# The National Emergency Laparotomy Audit: Impact for General Surgical Training and Service Provision.

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**Declaration**

I hereby declare that the work presented in this thesis is my own and has been completed at the Division of Medical Sciences and Graduate Entry medicine, School of Medicine, University of Nottingham.

Hannah Boyd-Carson January 2020

**Thesis Abstract**

Emergency Laparotomies (Em Lap) are one of the most commonly performed emergency general surgical procedures worldwide. They are invasive abdominal operations performed to treat conditions such as intestinal obstruction or perforation. Mortality rates are high compared to planned general surgical procedures and the post-operative sequelae may represent significant burdens to patients, families, and healthcare systems.

Prior to 2012, repeated observations were made regarding the deficiencies and variability of care received by the patients who required an Em Lap. Following this The National Emergency Laparotomy Audit (NELA) began in 2013. This collects detailed data about patients who have Em Lap and the care they receive within England and Wales, and hopes to improve outcomes for these patients.

The aim of this thesis was to use data from NELA to address issues specifically relating to general surgical service provision and training.

The first study (Chapter 3) explored the relationship between time to theatre and mortality in patients with intra-abdominal sepsis. The NELA annual reports have highlighted that the identification and management of patients with intra-abdominal sepsis is lacking. Patients with perforated peptic ulcer disease were used to model time to theatre as a continuous variable and investigate if a longer time to theatre led to increased mortality. Multivariate regression analysis demonstrated a cumulative increased risk of death by 90 days of 4% (Odds ratio (OR) 1.04, 95% Confidence Interval (CI) 1.02-1.07)

which increased to 6% (OR 1.06, 95% Cl 1.01-1.11) in patients with physiological derangements.

The second study (Chapter 4) addressed the impact of consultant surgeon elective special interest on post-operative outcomes. Procedures performed at Em Lap can be due to pathology from either end of the gastrointestinal tract and can be managed by general surgeons with an elective special interest at odds to the pathology.

This study found an increased post-operative mortality if Em Lap was performed by consultant surgeon with a special interest not in the area of pathology (Colorectal procedures OR 1.23, 95% CI 1.13-1.33 and Upper Gastrointestinal procedures OR 1.02, 95% Cl 1.05-1.20). Return to theatre was increased in the colorectal operative group.

The next two studies (Chapter 5 and 6) focused on training opportunities for general surgical trainees who are required to gain experience in Em Lap operating by recording at least 100 Em Laps in their training log books. Trainees complete their training in one geographical area (deanery) and Chapter 5 analysed, by deanery, the numbers of Em Laps and core emergency procedures occurring that are required for completion of training. This identified inter deanery variation in numbers of Em Lap. This raises questions relating to the number of training opportunities for trainees working in these areas.

The final chapter aimed to describe trends in trainee led operating by deanery, hospital size and time of day. The association between trainee led operating and mortality was also investigated. The analysis demonstrated trainees were

most likely to operate independently in the Health Education Yorkshire and Humber deanery, in high volume centres and at night. No increased risk of death was observed if a trainee was the most senior surgeon in theatre across all Em Lap and emergency procedural groups ($P <= 0.001$).

This thesis has provided data to inform and improve health care policy for patients who require high risk emergency surgery. It has also provided data to help shape, improve and inform the future generation of general surgeons.

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## III List of abbreviations

| | |
|---|---|
| ACPGBI | Association of Coloproctologists of Great Britain and Ireland |
| ARCP | Annual Review of Competence Progression |
| ASA | American Society of Anaesthesiology |
| ASGBI | Association of Surgeons of Great Britain and Ireland |
| AUGIS | Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland |
| CEU | Clinical Effectiveness Unit |
| CI | Confidence Interval |
| CSV | Comma Separated Values |
| CT | Computerised Tomography |
| ECG | Electro Cardio Gram |
| EGS | Emergency General Surgery |
| Em Lap | Emergency Laparotomy |
| ERAS | Enhanced Recovery after Surgery |
| GCS | Glasgow Coma Scale |
| GIT | Gastrointestinal tract |
| GMC | General Medical Council |
| HEE | Health Education England |
| HES | Hospital Episode Statistics |
| HPB | Hepato-pancreato-biliary |
| HR | Heart rate |
| HSRC | Health Services Research Centre |

| | |
|---|---|
| HST | Higher Surgical Training |
| ICD-10 | International Classification of Disease (Version 10) |
| IP | Index Procedures |
| IQR | Interquartile range |
| IRR | Incident rate ratio |
| ISCP | Intercollegiate Surgical Curriculum Programme |
| JCST | Joint Committee on Surgical Training |
| LGI | Lower gastrointestinal |
| LOS | Length of stay |
| NCEPOD | National Confidential Enquiry into Patient Outcome and Death |
| NELA | National Emergency Laparotomy Audit |
| NHS | National Health Service |
| OG | Oesphago-gastric |
| ONS | Office for National Statistics |
| OPCS | Operating Procedure Code Supplement |
| OR | Odds ratio |
| PUD | Peptic Ulcer Disease |
| RAG | Red, Amber, Green ratings |
| RCoA | Royal College of Anaesthetists |
| RCS(Eng) | Royal College of Surgeons of England |
| RCT | Randomised Control Trial |
| SAC | Speciality Advisory Committees |
| SBP | Systolic Blood Pressure |
| ST | Speciality Training |

| | |
|---|---|
| UGI | Upper gastrointestinal |
| UK | United Kingdom |

## IV. Publications and presentations

Papers

**Association between surgeon special interest and mortality after emergency laparotomy.**

**Boyd-Carson H**, Doleman B, Herrod PJJ, Anderson ID, Williams JP, Lund JN, Tierney GM; NELA Collaboration.

Br J Surg. 2019 Jun;106(7):940-948. doi: 10.1002/bjs.11146. Epub 2019 Apr 25.

**Delay in source control in perforated peptic ulcer leads to 6% increased risk of death per hour: A nationwide cohort study.**

**Boyd-Carson H,** Doleman B, Cromwell D, Lockwood S, Williams JP, Tierney GM, Lund JN, Anderson ID.

World J Surg. 2019 Oct doi: 10.1007/s00268-019-05254-x. [Epub ahead of print]

**A Review of Surgical and Peri-Operative Factors to consider in Emergency Laparotomy care**

**Boyd-Carson H**, Gana T, Lockwood S, Murray D, Tierney GM

Anaesthesia 2020, 75: e75-e82. doi:10.1111/anae.14821 [Epub ahead of print]

**Trainee-led emergency laparotomy operating.**

**Boyd-Carson H**, Doleman B, Lockwood S, Williams JP, Tierney GM, Lund JN; National Emergency Laparotomy Audit Collaboration.

Br J Surg. 2020 Apr 26. doi: 10.1002/bjs.11611. Online ahead of print.PMID: 32335905

Reports

**The National Emergency Laparotomy Audit Project Team. (2018) The Fourth report of the National Emergency Laparotomy Audit** (https://www.nela.org.uk/downloads/The%20Fourth%20Patient%20Report%20of%20the%20National%20Emergency%20Laparotomy%20Audit%202018%20-%20Full%20Patient%20Report.pdf)

**The National Emergency Laparotomy Audit Project Team. (2019) The Fifth report of the National Emergency Laparotomy Audit** (https://www.nela.org.uk/downloads/The%20Fifth%20Patient%20Report%20of%20the%20NELA%202019%20-%20Full%20Patient%20Report.pdf)

Conference Presentations

*Platform Presentations*

**Association between surgeon special interest and mortality after emergency laparotomy.**

In the Moynihan Session, Association of Surgeons for Great Britain and Ireland International Congress, Liverpool 2018

**Timing of Surgical Source Control, should we be operating out of hours?** Association of Surgeons of Great Britain and Ireland Emergency Laparotomy Meeting, Birmingham 2018 and Association of Surgeons for Great Britain and Ireland International Congress, Telford 2019

**Can we use NELA to predict Futility?**

Association of Surgeons of Great Britain and Ireland Emergency Laparotomy Meeting, Birmingham 2018

**The National Emergency Laparotomy Audit Update: Elderly Focus.**

Age Anaesthesia Association Annual Scientific Meeting, Nottinghamshire 2019

*Poster Presentations*

**Emergency laparotomy in the elderly; age does have impact on outcomes?**

Association of Surgeons for Great Britain and Ireland International Congress, Telford 2019

# 1. Introduction

## 1.1 Chapter Focus

This chapter provides a background to the themes within this thesis. It describes what is involved in a laparotomy, what the indications are and when it is performed. The background and previous history of emergency general surgery in the United Kingdom is introduced.

The National Emergency Laparotomy Audit is defined; who runs it, my role, and its aims. The Audit has been running for 5 years, and the work and findings of the Audit to date will be described.

The process of general surgical training in the United Kingdom including the emergency surgery components and the requirements for certification of completion of training are outlined in this chapter.

Observational research and clinical databases are widely used within healthcare research. These terms and current uses, benefits and also some of the limitations encountered, when using observational data, are set out in this section. Additionally, outlines and explanations surrounding the concept of bias and confounding are presented alongside potential methods for minimising this when working with observational data. The statistical methods used throughout this thesis are introduced and described.

## 1.2 What is a Laparotomy?

A laparotomy is a surgical procedure allowing access to the abdominal cavity. Most commonly this refers to a midline abdominal incision through the linea alba and can extend from the umbilicus superiorly to the sternum and inferiorly to pubic symphysis (Novell et al., 2013). The procedure was first described by Ephraim McDowell in 1809 and performed in Kentucky, United States of America (Ellis, 2009). McDowell initially described a paramedian (off midline) abdominal incision following which he performed an oophorectomy. Subsequently, he modified his technique to include an incision through the midline, taking advantage of the avascular nature of the linea alba. He closed the incision with interrupted sutures (Ellis, 2009).

The indication for laparotomy varies widely and can be used in both the elective (planned) and emergency setting. Within the elective setting preoperative diagnosis has often been established through clinical assessment, biochemical and imaging modalities and is most commonly performed for patients with cancer or who require gastrointestinal resections for benign conditions. However, in the emergency setting, indications vary widely. Sometimes patients have an Em Lap without a definitive diagnosis. With the increasing twenty four hour availability of Computerised Tomography (CT) scanning, this scenario is becoming less common (NELA Project Team, 2015a, 2016, 2017).

Acute presentation of abdominal pain combined with signs of systemic pathology often necessitate operative intervention. Underlying pathology is usually within the gastrointestinal tract or pelvic organs. Therefore, the majority

of Em Laps are performed by general surgeons with a small contribution from gynaecologists or urologists.

Approximately 30,000 Em Lap are performed within the United Kingdom (UK) per year (The Association of Surgeons of Great Britain and Ireland, 2007; Shapter et al., 2012), in a particularly heterogeneous patient population. The range of procedures performed after gaining access to the abdominal cavity is also wide and can range from removal of sections of the gastrointestinal tract (GIT), repair of perforations of the GIT, cessation of bleeding from the GIT or pelvic organs, or relief of an obstruction in the GIT. This is not an exhaustive list. Em Lap can also be performed as an exploratory procedure when the patient is very unwell or the diagnosis is unclear.

## 1.3 Emergency Laparotomy care in the United Kingdom prior to 2012.

Emergency abdominal surgery contributes significantly to the general surgical workload; 170,000 patients have high risk, non-cardiac surgery within the UK (Jhanji et al., 2008). High risk surgery is defined as operative intervention that carries a post-operative risk of death greater than 5% (Pearse et al., 2006). In England alone 30,000-50,000 Em Lap are performed each year which equates to an annual incidence of 1:1,000 (Shapter et al., 2012; Symons et al., 2013). International data indicates that morbidity and mortality following this operation far exceed elective surgery or other emergency high risk operations (Pearse et al., 2011, 2006; Ingraham et al., 2010).

Studies in heterogeneous cohorts have reported 30-day mortality following Em Lap between 13-18% (Saunders et al., 2012; Vester-Andersen et al., 2014; Awad et al., 2012; Al-Temimi et al., 2012), while long term, data suggests that more than a quarter of patients die within two years of an Em Lap (Awad et al., 2012).

Short term mortality, by 30 and 90 days post-operatively, is currently the most widely reported outcome after Em Lap. Mortality is unambiguous and easily recorded, making it an appealing measure for outcome evaluation and is the most commonly reported outcome in many other areas of healthcare research (Department of Health and Social Care, 2018). However, the effects of postoperative morbidity extend long beyond the operative period and definitions of longer-term outcomes are poorly defined. Within cardiology and cardiac surgery, the length of mortality follow up has been investigated with differing results. Edwards and Taylor investigated the disparity between 30-day morality

and 365-day mortality rates in patients who had heart valve replacements. They noted that 30-day mortality rates represented only 57% of year one mortality rates and concluded that 1-year post-operative survival may represent a more meaningful extension of life for the patient, rather than simply the chance of leaving hospital alive after their surgery (Edwards et al., 2003). A further study, in cardiac surgery, supported this finding and again reported differing mortality rates at 30 and 120 days post-operatively (Siregar et al., 2013).

Following this a large database study in America analysed 236,125 patients which included both cardiac and general surgical cases. They compared survival rates at 30 days post-operatively to survival at 365 post-operative days. They concluded 30-day mortality estimates are associated with significantly different survival outcomes than at 365 days (Smith et al., 2016).

While this previous literature has been performed in the cardiac population, it may be that the current outcome data underestimates the burden of Em Lap to not only patients, but also other healthcare and social systems (Moonesinghe et al., 2014; Khuri et al., 2005; Head et al., 2008). Work is currently in progress to address the longer-term outcomes following Em Lap (NELA Project Team, 2018b).

As it is common and associated with a high risk of death, emergency abdominal surgery has been a focus for investigation in successive National Confidential Enquiry into Patient Outcome and Death (NCEPOD) reports. The first NCEPOD report was published in 1987 and this initial enquiry immediately

identified deficiencies in the care of patients having emergency surgery within the United Kingdom. Specifically, they suggested that junior surgeons and anaesthetists were lacking support (Buck et al., 1987). Subsequent NCEPOD reports published in 1991, 1992, 1993, 1994, 1995 continued to raise concerns not only about junior doctors managing acutely unwell patients but also regarding a lack of intensive and critical care facilities (Campling et al., 1989; Campling E A, Devlin H B, Hoile R W, 1992; Lunn et al., 1994; Gallimore et al., 1995; Campling et al., 1997). It was not until 2001 that there was formal, national recognition that the patient cohort having emergency surgery was getting "sicker and older." The focus of the NCEPOD reports shifted from criticism of specific surgical and anaesthetic teams to improvement of resources and provision and management of surgical services (Burke et al., 2000). The subsequent report in 2003 demonstrated some improvement in care for emergency patients but there was evidence that "out of hours" care was suboptimal (Cullinane et al., 2003). Deficiencies in care remained with junior doctors acting unsupervised outside of normal working hours, specifically performing operations without consultant assistance, and managing acutely unwell surgical patients independent of supervision until the subsequent day (Cullinane et al., 2003). Additionally, lack of identification of the sickest patients, adequate resuscitation and paucity of intensive care beds was common (Cullinane et al., 2003).

With increasing numbers of elderly patients having emergency surgery, NCEPOD focused a specific investigation on the elderly population in 2010. They included all patients aged 80 years or older who died within thirty days of

a surgical procedure being carried out over a three-month period of time. They did not include patients who were discharged from hospital alive or who died greater than 30 days after their surgical procedure. They analysed 1120 patient records and reported that over a third had emergency abdominal surgery (Richards, 2007). The report highlighted that the majority (70% of over 80-year olds) of these medically complex older patients were initially managed and assessed by junior doctors either from the Emergency Department or the surgical team. A recurring theme throughout the NCEPOD report was the recommendation that elderly patients would benefit from early and continued post-operative input from a specialist doctor with an interest in the health care of older people. The role of geriatricians in the pre-operative period had yet to be investigated.

The report also highlighted that, of all the patients included, only half of the emergency operations (both orthopaedic and general surgical) were performed by consultants. However, general surgical procedures had the highest level of consultant involvement for this elderly cohort. An additional concern was, on review of case notes, junior doctors were failing to discuss or document their discussions with consultants. Once again, themes of poor pre-optimisation, lack of multi-disciplinary team (MDT) care, and inappropriate post-operative care were highlighted. The main recommendations from the report included routine daily input from the health care of the elderly team, that consultant surgeons and anaesthetists should be significantly involved in the patient journey from admission to discharge, and that elderly patients who present with non-specific

abdominal signs and symptoms (diarrhoea, vomiting, constipation etc.) should be assessed by a doctor with sufficient surgical experience.

Following these initial findings, the general surgical and anaesthetic/intensive care community sought to quantify the scale of the problem regarding care of general surgical patients. Pearse et *al* carried out a large UK based retrospective study in 2006; they identified 4,117,727 surgical procedures, over a 4 year period, of which 1,224,295 were emergency procedures (Pearse et al., 2006) Procedures were classified as emergency or elective via the use of the "Health Resource Groups" (National Health Service, 2015) which categorise surgical procedures based on clinical similarity, risk of death and resource homogeneity. Cases were not matched demographically or for pre-morbid state (American Society of Anaesthesiologists classification (ASA)). They documented a mortality rate of 5.4% in the emergency group compared to 0.44% in the elective cohort. It is important to note that this emergency cohort included all surgical emergency operations (included repair of fractured neck of femur and emergency aortic surgery) and not just Em Lap (Pearse et al., 2006). Saunders *et al* ran a multicentre prospective study involving 35 National Health Service (NHS) hospitals, solely focusing on patients having Em Lap in the UK (Saunders et al., 2012). Unadjusted 30-day mortality rate was 14.9% rising to 24.4% in the over 80 years of age group. An additional finding was the variation in provision of key beneficial interventions (consultant delivered care, goal directed fluid therapy and admission to intensive care.) The authors concluded that there was a need for a national quality improvement programme (Saunders et al., 2012).

Further evidence of the need for a nationwide prospective audit was provided by "The Higher Risk Surgical Patient" report (2011) by The Royal College of Surgeons of England (RCS) (The Royal College of Surgeons (Eng), 2011). The aim of this document was to provide key recommendations on management of emergency surgical patients. Firstly, hospitals were encouraged to recognise that emergency surgical admissions are at high risk of death and complications. Implementation of formal emergency admission pathways and processes for recognition of deteriorating patient were encouraged. Twenty four hour access to emergency operating theatres with an "NCEPOD" list was also recommended (The Royal College of Surgeons (Eng), 2011).

The RCS recommended that high risk patients should have this fact documented in the clinical case notes. By formally identifying the most unwell patients it was hoped that clinical teams would ensure they received optimal care. This was further extended to recommend that high risk patients should have "active" consultant input throughout their hospital stay. This included consultants being released from elective work and being involved in both the pre and post-operative care of the patients while also being present in the theatre at the time of the emergency operation. Patients with a documented post-operative mortality risk of >10% should be considered for admission to critical care post-operatively. Finally, the recommendations echoed that of the paper from Saunders *et al*, that a national audit of outcome should be conducted for all adult patients who have an unscheduled or emergency operation (The Royal College of Surgeons (Eng), 2011).

## 1.4 The National Emergency Laparotomy Audit

### *1.4.1 Introduction*

The National Emergency Laparotomy Audit (NELA) began in December 2012. It was commissioned in light of the high incidence of post-operative death and the wide variation in care pathways and mortality across England and Wales. The audit was prioritised for immediate funding due to these concerns.

It is a national audit project carried out by the National Institute of Academic Anaesthesia's Health Services Research Centre (HSRC) on behalf of the Royal College of Anaesthetists (RCoA) in conjunction with the RCS and other stakeholders. The project is run by a team of anaesthetists, surgeons and intensivists all of who have a clinical background in managing the acute surgical patient. Additional technical and methodological support is provided by the RCS Clinical Effectiveness Unit (CEU). The aim of the project is to describe, compare and ultimately enable improvement in the care of all patients having an Em Lap.

As NELA is a nationally funded project, all hospitals in England and Wales that perform Em Lap should participate and enter data. Eligible hospitals were identified in January 2013, when NELA contacted 163 English NHS trusts and Welsh local health boards to ascertain which of their hospital sites performed Em Lap. Responses were received from all NHS trusts and health boards, indicating that 191 hospitals were eligible to participate. To participate, these hospitals had to be providing emergency general surgery cover and performing Em Laps. Individual hospitals were required to nominate lead clinicians and audit staff for local contact and co-ordination (NELA Project Team, 2014b).

Non-NHS hospitals and hospitals in Scotland, Northern Ireland, the Republic of Ireland and the Channel Islands were also welcome to contribute to NELA, but funding from The Healthcare Quality Improvement Partnership (HQIP) only extended to England and Wales (NELA Project Team, 2014b).

The audit collects patient level data (information that has been collected about a patient or individual; for example age, gender, or blood pressure values) on adult patients having Em Lap. Organisational data (information about the services and workforce available within the hospital) on the hospitals where these operations are performed is also collected, but not on an annual basis.

The first data published was an organisational audit to assess the infrastructure within the 191 hospitals performing emergency abdominal surgery. This was published in May 2014 (NELA Project Team, 2014b). Data was received from 190 of 191 eligible hospitals. The lack of data from 1 hospital was due to a planned reconfiguration (NELA Project Team, 2014b). These figures were encouraging for ongoing high levels of engagement nationally for the audit process.

The organisational report identified hospital characteristics including ability to admit emergency general surgical (EGS) patients, tertiary referral centre status for Gastrointestinal (GI) surgery and number of inpatient and overnight hospital beds. Participating hospitals were markedly heterogeneous with respect to size and the above characteristics (NELA Project Team, 2014b; Oliver et al., 2018).

The first patient audit started in January 2014. The inclusion and exclusion criteria are displayed in Appendix 1 (NELA Project Team, 2014a). All patients over 18 years who have emergency abdominal surgery on the GIT can be included in the audit.

Collected data includes patient demographics, the admission pathway, pre-operative investigations, surgical, anaesthetic and intensive care team involvement, operative findings, post-operative investigations, and post-operative destination. Inpatient mortality, return to theatre and discharge destination are also recorded. The full patient data fields that are collected are shown in Appendix 2. The audit dataset has been specifically designed, following expert consensus (surgeons, anaesthetists, intensivists and geriatricians), to incorporate patient risk factors and organisational factors most pertinent to Em Lap cohorts. The data is entered via a webtool on the NELA website. Hospitals are required to "lock" each individual case prior to the audit year time period closing. Following this data can be extracted from the webtool as a Microsoft Excel "comma separated values" (CSV) spreadsheet and imported into and subsequently managed in Microsoft Excel (2010). Local hospital clinical teams and management are able to access their own data for use in quality improvement projects.

Thirty and ninety-day all cause post-operative mortality is derived through linkage of the patient dataset with Office for National Statistics (ONS) death register. All patient data is anonymised with a unique NELA Identification number for use within the Project Team.

Case ascertainment is also calculated. Historical Hospital Episode Statistics (HES) data is used to predict the number of Em Laps performed at each hospital. HES data contains records for all admissions to English NHS hospitals. Em Lap cases are identified using a combination of International Classification of Diseases (ICD-10) diagnosis and Operating Procedure Code Supplement (OPCS) codes, to provide a group of codes which describe Em Lap (NELA Project Team, 2014b).

Case ascertainment is then expressed as a percentage using the actual number of cases entered into the webtool divided by the number of expected cases calculated. Case ascertainment is important as it allows the assumption that results of individual hospital audit data is an accurate reflection of the true quality of care received. If hospital case ascertainment rates are low, this raises potential concerns about the accuracy of the picture of the care and service provision at a hospital. One limitation of this method of calculation is if a hospital has significantly changed or altered its service provision (for example increased capacity/or no longer accepting acute surgical admissions) the case ascertainment may be an inaccurate reflection. HES data is historical and this could lead to an inaccurate predicted caseload.

NELA judges the care received by patients against nine key processes of care which have been derived from the above reports and expert consensus and opinion. These processes of care are shown in detail in Appendix 3, but broadly speaking they focus on pre-operative risk assessment, consultant delivery of

care, timely pre-operative investigations, and arrival to theatre alongside post-operative care in high dependency/critical care for the highest risk patients. It is these standards against which NELA measures the care delivered by hospitals within England and Wales (Anderson and Murray, 2014). Each of the reports provide individual hospitals with a red, amber or green (RAG) rating for each of the standards to demonstrate performance. To achieve a "green" rating a hospital must have a case ascertainment level of at least 80% of patients in the recommendations in Appendix 3. The level required to achieve a green RAG rating was increased to 85% for all the standards, bar elderly care post-operative review, in fourth year of data collection. This was changed to encourage and promote continued improvement in all standards of care for Em Lap patients.

### *1.4.2 NELA: where are we now?*

Hospitals have been entering data into the NELA database for 5 years since December 2013 and the Project Team has published five annual reports so far. Currently there are over 125, 000 patients in the dataset which makes NELA one of the largest prospectively maintained clinical databases in the world.

#### *1.4.2.1 First NELA Report (December 2013 to November 2014)*

In the first report, three key themes were identified; timeliness of care, resources and assessment of risk. The report emphasised the value of early input from senior clinicians, and stated that there was huge variation between hospitals regarding consultant surgeon review of emergency patients. In only one hospital did more than 80% of the patients receive a review by a consultant surgeon within 12 hours of admission (NELA Project Team, 2015a). A deficiency in

prompt administration of antibiotics was also described. Nearly 50% of patients waited more than four hours to receive antibiotics, and 25% waited longer than seven hours. The first report also highlighted that patients were not being formally recognised as "high risk;" only 14% of hospitals documented a risk assessment in over 80% of patients. In patients who did have their risk of surgery formally assessed, high rates of consultant led care and admission to critical care post-operatively were evident. The importance of consultant level care was reiterated in the report. It was clear that consultant presence in theatre was reduced overnight between 2000 and 0759. Twenty-four-hour access to operating theatres and timeliness of patients arriving in theatre was emphasised. The most urgent cases (requiring theatre in under two hours following decision to operate) arrived in theatre appropriately in 77% of patients, whilst those requiring theatre less urgently (either within 6 or 18 hours) reached theatre within those time frames in 86% and 84% of cases respectively. Finally, 60% of patients were admitted to critical care post-operatively, but again variation was seen between hospitals. The report quoted a 30-day in patient mortality rate of 11%. However, this was not based on ONS figures as they had not been derived at time of publication. The report figure was based on local data from hospitals themselves. The overall case ascertainment for the data was 85%. This first report provided an overview of the current state of care being received by patients having Em Lap and highlighted the main areas that required improvement.

*1.4.2.2 Second NELA Report (December 2014 to November 2015)*

The second NELA report saw an increase in the number of patients entered into the database as increased clinical engagement followed publicity around the

audit. Further improvements were seen in the main processes of care. More patients had pre-operative risk assessment which led to more patients having post-operative care delivered at the appropriate level (i.e. patients with a post-operative risk of death great than 5% being admitted to critical care). Differences remained in consultant presence in theatre, with lower numbers of consultants present out of hours. Overall, the report concluded that while progress had been made regarding individual clinician and team behaviours (i.e. risk assessment and consultant presence) there were still deficits noted in areas that would require organisational change. Specifically, only 10% of the patients over 70 years of age had a post-operative review by an elderly care physician. The report also highlighted a reduction in post-operative length of stay, which equated to a reported saving of £22 million pounds to the National Health Service (NHS).

*1.4.2.3 Third NELA Report (December 2015 to November 2016)*

The Third NELA annual report was published in October 2017 and included data collected from both the third audit year and also the second organisational audit (which focused on hospital processes and service provision). Once again there was an increase in engagement, with 24,897 patients included in the annual analysis. This accounted for approximately 82% of the patients who had Em Lap in England and Wales during the timeframe. A continued reduction in 30-day mortality was seen (11.8% to 10.6%). There was also a noted improvement in the number of hospitals who were "green" RAG rated for the core emergency processes of care. The main message of the Year 3 report was to use quality improvement methodology and local hospital collaboration to reduce variability in the care received by patients.

There had been significant improvements in some aspects of care, while little or no improvement was seen in other areas. In particular, input from, or post-operative review by, an elderly medicine physician for those over 70 years of age remained low (less than 20% of patients over the age of 70 were reviewed by a geriatrician in the post-operative period (NELA Project Team, 2017).

While not the main focus of this thesis, it is important to comment on the effect of an ageing population on the provision of emergency surgical care. The ONS projections published in 2016 show that by mid-2041 there will be 3.2 million people aged 85 and over, doubled from the 1.6 million over 85s living in the UK today (Office for National Statistics., 2017). From these figures, it is clear that provision and workforce planning needs to be performed to ensure that this older group of patients can be cared for when they require emergency surgery. There has been little work published to date specifically focusing on the burden of frailty and its impact on outcomes following Em Lap. However, the results of a UK based multi-centre study suggested that that frailty is independently associated with mortality following Em Lap (Parmar et al., 2019).

*1.4.2.4 The Fourth NELA Report (December 2016 to November 2017)*

During the fourth year of data collection, further reductions in mortality were reported nationally, 30-day morality of 9.5% coupled with reductions in length of stay. The report also described long term outcomes for the first time, mortality rates of 23% by 1-year post Em Lap, 29% at 2 years and 34% by 3 years (NELA Project Team, 2018b).

Improvements across a range of the key processes of care were clear; more patients were being risk assessed than before (75%), a consultant surgeon was present in theatre over 90% of the time while anaesthetic consultants were present in 82% of cases. The highest rates of admission to critical care to date were noted (NELA Project Team, 2018b).

Several aspects of care saw little or no improvement, with the NELA team issuing a call for urgent action to address these areas. The input of specialists in elderly care medicine in the post-operative period still remained very low at only 23% of over 70s. Another concern was the management of patients requiring source control from intra-abdominal sepsis. Only a quarter of patients who were suspected to be septic received antibiotics within an hour of admission. Additionally, delays to theatre in these patients remained present (NELA Project Team, 2018b).

Sepsis is a leading cause of death in patients requiring Em Lap and is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection (Opal et al., 2016). Between 30-50% of patients have sepsis, or septic shock (a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality (Opal et al., 2016) at first presentation to hospital (NELA Project Team, 2018b; Al-Temimi et al., 2012). The “Surviving Sepsis Campaign” (Levy et al., 2018) recommends that broad spectrum antibiotics should be started as soon as a patient has been identified as having sepsis, ideally within one hour. Timeliness

of antibiotic therapy in sepsis has been investigated extensively (Kumar et al., 2006; Levy et al., 2010; Prospective et al., 2009; Sterling et al., 2016), but less so the timing of source control. A small study of 154 patients from Japan suggested that, in those with gastrointestinal perforation associated with septic shock, time to operation was significantly associated with 60-day survival and quoted a survival rate of 0% if patients had their operation more than six hours after admission (Azuhata et al., 2014). However, a larger population-based cohort study from Denmark examined a heterogenous group of patients having emergency laparoscopy and laparotomy and concluded that there was no association between mortality and surgical delay when risk adjusted analysis was performed (OR 1.003, 95% CI 0.989-1.017) (Vester-andersen et al., 2016). This population included all patients requiring emergency surgery and not just those patients with intra-abdominal sepsis. A paper using The Danish Clinical Register of Emergency Surgery, exclusively examined patients with perforated peptic ulcers who had emergency surgery. They concluded that every hour that elapsed between admission to hospital and operation was associated with a 2.4% increased chance of death at 30 days (Buck et al., 2013).

The conclusions of reports on delay to theatre are unclear, with no reports from the UK patient population. Additionally, none of these studies specifically investigated or were able to risk adjust for timeliness of anti-microbial therapy.

#### *1.4.2.5 The Impact of The National Emergency Laparotomy Audit on Patient Outcomes*

Since the start of NELA in 2012 there have been steady improvements in patient outcomes following Em Lap in England and Wales. Thirty-day mortality has

fallen from 11.7% in 2012 to 9.6% in 2017. Rates of death within 90 days of surgery have also decreased; from 14.5% to 12.9% in the most recent round of data collection (NELA Project Team, 2018b). This reduction in mortality represents almost 700 fewer deaths within 90 days of surgery per year since 2012.

