Invited Individual Review Report

Report on the clinical practice of:

Surgeon A,
Consultant General Surgeon at Norfolk and Norwich University Hospitals NHS Foundation Trust

Review carried out on: 22nd July 2020

Report issued: 11th September 2020

An individual review on behalf of:	Review team:
The Royal College of Surgeons of England	Name Redacted
The Association of Surgeons of Great Britain and Ireland	Name Redacted
	Name Redacted

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The Royal College of Surgeons of England
35-43 Lincoln's Inn Fields
London WC2A 3PE
T: 020 7869 6222
E: irm@rcseng.ac.uk
W: www.rcseng.ac.uk/irm

Contents

1. Introduction and background 3
2. Terms of reference for the review 5
3. Conclusions 6
3.1. Decision making prior to surgery in the acute setting. 6
3.2. Communication with patients and consent-taking. 7
3.3. Team working, including communication with colleagues, particularly in respect of surgical and non-surgical pathways 7
3.4. Peri-operative and post-operative care provided, including the recognition and communication of complications 7
3.5 Clinical practice in undertaking laparoscopic cholecystectomy 8
4. Recommendations 10
4.1. Urgent recommendations to address patient safety risks 10
4.2. Recommendations for individual performance improvement 10
4.3. Recommendations for Service Improvement 11
4.4. Additional recommendations for consideration 11
4.5. Responsibilities in relation to this report 11
4.6. Further contact with the Royal College of Surgeons of England 11

Appendices removed - identifiable information

1. Introduction and background

On 18th April 2020, Professor Erika Denton, Medical Director for Norfolk and Norwich University Hospitals NHS Trust ("the Trust"), wrote to the Chair of the Royal College of Surgeons of England (RCS England) Invited Review Mechanism (IRM) to request an invited individual review of Surgeon A's clinical practice, in relation to patients presenting with biliary-related pathology. The review request was prompted by three cases which were subject to a root cause analysis (RCA); two of which sustained significant biliary duct damage and had required transfer to the Trust's regional hepatobiliary centre. It was understood that Surgeon A was, at the time of the review, not undertaking biliary surgery and his surgical practice was being supervised by a consultant colleague.

The review request was considered by the Chair of the RCS England IRM and a representative of the Association of Surgeons of Great Britain and Ireland, and it was agreed that an invited individual review would take place.

A review team was appointed and a remote invited review was held on 22nd July 2020[1]. The appendices to this report removed - identifiable information.

Overview of the scope of the practice of the surgeon under review and any relevant context about the service or healthcare organisation at the time of the review. [2]

It was understood that, following the three serious incidents which had occurred in a relatively short space of time, Surgeon A's clinical practice had been restricted in the following ways; Not to undertake on call, not to undertake biliary tract surgery and all of his other surgical practice was to be supervised by a consultant surgeon colleague in theatre.

Several months after this arrangement had been put in place, Surgeon A was informed on 22nd June 2020, in a meeting with Trust management that, following the root cause analyses (RCA) reports[3], he could undertake non-biliary tract surgery (except for during out of hours) with the support of a nominated consultant surgeon colleague working in the building during the same timeframe as Surgeon A's surgical commitments, to be immediately available for support should Surgeon A require it.

Notwithstanding the existing situation regarding Surgeon A's clinical practice, since the three incidents, his job plan included both emergency and elective surgery. At the time of the review request, his on call commitment (category A) was 1:14 on weekdays and 1:7 at weekends. He covered eight wards plus a Critical Care Unit (CCU) and operated regularly in three theatres.

In terms of Surgeon A's surgical activity over the previous two years (1st April – 31st March), he performed:

(i) In 2018/19:

- 115 elective cases (104 of which were day cases). This represented 4% and 5.3% respectively of activity numbers for the unit as a whole.

[1] An RCS England invited review of the upper gastrointestinal and Emergency Surgical Service was also requested at the same time and this was held separately on 23rd and 24th July 2020 with separate report to be issued. Some of the issues which arose during the course of this review are explored further in the service review.

