

Mechanisms underlying between-hospital variation in mortality after emergency laparotomies in England and Wales: A structure - process analysis

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I, Charles Matthew Oliver confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis (below)

Chapter 1	Nil
Chapter 2	Identification and selection of relevant standards of care: Assistance by the National Emergency Laparotomy Audit (NELA) project team
Chapters 3 & 5	Development of NELA organisational and patient audit questionnaires and selection of basic analyses informing creation of NELA Reports: NELA project team and project board with oversight by the clinical reference group. Source data: NELA investigators at participating hospitals
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Chapters 5 - 8	Source data: NELA investigators at participating hospitals. Re-coding of primary operative procedures: Miss Emma Barrow (NELA Project Team)

My roles in the National Emergency Laparotomy Audit (NELA)

I joined the NELA Project Team in December 2012 as the Health Services Research Fellow. My work over the subsequent three years included:

- Identification of relevant research findings and recommendations
- Identification of candidate risk assessment models for emergency laparotomy
- Design, testing and modification of the first NELA organisational and patient audit questionnaires
- Analysis of the organisational and patient audit datasets and creation of the first NELA organisational and patient audit reports

Thesis abstract

Emergency laparotomies are highly invasive abdominal operations that are performed commonly across the globe for potentially life-threatening conditions. Up to 18% of patients die within the first month of surgery and the sequelae may represent significant burdens to patients, healthcare systems and wider societies long beyond the operative period.

Recent observations of marked between-hospital variation in mortality after emergency laparotomy offer opportunities to improve the quality of care and survival of these patients across the globe. However, the causes of between-hospital variation are poorly understood and methods for identifying high-risk patients poorly evidenced.

The aims of this thesis are to explore the complex interactions between organisational structures, processes of care and patient-level risk in order to determine the contributions of modifiable factors to patient outcomes after emergency laparotomy.

My research comprises three parts:

Firstly, univariate analysis of data submitted to the National Emergency Laparotomy Audit (NELA) first organisational and patient audits in order to identify and characterise variation in structural provisions for and delivery of care to emergency laparotomy patients.

Secondly, a systematic review to identify the best validated risk assessment tools for emergency laparotomy, informing the selection of patient risk factors included in NELA's first patient audit and my subsequent analyses.

Finally, statistical modelling to identify casemix adjusted between-hospital variation in postoperative mortality; and multivariable and mixed effects modelling to identify and compare the effects of processes of care and organisational structures associated with postoperative mortality, controlling for patient-level factors.

Data submitted by participants at 190 hospitals to the first NELA organisational audit demonstrated variation in the provision of recommended structures for the care of emergency general surgery (EGS) patients. Provisions were more comprehensive at large and tertiary surgical referral centres.

A systematic review identified 20 studies assessing 25 risk assessment tools in adult emergency laparotomy cohorts. APACHE II and P-POSSUM were the most widely studied prognostic models, but poor data reporting precluded comparisons of performance. POSSUM data items were included in the first NELA patient audit.

Following exclusions, the first NELA patient cohort comprised 20,183 patients. Overall inpatient 30-day mortality was 11.3%, marked between-hospital casemix variation was demonstrated and delivery of processes of care varied considerably between patient subgroups and between hospitals, but was poorly characterised by measured hospital characteristics.

Following the derivation and internal validation of a novel casemix adjustment model, substantial between-hospital variation in casemix adjusted mortality was demonstrated in the first NELA patient audit cohort.

Multiple logistic regression modelling identified only three processes as independent predictors of postoperative mortality in the NELA patient cohort: postoperative critical care admission (odds ratio (OR) 1.6 (95%CI 1.4-1.8, $p < 0.005$)), preoperative risk documentation (OR 1.1 (1.1-1.3, $p < 0.05$)) and postoperative review of older patients (>70 years) by a medicine for the care of the older person (MCOP) physician (OR 0.3 (0.2-0.4 $p < 0.005$)). Collectively, patient risk factors modelled up to 27% of the overall variation in mortality.

Finally, mixed effects analysis demonstrated significant between-hospital variation in inpatient 30-day mortality that persisted after controlling for patient-level risk factors and perioperative processes of care. Hospital size and specialty (tertiary GI surgical referral centre) status modelled a small but significant proportion of this variation. Mortality rates were significantly higher at the smallest hospitals and significantly lower at specialty centres.

Further work is required to evaluate whether comprehensive risk evaluation to inform the targeted delivery of augmented care bundles to high-risk patients can improve quality of care and postoperative survival and reduce the costs associated with emergency laparotomies.

In the context of ageing populations and policy discussions regarding the reconfiguration of EGS services, the effect of MCOP input and associations with hospital size and specialist status merit urgent investigation.

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Abbreviations

AAA	-	Abdominal aortic aneurysm
APACHE	-	Acute physiology and chronic health evaluation
ASA-PS	-	The American society of Anesthesiologists physical status classification
AUC	-	Area under the (Receiver operator characteristic) Curve
CI	-	Confidence interval
COM	-	Cardiac output monitoring
CRG	-	The NELA clinical reference group
CT	-	Computed tomography
EGS	-	Emergency general surgery
ELN	-	The Emergency Laparotomy Network
ESU	-	Emergency surgical unit
GCS	-	Glasgow coma scale
GDFT	-	Goal-directed fluid therapy
GI	-	Gastrointestinal
HES	-	Hospital episode statistics
HQIP	-	The Healthcare quality improvement partnership
ICU	-	Intensive care unit
IQR	-	Inter-quartile range
LHB	-	Local health boards
MCOP	-	Medicine for care of the Older Person
MOR	-	Median odds ratio
NELA	-	The National Emergency Laparotomy Audit
NHS	-	The National Health Service
NHSE	-	NHS England
NRLS	-	The NHS England National Reporting and Learning System
NSQIP	-	National surgical quality improvement program
ONS	-	The Office for National Statistics

OR	-	Odds ratio
PB	-	The NELA project board
POSSUM	-	The Physiological and Operative Severity Score for the enUmeration of mortality and morbidity
P-POSSUM	-	The Portsmouth modification of the logarithmic equation used to calculate POSSUM predicted 30-day mortality
PROMs	-	Patient-reported outcome measures
PT	-	The NELA project team
QI	-	Quality improvement
ROC	-	Receiver operator characteristic
SD	-	Standard deviation
SE	-	Standard error
UK	-	United Kingdom
US	-	United States

Standard of care documents: abbreviated titles

(ASGBI EGS) Association of Surgeons of Great Britain and Ireland
Emergency general surgery consensus statement (2007)
<http://bit.ly/1hMjuk7>

(ASGBI PS) Association of Surgeons of Great Britain and Ireland
Patient safety: A consensus statement (2009)
<http://bit.ly/1hMkaWM>

(CQUIN) Commissioning for quality and innovation Guidance for 2015/2016.
NHS England/ contracting and incentives team. CQUIN, 2015
www.england.nhs.uk/wp-content/uploads/2015/03/9-cquin-guid-2015-16.pdf

(NCEPOD Age) National Confidential Enquiry into Patient Outcome and Death
An age old problem: A review of the care received by elderly patients undergoing surgery (2010)
<http://bit.ly/1hMktB0>

(NCEPOD EA) National Confidential Enquiry into Patient Outcome and Death
Emergency Admissions: A journey in the right direction. NCEPOD, 2007
www.ncepod.org.uk/2007ea.htm

(NCEPOD KTR) National Confidential Enquiry into Patient Outcome and Death
Knowing the risk: A review of the peri-operative care of surgical patients (2011)
<http://bit.ly/1hMkTY8>

(NICE CG50) National Institute for Health and Care Excellence
Acutely ill patients in hospital: Recognition of and response to acute illness in adults in hospital (2007)
<http://bit.ly/1hMI7hV>

(NSF older people) Department of Health
The National Service Framework for older people (2001)
<http://bit.ly/1hMlljq>

(RCOA GPAS) Royal College of Anaesthetists
Guidance on the provision of anaesthesia services for emergency surgery (2014)
www.rcoa.ac.uk/node/14669

(RCS EESC) Royal College of Surgeons of England
Separating emergency and elective surgical care: Recommendations for practice (2007)
<http://bit.ly/1kCwCte>

(RCS HR) The Royal College of Surgeons of England/Department of Health
The higher risk general surgical patient: Towards improved care for a forgotten group (2011)
<http://bit.ly/1fH3b9H>

(RCS USC) The Royal College of Surgeons of England
Emergency surgery: Standards for unscheduled care (2011)
<http://bit.ly/NUhKLG>

“Every day you may make progress.

Every step may be fruitful.

Yet there will stretch out before you an ever-lengthening, ever-ascending, ever-improving path.

You know you will never get to the end of the journey.

But this, so far from discouraging, only adds to the joy and glory of the climb.”

Winston Spencer Churchill

In "Painting as a Pastime"

The Strand Magazine (Dec 1921 and Jan 1922)

1. INTRODUCTION

1.1 Overview of existing data and the analyses comprising this thesis

Emergency laparotomies are intra-abdominal surgical procedures that are performed commonly worldwide for a variety of potentially life-threatening emergency general surgical (EGS) events in heterogeneous patient cohorts. Older patients comprise high proportions of contemporary cohorts and, in the context of ageing populations, it is anticipated that the number of emergency laparotomies performed globally will increase dramatically over coming years.

In contemporary studies, morbidity frequently complicates postoperative recovery and up to 18% of patients die within 30 days of surgery. However, while many of the surgical events precipitating the need for an emergency laparotomy are potentially life-threatening, there are accumulating data indicating that short-term postoperative survival may vary substantially both between patient subgroups and between the hospitals at which these operations are performed.

These observations offer opportunities for improving patient outcomes and the standard of care received by patients undergoing emergency laparotomies. In order to succeed, strategies for improving outcomes and quality of care should be based on an understanding of factors associated with variation. However, while associations with patient characteristics have been studied extensively, the mechanisms underlying between-hospital outcome variations are poorly understood in emergency laparotomy cohorts.

Furthermore, patients undergoing emergency laparotomies consume disproportionate quantities of resources, due to prolonged and repeated inpatient and intensive care admissions and repeated operations. In an era of ever-increasing pressure on healthcare budgets, there are therefore also financial incentives to improving the quality of postoperative survival after these common operations.

This thesis aims to explore the complex interactions between organisational structures, processes of care and patient-level risk in order to determine the contributions of modifiable factors to variation in patient outcomes after emergency laparotomy.

In the remainder of this Chapter *the problem with emergency laparotomies* is discussed in greater detail and relevant evidence discussed.

In *Chapter 2*, the structure of the National Emergency Laparotomy Audit (NELA) is described.

In *Chapter 3*, the findings of the first NELA audit of hospital characteristics and structural provisions for emergency laparotomies at hospitals in England and Wales are reported. Accompanying these data are analyses of associations between structural provisions and hospital characteristics.

In *Chapter 4*, candidate risk estimation models for patients undergoing an emergency laparotomy are identified using Systematic Review methodology and their performance and utility compared.

In *Chapter 5*, the characteristics, received processes of care and outcomes of the largest cohort of prospectively identified patients undergoing an emergency laparotomy, the NELA year 1 patient audit cohort, are reported.

In *Chapter 6*, the data reported in the preceding chapters are drawn together to compare and derive casemix adjustment models in order to compare hospital-level risk adjusted mortality in the NELA year 1 patient audit cohort.

In *Chapter 7*, multivariable models are constructed, incorporating the findings of the previous three Chapters, in order to assess and quantify the ability of perioperative processes of care, in the context of patient-level variables, to explain variation in inpatient 30-day mortality after emergency laparotomy in the NELA year 1 patient audit cohort.

In *Chapter 8*, the final analysis Chapter, multilevel models are constructed, incorporating the findings of the previous five Chapters, in order to assess the effects of hospital-level differences, variables and factors on inpatient 30-day mortality in the NELA year 1 patient audit cohort.

In *Chapter 9*, the findings of the analyses reported across this thesis are discussed in the context of existing evidence, before the potential direction of future research is discussed.

1.2 The problem with emergency laparotomies

Emergency laparotomies are common intra-abdominal surgical procedures that are performed for a host of emergency general surgical (EGS) events that may be precipitated by heterogeneous pathologies (Appendix 1.1).*

In England alone, 30,000 - 50,000 emergency laparotomies are performed annually (equating to an annual incidence of 1:1,100 of the population) and there are in excess of 600,000 admissions for EGS conditions every year in England.^{1,2}

It has been estimated that almost 313 million major surgical procedures are performed globally each year, of which as many as a quarter of operations are unplanned and 15% are gastrointestinal.³⁻⁵ Therefore emergency laparotomies are likely also to comprise a substantial proportion of the global burden of surgery.

1.2.1 Postoperative patient outcomes

Despite being common operations, international data indicate that the incidence of morbidity and mortality and the duration of hospitalisation associated with emergency laparotomies substantially exceed that associated with other emergency and high-risk operations and after elective general surgery.^{4, 6-8}

Studies in heterogeneous cohorts have consistently reported that 13 - 18% of patients die within a month of an emergency laparotomy and that morbidity complicates postoperative recovery in more than a third.^{2, 9-13} Beyond this period, limited data suggest that in excess of a quarter of patients die within two years of an emergency laparotomy.¹³

Up to a quarter of patients continue to require hospital care three weeks after an emergency laparotomy, but other potential markers of the quality of care received, including readmission rates and the incidence of long-term mortality and morbidity are infrequently reported.^{2, 9-13}

Patient-reported outcomes (PROMs) including functional ability, quality of life and the impact of resulting morbidity are likely to be of greater interest to patients undergoing an emergency laparotomy than immediate postoperative mortality or morbidity. However PROMs have been reported only rarely.^{14, 15}

In common with many other areas of healthcare research, short-term mortality is currently the most widely reported outcome after emergency laparotomies. However, because the

* Emergency laparotomies may also be performed for gynaecological, vascular and trauma indications, but because the demographic and pathological characteristics of these cohorts differ substantially from those undergoing surgery for EGS pathologies, these populations are not considered further in this thesis

effects of postoperative morbidity on health and survival extend long beyond the operative period and because long-term outcomes remain poorly defined, existing outcome data may substantially underestimate the burden of emergency laparotomies not only to individual patients, but also across healthcare systems and wider societies.¹⁶⁻¹⁸

As a consequence of the lack of ‘non-mortality’ and longer-term outcome data, the frank discussions that underpin informed shared decision-making are problematic in these patients. Ongoing efforts to define minimum dataset core outcomes and patient reported outcomes are therefore welcome.^{15, 19}

1.2.2 The financial cost of emergency laparotomies

Patients requiring an emergency laparotomy comprise less than a tenth of EGS admissions,²⁰ but consume disproportionate quantities of resources.^{1, 21} This is in part due to the substantial costs associated with the surgery itself, since a host of staff, facilities and equipment are required.

Financial considerations may also pre-date surgery and extend long into the postoperative period, including; prolonged critical care and hospital admissions, repeated returns to theatre and the multidisciplinary management of postoperative complications; intensive hospital discharge planning and the requirement for long-term community input resulting from loss of function; and re-admissions and long-term outpatient follow up.^{1, 14, 21}

While an in-depth discussion of the financial burden of emergency laparotomies is beyond the scope of this work, it notable that financial compensation for the management of these complex patients may be inadequate at NHS Trusts and that, as discussed above, existing data underestimate the long-term burden of emergency laparotomies for individuals, healthcare systems and wider societies.¹

1.2.3 Ageing populations

In a report published in 2014, the Office for National Statistics projected that by mid-2039 in the UK there would be a ‘marked increase in the population at older ages’ (>65 years) and that ‘more than 1 in 12 of the population will be aged 80 or over’.²²

Currently, intra-abdominal malignancies are common precipitants of emergency laparotomies,²³ colorectal cancers are becoming increasingly common in older people²⁴ and postoperative outcomes vary with age and timing of presentation with malignancy.^{25, 26}

In a situation that is mirrored worldwide, the already considerable number, complexity and burden of EGS and emergency laparotomy admissions in the UK is therefore forecast to increase dramatically over coming decades.²⁷

1.3 Modelling variation in postoperative patient outcomes

In the previous section I presented population averages for patient outcomes and associated costs of care for emergency laparotomies in order to demonstrate the burden of disease. However, presenting these values as averages obfuscates the magnitude of variation that has been reported across these populations.

Variation in postoperative outcomes has been demonstrated between patient subgroups and between hospitals in emergency laparotomy cohorts and by temporal factors in other clinical contexts. Where variations in patient outcomes are observed, there is the opportunity to improve the quality of care received and to improve patient outcomes. Therefore, better understanding of the causes of variation in patient outcomes will lay the foundation for quality improvement initiatives in emergency laparotomy populations.

However, while variables have been associated individually and as groups with outcomes after emergency laparotomy, a comprehensive understanding of the mechanisms underlying the observed variations has yet to be established.

In this section I will present contemporary evidence of variation in patient outcomes after emergency laparotomy and in wider clinical contexts before discussing Donabedian and Iezzoni's models for characterising between-hospital variations.

1.3.1 Patient subgroups

Short-term mortality after emergency laparotomy has been demonstrated to vary substantially between subgroups of patients when defined by preoperative factors; 30-day mortality may exceed 24% in patients over the age of 80,^{9, 28} and exceed 30% in nonagenarians;^{29, 30} up to a third of patients with moderate liver disease[†] die within 30 days of an emergency laparotomy, whereas 30-day mortality exceeds 76% in those with severe liver disease;³¹ and mortality varies substantially by the nature of pathologies precipitating surgery.^{2, 6, 9, 10, 23, 26, 31, 32}

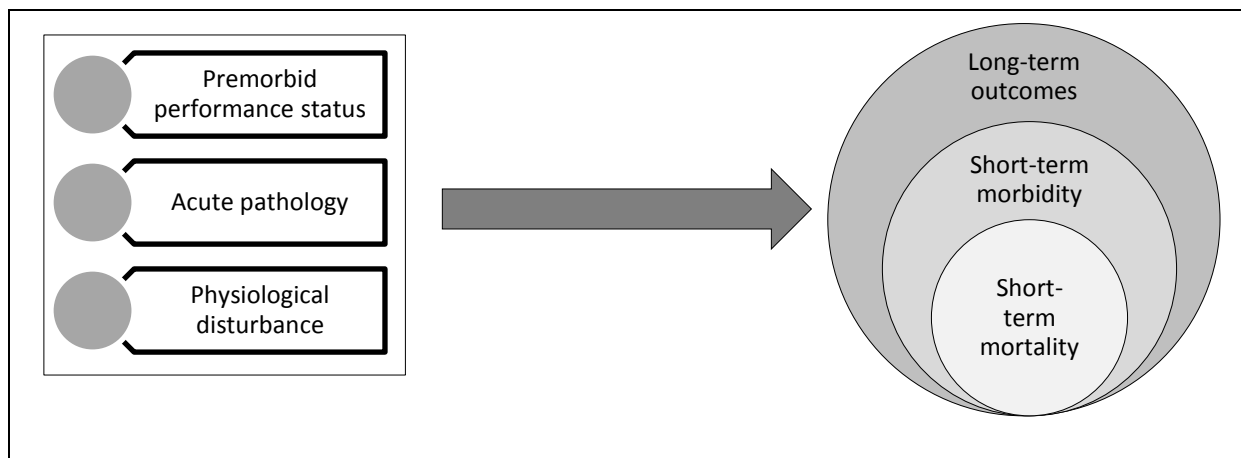


Figure 1 Model of the association between preoperative patient factors and postoperative patient outcomes

Furthermore, the characterisation of high-risk population subsets (in whom morbidity and mortality rates exceed population averages) has demonstrated that adverse events and treatment costs are not evenly distributed within heterogeneous populations.^{6, 33} These variations may be explained by differences in physiological reserve.

