Invited Service Review Report

Report on the Upper Gastrointestinal (GI) and Emergency Surgical Service

Norfolk and Norwich University Hospitals NHS Foundation Trust

Review carried out on: 23rd – 24th July

Report issued: 30th September 2020

A service review on behalf of:

The Royal College of Surgeons of England

The Association of Surgeons of Great Britain and Ireland

Review team:

Names Redacted

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Appendices removed - identifiable information

1. Introduction and background

On 18th April 2020, Professor Erika Denton, Medical Director for Norfolk & Norwich University Hospital NHS Foundation Trust wrote to the Chair of the Royal College of Surgeons of England (RCS England) Invited Review Mechanism (IRM) to request an invited service review of the healthcare organisation's Upper Gastrointestinal (GI) and Emergency surgical service. The request highlighted for review, the quality and safety of surgical care provided to patients presenting acutely with gallstone related pathology. It also highlighted a number of specific areas including: behaviour and team working, pre-operative clinical decision-making peri-operative care and service/network design (in particular, organisation and provision of theatre). The review request followed three serious incidents (SIs) and an internal review of the SIs.

This 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 service review would take place.

A review team was appointed and terms of reference (ToR) agreed between the Trust, the RCS England and the invited review team. A remote invited review was held on 23rd and 24th July, which involved:

- Consideration of background documentation regarding the upper GI surgery service.
- Interviews with members of the upper GI surgery service, those working with them to provide the service and other relevant members of Norfolk and Norwich University Hospital NHS Foundation Trust staff.

The appendices to this report provide: removed identifiable information.

Overview of healthcare organisation and Upper Gastrointestinal (GI) and Emergency surgery service at the time of the review request[1]

Norfolk & Norwich University Hospital NHS Foundation Trust ('the Trust') provides acute hospital services at Norwich and Cromer Hospitals.

The information provided indicated that there were seven consultant surgeons in the Upper Gastrointestinal (GI) and Emergency surgical service[2] plus eight surgical registrar posts and fifteen foundation doctors supporting the surgery service (eleven FY1 and four FY2[3]).

The consultant surgeon on call arrangements were 1:14 on weekdays and 1:7 at weekends.

There were 233 ward beds (spread over eight wards) dedicated to the service, ten HDU and ten ICU beds. Three theatres were utilised by the service.

In terms of the service surgical activity over the previous two years, 2896 and 2648 elective cases were performed respectively for 2018/19 and 2019/20. The numbers of day cases performed were 1964 and 1788 respectively for the same two years and there were also 1392 and 1301 emergency procedures.

[1] Provided in the service overview information - removed

[2] During interviews, eight consultant surgeons within the service were referred to during interviews; four consultant emergency general surgeons and four consultant upper gastrointestinal (GI) surgeons. It was also A fifth, recently appointed consultant Upper GI surgeon was reported during interviews as due to start soon.

[3] FY1 and FY2 refer to foundation year one and two respectively. All newly qualified doctors spend two years in training as foundation doctors.

2. Terms of reference for the review

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

In conducting the review, the review team will consider the standard of care provided by the upper GI surgery service, including with specific reference to:

1. Surgical pathways for patients presenting acutely with gallstone related pathology, including:

- The effectiveness of the current team based approach.
- The on call arrangements.
- Team working and communication within the surgical team and with colleagues working with them.
- Perioperative care, including whether systems and resources support providing high-quality care, including theatre capacity and scheduling.
- Post-operative care, including the recognition and communication of complications.

2. The impact of the service's scheduled and unscheduled care pathways on the overall standard of care provided to patients undergoing Upper GI surgery.

Conclusions and recommendations

The review team will, where appropriate:

- Form conclusions as to the standard of care provided by the upper GI surgery service including whether there is a basis for concern in light of the findings of the review.
- Make recommendations for the consideration of the Medical Director of Norfolk and Norwich University Hospital 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.

3. Conclusions

The following conclusions are based on the information provided to the review team from the interviews held and the documentation submitted. It is largely organised according to the Terms of Reference (TOR) agreed prior to the review but also takes account of the themes that emerged whilst reviewing this information.

It is noted that, whilst reference was made during some interviews to the three relatively recent serious incidents which had occurred within the service, these three cases were reviewed as part of a separate RCS England Invited review. Conclusions drawn in respect of these three cases, therefore, were included in a separate RCS England invited review report.