[2] Provided in the Practice Overview information at - removed

[3] Three RCA reports were provided pertaining to the three cases and a patient response to one of these. The reports were in draft form and it was understood that Surgeon A had not yet provided his comments.

- 97 emergency procedures. This represented 7% of activity numbers for the unit as a whole.

(ii) In 2019/20

- 65 elective cases (of which 57 were day cases). This represented 2.5% and 3.2% respectively of activity numbers for the unit as a whole.
- 77 emergency procedures. This represented 5.9% of activity numbers for the unit as a whole.

Surgeon A was responsible for one outpatient clinic, within which he saw, in 2018/19, 105 new patients and 80 follow ups, and in 2019/20, 107 new patients and 56 follow ups.

It was understood too that Surgeon A held the position of clinical governance lead for general surgery and had recently participated in three audits.[4]

In addition to Surgeon A, there were three consultant emergency general and a further four consultant Upper gastro-intestinal (GI) surgeons (with a fifth appointment having been made, but not yet in post). Of the eight surgical registrar posts[5] working within the service, none were assigned to Surgeon A.

[4] (i) Local Audit of Ileostomies output (2018), (ii) Local Audit of Documentation Standards (2019) and (iii) National audit of diverticulitis (Damascus audit 2020-on hold because covid-19)

[5] The eight surgical registrar posts: 2 x ST3 grade, 3 x ST5 grade, 1 x ST6 grade and 2 x ST8 grade.

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.

In conducting the review, the review team will consider the quality and safety of Surgeon A's management of patients presenting with biliary pathology. This will include specific reference to his:

1. Decision making prior to surgery in the acute setting.
2. Communication with patients and consent-taking.
3. Team working, including communication with colleagues, particularly in respect of surgical and non-surgical pathways.
4. Peri-operative and post-operative care provided, including the recognition and communication of complications.
5. Clinical practice in undertaking laparoscopic cholecystectomy.

3. Conclusions

The following conclusions are based on the information provided to the review team from the interviews held, the documentation submitted and any clinical records reviewed. They are largely organised according to the Terms of Reference (ToR) agreed prior to the review but also take account of the themes that emerged whilst reviewing this information.

The review team highlighted that the feedback from Surgeon A's colleagues given during interviews regarding his overall clinical practice, was consistently positive.

The review team did not identify patient safety concerns in respect of Surgeon A's non-biliary surgical practice.

Some concerns were identified concerning his biliary surgical practice in the three cases reviewed and conclusions drawn from these are outlined under the ToR headings below. The review team noted that Surgeon A demonstrated insight and reflection in respect of his management of these three cases.

3.1. Decision making prior to surgery in the acute setting.

In case A1, Surgeon A was not the surgeon who made the clinical decision in the acute setting regarding the surgical plan. Whilst he reported that he would have challenged the clinical decision which had been made if he had considered there to be any contraindications for the planned surgery, it was of concern that he saw the patient for the first time in the anaesthetic room and the review team considered that this is not acceptable practice. Further, this would likely have made it difficult for Surgeon A to get a good understanding of the patient's clinical picture and to change the plan or suggest other definitive treatments such as endoscopic retrograde cholangio-pancreatography (ERCP) with sphincterotomy[6].

The repeated cancellation of this patient's surgery, had meant that the handover of care had passed from the primary surgeon (who had made the clinical decision), to a second surgeon, before coming to Surgeon A to undertake the planned surgery. This would have been likely to have impacted the quality and detail of the handover and reduced the opportunity for Surgeon A to have been involved in the pre-operative decision making prior to seeing the patient in the anaesthetic room.

Inadequate theatre capacity appeared to be a significant factor in the earlier postponements of this patient's surgery, which resulted in Surgeon A being the third surgeon who was to undertake the planned surgery. The delay of eleven days between this patient's admission and their surgery, was not in line with NICE guidance[7], It appeared from what was heard during interviews and, the data provided on patient average length of stay prior to laparoscopic cholecystectomy surgery, that delays due to cancellation had been relatively common.