Precipitating pathologies may be associated with profound systemic physiological disturbances which, if not treated in a timely fashion, may pose an immediate threat to life, or progress to become life-threatening. Moreover, because intra-abdominal surgery is highly invasive, it may itself result in a host of physiological derangements (including the components of the surgical stress response), compounding the effects of acute and chronic pathologies (Figure 1).

These physiological disturbances have the potential to result in impairment or failure of the body's organ systems, but the capacity to tolerate these disturbances varies between individuals. This variation is likely to be determined by a complex interplay of patient factors (including nature and severity of comorbid disease, age, sex, lifestyle and environmental factors, medication use and genetic factors) with surgical factors (including the nature and systemic consequences of the pathology precipitating surgery).^{34, 35}

[†] When defined using the Child-Turcotte-Pugh classification system

1.3.2 Healthcare providers

In addition to the variations observed between patient groups, data indicate up to 8-fold variation in the incidence of short-term mortality and morbidity after emergency laparotomy between healthcare providers[‡], both in the United Kingdom and United States.^{2, 9, 27, 36}

These findings agree with the repeated observations of between-hospital variation in patient outcomes in other disciplines over recent decades; from the seminal cardiac surgical studies in the US in the 1980s;³⁷ to investigations of deaths after paediatric cardiac surgery in the UK in the 1990s;³⁸ to the routinely published hospital-level outcomes in the annual reports of national audits in recent years.

Furthermore, while direct comparisons may not be feasible, there are limited data indicating variation in patient outcomes between countries and between healthcare models.^{3, 4, 39}

Modelling between-provider variation

Surgical care is a multidimensional construct, involving multiple interventions by diverse clinical professionals over a protracted period. The identification of associations between healthcare provider-level factors and variations in patient outcomes must therefore account for a variety of simultaneous exposures across multiple hierarchical levels (Figure 2).

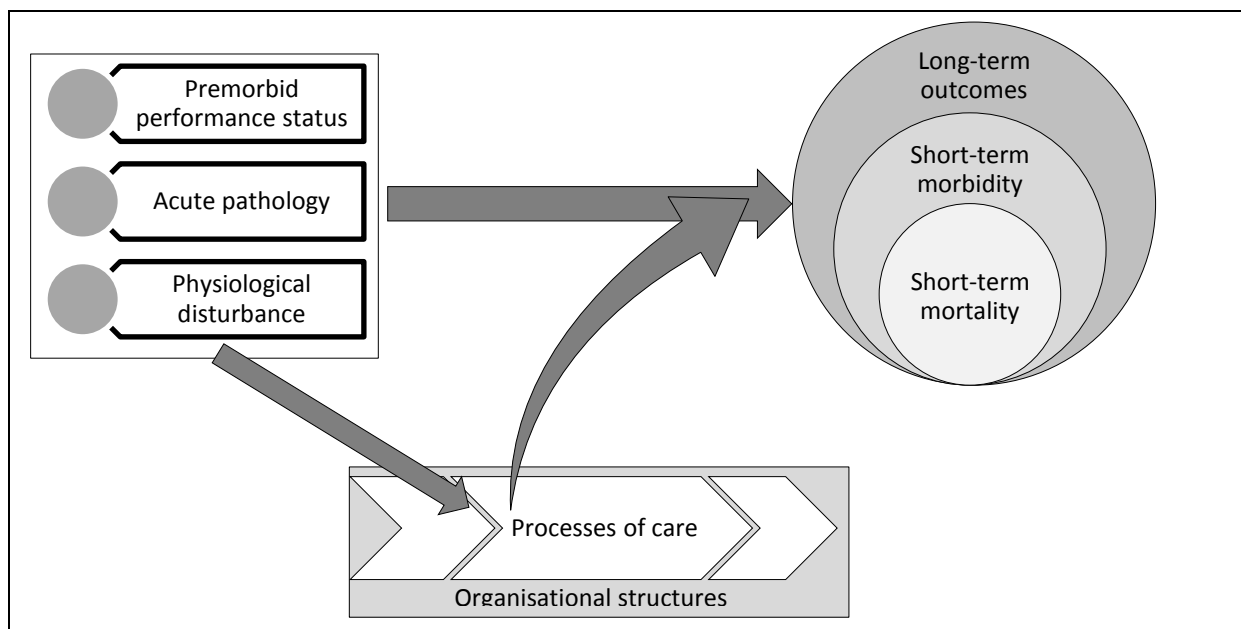


Figure 2 Model of associations between preoperative patient factors, organisational factors and postoperative patient outcomes

[‡] Outcome variation is predominantly reported at hospital-level, but may also be reported at the level of individual clinicians or clinical teams

In 1966 Donabedian proposed a Structure-Process model in order to evaluate the quality of medical care at healthcare provider institutions.⁴⁰ In this model, components of a hospital's *quality of care* are categorised as either processes of care or organisational structures (Figure 2).

Processes of care

Processes of care describe not only the nature of interventions (e.g. small bowel resection); but also the timeliness with which these intervention are delivered (within six hours of presentation); the manner in which they are delivered (by a consultant colorectal surgeon, following resuscitation directed by a consultant anaesthetist); and the appropriateness of an intervention relative to alternatives (following CT diagnosis of a small bowel perforation).

In emergency laparotomy care these processes may span an extended perioperative period, from initial diagnosis to the identification and management of postoperative morbidity.

Appropriate processes may be selected in response to a patient's clinical condition or determined by the availability of structural provisions.[§]

Organisational structures

Donabedian proposed that organisational structures underpin the delivery of processes of care, since adequacy of provisions will determine the selection and delivery of processes of care.** Using examples related to those outlined above, in emergency laparotomy these might include:

1. The availability at short notice of:
 - an operating theatre
 - experienced consultant anaesthetists and colorectal surgeons
 - adequately trained theatre personnel
 - radiological imaging facilities and experienced radiographers
2. Sufficient supporting surgical and other clinical team members to enable prompt decision-making without undue delay
3. Support staff to ensure the prompt and safe flow of patients through preoperative processes of care to arrival in theatre for surgery

[§] Selection of processes of care may also be guided by wider organisational factors including hospital size and cultural factors as outlined in Figure 4

** Adequacy of structural provisions may be associated with organisational characteristics and related factors including casemix selection, competition of resources and funding as outlined in Figure 4

Structural provisions therefore do not therefore directly affect patient outcomes; rather it is proposed that their influence on patient outcomes is exerted through the ability to deliver essential processes of care.

While Donabedian and others have cautioned against the use of outcomes as a measure of care quality,^{41, 42} the potential of the structure-process model to explain between-hospital variations in patient outcomes was recognised and structure-process models have been widely adopted by health service researchers (Figure 3).

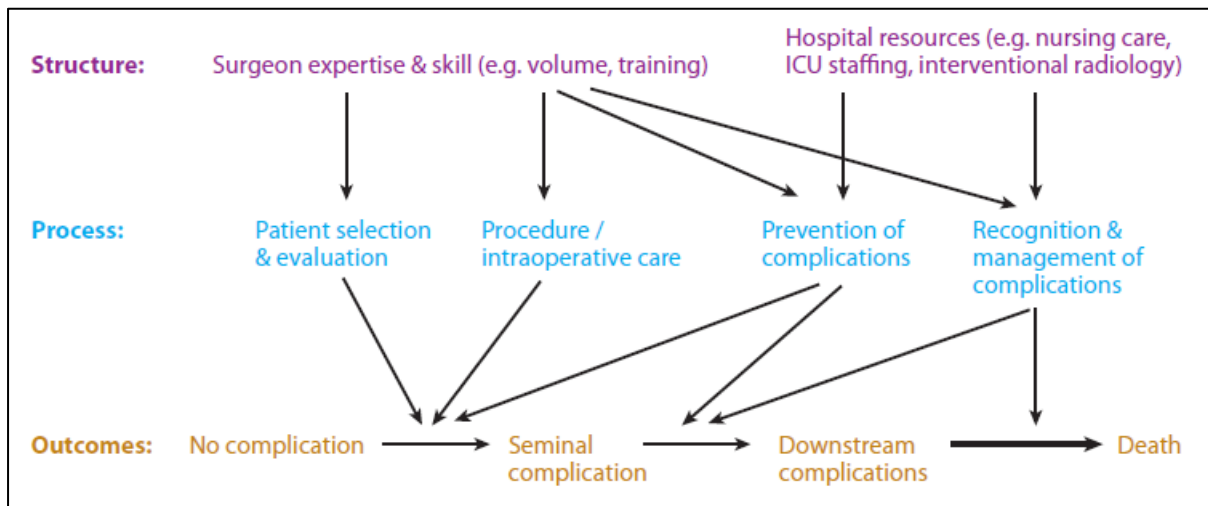


Figure 3 Model of associations between structures, processes, complications and mortality after surgery From Birkmeyer JD, Dimick JB. Understanding and Reducing Variation in Surgical Mortality. Annual Review of Medicine 2009; 60: 405-15⁴³

Donabedian’s model was subsequently incorporated into Iezzoni’s “algebra of effectiveness”, in which variations can be attributed (in isolation or in combination) to three contributing factors: casemix, quality of care and chance.⁴⁴

Casemix

Intrinsic patient characteristics may be associated with variation in the incidence of postoperative mortality^{2, 6, 9, 10, 23, 26, 28-33} and the distribution of these characteristics (casemix) may vary between hospitals. Whether systematic (for example due to selective admission of complex or high-risk patients at specialist centres) or “for the purposes of this thesis” at random, these casemix differences may confound between-hospital comparisons of mortality rates. In order to assess the contribution of hospital-level factors to between-hospital outcome variation it is therefore necessary to control for casemix differences.

Chance

Chance may result in apparent between-hospital variation in patient outcomes, particularly where sample sizes are small or the incidence of the outcome of interest is low. Differences in quality of care may explain as little as half of observed between-hospital variation in

mortality rates⁴² and a substantial proportion of overall variation may result from chance alone.⁴⁵ Therefore, even after casemix variation is accounted for, between-hospital variation in mortality after emergency laparotomy may not be explained in its entirety by organisational structures and processes of care.

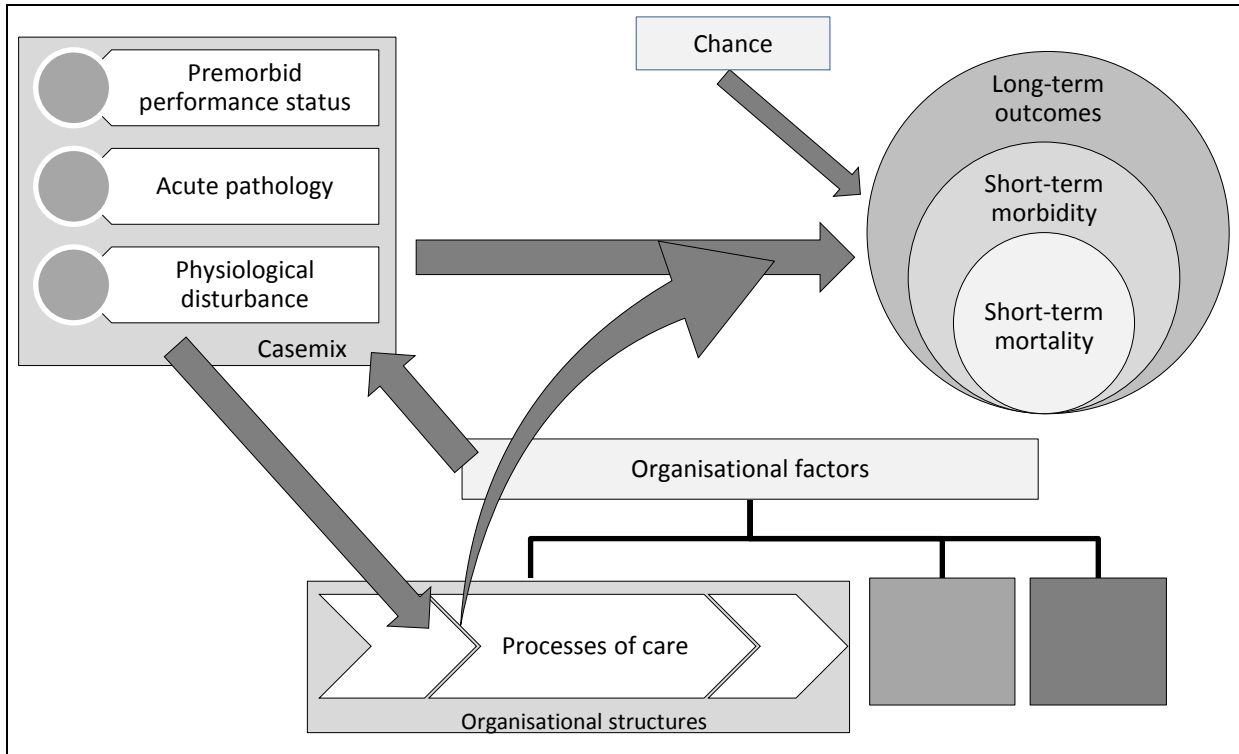


Figure 4 Model of associations and interactions between patient and organisational factors and postoperative patient outcomes, incorporating chance

In addition to the processes and structures that may define quality of care, associations between organisational characteristics (including size, specialty status and university affiliation) and variations in patient outcomes have been investigated. These characteristics may be associated not only with structural provisions, but also with the delivery of processes of care and casemix variation, exponentially increasing the complexity of the relationships modelled by Donabedian and Iezzoni (Figure 4).

In order to identify and determine the relative contributions of the multidimensional variables underlying between-hospital outcome variation, it is therefore necessary to deploy a variety of statistical techniques.

1.3.3 Evidence to support associations with provider-level factors

The gold standard method for testing the impact of an intervention on a patient-level outcome is the randomised control trial (RCT). However, in order to understand the impact of multiple simultaneous exposures across multiple hierarchical levels and complex interactions in the context of multidimensional perioperative care (Figure 4), epidemiological techniques are required.

Existing data regarding associations between hospital-level factors and patient outcomes in a variety of clinical contexts are limited and inconsistent (below). Furthermore, emergency general surgical cohorts are relatively under-represented and existing data may therefore not be generalisable to patients undergoing emergency laparotomies.

Processes of care

It is clinically plausible that processes of care might be associated with between-hospital variations in patient outcomes. However, evidence of associations with individual processes is limited, both in emergency laparotomy cohorts and in wider populations; and where implicated, processes of care may explain only a fraction of between-hospital variation in patient outcomes.⁴⁶

Reduced hospital-level mortality rates have been associated with increased hospital-level utilisation of CT imaging in a large retrospective database analysis of an emergency laparotomy cohort.² Conversely, high rates of delayed surgery;⁴⁷ low rates of intraoperative consultant surgical and anaesthetic presence,⁹ and high proportions of patients discharged from theatre initially to a ward bed but subsequently requiring critical care admission are associated with increased hospital mortality rates after emergency laparotomies.¹¹

In wider surgical populations, delayed identification and management of postoperative morbidity (failure to rescue) may be associated with increased institutional postoperative mortality rates.^{48, 49}

The reasons for the lack of consistent evidence identifying associations between individual processes of care and patient outcomes are uncertain,⁴³ however, more consistent data support the use of bundles and pathways of care, both in emergency laparotomy cohorts (discussed below)⁵⁰ and in wider contexts.^{51 52}

Structural provisions

The prompt delivery of identified processes of care in emergency laparotomy cohorts is determined by the timely availability of sufficient organisational structures and by the selection of these processes by clinicians. The latter may be influenced by incentivisation and the implementation of protocols and pathways of care.

Increased nurse-to-patient ratios and critical care provisions (beds, equipment and experience of consultant clinicians) have been associated with improved institutional patient outcomes.^{2, 53-55} Elsewhere, reduced institutional mortality rates following pancreatectomy were observed at US hospitals with facilities to perform open heart or organ transplantation surgery.⁵³

In wider contexts, the implementation of protocols, bundles and pathways to direct the delivery of select processes of care has been associated with improved quality of care⁵¹ and patient outcomes.⁵² And in emergency laparotomy cohorts, there is evidence that bundles to direct the delivery of perioperative processes of care may be associated with reduced postoperative mortality.⁵⁰

“The volume effect”

Relationships between procedural volumes and postoperative outcomes are complex and remain elusive to define. Data concerning associations between institutional procedure volumes and postoperative morbidity and mortality are markedly conflicting; variously indicating that postoperative outcomes are better at high-volume centres, worse at high-volume centres and that no volume-outcome association is observed.^{54, 56-62}

In emergency laparotomy cohorts, marked variation has been observed in institutional volumes of emergency laparotomies performed,^{2, 9, 27, 36, 63} but associations with postoperative patient outcomes have not been demonstrated.

Overall, the data indicate that postoperative outcomes are improved in patients undergoing high risk or uncommon procedures at high-volume centres, performed by surgeons who perform a large number of procedures^{††} across a wide range of conditions.^{56, 64}

^{††} It is uncertain whether this reflects decision making or practical proficiency

Hospital characteristics

As is the case with procedural volumes, generalisability of the findings of studies assessing the influence of hospital characteristics on patient outcomes after emergency laparotomy is limited by the under-representation of these cohorts and by methodological heterogeneity. University affiliation and number of hospital beds have variously been associated with decreased mortality after pancreatectomy,⁵³ increased mortality after elective general surgery⁶¹ and observed not to independently predict postoperative mortality.^{54, 65}

1.3.4 Temporal associations with variations in outcomes

Data in elective surgical and acute medical cohorts suggest that mortality rates may vary by day of the week of admission to hospital and day of the week that surgery is performed.^{66, 67}

Data in emergency laparotomy cohorts are again limited, but the findings of a recent study indicate that hospital admission at a weekend may be associated with increased postoperative mortality in emergency general surgery patients.⁶⁸

It has been proposed that these observations might reflect casemix variation, with sicker patients presenting at or requiring treatment at weekends, or variation in structural provisions by day of the week. However, there is currently very limited evidence indicating the relative associations of these factors and these findings therefore warrant further investigation.

1.4 Improving patient outcomes after emergency laparotomy

While many of the pathologies and surgical events precipitating emergency laparotomies are potentially life-threatening, postoperative survival may vary substantially between patient subgroups and between the hospitals at which these operations are performed.

These variations offer opportunities for improving not only patient outcomes but also the quality of care delivered to these patients. In order to succeed, strategies should be based on an understanding of factors associated with variation,⁶⁹ however, while physiological reserve may account for some of the variation observed between patient subgroups, the mechanisms underlying between-hospital outcome variations are poorly appreciated in emergency laparotomy cohorts but also in wider populations.

In this context, several standards of care documents have been published over the past decade, with the shared objective of safeguarding the quality of care delivered to emergency general surgical patients.^{21, 70-75} In the relative absence of evidence of improved patient outcomes associated with individual processes of care and supporting organisational structures, these standards almost exclusively represent the consensus of expert opinion.

More recently, several large-scale initiatives have been established internationally with complementary aims of compiling robust datasets to identify factors associated with variations in postoperative outcomes and translating this research into improving both survival and the quality of survival after emergency laparotomy.⁷⁶⁻⁷⁹

In the United Kingdom, the National Emergency Laparotomy Audit (NELA) began collecting and reporting data in 2012 (*Chapter 2*) and the implementation of the emergency laparotomy pathway quality improvement care (ELPQuiC) bundle was associated with a significant reduction in the risk of death following emergency laparotomy.⁵⁰ The findings of the enhanced perioperative care of high risk patients (EPOCH) trial and the emergency laparotomy collaborative (ELC) quality improvement projects are eagerly anticipated.

While discussions of surgical techniques are beyond the scope of this thesis, it is notable that while open surgery remains the mainstay of treatment, less-invasive treatment modalities are being advocated for an increasingly diverse range of pathologies.⁸⁰⁻⁸³ Whether these less-invasive modalities are associated with improved postoperative survival has yet to be determined.

