Quality Assurance Manual for Sterilization Services

Research Studies & Standards Division
Ministry of Health and Family Welfare
Government of India
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Quality assurance manual For Sterilization services

सत्यमेव जयते

Prasanna Hota
Health & PW Secretary
Tel.: 23061863 Fax: 23061252
Email: secyfw@nb.nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय,
निर्माण भवन, नई दिल्ली – 110011

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

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Foreword

Quality from the clients' perspective as well as from the provider's perspective becomes the overriding priority to establish the credibility of any Health Care Delivery System. In spite of the availability of sterilization services through the vast network of public health institutions, there is still a large unmet need in the country in the terminal methods of family planning. The Ministry of Health & Family Welfare, Government of India has been actively pursuing improvement in quality of sterilization services provided through its regular as well as camp outlets. Monitoring and constant assessment of services is very essential for providing quality services which also is a major thrust area under RCH-II/NRHM.

The manual on Quality Assurance prepared earlier needed updating in the light of rapid advances in the field of medical sciences and the rising expectations, and a demanding and conscious society regarding reproductive and clients' right. The manual provides the guidelines on the processes required for providing quality sterilization services and the monitoring mechanism required to operationalize its so as to bridge the gaps.

It is a matter of great satisfaction in seeing the fructification of an exhaustive year long exercise and I am sure that this manual will go a long way in improving and assuring quality of sterilization services in the public and private centers.

(PRASANNA HOTA)
Secretary to the Government of India

सत्यमेव जयते

DR. (SMT.) M.S. JAYALAKSHMI
Deputy Commissioner (RSS)
Telefax : 23062485
Email : jayalakshmi_dcrss@yahoo.com
jaya.ms@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय,
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GOVERNMENT OF INDIA
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NIRMAN BHAVAN, NEW DELHI - 110011

Acknowledgement

Quality of care has been identified as a cross cutting critical element for achieving the program goals and objectives. Improving the quality of services provided in contraception is a major element that would enhance the acceptance of services. This Quality Assurance Manual is specifically addressing the quality care in sterilization services provided in our country as the terminal methods are still the number one choice of our eligible couples and a stringent mechanism needs to be developed for monitoring these services for ensuring quality. However the methodology outlined here could be adopted for assuring quality care in other spacing methods also with minor modifications based on the specific guidelines issued for IUD, Oral pills.

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

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

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

Dr. M.S. Jayalakshmi
Deputy Commissioner
Research Studies & Standards Division
Ministry of Health & Family Welfare

Contents

Introduction

The National Population Policy 2000 and the Reproductive and Child Health Programme Phase II emphasize the importance of achieving population stabilization and attaining the goal of replacement-level fertility by 2010. To achieve this objective, it is vital to continue with the Community Needs Assessment Approach (CNAA) for identifying unmet needs and for emphasizing the importance of informed contraceptive choice and the need to provide quality services. The Reproductive and Child Health Programme provides a basket of choices of contraceptive methods, including terminal and spacing methods. Despite the general acceptance of sterilization, it is seen that the services being provided currently in the country are not meeting the needs of the people due to various factors, such as the absence of skilled providers, insufficient availability of service centres, etc. As per the National Family Health Survey II estimates, the unmet need for spacing is 8.3 per cent and the unmet need for limiting is 7.5 per cent, with wide interstate variations.

Sterilization services are largely being provided through a network of public and private sector facilities. In most states, camps are a major source of sterilization services. Hence, the camp approach is still being followed in several states. There has been growing concern about the quality of sterilization services being offered, particularly at the camp facilities. The increase in complications, failures, and deaths due to sterilizations has also resulted in increased litigation being faced by the providers, which is another barrier in scaling up the sterilization services.

The Quality Assurance Manual has been prepared with the objective of assessing quality and quality needs, including assessment of the gap between actual and desired practices in services. The aim is to move the services from 'actual practice' to 'desired practice'.

Section 1:

Need for a Quality Assurance Manual

To ensure the provision of quality services in sterilization, a Quality Assurance Manual was prepared in 1996 by the Government of India. The revision of the earlier manual has assumed significance as the Government of India has undertaken several new initiatives, such as the introduction of a family planning insurance scheme for public as well as private providers, accreditation of health facilities, and empanelment of doctors for family planning services.

This manual will 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. It is envisaged that programme managers and service providers will be encouraged to take remedial measures and corrective steps for ensuring adherence to standards in service delivery.

Section 2:

Target Audience

The scope of this manual is limited to sterilization services. It has been prepared for monitoring quality of care in sterilization and for outlining the steps and mechanisms for measuring the quality of services provided at both static facilities and camps. This manual is prepared for *programme managers* at various levels of the health system (such as state and district-level programme officers) who are responsible for monitoring the quality of care in terminal family planning methods. The service providers—i.e. medical officers at the primary health centres (PHCs), community health centres (CHCs), sub-district and district hospitals, medical colleges, trainers from training institutes, and private providers empanelled in the district—can use this manual for ensuring quality assurance in provision of sterilization services.

Section 3:

Definition of Quality Assurance

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. It is critical to ensure that QA is recognized as an essential element of the reproductive health approach within the domain of reproductive rights.

QA is viewed as a systematic process aimed at providing services that the client views as good, desirable, and of high quality. It means offering services that are safe and effective and that satisfy the clients' needs and wants. QA is a comprehensive and multifaceted concept that measures how well clients' expectations as well as providers' technical standards are being met.

Section 4:

Quality of Care

Quality is the way in which individuals and clients are treated by the system providing services (Bruce 1990; Jain 1989).

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'. The Reproductive Health Quality Framework as per the UNFPA technical report (1999) specifies nine elements of quality that can be categorized into generic and specific elements.

