



Standards and Quality Assurance in Sterilization Services

FAQs: Frequently Asked Questions



March 2016



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



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Government of India, Nirman Bhawan, New Delhi -110101

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Prologue

Quality of services forms the backbone of any health care delivery system. This is more so in the case of Family Planning services. Currently sterilization is the most preferred method in India and Government of India is committed to the provision of quality sterilization services. With a view to achieve this, the Family Planning Division, Ministry of Health and Family Welfare, has been conducting workshops on 'Quality Assurance in Sterilization Services' nationwide along with extensive supportive supervision visits in various states.

Experiences from workshops and visits has necessitated the need for development of a comprehensive compilation on Frequently Asked Questions (FAQs) which addresses the field level issues faced by service providers and program managers at various levels of health care system.

These FAQs are an addendum to the existing manual on 'Standards and Quality Assurance in Sterilization Services (2014)' and will act as a ready recknor for both service providers and program managers alike.

It is hoped that this compilation will go a long way in strengthening the provision of good quality sterilization services all across the country.

A. ELIGIBILITY OF PROVIDERS:

Q 1. Can allopathic doctors with specialization in other fields like orthopedics, ENT, ophthalmology, medicine etc. perform sterilization procedures?

A Yes, all allopathic doctors are eligible to perform sterilization procedures (minilap/laparoscopic tubal ligation/NSV/conventional vasectomy) after undergoing the mandatory formal training in the procedure.

Q 2. How can an MBBS doctor be nominated for training in laparoscopic sterilization procedure?

A An MBBS doctor can be nominated for training in laparoscopic sterilization procedure if she/he has been performing 'minilap' sterilization procedures for the last 3 years in a public or accredited private health facility.

Q 3. Can an MBBS doctor without any specialization perform laparoscopic sterilization?

A Yes, provided she/he has been performing 'minilap' sterilization for the last three years in a public or accredited private health facility and has been subsequently formally trained in the laparoscopic sterilization procedure.

Q 4. Can AYUSH doctors, after appropriate training, be permitted to conduct male and female sterilization procedures?

A No, as per 'Standards and Quality Assurance in Sterilization Services, 2014', only health practitioners from allopathic stream can perform sterilization procedures. Therefore, AYUSH doctors are not permitted to conduct the same.

Q 5. Is there a provision of incentives for AYUSH practitioners assisting the surgeons in sterilization procedures?

A No, currently as per GoI schemes, there is no provision of incentives for AYUSH practitioners assisting the surgeons in sterilization procedures.

Q 6. Can Life Saving Anaesthesia Skills (LSAS) trained doctors be utilized for administering anaesthesia during sterilization?

A LSAS trained doctors are authorized to provide anaesthesia only in cases of caesarian sections and not for stand alone sterilization procedures; however, in case of sterilization concurrent with caesarian section LSAS trained providers can administer anaesthesia.

Q 7. Can trained providers from private hospitals be considered for empanelment for laparoscopic sterilization by the government?

A Yes, trained providers from private hospitals can be considered for empanelment in laparoscopic sterilization if such institutions are accredited by the Government and fulfil all the eligibility criteria as per the 'Standards'.

B. EMPANELMENT OF PROVIDERS:

Q 8. If an empaneled provider retires, can she/he continue to deliver services post retirement?

A Yes, but prior to that the retired provider should be freshly empaneled for providing services.

Q 9. Do providers who have retired from service but had earlier been providing sterilization services need to be re-trained before fresh empanelment?

A No, retired providers, who had already been conducting/performing sterilization operations, are not required to undergo any re-training for a fresh empanelment.

Q 10. Who can empanel providers?

A The QACs (Quality Assurance Committee) formed at state/district levels are empowered to empanel providers.

Q 11. How will a provider know whether she/he is empaneled for providing services?

A Each district is required to maintain a list of empaneled providers which should be updated quarterly or sooner if warranted. The QACs should intimate the providers regarding their empanelment status. If a provider is not included in the empaneled list but satisfies all the criteria for inclusion, then she/he too can also approach the State Quality Assurance Committee (SQAC)/District Quality Assurance Committee (DQAC) for empanelment. Alternatively the SQAC/DQAC can empanel the provider to empower them to provide services and augment its pool of providers.

Q 12. Is a provider empaneled in one state/district eligible to perform surgeries in other states/districts of India?

A Yes, a provider empaneled in one state/district is eligible to perform surgeries in other states/districts of India.

Q 13. Can an empaneled private provider be allowed to provide sterilization services in her/his own private facility?

A Yes, an empaneled private provider can provide sterilization services in her/his own facility provided the facility is accredited by the SQAC/DQAC and is bound by the 'compensation' and Family Planning Indemnity Scheme (FPIS) of the GoI.

Q 14. Can an empaneled private provider charge money from clients for sterilization services provided at her/his facility?

A No, once a provider has been empaneled and her/his facility has been accredited, they cannot charge anything extra from the client. Upon accreditation they are bound by the 'compensation' scheme and Family Planning Indemnity Scheme (FPIS) of the GoI. The surgery must be cashless to the clients and no fee can be charged even under the garb of providing medicines, disposables etc.

C. COUNSELLING AND ELIGIBILITY OF CLIENTS (FEMALE/MALE):

Q 15. Can providers conduct group counselling or should be restricted to 'one to one' counselling as mentioned in the manuals?

A Ideally 'one to one' counselling gives a better scope to understand issues and concerns of the clients along with an opportunity to address myths and misconceptions in privacy. However, group counselling may be adopted in settings where counsellors are few or not available; clients are comfortable in a group and the counsellor is able to satisfy their queries and concerns.