[6] ERCP is a procedure that uses an endoscope and x-rays to look at the bile duct and pancreatic duct. It can also be used to remove gallstones or take a biopsy. ERCP with sphincterotomy involves making a small cut in the Ampulla of Vater to enlarge the opening of the bile duct to improve drainage or to remove stones in the ducts.

[7] The National Institute for Health and Care Excellence guideline *Gallstone disease: diagnosis and management* recommends early laparoscopic cholecystectomy (to be carried out within 1 week of diagnosis) for people with acute cholecystitis [NICE, 2014, last revised January 2017 and next planned review by December 2022)].

3.2. Communication with patients and consent-taking.

The review team considered that Surgeon A's description of his approach and methods in respect of patient communication and consent indicated that it was thorough and appropriate. The review team did not hear reported concerns from other interviewees regarding Surgeon A's communication with patients and process of gaining consent.

3.3. Team working, including communication with colleagues, particularly in respect of surgical and non-surgical pathways.

The review team considered that Surgeon A's communication and his team working with his consultant surgeon colleagues (both emergency and Upper GI), appeared to be appropriate. However, they did note that the clinical records seen for case A1 did not document communication with surgical colleagues although it was recognised that there may have been verbal communications which were not recorded.

Surgeon A reported that he had requested help from his upper GI surgeon colleagues on rare previous occasions and whilst, in respect of the three cases reviewed, he had not called for support, the review team were reassured by both his own view and that of other interviewees that, in situations where help had been requested by consultant surgeons, it had always been forthcoming.

The review team concluded that in cases A2 and A3, Surgeon A's failure to recognise the need for and to consult with a consultant surgeon colleague, was a short-coming in respect of team working. Whilst this was of concern, the review team were reassured by Surgeon A's reflection on these two cases involving bile duct injuries, that he should have sought intra-operative assistance from a consultant surgeon colleague when the situations had become challenging and highlighted that his learning from this was that he would do so in future.

Whilst the morning theatre meetings included attendance by the surgeons operating that day, the main purpose of this meeting was understood to be agreeing the listing and therefore, it was the opinion of the review team that it provided limited opportunity for involvement in clinical decision making.

Reportedly, it had not been an infrequent occurrence that the planned surgery following the clinical decision of the primary surgeon was subsequently undertaken by a second or sometimes a third consultant surgeon. A significant contributory factor appeared to have been the need to re-prioritise theatre lists in light of theatre capacity and, at times, cancelling cases. As outlined previously, (and illustrated in case A1), the quality and detail of the handover of patient care, may be impacted when a second or sometimes a third consultant surgeon undertakes the surgery following the clinical decision of the primary surgeon. There appeared to be an awareness amongst the surgery team of Trust best practice in the handover of patient care by the primary surgeon, (after the surgical pathway is agreed), to a different consultant surgeon to undertake the surgery. However, the detail of this best practice referred to was not made clear to the review team.

The review team observed that the problems of repeated cancellations because of inadequate theatre capacity, and of handovers, are by no means unique to this Trust. They also noted that these are service issues but were mentioned here in the context of Surgeon A's clinical practice and will be explored further in the service review.

3.4. Peri-operative and post-operative care provided, including the recognition and communication of complications.

Regarding Surgeon A's emergency biliary surgery outcomes (reported in audit), two bile duct injuries out of 200 plus cases undertaken in a two year period, was considered by the review

team to indicate that the incidence of bile duct injury in his practice was uncommon and, was not an unacceptably high number, particularly when a large number of these operations had been conducted in the acute setting. In case A2, the review team concluded that, given that the audit data indicated that Surgeon A was experienced in undertaking acute cholecystectomies, it was difficult to understand why he had not called for assistance when complications arose.

The review team also concluded that the complications which arose in cases A2 and A3, which resulted in two bile duct injuries, were hugely significant and they had significant concerns regarding Surgeon A's intraoperative decision-making in these two cases. He had failed to recognise that an alternative strategy was required and the need to consult with a consultant surgeon colleague. As outlined previously in 3.3 above, it was the opinion of the review team that this was a short-coming in respect of team working and noted is again here, in respect of the intraoperative care provided.