Generic elements (common to all RCH services):

a) service environment
b) client provider interaction
c) informed decision making
d) integration of services
e) women's participation in management

Service-specific elements (specific to each RCH service):

a) access to services
b) equipment and supplies
c) professional standards and technical competence
d) continuity of care

The elements of quality of care in the specific area of sterilization services are addressed in this manual by using a systems approach—Inputs, Processes, and Outcomes.

Inputs, Processes, and Outcomes for Quality of Care

4.1. INPUTS

Inputs include all programme efforts that facilitate the readiness of the facilities to provide services when a client visits the clinic. Inputs 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.

4.1.1. Eligibility criteria for performing sterilizations

A. Qualification requirements for service providers

- Female sterilization by minilap tubectomy should be performed by a trained MBBS/ post graduate doctor.
- Laparoscopic sterilization for females should be performed by a gynaecologist with DGO/MD/MS qualification or by a surgeon with an MS degree; these doctors should be trained in laparoscopic sterilization.
- The male sterilization procedures, both conventional vasectomy and no-scalpel vasectomy (NSV), should be performed by a trained MBBS doctor/or a post graduate doctor.

B. Empanelment of doctors for performing sterilization

- Approved panel of doctors: Each state will prepare a district-wise list of doctors (from both government and accredited private centres/NGOs) who are qualified to perform sterilization operations as per the prescribed eligibility criteria.
- Only those doctors whose names appear on the panel will be entitled to carry out sterilization procedures in the government and/or government-accredited institutions and will be covered under indemnity insurance. The panel will be updated quarterly.

4.1.2. Physical Infrastructure:

Standards for physical infrastructure for static services have been laid down in the documents Standards for Male and Female Sterilization and *Standard Operating Procedures* (SOP) on *Camps/ Mobile Services*, which provide details about input, requirements, and processes for camps. These documents can be accessed from the Research Studies & Standards (RSS) Division of the Ministry of Health and Family Welfare (MOHFW), Government of India or from the MOHFW website (www.mohfw.nic.in)

4.2. PROCESSES

The processes include technical and interpersonal dimensions and encompass a range of elements. The protocols for the following procedures are detailed in the Standards for Male and Female Sterilization, 2006.

- Counselling
- Minilap tubectomy
- Laparoscopic tubectomy
- Conventional vasectomy
- No-scalpel vasectomy
- Anaesthesia/analgesia/premedication
- Follow-up protocols
- Infection-prevention practices

The processes for observation and measurement of quality care are outlined in Sections 5 to 9 of this manual; they describe how to assess whether the providers are maintaining standards of care as specified in the service guidelines.

4.3. OUTCOMES

The outcomes of quality services should be seen from the perspectives of clients, providers, and managers. This will result in achieving reproductive intentions, leading to the attainment of 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

Section 5:

Quality Assurance Management

Monitoring for quality should be done at three different levels:

- At the central level, through proper and well-established reporting systems;
- At the state and district levels, through Quality Assurance Committees (QACs);
- At the service outlet levels, through Quality Circles.

5.1. Monitoring at the Central Level

Organization and Responsibilities

The Technical Officers of the Research Studies & Standards (RSS) Division of the MOHFW, Government of India will be responsible for directing and steering the quality assurance activities with inputs from the Monitoring and Evaluation (M&E) Division. The standards governing the sterilization services are finalized with inputs from state personnel but are applicable equally to all. Any state may exceed these or have more vigorous standards. However, all states will be required to attain at least the minimum standards set forth. Monitoring at the centre will be through:

i) Periodic evaluation surveys by the M&E Division with the help of Population Research Centres (PRCs) in different states and Regional Evaluation Teams (RETs);

ii) Visits by officials from the centre to the states on a random basis;

iii) Reports to be sent regularly and systematically by the states to the centre on the following basis:

- Annual report on centres/sites offering sterilization services (annual Monitoring, Information and Evaluation System (MIES) Report from the states)
- Quarterly report (**Annexure 1**) on:
  1. Number of persons sterilized as per method
  2. Number of deaths following sterilization
  3. Cases of major complications following sterilization requiring hospitalization
  4. Number of sterilization failures
- Sterilization Death Audit Report (**Annexure 2**)

The above-mentioned reports from the states will be reviewed and analysed on a quarterly basis, and relevant feedback will be provided to the states.

iv) Operational research to be undertaken on some specific areas based on the Audit Reports.

5.2. Monitoring at the State Level

Quality Assurance Committee

Many states have a functional cell named either a death review cell or a mortality review committee. As per the guidelines laid down by the Honorable Supreme Court of India, Quality Assurance Committees (QACs) are to be formed at the state and district levels to ensure that the standards for female and male sterilization as laid down by the Government of India are being followed in respect of preoperative measures, operational facilities, and post-operative follow-ups.

5.2.1. The composition of the state QAC will be as follows:

- Secretary, Medical and Health (Chairperson)
- Director, Family Welfare (Convener)
- Director, Medical Education
- One Empanelled Gynaecologist
- One Empanelled Vasectomy Surgeon
- One Anaesthetist
- State Nursing Adviser
- Joint Director, (FW)/Deputy Director (FW) or any other as determined by the Department of Health and Family Welfare
- One member from an accredited private sector
- One representative from the legal cell

The terms of reference for the state QAC are as follows:

- Visit both public and private facilities providing family planning services in the state to ensure the implementation of national standards.
- Review and report deaths/complications following sterilization in the state.
- Review and report cases of conception due to failure of sterilization in the state.
- Give directions on the implementation of measures for improving the quality of sterilization services in the state.

- Review the implementation of the National Family Planning Insurance Scheme/ payment of compensation in the state.
- Meet once every six months.
- A minimum of three members shall constitute the quorum.