There has also been a reduction in unplanned reoperations. Some patients require a planned or scheduled return to theatre after their first operation for a number of reasons (for example re-look operations to check viability of bowel, establishing continuity of the bowel or closure of the abdomen). However, non-scheduled or unplanned returns to theatre can be required for patients who develop a complication following their initial operation or when they do not appear to be progressing in the expected manner in the post-operative period. Having an additional anaesthetic and major operation can have an impact on the patient not only physically but also psychologically. A large meta-analysis demonstrated a significant negative impact on patients' postoperative psychological well-being following a surgical complication, although this was not exclusive to gastrointestinal surgery (Pinto et al., 2016). Returns to theatre have reduced in frequency over the preceding four years. In the first four years of data collection, the audit did not discriminate between a "planned" or "unplanned" return to theatre, and purely classed the event as "a return to theatre." During this time period reoperation was seen in 10.2% of patients. In 2016 this had almost halved to 5.9%. This is an important outcome not only for patients but also hospitals in terms of resource allocation and prolonged length of stay. For the fifth year of data collection, the return to theatre questions have

been clarified to allow clinicians to identify if the patients return to theatre was planned or unplanned (i.e an emergency for an anastomotic leak post primary anastomosis compared to a planned removal of intra-abdominal packs). This update to the dataset will allow a better understanding of how many patients have an expedited primary procedure, more in keeping with the methods employed in trauma and damage control surgery. It will also allow a more accurate picture of the numbers of patients who have a truly "unplanned" return to theatre.

There have also been reductions in post-operative length of stay (LOS) for this cohort of patients. A prolonged hospital admission provides a significant burden to the patient, family and healthcare resources. The post-operative length of stay(LOS) can be seen as a composite indicator of outcomes, processes (at hospital and community levels) and also patient experience (Oliver et al., 2018). In the first year of data collection, mean LOS was 19.2 days; this has reduced to 16 days in the fourth year (2016) of data collection (NELA Project Team, 2015a, 2018b). However, while LOS is quoted as an outcome measure in the literature, discharge from hospital is dependent on many factors, some social, outside of the hospital setting.

## 1.5 General Surgical Training in the United Kingdom.

### *1.5.1 What is General Surgery?*

In the UK there are ten recognised surgical specialities; cardiothoracic surgery, general surgery, neurosurgery, oral and maxillofacial surgery, otolaryngology,

paediatric surgery, plastic surgery, trauma and orthopaedic surgery, urology and vascular surgery (The Royal College of Surgeons (Eng), 2015).

General surgery is one of the two largest surgical specialities in the UK, contributing 31% of consultants to the overall consultant surgical body. The team and workforce include consultant surgeons, trainees (higher speciality trainees, core surgical trainees and foundation trainees), non-training grade doctors, advanced clinical practitioners and specialist nurses.

General Surgery involves management of conditions affecting the entire GIT; from oesophagus to anus. Additionally, trauma surgery, breast surgery, transplant surgery, endocrine surgery, management of herniae and initial assessment of patients with vascular problems are all included under the remit of a general surgeon (ISCP (Intercollegiate Surgical Curriculum Programme), 2016).

Within the last decade there has been a trend for development of an elective special interest for general surgeons. These include:

- Upper Gastrointestinal surgery (including specialised osesphago-gastric and hepato-pancreato-biliary surgery)
- Colorectal Surgery
- Oncoplastic Breast surgery
- Transplant surgery (renal, hepatic, pancreatic)

Two other areas of general surgery which are usually practised alongside one of the larger special interests are endocrine surgery and general surgery of childhood (ISCP (Intercollegiate Surgical Curriculum Programme), 2016).

In addition to elective practice, general surgeons participate in provision of Emergency General Surgery (EGS). Individual hospitals run their EGS services in different ways (Navarro et al., 2017; Tierney et al., 2014; Panagiotopoulou et al., 2019), but The RCS, in conjunction with The Association of Surgeons of Great Britain and Ireland, (ASGBI) (The Royal College of Surgeons (Eng) and ASGBI, 2015) describe seven aspects of EGS care:

1. Performing emergency operations at any time of day or night
2. Assessment and management of patients presenting with an acute surgical problem
3. Providing ongoing care to patients who have had an operation and to other patients in the hospital who many become suddenly unwell with a surgical problem
4. Performing "rescue" operations for complications in patients who have recently had operations
5. Assessment and advice for patients who have been referred from other areas of the hospital
6. Providing early and effective acute pain management
7. Communication with patients and relatives

Ultimately, a general surgeon is defined as a surgeon who is capable of independently managing an unselected general take and who also has developed

a special interest within elective practice. However, many surgeons' special interest will be exclusively focused in one specific area but are still required to maintain an emergency practice. In many hospitals EGS may be provided by consultants with oesophago-gastric, hepatobiliary, colorectal, endocrine, breast and vascular elective special interests (NELA Project Team, 2014b). Increasingly in the UK there is a reduction in the contribution of breast and vascular surgeons to the EGS service with the evolution of service provision and specialization (Scott et al., 2008; Maraqa et al., 2015). Smaller hospitals may still rely heavily on surgeons with non-gastrointestinal special interests for EGS provision (NELA Project Team, 2014b).

To date, there has been no formal evaluation of the impact of special interest on outcomes after Em Lap. Both the NELA Collaboration and the subspecialty surgical associations (Association of Coloproctologists of Great Britain and Ireland (ACPGBI) and Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland (AUGIS)) have identified this as an area requiring investigation (NELA Project Team, 2014b).

### *1.5.2 General Surgical Training*

After graduation from medical school those wanting to pursue a career in general surgery are required to complete two years of Foundation Training (The UK Foundation Programme., 2018). During these two years doctors rotate through a range of medical and surgical specialities and are encouraged to identify the area of medicine they wish to enter. Those who wish to pursue a career in surgery must apply for surgical training. There are two entry points into surgical training, either directly into speciality training (ST1) or into a generic training

period called core training (CT1). Entry to both streams is via open competition, requiring applicants to provide evidence for their suitability for a career in surgery (ISCP (Intercollegiate Surgical Curriculum Programme), 2016). Doctors who complete the core training programme are then selected into one of the recognised surgical specialities (The Royal College of Surgeons (Eng), 2015) at the level ST3. This is again a competitive application process.

Trainees follow a set curriculum which is compulsory and standardised across the United Kingdom (UK). Curriculum standards are set by the Royal Colleges of Surgeons who operate through the Joint Committee on Surgical Training (JCST) and its ten Speciality Advisory Committees (SACs). Each of these SACs has developed person specifications used for selection into Higher Surgical Training (HST). The provision of training programmes at local level is overseen and provided by education deaneries or Health Education England (HEE) local offices. Table 1 displays the local regions within the UK.

*Table 1: Health Education Deaneries in the United Kingdom*

| **England** | **Scotland** | **Wales** | **Northern Ireland** |
|---|---|---|---|
| Health Education East Midlands | East of Scotland | Health Education and Improvement Wales | Northern Ireland Medical and Dental Training Agency |
| Health Education East of England | North of Scotland | | |
| Health Education Yorkshire and Humber | South East of Scotland | | |
| Health Education Wessex | West of Scotland | | |
| Health Education Thames Valley | | | |
| Health Education North West London | | | |
| Health Education South London | | | |
| Health Education North Central and East London | | | |
| Health Education Kent, Surry and Sussex | | | |
| Health Education North East | | | |
| Health Education North West | | | |
| Health Education West Midlands | | | |
| Health Education South West | | | |

The current general surgical curriculum was updated in 2016 (ISCP (Intercollegiate Surgical Curriculum Programme), 2016), but surgical education and the curriculum has witnessed significant change over the last decade, with the traditional surgical apprenticeship no longer commonplace. The introduction of the European Working Time Directive (European Parliament and Council of the European Union, 2003) and Modernising Medical Careers (Scottish Executive et al., 2004) has led to a competency based approach to training, demanding that education outcomes are quantifiable with measured proof of ability (Fitzgerald and Caesar, 2012; Moonesinghe et al., 2011) .

The Intercollegiate Surgical Programme (ISCP (Intercollegiate Surgical Curriculum Programme), 2019) which provides a General Medical Council (GMC) approved curriculum (The General Medical Council, 2017) has reshaped surgical training, with the introduction of a online platform and work based assessments (ISCP (Intercollegiate Surgical Curriculum Programme), 2019). Prior to 2013 there was no set requirements of the curriculum, and the JCST published specific competency based guidelines (The Speciality Advisory Committee for General Surgery, 2013a). The aim of these guidelines is to ensure that all of the curriculum competency requirements are achieved and that new consultants have sufficient experience to deal with the varied presentations and clinical scenarios that will be met in independent practice. The general surgical curriculum includes six key procedures or Index procedures (IP) which are shown in Table 2 alongside the numbers required by Certification of Completion of Training (CCT) (The Speciality Advisory Committee for General Surgery, 2013b). These numbers of "General Surgical" procedures are required by all

trainees, however the curriculum also states that trainees are required to gain experience in their chosen special interest within general surgery (The Speciality Advisory Committee for General Surgery, 2013a).

Emergency General Surgery (EGS) is thought to contribute up to 50% of the total general surgical workload (The Royal College of Surgeons (Eng) and ASGBI, 2015) and therefore is the largest component of the speciality. Patients presenting with acute abdominal pain are the mainstay of the work for the EGS team and surgeon. Trainees are required to be competent in managing patients presenting with peritonitis and the conditions associated with this clinical picture. Ultimately, general surgical HST must be able to recognise the indications for and be able to perform independently an emergency/exploratory laparotomy (ISCP (Intercollegiate Surgical Curriculum Programme), 2016).

*Table 2: Indicative minimum operative numbers for all General Surgical Trainees required for Certification in General Surgery.*

| **Procedure** | **Number Required (n)** |
|---|---|
| Emergency Laparotomy | 100 |
| Emergency Hartmann's Procedure | 5 |
| Emergency Segmental Colectomy | 20 |
| Appendiectomy | 80 |
| Inguinal Hernia | 60 |
| Cholecystectomy | 50 |

The indicative numbers set are at a level which was felt should provide the sufficient experience required and also corresponds to the first quartile of previously successful general surgical trainees (Allu*m et al*, 2013). Adequate experience is confirmed by presentation of the trainee's logbook of surgical

experience at Annual Review of Competence Progression (ARCP.) The ARCP occurs annually and involves a panel, including regional trainers, external regional representation, lay representation and the Deanery Training Programme Director, reviewing the trainees portfolio and logbook of cases (Conference of Postgraduate Medical Deans of the United Kingdom, 2018).

The structure of training is also defined in the curriculum. Higher training is split into broad stages; Speciality training years (ST) 3-4 (early), ST5-6 (interim) and ST7-8 (higher). By ST6 level, trainees declare a special interest within general surgery (colorectal surgery, breast surgery e.t.c). Each special interest requires trainees to log a certain number of speciality specific procedures, for example 30 anterior resections for colorectal special interest trainees.

While trainees are not expected to be expert in each of the special interests by completion of training, they are all expected to reach the common level of ST8 in EGS by this period (The Speciality Advisory Committee for General Surgery, 2013b).

The EGS component of the syllabus, unsurprisingly, has a heavy focus on management of patients presenting with an "acute abdomen." This term describes patients with abdominal pain caused by a variety of intra-abdominal pathologies, most commonly of the GIT, however, urological and gynaecological problems can also present in this way. As EGS is such a central part of the scope of practice of a general surgeon, certification includes the requirement to perform at least 100 Em Lap and demonstrate competence in EGS through work placed based assessment. These numbers are in the curriculum to reassure trainers, employers and the public that someone certified

in general surgery has adequate exposure to the range of presentations, pathologies and technical difficulties at Em Lap that might be encountered when receiving an unselected general surgical take.

There appears to be little evidence in the literature for setting of these numbers. A recent systematic review and meta-analysis, looking at operative experience of surgical trainees at completion of training, highlighted there was limited published data on operative procedures completed by UK surgical trainees. Furthermore, from the data that was available, there appeared to be wide variation in number of cases, particularly "index procedures," performed by trainees (Elsey et al., 2017). The paper concluded that further studies of the relationship between operative experience and competency are required (Elsey et al., 2017).

Smaller studies have expressed concern regarding trainees specifically lacking experience in the procedure of Em Lap operating. This led to pan association published guidance citing the need for mandatory modular emergency surgery training becoming a central and compulsory part of the curricular pathway (ACPGBI et al., 2015). Additionally questions were raised, suggesting regional variation in the experience of Em Lap operating for trainees (Allum et al., 2013).

There is no robust literature addressing whether the Em Lap workload currently being performed provides sufficient experience and training opportunities for trainees in the UK. While the NELA annual reports describe overall numbers of

Em Laps occurring nationally, there is not a clear picture of the regional variation in workload of EGS.

With over 1600 HST trainees currently working in hospitals within the United Kingdom (NHS Digital, 2019; Stats for Wales, 2019) this information would be of value to trainees and trainers alike to allow sufficient workforce planning from an early stage. This information would also be of importance to doctors with an interest in pursuing a career in general surgery who have not yet entered a higher surgical training programme.

The limited literature on logbook numbers in UK demonstrates that a significant proportion (Allum et al., 2013; Thomas et al., 2015b) of general surgery HST are not hitting the CCT target of 100 Em Lap. While this could be due to a lack of cases or opportunity due to rota re-designs following the European Working Time directive, it could also be due to consultant concern that trainee involvement in high risk cases may have a detrimental effect on outcomes.

Prior to the introduction of NELA, Saunders *et al* reported that there were lower numbers of consultant surgeons present in theatre, particularly at night. This was associated with a 20.3% post-operative 30-day mortality (Saunders et al., 2012). There is limited literature focusing on the relationship between mortality, morbidity and consultant led care for Em Lap patients. Other medical specialities suggest that trainee participation may be associated with adverse outcomes (McLauchlan et al., 1997; Ryan et al., 2014). However, within surgical specialities in elective practice, the evidence is less convincing. While

Papandria *et al* reported increased operative times when trainees performed common general surgical procedures (laparoscopic cholecystectomy, laparoscopic appendiectomy and open inguinal hernia), no association with mortality has been reported (Singh and Aitken, 1999; Loiero et al., 2017; Tseng et al., 2011; Hwang et al., 2008; Kasten et al., 2018).

Investigation into trainee surgeon involvement in emergency general surgical procedures and its association with morbidity and mortality is limited. A large American database study investigated the impact of trainee led operating on outcomes after emergency general surgical procedures. They performed a multivariate regression analysis and suggested that trainee participation was independently associated with intra- and post-operative adverse events (Kasotakis et al., 2014). Their study included a range of emergency surgical procedures including exploratory laparotomy, appendiectomy, colectomy, hernia repair and diagnostic laparoscopy. To date there has been no studies investigating the role of trainees in Em Lap and the core competencies required for certification in general surgery.

## 1.6 Observational research in Emergency General Surgery

The National Emergency Laparotomy Audit is a large prospectively maintained clinical database (NELA Project Team, 2015a, 2016, 2017). Whilst high quality randomised controlled trials provide the highest level of evidence when investigating clinical outcomes (Morshed et al., 2009), the use of randomised controlled trials in Em Lap patients would be inappropriate when investigating the majority of research questions. In observational studies the researcher does not assign subjects to treatment or control groups. Therefore, non-randomised or observational studies can provide important insight into this patient group.

There are several benefits of observational studies in surgical research. The use of a large cohort reduces the ethical dilemma of exposing patients to a potentially harmful exposure or depriving them of a potentially beneficial intervention (Hoppe et al., 2009). Furthermore, when investigating rare or infrequent outcomes, randomised controlled trials require very large sample sizes to detect significant differences while observational studies are more representative of real-world patients. (Hoppe et al., 2009). Randomised control trials are extremely costly and also labour intensive with independent funding very competitive. To investigate long term outcomes, randomised controlled trials are not always practical, again due to lack of resources and time management (Benson and Hartz, 2000). The issues surrounding sample size are not exclusive to RCTs and similar problems regarding this can also be seen with non-randomised studies. Randomisation and blinding can also be difficult to achieve in surgical trials due to issues regarding standardisation of surgical technique and the difficulty of concealment (Benson and Hartz, 2000).

There is one ongoing randomised control trial in Em Lap patients; The Fluid optimisation in Emergency Laparotomy (FLOELA) trial. Patients who require Em Lap are randomised to receive either usual practice at the local hospital for monitoring central venous pressure intra-operatively or cardiac output-guided haemodynamic therapy intervention (FLOELA Project Team, 2018). The trial is still ongoing and aims to recruit 8000 patients, 4000 in each arm. The NELA dataset demonstrates that approximately 30,000 patients have an Em Lap in England and Wales annually, therefore demonstrating the significant advantage of observational studies which allow larger, representative populations.

It is clear that observational studies, in particular using databases, can play a vital and important part in surgical research.

## 1.7 Use of databases in clinical research.

The NELA database is a large electronic database that is hosted online. The use of electronic records within healthcare is a rapidly expanding entity leading to large amounts of data available that can be used for clinical, epidemiological and cost-effectiveness research (Miriovsky et al., 2012). These electronic health care records also facilitate improved co-ordination and standardisation of care and processes for patients (Blumenthal, 2009). However, electronic data for research and quality improvement also poses some challenges. Over the past decade there has been growth of the discipline of "data science" with production of data storage and analytic software to improve data usage. In America, The National Institute of Health derived a data knowledge initiative to identify obstacles associated with using "biomedical big data"(Ohno-machado, 2018; National Institutes of Health, 2012). The six issues they highlighted are as follows (Ohno-machado, 2018; National Institutes of Health, 2012):

1. Locating data and software tools
2. Accessing data and software tools
3. Extending policies and practices for data sharing
4. Training researchers who can use big biomedical data effectively
5. Organising, processing and managing big data

Before commencing work with a large dataset, it is important to appreciate the above hurdles and how to overcome them. Clearly the correct computer software with individuals who have the ability to use said software is essential to any project. Furthermore, one of the most time-consuming parts of data analysis is ensuring that the data is in a readable form for the analytical software package.

"Data cleaning" can be laborious, with the need to main detailed records of how each data element has been extracted or derived. One method of preserving this work for future replication and/or analysis is the use of codebooks, where the initial "coder" maintains a detailed record of decision rules and methodology to create each variable (Cohen et al., 2015). Training in this form of coding and analysis is time consuming but is essential to efficient and affect management and analysis of a large dataset.

## 1.8 Bias and confounding

Within all aspects of research, confounding and bias threaten to affect estimates of associations between risk factors and outcomes (Morshed et al., 2009). Specifically, selection bias, information bias, and confounding are the main concerns within observational studies (Morshed et al., 2009).

### *1.8.1 Selection Bias*

Selection bias can occur when the entry of participants into a study is related to the outcome or exposures being investigated. An example of this, within a surgical setting , could be including highly motivated and physically fit patients into studies investigating outcomes following "Enhanced Recovery After Surgery" (ERAS) Programmes. Retrospective studies are particularly at risk of selection bias, as participants are identified for inclusion after the outcome measure has occurred.

NELA is a prospectively maintained clinical database with patients entered into the database contemporaneously. This reduces the risk of selection bias. It is expected that hospitals will enter all their Em Lap cases into the NELA database regardless of outcome. NELA calculates case ascertainment figures as previously described to ensure hospitals are entering all the patients they should. If case ascertainment falls below 80%, hospitals are contacted and advised to review their data.

### *1.8.2 Information Bias*

Information bias can occur when observational, particularly database studies, lack diagnostic or full information on outcomes, study variables or confounders.

This can lead to errors in classification (misclassification) of outcomes, exposure and confounders (Jepsen et al., 2004). Errors with coding and data entry can also lead to misclassification errors. This is when an individual, a value or observation is assigned to a category other than that to which it should be assigned (Port*a et al*, 2014); a patient documented as receiving antibiotics at the start of surgery when they didn't receive antibiotics until after the operation. These errors can occur for a number of reasons including; incomplete medication records, recording errors in records, misinterpretation of records, or incorrect disease coding (Walraven, 2018). While steps can be taken to minimise the risk of this bias, they can be unavoidable due to human error which is innate to any study involving people, not observational research alone.

Differential misclassification errors can occur when the information errors differ between groups; bias is different for exposed and non-exposed groups (Porta et al., 2014). An example of this is, patients who smoke might be more frequently diagnosed with emphysema when compared to non-smokers, due to the fact that smokers may seek medical attention more regularly and therefore may be more likely to be diagnosed with emphysema purely because they go to the doctors more often. Non-differential misclassification occurs when classification of outcome or exposure status occurs equally in all groups. The probability of the outcome being misclassified is independent from the exposure and vice versa (Porta et al., 2014). An example of this would be a clinical coder inputting data on mortality status incorrectly into the data base when transcribing from paper data collection forms. Non differential misclassification errors will lead to bias towards the null hypothesis (Jepsen et al., 2004).

A further type of information bias can be related to inclusion of missing data. This type of bias is of particular relevance for large database studies, where full information may not have been collected, or entered as "unknown" or "missing." This must be accounted for when undertaken statistical analysis and also interpreting the results of the study. Missing data and how it has been dealt with will be specifically mentioned and described throughout this thesis.

### *1.8.3 Confounding*

A confounding factor is variable or exposure that has an association with the outcome and is not the primary relationship under investigation. It is an intrinsic limitation of observational studies (Port*a et al*, 2014). When identifying potential confounders it is important to have some form of causal knowledge about the outcome and exposure, usually in the form of clinical and pathophysiological understanding (Shah et al., 2016). It is suggested that there are three criteria for identifying confounders (Farrugia et al., 2009):

1. A confounder must be associated with the exposure under the study in the source population
2. A confounder must be a risk factor for the outcome
3. A confounder must not be affected by the exposure or the outcome.

### *1.8.4 Effect Modification*

Effect modification occurs when the effect of a factor is different for different subgroups. Effect modifiers differ from confounding factors as they have an association with the outcome only, while confounders have an association with

both the exposure and outcome (Rothman et al., 2008). Confounding factors can account for all or part of an apparent association between an exposure and a disease or outcome while effect modification can provide information on the how the effect of an exposure, on an outcome, will vary depending on the presence of third factor (for example gender) (Corraini et al., 2017). Studying effect modification can have multiple benefits (Rothman et al., 2008):

- it will allow high risk sub groups to be defined
- it can increase precision of effect estimation by understanding that may be affect differently
- increases ability to compare across studies that have different proportions of effect modifying groups
- aids in developing causal hypotheses for disease

### *1.8.5 Methods for controlling bias and confounding*

The NELA dataset contains a wide range of information about the patient, the operation and outcomes after operation. The inclusion of these were decided by a panel of experts within the field of emergency surgery. This wide range of available information will allow for risk adjustment of confounding factors in the proposed analysis.

Within randomised controlled trials, the randomisation process can take account of both the unknown and known confounders, with the ultimate aim of validating the statistical test used (Benson and Hartz, 2000). However, there are several methods that can be employed to control for confounding in observational studies:

*Matching*

This involves identification of confounders and subjects in treatment groups who are then matched on the basis of these factors. It is the hope that the two groups are then "the same." This process can be done on either a paired (one to one) basis or on a frequency basis (a confounder represents an equal proportion of subjects in each group.) Matching can be used in both prospective and retrospective observational studies (Morshed et al., 2009). The main limitation of this method is that it may be difficult to find exact matches between the other additional patient characteristics. This risk increases exponentially as the number of variables in the dataset increases. This can lead to a reduction in sample size and thus power of the study (Morshed et al., 2009). Matching should also only be undertaken on true confounders, due to the risk of generation of a new bias and overmatching. Ultimately, matching should be used with caution and only on factors that are thought to be very strongly associated with the outcome.

*Stratification*

This method can be performed to check for presence of effect modifiers; the sample is grouped by levels of this factor (for example; heavy smoker, moderate smoker, mild smoker, non-smoker are stratifications of the amount of a factor, in this case smoking). The required analysis can then be performed on each of the subgroups to check if there is a significant difference between the groups. If the stratum-specific measures of association are different to each other and the crude lies between them, then it's likely that the variable in

question is acting as an effect modifier. These results should be reported separately for each stratum of the covariable.

The benefit of stratification is that it allows investigation into whether the effect being studied is constant across all degrees or levels of the factor (Jepsen et al., 2004). This can provide valuable prognostic information, for example; a drug or treatment that doesn't appear to work in a subset of patients. The study should report which method was use to examine these differences and specify which subgroup analyses were predefined in the protocol and which were performed when analysing the data.

*Multivariable Regression*

Multivariable regression is a mathematical model that estimates the associations between multiple independent factors and one dependent outcome variable (Farrugia et al., 2009). A dependent outcome variable is the area of interest in a study; mortality after Em Lap. The independent factors are pieces of information that are known to be associated with the outcome but are not the principle association being investigated. For example, if we want to investigate the association of grade of surgeon performing the operation and outcomes after Em Lap we will collect data on the mortality (dependent outcome) and the grade of surgeon. We also collect information on other factors (independent factors) that we think could affect mortality (age, how unwell the patient is, what operation they had etc.)

Multivariable logistic regression is the most commonly used adjustment method in therapeutic and prognostic studies. As described above it allows the

association between a dependent and independent variable to be estimated while controlling for the influence of other independent variables (Farrugia et al., 2009). The type of model used depends on the outcome that is being assessed. For binary outcomes (e.g. dead or alive) logistic regression is the model used, with estimate of effect presented as odds ratios.

The OR is a measure of the association between the outcome and the exposure; the odds that an outcome will occur in the presence of exposure compared to the odds of the outcome occurring in absence of the exposure. An OR greater than one demonstrates an increased risk of the outcome occurring (Szumilas, 2010).

When analysing LOS data there are three different frameworks that can be used to analyse this is type of outcome. LOS data can be viewed as a continuous outcome (despite its discrete nature). In this scenario linear regression analysis should be used (Austin et al., 2002). Linear regression attempts to describe the relationship between an outcome and a variable by fitting a linear equation to the observed outcomes.

One variable is the explanatory variable (grade of surgeon operating, in categorical form) and the other the dependent or outcome variable (length of stay in hospital). The data is then plotted with the explanatory variable on the x axis and the outcome variable on the y axis and a best fit line drawn through the data points. The best fit line is chosen so that the vertical distance from each of the data points is a minimum (Aggarwal and Ranganathan, 2017).

LOS data can also be treated as duration data and can be analysed using survival models. Survival models are most commonly used in cancer studies when researchers are investigating time to relapse or time to death. Survival studies run for a set duration and therefore not all participants may develop disease recurrence or die. Survival models allow for censorship within their statistical methods. Censorship is when a patient is either lost to follow up, dies or has disease recurrence. Within the NELA dataset the full range of data to regarding LOS is available and therefore will be treated as a continuous variable.

Within multivariable models, "model fit" can also be presented. This provides explanation of the amount of variability in the data and will also give an indication for how well the model will actually predict individual outcomes for a given observation. Inclusion of a description of model fitting methods helps validate reported results (Morshed et al., 2009). It is also important as a confidence measure for when the model is used in the future. For example, the NELA risk score was developed to predict mortality after Em Lap, the "goodness of fit" of the statistical model used to develop the scoring scale is important as it demonstrates that the model is reliable in this cohort and can be applicable in the future.

*Propensity Score Analysis*

Propensity score analysis aims to mimic randomised controlled trials by reducing selection bias in observational research. A propensity score is the probability that a patient/individual with certain characteristics will be assigned to the treatment group within a study. These scores can then be used to reduce selection bias by balancing the characteristics of the patients between each of

the study groups. Propensity score matching uses the propensity score to create "matched" sets of participants and then assigns one to each of the groups under investigation. (Farrugia et al., 2009).

The advantages of propensity scores include the fact that they indicate the degree to which the treatment differs between groups, and also can be used when numbers of events are small or the number of covariates is larger than the number of events (Winkelmayer and Kurth, 2004). It is however, important to take note that the scores are obtained from observational data and that matching will therefore only control for observed variables and not account for bias that results from the unobserved co-variates. Additionally, propensity score matching is a relatively new statistical method and may not be as universally understood as the more traditional methods such as multivariable regression (Hoppe et al., 2009; Benson and Hartz, 2000).

Ultimately, no statistical method can remove bias due to confounders completely, especially if there are unmeasured or unknown confounders. An essential part of any good observational study is thorough collection of information on potential confounders to attempt to minimise the effect from unknown or unmeasured confounders. The NELA database will be analysed as a large cohort, with the common exposure being that the patient has had an Em Lap.

## 1.9 Summary and Aims

Em Laps are commonly performed operations that are associated with substantial postoperative mortality, morbidity and resource utilisation. There have been five NELA annual reports describing the basic trends of care received by patients having Em Lap, showing significant improvement in post-operative outcomes of this group. However, there has been no specific work looking at how general surgical workforce provision and organisation impacts on these outcomes. Furthermore, the potential impact on surgical training has not been explored.

Therefore, the aims of the thesis are to:

1. Assess the impact of delay to theatre on mortality in patients with intra-abdominal sepsis
2. Assess the impact of consultant surgeon special interest on post-operative outcomes
3. Quantify the number of Em Laps and general surgery index procedures being performed in the United Kingdom and in each deanery
4. Assess the impact of trainee involvement in Em Lap operating on post-operative outcomes

## 2. General Thesis Methods

## 2.1 My Role with the NELA Project Team

Access to the NELA data was granted to me within my role of NELA surgical research fellow. This role involves being a member of the NELA Project Team which is a group of anaesthetic, surgical and intensive care clinicians who are supported by a statistical and methodological team from the RCS CEU and University College London.

Within the project team, I am involved in production of the NELA annual reports, performing secondary analysis of the dataset, providing surgical clinical input in regards to the development and running of the audit and also attending and speaking at conferences and meetings about NELA and the ongoing projects. I have held this role for the past three years.

## 2.2 Data Sources

Data for this thesis is provided from the NELA database in raw unedited form. An extract of the dataset was downloaded from the NELA webtool on 11th of September 2017. This included data from 2013 to 2016. Year four data extract was received on 21st of March 2018, following the closing deadline for hospitals to input and finalise data.

Extracted data was downloaded as a Microsoft Excel comma separated values spreadsheet. I then imported this into Stata® version 15 (StataCorp LP, College Station, Texas USA). All further data management and statistical analysis was performed in Stata® version 15.

Mortality data was provided from the Office for National Statistics. This dataset linkage was performed by NHS Digital and provided by the Team from the CEU. They then provided a separate Microsoft Excel spreadsheet with NELA Patient Identification numbers and mortality status in a binary form (deceased; yes or no) for both 30-day and 90-day mortality. Using Stata® version 15, I merged the two datasets (clinical variables and mortality data) to produce a master dataset with outcome variables available for analysis.

## 2.3 Project approvals

NELA is an observational study collecting routinely available data and required no changes to patient pathways or treatment. Consequently, in the UK, this study was registered at individual participating centres by study collaborators as a clinical audit. Research ethics review was not required. However, each of the study questions in this thesis was approved by the Healthcare Quality Improvement Partnership who are the governing body of NELA. Within each of these proposal forms (Appendices 4 to 7) evidence has been provided that these secondary analyses fall under the scope of work for which NELA has been approved for. These studies are designed to answer questions relating to short-term, mortality and morbidity outcomes and to investigate reasons for variation in outcomes.

## 2.4 Data Training and Management

Before beginning data analysis, a ten-week course was attended, "Data Organisation and Management in Epidemiology: a Practical Course in Stata." This course was provided by the University of Nottingham as a module within

the Public Health, Public Health (International Health) and Applied Epidemiology (EPH) masters course.

Stata is a general purpose data management and statistical software package created in 1985 by StataCorp (StataCorp LLC, 2019). The programme is particularly useful for large datasets. The program's capabilities include data management, statistical analysis, graphics, regression and custom programming. I also attended a ten-week statistical course provided by the University of Nottingham EPH masters course; Advance Statistical Methods.

All data management was performed using Stata. When the NELA data is downloaded from the webtool it is transferred from Excel into Stata. Once in Stata, data cleaning is performed. Data cleaning refers to the process of changing the form of the data to one that is readable by the software programme selected by the researcher, in this case Stata. Data cleaning also involves detecting missing or inaccurate records within the data. An example of such inaccuracy is where a date of operation is recorded as occurring before the date of admission to hospital, or a time of arrival of a patient in theatre as the same time as admission to hospital. How these missing or inaccurate variables are handled will be described within individual chapter methodology.

A further example of the data cleaning that is required is working with dates, for example date of admission to hospital and date of discharge. There are many ways a date can be expressed; 13/7/19, 13$^{th}$ of July 2019, 13.7.2019 etc. To allow calculations of the time between two dates (e.g to calculate length of stay in

hospital) the dates must be in the same form but also in a form that the software can interpret. In Stata dates must be converted into whole integers, which is achieved using specific coding depending on the format of the original date input.

Another example of data cleaning is when text data is imported, such as the name of the operative procedure performed. Stata is unable to count or analyse text so all text has to be coded to numeric form which can then allow it to be calculated and analysed.

All methodology, statistical analysis, specifics of data handling, coding and how variables were managed are described specifically and in detail in each of the relevant chapters.

Stata code that was used for the statistical analysis is shown in Appendix 7.

## 3. Timing of Surgical Source Control; Does it Impact on Outcomes Following Emergency Laparotomy?

## 3.1 Chapter Focus

This chapter describes the variation in time to theatre for patients with intra-abdominal sepsis who have an Em Lap for perforated peptic ulcer disease. The chapter further reports the effect of increasing time from admission to theatre on the outcomes of both mortality and return to theatre.