Q 16. How do we define the term 'ever married' in the 'case selection' criteria?

A The term 'ever married' refers to a female/male client married at least once in their lifetime (irrespective of their current marital status).

Q 17. Can sterilization services be provided to unmarried women in the public health and accredited private health facilities?

A No, unmarried women can not be provided sterilization services in the public health and accredited private health facilities.

Q 18. Can sterilization be provided to live-in couples?

A No, either of the couple should be 'ever married' before they can be considered for provision of sterilization services in the public/accredited private health facilities.

Q 19. Can a widow with one or no children be offered sterilization services on demand?

A Any client who is ever married can be offered sterilization services on demand. The services can not be provided to the widow if she has no children. In case she has a child under 1 year of age then the procedure should be delayed till the child attains the age of 1 year.

Q 20. What is the rationale behind considering the minimum age of 22 years as a criterion for selecting women for sterilization?

A The legal age of marriage in India is 18 years. The Government also promotes delay in first pregnancy after marriage by at least 2 years. Therefore, the probability of a woman below the age of 22 years having a child of at least one year of age is remote. Hence, the minimum age of 22 years is a criterion for selecting women for sterilization.

Q 21. If a woman delivers at home, is she entitled and eligible for post-partum sterilization?

A Yes, a woman delivering at home is entitled and eligible for post-partum sterilization up to seven days' of delivery, provided the correct date of delivery is communicated to the provider. In case the date of delivery is disputable and the seven days' criteria is doubtful, then the woman should be motivated to undergo sterilization after six weeks (interval sterilization).

Q 22. Can PPS be offered to women immediately after birth of her first child?

A No, PPS cannot and should not be offered to women immediately after the birth of her first child. As per the GoI guidelines, the age of the child should be at least one year before a sterilization procedure can be considered.

Q

23. Can a sterilization procedure be performed on a client who is not in the eligible couple list of that area?

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Yes, the sterilization procedure can be performed even if their name is not included in the eligible couple list of that area provided the client fulfills all the criteria for undergoing a sterilization procedure. As per GoI guidelines, no client can be denied services if they fulfill the eligibility criteria.

A. INFORMED CONSENT:

Q 24. There may be cases of coercion or lack of understanding of conditions elaborated in the consent form on the part of the client. Hence consent forms should have space for clients to write that 'all the information in the consent form has been read and explained to me in my language' instead of taking thumb impression or signature of the client on pre written statement. What is the opinion of GoI on this suggestion?

A The GoI has developed the 'consent form' in consultation with all stakeholders. This 'form' has been in use for the last 20 years with minor modifications over the years and has stood the test of time. The consent form does have the phrase 'all information has been explained and read out to me in my own language'. Moreover, some clients are unable to read and write, as is evident from the varying literacy rates prevalent across the country and a signature or thumb impression has a legal sanctity whereas verbal communications cannot be admissible as evidence in a court of law. Therefore, in order to avoid any litigation/allegation of coercion or lack of understanding of conditions elaborated in the consent form there is a provision of signature of witness along with clients' signature/ thumb impression.

Q 25. If caesarian section concurrent with sterilization has been performed or any other sterilization procedure has been performed with the consent of the client but later the spouse of the client alleges that sterilization has been performed without her/his consent, how such cases should be dealt?

A As per the guidelines, consent of spouse is not required for sterilization and the signed consent of client suffices. The same may be communicated to the spouse. However, the GoI encourages joint counselling of couples, although it is not mandatory.

Q 26. Why is the word 'partner' mentioned in the consent form?

A A client can be married, divorced or separated. The word 'partner' in the consent form includes the spouse or the current partner.

Q 27. Are the 'Consent forms' in the manuals for various family planning procedures available in local languages?

A Manuals published by the GoI are in the English language only. However, states are free to translate them in their local language provided the contents translated are verbatim and convey the same meanings, intents and legal connotations.

Q 28. Who can provide 'consent' in case of a mentally unsound 'ever married' client?

A For mentally unsound 'ever married' client, a certificate from a psychiatrist indicating their unsound mental status is required. Thereafter, the legal guardian can provide consent, if the client is otherwise fit to undergo surgery.

Q 29. In a situation where the client does not turn up for a sterilization procedure even after giving a written 'consent', can the provider be held responsible for not providing services?

A No, the provider would not be held responsible and in such cases LAMA (Left Against Medical Advice) should be documented in the case sheets to avoid any litigation in future.

Q 30. If a client refuses to undergo sterilization operation in the operation theatre even after signing the 'Consent form', can the client be forced to undergo sterilization?

A No, in such cases the client cannot be forced to undergo sterilization at that juncture and instead should be counseled to come later for the same.

Q 31. Is it mandatory to take signature/ thumb impression of the client in case she/he refuses to undergo the procedure on the operating table after signing the 'informed consent' form?

A No, signature/thumb impression of the client is not mandatory if she/he refuses the procedure. Documentation of the refusal should mandatorily be done in the case sheet with a witness. However, it is preferable to have the client's signature/ thumb impression too in these cases.

Q 32. Can post-partum sterilization procedure be performed in a situation where client has given a 'conditional consent' before C-section? (Sterilization procedure depending on the sex of the baby born)

A No, there is no scope for 'conditional consent' in the sterilization programme. The client has to decide in advance whether she wants to get the procedure done or not, irrespective of the sex of the baby born and give a clear 'consent'.

B. PRE-ANAESTHETIC MEDICATION:

Q 33. Can xylocaine be administered with adrenaline for dilution?

