PRIVATE AND CONFIDENTIAL

THE ROYAL COLLEGE OF SURGEONS OF ENGLAND

INVITED REVIEW MECHANISM

A SERVICE REVIEW REPORT ON BEHALF OF:

THE ROYAL COLLEGE OF SURGEONS OF ENGLAND
35 – 43 LINCOLN'S INN FIELDS, LONDON WC2A 3PE

ASSOCIATION OF SURGEONS OF GREAT BRITAIN
35 – 43 LINCOLN'S INN FIELDS, LONDON WC2A 3PE

REPORT ON UPPER GASTROINTESTINAL SERVICE

MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST

2-4 OCTOBER 2013

REVIEWERS:

[redacted] **THE ROYAL COLLEGE OF SURGEONS OF ENGLAND**

[redacted] **ASSOCIATION OF SURGEONS OF GREAT BRITAIN**

[redacted] **LAY REVIEWER**

Acknowledgements

The reviewers would like to thank the Maidstone and Tunbridge Wells NHS Trust for the assistance given to them during the course of the review and in particular [redacted] for undertaking the pre-visit arrangements, and [redacted] for supporting the reviewers during the visit.

Contents

RCS
ADVANCING SURGICAL STANDARDS

1. Background to the review

Please note that the description in this section of the report, of the circumstances leading to this review being requested, is based on information that was provided to the Royal College of Surgeons (RCS) by the Trust when they completed the RCS' service review request pro-forma. It does not represent the view of the RCS or its reviewers on these circumstances.

On 22 May 2013, Dr Paul Sigston, Medical Director, Maidstone and Tunbridge Wells NHS Trust wrote to the Chair of the Invited Review Mechanism (IRM) to request an invited service review of the Trust's upper gastro-intestinal surgery service. This followed concerns about the outcomes for patients undergoing oesophageal cancer resections. The basis for requesting the review was to explore concerns about an increase in mortality, as well as issues with clinical team functionality and team working.

This request was considered by the Chair of the Royal College of Surgeons of England (RCS) IRM and a representative of the Association of Surgeons of Great Britain. It was agreed that an invited service review would take place and a review team was appointed. An invited review visit was held on 2-4 October 2013.

The background to the review is that concerns have been raised over the past few years about several aspects of the service. In December 2012, two deaths occurred on consecutive days (the operations for these patients had taken place several weeks apart). Both deaths were sudden and unexpected and the trust took the decision to delay operations over the Christmas period whilst an internal review was undertaken. Dr Foster data over the most recent 12 month period available, showed four deaths in 39 patients who had undergone oesophageal cancer resections. On investigation, the trust considered that the service was safe. It reported 'a good track record, with no deaths in 2011'.

The resection service resumed in January 2013. However, the service was again suspended following three deaths in February, April and July 2013. A briefing note provided to the review team indicates that the trust did not consider it appropriate to record these deaths as serious incidents, 'as each case has been examined and was not felt to be inappropriate'. The briefing note stated: 'The mortality reported in the literature is high, with a 1 year survival of approximately only 75%'.

Nevertheless, the Medical Director felt unable to assure the Chief Executive that the service remained safe and took the decision, on 25 July 2013, to suspend oesophageal resection surgery with immediate effect. Neighbouring trusts were informed at the beginning of August 2013 that 'oseophagectomy only' would be suspended and that 'gastrectomy and junctional tumours' would continue to be undertaken. This remained the position at the time of the invited review visit.

2. Terms of reference for the review

The following terms of reference for this review were agreed prior to the RCS's review visit between the RCS and the Trust commissioning the review, and were provided to the surgeon that is the subject of the review.

Review of the Specialist Oesophagus and Gastric Resection team at Maidstone and Tunbridge Wells NHS Trust, under the Invited Review Mechanism.

1. To consider concerns about the Upper Gastrointestinal Surgical Team, with specific reference to **outcomes for resection of oesophageal and gastric cancer**. These concerns were raised following a number of unexpected deaths. In addition, unsubstantiated claims about a high rate of complications have been made, some of which were anonymous. It is known that there is a difficult relationship between some surgeons and some of the anaesthetic team, but it is unknown whether this impacts on patient care.

2. The reviewers will then make recommendations for the consideration of the Chief Executive and Medical Director of the Hospital as to:

    - Whether there is a basis for concern about the Upper Gastrointestinal Surgical Team in light of the findings of the review;
    - Possible courses of action which may be taken to address any specific areas of concern which have been identified.

RCS
ADVANCING SURGICAL STANDARDS

3. Details of surgical team being reviewed

Maidstone and Tunbridge Wells NHS Trust provides the oesophageal resection service to the Kent and Medway population of 1.6 million. Patients are referred to the trust from East Kent Hospitals, Medway and Darent Valley.

The trust has 12 general surgeons (upper and lower gastro-intestinal) and services are provided over two sites situated 14 miles apart. Emergency surgery, endoscopy lists, outpatient clinics and some day surgery lists are undertaken at Tunbridge Wells Hospital. Elective gastro-intestinal services, including oesophageal cancer resection surgery, are provided at Maidstone Hospital. Outpatient clinics are held at a number of locations.

The oesophageal and gastric cancer resection service is provided by four upper gastro-intestinal surgeons. Mr Haythem Ali was appointed to the trust in 2005 and established the oesophageal and gastric resection service. He was joined by Mr Amir Nisar and Mr Maduabuchi Okaro in 2006. The fourth surgeon, Mr Ahmed Hamouda, was appointed in 2010. Mr Nisar is currently the clinical lead.

Three of the surgeons, Mr Ali, Mr Nisar and Mr Hamouda, operate as a distinct unit within the upper gastro-intestinal team, performing the majority of their cancer resections using minimally invasive surgery. There are slots for three trainee grade registrars, although there appears to be only two working at any one time. These trainees are assigned to the unit of three surgeons. Mr Okaro does not have any trainees assigned to him, but does have non-training grade doctors.

During the past five years there have been significant challenges for the Trust regarding the provision of emergency general surgery. This was split between both sites, but it is now provided only at Tunbridge Wells.

The surgical team are supported by five upper gastro-intestinal clinical nurse specialists (3.2 whole time equivalent). The specialist nurses provide a range of service, including a dedicated telephone follow up clinic for pancreatic/HPB (Hepatic, Pancreatic and Biliary) surgery patients.

There is currently no out of hours endoscopy service provided by the Trust. However, senior clinical management stated that gastroenterologists are being appointed and a seven day endoscopy service will be running by the end of 2013.

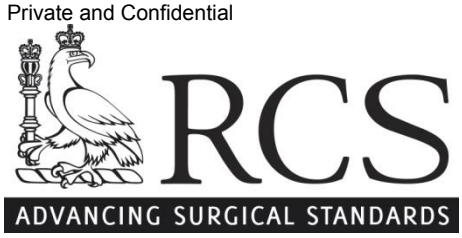
4. Royal College Review team	
Lead reviewer	[redacted] FRCS
Clinical reviewer	[redacted] FRCS
Lay reviewer	[redacted]
A brief biography of each member of the review team can be found at appendix one.	