## 3.2 Abstract


***Aims***

Delay to theatre for patients with intra-abdominal sepsis is cited as a particular risk factor for death. The aim was to evaluate the potential relationship between hourly delay from admission to surgery and postoperative mortality in patients with perforated peptic ulcer disease.

***Methods***

All patients entered in NELA who had an Em Lap for perforated peptic ulcer disease within 24 hours of admission from December 2013 to November 2017 were included. Time to theatre from admission was modelled as a continuous variable in hours. Outcome was 90-day mortality. Logistic regression, adjusting for confounding factors was performed.

***Results***

3809 patients were included, 90-day mortality rate was 10.61%. Median time to theatre was 7.5 hours (IQR 5- 11.6 hours.) The odds of death increased with time to operation once adjustment for confounding variables was performed (per hour after admission adjusted OR 1.04, 95% CI 1.02-1.07). In patients who were physiologically shocked (N=334), there was an increase of 6% in risk adjusted odds of mortality for every hour Em Lap was delayed after admission (OR 1.06, 95% Cl 1.01-1.11).

***Conclusions***

Hourly delay to theatre in patients with perforated peptic ulcer disease is independently associated with risk of death by 90 days. Therefore, it is suggested

that surgical source control should occur as soon as possible after admission regardless of time of day.

## 3.3 Introduction

Em Lap can be performed to treat patients presenting with perforated viscus (for example, perforated peptic ulcer.) While 30-day mortality for Em Lap in the England and Wales has decreased over the last four years from 11.7% in 2013 to 9.5% in 2017 (NELA Project Team, 2018b), higher mortality rates (17-34%) are seen following Em Lap performed for intra-abdominal sepsis compared to procedures without intra-abdominal contamination (NELA Project Team, 2018b).

Sepsis is known to be leading cause of death in patients requiring Em Lap and treatment for this patient group includes timely administration of broad-spectrum antibiotics and timely source control. However, the conclusions of reports regarding delay to theatre for surgical source control for patients with intra-abdominal sepsis are unclear. There are no studies from the UK population.

The aim of this study was to investigate the relationship between time to Em Lap for patients with perforated peptic ulcer disease and post-operative mortality using the NELA database.

## 3.4 Methods

### *3.4.1 Study Population*

Adult patients who had an Em Lap for perforated peptic ulcer disease and were entered into the NELA database between December 2013 and November 2017 were included. Patients with perforated peptic ulcer were selected for investigation as this pathology is associated with peritoneal contamination leading to intra-abdominal sepsis (Fong, 1983). Patients who had perforations from other sites in the GIT were not included as these could have resulted from pathologies where the accepted timing of surgery in relation to initial presentation is not always so clear cut. (For example, colonic perforations from progressing diverticular disease). Patients were excluded if they had their operation more than 24 hours after admission. This was to avoid bias caused by failure of an initially conservative management plan or a delay in intra-hospital referral. While previous papers have included patients who had their operation performed over 24 hours following admission, this was deemed to be a limitation of their study. Patients who had Em Lap for other complications of peptic ulceration were not included.

### *3.4.2 Data Management and Study Variables*

The main explanatory variable investigated in this study was time to theatre. Time to theatre was calculated in hours, using time of admission and time into theatre and was modelled as a continuous variable. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3) (*Opal et al*, 2016) were used to define tachycardia (heart rate (HR)>90 beats per minute), hypotension (systolic blood pressure (SBP) <100mmHg), physiological shock

(HR >90 and SBP <100mmHg) and raised lactate (serum blood lactate >2.0 mmol/L). When selecting patients with each of the derangements (for example "tachycardia" etc.), no limit was placed on the other physiological parameters.

The following variables were extracted; age, sex, American Society of Anaesthesiologist (ASA) grade, urgency category at time of case booking, pre-operative Electrocardiogram (ECG) findings, pre-operative cardiac signs, respiratory history, pre-operative serum creatinine, pre-operative serum urea, pre-operative serum sodium, pre-operative serum potassium, pre-operative serum white blood cell count, pre-operative heart rate, pre-operative systolic blood pressure, pre-operative Glasgow Coma Score (GCS). It was deemed more clinically relevant to use post-operative values for intra-operative blood loss, peritoneal soiling, operative severity and malignancy. The above data was used to calculate the NELA risk score for each individual (Eugene *et al*, 2018). Grade of operating surgeon and anaesthetist and whether the patient was directly admitted to a critical care unit post-operatively were also extracted.

### *3.4.3 Outcome measures*

Outcome of the study was all cause 90-day mortality from the date of the index surgical procedure. Mortality within these timeframes was captured through established dataset linkage of NELA with the Office for National Statistics (ONS) death register.

### *3.4.4 Statistical analysis*

Descriptive results are presented as mean (standard deviation), median (Inter Quartile range (IQR)) or number (%) as appropriate. To test the association

between time to theatre and post-operative mortality, logistic regression was performed. Logistic regression predicts the probability that an observation falls into one of two categories of a dichotomous dependent variable based on one or more independent variables that can be either continuous or categorical. As mortality by 90 days is a dichotomous variable and multiple independent variables were available for risk adjustment, logistic regression was used in this analysis.

Both unadjusted OR and OR adjusted for the following selected covariates are presented: NELA risk score, grade of operating surgeon and anaesthetist and admission to critical care unit post-operatively. These co-variates have been included based on clinical significance rather than statistical significance, therefore a likelihood ratio chi-squared test is not presented.

The NELA risk score is a pre-operative scoring system that includes, demographics, pre-operative blood tests, pre-operative physiology, surgical findings, intraabdominal contamination and blood loss. A score is calculated using these values and is representative of a percentage risk of post-operative mortality (Eugene et al., 2018). This score has been used here as a marker of how unwell the patient was prior to the operation due to the inclusion of the clinical factors mentioned above. It has been included as a single continuous variable rather than multiple variables for simplicity and also as individual components of the score violated the assumption of a logistic regression model that continues variables hold a linear relationship with the logit of the outcome.

Structural factors were not included in the risk adjustment model because previous analysis of NELA data demonstrated no increase in mortality associated with case volume, hospital size or hospital configuration (Oliver et al., 2018). Results are presented with 95% CI.

Participants with missing data in either outcome variable or variables required for risk adjustment were identified and excluded from analysis.

Subgroup analyses included patients with pre-operative tachycardia, pre-operative hypotension, pre-operative raised lactate, and pre-operative physiological shock.

## 3.5 Results

### *3.5.1 Cohort description*

The study cohort contained 4067 patients who had an Em Lap or Emergency Laparoscopy and repair of perforated peptic ulcer disease within 24 hours of admission. Patients with clinically recorded time to theatre of less than 30 minutes were not included as this was felt to be unrealistic (12 patients; 0.3%). Patients with missing mortality data (87; 2.1%) or variables required for risk adjustment (159; 3.9%) were excluded. This left a total study cohort of 3809 patients available for analysis.

The clinical characteristics are shown in Table 3.

*Table 3: Patient characteristics among 3809 patients with peptic ulcer perforation*

| | | | **Time to theatre in hours*** |
|---|---|---|---|
| **Age*** | | 56 (41-72)* | |
| **Age categories** | 18-39 | 890 (23.37) | 7.35 (5-11.25)* |
| | 40-49 | 594 (15.59) | 7.45 (4.65 -11.06)* |
| | 50-59 | 675 (17.72) | 7.55 (4.91-11.08)* |
| | 60-69 | 568 (14.91) | 6.99 (4.88-11.60)* |
| | 70-79 | 560 (14.70) | 8.32 (5.45-12.64)* |
| | 80-89 | 465 (12.21) | 8.48 (5.45-13)* |
| | >90 | 57 (1.50) | 7.58 (5.25-11.16)* |
| **Female sex** | | 1272 (40.12) | - |
| **Pre-operative NELA risk score; (%)*** | | 2.36 (0.57-12.07)* | |
| **ASA grade** | 1 | 718 (22.70) | 7.28 (4.81-10.86)* |
| | 2 | 992 (31.36 | 7.70 (5-12)* |
| | 3 | 829 (26.21) | 7.85 (5.25-11.82)* |
| | 4 | 560 (17.70) | 7.79 (5-12.01)* |
| | 5 | 64 (2.02) | 6.24 (3.73-7.71)* |
| **All patients** | - | - | 7.58 (5-11.66)* |
| **Pre-operative Systolic Blood Pressure <100mmhg** | | 474 (12.44) | 7.51 (4.75-12)* |
| **Pre-operative heart rate >90 beats per minute** | | 2302 (60.44) | 7.46 (4.86-11.68)* |
| **Pre-operative physiological shock** | | 334 (8.77) | 7.51 (4.66-12.16)* |
| **Pre-operative Lactate >2.0mmol/litre** | | 2372 (63.14) | 7.26 (4.75-11.50)* |
| **Surgical Approach** | | | |
| **Open** | | 2913 (76.48) | 7.53 (5.11)* |
| **Laparoscopic** | | 607 (15.94) | 7.46 (5.13)* |
| **Laparoscopic converted to open** | | 279 (7.32) | 8.25 (5.61)* |
| **Laparoscopic assisted** | | 10 (0.26) | 7.66 (4.45)* |

Values in parentheses are percentages unless indicated otherwise; * values are median (interquartile range)

### *3.5.2 Time of admission and time to theatre*

The numbers of patients admitted with perforated peptic ulcer disease during the day was reasonably stable, with a slightly greater number occurring in the 12

hours between 1200-2359 (0800-1159; 631 (16.6%), 1200-1759; 1064 (27.9%), 1800-2359; 1070 (28.1%) and 0000-0759; 1044 patients (27.4%)).

Within two hours of admission to hospital, 2.5% of patients had reached theatre. By four hours after admission, 14.9% of patients had arrived in theatre and 53.9% by eight hours. By sixteen hours only 7.8% of patients had not had surgery (Figure 1). The median time to theatre was the greatest (8.05 hours) in those admitted between 0000-0759 hours. In those admitted from 0800-1159, median time to theatre was 7.3 hours (Figure 2).

*Figure 1: Histogram demonstrating time from admission to theatre in patients having emergency laparotomy for perforated peptic ulcer disease*

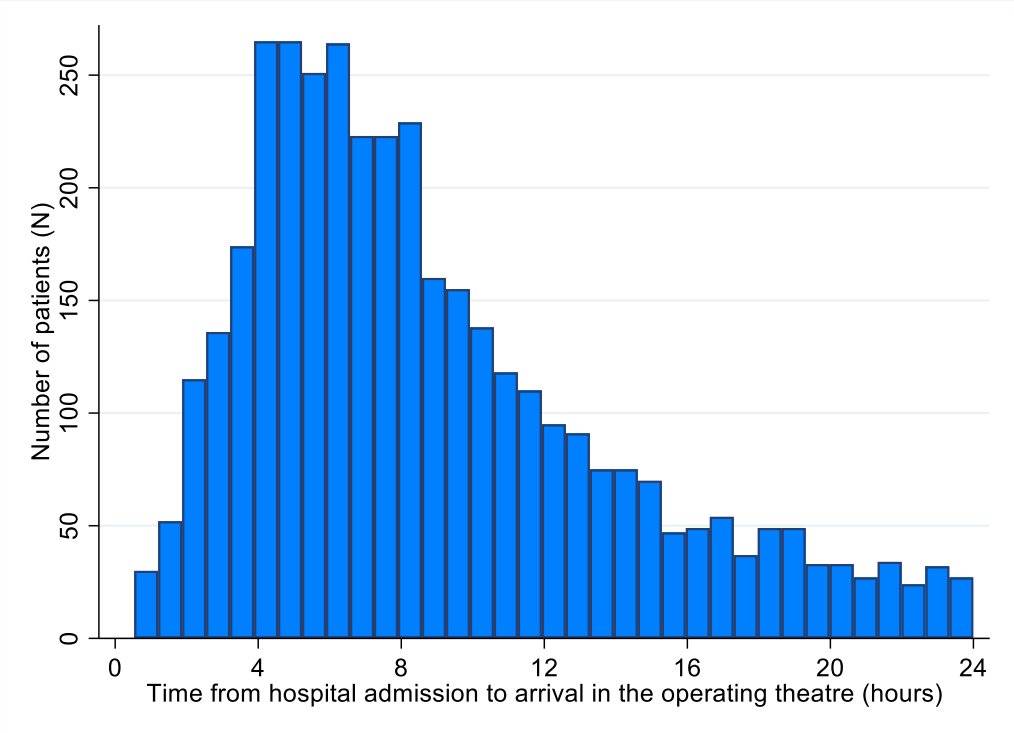
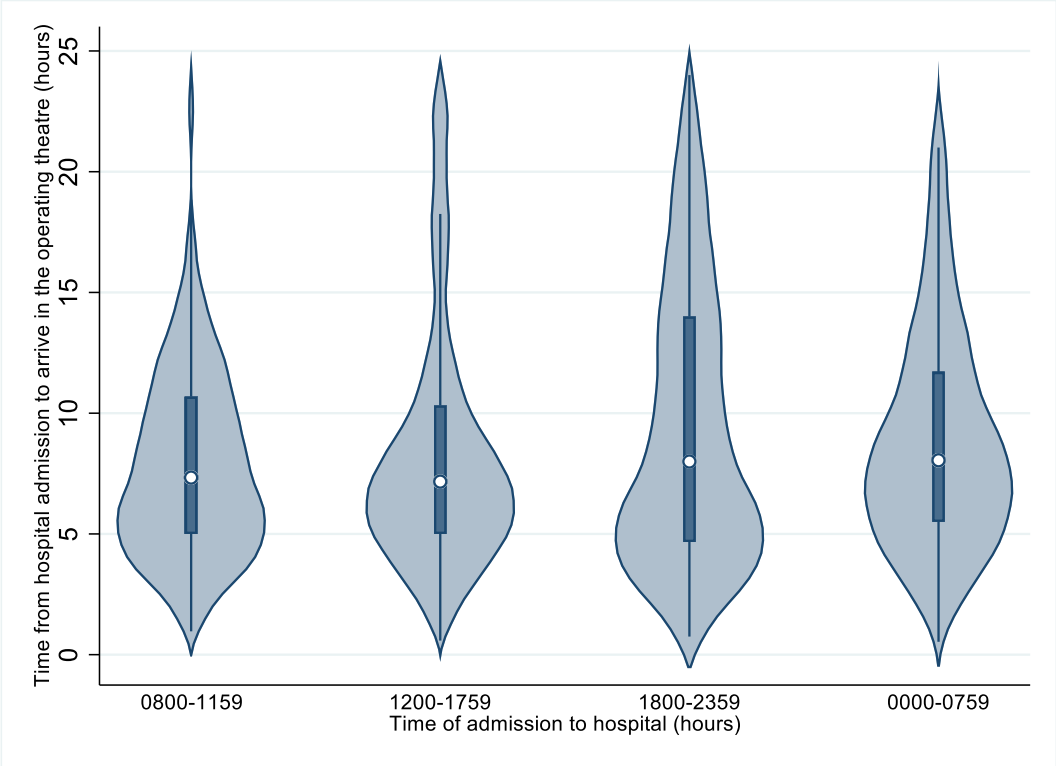


*Figure 2: Violin plot demonstrating time from admission to theatre for patients with perforated peptic ulcer by time of the day admitted to hospital.*

*A violin plot combines information that is usually available in both boxplots and histograms. The circle in the middle of each bar demonstrates the median value surrounded by the interquartile range. The middle line represents the upper and lower values of the data. The curved area around the middle rectangle reveals the distribution of the data. The data in this figure are unimodal as there is only one widening around the middle rectangle*




### *3.5.3 Outcomes*

Crude 90-day mortality was 10.6%. Unadjusted odds of death by 90 days increased by 3% for every hour surgery was delayed after admission (unadjusted OR 1.03, 95% Cl 1.01-1.05). This association remained with confounder adjustment (OR 1.04, 95% Cl 1.02-1.07) with an increased odds of mortality of 4% per hour of increasing time from admission to theatre (Table 4). When dividing time to theatre into quartiles, in patients who arrived to theatre in the

quickest quartile group (within 5 hours of admission) the mortality rate was 9.6%. This compares to 13% in the patients who had their operation within the slowest quartile (>11.5 hours) of study cohort.

The relationship between time to theatre and mortality in patients with each of the pre-operative physiological derangements defined previously (tachycardia, hypotension and raised serum lactate) was investigated. On adjusted analysis, death by 90 days increased by 4% for every hour after admission a patient arrived in theatre in those with pre-operative tachycardia (n=2298, adjusted OR 1.04 95% Cl 1.02-1.07, Table 5). In those with hypotension before operative intervention (n=474), a 5% increase in the odds of death by 90 days per hour delay to theatre was seen (n=474, adjusted OR 1.05 95% Cl 1.01-1.09, Table 3). A serum blood lactate of >2.0mmol/litre was recorded in 2372 patients before surgery and was associated with an increase odds of death by 90 days of 3% per hour post admission (Table 5).

Pre-operative physiological shock, defined as both systolic blood pressure less than 100mmHg and heart rate greater than 90 beats per minute (Opal et al., 2016), was present in 334 patients. In this group, unadjusted death at 90 days increased by 4% for every hour delay in reaching theatre. This increase remained at 6% odds of death per hour delay after adjustment for confounders (OR 1.06 (95% Cl 1.01-1.11) (Table 5.)

*Table 4: Logistic regression analysis of increasing time to theatre and 90-day mortality for all patients who had an Emergency Laparotomy for perforated peptic ulcer disease (N-3809).*

| 90-day mortality rate (%) | Unadjusted Odds Ratio | P value | Adjusted Odds Ratio | P value |
|---|---|---|---|---|
| 10.61 | 1.03 (1.01,1.05) | 0.001 | 1.04 (1.02,1.07) | <0.001 |

Values in parentheses are 95 per cent confident intervals

*Table 5: Logistic regression analysis of increasing time to theatre and 90-day mortality in patients with physiological derangements pre-operatively who had an Emergency Laparotomy for perforated peptic ulcer disease.*

| | 90-day mortality rate (%) | Unadjusted Odds Ratio | P value | Adjusted Odds Ratio | P value |
|---|---|---|---|---|---|
| **Pre-operative tachycardia (N=2298)** | 12.90 | 1.03 (1.01,1.05) | 0.004 | 1.04 (1.02,1.07) | 0.001 |
| **Pre-operative hypotension (N=474)** | 31.01 | 1.03 (1.00,1.07) | 0.057 | 1.05 (1.01,1.09) | 0.016 |
| **Pre-operative raised lactate (N=2372)** | 13.38 | 1.03 (1.01,1.05) | 0.008 | 1.03 (1.01,1.07) | 0.004 |
| **Pre-operative physiological shock (n=334)** | 31.44 | 1.04 (1.00,1.08) | 0.054 | 1.06 (1.01,1.11) | 0.018 |

Values in parentheses are 95 per cent confident intervals

## 3.6 Discussion

This is the largest study to date investigating the association between time to theatre and post-operative mortality in patients with perforated peptic ulcers. This study reports 90-day mortality of less than 11% in patients who have an Em Lap for perforated peptic ulcer disease in England and Wales. This compares favourably to studies from mainland Europe where death by 90-days are reported between 19.2% and 29.8% (Thorsen et al., 2017; Lolle et al., 2016). The perforated peptic ulcer cohort has been used to investigate the association between length of time to theatre and mortality, as it is known that this pathology is associated with peritoneal contamination and risk of developing intra-abdominal sepsis if left untreated (Boey et al., 1982; Fong, 1983). Perforated peptic ulcer is clearly defined, has a significant mortality and the treatment does not usually involve an initial period of conservative treatment unlike some other causes of abdominal sepsis. It is an ideal model in which to study the importance of the relationship between surgical source control and outcome.

This chapter reports quicker times from admission to theatre for patients in this study compared to previous similar studies (Buck et al., 2013). Buck *et al* suggest that by twelve hours over 30% of their cohort had not had their operation. By twelve hours post admission just 20% of this cohort had not reached theatre. These improved results may reflect increased awareness of acute surgical illness following the implementation of NELA and publicity around the "Surviving Sepsis Campaign." The NELA reports highlight improvements in time from admission to antibiotics administration in patients with peritonitis (NELA Project Team, 2018b) and an increase in the proportion

of Em Lap patients arriving in theatre in a time period appropriate to their clinical condition (NELA Project Team, 2018b).

When analysing the whole cohort, the adjusted odds of death increased as time to theatre rose, 3% per hour delay to theatre. These figures demonstrate that a patient (regardless of pre-morbid state) who arrives in theatre within 6 hours is 18% more likely to die by 90 days compared to a patient who has their operation within 1 hour. Similarly, patients who waited for 12 hours to arrive in theatre are 36% more likely to die than those who have expedited operative intervention.

These findings reflect those of Buck *et al* who analysed a similar cohort of patients having Em Lap exclusively for perforated peptic ulcer disease from Danish registry data. They reported a decreased probability of survival by 2% for every hour delay in reaching theatre (Buck et al., 2013). However, they did not describe how they calculated time from admission to surgery and included patients who had their operation more than 24 hours post admission. Additionally, in the risk adjustment, they reduced continuous variables, such as age and shock, to dichotomous outcomes, giving a less rigorous model.

Severity of physiological derangement varies among patients with perforated peptic ulcer disease but its presence is important and urgent source control all the more important in those cases. Patients with pre-operative physiological derangement were examined which suggested that there is an increased odds of death across all of the physiological derangement subgroups (Table 5). In patients with tachycardia there is a 4% increased risk odds of death per hour

with increases in patients with hypotension to 5% and the largest effect is seen in the group of patients who have pre-operative shock; 6% increased odds of 90-day mortality per hour delay on adjusted risk analysis. In this unwell group of patients these findings demonstrate that even in patients that arrive in theatre within 3 hours of admission, their risk of death is 18% higher than those within one hour. Furthermore, the risk of death rises even more to 36% and 72% for patients arriving in theatre at 6 and 12 hours, respectively, post admission. This is in keeping with a report from Japan which found that survival rate fell for every 2 hours delay to theatre (Azuhata et al., 2014). While not exclusively examining patients with perforated peptic ulcer disease, the Japanese study had a robust protocol with all patients having gastrointestinal perforation confirmed on Computerised Topography (CT) scan associated with septic shock. Additionally, they report that none of their patients who had their operation greater than six hours post admissions survived to 60 days.

Here, it is demonstrated that delay to theatre in patients with perforated peptic ulcer disease is independently associated with death by 90 days. It is suggested that patients with perforated peptic ulcer should have expedited access to theatre regardless of time of day. These patients should be treated with the same clinical urgency almost akin to those with ruptured aneurysmal disease. It is well documented that those with ruptured aneurysms should take priority with regards to use of emergency staffing and operating space (National Confidental Enquiry into Patient Outcome and Death, 2005) and these cases are considered the most urgent within the surgical division. While hourly delay to theatre for ruptured aneurysmal disease has not been specifically described in the published

literature, a crude mortality rate of 36% is reported (National Confidental Enquiry into Patient Outcome and Death, 2005), which is not dissimilar from this crude 90-day mortality rate of 31% in those with perforated peptic ulcer disease and pre-operative shock.

These findings support the most recent clinical guidance from The RCS in the "High Risk General Surgical Patient: Raising the Standard" document. Recommendations suggest that source control for patients with intra-abdominal sepsis, complicated by septic shock, should be within three hours and for those with sepsis without shock, arrival in theatre within 6 hours (The Royal College of Surgeons (Eng), 2018b).

It is not possible to define the cause for delays to theatre as this is not collected by NELA, but patterns emerge. One previous small Japanese study suggested that availability of surgeons and operating theatre space are the principle cause for delay (Azuhata *et al*, 2014). NELA demonstrates that delays incurred during the referral pathway from the Emergency Department to the point of senior surgical decision making also contribute significantly. Therefore, clear communication between Emergency department doctors and surgeons is advocated as well as sufficient prioritisation of surgical resources in the form of surgeon and theatre space to ensure timely care. A clear protocol can assist (Huddart et al., 2015). This is echoed by the key process measures recommended by the NELA reports; that "prioritisation of access is given to emergency surgical patients ahead of elective patients whenever necessary as significant delays are common and affect outcomes."

The strengths of this study are that it is a nationwide, multicentre centre, prospectively maintained database study linked with an externally validated mortality register. This is the largest study to date addressing this issue. The audit collects a wide range of variables and information allowing for confounder adjustment to be performed. Risk adjustment for potential patient factors was performed. This is in attempt to negate individual clinical patient factors (such as co-morbidity and age) that are known to impact on survival.

There are some limitations to this study. Case ascertainment was estimated at 65-70% in first two years of the audit (NELA Project Team, 2015b, 2016), which may have led to under or overestimation of adverse outcomes. Case ascertainment rates have increased subsequently. NELA does not collect data on duration of symptoms prior to presentation to hospital. The risk scoring tool uses some preoperative physiological values from when the patient is first reviewed by either the surgical or anaesthetic team. These risk scores may deteriorate if their Em Lap was delayed for any reason. Alternatively, if there was improvement after resuscitation there may be some overestimation of risk and this could dilute the effect of other factors in the risk adjustment model. In the fourth year of NELA data collection, questions on timing of antibiotic administration were introduced. It was not possible to include antibiotics in the risk adjustment model due to large amounts of missing data. It is hoped that with increasing awareness of the importance of antibiotics that data quality will improve in the next year of data collected to allow for further work in this area.

Time to theatre was calculated using the "time admitted to hospital" variable and "time into theatre" variable. There is no definition provided nationally as to what time should be recorded as the "admission time." Some hospitals may be recording this as time the patient arrived in the Accident and Emergency department while others may take this value as the time when the surgical team admitted the patient to the surgical unit. This lack of definition has been highlighted to the NELA project team to provide clarity going forward.

This is an observational study and results can be suggestive of associations but not causality whilst the possibility of residual confounding cannot be excluded.

## 3.7 Conclusion

Mortality by 90 days is independently associated with time from admission to hospital to arrival in theatres for source control among patients with perforated peptic ulcer disease. The risk increases on an hourly basis and the greatest risk of death was seen in patients with shock. Clinical teams should strive to get all suitable patients with perforated ulcer to theatre as soon as possible regardless of time of day due to rising mortality per hour.

## 4. Impact of Consultant Surgeon Special Interest on Morality following Emergency Laparotomy

## 4.1 Chapter Focus

This chapter describes the elective special interests of the consultant surgeons who are responsible for the care of patients having Em Lap in England and Wales.

This chapter reports the association between post-operative outcomes and special interest of a consultant surgeon when the area of intra-abdominal pathology is distinct from said special interest.

## 4.2 Abstract


***Background***

Patients with pathology of the gastrointestinal tract requiring Em Lap will be managed by general surgeons with an elective special interest focused on either the upper or lower GIT. The aim was to investigate the impact of special interest on mortality after Em Lap.

***Methods***

Adult patients having Em Lap with either colorectal or gastroduodenal surgery were identified from the NELA database and grouped according to operative procedure. Outcomes included all cause 30-day mortality, length of stay and return to theatre. Logistic and Poisson regression were used to analyse the association between consultant specialist interest and the three outcomes.

***Results***

33,819 patients (28,546 Colorectal, 5,273 UGI) were included. Patients who had colorectal procedures performed by a consultant without a special interest in colorectal surgery had an increased adjusted 30-day mortality (OR 1.23, 95% CI 1.13-1.33). Return to theatre also increased in this group (OR 1.02, 95% Cl 1.05-1.20). UGI procedures performed by non-UGI special interest surgeons carried an increased adjusted risk of 30-day mortality (OR 1.24. 95% Cl 1.02 to 1.53). Return to theatre was not increased (OR 0.88, 95% Cl 0.70-1.11).

***Conclusion***

Em Lap performed by a surgeon whose special interest is not in the area of the pathology carries an increased risk of mortality at 30 days. This finding has potential significant implications for emergency service configuration, training and workforce provision, and should stimulate discussion amongst all stakeholders.

## 4.3 Introduction

The patients having Em Lap are markedly heterogeneous in relation to presentation, co-morbid status and pathological findings (Saunders et al., 2012; NELA Project Team, 2015a, 2016, 2017). A range of operations are performed at time of Em Lap. Traditionally, general surgical training has always produced a surgeon who is able to manage an unselected general surgical take and who has the technical skills to deal themselves with the vast majority of conditions found at Em Lap.

Competency in Emergency General Surgery (EGS) procedures is required for all UK surgical trainees prior to obtaining Certification of Completion of Training (CCT) in General Surgery (Joint Committee on Surgical Training, 2013), regardless of special interest development. However, many will continue to deepen a special interest once in a consultant post, leading to an elective practice focused, sometimes exclusively, in one area and an emergency practice at odds with this. In many hospitals EGS may be provided by consultants with oesphago-gastric, hepatobiliary, colorectal, endocrine, breast and vascular elective special interests (NELA Project Team, 2014b). Smaller hospitals may still rely heavily on non-gastrointestinal special interests for EGS provision (NELA Project Team, 2014b).

The aim of this analysis is to determine the impact of specialist interest of operating surgeon on outcomes and mortality after Em Lap in England and Wales.

## 4.4 Methods

### *4.4.1 Study Population*

Adult patients who had an Em Lap and were entered into the NELA database between December 2013 and November 2016 were included in this study.

For the purpose of this study, the cohort was analysed according to operative procedure. Patients included had an Em Lap as either a "Colorectal Procedure" or an "Upper Gastrointestinal Procedure (UGI)" as their first, main surgical procedure after admission. Patients were excluded if they had incomplete data for variables and outcomes required for analysis (1653 (4.6%) total cases; 641 colorectal, 1012 UGI.)

Patients were classed as having had a "Colorectal Specialty Procedure" if they had Em Lap leading to right hemicolectomy, left hemicolectomy (including anterior resection and sigmoid colectomy), subtotal or panproctocolectomy, Hartmann's procedure, stoma formation or stoma revision. Patients were classed as having had an "UGI Specialty Procedure" if they had Em Lap leading to peptic ulcer suture or repair of perforation, peptic ulcer under-running of bleeding peptic ulcer, gastrectomy (partial or total) or other gastric surgery. Patients with small bowel pathology were not included as this was not deemed to be either a colorectal or UGI specific procedure.

### *4.4.2 Data Management and Study Variables*

The main exposure variable of interest was consultant surgeon specialist interest. NELA defines a consultant surgeon as; "a surgeon whose name appears

on the specialist register and is appointed as a substantive, fixed term or honorary consultant within the NHS" (NELA Project Team, 2018a). "Special interest" of a consultant was defined as an area within the scope of general surgery in which a consultant focuses their elective practice, for example breast or colorectal surgery (The Speciality Advisory Committee for General Surgery, 2013b).

When a case is entered on the NELA database, the consultant responsible for their care and operation is entered by the hospital alongside their General Medical Council (GMC) registration number. The special interest of the responsible consultant is entered by the hospital and linked to their GMC number. The GMC number and personal details are fully anonymised prior to analysis. This anonymization means that it is not possible to tell how long a surgeon has been a consultant and therefore "experience in role" was not included as a variable in the risk adjustment model. "Colorectal consultants" were those with a Colorectal special interest. Oesphago-gastric and hepatobiliary special interest surgeons were classified together as "Upper gastrointestinal (UGI) surgeons", as it is the latter which is the special interest defined by the General Surgery curriculum (ISCP (Intercollegiate Surgical Curriculum Programme), 2016). All other special interests (Breast, Vascular, Endocrine, Transplantation) were classified as "non-special interest" for the purpose of this analysis.

Data on age, sex, pre-operative ASA grade, pre-operative predictive mortality (derived from Portsmouth-Physiological and Operative Severity Score for the

enumeration of Mortality and morbidity (POSSUM) score) (Prytherch et al., 1998) and morbidity (P-POSSUM) (Copeland et al., 1991), grade of senior operating surgeon, the specialist interest of the consultant surgeon responsible for the patients care were extracted and whether the patient was directly admitted to a critical care unit post-operatively.

The P-POSSUM score is a model used to estimate the short-term risk of death after emergency bowel surgery (Prytherch et al., 1998). This score is presented as a percentage risk of death by 30 days. It calculated using patient specific data including the patient's demographics, physiology (heart rate, systolic blood pressure), cardiac and respiratory signs, serum renal function, serum white blood cell count and haemoglobin, the GCS score and predictions of the operative severity and blood loss (Copeland et al., 1991; Prytherch et al., 1998). It has been included in the risk adjustment model to account for severity of illness and physiological derangement in the preoperative stage.

Previous reports from this same cohort of Em Lap patients have demonstrated that there is no increase in mortality associated with case volume, hospital size or hospital configuration (Oliver et al., 2018). Therefore, these structural factors were not included in the risk adjustment model.