Finally, given that the complications of intra-abdominal malignancies commonly precipitate emergency laparotomies²³ and observations that up to a third of colorectal cancer diagnoses are made in the emergency setting,^{20, 84} there are promising data to suggest that the

incidence of emergency presentations in colorectal cancer may be reduced with comprehensive screening programmes.⁸⁵

1.5 Summary

Emergency laparotomies are commonly performed operations that are associated globally with substantial postoperative morbidity, mortality and resource utilisation, which may extend well beyond the immediate perioperative period.

Furthermore, older patients are relatively over-represented in contemporary emergency laparotomy cohorts and the incidence of adverse events following major surgery increases with age. Therefore, in the context of ageing global populations, the volume of and burden associated with emergency laparotomies is expected to rise substantially over coming decades.

While many of the pathologies and surgical events precipitating emergency surgery are potentially life-threatening, accumulating data indicate that short-term survival and morbidity may vary substantially between patient groups and between the hospitals at which these operations are performed.

Theoretical modelling of variation in quality of care and patient outcomes indicates that, when casemix differences and chance are accounted for, between-hospital variation in mortality after emergency laparotomy may be associated with differences in organisational characteristics, structures and the delivery of processes of care.

The National Emergency Laparotomy Audit (NELA) commenced in 2012 in the United Kingdom. NELA undertook an audit of organisational structures for emergency general surgery in 2013 and, in 2014, collected data for the largest contemporary cohort of prospectively identified emergency laparotomy patients to date. Analysis of these datasets, using a variety of statistical techniques, provides the opportunity to identify mechanisms associated with between-hospital variation in postoperative mortality; and subsequently to inform quality improvement initiatives after this common surgery that is associated with a high burden of disease for both individuals and wider societies.

1.6 Aims of this thesis

The aims of the analyses presented in this thesis were to:

1. identify between-hospital variation in casemix adjusted postoperative mortality in the largest prospectively identified cohort of emergency laparotomy patients;
2. identify and characterise between-hospital variation in the provision of organisational structures and the delivery of perioperative processes of care for patients undergoing emergency laparotomies;
3. identify potentially modifiable processes of care and underpinning hospital factors that are associated with between-hospital variation in postoperative mortality;

Appendix 1.1: Surgical events precipitating emergency laparotomies

Surgical event precipitating emergency laparotomy	Patients (%)
Bowel perforation	30
Bowel obstruction	25
Ischaemia or necrosis	12
Haemorrhage	7
Incarceration	7
Abscess or collection	7
Anastomotic leak	4
Toxic colitis	3
Fistulation	1

Table 1 surgical events precipitating emergency laparotomies

From Barrow E, Anderson ID, Varley S, et al. Current UK practice in emergency laparotomy. *Annals of the Royal College of Surgeons of England* 2013; 95: 599-603⁸⁶

2. THE NATIONAL EMERGENCY LAPAROTOMY AUDIT: OVERVIEW OF METHODOLOGY AND AUDIT STANDARDS

2.1 Background

In 2011 the Healthcare Quality Improvement Partnership (HQIP) tendered proposals for a national audit of emergency laparotomies in the United Kingdom. This audit was commissioned in response to concerns of professional bodies and the findings of high-profile studies reporting not only poor postoperative outcomes, but also between-hospital variations in patient outcomes after emergency laparotomy.

The contract for the provision of the audit was awarded to the Royal College of Anaesthetists in June 2012. The National Emergency Laparotomy Audit (NELA) began work in December 2012, with the following stated aims:

‘To enable the improvement of the quality of care for patients undergoing emergency laparotomy through the provision of high-quality comparative data from all providers of emergency laparotomy.’

In 2013 NELA conducted an audit of structural provisions for the perioperative care of patients undergoing an emergency laparotomy (and the wider population of emergency general surgery patients). Then in 2014 NELA commenced an annual cycle of audits of perioperative processes in emergency laparotomy patients.

The identification of participating hospitals in England and Wales

In January 2013 NELA approached the 163 English NHS trusts and Welsh local health boards (LHBs) to ascertain the hospitals at which emergency laparotomies were performed and therefore required to participate in the audit. Responses from all NHS trusts and LHBs indicated that 191 hospitals were eligible to participate. Individual hospitals were then required to nominate lead clinicians and audit staff for local contact and co-ordination of data collection.

Non-NHS English and Welsh hospitals and hospitals in Scotland, Northern Ireland, the Republic of Ireland and the Channel Islands were welcome to contribute data, but HQIP funding arrangements did not extend beyond mainland English and Welsh hospitals.

During the course of the first NELA patient audit an additional four hospitals were identified and were invited to participate in collection of patient-level data.

2.2 The first NELA organisational audit

The objective of the NELA organisational survey was to collect high-quality descriptive data detailing the provision of organisational structures for emergency general surgical patients from all English and Welsh hospitals at which emergency laparotomies were undertaken.

The format of the first NELA organisational audit was the dissemination of a purpose-built questionnaire to the 191 identified hospitals in England and Wales.

In the absence of evidence supporting individual organisational structures and processes of care, standards of care for patients undergoing emergency laparotomies are almost exclusively based upon expert opinion. Component questions were constructed to assess the provision of organisational structures for emergency laparotomies at participating hospitals against identified standards of care and research findings where available.

Non-surgical (radiological or endoscopic) interventions may be superior in the management of some emergency general surgical (EGS) pathologies, including gastrointestinal haemorrhage and colorectal stenting for malignant bowel obstruction.^{82, 83} Furthermore, organisational factors influencing patient outcomes after emergency laparotomies may not be confined to the immediate perioperative period.

The scope of published research, recommendations and standards of care considered for inclusion in the questionnaire was therefore not restricted solely to intraoperative care during emergency laparotomy; rather an inclusive approach was adopted, identifying standards relating to the wider provisions required to deliver a comprehensive EGS service (Appendix 2.1).^{21, 70-75}

Candidate structural provisions for inclusion in the organisational audit questionnaire were identified from existing research and standards of care documents (Appendix 2.2); and candidate contextual items identified by members of the NELA project team (PT). Through an iterative process, questions were constructed and refined by members of the NELA PT, with input by the NELA project board (PB) and clinical reference group.^{‡‡}

The questionnaire was piloted by members of the emergency laparotomy network (ELN) prior to dissemination and as a result of this process, accompanying explanatory materials were developed.

The questionnaire was disseminated to participating hospitals in the first week of October 2013. Questionnaires were completed by clinicians and audit staff at these hospitals and certified for correctness by local NELA leads prior to submission.

^{‡‡} Lay representatives are included in the NELA clinical reference group

The dataset was extracted from the webtool as a Microsoft Excel comma separated values (CSV) spreadsheet on 21st October 2013 following closure of the audit webtool.

Where data were missing or their validity of concern, participants were contacted to allow them the opportunity to clarify or amend their responses.

Very high levels of engagement by participants and of data completeness permitted detailed exploration of contemporary structural provisions for emergency laparotomy. Of the 191 identified hospitals across England and Wales, participants at 190 institutions submitted completed Audit questionnaires: one hospital withdrew from the audit due to reconfiguration of services.

Prior to publication, the first NELA organisational audit Report underwent review by members of the PT, PB and CRG before final review by NHS England and The Healthcare Quality Improvement Partnership (HQIP).

2.3 The first NELA patient audit

The objectives of the NELA patient audit were to collect high-quality descriptive data detailing the delivery of processes of care and patient descriptive data (in order to calculate risk adjusted between-hospital postoperative mortality rates) in patients undergoing emergency laparotomies at hospitals in England and Wales.

A purpose-built webtool was constructed, through which clinicians and audit staff at the 195 participating hospitals submitted pseudoanonymised data.

As with the organisational audit, because the evidence base for individual processes of care is limited, standards of care for patients undergoing emergency laparotomies are almost exclusively based upon expert opinion. Component questions were therefore constructed to assess the delivery of processes of care to patients undergoing emergency laparotomies against identified standards of care and research findings where available.

Candidate processes of care to be included in the patient audit webtool were identified by members of the NELA project team (PT) from existing research and standards of care documents and matched with supporting standards (Appendix 2.3).^{21, 70-75} Final selection of processes for inclusion in the webtool was guided by the opinion of expert multidisciplinary members of NELA stakeholder groups.

Contextual data items (describing patient characteristics, surgical pathology and operative procedural factors), administrative fields and outcome measures underwent a similar iterative process before inclusion.

Through an iterative process, the questionnaire was constructed and refined by members of the NELA PT, with input by the NELA project board (PB) and clinical reference group (CRG) in order to assess the delivery of these processes of care at participating hospitals.

Finally, informed by the findings of the systematic review reported in *Chapter 4*, POSSUM^{§§} data items were included, with which to risk adjust outcome data.

The webtool was piloted by members of the NELA PT, PB and CRG as well as members of the emergency laparotomy network (ELN). The webtool was launched in late November 2013 with considerable administrative support provided by members of the PT at the Royal College of Anaesthetists.

^{§§} The Physiological and Operative Severity Score for the enUmeration of mortality and morbidity: Copeland GP, Jones D, Walters M. POSSUM: a scoring system for surgical audit. *British journal of surgery* 1991; **78**: 355-60

The dataset was extracted from the webtool at 08.00 on 15th January 2015 as a Microsoft Excel comma separated values (CSV) spreadsheet.

Prior to publication, the first NELA organisational audit Report underwent review by members of the PT, PB and CRG before final review by NHS England and The Healthcare Quality Improvement Partnership (HQIP).

Appendix 2.1: Standard of care documents

Emergency general surgery. The future: a consensus statement. *ASGBI*, 2007

www.asgbi.org.uk/en/publications/consensus_statements.cfm

Patient safety: a consensus statement. *ASGBI*, 2009

www.asgbi.org.uk/en/publications/consensus_statements.cfm

Guidance for 2015/2016. NHS England/contracting and incentives team. *CQUIN*, 2015

www.england.nhs.uk/wp-content/uploads/2015/03/9-cquin-guid-2015-16.pdf

An age old problem: A review of the care received by elderly patients undergoing surgery.

NCEPOD, 2010. www.ncepod.org.uk/2010report3/downloads/EESE_fullReport.pdf

Emergency Admissions: A journey in the right direction. *NCEPOD*, 2007

www.ncepod.org.uk/2007ea.htm

Knowing the risk: a review of the perioperative care of surgical patients. *NCEPOD*, 2011.

www.ncepod.org.uk/2011report2/downloads/POC_fullreport.pdf

Clinical Guideline 50: Acutely ill patients in hospital. *NICE*, 2007

www.publications.nice.org.uk/acutely-ill-patients-in-hospital-cg50

Medical Technologies Guidance: Cardio-Q-ODM. *NICE*, 2011

www.nice.org.uk/guidance/MTG3

The National Service Framework for older people. *Department of Health*, 2001

[www.gov.uk/government/uploads/system/uploads/attachment_data/file/198033/National Service Framework for Older People.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/198033/National_Service_Framework_for_Older_People.pdf)

The Higher Risk General Surgical Patient: towards improved care for a forgotten group.

RCS England and DH, 2011. www.rcseng.ac.uk/publications/docs/higher-risk-surgical-patient/

Emergency Surgery Standards for unscheduled surgical care. *RCS England*, 2011.

www.rcseng.ac.uk/publications/docs/emergency-surgery-standards-for-unscheduled-care

Appendix 2.2: Standards relating to structural provisions

Facilities

All hospitals admitting emergency general surgical patients should have a dedicated, fully staffed, theatre available at all times for this clinical workload (*ASGBI EGS*)

Even in the smallest centres the principle of dedicated commitment to emergency general surgery still applies (*ASGBI EGS*)

Adequate emergency theatre time is provided throughout the day to minimise delays and avoid emergency surgery being undertaken out-of-hours when the hospital may have reduced staffing to care for complex post-operative patients (*RCS USC*)

Trusts should ensure emergency theatre access matches need and ensure prioritisation of access is given to emergency surgical patients ahead of elective patients whenever necessary, as significant delays are common and affect outcomes (*RCS HR*)

Delays in surgery for the elderly are associated with poor outcome. They should be subject to regular and rigorous audit in all surgical specialties, and this should take place alongside identifiable agreed standards (*NCEPOD Age*)

There must be a clear and identifiable separation of delivery of emergency and elective care (*ASGBI EGS*)

Wherever possible, emergency and elective surgical pathways are separated (*RCS EESC*)

The delivery of quality clinical care is dependent on access to supporting facilities. Rapid access to CT imaging, ultrasound (US) scanning and laboratory analyses are critical to the efficient diagnosis, resuscitation and prioritisation of these patients (*ASGBI EGS*)

Where imaging will affect immediate outcome, emergency surgical patients have access to CT, plain films and US within 30 minutes of request. When MRI is required and not available, patients are transferred to the appropriate centre. Advice on appropriate imaging is available immediately (*RCS USC*)

Definitive diagnostic CT as early as possible but should be within four hours of identification as high-risk. Hospitals should (also) ensure that there are clear arrangements in place for interventional radiology, especially out-of-hours (*RCS HR*)

Emergency surgical services delivered via a network have arrangements in place for image transfer and telemedicine and agreed protocols for ambulance bypass/transfer (*RCS USC*)

Hospitals providing emergency surgical services have access to 24/7 interventional radiology. Interventional radiology services are staffed by fully trained interventional radiologists, interventional nurses and interventional radiographers.

Interventional radiology services have an identified consultant radiologist available 24/7 and services for emergency patients are available within one hour of request (*RCS USC*)

Scheduled seven-day access to diagnostic and treatment procedures such as diagnostic gastrointestinal (GI) endoscopy, bronchoscopy, echocardiography, diagnostic ultrasound, CT and MRI (*RCS USC*)

The delivery of quality clinical care is dependent on access to supporting facilities. Rapid access to CT imaging, ultrasound scanning and laboratory analyses are critical to the efficient diagnosis, resuscitation and prioritisation of these patients (*ASGBI EGS*)

Wherever general and regional anaesthesia is administered, there is access to an appropriate range of laboratory and radiological services (*RCS USC*)

24-hour test availability including full blood count, sickle cell screen, coagulation screen, group and save, and availability of blood components. And clinical telephone haematology advice is available 24/7 (*RCS USC*)

Prompt availability of blood components and massive haemorrhage protocol available in all key areas (*RCS USC*)

Clinical staffing

A consultant surgeon (CCT holder) and consultant anaesthetist are present for all cases with predicted mortality >10% (*RCS USC*)

All hospitals admitting emergency general surgical patients should have 24-hour cover by a consultant with a general surgical Certificate of Completion of Training (CCT) or equivalent (*ASGBI EGS*)

It is important that there are effective arrangements for refereeing the priority of competing interests at all times of the day and night. ASGBI considers that this is best delivered by dedicated clinical leadership (*ASGBI EGS*)

The assessment, prioritisation and management of emergency general surgical patients should be the responsibility of accredited general surgeons (*ASGBI EGS*)

A consultant surgeon (CCT holder) and consultant anaesthetist are present for all cases with predicted mortality >10% (*RCS USC*)

For a typical major hospital, the emergency general surgical team will comprise a consultant surgeon (CCT holder), middle grade (MRCS holder), core trainee and foundation doctor. As major procedures often require three surgeons, the effect on other activities during major surgery should be anticipated (*RCS USC*)

Specialty teams develop rotas of clearly identified, adequately experienced staff who can provide advice or attend and review patients expeditiously on the acute medical unit within a maximum of four hours of a request and ideally sooner (*RCS USC*)

All patients undergoing emergency surgery requiring anaesthesia should be seen by an anaesthetist for assessment and pre-operative optimisation; the exact timing of this visit will be dependent upon the urgency of surgery (*RCoA GPAS*)

The peri-operative anaesthetic care of ASA3 and above patients requiring immediate major surgery (and therefore with an expected higher mortality) is directly supervised by a consultant anaesthetist (*RCS USC*)

Structured arrangements are in place for the handover of patients at each change of responsible consultant/medical team. Time for handover is built into job plans and occurs within working hours (*RCS USC*)

Patients admitted via the emergency general surgical service should remain under the care of this service until formally transferred to another team and accepted by them (*ASGBI EGS*)

Perioperative care and pathways of care

Trusts should formalise their pathways for unscheduled adult general surgical care. The pathway should include the timing of diagnostic tests, timing of surgery and post-operative location for patients *(RCS HR)*

Each patient should have his or her expected risk of death estimated and documented prior to intervention and due adjustments made in urgency of care and seniority of staff involved *(RCS HR)*

High-risk patients are defined by a predicted hospital mortality $\geq 5\%$: they should have active consultant input in the diagnostic, surgical, anaesthetic and critical care elements of their pathway *(RCS HR)*

A consultant surgeon (CCT holder) and consultant anaesthetist are present for all cases with predicted mortality $>10\%$ *(RCS USC)*

Surgical patients often require complex management and delay worsens outcomes. The adoption of an escalation strategy which incorporates defined time-points and the early involvement of senior staff when necessary are strongly advised *(RCS HR)*

Best practice: hospital has agreed integrated pathway to facilitate the following within a defined timescale: urgent access to imaging (CT); timely definitive treatment (surgery/radiology/medical) *(RCS USC)*

The postoperative care of the high-risk surgical patient needs to be improved. Each trust must make provision for sufficient critical care beds or pathways of care to provide appropriate support in the post-operative period *(NCEPOD KTR)*

There is good evidence to demonstrate that inappropriate peri- and post-operative fluid therapy is harmful. Dynamic monitoring of stroke volume and cardiac output avoids this, and should be considered in all patients undergoing major surgery *(ASGBI PS)*

There should be clear strategies for the management of intra-operative low blood pressure in the elderly to avoid cardiac and renal complications. Non invasive measurement of cardiac output facilitates this during major surgery in the elderly *(NCEPOD Age)*

Adverse events should be studied using morbidity and mortality (M&M) meetings *(ASGBI PS)*

Trusts should audit delays in proceeding to surgery in patients requiring emergency or urgent abdominal surgery and implement appropriate mechanisms to reduce these *(NCEPOD Age)*

All deaths/serious morbidity should be reviewed formally by a senior member of the anaesthetic department *(RCS USC)*

Critical care and outreach

All high-risk patients should be considered for critical care and as a minimum, patients with an estimated risk of death of $\geq 10\%$ should be admitted to a critical care location (*RCS HR*)

Given the high incidence of post-operative complications demonstrated in the review of high-risk patients, and the impact this has on outcome there is an urgent need to address postoperative care (*NCEPOD KTR*)

The post-operative care of the high-risk surgical patient needs to be improved. Each Trust must make provision for sufficient critical care beds or pathways of care to provide appropriate support in the post-operative period (*NCEPOD KTR*)

To aid planning for provision of facilities for high-risk patients, each trust should analyse the volume of work considered to be high-risk and quantify the critical care requirements of this cohort (*NCEPOD KTR*)

Hospitals should plan their critical care resource to match need in order to avoid shortages and define critical care areas accordingly (*RCS HR*)

Critical care facilities are available at all times for emergency surgery. If this is not the case, agreed protocols for transfer are in place (*RCS USC*)

There is 24-hour cover of the ICU by a named consultant with appropriate experience and competences (*RCS USC*)

Each hospital should ensure that there is a system to rapidly recognise and deal appropriately with post-operative deterioration (*NCEPOD KTR*)

Prompt recognition and treatment of emergencies and complications is essential to improve outcomes and reduce costs (*RCS HR*)

Prompt intervention is fundamental to the successful treatment of the patient who deteriorates after surgery (*RCS HR*)

Multidisciplinary input

Routine daily input from Medicine for the Care of Older People (MCOP) should be available to elderly patients undergoing surgery and is integral to inpatient care pathways in this population (*NCEPOD Age*)

Clear protocols for the post-operative management of elderly patients undergoing abdominal surgery should be developed, which include, where appropriate, routine review by a MCOP consultant and nutritional assessment (*NCEPOD Age*)

Comorbidity, disability and frailty need to be clearly recognised as independent markers of risk in the elderly. This requires skill and multidisciplinary input, including early involvement of Medicine for the Care of Older People (*NCEPOD Age*)

All elderly surgical admissions should have a formal nutritional assessment during their admission so that malnutrition can be identified and treated (*NCEPOD Age*)

Appendix 2.3: Standards relating to processes of care

Review within 12 hours of hospital admission by a consultant surgeon.