5. Visit timetable	
Wednesday 2 October 2013	
08.00-9.00	Case note review
09.00-9.30	Dr Paul Sigston, Medical Director
09.30-10.30	Case note review
10.30-13.00	Case note review
12.50-13.15	[redacted] Associate Director of Nursing, Planned Services
13.15-15.00	Case note review
15.00-15.45	Glenn Douglas, Chief Executive
15.45-16.00	Case note review
16.00-16.30	[redacted] Consultant Anaesthetist
16.30-17.00	[redacted] Consultant Anaesthetist
Thursday 3 October 2013	
07.30-09.00	Case note review
09.00-09.30	[redacted] Locum Consultant Surgeon
09.30-10.00	[redacted] Sister, Cornwallis Ward [redacted] ICU Clinical Educator [redacted] ITU Senior Sister
10.00-10.30	[redacted] Clinical Director, Critical Care
10.30-11.00	[redacted] Specialist Trainee
11.00-11.30	[redacted] Clinical Director, Surgery
11.30-12.00	[redacted] Consultant Anaesthetist
12.00-13.00	Case note review / lunch
13.00-13.30	[redacted] Senior ITU Dietician [redacted] Clinical Specialist in Respiratory Physiotherapy [redacted] Clinical Nurse Specialist, Palliative Medicine
13.30-14.00	[redacted] General Manager, Surgery [redacted] Complaints Manager
14.00-14.30	[redacted] Consultant Upper Gastro-intestinal Surgeon

14.30-15.00	[redacted] Cancer Data Manager
15.00-15.30	[redacted] Consultant Anaesthetist
15.30-16.00	Case note review / break
16.00-16.30	[redacted] Consultant Radiologist [redacted] Consultant Pathologist
16.30-17.00	[redacted] Consultant Upper Gastro-intestinal Surgeon
Friday 4 October 2013	
07.30-08.00	Case note review
08.00-08.30	[redacted] Consultant Gastroenterologist [redacted] Consultant Gastroenterologist
08.30-09.00	[redacted] Consultant Anaesthetist
09.00-09.30	[redacted] Consultant Upper Gastro-intestinal Surgeon
09.30-10.00	[redacted] Upper Gastrointestinal Clinical Nurse Specialist [redacted] Upper Gastrointestinal Clinical Nurse Specialist
10.00-10.30	[redacted] Consultant Medical Oncologist [redacted] Consultant Medical Oncologist [redacted] Consultant Oncologist
10.30-11.00	[redacted] ST3, General Surgery
11.00-11.30	[redacted] Consultant Upper Gastro-intestinal Surgeon
11.30-12.00	[redacted] Consultant Upper Gastro-intestinal Surgeon (Benign Surgery)
12.00-12.20	[redacted] MDT Co-ordinator
12.20-13.45	Reviewer discussion
13.45-14.00	Feedback to: Dr Paul Sigston, Medical Director Glenn Douglas, Chief Executive

No patients were interviewed or examined during the course of the Invited Review visit.

6. Documents reviewed as part of the Invited Review visit
Trust management structure; Clinical directorate and management structure
Job planning, appraisal and related documentation: • Shared job plan for Mr Ali, Mr Nisar, and Mr Hamouda. • Summary information showing job plans across surgery. • Curruiculum vitae for Mr Ali, Mr Okaro, Mr Hamouda, and Mr Nisar, and a statement from Mr Nisar detailing his personal contribution to the trust. • Medical appraisal forms for Mr Ali, Mr Hamouda, Mr Okaro, and an extract of an appraisal form for Mr Nisar.
Rota documentation: • Shared weekly timetable for Mr Ali, Mr Hamouda and Professor Nisar. • Weekly timetable for Mr Okaro. • Team rota for the consultants, associate specialists, staff grades and registrars. • Upper gastrointestinal oncall rota. • Surgical on call rota for Maidstone and Tunbridge Wells at Pembury Hospital.
Policies and pathways: • Pathway for upper gastrointestinal clinical nurse specialist/dietician led follow up clinic for postoperative gastrectomy and distal gastrectomy patients. • Operational policy for upper gastrointestinal clinical nurse specialist follow up clinic of postoperative resection patients. • Cancer waiting times quick guide. • MDT policy documentation: local and specialist management of upper gastrointestinal cancers. • Oesophageal, gastric and pancreatic rapid access referral proforma (2 week wait). • Care of patients on intensive care unit following transhiatal or multi-stage, open or minimally invasive oesophago-gastrectomy. • Details of the process for the verification of positive histologies.
Documentation regarding Clinical Nurse Specialist services: • Note by [redacted] Upper Gastrointestinal Clinical Nurse Specialist, about the nurse led clinics to support major post op resection patients with upper gastrointestinal cancer. • Survey of psychological support, wound review and dietary advice for patients in post op follow up clinics. • Proforma for nurse led follow up clinic for upper gastrointestinal patients following oesophago-gastrectomy surgery.



• Clinical supervision log/competency document for upper gastrointestinal nurse led follow up clinic.
Complaints and incidents: • Upper gastrointestinal surgery complaints August 2011-August 2013. • SIRI (Serious Incident Requiring Investigation) Root Cause Analysis reports for two cases. • Incident forms relating to upper gastro-intestinal service: Ref: Web1064 ID: 43119; Ref: Web2313 ID: 45125; Ref: Web11697 ID: 55216; Ref:Web17663 ID:61184; Ref:Web17360 ID:60881; Ref: 2010/14339 ID: 39819; Ref: 86215 ID: 44593; Ref: Web696 ID: 42544; Ref: Web11211 ID: 54730; Ref: Web14757 ID: 58276; Ref: 78005 ID: 36644; Ref: Web4408 ID: 47882; Ref: Web12406 ID: 55925; Ref: Web10338 ID: 53857; Ref: Web1550 ID: 43746; Ref: 2010/1929 ID: 35984; Ref: Web9257 ID: 52775; Ref: 68897 ID:41246; Ref: 82388 ID: 40499; Ref: 83453 ID:39933; Ref:81176 ID:37048.
Activity data: • Upper gastro-intestinal activity by consultant by year, April 2011-September 2013 (daycase, elective and non-elective). • Mortality data provided by Mr Ali, Mr Nisar and Mr Hamouda. • Surgeon level reporting for oesophageal and gastric resections. • Surgical procedures for patients diagnosed in the period 1 April 2011 to 31 March 2012.
Correspondence: • Email exchange between Dr Paul Sigston, Medical Director and [redacted] Consultant Physician and Gastroenterologist, and Division Director for Planned Care, following inquest into a patient death following an oesophago-gastrectomy (5-7 October 2010). • Letter from Dr Paul Sigston, Medical Director, to Medical Directors, Kent and Medway, informing them of decision to temporarily suspend oesophageal resection surgery in Maidstone (6 August 2013). • Email exchange between [redacted] Quality Manager, National Peer Review and Dr Paul Sigston, Medical Director, and [redacted] concerning communication of the decision to suspend services (30 July 2013). • Letter from Dr Paul Sigston, Medical Director, to Amir Nisar, detailing decision to suspend oesophageal resection surgery with immediate effect (25 July 2013). • Email from Dr Paul Sigston, Medical Director, to Ian Abbs, Guys and St Thomas' NHS Foundation Trust, informing him of decision to suspend the service (25 July 2013). • Letter from Dr Paul Sigston, Medical Director, to Professor David Black, KSS Deanery, in response to details of patient safety concern highlighted in the GMC National Training Survey (17 May 2013). • Letter from Professor David Black, KSS Deanery, to Glenn Douglas, Chief

Executive, regarding a patient safety issue raised by the GMC (13 May 2013).

- Letter from Dr Paul Sigston, Medical Director, to Mr Simon Bailey, Clinical Director – Surgery, regarding two postoperative deaths in December 2012 and suggesting that surgery resume. (10 January 2013).
- Email from Dr Paul Sigston, Medical Director, to Mr Simon Bailey, Clinical Director – Surgery, requesting data on oesphagectomies from 1st October and delaying all oesphagectomies until data has been reviewed (21 December 2012).
- Letter from [redacted] MP to Glenn Douglas, Chief Executive, regarding allegations in the local press from a surgeon representing the consultant general surgical group (10 May 2012).
- Letter from Glenn Douglas, Chief Executive, to [redacted] MP, in response to [redacted] correspondence (16 May 2012).
- Letter from Mr Amir Nisar, Consultant General and Upper GI Surgeon, to Dr Walter Melia, Consultant Gastroenterologist, Darent Valley Hospital, informing him of suspension of 'oesophagectomy only' (1 August 2013).
- Letter from Mr Amir Nisar to Dr Paul Sigston, Medical Director, requesting a meeting to discuss issues regarding the Upper GI department (9 December 2011).
- Anonymous letter (from 'concerned staff at Maidstone Hospital') to the General Medical Council reporting 'dangerous and unethical practices' in surgery, and specifically concerns about the consultant upper gastrointestinal surgeons, theatre administration, and cross cover arrangements for oncology and urology (May 2011).
- Letter from [redacted] Investigation Officer, General Medical Council, to Dr Paul Sigston, Medical Director, enclosing the anonymous complaint received by the General Medical Council (2 June 2011).
- Letter to Mr Simon Bailey, Clinical Director – Surgery, raising issues about the surgeons relating to the wards at Tunbridge Wells Hospital (20 September 2013).
- Email exchange between [redacted] Consultant Anaesthetist and Clinical Director, Ali Haytham, Upper gastro-intestinal consultant surgeon, and Amir Nisar, Upper gastro-intestinal consultant surgeon (18 March 2013).
- Letter to Mr Simon Bailey, Clinical Director – Surgery, regarding surgical attendance at the Upper GI MDM (5 August 2013).
- Email to Mr Simon Bailey, Clinical Director – Surgery, regarding surgical and radiological attendance at a specific, undated, MDM meeting.
- Email to Mr Simon Bailey, Clinical Director – Surgery, regarding surgical attendance at an upper GI MDM on 29 August.
- Letter from six consultant anaesthetists to Mr Simon Bailey, Clinical

