Clinical Record Review Report

Royal College of Surgeons of England
ADVANCING SURGICAL CARE

Report on one set of clinical records relating to General Surgery on behalf of Wrightington, Wigan and Leigh NHS Foundation Trust

Report issued: 06 April 2021

A clinical record review on behalf of:	**Review team:**
The Royal College of Surgeons of England	[redacted]
Association of Surgeons of Great Britain & Ireland	[redacted]
	[redacted]

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1. Introduction and background

On 16 November 2020, Dr Sanjay Arya, Medical Director for Wrightington, Wigan & Leigh NHS Foundation Trust ('the Trust'), wrote to the Chair of the Invited Review Mechanism (IRM) to request an invited clinical record review of one set of general surgical clinical records. In particular, the request highlighted concerns that had been raised regarding the quality and safety of the care provided to the patient. Following a RCS England invited clinical record review carried out of 31 general surgery records in June 2020, the Trust requested the review of this case that had previously been internally investigated and closed by the Divisional Director of Surgery and the Medical Director.

This request was considered by the Chair of the RCS England IRM and a representative of the Association of Surgeons of Great Britain & Ireland (ASGBI), and it was agreed that an invited clinical record review would take place.

A review team was appointed and the Trust provided the team with copies of the relevant clinical record on 29 January 2021. The appendix to this report provides biographic information for the members of the review team and the documents that were provided to the review team.

The review team has considered the standard of care provided to one patient in the clinical records provided by Wrightington, Wigan and Leigh NHS Foundation Trust. Information relating to the care of the patient is included in section three. The review team has highlighted areas of concern and overall conclusions in section four. The review team made four recommendations for consideration by the Trust, which are detailed in section five.

For the purpose of this report, the admitting consultant surgeon has been referenced as 'Consultant A', and the operating consultant surgeon 'Consultant B'.

2. Terms of reference for the review

The following terms of reference for this review were agreed prior to the RCS England review visit between the RCS England and the healthcare organisation commissioning the review.

Review

The review will involve:

- A clinical record review of one case put forward by Wrightington, Wigan and Leigh NHS Foundation Trust
- Consideration of the Trust's Rapid Review Investigation Report
- Consideration of a statement provided by the operating surgeon

Terms of Reference

In conducting the review, the review team will consider the clinical records provided by the Wrightington, Wigan and Leigh NHS Foundation Trust, including with specific reference to:

- Assessment including history taking, examination and diagnosis;
- Investigations and imaging undertaken;
- Treatment including clinical decision-making, case-selection, operation or procedures;
- Team-working including communication, MDT discussions and working with colleagues;
- Whether the care provided was what would be expected from a consultant general surgeon working in similar circumstances;
- The operating surgeon's ability to recognise surgical anatomy.

Conclusions and recommendations

The review team will, where appropriate:

- Form conclusions as to the standard of care provided and whether there is a basis for concern in light of the findings of the review.

- May make recommendations for the consideration of the Medical Director of Wrightington, Wigan and Leigh NHS Foundation Trust as to courses of action which may be taken to address any specific areas of concern which have been identified or otherwise improve patient care.

The above terms of reference were agreed by the College, the healthcare organisation and the review team on 11 January 2021.

3. Case description

Between August 2017 and May 2018, the patient, a [redacted], had been complaining of right upper quadrant pain and diarrhoea. During this period, ultrasound scans (US) had confirmed the presence of gall stones. The colonoscopy and computerised tomography (CT) scans showed no other significant pathology and the patient did not attend a scheduled appointment six months later. No action had been taken for the management of symptomatic gall stones.

The patient was admitted at Wigan Hospital on [redacted] with gallstone pancreatitis (Amylase[1] 2153, Bilirubin[2] 42). The patient was managed with Intravenous therapy (IV) fluids, analgesia, monitoring of vital signs and blood tests.

On [redacted] the patient's MRCP[3] scan showed the gall bladder containing small gall stones, no common bile duct (CBD) dilatation or ductal stones and minor inflammatory changes around the pancreas indicating acute pancreatitis.