A Mixing adrenaline with xylocaine does not reduce the concentration of xylocaine. Adrenaline is used for vasoconstriction to reduce bleeding from the operation site. The disadvantage of this is that it initially causes vasoconstriction followed by vasodilatation when the effect of adrenaline wears off, which ultimately may result in haematoma formation at the operation site. Therefore, it is better to identify the bleeders and tie them instead of using adrenaline to reduce bleeding from the operation site. Hence, xylocaine should not be administered with adrenaline.

Q 34. Should a sensitivity test be done for xylocaine before administering it as an anaesthetic?

A No, the chances of developing an anaphylactic shock following xylocaine administration are extremely rare. Hence, the sensitivity test is not recommended as per 'Standards'.

Q 35. Why is atropine not recommended as a pre-anaesthetic medication in clients undergoing sterilization?

A Atropine as a prophylactic does not prevent vaso-vagal attacks. Further, it is well established that under local anaesthesia (LA) there are only rare chances of bronchial secretions and constriction. Studies show that if atropine is administered prophylactically, then the drug fails to act as a therapeutic agent in cases where an actual vaso-vagal attack, bradycardia or heart block takes place.

Q 36. What are the routes of administration for Pethidine and Promethazine?

A Pethidine and Promethazine can be administered intramuscularly or intravenously. The intramuscular dose should be administered 30 to 45 minutes prior to surgery and the intravenous dose should be administered 5 minutes prior to the surgery.

Q 37. Is an anaesthetist required for emergency or back up while administering pre-anaesthetic and analgesic drugs before sterilization?

A Pethidine, promethazine and pentazocine are the pre-anaesthetic/analgesic medication recommended in the GoI guidelines. These medications are safe to be administered to the clients and do not require anaesthetists for management as these do not cause respiratory or cardiovascular depression.

Q 38. Can general or regional anaesthesia be used for female sterilization?

A Although general and regional anaesthesia can be used safely and effectively for abdominal tubectomy and laparoscopic tubal occlusion, the number of unexpected and life-threatening complications related to it is higher than the number associated with local anaesthesia (WHO, 1992). Local anaesthesia has proven to be the most appropriate mode of anaesthesia for female sterilization procedures (both minilap tubectomy and laparoscopic tubal occlusion) and can be safely administered even in settings with limited resources. General and regional anaesthesia should be used in cases with specific indications and only in settings that are properly equipped and staffed by qualified anaesthetists to provide such anaesthesia and to handle emergencies.

C. FEMALE STERILIZATION PROCEDURES:

Q 39. What should be done if the facility has inadequate minilap kits?

A State should do a gap assessment and propose adequate numbers of minilap kits and other equipment in the state PIP. There is an option of proposing the same in the supplementary PIP also, if the state wants to procure it in the same financial year.

Q 40. Which suture material viz. Vicryl or Chromic Catgut is recommended for sterilization procedure?

A Vicryl is costlier than chromic catgut. Hence, GoI recommends the use of chromic catgut. However, the states are free to procure suture materials as per their preference.

Q 41. What kind of suture materials are used for ligating the tubal stumps?

A Only 1-0 chromic catgut is used for ligating the tubal stumps while performing tubectomy. Use of other suture materials is discouraged since it can lead to recanalization of the tubes.

Q 42. Can a provider perform laparoscopic tubal occlusion in case of a history of previous surgery (e.g. C-section)?

A The 'Standards and Quality Assurance in Sterilization Services, 2014' mentions that no medical condition can prevent a woman from undergoing female sterilization but may limit when, where or how the female sterilization procedure be performed. In case of a previous surgery (e.g. C-section) if the uterus is mobile then it can be performed with caution and if the uterus is immobile then it falls under special category and can only be performed in a setting with an experienced surgeon, equipment to provide general anaesthesia and other back-up medical support.

Q 43. Under what circumstances can a provider deny female sterilization services to a client?

A There are no absolute contraindications for not performing female sterilization operations; however, there are certain conditions that may require caution, delay or referral to a specially

equipped centre. The 'Reference Manual for Female Sterilization, 2014' has clearly mentioned these conditions based on the WHO Medical Eligibility Criteria.

Q 44. What is the cut off limit for haemoglobin that is considered safe for sterilization procedure?

A There has been a revision in the criterion which now states that the hemoglobin level should be at least 7 gms/dl (instead of the 8 gms/dl considered earlier) to undergo sterilization.

Q 45. Why is HIV testing not recommended for clients before a sterilization procedure?

A HIV testing is not recommended since even a positive case may give a negative result if performed within the window period. There are chances of false positives as well as false negatives. Moreover, even if a client shows a true positive result he cannot be denied a sterilization procedure. It is therefore prudent to consider every case to be HIV positive and adhere to Universal Safety Precautions (USP).

Q 46. Can pregnant women be considered for sterilization procedures?

A No, pregnant women should not be consider for sterilization procedure as there is a risk of abortion associated with it. Moreover, these cases may subsequently file undue claims of compensation for failures which would be difficult to counter, if proper documentation of such cases is not done. Women should be counselled about risks and post-partum sterilization can be offered to the clients immediately after delivery.

Q 47. Can the clients be offered MTP and ligation in the early stages of pregnancy on demand?

A Yes, the clients can be offered MTP services (if within the stipulated period) free of cost in public health facilities and thereafter post-abortal or interval ligation can be performed after proper screening.

Q 48. Why should the Trendelenburg position for conducting laparoscopic sterilization not exceed 20 degrees?

A Trendelenburg position of more than 20 degrees increases the chances of respiratory arrest and can elicit cardiac arrest due to increase in pressure on the diaphragm as also increased chances of hypotension.

Q 49. Why should Post-Partum sterilization not be performed beyond seven days of delivery?