Director – Surgery, regarding the scheduling of patients having oesophago-gastrectomy for intensive care (26 April 2012). • Letter to Mr Simon Bailey, Clinical Director – Surgery, regarding concerns about the numbers of patients requiring multiple dilatations following fundoplication (21 September 2012). • Letter to Mr Simon Bailey, Clinical Director – Surgery, raising concerns about one of the upper gastrointestinal surgeons (20 December 2012). • Letter to Mr Ali, Consultant Surgeon, raising concerns about interprofessional communication and junior staff competencies (4 December 2012). • Email to Mr Simon Bailey, Clinical Director – Surgery, concerning a planned [redacted] (6 August 2013).
Documentation provided by clinical nurse specialists: • Upper gastro-intestinal cancer support group patient involvement forum (June 2012, September 2011). • Audit of copy letters to patients (March 2013, April 2012). • Audit for 'Policy for communication of diagnosis to GP' (April 2012). • Survey: Outcomes for patients' in postoperative upper gastrointestinal nurse led follow up clinic (August 2012). • Report following data collection for the period of March and April 2013 of upper gastro-intestinal clinical nurse specialist (CNS) calls into the CNS office and outcomes from CNS calls returned (June 2013). • Audit of surgical pathway (March 2012). • Audit of the non-surgical patient follow up calls with outcomes recorded on KOMS (September 2013). • Kent and Medway oncology patient experience audit (Spring/Summer 2010). • Survey of pathway timescales for patients receiving neo-adjuvant chemotherapy and surgery (May 2012). • Surgical pathway audit (May 2013). • East Kent upper gastro-intestinal referral to specialist centre audit (2011).
Multidisciplinary Team Meeting documentation: • Upper gastro-intestinal morbidity and mortality meeting diary 2011/2012. • Multidisciplinary team minutes (13 April 2011). • Upper gastro-intestinal morbidity and mortality meeting attendance record (7 September 2011, 8 February 2012, 2 March 2012, 7 March 2012, 6 June 2012). • Upper gastro-intestinal morbidity and mortality meeting agendas (7 September 2011, 8 February 2012, 7 March 2012, 6 June 2012). • Minutes of the Diagnostic Radiology Audit and Clinical Governance meeting (13 June 2013).

RCS
ADVANCING SURGICAL STANDARDS

7. Information reviewed that supports the conclusions reached

The following information represents a summary of the information gathered by the reviewers during the interviews held during the service review visit and from the documentation submitted. It is organised under the headings of the themes that emerged. The information presented reflects the viewpoints of those individual staff members being interviewed; it does not necessarily reflect the views of the RCS or its reviewers on these circumstances.

(i) Surgical outcomes

This invited review was triggered by concern about two unexpected deaths in December 2012, followed by three deaths that occurred in February, April and July 2013. A further, sixth death relating to this type of surgery had occurred earlier in 2012. The terms of reference directed the review team to consider postoperative mortality in addition to "unsubstantiated" claims about a high rate of complications.

The reviewers considered the following evidence relating to surgical outcomes:

- Documentary evidence provided by the Trust, including correspondence from staff;
- Verbal accounts provided by interviewees during the invited review visit;
- The case notes relating to each of the six deaths. In order to put these deaths in context, and also to reach a view on claims of a high rate of complications, 84 sets of notes relevant to the terms of reference were also reviewed. The reviewers were provided with patient records dating back to 2006. Records were then randomly selected by the reviewers. The number of records reviewed represented approximately half the oesophogastric cancer resections performed in Maidstone since 2006.

Postoperative mortality

The review team has had sight of only limited data on patient outcomes following oesophageal and gastric cancer resection surgery. The data showed the following:

- In 2012, 40 oesophago-gastrectomies were performed (this compared with 49 in 2011, and 56 in 2010). There were three deaths following this surgery during 2012.
- Overall 30 day mortality was reported as having been 4.6% since 2005, however the total and in hospital mortality combined was 7.1% in 2010, 7.5% in 2012 and peaked at 15% in 2013 just before the service was suspended.
- A cluster of mortality in 2010 was attributed to the introduction of enteral feeding protocols, and two consultants operating and building job plans to accommodate this.

The invited review team was asked to consider the more recent cluster of deaths between December 2012 and July 2013. Following the deaths of two patients in December 2012 who had undergone oesophageal resections, a review took place. The Medical Director formally reported that this review of oesophageal resections over the previous four years had confirmed the death of seven patients, out of a total of 206 (3.4%). This compared with national data of 3.2%. He reported that outline data suggested a mortality for open cases of less than 5% and half that for minimally invasive cases.

A decision was made to resume oesophageal surgery, on the grounds that: 'It appears that there is no link between the two recent deaths and whilst we will keep a close eye on outcome data, there is no reason to alter the majority of the unit's practice'.

The reviewers were told that the operating surgeon was the same for four of the six postoperative deaths in oesophageal resections.

Some of the interviewees suggested that the mortality rate would have been higher were it not for the skills of the intensivists. The quality of care provided by the intensive care unit appears to be high. This is supported by the observation that despite high postoperative complication rates, the minimally invasive oesophago-gastric surgical unit had mortality rates within acceptable limits compared to national figures. The anaesthetist team appeared well motivated and highly engaged in providing the best possible outcomes for patients, which seems to have kept the postoperative mortality at an acceptable level.

Postoperative complications

The reviewers considered the following documentary and verbal evidence about complications:

Length of stay

- Data showed that the average hospital stay for patients undergoing oesophago-gestrectomy was 23 days, with an average intensive care unit stay of 12 days. Both the overall length of stay and intensive care stay are long by national standards.

- Oral evidence was that the length of intensive care stay reflects that the unit also provides high dependency care; there is no step down ward. However, some interviewees considered that the length of stay also reflected the rate of postoperative complications.

- In 2012, consultant anaesthetists formally raised concerns about scheduling of patients having oesophago-gastrectomomy for intensive care. The Intensive Care Unit post-oesophagectomy protocol aims to discharge patients to the ward on the third postoperative day, however the anaesthetists reported 'this rarely occurs'. Uncomplicated patients – reported to comprise about 30% of oesophago-

gastrectomomy – were described as usually having a five day stay, but most patients were reported to stay on the intensive care unit for between eight to 10 days, with some staying several weeks or even months. The presence of a large number of upper gastro-intestinal patients was cited as creating issues in terms of patient safety (by compromising the ability of intensive care to manage unplanned, acutely critically ill patients), for other major planned surgery, and having financial implications for the intensive care unit.

Unexpected complications

- Many interviewees expressed concern about complication rates, particularly for anastomotic leaks. Some staff had formally documented their concerns in correspondence with clinical managers.

- Following review of the two deaths in December 2012, the Medical Director reported that the unit's rates for anastomotic leak were 4% and 10.6% in the preceding two years. He had described these rates as being within the expected range. However, an internal audit suggested the leak rate might be higher; this issue remained unresolved as no definition of anastomotic leakage could be agreed upon.

- The reviewers observed from the case notes a number of unexpected complications, namely bleeding from the liver following injury during a thoracoscopic port insertion, colonic necrosis following injury to the colonic blood vessels during gastric mobilisation, and aorto-enteric fistulae following thoracoscopic mobilisation of the oesophagus.

Complications associated with laparoscopic techniques

- Interviewees repeatedly raised concerns about complications experienced by patients who have undergone minimally invasive oesophago-gastrectomy. Often interviewees were not able to quantify these complications, but the recurring message from staff from different disciplines was that more postoperative problems seemed to occur in patients undergoing minimally invasive or laparoscopic surgical techniques.

