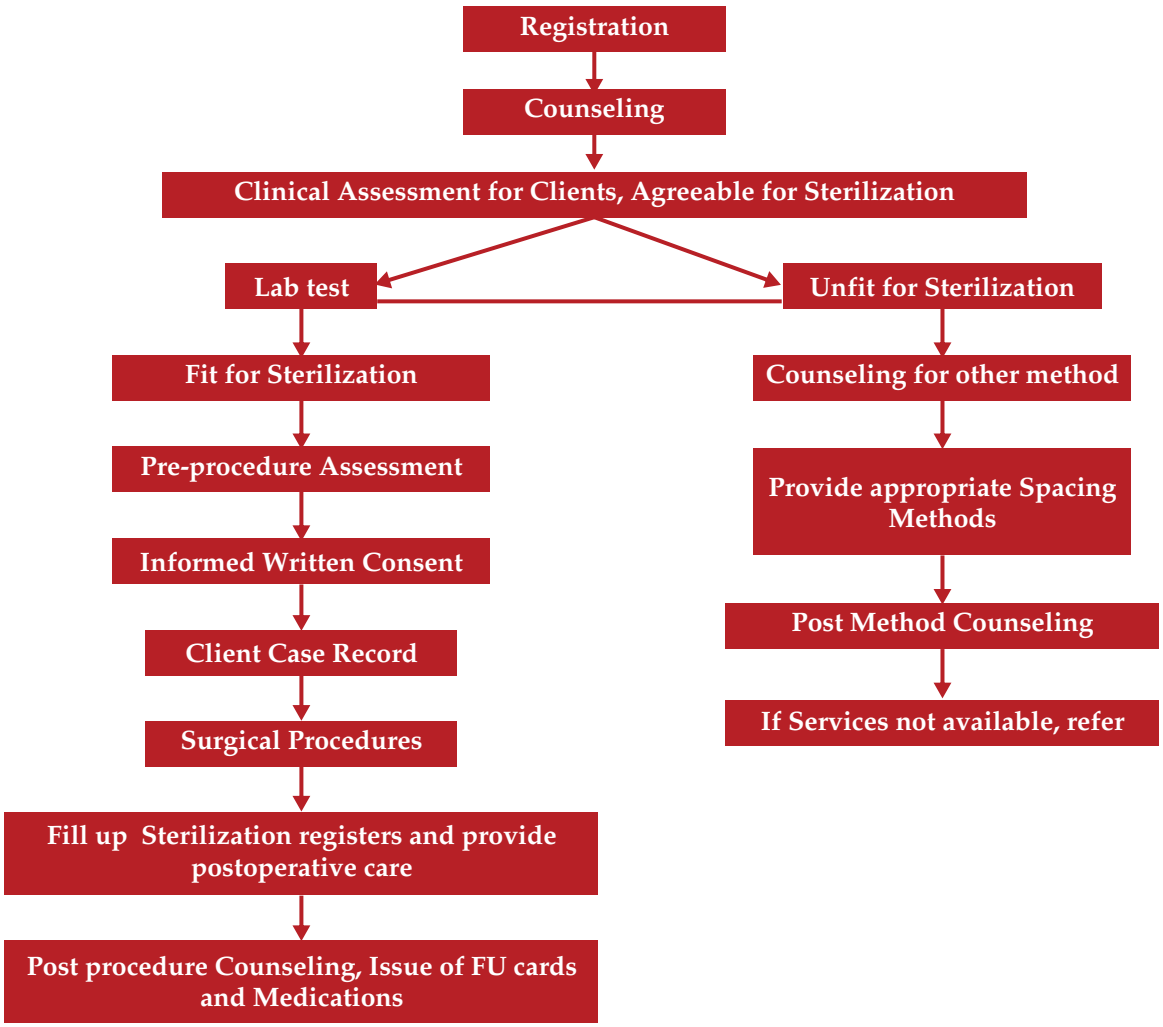
4.5.3 During Camps

For the delivery of services in the camps, two teams are required to work in close coordination, i.e. the local team at the camp site and the visiting team.

The **Camp Manager** should:

- ensure all members of visiting team reach in time
- ensure that camp is organized as per guidelines
- ear mark staff and assign responsibilities for manning different service stations
- check that OT complex has been disinfected in advance
- ensure that emergency medicines and other supplies are available at designated places
- ensure all procedures are followed in sequential manner
- ensure site staff understand and carry out their duties

Flow Chart for Camp Services



- Provide follow-up care as laid down in this manual
- Attend to complications of procedures, if any.

All staff of the health care facility should preferably be trained in emergency management. Guidelines for emergency management should be followed as given in 'Reference Manual for Female Sterilization (2014)'.

4.6 Assurance of Quality in Camp Setting

The quality of sterilization services provided can be assessed through the already existing documentation tools available at the facilities specifically designed for this purpose. The areas requiring improvement should be identified using these tools and this will ultimately be beneficial in improving the quality of the services delivered.

The following need to be monitored for assuring quality care in a camp:

- Facility inputs
- Procedures adopted
- Maintenance of records and registers
- Client care and satisfaction

The District Quality Assurance Committee (DQAC) as well as the Quality Control Circle is responsible for monitoring quality.

Chapter 5.
Sterilization Services in 'Fixed Day Static' Mode

5.1 Background

'Fixed Day Static' Strategy (FDS) is envisioned as one of the long term strategies to fulfil the unmet demand for family planning, throughout the year on a regular and routine manner. Currently camp approach for sterilization services is still being followed in most parts of the country. The only improvement that has happened is that the 'fixed day camps' have replaced the irregular and infrequent 'camps' in most places so that the clients are at least aware that services are going to be rendered to them on a particular day and place for which they can prepare for. This approach of providing FP services is acknowledged as a temporary solution to the availability of routine services as it raises concerns on quality.

In view of this fact, the government advocated 'Fixed Day Static' Approach to provide assured, accessible, quality sterilization services in a health facility through trained providers posted in the same facility, on fixed days, throughout the year.

Under this strategy, health facilities designated by the state are identified to provide sterilization services ranging from No Scalpel/Conventional Vasectomy, Minilap Tubectomy/ Laparoscopic tubal occlusion. The type and periodicity of services are dependent on the type of trained providers available at all levels of facilities viz. District/Sub District Hospitals, CHCs/Block PHCs/ PHCs to provide different sterilization services on weekly/ fortnightly/ monthly basis respectively.

Promoting the 'Fixed Day Static' approach may act as a long term solution to the existing challenge of dearth of trained human resource and infrastructural weaknesses.

The provision of services in States with high TFR and unmet needs reveals that majority of sterilizations services are performed in the latter half of the year (October to March - winter months) on camp mode due to paucity of trained service providers in sterilization at the DHs/ SDHs/ CHCs and PHCs, necessitating deputation of gynaecologists/surgeons from usually higher centers like district hospitals whereas evidence from the Southern states suggest (which have long since achieved the TFR norm of 2.1 or much less) that sterilization performed throughout the year in even mode through trained providers posted in the facility itself, not only help in catering to the huge unmet need but also maintaining quality and therefore leading to less complications, failures and deaths.

Based on the reasons enumerated above, there is a need to shift from camp approach to 'Fixed Day Static' mode.

5.2 'Fixed Day Static' Approach

FDS ('Fixed Day Static') approach in Sterilization Services is defined as "providing sterilization services in a health facility by trained providers posted in the same facility, on fixed days, throughout the year on a regular and routine manner".

5.3 Advantages of FDS

- Availability of regular services (breaking the seasonal trend).
- Availability of trained provider at the facility.
- Larger pool of providers for sterilization services.

- Increased opportunity for conducting PPS .
- Increased availability of services below district and sub district level.

5.4 Steps to Enhance focus on Static Services in Sterilization

5.4.1 Advocacy at State/District/Facility level

Considering the high unmet need of family planning services, especially sterilization services, it is vital to focus on Fixed day static centres where regular services are available. GOI regularly conducts State level workshops to emphasize the need to increase static facilities providing regular sterilization services and the same are reflected well in the action plans developed by districts keeping in view the expected level of achievement.

5.4.2 Estimating state/district/facility level of achievement based on the local unmet need

Under FP2020 roadmaps, State and District wise expected level of achievement has been calculated to fulfill the unmet need of sterilization based on the District Action Plans. The basic principle is to operationalize the static centers so as to fulfill the unmet need. To calculate the expected level of achievement, FP 2020 factors in the population share of eligible couples and the unmet need of the district. So the district with higher unmet need will have higher ELAs as compared to the one with lower unmet need.

5.4.3 Assessment of Resources (Facility Mapping)

i) Identification of centers for providing sterilization services

The following health facilities in a district should provide female and male sterilization in a regular and routine manner throughout the year.

- District Hospitals.
- Sub District Hospitals.
- CHCs / Block PHCs and PHCs with availability of functioning operation theatre.
- Other public health facilities with availability of functioning operation theatre.

ii) Range of services

1. NSV / Conventional Vasectomy.
2. Minilap Tubectomy.
3. Laproscopic Tubal Occlusion.

iii) Periodicity of services (Suggestive)

• District Hospital	Twice a week
• Sub District Hospital	Weekly
• CHC Block PHC	Fortnightly
• 24X7 PHC	Monthly

However those facilities which are already providing the services in a frequency more than what is suggested above may rationalize the distribution of the providers among the various facilities in the district and strive to augment the services even further to address the prevailing huge unmet need.

5.4.4 Assessment of Capacity (Sterilization Services Possible)

Number of facilities to be providing FDS services in a district of 20 and 10 lakhs population respectively is approximately as follows:

S. No	Facility	District with 20 Lac population	District with 10 Lac population
1	DH	1	1
2	SDH	1	1
3	CHC/Block PHC	10	5
4	24X7 PHC	10	5
	Total	**22**	**12**

Illustration: 1

Sterilization services possible in a year in a district of an average population of 20 lakhs are around 16,080 as illustrated below:

S. No	Sterilization Services Possible		Total
1	DH @ 2 per week = (52 weeks x 30 cases / provider x 2 provider per facility)	3120	16080
2	SDH@ 1 per week = (52 weeks x 30 cases / provider x 1 provider per facility)	1560	
3	CHC / BPHC@ 1 per fortnight = (26 weeks x 30 cases/ provider x 10 facilities with 1 providers per facility	7800	
4	24x7 PHC @ 1per month= 12 monthx 30 cases/ provider x 10 facilities with 1 provider per facility	3600	

Illustration: 2

Sterilization services possible in a district of an average population of 10 lakhs are around 10,380 cases as illustrated below:

(This illustration is also applicable for a district with a population of 20 lacs approximately but in a high focus state with weak infrastructure and low density and penetration of primary health care structures)

S. No	Sterilization Services Possible		Total
1	DH @ 1 per week = (52 weeks x 30 cases / provider x 2 provider x 1 facility)	3120	10380
2	SDH@ 1 per week = (52 weeks X30 cases / provider x 1 provider x 1facility)	1560	
3	CHC / BPHC@ 1 per 2 wks = (26 weeks x 30 cases/ providerx 5 facilities with 1 providers per facility	3900	
4	24x7 PHC @ 1per month= 12 monthx 30 cases/ provider x 5 facilities with 1 provider per facility	1800	

5.4.5 Human Resource Development for FDS in Male and Female Sterilizations

a) Qualification and Eligibility of Providers

Qualification and eligibility of providers for various type of sterilization services has been detailed in section-I under General aspects of Sterilization

b) Human Resource requirement for sterilization services:

Illustration: 1

Approximate number of providers required for the following procedures in a district with 20 lac population is around 30

S. No	Facility	Number of facilities	Number of providers for Procedures			
			NSV	Minilap Sterilization	Laproscopic Sterilization	All Procedures
1	DH	1	1	2	1	4
2	SDH	1	1	1	1	3
3	CHC/Block PHC	10	4	10	0	14
4	24X7 PHC	10	4	5	0	9
	Total	**22**	**10**	**18**	**2**	**30**

Illustration: 2

Approximate number of providers required for the following procedures in a year in a district with 10 lac population is around 18

S. No	Facility	Number of facilities	Number of providers for Procedures			
			NSV	Minilap Sterilization	Laproscopic Sterilization	All Procedures
1	DH	1	1	2	1	4
2	SDH	1	1	1	1	3
3	CHC/Block PHC	5	2	5	0	7
4	24X7 PHC	5	2	2	0	4
	Total	**12**	**6**	**10**	**2**	**18**

5.4.6 Strengthening Physical Infrastructure of Identified Facilities

The facility identified for providing female/male sterilization services should have the infrastructure requirement as per the guidelines provided in this manual at Annexure 5. Accordingly efforts should be made to upgrade to those levels

5.4.7 Publicizing Information on FDS Service in Sterilization in Designated Centres

To generate enough client load, regular and systematic demand generation activity in the form of posters, pamphlets and audio and video materials should be undertaken by the district to make the community aware of the sterilization service availability in the various health facilities. The ANMs, AWWs, ASHAs should also disseminate this information during the Village Health and Nutrition Days. The IEC budget provided under NHM may be utilized for publicizing Information.

