

GIRFT & RCOG Best Practice for Laparoscopic Sterilisation

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Royal College of
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Background and justification

This guidance has been produced by GIRFT in partnership with the Royal College of Obstetricians & Gynaecologists (RCOG). Its aim is to provide advice on various aspects of surgery which should be available and clearly documented in the laparoscopic sterilisation operation record. The document is not a comprehensive guide to this diagnostic procedure; however, it is hoped that gynaecologists will find the advice it offers helpful.

This document was developed from the analysis of existing guidance, medical negligence claims notified to NHS Resolution by NHS trusts, feedback from NHS panel firm lawyers and expert witnesses. It has been established that poor operative documentation has made the investigation of incidents leading to claims difficult and has prevented the defence of good clinical practice. This guidance seeks to provide (non-mandatory) recommendations of what would reasonably be expected to be documented to support both good clinical communication with colleagues and potential review of operations in response to a patient complaint.

It is expected that the recommendations listed would be included within the documentation of patient care and although the majority will be included in the operation note, the information could be contained elsewhere in the patient record including assessment in A&E, ward round entries, a separate WHO Surgical Safety Checklist and drug charts. It is preferable where possible that the operation record is typed. The documentation where appropriate may be made by other members of the surgical team apart from the operating clinician. However, it is the operating clinician's responsibility to ensure that completion of the appropriate documentation has occurred. The operating record should accompany the patient into recovery and to the ward.

This guidance includes case studies which provide useful context and should be read in parallel with the recommendations.

Recommendations for documentation of practice in all patients undergoing laparoscopic sterilisation

1. The indication for the operation.
2. Documentation of the informed consent process including discussion about irreversibility and regret, the discussions of material risks to the individual patient (which may include failure rate, risk of ectopic pregnancy) and the reasonable alternative treatment options, including discussion on alternative methods of contraception and the risks and benefits of not operating. This should include whether any form of patient decision aid or another patient information resource has been provided.
3. Safety briefing, sign in, time out, and sign out as part of WHO Surgical Safety Checklist. Presence of required surgical equipment should be confirmed.
4. Record the name and grade of all surgeons and assistants.
5. Record the names and grade of anaesthetist(s) and type(s) of anaesthetic used.
6. Record the date and time of the procedure.
7. Record the drugs given pre-operatively and during surgery e.g. antibiotics, local anaesthetic.
8. Record the insertion of a urinary catheter if carried out.
9. Record if vaginal instrumentation was used.
10. Record the patient position and skin preparation.
11. Record any preventative measures taken designed to reduce risks associated with the procedure, if any.
12. Describe or draw the location of the incisions made in reference to anatomical landmarks and previous surgical wounds.
13. Describe entry into abdomen and any difficulty encountered:
 - a. Confirm type of entry (open, direct optical entry or Veress needle technique).
 - b. If open entry:
 - i. confirm that the trocar was inserted into the abdomen under direct vision.
 - ii. document size and position of incision made in umbilicus.
 - c. If Veress needle entry:
 - i. confirm entry pressure (< 8 mmHg), number of attempts and pneumoperitoneum pressure prior to insertion of trocar.

- ii. document the insertion of the other ports both in terms of position (suprapubic, etc.) and size (5/10/12mm) and that they were inserted under direct vision +/- use of local anaesthetic.
 - iii. record the level at which the intra-abdominal pressure was set (usually 25 mmHg).
 - iv. record if the patient was placed in the reverse Trendelenburg position.
 - 14. Document the findings at the time of surgery: relevant organs, pathology such as adhesions and degree of anatomic distortion if any, fibroids, ovarian cysts, etc.
 - 15. Record that the fallopian tubes were identified by visualising the fimbrial ends prior to application of Filshie clips.
 - 16. Record placement of Filshie clips at 90 degrees to the isthmic portion of the fallopian tube, and the clips encompass the whole tube.
 - 17. Record photographic evidence taken of clip placement.
 - 18. Record that haemostasis was achieved before beginning closure.
 - 19. Record any intraoperative checks carried out to identify/confirm the absence of damage to any surrounding structures and the findings of the same.
 - 20. Record that the ports were removed under direct vision. Document the release of pneumoperitoneum.
 - 21. Document sequential method of wound closure, (formal rectus sheath closure of lateral wounds if $\geq 10\text{mm}$), a dressing was applied and any local anaesthetic given.
 - 22. Record any intra-operative complications and what action was taken to remedy them including any additional procedures performed and the rationale for them.
 - 23. Document an estimate of the intraoperative blood loss.
 - 24. The post-operative plan including:
 - a. post-operative recovery including when the patient should eat and drink;
 - b. discharge plans;
 - c. removal of sutures/staples where required; and
 - d. any follow up requirements.
- Any concerns or deviation from standard practice should be identified and explained.
25. Clear instructions should be given regarding post-operative recovery including when the patient can eat and drink, discharge, removal of sutures where required and any follow up. Any concerns or deviation from standard practice should be identified with an explanation for any deviation.