- All interviewees were asked by the reviewers whether they would recommend the oesophago-gastric unit at Maidstone Hospital to family and friends who needed surgery for upper gastro-intestinal cancer. Many said they would not recommend the unit. Of these, many volunteered that their lack of faith in the unit related to the minimally invasive approaches to surgery and not to open operations.

- One of the three surgeons who has been performing laparoscopic oesophago-gastrectomomy reported that, recently, he had stopped undertaking oesophageal surgery using laparoscopic techniques due to concerns about complications. The

fourth surgeon only performs open oesophago-gastrectomy and said this was because he was unconvinced of the benefits of laparoscopic techniques.

Management of complications

- Verbal accounts raised concern about the way the upper gastro-intestinal surgeons have tended to respond to complications in their patients. One interviewee said: 'There are no proper discussions of an anastomotic leak and when you mention the word 'leak' to a surgeon they become very defensive.' Others described at least two of the surgeons as being unreceptive to feedback or challenge. One said: 'There is no ethos with them to look at leaks and consider how to do things differently'.

- There was verbal evidence of a defensive response to an investigation into the incidence of anastomotic leakage by one of the ICU consultants. Some of the surgeons were reported as having said that the wrong definition of a leak was being used.

- Case note review identified that some cases of postoperative leakage had been managed by using stents, when revisional surgery/insertion of a t-tube etc. would have been a more appropriate and accepted treatment.

- A letter to one of the upper gastro-intestinal surgeons at the end of 2012, raised concerns about a 'complete lack of communication over some patients' and a lack of understanding by junior staff regarding biliary drainage of a patient.

- The reviewers observed from the case notes that the surgeon who had operated on a patient with complications postoperatively was often not involved in the subsequent care of that patient. The reviewers heard that, on occasions, the operating surgeon was not contactable by phone when the intensive care team tried to involve him in the decision making process about next steps for the patient.

Clinical decision-making

Concerns were expressed to the reviewers by some interviewees about the quality of the decision-making by the three upper gastro-intestinal surgeons who favour laparoscopic approaches. There was evidence to support this in the following areas:

Palliative pathway

Some interviewees questioned whether patients with advanced disease have been put down a radical treatment pathway when palliation would have been more appropriate. There was a belief that some palliative care patients were being kept in hospital for too long.

There was some suggestion that the surgeons placed little importance on certain services (for example, palliative care) that patients might have expected elsewhere. Furthermore, patients undergoing an oesophago-gastrectomomy underwent CPEX testing (a fitness for major surgery test), but such testing was not routinely requested for patients having a gastrectomy; the rationale for this was not clear to the reviewers.

Management of complications

The management of some post- oesophago-gastrectomomy complications raised questions about some of the clinical decision-making of the surgeons. An example of this, mentioned previously, is multiple stent insertion for anastomotic leakage.

TPN

The use of TPN (total parenteral nutrition) for all oesophago-gastrectomomy patients and for prolonged periods, raises concerns about clinical decision-making. The upper gastro-intestinal surgeons explained that this was their response to two cases of small bowel necrosis with a feeding jejunostomy (a feeding tube placed surgically into the small intestine at the time of the operation). This is a recognised complication of these tubes and is thought to be due to an excess feed rate soon after surgery. The reviewers were not aware of other units routinely using TPN as an alternative, or of an evidence base for such practice. Any worry about complications from feeding jejunostomies should have been addressed by changing technique, changing the feeding regimen or stopping the use of feeding jejunostomies.

Benign surgery

Benign surgery was outside the scope of the terms of reference for this invited review, however the verbal reports indicated the following: a high incidence of dysphagia after routine anti-reflux surgery; a case of stenting or dysphagia after anti-reflux surgery; and a case of [redacted]

With regard to the latter, the reviewers saw correspondence from August 2013, which had formally questioned the rationale for a [redacted] by one of the surgeons on a [redacted] In 2012, documentation shows that concerns were raised about the numbers of patients requiring multiple dilatations following fundoplication (a routine operation to treat acid reflux and heartburn).

(ii) Team working

Intra-departmental

The four upper gastro-intestinal surgeons were repeatedly described by interviewees as being a 'dysfunctional team'. Three of the surgeons work as a distinct unit, agreeing amongst themselves at short notice who will attend a fixed clinical session such as an operating list. One of the three consultants told reviewers that managers had encouraged them to work together in this way but there was no evidence available to support this claim. When pressed, the same surgeon admitted that this style of working was not ideal and that it would be better if each consultant looked after their own patients. The reviewers noted that trust headed paper for the department listed only the three surgeons, although reportedly this had been changed more recently. One interviewee described the working practices of the three surgeons as 'secretive'. Many interviewees highlighted problems caused by this way of working, which are covered in the following section.

The fourth surgeon works very much in isolation to the other three, undertaking his own lists and clinics, and reviewing his own patients. Some interviewees expressed concern about this surgeon working in an isolated way and about a lack of cover in his absence. Nevertheless interviewees commented that they knew that he would be present at clinic and endoscopy, and that his patients knew that he would be the surgeon in charge of their surgery. This was not the case with the other three. The surgeons reported that they cross-cover each other's patients, including those of the fourth surgeon. However, oral accounts suggested that this was not borne out in practice. Furthermore, a number of interviewees observed tensions between the unit of three surgeons and the fourth surgeon. For example, accounts were given of confrontations between the fourth surgeon and the other three at multidisciplinary meetings.

Inter-departmental

The terms of reference for this review indicated: 'a difficult relationship between some surgeons and some of the anaesthetic team, but it is unknown whether this impacts on patient care'.

The reviewers were told that tensions have existed for some time between some of the consultant anaesthetists and the upper gastro-intestinal surgeons. It was reported that problems have persisted despite a mediation meeting between the two teams some time ago.

Interviews with members of the two teams suggested a complex picture. On the one hand, working relationships between the upper gastro-intestinal surgeons and anaesthetists were described as 'dangerous'. Personality issues were cited between two consultant anaesthetists and two of the upper gastro-intestinal surgeons. However, a number of the anaesthetists were reported as having concerns about working with one

surgeon in particular, and broader concerns about the three. One described one of two surgeons who attracted most concern as having 'zero insight'.

A general lack of communication between the gastro-intestinal surgeons and the anaesthetists was reported to be a problem. This was supported by documentary evidence highlighting tensions between the two teams over the scheduling of oesophago-gastrectomomy patients. More than one interviewee reported that they do not know when oesophago-gastrectomomies are to be appear on a theatre list, which creates planning problems for the anaesthetic team in making sure that a suitably experienced consultant anaesthetist is available.

An internal email exchange highlighted difficulties between the upper gastro-intestinal surgeons and one anaesthetist, such that the surgeons felt unable to work in theatre with that anaesthetist. However, in interview none of the upper gastro-intestinal surgeons expressed any concerns or reported problems about working with their anaesthetic colleagues.

Good working relationships were reported between the anaesthetists and the fourth surgeon who undertakes open surgery. No concerns were reported about working relationships amongst the team of anaesthetists.

With nursing staff

The working practices of the three surgeons were reported to result in frequent changes to a patient's management plan, which undermined team working on the ward. The reviewers heard that one surgeon would prescribe a plan, which might be altered by another of the three surgeons on review of the patient. Staff described having to cope with this inconsistency and the confusion that sometimes arose.

Staff reported that patients needed to explain to the surgeon what had happened to them in the previous days because the surgeon had not visited the patient previously and may not have even scanned their notes. Interviewees described how this undermined patient confidence in the surgeons and impacted negatively on their experience of care. Patient feedback about their experiences on the ward was reported to highlight problems around a lack of consistency and continuity of care (explored further in the following section).

An anonymous complaint to the General Medical Council from 'concerned staff at Maidstone Hospital', in May 2011, alleged: 'The consultant upper gastrointestinal surgeons very rarely see their patients either after admission or after operations. This task is left for registrars and nurses.' This was supported by correspondence in the run up to the invited review visit, which highlighted a range of concerns by nursing staff at Tunbridge Wells Hospital, including an alleged failure by one upper gastrointestinal surgeon to attend 8am handover when on-call or to see patients at weekends as the on-call consultant, and a failure by all the upper gastrointestinal surgeons to follow the

agreed upper gastrointestinal pathway, specifically by not following up patients transferred to Tunbridge Wells Hospital. This was resulting in poor patient experience, delays in implementation of the pathway and an increase in length of stay. The author of the correspondence stated: 'I cannot accept this level of service to our patients'.