3.1. Surgical pathways for patients presenting acutely with gallstone related pathology

The review team concluded that the ambulatory pathway assessment undertaken in the ambulatory emergency care (AEC) unit for patients presenting acutely with gallstone related pathology, appeared to work to the standard that would be expected by the review team. Patients at this stage were appropriately assessed and diagnosed and, for those whom a surgical pathway was to be followed, were transferred to a ward for listing on an emergency theatre list.

3.1.1. The effectiveness of the current team based approach.

It appeared that the arrangement in place at the time of the review whereby the emergency general surgery service undertook all emergency gallbladder cases provided sufficient capacity, with some support from the on-call consultant upper GI surgeons. It was the review team's opinion, however, that the consultant general surgeon with extensive hepatobiliary (HPB) and laparoscopic cholecystectomy (LC) surgical experience had been under-utilised in the hot gallbladder work of the service. It was recognised by the review team that the reportedly large elective waiting list assigned to this post, would likely make reassigning some of the surgery time to the hot gallbladder service challenging but not impossible. The review team concluded that the integration of some operating time of an experienced HPB surgeon into the hot gallbladder service would likely be of significant benefit, particularly in supporting colleagues and in overseeing the service. In addition, this would enable discussion and collaboration when undertaking more complex cholecystectomy cases.

The review team considered that the current team-based approach had frequently meant that the consultant surgeon responsibility for patient care changed, sometimes several times. This presented the potential for different clinical opinions and the challenges involved in how to include these in the clinical decision making process, particularly in cases where the patient's consent had been previously obtained. In this respect, the review team highlighted the importance of opportunities for team discussion and comprehensive handover for patients admitted with acute biliary pathology following a surgical pathway. This would help mitigate challenging situations where a consultant surgeon preparing for planned surgery, may not agree with the management plan in place. The handover should be a formally documented process, reviewed by the Trust periodically (the review team heard during interviews that there was a formal process in place but the review team were not provided specific detail and did not have sight of it).

3.1.2. On-call arrangements

Current on-call arrangements were outlined in the course of interviews and those interviewed did not report any concerns. Therefore, the review team concluded that the arrangements for on-call at the time of the review appeared to be satisfactory.

3.1.3. Team working and communication within the surgical team and with colleagues working with them

The review team concluded from numerous reports during interviews that the consultant emergency general surgeons appeared to work well as a team. They also noted some reports by interviewees of good team working amongst the consultant upper GI surgeons and with the wider upper GI surgery service.

However, in respect of the consultant upper GI surgery team, the review team concluded that there appeared to be unresolved issues remaining, some of which were perceived to have been raised in the context of previous reviews of the service. From the interviews, these issues (some historical) had evidently included: interpersonal difficulties [redacted - opinion/identifiable individuals] , limited opportunity for open and supported discussion of complications, a perception of inconsistent support and trust, the distribution of types of sub-specialty procedures and a lack of strong leadership. There had been a number of reports during interviews that one or more of these issues had contributed to the interpersonal and team working difficulties widely reported by interviewees.

The review team were not in the position to comment on the merit or otherwise of issues and concerns reported as these were varied, not always first hand and at times, with divergent opinions. However, what was clear to the review team was that there were issues which had contributed to team working and interpersonal difficulties and that, whilst, reportedly, there had been an improvement over recent months, some issues remained unresolved. It was the opinion of the review team that, whilst there were unresolved issues remaining, this has the potential to impact the ability of the upper GI surgeons to function as a cohesive, mutually supportive team underpinned by trust. In addition, there was the potential for reported recent improvements reported to regress, if behaviours related to unresolved issues re-emerge or if it was felt that there was not an agreed way in which to raise issues of concern. In both these scenarios, the review team, (whilst they did not hear any reports of service delivery or patient care being affected), were concerned that there was the potential for these to happen going forward.