5.4.8 Monitoring FDS Service Output

For ensuring fixed day service in sterilization the District Family Welfare officer has to monitor

- Regularity of services
- Performance in terms of numbers with quality achieved

5.4.9 Monitoring Performance Standards of Trained Service Providers

Monitoring of quality of service by the District Quality Assurance Committee need to be conducted as per Annexure 6 (Facility Audit).

Adherence to the guidelines of GOI on norms and quality of services provided is essential for achieving the goals and objectives set out for FDS services.

5.4.10 Providing Clear Financial Guidelines for FDS

Based on the guidelines presented here the states need to incorporate their strategy, action plan and budget requirement for FDS services in their annual NHM PIPs.

5.4.11 Ensuring Prompt Payment of Compensation Money to Clients and Team of Providers

The compensation money to clients should be paid immediately after the surgery as this is a compensation for loss of wages. The amount due for service providers also needs to be paid promptly as these are performance based compensations and act as an enabling factor for providing services, especially in low infrastructure setting facilities.

Chapter 6.
Prevention of Infection

Health care facilities are primary settings for infection transmission. It is mandatory to practise appropriate infection-prevention procedures at all times, with all clients. The objectives of infection prevention practices are to minimize the risk of transmission of infections including HIV, Hepatitis B and C to service providers, clients and community, prevent spread of antibiotic-resistant micro-organisms, reduce the overall cost of health care services and provide high-quality, safe services for greater client satisfaction.

Standard Universal Precautions of infection prevention include: hand wash, self-protection by using attires, safe practices to prevent injuries from sharps, maintaining proper environmental asepsis, processing of instruments and reusable items and proper waste-disposal.

6.1 Hand Wash: Most effective way to reduce transmission of infection

- **Routine Hand Wash using Soap & water:** should be done before wearing and after removing gloves, after having any direct contact with a client and after contact with body fluids.
- **Surgical Scrub** The surgeon and assistants must scrub both their hands and forearms above the elbows thoroughly with soap and running water or antiseptic agents for 3-5 minutes repeating procedure for at least three times. The hands and forearms should be dried with sterile towel or air dried.
- **Hand Wash with antiseptic hand-rub:** Ideally, the surgeon and the assistant should scrub thoroughly between each procedure. In high case load (like camp settings), in order to prevent re-colonization of the skin by micro-organisms, the surgical staff should do surgical scrub every hour or after every five cases (whichever is earlier) 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. In between antiseptic alcohol scrub should be done

6.2 Self-protection by using Attires: like gloves, cap, eye shield, mask, apron OT shoes

All health service providers should wear protecting gloves during all procedures involving contact with any client and biological fluids. Three types of gloves are used in the clinical practice:

- **Examination:** used for taking intravenous samples; in OPD while performing bimanual examination of non-pregnant women; touching intact skin and mucosa.
- **Surgical:** used for surgical procedures.
- **Utility:** used to clean the used instruments, linens, surfaces and handling waste.

For female sterilizations, all medical personnel working in the OT must change their shoes, wear theatre gowns/short-sleeved shirts, pyjamas, caps, masks, glasses for eye protection and surgical gloves. For vasectomy procedures that are not done in the OT, all medical personnel must at least wear caps, masks, surgical apron and sterile surgical gloves. The surgical mask should cover the bridge of the nose at all times.

6.3 Safe Work Practices: Handling Sharp Items

Sharps have the highest potential to spread infection by transferring the micro-organisms directly into the blood and it is vital that sharp items used during the procedure be handled with great care to avoid chances of injury by them. Safe handling of sharp instruments requires using

the '**Hands Free** technique' by placing them in a kidney tray. Accidental needle-stick injuries occur mostly during the removal of the needle from the syringe or during cap replacement. Therefore before disposal, used needles should not be bent, broken, recapped or removed from the syringe. If recapping is absolutely necessary, use one hand technique. Immediately after use, sharp objects should be disposed off in a puncture-resistant container. In case, despite best efforts, accidental exposure to needle pricks or cuts occurs, follow the NACO PEP guidelines.

6.4 Environmental Asepsis

Asepsis protocols should be followed at all the facilities. 0.5% chlorine solution and detergent should be used for scrubbing of procedure rooms from top to bottom and before surgery and after surgery, operating table, table/counter top and light handles with a cloth. 0.5% chlorine solution should be used for cleaning floor and managing spills. OT, when not in use should be locked and cleaned weekly by scrubbing top to bottom with 0.5% chlorine solution and detergent. The entry of people and their movement inside the OT should be minimal.

6.5 Processing of Equipment, Instruments and Other Reusable Items

Proper processing of instruments and other reusable items minimizes the risk of transmission of infection.

Steps for Instrument Processing:

a) **Decontamination:** Used Surgical instruments, reusable gloves and other items before cleaning should be decontaminated by soaking in 0.5% Chlorine solution for 10 minutes. It assists disinfection and protects from HIV, HBV/HCV and removes tissue and body fluids. A fresh chlorine solution should be prepared at the beginning of each day. The chlorine solution should be discarded after 24 hours or earlier when it is visibly dirty. Laparoscope should be decontaminated prior to HLD with cotton/gauge swab soaked in spirit. **Chlorine solution should not be used for decontamination of laparoscope.**

b) **Cleaning:** The instruments and other items should be scrubbed vigorously with a tooth brush in water with detergent solution to remove all blood, tissue, other residue and reduces the number of micro-organisms and endospores. The items should then be rinsed thoroughly with water and allowed to dry with soft cloth or air-dried or placed directly for HLD by boiling.

c) **High-level Disinfection (HLD):** is effective in eliminating all micro-organisms except endospores and acceptable 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 for 20 minutes by soaking in a chemical solution like 2% glutaraldehyde solution.

d) **Sterilization:** eliminates all micro-organisms, including endospores. It can be done by using steam (autoclaving at 15 lb/sq inch pressure for 20 minutes for unwrapped and 30 minutes for wrapped instruments and linen or by soaking in a chemical solution like 2% glutaraldehyde solution for at least 8 hours.

e) **Storage**: Use high-level disinfected or sterilized instruments and linens immediately, or store them for up to 1 week in a high-level disinfected or sterilized air tight container accordingly with a tight fitting cover.

ITEM-WISE RECOMMENDED METHODS

Material	Method	Procedure
Linens (drapes, sponges, scrub suits etc)	Autoclave	At 15 lbs/Sq. inch pressure for 30 minutes. Use within one week but if drum is opened, use within 24 hours.
Rubber items (gloves, catheters and rubber tubing)	Autoclave	Wrap rubber items in paper/newspaper before Autoclaving at 15 lbs/Sq. inch pressure for 30 minutes. Gloves should always be used 24 - 48 hours after Sterilization, so that they regain their elasticity.
	HLD by boiling	Boil them in an immersed state for 20 minutes after water comes to rolling boil, then use immediately.
Surgical Instruments	Sterilization by Chemical	Immerse in either Paracetic acid: for 30 minutes (or)Glutareldehyde 2%: 8-10 Hours
	Autoclave	At 15 lbs/Sq. inch pressure, 30 minutes for wrapped and 20 minutes for unwrapped items.
	HLD by boiling	After water comes to rolling boil, boil in immersed state for 20 minutes
	HLD by Chemical	Paracetic acid: 10 Minutes (or) Glutareldehyde 2%: 20 Minutes

6.6 Waste Management

It is important to dispose off all kinds of waste properly as improper disposal of biomedical waste poses health risk to the health care providers and community. All waste in a health facility can be divided into:

1. **General waste:** The waste that poses no risk of infections. It is similar to household trash.
2. **Biomedical waste:** Material generated in the management of clients, including blood, blood products and other body fluids, bandages/surgical sponges and organic waste such as human tissues, body parts,placenta and products of conception.
3. **Sharps:** Like needles, blades, broken glass etc.

There are four steps in the waste management plan:

1. **Segregation:** Health facilities should use color coded bags or containers to collect different types of waste like
   - Black bin: for general waste.
   - White/Blue bin/Puncture-proof container: for sharps such as needles, blades, broken glass etc.
   - Yellow bin: for anatomical waste such as placenta, body parts, swabs etc.
   - Red bin: for infected plastics, syringes, dressings, gloves, masks, blood bags, urine bags.
2. **Collection and Storage:** Waste should always be collected in covered bins and filled upto not more than three-fourth level. Never overfill the bins and store waste beyond 48 hours.
3. **Transportation:** Transportation of waste should always be in closed containers.
4. **Disposal of Waste:** Should be done as per GOI guidelines.

Chapter 7.
Skill Training in Sterilization for Doctors

7.1 Training Needs Assessment

An important element of Quality of care is dependent on the knowledge, skill and attitude of health care providers during their service delivery. A situational analysis of the current status of service providers at the different levels of health facilities in the district will help to identify the gaps and performances. This will help to determine and plan the most appropriate interventions such as Refresher Training and Induction Skill Training, so that a cadre of competent service providers can be developed. Based upon the need of the districts the service providers can be trained in various sterilization procedures. The training load can be calculated using the following RAG analysis.

Calculation of the Training Load

Technique of Sterilization	DH/SDH			CHC/BPHC			PHCs		
	R	A	G	R	A	G	R	A	G
Minilap									
Laparoscopy									
Conventional Vasectomy									
NSV									

R- Required; A- Available; G – Gap (RAG)

7.2 Criteria for Designation of 'Training Centres'

The public health care facilities conducting an average of 600 sterilization (laparoscopic and minilap abdominal tubectomy each) cases per year (an average of 50 cases per month) and an average of 300 NSV cases per year (an average of 25 cases per month) can be designated as 'Training Centers'. These training centres should have a training room and audio visual aids. The States should aim at developing at least 1 'Clinical Training Centre' per district. These training centres can be in district and sub district facilities providing RCH services. Identification and designation of these training centres at State and District level will be the responsibility of SQAC/ Director Family Welfare and DQAC/ CMO whichever is applicable.

7.3 Criteria for Designation of 'Trainers'

Trained service providers (MBBS and above) with competency/proficiency in the skills of counselling and technique of sterilization procedures (either female or male) and have experiences in such service for at least three years, in a static center which performs an average of 600 sterilization cases per year (an average of 50 cases per month) and also willing to become a trainer and spare time to conduct training and followup visits for onsite support/handholding, if required, can be designated as a trainer by SQAC/Director Family Welfare at State level and by DQAC/CMO at District level.

7.4 Criteria for selection of 'Trainee':

The eligibility criterion for selection of a trainee is detailed as follows

Sterilization	Training	Basic Qualification Requirement of Service Provider
Female	Minilap sterilization	• Specialists in surgical fields other than ObGyn • MBBS
	Laparoscopic sterilization	• DGO, MD/MS in ObGyn • Specialists in other surgical fields • MBBS performing Minilap sterilization
Male	Conventional vasectomy	• MBBS and above
	No-scalpel vasectomy (NSV)	• MBBS and above

Selection of the trainee should be done by the CMO/District Training Coordinator from the facilities where:

- There is need for the service.
- The trainee has basic knowledge to master the specific training objectives.
- The trainee is interested to seek training to become a service provider.

7.5 Duration of Training

- Refresher Training: 03 working days
- Induction Skill Training: 12 working days (for female sterilization) and
  05 working days (for male sterilization)

7.6 Number of Trainees per Batch

Upto 4 doctors in a batch depending on the case load of that particular method per day in the training center both for female & male sterilization. Districts may propose to train a batch of Medical Officer, Staff Nurse and OT Technician from a health centres as a team for female sterilization.

7.7 Training Design

The goal of clinical training is to assist trainees in learning to provide safe high quality sterilization services through improved work performances.