(iii) Working practices

Joint job planning

The three surgeons who work as a unit reported that they have a combined job plan and that programmed activities (PAs) are shared between them equally. The fourth surgeon has his own individual job plan. This arrangement appears to have been instigated when Mr Ali was the clinical lead.

The reviewers were provided with conflicting information regarding the PAs of the four surgeons. In interview, clinical managers reported PAs for the upper gastro-intestinal surgeons that were significantly higher than was indicated in documentary evidence. The surgeons themselves reported PAs that did not marry with the numbers described by clinical managers or was supported by documentary evidence.

Documentary evidence showed totals for the four upper gastro-intestinal surgeons, ranging from [redacted] PAs each. Yet the job plans for Mr Ali, Mr Nisar and Mr Okaro, which were in discussion stage as of April 2012, indicated PAs ranging from [redacted]. These appeared to represent proposed changes for 2013/14. No job plan was provided to the reviewers for Mr Hamouda.

The evident disparity in PAs for the three surgeons with a shared job plan was difficult for the reviewers to understand. Managers similarly described being unable to comprehend how many fixed sessions each of the three surgeons was meant to be doing.

The way the weekly timetable worked was unclear and it proved impossible to understand how the three surgeons covered all the fixed sessions detailed on the timetable. The reviewers were told by the one of the surgeons that the timetable was 'aspirational'. It was commonly reported to the reviewers that the physical whereabouts of the three surgeons was often unknown due to the incomprehensibility of their joint job plan. The reviewers developed the impression that this may have not been accidental.

There was evidence of difficulties caused by the joint job planning arrangement across the patient pathway:

- Outpatient clinics: A backlog of patients are on the waiting list, and over 85% of patients waiting more than 18 weeks are upper gastro-intestinal patients. Yet attendance at clinics by the three upper gastro-intestinal surgeons was reported to be poor. Staff were routinely uncertain which of the three surgeons would turn up

to clinic. Oral evidence was that clinics were often undertaken by registrars. The endoscopy clinic at Maidstone is, according to one of the three surgeons, 'almost exclusively' covered by Associate Specialists. One reported incident (Ref: Web11697 ID: 55216), labelled 'shortage of doctors', highlighted that at one upper gastro-intestinal clinic (on 31 Aug 12), no doctors had arrived in clinic. The incident form indicates that patients received apologies, but no investigation was recorded. The fourth surgeon's attendance at clinics was considered to be reliable and consistent. An audit of the surgeons' attendance at outpatient clinics was underway at the time of the review visit.

- Operating lists: Members of the team working alongside or supporting the surgeons in theatre described not knowing which of the three surgeons is operating until the day of surgery. Numerous attempts have been made to pin down the three surgeons to a specific operating list. Some oral accounts suggested that patients receive little notice of their operation date, as the surgeons decide at their Wednesday meeting who to operate on the following Monday. Others said it is known which patients are on the list two weeks in advance. However, difficulties scheduling surgery were also reported amidst accounts that it was not unusual for operations to be cancelled. Two of the three surgeons have been operating jointly since the cluster of deaths. It should be noted that some of the theatre staff were very positive about the care patients receive in theatres. No concerns were raised about the practice of the fourth surgeon in theatres.

- Intensive care unit (ICU): One of the minimally invasive surgeons would attend the ICU daily but evidence from the case note review found that most daily input was from the Associate Specialist surgeon working on the oesophago-gastric unit (this individual has since left the department). It is possible that one of the consultants was seeing patients daily but this is not recorded in the notes. There were mixed accounts of how accessible the surgeons are when their input is needed on ITU because of complications.

- The wards: The reviewers heard that there is no fixed ward round at Maidstone. At least one ward round will be conducted daily, but ward staff are unclear which of the three surgeons will conduct the ward round, or when. Ward rounds by the three surgeons are not considered to be consultant led, raising issues for trainee learning as well as patient care. Uncertainty over where the three surgeons are at any one time was a recurring theme. One interviewee talked about a 'return to old ways of working in the past' citing reports that one surgeon would often arrive late to the ward, leave early and only see some patients. The three surgeons were described as 'not easy' to get hold of, and not often visible on the wards. Locum staff and senior trainees were described as the constant presence on the ward and kept the service going – although communication issues with locums, resulting in poor handovers and delays in management plans, was also reported to be an issue. The working

pattern for the fourth surgeon was considered to be more predictable and transparent, and his presence on the wards at Maidstone was consistent.

Joint patient care

The three surgeons have decided on a very unusual way of managing individual patients. This might involve one of them seeing a patient to tell them the diagnosis, another surgeon consenting the patient for surgery, a different surgeon actually doing the surgery and the postoperative care provided by someone else. The result was that no-one was clear about who was ultimately in charge of a patient's care. Although the reviewers were not able to interview any patients, there was concern that patients would not feel any sense of continuity of their surgical care with this model of joint working.

A number of interviewees observed that by working interchangeably to provide services to patients, the three surgeons do not provide continuity of patient care. Some interviewees reported that patients will often request to see a particular consultant at clinics, but staff have no idea whether that consultant will be attending the clinic. Interviewees reported that patients like to see people they 'know and trust' all the way through the process. Confusion over who has responsibility for patients was evident and interviewees highlighted a lack of 'ownership' of patients and the patient pathway. Some interviewees said the service felt disjointed and one said: 'it feels less and less of a consultant service'.

Interviewees articulated the particular importance of continuity of care for patients with cancer. One said: 'You need to see the same face when you are dealing with long term care for cancer. That's how I'd like to be treated.' Some interviewees advise friends and family, or private patients, to go elsewhere for oesophageal surgery as they are not confident they will receive the quality of care that they should be able to expect.

One of the three surgeons conceded in interview that there was no continuity of care, but he considered this to reflect practice across the NHS. However, he added that if he was redesigning the system he would have consultants following patients through the pathway to facilitate continuity of care. Another of the three surgeons explained that their working arrangements enable patients to be seen and operated on in time, and that they always receive consultant input. He added that there was continuity of care by the consultant team, and that their arrangements allowed them to standardise and provide for equality of care.

However, the evidence was that their joint working arrangements did not provide for standardised care and in fact undermined the quality of patient care. The three surgeons said that they provide cross cover for each other's patients, but this was not borne out in practice when colleagues approached them with queries about a patient. Reports that the three surgeons sometimes contradicted each other with requests, creating confusion for colleagues and patients, was further evidence that their joint approach does not provide

for better standardised care.

Further evidence that raised questions about the patient focus of the surgeons came from reports that one of the surgeons performs surgery under live televised links beamed to trainees in other locations. Interviewees had mixed views about these 'live links': some said they made them feel under pressure in theatre, while others were content that they did not impact on patient care. One live broadcast required theatre staff to attend the theatre at 5am, which some interviewees considered compromised the team.

(iv) Consent

The reviewers received evidence that the three upper gastro-intestinal surgeons have not been consenting patients properly.

The four surgeons receive referrals according to geographical patch. The three surgeons who work as a unit explained how they cover the pool of patients referred to them. Patients are told that they will be operated on by one of the three. The bias of these three surgeons has been to undertake oesophago-gastrectomomy using minimally invasive surgical techniques (although one has more recently ceased taking this approach due to complications).

The reviewers heard that all patients referred to the three surgeons are not routinely presented with the option of laparoscopic or open surgery, or given an appraisal of the risks and benefits of each approach, which would enable them to make an informed choice. At the MDM, the three surgeons will discuss treating the patient using minimally invasive surgical techniques. The evidence was that these surgeons will agree with the patient to start the operation with minimally invasive techniques and only proceed to open surgery if necessary. The fourth surgeon, who undertakes open surgery, reported that he never receives referrals from his surgical colleagues of patients wanting to have open surgery.