Patients admitted as an emergency should be seen by a consultant at the earliest opportunity. Ideally this should be within 12 hours and should not be longer than 24-hours (*NCEPOD EA*)

Preoperative imaging

Hospitals which admit patients as an emergency must have access to both conventional radiology and CT scanning 24-hours a day, with immediate reporting (*NCEPOD EA*)

The delivery of quality clinical care is dependent on access to supporting facilities. Rapid access to CT imaging, U/S scanning and laboratory analyses are critical to the efficient diagnosis, resuscitation and prioritisation of these patients (*ASGBI EGS*)

Preoperative documentation of risk

An assessment of mortality risk should be made explicit to the patient and recorded clearly on the consent form and in the medical record (*NCEPOD KTR*)

Patients must be actively involved in shared decision making and supported by clear information from healthcare professionals to make fully informed choices about treatment and on-going care that reflect what is important to them. This should happen consistently, seven days a week (*NHS 7 day services*)

We recommend that objective risk assessment become a mandatory part of the pre-operative checklist to be discussed between surgeon and anaesthetist for all patients. This must be more detailed than simply noting the ASA score (*RCS HR*)

Timeliness of emergency care

Those with septic shock require immediate broad-spectrum antibiotics with fluid resuscitation and source control (*RCS HR*)

The number of patients who present to emergency departments and other wards/units that directly admit emergencies with severe sepsis, Red Flag Sepsis or Septic Shock who received intravenous antibiotics within 1 hour of presenting (*CQUIN*)

Trusts should ensure emergency theatre access matches need and ensure prioritisation of access is given to emergency surgical patients ahead of elective patients whenever necessary as significant delays are common and affect outcomes (*RCS HR*)

Timeliness of arrival in an operating theatre

Trusts should ensure emergency theatre access matches need and ensure prioritisation of access is given to emergency surgical patients ahead of elective patients whenever necessary as significant delays are common and affect outcomes (*RCS HR*)

The time from decision to operate to actual time of operation is recorded in patient notes and audited locally (*RCS USC*)

Delays in surgery for the elderly are associated with poor outcome. They should be subject to regular and rigorous audit and this should take place alongside identifiable agreed standards (*NCEPOD Age*)

Consultant-delivered perioperative care

Each higher risk case (predicted mortality $\geq 5\%$) should have the active input of consultant surgeon and consultant anaesthetist (*RCS HR*)

A consultant surgeon (CCT holder) and consultant anaesthetist are present for all cases with predicted mortality $\geq 10\%$ and for cases with predicted mortality $> 5\%$ except in specific circumstances where adequate experience and manpower is otherwise assured (*RCS USC*)

Each higher risk case (predicted mortality $\geq 5\%$) should have the active input of consultant surgeon and consultant anaesthetist. Surgical procedures with a predicted mortality of $\geq 10\%$ should be conducted under the direct supervision of a consultant surgeon and a consultant anaesthetist unless the responsible consultants have actively satisfied themselves that junior staff have adequate experience and manpower and are adequately free of competing responsibilities (*RCS HR*)

Goal directed fluid therapy.

There should be clear strategies for the management of intra-operative low blood pressure in the elderly to avoid cardiac and renal complications. Non-invasive measurement of cardiac output facilitates this during major surgery in the elderly (*NCEPOD Age*)

Direct postoperative admission to critical care

All high risk patients should be considered for critical care and as minimum, patients with an estimated risk of death of $\geq 10\%$ should be admitted to a critical care location (*RCS HR*)

Intensive care requirements are considered for all patients needing emergency surgery. There is close liaison and communication between the surgical, anaesthetic and intensive care teams peri-operatively with the common goal of ensuring optimal safe care in the best interests of the patient (*RCS USC*)

The outcome of high-risk general surgical patients could be improved by the adequate and effective use of critical care in addition to a better pre-operative risk stratification protocol (*ASGBI PS*)

Assessment by a Medicine for the Care of Older People specialist

Clear protocols for the post-operative management of elderly patients undergoing abdominal surgery should be developed which include where appropriate routine review by a MCOP (Medicine for care of older people) consultant and nutritional assessment (*NCEPOD Age*)

Comorbidity, disability and frailty need to be clearly recognised as independent markers of risk in the elderly. This requires skill and multidisciplinary input, including early involvement of Medicine for the Care of Older People (*NCEPOD Age*)

All emergency inpatients must have prompt assessment by a multi-professional team to identify complex or on-going needs, unless deemed unnecessary by the responsible consultant (*NHS 7 day services*)

3. NELA ORGANISATIONAL AUDIT: CONTEMPORARY STRUCTURAL PROVISIONS FOR EMERGENCY LAPAROTOMY AT HOSPITALS IN ENGLAND AND WALES

3.1 Introduction

Background

The overall incidence of mortality after emergency laparotomy exceeds that observed after most 'high-risk' surgical procedures and substantial variation has been observed between patient subgroups and between hospitals in both the United Kingdom and in the United States.^{2, 9, 36}

Donabedian's structure-process model proposes that some between-hospital variation in patient outcomes can be explained by differences in the provision of organisational structures and delivery of processes of care;⁴⁰ and associations between individual organisational and patient variables with healthcare-related outcomes have been indicated in a variety of clinical contexts.^{2, 6, 9-11, 23, 26, 28-33, 43, 46-62***}

However, relationships are complex; because organisational factors do not exert an influence in isolation of one another, associations with patient outcomes may be modified by other organisational variables (interactions). Furthermore; some processes are applicable only to subgroups of patients (MCOP input in patients over the age of 70); while the indications and evidence for other processes may be clearly defined in some subgroups (timing of antibiotics and surgery in intra-abdominal sepsis) but less clearly defined in other subgroups. Interactions between organisational and patient factors are therefore also expected.

The identification of multiple multilevel factors that are associated with between-hospital variation in patient outcomes may be time consuming and ultimately of little real benefit to patient care. Alternative approaches include qualitative assessment of structures and processes at hospitals that have been identified as high- and low-mortality outliers and the identification of marker variables to identify outlier hospitals, preceding more detailed investigation.

The provision of systems that are responsive to the needs of individual emergency general surgical patients is therefore founded upon the provision of adequate hospital structures (facilities, equipment and staff) at the hospitals at which these patients are treated. To this

*** Other variables including time of day and day of week are discussed in subsequent Chapters

end, standards of care for emergency general surgical patients have been published in the United Kingdom, specifying minimum structural provisions and processes of care, with the intention of safeguarding the quality of care received by these patients.^{21, 70-75}

However, until 2012, the approach to the collection of baseline organisational data relating directly to the care of emergency laparotomy patients was not systematic and due primarily to methodological and inclusion criteria differences, exploration of these complex associations was limited.

In 2012 the National Emergency Laparotomy Audit (NELA) was commissioned. It undertook an audit of structural provisions for patients undergoing emergency laparotomies and the wider population of patients admitted to hospital with emergency general surgical (EGS) conditions in 2013.

Aims

1. To identify and characterise variation in the provision of recommended organisational structures for emergency laparotomies at hospitals in England and Wales
2. To identify structures as potential markers of high-quality care in emergency laparotomy

Objectives

1. To compare the provision of structures for emergency general surgery at participating hospitals against contemporary recommendations, standards of care and health services research publications
2. To characterise participating hospitals using data provided by audit participants and relevant external sources of data
3. To assess the validity of self-reported number of hospital beds as a marker of hospital size using externally sourced data
4. To investigate associations between hospital characteristics and the provision of recommended structures for emergency general surgery
5. To investigate associations between structural provisions as potential markers of high-quality EGS services

3.2 Methods and materials

3.2.1 The first NELA organisational audit

A purpose-built questionnaire was created by the NELA project team and disseminated to the 191 identified hospitals in England and Wales. Methods for the identification of the English and Welsh hospitals at which emergency laparotomies are performed are outlined in *Chapter 2*.

The process for the selection of data items assessed in the questionnaire is outlined below. The content of the questionnaire was reviewed by multidisciplinary stakeholders associated with NELA^{†††} and the questionnaire piloted by members of the emergency laparotomy network (ELN) prior to dissemination. As a result of this process, accompanying explanatory materials were developed.

The questionnaire was disseminated to participating hospitals in early October 2013. Questionnaires were completed by clinicians and audit staff at these hospitals and certified for correctness by local NELA leads prior to submission.

3.2.2 Selection of variables

Standards of care for EGS patients and those undergoing emergency laparotomies are almost exclusively the result of expert consensus. Candidate organisational structures for assessment in the NELA organisational audit and hospital characteristics were therefore identified from contemporary standards of care and recommendations (Appendix 2.1 and Appendix 2.2).^{21, 70-75}

The consensus opinion of expert multidisciplinary members on NELA stakeholder groups guided the selection of these candidate organisational structures and hospital characteristics for inclusion in the organisational audit questionnaire. The wording of individual questions within the questionnaire was an iterative process, which again involved multidisciplinary stakeholder engagement. The organisational audit questionnaire is provided in Appendix 3.1 and the process of selection of structures and characteristics detailed in *Chapter 2*.

Identified hospital characteristics included hospital configuration to admit emergency general surgical (EGS) patients, tertiary referral centre status for Gastrointestinal (GI) surgery and number of inpatient and overnight hospital beds.

^{†††} With representation on the NELA project team, project board and clinical reference group

Essential provisions

Among those structures selected for inclusion in the first NELA organisational audit questionnaire, eight were identified by experts within the project team as being required to underpin the safe management of emergency laparotomy patients (Figure 5).⁷⁶

24-hour provision of:

1. a fully staffed operating theatre in which emergency general surgery may be performed
2. an on-call consultant surgeon to supervise clinical decisions and surgery
3. an on-call consultant anaesthetist to supervise clinical decisions and perioperative care
4. biochemistry, haematology and transfusion laboratories, supported by consultant advice
5. CT facilities and contemporaneous image reporting
6. interventional radiology expertise
7. interventional endoscopy expertise
8. critical care facilities and expertise appropriate to manage EGS patients

Figure 5 Structures required for the care of patients undergoing an emergency laparotomy

Potential markers of high-quality care

In addition to these provisions, I identify four further structures as potential markers of high-quality care (Figure 6). In contrast with the structures identified in Figure 5, these structures may not be essential to ensuring the delivery of safe care to emergency laparotomy patients; rather, I hypothesise that their implementation may be indicative of the high-quality of care of emergency laparotomy patients, as outlined below.

1. 24-hour provision of a fully staffed operating theatre reserved for EGS cases
2. Perioperative EGS patient care pathway
3. Provision of an Emergency Surgical Unit (ESU)
4. Bimonthly meetings to morbidity and mortality following emergency laparotomy

Figure 6 Structural provisions that may be associated with high-quality care

Inclusion of the provision of a fully staffed operating theatre exclusively for EGS cases and of an emergency surgical unit recognises that while it is hypothesised that these structures are associated with more efficient pathways of care for patients requiring an emergency laparotomy, it is unlikely that all hospitals are sufficiently well resourced to implement these structures.

Regular review of morbidity and mortality is a recognised component of good practice for clinicians.⁸⁷ However, in contrast with the structures identified in Figure 5, these provisions do not relate directly to the delivery of a process of care, instead they represent potential markers of high quality care emergency general surgical patients.

Evidence suggests that pathways and bundles for directing the delivery of care and clinical decision-making may be associated with improved patient outcomes^{50, 51} and contemporary standards of care support their use (Appendix 2.1). However, despite financial incentivisation, pathways and bundles have not been universally adopted. This structure was therefore selected as a potential marker of high-quality care.

3.2.3 External sources of data

Structural provisions and competition for resources may vary by hospital size. In order to assess validity as a marker of hospital size, reported number of beds was compared with an external system used to classify size of hospital Trusts and Health Boards.

The NHS England National Reporting and Learning System (NRLS) cluster classification system is a publically available resource provided for the interpretation and contextualisation of patient safety incident reporting data. The system categorises Trusts and Health Boards by specialisation and size.

Five of the ten NHS England NRLS cluster categorisation groups are relevant to hospitals at which adult emergency laparotomies are performed:

- Acute teaching Trusts
- Acute large Trusts
- Acute medium Trusts
- Acute small Trusts
- Welsh Local Health Boards (LHBs)

The March 2013 NRLS cluster classification was downloaded^{###} on 29th January 2014 and matched to hospitals in the organisational audit dataset in Microsoft Excel (2010).

^{###} <http://www.nrls.npsa.nhs.uk/resources/?entryid45=135145>

3.2.4 Data management

Following closure of the NELA audit webtool, the dataset was extracted as a Microsoft Excel comma separated values (CSV) spreadsheet on 21st October 2013 and imported into and subsequently managed in Microsoft Excel (2010).

Participants were contacted to clarify or amend submitted hospital characteristic data where inconsistent with external sources of data.

Cleaning and validation

- Variables were renamed in order to be compatible with Stata® (version 12, StataCorp LP, College Station, Texas USA) statistical software
- Variables recorded as yes/no responses were converted to binary (1/0) data
- Hospitals were assigned numerical identifier codes
- Summary binary variables were constructed (indicating 24-hour provisions) for structures that were reported as multiple data items over multiple timepoints
- Summary ordinal variables were constructed (indicating overall provisions) for structures that were reported as multiple binary variables

3.2.5 Statistical analyses

Dataset management was performed using Microsoft Excel (2010) and analyses performed in Stata® version 12 (StataCorp LP, College Station, Texas USA).

Hospital characteristics

Configuration to admit emergency general surgery patients

Organisational structures for emergency general surgery (EGS) may be less comprehensively provided at hospitals that are not configured to admit emergency general surgery patients. Accordingly, hospitals were classified by this characteristic.

Hospital size

Organisational structures for EGS may be more comprehensively provided at the largest hospitals. Hospitals were therefore categorised into quartiles of the number of reported inpatient and overnight beds.^{§§§}

Descriptive analyses

Parametrically distributed continuous data were reported as mean and standard deviation and non-parametrically distributed data as median and interquartile range. Operating theatre, general surgical and critical care bed provisions were also reported per 100 hospital beds to assess competition for resources.

Binary format variables were reported as percentages and categorical and ordinal variables reported as within-group percentages.

Validation of reported number of hospital beds as a marker of hospital size

Healthcare Trusts rather than individual hospitals are classified in the NRLS cluster system and Welsh hospitals (and Local Health Boards) are not sub-classified. Using NHS England data, English Trusts comprising only one hospital were therefore identified and reported bed numbers compared between these Trusts.

Bed numbers were reported as medians and interquartile ranges and the statistical significance of differences across clusters assessed using the Kruskal-Wallis one-way analysis of variance.

^{§§§} Including only hospitals configured to admit emergency general surgery patients

Hospital characteristics and the provision of organisational structures

Hospital size

Comprehensiveness of provisions were compared between the largest and smallest hospital quartiles using the Wilcoxon matched pairs rank sum test for non-parametric continuous data and Pearson's χ^2 test for dichotomous data.

Tertiary gastrointestinal (GI) surgical referral centre status

This hospital characteristic was recorded as a dichotomous variable. Provisions of organisational structures were compared between groups using the Wilcoxon matched pairs rank sum test for non-parametric continuous data and Pearson's χ^2 test for binary data.

Configuration to admit emergency general surgery patients

Provisions of organisational structures were compared between groups using the Wilcoxon matched pairs rank sum test for non-parametric continuous data and Pearson's χ^2 test for binary data.

Bonferroni corrections

Between-quartile testing requires multiple between-class analyses, p values were corrected using the Bonferroni method. Corrected p values are denoted as p'.⁸⁸

Associations between potential markers of a high-quality EGS care

Clustering of identified provisions was assessed by using a correlation matrix of Pearson's χ^2 values.

3.3 Results

Key findings

- 190 hospitals in England and Wales provided data for the first NELA organisational audit
- 176 hospitals (93%) were configured to admit emergency general surgical (EGS) patients; 34% of which were tertiary gastrointestinal (GI) surgical referral centres
- Numbers of inpatient and overnight beds varied considerably (median 459: IQR 368-649)
- With the exception of X-ray and CT facilities, which were provided universally, substantial between-hospital variations were observed in the provision of all recommended facilities, staff, equipment, care pathways and arrangements for cross-disciplinary team involvement
- Reported numbers of inpatient and overnight beds demonstrated good agreement with NRLS cluster categories for English hospitals. Quartiles of reported number of beds was therefore used in assessments of structural provisions by hospital size
- Many structures were more comprehensively provided at larger hospitals. However when assessed per 100 hospital beds, general surgical bed and operating theatre provisions were demonstrated to be inversely related to hospital size
- Many EGS structures were also more comprehensively provided at tertiary GI surgical referral centres. However, when assessed per 100 hospital beds, fewer general surgical beds were provided at these hospitals
- All six of the structures identified as essential for the safe care of emergency laparotomy patients were provided at only three hospitals
- Provision of structures identified as potential markers of a high-quality EGS service was poorly correlated
- Hospitals that were not configured to admit EGS patients were relatively smaller, with fewer operating theatres in which to perform emergency laparotomies. Other differences in provisions were not statistically significant

3.3.1 Data quality

Datasets were submitted by 190 of the 191 hospitals (99.5%) identified by NELA. The remaining hospital submitted no data to the audit.

Less than 3% of fields were submitted with missing data items. These data items included policies for consultant surgeons to formally handover in person and disciplines represented at reviews of mortality after emergency laparotomies. These structures were therefore not included in the reported analyses.

Descriptive analysis of consultant anaesthetist provisions demonstrated a very broad spread of responses, indicating variable interpretation of the questions by participants. These data were therefore excluded from further analysis.

Due to the complexity and volume of data assessed, results are presented in two sections, as descriptive reporting and data analyses.