The review team were reassured however, that Surgeon A, in reflecting on these two cases involving bile duct injuries, had accepted that his recognition of the complications had not been optimal and should have been quicker. He acknowledged that he should have sought intra-operative assistance from a consultant surgeon colleague when the situations had become challenging and/or that an alternative strategy was required. He also highlighted that his learning from this was that he would do so in future.

In case A1, the learning which Surgeon A outlined that he will give earlier consideration to changing the “course” of the planned surgery, in the review team’s view, demonstrated insight.

3.5 Clinical practice in undertaking laparoscopic cholecystectomy

Surgeon A indicated that in undertaking laparoscopic cholecystectomy, that if in his clinical opinion, progress was not following the anticipated course or it had become unacceptably difficult, he would convert to open surgery or call a consultant surgeon colleague for their opinion. The review team concluded that this seemed a sensible approach, although it was noted that he had not followed this course in the three serious incidents reviewed.

Surgeon A's statement that he would undertake a sub-total cholecystectomy in cases in which confirmation of anatomy would likely be difficult, was, in the review team’s view an acceptable approach. He did appear however, to indicate a reluctance to endorse this approach due to a perceived tendency of a higher incidence of problems. The review team’s impression from interviews was that this view was reflected in the overall surgical culture within the service (with the exception of one surgeon). The review team were concerned, from Surgeon A's description of sub-total cholecystectomy, about his understanding of this operation and they concluded that this could be in part related to his view of this approach. This, in their view indicated a need for some targeted training in this procedure.

It appeared that the initial restrictions placed by the Trust on Surgeon A's practice (pending review)[8] had been communicated verbally to him by the Service Director. The review team were not made aware of the exact date of this verbal communication but understood it to be on or before 17th April 2020[9].

It was unclear why it had been agreed that Surgeon A had been unable to undertake non-biliary surgery independently at this time when he had not been informed of any concerns regarding this part of his clinical practice (nor, it appeared were interviewees aware of any concerns in this respect). The review team were concerned that the initial restrictions placed on Surgeon A's clinical practice had not been communicated to him in writing with accompanying documented

[8] The initial restrictions were reported as Surgeon A not undertaking biliary tract surgery and whilst awaiting completion of the RCA all of his surgery is supervised by a consultant colleague.

[9] The RCS Eng invited review request information was dated 17th April 2020 and included information on the initial restrictions as part of the steps taken.

rationale for the decisions taken. This would have been expected in order to ensure absolute clarity and understanding regarding any restrictions placed and the reasons for these decisions. Further, documented restrictions with a clear rationale, would have been helpful for reference in the subsequent meeting on 22nd June 2020, held between Trust management and Surgeon A to discuss possible changes to the initial restrictions. It would have also been helpful to reference in the letter from the Trust which summarised the meeting of 22nd June 2020 and documented the changes agreed to the initial restrictions placed. This letter was reportedly received by Surgeon A approximately one month after the meeting was held on 22nd June 2020, which in the review team's view was an unacceptable delay.

Surgeon A's colleagues had, reportedly not been made aware of the initial restrictions on his practice. The review team emphasised that it would have been helpful for both Surgeon A and his colleagues if the Trust could have agreed with him how the matter was to be communicated to them in a way which satisfied the Trust's obligations regarding confidentiality, privacy and data protection.

Going forward

The review team concluded that Surgeon A's reported reflection and identification of key areas for action and/or support following the three serious incidents, demonstrated insight and learning. In addition, his willingness, going forward, to be supported by a consultant surgeon colleague demonstrated his commitment to giving careful consideration to the support he will require, should it be agreed that he resumes laparoscopic cholecystectomy surgical practice.