### *4.4.3 Outcomes Measures*

The outcomes for this study included all cause 30-day mortality, return to theatre within the same hospital admission and length of stay in acute hospital setting. Length of stay in hospital is defined as time from admission to date of discharge

or death. All-cause 30-day mortality was derived through linkage of the dataset with the ONS death register.

on death by 90 days (90-day mortality outcome) were not available from the ONS at the time this analysis was performed (December 2017.) When the data was available, this analysis had been presented internationally and also accepted for publication therefore only 30-day mortality has been presented in this chapter.

### *4.4.4 Statistical Analysis*

Descriptive data is presented as mean (± standard deviation), median (IQR) or number (%) as appropriate. To test the association between surgeon special interest and mortality and return to theatre outcomes, logistic regression was initially performed.

As previously described in Chapter 3; logistic regression has been used as the mortality by 30 days and return to theatre outcomes are both dichotomous variables and multiple independent variables were available for risk adjustment.

Propensity score analysis has not been performed, as this form of analysis provides population-averages, which are of interest when trying to replicate a randomised control trial which is not the case in this analysis. Additionally, a regression analysis provides (conditional) relative increases in risk.

Both unadjusted OR and OR adjusted for the following selected covariates: patient age, sex, ASA grade, P-POSSUM predicted mortality/morbidity and grade of surgeon are presented. Direct admission to a critical care unit was added as a post hoc covariate into logistic regression models. Only patient age and P-POSSUM scores were modelled as continuous. Due to collinearity, only one of the P-POSSUM variables were used in each model as appropriate. Inclusion of variables in the risk adjustment model was based on clinical rather than statistical significance, therefore a likelihood ratio chi-squared test is not presented.

Separate analyses for colorectal versus non-colorectal surgeon and upper GI versus non-upper GI surgeons for their respective procedures are presented. Results are displayed with 95% CI.

For length of stay, Poisson regression was performed with the same covariates listed above. Poisson regression is used to predict a dependent variable that consists of "count data" given one or more independent variables. In this analysis, length of stay has been “counted” in days, hence the selection of this test. Results for this analysis are presented as incident rate ratios (IRR) with 95% CI.

Subgroup analyses performed included: 1) excluding non-GI surgeons from the analysis; 2) limiting analysis to National Confidential Enquiry into Perioperative Deaths (NCEPOD) category 1 patients; 3) limiting analyses to consultant surgeons only; 4) removal of “Other Gastric surgery” patients from the UGI

cohort group. Subgroup analyses included procedures performed on patients aged 65 years or above.

## 4.5 Results

### *4.5.1 Patient Characteristics*

The study cohort contained 28,546 patients who had an Em Lap and a colorectal procedure and 5,273 patients who had an Em Lap and an UGI procedure in 195 hospitals in England and Wales. The baseline characteristics for each group are shown in Table 6

### *4.5.2 Operative procedures*

The distribution of operations performed are shown in Tables 7 and 8. Consultant special interest is shown in Figure 3 and 4. Right hemicolectomy was the most common colorectal procedure performed followed by Hartmann's procedure. The most common UGI procedure was suture or repair of perforated peptic ulcer followed by patients having "other gastric surgery." For this group, further details on the actual procedure performed was not available. Consultant surgeons were recorded as the senior surgeon in the majority of cases. Consultants were present in theatre in 91% of all colorectal procedures and in 80% of all UGI procedures (Table 6).

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*Table 6: Characteristics of patients undergoing colorectal and upper gastrointestinal surgery according to special interest of consultant*

| | **Colorectal procedures** | | **UGI procedures** | |
|---|---|---|---|---|
| | **Colorectal consultant (*n* = 16 889)** | **Non-colorectal consultant (*n* = 11 657)** | **UGI consultant (*n* = 1771)** | **Non-UGI consultant (*n* = 3502)** |
| **Age (years)*** | 63.7 (17.3) | 65.6 (16.1) | 60.2 (18.1) | 58.4 (18.2) |
| **Men** | 8262 (48.9) | 5684 (48.8) | 981 (55.4) | 2101 (60.0) |
| **ASA fitness grade** | | | | |
| I | 1468 (8.7) | 1059 (9.1) | 280 (15.8) | 715 (20.4) |
| II | 6441 (38.1) | 3931 (33.7) | 514 (29.0) | 988 (28.2) |
| III | 6152 (36.4) | 4074 (34.9) | 491 (27.7) | 933 (26.6) |
| IV | 2600 (15.4) | 2337 (20.0) | 427 (24.1) | 734 (21.0) |
| IV | 228 (1.3) | 256 (2.2) | 59 (3.3) | 132 (3.8) |
| **P-POSSUM scores*** | | | | |
| Predicted mortality* | 17.07 (21.72)* | 20.91 (24.39)* | 22.47 (26.64)* | 23.35 (27.62)* |
| Predicted morbidity* | 71.10 (22.46)* | 74.54 (22.09)* | 73.71 (23.45)* | 74.74 (22.73)* |
| **Consultant present in theatre** | 15 440 (91.4) | 10 474 (89.9) | 1442 (81.4) | 2758 (78.8) |

Values in parentheses are percentages unless indicated otherwise; *values are mean (standard deviation). UGI, upper gastrointestinal.

*Table 7: Distribution of Colorectal procedures performed in study cohort*

| | **Colorectal consultant (*n* = 16889)** | **Non-colorectal consultant (*n* = 11657)** |
|---|---|---|
| Left hemicolectomy (including sigmoid colectomy and anterior resection) | 1349 (8.0) | 809 (6.9) |
| Right hemicolectomy (including ileocaecal resection) | 5032 (29.8) | 3737 (32.1) |
| Subtotal or Panproctocolectomy | 2413 (14.3) | 1328 (11.4) |
| Hartmann's procedure | 4739 (28.1) | 3868 (33.2) |
| Other colorectal resection | 739 (4.4) | 483 (4.1) |
| Stoma formation | 2315 (13.7) | 1294 (11.1) |
| Stoma revision | 302 (1.8) | 138 (1.2) |

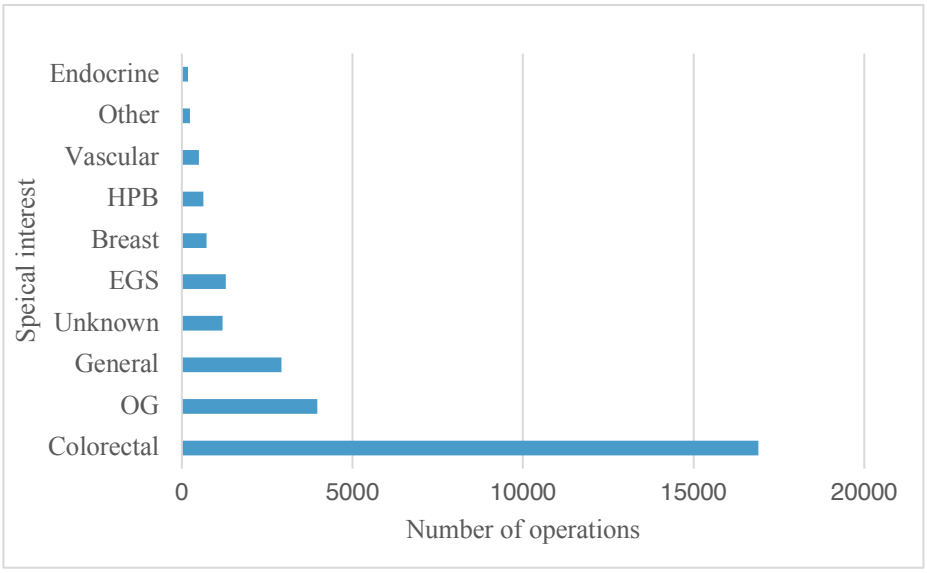
Values in parentheses are percentages.

*Table 8: Distribution of Upper gastrointestinal procedures performed in study population*

| | **UGI consultant (*n* = 1771)** | **Non-UGI consultant (*n* = 3502)** |
|---|---|---|
| Peptic ulcer: suture or repair of perforation | 1001 (56.5) | 2732 (78.0) |
| Peptic ulcer: oversew of bleed | 175 (9.9) | 381 (10.9) |
| Partial or total gastrectomy | 78 (4.4) | 57 (1.6) |
| Other gastric surgery | 517 (29.2) | 332 (9.5) |

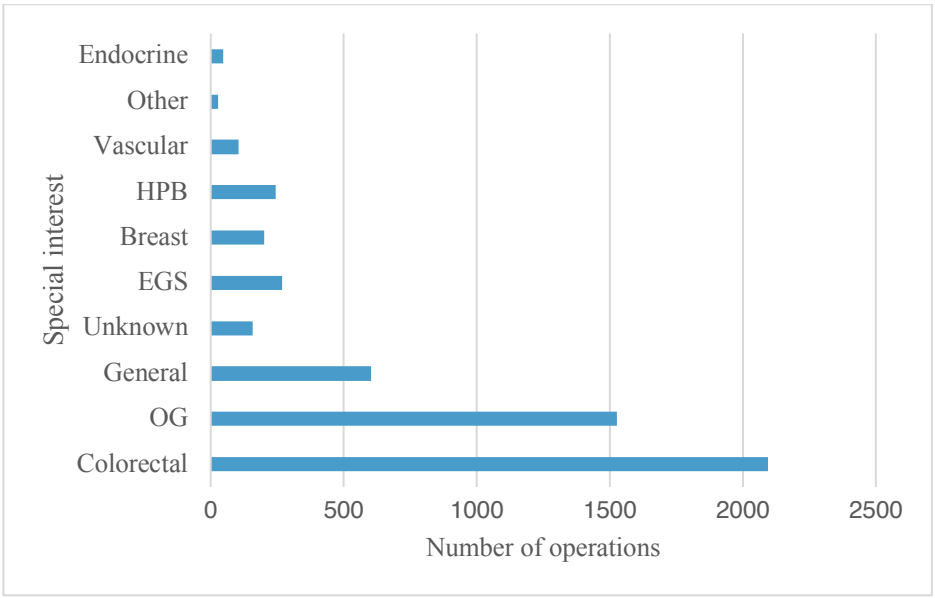
Values in parentheses are percentages. UGI; Upper gastrointestinal

*Figure 3: Bar chart demonstrating distribution of consultant surgeon special interest: Colorectal Procedures*




HPB; Hepato-Pancreato-Biliary, EGS; Emergency General Surgery. OG; Oesphago-Gastric

*Figure 4: Bar chart demonstrating distribution of consultant surgeon special interest: Upper gastrointestinal procedures*




HPB; Hepato-Pancreato-Biliary, EGS; Emergency General Surgery. OG; Oesphago-Gastric

### *4.5.3 Outcomes*

All cause, 30-day mortality for patients having a colorectal procedure was 11.1% and 12.2% for patients having an UGI procedure. Analysis with special interest of consultant as main variable was performed for each procedure group (Table 9 and 10). For colorectal procedures, there was an increased risk of mortality when operated on by a non-colorectal specialist interest surgeon (unadjusted OR 1.50 95% Cl 1.40-1.62). This increased risk remained following adjustment for potential confounders (adjusted OR 1.23; 95% Cl 1.13-1.33). Return to theatre was also found to be increased in those having Em Lap for colorectal conditions performed by non-colorectal special interest surgeons (unadjusted OR 1.20; 95% Cl 1.10-1.29), and again remained significant with adjustment for confounders (adjusted OR 1.13; 95% Cl 1.05-1.20). There was a small increase in length of stay if operations were conducted by non-colorectal special interest surgeons (IRR 1.02; 95% CI 1.02 to 1.03).

For UGI procedures, a possible increased risk of 30-day mortality was seen if the operative procedure was performed by non-UGI special interest surgeon although the confidence interval included a mortality reduction (unadjusted OR 1.16 95% Cl 0.97-1.39). This risk of 30-day mortality increased slightly when adjustment for confounders was performed (adjusted OR 1.24 95% Cl 1.02-1.53). Special interest of consultant operating did not appear to have an impact on return to theatre although estimates were more uncertain than the colorectal analysis (adjusted OR 0.89, 95% Cl 0.70-1.12). However, LOS was shorter when patients were operated on by a non-UGI surgeon on adjusted analysis (IRR 0.91, 95% CI 0.90 to 0.92).

*Table 9: Logistic and Poisson regression analysis of non-colorectal* versus *colorectal special interest*

| | **Non- colorectal consultant** | **Colorectal consultant** | **Unadjusted OR/IRR** | **Adjusted OR/IRR** |
|---|---|---|---|---|
| 30-day mortality (%) | 14.2 | 9.5 | 1.50 (1.40, 1.62) | 1.23 (1.13, 1.33) |
| Return to theatre (%) | 9.8 | 8.8 | 1.20 (1.10, 1.29) | 1.13 (1.05, 1.20) |
| Median LOS (days) | 16 | 16 | 0.99 (0.98, 0.99) | 1.02 (1.02, 1.03) |

Values in parentheses are 95 per cent confidence intervals. Logistic regression was used for analysis of mortality and return to theatre, and Poisson regression for length of hospital stay (LOS), with results expressed as odds ratios (ORs) and incident rate ratios (IRRs) respectively.

*Table 10: Logistic and Poisson regression analysis of non-upper gastrointestinal* versus *upper gastrointestinal special interest*

| | **Non-UGI consultant** | **UGI consultant** | **Unadjusted OR/IRR** | **Adjusted OR/IRR** |
|---|---|---|---|---|
| 30-day mortality (%) | 12.72 | 11.14 | 1.16 (0.97, 1.39) | 1.24 (1.02, 1.53) |
| Return to theatre (%) | 6.7 | 7.0 | 0.87 (0.70, 1.10) | 0.89 (0.70, 1.12) |
| Median LOS (days) | 10 | 12 | 0.89 (0.88, 0.90) | 0.91 (0.90, 0.92) |

Values in parentheses are 95 per cent confidence intervals. UGI, upper gastrointestinal. Logistic regression was used for analysis of mortality and return to theatre, and Poisson regression for length of hospital stay (LOS), with results expressed as odds ratios (ORs) and incident rate ratios (IRRs) respectively.

### *4.5.4 Subgroup analyses*

When non-GI special interest surgeons were removed from the analyses, (Vascular, Endocrine, Breast, Emergency, General and Unknown) an increased risk of death remained in the colorectal procedure group (30-day mortality; adjusted OR 1.28, 95% CI 1.14-1.43). For UGI procedures the increase in risk of death was no longer significant, although estimates were wider, reducing the confidence in this outcome (adjusted OR 1.19, 95% Cl 0.91-1.15). No increased risk of return to theatre was seen in either procedural group once non-GI specialists had been removed from analyses although again confidence intervals were wide (colorectal adjusted OR 1.02, 95% Cl 0.91-1.15; UGI adjusted OR 0.96, 95% Cl 0.7-1.24).

The impact of special interest on the most urgent cases, booked as NCEPOD category 1 patients, was investigated. All surgical specialist interests were included in analyses. NCEPOD 1 priority was given to 5782 colorectal procedures and 216 UGI procedures. Adjusted risk of 30-day mortality was increased in the colorectal NCEPOD 1 group (adjusted OR 1.33, 95% Cl 1.04-1.69.). No significant increased risk of death was demonstrated in the NCEPOD 1 UGI group although confidence intervals were wide, likely from the low number of patients in this analysis (adjusted OR 1.67, 95% Cl 0.39-7.02).

Limiting analyses to consultant surgeons only and procedures performed on patients aged 65 years or above did not affect results. Additionally, removal of "Other Gastric surgery" patients from the UGI cohort group did not alter the statistical significance of results in this group.

## 4.6 Discussion

This study has shown that patients having Em Lap and emergency colorectal and UGI procedures have increased risk of death when the surgery is performed under the care of someone who does not have an elective special interest in the area of the pathology. Whilst there has been some work performed regarding this topic in the paediatric surgical population (Shah et al., 2016), the literature in the adult Em Lap population is sparse. Biondo *et al* investigated impact of surgical specialisation on patients having emergency colorectal surgery and concluded that specialisation in colorectal surgery improved morbidity, mortality and complication rates (Biondo et al., 2010). Furthermore a Scottish paper demonstrated decreased mortality and complications in patients who had emergency operations for diverticulitis performed by colorectal surgeons, however there was no evidence of risk adjustment in their analysis (Boyce et al., 2013).

Within this study mortality rates were 11% and 12% respectively for Colorectal and UGI procedures. These reported results compare favourably to previous literature. Prior to the implementation of NELA, multiple UK sources reported mortality rates of up to 15% in those who had Em Lap (Symons et al., 2013; Saunders et al., 2012). A similar mortality rate was seen in Denmark following a large population based study in those having emergency gastrointestinal surgery (Vester-Andersen et al., 2014). Furthermore, a 2009 Swiss study quoted mortality rates of 14% for patients having emergency colonic resections (Skala et al., 2009) while a recent European study has described 90-day mortality rates of up 19% for patients with perforated peptic ulcers following surgery (Thorsen

et al., 2017). Results from this study demonstrate an improvement in outcomes since those reported previously. This may be partly attributable to the implementation of NELA, which over the last three years has reported reductions in mortality rates for all patients undergoing Em Lap. This has been achieved through promotion of early identification of high-risk patients, adequate resuscitation, early radiology input, intra-operative consultant delivered care and postoperative stay in high dependency or intensive care units for all high-risk patients (NELA Project Team, 2015a, 2016, 2017).

Higher mortality rates in the groups who did not have their operation performed by a consultant with a special interest in the field are demonstrated in this study. Data available provided no firm explanation as to the cause of this difference. Contributing factors may be non-technical, such as delay in decision making in less familiar areas, reluctance to enter the abdomen when the pathology is outside the elective area of expertise, or technical, such as unfamiliarity with techniques for operating on organs not encountered in elective practice. However, when non GI specialist interest surgeons were removed from analysis, an increased risk of death and complications remained. A previous systematic review identified that subspecialisation of surgeon was associated with better outcomes (Chowdhury et al., 2007). While this paper included patients from all general surgical specialist interests in both the emergency and elective setting, they did find a statistically significant difference in outcomes (Chowdhury et al., 2007).

Within elective general surgery there has been a rapid shift towards specialist interest practice in the last 20 years. This move is supported by those in training (The Association of Surgeons in Training., 2015) and the majority of UK consultants in General Surgery affiliate themselves with subspecialty associations (Scott et al., 2008) (e.g. ACPGBI, AUGIS), whilst still contributing to Emergency General Surgery (EGS) as a significant part of their scope of practice (NELA Project Team, 2014b). EGS patients represent around half of the overall surgical workload (The Speciality Advisory Committee for General Surgery, 2013b). Approximately 80% of all general surgical deaths follow emergency admission (Pearse et al., 2006; Jhanji et al., 2008). Variation in outcome between units and individual surgeons has been flagged and the benefits of surgeons treating emergency conditions in their elective area of interest proposed (Watson et al., 2016; The Association of Surgeons in Training., 2015; The Royal College of Surgeons (Eng) and ASGBI, 2015). However, it was acknowledged that implementation of special interest specific on call would have implications for elective service provision (ACPGBI et al., 2015). Currently, approximately 20% of Emergency General Surgical units are running a speciality interest on-call, however this is rarely a 24/7 service (ACPGBI et al., 2015). It is not yet known whether these units report outcomes different from those employing the traditional unselected model.

Pressure of acute care has prompted increased ring-fencing of time in job plans for EGS (Lewis and Attwood, 2013), with some consultant posts being advertised with EGS as the sole, or major focus of the scope of practice (Pearce

et al., 2016). It is too early to know whether specialisation in EGS leads to improvement in outcomes.

This is the first report investigating the impact of special interest of consultant surgeon on outcomes after Em Lap in the United Kingdom. Special interest seems to have a significant impact on the risk of both return to theatre and 30-day mortality. The underlying causes for this observation cannot be deduced from this dataset, and are most likely multi-factorial and related to more factors than technical skills related to special interest. However, while control for all confounders possible from the dataset has been performed, and the effect seems to be real, residual confounding cannot be fully excluded. These findings have potential implications for configuration of emergency services and the workforce available to receive surgical emergencies. These findings may also have implications for training in general surgery and scope of practice thereafter. Whilst development of a special interest may have had an impact on elective outcomes, it may be desirable to support exposure to a greater range of elective procedures, so that surgeons participating in the unselected emergency take are exposed electively to colonic resection. Also, it is difficult to suggest a solution that will be feasible across the UK. Larger hospitals may have the capacity to have both UGI and colorectal special interest surgeons available to perform Em Lap in their area, but this may be much less practical in smaller hospitals, where there may not be enough surgeons to deliver this model. In addition, special interest emergency provision may have a considerable impact on elective services whatever the size of a hospital, doubling the workforce commitment to emergency care. There are not clear answers to these questions, but it is hoped

that this study will stimulate discussion amongst the profession, its professional associations, training bodies and other stakeholders, not least patients, whose outcomes may be affected by the special interest of the surgeon who performs their Em Lap.

This study has several strengths as a nationwide, multicentre, prospective audit linked with an externally validated national mortality data registry. The audit collects a wide range of variables and information allowing risk adjustment to be performed. Death by 30-days has been used as the main outcome. Short-term mortality is currently the most widely reported outcome after Em Lap and is the most commonly reported outcome in many other areas of healthcare research. However, the effects of postoperative morbidity extend long beyond the operative period and definitions of long-term outcomes are poorly defined. It may be that the current outcome data underestimates the burden of Em Lap to not only patients but also other healthcare and social systems (Khuri et al., 2005; Head et al., 2008; Moonesinghe et al., 2014).

There are some limitations to this study. Case ascertainment was estimated at 65-70% in first two years of the audit (NELA Project Team, 2015a, 2016), which may have led to under or overestimation of adverse outcomes. As it is not possible to access data on patients who were not included in the audit, no further comment can be made. However, case ascertainment rates have increased through each cycle of the NELA audit. Urgency code of surgery was not included as a potential confounder as when the raw data was interrogated there was a clear discrepancy between NCEPOD booking codes and the entered

timings of surgical intervention into the dataset. Data was not collected on the presence of sepsis within the Years 1-3 cohort and therefore could not be included into the risk adjustment model. Direct questions on sepsis have now been added into the data entry form and can be included in future analysis. Additionally, the risk scoring tools used are calculated pre-operatively when the patient is first reviewed by either the surgical or anaesthetic team. These risk scores may deteriorate if their Em Lap was delayed for any reason. Alternatively, if there was improvement after resuscitation there may be some over estimation of risk and this could dilute the effect of other factors in the risk adjustment model. While grade of senior surgeon operating was included in the risk adjustment model, it is not certain that this meant that consultant was the lead operator as the definition in the NELA dataset is that the "surgeon is present in theatre." However, one would hope that if a consultant were present, supervision would include stepping in and taking over from a junior colleague if there were difficulty or the procedure taking too long to the detriment of the patient. Additionally, as NELA only records data for patients who actually had Em Lap, the proportion of patients who were turned down for surgery because of fitness or patient choice is unknown. This is an observational study and as such associations can be can highlighted but causality not confirmed. Indeed, the underlying reasons for the observations in this paper are not clear and may still represent residual confounding.

## 4.7 Conclusion

Emergency laparotomy performed by a surgeon whose special interest is not in the area of the pathology carries an associated increased risk of return to theatre after surgery and of mortality by 30 days. This finding has potential significant implications for emergency service configuration, training and workforce, and should stimulate discussion amongst all stakeholders, including patients.

**5. Variation in Emergency Laparotomy Case Volume by Hospital Size and Geographical Area; Impact for Training.**

## 5.1 Chapter Focus

This chapter describes the number of Em Lap and procedures required for certification in general surgery occurring annually in England and Wales. These numbers are described by educational deanery and hospital size.

## 5.2 Abstract


***Background***

Management of an unselected emergency general take is one of the core elements of General Surgery. Certificate of completion of training in general surgery in the UK requires demonstration of competence in Em Lap and associated procedures for the treatment of peritonitis, obstruction, perforation etc. Whether trainees are gaining sufficient Em Lap experience has been debated in the literature. The aim was to quantify the numbers of Em Laps occurring in each deanery in England and Wales.

***Methods***

Data extracted from NELA between November 2013 and November 2017 was used, while numbers of general surgical trainees by deanery was gained from NHS Digital and Stats For Wales. Number of trainees, high volume centres and numbers of Em Lap, segmental colectomy, Hartmann's procedure, small bowel resection, repair of perforated peptic ulcer and adhesiolysis were calculated by deanery. Negative binominal regression analysis was performed.

***Results***

Across 14 deaneries, in 196 hospitals in England and Wales, 57 464 patients had an Em Lap followed by either a segmental colectomy, Hartmann's procedure, small bowel resection, repair of perforated peptic ulcer or adhesiolysis. There was significant inter deanery variation in total number of Em Laps performed. The greatest incidence of Em Lap operating was observed

in Health Education North West (IRR 1.69, 95% CI 1.67-1.70). Further variation in rates of cases were observed across all operative subgroups.

***Conclusion***

There is a significant difference between deaneries in Em Lap numbers and in the number of index procedures performed in the emergency setting. This information is important for trainees and trainers to proactively manage emergency general surgical training.

## 5.3 Introduction

Surgical training in the UK is entered after completion of 2 postgraduate foundation years of training (The British Medical Association, 2017). For those choosing general surgery, two years of core training (CT) is necessary before competitive entry into 6 years of higher surgical training (The Royal College of Surgeons (Eng), 2018a; ISCP (Intercollegiate Surgical Curriculum Programme), 2016).

Health Education England (HEE) (Health Education England, 2019), NHS Education for Scotland (NES) (NHS Education for Scotland, 2019), Health Education and Improvement Wales (HEIW) (Health Education and Improvement Wales, 2018) and the Northern Ireland Medical and Dental Training Agency (NIMDTA) (Northern Ireland Medical and Dental Training Agency, 2017) are responsible for implementing specialty training in accordance with GMC approved specialty curricula in the respective home nations. These organisations have smaller, local units that administer postgraduate training, known by different terms depending on home nations. The word "deanery" has been used in this chapter to refer to these training regions for simplicity.

There are 13 postgraduate deaneries in England, 4 in Scotland, 1 in Northern Ireland and 1 in Wales (Health Education England, 2018; The British Medical Association, 2019) (Table 1). Each of these deaneries covers a geographical area and includes a range of hospital Trusts which provide services according to size, with regional specialised services (e.g. major trauma) being delivered,

generally, in the larger hospitals in the region. As NELA only collects data in England and Wales, the deaneries in Scotland and Northern Ireland are not included in this study.

Doctors in higher surgical training will usually train within a single deanery, (The Royal College of Surgeons (Eng), 2018a) rotating between hospitals through a range of special interests in general surgery. These placements typically last 6 months (ISCP (Intercollegiate Surgical Curriculum Programme), 2016) and trainees will participate in the unselected emergency take in all placements.

The general surgery curriculum requires demonstration of competence in certain index procedures, defined as: 'operations which are either common or represent important areas of technical expertise' (The Speciality Advisory Committee for General Surgery, 2013b). There are also indicative numbers of index procedures to be performed by certification, so that the trainee may be exposed to a range of complexity and difficulty of cases to prepare them to be able to practice at the level of a day 1 consultant in General Surgery. One of these index procedures is Em Lap, with an indicative 100 Em Laps to be recorded by CCT. It is recognised that competence could be achieved with fewer cases but meeting the numbers does not, in itself, imply competence

In addition to the 100 Em Lap, there are indicative numbers of 5 Hartmann's procedures and 20 segmental colectomies to be achieved by the end of training period. These can either be supervised or performed independently. Currently

there are no set requirements in the curriculum for small bowel resection, adhesiolysis or drainage of intra-abdominal sepsis.

Some report that trainees exceed these indicative numbers by the end of training (Allum et al., 2013) but Thomas *et al* found that only 67% of general surgical trainees reached the indicative target (Thomas et al., 2015b). These findings are supported by a meta-analysis which concluded that there is a lack of robust literature detailing the operative experience of general surgical trainees not only in the UK but also internationally (Elsey et al., 2017). There is no study from a national database reporting the numbers of Em Lap and associated common abdominal emergency procedures.

The aim was to quantify the numbers of specific emergency operations, in those index procedures required for certification, that occur in hospitals in England and Wales and to describe these figures by deanery and hospital size.

## 5.4 Methods

### *5.4.1 Study population*

Adult patients who had an Em Lap and were entered into the NELA database between December 2013 and November 2017 where initially extracted from the database. Patients who had an Em lap and a Hartmann's procedure, segmental colectomy, small bowel resection, perforated peptic ulcer, or adhesiolysis were included. These procedures were chosen to reflect the competencies required for certification in general surgery and the most common emergency general surgical procedures that are described in the NELA annual reports.

The number of general surgical trainees, by deanery, was gained from The NHS Digital workforce statistics for English Educational Deaneries (NHS Digital, 2019) and from The Welsh Government, "Stats for Wales" (Stats for Wales, 2019) for the period May 2013-May 2019. These are freely available for public use via the NHS Digital and Stats for Wales's websites' and are updated on a monthly basis.

### *5.4.2 Data Management and Study Variables*

"Segmental colectomy" was defined as; colectomy: left (including sigmoid colectomy and anterior resection, colectomy: right (including ileocaecal resection); colectomy: subtotal or panproctocolectomy and colorectal resection: other. Hartmann's procedure was not included in the colectomy subgroup and analysed as a separate subgroup.

Individual hospitals were grouped by deanery. Inclusion of hospitals in each deanery was based on information from the General Surgery Training section of each Health Education region website (Health Education East Midlands,

2016; Health Education East of England, 2017; Health Education Yorkshire and Humber, 2019; Health Education Wessex, 2018; Health Education Thames Valley, 2019; London and South East Postgraduate Medical and Dental Education, 2017; Health Education Kent Surry Sussex, 2019; Health Education North East, 2018; Health Education North West, 2019; Health Education and Improvement Wales, 2018; Health Education South West, 2019).

The total number of Em Laps and each procedure performed annually over the 4-year period was calculated for each individual hospital. To gain a more accurate picture of the number of Em Lap cases occurring, case ascertainment figures for each hospital were used to calculate the total number of Em Lap cases performed annually per hospital (number of cases entered into the NELA database/case ascertainment percentage x 100). These yearly hospital totals were then used to calculate a total number of Em Laps performed in each deanery over the study period (four years). Finally, a mean number of Em Lap per hospital for each deanery was calculated for the four-year period. While case ascertainment figures were used for the total number of Em Laps performed in each hospital, data from HES (used to generate case ascertainment figures) does not specify what procedures were performed, only that an Em Lap occurred. Therefore, for the subgroup procedural analysis, only cases entered into NELA database have been used. The same methodology as described applies. Additionally, due to issues with linking of data from Welsh sources, case ascertainment was only available for the fourth year of the data, therefore calculations for Welsh hospitals use the case numbers entered into the NELA database.

Hospital volume was defined by dividing hospitals into quartiles based on the total number of Em Lap cases. The number of Em Laps each hospital had performed over the 4-year study period was calculated, using case ascertainment predicted values, and the range and 25%, 50% and 75% centiles calculated. Each hospital was then allocated case volume quartile (1 the least to 4 the highest).

Annual average number of general surgical trainees working in clinical practice in each deanery was calculated using the yearly number of trainees from May 2013-May 2017. This period was used to capture the same time period as the NELA database used. The mean number of procedures per trainee in each region was calculated.

### *5.4.3 Statistical Analysis*

The main outcome measure was the total number of Em Laps performed within each deanery. Clinical characteristics of the patients within each deanery are reported (age, gender distribution, ASA grades, pre-operative mortality risk and mortality by 90 days. Summary statistics are reported for each procedure by deanery and hospital size quartile. These are presented as mean (± standard deviation), median (IQR) or number (%) as appropriate. Negative binominal regression using deanery as main explanatory variable, was performed to assess variation in total number (counts) of Em Lap that had taken place over the 4-year period. This was used for this count analysis due to over dispersion (greater variability) in the data and also that there are no "0" values present in the cohort.

As training requirements are nationally set, trainees in all regions are required to achieve the same competencies. Therefore, Health Education East Midlands was used as comparator in the analysis as it was the home deanery of the author and no deanery is used as the "standard setter" nationally.

Subgroup analysis included total number of segmental colectomies, Hartmann's procedures, small bowel resections, repair of perforated peptic ulcer disease and adhesiolysis operations.

Results are presented as incident rate ratios (IRR) with 95% confidence intervals. An incident rate ratio compares the occurrence (incidence) of events (Em Lap) over a set study time period. An IRR greater than 1 suggests that the investigative variable has a great rate of occurrence compared to the comparator variable.

All analyses were performed using Stata Version 15 (StataCorp, College Station, Texas).