Urgent laparoscopic cholecystectomy was planned for [redacted], which the patient agreed and consented to. It was noted on the Rapid Review Investigation Report that the Specialty Registrar (StR) was not comfortable operating without consultant supervision. The operation was cancelled due to the volume of emergencies and lack of availability of an appropriate consultant surgeon at Wigan.

On [redacted] the patient was seen by the Clinical Director of Surgery and was discharged with a plan for surgery within two weeks.

It was noted on the Rapid Review Investigation Report that on [redacted] an email had been sent from Consultant Surgeon A's office to admissions requesting that the patient be urgently added to the theatre list at Leigh Infirmary for [redacted]. The pre-operative assessment sister queried the suitability of the patient's operation to be carried out at Leigh Infirmary in view of the patient's recent history of pancreatitis. However, this was affirmed by Consultant A in an email response, confirming that the patient was suitable for Leigh Infirmary, stating that this had been agreed with the Clinical Director of Surgery.

The patient was admitted to the day case unit in Leigh Infirmary for an elective laparoscopic cholecystectomy on [redacted]. [redacted] was assigned to the operating surgeon's ('Consultant B') list against Trust Guidelines[4] due to its location. The decision was made to proceed after learning that the patient had been previously cancelled from an emergency list at Wigan and that there was a long waiting list for such an urgent surgery. The decision by Consultant B to proceed was taken after careful consideration of the whole situation and with agreement of the theatre and anaesthetic team. The operation was extremely challenging with inflammation and blood vessels around Calot's triangle and gall bladder fossa. During the procedure about 1400 mls of blood was lost, although the intention to remove the gallbladder and its stones was otherwise successfully completed. It was noted on the Rapid Review Investigation Report that the appropriate sutures were not available to Consultant B in theatre. The incident report was completed by Consultant B as the case was outside Trust protocol.

As Leigh Infirmary did not have the facility to manage post-operative high dependency cases, the patient was transferred to Wigan [redacted] for their post-operative

[1] An **amylase** is an enzyme that catalyses the hydrolysis of starch (Latin amylum) into sugars.
[2] **Bilirubin** is a yellowish pigment that is made during the normal breakdown of red blood cells.
[3] Magnetic resonance cholangiopancreatography scan
[4] Inclusion criteria for day case Laparoscopic Cholecystectomy surgery on the Leigh Site: Guidelines states that patients with a history of pancreatitis should not be listed as day case patients at Leigh Infirmary as there is no provision for overnight stays.

management. The patient required a four unit blood transfusion but otherwise made a satisfactory recovery and was discharged on [redacted].

4. Conclusions

The following conclusions are based on the information provided in the documentation submitted and the clinical record reviewed. These are overall conclusions based on the one case provided and focused on highlighting areas of concern or improvement.

Overall, the review team were of the opinion that the care provided to the patient, following admission for surgery, was of an acceptable standard, although it was noted that it was provided in the wrong setting in breach of the Trust's own policy. The review team noted that the majority of the complications experienced by the patient were within the expected range of outcomes in providing surgical care. However, there were some areas of concern identified by the team and these are highlighted below.

It was the review team's understanding that Leigh Infirmary had a policy of not performing elective laparoscopic cholecystectomy in patients who had previous pancreatitis. In the review team's opinion, this was a sensible policy, as cases where there has been previous pancreatitis are often much more challenging and are best performed in a fully equipped hospital with the appropriate recovery facilities including, if necessary, an HDU or intensive treatment unit (ITU).

4.1. Assessment including history taking, examination and diagnosis

The review team noted that the patient was assessed in clinic with symptomatic gall stones and other pathology was appropriately excluded. However, no action was taken concerning [redacted] gall stones once colonoscopy and CT scan had been performed although the patient DNA'd[5] a routine appointment six months later. The review team were concerned that there was no initial plan to treat a young patient with symptomatic gall stones following assessment.