3.3.2 Descriptive reporting

1. Classification and characterisation of participating hospitals

Hospital characteristic	Hospitals (%)
24-hour configuration to admit EGS patients ****	176 (93)
Tertiary referral centres for gastrointestinal surgery	60 (34)
<i>Geographical location</i>	
England	163 (93)
Wales	13 (7)

Table 2 Characteristics of the participating hospitals
(EGS: emergency general surgery)

**** All other data relating to the 14 hospitals that were not configured to admit patients with emergency general surgical conditions are reported separately

Reported inpatient and overnight bed provisions

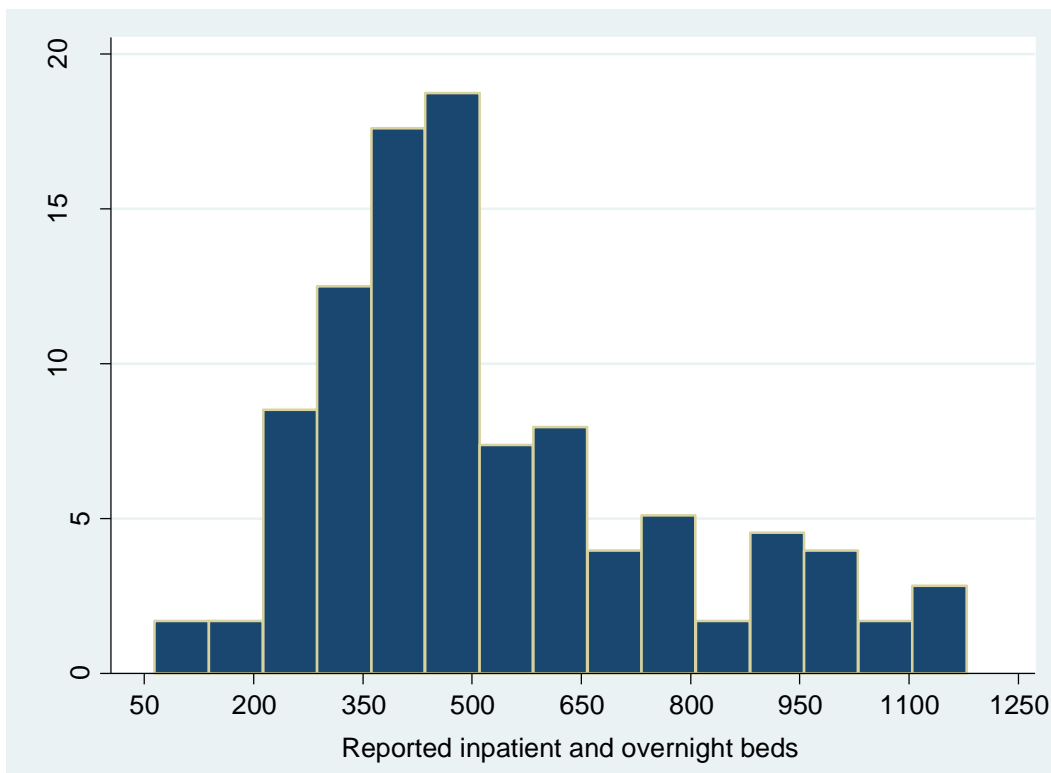


Figure 7 Frequency distribution of reported inpatient and overnight bed provisions at the 176 institutions configured admit emergency general surgical patients (Range 64-1179 beds, Median 459 (IQR 368-649))

	Range of adult in-patient and overnight beds	Number of hospitals
Quartile 1	64–364	44
Quartile 2	371–457	43
Quartile 3	459–648	45
Quartile 4	649–1,179	44
All hospitals	64-1,179	176

Table 3 Quartiles of reported number of inpatient and overnight beds at the 176 institutions configured to admit emergency general surgical patients

2. Facilities

Hospital structure	Median (Interquartile range)
General surgical inpatient beds	72 (54-91)
Operating theatres	12 (9-17)

Table 4 Provisions for the care of emergency general surgery patients
(EGS: emergency general surgery)

Hospital structure	Hospitals (%)
One or more fully staffed operating theatres, capable of accepting adult EGS patients	137 (78)
One or more fully staffed operating theatres, reserved exclusively for adult EGS patients	50 (28)
An ESU in which patients may receive ongoing care	55 (31)
<i>Radiological facilities</i>	
On-site X-ray	176 (100)
On-site Computed Tomography (CT)	176 (100)
On-site Ultrasound	113 (64)
Contemporaneous CT reporting by a radiologist	160 (91)
Contemporaneous CT reporting by a radiologist with gastrointestinal specialisation	3 (2)
<i>Interventional radiology and endoscopy services</i>	
Formal site-specific rota of interventional radiologists	58 (33)
Formal site-specific rota of clinicians to perform Diagnostic Endoscopy	113 (64)
Formal site-specific rota of clinicians to perform Interventional Endoscopy	116 (66)
<i>Laboratory facilities and consultant advice</i>	
On-site biochemistry, haematology and blood transfusion laboratories	175 (99)
Consultant advice for biochemistry, haematology and blood transfusion	156 (89)

Table 5 Provision of 24-hour facilities for the care of emergency general surgery patients
(EGS: emergency general surgery, ESU: emergency surgical unit, CT: computed tomography)

3. Surgical staffing

Consultant surgeons

Across the 176 hospitals, emergency general surgery on-call rotas comprised a median of 8 consultant surgeons (IQR 7-10).

Consultant surgeon specialisation	Number of hospitals with subspecialty representation on the consultant surgical EGS rota (%)
Colorectal surgery	176 (100)
Upper gastrointestinal surgery	152 (86)
General surgery	137 (78)
Vascular surgery	47 (27)
Breast surgery	80 (45)
Endocrine surgery	56 (32)

Table 6 Subspecialty representation in consultant surgical emergency general surgical (EGS) rotas

Surgical teams

On-call emergency general surgical teams comprised at least four surgical tiers at 85 hospitals (48%).

Surgical grade	Hospitals (%)
Consultant	151 (86)
Middle grade	157 (89)
Core trainee	160 (91)
Foundation trainee	156 (89)

Table 7 Sites at which the clinician was free from non-acute commitments when covering the emergency workload on the EGS rota

4. Perioperative care

Perioperative cardiac output monitoring

Equipment for monitoring cardiac output was provided for use in the perioperative care of EGS patients at 170 hospitals (97%).

Pathways and protocols

In total 13 perioperative pathways of care were assessed. The median number of pathways instituted at participating hospitals was five (IQR: 3-8).

Perioperative pathway of care	Hospitals (%)
<i>Institutional pathways and protocols</i>	
1 NICECG50 compliant monitoring of patients at risk of deterioration	130 (74)
2 A formal pathway for the management of patients with sepsis	148 (84)
3 Explicit arrangements with elderly medicine for review of selected patients	24 (14)
<i>Pathways and protocols specific to patients undergoing surgery</i>	
4 Timing of surgery according to clinical urgency	118 (67)
5 Deferment of elective activity in order to appropriately prioritise unscheduled admissions	60 (34)
6 Calculation of risk that provides an estimation of perioperative mortality	44 (25)
7 Seniority of anaesthetist present in theatre according to calculated risk of death	58 (33)
8 Seniority of surgeon present in theatre according to calculated risk	59 (34)
9 Location of post-operative care according to calculated risk of death	65 (37)
<i>Pathways and protocols specific to Emergency general surgery (EGS)</i>	
10 Single pathway or policy for the care of the unscheduled adult general surgical patient	54 (31)
11 Provision for the transfer of care of emergency surgical patients between consultants to ensure that they receive appropriate subspecialty care	97 (55)
12 Involvement of diagnostic and interventional radiology in the care of emergency general surgical patients	64 (36)
13 Enhanced recovery of the emergency surgical patient	53 (30)

Table 8 Hospitals at which formal pathways, of relevance to the perioperative care of emergency general surgical patients, have been instituted

5. Multidisciplinary and postoperative care

Critical care and outreach

Across the 176 hospitals a median of 12 beds were accessible by gastrointestinal surgical patients (IQR: 9-18).

Critical care structure	Hospitals (%)
24-hour cover by a consultant with regular critical care sessions	153 (87)
24-hour provision of a critical care outreach service	64 (36)

Table 9 Provision of critical care (Level 2 and Level 3 care) structures

Multidisciplinary reviews of perioperative morbidity and mortality

A review of all deaths after emergency laparotomy was undertaken at least bi-monthly at 144 hospitals (82%).

Discipline	Hospitals (%)
Surgery	143 (81)
Anaesthesia	60 (34)
Critical care medicine	60 (34)
Radiology	21 (12)
Elderly medicine	16 (9)
Surgical, anaesthetic and critical care medicine	47 (27)

Table 10 Disciplines providing input into bi-monthly reviews of mortality following EGS

Elderly medicine

On-site elderly medicine expertise was provided at 172 hospitals (98%).

Arrangements for input	Number of hospitals (%)
None	15 (9%)
Proactive	11 (6%)
On request	150 (85%)

Table 11 Provision of postoperative input into the care of EGS patients by Elderly Medicine clinicians

6. Hospitals not configured to admit emergency general surgical patients

In total 14 hospitals (7%) were not configured to admit emergency general surgical (EGS) patients. Characteristics and EGS structural provisions are reported here.

Hospital size

The median reported number of inpatient and overnight adult beds was 255 (IQR 180-409).

Surgical subspecialisation

Nine hospitals (64%) were surgical subspecialty centres for cancer, cardiothoracic or neurosurgery. The remaining 5 hospitals were elective surgical centres. Elective adult gastrointestinal surgery was routinely performed at nine hospitals (64%).

Facilities and staffing

Structure	Median (IQR)
Total operating theatres	7 (6-13)
Surgical consultants participating in EGS rota	6.5 (5-11)

Table 12 Structural provisions at hospitals that were not configured to admit EGS patients

Service component	Hospitals (%)
Fully staffed OT for EGS	6 (43)
Fully staffed OT reserved exclusively for EGS	0 (0)
On-site X-ray	14 (100)
On-site CT	14 (100)
Contemporaneous CT reporting by a radiologist	13 (93)
Site-specific interventional radiology	6 (43)
Diagnostic Endoscopy	6 (43)
Interventional Endoscopy	8 (57)
On-site biochemistry, haematology and blood transfusion laboratories	12 (86%)
Consultant laboratory advice	10 (71%)
24-hour cover by a consultant with regular critical care sessions	13 (93)

Table 13 24-hour provisions at hospitals that were not configured to admit EGS patients

3.3.3 Data analyses

1. Classification and characterisation of participating hospitals

Validation of reported number of beds using NHS England NRLS categories^{†††}

	Small acute Trust	Medium acute Trust	Large acute Trust	Acute teaching Trust	Wales LHB
Hospitals (%)	27 (15)	46 (26)	55 (31)	35 (20)	13 (8)
<i>Number of beds reported in the first NELA organisational audit</i>					
Range	79-540	206-767	64-1150	278-1179	152-804
Median (IQR)	344 (272-445)	500 (410-594)	447 (353-1150)	758 (429-975)	394 ^{***} (300-509)

Table 14 Reported bed numbers by NHS England NRLS cluster categories (2014)
(* p<0.05, **p≤0.005, ***p≤0.001)

	Small acute (n = 27)	Medium acute (n = 44)	Large acute (n = 23)	Acute teaching (n = 26)
Range	79-540	206-767	278-1150	398-1179
Median (IQR)	344 (272-445)	505 (411-595)	684 (447-885)	904 ^{**} (587-1000)

Table 15 Reported bed numbers by NHS England NRLS cluster categories at single-site English Trusts
(* p<0.05, **p≤0.005, ***p≤0.001)

Numbers and characteristics of single-site and multi-site English Trusts and Wales LHBs are reported in Appendix 3.2

^{†††} NRLS cluster classification data were available for all 176 English and Welsh hospitals

Tertiary referral centres for gastrointestinal surgery

	Tertiary GI referral centres (n=60)	Non-tertiary GI referral centres (n=116)
Median (IQR)	636 (460-935)	413 (330-518)**

Table 16 Reported number of inpatient and overnight beds by tertiary GI surgical referral centre status (* p<0.05, **p≤0.005, ***p≤0.001)

NHS England NRLS cluster category	Number of tertiary GI referral centres (%)
Small acute trust	2 (3)
Medium acute trust	10 (17)
Large acute trust	16 (27)
Acute teaching trust	29 (48)
Wales local health board (LHB)	3 (5)
Total	60 (100)

Table 17 NRLS cluster category of tertiary GI surgical referral centres

2. Facilities

	Quartile 1 (n=44)	Quartile 2 (n=43)	Quartile 3 (n=45)	Quartile 4 (n=44)
Total general surgical beds	58 (43–73)	67 (53–86)	72 (63–96)	89 (71–115)***
General surgical beds per 100 hospital beds	20 (15–28)	16 (13–20)	14 (12–18)	10 (8–14)***
Total operating theatres	8 (7–10)	11 (8–13)	13 (11–16)	21 (17–26)**
Operating theatres per 100 hospital beds	2.8 (2.4-3.4)	2.5 (1.9-3.0)	2.5 (2.0-3.0)	2.4 (2.0-2.8)*

Table 18 Structural provisions by quartile of hospital size
Reported as median and interquartile range (* p<0.05, **p≤0.005, ***p≤0.001)

	Hospitals (%)			
	Quartile 1	Quartile 2	Quartile 3	Quartile 4
24-hour fully staffed OT for EGS	24 (55)	31 (72)	42 (93)	40 (91)**
24-hour fully staffed OT exclusively for EGS	9 (21)	14 (33)	15 (33)	12 (27) NS
Emergency surgical unit	12 (27)	11 (26)	16 (36)	16 (36) NS
<i>Radiological, interventional radiology and endoscopy services</i>				
24-hour contemporaneous CT reporting	39 (89)	38 (88)	40 (89)	43 (98) NS
24-hour ultrasound provision	23 (52)	26 (60)	26 (58)	38 (87)**
24-hour formal interventional radiologist rota	7 (16)	8 (19)	17 (38)	26 (59)***
24-hour formal endoscopy clinician rota	27 (61)	23 (53)	27 (60)	36 (82)*
<i>Laboratory facilities and consultant advice</i>				
Laboratory consultant advice	36 (82)	39 (91)	40 (89)	41 (93) NS

Table 19 Structural provisions by quartile of hospital size
Reported as hospitals reporting specified provision (OT: operating theatre, EGS: emergency general surgery, * p<0.05, **p≤0.005, ***p≤0.001, NS: not significant)

	Tertiary GI referral centres (n=60)	Other hospitals (n=116)
Total general surgical beds	82 (58-119)	70 (53-87)*
General surgical beds per 100 hospital beds	12.2 (9.7-17.7)	15.6 (12.3-20.3)*
Total operating theatres	17 (13-24)	10 (8-13)***
Operating theatres per 100 hospital beds	2.7 (2.3-3.1)	2.5 (2.0-2.9)***

Table 20 Structural provisions by tertiary gastrointestinal surgical referral centre status
Reported as median and interquartile range (* p<0.05, **p≤0.005, ***p≤0.001)

	Hospitals (%)	
	Tertiary GI referral centres (n=60)	Other hospitals (n=116)
24-hour fully staffed OT for EGS	52 (87)	85 (73)*
24-hour fully staffed OT exclusively for EGS	13 (22)	37 (32) NS
Emergency surgical unit	20 (33)	35 (30) NS
<i>Radiological, interventional radiology and endoscopy services</i>		
24-hour contemporaneous CT reporting	102 (88)	58 (97) NS
24-hour ultrasound provision	44 (73)	69 (59) NS
24-hour formal interventional radiologist rota	33 (55)	25 (22)***
24-hour formal endoscopy clinician rota	46 (77)	70 (60)*
<i>Laboratory facilities and consultant advice</i>		
24-hour laboratory consultant advice	57 (95)	99 (86) NS

Table 21 Structural provisions by tertiary gastrointestinal surgical referral centre status
Reported as hospitals reporting specified provision (OT: operating theatre, EGS: emergency general surgery * p<0.05, **p≤0.005, ***p≤0.001, NS: not significant)

3. Surgical staffing

	Quartile 1 (n=44)	Quartile 2 (n=43)	Quartile 3 (n=45)	Quartile 4 (n=44)
Consultant surgeons participating in EGS rota (median (interquartile range))	7 (6-8)	8 (6-9)	8 (8-9)	10 (9-12)*
24 hour provision of ≥ four tier EGS rota (hospitals reporting provision)	11 (25%)	14 (33%)	23 (51%)	37 (84%)**

Table 22 Staffing provisions by quartile of hospital size
(* p<0.05, **p≤0.005, ***p≤0.001)

	Tertiary GI referral centres (n=60)	Other hospitals (n=116)
Total consultant surgeons participating in EGS rota (median (interquartile range))	10 (8-12)	8 (6-9)***
24 hour provision of ≥ four tier EGS rota (hospitals reporting provision)	41 (68%)	44 (38%)**

Table 23 Staffing provisions by tertiary gastrointestinal surgical referral centre status
(* p<0.05, **p≤0.005, ***p≤0.001)

4. Perioperative care

	Quartile 1 (n=44)	Quartile 2 (n=43)	Quartile 3 (n=45)	Quartile 4 (n=44)
Number of perioperative pathways of care (median (interquartile range))	4 (2-8)	6 (4-9)	5 (3-8)	4 (3-8) NS
Bi-monthly reviews of deaths after emergency laparotomy (hospitals reporting provision)	40 (91%)	31 (72%)	37 (82%)	36 (82%) NS

Table 24 Perioperative provisions by quartile of hospital size (NS: not significant)

	Hospitals (%)	
	Tertiary GI referral centres (n=60)	Other hospitals (n=116)
Number of perioperative pathways of care (median (interquartile range))	4 (3-8)	5 (3-8) NS
<i>Individual perioperative care pathways</i>		
Sepsis	47 (78)	101 (87) NS
Risk calculation	13 (22)	31 (27) NS
Care of the adult EGS patient	16 (27)	38 (33) NS
<i>Reviews of morbidity after emergency laparotomy</i>		
Bi-monthly reviews of postoperative deaths	46 (77)	98 (84) NS

Table 25 Perioperative provisions by tertiary gastrointestinal surgical referral centre status
Reported as hospitals reporting specified provision unless otherwise stated (NS: not significant)

5. Multidisciplinary and postoperative care

	Quartile 1 (n=44)	Quartile 2 (n=43)	Quartile 3 (n=45)	Quartile 4 (n=44)
<i>Critical care and outreach</i>				
Critical care beds (median (IQR))	8 (7-10)	11 (9-14)	13 (11-16)	21 (16-39)*
Critical care beds per 100 hospital beds (median (IQR))	2.9 (2.4-3.6)	2.5 (2.0-3.4)	2.6 (2.0-3.1)	2.6 (1.9-4.2) NS
24-hour cover by a consultant with regular critical care sessions	32 (73)	36 (84)	41 (91)	44 (100)**
24-hour critical care outreach service	12 (27)	12 (28)	17 (38)	23 (52) NS
<i>Proactive input into patient care by medicine for the care of the older person</i>				
Preoperative review	0	1 (2)	2 (4)	4 (9) NS
Postoperative review	1 (2)	3 (7)	2 (4)	5 (11) NS

Table 26 Postoperative provisions by quartile of hospital size
Reported as hospitals (%) reporting specified provision unless otherwise stated (* p<0.05, **p≤0.005, ***p≤0.001, NS: not significant)

	Tertiary GI referral centres (n=60)	Other hospitals (n=116)
<i>Critical care and outreach</i>		
Critical care beds for GI surgical patients (median (IQR))	21 (14-38)	11 (8-13)**
24-hour cover by a consultant with regular critical care sessions	58 (97)	95 (82)*
24-hour critical care outreach service	54 (90)	101 (87) NS
<i>Proactive input by medicine for the care of the older person</i>		
Preoperative review	3 (5)	4 (3) NS
Postoperative review	3 (5)	3 (3) NS

Table 27 Postoperative provisions by tertiary GI surgical referral centre status
Reported as hospitals (%) reporting specified provision unless otherwise stated (* p<0.05, **p≤0.005, ***p≤0.001, NS: not significant)

6. Summary of the provision of structures required to safely perform emergency laparotomies

Structure	Hospitals (%)
A fully staffed operating theatre in which emergency general surgery may be performed	137 (78)
Biochemistry, haematology and transfusion laboratories, supported by consultant advice	156 (89)
Contemporaneous CT reporting by a radiologist	160 (91)
A formal site-specific interventional radiology rota	58 (33)
A formal site-specific interventional endoscopy rota	116 (66)
Critical care cover by a named consultant with regular critical care sessions	153 (87)
Provision of all structures*	37 (21)

Table 28 Patterns of provision of hospital structures required to safely perform emergency laparotomies (* consultant surgeon and anaesthetist data were not included in this table)

7. Summary of the provision of structures identified as potential markers of a high-quality EGS service

	24-hour provision of a fully staffed operating theatre reserved for EGS cases	Perioperative EGS patient care pathway	Emergency Surgical Unit (ESU)	Bimonthly morbidity and mortality meetings
24-hour provision of a fully staffed operating theatre exclusively for EGS cases	-	p=0.55	p=0.12	p=0.21
Perioperative EGS patient care pathway	-	-	p=0.15	p=0.73
Emergency Surgical Unit (ESU)	-	-	-	p=1.0
Bimonthly morbidity and mortality meetings	-	-	-	-