The review team considered that it would not be helpful nor appropriate to draw conclusions in respect of the detail or findings of the two previous reviews which had been undertaken relating to the upper GI surgery team. The review team became aware, quite late during the course of the interviews, that these reviews had taken place, and, as such had not had the opportunity to explore issues arising from these reviews with all interviewees in the context of the terms of reference for this review. However, it was clear that, with regard to these previous reviews, that there were wide variations in understanding amongst interviewees regarding as to their scope, how information had been gained and shared, what the outcomes or any actions taken had been and the reasons for commissioning the RCS England invited review. The review team considered that there had not been effective communication by Trust management of appropriate information in respect of the previous reviews to those involved with the service and, it had seemed to some interviewees, that they were now being asked about some of the similar issues for a third time. The review team also noted that staff reportedly had not been made aware in an appropriate way of the outcomes and actions taken in respect of the previous reviews. They considered that this was indicative of the reported need for improvement in communication between Trust management and the upper GI surgery team which had emerged as a consistent theme during this review.

It was the opinion of the review team that the team working and interpersonal difficulties within the consultant upper GI surgeons had impacted the effectiveness of clinical leadership and that, on the other hand, stronger clinical leadership may have helped with some of these difficulties.

3.1.4. Perioperative care, including whether systems and resources support the provision of high-quality care, including theatre capacity and scheduling.

The review team concluded that the delays in surgery being undertaken and (reportedly frequently repeated) cancellations for patients presenting acutely with gallstone related

pathology, were not in line with guidance from NICE[4] and other national organisations. The internal audit data provided for a thirteen month period in 2016/17 reported that only 15% of patients had been operated within 48 hours and only 28% within 72 hours.[5]

In the review team's experience, surgery for this sub-group of patients may be very challenging and is associated with a higher incidence of complications, (in particular, if there are undue or excessive delays) and a higher conversion (laparoscopic to open surgery) rate (see section 3.1.5 for conclusions in respect of complications). A delay in undertaking laparoscopic cholecystectomy (LC), in line with national guidance, may contribute to a deterioration and/or change in clinical condition and in the surgery becoming more challenging or alternative treatment pathways needing to be considered. In addition, the review team highlighted that it is best practice for patients diagnosed with acute cholecystitis (AC) to undergo LC on the same admission. In cases where the resources are not available locally, it was the review team's opinion that it would be preferable to transfer patients to a specialist alternative provider with capacity to treat patients within established guidelines, rather than delaying the procedure.[6]

The review team highlighted that, if cancellations to surgeries meant that the consultant surgeon who undertakes the surgery had not been part of the clinical decision making for the planned surgery, they may have a different clinical view. This could present challenges in terms of reviewing the original plan and considering an alternative treatment pathway.

From a patient perspective, the patient may feel that change(s) in consultant surgeons responsible for their care limits continuity, although robust and detailed handover would help to ensure that this would not be the case. In addition, cancellations of planned surgery may necessitate repeated episodes of fasting, which in itself may impact patient physical and psychological health and well-being.

A number of factors appeared to have contributed to delays and cancellations in cholecystectomy surgery which had meant that it had frequently not been possible to comply with national guidelines. These included: availability of imaging resources and further strain being placed on emergency theatre capacity by other non-emergency cases being listed.

The review team highlighted that, whilst the Trust had taken steps (including establishing the hot gallbladder service) to address the challenges of emergency theatre capacity for patients presenting acutely with gallstone related pathology, going forward, it was likely to continue to be difficult to match capacity to demand. Whilst undoubtedly, this is important and of concern, in the review team's experience, similar problems are faced by almost all large hospitals.

The review team noted that interviewees had provided examples of ideas (including improvements to the structure, booking system and theatre listing) on how to make better use of theatre capacity. They were not made aware, however, of if there had been a mechanism for these ideas to be communicated to Trust management or of any communication from Trust management in respect of any ideas or suggestions provided by staff. The theme of effective communication between Trust management and the upper GI surgery team was previously highlighted in section 3.1.3 above.

The hot gallbladder service introduced several years ago had provided two additional half-day theatre lists a week (every other week in the case of one of these lists). It was concluded by the review team that, whilst these additional dedicated theatre lists were a valuable resource in addressing the increasing demand for acute biliary surgery (and the finite capacity of emergency theatre resources), they had not been used in a way to maximise the potential for hot gallbladder cases. This conclusion is supported by the interviewees reporting that it had repeatedly been raised that the hot gallbladder afternoon lists had almost always started late (due to the

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[4] 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)].

[5] Power point – audit of "hot gallbladder" service. 2/8/18. names redacted

[6] Management of acute gallstone diseases. Association of Upper Gastrointestinal surgeons of Great Britain and Ireland (AUGIS) September 2015.

preceding morning lists consistently overrunning), and yet no remedial action appeared to have been taken.