26. Signature of the first surgeon alongside their name and grade to confirm the record is complete and accurate.

Duty of candour

It is important that appropriate duty of candour be exercised informing the patient of any events or perioperative complications which could cause harm or compromise their outcome, at the earliest opportunity following detection and as deemed appropriate by the treating team. This includes meeting the requirements of the statutory duty of candour in the event of a notifiable safety incident and should be carried out with both the statutory requirements, and with local policy. A notifiable safety incident is an unintended or unexpected incident (not outcome) which occurs during the procedure which could result or appears to have resulted in death (other than by natural causes), severe harm or moderate harm as defined in Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The process should include a clear apology, an offer of an appropriate remedy (if possible) and/or support. The communication should detail the short and long-term effects of what has happened, to the patient.¹

¹ Openness and honesty when things go wrong: the professional duty of candour, [Duty of candour - GOV.UK](https://www.gov.uk/government/publications/duty-of-candour)

Case vignettes

Case vignette 1

Consent for laparoscopic sterilisation

A woman with learning difficulties had all her previous children removed from her care. It was alleged that she did not have capacity to consent to laparoscopic sterilisation, and that there was a better, less invasive form of contraception that should have been offered.

Claim was settled for damages of £35,000 on the basis that she would never keep any children even though she wanted more children. Claimant costs were £33,000, defence costs £14,000.

Message

If there are capacity concerns, look at them early prior to the day of surgery and involve professional such as a learning disability nurse to facilitate. Include discussion of all treatment options in the consent process.

Case vignette 2

Consent in advance of the day of intrauterine device (IUD) insertion

This case does not relate directly to laparoscopic sterilisation but to the wider consent discussion of contraceptive options. Allegedly negligent consent discussions for insertion of an IUD (Mirena coil). It was noted that some risks were contained in the consent form, but it was admitted that there was no mention of specific risks and in particular the long-term side effects/risks. Whilst it was for the patient to prove she would not have proceeded with the IUD if there was a reasonable consent discussion, the defendant's expert evidence was that the patient would have suffered the same symptoms of heavy and painful periods in any event. However, there were risks as the patient suffered increased pain during the whole of her menstrual cycle for 8 months while the IUD was in place, rather than just pain during her period. The patient also alleged she should have been consented appropriately in advance of the insertion, rather than just on the day of the procedure.

Claim resolved by solicitor to solicitor negotiations resulting in costs of £40-50,000, most of which is claimant legal costs

Message

Make every effort to consent for procedures before the day of the procedure. Discuss all material risks with patients as per the Montgomery judgment (2015). Ensure that consent forms and any other records in the medical notes contain all risks and benefits which have been discussed with patients and include the alternative including the outcome if no treatment is given.

Acknowledgements & references

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About GIRFT

Getting It Right First Time (GIRFT) is a clinically led national programme designed to identify and minimise unwarranted variation in treatment and care delivered. It undertakes clinically led reviews of specialties, combining wide-ranging data analysis with the input and professional knowledge of senior clinicians to examine how things are currently being done and how they could be improved.

The programme has the backing of the Royal Colleges and professional associations and has a significant and growing presence on the Model Health System portal, with its data-rich approach providing the evidence for hospitals to benchmark against expected standards of service and efficiency.

The GIRFT model has now been applied in more than 50 different areas of clinical practice. It consists of five key strands:

1. **Data gathering** – a broad data gathering and analysis exercise, generating a detailed picture of current national practice and outcomes.
2. **Peer reviews** – direct clinical engagement via visits or virtual meetings between clinical leads and trust teams; an opportunity to examine trust behaviour in the context of the national picture, enabling teams to understand where they are performing well and what they can do better.
3. **National report and academy resources** – production of national reports that draw on data analysis and discussions with provider teams to identify opportunities for improvement, locally, regionally and nationally, alongside - clinical resources such as best practice pathways and guides.
4. **Support to deliver** – the implementation phase where the GIRFT team supports trusts, commissioners and integrated care systems to deliver the improvements recommended.
5. **Research** – GIRFT fellowships support resident doctors, nurses and allied health professionals to develop their research and clinical improvement skills, delivering research projects and GIRFT identified improvements in their host provider, system or region.



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GIRFT is part of an aligned set of programmes within NHS England