A By the seventh day of delivery access to the fallopian tubes becomes difficult as the uterus descends in to the pelvis. Moreover, as one nears the seventh day, the endometrial shedding which prevents bacterial colonization also reduces; hence the risk of pelvic infection is higher. Therefore, it is advisable to delay the procedure beyond 42 days (six weeks) after delivery and conduct an interval procedure either through minilap or laparoscopic mode when the uterus has fully involuted, become less vascular and the risk of pelvic infection is much reduced.

Q 50. Why is crushing of tubes not recommended in a sterilization procedure?

A Crushing of tubes increases the chances of bleeding and opening of the suture. The tubes should be cut such that they fall apart to avoid spontaneous recanalization.

Q 51. What is the recommended number of 'Falope' rings required to ligate fallopian tubes in case of laparoscopic tubal occlusion?

A A single 'Falope' ring each is enough for ligation of the fallopian tubes, if applied correctly.

Q 52. Is the repair of peritoneum required in case of female sterilization?

A The repair of peritoneum is not required in case of female sterilization. However, the surgeon may opt to do so if she/he feels the need for the same.

Q 53. If the fimbrias are cut in sterilization, can recanalization occur?

A No, the chances of recanalization are rare in such instances.

Q 54. What is the ideal duration for post-operative hospital stay in female sterilization?

A As per GoI norms, a client with stable vitals can be discharged after 4-6 hours of surgery. Extended stay beyond the recommended period is not advised in uncomplicated cases since the chances of contracting nosocomial infection is high in the extended period.

D. MALE STERILIZATION PROCEDURES:

Q 55. Is complete hernia a contraindication for NSV?

A No, there are no absolute contraindications for conducting NSV; however, some conditions may fall under the category where sterilization procedure needs to be delayed but not denied (Please see 'Reference Manual for Male Sterilization, 2013').

Q 56. Is suprapubic incision recommended for taking out both the vas during male sterilization?

A Supra pubic incision is not recommended in public health facilities and in camp settings as the vas may get stretched and torn when taken out through supra pubic incision.

Q 57. Can state/district support a client demanding re-canalization at a private health facility under NHM?

A No, at present there is no scheme under NHM where a client can avail of recanalization surgeries in a private facility.

E. STERILIZATION DOCUMENTATION:

Q 58. What needs to be done by providers in cases where the client's vas was already found to be ligated?

A The surgeon should document the finding in the case sheet. No compensation may be given in such cases as the client may have deliberately suppressed information in the hope of getting compensation money. Despite this if the client insists upon sterilization he may be asked to get his semen examination done from a designated public health facility to establish the failure/success of the previous operation.

Q 59. What should the surgeon do if he is unable to identify vas tubes on one or both the sides during sterilization procedure?

A A. The surgeon should communicate to the client that the procedure was not successful and document it in his case sheet as well as get it countersigned by the client. Compensation would however be paid as per the scheme to both the client as well as the providers' team

Q 60. Can the document be countersigned by a client's relative if client is in sedation and the surgeon was unable to identify the vas/tubes and document non-identification of vas/tubes as a reason of failed operation?

A The signature of the client on the document is important. Since most of the sterilization operations are performed under local anaesthesia, the clients are fully conscious and are otherwise normal, hence obtaining the signature of client after the procedure is not difficult. If the client is unconscious due to other forms of anaesthesia one can wait till the client regains consciousness and the circumstances are explained to her/him.

Q 61. Is confirmation/consultation mandatory from a second surgeon if the vas/tubes cannot be identified and hence not ligated?

A No, confirmation/consultation is not mandatory from a second surgeon if the tubes cannot be identified and hence not ligated. Document it in the case sheet and get it countersigned by the client. No sterilization certificate should be issued in such cases. Such clients should be motivated to come for sterilization at a later date and the procedure should preferably be performed under general anaesthesia.

F. STERILIZATION CERTIFICATE:

Q 62. Can a provider issue a provisional certificate of sterilization on the day of sterilization procedure and subsequently issue the certificate of successful sterilization at the end of three months in case of male sterilization (negative semen examination report) and one month in case of female sterilization (negative pregnancy test or if the menses have resumed)?

A A provider may issue discharge card or slip with post-operative instructions stating that the client underwent the procedure on the same day itself. However, the certificate of successful sterilization should only be issued at the end of three months of male sterilization (negative semen examination report) and one month after the female sterilization (negative pregnancy test or if the menses have resumed). This will help in reducing the number of undue claims of failures attributed to sterilization.

Q 63. Can vasectomy certificate be issued if few/occasional sperms are seen in semen examination even after 3 months of procedure?

A No, vasectomy certificate should not be issued to the client even if occasional live sperms are found in semen examination report after 3 months of vasectomy. If the report does not reflect azoospermia even after 6 months of sterilization, the sterilization certificate should not be issued to the clients. Such cases where a certificate of successful sterilization has not been issued are not eligible for compensation under the 'failure of sterilization' clause of the Family Planning Indemnity Scheme (FPIS).

Q 64. Is it mandatory to provide sterilization certificate to all the clients opting for sterilization?

A It is the right of every client to receive the sterilization certificate after successful sterilization has been established.

Q 65. Can a facility issue a duplicate sterilization certificate to a client who has lost/misplaced it?

A The facility should issue sterilization certificates usually with a counterfoil/carbon copy. The client should acknowledge the receipt of the original certificate on the counterfoil/carbon copy before receiving it. The counterfoil/carbon copy should be maintained as a record in the facility as per state norms. In the event of loss/misplacement of certificate by the client, an attested photocopy of the counterfoil/carbon copy can be issued.

Q 66. Can sterilization certificate be issued to a female client who has not resumed her menses after one month of sterilization procedure?