This view was reflected in the audit data provided which, whilst covering the period 2016/17, indicated that during a thirteen month period an additional "110 more patients could have been operated on the hot chole list." [7]

In addition to cases being cancelled, the reportedly frequent late starts (due to overrun of previous lists) and difficulties in continuing beyond 4.30 or 6.00 pm had meant that only one or, at times, neither of the two cases listed had been able to proceed. Furthermore, it appeared that, at times, inadequate availability of theatre staff had also been a resource which had impacted upon effective use of theatre time.

The review team concluded that, whilst there is a need for additional emergency theatre resources for patients presenting acutely with biliary pathology, there is also a need for review of the effectiveness of the hot gallbladder theatre lists for this service.

It appeared that, in respect of more recent changes to emergency theatre capacity made as a result of the COVID-19 pandemic, some plastic surgery cases being removed from the emergency theatre listing had somewhat reduced overall demand. If this arrangement were to continue, coupled with the reportedly imminent readiness of the intensive radiology suite (IRS) which would take all vascular cases, there may be a reduction in overall demand for emergency theatre resources.

In respect of the reportedly routine practice of undertaking cholangiogram[8] (primarily to confirm anatomy and secondarily to identify stones), the review team acknowledged that there are different views and practices amongst the surgical community on the use of cholangiography. These range from undertaking it routinely in all cases, undertaking it selectively and not undertaking it at all. The review team favours a selective approach to undertaking this procedure which enables the use of professional judgment to decide on the requirement of cholangiography, based on the clinical context.

3.1.5. Post-operative care, including the recognition and communication of complications.

There were no reported concerns raised with the review team regarding post-operative care and the recognition of complications in acute cholecystectomy cases.

From what was reported during interviews and the documentation provided[9], prior to the two bile duct injuries which had been the subject of SIs, the rate of complications for acute LC cases for the service had appeared to have not been an outlier. The review team did highlight however, that the audit information seen had been presented in 2018 and they had not seen any more recent audit information.

The review team were concerned by reports that there had not been effective discussion of complications amongst the consultant surgery team. It was not clear to the review team if morbidity and mortality (M&M) meetings were happening at the time of the review. Documents provided[10] indicated that there had been a general surgery M&M meeting on 10th March 2020 but neither the minutes nor attendance information were seen. The review team highlighted the importance of documented minutes and attendance information for M&M meetings as part of clinical governance.

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[7] Power point – audit of "hot gallbladder" service. 2/8/18. names redacted

[8] An intra-operative cholangiogram is an x-ray that is done to image the bile ducts during the course of the cholecystectomy operation.

[9] Power point – audit of "hot gallbladder" service. 2/8/18. names redacted

10 Record of general surgery M&M meetings on 10th December 2019, 11th February 2020 and 10th March 2020.

3.2. The impact of the service's scheduled and unscheduled care pathways on the overall standard of care provided to patients undergoing Upper GI surgery.

It appeared to the review team that both the numbers of cholecystectomies on the elective waiting list and the average length of wait time had been significant. Whilst this situation was unlikely to be unique to this Trust, in the review team's view, the reported readmission rate (56% following discharge of acute cholecystectomy cases without surgery[11]) had potentially exacerbated the situation. The conclusions made in respect of the challenges faced in acute cholecystectomy cases undergoing surgery in line with national recommendations, were outlined in section 3.1.4 above.

3.3. Other

Some of those interviewed observed that there had been some improvements in ways of working within the upper GI surgery service since the change in clinical leadership of upper GI cancer.

The review team also noted that, in respect of one of the recent bile duct injury cases which had been party to a root cause analysis (RCA), it was reported that the ERCP[12] report had not been clear and required more detailed documentation.

Whilst issues in respect of communication between the upper GI Surgery service and Trust management have been raised in previous sections, the review team were able to draw some general conclusions that were considered worthy of note here, as a separate section. The review team concluded that communication between the upper GI Surgery service and Trust management appeared to have been rather "top down" and hierarchical, and raised the following points in this respect:

- It appeared from what was reported, that there had been limited opportunity for staff to be involved in decision making about the service. As outlined in section 3.1.4 above, ideas heard during interviews regarding potential improvements to the service, including better use of theatre time and restructuring of the surgical timetable, appeared not to have been acted upon. In the review team's view, limited opportunities and/or any barriers to the ideas of staff being considered, will likely stifle creativity and ultimately productivity.