To achieve this, the whole training is to be competency based, that require knowledge, attitude and skills, provided sufficient time is allowed and appropriate training methodology are used. The emphasis during both female & male sterilization training is on demonstration, model practice and supervised surgical practice. Though there are some theoretical sessions but more emphasis should be laid on participatory methods such as questioning, role plays, case studies, observation and discussion.

Each trainee must observe/assist at least five sterilization procedures (minilap/ laparoscopic sterilization / conventional/ no-scalpel vasectomy) and perform at least five independently to be certified as service provider for that method.

7.8 Knowledge Assessment

The knowledge assessment questionnaires as provided in the Annexure in the 'Reference Manual for Female & Male Sterilization' respectively, is designed to assess the knowledge before, during and after the training. The trainer can use the result to customize the training to best suit the trainees.

7.9 Skill Assessment

In a competency based training the performance of trainees will be assessed using the skill check lists as provided in the Annexure in the 'Reference Manual for Female & Male Sterilization'. Trainees should not begin supervised surgical practice until the trainer is satisfied of their skill on the model. Although the minimum number of cases to assist & perform has been specified, trainee may not still be competent and confident to perform independently and require some more clinical practice than others. Trainer should evaluate the clinical performances of trainee as satisfactory using the score sheet for the specific method.

If the client caseload is not sufficient for all trainees to receive enough surgical practice, make arrangements for follow-up training. Trainer may choose to invite participants back individually or as a group or may choose to visit their facilities to provide training, follow-up and certification.

7.10 Follow-up

Learning about sterilization technique does not end at the completion of the course. At the end of training, most trainees will have gained skill in a new technique; with practice they will gain competency over the next few months and gradually proficiency. The follow-up should be conducted within 2 to 3 months by District Training Coordinator or CMO.

7.11 Certificate of Training

Certification of the trainee will depend on the trainees' skill and ability to perform the sterilization procedure of the respective method, which indicates that the trainee has demonstrated the competency needed to perform the procedure independently. Once the trainer is fully satisfied about the trainees' skill acquisition and competency to perform the procedure independently, the Hospital that conducts the training shall issue a 'Certificate of Training' to be signed by the Trainer and In Charge of the hospital (MS/CS/MO I/C)

Schedule for Refresher and Skill Induction Trainings for different procedure of Female and Male Sterilization are given in the 'Reference Manual for Female and Male Sterilization'.

SECTION -II
QUALITY ASSURANCE

Chapter 8.
Quality Assurance in Sterilization Services

The Quality in Sterilization services is an essential component to assure client's satisfaction. This section is important for the service providers to enable them in delivering sterilization services as per the standards and guidelines. It is also important for program managers as it helps them in monitoring of the program as per standards.

8.1. Definition

Quality Assurance (QA) may be defined as a cyclical process involving assessment leading to improvement, followed by further assessment and improvement. It is designed to objectively and systematically monitor and evaluate services offered to clients in accordance with pre-established standards and to resolve identified problems and pursue opportunities for improving services, leading to client satisfaction.

8.2 Quality of Care

Quality of care is defined as 'attributes of a service programme that reflects adherence to professional standards, a congenial service environment and satisfaction on the part of the user'.

8.2.1 Inputs, Processes and Outcomes for Quality of Care

INPUTS

Inputs denote programme efforts that facilitate the readiness of the facilities to provide services when a client visits the clinic. Inputs also include qualified providers, physical infrastructure, supplies and equipment etc. The availability of inputs is critical for delivery of services as per the service-delivery guidelines and protocols in place.

Please refer to Section I, chapter 1 for following:

- Qualification requirements for service providers.
- Empanelment of doctors for performing sterilization.
- Eligibility criteria for performing sterilizations.

Standards for physical infrastructure for static services is mentioned in Annexure 5.

PROCESSES

The processes include technical and interpersonal dimensions and encompass a range of elements. The protocols for the key processes are detailed in Chapter 1.

The processes for observation and measurement of quality care are discussed in subsequent sections of this chapter.

OUTCOMES

The outcomes of quality services result in achieving the programme goals.

Provision of sterilization services as per the guidelines and standards in place will result in satisfied clients by:

- Meeting the unmet needs for limiting methods.
- Reducing failures.
- Minimizing complications.
- Preventing mortality.

8.3 Quality Assurance Committee

Subsequent to the orders of the hon'ble Supreme Court of India in the Ramakant Rai vs. Union of India case dated 1.3.2005 regarding quality of sterilisation services in India, Quality Assurance Committees have been formed by all states at the State and District level to ensure that the standards for female and male sterilization as laid down by the GOI are followed in respect of pre-operative measures, operational facilities etc. The committee consisted of 10 members at the state level and 9 members at the district level.

The Government of India has now taken a decision to expand the scope of this committee beyond Family Planning to include all services under RMNCH+A, disease control programmes and other hospital services.

Keeping in mind the expanded scope of activities that has now been brought under the ambit of the QA structures at the state and district levels, these committees have been revised as per structure and function described below.

The composition of the Committee would now be as follows:

8.3.1 At State Level: State Level Quality Assurance Committee (SQAC)

Composition:

1. Secretary, Medical and Health (Chairperson)
2. Mission Director –NRHM (Vice Chairperson)
3. Director Family Welfare/Director Health Services/Director Public Health/Equivalent (Convener)
4. Additional/Joint Director (FW)/Deputy Director (FW)/Equivalent, designated by the state government as the nodal officer for the Quality Assurance Cell (Member Secretary)
5. Director, Medical Education
6. Director/Principal of state training institution e.g. SIHFW/ CTI/ RHFWTC
7. One Empanelled Gynaecologist (from public institutions)
8. One Empanelled Surgeon (from public institutions)
9. One Anaesthetist (from public institutions)
10. One Paediatrician (from public institutions)
11. State Nursing Adviser/ Equivalent
12. One member from an accredited private sector hospital/ NGO (health care sector)
13. One representative from the legal cell
14. One representative from medical professional bodies e.g. FOGSI/IMA/ IAP/IAPSM/ Association of Public Health
15. Any other member or representatives of public health organisations of eminence as nominated by the state government

Terms of Reference of SQAC:

- Developing the Quality Assurance Policy& Guidelines for the State.
- Ensuring attainment of the Standards for Quality of Care by Public Health Facilities.

- Mentoring the state/district level units.
- Periodic Review of the progress of QA activities.
- Review and adjudicate compensation claims under the National Family Planning Indemnity Scheme for cases of deaths, complications and failures following male and female sterilisation procedures.
- Supporting quality improvement process.
- Reviewing Key performance indicators of quality.
- Reporting and sharing the reports of committee on website and with all stakeholders .

A 5 member SFPIS "State Family Planning Indemnity Subcommittee" from within the SQAC would redress, dispose and disburse claims/complaints received through the DQAC, to the district health society as per procedure and time frame laid down in the FPIS manual.

The SFPIS would comprise of the following:

1. Mission Director –NRHM (Chairperson)
2. Director Family Welfare/Director Health Services/Director Public Health/ Equivalent (Convener)
3. Additional/Joint Director (FW)/Deputy Director (FW)/Equivalent (Member Secretary)
4. Empanelled Gynaecologist (from public institutions)
5. Empanelled Surgeon (from public institutions)

Terms of Reference of the Subcommittee:

- Visit both public and private facilities providing family planning services in the state to ensure implementation of national standards.
- Review and report deaths/complications attributable to Sterilization in the state.
- Review and report conception due to failure of sterilization in the state.
- Give directions on implementation of measures to improve quality of sterilization services.
- Review the implementation of the National Family Planning Indemnity Scheme / payment of compensation in the state.
- **The "State Family Planning Indemnity Subcommittee" would meet every six months or sooner if warranted.**
- **At least three members would constitute the quorum of this sub-committee.**

8.3.2 At District Level: District Level Quality Assurance Committee (DQAC)

Composition:

1. District Collector, Chairperson
2. Chief Medical Officer/District Health Officer (convener)
3. District Family Welfare Officer/RCHO/ ACMO/ equivalent (member secretary)
4. Nodal Officers of Programme Divisions at districts

5. One empanelled gynaecologist (from public institutions)
6. One empanelled surgeon(from public institutions)
7. One anaesthetist (from public institutions)
8. One paediatrician (from public institutions)
9. One representative from the nursing cadre
10. One representative from the legal cell
11. One member from an accredited private sector hospital / NGO (health care sector)
12. One representative from medical professional bodies e.g. FOGSI/IMA/IAP/IAPSM/ Association of Public Health

Terms of reference of DQAC:

- Dissemination of QA policy and guidelines.
- Ensuring Standards for Quality of Care.
- Review, report and process compensation claims for onward submission to the SQAC under the National Family Planning Indemnity Scheme for cases of deaths, complications and failures following male and female sterilisation procedures.
- In case a facility reports a sterilisation related death, the convenor of the DQAC should inform the convenor of the SQAC within 24 hours. Death audit needs to be undertaken by the DQAC and report sent to the state with a copy to the Ministry of Health & Family Welfare, Govt. of India, within one month of the death being reported.
- Capacity building of DQAU and DQT.
- Monitoring QA efforts in the district.
- Periodic Review of the progress of QA activities.
- Supporting quality improvement process.
- Coordination with the state for dissemination and implementation of guidelines, support for the visits of SQAC/SQAU to the districts,sharing minutes of DQAC meeting and monthly reports,corrective actions & Preventive actions.
- Reporting and sharing the reports of committee on website and with all stakeholders .

However a 5 member DFPIS "District Family Planning Indemnity Subcommittee" from within the DQAC would process claims received from the clients and complaints/ claims lodged against the surgeons and accredited facilities, as per procedures and time frame laid down in the FPIS manual.

The subcommittee would comprise of the following

1. District Collector, (Chairperson)
2. Chief Medical Officer/District Health Officer (convener)
3. District Family Welfare Officer/RCHO/ ACMO/ equivalent (member secretary)
4. Empanelled gynaecologist (from public institutions)
5. Empanelled surgeon (from public institutions)

Terms of Reference of the Subcommittee:

- Conducting medical audit of all deaths related to Sterilization and sending reports to the State QA committee Office.

- Collecting information on all hospitalization cases related to complications following sterilization, as well as sterilization failure.
- Reviewing all static institutions i.e., Government and accredited Private/NGOs and selected Camps providing sterilization services for quality of care as per the standards and recommend remedial actions for institutions not adhering with standards.
- Review, report and process compensation claims for onward submission to the SQAC under the National Family Planning Indemnity Scheme for cases of deaths, complications and failures attributable to male and female sterilization procedures (for detailed procedures to be followed please refer to the manual on "Family Planning Indemnity Scheme 2013, Ministry of Health & Family Welfare, Government of India").
- In case a facility reports a sterilization related death, the convenor of the DQAC should inform the convenor of the SQAC within 24 hours. Death audit needs to be undertaken by the DQAC and report sent to the state with a copy to the Govt. of India, within one month of the death being reported.
- **The "District Family Planning Indemnity Subcommittee" would meet every three months or sooner if warranted.**
- **At least three members would constitute the quorum of this sub-committee.**

Please refer to "Manual for Family Planning Indemnity Scheme", Oct. 2013 of MoHFW for further details.

8.3.3 AT FACILITY LEVEL: Quality Circle (QC): (Suggestive)

Sterilization services are being provided to the people at various government and accredited private/NGO outlets. At each service delivery site, sterilization service needs to be monitored and reviewed periodically. This task can be performed by service providers from the facility itself through a process of self-assessment that will identify issues related to quality improvement, help in resolving the identified problems, recommend solutions and ensure that high-quality services are provided. Empirical evidence suggests that over a period of time such processes engage the attention of the personnel working in the facility, leading to improvements that are more sustainable.

For institutions such as District/Civil/Sub-divisional/Referral/Rural Hospitals/ CHCs/ BPHCs Quality Circles comprising of a team of medical, paramedical and other support staff should be constituted, depending on the size of the institution being monitored, for reviewing the quality of services periodically.

The suggested composition of the Quality Circles is as follows:

- I/C Hospital/Medical Superintendent: Chairperson
- I/C Operation Theatre/ I/C Anaesthesia,
- I/C Surgery
- I/C Obstetrics and Gynaecology
- I/C Nursing
- I/C Ancillary Services (ward boys)
- I/C Transport
- I/C Stores
- I/C Records

At the level of CHC, a smaller committee of 4 to 5 members comprising of the Medical Superintendent, I/C Surgery, I/C Obstetrics and Gynaecology, I/C OT and I/C Nursing should be constituted.

