NHS England

GIRFT
GETTING IT RIGHT FIRST TIME

GIRFT and RCOG Best Practice for Total Laparoscopic Hysterectomy +/- Bilateral Salpingo-Oophorectomy (BSO)

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Royal College of Obstetricians & Gynaecologists

NHS Resolution

Contents

Background and justification

This guidance has been produced by GIRFT in partnership with the RCOG (and other relevant specialists associations can be added) and aims to provide advice on various aspects of surgery which should be available and clearly documented in the total laparoscopic hysterectomy +/- bilateral salpingo-oophorectomy 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 some incidents leading to claims difficult and has in some cases 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 standards 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 surgeon. However, it is the operating surgeon's responsibility to ensure that 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 total laparoscopic hysterectomy +/- bilateral salpingo-oophorectomy (BSO)

1. The indications for the operation and the evidence both in terms of serological markers, imaging, presenting complaint and clinical examination that has led to the decision to perform this operation.
2. Documentation of the informed consent process including information about the discussions any alternative surgical procedures and alternative treatments including not operating should be available. Records of the increased risk of urinary tract injuries with a laparoscopic approach compared to the vaginal approach and other material risks to the individual patient. The likelihood of a blood transfusion or the need to proceed with any other additional procedures as relevant, should be recorded. It should be clearly documented if the patient does or does not consent to any of these relevant procedures including transfusion. Documentation should include whether any 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.
9. Record the type of vaginal instrumentation device used e.g. uterine manipulator, cervical delineator.
10. Record the energy devices used.
11. Record patient position and skin preparation.

12. Record any preventative measures taken designed to reduce risks associated with the procedure, if any.

13. Describe or draw the location of the incisions made in reference to anatomical landmarks and previous surgical wounds. Describe adhesions or any other difficulty encountered.

14. 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.

15. 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.

16. Document identification of ureter(s) following opening and dissection of the broad ligament or by visualisation transperitoneally.

17. Describe coagulation and transections of round ligaments if applicable.

18. If the ovaries are retained, describe the coagulation and transection of the fallopian tubes (if applicable) and ovarian ligaments to separate the ovaries from uterine corpus.

19. If BSO planned, describe the isolation, coagulation and transection of the infundibulopelvic ligament.

20. Describe the isolation (whether skeletonization), coagulation and transection of the uterine pedicles.

21. Record dissection of the vesico-uterine space and bladder mobilisation to allow safe colpotomy without damaging the bladder.

22. Document the procedure for amputation of the uterus and cervix including what energy devices were used, what colpotomy ring (delineator) was used (if applicable) and the removal of the specimen vaginally and whether mechanical or power morcellation was required.

23. Document the vaginal vault closure and the materials used.

24. Record that haemostasis was achieved before beginning closure and whether any irrigation was performed. If additional haemostasis required using energy devices or sutures, describe the anatomical site(s) of bleeding.

25. Record that the ports were removed under direct vision. Document the release of the pneumoperitoneum.

26. Document sequential method of wound closure, (formal rectus sheath closure of lateral wounds if ≥ 10mm), a dressing applied and any local anaesthetic given.

27. Record any intraoperative checks carried out to identify/confirm the absence of damage to any surrounding structures and the findings of the same.

28. Record any intra-operative complications and what action was taken to remedy them including any additional procedures performed and the rationale for them.

29. Document an estimate of the intraoperative blood loss.

30. Document any tissue sent to histology.

31. 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;
l. any follow up requirements.

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

32. 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

Case vignettes

Case vignette 1

Failure to consent for alternative treatment

Patient suffered with lower abdominal pain and underwent excision of the endometriosis. Zoladex injections were prescribed. Patient proceeded to laparoscopic hysterectomy and left salpingo-oophorectomy. Right salpingo-oophorectomy was also subsequently performed. There was uncertainty as to the advice given to the patient regarding the Zoladex injections and the length of time over which they were to be administered prior to being able to determine their success and/or when surgery was indicated. There was a lack of documentary evidence as to the risk of the possible need for further surgery having been discussed with the patient at the time of the initial excision surgery.

The patient alleged that had proper advice and counselling been provided then she would have proceeded with the injections for a longer period, her condition would have improved and she would have avoided the need for subsequent surgical intervention. Partial admissions were made and a financial settlement agreed.

Message

It was accepted by the treating clinician that the consent process, documentation and record keeping was not of the necessary standard leading to uncertainty as to the information given to the patient.