4.2. Investigations and imaging undertaken

The review team reviewed the clinical record of the patient and concluded that the patient was provided with appropriate and prompt investigations which served [redacted] needs.

4.3. Treatment including clinical decision-making, case-selection, operation or procedures

The review team were of the opinion that this patient should not have had [redacted] operation in Leigh Infirmary, and the fact that [redacted] was listed for surgery there was an error that should have been corrected before the patient was admitted. At the preoperative assessment, it was correctly highlighted that the patient perhaps should not have [redacted] surgery at Leigh Infirmary, and a query was raised with Consultant A for clarification. Consultant A referred the matter to his Clinical Director who made the decision that it should proceed as planned.

The review team were concerned that the Trust has no acceptable pathway to treat patients with acute biliary pathology and recommendation should be given to explore the possibilities of 'hot' gall bladder lists appropriately staffed with back up on their main hospital site. The review team considered it unacceptable to cancel patients on consecutive days as a result of lack of theatre time on emergency lists.

In the opinion of the review team, Consultant B was placed in a difficult position and chose in the circumstances to proceed with surgery. In making this judgement the review team considered that he was intending to act in the best interests of the patient.

[5] Did not attend

In the review team's view, it did not appear that the eventual outcome, on this occasion, would have been different if surgery had been performed in Wigan Hospital. However, this was clearly a stressful situation for all concerned and could have been avoided.

4.4. Communication with the patient, their family and GP, and patient consent

The review team were concerned that Consultant B had not met the patient beforehand and was unaware that he was being expected to perform the operation in a facility which would not normally be used for such a procedure. The review team observed that Consultant B only learned about the case being added to his list while he was on his way to the hospital. He was then faced with a very difficult dilemma of whether to cancel the case as per the normal agreed protocols, or whether to exercise judgement as to whether, despite the risks, it might be possible to proceed. Cancelling and thus delaying the patient's surgery would have had significant drawbacks - further attacks of pancreatitis whilst awaiting a revised date for surgery in the main hospital, as well as any effects of delay on the patient's psychological state as [redacted] struggled to cope whilst unwell with a [redacted].

4.5. Team working including communication with other members of the care team, MDT[6] discussions and working with colleagues

In the review team's view, it was a lack of good team working and communication that led to Consultant B being presented with a case on which he was supposed to operate, even though it should have never appeared on his list in the first place. There appeared to be lack of communication around the booking of urgent cases between colleagues when a potentially difficult case was placed on another consultant's routine day case list. There was also apparent disagreement over the protocols in place for listing certain categories of patients in the day unit at Leigh Infirmary.

The review team were not aware of the mechanism by which patients were booked onto specific consultant lists or if there was an agreement that patients should be pooled. However, it appeared to the review team that there was no apparent communication between the admitting consultant ('Consultant A') and Consultant B for that particular list. There appeared to be a local policy in place that Leigh Infirmary day unit would only expect cases ASA[7] 1 or 2 and exclude those with a history of pancreatitis. The review team noted that this policy had overrun its review date. It was also apparent to the review team that, following this incident, the clinical teams had differing views as to whether this policy should exclude those with pancreatitis.

The review team noted that Consultant B discussed the situation with the anaesthetist and with the senior nursing staff involved, and that a mutually agreed conclusion was made to proceed with the surgery. In the review team's view, the surgeon acted appropriately in involving the whole team in the decision. The review team recognised that it must have been a difficult judgement call and noted that Consultant B completed an incident form after the procedure so that it could be properly investigated. In the opinion of the review team, Consultant B and the rest of the team involved in this operation should be commended on a satisfactory outcome, despite what must have been very challenging circumstances, especially for all the nursing staff who would have probably not been used to such a difficult case being performed in their theatre.