## 5.5 Results

### *5.5.1 Cohort description*

Within the study period 95 520 adult patients had an Em Lap in 1 of 196 hospitals and were entered into the NELA database. Of these, 22 685 had a segmental colectomy, 15 737 had a small bowel resection, 11 965 had a Hartmann's procedure, 16 042 adhesiolysis and 5 235 had repair of perforated peptic ulcer disease. Using case ascertainment figures, the predicted total number of Em Lap cases over the 4-year period was 121 908. The median number of cases per hospital over the 4-year study period was 621 (IQR 379-821.) Table 11 shows the quartiles of hospitals based on case volume size. Clinical characteristics of the patients within each deanery is presented in Table 12. The average number of trainees per deanery in one year are demonstrated in Table 15. This figure is presented alongside total number of cases occurring to allow a comparison of the number of trainees that require experience in Em Lap and Index Procedures.

*Table 11: Number of Emergency Laparotomy cases and hospitals by quartile based on case volume using case ascertainment figures*

| | Number of Cases | Number of hospitals in each quartile |
|---|---|---|
| Quartile 1 | 0-378 | 49 |
| Quartile 2 | 379-621 | 49 |
| Quartile 3 | 622-821 | 49 |
| Quartile 4 | >=822 | 49 |

*Table 12: Clinical characteristics of Emergency Laparotomy patients by Deanery.*

| Deanery | Mean age * | Male patients | ASA grade | | | | | Median NELA risk score # | 90-day mortality rate |
|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | | |
| Health Education East Midlands (North and South) | 63 (17) | 3301 (49.17) | 667 (9.94) | 2358 (35.13) | 2424 (36.11) | 1133 (16.88) | 131 (1.95) | 4.377 (1.14-13.39) | 881 (13.33) |
| Health Education East of England | 65 (17) | 4821 (47.40) | 962 (9.52) | 3547 (35.10) | 3619 (35.81) | 1800 (17.81) | 178 (1.76) | 4.61 (1.32-13.55) | 1466 (14.79) |
| Health Education Yorkshire and Humber | 63 (18) | 3875 (48.35) | 910 (11.36) | 2838 (35.41) | 2753 (34.35) | 1375 (17.81) | 138 (1.72) | 4.54 (1.16-13.78) | 1163 (14.86) |
| Health Education Wessex | 65 (17) | 2335 (45.85) | 517 (10.15) | 1863 (26.58) | 1792 (35.19) | 829 (16.28) | 92 (1.81) | 4.55 (1.28-13.48) | 642 (12.97) |
| Health Education Thames Valley | 63 (18) | 1048 (48.36) | 236 (10.89) | 824 (38.02) | 758 (34.98) | 314 (14.49) | 35 (1.62) | 4.52 (1.07-12.68) | 313 (14.60) |
| Health Education North West London | 62 (18) | 1047 (52.04) | 281(13.97) | 682 (33.90) | 706 (35.09) | 299 (14.49) | 44 (2.19) | 3.67 (0.92-11.62) | 252 (12.96) |
| Health Education South London | 63 (18) | 1753 (47.90) | 406 (11.09) | 1197 (32.70) | 1307 (35.71) | 673 (18.39) | 77 (2.10) | 4.65 (1.13-14.09) | 521 (14.71) |
| Health Education North Central and East London | 61 (19) | 1922 (49.01) | 477 (12.16) | 1225 (31.23) | 1367 (34.85) | 744 (18.97) | 109 (2.78) | 4.13 (0.88-14.30) | 579 (15.23) |
| Health Education Kent, Surry and Sussex | 65 (17) | 4221 (48.11) | 987 (11.25) | 3305 (37.67) | 3053 (34.80) | 1299 (14.81) | 129 (1.47) | 4.63 (1.27-13.46) | 1145 (13.42) |
| Health Education North East | 64 (17) | 2923 (48.42) | 530 (8.78) | 1967 (32.58) | 2237 (37.05) | 1207 (19.99) | 96 (1.59) | 4.84(1.31-14.61) | 885 (14.99) |
| Health Education North West (East Sector and West Sector) | 63 (17) | 6430 (48.62) | 1391 (10.52) | 4368 (33.03) | 4551 (34.41) | 2556 (19.33) | 360 (2.72) | 4.80 (1.31-15.04) | 1944 (14.94) |
| Health Education West Midlands | 64 (18) | 4679 (49.16) | 988 (10.38) | 3338 (35.07) | 3421 (35.94) | 1609 (16.90) | 162 (1.70) | 4.52 (1.19-13.20) | 1448 (15.48) |
| Health Education South West | 65 (17) | 4497 (47.42) | 847 (8.93) | 3264 (34.42) | 3501 (36.92) | 1682 (17.74) | 189 (1.99) | 4.69 (1.30-13.94) | 1282 (13.82) |
| Wales | 65 (17) | 3328 (49.02) | 529 (7.79) | 2487 (36.63) | 2369 (34.89( | 1238 (18.24) | 166 (2.45) | 5.46 (1.43.15.73) | 1226 (18.35) |

Values in parenthesis are percentages unless otherwise indicated; *values are mean (standard deviation), # values are median (Interquartile range).

### *5.5.2 Hospital Distribution*

England and Wales are divided into fourteen deaneries, listed in Table 1. The number of hospitals per and deanery is shown in Table 13. The largest deanery, with 27 hospitals is Health Education North West. The smallest deanery, by number of hospitals, is Health Education Thames Valley (5 hospitals).

Health Education Kent, Surry and Sussex contains the greatest proportion of quartile 4 centres (12/16) hospitals, 75%), followed by Health South West (10/15 hospitals, 66%) and Health Education East Midlands 8/12 hospitals, 66%). Only 1/10 hospitals within the Health Education North West London deanery was a high-volume Quartile 4 centre.

### *5.5.3 Case Volume Variation*

Distribution of total number of Em Lap performed over four years is presented in Table 13 and Figure 5. There was significant variation in the number of Em Lap cases occurring in each deanery. Incidence of Em Lap operating was highest in Health Education North West (Incident Rate Ratio (IRR) 1.69 95% CI 1.67-1.70). The lowest incidence of Em Lap operating was in Health Education Thames Valley (IRR 0.31 95% CI 0.30-0.32).

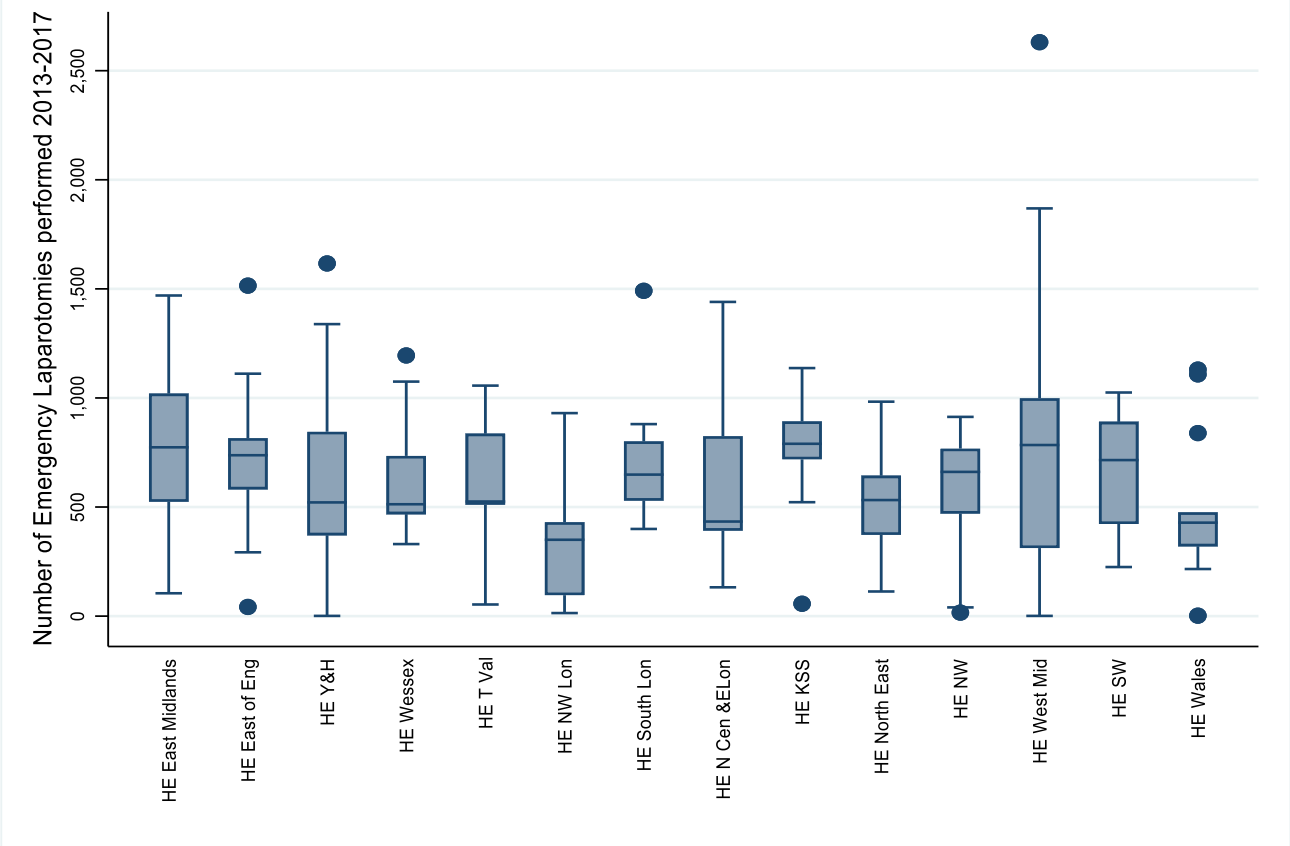
*Table 13 Binomial regression analysis of total number of all Emergency Laparotomies by deanery over 4 years.*

| **Deanery** | **Total Number hospitals** | **Number of high volume centres** | **Mean No. of general surgical speciality trainees per region per year** | **Total Em Lap over 4 years using case ascertainment** | **Mean (SD) cases per hospital over four years $** | **Incidence rate ratio** | **P-value** |
|---|---|---|---|---|---|---|---|
| Health Education East Midlands (North and South) | 12 | 8 | 110 | 9526 | 793 (389)$ | Comparator | |
| Health Education East of England | 19 | 12 | 138 | 12938 | 680 (317)$ | 1.36 (1.35,1.37) | 0.000 |
| Health Education Yorkshire and Humber | 18 | 8 | 150 | 12024 | 668 (408)$ | 1.26 (1.25,1.27) | 0.000 |
| Health Education Wessex | 9 | 4 | 72 | 5879 | 653 (303)$ | 0.62 (0.61,0.62) | 0.000 |
| Health Education Thames Valley | 5 | 2 | 57 | 2982 | 596 (379)$ | 0.31 (0.30,0.32) | 0.000 |
| Health Education North West London | 10 | 1 | 100 | 3319 | 332 (277)$ | 0.35 (0.34-0.35) | 0.000 |
| Health Education South London | 9 | 5 | 126 | 6609 | 734(321)$ | 0.69 (0.68,0.71) | 0.000 |
| Health Education North Central and East London | 11 | 3 | 153 | 6701 | 609 (384)$ | 0.70 (0.69,0.71) | 0.000 |
| Health Education Kent, Surry and Sussex | 16 | 12 | 161 | 12261 | 766 (239)$ | 1.29 (1.28,1.30) | 0.000 |
| Health Education North East | 13 | 4 | 94 | 6609 | 508 (233)$ | 0.69 (0.68,0.70) | 0.000 |
| Health Education North West (East Sector and West Sector) | 27 | 16 | 211 | 16072 | 595 (253)$ | 1.69 (1.67,1.70) | 0.000 |
| Health Education West Midlands | 18 | 11 | 148 | 14592 | 810 (652)$ | 1.53 (1.52,1.54) | 0.000 |
| Health Education South West | 15 | 10 | 128 | 10302 | 686 (243)$ | 1.08 (1.07.1.09 | 0.000 |
| Wales | 14 | 0* | 108 | 6789* | 484 (325)$ | 0.71 (0.70,0.72) | 0.000 |

Values in parentheses are 95 per cent confidence intervals unless indicated otherwise;$ values are mean (standard deviation)

**Numbers for Wales are provided directly from the National Emergency Laparotomy database and do not included case ascertainment calculations*

*Figure 5 Box plot demonstrating Emergency Laparotomy case variation by Deanery*




HE: Health Education, Y&H: Yorkshire and Humber, T Val: Thames Valley, N Cen: North Central, KSS: Kent, Surrey and Sussex, Mid: Midlands, SW: South West

Subgroup analyses of procedure specific count rates are presented in Tables 14-16. Emergency segmental colectomies were performed most commonly in Health Education North West, total number of cases 3104, IRR 1.77 (95% CI 1.74-1.79). Hartmann's procedures were most commonly performed in Health Education North West, total count of cases 1675, IRR 1.62 (95% CI 1.59-1.66). Hospitals within the Health Education East of England deanery performed the greatest number of small bowel resections, total case number 1712, IRR 1.51 (95% CI 1.49-1.55). In the perforated peptic ulcer group, rates were highest in Health Education North West, total case number 818, IRR 1.90 (95% CI 1.84-1.96). Cases of Em Lap and adhesiolysis were most common in Health Education North West, total cases 2105, IRR 1.94 (95% CI 1.91-1.97). The potential number of Em Lap cases per trainee is displayed in Figure 6. Within the West Midlands deanery, there was the greatest number of Em Lap per trainee, on average 25 per year. While in Health Education North West London, there was the potential for 8 Em Lap per trainee per year.

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*Table 14: Distribution and negative binominal regression analysis of segmental colectomy and Hartmann's procedure by Deanery.*

| Deanery | Segmental Colectomy | | | | Hartmann's Procedure | | | |
|---|---|---|---|---|---|---|---|---|
| | **Total number of procedures over 4 years** | **Mean (SD) no. procedures per hospital*** | **Incidence rate ratio** | **P value** | **Total number of procedures over 4 years** | **Mean (SD) no. procedures per hospital per year** | **Incidence rate ratio** | **P value** |
| Health Education East Midlands (North and South) | 1753 | 146 (91)* | Comparator | | 1031 | 86 (52)* | Comparator | |
| Health Education East of England | 2405 | 127 (69)* | 1.37 (1.35,1.39) | 0.000 | 1275 | 67 (38)* | 1.24 (1.21,1.26) | 0.000 |
| Health Education Yorkshire and Humber | 1787 | 99 (85)* | 1.02 (1.00,1.04) | 0.030 | 964 | 54 (35)* | 0.94 (0.91.0.96) | 0.000 |
| Health Education Wessex | 1153 | 128 (69)* | 0.66 (0.64,0.67) | 0.000 | 573 | 64 (34)* | 0.55 (0.54,0.57) | 0.000 |
| Health Education Thames Valley | 520 | 104 (68)* | 0.30 (0.28,0.31) | 0.000 | 274 | 55 (34)* | 0.27 (0.25,0.28) | 0.000 |
| Health Education North West London | 430 | 43 (39)* | 0.25 (0.24,0.25) | 0.000 | 231 | 23 (20)* | 0.22 (0.21,0.23) | 0.000 |
| Health Education South London | 741 | 82 (24)* | 0.42 (0.41,0.43) | 0.000 | 412 | 46 (22)* | 0.40 (0.38,0.41) | 0.000 |
| Health Education North Central and East London | 828 | 75 (42)* | 0.47 (0.46, 0.48) | 0.000 | 409 | 37 (28)* | 0.39 (0.38,0.41) | 0.000 |
| Health Education Kent, Surry and Sussex | 2130 | 133 (61)* | 1.22 (1.19,1.23) | 0.000 | 1232 | 77 (40)* | 1.19 (1.17,1.22) | 0.000 |
| Health Education North East | 1459 | 122 (92)* | 0.83 (0.82,0.85) | 0.000 | 589 | 45 (26)* | 0.57 (0.55,0.59) | 0.000 |
| Health Education North West (East & West Sectors) | 3104 | 115 (52)* | 1.77 (1.74,1.79) | 0.000 | 1675 | 62 (28)* | 1.62 (1.59,1.66) | 0.000 |
| Health Education West Midlands | 225 | 125 (92)* | 1.29 (1.26,1.30) | 0.000 | 1154 | 64 (47)* | 1.12 (1.09,1.14) | 0.000 |
| Health Education South West | 2434 | 162 (81)* | 1.38 (1.36,1.41) | 0.001 | 1216 | 81 (43)* | 1.18 (1.15,1.21) | 0.170 |
| Wales | 1687 | 121 (79)* | 0.96 (0.94,0.98) | 0.000 | 930 | 66 (50)* | 0.90 (0.88,0.92) | 0.000 |

Values in parentheses are 95 per cent confidence intervals unless indicated otherwise; * values are mean (standard deviation)

*Table 15:Distribution and negative binominal regression analysis of repair of perforated peptic ulcer and adhesiolysis by Deanery.*

| Deanery | Repair of Perforated Peptic Ulcer | | | | Adhesiolysis | | | |
|---|---|---|---|---|---|---|---|---|
| | **Total number of procedures over 4 years** | **Mean (SD) no. procedures per hospital per year*** | **Incidence rate ratio** | **P value** | **Total number of procedures over 4 years** | **Mean (SD) no. procedures per hospital per year *** | **Incidence rate ratio** | **P value** |
| Health Education East Midlands (North and South) | 430 | 36 (25)* | Comparator | | 1087 | 91 (57)* | Comparator | |
| Health Education East of England | 515 | 27 (15)* | 1.19 (1.16,1.24) | 0.000 | 1744 | 92 (48)* | 1.60 (1.57,1.64) | 0.000 |
| Health Education Yorkshire and Humber | 486 | 27 (21)* | 1.13 (1.09,1.17) | 0.000 | 1349 | 75 (61)* | 1.24 (1.21,1.27) | 0.000 |
| Health Education Wessex | 220 | 24 (18)* | 0.51 (0.49,0.54) | 0.000 | 978 | 109 (64)* | 0.90 (0.87,0.92) | 0.000 |
| Health Education Thames Valley | 108 | 22 (14)* | 0.25 (0.23,0.27) | 0.000 | 350 | 70 (46)* | 0.32 (0.31,0.33) | 0.000 |
| Health Education North West London | 151 | 15 (15)* | 0.35 (0.33,0.37) | 0.000 | 314 | 31 (26)* | 0.29 (0.27,0.30) | 0.000 |
| Health Education South London | 237 | 26 (6)* | 0.55 (0.52,0.57) | 0.000 | 755 | 84 (33)* | 0.69 (0.67,0.72) | 0.000 |
| Health Education North Central and East London | 293 | 27 (12)* | 0.68 (0.65,0.71) | 0.000 | 682 | 62 928)* | 0.63 (0.61,0.64) | 0.000 |
| Health Education Kent, Surry and Sussex | 381 | 24 (11)* | 0.88 (0.85,0.92) | 0.000 | 1610 | 101 (45)* | 1.48 (1.45,1.51) | 0.007 |
| Health Education North East | 400 | 31 (18)* | 0.93 (0.90,0.97) | 0.000 | 941 | 72 (41)* | 0.87 (0.84,0.89) | 0.000 |
| Health Education North West (East and West Sectors) | 818 | 30 (16)* | 1.90 (1.84,1.96) | 0.000 | 2105 | 78 (34)* | 1.94 (1.91,1.97) | 0.000 |
| Health Education West Midlands | 504 | 28 (21)* | 1.17 (1.12,1.21) | 0.000 | 1416 | 81 (55)* | 1.34 (1.31,1.37) | 0.000 |
| Health Education South West | 402 | 27 (14)* | 0.93 (0.90,0.97) | 0.000 | 1617 | 108 (48)* | 1.48 (1.45,1.51) | 0.000 |
| Wales | 308 | 22 (15)* | 0.71 (0.69,0.76) | 0.000 | 1049 | 75 (58)* | 0.96 (0.94,0.98) | 0.003 |

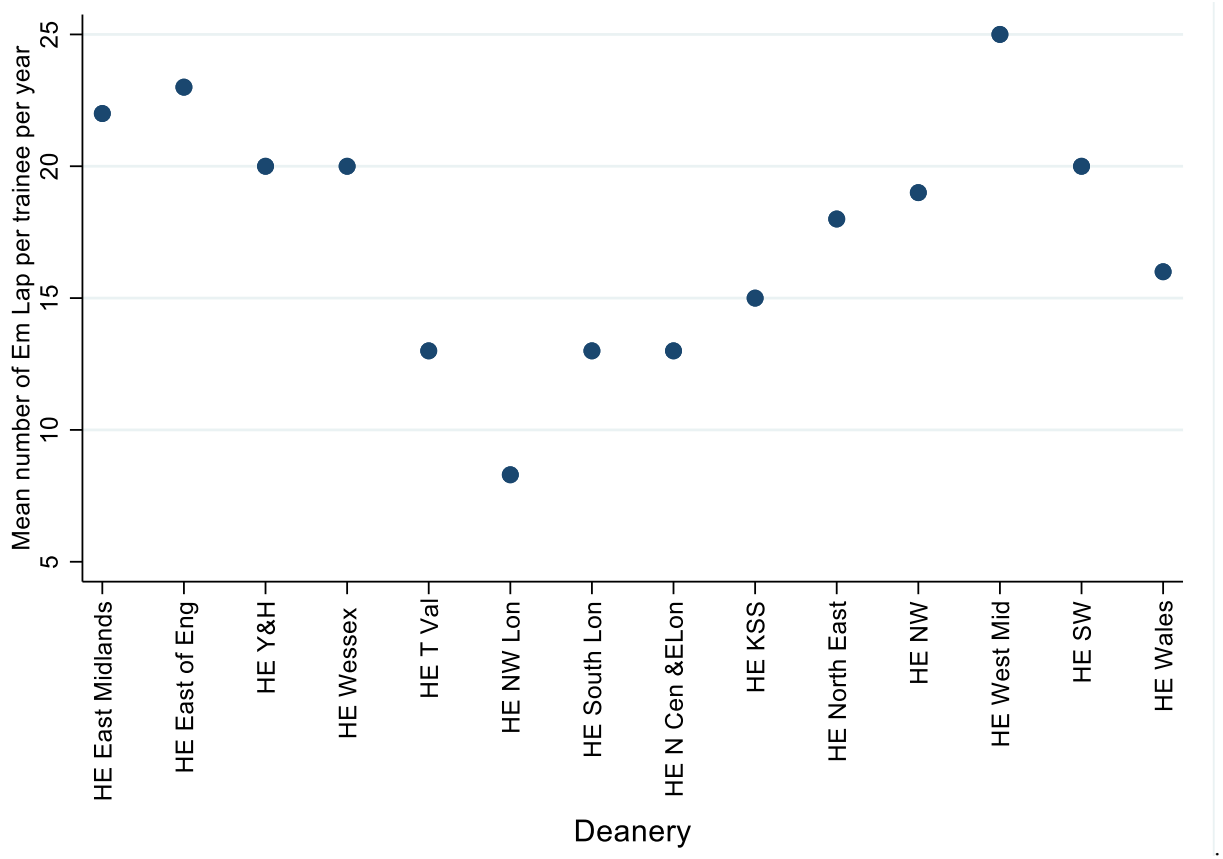
Values in parentheses are 95 per cent confidence intervals unless indicated otherwise; * values are mean (standard deviation)

*Table 16: Distribution and negative binominal regression analysis of small bowel resection by Deanery.*

| Deanery | Small Bowel Resection | | | |
|---|---|---|---|---|
| | **Total number of procedures over 4 years** | **Mean (SD) no. procedures per hospital per year*** | **Incident rate ratio** | **P value** |
| Health Education East Midlands (North and South) | 1128 | 94 (60)* | Comparator | |
| Health Education East of England | 1712 | 90 (48)* | 1.51 (1.49,1.55) | 0.000 |
| Health Education Yorkshire and Humber | 1463 | 81 (66)* | 1.30 (1.27,1.32) | 0.000 |
| Health Education Wessex | 855 | 95 (56)* | 0.76 (0.73,0.78) | 0.000 |
| Health Education Thames Valley | 364 | 73 (45)* | 0.32 (0.31,0.34) | 0.000 |
| Health Education North West London | 358 | 26 (30)* | 0.31 (0.30,0.33) | 0.000 |
| Health Education South London | 621 | 69 (18)* | 0.55 (0.53,0.58) | 0.000 |
| Health Education North Central and East London | 684 | 62 (34)* | 0.61 (0.60,0.62) | 0.000 |
| Health Education Kent, Surry and Sussex | 1450 | 91 (41)* | 1.29 (1.29,1.31) | 0.000 |
| Health Education North East | 1013 | 78 (43)* | 0.89 (0.87,0.91) | 0.000 |
| Health Education North West (East and West Sectors) | 2145 | 80 (39)* | 1.90 (1.86,1.93) | 0.000 |
| Health Education West Midlands | 1373 | 76 (50)* | 1.22 (1.19,1.24) | 0.000 |
| Health Education South West | 1466 | 98 (40)* | 1.30 (1.27,1.33) | 0.000 |
| Wales | 1105 | 78 (35) | 0.97 (0.95,1.00) | 0.080 |

Values in parentheses are 95 per cent confidence intervals unless indicated otherwise; * values are mean (standard deviation)

*Figure 6: Mean number of Emergency Laparotomies per trainee per year by Deanery*




HE: Health Education, Y&H: Yorkshire and Humber, T Val: Thames Valley, N Cen: North Central, KSS: Kent, Surrey and Sussex, Mid: Midlands, SW: South West

## 5.6 Discussion

This is the first study to describe the variation, by deanery, in performance of Em Lap and the index procedures associated. This study reports significant case load variation between deaneries. This variation may inform trainee choice when considering which deanery to preference in national selection and also provide important information for trainers and workforce planners.

This study suggests that there is significant inter deanery variation in the number of Em Lap performed for IP, specifically for emergency segmental colectomy and emergency Hartmann's procedure. Additionally, while not an IP, regional variance in Em Lap and adhesiolysis, small bowel resection and repair of perforated peptic ulcer disease are described here. All three of these procedures are within the ten most commonly occurring emergency general surgery procedures, therefore experience and competence in managing these cases would be of benefit to all trainees in general surgery. Trainees in particular regions are more at risk of not gaining sufficient experience to meet the requirements for certification. Competence and exposure to a wide enough range of presentations is essential for safe practice and lack of exposure may affect the confidence of a trainee to act as a day one consultant general surgeon. The latter is an area in which there is data: the small body of work that has addressed this suggests that trainees feel more anxious about the non-clinical aspects of the consultant role rather than technical issues, but these studies were performed in non-surgical, non-craft specialties where procedural competence is less central to the role (Beckett et al., 2006; Loane and Barker, 1996; Morrow et al., 2009). More work on the readiness of trainees to begin as

a day 1 consultant is needed, and will be important as training in medicine moves to an outcomes based curricula.

Currently general surgical training is a six-year training programme for most, in which trainees follow a curriculum that is compulsory and standardised across the country (ISCP (Intercollegiate Surgical Curriculum Programme), 2016). Operative competence is assessed using a work-based assessment tool, termed procedural based assessment (PBA) (Beard et al., 2011). While competence is important, in a speciality like surgery, experience is also essential so trainees are required to have performed a minimum number of "index procedures." Index procedures are some of the more commonly performed clinical interventions and operations in the specialty. They represent evidence of technical competence across the whole range of specialty procedures in supervised settings.

Previous reports examining trainee experience have analysed operative logbooks. In 2013, Allum *et al.* assessed the logbook consolidation sheets of general surgical trainees applying for Certification in general surgery (Allum et al., 2013). They noted that assessing the number of emergency surgery procedures was difficult as "laparotomy for acute abdomen" was not defined in the logbook. The authors included laparotomy for intestinal obstruction, peritonitis, palliative bypass, and post-operative complications when counting Em Lap numbers. They reported that the median number of laparotomies for acute abdomen, recorded in the logbooks of 58 trainees included in the study, was 68 with a range of 18-227 by certification. The authors concluded that

more robust work was needed to quantify the operative numbers using a large sample size (Allum et al., 2013). Regional variation in Em Lap exposure was demonstrated in a larger study (98 trainees) examining logbook numbers in two deaneries, the East Midlands and Wales (Thomas et al., 2015a). They suggested that the median number of Em Lap performed by a trainee every six months, was 7 (range 0-40) and only 1 (range 0-13) Hartmann's procedure was performed per 6 months. They noted significant differences in numbers recorded between trainees in the Welsh deanery. The authors concluded that the trainees experience of Em Lap fell well below the required standard with only 35% of trainees, recording the indicative number of cases (Thomas et al., 2015a).

Thomas *et al*. (Thomas et al., 2015b) conducted the first investigation into log book numbers using data received from the Intercollegiate Surgical Curriculum Programme (ISCP (Intercollegiate Surgical Curriculum Programme), 2019), which all trainees in the UK use as their training management system. Of those successfully reaching certification between 2012 and 2013 only 55% recorded at least 100 Em Lap and only 86% achieved the indicative numbers of segmental colectomies and Hartmann's procedures. However, the authors noted that, due to previous log book design, it was not always possible to identify which procedures were carried out as emergencies and felt that the data analysed may not have been accurate. They concluded that trainees were more likely to have performed more cases that were actually recorded (Thomas et al., 2015b).

While significant disparity between deaneries is reported here, with London and Thames Valley deaneries providing the least number of opportunities despite a comparable number of trainees, Thomas *et al* suggest that training region did not have an effect on operative numbers although this was in relation to total operative experience rather Em Lap specifically. They found only one trainee in 2013 who achieved all of the then new JCST indicative numbers (Thomas et al., 2015b).

A further study using ISCP data was published in 2018 (Elsey et al., 2019). This paper again looked at trainees who had completed general surgical training between 2007 and 2016, but used more robust data management methodology to ensure validity of data. They reported that the mean number of Em Lap per trainee was 114 (SD 42), 82 (SD 48) segmental colectomies, and 14 (SD 8) Hartmann's procedures. While they stated in their methods that they recorded the training region, no results were presented on regional variation in case number.

The data presented here has predicted the number of Em Laps that a trainee could be exposed to during a training year. The data suggests that trainees working in some deaneries (Health Education Thames Valley, Health Education North West London, Health Education South London, Health Education, Health Education North and Central and East London and Health Education Kent, Surrey, Sussex) may not reach the total of 100 Em Lap during the six years of surgical training. However, these figures should be interpreted with caution. They are merely predictions. It may be that trainees gain more

experience than suggested here. However it may be that they also have less experience than the case numbers suggested here due to rota scheduling and annual leave.

This study also demonstrates regional variation in specific procedural subgroups. Incidence of Hartmann's procedure is much higher in the North West. This finding may represent differences in local surgical practice or decision making. For example, some regions may perform laparoscopic washouts for less severe cases of colonic diverticulitis rather than resection or perform more primary anastomoses rather than stoma formation. Other potential explanations for procedural case mix variation by deanery may be due differences in demographics and co morbidities of the population (e.g higher rates of Helicobacter Pylori in some regions). Regardless of this potential explanation, Hartmann's procedure and segmental colectomy remain index procedures and therefore trainees must gain experience in this.

In summary, this analysis has shown that there are large numbers of Em Laps occurring in hospitals throughout England and Wales. However, it is important to note that logbook data for the trainees during this time period has not been included. It may be that, while some deaneries do not have comparable numbers of Em Lap cases to other deaneries, trainees may still be achieving the required number of cases, and thus experience, to meet the standard for certification. At local level this study could be used as aide for trainers and trainees for those who are found to be not achieving the required operative experience at annual review. A further limitation is the lack of specific case

ascertainment data for emergency procedures. This could lead to an underestimation of the case numbers occurring. However, strengths of this paper include the large cohort linked with an additional externally validated source (HES) and the ability to quantify patients by deanery and hospital size. This defines the "denominator" of potential cases and training opportunities for trainee general surgeons.

This data provides trainees, training programme directors, Heads of School, Deans and workforce planners with data on which to base distribution of trainees through England and Wales and within regions and deaneries to ensure adequate exposure to emergency laparotomy cases. Adequate exposure underpins achievement of necessary competence, which in turn underpins patient safety.

## 5.7 Conclusion

There is significant variation across educational deaneries in the numbers of emergency laparotomies and emergency index procedures performed. This should be taken into consideration when planning general surgical training across England and Wales.

# 6 Trainee involvement in Emergency Laparotomy Operating; does it Impact on Outcomes?

## 6.1 Chapter Focus

This chapter builds on the analysis from the previous study and describes the trends in trainee led operating in Em Lap cases.

The impact of trainee led operating on mortality and morbidity outcomes is then investigated.

## 6.2 Abstract


***Introduction***

To achieve completion of training in general surgery, trainees are required to demonstrate competency in common procedures performed at Em Lap. The aim was to describe patterns of trainee led Em Lap operating and investigate the association between post-operative mortality and morbidity.