The procedures to be followed are:

- The state government will issue a notification on the constitution of the committee and its institutional arrangements.
- District-level committees will submit quarterly reports in the prescribed formats to the state committee.
- The state committee will meet every six months to review the reports being received from the districts. The committee may ask for additional information from the district committees if needed.
- The state committee will also have a supervisory role in the functioning of the district-level committees. If needed, the state committee may organize orientation programmes for the members of the district-level committees on a periodic basis.
- It would be ideal to have at least one professional responsible for coordinating the state committee's activities, preparing reports, and conducting selective investigations. The Joint Director (FW) or the Deputy Director may be the designated officer responsible for this activity.

5.3. Monitoring at the District Level

The composition of the District QAC (DQAC) shall be as follows:

- District Collector, Chairperson
- Chief Medical Officer/District Health Officer (convener)
- One empanelled gynaecologist
- One empanelled vasectomy surgeon
- One anaesthetist
- District Family Welfare Officer/RCHO
- One representative from the nursing cadre
- Any other as determined by the Department of Health and Family Welfare (state government)
- One representative from the legal cell

The terms of reference of the District QAC will be as follows:

- Conducting medical audit of all deaths related to sterilization and sending reports to the State QAC office.
- Collecting information on all hospitalization cases related to complications following sterilization as well as sterilization failure.
- Processing all cases of failure, complications requiring hospitalization, and deaths following sterilization for payment of compensation, and pursuing these cases with the insurance company or otherwise.
- 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 laid down, and recommending remedial action for institutions not adhering to the standards.
- Meeting once every three months.
- A minimum of three members shall constitute the quorum.

Procedures

- In the event of a sterilization death, it will be the responsibility of the medical officer at the institution where the death occurred to inform the convener of the District QAC within 24 hours of the event. The convener of the District QAC should inform the convener of the state committee immediately. The District QAC should conduct a medical audit and submit the final audit report to the State-Level Committee (i.e. to the Director of Family Welfare) within one month from the date of reporting the death. In case no deaths have been reported during the quarter, the committee should meet at least once in three months and send a nil report.
- The committee should also thoroughly investigate and ascertain details of each case of complication/failure of sterilization in the district, review the reasons, and take/recommend appropriate measures.
- The committee should also suggest measures for improving the quality of sterilization services in the district.
- The committee will have access to reports and records being maintained by private providers for sterilization services in accredited centres.

5.4. Monitoring at the Facility Level

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 Hospitals/Civil Hospitals/Sub-divisions/Referral Hospitals/ CHCs, Quality Circles comprising 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/Anaesthesia I/C, Surgeon
- 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 the Medical Superintendent, I/C Surgery, I/C Obstetrics and Gynaecology, I/C OT, and Nursing I/C 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.

The responsibilities of the QC will be as follows:

- Identifying critical quality processes in light of the standards for sterilization;
- Reviewing the processes with the help of the checklists on client case audit / facility audit/observation of sepsis and surgical procedure (**Annexures 3, 4, and 5**);
- 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.

Section 6:

Quality Assessment and Improvement

The quality of sterilization services provided can be assessed through the already existing documentation tools available at the facilities and instruments/tools 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.

6.1. 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, 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.

6.2. Client Case Audit

In addition to this, the visiting team should conduct a client case audit as per the guidelines placed at **Annexure 3** to ensure that client care is provided as per the standards established for sterilization services.

6.3. Facility Audit

Facility assessment (using the facility observation checklist provided in **Annexure 4**) 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 administered 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.

6.4. 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 5**.

6.5. 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 6**) is useful in measuring the client's satisfaction and also in addressing the gaps in service quality. It should be administered 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.

6.6. Reporting of Sterilization Deaths, Complications, and Failures

6.6.1. Reporting of Sterilization Deaths

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

6.6.1.1. Sterilization Death Notification

Sterilization deaths are to be reported in the Death Notification Form (**Form 1, Annexure 7**) to the District CMO, i.e. the convener of the District QAC, within 24 hours of death by telephone, telegram, or in person. The operating surgeon on the case should also be informed simultaneously of the occurrence of death so that he/she may fill up **Form 2** 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 Form 1.
- 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 **Form 2 (Annexure 8)** 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.

6.6.1.2. 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 (**Annexure 9**).

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.

6.6.2. Report and Medical Audit on Complications Following Sterilization

The report on complications requiring hospitalization following sterilization is to be filled in by the District QAC of the district where the client has reported (**Annexure 10**).

The reportable complications are as follows:

- Any problem directly related to surgery and/or anaesthesia that occurs within 30 days of the operation and intervention or management beyond what is normally required and that necessitates hospitalization;
- Blood transfusion is required;
- Any 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 QAC should conduct a field investigation/enquiry, review the case record, discuss the findings, and make recommendations for corrective action. **The processing and settlement of the claim should be done by the District QAC where the client has reported**.

6.6.3. Report and Medical Audit on Sterilization Failure

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 analysis (in the case of male clients) should be conducted.

The report on failure following sterilization is to be filled in by the District QAC of the district where the client has reported within two weeks of reporting (**Annexure 11**). The District QAC will conduct a field investigation/enquiry, review the case record, and report the findings to the state committee.

The District QAC will also be responsible for communicating such information to the concerned insurance service providers for compensation in case of death/failure/complications. **The processing and settlement of the claim should be done by the District QAC where the client has reported**.

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

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

7. Periodicity of Assessment

The following schedule depicts the frequency of quality assessment to be undertaken by the District QAC.

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. 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.

9. 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.