[6] Multidisciplinary team
[7] aminosalycilate

4.6. The operating surgeon's ability to recognise surgical anatomy

The review team concluded that they have no concerns regarding the standard of surgery or the technical ability of the operating surgeon ('Consultant B') from the clinical records reviewed in this case. The review team did not find anything on the records to suggest that the performance of the operation was in any way substandard.

In addition, they considered that surgeons who do laparoscopic cholecystectomy often find cases to be extremely challenging and this was a particularly difficult case. In situations where the operation is difficult, it is especially important not to damage any important biliary structures or blood vessels, whilst controlling any bleeding. There was no biliary damage that occurred, and the bleeding was eventually controlled. There was no indication that the bleeding was caused by the surgeon's inability to recognise the anatomy, but more likely by the pathology encountered due to the recent pancreatitis and inflammation.

4.7. Other

It was the review team's understanding that the Trust's Rapid Review Investigation Report had also concluded that this operation should not have been performed at Leigh Infirmary. They noted that there has subsequently been a review of the inclusion criteria for day case laparoscopic cholecystectomy as a result of this case, however, the review team was unaware of its conclusion. The Trust's Rapid Investigation Review has highlighted the need to re-examine the policy of not performing cases like this (laparoscopic cholecystectomy after acute pancreatitis) in Leigh Infirmary. The review team were also concerned that the RCSEng Invited Review Request Form stated that the Rapid Review investigation was led by the Clinical Director of Surgery – yet he was the senior surgeon who gave approval for the case to be performed in Leigh Infirmary. The review team did not find this to be appropriate.

The review team were also concerned about the lack of available sutures, equipment for conversion and having no back up at Leigh Infirmary. The Trust should ensure that if cases of laparoscopic cholecystectomy are performed at Leigh Infirmary then there should be adequate equipment and trained personnel to deal with the unanticipated conversion and complications.

5. Recommendations

5.1. Urgent recommendations to address patient safety risks

The recommendations below are considered to be highly important actions for the healthcare organisation to take to ensure patient safety is protected.

1. The Trust should consider how to manage the pathway for urgent laparoscopic cholecystectomy more consistently and effectively, including but not limited to, the provision of urgent gall bladder lists, appropriately experienced surgeons and sufficient theatre resources to manage such patients. Policies supporting this should be reviewed and updated.

2. The Trust should ensure that if cases of laparoscopic cholecystectomy are performed at Leigh Infirmary then there should be adequate equipment and trained personnel to deal with the unanticipated conversion and complications. There should also be agreed protocols for 'pooling' of patients as a general surgical department based on clinical priority and need rather than placement of a case on another's operating list as appears in this case.

5.2. Recommendations for Service Improvement

The following recommendations are considered important actions to be taken by the healthcare organisation to improve the patient care provided by the service.

3. The Trust should review the interpersonal and team-working dynamics in the general surgery team, and whether team-working supports high quality and safe care for patients. The RCS England may be able to support the Trust to seek assurance on these matters through an invited service review, if the Trust considers this the most appropriate course of action.

5.3. Additional recommendations for consideration

The following recommendations are for the healthcare organisation to consider as part of future efforts to improve patient care.

4. The Trust may wish to further consider the independence of staff undertaking Rapid Review Investigations.

5.4. Responsibilities in relation to this report

This report has been prepared by The Royal College of Surgeons of England and Association of Surgeons of Great Britain & Ireland (ASGBI) under the IRM for submission to the healthcare organisation which commissioned the invited review. It is an advisory document and it is for the healthcare organisation concerned to consider any conclusions and recommendations reached and to determine subsequent action.

It is also the responsibility of the healthcare organisation to review the content of this report and in the light of these contents take any action that is considered appropriate to protect patient safety and ensure that patients have received communication in line with the responsibilities set

out in the Health and Social Care Act 2008 (Regulated activities) Regulations 2014, Regulation 20.[8]

5.5. Further contact with the Royal College of Surgeons of England

Where recommendations have been made that relate to patient safety issues the Royal College of Surgeons of England will follow up with the healthcare organisation that commissioned the invited review to ask it to confirm that it has taken to action to address these recommendations.