***Methods***

All patients who had an Em Lap were extracted from the NELA database from December 2013 to November 2017. Patients were grouped by grade of operative surgeon; trainee (speciality registrar) or Consultant (including Post (CCT) fellows). Trends in trainee operating by education deanery, hospital size and time of day of surgery were investigated. Both univariate and adjusted regression analysis for the outcomes of 90-day mortality and return to theatre were performed in operative subgroups of segmental colectomy, Hartmann's procedure, adhesiolysis and repair of perforated peptic ulcer disease.

***Results***

The study cohort contained 95 520 patients. There were no increased odds of death by 90 days or of return to theatre across any of the operative groups when the operation was performed with a trainee listed as the most senior surgeon in theatre. Trainees were more likely to operate independently in high volume centres and at night ($p \leq 0.001$).

***Conclusion***

There is significant variation in trainee led operating in Em Lap cases by geographical area, hospital size and by time of day. However, this involvement in cases required for CCT in general surgery does not appear to impact on mortality or return to theatre in patients when adjusting for various pre-operative features.

## 6.3 Introduction

In the United Kingdom general surgical trainees are required to demonstrate competency in emergency surgical procedures as a component of the curriculum (ISCP (Intercollegiate Surgical Curriculum Programme), 2016). Specifically, trainees have to be competent to a level defined by the syllabus in a group of procedures performed at Em Lap (The Speciality Advisory Committee for General Surgery, 2013b), as well as having performed (either supervised or independently) 100 Em Lap by the end of training, to include Hartmann's procedure and segmental colectomy.

The NELA annual reports promote consultant presence in theatre for patients who have a greater than 5% risk of death in the post-operative period. In the most recent NELA report both consultant surgeons and anaesthetists were present in theatre for 83% of high risk patients having Em Lap (NELA Project Team, 2018b).

Before NELA, Saunders *et al* reported that there were lower numbers of consultant surgeons present in theatre, particularly at night. Greater 30-day mortality was seen in those operated on at night compared to before 6pm (20.3% vs. 14.2%), and it was suggested that the excess mortality was at least in part related to the absence of consultants (Saunders et al., 2012). Currently there is little literature focusing on the relationship between mortality, morbidity and consultant led care for Em Lap patients. Trainee participation has been associated with adverse outcomes in other specialties (McLauchlan et al., 1997; Ryan et al., 2014). In elective surgical practice the association of trainee

performance with adverse outcome is less convincing; whilst increased procedure time has been observed if trainees operate (e.g. laparoscopic cholecystectomy and open inguinal hernia) several studies found no increased mortality (Singh and Aitken, 1999; Loiero et al., 2017; Tseng et al., 2011; Hwang et al., 2008; Kasten et al., 2018).

A large American database study (141 010 cases) investigated the impact of trainee operative participation on outcomes after emergency general surgical procedures. They performed a multivariate regression analysis and suggested that trainee supervised operating was independently associated with intra- and post-operative adverse events (Kasotakis et al., 2014). Their study included a range of emergency surgical procedures including exploratory laparotomy, appendiectomy, colectomy, hernia repair and diagnostic laparoscopy.

To date there have been no large reports of the association between outcomes and trainee operative involvement in Em Lap in the UK. The aim of this study was to describe the current patterns of trainee led Em Lap operating and investigate the impact of this on mortality and morbidly following Em Lap in England and Wales.

## 6.4 Methods

### *6.4.1 Study Population*

Adult patients who had an Em Lap and were entered into the NELA database between December 2013 and November 2017 were included. Patients were excluded if the most senior surgeon was listed as a "Speciality or associate speciality (SAS) grade, research/clinical fellow, senior house office, other or unknown". This was to compare consultants with junior surgeons who were currently completing a recognised higher general surgical training programme with a defined curriculum. While SAS doctors and research/clinical fellows may have considerable experience in Em Lap, it was not possible to account for this within the limitations of the dataset and thus operations performed by these surgeons added additional confounding and were excluded.

### *6.4.2 Data Management and Study Variables*

The main exploratory variable in this study was the grade of most senior surgeon present in theatre during Em Lap. NELA defines a Consultant as 'a surgeon whose name appears on the specialist register and is appointed as a substantive, fixed term or honorary consultant within the NHS'. "Trainees" were defined as a surgeon entered into the NELA database as a "Speciality Trainee or Registrar." "Consultants" were defined as surgeons who were entered into the NELA database as "Consultants" or "Post CCT-Fellows." Post CCT fellows were included in the consultant group, as the award of CCT indicates the capability of being able to work as day one consultant surgeon (Conference of Postgraduate Medical Deans of the United Kingdom, 2018).

To define “Hospital Volume”, the number of Em Lap performed annually during the 4-year period for each individual hospital was calculated. These yearly totals per hospital were then used to calculate a mean number of procedures performed in the 4-year period for each individual hospital. These totals were then used to calculate the range and 25%, 50% and 75% centiles of cases of Em Lap in the study hospitals. Each hospital was then allocated a case volume quartile (1 the least cases performed to 4 the highest.)

Individual hospitals were grouped by region and local deanery. Inclusion of hospitals in each deanery was based on information from the General Surgery Training section of each Health Education region website (Health Education East Midlands, 2016; Health Education East of England, 2017; Health Education Yorkshire and Humber, 2019; Health Education Wessex, 2018; Health Education Thames Valley, 2019; London and South East Postgraduate Medical and Dental Education, 2017; Health Education Kent Surry Sussex, 2019; Health Education North East, 2018; Health Education North West, 2019; Health Education and Improvement Wales, 2018; Health Education South West, 2019).

The following patient variables were extracted; age, sex, ASA grade, urgency category at time of case booking, pre-operative ECG findings, pre-operative cardiac signs, respiratory history, pre-operative serum creatinine, pre-operative serum urea, pre-operative serum sodium, pre-operative serum potassium, pre-operative serum white blood cell count, pre-operative heart rate, pre-operative systolic blood pressure and pre-operative GCS. It was deemed more clinically

relevant to use post-operative values for intra operative blood loss, peritoneal soiling, operative severity and malignancy in the risk adjustment model therefore values for the aforementioned variables were extracted from the post-operative section of the database. The above data was used to calculate the NELA risk score for each individual as per the NELA risk score methodology (Eugene et al., 2018). Actual operative procedure performed at Em Lap, grade of most senior anaesthetist present in theatre and whether the patient was directly admitted to a critical care unit post-operatively were also extracted from the dataset. Only NELA risk score was modelled as a continuous variable.

When investigating impact of trainee involvement in procedures required for certification in General Surgical, "segmental colectomy" was defined as; colectomy: left (including sigmoid colectomy and anterior resection, colectomy: right (including ileocaecal resection); colectomy: subtotal or panproctocolectomy and colorectal resection: other. Hartmann's procedure was not included in the colectomy subgroup and analysed as a separate subgroup as it is listed as a separate index procedure in the General Surgical curriculum.

### *6.4.3 Outcome measures*

Outcomes of the study were all cause 90-day mortality and post- operative return to theatre. Mortality data was captured through NELA dataset linkage with the ONS death register. Post-operative return to theatre was defined as a return to theatre in the same hospital admission as index Em Lap.

### *6.4.4 Statistical Analysis*

Descriptive data are presented as mean (± standard deviation), median (IQR) or number (%) as appropriate.

To test the variance between trainee led cases and regional location, hospital case volume and time of day of operation logistic regression was performed. The dependent variable was modelled in binary form (trainee performed operation ;yes or no), therefore logistic regression was chosen.
As previously described in Chapter 5, Health Education East Midlands was used as comparator in the analysis.

To test the association between grade of most senior surgeon present in theatre and mortality and return to theatre, logistic regression was performed. Both unadjusted OR and OR adjusted for the following selected covariates: NELA risk score, grade of most senior anaesthetist in theatre, admission to critical care unit post-operatively and procedure performed.

Previously reported data from the same cohort of patients having Em Lap demonstrated no increase in mortality associated with case volume, hospital size or hospital configuration (Oliver et al., 2018). Therefore, these structural factors were not included in the risk adjustment model here.

Results are presented with 95% confidence intervals (CI). Inclusion of variables in the risk adjustment model was based on clinical rather than statistical significance. Patients were analysed by operative procedural group; Em Lap

followed by segmental colectomy, Em lap followed by Hartmann's procedure, Em lap and adhesiolysis, Em Lap and repair of perforated peptic ulcer disease. These groups were chosen as they are core requirements for certification in in general surgery and also within the top ten most common procedures performed following Em Lap (NELA Project Team, 2015b, 2016, 2017, 2018b).

## 6.5 Results

### *6.5.1 Cohort description*

The extracted data contained 95,520 patients who had an Em Lap between December 2013 and November 2017, with 3014 (3.16%) patients excluded as the most senior surgeon was not a consultant or trainee. A further 1957 (2.05%) were removed due to lack of mortality outcome data and 970 (1.02%) due to missing return to theatre outcome data. Finally, patients without full data for risk adjustment were excluded (3182 (3.33%) in mortality outcome group and 4504 (4.7%) in return to theatre outcome group. Therefore, the study cohort available for analysis was 87,367 (91.46%) patients for mortality analysis and 86,710 (90.48%) patients for return to theatre outcome analysis. The clinical characteristics of the cohort are displayed in Table 17.

### *6.5.2 Procedures performed*

The distribution of procedures by grade of surgeon is displayed in Table 18. The procedure with a trainee listed as the most senior surgeon most commonly was suture repair of perforated peptic ulcer (15.7%) followed by adhesiolysis (10.86%). The procedure least likely to have a trainee as most senior surgeon was left sided colectomy (including anterior resection and sigmoid colectomy); 2.53% of operations.

*Table 17: Cohort description of 87 367 patients who had Emergency Laparotomy.*

| | | **Whole cohort N=87367** | **Consultant as most senior surgeon N=80 542** | **Trainee as most senior surgeon N=6825** |
|---|---|---|---|---|
| **Age*** | | 67 (53-77)* | 67 (53-77)* | 68 (52-78)* |
| **Age categories** | 18-39 | 9741 | 8706 (10.81) | 774 (11.34) |
| | 40-49 | 8311 | 7631 (9.47) | 693 (10.15) |
| | 50-59 | 12312 | 11404 (14.16) | 923 (13.52) |
| | 60-69 | 17983 | 16692 (20.72) | 1344 (19.69) |
| | 70-79 | 21907 | 20337 (25.25) | 1658 (24.29) |
| | 80-89 | 15063 | 13874 (17.23) | 1258 (18.43) |
| | >90 | 2064 | 1898 (2.36) | 175 (2.56) |
| **Female sex** | | 45105 (51.63) | 41610 (51.66) | 3495 (51.21) |
| **Pre-operative NELA risk score* (%)** | | 10.96 (15.01)* | 4.48 (1.28-14.42 )* | 3.54 (0.98-10.60)* |
| **ASA grade N (%)** | 1 | 8689 (9.95) | 7723 (9.59) | 996 (14.15) |
| | 2 | 30296 (34.68) | 27694 (34.38) | 2602 (38.12) |
| | 3 | 31100 (35.60) | 28787 (35.74) | 2313 (33.89) |
| | 4 | 15535 (17.78) | 14669 (18.21) | 866 (12.69) |
| | 5 | 1747 (2.00) | 1669 (2.07) | 78 (1.14) |
| **90-day mortality rate (%)** | | 14.78 | 15.10 | 11.03 |
| **Patients with a return to theatre post-operatively** | | 7560 (8.72) | 7105 (8.89) | 455 (6.71) |

Values in parentheses are percentages unless indicated otherwise; * values are median (interquartile range)

*Table 18: Ten most common operative procedures performed at Emergency Laparotomy by grade of most senior surgeon present in theatre.*

| **Procedure (N)** | **Consultant** | **Trainee** |
|---|---|---|
| Adhesiolysis (15404) | 13731 (89.14) | 1673 (10.86) |
| Small Bowel Resection (15136) | 13670 (90.31) | 1466 (9.69) |
| Colectomy: right; including ileocaecal resection (12305) | 11617 (94.41) | 688 (5.59) |
| Hartmann's procedure (11676) | 11054 (94.67) | 622 (5.33) |
| Colectomy: Subtotal or panproctocolectomy (5122) | 4968 (96.99) | 154 (3.01) |
| Peptic ulcer-suture repair of perforation (4919) | 4145 (84.27) | 774 (15.73) |
| Stoma formation (4750) | 4387 (92.36) | 363 (7.64) |
| Colectomy: left; including anterior resection and sigmoid colectomy (3167) | 3087 (97.47) | 80 (2.53) |
| Drainage of abscess or collection (2465) | 2303 (93.43) | 162 (6.57) |
| Washout only (2240) | 2071 (92.46) | 169 (7.54) |

Values in parentheses are percentages unless indicated otherwise

### *6.5.3 Variation by region*

The distribution of trainee led operating by Educational Deanery is demonstrated in Table 19. Health Education Yorkshire had the greatest proportion of Em Laps with a trainee listed as the most senior surgeon (11%). In the North East Health Education deanery only 4% of Em Lap cases were recorded as being performed by a trainee without supervision. Regression analysis (Table 19) demonstrated there were increased odds of trainee led operating in Health Education Yorkshire and Humber (OR 1.62, 95% CI 1.44-1.83), Health Education West Midlands (OR 1.46, 95% CI 1.30-1.65), Health Education South West (OR 1.20, 95% CI 1.06-1.36) and Wales (OR 1.66. 95% CI 1.45-1.88.) Reduced odds of trainee led operating was seen in Health Education North West London (OR 0.73, 95% CI 0.58-0.92), Health Education South London (OR 0.82, 95% CI 0.68-0.98), Health Education North Central and East London (OR 0.78, 95% CI 0.65-0.92, Health Education Kent, Surry and Sussex (OR 0.83, 95% CI 0.73-0.96) and Health Education North East (OR 0.60, 95% CI 0.51-0.71).

*Table 19: Deanery break down of consultant and trainee led Emergency Laparotomy cases*

| | **Total N** | **Consultant as most senior surgeon *** | **Trainee as most senior surgeon *** | **Odds ratio** | **P value** |
|---|---|---|---|---|---|
| Health Education East Midlands (North and South) | 6219 | 5783 (92.99) | 436 (7.01) | Comparator | |
| Health Education East of England | 8947 | 8262 (92.34) | 685 (7.66) | 1.09 (0.97,1.24) | 0.135 |
| Health Education Yorkshire and Humber | 7243 | 6451 (89.07) | 792 (10.93) | 1.62 (1.44,1.83) | 0.000 |
| Health Education Wessex | 4828 | 4523 (93.68) | 305 (6.32) | 0.89 (0.76,1.04) | 0.149 |
| Health Education Thames Valley | 2009 | 1845 (91.84) | 164 (8.16) | 1.18 (0.97,1.42) | 0.084 |
| Health Education North West London | 1830 | 1734 (94.75) | 96 (5.52) | 0.73 (0.58,0.92) | 0.008 |
| Health Education South London | 3033 | 2856 (94.16) | 177 (5.84) | 0.82 (0.68,0.98) | 0.033 |
| Health Education North Central and East London | 3649 | 3446 (94.44) | 203 (5.56) | 0.78 (0.65,0.92) | 0.005 |
| Health Education Kent, Surry and Sussex | 7745 | 7284 (94.05) | 461 (5.95) | 0.83 (0.73,0.96) | 0.011 |
| Health Education North East | 5747 | 5495 (95.62) | 252 (4.38) | 0.60 (0.51,0.71) | 0.000 |
| Health Education North West (East Sector and West Sector) | 12140 | 11199 (92.25) | 941 (7.75) | 1.11 (0.99,1.25) | 0.072 |
| Health Education West Midlands | 8893 | 8008 (90.05) | 885 (9.95) | 1.46 (1.30,1.65) | 0.000 |
| Health Education South West | 8845 | 8109 (91.68) | 736 (8.32) | 1.20 (1.06,1.36) | 0.003 |
| Wales | 6239 | 5547 (88.91) | 692 11.09 | 1.66 (1.45,1.88) | 0.000 |

Values in parentheses are 95 per cent confidence intervals unless indicated otherwise; * values are number (per cent)

### *6.5.4 Variation by hospital size*

Numbers of Trainee led Em Lap cases by hospital size are presented in Table 20. The greatest proportion of operations with a trainee recorded as being the most senior surgeon was in high volume centres. Of all the Em Laps performed in the highest volume quartile hospitals, 10% of these had a trainee as most senior surgeon while in lowest volume quartile hospital only 5% were trainee led cases OR 2.11, 95% CI 1.91-2.33).

### *6.5.5 Variation by time of day of operation*

The time of surgery by grade of surgeon, is shown in Table 20. Trainees recorded as the most senior surgeon was most common between 0000-and 0759; 17% of all these operations had a trainee listed as the most senior operator. Between the hours of 1200-1759 only 6% of cases did not have a consultant present. Trainees were over three times more likely to operative independently after midnight than during the daytime (OR 3.20, 95% CI 2.95-3.48).

*Table 20: Number of Trainee and Consultant led Emergency Laparotomy cases by Hospital size and time of day of surgery*

| | **All patients *** | **Consultant led cases*** | **Trainee led cases*** | **Odds ratio** | **P value** |
|---|---|---|---|---|---|
| **Hospital size, by case volume** | | | | | |
| Quartile 1 | 9331 (10.68)* | 8857 (94.92)* | 474 (5.08)* | Comparator | |
| Quartile 2 | 19926 (22.81)* | 18866 (94.68)* | 1060 (5.32)* | 1.04 (0.93,1.17) | 0.391 |
| Quartile 3 | 27285 (31.23)* | 25128 (92.09)* | 2157 (7.91)* | 1.60 (1.44,1.77) | 0.000 |
| Quartile 4 | 30825 (45.92)* | 27691 (89.83)* | 3134 (10.17)* | 2.11 (1.91,2.33) | 0.000 |
| **Time of day of surgery** | | | | | |
| 0800-1159 | 20504 (24.41)* | 19266 (93.96)* | 1238 (6.04)* | Comparator | |
| 1200-1759 | 35831 (42.65)* | 33713 (94.09)* | 2118 (5.91)* | 0.97 (0.90,1.05) | 0.541 |
| 1800-2359 | 20645 (24.57)* | 18643 (90.30)* | 2002 (9.70)* | 1.67 (1.55,1.79) | 0.000 |
| 0000-0759 | 7032 (8.37)* | 5832 (82.94)* | 1200 (17.06)* | 3.20 (2.95,3.48) | 0.000 |

Values in parentheses are 95 per cent confidence intervals unless indicated otherwise; * values are number (per cent)

*6.5.6 Outcomes*

Crude post-operative 90 day mortality for the whole cohort was 14.8% (12,917 patients). In Em Lap operations, where a consultant was the most senior surgeon, mortality by 90 days was 15.1% (12,164) compared to Em Lap with a trainee as the most senior surgeon, where 90 day mortality rate was 11.0% (753).

There were no increased odds of death if a trainee was the most senior surgeon in any of the operative subgroups seen. This finding remained true following risk adjustment (segmental colectomy OR 0.94, 95%CI 0.76-1.18, Hartmann's Procedure OR 1.16, 95% CI 0.88-1.53, suture repair of perforated peptic ulcer disease OR 1.14, 95% CI 0.81-1.61. The risk adjustment model accounts for derangements in physiology, pre-operative blood tests, co-morbidity and grade of anaesthetic and care received post-operatively (admission to critical care) (Table 20.)

Slight crude increased rates of return to theatre were observed in Em Lap and procedures in the consultant group; 8.9% (7105) consultants v 6.7% (455) trainees (Table 21).However no significant difference was observed on risk adjusted analysis in rates of return to theatre between trainee and consultant groups (segmental colectomy OR 1.11, 95% CI 0.88-1.38, Hartmann's Procedure OR 0.98, 95% CI 0.73-1.34, suture repair of perforated peptic ulcer disease OR 0.98, 95% CI 0.65-1.48 (Table 21).

*Table 21: Logistic regression analysis of trainee verses consultant as most senior surgeon in all Emergency Laparotomy procedures.*

| Outcome measure | Event rate* | | Unadjusted Odds Ratio | P value | Adjusted Odds Ratio | P value |
|---|---|---|---|---|---|---|
| | Trainees | Consultants | | | | |
| *Segmental colectomy at Emergency Laparotomy* | | | | | | |
| **90-day mortality** | 122 (12.55)* | 2843 (14.14)* | 0.87 (0.71,1.05) | 0.165 | 0.94 (0.76,1.18) | 0.165 |
| **Return to theatre** | 92 (9.49)* | 1831 (9.16)* | 1.03 (0.83,1.29) | 0.727 | 1.11 (0.88,1.38) | 0.373 |
| *Hartmann's Procedure at Emergency Laparotomy* | | | | | | |
| **90-day mortality** | 83 (13.72)* | 1468 (13.99)* | 0.97 (0.77,1.24) | 0.849 | 1.16 (0.88,1.53) | 0.264 |
| **Return to theatre** | 47 (7.82)* | 858 (8.23)* | 0.95 (0.69,1.28) | 0.989 | 0.98 (0.73,1.34) | 0.947 |
| *Adhesiolysis at Emergency Laparotomy* | | | | | | |
| **90-day mortality** | 80 (5.02)* | 1034 (7.99)* | 0.61 (0.48,0.76) | 0.000 | 0.79 (0.61,1.01) | 0.066 |
| **Return to theatre** | 57 (3.60)* | 681 (5.28)* | 0.67 (0.50,0.88) | 0.004 | 0.74 (0.56,0.98) | 0.037 |
| *Suture or repair of perforation of peptic ulcer at Emergency Laparotomy* | | | | | | |
| **90-day mortality** | 61 (8.29)* | 564 (14.57)* | 0.52 (0.40,0.69) | 0.000 | 1.14 (0.81,1.61) | 0.439 |
| **Return to theatre** | 29 (3.96)* | 208 (5.42)* | 0.72 (0.48,1.07) | 0.103 | 0.98 (0.65,1.48) | 0.940 |

Values in parentheses are 95 per cent confidence intervals unless indicated otherwise; * values are number (per cent)

## 6.6 Discussion

Every surgeon needs to be trained, but this needs not to be at the expense of patient safety or healthcare efficiency. Using a large, nationwide, externally validated database, no difference in mortality between cases performed by consultants and cases performed by trainees is found.

A similar large database study addressed trainee participation in emergency general surgery in the USA. They performed a multivariate regression analysis and suggested that trainee participation was independently associated with intra- and postoperative adverse events (Kasotakis et al., 2014), specifically return to theatre, post-operative transfusions and wound infections. Their cohort contained a large range of emergency general surgical procedures with appendiectomy making up the majority of cases analysed. Subsequent correspondence highlighted significant limitations, especially that the database used did not report the level of trainee participation or supervision (Singh et al., 2016), that the complications were not matched to specific procedures (Graat et al., 2016) (for example mortality after appendiectomy is extremely rare) and that adjustment for grade of anaesthetist involved in the case was not performed (Li et al., 2017).

While this previous study suggested that trainee involvement was adversely associated with outcomes, other reports do not support their conclusions. Hwang et *al* (Hwang et al., 2008) conducted a single centre study in the USA investigating outcomes of trainee involvement in the five most common general surgery cases in their institution (major small/large bowel resection,

laparoscopic cholecystectomy, hernia, mastectomy and appendiectomy). They suggested that there was no significant association between post-operative mortality and complications if a consultant had a trainee surgeon involved in any aspect of the patients care (in clinic, intra operatively, and post-operative care on the ward). They did not describe the level of trainee involvement during surgery. These findings were supported by a large multicentre study using the American College of Surgery National Surgical Quality Improvement Program (ACS NSQIP) database which also focused on low risk elective general surgical procedures (open inguinal hernia, laparoscopic inguinal hernia, laparoscopic cholecystectomy, open right hemicolectomy, total thyroidectomy, laparoscopic Niessen fundoplication, and laparoscopic Roux-en-Y gastric bypass) and concluded that trainee involvement was safe and conferred no increased risk of morbidity or mortality following risk adjustment (Tseng et al., 2011). However, again the authors did not define the term "trainee involvement."

These study findings are further supported by another US study, again using the ACS NSQIP database, focussing on trainee involvement with higher risk general surgical cases (oesphagectomy, open abdominal aortic aneurysm, laparoscopic paraoesphageal hernia repair, pancreaticoduodenectomy, abdominoperineal resection and hepatectomy) concluding that trainee participation was not predictive of mortality or complications in these "higher risk" general surgical procedures (Cobb et al., 2018). While these operations are considered more complex with higher risk of complication, an elective patient cohort is less likely to be physiologically unwell or have evidence of sepsis that is almost always present in an Em Lap patient.

Conflicting data is published concerning elective and emergency colorectal surgery. One national database study reported an increased unplanned return to theatre when trainees performed segmental colectomies compared to consultants (OR 1.18 95% CI 1.09-1.27) (Iannuzzi et al., 2013b). However, a meta-analysis on trainee performed compared to "expert surgeon-performed" colorectal resections found there was a significantly lower rate of anastomotic leak and return to theatre in the trainee group. This meta-analysis also reported that there was no significant risk of patients developing pelvic abscesses or wound infections in trainee led operations (Kelly et al., 2014). This was despite the trainee group performing more emergency cases, however, the authors attributed this finding to case selection bias. One UK based study using the Northern Region Colorectal Cancer Audit, described increased mortality in trainees who performed unsupervised operations (Borowski et al., 2008). This differs from a study from Edinburgh, where Singh *et al* showed no significant difference in mortality or survival between unsupervised trainees and consultants (Singh and Aitken, 1999). While this paper was clear on descriptions of "supervision," they made no comment on the level of experience of the trainee. The study cohort included 306 operations from a single consultant, performed from November 1989 to November 1996, during which time surgical trainees would have been following a completely different training programme and curriculum from today's trainees and would likely have been considerably more experienced. Meta-analysis found no association between death and trainee involvement in colorectal operations. Studies including both emergency and elective resections were included. The analysis included 11 studies (a total of 14,344 colorectal

resections) with 30-day post-operative mortality as an outcome, and reported a non-significant pooled OR of 0.90 (95% Cl 0.78-1.04) (Kelly et al., 2014).

Other studies have examined the association between trainee involvement and outcomes across several different surgical specialities with varying conclusions. Within other general surgical specialties (endocrine and breast surgery) no adverse association was described with trainee involvement. While in Trauma surgery, less favourable outcomes following lower limb amputation were reported (Patel et al., 2010; Clark et al., 2014; Aguilar et al., 2011; Iannuzzi et al., 2013a).

Here, risk adjustment has been performed to ensure that patient characteristics and pre and peri operative factors that are known to contribute to post-operative outcomes, do not influence the observed results. While physiological factors can be accounted for, there are some variables that cannot be adjusted for due to the limitations of the dataset. While it is appreciated that a raised body mass index (BMI) can contribute to the ASA grade assigned to a patient, the impact of a raised BMI on the technical aspects of surgery cannot be accounted for in this study. Similarly, the number of previous surgeries a patient may have had in the past remains unknown within the NELA database.

This study demonstrates significant variation in the number of cases performed by trainees by hospital size and time of day of surgery. This finding is supported by the NELA annual reports which highlight that consultant presence remains at its lowest out of hours (NELA Project Team, 2015b, 2016, 2017, 2018b).

There may be a number of explanations for this finding including that in high volume centres consultants may be engaged in other aspects of an emergency take or be involved in other cases, or that the trainees placed in higher volume centres tend to be more experienced and therefore competent and trusted to operate unsupervised. As NELA does not collect data on the level of experience of a trainee no further comment can be made.

NELA promotes consultant led care at all points of the patient's Em Lap journey and in particular for high risk patients (NELA Project Team, 2015b, 2016, 2017, 2018b). Over the last four years consultant presence in theatre has steadily increased (NELA Project Team, 2018b). From these findings it can be suggested that Em Lap can provide multiple training opportunities for trainees while under guidance of the supervising consultant. However, these data suggest that the presence of a consultant is not necessary for all cases, although how patients are selected for independent trainee operating is not clear from the data set available and requires further analysis.

The strengths of this study are that data are taken from a large, nationwide, multicentre, prospectively maintained database linked with an externally validated mortality register. The NELA risk score has been formulated specifically for use in Em Lap patient and takes account of clinical intra-operative findings which makes it a more accurate risk adjustment tool compared to the Physiological and Operative Severity Score for the enumeration of Mortality and morbidity (POSSUM) score (Eugene et al., 2018).

Limitations include lack of data on trainee level of experience, and more detailed surgical factors as discussed above. Case ascertainment was estimated at 65-70% in first two years of the audit (NELA Project Team, 2015b, 2016), which may have led to under or overestimation of adverse outcomes. Case ascertainment rates have increased subsequently. The risk scoring tool uses some preoperative physiological values from when the patient is first reviewed by either the surgical or anaesthetic team. These risk scores may deteriorate if their Em Lap was delayed for any reason. Alternatively, if there was improvement after resuscitation there may be some over estimation of risk and this could dilute the effect of other factors in the risk adjustment model.

While it is clear that the trainee will have performed the case independently in the trainee group, it is not clear on the level of trainee involvement in the consultant led cases. It may be that a consultant supervised a trainee performing some or all aspects of the Em Lap case. However, if a consultant were present, one would hope that supervision would include stepping in and taking over from a junior colleague in the event of difficulty or if the procedure was taking a prolonged period of time at the detriment to the patient. It may be that unsupervised trainees are senior and so independent operating judged to be safe by the consultant responsible for the patient's care on a case by case basis. Independence in the later stages of training is important as it is only then that competence at the level of a day 1 consultant can be demonstrated.

This is an observational study and the results can be suggestive of associations and trends but not causality. Moreover, effects from residual confounding from

variables not considered here and not included in this regression model cannot be excluded.

## 6.7 Conclusions

Trainee led operating is more likely to occur in large volume centres and at night. However, trainee involvement in Em Lap is not associated with increased mortality or return to theatre

# 7 Thesis Conclusions

## 7.1 Conclusions from this thesis

Em Lap are commonly performed in England and Wales with morbidity and mortality representing significant burden to both individual patients, families, healthcare providers and wider stakeholders. Over the last 5 years the NELA database has facilitated high quality data collection regarding this cohort of patients. Purely descriptive trends in care and outcomes have been published annually. This is the first piece of work to analyse and discuss specific aspects of care of interest to surgeons and trainee surgeons, with particular regard to service configuration and discussion around implications for training.

A common theme not only within the NELA annual reports, but also addressed in other national guidelines (The Royal College of Surgeons (Eng), 2018b), is the management of intra-abdominal sepsis. The need for improvements in timely delivery of antibiotics and also surgical source control has been noted. In Chapter 3, using the perforated peptic ulcer disease cohort, trends are described in timeliness to theatre for patients with intra-abdominal sepsis. Wide variation in the speed of arrival in theatre is identified. Additionally, this analysis demonstrates that there is a significant increase in mortality for every hour a patient is delayed in arriving in theatres for source control via Em Lap. The risk of death rises to 6% per hour following admission if a patient displays derangements in physiology at presentation to hospital. These analyses are of particular importance, as gaining early access to theatres is a potentially modifiable factor in the patient journey and improvements could led to decreased mortality. A multi-professional dissemination of these findings should be undertaken.

It may be that a culture change is required. Emergency aortic surgery has always been viewed as the most urgent operative case. The work in this thesis demonstrates that mortality for physiologically unstable patients with perforated peptic ulcer disease is comparable to those who have surgery for aortic rupture. It is therefore imperative that this message is disseminated widely within local and national networks. While not addressed specifically in this thesis, improvement in antibiotic administration must be improved. It has not been possible to quantify the issues underpinning the delays to theatre for this cohort due to limitations of the dataset, however local investigation into these factors is encouraged. It is hoped that this study will raise the awareness of the importance of source control and stimulate local teams to change and improve practice.

In recent years, some larger hospitals have begun a speciality specific on-call service for the Emergency General Surgery. No work had investigated the association between post-operative mortality and the elective special interest of consultant surgeon responsible for the care of the patient. In Chapter 4, both upper GI (UGI) and lower GI (LGI) procedure specific groups have been analysed, showing that there is increased risk of post-operative mortality and morbidity if an LGI procedure is not performed by a consultant surgeon with a special interest in coloproctology. Similar increased risks were observed if an UGI procedure was performed by a surgeon other than a one with an elective special interest in UGI surgery.

The work in this chapter also has implications nationally. We do not know numbers of hospitals that run a special interest on call. It is important to

appreciate that not all hospitals that perform emergency surgery will be able to provide special interest specific cover 24 hours a day. However, when at all possible, input for all emergency patients from a surgeon with the appropriate elective special interest should be encouraged. This message is echoed by national guidelines, that recommend specialist colorectal input should be available at all times of day for patients that present as an emergency with bowel cancer (Colorectal Cancer Clinical Expert Group, 2017), although this recommendation has not been based on outcomes evidence. To really improve patient care and outcomes, these study findings need to be debated and discussed firstly at national level and then locally where hospitals can formulate solutions to these questions that work for their specific hospital service. There will be considerable direct and opportunity cost of implementing a special interest specific on call. Policy makers may push instead for training, and maintenance of skills, in both elective and emergency GI surgery rather than allow further specialisation. Resources and the tension between elective and emergency priority will decide. Centralisation of many but basic general surgical procedures may make surgical practice in smaller hospitals unattractive to trainees as prestige is currently not in generalism which may led to smaller hospitals having difficulty in recruiting consultants of the future.