For example:

Problem	Specific Action	Time Frame	Person Responsible
Providers do not request return of clients for follow- up	Instruct providers to request follow-up and note details on the chart	November	I/c Facility
Clients do not return for follow-up even after they have been requested to do so	Design postcard reminder system	December	I/c Facility
Non-compliant with standards for skin preparation for tubectomy	Emphasize importance of using povidone iodine through discussions	January	I/c Facility
Provider does not change gloves and masks in between procedures	Discuss importance of using gloves and masks, and ensure availability of adequate numbers of these	November	I/c OT

- 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 personnel file and a copy should be given to the provider. Depending on the situation, the administrator should take further disciplinary action if required.

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.

10. 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.

Annexures

Annexure 1

Quarterly report on method-specific sterilization operation, failure, complications, and deaths following sterilization

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

Report for the quarter ending.....

Number of districts reported for the quarter.....

Number of districts performing sterilization .....

Sl. No.	Method/ Type of sterilization	Total number of operations done		Total number of complications requiring hospitalization reported after sterilization		Total number of failures reported after sterilization		Total number of deaths reported due to sterilization	
		During the quarter	Cumulative of current year	During the quarter	Cumulative of current year	During the quarter	Cumulative of current year	During the quarter	Cumulative of current year
1	VASECTOMY								
a	Conventional								
b	NSV								
2	TUBECTOMY								
a	Minilap								
b	Laparoscopic								
c	Post-partum sterilization								
d	Concurrent with other surgeries								

Date

Signature

Name

Designation

Annexure 2

Quarterly sterilization death audit report

(report from state to centre)

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

Report for the quarter ending.....

Number of districts reported for the quarter.....

Number of districts performing sterilization.....

Sl. No.	Name and address of the client	Date of steriliza-tion	Place of steriliza-tion	Type of steriliza-tion	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

Name

Designation

Annexure 3

Client case audit for female and male sterilization

Audit Process

The Client Case Audit System is designed to ensure that client care is being performed according to the Government of India Standards for Sterilization Services. This process requires reviewing medical records to find documentation that services are being provided according to the criteria specified in the established programme standards.

The assumption is that a particular criterion has been adhered to only if it can be confirmed in the medical record. Accordingly, it is necessary that clinicians maintain complete medical records and document all pertinent information relating to treatment and care.

- **Frequency of the audit**: Quarterly or more frequently if indicated.
- **Sample**: 20 surgical records, randomly obtained for review.
- Source: Medical records of sterilization cases.
- **Staff responsibility**: The convener of the District Quality Assurance Committee (DQAC) will be assigned the responsibility of obtaining the records and calling a meeting to review the records and summarize the findings. A clinical member of the DQAC will be assigned the responsibility of reviewing the findings and making recommendations for a change in practice if so indicated. If the findings indicate a significant or serious deviation from the prescribed standards, the clinical member can recommend that a re-review be performed. The re-review should not take place until after sufficient time has been allowed for the deficiencies to be corrected.
- **Report to**: A copy of the report will be forwarded to the convener of the DQAC, who is ultimately responsible for this activity. He/she shall review the audit, confirm the adequacy of the plan to correct the deficiencies, and make recommendations as necessary.

All recommendations and findings are to be shared with the concerned staff, so that they can all further their commitment to improving client services.

Copies are to be kept in a file for review by the DQAC.

Methodology for the Audit Process

The audit criteria are numbered and recorded in the left-hand column of the page. The 20 case records are reviewed, and each record in turn has the status of each criterion reported by recording it as follows:

A (+) is recorded when the criterion has been noted in the record and if the status of the criterion is positive (as per GOI Standards).

A (-) is recorded when the criterion has not been noted in the record, or if the criterion is noted but the status of the criterion is negative (not as per GOI Standards).

Example: A record indicates that the patient had severe hypertension (contraindication for surgery), but despite this condition surgical sterilization was performed. In this case, the criterion 'BP Recorded' should be recorded as A (-).

The results are then tallied in the far right column. The percentage compliance is noted as the number of positive (+) responses divided by the total number of responses and multiplied by 100.

Example: Out of the 20 records reviewed, a particular criterion received 17 positive (+) and 1 negative (-) response. The percentage compliance is calculated as follows: (17/18= .944) X 100= 94.4 per cent.

A criterion is considered to be out of compliance if it has less than 95 per cent compliance. In general, if only one criterion in 20 case records is found to be out of compliance, no response will be required. However, if two or more criteria are found to be out of compliance, a response and a plan for correction will be required.

CLIENT CASE AUDIT RECORD

AUDIT TOPIC: _____

DATE: _____ SITE: _____ BY: _____

CLIENT NUMBERS: _____

CRITERIA	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Total No. Pos. (+)	Total No. Neg. (-)	Compliance %
1. Married																							
2. Has one or more living children																							
3. Previous contraceptive history taken																							
4. Haemoglobin more than 8 gm%																							
5. Afebrile																							
6. Mental illness checked																							
7. BP recorded																							
8. Method-specific counselling done																							
9. Informed consent form signed																							
10. No skin conditions involving the operative site such as infection or oedema were present																							
11. Written and oral post-operative instructions provided to the patient																							

CRITERIA	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Total No. Pos. (+)	Total No. Neg. (-)	Compliance %
12. Skin preparation with betadine was performed																							

The criteria items given are only an example. This can vary depending on the topic chosen

$$\text{COMPLIANCE PERCENTAGE} = \frac{\text{TOTAL NUMBER OF (+)VE RESPONSES}}{\text{TOTAL NUMBER OF RESPONSES}} \times 100$$

Absolute criteria are those criteria where even a single case sheet should not be out of compliance such as Items 1, 2, 6, 9, and 11.