Table 29 Pearson's χ^2 matrix of associations between potential markers of high-quality EGS services (EGS: emergency general surgery)

8. Hospitals not configured to admit emergency general surgical patients

	Sites not configured to admit EGS patients (n=14)	Sites configured to admit EGS patients (n=176)
Inpatient and overnight beds (median (interquartile range))	255 (180-409)	459 (368-649)**
Total operating theatres (median (interquartile range))	7 (6-13)	12 (8.5-16.5)*
Surgeons participating in EGS rotas	6.5 (5-11)	8 (7-10) NS
24-hour fully staffed OT for EGS	6 (43)	137 (78)**
Contemporaneous CT reporting by a radiologist	13 (93)	160 (91) NS
Site-specific interventional radiology	6 (43)	58 (33) NS
Diagnostic Endoscopy	6 (43)	113 (64) NS
Interventional Endoscopy	8 (57)	116 (66) NS
Biochemistry, haematology and blood transfusion laboratories	12 (86)	175 (99)**
Consultant advice for biochemistry, haematology and blood transfusion	10 (71)	156 (89) NS

Table 30 Provisions by configuration to admit emergency general surgical (EGS) patients

Reported as hospitals reporting specified provision (%) unless otherwise stated (OT: operating theatre, * p<0.05, **p≤0.005, ***p≤0.001, NS: not significant)

3.4 Discussion

Key points

- These data represent the most comprehensive collection of EGS structural provision data in the United Kingdom
- Participating hospitals were markedly heterogeneous with respect to size, specialty gastrointestinal (GI) surgical status and configuration to admit emergency general surgical (EGS) patients
- Submitted number of inpatient and overnight hospital beds was externally validated as a marker of hospital size
- These findings support previous indications of substantial variation in the provision of organisational structures for the care of EGS patients
- Every structure was provided at several hospitals, demonstrating that these standards of care were achievable
- Organisational structures were more comprehensively provided at large and specialty GI surgical referral centres, but differences by configuration to admit EGS patients were not statistically significant
- Adequacy of provisions may be determined by supply and demand dynamics

3.4.1 Overview

Emergency laparotomies are frequently performed for potentially life-threatening pathologies and while postoperative mortality and morbidity within a month of surgery are common overall,^{2, 9-13, 89} substantial variation has been indicated between patient groups^{2, 6, 9, 10, 23, 26, 28-33} and between healthcare providers.^{2, 9, 36}

These observations of variation offer opportunities for improving patient outcomes and standards of care received by patients undergoing emergency laparotomies. Modelling of between-hospital outcome variation suggests that, having modelled patient-level risk, residual variation may be explained by differences in hospital-level factors and chance.^{40, 44} It is therefore anticipated that the identification of associations may provide targets for quality improvement strategies in emergency laparotomy populations.²⁷

However, relationships between organisational factors and patient outcomes represent multiple simultaneous exposures across multiple hierarchical levels and remain poorly defined in emergency general surgical (EGS) populations. The National Emergency Laparotomy Audit (NELA) was established to address the lack of systematically collected hospital-level and patient-level data in emergency laparotomy cohorts.

Organisational structural provisions underpin the ability to deliver processes of care. The aims of the analyses reported in this Chapter were therefore: firstly to report baseline EGS structural provision data; secondly to identify between-hospital variation in the provision of these structures; thirdly to characterise these variations; and finally to identify potential markers of high-quality care.

Analyses of the first NELA organisational audit dataset reported in this Chapter demonstrate substantial variation in the provision of many of the diverse facilities, staff and equipment assessed by the audit; and marked heterogeneity of the 190 participating hospitals, with respect to size, configuration to admit EGS patients and subspecialty status.

Characterisation of the observed variation indicated that many organisational structures were significantly more comprehensively provided at large hospitals and at tertiary GI surgical referral centres and provisions significantly less comprehensive at hospitals that were not configured to admit patients with EGS conditions.

While organisational structures may not directly impact upon patient outcomes, if provisions are inadequate to enable the delivery of key processes of care to emergency laparotomy patients, this may compromise quality of care; if the delivery of potentially life-saving

treatments is delayed; if inappropriate treatment decisions ensue; or if the most appropriate treatment (which may include non-surgical interventions) is not available.

In subsequent Chapters I will develop these themes and go on to analyse associations between the organisational factors reported here and the delivery processes of care in the NELA year 1 patient audit cohort.

3.4.2 Hospital characteristics

Marked heterogeneity was observed in the characteristics of the 190 participating hospitals.

Configuration to admit patients with emergency general surgical (EGS) conditions

In total, 93% of hospitals were configured to admit patients with EGS pathologies 24 hours per day, 7 days per week. The 14 hospitals that were not configured to admit EGS patients were significantly smaller (Table 12) and, due to casemix selection (subspecialty surgical or elective surgical), patient characteristics are anticipated to be different from hospitals admitting EGS patients.

Hospital size

Reported numbers of inpatient and overnight beds varied widely between participating hospitals (Figure 7).

Validation of reported number of beds as a marker of hospital size (making comparisons with NHS England National Reporting and Learning System (NRLS) cluster categories) demonstrated moderate agreement (Table 14), and agreement was improved by the removal of multi-site Trusts and Welsh Health Boards (Table 15).

Subspecialty institutions

In total, 34% of the hospitals configured to admit EGS patients were reported to be tertiary referral centres for gastrointestinal (GI) surgery. Comparison with reported bed numbers indicated that these were large hospitals (Table 16 and Table 17).

3.4.3 Structural provisions

The organisational structures assessed in the first NELA organisational audit were diverse, including a range of hospital facilities, staff and equipment. Each structure may support the provision of an emergency laparotomy service; however some structures are essential for safe care whilst others may be independently or collectively associated with high-quality patient care.⁴⁰

Marked variation was observed in the provision of many organisational structures and very few were provided at every hospital at the levels specified in identified standards of care (Appendix 2.1).^{21, 70-75} Some elements were provided at only a small minority of hospitals and no institution was found to have met every standard. However, every structure was provided at several hospitals, demonstrating that these standards of care are achievable within the modern NHS.

Associations between structural provisions, the delivery of perioperative processes of care and patient outcomes are explored in *Chapters 5, 7 and 8*.

Hospital structures required to safely perform emergency laparotomies

In total, eight structures were identified as being fundamental to the safe management of patients undergoing an emergency laparotomy (Figure 5) as detailed in the methods. Individually, these structures were provided at 33 - 91% of hospitals and all six assessed structures^{††††} were provided at only 37 of the hospitals (21%) configured to admit EGS patients (Table 28).

Inadequate provision of these structures might result in delayed delivery of time-sensitive intervention,^{47, 90} insufficient data upon which to base clinical decision-making^{91, 92} and the limitation of interventional treatment options, all of which may adversely affect patient outcomes. I will now go on to discuss these in greater detail.

Timely intervention

The speed with which emergency surgery is indicated is determined by the nature of the surgical event and resulting systemic compromise. Delayed surgery may result from inadequate provisions to ensure: timely access to the results of clinical investigations; the availability of experienced clinicians to make timely clinical decisions and supervise perioperative care; and timely access to an adequately staffed operating theatre, all of which

^{††††} The distribution of responses concerning consultant anaesthetic provisions suggested inconsistent interpretation of the wording of the questions. These provisions were therefore not included in this summary statistic.

were variably provided (Table 5). Inadequate provision of these structures may therefore indirectly result in increased morbidity and mortality.

Appropriate clinical decision-making

Informed clinical decision-making requires the availability of the results of clinical investigations and the provision of experienced clinicians.

Radiological imaging commonly informs clinical decision-making in emergency general surgery and delayed or inappropriate treatment may result from misinterpretation by non-specialist radiologists or clinicians.^{91, 92} Inadequate provision of facilities and experienced radiologists to interpret and report this imaging in a timely manner (Table 5) and of clinicians may therefore also result in increased morbidity and mortality.

Availability of treatment modalities

The incidence of adverse events may be lower for non-surgical rather than surgical interventions for selected acute EGS pathologies.^{21, 82, 83} Failure to provide comprehensive interventional radiology and endoscopy services (Table 5) may therefore unnecessarily expose patients to the attendant risks of an emergency laparotomy.^{21, 93, 94}

While the demand for interventional radiology and endoscopy services has increased steadily over recent years, a recent survey revealed unfilled consultant posts at several hospitals and an acute shortage of trained interventional radiologists.⁹⁵ The extent to which informal rotas and regional networks are used to meet demand is not known.

Postoperative care

High-quality care after surgery is essential. Postoperative complications following general surgery are common⁸ and are associated with greatly increased postoperative mortality.⁹⁶ Short-term survival may be improved by direct admission to critical care after an emergency laparotomy,¹¹ and therefore inadequate provisions of facilities and appropriately trained staff (Table 5) may increase the risk of complications and associated mortality following emergency laparotomy.

Potential markers of high-quality care

In total, four structures were identified as potential markers of high-quality care (Figure 6). Of these structures, only regular review of postoperative morbidity and mortality was provided at more than a third of participating hospitals.

If these structures are associated with the delivery of high-quality care, their provision might be expected to be clustered at high performing hospitals. However, no significant associations were demonstrated between provisioning of these structures at participating hospitals (Table 29).

3.4.4 Characterisation of observed variation in provisions

Provisions of the assessed EGS structures were compared by hospital characteristics in order to support the interpretation of between-hospital variation in processes of care and patient outcomes after emergency laparotomy using the structure-process model in subsequent analyses (*Chapters 5, 7 and 8*).

Configuration to admit patients with emergency general surgical conditions

Characterisation of the 14 hospitals that did not admit emergency general surgical patients demonstrated that these hospitals were small (Table 30), subspecialty surgical or elective surgical centres. It is anticipated that the casemix may also differ from the main body of hospitals.

Statistically significant differences in the provision of some structures were observed (Table 30). Most notably, a fully-staffed operating theatre in which to perform emergency laparotomies was provided at less than half of hospitals not configured to admit EGS patients and, while the number of consultant surgeons participating in EGS rotas was not significantly different, no EGS consultant rota was in use at three of these hospitals.

Arrangements with other hospitals and local networks to meet clinical need were not explored in the first NELA organisational audit. However, the failure to comprehensively provide the resources that underpin essential processes of care at these hospitals at could result in delayed clinical decision-making and surgical intervention, potentially compromising quality of care delivery and patient outcomes.

Hospital size

Provisions were observed to vary relative to hospital size and to be substantially more comprehensive at the largest hospitals (Table 18, Table 19, Table 22, Table 24 and Table 26). Most notably, operating theatre and critical care bed provisions; and staff to provide comprehensive non-surgical interventional services and critical care consultant input.

The observed associations may indicate funding constraints or the inability to recruit and to retain staff at the smallest hospitals. However, it should be noted that while provisions were more comprehensive at the largest hospitals, the data indicated greater competition for these resources when assessed per 100 beds.

Tertiary gastrointestinal surgical referral centres

Tertiary GI surgical referral centres were demonstrated to be large hospitals (Table 16). The provision of some facilities and staff was demonstrated to be significantly more comprehensive at tertiary GI surgical referral centres than at other hospitals (Table 20, Table 21, Table 23, Table 25 and Table 27). However, in many respects, patterns of provisions at tertiary GI surgical referral centres were similar to those at the largest hospitals, perhaps simply reflecting hospital size.

Tertiary GI surgical referral centres might be expected to be better configured to provide a high-quality EGS service and to separate acute from elective caseload. It is therefore notable that no associations were demonstrated with provisions of the structures identified as potential markers of high-quality care (Figure 6).

3.5 Limitations

The findings of the analyses reported in this Chapter should be interpreted in the context of the following limitations of the dataset.

While levels of engagement were extremely high, one of the 191 identified hospitals submitted no data to the audit. It should therefore be noted that the analyses of characteristics, provisions and their associations may not be generalisable to this hospital.

The veracity of submitted data was not assessed externally prior to analysis and while participants were contacted to clarify some responses (hospital configuration to admit EGS patients and radiological and laboratory provisions), other data items were not followed up in this way.

While questions were constructed with care and the questionnaire piloted prior to dissemination, responses to some items (including on-call consultant anaesthetist provisions) indicated that interpretation of questions was inconsistent. The reliability of the analysed data items unknown.

Finally, validation of number of beds as a marker of hospital size using a contemporary NRLS dataset was hampered by differences between datasets and the absence of subcategories of Welsh local health boards.

3.6 Conclusions

Processes of care that may be associated with variations in patient outcomes are underpinned by individual organisational structures and their configuration as services. Failure to provide structures for an EGS service and to perform emergency laparotomy may therefore compromise the quality of care and ultimately patient safety.

The National Emergency Laparotomy Audit (NELA) collected data relating to organisational structures and hospital characteristics from 190 out of 191 hospitals identified to have provided emergency laparotomy services.

Recommended organisational structures for the safe care emergency general surgical (EGS) patients were not provided at every participating hospital. Provision of these structures was generally more comprehensive at large hospitals and tertiary gastrointestinal surgical referral centres and some key provisions were significantly less comprehensive at hospitals not configured to admit patients with emergency general surgical conditions.

Organisational structures identified as potential markers of high-quality EGS services were not demonstrated to be clustered at hospital-level. Analysis of process and outcome data is therefore required to identify high-performing hospitals.

These observations of variation in EGS structural provisions are notable; however the implications of failure to conform to contemporary standards of care are uncertain. Associations between hospital characteristics, structural provisions, delivery of perioperative processes of care and patient outcomes following emergency laparotomy are explored using a variety of statistical techniques in *Chapters 5, 7 and 8*.

Appendix 3.1: The first NELA organisational audit questionnaire

1.	Hospital characteristics	
1.1a	How many adult inpatient or overnight beds (including 23-hours stay) are currently available within the hospital? Do not include day-case beds	
1.1b	How many of these beds are found on adult general surgical inpatient wards? This means beds found on either specialist GI wards (e.g. upper-GI, lower-GI), or wards that accept any type of general surgical admissions. Do not include 23-hour beds in this answer, or specialist non-GI wards (e.g. ENT, urology, neurosurgery)	
1.2	Does your hospital accept acute general surgical admissions?	Yes/No If No go to Q1.3
1.2a	If Yes , when does your hospital accept acute general surgical admissions?	
	<ul style="list-style-type: none"> • 24-hours per day, seven days per week 	
	or	Please select all that apply
	<ul style="list-style-type: none"> • Monday–Friday 	_____ 08:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59
	<ul style="list-style-type: none"> • Saturday–Sunday 	_____ 08:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59
1.3	Do you have a dedicated emergency surgical unit that is separate from elective workload? i.e. a ward area where patients receive ongoing care, NOT a surgical admissions unit from which patients are relocated for continuing inpatient care.	Yes/No
1.4	Is your hospital a tertiary referral centre for any gastrointestinal surgical specialties?	Yes/No
1.5	Is cardiothoracic surgery undertaken at this hospital?	Yes/No
1.6	Does your hospital accept acute medical admissions?	Yes/No
1.7	Do you have elderly medicine services on site?	Yes/No
2	Hospital facilities	
2.1	How many operating theatres are at this hospital? <i>Please exclude interventional radiology suites and dedicated obstetric and minor ops theatres, but include day-case theatres</i>	

<p>2.2a</p>	<p>In a usual week, what is the total number of fully staffed operating theatres available for adult general surgical emergency cases?</p> <ul style="list-style-type: none"> • <i>‘Fully staffed’ refers to a full complement of nonmedical personnel; anaesthetic and scrub nurses, operating department practitioners (ODPs), healthcare assistants (HCAs) etc.</i> • <i>Please exclude trauma theatres, interventional radiology suites and dedicated obstetric and minor ops theatres.</i> 	
	<ul style="list-style-type: none"> • Monday–Friday 	<p>_____ 08:00–13:00 _____ 13:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59</p>
	<ul style="list-style-type: none"> • Saturday–Sunday 	<p>_____ 08:00–13:00 _____ 13:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59</p>
<p>2.2b</p>	<p>In a usual week, how many dedicated and planned consultant anaesthetic sessions (i.e. outside of on-call and other duties) support the theatres in question 2a? <i>Please note figures are per week, not per day. Please round answers to the nearest 0.5 sessions</i></p>	
	<ul style="list-style-type: none"> • Monday–Friday 	<p>_____ 08:00–13:00 _____ 13:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59</p>
	<ul style="list-style-type: none"> • Saturday–Sunday 	<p>_____ 08:00–13:00 _____ 13:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59</p>
<p>2.2c</p>	<p>Of the theatres in 2a, how many of these are reserved exclusively for emergency general surgical cases? <i>These theatres might be considered a ring-fenced ‘general surgery theatre’, similar to the provision of ‘trauma theatres’. We accept that these theatres will be used for other specialties if there are no general surgical cases</i></p>	
	<ul style="list-style-type: none"> • Monday–Friday 	<p>_____ 08:00–13:00 _____ 13:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59</p>

	<ul style="list-style-type: none"> • Saturday–Sunday 	_____ 08:00–13:00 _____ 13:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59
2.3	Can any member of the surgical team book emergency general surgical cases for emergency theatre(s)? <i>i.e. regardless of seniority</i>	Yes/No
2.4	Are emergency theatres staffed at all times by non-medical personnel (i.e. anaesthetic and scrub nurses, ODPs, HCAs) such that emergency cases can continue regardless of elective and emergency workload elsewhere (e.g. overrunning elective lists, recovery workload, obstetric emergencies, trauma and cardiac arrest calls)?	Yes/No
2.5	Please indicate whether the following individuals are required to be resident when covering the out-of-hours emergency general surgical workload:	
2.5a	<ul style="list-style-type: none"> • anaesthetic ODP/nurse 	Resident/Non-resident
2.5b	<ul style="list-style-type: none"> • scrub nurse/ODP/HCAs 	Resident/Non-resident
2.6	Is non-invasive cardiac output monitoring equipment available for use in the care of the patient undergoing emergency general surgery?	Yes/No If No go to Q2.7
2.6b	If yes , is it for exclusive use in emergency theatre(s)?	Yes/No
2.7	Have you audited adequacy of provision of emergency theatres within the last two years?	Yes/No
2.8	Does your hospital have plans in place to increase emergency theatre provision within the current or next financial year?	Yes/No
2.9	Are there currently plans to reconfigure emergency surgical services with neighbouring trusts within the next two years?	Yes/No/Not known
2.10	Is there 24-hour on-site access to the following?	
	<ul style="list-style-type: none"> • Biochemistry 	Onsite laboratory Consultant advice (resident or on-call)
	<ul style="list-style-type: none"> • Haematology 	Onsite laboratory Consultant advice (resident or on-call)
	<ul style="list-style-type: none"> • Microbiology 	Onsite laboratory Consultant advice (resident or on-call)
	<ul style="list-style-type: none"> • Blood bank/transfusion 	Onsite laboratory Consultant advice (resident or on-call)
3.	Peri-operative Care	

	At your trust are there formal written pathways/ protocols/policies applicable to the emergency general surgical patient, incorporating the following: <i>These may exist within pathways/protocols, or be incorporated into a single policy relevant to the unscheduled adult surgical patient.</i>	
3.1	• Monitoring plan compliant with NICE CG50 pathway ('Acutely ill patients in hospital')?	Yes/No
3.2	• Timing of surgery according to clinical urgency?	Yes/No
3.3	• A formal calculation of risk that provides an estimation of peri-operative mortality?	Yes/No
3.4	• Seniority of anaesthetist present in theatre according to calculated risk of death?	Yes/No
3.5	• Seniority of surgeon present in theatre according to calculated risk of death?	Yes/No
3.6	• Location of post-operative care according to calculated risk of death?	Yes/No
3.7	• Explicit arrangements with elderly medicine for review of selected patients?	Yes/No
3.8	• Formalised provision for the deferment of elective activity in order to give adequate priority to unscheduled admissions?	Yes/No
3.9	• Formalised provision for the transfer of care of emergency surgical patients between consultants, to ensure that they receive appropriate subspecialty care?	Yes/No
3.10	• A formal pathway for the involvement of diagnostic and interventional radiology in the care of emergency general surgical patients?	Yes/No
3.11	• A formal pathway for the management of patients with sepsis?	Yes/No
3.12	• A formal pathway for the enhanced recovery of the emergency surgical patient?	Yes/No
3.13	Do you have a single pathway/policy for the care of the unscheduled adult general surgical patient?	Yes/No
3.14a	Is there a regular (i.e. at least bi-monthly) review of all deaths following emergency general surgery?	Yes/No If No go to Q4
3.14b	If Yes , which of the following specialties provide input into this review:	
	• Surgery	Yes/No
	• Anaesthesia	Yes/No
	• Radiology	Yes/No
	• Critical care	Yes/No
	• Elderly medicine	Yes/No

4	Critical care and outreach	
4.1	Is there a dedicated critical care unit with 24-hour cover by a named consultant with regular sessions in critical care?	Yes/No
4.2	Please specify the number of funded Level 2 and Level 3 beds routinely available for adult (>18 years) general surgical patients? <i>If the numbers vary according to Level 2/3 occupancy, please indicate nominal figures:</i>	
4.2a	• Level 2	
4.2b	• Level 3	
4.3	What was the total number of level 2 admissions between 1st April 2012 and 31 March 2013? (<i>do not include patients who required admission, but who were not admitted due to bed-space issues</i>)	
4.3a	• All specialties	
4.3b	• General surgery (include upper and lower GI)	
4.4	What was the total number of Level 3 admissions between 1 April 2012 and 31 March 2013? (<i>do not include patients who required admission, but who were not admitted due to bed-space issues</i>)	
4.4a	• All specialties	
4.4b	• General surgery (include upper and lower GI)	
4.5	Is there a critical care outreach service responsible for the review patients 'at risk' and those with deranged physiological parameters? (<i>other names might include rapid response team etc</i>)	Yes/No If No go to Q5
4.5a	If Yes, please indicate when it is available:	
	• 24-hours per day, 7 days per week	
	or	Please select all that apply
	• Monday–Friday	08:00–17:59 18:00–23:59 00:00–07:59
	• Saturday–Sunday	08:00–17:59 18:00–23:59 00:00–07:59
5	Surgical on-call commitments	
5.1	How many consultant surgeons participate in the general surgical emergency rota?	