A Yes, sterilization certificate can be issued to the client who has not resumed her menses provided her pregnancy test is negative.

Q 67. Why is there a criterion to wait for one month after female sterilization to issue sterilization certificate?

A The criterion rules out any luteal phase pregnancy which usually cannot be detected through any available tests and thus reduces the number of undue claims of 'failure' under FPIS.

Q 68. What should be the duration of maintaining sterilization records in the facility?

A Sterilization records should be maintained as per the existing state policy/norms for medico-legal records.

Q 69. Can a case of unsuccessful sterilization due to non-identification of the tube/vas on one side or both, be included in the reported sterilization figures?

A No, an event of unsuccessful sterilization operation due to non-identification of the tube/ vas on one or both sides can not be counted in the sterilization figures reported by the facility. However, it should be documented and the same should ideally be countersigned by the client (thumb impression, if illiterate). The compensation money should be paid to both provider's team and client for conducting and undergoing sterilization respectively.

Q 70. Can a surgeon perform sterilization operation on the same client twice?

A Yes, in case the surgery was not successful in the first attempt. Moreover, both the client and the providers' team are also entitled for compensation as per the scheme each time.

Q 71. What should be done if the particulars declared by the client and entered in the 'application cum consent form' before sterilization differs from the documents produced by her/him later on?

A The particulars declared by the client and entered in the 'application cum consent form' shall be considered final for any legal issues that may crop up later on (Self declaration of the client is the basis for defining her/his eligibility criteria). The onus is on the client if any advertent or inadvertent lacunae in reporting or documentation is revealed later on.

G. STERILIZATION COMPENSATION PAYMENT:

Q 72. Will compensation for death be paid in case the client signs the consent form for caesarian section concurrent with sterilization procedure but dies before caesarian section during administration of anaesthesia?

A Yes, once the consent form has been signed, the client comes under the ambit of the FPIS and hence can be paid Rs. 50,000 immediately from the district health society funds in the event of death. However, the balance Rs. 1,50,000 can only be paid if the death audit reveals that the death was attributable to the sterilization procedure.

Q 73. Is the client eligible for payment of compensation for sterilization in case the first sterilization procedure was unsuccessful and client returns for a repeat sterilization procedure again?

A Yes, the client as well as the providers' team is eligible for compensation for repeat sterilization procedures.

Q 74. Who is entitled to receive compensation money in case of death of a client?

A In case of death of a client, compensation money should be paid to the spouse and dependent unmarried children whose names appear in the relevant rows of the 'application cum consent form' for sterilization submitted by the client.

Q 75. Will compensation be paid to a vasectomy/tubectomy client whose spouse is already sterilized?

A No, compensation will not be paid to a client whose spouse has already undergone sterilization procedures.

Q 76. Can a client with an unsuccessful sterilization claim compensation for sterilization failure if his wife conceives?

A No, in case of an unsuccessful sterilization operation a sterilization certificate cannot be issued. Therefore, he is not eligible for compensation of failure under FPIS.

Q 77. Who will receive the compensation amount earmarked for the anaesthetist in the operating team, if local anaesthesia has been administered?

A Sterilization compensation money for anaesthetist will be paid to the person administering anaesthesia (surgeon/anaesthetist). Compensation scheme details the financial compensation paid against the services offered by the providers' team.

Q 78. Can a single provider conduct more than one camp on a single day at different locations?

- A** A single provider can conduct more than one camp in a single day provided
- The total number of cases on that day does not exceed 30.
 - The sites are in proximity allowing the provider to move from one place to another quickly, comfortably and
 - The last case is performed before 05.00pm on that day

However, the GoI is encouraging a shift from the 'camp approach' to the 'fixed day static/daily service approach' in order to provide quality sterilization services. Ideally till the 'camp approach' is being followed, the camp calendar should be prepared in advance in such a way that it caters to the demand for sterilization services adhering to the GoI guidelines for sterilization camps. Restricting to 30 cases per day for any type of sterilization procedure by a team will help in managing both the number of clients provided services as well as timings on a given day.

Q 79. On the day of camp more than 100 cases turn up for sterilization. With a high client load and limited laparoscopes it is difficult to decontaminate the laparoscope maintaining its turn around time of 25 minutes. What approach should be followed to ensure timely provision of services without turning away clients?

- A** Maintaining quality and standards is the collective responsibility of the entire team at the facility. Camps should be planned in advance and accordingly cases should be registered prior to the day of camp. Estimation of likely number of clients to turn up for accessing services will help in determining the number of teams. In case of laparoscopic tubal occlusion, 30 cases can be performed with two sets of laparoscopes maintaining decontamination time of 20 minutes for each laparoscope following each procedure. For serving more number of clients proportionately more number of laparoscopes would be required and if the number exceeds 30 then proportionately more surgical teams would be required. Under no circumstances, the laid down criteria by the GoI should be compromised with. In absence of additional providers' team and resources the surplus clients should be motivated to come on a subsequent day and be explained that the unforeseen delay is for ensuring their own safety and quality services.

Q 80. Can a surgeon conduct more than 30 cases in a single day, if the assigned second surgeon is unable to provide the services due to some unavoidable reasons?

- A** No, one surgeon should restrict herself/himself to 30 cases in a single day.

Q 81. Camp timings are from 9 am- 5 pm, however, camps get delayed in some hard to reach areas as it takes a lot of time to reach those facilities. In such instances can there be a provision for overnight stay of the teams?

- A** Yes, states can budget for overnight stay at hard to reach areas where travel to the camp site on same day is a challenge. The same can be reflected in their NHM state PIPs and approved at the GoI level.

