NHS England

GIRFT
GETTING IT RIGHT FIRST TIME

GIRFT and RCOG Best Practice for Laparoscopic Salpingectomy for Ectopic Pregnancy

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Royal College of Obstetricians & Gynaecologists

NHS Resolution

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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 salpingectomy for ectopic pregnancy 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 salpingectomy for ectopic pregnancy

1. Document 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 of material risks to the individual patient, and the reasonable alternative treatment options (including salpingostomy, methotrexate and the risks and benefits of conservative management). 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. 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 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 and whether the

procedure is laparoscopic or open. Describe adhesions or any other difficulty encountered.

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 pneumoperitneum 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:
    a. Haemoperitoneum and its volume, presence or absence of tubal mass and its location or tubal rupture, appearance of contralateral tube.
    b. Relevant organs, pathology such as adhesions and degree of anatomic distortion if any, fibroids, ovarian cysts, etc.
15. Record the presence or absence of tubal mass/ectopic pregnancy.
16. Record the affected side (left or right sided tubal ectopic).
17. Record if any tissue sample was sent to pathology.
18. Note steps taken to washout haemoperitoneum or carry out routine irrigation prior to closure.
19. Record that haemostasis was achieved before beginning closure.
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. Document sequential method of wound closure, (formal rectus sheath closure of lateral wounds if ≥10mm), whether any drains were used and what dressing was applied.
22. If laparoscopic, record that the ports were removed under direct vision. Document the release of pneumoperitoneum.
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. 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. the need for Anti-D;
    g. post-operative recovery including when the patient should eat and drink;
    h. if used, when drains should be removed;
    i. removal of indwelling catheter;
    j. discharge plans;
    k. removal of sutures/staples where required;
    l. the need to check pathology results for the specimen sent;
    m. any follow up requirements.

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

Case vignette

Failure to diagnose ectopic pregnancy leading to laparoscopy and salpingectomy

Patient attended the early pregnancy assessment unit with a history of previous miscarriages and had attended the A&E department the previous day, complaining of abdominal pain radiating to shoulder pain. She was in the very early stages of pregnancy and was referred to the hospital where she underwent an ultrasound scan. A non-viable intrauterine pregnancy (miscarriage) was reported. Approximately four days later the patient developed severe suprapubic pain after sexual intercourse. She called an ambulance which took her to the A&E department and she was then admitted the same day for observation. Pain relief was given and she was allowed home. The patient returned to the hospital the following day with ongoing, constant pain and vomiting and a repeat ultrasound was arranged. When the ultrasound was performed the findings were consistent with a ruptured ectopic pregnancy. A laparoscopy and left salpingectomy were performed.

It was alleged by the patient that if the original ultrasound scan had been performed and reported correctly she would have been prescribed methotrexate, avoided rupture of the fallopian tube, avoided laparoscopy and salpingectomy and retained the ability to conceive naturally. It was admitted by the trust that the original ultrasound was negligently reported and failed to report the ectopic pregnancy. It was admitted that timely diagnosis would have avoided the severe pain which developed and the subsequent rupture of the fallopian tube. However, it was argued that given the levels of pain described by the claimant, even if the ectopic pregnancy had been diagnosed earlier, treatment with methotrexate would have been contraindicated. The trust's expert advised that had a diagnostic laparoscopy been performed earlier, the ectopic pregnancy would have been identified in the left fallopian tube and the tube would have been removed in any event. Therefore, while the surgery would have been performed sooner, the same surgery would have been required in any event, resulting in the consequential reduced fertility. Given the breach of duty identified and some causative loss arising the claim was settled albeit at a discount.

Message

Accurate and timely diagnosis is key to avoid further injury. Clinical pathways in treating patients with suspected ectopic pregnancy, was also flagged as important when patients attend non-specialist settings i.e. the A&E department.

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