The scope of work of this QC will include all the processes involved in the sterilization services being provided at the facility.

Terms of Reference of the QC:

- Identifying critical quality processes in light of the standards for sterilization;
- Reviewing the processes with the help of the checklists on facility audit/observation of sepsis and surgical procedure (Annexures 6, 17)
- Developing a work plan listing activities for improvement and putting this into action.
- The committee should meet each quarter; it should minute the meetings and keep a record of its discussions.

8.4 Quality Assessment and Improvement

The quality of sterilization services provided can be assessed through the already existing documentation tools available at the facilities specifically designed for this purpose. The areas requiring improvement should be identified using these tools and this will ultimately be beneficial in improving the overall quality of the services delivered.

8.4.1 Review of Registers and Records

The facility registers and client records need to be reviewed frequently to check if record keeping is being done correctly and completely. It should be ensured that these registers and records contain information pertaining to the demographic details of the clients, informed consent, complete examination, details about the procedure done etc. The eligible couple registers (EC Registers) and the sterilization registers maintained at the government health facilities provide detailed information on the sterilization services provided to the eligible couples. During the routine monitoring visits by the programme managers, a sample of these records should be reviewed. The report on the basis of the routine record reviews undertaken by the different members of the team should be compiled quarterly.

8.4.2 Facility accreditation and Monitoring Audit

Facility assessment (using the facility observation checklist provided in Annexure 6) should be done quarterly by the District QAC to assess at least 10 per cent of the facilities. The purpose of this tool is to assess the readiness of facilities in terms of the requisite inputs for providing sterilization services. This checklist will be uniformly enforced to all identified static facilities, camps and accredited private facilities. Senior officers from the Directorate will also be required to assess the camps and static facilities on a routine basis. Feedback should be given in writing to the person responsible for this activity/area. If there is a pattern in the problems identified, then a detailed note should be prepared discussing the adoption of remedial measures and this note should be shared with the state-level committee.

8.4.3 Procedure Observation

In order to assess whether correct surgical procedures and asepsis practices are being followed, the observation of procedures should be adopted by members of the District QA team visiting the health facilities/camps where sterilization services are being provided using the checklist given in Annexure 17.

8.4.4 Client Exit Interview

A quick assessment of the quality of sterilization services provided at the health facilities/ camps from the perspective of the clients should be obtained through client exit interviews. This tool (Annexure 19) is useful in measuring the client's satisfaction and also in addressing the gaps in service quality. It should be uniformly enforced by the District QA team to the clients coming out of the facility after accepting sterilization services and should be undertaken on a voluntary basis.

8.5 Reporting of Sterilization Deaths, Complications and Failures

8.5.1. Report on Sterilization Deaths

Following procedures are to be adhered to for reporting of sterilization deaths.

8.5.1.1 Sterilization Death Notification

Sterilization deaths are to be reported in the Death Notification Form (Annexure 12) to the District CMO, i.e. the convener of the District QAC, within 24 hours of death by telephone, e-mail, or in person. The operating surgeon of the case should also be informed simultaneously of the occurrence of death so that he/she may fill up Death Notification Form within 7 days of intimation and send it to the District QAC.

- It is the responsibility of the Medical Officer at the institution where the death occurred to fill in Death Notification Form.
- A copy of the Death Notification Form must also be sent to the state-level convener.

Following the immediate notification of death by the medical officer, the operating surgeon should review the records and complete (Annexure13) on sterilization deaths and send it to the convener of the District QAC within 7 days. A copy of the records and the autopsy report and other pertinent information should be forwarded along with this report to officials as indicated earlier.

8.5.1.2 Death Audit Report

The District QAC will review the report, discuss the findings, conduct a field investigation and make recommendations for corrective action. The District QAC will then complete the Death Audit Report (Annexure14).

The Death Audit Report should be presented by the District QAC within 30 days to the state-level committee, which will then forward it to the Government of India with their comments on Annexure 18.

8.5.2 Report on Sterilization Complications

The report on complications requiring hospitalization attributable to sterilization is to be filled in by the District QAC of the district where the client has reported (Annexure 16).

The reportable complications are as follows:

- Any problem directly related to surgery and/or anaesthesia that occurs within 60 days of the operation and intervention or management beyond what is normally required and that necessitates hospitalization;
- Blood transfusion is required;

- Any problem arising out of additional unplanned surgery other than that of the fallopian tubes, mesosalpinx or vas deferens at the time of the sterilization procedure;
- Any subsequent operation/operations related to the original surgery.

The DQAC should conduct a field investigation/enquiry, review the case record, discuss the findings and make recommendations for corrective action.

8.5.3 Report on Sterilization Failures

Sterilization failure is defined as any pregnancy that occurs after certification of the sterilization operation. In case of suspected pregnancy after the sterilization procedure, investigations such as urine test for pregnancy, USG and semen examination (in the case of male clients) should be conducted.

The report on failure attributable to sterilization is to be filled in by the District QAC of the district where the client has reported within two weeks of reporting (Annexure 16). The District QAC will conduct a field investigation /enquiry, review the case record and report the findings to the state committee.

A final report of the audit is to be sent to all those who are involved in the audit process, including the Medical Superintendent /Officer In-Charge/Administrator and other appropriate persons concerned at the institution where the death has occurred. The recommendations are to be shared with the concerned staff.

The audit records should be kept for ten years for the purpose of comparison and for facilitating future audits. Copies are to be kept in a medical audit binder.

The processing and settlement of the death, failure and complication claim should be done by the District QAC where the client has reported.

The District QAC will also be responsible for communicating information related to the concerned SQACs for compensation in case of complications/ failures/deaths.

8.6 Family Planning Indemnity Scheme

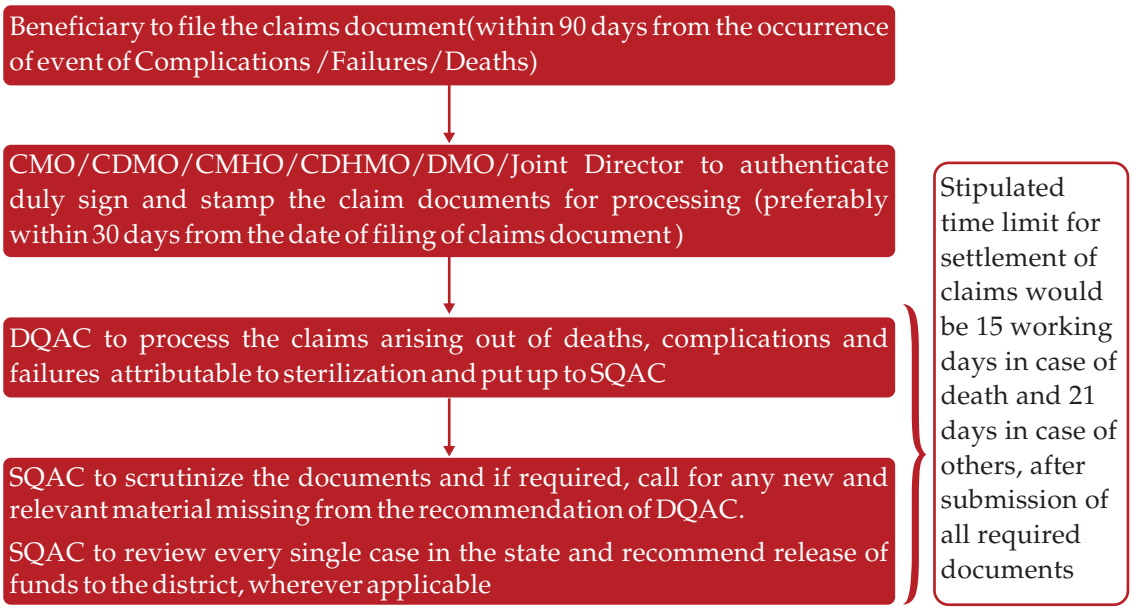
Family Planning Indemnity Scheme indemnifies all clients of sterilization as also doctors/ health facilities conducting sterilization operation in both public and accredited private/NGO sector health facilities for unlikely events of complications/failures/deaths attributable to sterilization operations.

The available benefits under the Family Planning Indemnity Scheme are as under:

Section	Coverage	Limits
IA	Death attributable to sterilization (inclusive of death during process of sterilization operation) in hospital or within 7 days from the date of discharge from the hospital	Rs. 2 lakh
IB	Death attributable to sterilization within 8 - 30 days from the date of discharge from the hospital	Rs. 50,000/-
IC	Failure of sterilization	Rs 30,000/-
ID	Cost of treatment in hospital and upto 60 days arising out of complication attributable to sterilization operation (inclusive of complication during process of sterilization operation) from the date of discharge	Actual not exceeding Rs. 25,000/-
II	Indemnity per Doctor/Health Facilities but not more than 4 in a year	Upto Rs. 2 Lakh per claim

Note: The details of the scheme is available in the 'Manual for Family Planning Indemnity Scheme', available on http://nrhm.gov.in/nrhm-components/rmnch-a/family-planning/ schemes.html

Steps of the Claim Process



8.7 Periodicity of Assessment

The DQAC should conduct quality assessments as per schedule below.

Service Venue	Frequency	Responsibility
Camps	5 per cent camps in each quarter	1-2 members of the District QAC
Static facilities	2 each month	1-2 members of the District QAC
Accredited private/NGO facilities	1 each month	1-2 members of the District QAC

8.8 Things to Assess during Monitoring Visits

Members of DQAC monitoring service venues (Camps, Facilities and Accredited private/NGO facilities) need to assess following things:

1. Facility readiness as per Annexure 6.
2. Asepsis and surgical procedure as per Annexure 17.
3. Clients' perspective on quality of sterilization services (10 percent of clients in each camp / facilities visited need to be interviewed as per Annexure 19.)

These filled in checklists duly signed by the visiting DQAC members may be compiled and stored for at least one year. Issues emerging from the visits should be discussed for remedial action during DQAC meetings and must be reflected in the minutes of the meeting.

DQAC should be able to share the findings of the assessment along with filled checklist to the monitoring authorities from state and centre

8.9 Orientation for Assessors

From the programmatic point of view, the State QAC needs to organize an orientation programme for the members of the QAC for implementation of quality assurance activities with special reference to the use of monitoring tools and checklists.

8.10 Implementing Remedial Action

The basic thrust of audit activities is to improve the quality of client care through educating the provider. Remedial actions should be specific, including setting a target date and identifying the person who will be responsible for the activity.

- Ensure that the type of action proposed is **simple to implement, the least expensive and the most effective** for achieving long-term results.
- Providers should correct individual record deficiencies when possible (for example, completion of required lab tests for a client who is still under treatment).
- The individual in charge of quality assurance should monitor progress in remedial implementation.
- The administrator is responsible for ensuring that remedial actions are implemented.
- In the case of continued and consistent non-compliance, the administrator or medical superintendent should inform the person personally and, if necessary, the provider should be requested to attend a training programme or refresher course on the topic.
- A written note of non-compliance should be kept in the provider's personal file and a copy should be given to the provider. Depending on the situation, the administrator should take further disciplinary action if required.

8.11 Re-audit

A re-audit of issues that have not been resolved should be conducted within three months. In case the results have improved to the point of acceptance by the audit committee, then that issue need not be audited again unless a problem develops. On the other hand, if non-compliance is noted, a re-audit of the unaddressed issue will be required until compliance is achieved.

8.12 Conclusion

In sum, it is vital to objectively and systematically monitor and evaluate family planning services from time to time in accordance with pre-established standards, resolve identified problems and pursue opportunities to improve client care so that high-quality, safe and effective services that satisfy clients' needs are provided and providers' standards are met.

SECTION -III
ANNEXURES

Annexure – 1.

Application cum Consent Form for Sterilization Operation

An informed consent is to be taken from all clients of sterilization before the performance of the surgery as per the consent form placed below

Name of Health Facility: .....

Client Hospital Registration Number: .....

Date: ...../...../20.....

1. **Name of the Client: Shri/Smt.** .....
2. **Name of Husband/Wife: Shri/Smt**. .....
3. **Address** .....
4. **Contact No:** .....
5. **Names of all living, unmarried dependent Children**

   I) .....Age.....

   ii).....Age.....

   iii).....Age.....

   iv).....Age.....