Q 82. Is the surgeon solely responsible for any mishap that may occur during services rendered in the fixed day/camp mode?

- A** No, the surgeon cannot be held solely responsible for the procedure conducted in the fixed day/camp mode. The entire team involved in the camp or facility is responsible for the mishap, if any.

Q 83. Can there be a provision for providing compensation to the 'safai karamcharis' (cleaners) for rendering services?

A No, at present there is no separate compensation earmarked for them. However, states can make provisions for such incidentals from the 'camp management' head.

Q 84. How should extra client load be managed in a facility with limited bed availability on the day of camp?

A In case a facility with limited bed strength is selected for a camp, then the district should plan in advance and hire extra cots on rent for the duration of the camp.

Q 85. Is there a provision for drop back facility/overnight stay for sterilization clients from identified hard to reach and difficult areas?

A GoI has initiated the 'drop back' facility to the clients of sterilization as per DO. No. 11024/2/2014-FP issued on 30th January 2015. States may utilize existing empaneled vehicles for pick up and drop back of clients in hard to reach areas or areas with poor public transport. The state may also propose for the same under budget head 'B.12' in the state PIP in case existing vehicles are not sufficient.

Q 86. Given the shortage of laparoscopes, how can a district ensure 2 laparoscopes per surgeon for conducting 30 cases during a sterilization camp?

A Pre camp planning can reflect the number of laparoscopes needed and the state can thereafter budget it under NHM. There is no limit on the number of laparoscopes per team, however, a set of two is the bare minimum and should preferably be made available. There is also provision for repair of faulty laparoscopes.

Q 87. How can a district or state ensure availability of 'Trendelenburg' operating tables during camp?

A District/State may carry out of gap assessment to identify the need for 'Trendelenburg' operation tables across facilities providing sterilization services and budget the same in their district/state PIP.

Q 88. Can states plan for dedicated mobile teams to conduct camps and thereby ensure that routine services at health facilities do not suffer due to prior engagement of providers in the camp?

A GoI has recommended establishment of dedicated mobile teams in EAG states where there is a dearth of human resources. State may submit proposals for these mobile teams in their NHM state PIPs which can be approved and funded by the GoI.

Q 89. Is there a minimum number of clients who can be catered to in a sterilization camp?

A No, there is no minimum limit. However, GoI recommends that camp planning should be initiated at the beginning of the year so that demand generation activities can be accordingly synergised. The number of camps and surgeon teams should be based on the client load in such a way that adequate number of cases turn up so as to make the camps productive.

Q 90. What is the role of an anaesthetist in a camp where the operating surgeon himself can provide local anaesthesia?

A Sterilization is a simple procedure done preferably under local anaesthesia and the services of an anaesthetist are not routinely required. However, it is up to the state governments to decide whether to make the presence of an anaesthetists mandatory in the camps.

Q 91. What is the difference between 'fixed day static' services and 'camp' services as both are done on fixed days?

A In 'fixed day static' services the trained provider is posted in the same facility and provides services in a regular manner whereas in a camp conducted on a fixed day the trained provider travels from one facility (usually higher) to another facility (usually lower) to provide services on fixed days.

Q 92. Can a District Hospital (DH) be utilized every day for conducting sterilization?

A Yes, a District Hospital should ideally provide sterilization services daily on walk in basis with trained providers posted in the facility.

Q 93. What is the definition of a 'Functional Operational Theatre' (OT)?

A An operation theatre used daily for surgeries or a closed OT cleaned at least once a week is a 'Functional OT'.

Q 94. Can a facility providing services in a Fixed Day Static (FDS) manner extend the number of sterilization cases beyond 30 per day with a single provider?

A No, the facility cannot extend the number beyond 30 sterilization cases in a day with a single provider. The FDS approach recommends a minimum of biweekly service at District Hospitals, weekly at Sub District Hospitals, fortnightly at CHCs and monthly at PHCs level. Frequency and/or number of teams may be increased to cater to a higher client load. Hence the facility can increase the frequency of FDS to accommodate more cases but not beyond 30 per day per surgeon.

Q 95. If a surgeon is performing sterilization cases in the facility where she/he is posted, will it be designated as a camp?

A No, it will be considered a 'fixed day static' facility and not a 'camp'.

Q 96. Can the number of sterilization cases be extended beyond 30 in a static facility with an additional visiting doctor?

A The facility is designated as a static centre only when the provider is posted in the facility. As per GoI guidelines, a surgeon can perform 30 cases in a day. With a second surgeon (visiting doctor) the number can go up to 60 in a day without compromising on the quality parameters.

Q 97. Usually the laparoscopic procedure on a client takes 5-7 minutes which means 10-20 cases can be completed within 2 hours. However, decontamination of laparoscopes takes at least 20 minutes following each procedure and practising this might increase the waiting period of attending clients. What should be done to address this issue?

A GoI norms recommend a minimum of 2 laparoscopes per team of one surgeon conducting 30 sterilization cases in a day. However, state may budget for more laparoscopes in their PIP to ensure quality service delivery without compromising on infection prevention practices. It is important to note that due to the risk of infections like Hepatitis, HIV etc, decontamination of laparoscopes is mandatory after each procedure even if it leads to an increase in the waiting period of attending clients. Client may accordingly explained that the increase waiting period is in their interest of receiving safe and quality services.

Q 98. What should be the frequency of cleaning an Operation Theatre (OT) where high client load camps are held?

A The operation theatre should be cleaned every 2 hours as the bacterial and viral count increases in 2 hours.

Q 99. How should the Operation Theatre (OT) be cleaned?

A Operation theatre should be mopped with a cloth soaked in chlorine solution to remove dust from window panes and walls. Broom and dusting should never be practised as it spreads dust even to clean areas.