Case vignette 2

Failure to detect haemorrhage earlier during post-operative care

During recovery from a hysterectomy, a patient suffered persistent low blood pressure. An exploratory laparotomy was performed the following day and the left uterine pedicle artery was inadvertently ligated. Diagnosis of haemorrhage was delayed, during which perfusion of blood to the brain and heart was limited. The patient suffered neurological injury and heart failure.

A clinical negligence case was brought for failure to perform post-operative observations to an appropriate standard and a failure to identify the haemorrhage earlier. It was alleged that

but for these failures the patient would not have suffered inadequate perfusion, heart failure and brain injury.

The claim was resolved by way of negotiation between the parties. A response to the allegations was provided, following receipt of independent expert evidence and the extent of injury suffered, as a result of the admitted negligence, was investigated. The NHS trust took on board the learning from the claim, reviewing post-operative care procedures in gynaecology.

Message

Ensure post-operative management plan is focused and clearly documented on the needs of the patient. Particularly where the surgery being undertaken is as a result of earlier surgery, where the patient has suffered an unusual and/or an ongoing difficulty.

Case vignette 3

Failure to adequately examine vaginal vault

The patient underwent a total laparoscopic hysterectomy and bilateral salpingectomy with ovarian conservation for symptoms of longstanding pelvic pain and heavy bleeding.

Some months later the patient attended with lower abdominal pain and vaginal bleeding following penetrative intercourse. Examination revealed complete dehiscence of the vaginal vault and emergency laparoscopic surgery was undertaken.

The patient then re-attended two days following discharge with further abdominal pain. She was examined and the vault was felt to be intact. A month following surgery she was re-reviewed without examination and discharged. A few months later she was re-admitted after penetrative intercourse and examination revealed repeat vault dehiscence. A second vaginal vault repair was undertaken.

A clinical negligence case followed on basis that there had been a negligent failure to examine the vaginal vault, either adequately or at all, on her follow up after the first vaginal vault repair. It was alleged that had the care been of the appropriate standard, then she would have been advised to abstain from intercourse until after examination confirmed the vault had healed. The second vault dehiscence, and subsequent repair, would have been

avoided. The opportunity was taken to remind staff of the need for sufficiently detailed correspondence to patients, and their GPs, following post-operative review.

Message

Ensure that the findings of follow-up appointments and subsequent advice on aftercare is detailed by way of correspondence to patients, with copies stored in the medical records. In particular ensuring that any restrictions in relation to sexual intercourse are clearly explained and documented.

Case vignette 4

Failure to accurately record cancer stage and substandard hysterectomy

The patient had an abnormal smear test result and a cervical polypectomy and LLETZ (large loop excision of the transformation zone – a treatment for abnormal cervical cells following cervical screening) was performed a month later. Dimensions of the cervical cancer could not be accurately assessed. However, it was anticipated that Stage 1A1 had been reached.

A further LLETZ procedure was performed two months after the first. At that point the disease was assessed as being at Stage 1B1. The parties' recollections differed as to whether chemo-radiotherapy had been discussed. Given the above, the patient opted for radical hysterectomy and the residual cancerous lump was removed.

Unfortunately, during the above operation, bowel perforation was suffered, together with damages to the sacral nerves. She went on to suffer post-operative urinary dysfunction.

A clinical negligence case was brought both for the alleged failure to correctly identify staging of the cancer but also for the alleged negligent performance of the hysterectomy. It was argued that, but for these failures, the patient would have opted for chemo-radiotherapy and avoided surgery and all subsequent complications.

The parties negotiated settlement. A detailed and meaningful response to the allegations was provided to the patient and an apology offered.

Message

Better dialogue with the patient, and recording of that dialogue in the records, was required. It transpired that had a better assessment been made, at an earlier point, then an alternative treatment plan would, on balance, have followed. This would have avoided the further surgery and associated difficulties.

Case vignette 5

Failure to accurately record intra-operative injury

The patient alleged that a negligently performed laparoscopic hysterectomy and bilateral salpingo-oophorectomy caused a bladder injury. They key issue on this claim was record keeping, as there was a discrepancy between the recorded operation note and subsequent clinical concerns of a possible bladder injury during the immediate post-operative recovery period.

This claim reached a risk-based settlement without any admission of liability by the trust. The claim was settled pre-action before the cost of court proceedings was incurred. Claimant accepted the NHS offer of £13,000 plus her legal costs which totalled £24,000.

Message

Record keeping should be comprehensive, and any injury should be recorded intra-operatively. In cases where clinicians have left post and cannot be contacted, the only evidence the defendant has is the records, and where these are inadequate it is very difficult to successfully defend a claim.

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