There also appeared to be support for his return to this aspect of his surgical practice from consultant surgeon colleagues and some support measures had been identified by interviewees as potentially helpful. These included: the opportunity for further external training, the possibility for his biliary surgical practice to be observed by specialist hepatobiliary (HPB) surgeon(s) and independent assessment of his practice and anatomical knowledge. It was the review team's opinion that there are sufficiently capable surgeons within the Trust to ensure that training for Surgeon A may be able to be organised internally. On a practical note, in their experience, they considered that it may be difficult to organise external training for laparoscopic cholecystectomy.

4. Recommendations

4.1. 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. If the Trust and Surgeon A agree that he is to resume undertaking biliary surgery, his clinical and pastoral support needs should be identified. A clear training and support plan should be mutually agreed and documented. This should include but is not limited to:
   (i) Providing opportunity for further training internally or externally (it is recommended that consideration is given to this being arranged internally if there is availability of appropriate in-house consultant surgeon(s));
   (ii) Targeted training in sub-total cholecystectomy;
   (iii) Providing opportunity for Surgeon A's biliary surgical practice to be supported and mentored by specialist HPB surgeon(s). Surgeon A's progress should be monitored both during an agreed period of mentoring and for an agreed period afterwards.

2. During his clinical practice, Surgeon A is strongly encouraged to request advice, support or help from consultant surgeon colleague(s) intraoperatively if needed at the earliest opportunity. The threshold for requesting advice, support or help should be agreed between Surgeon A and his mentor during his period of mentoring.

3. Cancellations (at times reportedly repeatedly) of laparoscopic cholecystectomy cases in an acute setting, as a result of inadequate theatre capacity, needs to be addressed. The review team would draw attention to the NICE guidelines for managing gallstone disease[10] and highlighted that there are a number of other national guidelines[11] and commissioning guidance.[12]

4. The system for handover of patient care by the (primary) consultant surgeon who has made the clinical decision regarding the surgical pathway, needs to be robust and timely. It must ensure that the operating surgeon has the opportunity to inform the clinical decision and/or to review the planned surgical pathway.

4.2. Recommendations for individual performance improvement

The following recommendations are considered important actions to be taken by Surgeon A and the healthcare organisation in order to improve patient care.

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[10] National Institute for Health and Care Excellence guidelines "*Gallstone disease: diagnosis and management."* [NICE, 2014, last revised January 2017 and next planned review by December 2022)].
[11] Other national guidelines include but are not limited to the following:
(i) "Treat the cause: a review of the quality of care provided to patients treated for acute pancreatitis" – NCEPOD (National Confidential Enquiry into Patient Outcomes and Death). 7th July 2016.
(ii) "UK guidelines for the management of acute pancreatitis." UK Working Party of the British Society of Gastroenterology, Association of Surgeons of Great Britain and Ireland, Pancreatic Society of Great Britain and Ireland, and Association of Upper GI Surgeons of Great Britain and Ireland. First published April 14, 2005, online issue publication April 14, 2005.
(iii) "Pathway for the management of acute gallstone diseases." Association of Upper Gastrointestinal surgeons of Great Britain and Ireland (AUGIS). September 2015.
[12] Commissioning guide: gallstone disease, 1 December 2016. Royal College of Surgeons of England (RCSEng) , Association of Upper Gastrointestinal surgeons of Great Britain and Ireland (AUGIS)

5. Following recommendation 1 above, if Surgeon A is to resume his biliary surgical practice, it is recommended that he should be mentored/supervised until the mentor is prepared to sign him off as competent to undertake independent practice.

4.3. 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.

6. Following recommendation 4 above, the Trust should review its policy for handovers and ensure that compliance is regularly reviewed.

4.4. Additional recommendations for consideration

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

7. It is important that the Trust communicate in writing to any surgeon, any restriction(s) on their clinical practice and the reason for the restriction(s). In addition, what this means for the service and colleagues as a whole should be shared with colleagues in an appropriate way, agreed with the surgeon concerned and compliance with the Trusts' obligations relating to confidentiality, privacy and data protection.

4.5. Responsibilities in relation to this report

This report has been prepared by The Royal College of Surgeons of England and The Association of Surgeons of Great Britain and Ireland 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.[13]

4.6. 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.

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