Q 100. Can the Operation Theater (OT) be fumigated as a part of Infection Prevention protocol?

A No, fumigation of operation theatre is an obsolete method and studies have shown that formaldehyde is carcinogenic in nature and irritant to eyes and lungs. Moreover, it is a weak antiseptic. As per GoI guidelines, the following instructions for infection prevention in OT must be ensured:

- **Before Surgery:** Clean the floor with a mop soaked in 0.5% chlorine solution (broom should never be used).
- **In between Surgeries:** Clean the operation table/counter top with cloth soaked in detergent and then with 0.5% chlorine solution.
- **After Surgery:** Clean operation table/counter top and light handles by swabbing with 0.5% chlorine solution.
- **When not in use:** OT should be locked after cleaning.
- **Weekly Cleaning:** Clean walls, floor, and other surfaces by scrubbing with detergent and plain water from top to bottom followed by 0.5% chlorine solution.
- Movement in and around the OT should be minimized to reduce the number of micro-organisms.

Q 101. Why is there a need to wash hands after removing gloves?

A Gloves have micro-pores which may act as a passage for infected body fluids and contaminate the hands while conducting examinations or performing the operation. Therefore, it is advisable to wash hands after removing gloves.

Q 102. Can the provider use tissue paper/napkin to dry hands after handwashing?

A Yes, the provider can use tissue paper to dry hands after hand washing, provided it is clean and untouched.

Q 103. Can 2 laparoscopes be disinfected in a single glutaraldehyde tray?

A Yes, 2 laparoscopes can be disinfected in a single glutaraldehyde tray. The only precaution is to ensure that the laparoscopes are fully immersed for 20 minutes each. Moreover, the sequence of entry and exit of each immersed laparoscopes from the glutaraldehyde tray should be maintained in a logbook.

Q 104. For how long can glutaraldehyde be used?

A Once the activator is put in the glutaraldehyde, it can be used upto 14 days.

Q 105. Does the surgeon need to change gloves before every case?

A Yes, gloves should be changed before every case.

Q 106. How should one manage 'trained' providers who are not confident in providing sterilization services?

A A three-day refresher training can be provided to these service providers. If even after that they are not confident then she/he should be provided a repeat full 12 working days' curricular training.

Q 107. If a district hospital/facility conducting 600 sterilizations cases every year does not fulfill the minimum criteria of infrastructure (as laid down in the QA manual) for its designation as a training centre, what measures can be undertaken?

A The district may budget for infrastructure strengthening in the NHM state PIP for approval from the GoI. The DQAC is empowered to designate the district hospital/ facility as a training center once the criteria of case load and infrastructure is fulfilled.

Q 108. What should be done for certification of providers who have been trained in laparoscopic sterilization as per curriculum during their post MBBS phase but did not receive certificate after the completion of training?

A Providers trained in laparoscopic sterilization during their post MBBS phase can obtain their certificate from their medical colleges and hence would not require formal training again.

Q 109. Can a private provider be trained for providing sterilization services?

A Yes, a private provider who fulfills the eligibility criteria can be trained for providing sterilization services. However, priority should be given to the providers serving in the public health facilities. Once the public health facilities are saturated with trained providers, only then should training be provided to the private providers.

Q 110. Who is responsible for managing complications that may arise during training of trainees on clients?

A The trainer should take charge of managing any complications which may arise during training and complete the surgical procedure.

Q 111. Is there any provision for conducting FPIS meetings in the absence/unavailability of the District Collector? Can rest of the members proceed with the meeting in this case?

A District Collector is the chairperson of the District Indemnity Subcommittee (DISC) and it is ideal for her/him to chair the meeting. Since the collector is usually a very busy official, the meeting can be held, in her/his absence, if prior meeting notice has been issued with his approval and the quorum has been met. The meeting can be then chaired by the next senior member of the committee present at the meeting .

Q 112. What is the time line to report cases for insurance claims under NFPIS (National Family Planning Indemnity scheme)?

A The client should submit 'claim' documents to the DQAC within 90 days from the occurrence of an event of complication/failure/death.

Q 113. What documents are required to file claims of failure in case of sterilization?

A The following documents are required to file claims of failure in case of sterilization:

- a) Claim form cum medical certificate duly filled in original
- b) Copy of sterilization certificate
- c) Copy of any diagnostic report confirming failure of sterilization

Q 114. In case of death following sterilization, if an FIR is lodged against the provider by the client then how should this matter be tackled?

A Sterilization deaths are to be reported in the Death Notification Form (Annexure 12 of Standards and Quality Assurance in Sterilization Services, 2014') to the District CMO, i.e. the convener of the District QAC, by Medical officer incharge of the facility, within 24 hours of death through telephone, e-mail, or in person. The operating surgeon of the case should also be informed simultaneously of the occurrence of death so that she/he may fill the 'proforma for death following sterilization' (Annexure 13 of Standards and Quality Assurance in Sterilization Services, 2014') within 7 days of intimation and send it to the District QAC. The case should then be handled by State/District QAC on behalf of the provider.

Q 115. Who should investigate the case of a death following sterilization?

A The facility in-charge and CMO should be informed immediately in case of a death. The DISC should investigate the cause of the death and submit their finding to SQAC.

Q 116. What should be done in the event of a death occurring within 1 month after sterilization or before the issue of a certificate of sterilization?

