GIRFT and RCS
Best practice for Laparoscopic Cholecystectomy Documentation

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GIRFT is part of an aligned set of programmes within NHS England
1. Background and Justification

This guidance has been produced by GIRFT in partnership with the Royal College of Surgeons of England (RCS). It is aimed to provide advice on various aspects of surgery which should be available and clearly documented in a laparoscopic cholecystectomy operation record. The document is not a comprehensive guide to this surgical procedure, however it is hoped that surgeons 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 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.
2. Recommendations for documentation of practice in all patients undergoing laparoscopic cholecystectomy

1. The indications for the operation (symptomatic cholelithiasis/ gallstone pancreatitis) and the evidence both in terms of serological markers, imaging, presenting complaint and clinical examination that has led to the recommendation to perform this operation.

2. Documentation of the informed consent process including the risks of not operating should be available. The likelihood of a blood transfusion or the need to proceed to an open procedure, a laparotomy or any other additional procedures as relevant should be recorded along with the associated risks. It should be clearly documented if the patient does not consent to any of these procedures including transfusion.

3. Safety briefing, sign in, time out, and sign out as part of WHO Surgical Safety Checklist\(^1\). Presence of required surgical equipment for both laparoscopic and open procedures should be confirmed\(^2\).

4. Record names of all surgeons with name/grade of lead surgeon and assistants.

5. Record names and grade of anaesthetist(s) and type(s) of anaesthetic used.

6. Record the date and time of the procedure.

7. Record drugs given pre-operatively and during surgery e.g. antibiotics, local anaesthetic.

8. Record the insertion of a urinary catheter if carried out.


10. Describe or draw the location of the incisions made.

11. Record the open or closed technique used to enter the peritoneal cavity with Hasson or Verres needles and that the pneumoperitoneum was established prior to the laparoscope insertion.

12. Confirm that the laparoscope was inserted into the abdomen under direct vision.

13. Document the insertion of the other ports both in terms of position (epigastric, right costal margin etc.) and size (5/10/12mm) and that they were inserted under direct vision +/- use of local anaesthetic.

14. Record the level at which the intra-abdominal pressure was set.

15. Record if the patient was placed in the reverse Trendelenburg position with right side up.

16. Document the findings at the time of surgery, unusual anatomy which affected how the procedure was performed, whether the gall bladder had a thick or thin wall, whether there were adhesions and the manner in which they were divided, if appropriate.

17. Record the dissection of Calot’s triangle: whether the cystic duct was identified and traced to gallbladder, whether the cystic artery was identified and traced to gallbladder and whether a safe view was established.
18. Document if a cholangiogram was carried out and its interpretation including if there was good flow of bile into the duodenum, an intact biliary tree and any filling defects
19. Record the type and number of clips applied to the cystic duct and cystic artery
20. Record whether there was any bile or stone spillage, the presence of stones and whether all split stones were fully or partially retrieved
21. Record the volume of saline used to washout the abdomen.
22. Document the method and port used to extract the gallbladder including use of an endoscopic retrieval bag.
23. Record that the tissue sample was sent to pathology.
24. Record that haemostasis was achieved
25. Record that the ports were removed under direct vision.
26. Record any intra-operative complications and what action was taken to remedy them including conversion from laparoscopic to open, any additional procedures performed and the rationale for them.
27. Record details of closure including whether fascia needed to be closed and use of drains.
29. The post-operative plan including:
   a. Antibiotics;
   b. Blood tests if 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. If used, when drains should be removed;
   f. The need to check pathology results for the specimen sent;
   g. VTE thromboprophylaxis (including risk assessment and deviations from local protocol).
   h. Post-operative recovery including when the patient should eat and drink;
   i. Discharge plans;
   j. Removal of sutures where required
   k. Any follow up.
30. Any concerns or deviation from standard practice should be identified and recorded. The reasons for any decisions to deviate from standard practice should be recorded.
31. Any images taken during the procedure should attached to the patient's record.
32. Signature of the first surgeon alongside their name and grade to confirm the record is complete and accurate.
3. Duty of Candour

It is important that appropriate duty of candour be exercised informing the patient of any events or peri operative complications which could cause harm or compromise their outcome, at the earliest opportunity following detection and as deemed appropriate by the treating team. This should be carried out in accordance with local policy and 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.  

4. Case Vignettes

**Case vignette 1**

**Failure to interpret operative cholangiogram correctly**

A patient was admitted for a laparoscopic cholecystectomy. A large stone had been identified in the gallbladder and this proved difficult to retract. The Calot’s triangle was fully dissected and the presumed cystic duct was tied distally. An on-table cholangiogram was undertaken. The operative cholangiogram was interpreted wrongly and this led to excision of the bile duct with transection in its distal portion and proximally in the hilum of the liver. The above was not recognised during the operation and the patient was subsequently discharged. All appeared to have gone well. The patient then suffered severe pain and was readmitted with sepsis. The patient had to undergo further, and this time urgent, surgery where the previous error was recognised and addressed. Admission to intensive care was then required.

Unfortunately, the negligent interpretation of the cholangiogram and therefore inaccurate documentation of the intra-operative findings did lead to significant ongoing difficulties for this patient. Whilst not appreciated at the time, it did not take long for clinicians to reflect and for an early admission of substandard care to follow. Liability was admitted at an early stage and the clinical negligence claim was swiftly resolved. An apology from the Trust’s Chief Executive was provided. The settlement has been delayed pending completion of further treatment but the damages are in excess of £50,000 plus legal costs.

