NHS England

GIRFT
GETTING IT RIGHT FIRST TIME

GIRFT and RCOG Best Practice for Total Abdominal 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 Royal College of Obstetricians & Gynaecologists (RCOG). It aims to provide advice on various aspects of surgery which should be available and clearly documented in the total abdominal hysterectomy +/- bilateral salpingo-oophorectomy 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 total abdominal 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 the discussions of material risks to the individual patient and the reasonable alternative treatment options, including the risks and benefits of not operating. 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 whether the patient does or does not consent to any of these relevant procedures including transfusion. The documentation 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.
9. Record the patient position and skin preparation.
10. Record any preventative measures taken designed to reduce risks associated with the procedure, if any.
11. Document the findings at the time of surgery:
    a. Size of uterus, distorted anatomy, previous surgery scars.
    b. Relevant organs, pathology such as adhesions and degree of anatomic distortion if any, fibroids, ovarian cysts, endometriosis, etc.
12. 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.

13. Document identification of ureters either by following opening and dissection of the broad ligament or by direct visualisation or palpation transperitoneally.
14. Describe isolation, clamping, transection, and suture ligation of infundibulopelvic ligament (if BSO is planned) or ovarian ligament (if ovaries retained).
15. Document dissection of vesico-uterine plica or fold and bladder mobilisation to allow safe colpotomy without damaging the bladder.
16. Describe pedicles which were clamped, transected and suture ligated. Document the placement.
17. Document whether uterine corpus was amputated if supracervical hysterectomy was planned.
18. Document if vault was left open or closed and materials used.
19. 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.
20. Record any intraoperative checks carried out to identify/confirm the absence of damage to any surrounding structures and the findings of the same.
21. Record materials and technique used to close parietal peritoneum (if closed), rectus sheath, subcutaneous fat (if required) and skin.
22. Document the type of wound dressing and any local anaesthetic given.
23. Record any intra-operative complications and what action was taken to remedy them including any additional procedures performed and the rationale for them.
24. Document an estimate of the intraoperative blood loss.
25. Document if the urine was clear at the end of the operation.
26. Document if vaginal swabbing was performed.
27. Document any tissue sent to histology.
28. The post-operative plan including:
    a. antibiotics;
    b. if blood tests required e.g. haemoglobin; and when to be done;
    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. when to remove the indwelling catheter, if in place;
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.

29. 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 options

Patient suffered with menorrhagia and claimed that the trust failed to offer reasonable treatment options for her condition and that a hysterectomy and bilateral salpingo-oophorectomy was performed without adequate consent. The procedure was subsequently not appropriately performed and trauma was caused to the bladder, resulting in a vesicovaginal fistula.

Admissions were made that, while conservative treatment was discussed, there was a failure to document the treatment options available to the claimant and there was therefore a failure to obtain fully informed consent. Expert evidence for the trust considered that there was limited information documented regarding the discussion of treatment options that were put to the patient. The outpatient assessment was considered to have been inadequate and the expert found no evidence that the treating clinician had assessed the size of the uterus in relation to the treatment options and the discussions about them. It was denied that surgery was performed negligently but there was a dispute as to whether the formation of the fistula was as a result of the failures identified. Due to the admissions made and the litigation risk as to which injuries were causative of the failures identified the matter was settled out of court.

Message

Documentation is key to evidencing informed consent. This must include alternative treatments and the option of doing nothing at all and the respective prognosis of the treatment options. If a patient can establish that with proper advice they would not have proceeded to surgery then the claim will be resolved in their favour.

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. 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, when a patient is being taken back to surgery after they have suffered an unusual and/or ongoing difficulty.

Case vignette 3

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 intraepithelial neoplasia (CIN) 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, the bowel was perforated, 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 complex surgery and associated difficulties.

Case vignette 4

Failure to achieve pain relief and discuss appropriate options in timely manner

The patient referred with a history of pelvic pain. An MRI scan showed evidence of adenomyosis and pelvic vein congestion. Gonadotrophin-releasing hormone (GnRH) analogue injections were recommended.

Following the first two injections the patient was found to have good relief from symptoms, but the third injection was ineffective. Continued injections were recommended, together with hormone replacement therapy (HRT). The patient, however, went on to suffer significant side effects.

The patient underwent a total abdominal hysterectomy with ovaries remaining intact but continued to suffer pain and was referred for a second opinion. Further GnRH analogue injections were recommended and 18 months later she underwent bilateral salpingo-oophorectomy.

A claim was brought for failure to advise of all appropriate options in a timely manner. It was alleged that but for these failures, the patient would have agreed to removal of ovaries, and therefore achieved relief from symptoms,18 months earlier.

Settlement was reached between the parties via mediation. At that mediation the clinician attending, who was not part of the patient's treatment was able to explain why various recommendations were made at the time that they were made. Clinicians in gynaecology at

the NHS Trust now evidence, in greater detail, in the medical records what the patient desires (what is material to the patient). In particular with regard to the balance between conservative approaches and surgical options.

Message

The patient should have been more involved in the discussion, and therefore decision-making process, before the first operation. Had the option to remove ovaries been made clear, with associated risks and benefits set out, plus evidenced in the medical records, then the patient would have chosen this option at the time of the first operation and received pain relief earlier. The need to return for further surgery could have been avoided.

Case vignette 5

Failure to document discussion of treatment options and patient specific concerns in relation to having children

A patient with a diagnosis of stage four endometriosis underwent hysterectomy and bilateral salpingectomy on the recommendation of her consultant gynaecologist. She subsequently brought a clinical negligence claim alleging that she should have been advised of the alternatives of radical laparoscopic excision of the endometriosis and laparoscopic myomectomy, which would have enabled her to have children.

Liability was disputed, primarily on the basis of evidence from the consultant gynaecologist that the patient told her that she did not want to have children. The claim was therefore litigated, but it was ultimately settled before it reached trial. The documentary evidence was not sufficiently robust in relation to the recording of the patient's wishes, and there was a significant risk that the judge would find that the consenting process did not comply with Montgomery (2015) *principles. Damages of £50,000 and costs of approximately £175,000 were paid to the patient.*

Message

The wishes of patients undergoing hysterectomy in terms of having children, and alternatives to hysterectomy that could preserve their ability to have children, should be thoroughly explored and documented in the notes.

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