A An amount of Rs. 50,000 should be released immediately from the state or district health society funds if the death occurs within the first 7 days of discharge. The DISC should examine the case and establish the cause of death. If DISC attributes the death to sterilization, then recommend to the State Indemnity Subcommittee (SISC) for release of the balance amount of Rs. 1.50 lakh to the spouse and dependent unmarried children as entered in the application cum consent form (if within seven days). If the death has occurred after seven days to one month of discharge then the payment of Rs. 50,000 will be subject to attribution of the death to

sterilization by the SISC. In all cases of death SISC has the mandate and the right to re-examine and review the case if it feels the necessity for it and releases the funds accordingly.

Q 117. Is the client entitled to claim for 'complication following sterilization' procedure if a wound abscess develops following the procedure?

A Yes, the client is entitled to claim provided complications occur within 60 days from the date of discharge following a sterilization procedure. All claims needs to be processed through DQAC and the client is paid as per actuals, the amount not exceeding Rs. 25000/-. The client should submit claim documents, including original receipts of the expenses borne, within 90 days from the occurrence of the event of complication.

Q 118. What are the basic HR requirements for accreditation of private health Facilities/ NGOs for sterilization services?

A	Female Sterilization	Male Sterilization
	<ol style="list-style-type: none"> 1. • Empaneled Gynaecologist (DGO/MD/MS)/ • Surgeon with MS Degree/ • MBBS <p style="text-align: center;">} trained in Minilap sterilization</p> <p style="text-align: center;">OR</p> <ol style="list-style-type: none"> • Empaneled Gynaecologist (DGO/MD/MS)/ • Surgeon with MS Degree/ • MBBS already performing Minilap <p style="text-align: center;">} trained in Laparoscopic sterilization</p> <ol style="list-style-type: none"> 2. One OT Staff Nurse/ LHV/ ANM 3. One OT Assistant/Helper 4. Anaesthetist – if required. 5. Laboratory Technician 	<ol style="list-style-type: none"> 1. Empaneled MBBS doctor and above trained in Vasectomy 2. One Staff Nurse LHV/ ANM / 3. One OT Assistant /Helper 4. Laboratory Technician

Q 119. Are all providers performing sterilization procedure at public/accredited private/NGO facilities covered under the National Family Planning Indemnity Scheme (NFPIS)?

A Only empaneled providers in public/accredited private/NGO facilities are covered under the National Family Planning Indemnity Scheme (NFPIS).

Q 120. Are compensation schemes and FPIS applicable for sterilization camps done at private health facilities?

A Yes, provided the private facilities are accredited by the State/District QACs.

Q 121. Who releases the compensation amount in the event of death occurring between 8-30 days of discharge of a client following sterilization ?

A In such cases of death, the DQAC can be convened immediately to investigate the case and ascertain whether the death was attributable to sterilization. The DQAC then recommends the case to the SISC for release of compensation as per the NFPIS from the FPIS head of the State/District NHM funds.

Q 122. Can FPIS claim be paid to a client who underwent a sterilization procedure and submitted the 'application cum consent form' but died of some reason not directly related to sterilization within seven days' of discharge?

A In these cases, Rs. 50,000 can be paid to the kin of the deceased from the RKS fund immediately after the death when the investigation has not been carried out and the causes were not identified immediately. However, the release of the remaining amount of Rs. 1,50,000 should be done only after the DQAC/SQAC ascertain and documents that death was attributable to sterilization procedure in the death audit report.

Q 123. What are the norms of Indemnity coverage under NFPIS for doctors/facilities in public and private accredited/NGO sector?

A Indemnity coverage of amount upto Rs 2 lakh per litigation per doctor and per facility in a year is applicable under NFPIS.

A maximum of 4 cases of litigation per doctor is covered, irrespective of the number of cases she/he performs and irrespective of the number of health facilities where she/he conducts surgery. Similarly a maximum of 4 cases of litigation per facility is covered irrespective of the number of cases performed in that facility and irrespective of the number of empaneled providers conducting surgeries in that facility.

Q 124. Does FPIS cover claims for deaths following sterilization concurrent with a caesarian section?

A Yes, FPIS covers such claims of death and the case should be reported to the District Family Planning Indemnity Sub Committee. The committee has to establish whether the death was due to obstetric complications or sterilization procedure. The DQAC after ascertaining death to be as attributable to sterilization recommends to the SQAC who inturn release the fund after re-examining and endorsing the same.

Q 125. In a situation where a client with a certificate of successful sterilization got pregnant and underwent MTP but did not claim compensation under failure for that particular pregnancy, can she claim the same if she gets pregnant again a second time?

A No, claims for failure can be entertained only once after sterilization, if the documents are submitted within the stipulated time of 90 days of the confirmation of the pregnancy. The same cannot be entertained for any subsequent pregnancies

Q 126. Is the State Indemnity Sub Committee (SISC) required to verify the claims submitted by the DQACs under FPIS?

A SISC has a right to verify the claims but may be unable to do so for all claims. In case a district is reporting a suspiciously large number of claims, SISC should verify them and can seek explanation from the DISC as well as examine all the cases to rule out any foul play. However, each case of death should be reviewed mandatory by the SQAC/SISC before release of funds.

Q 127. How is the issue of data mismatch addressed in situations where sterilization case sheets are retained in the medical record department while the sterilization consent forms are maintained by the family planning/welfare department?

A An internal system can be developed and managed wherein case sheets are kept along with the consent forms of 'sterilization' procedures in the medical records department separately.

Q

128. What documents are required to be submitted to file a claim of death attributable to Sterilization?

A

The following forms need to be submitted after due attestation by a convener of DQAC (CMO/or equivalent) designated at district level.

- a) Claim Form cum Medical Certificate duly filled in original.
- b) Copy of Post-Operative instruction/Discharge Certificate.
- c) Copy of Death certificate issued by Hospital/Municipality or authority.

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