NHS England

GIRFT
GETTING IT RIGHT FIRST TIME

GIRFT and RCOG Best Practice for Vaginal Hysterectomy

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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 vaginal hysterectomy consultation and 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 vaginal hysterectomy

1. The indications for the operation and the evidence in terms of presenting complaint, clinical examination and where appropriate imaging 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 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 if carried out.
9. Record 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: grade of prolapse, size of uterus, distorted anatomy, previous surgery.
12. Document insertion of local anaesthetic into vaginal mucosa if used.
13. Document opening of POD and vesico-uterine pouch under direct vision.
14. Document pedicles which were clamped, transected and suture ligated. Include documentation of suture material.
15. Record that haemostasis was achieved before beginning closure.
16. Record any intraoperative checks carried out to identify/confirm the absence of damage to any surrounding structures and the findings of the same.

17. Record whether anterior or posterior repair or McCall culdoplasty were also performed and document the steps for this.
18. Document vaginal vault closure and materials used.
19. Record any intra-operative complications and what action was taken to remedy them including any additional procedures performed and the rationale for them. Document any checks to bowel or bladder.
20. Document an estimated blood loss and if urine was clear or not at the conclusion of surgery.
21. Document insertion of vaginal pack if used.
22. Document any difficulties identified such as difficulty gaining access to VUF or POD, or difficulty delivering the uterus, presence of fibroids.
23. Document the ovaries were checked and report if appeared normal or abnormal and if any further steps are required.
24. 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 and vaginal pack;
    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.
25. 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 adequately consent for vaginal hysterectomy

A patient with a BMI of 35 underwent a hysterectomy. They sustained a bladder injury and the hysterectomy had to be abandoned. The patient brought a clinical negligence claim alleging that there was a negligent failure to obtain adequate consent in respect of the hysterectomy because the risks associated with their weight were not discussed and they were not advised of any conservative alternatives to vaginal hysterectomy. The patient argued that had they known that their raised BMI carried a greater than average risk of bladder injury, they would have opted to defer the surgery so that they could lose weight and reduce the risks.

The medical records showed that the consultant gynaecologist had '…discussed risks and benefits…' with the patient. However, by the date of the claim, they could not recall the specifics of the discussions they had with the patient about material risks and reasonable alternative treatment options. The gynaecologist did say that it would have been their usual practice to discuss the risks associated with a high BMI and alternative treatment options, including conservative management, the fact the detail of these discussions were not recorded created a significant litigation risk. The claim was settled with damages of £45,000 with costs of £82,000.

Message

It is vital when consenting a patient that they are informed of the alternative treatment options specific to their circumstances and that the discussions are documented in appropriate detail. All material *risks involved in any recommended treatment and any reasonable alternative or variant treatment must be explained to the patient. This includes risks to which a* reasonable *person in the patient's position would attach significance.*

Case vignette 2

Failure of shared decision-making

A patient was referred with a history of vaginal discomfort during exercise. Examination demonstrated hymenal tags and a small rectocele. The patient reported some difficulty

defecating. The patient requested removal of the tags. She was offered pelvic floor repair surgery, which the patient misunderstood would involve simply removing the skin tags. She was listed for a pelvic floor repair +/- vaginal hysterectomy. The patient's evidence was that no alternative treatments were offered. On the day of surgery the consultant undertook only a brief discussion with the patient, who asked the consultant if the hysterectomy was essential. Her evidence is that the consultant indicated the decision would be made during surgery. The patient proceeded but subsequently discovered that the hysterectomy was not, in fact, essential and that the hymenal tags had not been removed.

The patient brought a claim which focused on failure of consent. She alleged that she had suffered impaired vaginal sensation and psychiatric injury. Liability was denied, however a settlement was agreed at £40,000 plus total costs of over £60,000.

Message

There was a clear logic to the clinical plan but the patient did not understand the reasoning. The consultant on the day of surgery did not enquire with the patient regarding their understanding of what was to be done and why. The message is to ensure that consent has been effective by checking the patient's understanding of what is proposed, especially where what is being proposed is radically different to what the patient had originally requested.

Case vignette 3

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. Following receipt of independent expert evidence a response to the allegations was provided, 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 was being undertaken is as a result of earlier surgery, where the patient has suffered an unusual and/or ongoing difficulty.

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.

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