**Message**

Recognition of an error by the surgeon who was prepared to go on record to diagnose the complication and admit liability allowed the patient to receive the right treatment for the complication and for the claim to be resolved swiftly reducing the risk of additional costs for failure to follow up.
Case vignette 2

Failure to correctly identify anatomy, interpret cholangiogram and record correctly

A claim was brought for a negligently performed cholecystectomy and a failure to provide adequate post-operative care. It was alleged that an injury was caused to the patient’s right hepatic duct which was not recognised during the on-table cholangiogram. Thereafter, a delay in providing appropriate treatment caused the deceased to suffer critical illness sepsis and hypokalaemia. Over 5 years later, the patient died following a bowel perforation caused by a biliary stent which had migrated.

The NHS had to pay £425,000 in damages on the basis that not only did the trust negligently perform the laparoscopic cholecystectomy which caused the patient to be in permanent pain and bed ridden, as a result of treatment to correct the negligence (which would have otherwise been avoided), the negligence brought about her untimely death.

Message
Document any complication that is identified at the time of surgery and steps taken to overcome. Careful investigation post-operatively of patients that are not recovering as expected can be aided by accurate operative documentation to highlight difficulties encountered.
Case vignette 3

Division and removal of segment of hepatic duct

A patient was admitted to hospital for a laparoscopic cholecystectomy. The operating surgeon inadvertently divided and removed a segment of hepatic duct with the gallbladder specimen. This was not recognised during surgery. It was later established that the surgeon had, on balance, placed at least one clip across the common bile duct and the other clip across the cystic duct which was then divided. The patient was discharged and then readmitted with a large collection of bile in the abdomen. The bile duct had to be repaired and she suffered significant post-operative complications, which included anastomotic strictures, recurrent cholangitis and secondary biliary cirrhosis.

Following a claim for clinical negligence, liability was admitted and the claim settled for in excess of £200,000.

Message

Careful placing of clips which is clearly documented, rather than the hurried approach adopted, would have avoided such an error and the subsequent post-operative complications.
Case vignette 4

Exposure of Calot’s triangle

No record to confirm whether reasonable and adequate exposure of Calot’s triangle was achieved. Claimant suffered avoidable major bile duct injury due to failure to appropriately delineate anatomy.

The expert witness recommended that alternative strategies should have been adopted if the common bile duct could not be clearly delineated from the cystic duct and the operative note should have recorded whether an adequate critical view of Calot’s window was achievable. These options include:

1. Perform an intra-operative cholangiogram to clarify the anatomy before dividing or clipping any structures.
2. Perform a retrograde cholecystectomy
3. Perform a sub-total cholecystectomy if the anatomy was still unclear after performing cholangiography or retrograde mobilisation of the gallbladder.
4. Abandon the procedure and refer to a specialist HPB centre.

Such procedures could have been performed laparoscopically but it is equally acceptable to convert to open surgery in such circumstances. This should be supported by clear rationale for conversion of procedure to open. The failure to adopt any of these options in this case was regarded as a breach of duty of care.

An admission of breach of duty was made and it was accepted that absent this breach the Claimant would have made an uneventful recovery, avoiding jaundice, recurrent cholangitis, multiple further admissions and procedures, including eventual reconstruction surgery. The Claimant’s Schedule values the claim at over £1million. Negotiations are ongoing. An apology and an interim payment have been made in the meantime.

Message

Record the exposure of Calot’s triangle, what structures were identified any problems encountered and what actions were taken to ensure an adequate view as with any intra-operative complication. If a safe view of the anatomy cannot be achieved (after considering the options above) this should be documented and the procedure terminated and refer to a specialist centre and explanation provided to the patient which is documented in the medical records.
**Case vignette 5**

**Failure to document rationale for partial cholecystectomy**

A partial laparoscopic cholecystectomy was performed without an attempt to convert to open to complete the procedure. The surgeon commented that an open procedure was deemed unnecessary and at the time he had finished surgery, he firmly believed a full cholecystectomy had been performed. The surgeon accepted some may have been left, in hindsight, but comments that this was a difficult procedure due to patient size and the poor view of the gall bladder at the start.

The claim was settled for £4000 with claimant costs for £28,000 and defence costs of £5000 with the entire cost of the claim reaching £37,000.

**Message**

Complete intra-operative findings need to be recorded to explain rationale if only partial cholecystectomy is carried out. The surgeon must achieve a view to ensure he has completed the intended procedure and convert to open if necessary. The reasons for not converting to open procedure in such scenarios should be documented and other solutions such as referral to a specialist unit must be explored. All of this needs to be clearly communicated to the patient after the procedure and what effect on their prognosis is expected in order to fulfil the duty of candour.
5. Acknowledgements & References

Authors:

John Machin, Co-lead for Litigation - Getting It Right First Time Programme (GIRFT), NHS England

Mark Cheetham, National Clinical Lead – General Surgery, Getting It Right First Time Programme (GIRFT), NHS England (current)

John Abercrombie, National Clinical Lead – General Surgery, Getting It Right First Time Programme (GIRFT), NHS England (previous)

Tim Briggs, Co-lead for Litigation and Chair of the Getting It Right First Time Programme (GIRFT); National Director of Clinical Improvement for the NHS, NHS England

Contributors:

Giles Toogood, The Leeds Teaching Hospitals NHS Trust

Paul Leeder, University Hospitals of Derby and Burton NHS Foundation Trust

Simon Hammond and Denise Chaffer, NHS Resolution

Joanna Lloyd, Bevan Brittan LLP

William Reynolds and Amelia Newbold, Browne Jacobson LLP

Majid Hassan, Capsticks LLP

Sean Doherty, DAC Beachcroft LLP

Ed Glasgow, Kennedys Law LLP

Amanda Mead, Kennedys Law LLP

Maryam Storr, Weightmans LLP

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