Trainee general surgeons are required to gain experience, with the aim of becoming competent in managing and operating on patients who require Em Lap. In order to improve training, it is important to understand the current situation and operations that are occurring. As trainees receive the majority of

their training in one deanery, the numbers of Em Lap cases have been analysed by deanery and the numbers reported by the number of trainees within each region in Chapter 5 of this thesis. There is significant variation between deaneries across the number of Em Laps performed and also the index procedures required for certification in general surgery. Analysis has also suggested that trainees in some deaneries may struggle to reach the target of 100 Em Laps during the six years of general surgical training.

This information is vital to trainees who hope to become well rounded and effective general surgeons with a safe emergency practice, and not least to help them maximise chances of meeting curricular requirements. Trainees and stakeholders within general surgery should use this information to take a proactive approach to improving training and to ensure adequate exposure to emergency general surgery. It may be that trainees use this information prior to selecting a deanery to apply to for a national training job or trainees who may not be achieving adequate operative numbers apply for an out of programme experience in a deanery with a higher number of Em Lap cases annually.

We do not have access to specific "log book" data for the actual numbers of procedures that trainees are performing. However, this current study defines the denominator for training opportunities with Em Lap operating in England and Wales and the results presented here should be examined with respect to the future setting of general surgery index procedure indicative numbers. Further investigation into actual numbers of log book numbers with trainee involvement should be performed. Logbook data, coupled with this current work will allow trainees, training program directors, heads of schools and national stakeholders the opportunity for improvement and development of

training in Em Lap care and map training number allocation to the current workload within in this country.

The work presented in Chapter 6 builds on these findings, and investigates the association between trainee led operating and post-operative outcomes. The chapter highlights that there is significant inter deanery variation in the number of cases performed independently by trainees. Reassuringly for training opportunities, following risk adjustment for patient characteristics, there was no increase in mortality or morbidity if an Em Lap was performed by trainee compared to operations with a consultant present. In this study the trainee group is clearly defined, however there is not an understanding of the level of trainee performing the operation. Previously there has been mixed conclusions from work addressing these issues and this study is the first to exclusively examine the Em Lap cohort.

It is hoped that this paper will encourage consultants to consider Em Lap as a training opportunity for all levels of trainee. It may be that more junior trainees require a higher level of supervision compared to those who are towards the end of training.

In summary, new knowledge and insight into Em Lap operating and outcomes in England and Wales has been presented in this thesis. This work has the potential to impact on national policies throughout several aspects of general surgery. However, several limitations in the data do exist. Of particular reference to these analyses; the level of trainee surgeon operating may play a significant role in outcomes measure here; this information is not currently

available in the data. A junior trainee (ST3 level) will be much less competent than a senior trainee surgeon who may be in their final year of training and acting as an independent practitioner. Furthermore, data on hospitals that run an emergency general surgery service is an unknown. These hospitals may employ surgeons who only operate on acute surgical pathology or may have processes to streamline emergency surgical admissions.

At this current time, NELA does not assess how hospitals enter and manage their data collection. Some hospitals contemporaneous enter the data at the time of operation while others employ a research assistant who enters the data when the patient is discharged. National data validation is not currently performed by the NELA team, but is a process that is under development to ensure continuity and parity with data entry protocols.

Following the work presented here further areas for investigation could include:

- Timeliness of antibiotics in patients with intra-abdominal sepsis.

  Data quality should improve over the next years in regards to timing and delivery of antibiotics in the Em Lap cohort following promotion and quality improvement initiatives. This will allow not only specific investigation into this metric but also will allow the presence or absence antibiotic administration to be used in risk adjustment models for further research.
- The impact of running a split speciality on-call service on outcomes following Em Lap.

It is hoped, that in the next organisational audit of NELA, data will be collected relating to how the EGS service in each hospital is configured. This will firstly allow an understanding of how many hospitals are running a split speciality on-call. It will also allow, using similar methods presented in this thesis, investigation into the impact of split speciality on calls on outcomes in Em lap performed for all indications.

Small bowel emergencies are neither considered an UGI or LGI procedure. With the importance of speciality specific management for the emergency patient, it would be of interest to understand the outcomes of patients with small bowel pathologies that are managed but either an UGI or LGI consultant.

- Trainee case load

There were some limitations to the work presented on case load variation in trainee Em Lap operating. It was not possible to gain access to raw trainee log book data via the ISCP website. In the future it would be beneficial to analyse by deanery, the actual numbers of cases that trainees are recording in their surgical log books. This will allow comparison with the denominator numbers presented in this thesis and will add further clarity to the issue surrounding training numbers in Em lap and whether trainees are receiving adequate exposure and experience.

It would also be of interest to understand the level of trainee involvement in Em lap cases that are listed as “consultant as most

senior surgeon in theatre." A change to the NELA data collection tool, to facilitate this work at a later date, has been requested.

# 8 Appendices

## 8.1 National Audit Inclusion and exclusion criteria

*Appendix 1: National Emergency Laparotomy Audit inclusion and exclusion criteria (NELA Project Team, 2014a)*

| Inclusion | Exclusion |
|---|---|
| >18 years | <18 years |
| Non elective, open, laparoscopic, or laparoscopically-assisted procedures | Elective laparotomy/laparoscopy |
| Procedures involving the stomach, small or large bowel, or rectum for conditions such as perforation, ischaemia, abdominal abscess, bleeding or obstruction | Diagnostic laparotomy/laparoscopy where no subsequent procedure is performed |
| Washout/evacuation of intra-peritoneal abscess or haematoma | Appendicectomy +/- drainage of localised collection unless the procedure is incidental to a non-elective procedure on the GI tract |
| Bowel resection/repair due to incarcerated incisional, umbilical, inguinal and femoral hernias | Cholecystectomy +/- drainage of localised collection unless the procedure is incidental to a non-elective procedure on the GI tract |
| Bowel resection/repair due to obstructing/incarcerated incisional hernias provided the presentation and findings were acute. This will include large incisional hernia repair with division of adhesions | Non-elective hernia repair without bowel resection or division of adhesions |
| Laparotomy/laparoscopy with inoperable pathology (e.g. peritoneal/hepatic metastases) where the intention was to perform a definitive procedure. This does not include purely diagnostic procedures | Minor abdominal wound dehiscence unless this causes bowel complications requiring resection |
| Adhesiolysis | Non-elective formation of a colostomy or ileostomy as either a trephine or a laparoscopic procedure |
| Return to theatre for repair of substantial dehiscence of major abdominal wound (i.e. “burst abdomen”) | Vascular surgery, including abdominal aortic aneurysm repair |

| | |
|---|---|
| Any reoperation/return to theatre for complications of elective general/upper GI surgery meeting the criteria above is included. | Caesarean section or obstetric laparotomies/gynaecology laparotomies/laparotomy for ruptured ectopic or pelvic inflammatory disease |
| | Trauma laparotomy |
| | Laparotomy for pathology of spleen, renal tract, kidneys, liver, gallbladder, or urinary tract. |
| | Returns to theatre for complications following non GI surgery. |

# 8.2 National Emergency Laparotomy Audit Data Collection Form

*Appendix 2 Data collected within the National Emergency Laparotomy Webtool (NELA Project Team, 2015a, 2016, 2017)*

| 1. | Demographics and Admission | Notes |
|---|---|---|
| 1.2 | Age on arrival | *Age will automatically be calculated on web tool* |
| 1.5 | Sex | ○Male / ○Female |
| 1.9 | Date and time the patient first arrived at the hospital/Emergency department | |
| 1.10 | What was the nature of this admission? | ○Elective / ○Non-elective |
| 1.10b | If non-elective, what was the initial route of admission/assessment? | ○ Assessed initially in Emergency Department<br>○ Assessed initially in "front of house" acute surgical assessment unit<br>○ Direct referral to ward by GP<br>○ Direct admission from Clinic<br>○ Hospital Transfer |
| 1.11 | Which specialty was this patient first admitted under?<br><br>***Do not** use "other" if the patient spent a period of observation under Emergency Medicine* | ○ General surgery<br>○ General medicine<br>○ Gastroenterology<br>○ Elderly Care<br>○ Other |
| 1.12 | Residence before this hospital admission | ○ Own home/sheltered housing<br>○ Residential care<br>○Nursing care<br>○ Unknown |
| 2 | **Pre-op**<br><br>**If the patient is returning to theatre as an emergency following previous elective surgery, all answers should relate to the Emergency Laparotomy, not the previous elective surgery.** | |
| 2.1 | Date and time first seen by consultant surgeon following admission with acute abdomen. If under care of a non-surgical specialty, this should be the time 1st seen after referral to general surgeons. | Date _____(DD/MM/YYYY)<br>○ Date not known<br>Time_____ (HH:MM)<br>○ Time not known<br>○ Not Seen |
| 2.2 | Date and time that the decision was made to operate<br>*If this is unavailable please enter date and time that this patient was first booked for theatre for Emergency Laparotomy* | Date _____(DD/MM/YYYY)<br>○ Date not known<br>Time_____ (HH:MM)<br>○ Time not known |
| 2.4 | Was the decision to operate made by consultant surgeon? | ○ Yes<br>○ No<br>○ Not known |
| 2.4 | Was there consultant surgeon input into the decision to operate?<br>*can refer to situations where eg decision is made on consultant ward round pending CT results, which then confirms need for surgery<br>#refers to situations where consultant has not seen patient but has been discussed with consultant | ○ Yes, consultant reviewed patient at time of decision *<br>○ Yes, following discussion with junior team member #<br>○ Decision made by junior team member **without** consultant input<br>○ Unknown |
| 2.7 | Was an abdominal CT scan performed in the pre-operative period as part of the diagnostic work-up? | ○ Yes<br>○ No<br>○ Unknown |
| 2.7a | If performed, how was this CT reported pre-operatively?<br>*(If CT is reported by a registrar and validated by a consultant **before** surgery, select "in-house consultant". If **not validated** by consultant before surgery, select "registrar")* | ○ In-house consultant<br>○ In-house Registrar<br>○ Outsourced service<br>○ Not reported pre-operatively<br>○ Unknown |
| 2.7b | Was there a preoperative discussion between the radiologist and the requesting team about the CT findings? | ○ Yes<br>○ No<br>○ Unknown |

| | | |
|---|---|---|
| **2.7c** | Was there a discrepancy between the CT report and surgical findings that altered or delayed either the diagnosis or surgical management? | O Yes<br>O No<br>O Unknown |
| **2.8a** | Consultant Anaesthetist involvement in planning perioperative care. *This can include preoperative assessment, discussion about decisions for & risk/benefits of surgery, or need for critical care* | O Yes – seen by consultant anaesthetist in person<br>O Yes – discussion between consultant anaesthetist & other team member (of any specialty)<br>O No consultant anaesthetist input before surgery<br>O Unknown |
| **2.8b** | Intensive care involvement in planning perioperative care. *This can include preoperative assessment, discussion about decisions for & risk/benefits of surgery, or need for critical care* | O Yes – seen by consultant intensivist in person<br>O Yes – discussion between consultant intensivist & other team member (of any specialty)<br>O Seen by or discussion with junior ITU team member only<br>O No intensive care input before surgery<br>O Unknown |
| **2.10** | What was the date and time of the first dose of antibiotics following presentation to hospital? *(only relevant for non-elective admissions)* | O In theatre, or<br>Date _____(DD/MM/YYYY)<br>O Date not known<br>Time_____ (HH:MM)<br>O Time not known<br>O Not Administered |
| **2.11a** | Was sepsis suspected on admission? | OYes<br>ONo<br>OUnknown |
| **2.11b** | Was sepsis suspected at the time the decision for surgery was made? | OYes<br>ONo<br>OUnknown |
| **2.12** | Was the patient assessed by a specialist from Elderly Medicine in the pre-operative period? *(Can include physician or nurse specialist)* | O Yes<br>O No<br>O Unknown |
| **3** | **Pre-op Risk stratification** | |
| **3.1** | Prior to surgery, what was the risk of death for the patient that was entered into medical record?<br>*For info, wording of relevant standard "An assessment of mortality risk should be made explicit to the patient and recorded clearly on the consent form and in the medical record."* | O Lower (<5%)<br>O High (5-10%)<br>O Highest (>10%)<br>O Not documented |
| **3.2** | If documented, how was this assessment of risk made? (Please select all that apply) | □ Risk prediction tool (e.g. P-POSSUM)<br>□ Clinical Judgement<br>□ Surgical APGAR<br>□ Physiological criteria<br>□ Other e.g. hospital policy |
| **3.3** | What was the **ASA** score? | O 1: No systemic disease<br>O 2: Mild systemic disease<br>O 3: Severe systemic disease, not life-threatening<br>O 4: Severe, life-threatening<br>O 5: Moribund patient |
| **3.4** | What was the most recent pre-operative value for serum Creatinine (micromol/l) | O Not performed |
| **3.5** | What was the most recent pre-operative value for blood lactate – may be arterial or venous (mmol/l) | O Not performed |
| **3.5i** | What was the highest CRP in pre-operative period (mg/l)? | O Not performed |
| **3.5ii** | What was the lowest albumin in pre- operative period (g/l)? | O Not performed |
| **3.6** | Serum Sodium concentration (mmol/l) | |
| **3.7** | Serum Potassium concentration (mmol/l) | |
| **3.8** | Serum Urea concentration (mmol/l) | |
| **3.9** | Serum Haemoglobin concentration (g/dl) | |

| | | |
|---|---|---|
| **3.10** | Serum White cell count (x10∧9 / l) | |
| **3.11** | Pulse rate(bpm) | |
| **3.12** | Systolic blood pressure (mmHg) | |
| **3.13** | Glasgow coma scale | |
| **3.14** | Select an option that best describes this patient's **ECG** | ○ No abnormalities<br>○ AF rate 60-90<br>○ AF rate >90/ any other abnormal rhythm/paced rhythm/ >5VE/min/ Q, ST or T wave abnormalities |
| **3.15** | Select an option that best describes this patient's **cardiac signs** and chest xray appearance | ○ No failure<br>○ Diuretic, digoxin, antianginal or antihypertensive therapy<br>○ Peripheral oedema, warfarin Therapy or CXR: borderline cardiomegaly<br>○ Raised jugular venous pressure or CXR: cardiomegaly |
| **3.16** | Select an option that best describes this patient's **respiratory history** and chest xray appearance | ○ No dyspnoea<br>○ Dyspnoea on exertion or CXR: mild COAD<br>○ Dyspnoea limiting exertion to < 1 Flight or CXR: moderate COAD<br>○ Dyspnoea at rest/rate > 30 at rest or CXR: fibrosis or consolidation |
| **3.16a** | Patient was ventilated prior to Emergency Laparotomy | ○ Yes<br>○ No |
| | *Online web tool will automatically calculate Physiology severity score* | |
| **3.17** | Select the **operative severity** of the intended surgical intervention (see help box for examples) | ○ Major<br>○ Major+ |
| **3.18** | Including this operation, how many operations has the patient had in the 30 day period prior to this procedure? | ○ 1<br>○ 2<br>○ >2 |
| **3.19** | Based on your clinical experience of the intended surgery, please estimate the likely ***intra*operative blood loss** (ml) | ○ <100<br>○101-500<br>○ 501-999<br>○ >=1000 |
| **3.20** | Please select a value that best describes the likely degree of **peritoneal soiling** | ○ None<br>○ Serous fluid<br>○ Localised pus<br>○ Free bowel content, pus or blood |
| **3.21** | What severity of malignancy is anticipated to be present? | ○ None<br>○ Primary only<br>○ Nodal metastases<br>○ Distant metastases |
| **3.22** | Please select **urgency** of surgical intervention<br>*(see help notes for additional information, including equivalent Possum categories)* | ○ 3. Expedited (>18 hours)<br>○ 2B. Urgent (6-18 hours)<br>○ 2A. Urgent (2-6 hours)<br>○ 1. Immediate (<2 hours) |
| **3.23** | Pre-op P-POSSUM predicted **mortality**<br>***CAUTION: P-POSSUM can over predict mortality (up to two-fold) at risk levels above 15%. See 3.26 for NELA risk model estimate.*** | Calculated |
| **3.24** | Pre-op POSSUM predicted **morbidity** | Calculated |
| **3.25** | Not all P-POSSUM investigations available | ○ |
| **3.26** | Estimated mortality using NELA risk adjustment model *(Figure only provided if all data available)* | Calculated |

| | | |
|---|---|---|
| **4** | **Intra-op** | |
| **4.1** | Date and time of entry in to operating theatre/anaesthetic room (not theatre suite) | Date<br>_____(DD/MM/YYYY)<br>Time_____ (HH:MM)<br>□ Time not known |
| **4.2** | Senior surgeon grade<br>*(this can include surgeon supervising in theatre but not necessarily scrubbed)* | ○ Consultant<br>○ Post-CCT fellow<br>○ SAS grade<br>○ Research Fellow / Clinical Fellow<br>○ Specialty trainee<br>○ Other |
| **4.3** | Senior anaesthetist present in theatre | ○ Consultant<br>○ Post-CCT fellow<br>○ SAS grade<br>○ Research Fellow / Clinical Fellow<br>○ Specialty trainee<br>○ Other |
| **4.4** | How did you provide goal directed fluid therapy? | ○ Not provided<br>○ Dynamic index e.g. Stroke volume, PPV, SVV<br>○ Static index e.g. CVP<br>○ Other, eg bioimpedence |
| **4.4** | How did you provide goal directed fluid therapy? | ○ Not provided<br>○ Cardiac output monitor<br>○ Other |
| **5** | **Procedure** | |
| **5.1** | Is this the first surgical procedure of this admission, or a complication of previous surgery within the same admission? | ○ First surgical procedure after admission<br>○ Surgery for complication of previous surgical procedure within the same admission |
| **5.2** | What is the indication for surgery?<br>*(Please select all that apply)* | ○ Peritonitis<br>○ Perforation<br>○ Abdominal abscess<br>○ Anastomotic leak<br>○ Intestinal fistula<br>○ Phlegmon<br>○ Pneumoperitoneum<br>○ Necrosis<br>○ Sepsis<br>○ Small bowel obstruction<br>○ Large bowel obstruction<br>○ Volvulus<br>○ Internal hernia<br>○ Pseudo-obstruction<br>○ Intussusception<br>○ Incarcerated hernia<br>○ Obstructing incisional hernia<br>○ Haemorrhage<br>○ Ischaemia<br>○ Colitis<br>○ Abdominal wound dehiscence<br>○ Abdominal compartment syndrome<br>○ Acidosis<br>○ Iatrogenic injury<br>○ Foreign body<br>○ Planned relook<br>(○ Int obstruction: Yr1/2) |
| **5.3.a** | Main procedure | ○ Peptic ulcer – suture or repair of perforation<br>○ Peptic ulcer – oversew of bleed<br>○ Gastrectomy: partial or total<br>○ Gastric surgery - other<br>○ Small bowel resection<br>○ Resection of Meckel's diverticulum<br>○ Colectomy: left (including sigmoid colectomy and anterior resection)<br>○ Colectomy: right (including ileocaecal resection) |

| | | |
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| | | O Colectomy: subtotal or panproctocolectomy<br>O Hartmann's procedure<br>O Colorectal resection - other<br>O Abdominal wall closure following dehiscience<br>O Abdominal wall reconstruction<br>O Adhesiolysis<br>O Reduction of volvulus<br>O Enterotomy<br>O Stricturoplasty<br>O Drainage of abscess/collection<br>O Evacuation of haematoma<br>O Debridement<br>O Exploratory/relook laparotomy only<br>O Haemostasis<br>O Intestinal bypass<br>O Laparostomy formation<br>O Repair of intestinal perforation<br>O Repair or revision of anastomosis<br>O Repair of intestinal fistula<br>O Resection of other intra-abdominal tumour(s)<br>O Defunctioning stoma via midline laparotomy<br>O Revision of stoma via midline laparotomy<br>O Large incisional hernia repair with bowel resection (Yr4)<br>O Large incisional hernia repair with division of adhesions (Yr4)<br>O Washout only<br>O Removal of foreign body<br>O Not amenable to surgery |
| **5.3.b** | Second procedure (at same laparotomy) | O Peptic ulcer – suture or repair of perforation<br>O Peptic ulcer – oversew of bleed<br>O Gastrectomy: partial or total<br>O Gastric surgery - other<br>O Small bowel resection<br>O Resection of Meckel's diverticulum<br>O Colectomy: left (including sigmoid colectomy and anterior resection)<br>O Colectomy: right (including ileocaecal resection)<br>O Colectomy: subtotal or panproctocolectomy<br>O Hartmann's procedure<br>O Colorectal resection – other<br>O Splenectomy<br>O Abdominal wall closure following dehiscience<br>O Abdominal wall reconstruction<br>O Abdominal hernia repair<br>O Adhesiolysis<br>O Reduction of volvulus<br>O Enterotomy<br>O Stricturoplasty<br>O Drainage of abscess/collection<br>O Evacuation of haematoma<br>O Debridement<br>O Haemostasis<br>O Intestinal bypass<br>O Laparostomy formation<br>O Repair of intestinal perforation<br>O Repair or revision of anastomosis<br>O Repair of intestinal fistula<br>O Resection of other intra-abdominal tumour(s)<br>O Defunctioning stoma via midline laparotomy |

| | | |
|---|---|---|
| | | ○ Revision of stoma via midline laparotomy<br>○ Large incisional hernia repair with bowel resection<br>○ Large incisional hernia repair with division of adhesions<br>○ Removal of foreign body |
| **5.3.c** | Third procedure (at same laparotomy) | |
| **5.4** | Procedure approach | ○ Open<br>○ Laparoscopic<br>○ Laparoscopic assisted<br>○ Laparoscopic converted to open |
| **5.5** | Operative findings:<br>*(Please select all that apply)*<br>*If unsure whether this patient is eligible for NELA please refer to help box* | ○ Abscess<br>○ Anastomotic leak<br>○ Perforation – peptic ulcer<br>○ Perforation – small bowel/colonic<br>○ Diverticulitis<br>○ Intestinal fistula<br>○ Adhesions<br>○ Incarcerated hernia<br>○ Volvulus<br>○ Internal hernia<br>○ Intussusception<br>○ Stricture<br>○ Pseudo-obstruction<br>○ Gallstone ileus<br>○ Meckel's diverticulum<br>○ Malignancy – localised<br>○ Malignancy – disseminated<br>○ Colorectal cancer<br>○ Gastric cancer<br>○ Haemorrhage – peptic ulcer<br>○ Haemorrhage – intestinal<br>○ Haemorrhage – postoperative<br>○ Ulcerative colitis<br>○ Other colitis<br>○ Crohn's disease<br>○ Abdominal compartment syndrome<br>○ Intestinal ischaemia<br>○ Necrotising fasciitis<br>○ Foreign body<br>○ Stoma complications<br>○ Abdominal wound dehiscence<br>○ Normal intra-abdominal findings |
| **5.6** | Please describe the peritoneal contamination present *(select all that apply)* | ○ None or reactive serous fluid only<br>○ Free gas from perforation +/- minimal contamination<br>○ Pus<br>○ Bile<br>○ Gastro-duodenal contents<br>○ Small bowel contents<br>○ Faeculent fluid<br>○ Faeces<br>○ Blood/haematoma |
| **5.7** | Please indicate if the contamination was; | ○ Localised to a single quadrant of the abdomen<br>○ More extensive / generalised |
| **6** | **End of Surgery** | |
| **6.1** | At the end of surgery, what risk of death was the patient documented as having? | |
| **6.1** | Was the patient classified as high risk at the end of surgery? | |
| **6.2** | How was this assessment of risk made? (Please select all that apply) | |
| **6.3** | Blood lactate – may be arterial or venous (mmol/l) | |
| | **Post-operative P-POSSUM calculation**<br>Q 6.4 – 6.14 No Longer Required | |

| | | |
|---|---|---|
| | Physiology severity score: | |
| **6.15** | What was the operative severity? (see help box for examples) | |
| **6.16** | Including this operation, how many operations has the patient had in the 30 day period prior to this procedure? | |
| **6.17** | Please select this patient's measured/estimated intraoperative blood loss (ml) | |
| **6.18** | Please select the option that best describes this patient's degree of peritoneal soiling | |
| **6.19** | What was the level of malignancy based on surgical findings | |
| **6.20** | What was the NCEPOD urgency?<br>*(see help notes for additional information, including equivalent Possum categories)* | |
| | *Online web tool will automatically calculate Operative severity score* | |
| **6.21** | Post-op P-POSSUM predicted **mortality**: | |
| **6.22** | Post-op POSSUM predicted **morbidity**: | |
| **6.23** | Not all P-POSSUM investigations available | |
| **6.24** | Where did the patient go for continued post-operative care following surgery? | |
| **6.24a** | At the end of surgery, was the decision made to place the patient on an end of life pathway? | |
| **6.25** | No Longer Required | |
| **6.26** | Estimated mortality using NELA risk adjustment model<br>*(Figure only provided if all data available)* | |
| **7** | **Post-op – *Some fields will need to be completed on discharge or death*** | |
| **7.1** | Total length of post-operative critical care stay (rounded up to whole days). *Includes both ICU and HDU stay -see help box for additional information. Do not include LOS in PACU/other enhanced recovery area* | Number required |
| **7.2** | No Longer Required | |
| **7.3** | Was the patient assessed by a specialist from Elderly Medicine in the post-operative period? *(Can include physician or nurse specialist)* | O Yes<br>O No<br>O Unknown |
| **7.4** | Within this admission, did the patient have an **unplanned** return to theatre in the post-operative period following their initial Emergency Laparotomy? *(do not include planned returns for eg closure of abdomen)* | O Yes<br>O No<br>O Unknown |
| **7.4a** | What was the main indication for the return to theatre?<br>*(Only one option to be chosen)* | OAnastomotic leak<br>OAbscess<br>OBleeding or Haematoma<br>ODecompression of abdominal compartment syndrome<br>OBowel obstruction<br>OAbdominal wall dehiscence<br>OAccidental damage to bowel or other organ<br>OStoma viability or retraction<br>OOther<br>OUnknown |
| **7.5** | Did the patient have an unplanned move **from the ward** to a higher level of care within 7 days of surgery? (do not include moves from HDU to ITU, or escalation from other enhanced area/PACU) | O Yes<br>O No<br>O Unknown |
| **7.6** | No Longer Required | |
| **7.7** | Status at discharge | O Dead O Alive<br>O Still in hospital at 60 days |

| | | |
|---|---|---|
| **7.8** | Date discharged from hospital | (DD/MM/YYYY)<br>Date required |
| **7.9** | Discharge destination | ○Own home/sheltered housing<br>○Residential care<br>○Nursing care<br>○unknown |

## 8.3 National Emergency Laparotomy Audit Key Processes of Care

*Appendix 3: Key Processes of care to be received by all Emergency Laparotomy patients as recommended by The National Emergency Laparotomy Audit* (NELA Project Team, 2015b).

| **Process measure** | **Percentage of patients receiving care required to achieve Green Rating** |
|---|---|
| Case Ascertainment | 80 |
| CT scan reported before surgery | 80 |
| Risk Documented pre operatively | 80 |
| Arrival in theatre in timescale appropriate to urgency | 80 |
| Preoperative review by consultant surgeon and anaesthetists when risk of death is >=5% | 80 |
| Consultant surgeon and anaesthetist present in theatre when risk of death is >=5% | 80 |
| Consultant surgeon present in theatre when risk of death >=5% | 80 |
| Consultant anaesthetist present in theatre when risk of death >=5% | 80 |
| Admitted to critical care post op when risk of death >=5% | 80 |
| Assessment by elderly medicine specialist in patients aged >70 | 80 |

## 8.4 Health Care Quality Improvement Partnership Approval Forms

*Appendix 4: Approval form for Chapter 3*

Extended output scope and decision template V1.1.

(to be used in conjunction with the self-assessment tool for academic papers and other extended outputs)

| |
|---|
| 1. **PROPOSAL OVERVIEW: please summarise:**<br>• ***Project title***<br>• ***the question(s) to be investigated***<br>• ***the dates for the relevant patient cohort being processed, and the associated audit report publication date for that cohort.***<br>• ***the sources of data to be used: England / Wales / other as well as from which data provider: audit dataset / NHSD / NWIS / other NCA***<br>• ***the methodology proposed***<br>• ***the anticipated outputs and benefits***<br>• ***the anticipated project completion date*** |
| **Proposal overview: audit provider to complete:** |
| Investigation into the variation of outcomes of patients with intra-abdominal sepsis regarding timing of source control.<br><br>Aim: We aim to investigate whether the time taken from admission to theatre for patients with intra-abdominal sepsis impact on outcomes following emergency laparotomy.<br><br>Multiple pieces of literature internationally have identified that delays in source control for patients with intra-abdominal sepsis lead to increased post-operative mortality. However, the published literature has significant flaws regarding the patient cohorts they have included (a mixed caseload of all patients having emergency surgery rather than those with "true" peritonitis.) Currently there is no literature describing the relationship between time to theatre and mortality in patients who have confirmed peritonitis and intra- |

abdominal sepsis.

Within the NELA annual reports, we have previously reported the descriptive relationship between operative time of day and mortality. This has been on the whole cohort of Emergency Laparotomy patients, not specifically those with peritonitis or intra-abdominal sepsis. We aim to quantify if there is variation in the outcomes of patients with confirmed intra-abdominal sepsis, specifically relating to time of surgery and also specific factors within this cohort that lead to increased mortality. Our hope is that we can formulate a specific care pathway for these confirmed intra-abdominal sepsis patients, specifically providing guidance on which patients require expedited surgery.

**Dates included:** Years 1-4 of the audit: Year 1 report 30/6/2015, Year 2 report 5/7/2016, Year 3 report 13/10/17, Year 4 report 8/11/18

**Data sources:** All variables within the NELA data set (England and Wales), ONS linked data.

**Methodology and publication plan:** We will use all patients who had an emergency laparotomy for perforated peptic ulcer disease as our study cohort, from Years 1-4 of the dataset. Outcome measures: ONS 30 and 90 day mortality (date of death is not required), return to theatre and post-operative length of stay in hospital. No other sources of data will be used and no other dataset linkage is required.

Multi-level logistic and linear regression analysis will be performed using time to theatre as the main independent variable under investigation. Risk adjustment using other variables in the dataset will also be performed.

This will be written up as an academic paper and will be disseminated to national bodies, in particular the Emergency Surgery Working

group within The Royal College of Surgeons (Eng.)

Anticipated completion date: Mid 2019.

