

GIRFT and RCOG Best Practice for Diagnostic Laparoscopy

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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 diagnostic laparoscopy operation record. The document is not a comprehensive guide to this surgical 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 diagnostic laparoscopy

1. Record the indication for the operation.
2. Documentation of the informed consent process, including information about the discussions of material risks to the individual patient and the reasonable alternative treatment options, including the risks and benefits of not operating, should be available. The likelihood of a blood transfusion or the need to proceed with any other additional procedures as relevant should be recorded. It should also be clearly documented if the patient does not consent to any of these relevant procedures including transfusion. Document any form of patient decision aid or patient information resource that has been used.
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: adhesions, abdominal organs, pelvic organs, etc.
- 15. Record that the ports were removed under direct vision. Document the release of pneumoperitoneum.
- 16. Document sequential method of wound closure (formal rectus sheath closure of lateral wounds if $\geq 10\text{mm}$), dressing was applied and any local anaesthetic given.
- 17. Record any intraoperative checks carried out to identify/confirm the absence of damage to any surrounding structures and the findings of the same.
- 18. Record any intra-operative complications and what action was taken to remedy them including any additional procedures performed and the rationale for them.
- 19. Document an estimate of the anticipated blood loss.
- 20. The post-operative plan including:
 - a. antibiotics;
 - b. if blood tests required e.g. haemoglobin;
 - c. the location the patient should be transferred to if they need higher level care e.g. HDU, ITU;

- d. frequency of clinical observations in the post-operative period;
- e. VTE thromboprophylaxis (including risk assessment and deviations from local protocol);
- f. post-operative recovery including when the patient should eat and drink;
- g. if used, when drains should be removed;
- h. removal of indwelling catheter;
- i. discharge plans;
- j. removal of sutures/staples where required;
- k. the need to check pathology results for the specimen sent; and
- l. any follow up requirements.

Any concerns or deviation from standard practice should be identified and explained.

21. 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/guidance/duty-of-candour)

Case vignettes

Case vignette 1

Uterine perforation during hysteroscopy and laparoscopy

A patient underwent a diagnostic hysteroscopy and laparoscopy following complaints of heavy periods with clots and severe abdominal pain. The procedures were performed seemingly without issue. The uterine cavity, fallopian tubes and ovaries were all noted to be normal but endometriosis was found.

Same day discharge was arranged with two-week follow up. All was noted to be normal at the time. However, a little over two weeks after the procedure the patient presented with severe generalised abdominal pain, nausea and urinary and bowel urgency. A laparotomy was performed which identified a uterine perforation and a necrotic left fallopian tube. This was removed and a loop sigmoid colostomy formed due to concerns about bowel wall integrity.

The patient brought a clinical negligence claim alleging that there was a negligent failure to identify the perforation during the index hysteroscopy and laparoscopy. Due to an inadequate surgical note, which was missing key information including details of whether or not a sound dilator was passed, how far the cervix was dilated, and what pre-completion checks were carried out, the case was settled. Damages of £365,000 were paid along with costs of £225,000.

Message

A detailed operative note setting out key aspects of the procedure, such as the level of cervical dilation, what equipment was used and what checks for potential intra-operative complications, such as damage to associated structures, have been carried out, is vital. Such documentation can greatly assist with post-operative management when complications arise by either ruling out or raising suspicion of intra-operative complications as the likely cause.

Case Vignette 2

Failure to consent for risks of perforated bowel during a diagnostic laparoscopy

Patient suffered a perforated bowel during a gynaecological diagnostic laparoscopy which was discovered two days later when she underwent a laparotomy. The patient stated that she

would not have undergone the original procedure if she had been appropriately informed of the risks and therefore, she would have avoided the bowel injury, additional surgery and the need for an ileostomy which was reversed 4 months later. The clinician involved was of the firm belief that they did discuss the risk of injury to the small bowel with the patient and that the discussion held was adequate. However, the consent form did not mention the risk of bowel injury. The consent process was not consistent with the Royal College of Obstetricians and Gynaecologists guidance (RCOG) which requires a clinician to stipulate risks of a bowel injury and that this could possibly lead to requiring a stoma.

In respect of the injury to the small bowel it was accepted by the clinician that a “through and through” injury occurred although this was not identified at the time of surgery. The expert advised that this was a direct consequence of the primary trocar being placed at a substandard level, which could have been avoided. It was considered that whilst a through and through small bowel injury is a recognised complication of a closed laparoscopy, the patient had no risk factors; she was slim, had no adhesions/had not undergone previous surgery and so her small bowel should have been freely mobile and not within the operative field when the primary trocar was inserted. It was accepted that bowel injuries are often not recognised at laparoscopy, and therefore not identifying the bowel injury at the time of the laparoscopy was not a breach of duty. There is the possibility that a bowel injury can worsen over time and hence why it may not have been detectable during surgery in any event. Whilst liability was initially denied having obtained the expert evidence described above, the denial could not be maintained and the claim was settled in favour of the patient.

Message

In accordance with the gynaecological expert evidence obtained, the trust was advised that patients must be given information about surgery. This should be recorded, and consent should be taken in accordance with RCOG guidance. A clinician should stipulate risks of a bowel injury including that this could possibly lead to requiring a stoma.

Case Vignette 3

Failure to check laparoscopic port sites

The claim relates to a laparoscopy procedure to investigate the claimant’s pelvic pain with a view to adhesiolysis, which had been successful in the past. Unfortunately, a bowel perforation occurred and resulting in a temporary stoma.

The NHS expert witness found that the clinician had not documented steps to completely satisfy himself that the trocar had not passed through loops of bowel given the known history of bowel adhesions. He should have documented inserting another laparoscopic port under direct vision into the abdominal cavity and then removing the laparoscope and inserting it through the additional port and looking upwards at the umbilical port to see if the trocar had damaged the bowel. Unfortunately, there was no evidence this was done.

Message

Based on the evidence of the expert witness, it is clear where there is suspicion of bowel perforation in a laparoscopic procedure, that efforts to identify this should be documented. It is important that the method used for entry into the abdomen is described and steps taken to protect the bowel.

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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