6. **Father's Name of beneficiary:** Shri.....
7. **Address:** .....
8. **Religion/Nationality:** .....
9. **Caste- SC/ST/General:** .....
10. **Status- APL/BPL**
11. **Educational Qualifications**.....
12. **Business/Occupation:** .....
13. **Operating Centre:** .....

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

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 have/has not been sterilized previously **(not 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 and I also know that there are chances of failure of the operation for which the operating doctor and health facility will not be held responsible by me or by my relatives or any other person whomsoever.

c) I am aware that I am undergoing an operation, which 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, which the doctor/health facility thinks suitable for me and to be given other medicines as considered appropriate by the doctor/health facility concerned. I also give consent for any additional life-saving procedure, if required.

f) 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.

g) If, after the sterilization operation, I experience a missed menstrual cycle, then I 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. I shall be responsible for the consequences, if any.

h) I understand that Vasectomy does not result in immediate sterilization. *I agree to come for semen examination **3 months after the operation** to confirm the success of sterilization surgery (Azoospermia) failing which I shall be responsible for the consequences, if any. **(* Applicable for male sterilization cases)**

i) **In case of complications, failure and the unlikely event of death attributable to sterilization, I/my spouse and dependent unmarried children will accept the compensation as per the existing provisions of the Government of India "Family Planning Indemnity Scheme" as full and final settlement and will not be entitled to claim any other compensation including compensation for upbringing of the child, if any, born on account of failure of sterilization, over and above the one offered, from any court of law in this regard.**

I have read the above information or the above information has been read out and explained to me in my own language and that this form has the authority of a legal document.

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.

Date: ……..…. **Signature or Thumb Impression of the Client**

Name of client: ……..……

Signature of Witness (Clients side):

Full Name: ……..……

Full Address:…….....

I am aware that client is ever married and has 1 living child over one year of age

Signature of ASHA/ Counsellor/Motivator:……

Full Name: ……

Full Address: ……

I certify that I have satisfied myself that -

a. Shri/Smt……is within the eligible age-group and is medically fit for the sterilization operation.

b. I have explained all clauses to the client and that this form has the authority of a legal document.

c. I have filled the Medical record–cum-checklist and followed the standards for sterilization procedures laid down by the Government of India.

Signature of Operating Doctor

(Name of Operating Doctor)

Date: ……

Seal

Signature of Medical Officer in-charge of the Facility

(Name of Medical Officer in-charge of the Facility)

Date: ……

Seal

DENIAL OF STERILIZATION

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

1 ……

2 ……

He/ She has been advised the following alternative methods of contraception.

1 ……..

2. ……

Signature of the Doctor making the decision

Date: ……

Name and full Address: ……

Annexure – 2.

Medical Record & Check List for Female and Male Sterilization

This checklist is to be filled by the doctor before commencing the sterilization procedure for ensuring the eligibility and fitness of the client for sterilization.

Name of Health Facility: ……

Beneficiary Registration Number: ……

Date……

A. Eligibility Checklist

Client is within eligible age	Yes..... No.....
Client is ever married	Yes..... No.....
Client has at least one child over one year of age	Yes..... No.....
Lab investigations (Hb, urine) undertaken are within normal limits (7.0 gms or more)	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 given by the client	Yes..... No.....
Explained to the client that consent form has uthority of a legal document	Yes..... No.....
Abdominal/Pelvic examination has been done in the female and is within normal limits	Yes..... No.....
Infection prevention practices as per laid down standards	Yes..... No.....

B. Menstrual History (for female clients)

Cycle Days	
Length	
Regularity	Regular……... Irregular……
Date of LMP (DD/MM/YYYY)	...../...../.....

C. Obstetric History (for female clients)

Number of Spontaneous Abortions	
Number of Induced Abortions	
Currently Lactating	Yes..... No.....
Amenorrheic	Yes..... No.....
Whether Pregnant	Yes..... No..... If Yes (No. of weeks pregnancy)……..
No. of Children	Total No……..
Date of Birth of Last Child (dd/mm/yyyy)	...../...../.....

D. Contraceptive History

Have you or your spouse ever used contraception?	Yes..... No.....
Are you or your spouse currently using any contraception or have you or your spouse used any contraception during the last six months? *(✓) Tick the option*	• None……..…….. • IUCD……...…….... • Condoms……...……..…… • Oral Pills……...……...… • Any Othe (specify)……

E. Medical History

Recent medical Illness	Yes..... No.....
Previous Surgery	Yes..... No.....
Allergies to medication	Yes..... No.....
Bleeding Disorder	Yes..... No.....
Anemia	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 (Male sterilization)	Yes..... No.....
Epididymitis (Male Sterilization)	Yes..... No.....
H/O Blood Transfusion	Yes..... No.....
Gynecological problems (Female Sterilization)	Yes..... No.....
Currently on medication (if yes specify)	Yes..... No.....

Comments……

……

……

F. Physical Examination

BP……Pulse……..Temperature……..

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

G. Local Examination (Strikeout whichever is not applicable)

1. 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….....……

2. Female Sterilization

External Genitalia	Normal…….....…...…….. Abnormal….....……
PS Examination	Normal…….....…...…….. Abnormal….....……
PV Examination	Normal…….....…...…….. Abnormal….....……
Uterus Position	A/V…….....…R/V…….....……. Mid position….....Not determined….....…
Uterus size	Normal…….....…Abnormal - Size……
Uterus Mobility	Yes……No..... (Restricted / Fixed)
Cervical Erosion	Yes….....…...….....….. No….....……
Adnexa	Normal…….....…...…….. Abnormal….....……

Comments…….....

…….....

H. Laboratory Investigations

Hemoglobin level	…….....……Gms%	
Urine: Albumin	Yes…….....….	No….....……
Urine- Sugar	Present…….....……	Absent…….....……
Urine test for Pregnancy	Positive: …….....….	Negative: ……..
Any Other (specify)	……..……	

Name:..... Signature of the Examining Doctor

Date: ..... **HOSPITAL SEAL**

I. Preoperative Preparation

Fasting	Yes..... duration…….hrs. No…..……
Passed urine	Yes No…….
Any other (specify)	

J. Anaesthesia/Analgesia

Type of anaesthesia given *(✓) Tick the option*	• 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

K. Surgical Approach (Strikeout whichever is not applicable)

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.....2-0 Catgut.....
Fascial interposition	Yes.....No…… If no, give reasons..... ....
Length of vas resected	.....Cm
Suture of skin 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:..... **Signature of the operating surgeon**

Date: .....

Female sterilization

Local anaesthesia	Lignocaine .....% Other
Timing of procedure *(✓) Tick the option used*	• Within 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 *(✓) Tick the option used*	• Minilap Tubectomy ♦ With C section ♦ With other surgery..... • Laparoscopy Tubal Occlusion ♦ SPL/DPL.....
Method of occlusion of fallopian tubes *(✓) Tick the option used*	• 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:..... **Signature of the operating surgeon**

Date: .....

L. Vital Signs: Monitoring Chart (For Female Sterilization)

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

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

Name:..... **Signature of the attending staff nurse**

Date: .....

M. Post-Operative Information

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

N. 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 postoperative instructions	Yes..... No.....
Comments	

Name:..... **Signature of the discharging doctor**

Annexure – 3.

Post Operative Instruction Card

Name and type of hospital/facility	
Client's name	
Father's name	
Husband's name/Wife's Name	
Address	
Contact number (if available)	
Date of operation (dd/mm/yyyy)	...../...../.....
Type of operation	Minilap/Post-partum/Laparoscopic (SP/DP)/Conventional Vasectomy/NSV.....

1. Follow-up:
   a) After 48 hours, first contact is established.
   b) On the 7th day for stitch removal.
   c) **Female Sterilization:** After one month or after first menstrual period, whichever is earlier.
      Male Sterilization: After 3 months, for semen examination for sperm count.
   d) In an emergency, as and when required to the nearest health facility.
2. Medication as prescribed
3. Return home and rest for the remainder of the day.
4. **Female Sterilization:** -Resume only light work after 48 hours and gradually return to full activity in two weeks following surgery.
5. **Male Sterilization:** - Scrotal support or snug undergarment for 48 hours.
   -Resume normal work after 48 hours and return to full activity, including cycling, after one week following surgery.
6. Resume normal diet as soon as possible.
7. Keep the incision area clean and dry. Do not disturb or open the dressing.
8. 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.
9. Sexual intercourse:

   Vasectomy / Tubectomy does not interfere with sexual pleasure, ability, or performance

   Female Sterilization: In the case of interval sterilization (Minilap and Laparoscopic), the client may have intercourse one week after surgery or whenever she feels comfortable thereafter.

   In case of post partum sterilization (after caesarian or normal delivery) client may have intercourse 2 weeks after sterilization or whenever she feels comfortable.

Male Sterilization: The client may have intercourse whenever he is comfortable after the surgery but must ensure use of condom if his wife/partner is not using any method of contraception.

10. 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.

11. Contact health personnel or a doctor in case of any doubt.

12 **Female Sterilization:** Return to the facility if there is any missed period/suspected pregnancy, within two weeks to rule out pregnancy.

13. **Male Sterilization:** Return to the facility after three months for semen examination to see if azoospermia has been achieved. If semen still shows sperm return to facility every month till 6 months.

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 (Female Sterilization)			
	After 3 months for semen examination (Male Sterilization)			
Emergency				

Comment .....

.....

Result of Semen Examination:

Name: ..... **Designation:** .....

Signature of the person filling out the report

Annexure – 4.

Sterilization Certificate

Hospital Registration No. (IPD/OPD) _____

1. This is to certify that Smt/ Shri……..... S/O; W/O Shri ..... working as ..... residing at .... has undergone Minilap Tubectomy – (Interval/Post-Partum/Post Abortion/Concurrent with other procedures)//Laparoscopic Tubal Occulsion (Interval/Post Abortion/Concurrent with other surgeries)/Vasectomy Conventional/ NSV) in this facility/hospital .....(Name of facility/Hospital) on ..... by Dr.....

For Female Sterilization:

2. She has resumed her menstrual Cycle (LMP_____) or she has not resumed her menses within the month of sterilization but pregnancy test is negative.

For Male Sterilization:

3. His semen examination undertaken on (Date)_____ revealed no sperm (azoospermia)

**Strike out whichever is not applicable*

She/ He is therefore certified to be sterile

Signature of Medical Officer I/c

Name……..

Date .....

Seal .....

Note: Client should acknowledge 'received' on the duplicate copy before receiving the original copy. The duplicate to be maintained as a record in the facility as per state norms.

Annexure – 5.

Physical Requirement for 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 which offers privacy and ensures avoidance of any interruptions • Laboratory with facilities for urine examination, blood examination (female sterilization), semen examination (male sterilization) • 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 • OT: 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 space available, 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
2	Equipment and Supplies	
3A	Examination Room Requirements	• Examination table • Foot stool • Blood pressure apparatus • Thermometer • Stethoscope **Equipment specific for female sterilization:** • Examination light • Weighing scale • Instrument for pelvic examination

Sr. No	Item	Requirements
3B	Laboratory	• Haemoglobinometer and accessories • Apparatus to estimate albumin and sugar in urine • Reagents
3C	Sterilization Room	• Autoclave • Boiler • Surgical drums • SS Tray • Glutaraldehyde solution 2% / Paracetic acid
3D	Cleaning Room	• Hand Brushes • Utility Gloves • Basins • Detergents • Chlorine Solutions 0.5%
3E	Operation Theatre	• Operating table capable of Trendelenburg position • Step-up stool • Spot light in OT • Instrument trolley • 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 • *Additional for Female Sterilization:* • Minilaparotomy kit • Laparoscopy kit • *Additional for Male Sterilization:* • Conventional vasectomy kit • No-Scalpel vasectomy kit
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

Sr. No	Item	Requirements
		• Tubing and oxygen nipple • Oxygen cylinder with reducing valve and flowmetre and ranch for opening • Blanket • Gauze pieces • Kidney tray • Torch • Syringes and needles, including butterfly sets, IV cannula • Intravenous infusion sets and fluids • Endotrachael tube size 6, 6.5 , 7, 7.5, 8.0 • Laryngeal mask airway size 3, 4, 5 • Combitube • Cricothyroidectomy set • Sterile laparotomy instruments (Additional requirement for female sterilization)
5	Essential Drugs	• Injection Adrenaline • Injection Midazolam • Injection Atropine • Injection Diazepam • Injection Deriphylline • Injection Physostigmine • Injection Xylocaine • 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 (Additional for female Sterilization) • Injection Oxytocin (Additional for Female Sterilization) • Water-soluble jelly • Electrode jelly • IV fluids : 5% Dextrose, 0.9% sodium chloride (normal saline) • Ringer lactate • Plasma Expanders • Glucose 25% • Heta Starch (HES 6%) (Additional for Male Sterilization)

Annexure – 6.