**HBC 19/12/18**

| Additional Questions | Audit provider response – Yes/No, and if Yes then please provide rationale and detail (initialled and dated) | HQIP position – agreed or not agreed and why. (Initialled and dated) |
|---|---|---|
| 2. **Is the purpose of the data processing *explicitly included* in the HQIP contract specification or tender response?**<br><br>**If yes, provide evidence and go to question 4.**<br><br>**If no go to question 3.** | No<br><br>HBC 19/12/18 | N/A<br><br>**YS 22/01/19** |
| 3. **Is the purpose of the data processing *implicit* in the contract specification or tender response?** | Yes: The Audit was designed to answer questions relating to short-term patient outcomes relating to inpatient morbidity/ complications and to investigate reasons for variation in outcomes:<br>• "High incidence of adverse outcomes should promote shared decision making which should include discussion of individual risk, implications of critical care admission, alternative treatment options."<br>• "Once identified, those factors in the delivery of care which are shown to reduce rates of morbidity and mortality in patients undergoing EL will be disseminated | Agreed – this is an extended analysis similar in type to those included in typical NELA reports and clearly within scope.<br><br>**YS 22/01/19** |

| | | |
|---|---|---|
| **/ or consent materials and / or legal requirements outside England and Wales).**<br><br>**b. If data from another data controller (such as NHSD or NWIS) will be processed, please insert evidence from the relevant data sharing agreement that the processing is permitted.** | *1. the process of care prior to surgery, such as diagnostic imaging*<br>*2. the type of surgery undertaken.*<br>*3. the short-term outcomes of surgical treatment*<br>*4. the longer-term survival of patients*<br><br>*Specific objectives related to the clinical outcomes of care will be to examine:*<br>*1. 30-day mortality and*<br>*2. inpatient complications*<br><br>*Describe how the proposed use of patient information will improve patient care and serve the wider public interest?*<br>*Once identified, those factors in the delivery of care which are shown to reduce rates of morbidity and mortality in patients undergoing EL will be disseminated nationally and standards of care introduced.*<br>*Audit results will also be communicated in conference presentations and peer-reviewed publications.*<br><br>*Please list each of the data items you will hold in relation to each patient, and describe against each why the data item is require*<br><br>*We propose to link the prospective patient-level dataset to:*<br><br>• *Mortality database from the Office for National Statistics*<br>• *The following demographic data will be used in the statistical analysis of outcome data to permit assessment of the relative influence of patient factors and organisational factors on outcome*<br>  ○ *Date of birth – Age*<br>  ○ *Sex*<br><br>*The following procedural data will be used in the statistical analysis of outcome data to permit assessment of the relative influence of patient factors and organisational factors on outcome*<br>*Date and time of admission*<br>*Date and time of surgery*<br>*Procedure type*<br>*Physiological data will be used in the statistical analysis of outcome data to permit* | |

| | | |
|---|---|---|
| | *assessment of the relative influence of patient factors on outcome*<br>*The following outcome data will be collected:*<br><br>o *Date of hospital discharge"*<br><br>The processing of this extended analysis falls within the S251 approved application above<br><br>b. Yes<br><br>The below has been taken verbatim the NELA NHS Digital Data Sharing Agreement v1.01 (December 2017), specifically from Section 5 "Purpose/Methods/Outputs":<br><br>*"The RCoA and RCS also wish to link the patient records submitted to NELA with the Office for National Statistics (ONS) Death Register on a quarterly basis to enable the Audit to monitor changes in postoperative outcomes (both short and longer-term mortality) for those patients. Access to this linked information will support this national clinical audit to improve the quality of care within NHS hospitals for a high-risk patient group.*<br>*The objectives of the Audit are:*<br>*1. To enable secondary care providers to improve the delivery of care to patients undergoing emergency laparotomy using information produced by the audit;*<br>*2. To provide comparative information on the organisation of care by providers of Emergency Laparotomy.*<br>*3. To provide comparative information on patient outcomes following surgery for Emergency Laparotomy.*<br>*4. To facilitate the development of effective change (quality improvement) initiatives and thereby spread examples of best practice and help local providers make the best possible use of audit results.*<br><br>*In summary, the purpose of this request is to support national clinical audit, quality improvement within hospitals, and research on methods to monitor surgical outcomes."*<br><br>And in Section 5c (specific outputs) the DSA states:<br><br>*"In order to more widely disseminate the findings of the audit, additional scientific publications will be produced. These outputs will be in the form of peer-review articles and conference presentations.* | |

| | | |
|---|---|---|
| | *The results of the audit will also be disseminated at professional medical conferences and in peer-reviewed journals e.g.BMJ (British Medical Journal), BJA (British Journal of Anaesthesia), ASGBI (Association of Surgeons of Great Britain and Ireland) journal, and AAGBI (The Association of Anaesthetists of Great Britain and Ireland) journal at the time of the launch of the report or shortly after. Publications related to the Audit methods (e.g., a risk-adjustment model) rather than information of clinical practice and outcomes will be published on an ad hoc basis."*<br><br>The processing of this extended analysis falls within the NHS digital DSA approved application above.<br><br>HBC 19/12/18 | |

Confirmation from the NCAPOP project manager and clinical lead that the information provided is complete and accurate

NCAPOP Project Manager: Name……Jose Lourtie……Signature…………Date……17/01/2019……

NCAPOP Clinical Lead: Name……Dr Dave Murray……Signature…………Date……17/01/2019……

HQIP position: one option only must be selected

☒ I confirm HQIP's agreement that this proposal for extended analysis and output **does not** require HQIP DARG approval

☐ The audit provider **must seek HQIP DARG approval** before commencing the work outlined above

*Appendix 5: Approval form for Chapter 4&6*

Extended output scope and decision template V1.1.

(to be used in conjunction with the self-assessment tool for academic papers and other extended outputs)

| |
|---|
| **1. PROPOSAL OVERVIEW: please summarise:**<br>• ***Project title***<br>• ***the question(s) to be investigated***<br>• ***the dates for the relevant patient cohort being processed, and the associated audit report publication date for that cohort.***<br>• ***the sources of data to be used: England / Wales / other as well as from which data provider: audit dataset / NHSD / NWIS / other NCA***<br>• ***the methodology proposed***<br>• ***the anticipated outputs and benefits***<br>• ***the anticipated project completion date*** |
| **Proposal overview: audit provider to complete:** |
| Impact of grade and speciality of surgeon on variation in outcomes following Emergency Laparotomy.<br><br>Aim: We are aiming to investigate whether the grade of surgeon or speciality of consultant surgeon impacts on outcomes following emergency laparotomy.<br><br>The National Confidential Enquiries in Perioperative deaths have repeatedly advocated consultant led care for high risk surgical patients. The NELA report promotes consultant led care and we have seen increased numbers of cases being managed by both consultant surgeon and anaesthetist. We are still unclear what the overall impact of non- consultant care is. Additionally within general surgery as a speciality, there has been a shift to development of a special interest (for example colorectal or breast surgery.) |

| Additional Questions | Audit provider response – Yes/No, and if Yes then please provide rationale and detail (initialled and dated) | HQIP position – agreed or not agreed and why. (Initialled and dated) |
|---|---|---|
| 2. **Is the purpose of the data processing *explicitly included* in the HQIP contract specification or tender response?**<br><br>**If yes, provide evidence and go to question 4.**<br><br>**If no go to question 3.** | No<br><br>HBC 19/12/18 | Agreed<br><br>**YS 22/1/19** |
| 3. **Is the purpose of the data processing *implicit* in the contract specification or tender response?** | Yes: The Audit was designed to answer questions relating to short-term patient outcomes relating to inpatient morbidity/ complications and to investigate reasons for variation in outcomes:<br>• "High incidence of adverse outcomes should promote shared decision making which should include discussion of individual risk, implications of critical care admission, alternative treatment options."<br>• "Once identified, those factors in the delivery of care which are shown to reduce rates of morbidity and mortality in patients undergoing EL will be disseminated nationally and standards of care introduced. As a result of this audit and on-going Quality Improvement work, NELA seeks to standardise and continually improve the quality and components of care, reducing overall morbidity and mortality of subsequent patients undergoing EL in the UK"<br>• "Looking forward, the NELA dataset provides a valuable resource to further investigate the relationship between process and outcome<br><br>Ref: Tender Documentation for NELA Part 5-Specification and NELA Section 251 Non- | Agreed – this is an extended analysis of the inputs/processes of care which affect patient outcomes after EL, and therefore within scope.<br><br>**YS 22/1/19** |

| | | |
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| | Research Application, (July 2013):<br><br>HBC 19/12/18 | |
| **4. Regarding the processing of record level data and / or aggregate data which cannot be fully anonymised: Do the data flows and locations for the processing of the data to achieve this output exactly match the normal project pattern as reflected in the project's Data Flow Map?** | Yes.<br>Data flow is the same as the normal project flow as per the NELA dataflow chart v 9.<br>The only people who will be processing/analysing the data will be members of the NELA project team who are included within the NELA data flow chart.<br><br>19/12/18 | Agreed<br><br>**YS 22/1/19** |
| **5.**<br>**a. Is the legal basis for this processing of personal data (or data derived from personal data) clearly established? (e.g. within the NCAPOP project's S.251 application (research or non-research), fair processing information and / or consent materials and / or legal requirements outside England and Wales).** | a. Yes.<br><br>This wording has been pasted verbatim from NELA Section 251 Non-Research Application, (July 2013): Sections of particular relevance are highlighted<br><br>*"Cohort/Population being studied: Patients aged 18 years and over undergoing emergency laparotomy in England and Wales.*<br><br>*Detailed Description of purpose:*<br>*The Audit has been designed to answer audit questions related to:*<br>*1. the process of care prior to surgery, such as diagnostic imaging*<br>*2. the type of surgery undertaken.*<br>*3. the short-term outcomes of surgical treatment*<br>*4. the longer-term survival of patients* | Agreed – scope falls within the expectations set in both the S.251 application and the NHSD DSA, and the intent to publish in academic journals is explicit in both<br><br>**YS 22/01/19** |

| | | |
|---|---|---|
| **b. If data from another data controller (such as NHSD or NWIS) will be processed, please insert evidence from the relevant data sharing agreement that the processing is permitted.** | *Specific objectives related to the clinical outcomes of care will be to examine:*<br>*1. 30-day mortality and*<br>*2. inpatient complications*<br><br>*Describe how the proposed use of patient information will improve patient care and serve the wider public interest?*<br>*Once identified, those factors in the delivery of care which are shown to reduce rates of morbidity and mortality in patients undergoing EL will be disseminated nationally and standards of care introduced.*<br>*Audit results will also be communicated in conference presentations and peer-reviewed publications.*<br><br>*Please list each of the data items you will hold in relation to each patient, and describe against each why the data item is require*<br><br>*We propose to link the prospective patient-level dataset to:*<br><br>• *Mortality database from the Office for National Statistics*<br>• *The following demographic data will be used in the statistical analysis of outcome data to permit assessment of the relative influence of patient factors and organisational factors on outcome*<br>  ○ *Date of birth – Age*<br>  ○ *Sex*<br><br>*The following procedural data will be used in the statistical analysis of outcome data to permit assessment of the relative influence of patient factors and organisational factors on outcome*<br>• *Date and time of admission*<br>• *Date and time of surgery*<br>• *Procedure type*<br>*Physiological data will be used in the statistical analysis of outcome data to permit assessment of the relative influence of patient factors on outcome.*<br><br>*The following outcome data will be collected:* | |

| | | |
|---|---|---|
| | ○ *Date of hospital discharge"*<br><br>The processing of this extended analysis falls within the S251 approved application above.<br><br>b. Yes<br><br>The below has been taken verbatium the NELA NHS Digital Data Sharing Agreement v1.01 (December 2017), specifically from Section 5 "Purpose/Methods/Outputs":<br><br>*"The RCoA and RCS also wish to link the patient records submitted to NELA with the Office for National Statistics (ONS) Death Register on a quarterly basis to enable the Audit to monitor changes in postoperative outcomes (both short and longer-term mortality) for those patients. Access to this linked information will support this national clinical audit to improve the quality of care within NHS hospitals for a high-risk patient group.*<br>*The objectives of the Audit are:*<br>*1. To enable secondary care providers to improve the delivery of care to patients undergoing emergency laparotomy using information produced by the audit;*<br>*2. To provide comparative information on the organisation of care by providers of Emergency Laparotomy.*<br>*3. To provide comparative information on patient outcomes following surgery for Emergency Laparotomy.*<br>*4. To facilitate the development of effective change (quality improvement) initiatives and thereby spread examples of best practice and help local providers make the best possible use of audit results.*<br>*In summary, the purpose of this request is to support national clinical audit, quality improvement within hospitals, and research on methods to monitor surgical outcomes."*<br><br>And in Section 5c (specific outputs) the DSA states:<br><br>*'In order to more widely disseminate the findings of the audit, additional scientific publications will be produced. These outputs will be in the form of peer-review articles and conference presentations.*<br><br>*The results of the audit will also be disseminated at professional medical conferences and in peer-reviewed journals e.g.BMJ (British Medical Journal), BJA (British Journal of Anaesthesia),* | |

| | | |
|---|---|---|
| | *ASGBI (Association of Surgeons of Great Britain and Ireland) journal, and AAGBI (The Association of Anaesthetists of Great Britain and Ireland) journal at the time of the launch of the report or shortly after. Publications related to the Audit methods (e.g., a risk-adjustment model) rather than information of clinical practice and outcomes will be published on an ad hoc basis."*<br><br>The processing of this extended analysis falls within the NHS digital DSA approved application above.<br><br>HBC 19/12/18 | |

Confirmation from the NCAPOP project manager and clinical lead that the information provided is complete and accurate

NCAPOP Project Manager: Name.....Jose Lourtie.....Signature..... .....Date.....16/01/2019.....

NCAPOP Clinical Lead: Name.....Dr Dave Murray.....Signature..... .....Date.....16/01/2019.....

HQIP position: one option only must be selected

☒ I confirm HQIP's agreement that this proposal for extended analysis and output **does not** require HQIP DARG approval

☐ The audit provider **must seek HQIP DARG approval** before commencing the work outlined above

HQIP Associate Director: Name.....Yvonne Silove.....Signature..... .....Date.....22nd January, 2019.....

*Appendix 6: Approval form for Chapter 5*

Extended output scope and decision template V1.4.

(to be used in conjunction with the 'Decision Aid for Accessing and Publishing Data Commissioned by HQIP')

1. **PROPOSAL OVERVIEW: please summarise:**
   - ***project title***
   - ***the question(s) to be investigated***
   - ***the dates for the relevant patient cohort being processed, and the associated audit report publication date for that cohort.***
   - ***the sources of data to be used: England / Wales / other as well as from which data provider: audit dataset / NHSD / NWIS / other NCA***
   - ***which (if any) personal data fields will be processed for the purposes of this project***
   - ***the methodology proposed***
   - ***the anticipated outputs and benefits***
   - ***the anticipated project completion date***

**Proposal overview: audit provider to complete:**

**Variation in Emergency Laparotomy case volume by hospital size and geographical area, impact for surgical training.**

**Aim**: To investigate if there is a regional variation in the number of Emergency Laparotomies performed, specifically in the surgical procedures that are required for completion of training within general surgery.

General surgical trainees complete the majority of their training within one geographical area (deanery.) There are 15 educational deaneries within England and Wales. To become a consultant surgeon, trainees are required to have performed at least 100 Emergency Laparotomies and a specific number of core procedures (bowel resections, repair of perforated ulcers and drainage of intra-abdominal sepsis.) Previous literature has suggested that surgical trainees do not reach these targets. We aim to clarify, firstly the number of high volume Emergency Laparotomy centres

within each deanery, followed by the number of Emergency Laparotomies and the core procedures being performed in each educational deanery.

This study is important as it has the potential to impact on service configuration of emergency general surgery and will be of interest to stakeholders and policy makers in this country and ultimately improve outcomes for patients. Additionally, if trainee surgeons do not gain adequate experience in Emergency Laparotomy operating, this will lead to a paucity of qualified consultants in later years, ultimately impacting on patient care and outcomes.

We hope to be able to demonstrate that there are adequate training opportunities and exposure for surgical trainees across the country in the most common procedures performed at Emergency Laparotomy.

**Dates included: Years 1-5 of the audit:** Year 1 report 30/6/2015, Year 2 report 5/7/2016, Year 3 report 13/10/17, Year 4 report 8/11/18, Year 5 report not yet published (audit dates December 2017- November 2018)

***No data from this project will be presented or published until AFTER the publication of the Year 5 annual report***

**Data sources:** NELA ID and NELA hospital ID and geographical location will be required for each patient to accurately calculate the total number of Em Lap per hospital, followed by the individual procedures as listed above (Segemnetal colectomy, small bowel resection, perforated peptic ulcer disease). No patient level data is otherwise required. **No ONS or mortality data is required**

**Methodology and publication plan:** We will include all patients who underwent an emergency laparotomy or laparoscopy for the ten most common procedures. We will first quantify the numbers of cases for each of the procedural groups by hospital. Hospitals will then be assigned a

quartile depending on case volume. Hospitals will not be identifiable and will only be referred to as quartile number. Hospitals will also be divided into Educational deaneries which will be defined as per Health Education Local Offices.

We will perform non parametric statistical analysis (Krushnall Wallis) to assess for significant differences between the educational deaneries in relation to case load and experience.

This will be written up as an academic paper and will be disseminated to national bodies, in particular the Emergency Surgery Working group within The Royal College of Surgeons (Eng.)

**Anticipated completion date**: Spring 2020

**HBC**
**23/08/2019**

| **Additional Questions** | **Audit provider response** |
|---|---|
| **2. Is the purpose of the data processing *explicitly included* in the HQIP contract specification or tender response?**<br><br>**If yes, provide evidence and go to question 4.**<br><br>**If no go to question 3.** | ***Yes/No, and if Yes then please provide rationale and detail (initialled and dated)***<br><br>***No***<br>***HBC 23/08/2019*** |

| | |
|---|---|
| **3. Is the purpose of the data processing *implicit* in the contract specification or tender response?** | Yes: The Audit was designed to answer questions relating to patient outcomes relating to inpatient morbidity/ complications and to investigate **reasons for variation** in outcomes. **Variation in the case load will lead to disparity in operative experience around the country and has the potential to impact on future patient outcomes.**<br><br>The below is take directly from the NELA Tender Document:<br>• "High incidence of adverse outcomes should promote shared decision making which should include discussion of individual risk, implications of critical care admission, alternative treatment options."<br>• "Once identified, those factors in the delivery of care which are shown to reduce rates of morbidity and mortality in patients undergoing EL will be disseminated nationally and standards of care introduced. **As a result of this audit and on-going Quality Improvement work, NELA seeks to standardise and continually improve the quality and components of care, reducing overall morbidity and mortality of subsequent patients undergoing EL in the UK**<br>• **"Looking forward, the NELA dataset provides a valuable resource to further investigate the relationship between process and outcome**<br><br>Ref: Tender Documentation for NELA Part 5-Specification and **NELA Section 251 Non-Research Application, (July 2013)**<br><br>HBC 23/08/2019 |
| **4. Regarding the flows and processing locations of all record level data and / or aggregate data for this output which cannot be fully anonymised…** | X Yes I confirm that the data flows and locations for the processing for this output exactly match the normal project pattern as reflected in the project's Data Flow Map?<br><br>***(initialled and dated)***<br>***HBC 23/08/2019*** |

| | |
|---|---|
| **5. Regarding the legal basis, other information governance requirements and any requirements from third party data providers (e.g. NHS Digital, Public Health England, NWIS, other registries and audits)** | X Yes I confirm that all proposed processing activities have an established legal basis (e.g. within the NCAPOP project's S.251 application (research or non-research), fair processing information and / or consent materials and / or legal requirements outside England and Wales).<br><br>X Yes I confirm that any proposed processing of data from a third party data controller is permitted under the agreement by which that data has been accessed.<br>*HBC 23/08/2019* |

Confirmation from the NCAPOP project manager and clinical lead that the information provided is complete and accurate

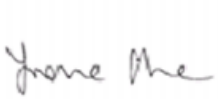
NCAPOP Project Manager: Name…Jose Lourtie……Signature…………Date……24/10/19……

NCAPOP Clinical Lead: Name……Dr Dave Murray……Signature…………Date……24/10/19……

HQIP position: one option only must be selected

☒ I confirm HQIP's agreement that this proposal for extended analysis and output is approved and **does not** require HQIP DARG approval

☐ The NCAPOP provider **must seek HQIP DARG approval** before commencing the work outlined above



HQIP Associate Director: Name……Yvonne Silove…..Signature…………Date……28/10/19……

## 8.5 Stata Code

*Appendix 7: code use for data analysis in each discussion chapter.*

Chapter 3: Timing of surgical source control

```
**consultant surgeon in theatre variable**
gen op_cons = 0
replace op_cons = 1 if grade_s_op == 1
replace op_cons = . if grade_s_op == .

**consultant anaesthetist present in theatre
variable**
gen op_conan = 0
replace op_conan = 1 if grade_an_op == 1
replace op_conan = . if grade_an_op == .

**admitted to critical care post op**
gen ccu_adm = .
replace ccu_adm = 1 if inlist(proc_dest,2,3,6)
replace ccu_adm = 0 if inlist(proc_dest,1,5)
replace ccu_adm = .a if proc_dest == 4

** time to theatre variable*
gen adm_ot = vt_adm_ot / 3600000
replace adm_ot = . if vt_adm_ot < 0
replace adm_ot = . if adm_time == 0 | ot_time == 0
label variable adm_ot "Time from hospital admission
to arrival in the operating theare"

**mortality analysis**
Logistic ONS90 adm_ot
Logistic ONS90 adm_ot nelarisk op_cons op_conan
ccu_adm
```

Chapter 4: Impact of consultant Surgeon specialist

```
**labels consultant surgeon specialty**
replace resp_cons_spec = "1" if resp_cons_spec ==
"GENERAL"
replace resp_cons_spec = "2" if resp_cons_spec ==
"COLORECT"
replace resp_cons_spec = "3" if resp_cons_spec ==
"OESPHAG"
replace resp_cons_spec = "4" if resp_cons_spec ==
"EMGEN"
```

```
replace resp_cons_spec = "5" if resp_cons_spec ==
"HEPATOB"
replace resp_cons_spec = "6" if resp_cons_spec ==
"BREAST"
replace resp_cons_spec = "7" if resp_cons_spec ==
"ENDOCRINE"
replace resp_cons_spec = "8" if resp_cons_spec ==
"VASCULAR"
replace resp_cons_spec = "9" if resp_cons_spec ==
"OTHER"
replace resp_cons_spec = "10" if resp_cons_spec ==
"UNKNOWN"
replace resp_cons_spec = "11" if resp_cons_spec ==
""
destring resp_cons_spec, replace
replace op_cons_spec = "1" if op_cons_spec ==
"GENERAL"
replace op_cons_spec = "2" if op_cons_spec ==
"COLORECT"
replace op_cons_spec = "3" if op_cons_spec ==
"OESPHAG"
replace op_cons_spec = "4" if op_cons_spec ==
"EMGEN"
replace op_cons_spec = "5" if op_cons_spec ==
"HEPATOB"
replace op_cons_spec = "6" if op_cons_spec ==
"BREAST"
replace op_cons_spec = "7" if op_cons_spec ==
"ENDOCRINE"
replace op_cons_spec = "8" if op_cons_spec ==
"VASCULAR"
replace op_cons_spec = "9" if op_cons_spec ==
"OTHER"
replace op_cons_spec = "10" if op_cons_spec ==
"UNKNOWN"
replace op_cons_spec = "11" if op_cons_spec == ""
destring op_cons_spec, replace
replace resp_cons_spec = .a if resp_cons_spec == 10
replace resp_cons_spec = .b if resp_cons_spec == 11
replace op_cons_spec = .a if op_cons_spec == 10
replace op_cons_spec = .b if op_cons_spec == 11
label define cons_spec 1 "General" 2 "Colorectal" 3
"Upper GI" 4 "Emergency General Surgery" 5
"Hepatobiliary" 6 "Breast" 7 "Endocrine" 8
"Vascular" 9 "Other" .a "Unknown" .b "Missing"
label values resp_cons_spec op_cons_spec cons_spec
gen colo_cons=0
replace colo_cons=1 if cons_spec==2
gen ugi_cons==0
replace ugi_cons=1 if cons_spec ==3|cons_spec==5
gen non_GIcons==0
```

```
replace if non_GIcons=1 if cons_spec==2| cons_spec
==3|cons_spec==5
gen non_colo=1 if ugi_cons==1 |non_GIcons==1
gen non_UGI=1 if colo_cons==1|non_GIcons==1

**colorectal procedure mortality analysis **
logistic ONS30 non_colo
logisitic ONS30 non_colo age gender i.asa
PreOpPossumMort ccu_adm

**UGI procedure mortality analysis**
logistic ONS30 non_UGI
logisitic ONS30 non_UGI age gender i.asa
PreOpPossumMort ccu_adm

**Colorectal return to theatre analysis**
gen up_rtt = .
replace up_rtt = 1 if comp_theatre == 1
replace up_rtt = 0 if comp_theatre == 0
replace up_rtt = .a if comp_theatre == 9
logistic up_rtt non_colo
logisitic up_rtt non_colo age gender i.asa
PreOpPossumMort ccu_adm

**UGI procedure return to theatre analysis**
logistic up_rtt non_UGI
logisitic up_rtt non_UGI age gender i.asa
PreOpPossumMort ccu_adm

**Colorectal length of stay analysis**
gen ot_dc = vt_ot_dc
replace ot_dc = . if vt_ot_dc < 0
label variable ot_dc "Postoperative length of
hospital stay"
poisson ot_dc non_colo, irr
poisson ot_dc non_colo age gender i.asa
PreOpPossumMort ccu_adm, irr

**UGI length of stay analysis**
poisson ot_dc non_UGI, irr
poisson ot_dc non_UGI age gender i.asa
PreOpPossumMort
```

Chapter 5: Variation in Emergency Laparotomy

```
**counting how many hospitals were in each
quartile**
egen tag = tag(hospitalid)
egen distinct_values = total(tag), by(size_quart)
```

```
**make a new variable with the total of each
procedure"
egen segmental_count = total(segmental),
by(hospitalid)
egen SB_count =total(SB), by(hospitalid)
egen Hartmans_count =total(Hartmans), by(hospitalid)
egen adhesio_count =total(adhesio), by(hospitalid)
egen PUD_count=total(PUD), by(hospitalid)
**make a new variable of total number of cases by
surg year and hospital**
egen segmental_count_year = total(segmental),
by(surg_year hospitalid)

**make variable of average number of procedures over
four years by hospital**
egen year_av_seg= mean(segmental_count_year), by
(hospitalid)


**to create variable for number of cases by trainees
per hospital**
egen trainee_count = total(trainee), by(hospitalid)


**to create variable with hospital size_quart in
whole dataset not just one hospital**
bysort hospitalid: gen num_case  = _N
gen size_quart=0
replace size_quart=1 if num_case >311 & num_case<459
replace size_quart=2 if num_case >=459 & num_case
<662
replace size_quart=3 if num_case>662
label define size 0 "Quartile 1" 1 "Quartile 2" 2
"Quartile 3" 3 "Quartile 4"
label values size_quart size

**put hospitals into deaneries*
replace deanery =1 if
hospitalid==28|hospitalid==77|hospitalid==58|hospita
lid==259|hospitalid==64|hospitalid==106|hospitalid==
166|hospitalid==167|hospitalid==40|hospitalid==22|ho
spitalid==176|hospitalid==175
replace deanery =2 if
hospitalid==126|hospitalid==127|hospitalid==24|hospi
talid==48|hospitalid==76|hospitalid==83|hospitalid==
88|hospitalid==91|hospitalid==111|hospitalid==68|hos
pitalid==160|hospitalid==161|hospitalid==67|hospital
id==136|hospitalid==181|hospitalid==183|hospitalid==
30|hospitalid==116
replace deanery=3 if
hospitalid==117|hospitalid==122|hospitalid==19|hospi
```

```
talid==23|hospitalid==41|hospitalid==107|hospitalid=
=113|hospitalid==114|hospitalid==152|hospitalid==257
|hospitalid==154|hospitalid==153|hospitalid==61|hosp
italid==60|hospitalid==105|hospitalid==194|hospitali
d==195|hospitalid==162
replace deanery=4 if
hospitalid==237|hospitalid==17|hospitalid==55|hospit
alid==247|hospitalid==70|hospitalid==71|hospitalid==
163|hospitalid==102|hospitalid==172
replace deanery=5 if
hospitalid==21|hospitalid==90|hospitalid==65|hospita
lid==66|hospitalid==72
replace deanery=6 if
hospitalid==151|hospitalid==27|hospitalid==182|hospi
talid==115|hospitalid==32|hospitalid==236|hospitalid
==47|hospitalid==73|hospitalid==74|hospitalid==164
replace deanery=7 if
hospitalid==38|hospitalid==11|hospitalid==54|hospita
lid==78|hospitalid==130|hospitalid==79|hospitalid==1
31|hospitalid==81|hospitalid==139
replace deanery=8 if
hospitalid==119|hospitalid==120|hospitalid==124|hosp
italid==123|hospitalid==125|hospitalid==112|hospital
id==95|hospitalid==121|hospitalid==97|hospitalid==16
8|hospitalid==187
replace deanery=9 if
hospitalid==118|hospitalid==20|hospitalid==39|hospit
alid==52|hospitalid==56|hospitalid==8|hospitalid==10
|hospitalid==110|hospitalid==12|hospitalid==84|hospi
talid==85|hospitalid==86|hospitalid==99|hospitalid==
146|hospitalid==184|hospitalid==185
replace deanery=10 if
hospitalid==36|hospitalid==37|hospitalid==13|hospita
lid==155|hospitalid==156|hospitalid==57|hospitalid==
63|hospitalid==262|hospitalid==132|hospitalid==133|h
ospitalid==134|hospitalid==62|hospitalid==29
replace deanery=11 if
hospitalid==5|hospitalid==25|hospitalid==128|hospita
lid==6|hospitalid==149|hospitalid==7|hospitalid==49|
hospitalid==9|hospitalid==80|hospitalid==82|hospital
id==171|hospitalid==51|hospitalid==94|hospitalid==15
8|hospitalid==159|hospitalid==98|hospitalid==101|hos
pitalid==137|hospitalid==144|hospitalid==145|hospita
lid==147|hospitalid==178|hospitalid==177|hospitalid=
=142|hospitalid==180|hospitalid==188|hospitalid==191
replace deanery=12 if
hospitalid==150|hospitalid==165|hospitalid==14|hospi
talid==166|hospitalid==103|hospitalid==104|hospitali
d==260|hospitalid==140|hospitalid==135|hospitalid==1
69|hospitalid==109|hospitalid==108|hospitalid==173|h
```

```
ospitalid==89|hospitalid==170|hospitalid==179|hospit
alid==189|hospitalid==190|hospitalid==192
replace deanery=13 if
hospitalid==248|hospitalid==15|hospitalid==16|hospit
alid==93|hospitalid==92|hospitalid==100|hospitalid==
148|hospitalid==174|hospitalid==186|hospitalid==193|
hospitalid==59|hospitalid==69|hospitalid==75|hospita
lid==96|hospitalid==129
replace deanery=14 if super_region==5
label define dean 1 "Health Education East Midlands"
2 "Health Education East of England" 3 "Health
Education Yorkshire and Humber" 4 "Health Education
Wessex " 5 "Health Education Thames Valley" 6
"Health Education North West London" 7 "Health
Education South London" 8 "Health Education North
Central and East London" 9 "Health Education Kent,
Surry, Sussex" 10 "Health Education North East" 11
"Health Education North West" 12 "Health Education
West Midlands" 13 "Health Education South West" 14
"Health Education and Improvement Wales"
label define dean 1 "HE East Midlands" 2 "HE East of
Eng" 3 "HE Y&H" 4 "HE Wessex " 5 "HE T Val" 6 "HE NW
Lon" 7 "HE South Lon" 8 "HE N Cen &ELon" 9 "HE KSS"
10 "HE North East" 11 "HE NW" 12 "HE West Mid" 13
"HE SW" 14 "HE Wales"

**negative binonminal regression analysis*
Nbreg segmental_count i.deanery, irr
Nbreg SB_count i.deanery, irr
Nbreg Hartmans_count i.deanery, irr
Nbreg adhesio_count i.deanery, irr
Nbreg PUD_count i.deanery, irr
```

Chapter 6: trainee involvement in Emergency Laparotomy

```
**create trainee variable**
Gen trainee=0
Replace trainee=1 if grade_s_op==5
Drop if
grade_s_op==3|grade_s_op==4|grade_s_op==6|grade_s_op
=9

**create time of day surgery variable**
gen double time_ot = clock(timeot, "hm")
gen surg_tod = .
replace surg_tod = 1 if time_ot >=28800000 & time_ot
< 43200000
replace surg_tod = 2 if time_ot >=43200000 & time_ot
< 64800000
replace surg_tod = 3 if time_ot >=64800000 & time_ot
<= 86340000
```

```
replace surg_tod = 4 if time_ot < 28800000
replace surg_tod =. if s04arrivalintheatretimene ==
"TRUE"
3600000=1 hour 8am =28800000

**association between hospital volume and time of
day and trainee operating
logistic trainee i.size_quart
logistic trainee i.surg_tod

**mortality analysis**
logistic ONS90 trainee if segmental==1
logistic ONS90 trainee if SB==1
logistic ONS90 trainee if Hartmans==1
logistic ONS90 trainee if adhesio==1
logistic ONS90 trainee if PUD==1

logistic ONS90 trainee nelarisk ccu_adm grade_an_op
if segmental==1
logistic ONS90 trainee nelarisk ccu_adm grade_an_op
if SB==1
logistic ONS90 trainee nelarisk ccu_adm grade_an_op
if Hartmans==4
logistic ONS90 trainee nelarisk ccu_adm grade_an_op
if adhesio==22
logistic ONS90 trainee nelarisk ccu_adm grade_an_op
if PUD==8

**return to theatre analysis**
logistic up_rtt trainee if segmental==1
logistic up_rtt trainee if SB==1
logistic up_rtt trainee if Hartmans==1
logistic up_rtt trainee if adhesio==1
logistic up_rtt trainee if PUD==1

logistic up_rtt trainee nelarisk ccu_adm grade_an_op
if segmental==1
logistic up_rtt trainee nelarisk ccu_adm grade_an_op
if SB==1
logistic up_rtt trainee nelarisk ccu_adm grade_an_op
if Hartmans==4
logistic up_rtt trainee nelarisk ccu_adm grade_an_op
if adhesio==22
logistic up_rtt trainee nelarisk ccu_adm grade_an_op
if PUD==8
```

## 9 References


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