Results of Audit

Criteria out of compliance:

Action recommended:

Signature of Facility I/C

Name

Date

Action taken:

Findings of re-audit:

Signature of Facility I/C

Name

Date

Annexure 4

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, windows, roof, and floor)?			
2	Is the facility clean?			
3	Is running water available at the 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 available?			
8	Is Petrol Oil & Lubricants (POL) available for the generator?			
9	Is there space earmarked for examination and counselling to assure privacy?			
10	Is a waiting area with adequate seating facility available?			
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**) available?			
14	Is a functional shadowless lamp available?			
15	Is functional suction apparatus available?			
16	Is functional emergency light (through a functional inverter) available?			
17	Is an oxygen cylinder with gas and accessories available?			
18	Availability of: Minilap instrument Laparoscopic set NSV sets			

		Yes/No	Comments	Suggestions/ Recommendations
19	Instruments for laparotomy			
20	Emergency resuscitation equipment like ambu bag, face mask, airways, etc.			
21	Emergency medicine tray			
22	Sterilized consumables in dressing drum			
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 Copper T 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 logistics system that tracks stock levels and notifies staff when supplies need reordering?			
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?			
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 posters, banners, and handbills available at the site and displayed			
39	Suggestion and complaint system for clients (complaint box and/or a book)			
Management Information System				
40	Client registration record maintained			

		Yes/No	Comments	Suggestions/ Recommendations
41	Records on family planning (FP) (including the number of clients counselled and the number of acceptors)			
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?			
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 state?			
Infection Prevention				
50	Are the autoclave and instrument boiler functional?			
51	Are needle destroyers available?			
52	Is there a container for the disposal of sharp instruments available in the dispensing room?			
53	Mopping of floor by liquid bleach			
54	Utility gloves in use for cleaning floor, instruments, and linen			
55	Availability of proper waste disposal mechanisms (incinerator/other)			

Annexure 5

Observation of asepsis and surgical procedure

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	.....
Asepsis issues (observe for 60 minutes in one session inside operation room)		
1	Was 0.5% chlorine solution prepared and used correctly?	Yes ..... No.....
2	Did the theatre personnel (those involved directly or indirectly in the procedures) **change into** the following theatre attire?	Gowns.....Yes ..... No..... Caps..... Yes ..... No..... Masks .....Yes..... No..... Theatre shoes..... Yes ..... No.....
3	Did the surgeon and the assistant scrub before starting?	Yes ..... No.....
4	For approximately how many minutes did the surgeon scrub using soap?	<5 minutes..... 3–5 minutes..... >5 minutes.....
5	Was the scrubbing procedure followed properly?	Yes ..... No.....
6	Was the mask kept over the bridge of the nose at all times by the surgeon (s) and the assistant(s)?	Yes ..... No.....
7	Were the gloves changed after operating each case?	Yes ..... No.....
8	After how many cases did the surgeon scrub again?	After 1–5 cases ..... After 6–10 cases ..... After 10 cases..... Did not scrub again .....
9	Did the surgeon/assistant leave the OT at any time between cases?	Yes ..... No.....
10 a	**If yes,** did the surgeon/assistant change his/her shoes while going out?	Yes ..... No.....

b	Did he/she change his/her gown on returning?	Yes ..... No.....						
c	Did he/she scrub on returning?	Yes ..... No.....						
Surgery and anaesthesia (observe at least 3 procedures, but more if possible)								
	Client Number	1	2	3	4	5	6	7
1	Name of procedure: Tubectomy/Laparoscopy/Vasectomy/ NSV							
2	Type of anaesthesia used: Local/Spinal/General: If Local Anaesthesia (LA) was used, what was the approximate interval between injecting LA and starting surgery (**in minutes**)?							
3	Was the skin scrubbed adequately before surgery? (**Yes/No**)							
4	Were sterile drapes used? (**Yes/No**)							
5	Did the client wince at any time during the operation? (**Yes/No**)							
6	What was the total duration of the surgery (from skin incision to skin closure) (**in minutes**)?							
7	**If laparoscopy was performed:**							
a	Which gas was used for creating pneumoperitoneum?	CO_2..... N_2O ..... Air.....						
b	How was it insufflated?	Insufflation apparatus..... Bicycle pump ..... Any other (specify.....						
c	How was the laparoscope cleaned in between procedures?	Immersed in cidex ≥ 20 minutes..... Immersed in cidex < 20 minutes..... (specify minutes)..... Cleaned with antiseptic solution..... Cleaned with water..... Any other (specify).....						
8	**Are the following surgical instruments used for sterilization in working condition?**							
i)	Light source for laparoscope	Yes ..... No.....						
ii)	Operating laparoscope/laparocator	Yes ..... No.....						

iii)	Pneumoperitoneum insufflation apparatus	Yes ..... No.....
	Gas cylinders: CO_2	Yes ..... No.....
	N_2O	Yes ..... No.....
	Any other/air	Yes ..... No.....
iv)	Veres needle	Yes ..... No.....
v)	Trocar with cannula	Yes ..... No.....
vi)	Minilap kit	Yes ..... No.....
vii)	Conventional vasectomy kit	Yes ..... No.....
viii)	NSV kit	Yes ..... No.....

Annexure 6

Client exit interview

(Prior consent to be taken for conducting Interview)

General Information		
i)	Date (D/M/Y)	..... /..... /.....
ii)	Clinic venue: Subcentre/PHC/CHC/DH/Any other (specify)	.....
iii)	Name of the block, district, and state	.....
iv)	Name and designation of observer	.....
Client Information		
i)	Name of client (**Optional**)	.....
ii)	Age of client	.....
iii)	Sex of client	Male..... Female.....
iv)	Age of spouse	.....
v)	Number of living children	.....
vi)	Religion	Hindu ..... Muslim ..... Christian..... Other.....
1	How did you come to know about sterilization?	Radio ..... TV..... Cinema..... Newspapers/magazines ..... Posters/hoardings/banners..... Religious leaders ..... PRIs..... Friends/relatives..... Health worker ..... Any other (specify.....
2	Was it your own choice to adopt the method or was it because it was suggested by someone else?	Own choice ..... Suggested by someone .....
3	How long did you have to wait before surgery from the time of admission?	..... hrs ..... mins
4	While waiting, did you have a place to sit? Were toilet facilities available? Did you experience any discomfort?	Yes ..... No..... Yes ..... No..... Yes ..... No.....