Facility Audit

General Information		
i	Date (D/M/Y)	...../...../.....
ii	Clinic Venue: PHC/CHC/DH/Any Other (Specify)	
iii	Name of the block, district and state	
iv	Name and designation of observer	

		Yes/No	Comments	Suggestions/Recommendations
Infrastructural Facilities				
1	Is the building in good condition (walls, doors, window, roof and floor)?			
2	Is the facility clean?			
3	Is running water available at service points?			
4	Is clean and functional toilet facility available for staff and clients?			
5	Is electricity available?			
6	If there is no running water or electricity, are alternatives available that permit providers to deliver the available services hygienically?			
7	Is there a functional generator/alternative power source available ?			
8	Is petrol oil and Lubricants (POL) available for the generator?			
9	Is there space earmarked for examination and counselling to assure privacy?			
10	Is waiting area with adequate seating facility availabile?			

		Yes/No	Comments	Suggestions/Recommendations
Facilities available at OT				
11	Is there a proper OT Facility available?			
12	Does the OT have running water available?			
13	Is an operation table with Trendelenburg facility (For female sterilization) ?			
14	Is a functional shadow less lamp available?			
15	Is functional suction apparatus available?			
16	Is functional emergency light (through a functional inverter available)?			
17	Is oxygen cylinder with gas and accessories available?			
18	Availability of : • Minilap Instrument • Laparoscopic Set • NSV Set			
19	Instruments for laparotomy (applicable to female sterilization)			
20	Emergency resuscitation equipment like Ambu bag, face mask, airways etc.			
21	Emergency Medicine Tray			
22	Sterilized consumables in dressing			
23	Sterilized surgical attire such as apron, gloves, mask and cap			
24	Other essential requirements			
Contraceptive Stock Position				
25	Buffer stock available for one month: Oral pills, Condoms, IUCD, EC pills			
26	Does the facility have adequate storage facility for contraceptives (away from water and sources of heat, direct sunlight, etc) on the premises?			
27	Do stock outs occur?			
28	Is there an effective logistic system that tracks stock levels and notifies staff when supplies need recording?			

		Yes/No	Comments	Suggestions/Recommendations
Contraceptive Stock Position				
29	Are supplies in good condition (not expired, not damaged, etc)?			
30	Are expired contraceptives destroyed to prevent resale or other inappropriate use?			
Availability of Vehicle				
31	Does the facility have a vehicle/Ambulance in running condition or suitable referral service?			
32	Availability of POL for vehicle			
Information, Education, Communication (IEC) Materials				
33	Clients' rights displayed at a prominent place at the facility			
34	Board displaying service timings			
35	Availability of free and paid services displayed on wall painting			
36	Signboard indicating the direction for each service point displayed			
37	Flip charts, models, specimens and samples of contraceptives available in the counselling room			
38	IEC materials such as poster, banner and handbills available at the site and displayed			
39	Suggestion and complaint system for clients (Complaint box or book)			
Management Information system				
40	Client register and record maintained			
41	Records on Family Planning (FP) (including number of clients counselled			
42	Sterilization records			
43	Follow up records for FP Clients			
44	Regular furnishing of Monthly Progress Reports (MPR)			
45	Does staff complete client records by including information essential for the continued care of clients?			

		Yes/No	Comments	Suggestions/Recommendations
Management Information system				
46	When clients return for follow up services, can staff retrieve their records easily?			
Human Resources				
47	Availability of all staff as per sanctioned posts			
48	Are the various categories of staff adequate for the activities of the centre?			
49	Are the doctors empanelled in the district/ state?			
Infection Prevention				
50	Are the autoclave and instrument boiler functional?			
51	Are needle destroyers available?			
52	Is there a container for disposal of sharp instruments available in the dispensing room?			
53	Mopping of floor and surfaces by liquid bleach			
54	Utility gloves in use for cleaning floor, instruments and linen?			
55	Availability of proper waste disposal mechanisms (Incinerator/ Other)			
56	Final remarks of observer			

Name: ..... **Designation of Observer:**.....

Date: ..... **Signature**

Annexure – 7.

Emergency Equipment, Supplies and Drugs for Sterilization

1	Emergency Equipment	• 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 flowmeter Blanket
2	Emergency Supplies	• Gauze pieces Kidney tray Torch • Syringes and needles, including butterfly sets, IV cannula • IV stand • Intravenous infusion sets and fluids Endotracheal tube, sizes 6, 6.5, 7, 7.5, 8.0 • Laryngeal mask airways, sizes 3,4, 5 Combitube • Cricothyroidectomy set
3	Emergency Drugs	• Injection Adrenaline Injection Atropine Injection Diazepam Injection Deriphylline 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 Mephentermine • Injection Frusemide Water-soluble jelly • Electrode jelly
4	IV fluids	• Ringer lactate • 0.9% Sodium Chloride (normal saline) 5% Dextrose • Glucose 25% • Heta starch (HES 6%)

Annexure – 8.

Mini Laparotomy Kit

Item	Quantity
Sponge-holding forceps	2
Surgical drape (towel with central hole)	1
Syringe, 10 cc	2
Needle, 22-G, 1V2"	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
vulsellum	1
Tubal hook	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 – 9.

Laparoscopic Tubal Occlusion 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
vulsellum	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,	1
Gauze	4
Glutaraldehyde container (plastic with cover)	1
SS tray (to rinse the laparoscope)	2
SS small bowls	2
SS kidney tray	1

Annexure – 10.

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/Small Mayo	1
Scalpel handle	1
Scalpel blade, size 15	2
Stainless-steel bowl, small	1
Sponge holder	1
Surgical tray with cover	1
Gloves, sizes 6/ , 7 and 7/	2 pairs each
Silk suture, 2—0/non-absorbable suture	1
Small round-bodied curved cutting needle	1
Syringe, 5 cc	2
Needle, , 24-G,26G	1
Suspensory bandage	1
Iodophor solution 5%	1 Q.S.
Adhesive Tape	1

Annexure – 11.

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
Metzenbaum scissors	1
Extra-cutaneous vas fixation ring forceps	1
Vas dissecting forceps	1
Non-absorbable suture (2—0 silk)	1
Gloves, sizes 6/ , 7 and 7/	2 pairs each
Syringe, 5 ml	2
Needle, 1.5 inch length, 24-G,26G	2
Iodophor solution 5%	Q.S.
Suspensory bandage	1
Dressing material	2
Adhesive Tape	1

Annexure – 12.

Death Notification Form

Instructions: The Medical Officer (MO) at the institution where the death occurred is responsible for filling out this form and notifying the convener of the district quality assurance committee (DQAC) within 24 hours of death. The information is to be provided mandatorily.		
1	Date of this report (D/M/Y)	……../……./……
2	Date of death (D/M/Y)	……../……./……
3	Name of the deceased	
4	Age	
5	Sex	Female/Male……
6	Address of the deceased	
7	Name of husband/father	
8	Where procedure performed (specify the name of the site) *(✓) Tick the option*	• Camp…… • PP Center…….. • District Hospital…… • Medical College…… • Accredited Private/NGO Facility……
9	Type of procedure A. Female Sterilization *(✓) Tick the option*	• Postpartum…… • Minilap…… • Laparoscopy…… • Any Other……
	B. Male Sterilization *(✓) Tick the option*	• Conventional…… • NSV……..
	C. Other with MTP/CS,etc *(✓) Tick the option*	Yes/No…… If yes, give details……
10	Date of sterilization procedure	D/M/Y……/……/……
11	Describe in detail what happened in chronological order. Include all symptoms and signs and describe all actions taken during the course of addressing the complication (s), beginning with the initial identification of the problem until the occurrence of death. Whenever possible record the time and date of each incident.(Use an appropriate additional sheet of paper if more space is required)	
12	Cause of death	
13	Contributing factor, if any	

14	Postmortem examination performed?	Yes/No…….....………..
15	Name and designation of surgeon who performed the sterilization	
16	Name and Institution where death occurred	
17	Name and designation of reporting officer	

Name: ..... **Designation .....**

Date ..... **Signature .....**

Annexure – 13.

Proforma for Death following Sterilization

Instructions: The surgeon who performed the sterilization operation shall fill out this form within 7 days of receiving intimation of the death from the MO in charge (I/C) of the centre where the death occurred. Copies of the records and the autopsy report and other pertinent information if available, shall be forwarded with this report to the convener of the DQAC.

1	Date of this report (D/M/Y) Type of Institution where the death occurred *(✓) Tick the option* Name of the institution Address Village/Town/City District/State	……/……/…… •Camp…… •PPCentre…… •PHC/CHC…… •District Hospital…… •Medical College Hospital…… •Accredited private/NGO Facility…… …… …… …… ……
2	Name of the person filling out the report Designation Signature	…… …… ……
3	Date of Sterilization (D/M/Y)	……/……/……
4	Location where the procedure was performed *(✓) Tick the option*	•Camp…… •PPCentre…… •PHC/CHC…… •District Hospital…… •Medical College Hospital…… •Accredited private/NGO Facility…… (Also specify the name of the facility)…… ……
5	Type of surgical approach *(✓) Tick the option*	•Minilap…… •Laparoscopy…… •Post-Partum Tubectomy…… •Conventional Vasectomy…… •NSV…… •Any other specify……
6	Date of death	……/……/……
7	Time of death	……am/pm

Client Details		
8	Name	
9	Age	
10	Sex	Female/Male……
11	Spouse Name	
12	Address	
13	Relevant past medical history	
14	Pertinent postoperative physical and laboratory findings	
Sterilization Procedure		
15	Timings of procedure (Females only) as per standard *(✓) Tick the option*	• Upto 7 days postpartum…… • Interval(42 days or more after delivery or abortion)…….. • With Abortion, Induced or spontaneous ♦ Less than 12 weeks……. ♦ More than12 weeks……. ♦ Any other specify…….
16	Type of anaesthesia *(✓) Tick the option*	• Local without sedation…….....…… • Local with sedation…….....…… • Spinal/Epidural/General…….....……
17	Endotracheal Intubation	Yes/No……..
18	List all anaesthetic agents, analgesics, sedatives and muscle relaxants	Time given Drug Name Dosage Route
19	Vital signs during surgery	Time…….....…BP…….....…Pulse…….....…..Resp Rate…….....……
20	Duration of surgery	Time of starting…….....……am/pm Time of closure…….....……am/pm Total Time spent…….....……..min/hrs
21	Vital signs after surgery	Time……BP……Pulse…… Resp Rate…….
22	Emergency equipments/ drugs available in facility as per standards If not available, give details	Available/Non available…….....…… ……
23	Overall Comments	
24	Name and signature of operating surgeon	

Name ..... **Designation** .....

Date ..... **Signature** .....

Annexure – 14.

Proforma for Conducting Audit of Death

(To be submitted within one month of sterilization by DQAC and sent to state)

Name of the state/ District/Union Territory…….

Details of the deceased		
1	Name	
2	Age	
3	Sex	Female/Male……
4	Name of Spouse (his or her age)	
5	Address of the deceased	
6	Number of living children(with details concerning age and sex)	
7	Whether operation was performed after delivery or otherwise	
8	If after delivery Date of delivery Place of delivery Type of delivery Person who conducted the delivery	
9	Whether tubectomy operation was done with MTP	
10	Whether written consent was obtained before the operation	D/M/Y……/……/……
11	Whether the operation was done at a camp or as a fixed day static procedure at the institution	
Details of operations		
12	Place of operation	
13	Date and time of operation (D/M/Y)	
14	Date and time of death (D/M/Y)	
15	Name of surgeon	
16	Whether surgeon was empanelled or not	Yes/No……
17	If the operation was performed at a camp who primarily screened the client clinically	
18	Was the centre fully equipped to handle any emergency complications during the procedure?	Yes/No……
19	Number of clients admitted and number of clients operated upon on the day of surgery	
20	Did any other client develop complications? If so, give details of complications?	