Oral accounts were that patients of the three surgeons are usually consented on the day of surgery. One surgeon reported that he takes consent, but another said that most patients were consented by associate specialists. The reviewers heard accounts that trainees would sometimes take consent.

(v) Multidisciplinary Team Meeting (MDM)

A recurring theme from interviewees was poor attendance by the upper gastro-intestinal surgeons at the MDM, including by the MDM Chair. There were reports that rarely more than one of the four surgeons attends, even though the meeting is meant to be led by the surgical team and chaired by the lead upper gastro-intestinal surgeon. The surgeon who operates outside the unit of three was reported to attend the MDM most frequently and to stay for the whole meeting. Attendance by the others was described as sporadic and even when they attended, interviewees reported that they will stay for only about an hour.

Other MDM attendees described frustration at this and observed that treatment plans for patients were discussed without their surgeon being present. The patient caseload is structured on a geographical basis, with Dartford patients discussed last, when attendees are reduced in number and fatigued. Insufficient focus on the patient was highlighted as an issue.

'Significant concerns' regarding the attendance record of the upper gastrointestinal consultants at the upper gastro-intestinal MDM were raised formally by the radiological department in August 2013. These concerns were also highlighted in the minutes of the Diagnostic Radiology Audit and Clinical Governance meeting held in June 2013, which reported that attendance by the upper gastro-intestinal surgeons 'is consistently poor and is affecting the quality of the MDM therefore placing patients management at risk. Large numbers of patients have been discussed in the absence of the managing surgeon. Patients are therefore repeatedly discussed week on week'. The minutes continue that the gastro-intestinal surgeon who chairs the MDM 'rarely attends the meeting himself' and reports that in the preceding weeks 'a single MTW [Maidstone and Tunbridge Wells] surgeon was present for only half an hour on two occasions.' It was even suggested that radiological support for the upper gastro-intestinal MDM should be withdrawn until the issue with surgical attendance was resolved.

Other MDM attendees try to work around what are clearly perceived as shortfalls in the surgical input to these meetings. One member of the anaesthetics team said: 'As anaesthetists we try very hard to patch up the difficulties'. The oncology team was also perceived as being 'strong' and pulling the meeting along.

Confrontations between the upper gastro-intestinal surgeons caused other attendees to feel uncomfortable at the meetings. A lack of visible chairing was reported to be an issue.

Interviewees observed that other cancer specialists take 'full ownership' of their patients from discussing them at MDM meetings and along the patient pathway. One interviewee said: 'these three don't take responsibility in the same way….they just do not know their patients'. The three surgeons were perceived as being hampered from inputting into

MDM discussion by uncertainty over which of them will perform the operation.

In interview, the three surgeons reported that they regularly attend the MDM. One said that any perceived dysfunction in their interactions with each other reflected that they were trying 'to do our best for patients'. The surgeons also reported that they attend two local MDMs (at Dartford and Gravesend) in addition to the Maidstone MDM. It was not evident to the reviewers which patients are discussed at the local MDMs and which at the main one.

The reviewers observed that the MDM printed outcomes were poorly structured, making it difficult to pinpoint the patients pre-treatment stage and management plan. It was impossible from the MDM outcomes to see which clinician was in charge of the patient's care or to identify their keyworker.

The reviewers heard that there is a process for verifying all positive histologies to ensure that these are discussed at MDMs. This was described as a 'backup process' to the clinical process, where clinicians and histopathologists add patients to the MDM as required. The Cancer Data Manager outlined what appears to be a robust process for recording and extracting treatments from the database and validating that patients are appropriately discussed in the MDM.

(vi) Clinical governance

Interviewees generally considered clinical governance arrangements within the trust to be robust. Staff surveys were reported by senior management to reflect a culture of openness. However, documentary evidence showed almost two months had lapsed before one serious incident requiring investigation (SIRI) was declared (incident 2010/14339). The evidence also showed a death from pulmonary embolism in a patient who had an oesophago-gastrectomomy for cancer (ref:Web17663 ID:61184). Trust staff had considered that there was 'no learning to be gained' from raising this death as a serious incident. One of the allegations made in May 2011 as part of the anonymous complaint to the General Medical Council was that the upper gastro-intestinal service had a high complication rate that was not reported at local clinical governance meetings.

Specialty-specific mortality and morbidity (M&M) meetings

The upper gastro-intestinal surgeons had conducted a number of specialty-specific M&M meetings between 2011 and 2012. These meetings provided for internal scrutiny of upper gastro-intestinal outcomes. However, no minutes were shared with clinical managers (or the review team), only four meetings had been held and they had been discontinued since June 2012. Only one upper gastro-intestinal surgeon had attended the March 2012 meeting and no upper gastro-intestinal surgeons had been present at the June 2012 meeting.

One interviewee described discussion of cases at these meetings as being 'at a rudimental level'. Another said that there had not been complete 'buy-in' to the meeting due to a perception that it was 'a boxing ring' between the surgeons.

General surgery M&M meetings

The only other mechanism that exists for the gastro-intestinal surgeons to discuss complications as a team is the monthly general surgery M&M meeting. However, some interviewees expressed concern that a full agenda of general surgery cases means that 'learning experiences' for upper gastro-intestinal surgery are not explored sufficiently at this meeting.

Complaints

An overview of themes arising from upper gastro-intestinal surgery complaints received during August 2011 to August 2013 highlighted some concerns about communication, waiting for treatment, postoperative complications and uncertainty over diagnosis.

Audits

The Clinical Nurse Specialist (CNS) team undertake a range of annual audits, including of GP communication, patients receiving copy letters, and patient satisfaction. An audit of the nurse led postoperative clinics for 2012 and 2013 was being processed at the time of the Invited Review. The review team observed that these audits were well conducted but may have given false reassurance to all concerned that everything was functioning appropriately and safely.

(vii) Clinical leadership

There has been a change in clinical leadership within the upper gastro-intestinal surgeons. Unfortunately, the lead surgeon has been absent from the trust for an extended period during the last year.

Senior clinical managers made reference to long-standing 'noise' in the system about the upper gastrointestinal consultant surgeons. The reviewers also saw numerous emails and letters to clinical managers raising concerns. Mostly the correspondence highlights concerns about the upper gastrointestinal surgeons as a group, however specific and serious concerns have been raised about one individual surgeon. Verbal accounts supported the concerns about this particular surgeon, but also frequently cited difficulties working with a second surgeon as well.

The documentary evidence showed whistleblowing by staff from different disciplines. The evidence shows that some staff have felt obliged to speak out in the interests of patient safety. This invited review was initiated to inform management whether there is a basis for concern regarding mortality and complications of oesophageal and gastric cancer resections. The managerial response to other concerns relating to the surgeons, either as

a group or as individuals, was not evident. The clinical manager who looked into the allegations made to the General Medical Council described the letter as 'inaccurate and malicious'. Yet interviewees supported some aspects of the allegations – for example, in terms of a lack of ward presence. This led the reviewers to question the robustness of the management response to whistleblowers' concerns.

In interview some staff described feeling intimidated about raising concerns, even suggesting that the team of upper gastro-intestinal surgeons enjoy a special status within the trust. One interviewee described the three surgeons as 'untouchable'. A lack of consistency by clinical managers in responding to concerns was reported to be an issue.

At the end of 2011, one of the gastro-intestinal surgeons wrote to the trust Medical Director noting 'an ongoing resistance and malicious campaign against us from various directions over the last few years and currently this is being conducted with unparalleled ferocity which makes us all concerned.' This letter referred to the anonymous allegations made to the General Medical Council, as well as to a local MP and the media. This surgeon said that the service had embedded itself well and become 'a well-known centre running a high standard practice at national level'. He reported that 2011 had been 'an excellent year' with no mortality from oesophago-gastric cancer patients and very low morbidity.

The appraisal forms for some of the upper gastrointestinal surgeons allude to difficulties experienced as a result of service reconfiguration and split site working. One of the surgeons described the latter part of 2012 as very stressful 'with major leadership and managerial challenges' and 'a lot of outside scrutiny' of the upper gastro-intestinal team.

8. Conclusions

Basis on which conclusions are reached

The following conclusions are reached on the basis of the documentation reviewed (as set out in section 6 above) and the interviews held with staff at Maidstone and Tunbridge Wells NHS Trust (as described in section 5 above).