5	Was the camp/static facility clean?	Yes ..... No.....
6	How was the behaviour of the staff at the facility?	Polite ..... Courteous ..... Rude ..... Indifferent .....
7	Did you feel free to ask questions?	Yes ..... No.....
8	Did you change from street clothes to theatre clothes at the camp/static facility?	Yes ..... No.....
9	Did you have adequate **privacy**? During the examination? During the procedure?	 Yes ..... No..... Yes ..... No.....
10	Did the doctor examine you before discharging you?	Yes ..... No.....
11	Did you receive written instructions about post-operative care?	Yes ..... No.....
12	How will you take your medicines during the post-operative period?	Knows well..... Does not know.....
13	When can you resume sexual intercourse?	Knows well..... Does not know.....
14	In the case of **Male Client**s: Do you need to use some other method of contraception for a certain period? If yes, for how long?	Yes ..... No.....
15	When can you resume **Light Activity** and **Full Activity**?	Knows well..... Does not know.....
16	How long did you stay at the camp/site after surgery?	.....**hrs**)
17	Did you get any compensation money for undergoing sterilization?	Yes ..... No.....
a	**If yes**, how much?	....
18	Did you have any problems after sterilization?	Yes ..... No.....
a	**If yes**, what sorts of problems?	....
19	Do you have any suggestions for improving sterilization services?	More cleanliness ..... More privacy ..... Better care by doctor ..... Better care by other staff ..... Shorter waiting time..... Low cost ..... Any other (specify..... None .....

Annexure 7

Form 1

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 by telephone, telegram, or in person.

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	Place where procedure performed	Camp.....
	(**specify name of site**)	PP centre .....
		PHC/CHC.....
		District hospital.....
		Medical college hospital .....
		Accredited private/NGO facility.....
9	Type of procedure	Post-partum .....
A	**Tubectomy**	Minilap .....
		Laparoscopy.....
		Any other (specify.....
B	**Vasectomy**	Conventional.....
		NSV.....
C	**Other with MTP/CS, etc.**	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 additional sheet of paper if more space is required.)	.....
		.....
		.....
		.....
		.....
		.....
		.....

		....
12	Cause of death	.....
13	Contributing factors (if any)	....
14	Was a post-mortem examination performed?	Yes ..... No..... **If yes, describe the pertinent findings**..... ....
15	Name and designation of surgeon who performed the sterilization operation	....
16	Name and address of institution where death occurred	....
17	Name and designation of reporting officer	....

Date

Signature

Name

Designation

Annexure 8

Form 2

Proforma on death following sterilization {To be filled in by the operating surgeon}

(death within one month of 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 (Form 2) to the convener of the DQAC.

1	Date of this report (D/M/Y)	..... /..... /.....
	Type of institution where the death occurred	Camp.....
		PP centre .....
		PHC/CHC.....
		District hospital.....
		Medical college hospital .....
		Accredited private/NGO facility.....
	Name of the institution	.....
		.....
	Address	.....
	Village/Town/City	.....
	District/State	.....
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	Camp.....
		PP centre .....
		PHC/CHC.....
		District hospital.....
		Medical college hospital .....
		Accredited private/NGO facility.....
		(**Also specify the name of the facility**)
5	Type of surgical approach	Minilap.....
		Laparoscopy.....
		Post-partum tubectomy.....
		Conventional vasectomy .....
		NSV.....
		Any other (specify.....

6	Date of death (D/M/Y)	..... /..... /.....
7	Time of death	.....a.m./p.m.
Client Details		
8	Name	.....
9	Age	.....
10	Sex	Female..... Male.....
11	Spouse's name	.....
12	Address	....
13	Relevant past medical history	....
14	Pertinent preoperative physical and laboratory findings	....
Sterilization Procedure		
15	Timing of procedure (females only) as per standards	24 hours to 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.....
16	Type of anaesthesia	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 ..... a.m./p.m. Time of closure .....a.m./p.m. Total time spent .....min/hrs
21	Vital signs after surgery	Time BP Pulse Resp. Rate ....
22	Emergency equipment/drugs available in facility as per standards If not available, give details	Available..... Not available ....
23	Overall comments	....
24	Name and signature of operating surgeon	....

Date

Signature

Name

Designation

Annexure 9

Proforma for conducting death audit following sterilization

(to be submitted within one month of sterilization)

Name of the State/District/Union Territory .....

1	Details of the deceased	
i	Full name	.....
ii	Age	.....
iii	Name of spouse and his/her age	.....
iv	Address	....
v	Number of living children (with details concerning age and sex)	.....
vi	Whether the operation was performed after delivery or otherwise	.....
vii	If after delivery: Date of delivery Place of delivery Type of delivery Person who conducted the delivery	 ....
viii	Whether tubectomy operation was done along with MTP	.....
2	Whether written consent was obtained before the operation	.....
3	Whether the operation was done at a camp or as a routine procedure at the institution	.....
4	Details	
a	Place of operation	.....
b	Date and time of operation (D/M/Y)	.....
c	Date and time of death (D/M/Y)	.....
d	Name of surgeon	.....
e	Whether surgeon was empanelled or not	Yes ..... No.....
f	If the operation was performed at a camp, who primarily screened the client clinically?	.....
g	Was the centre fully equipped to handle any emergency complications during the procedure?	Yes ..... No.....