5.2	What are the subspecialties of the consultants on the general surgical emergency rota?	
5.2a	• Colorectal	Yes/No
5.2b	• Upper GI	Yes/No
5.2c	• General	Yes/No
5.2d	• Vascular	Yes/No
5.2e	• Breast	Yes/No
5.2f	• Endocrine	Yes/No
5.3	How many surgical tiers cover the emergency general surgical workload for each time frame?	
	• Monday–Friday	_____ 08:00–13:00 _____ 13:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59
	• Saturday–Sunday	_____ 08:00–13:00 _____ 13:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59
5.4	For each tier, please indicate whether at least one individual is free from all elective and non-acute commitments (e.g. elective lists, outpatient clinics) for the whole period while they are covering emergency general surgical workload: <i>(please refer to definitions if clarification is required)</i>	
5.4a	• Consultant (CCT holder)	Yes/No/Not on rota
5.4b	• Middle grade (with MRCS)	Yes/No/Not on rota
5.4c	• Core trainee/SAS doctor (without MRCS)	Yes/No/Not on rota
5.4d	• Foundation doctor	Yes/No/Not on rota
5.4e	• Nurse practitioner	Yes/No/Not on rota
5.5	Please indicate whether any of these tiers cover more than one hospital site when providing cover for emergency general surgical cases?	
5.5a	• Consultant (CCT holder)	Yes/No/Not on rota
5.5b	• Middle grade (with MRCS)	Yes/No/Not on rota
5.5c	Core trainee/SAS doctor (without MRCS)	Yes/No/Not on rota
5.5d	Foundation doctor	Yes/No/Not on rota
5.5e	Nurse practitioner	Yes/No/Not on rota

5.6a	Are emergency patients that still require assessment and treatment at the end of the consultant's period of oncall retained by the admitting consultant?	Yes/No If Yes go to Q5.6c
5.6b	If No , do you have a policy requiring consultant surgeons to formally hand over to one another in person?	Yes/No
5.6c	Is there a formal handover time built into the shifts for others?	Yes/No
6	Anaesthetist on-call commitments	
6.1	How many anaesthetic tiers cover the emergency general surgical workload for each time frame? <i>This includes consultants, fellows, middle and SAS grades, core trainees and foundation doctors. Include all those whether resident or non-resident. If the number drops, e.g. at 9pm, enter the lesser value. Enter the daily figures, not the weekly totals. See 'help' for more information</i>	
	• Monday–Friday	_____ 08:00–13:00 _____ 13:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59
	• Saturday–Sunday	_____ 08:00–13:00 _____ 13:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59
6.2	While covering the emergency general surgical workload, please indicate whether at least one individual from each of the following tiers is free at all times from covering other areas of the hospital (such as critical care, obstetrics and trauma calls) so they can immediately return to theatre	
6.2a	• Consultant (CCT holder)	Yes/No Not on rota
6.2b	• Middle grade (with FRCA)	Yes/No Not on rota
6.2c	• Core trainee/SAS grade (without FRCA)	Yes/No Not on rota
6.2d	• Foundation doctor	Yes/No Not on rota
6.2e	• Physician's assistant (anaesthesia)	Yes/No Not on rota
6.3a	Do you have a policy requiring consultants to formally hand over to one and other in person?	Yes/No
6.3b	Is there a formal handover time built into the shifts for others?	Yes/No
7	Multidisciplinary input	

7.1	What type of input does elderly medicine provide in the pre-operative period for patients admitted as emergency general surgical patients?	None Proactive (case finding by elderly medicine) On-request only
7.2	What type of input does elderly medicine provide in the post-operative period for emergency general surgical patients?	None Proactive (case finding by elderly medicine) Routine provision On request only
7.3	In the elderly patient undergoing emergency general surgery, are there formal pathways/protocols for the routine assessment of:	
7.3a	• Frailty	Yes (score used) Yes (not scored) No
7.3b	• Nutritional status	Yes (score used) Yes (not scored) No
7.3c	• Cognitive function	Yes (score used) Yes (not scored) No
7.3d	• Functional status	Yes (score used) Yes (not scored) No
7.4	What type of input is available from general internal medicine for emergency general surgical patients who suffer acute medical complications in the peri-operative period?	None Proactive (case finding) On request only
8	Radiology, imaging and endoscopy	
8.1	Is there 24-hour on-site access to diagnostic X-ray ?	Yes/No
8.2	Is there 24-hour on-site access to diagnostic ultrasound ?	Yes/No
8.3	With regard to access to on-site diagnostic CT , please indicate how this is provided:	Available and reported contemporaneously by radiologist with GI subspecialisation Available and reported contemporaneously by general radiologist Available, but unreported by radiology at time of scanning Not available
	• Monday–Friday	_____ 08:00–17:59 _____ 18:00–23:59 _____ 00:00–07:59

	<ul style="list-style-type: none"> • Saturday–Sunday 	<input type="checkbox"/> 08:00–17:59 <input type="checkbox"/> 18:00–23:59 <input type="checkbox"/> 00:00–07:59
8.4	<p>Is there a formal rota of radiologists who provide onsite interventional radiology:</p> <ul style="list-style-type: none"> • 24-hours per day, 7 days per week 	
	or	Please select all that apply
	<ul style="list-style-type: none"> • Monday–Friday 	<input type="checkbox"/> 08:00–17:59 <input type="checkbox"/> 18:00–23:59 <input type="checkbox"/> 00:00–07:59
	<ul style="list-style-type: none"> • Saturday–Sunday 	<input type="checkbox"/> 08:00–17:59 <input type="checkbox"/> 18:00–23:59 <input type="checkbox"/> 00:00–07:59
8.5	<p>Is there a formal rota of clinicians for the provision of on-site diagnostic endoscopy:</p> <ul style="list-style-type: none"> • 24-hours per day, 7 days per week 	
	or	Please select all that apply
	<ul style="list-style-type: none"> • Monday–Friday 	<input type="checkbox"/> 08:00–17:59 <input type="checkbox"/> 18:00–23:59 <input type="checkbox"/> 00:00–07:59
	<ul style="list-style-type: none"> • Saturday–Sunday 	<input type="checkbox"/> 08:00–17:59 <input type="checkbox"/> 18:00–23:59 <input type="checkbox"/> 00:00–07:59
8.6	<p>Is there a formal rota of clinicians for the provision of on-site interventional endoscopy?</p> <ul style="list-style-type: none"> • 24-hours per day, 7 days per week 	
	or	Please select all that apply
	<ul style="list-style-type: none"> • Monday–Friday 	<input type="checkbox"/> 08:00–17:59 <input type="checkbox"/> 18:00–23:59 <input type="checkbox"/> 00:00–07:59
	<ul style="list-style-type: none"> • Saturday–Sunday 	<input type="checkbox"/> 08:00–17:59 <input type="checkbox"/> 18:00–23:59 <input type="checkbox"/> 00:00–07:59
8.7	<p>Are clinicians performing endoscopy supported by dedicated endoscopy staff as opposed to other nursing staff (e.g. from theatre)?</p> <ul style="list-style-type: none"> • 24-hours per day, 7 days per week 	

	or	Please select all that apply
	• Monday–Friday	<input type="checkbox"/> 08:00–17:59 <input type="checkbox"/> 18:00–23:59 <input type="checkbox"/> 00:00–07:59
	• Saturday–Sunday	<input type="checkbox"/> 08:00–17:59 <input type="checkbox"/> 18:00–23:59 <input type="checkbox"/> 00:00–07:59

Appendix 3.2: Number of reported beds by NRLS Cluster categories

NHS England NRLS cluster category	English hospitals in a multi-site Trust (% of hospitals within category)	Percentage of all hospitals (n=176)
Small acute Trust	0	0
Medium acute Trust	2 (4%)	1%
Large acute Trust	32 (58%)	18%
Acute teaching Trust	9 (26%)	5%
Total	43	24%

Table 31 Distribution of NRLS cluster categories within English multi-site Trusts

	Single-site English Trusts (n=120)	Hospitals within Multi-site English Trusts (n=43)	Welsh hospitals (n=13)
Range	79-1179	64-1100	152-804
Median (IQR)	501 (400-707)	392 (338-467)	394 (300-509)**

Table 32 Distribution of reported bed numbers by Trust type
(* p<0.05, **p≤0.005, ***p≤0.001)

4. SYSTEMATIC REVIEW OF RISK ASSESSMENT TOOLS VALIDATED IN COHORTS OF ADULT PATIENTS UNDERGOING AN EMERGENCY LAPAROTOMY

4.1 Introduction

4.1.1 Background

The likelihood of morbidity and mortality after emergency laparotomy is associated with clinical, descriptive and demographic variables, (risk factors).^{2, 6, 9, 10, 23, 26, 28-33} As a consequence of the broad spectrum of acute presentations and existing comorbidities encountered in clinical practice, populations of patients undergoing emergency laparotomies are particularly heterogeneous. Therefore risks of death, morbidity and complications may be unequally distributed within patient cohorts and there is evidence that high-risk subpopulations, in which the incidence of adverse events is substantially increased, exist within larger populations.^{6, 33, 97}

Several international initiatives are underway with the shared objective of reducing the considerable morbidity and mortality associated with emergency laparotomy. These efforts focus on delivering high quality care to all patients, informed by exploration of inter-institutional variations in postoperative outcomes, and targeting higher risk patients for perioperative interventions and augmented pathways of care.^{77-79, 98}

Patient outcomes after emergency laparotomy may be determined predominantly by patient-level risk and by processes of care delivered throughout the acute episode.^{40, 44} Assessment of patient-level risk is central to the success of these initiatives, since risk adjustment may be used to understand causes of hospital-level variation in patient outcomes; and real time risk assessment to identify high-risk individuals who may benefit from augmented care.

However, no method of assessing individual risk has been widely incorporated into routine practice, or demonstrated to be practical and reliable across the spectrum of presentations, comorbidities and operative procedures in cohorts of patients undergoing an emergency laparotomy.

Assessment of individual risk may be informed by clinical judgement, use of risk assessment tools, evaluation of functional capacity or plasma biomarker assay.⁹⁹ However, clinical judgement has been shown to vary with experience, patients requiring emergency laparotomy are often too unwell and time too limited for observations of exercise tolerance and evidence to support the routine use of biomarkers is yet to be established.¹⁰⁰⁻¹⁰²

Risk assessment tools, which incorporate clinical variables into a score or prognostic model, currently represent the most practical means of estimating risk in patients undergoing unplanned surgery and there is good evidence to support their routine use in other clinical contexts.¹⁰³

Patients undergoing emergency laparotomy are distinct from those who have planned general surgery, due to acute and chronic pathologies, physiological consequences of the acute disease and time for preoperative workup.⁷ Therefore, while evidence to support their use exists in other clinical contexts, generalisability of performance to patients undergoing emergency laparotomy cannot be assumed.⁵⁷⁻⁵⁹

4.1.2 Notes on the evaluation of risk assessment tools

In consideration of the suitability of risk assessment tools for clinical practice, a number of features and characteristics are essential, whereas others may be desirable.¹⁰⁴

Clinical application

As with other methods of risk evaluation, risk assessment tools may be used for a variety of purposes (communication of risk, individualised care and outcomes adjustment) and may be used in many, disparate clinical contexts. Most tools are designed with a patient population in mind (whether specific or general) and because component variables differ, performance varies with clinical context. Selection of the most appropriate tool by *application* for which it will be used is therefore of primary importance.

The selection of a tool for any given clinical application is determined principally by its demonstrated *performance* in similar or related contexts and its credibility within that context: A tool designed for the purpose of predicting risk of 30 day mortality following emergency repair of perforated peptic ulcer is unlikely to be used in the prediction of postoperative morbidity following emergency AAA repair due to expected poor performance resulting from component variables (independent outcome predictors) and perhaps the method of tool application. This is discussed in greater detail subsequently.

In considering the purposes for which a tool may be used, predictive models are more flexible than risk scores and may therefore be used in a greater variety of contexts. For the purposes of outcomes adjustment and research, tool output presented as percentage predicted risk permits more detailed analysis than simple risk scores, but for the communication of risk and in every day patient management it may be overly complex. For simplicity, the output of both scores and predictive models may therefore be categorised, permitting the stratification of patients as low, medium or high risk for example. The delineation of cut-off values should be informed by the results of validation studies assessing tool performance rather than arbitrarily (for example by Youden Index analysis of Receiver Operator Characteristic curves).

Performance

The performance of a risk assessment tool is measured across the following domains:

Discrimination

In order to be useful, a tool must firstly demonstrate the capacity to correctly identify whether individuals will or will not suffer the adverse event of interest. This quality is usually the primary objective of validation studies of risk assessment tools and is variably termed 'discrimination' or 'accuracy'.

The Receiver operator characteristic (ROC) curve is a plot of the relative true- and false-positive proportions obtained through analysis of patient outcomes against risk tool output and is characteristic of the tool being evaluated. Discrimination is most conveniently presented as area under the receiver operator characteristic curve (AUROC or AUC). The AUC is a single, quantitative summary of discrimination, which permits the comparison of dissimilar systems through use of a common scale and unlike alternative methods is independent of the incidence of the outcome(s) of interest.¹⁰⁵

In interpreting AUC values the following ranges are used;¹⁰⁵ AUC >0.9 represents *good* discrimination of outcome; 0.7-0.9 *moderate*; and 0.5-0.7 *poor* discrimination. An AUC of 0.5 is said to equate to a 'coin-toss'. AUC should be reported with 95% confidence intervals.

Generalisability

In order for a tool to be used in clinical practice its output should be reliably similar between cohorts. Perhaps the most important component of demonstration of tool validity is therefore consistently good discrimination in multiple cohorts and in order to prove consistency, its performance should also be analysed of subgroups of interest.

Systematic review and meta-analysis therefore represent effective means of evaluating and comparing the performances of existing risk assessment tools in order to identify the most suitable tool for everyday use from the overwhelming array available.

Calibration

For those tools capable of likelihood estimation, it is desirable that the predicted probability of an individual suffering an adverse event should approximate the incidence subsequently measured. This quality is calibration. Tool calibration is evaluated using statistical methods to determine how closely a model's prognostic estimations of a specified outcome match the observed incidence across the entire study population. It may be performed using Hosmer-Lemeshow (H-L)¹⁰⁶⁻¹⁰⁸ or Pearson chi-squared techniques.

In common with other χ^2 techniques, a non-significant p value (≥ 0.05) indicates no significant difference between observed and expected event counts and thus no lack-of-fit to the patient

cohort. If event counts are significantly different ($p < 0.05$), the H-L statistic reports the magnitude of discordance.

It should however be noted that, in common with other χ^2 tests, even if the expected incidence differs little from the observed incidence of the outcome of interest, small differences are magnified and can become statistically significant ($p < 0.05$).^{10, 109}

It is convenient to attempt to quantify individual risk, because thresholds may be used to direct clinical decisions, including consent for surgery, appropriate seniority of clinicians in theatre and the location of postoperative care. Use of thresholds to withhold or withdraw treatment is controversial. The advantages for informed consent and shared decision making are less clearly defined.

Applicability and utility

A tool which has proven accuracy, calibration and generalisability is unlikely to enter routine clinical practice if it is unwieldy and alters neither patient management (nor outcome)^{104, 105}. Desirable characteristics in addition to discrimination and calibration are therefore *utility* and *clinical effectiveness*.

Factors determining tool utility in clinical practice include the number of variables required and the burden that their collection imposes. The value of tools which require tests outside normal practice may therefore need to be balanced against resource utilisation implications and the ethical considerations of subjecting patients to additional investigations.

In addition to variable collection, consideration must also be given to ease of tool use; the calculation of risk scores usually involves simple arithmetic, whereas risk prediction models require use of logarithmic equations. Increasingly this is not a reason to preclude the bedside use of more complex models due to the increasing availability of handheld applications and access to internet resources.

In order to be effective clinically, a tool must have the *potential* to alter the course of a patient episode (proving this may be more challenging). The advantages of risk assessment as early as possible in the admission episode are self-evident. Considering the purposes of risk assessment, quantification of individual risk may be used to permit fuller discussions of available treatment alternatives and informed decision making and to direct tailored care throughout the preoperative, perioperative and postoperative periods.

Aims

1. To identify the most appropriate tool for the baseline risk-adjustment of emergency laparotomy patients; to be subsequently incorporated into the National Emergency Laparotomy Audit (NELA) Patient Audit webtool

Objectives

Through qualitative systematic review of the contemporary literature:

1. To identify validation studies of risk assessment tools undertaken in the perioperative period in cohorts of adult patients undergoing an emergency laparotomy
2. To assess and compare the performance of the tools identified in these validation studies
3. To identify strengths and weaknesses of relevance to clinical practice for the identified tools

4.2 Materials and methods

This systematic review was registered with the PROSPERO database (CRD42014009062). Methods and reporting conform to PRISMA, BMC and Cochrane guidelines.¹¹⁰⁻¹¹²

4.2.1 Definitions for the purposes of this review

Emergency: Urgent, emergent and immediately indicated surgical interventions.

Laparotomy: Open intra-abdominal surgery performed for non-aortic pathologies.

Risk assessment tool: A scoring system or prognostic model incorporating two or more variables to stratify or predict the likelihood of a specified adverse event.