Overall conclusions about the surgical service under review

Surgical outcomes

The reviewers have serious concerns about the clinical quality of the oesophageal and gastric cancer resection service. The review team had understood that the risks to patient safety had been mitigated by the suspension of the service. However, it has become evident from correspondence with the trust since the visit that oesophagectomy only has been suspended and that gastric cancer surgery has continued. Given that many tumours occur at the oesophageal-gastric junction, there is little sense in suspending only oesophagectomy. Moreover, the terms of reference for this review were to consider concerns relating to outcomes for resection of oesophageal *and* gastric cancer. The reviewers therefore considered the service in the round and have identified concerns that apply to the whole service, not only to oesophagectomy.

The reviewers conclude that patient safety concerns exist for the following reasons:

1. A high complication rate associated with the laparoscopic techniques that have been used;
2. Poor management of complications that have arisen;
3. Some deaths have occurred as a result of unusual complications, probably associated with the minimally invasive surgical techniques that have been used;
4. Poor insight by the minimally invasive consultants into deficiencies in the service they have provided;
5. Dysfunctional working relationships between the three minimally invasive surgeons and the fourth surgeon;
6. Inadequate consent process by the minimally invasive surgeons prior to oesophago-gastrectomy;
7. Ineffective MDM working due to poor attendance by the minimally invasive surgeons (particularly by the Chair of this MDM), reports of unproductive discussions between the surgeons at the MDM, and a number of questionable decisions to proceed with radical surgery in the presence of advanced and incurable cancer.

The reviewers conclude that a number of patients with pre-treatment staging of advanced disease (T3N2-3), with significant co-morbidities, were put down a radical curative pathway when a palliative pathway would have been more appropriate. Some of these patients had poor outcomes, such as early recurrence of cancer, within 3-6 months of having chemotherapy and surgery. This is a marker of poor patient selection and/or poor treatment – one year survival is accepted to be a good indicator of the quality of a service, and most

teams would expect 70-80% of their patients who had radical therapy to be alive at one year.

Based on the case notes, the reviewers identified a high complication rate associated with the laparoscopic techniques that have been used. A common complication was anastomotic leakage, which resulted in long intensive care and total hospital stays. The National Oesophago-gastric Cancer Audit 2013, shows that an anastomotic leak increases the median length of stay from about 14 days to 30 days and increases the in-hospital mortality five times. The risk of needing further surgery after a leak is 10 times higher.

The management of anastomotic leaks was substandard and often involved the inappropriate use of oesophageal stents. Principles of drainage of sepsis and establishment of cutaneous fistula were not in evidence. Stents rarely control anastomotic leaks, have a very limited role in their management and are potentially dangerous due to erosion of the stent into the airway and into major vascular structures.

The reviewers also observed that functional problems, relating to vomiting and poor eating, were commoner than would be expected after oesophago-gastrectomy. This may have been due to the way the surgeons made the gastric conduit, formation of the oesophago-gastric anastomosis too low in the chest, not performing a pyloroplasty, or a combination of all three factors. Consequently, many patients have undergone multiple endoscopies and pyloric dilatations after surgery, suggesting that they have experienced gastric conduit dysfunction which is usually avoidable if preventative measures are taken.

Open surgery, which was mostly performed by the surgeon who operated outside the group of three, appeared to be less likely to result in serious life threatening complications compared with the laparoscopic surgery performed by the other three surgeons. Furthermore, the complications seen after laparoscopic surgery tended to be unusual and severe. For example, necrotic transverse colon after distal gastrectomy, liver injury causing fatal haemorrhage after thoracoscopy and early tumour recurrence in thoracotomy or port site wounds. Other unusual complications were Aorto enteric/tracheal fistulae, Colonic ischaemia and a high anastomotic/partial gastric dehiscence rate.

The reviewers conclude that the management of complications was sometimes poor, and on occasion haphazard and even illogical. Discussion about complications was often not evident in the patient's notes.

The case note review found that much of the day to day postoperative care for patients having minimally invasive oesophago-gastric surgery was provided by an Associate Specialist. This individual provided a high level of care and continuity. However, there was little evidence of a regular involvement by the three minimally invasive consultant surgeons. The Associate Specialist doctor has since left the department, leaving a gap in the postoperative care provided to patients of these three surgeons.

Patient centred care

There is ample evidence to support a conclusion that the working practices of the three upper gastro-intestinal surgeons do not provide for a patient-centred, consultant delivered service, and are not in the interests of patients in several respects. To the contrary, the working arrangements appear to exist to support the surgeons, by accommodating opaque job plans on multiple sites.

The consequence of this is a lack of personal responsibility for patient care by the three surgeons, and a lack of responsibility for their professional practice. This has an impact for the fourth surgeon, who from all accounts demonstrates a much more patient-centric approach. By excluding and isolating this fourth surgeon from the team, his patients risk a lack of cover in his absence. This creates issues about the long-term sustainability for services provided by an isolated surgeon.

The reviewers agree with the observations by a number of staff that, by working interchangeably to provide services to patients, the three surgeons do not provide continuity of patient care. These working arrangements can create inconsistency in requests to staff and confusion for patients. This can only add to the anxiety patients feel when undergoing major surgery for life-threatening conditions. Continuity of care is particularly important for patients with cancer, and a lack of such continuity is undoubtedly to the detriment of patient experience.

The reviewers are concerned that patients are not being provided with sufficient information to enable them to provide informed consent for oesophageal surgery. There is evidence that patients living in geographical locations that see them referred to one of the three surgeons with a laparoscopic bias have not been given a full appraisal of the pros and cons of open surgery. This is particularly concerning in the light of the conclusions reached about complications associated with laparoscopic surgical techniques.

Other concerns about consent include about the timing, with patients consented on the day of surgery. This reflects the particular working practices of the three surgeons and the late decision-making over who will conduct surgery on a given list. It is not in the interests of patients, who are likely to feel anxious on the day of surgery and may feel under pressure to give their consent. Further investigation needs to be undertaken by the trust to establish who is taking consent.

Consent for complex surgery such as oesophago-gastrectomomy should be done by the consultant surgeon proposing this treatment and be obtained well before the day of surgery. Written information about the risks and benefits should preferably be provided to the patient and their relatives early in the clinical work-up so that they have had an opportunity to consider the issues and ask questions at the time of consent.

Leadership

Concerns about the upper gastrointestinal service have persisted for some time. A number of staff have bravely and openly escalated their concerns to management. Others have felt it necessary to raise issues anonymously. Some staff have clearly felt intimidated about raising concerns, even suggesting that the team of upper gastro-intestinal surgeons enjoy a special status within the trust.

The reviewers conclude that senior management has not demonstrated sufficient responsiveness to the breadth of concerns raised of staff. It has understandably found it difficult to establish whether there has been a case to answer regarding concerns about mortality and complications; this invited review seeks to assist in this respect. However, other concerns about the working practices, and sometimes behaviour, of three of the upper gastro-intestinal surgeons, appear to have been brushed aside too readily. This has created a perception that the upper gastro-intestinal surgeons have a privileged position within the trust.

There is a case to answer regarding dysfunctional team working, a lack of accountability for working practices and attendance at fixed sessions – including endoscopy, clinics and the MDM – and it is for managers to ensure that the three surgeons are accountable in these and other areas. Job plans should make clear the commitments that each surgeon is individually accountable for.

Clinical leadership within the upper gastro-intestinal surgeons has been subject to change and has suffered from unavoidable staff absence. Nevertheless, evidence of split team working, disparate working practices, and failing team functionality, suggest that leadership within the department has been extremely weak. The paucity of surgical leadership at the MDM meetings is a concern for the overall effectiveness of the MDM.

The upper gastro-intestinal surgeons and anaesthetists

The reviewers did not find evidence that working relationships between the upper gastro-intestinal surgeons and the anaesthetic team were impacting negatively on patient care. However, this is primarily because the anaesthetists, particularly the intensivists, demonstrate a strong patient-focused approach. Difficulties in the past between particular individuals appear to have receded. Reservations about some of the upper gastro-intestinal surgeons persist for some staff, but not others who describe the surgeons more favourably.

9. Recommendations

The following recommendations are for Maidstone and Tunbridge Wells NHS Trust to consider.