h	Number of clients admitted and number of clients operated upon on the day of surgery	.....
i	Did any other clients develop complications? If so, give details of complications.	.....
5	Anaesthesia/Analgesia/Sedation	
a	Name of anaesthetist, if present	.....
b	Details of anaesthesia drugs used	.....
c	Type of anaesthesia/analgesia/sedation	.....
6	Post-operative complications (according to sequence of events)	
i	Details of symptoms and signs	.....
ii	Details of laboratory and other investigations done	.....
iii	Details of treatment given, with timings, dates, etc. from time of admission until the death of the patient	.....
7	Cause of death (primary cause)	.....
8	Has post-mortem been done? If yes, attach the post-mortem report.	.....
9	Whether first notification of death was sent within 24 hours.	Yes ..... No..... If not, give reasons .....
10	Details of the officers from the District Quality Assurance Committee (QAC) who conducted the enquiry	.....
11	In the opinion of the chairman of the District QAC, was death attributable to the sterilization procedure?	Yes ..... No.....
12	What factors could have helped to prevent the death?	.....
13	Were the sterilization standards established by GOI followed?	Yes ..... No.....
14	Did the facility meet and follow the sterilization standards established by GOI? If no, list the deviation[s].	Yes ..... No.....
15	Additional information	.....

16	Recommendations made	....
17	Action proposed to be taken	....

Date

Signature

Name

Designation

Note: If any member of the QAC has performed the operation, he/she should not act as a chairman/member for this report.

Annexure 10

Report on complications / failure following sterilization to be filled in by the district quality assurance committee

Name of district/state/union territory .....
Date of this report (D/M/Y) ...../ ..... / .....

1	Name and address of client	.....
		.....
2	Name of spouse	.....
3	Date of sterilization procedure (D/M/Y)	..... / ..... / .....
4	Place where surgery was performed	Camp .....
		PP centre .....
		PHC/CHC .....
		District hospital .....
		Medical college hospital .....
		Accredited private/NGO facility .....
5	Type of procedure	Minilap .....
		Laparoscopy .....
		Post-partum tubectomy .....
		Conventional vasectomy .....
		NSV .....
		Any other (specify .....
6	Level of experience of the person who performed the sterilization procedure	Trainee .....
		Empanelled surgeon .....
7	Type of anaesthesia	Local without sedation .....
		Local with sedation .....
		Spinal/epidural .....
		General .....
PART A: Complications Following Sterilization Requiring Hospitalization		
8	Date when complication was first reported (D/M/Y)	..... / ..... / .....
	Type of Complication(s)	
a	Complications related to anaesthesia	
	If complications were related to anaesthesia, list all anaesthetic agents, analgesics, sedatives, and muscle relaxants	

b	***Injury/Trauma***	Injury to bladder..... Injury to fallopian tubes..... Mesosalpinx ..... Injury to bowel ..... Uterine perforation ..... Testicular artery ..... Spermatic cord..... Any other (specify..... .....
	What factors contributed to the injury/trauma?	....
c	***Haemorrhage***	Epigastric vessel ..... Fallopian tube ..... Haematoma requiring intervention/hospitalization..... ..... Any other (specify..... .....
	(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..... .....
e	Complication not mentioned in 9 A-D (specify)* * **including need to abandon the procedure or adopt a change in approach**	....
f	Was sterilization done post-partum 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 procedures leading to the complication	....

9	Describe the type of treatment administered following the complication **Medical** **Surgical**	....
10	Date of recovery (D/M/Y)	..... /..... /.....
11	Number of days of hospitalization	.....
PART B: Pregnancy or Failure following MALE STERILIZATION (*pregnancy following certification of vasectomy*)		
12 a	If pregnant, estimate date of conception (D/M/Y)	..... /..... /.....
b	Was semen analysis done?	Yes ..... No.....
c	If yes, give date (D/M/Y) Results of the analysis	..... /..... /..... ....
d	In the opinion of the 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.....
PART C: Pregnancy or failure following FEMALE STERILIZATION		
13 a	Date pregnancy was detected (D/M/Y)	..... /..... /.....
b	Estimated date of conception (D/M/Y)	..... /..... /.....
c	Confirmation of pregnancy Pregnancy test done: USG done	 Yes ..... No..... Yes ..... No.....
d	Location of pregnancy	Intrauterine..... Ectopic..... Undetermined/Unknown.....
e	Was the woman already pregnant at the time of sterilization?	Yes ..... No.....

f	In the 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	Signatures	Designation
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....

Note: If any member of the QAC has performed the operation, he/she should not act as a chairman/member for this report.

Annexure 11

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?.....

.....

Name, signature, and designation of the visiting officer.....

References

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List of Experts

1.	Dr. Syed Iqbal Hussain State RCH Training Coordinator, Directorate of Health Services, Nepal House Doranda, Ranchi-834001 Jharkhand Telephone: 0651-2508411
2.	Dr. H.C.Das Chief Medical Officer - CMO (Non Functional Selection Grade - NFSC) Room No. 47 Lok Nayak Hospital 1 Jawahar Lal Nehru Marg Delhi Gate New Delhi – 110 002 Telephone: 23236000 / 23232400
3.	Dr. P. Bandopadhyay Programme Officer (HIV/AIDS – Research) International Planned Parenthood Federation – IPPF South Asia Regional Office - SARO 66, Sunder Nagar New Delhi - 110 003 Telephone: 24359221/2/3
4.	Dr. B.P. Singh, Senior Training Manager Engender Health, India Country Office F-6/8 B, Vasant Vihar, Poorvi Marg, New Delhi-110 057 Telephone: 2614 7123 / 4 / 5
5.	Dr. Ajesh Desai, Association Prof. cum-maternal Health Consultant Commissionerate of Health Medical Service & Medical Education (HS) Government of Gujarat Dr. Jeevraj Mehta Bhawan Block No. 5 Gandhinagar – 382 010 Telephone: 09825442920