If further support is required by the healthcare organisation the College may be able to facilitate this. If the healthcare organisation considers that a further review would help to assess what improvements have been made the College's Invited Review service may also be able to provide this assistance.

[8] The Health and Social Care Act 2008 (Regulated Activities) Regulations, 2014: http://www.legislation.gov.uk/uksi/2014/2936/contents/made

Appendix A – Documents provided to the review team

- Clinical Record of Patient
- Incident Report (Web74380. ID 115497)
- Rapid Review Investigation Report (WEB74380)
- Overview of training and experience of operating surgeon (provided by Consultant B)
- Written statement by operating surgeon

Appendix B – Royal College Review Team

[redacted] — **The Royal College of Surgeons of England**

[redacted] BSc, MB BS, MD, FRCS (Gen Surgery) graduated from St. Mary's Hospital Medical School in 1990 and undertook surgical training in the St. Mary's Hospital group and the Yorkshire Hospitals. [redacted] completed surgical training in the United States as International Fellow in Surgical Oncology at Memorial Sloan Kettering Cancer Centre, New York (1999-2000) and Fellow in Colon and Rectal Surgery at the Cleveland Clinic Foundation, Cleveland, Ohio (2000-2001).

[redacted] was appointed Consultant Surgeon to the Hull and East Yorkshire Hospitals in 2002. From 2007 to 2010 he served as Specialty Tutor in Coloproctology in the Raven Department of Surgical Education at the Royal College of Surgeons of England. From 2010 to 2013 [redacted] Chaired the Education and Training Committee and sat on the National Executive of the Association of Coloproctology of Great Britain and Ireland. From 2012 to 2014 [redacted] served as Regional Specialty Adviser for General Surgery for the Yorkshire Region. [redacted] is a former Director of Professional Practice member of the National Executive of the Association of Surgeons of Great Britain and Ireland (2014-2016). During that time [redacted] represented the Association of Surgeons on the Royal College of Surgeons Invited Review Mechanism. [redacted] elective surgical practice is concerned almost exclusively with the treatment of colorectal disease.

[redacted] — **Association of Surgeons of Great Britain & Ireland**

[redacted] graduated from the University of Cambridge in 1989 and trained in oesophago-gastric cancer surgery in London, Hong Kong and Tokyo. [redacted] was appointed as oesophago-gastric surgeon in Middlesbrough in 2002, where [redacted] has held trust positions of Clinical Director and Assistant Medical Director. [redacted] is an experienced clinical assessor having worked with the National Clinical Assessment Service for ten years. [redacted] is currently the chair of the upper GI MDT as well as the chair of the Northern region upper GI tumour board. Since 2017, [redacted] has been the Northern Regional Director for the Royal College of Surgeons of England.

[redacted] — **Association of Surgeons of Great Britain & Ireland**

[redacted] qualified from St Bartholomew's Hospital London in 1977. Following surgical training in Oxford and Cambridge, [redacted] gained an MS at The Ludwig Institute of Cancer Research in Cambridge. [redacted] was appointed Lecturer in Surgery at the Royal Free Hospital London in 1988. [redacted] spent a year as Visiting Lecturer in the Department of Surgery at the Chinese University of Hong Kong in 1989/90, before being appointed Consultant Surgeon at The North Devon District Hospital in 1992.

[redacted] became heavily involved in surgical education, firstly as a Royal College of Surgeons Tutor, then as Programme Director for the South West Higher Surgical Training Programme. In 2006 [redacted] was appointed as the inaugural Head of the South West Peninsula School of Surgery, a post [redacted] held until 2011.

[redacted] was on the Executive Board and Director of Informatics at the Association of Surgeons of Great Britain and Ireland (ASGBI) from 2005 to 2015. [redacted] was elected to the Council of the Royal College of Surgeons of England, representing ASGBI, in June 2015, serving for four years. [redacted] was Chair of the College's Invited Review Mechanism from 2016-2017.