Prioritised patient safety actions for the Trust

1. **The oesophageal *and* gastric cancer resection service should be suspended until the other recommendations made below have been addressed**, and significant improvements have been demonstrated to the working practices, team working and insight of the three upper gastro-intestinal surgeons who have been working as a distinct unit.

2. **Oesophageal *and* gastric cancer resections performed using laparoscopic techniques should be suspended indefinitely**, as the upper gastro-intestinal surgeons in post have not been able to demonstrate sufficient attention to the detail of surgical outcomes or clinical decision-making to provide a safe service to patients.

Consideration should be given to the implications of these recommendations for upper gastro-intestinal surgery for benign conditions and particularly using laparoscopic surgical techniques.

3. **The structure of MDM printed outcome forms should be reviewed** to make clear the patient's pre-treatment stage, management plan, keyworker and the clinician in charge.

4. **Improved surgical attendance at MDMs should be mandated**. The gastro-intestinal surgeons should be present for at least 75% of MDM meetings, as per peer review requirements, and when they attend they should be there for the whole meeting.

5. **The clinical decision-making of the upper gastro-intestinal surgeons must be improved**, with particular attention given to the appropriate pathway for patients with pre-treatment staging of advanced disease and with significant co-morbidities, and to the appropriate treatment response to postoperative complications.

6. **The management of postoperative upper gastro-intestinal complications requires attention**. In particular:

a) The upper gastro-intestinal surgeons should make contemporaneous entries into a patient's records documenting any discussions about complications and their management;
b) It should be clear to all staff within the multidisciplinary team which surgeon has

responsibility for a patient and is overseeing their ongoing care;

c) The three upper gastro-intestinal surgeons who have operated as a distinct unit need to individually increase their presence on the intensive care unit and on the wards; and
d) The job plans of the upper gastro-intestinal surgeons should be organised in such a way that other staff within the multidisciplinary team know where the surgeons are should they need their advice about the management of postoperative complications.

7. **Monitoring of postoperative complications must be strengthened and systematised**. Complications associated with the upper gastro-intestinal surgeons should be recorded and collated by an independent person suitably experienced in this type of surgery and monitored in real-time, with external scrutiny by a consultant from another trust who is completely impartial. The impact on patients of any postoperative complications should be discussed as part of a more patient-centred approach to upper gastro-intestinal surgery, and this may be a role for the Clinical Nurse Specialists to lead.

8. **Arrangements for consenting patients must be reviewed.** All patients must be provided with adequate written and verbal information and consent obtained by the consultant intending to operate, well in advance of the proposed day of surgery. This should be documented clearly in the patient's records.

9. **The working practices of the consultant surgeons should be reorganised to provide for continuity of patient care in a consultant-delivered service**. Annual appraisal should include discussion about how the surgeons demonstrate their commitment to patients.

10. **Live links of upper gastro-intestinal surgery should not be conducted outside of standard operating times**.

11. **Consultant surgeons should attend fixed sessions in person and not delegate these responsibilities to others**.

12. **Chairing of the upper gastro-intestinal multidisciplinary meeting should be given to the consultant oncologists**. A review of the caseload discussed at these meetings should be undertaken with a view to making the meetings shorter and more tightly focused. The upper gastro-intestinal surgeons should be freed of other commitments (with the exceptions of on-call) and held to account for their attendance for the duration of the meeting.

13. **There should be a separate MDM for HPB cancer patients**. This is a requirement if the hospital is to run an Oesophago-gastrectomy Cancer Centre. If, however, this ambition is not realised then a generic upper gastro-intestinal MDM is acceptable.

Given the breadth and seriousness of these recommendations, the trust is advised to share this report with the Care Quality Commission and to involve commissioners in discussions about the future provision of this service.

The trust should also discuss the contents of this invited review report with its GMC Employment Liaison Adviser and with NCAS, to seek advice on the ongoing management of the individual surgeons named here and to ensure that patient safety is preserved.

Responsibilities of the Trust in relation to the recommendations of this report.
This report has been prepared by The Royal College of Surgeons of England and the Association of Surgeons of Great Britain under the IRM for submission to the Maidstone and Tunbridge Wells NHS Trust. It is an advisory document and it is for the Trust concerned to consider any conclusions and recommendations reached and to determine subsequent action. It is also the responsibility of the Trust to review the content of this report and in the light of these contents take any action to protect patient safety that is considers appropriate.
Further contact from the Royal College of Surgeons following final report.
Where recommendations are made that relate to patient safety issues, the Royal College of Surgeons will follow up this report with the Trust to ask them to confirm that the Trust has addressed these recommendations. The College's Lead Reviewer may be available to support this process. Where the College is not satisfied that these recommendations have been addressed within a reasonable period of time following the issue of the final report, the College, the Association and/or the Reviewers reserve to themselves the right to disclose in the public interest but still in confidence to a regulatory body such as the General Medical Council, the National Patient Safety Agency or the Care Quality Commission or any other appropriate recipient, the results of any investigation and/or of any advice or recommendation made by the College, the Association and/or the Reviewers to the Hospital. The College will also contact the Trust to carry out an evaluation of its services following the issue of the final report.

10. Signature of Reviewers

[redacted] FRCS DATE: 9th December 2013

[redacted] FRCS DATE: 9th December 2013

[redacted] DATE: 9th December 2013

11. Appendices to the Report

[redacted]

[redacted]

[redacted]

RCS
ADVANCING SURGICAL STANDARDS

11.2 Appendix 2 - Review of patient notes

Scope of the case note review

In total, 83 patients' records were assessed by the two Clinical Reviewers. This included the notes of the six patients who died postoperatively in 2012 and 2013, referred to in the Terms of Reference for this review, and 77 patients chosen at random from the records provided by the Trust.

Reviewer One

38 randomly selected case notes examined of patients having oesophageal or gastric resections for cancer from 2006 – 2013

Of the 38 case notes reviewed, 27 patients had an oesophagectomy (24 had minimally invasive surgery) and 11 had a gastrectomy (eight minimally invasive).

Deaths

Nine postoperative deaths (9/38 = 23% 30 day/in-hospital) were identified; six after oesophagectomy and three after gastrectomy.

Cause of death was anastomotic leak/conduit necrosis (3), Bleeding (3), ARDS (1), MI (1) & MOF (1).

Two of the patients who died were clearly high risk for surgery due to respiratory disease and cirrhosis but the remaining seven patients were not high risk.

Unexpected complications

One of the eight patients undergoing a laparoscopic gastrectomy developed an ischaemic colon due to an injury to the colonic blood supply. This resulted in the patient returning to theatre and having a right hemi-colectomy. This is an unusual complication.

Two patients undergoing a minimally invasive oesophagectomy developed loco-regional recurrence of their tumour within three months of surgery and died of their recurrent disease. Both had advanced disease (T3N3) on pathology and the notes suggest that there was enough pre-operative evidence to have predicted this before submitting them to radical surgery. A palliative care plan would have been more appropriate.

One patient (included in the nine postoperative deaths) developed an early anastomotic leak after a minimally invasive oesophagectomy and then died from bleeding secondary to an aorto-enteric fistula.

Reviewer Two

45 randomly selected case notes examined of patients having oesophageal or gastric resections for cancer from 2006 – 2013

Of the 45 case notes reviewed, 28 patients had an oesophagectomy (18 had minimally invasive surgery) and 16 had a gastrectomy (six were performed minimally invasively). One further patient had surgery for benign pathology.

Deaths

Eight postoperative deaths (8/45 = 18% 30 day/in-hospital) were reviewed from 2006-2013; four after oesophagectomy and four after gastrectomy.

Cause of death was anastomotic leak or conduit dehiscence in three (including one with colonic infarction), Aorto-enteric fistula in two, small bowel perforation in one, Cardiac in one and Pulmonary Embolism in another.

Unexpected complications

Two patients developed aorto-enteric fistulae, which is a very unusual complication. One of the anastomotic leak patients suffered ischaemic bowel after division of the Middle Colic artery intraoperatively; again a very rare complication after oesophago-gastric resection.

Of the 18 minimally invasive oesophagectomies, seven (39%) had major open surgery (thoracotomy/laparotomy or both) to deal with postoperative complications.