6.	Dr. Manoranjan Jha Senior Medical Officer & State Trainer, NSV Regional Office for Health & Family Welfare (Bihar & Jharkhand) Government of India Danara House Salimpur Ahar Patna – 800 003 Telephone: 0612-2320645
7.	Dr. A. Jayasankaraiah Joint Director(FW) Office of the Commissioner Family Welfare Government of Andhra Pradesh DM&HS Campus Sultan Bazaar Hyderabad – 500 095 Telephone: 040-24600820
8.	Dr. (Mrs.) Harinder Rana Director - Health Services (Family Welfare) Parivar Kalyan Bhawan Sector 34-A Opp. Radio Station Chandigarh – 160022 Punjab Telephone: 0172-2646811
9.	Dr. G.N. Sahoo Deputy Director Surgery/State Trainer NSV Bokaro General Hospital Bokaro Steel City, Bokaro-827004
10.	Mrs. Madhubala Nath Regional Director International Planned Parenthood Federation – IPPF South Asia Regional Office - SARO 66, Sunder Nagar New Delhi - 110 003 Telephone: 24359221/2/3
11.	Dr. Jaya Lal Mohan RCH Consultant, National Institute of Health & Family Welfare New Mehrauli Road, Near DDA Flats, Munirka New Delhi – 110 067 Telephone : 26165959/26188485/26160156/26160158/26166441

12.	Dr. P.P. Doke Director General – Health Services Government of Maharashtra Government Dental College 4th Floor, Saint George Hospital Campus Victoria Terminal Mumbai- 4 00 001 Telephone: 022-22621006
13.	Dr. Baljit Kaur, State NSV Trainer Urban Family Welfare Bureau Sakatri Bagh Amritsar, Punjab
14.	Dr. Sarala Gopalan Formerly Professor & Head Department of Obstetric & Gynaecology. Post Graduate Institute of Medical Education and Research (PGIMER) Sector 12 Chandigarh-160 012 Telephone: 0172-2744993 / 2747585
15.	Dr. Sudha Salhan Professor and Head, Obstetric Gynaecology Safdarjung Hospital New Delhi – 110 024 Telephone: 26198108 / 26165060
16.	Dr. R.C.M Kaza Professor of Surgery Maulana Azad Medical College Bahadur Shah Zafar Marg New Delhi – 110 002 Telephone: 9312210987
17.	Dr. Dinesh Agarwal Technical Adviser (RH) United Nations Population Fund - UNFPA 53, Jorbagh New Delhi – 110 003 Telephone: 24649247
18.	Dr. Arvind Mathur National Professional Officer, CHS World Health Organisation (WHO) India Country Office Room No. 534-A, 5th Floor Nirman Bhawan New Delhi – 110 011 Telephone: 23061955 / 23061993

19.	Ms. Antigoni Koumpounis Technical Officer World Health Organisation (WHO) Department of Family and Community Health 9 Jor Bagh New Delhi – 110 003 Telephone: 23061922 / 23061923
20.	Dr. Jyoti Vajpayee Country Director ENGENDER HEALTH India Country Office F-6/8 B, Vasant Vihar, Poorvi Marg, New Delhi – 110 057 Telephone: 2614 7123 / 2614 7124 / 2614 7125
21.	Dr. Bulbul Sood Director CEDPA/India C-1 Hauz Khas New Delhi-110 016 Telephone: 41656781 / 41656782
22.	Dr. Alok Banerjee, Sr. Medical Consultant, Parivar Seva (PSS) Reproductive Health Services C-374, Defence Colony New Delhi – 110 024. Telephone: 2433 7712 / 2433 2524
23.	Dr.V.G.Yeole Assistant Director Health Services State Family Welfare Bureau Kutumb Kalyan Bhavan Naidu Hospital Compound Raja Bahadur Main Road Pune Maharashtra Tel.No.020-26058739
24.	Dr.S.N. Mukherjee Retd. Prof. & Head, Dept of Obstetric & Gynaecology Maulana Azad Medical College Bahadur Shah Zafar Marg New Delhi – 110 002 Telephone: 23239271
25.	Dr. K.Kalaivani Director In charge, National Institute of Health & Family Welfare

	New Mehrauli Road, Near DDA Flats, Munirka New Delhi – 110 067 Telephone : 26165959/26188485/26160156/26160158/26166441
26.	Dr. Usha Sharma Principal cum Professor of Gynaecology & Obstetrics Lala Lajpat Rai Memorial Medical College Meerut – 250 004 Uttar Pradesh Telephone: 0121-2760555 / 2760888
27.	Dr. J. S. Dali Professor Department of Anesthesia Maulana Azad Medical College Bahadur Shah Zafar Marg New Delhi – 110 002 Telephone: 23239271
28.	Dr. J. Amala Devi Head of Department Department of Obstetric & Gynaecology Directorate of Family Welfare, 359, Anna Salai, DMS Complex Chennai 600 006 Tamil Nadu Telephone: 040- 24321021
29.	Dr. Mandakini Parihar Consultant, Gynaecologist Chairman, Family Welfare Committee The Federation Of Obstetric & Gynaecological Societies of India - FOGSI Mangal Anand Hospital 48, Swastik Park Chamber Mumbai 400 071 Telephone: 022-25224845
30.	Dr.M.S.Jayalakshmi Deputy Commissioner (RSS) Room No. 311 'D' Wing Ministry of Health and Family Welfare Nirman Bhawan New Delhi – 110 011 Telephone: 23062485
31.	Dr.S.K.Sikdar Assistant Commissioner Room No. 452, 'A' Wing Ministry of Health & Family Welfare Nirman Bhawan New Delhi – 110 011 Telephone: 23062427

Notes