Anaesthesia/Analgesia/Sedation		
21	Name of the Anaesthetist, if present	
22	Details of anaesthesia drugs used	
23	Types of anaesthesia/analgesia/sedation	
24	Post-operative complications (according to sequence of events)	
	A. Details of symptoms and signs	
	B. Details of laboratory and other investigations	
	C. Details of treatment given, with timings,dates, etc from time of admission until the death of client	
Details of Death Audit		
25	Cause of death (Primary Cause)	
26	Has postmortem been done? If yes, attach the post mortem report	
27	Whether first notification of death was sent within 24 hours	Yes/No…….....…… If not, give reasons…….....……..
28	Details of the officers from District Quality Assurance Committee (DQAC) who conducted the enquiry	
29	In opinion of the chairman of DQAC, was death attributable to the sterilization procedure	Yes/No…….
30	What factors could have helped to prevent the death?	
31	Were the sterilization standards established by GOI followed?	Yes/No…….
32	Did the facility meet and follow up the sterilization standards established by GOI? If no list the deviation(s)	
33	Additional Information	
34	Recommendations made	
35	Action proposed to be taken	

Name ..... **Designation** .....

Date ..... **Signature** .....

Note: If any member of the SQAC/DQAC has performed the operation, he/she should recuse himself/ herself from the proceedings of this audit.

Annexure – 15.

Sterilization Death Audit Report

(Report from State to Centre)

Name of the state/union territory.....

Report for the quarter ending .....

Sl. No.	Name and address of the client	Date of sterilization	Place of sterilization	Type of sterilization	Qualification of surgeon who operated the case	Date and place of death	Under-lying cause of death	Death audited by	Remedial action initiated for correction

Medical death audit report must be annexed for each case.

Date:..... **Signature.....**

Annexure – 16.

Report on Complications/Failures following Sterilization

(To be filled in by the District Quality Assurance Committee)

Name of the State/ District/Union Territory……

Date of this report (D/M/Y)……/……/……

Details of Client and Surgery Performed		
1	Name and Address of client	
2	Name of Spouse	
3	Date of sterilization (D/M/Y)	……/……/……
4	Place where surgery was performed *(✓) Tick the option*	• Camp…… • PPCentre…… • PHC/CHC…… • District Hospital…… • Medical College Hospital…… • Accredited private/NGO Facility…… • (Also specify the name of the facility)…… ……
5	Type of surgical approach *(✓) Tick the option*	• Minilap…… • Laparoscopy…… • Post-Partum Tubectomy…… • Conventional Vasectomy…… • NSV…… • Any other specify……
6	Level of experience of the person who performed the sterilization procedure. *(✓) Tick the option*	• Trainee…… • Empanelled surgeon……
7	Type of anaesthesia *(✓) Tick the option*	• Local without sedation…… • Local with sedation…… • Spinal/Epidural/General……
Complications attributable to sterilization requiring hospitalization		
8	Date when complication was first reported(D/M/Y) Types of complication(s)	……/……/……
	A.If complications related to anaesthesia, list all anaesthetic agents, analgesics, sedatives and muscle relaxants	
	B.Injury/Trauma • Injury to bladder…… • Injury to fallopian tube…… • Mesosalpinx…… • Injury to bowel…… • Uterine perforation……	 Yes/No…… Yes/No…… Yes/No…… Yes/No…… Yes/No……

	• Testicular artery…….....…… • Spermatic cord…….....…… • Any other (specify)……..……..	Yes/No…….....…. Yes/No…….....…. Yes/No…….....….
	I. What factors contributed to injury/trauma?	
	C.Haemaorrhage • Epigatric vessel….....…….. • Fallopian Tube…….....……... • Haematoma requiring intervention/hospitalization… • Any other(specify)	 Yes/No…….....…. Yes/No…….....…. Yes/No…….....…. Yes/No…….....….
	I. What factors contributed to the haemorrhage?	
	ii. Did the client have a blood transfusion?	Yes/No…….....…….
	D.Infection • Wound Infection….....…….. • Pelvic Infection….....….....….. • Epididymoorchitis…….....…… • Generalized peritonitis….....…… • Any other (specify)…….....……..	 Yes/No…….....…. Yes/No…….....…. Yes/No…….....…. Yes/No…….....…. Yes/No…….....….
	E. Complications not mentioned in 8A-D (specify)** including need to abandon the procedure or adopt a change in approach	
	F. Was sterilization done postpartum or with MTP? If Yes, was hospitalization a result of complications arising from those procedures and not from sterilization?	Yes/No…….....…. Yes/No…….....….
	G.Describe the procedure leading to the complication	
9	Describe the type of treatment administered following complication. Medical/surgical	
10	Date of recovery(D/M/Y)	……/……/……
11	Number of days of hospitalization	
Pregnancy or Failure attributable to male sterilization (Pregnancy after certification of vasectomy)		
12	If Pregnant A.Estimate date of conception (D/M/Y)	……/……/……
	B.Was semen examination done	Yes/No……
	C.If yes, give date Result of analysis	……/……/……
	D.In the opinion of Medical Officer • Pregnancy was due to unprotected intercourse before azoospermia was achieved…….....…… • Pregnancy existed before vasectomy • Cause of pregnancy could not be determined….....…… • Any Other (Specify)…...……	 Yes/No…….....…. Yes/No…….....…. Yes/No…….....…. Yes/No…….....….

Pregnancy or failure attributable to female sterilization		
13	A. Date pregnancy was detected (D/M/Y)	……/……/……
	B. Estimated date of conception	……/……/……
	C. Confirmation of pregnancy test done USG	Yes/No…… Yes/No……
	D. Location of pregnancy *(✓) Tick the option*	• Intrauterine…… • Ectopic…….. • Undetermined……
	E. Was the women already pregnant at time of sterilization	Yes/No……
	F. In opinion of the Committee Members, the pregnancy was due to:	

Names, designations and signatures of the Committee Members

…… ……

…… ……

…… ……

…… ……

Comments by QAC

In the opinion of the QAC:

(a) Were the sterilization standards established by GOI followed? Yes/No

(b) Was the complication/failure attributable to the sterilization procedure? Yes/No

(c) What factors contributed to the complication/failure……

……

……

……

(e) Was the woman already pregnant at the time of sterilization? Yes/No

(f) Does the facility meet all the physical and other requirements as laid down in the GOI Standards for Sterilization? Yes/No

If no, list the deviation[s]:……

……

……

Additional information discussed, not presented in the report:]:……

……

……

Based on the investigation report, the following recommendations are made:…….....…… ….

……

…….....……

Reviewed by..... Designation.....

Signatures .....

Note: If any member of the QAC has performed the operation, he/she should recuse himself/herself from the complication of this report.

Annexure – 17.

Observation of Asepsis and Surgical Procedure

General Information		
1	Date (D/M/Y)	
2	Clinic Venue: PHC/CHC/DH/Any Other (Specify)	
3	Name of the block, district and state	
4	Name and designation of observer	
Asepsis Issues (Observe for 60 minutes in one session inside operation room)		
5	Was 0.5% chlorine solution prepared and used correctly	Yes/No……
6	Did the theatre personnel (those involved directly or indirectly in the proceedures) change into the following theatre attires	Gowns : Yes/No…… Caps : Yes/No…… Masks : Yes/No…… Theatre shoes : Yes/No……
7	Did the surgeon and the assistant scrub before starting	Yes/No……
8	For approximately how many minutes did the surgeon scrub using soap	<5 min…….. 3-5 min…….. >5 min……
9	Was the scrubbing procedure followed properly	Yes/No……
10	Was the mask kept over the bridge of nose at all times by the surgeon (s) and the assistant (s)	Yes/No……
11	Were the gloves changed after operating each case?	Yes/No……
12	After how many cases did surgeon scrub again	After 1-5 cases……. After 6-10 cases…… After 10 cases…….. Did not scrub again…….
13	Did the surgeon/assistant leave the OT at any time between cases	Yes/No……
14	**A.** If yes, did the surgeon /assistant change her/his shoes while going out	Yes/No……
	B. Did she/he change his/her gown on returning	Yes/No……
	C. Did she/he scrub again on returning	Yes/No……

Surgeon and anaesthesia (Observe atleast 3 procedures, but more if possible)				
	Client Number	**1**	**2**	**3**
15	Name of procedure: Minilap Tubectomy/Laproscopy/ Vasectomy/NSV			
16	Type of anaesthesia used: Local/Spinal/General If Local Anaesthesia was used , what was the approximate interval between injecting LA and starting surgery (in minutes)			
17	Was the skin scrubbed adequately before surgery (Yes/No)			
18	Were sterile drapes used? (Yes/No)			
19	Did the client wince at any time during the operation? (Yes/No)			
20	What was the total duration of the surgery (from skin incision to skin closure) (in minutes)			
21	If Laproscopy was performed:			
	A. Which gas was used for creating pneumoperitoneum? *(✓) Tick the option*	• CO_2 • N_2O • Air		
	B. How was it insuffulated? *(✓) Tick the option*	• Insuffulation apparatus • BP instrument bulb • Any other		
	C. How was the laproscope cleaned in between procedures? • Immersed in cidex >20 min • Immersed in cidex<20 min (specify minutes) • Cleaned with antiseptic solution (spirit)…… • Cleaned with water…….. • Any other (specify)…….....……	 Yes/No…… Yes/No…… Yes/No…… Yes/No…… Yes/No……		
22	Have the following surgical instruments been used			
	A. Light source for laparoscope	Yes/No……		
	B. Operating Laparoscope	Yes/No……		
	C. Pneumoperitoneum Insuffulation Apparatus Gas cylinder Co_2 Air Any other	Yes/No…… Yes/No…… Yes/No…… Yes/No……		
	D. Veress needle	Yes/No……		
	E. Trocar with cannula	Yes/No……		
	F. Minilap Kit	Yes/No……		
	G. Laproscopic Kit	Yes/No……		
	H. Conventional Vasectomy Kit	Yes/No……		
	I. NSV kit	Yes/No……		

Annexure – 18.

Assessment of District Quality Assurance Committee

(To Be Used by officials from the State/Centre)

Name of state .....

Name of district .....

Date of visit (D/M/Y)...../...../.....

Is there a Quality Assurance Committee (QAC) existent in the district?.....Yes/No

Is it functional.....Yes/No

Who are the members of the District QAC?.....

How many times has the District QAC met during the last one year

What are the existing recording mechanisms.....

Number of sterilization cases audited by the District QAC in the last one year on

- Deaths
- Complications
- Failures

Out of the above, how many compensation payments have been settled?

Are there any suggestions/remarks/recommendations made by the QAC?.....Yes/No

What are the suggestions/remarks/recommendations made?.....

Have any corrective measures been taken in the district? .....Yes/No

What are the corrective measures/actions being taken up in the district?.....

(Visiting Officers)

Name..... **Designation**.....

Signatures .....

Annexure – 19.

Client Exit Interview

(Prior consent to be taken for the interview)

	General Information	
1	Date (D/M/Y)	
2	Clinic Venue: HC/CHC/DH/Any Other (Specify)	
3	Name of the block, district and state	
4	Name and designation of observer	
	Client Information	
5	Name of the client (Optional)	
6	Age of client	
7	Sex of client	Male/Female
8	Age of spouse	
9	Number of living children	
10	Religion *(✓) Tick the response*	• Hindu……..... • Muslim……..... • Christian…….....…. • Other…….....……
11	Status	SC/ST/BPL/APL/Others……
12	How did you come to know about sterilization? *(✓) Tick the response*	• Health Worker……...…….. • Friends/Relatives……...……. • Posters/hoardings/banners……..……. • PRIs…….....…… • TV…….....…….. • Newspapers/Magazines……. • Radio…….....…….. • Cinema…….....…….. • Religious leaders…… • Any other……..……..
13	Was it your own choice to adopt the method or was it because it was suggested by someone else?	• Own choice…… • Suggested by someone……
14	How long did you have to wait before surgery from the time of admission?	……..hrs……..min
15	While waiting, did you have a place to sit? Were toilet facilities available Did you experience any discomfort?	Yes/No……. Yes/No……. Yes/No…….
16	Was the facility static/camp?	Yes/No…….