- There appeared to have been situations where staff had not been made fully aware of actions that were taking place and the reasons for these. An example of this, as outlined in more detail in section 3.1.3 , was the apparent lack of appropriate information shared with the team following the previous reviews of the upper GI surgery service and the apparent lack of clarity concerning the reasons for the RCS England invited review.

The perception of some interviewees was that if a collective view were to be agreed at the emergency surgery meetings, this was more likely to be heard by Trust management. These meetings therefore, appeared to be important for discussion and a vehicle for raising or escalating issues.

[11] Power point – audit of "hot gallbladder" service. 2/8/18. names redacted

[12] Endoscopic retrograde cholangio-pancreatography (ERCP) is a procedure that can be used to remove gallstones from the bile duct. The gallbladder isn't removed during this procedure, so any stones in the gallbladder will remain unless they're removed using other surgical techniques.

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. Reported and at times repeated cancellations and delays to laparoscopic cholecystectomy surgery for acute cholecystectomy cases needs to be addressed. The Trust should continue to prioritise an increased emergency surgical provision for patients presenting with acute gallstone related pathology. The review team would draw attention to national guidelines[13] and commissioning guidance.[14] This should include but is not limited to:

    (i) Improving the effective and efficient utilisation of the current hot gallbladder theatre lists by taking steps to minimise late starts and ensure theatre staff availability.

    (ii) Taking steps to change the current hot gallbladder theatre list arrangement of two half-days to one full day or to move at least one of the two afternoon lists to a morning.

    (iii) Continue with the recent changes (including appropriate plastics cases being diverted), which had reportedly reduced the demand on emergency theatre lists.

2. The issues which have affected, and, appear to continue to affect team working in the consultant upper GI service must be explored. Any which remain unresolved should be identified and addressed by the Trust in order to build a cohesive and mutually supportive team. These issues include but are not limited to:

    (i) The difficulties reported in interpersonal interactions identifiers redacted.

    (ii) Perceived limited opportunity for open and supported discussion of complications.

    (iii) Uncertainty in respect of mutual trust and support.

    (iv) Lack of strong leadership.

    (v) The distribution of types of sub-specialty procedures.

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[13] 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)].
"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.
"Pathway for the management of acute gallstone diseases." Association of Upper Gastrointestinal surgeons of Great Britain and Ireland (AUGIS). September 2015.
"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.
[14] 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).

3. The current team based approach for patients admitted with acute biliary pathology, needs to ensure that changes in consultant surgeon responsibility of care does not negatively impact the quality and continuity of care. Improvements should include, but are not limited to:

    (i) The consultant surgeon who undertakes the surgery is able to be part of the clinical decision making regarding the planned surgical pathway and/or there is a system in place which supports the ability to review and challenge the planned surgical pathway.

    (ii) The systems in place for handover are robust, agreed, documented and adhered to.

4. Audit information seen by the review team in respect of complications of acute laparoscopic cholecystectomy cases, had been presented in 2018. There is a need for a more up to date audit (and regular audits going forward) to be undertaken as part of clinical governance and to be shared to support the discussion of complications as part of shared learning.

5. Regular morbidity and mortality (M& M) meetings must be scheduled and attendance monitored to ensure opportunity for discussion of complications amongst the consultant surgeon team as part of good clinical governance. There should be documented minutes and attendance records maintained.

4.2. Recommendations for service improvement

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

6. Consideration should be given to integrating into the hot gallbladder service some of the operating time of the consultant general surgeon who is an experienced HPB surgeon and has significant experience in performing cholecystectomy. This should include the availability of specialist HPB support and oversight of the service and also discussion and collaboration in cases of complex disease.

4.3. Additional recommendations for consideration

The following recommendations are for the healthcare organisation to consider as part of its future development of the service.

7. Steps should be taken to improve two-way communications between Trust management and the upper GI surgery service. These should include but are not limited to:

    (i) Improving opportunities for staff to be involved in decisions about the service.

    (ii) Improving the communication and timeliness of appropriate information to staff.

    (iii) Improved utilisation of the emergency surgery meetings as a vehicle for the flow of two way communication.

4.4. 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.[15]

4.5. 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.

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