Client Information		
17	How was the behavior of the staff at the facility? *(✓) Tick the response*	• Very Good …… • Good…… • Indifferent…… • Rude……
18	Did you feel free to ask questions?	Yes/No……
19	Did you change from street clothes to theatre clothes at the camp/static facility	Yes/No……
20	Did you have adequate privacy during the examination? During the procedure?	Yes/No…… Yes/No……
21	Did the doctor examine you before discharging you?	Yes/No……
22	Did you receive written instructions about post-operative care	Yes/No……
23	How will you take your medicines during the post-operative period?	Knows well…… Does not know……
24	When can you resume sexual intercourse?	Knows well…….. Does not know well……...
25	In the case of Male clients: Do you need to use some other method of contraception for a certain period? If yes for how long?	Yes/No…….
26	When can you resume light and full activity?	Knows well……. Does not know……
27	How long did you stay at the camp/site after surgery?	……hrs
28	Did you get any compensation money for undergoing sterilization? If yes how much?	Yes/No……. ……..Rs
29	Did you have any problem after sterilization? If yes what sort of problem?	Yes/No……. ……
30	Do you have any suggestions for improving sterilization services? *(✓) Tick the response*	• More Cleanliness…… • More Privacy…….. • Better care by doctor…….. • Better care by other staff…… • Shorter waiting time…… • Low cost…….. • Any other(Specify)…… • None……

Grading of services by the client

1-Very Good 2-Good 3-Average 4-Unsatisfactory

Annexure – 20.

Claim Form for Family Planning Indemnity Scheme

The state will ensure that Claim Form cum Medical Certificate required for submitting claims under the FPIS Scheme are made available with all medical facilities conducting sterilization procedures, office of CMO/CDMO/CMHO/CDHMO/ DMO/DHO/ Joint Director designated for this purpose at district level etc. in local language along with their english version.

1. This form is required to be completed for lodging claim under Section-I of the scheme.
2. This form is issued without admission of liability and must be completed and returned to the District Health Society/State Health Society for processing of claim.
3. No claim can be admitted unless certified by the convener of **DQAC/CMO/ CDMO/CMHO/CDHMO/DMO/DHO/JOINTDIRECTOR/Equivalent designated for this purpose at district level by the state government.**

Claim No.: _____

1. **Details of the Claimant:**

   Name in full: _____ Present Age: _____ Years

   Relationship with the client of Sterilization: _____

   Residential Address:

   _____

   _____ Telephone no. _____

2. **Details of the person undergone sterilization operation:**

   Name in Full: _____ Age: _____ Years

   Son /daughter of: _____

   Name of the Spouse: _____ Age of the Spouse: _____ Years

   Address: _____

3. **Occupation/Business:** _____

4. **Details of Dependent children:**

S. No.	Name	Age (Yrs)	Sex (M/F)	Whether Unmarried	If unmarried, Whether dependent
1					
2					
3					
4					
5					

5. **(a) Date of Sterilization Operation:**_____

(b) Nature of Sterilization operation:

(i) Tubectomy: _____

(ii) Vasectomy: _____

(iii) MTP followed by sterilization: _____

(iv) Caesarean operation followed by Sterilization: _____

(v) Any other surgery followed by sterilization: _____

6. **(a) Name and address of the doctor who conducted the operation:**

_____

(b) Name and address of the hospital where operation was conducted:

_____

(c) Nature of claim:

1) Failure of sterilization not leading to child birth:_____

2) Failure of Sterilization leading to child birth: _____

3) Medical Complication due to Sterilization (state exact nature of complication):

a. Date: _____

b. Details of Complication:_____

c. Doctor / Health facility: _____

(d) Death attributable to sterilization:

a. Date of Admission: _____ Time:_____

b. Date of Discharge :_____ Time:_____

c. Date of Death:_____ Time:_____

7. **Give details of any disease suffered by client prior to undergoing sterilization operation:**

_____

I hereby declare that the particulars are true to the best of my knowledge and warrant the truth of the foregoing particulars in every respect and I agree that if I have made, or shall make any false of untrue statement, suppression or concealment of fact, my right to the compensation shall be absolutely forfeited.

I hereby claim a sum of Rs._____/- under the scheme, which I agree in full settlement of my claim and shall have no further right whatsoever to claim under the scheme.

Date: _____ **Name of Client/Claimant:** _____

Place: _____ **Signature (in full) or thumb impression**

MEDICAL CERTIFICATE ISSUED BY CMO/CDMO/CMHO/CDHMO/ DMO/DHO/JOINT DIRECTOR (DESIGNATED FOR THIS PURPOSE AT DISTRICT LEVEL.)

It is certified that Smt/Shri. _____

S/o/W/o: _____

R/o_____ had undergone ..... (Specify which procedure was done) sterilization operation on_____ at _____ (hospital) and conducted by Dr. _____

Qualifications _____empanelled for _____ procedure posted at _____

Nature of Sterilization operation done:

(i) Tubectomy: _____

(ii) Vasectomy: _____

(iii) MTP followed by Sterilization: _____

(iv) Caesarean operation followed by Sterilization: _____

(v) Any other surgery followed by Sterilization: _____

I have examined all the medical records and documents and hereby conclude that the sterilization operation is the antecedent cause of:

(a) Failure of Sterilization not leading to child birth: (Attach documentary evidence)

(b) Failure of Sterilization leading to child birth: (Attach documentary evidence).

(c) Medical Complication: (please give the details as under)

(i) Nature of Complication:_____ _____

(ii) Period: _____

(iii) Expenses incurred for treatment of complication Rs. _____ (Attach Original Bills/Receipts/Prescriptions)

(d) Death of Person (cause): _____

a. Date of Admission: _____ Time: _____

b. Date of Discharge:_____ Time: _____

c. Date of Death: _____ Time: _____ (Attach death certificate)

I have further examined all the particulars stated in the claim form and are in conformity with my findings and is eligible for a compensation of Rs……..…… due to……(Cause).

Please pay Rs…… to the beneficiary.

Documents enclosed:

(a) Original Claim cum Medical certificate ( )

(b) Attested copy of sterilization certificate ( )

(c) Attested copy of consent form ( )

(d) _____ ( )

(e) _____ ( )

Date:…… **Seal:**

Name ..... **Designation.....**

Tel/Mob. No ..... **Signature .....**

Annexure – 21.

Checklist for submission of Claim under Family Planning Indemnity Scheme

Before forwarding the Claim Form cum Medical Certificate and other required documents a checklist for assisting the CMO/CDMO/CMHO/ CDHMO /DMO/DHO/Joint Director designated for this purpose at district level has been prepared.

CHECK LIST

Before forwarding the Claim Form and other Required Document, it has to be checked that:

A. Consent form:

1. **Registration number of the beneficiary, date and** signature or thumb impression of the client are properly placed in respective columns.
2. **Examination of patient record** is filled in properly and doctor has put his signature and date.
3. **Details of dependents** of client are filled in.
4. All columns of Consent form and Medical Record & Check List for female / male sterilization are filled properly

B. Claim form:

1. Claim is submitted in a prescribed **Claim Form in original**.
2. Claim **forwarded through Medical Officer/Health Facility** conducting sterilization procedures.
3. **Name and address of the client** are same as mentioned on Consent form.
4. **Signature or thumb impression** of client is same as mentioned on Consent form.
5. **Date of sterilization** is same as mentioned in the Sterilization Certificate and Consent form.
6. **Other details filled in are tallied** with other relevant documents which are part of claim form.
7. **All columns of Medical Certificate** which is a part of Claim Form are filled in and date, signature and seal of CMO/ CDMO/ CMHO/ CDHMO/ DMO/ Joint Director designated for this purpose at district level has been placed.

C. Sterilization Certificate:

1. **Name of client** is same as filled in Consent Form.
2. **Date of sterilization** is mentioned under specific column.
3. **Certificate issued** has signature and date of issuing authority.
4. Sterilization Certificate is in **proper format as prescribed by the State** and having **Registration Number and date.**

D. Diagnostic Report Issued For Failure Of Sterilization:

1. **Report issued should be in a proper document i.e**. hospital case sheet/ proper diagnostic report.

2. It should have **registration number and date.**
3. Cause detected for **failure has been properly recorded** by the issuing authority on the document.
4. First **diagnostic report by which a failure is detected is attached.**

E. Birth Certificate:

1. Issued on a **proper format.**
2. **Name of the client** tallies with other records.
3. **Date of birth** has been properly recorded.
4. The certificate is **signed and duly stamped** with date by proper authority.

F. Complications:

1. The case sheet / prescription bear the **name of client.**
2. Case sheet/ prescription have proper **hospital registration number and date.**
3. Case sheet/ prescription bear the **date of sterilization.**
4. **Nature of post-operative complication** has been recorded.
5. **Medicines prescribed** should tally with cash memo.
6. Case sheet/prescription and bills/cash memo **are in original.**

G. Death Certificate:

1. Death certificate has been issued by the **proper authority.**
2. **Name of deceased, date of death** etc are rightly filled in on the certificate.
3. Certificate should have **registration number and date of issue and signature** of issuing authority

List of Experts:

Dr. Alok Banerjee
Technical Advisor
Parivar Sewa Sanstha
New Delhi

Dr. Pratima Mittal
HOD, Obs and Gynae
Safdarjung Hospital
New Delhi

Dr. Shubhra Philips
Director Health Services
PSI Head office
New Delhi

Dr. Sunita Singhal
Senior Clinical Advisor
EngenderHealth
New Delhi

Dr Sreedharan Nair
Director external relation
FPAI

Dr. Lalrin Tluangi
RCH Consultant
Govt. of Meghalaya

Dr. Anupama Arya
Clinical Training Specialist
EngenderHealth
New Delhi

Dr. K. Kalaivani
RBM
NIHFW,
New Delhi

Dr Nayara Shakeel
Senior Technical Specialist,
STSU, EngenderHealth
Lucknow - Uttar Pradesh

Dr. Vijayakumar,
Deputy Director (FW)
Kanchi Puram
Tamil Nadu

Dr. L. M. Pant
Surgical Specialist
Indore ,
Madhya Pradesh

Dr. B.P. Singh
President
Enable Health Society
New Delhi

Dr. Jyoti Sachdeva
Assistant Director SPO (FP)
Delhi NCR

Dr. Jyoti Vajpayee
FP Lead
BMGF
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Dr. Rupali Diwan
Dept. of Obs. and Gynae
Safdarjung Hospital
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Dr. Anchita Patil
NPO
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New Delhi

Dr. Saswati Das
Director Clinical services &
Training
Jhpiego, New Delhi

Dr. Meenu Sagar
JD-Directorate of Health and
Family Welfare
Uttar Pradesh

Dr. Tapasvi Puwar
Deputy Director SRU,
CARE
Patna

Dr.S.Kathirvelu,
Joint Director
Directorate of FW
Tamil Nadu

Dr. S.J. Kulkarni
Assistant Director, PHD
Family Welfare Dept.
Pune- Maharashtra

Dr. Rajkumar
District FW Officer
Kolar District
Karnataka

Dr. R. C. M Kaza
Consultant Surgeon
Ex-Professor of Surgery,
Maulana Azad Medical
College
New Delhi

Dr. Dinesh Agarwal
Consultant
IPE Global
New Delhi

Dr. Amit Shah
Reproductive Health Advisor
USAID
New Delhi

Dr. Arvind Mathur
Medical Officer
WHO IP ESTATE
New Delhi

Dr Manish Ranjan
Director – Clinical Services,
Maries Stopes International
New Delhi

Dr Shobha N Gudi
National Coordinator
FOGSI
Bangalore - Karnataka

Ravi Subbiah
Technical Director Health
CARE
India

Dr. Veena Bajpai
GM –FP & PC PNDT
SPMU
Uttar Pradesh

Dr. Akhilesh Tripathi
Deputy Director
National Health Mission
Raipur- Chattisgarh

Dr. Meenakshi Sundari
Senior Civil Surgeon
Govt of Tamil Nadu

Dr Milind D Pore
DRCHO Health Dept ZP
District -Satara
Maharashtra

List of Experts:

Dr. Vinod Kumar
SMO Family Planning
Govt of Rajasthan
Dept. of M& H

Dr. Mushtaq Khan
CMO
Rajasthan

Dr. Gurmeet Dugal
Programme Officer,
District Family Welfare District
-Jalandhar
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Dr. Teja Ram
DC FP
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NHM, Assam

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November 2014
Family Planning Division
Ministry of Health and Family Welfare
Government of India