Validation study: Assessment of the accuracy of one or more risk assessment tools through application to a study population. Classified as; *internal* (application of a newly created tool to the cohort from which it was derived by practical or mathematical techniques); *temporal* (application of a tool to a cohort distinct in time from the derivation cohort at the institution(s) in which it was created); or *external* (application to patients in institutions other than that from which the tool was derived).^{104, 113}

Discrimination: How well a tool is able to discriminate between dichotomous outcomes (e.g. death and survival at 30 days) across a spectrum of risk profiles within a population of patients. Presentation as area under the receiver operator characteristic curve (AUC) provides a single, quantitative measure of the accuracy of a prognostic tool and also facilitates the comparison of dissimilar systems.¹⁰⁵ In interpreting AUC values: >0.9 good discrimination; 0.7-0.9 moderate; and <0.7 poor.¹⁰⁵

Calibration: How closely a prognostic model's estimations match the observed incidence of a specified outcome across a study population. Assessed using χ^2 techniques, $p > 0.05$ indicates that observed and expected outcomes are similar and $p < 0.05$ differences are statistically significant.

4.2.2 Search methods and inclusion criteria

The literature search was undertaken with reference to methods of bias mitigation.¹¹⁴ Embase® (Embase is a registered trademark of Elsevier B.V.) and Medline® (Medline is the U.S. National Library of Medicine) were searched using database specific search terms (a complete list of search terms is included in Appendix 4.1).

Because the term emergency laparotomy is used internationally in association with a wide and varied assortment of both surgical procedures and pathologies, an inclusive search strategy was adopted to achieve the aims of this systematic review.

The search was restricted to publications relating to adult humans since 1980, but was not limited to English language publications. The last complete search was performed on 27th March 2013. The Cochrane database of systematic reviews was accessed on 2nd November 2014. Secondary searching included hand-searching of references (snow-balling) and review of citation listings in Web of Knowledge ® ('Web of Knowledge' is a trademark of Thomson Reuters).

Inclusion criteria: Studies assessing the discrimination of a specified outcome, presented as AUC, by one or more risk assessment tools in adult patients undergoing emergency laparotomy. Studies including both emergent and elective cases were included if discrimination was reported for patients who had undergone emergency surgery.

Exclusion criteria: In order to identify useful perioperative decision making tools, studies were excluded if no assessment of risk was made using preoperative or intraoperative data items. Validation studies confined to cohorts undergoing emergency aortic surgery and those including extra-abdominal procedures were excluded due to overt differences in patient characteristics, operative procedures and patient outcomes.

4.2.3 Data extraction

Data extraction was performed by the authors CO and EW and recorded directly into purpose-built tables, summarising study characteristics, design quality, patient outcomes and tool performance. Differences in extracted data were discussed and consensus reached.

Extracted study characteristics included; geographical region; patient cohort size and characteristics; nature of included surgical procedures; timing of data collection (relative to emergency laparotomy); and risk assessment tools studied. Tool applicability was classified as either general (heterogeneous and multiple subpopulation cohorts) or subpopulation-specific (applicable only to cohorts defined by patient or surgical characteristics).

Extracted indicators of quality included: number of patients in study cohort; number of institutions collecting data (single vs. multicentre); timing of data collection (prospective vs. retrospective); reporting of cohort baseline characteristics; reporting of inclusion criteria and excluded patients; and validation methodology.^{104, 115}

Extracted outcomes were as reported in the manuscript and included the incidence of mortality and morbidity at specified time points for identified pathologies and operative indications.

Extracted tool performance characteristics included AUC for a specified outcome and prognostic tool calibration and AUC 95% confidence interval where reported.

4.2.4 Data analysis

Decisions to pool data for meta-analysis of the performance of individual tools were informed by assessment of the homogeneity of extracted study characteristics, where overt heterogeneity of patient outcomes would preclude statistical assessment of homogeneity.

Tool generalisability was determined by assessment of discrimination across dissimilar populations, including heterogeneous patient cohorts and subpopulations defined by patient or surgical characteristics.

4.3 Results

Key findings

- In total, 20 validation studies were identified, assessing 25 risk assessment tools in international emergency laparotomy cohorts
- No similar systematic review was identified in the Cochrane database of systematic reviews
- Overt methodological, population and endpoint heterogeneity was observed, precluding meta-analysis
- Postoperative mortality varied considerably and was greatest in cohorts of older patients
- Overall, 13 general tools, 12 subpopulation-specific tools and two emergency laparotomy tools were assessed in the identified studies
- The emergency laparotomy tools were not assessed in external populations
- Only seven general tools were assessed in multiple external cohorts; of which, APACHE II, ASA-PS and P-POSSUM were the most frequently assessed
- APACHE II demonstrated moderately good discrimination (AUC 0.76-0.98) across heterogeneous emergency laparotomy cohorts, utilising preoperative and perioperative data items
- The ASA-PS demonstrated moderate discrimination in a heterogeneous population (AUC 0.81) moderately good performance in patients with perforated peptic ulcers (AUC 0.73-0.91), respectively, but poor performance in older patients (AUC 0.66)
- P-POSSUM demonstrated moderate or poor discrimination in heterogeneous cohorts (AUC 0.65-0.82) and in patients with colorectal cancer (AUC 0.65-0.75)
- Reporting of calibration was inconsistent

4.3.1 Overview

In total 23,073 papers were identified in the primary electronic databases search, leaving 15,030 after restrictions. A further 802 papers were identified in the secondary search. After exclusions 20 studies were eligible for data analysis and synthesis (Appendix 4.2). In these studies, the performance of 25 tools was assessed in more than 110,000 patients undergoing unplanned intra-abdominal surgery across 12 countries (Table 34). No similar systematic review was identified in the Cochrane database of systematic reviews.

Study design and populations are summarised in Table 34. External validity was assessed in 13 studies and temporal validity in 2 studies. Internal validation techniques included split cohorts, crossover and bootstrapping.

Markers of methodological quality are presented in Table 34. Seven studies were conducted across multiple institutions; validation cohort size varied from 49 to more than 68,000 patients;^{116, 117} data collection was performed entirely prospectively in 15 studies; and demographic data were presented in 19 papers. Reporting of inclusion criteria, exclusions and surgical procedures was universally adequate. Reporting of calibration and AUC 95% confidence intervals was inconsistent. Statistical comparison of tool discrimination was reported in only one study.¹¹⁸

Short-term (30 day or inpatient) mortality endpoints were reported in all studies; 30 day mortality was reported in 11 studies and inpatient mortality in 9 studies. 30 day mortality ranged from 9-27% and inpatient mortality 3-26%, varying by operative procedure, surgical indication and patient age (Table 33). Other identified endpoints included postoperative morbidity and complications,^{119, 120} which were reported only in patients undergoing surgery for perforated peptic ulcer (Table 34).

Overt heterogeneity of study design, patient characteristics and presented outcomes (Table 34) precluded meta-analysis, necessitating a qualitative approach to tool comparison.

SURGICAL INDICATION OR PROCEDURE		POSTOPERATIVE MORTALITY (%)	
		30 day	Inpatient
	<i>Subgroup</i>		
Emergency laparotomy		8-20	9-21
Peritonitis		21	16-26
Colorectal cancer		11-20	3
	<i>>80 years</i>	26	
Perforated peptic ulcer		9-27	

Table 33 Mortality rates after emergency laparotomy

<i>First Author</i>	<i>Year</i>	<i>Region</i>	<i>Cohort size</i>	<i>Single /multi-centre</i>	<i>Data acquisition</i>	<i>Baseline data reported</i>	<i>Inclusion criteria</i>	<i>Exclusions</i>	<i>Models assessed</i>	<i>Outcome</i>	<i>Validation methodology</i>
<i>Al-Temimi</i>	2012	USA	37,553	Multi	Prospective	Yes	>16 years, EL for general surgical indications or mesenteric insufficiency	Missing data, urgent or vascular surgery, laparoscopic procedure converted to open	1) EL Perioperative Model, 2) EL Preoperative Model	30 day mortality	Internal: crossover by year
<i>Biondo</i>	2000	Spain	55	Single	Prospective	Yes	Consecutive patients, emergency surgery for distal colonic peritonitis	'complicated nonspecific inflammatory disease of the colon'	1) Colonic peritonitis severity score	Inpatient mortality	Internal: split
<i>Biondo</i>	2006	Spain	156	Single	Prospective	Yes	Clinical diagnosis of peritonitis, emergency surgery	None declared	1) Colonic Peritonitis Severity Score, 2) Mannheim Peritonitis Index	Inpatient mortality	Temporal
<i>Buck</i>	2012	Denmark	117	Multi	Prospective	Yes	Surgical treatment for perforated peptic ulcer	Pregnant or breastfeeding, malignant ulcers, perforation of another organ	1) Boey score, 2) ASA-PS, 3) APACHE II, 4) sepsis score	30 day mortality, septic shock	External
<i>Ertan</i>	2008	Turkey	102	Single	Retrospective	Yes	Emergency colorectal surgery for complications of colorectal carcinoma	Uncertain Diagnosis, Insufficient data	1) APACHE III, 2) MPM II, 3) CR-POSSUM	30 day mortality	External
<i>Ferjani</i>	2007	UK	158	Single	Prospective	Yes	Consecutive patients, histologically confirmed colorectal cancer, abdominal surgery to remove primary tumour	Laparoscopic surgery	1) ACPGBI, 2) POSSUM, 3) P-POSSUM, 4) CR-POSSUM	30 day mortality	External
<i>Garcea</i>	2010	UK	280	Single	Retrospective	Yes	EL for suspected perforation of a viscus / obstruction / fulminant colitis / upper gastrointestinal bleeding / surgery for strangulated ventral or groin herniae	None declared	1) Early Warning Score, 2) ASA-PS, 3) POSSUM, 4) APACHE II	ICU and total LOS, Inpatient mortality,	External
<i>Goffi</i>	1999	Italy	49	Single	Prospective	Yes	Major emergency operations, including trauma	None declared	1) APACHE II	30 day mortality	External

<i>Kermani</i>	2013	USA	68,344	Multi	Retrospective	Yes	ICD9 coding: >18 years, admitted non-electively, colectomy	Missing data	1) Practical mortality risk score for emergent colectomy	Inpatient mortality	Internal: Crossover (10-fold k-partitions)
<i>Koc</i>	2007	Turkey	75	Single	Prospective	Yes	Emergency surgery for perforated peptic ulcer	Surgery for perforated ulcer at the site of a previous anastomosis, Malignancy	1) APACHE II, 2) APACHE III, 3) SAPS II, 3) MPM II	30 day mortality	External
<i>Kologlu</i>	2001	Turkey	473	Single	Retrospective	No	Operation for intra-abdominal infection without continuous post-operative peritoneal lavage	Missing data, Percutaneous drainage of intra-abdominal abscess, uncomplicated appendicitis, uncomplicated cholecystitis, planned re-laparotomy	1) Mannheim Peritonitis Index, 2) Peritonitis Index of Altona, 3) Combined peritonitis score	Inpatient mortality	External
<i>Kulkarni</i>	2007	India	50	Single	Prospective	Yes	Peritonitis due to perforation of hollow viscus	Blunt abdominal trauma with associated solid organ / vascular / neurological injury or fracture	1) APACHE II	Inpatient mortality	External
<i>Kwok</i>	2011	USA	372	Multi	Prospective	Yes	>80 years, CPT code: emergency colectomy	Laparotomy resulting in 'diversion only' i.e. without colonic resection, Missing data,	1) Targeted risk prediction score, 2) ASA-PS, 3) Surgical Risk Scale, 4) ACS Colorectal surgery risk calculator	30 day mortality	Temporal
<i>Lohsiriwat</i>	2008	Thailand	152	Single	Prospective	Yes	Emergency surgery for perforated peptic ulcer	Perforated gastric cancer	1) Boey score, 2) ASA-PS, 3) Mannheim Peritonitis Index	30 day mortality, complications	External
<i>Merad</i>	2012	France	575	Multi	Prospective	Yes	> 16 years, major digestive surgery	>1 missing P-POSSUM value	1) P-POSSUM	Inpatient mortality	External
<i>Moller</i>	2012	Denmark	2668	Multi	Prospective	Yes	Surgical treatment of benign gastric or duodenal perforated peptic ulcer	Malignant Peptic Ulcer	1) Peptic ulcer prediction score, 2) ASA-PS, 3) Boey score	30 day mortality	Internal: bootstrapping for PULP

<i>Notash</i>	2005	Iran	80	Single	Prospective	Yes	Consecutive patients, EL for secondary peritonitis	Primary peritonitis (no identified cause)	1) Mannheim Peritonitis Index	Inpatient mortality	External
<i>Ohmann</i>	1993	Europe	271	Multi	Prospective	Yes	Diffuse or localised intra-abdominal infection, confirmed at laparotomy	None declared	1) APACHE II, 2) Mannheim Peritonitis Index, 3) Peritonitis index of Altona	30 day mortality	External
<i>Poon</i>	2005	Hong Kong	160	Single	Prospective	Yes	Consecutive patients, urgent surgery for malignant colorectal obstruction	None declared	1) P-POSSUM	30 day mortality	External
<i>Ren</i>	2009	China	90	Single	Retrospective	Yes	Colorectal cancer	None declared	1) P-POSSUM, 2) modified P-POSSUM, 3) modified CR-POSSUM	Inpatient mortality	Internal: Split cohorts

Table 34 Study characteristics and quality
(EL: emergency laparotomy)

4.3.2 Risk assessment tools

Thirteen general tools and 12 subpopulation-specific tools were assessed in the identified studies (Table 35 and Table 36). In addition to the Physiological and Operative Severity Score for the enumeration of Mortality and morbidity (POSSUM), several previously derived POSSUM systems and novel coefficients were assessed.^{121, 122}

Many tools were not created for the purpose of preoperative or intraoperative evaluation of individual risk, including; tools for critical care (Acute Physiology and Chronic Health Evaluation II (APACHE II),¹²³ APACHE III, the Simplified Acute Physiology Score II (SAPS II) and the Mortality Probability Model II (MPM II);^{124,124} the Early Warning Score and the 'sepsis score';¹²⁵ and POSSUM systems, which were created for comparative audit.¹²²

Only two tools specific to cohorts undergoing emergency laparotomy were identified; the preoperative and perioperative NSQIP Emergency Laparotomy models.¹⁰ These were assessed in a single, large internal validation study.

Tool characteristics are summarised in Appendix 4.3. There was notable variation in the required number of data items (ranging from the one composite measure of the ASA physical status classification (ASA-PS)¹²⁶ to the 41 variables comprising the NSQIP perioperative Emergency Laparotomy model),¹⁰ the preoperative availability of data items, complexity of calculation and the requirement for subjective interpretation of clinical data items.

General tools

Of the 13 identified general tools (Table 35), the most frequently assessed were APACHE II (7 studies), ASA-PS (5 studies) and P-POSSUM (4 studies). Each tool was assessed in both heterogeneous patient cohorts and subpopulations defined by demographic characteristics, surgical indication or operative procedure.

The ability of APACHE II to discriminate between short-term death and survival was moderate to good (AUC 0.76-0.98) when applied to heterogeneous cohorts undergoing unplanned intra-abdominal surgery for a variety of indications including peritonitis, colorectal malignancy and perforated peptic ulcer.^{117, 119, 127-131} Notably APACHE II was scored using exclusively preoperative data in four studies: at hospital admission in three studies and on booking for theatre in one study.^{117, 119, 128, 129}

Discrimination between short-term outcomes by the ASA-PS was moderate or good in patient cohorts undergoing emergency laparotomy or repair of perforated peptic ulcer (AUC 0.81 and AUC 0.73-0.91 respectively), but poor in an elderly cohort (AUC 0.66).^{29, 119, 120, 130, 132}

Reported AUC values for the discrimination of short-term outcomes by P-POSSUM in cohorts undergoing unplanned intra-abdominal surgery ranged from of 0.65-0.82. Discrimination was moderate or poor in patients with colorectal cancer (AUC 0.65, 0.66, 0.75).^{121, 133, 134}

Discrimination of 30 day survival by NSQIP emergency laparotomy models was moderately good (AUC 0.87-0.88) in a single internal validation study.¹⁰

Reporting of the calibration of prognostic tools was inconsistent and, where reported, performance was variable (Table 35).

Tool	Total patients	Region	First Author (Year)	Cohort size	Surgery subtype	Inclusion criteria	Primary endpoint	Incidence of primary endpoint	AUC (95%CI)	Calibration p value	H-L value (unless stated)
APACHE II											
	944	Turkey	Ertan (2008)	102	General Surgery	Colorectal cancer	30 day mortality	17%	0.78	0.49	4.448
		Italy	Goffi* (1999)	49	General Surgery	Mixed	30 day mortality	20%	0.87	0.63	χ ² quintiles
		Europe	Ohmann (1993)	271	General Surgery	Peritonitis	30 day mortality	21%	0.87	>0.05	
		Turkey	Koc* (2007)	75	PPU Repair	PPU	30 day mortality	11%	0.87	0.007	17.58
		Denmark	Buck* (2012)	117	PPU Repair	PPU	30 day mortality	17%	0.76		
		UK	Garcea* (2010)	280	General Surgery	Mixed	inpatient mortality	15%	0.76		
		India	Kulkarni* (2007)	50	General Surgery	Perforative peritonitis	Inpatient mortality	16%	0.98		
APACHE III											
	177	Turkey	Ertan (2008)	102	General Surgery	Colorectal cancer	30 day mortality	17%	0.77	0.9	2.208
		Turkey	Koc* (2007)	75	PPU Repair	PPU	30 day mortality	11%	0.84	0.01	15.08
ASA-PS											
	3589	USA	Kwok* (2011)	372	General Surgery	>80 years: colectomy	30 day mortality	26%	0.66	0.14	Residual GOF
		Denmark	Buck* (2012)	117	PPU Repair	PPU	30 day mortality	17%	0.73		
		Denmark	Moller* (2012)	2668	PPU Repair	PPU	30 day mortality	27%	0.78 (0.76-0.80)		

		UK	Garcea* (2010)	280	General Surgery	Mixed	Inpatient mortality	15%	0.81		
		Thailand	Lohsiriwat* (2008)	152	PPU Repair	PPU	30 day mortality	9%	0.91 (0.85-0.95)		
Early Warning Score											
	280	UK	Garcea* (2010)	280	General Surgery	Mixed	Inpatient mortality	15%	0.71		
Emergency Laparotomy perioperative model											
	37,553	USA	Al-Temimi (2012)	37,553	General Surgery	Mixed	30 day mortality	14%	0.88	<0.001	
Emergency Laparotomy preoperative model											
	37,553	USA	Al-Temimi* (2012)	37,553	General Surgery	Mixed	30 day mortality	14%	0.87	<0.001	
Mortality Probability Model (MPM) II											
	177	Turkey	Ertan (2008)	102	General Surgery	Colorectal cancer	30 day mortality	17%	0.71	0.46	7.736
		Turkey	Koc (2007)	75	PPU Repair	PPU	30 day mortality	11%	0.98	0.99	1.36
POSSUM											
	438	UK	Ferjani (2008)	158	General Surgery	Colorectal cancer	30 day mortality	20%	0.63 (0.55-0.70)	0.037	
		UK	Garcea (2010)	280	General Surgery	Mixed	Inpatient mortality	15%	0.81		
P-POSSUM											
	983	China	Ren (2009)	90	General Surgery	Colorectal cancer	Inpatient mortality	3%	0.66	0.25	2.81
		Hong Kong	Poon (2005)	160	General Surgery	Colorectal cancer - obstructing	30 day mortality	11%	0.75	0.11	5.98
		France	Merad (2012)	575	General Surgery	Mixed	Inpatient mortality	21%	0.82 (0.78-0.86)	<0.001	68.7

		UK	Ferjani (2008)	158	General Surgery	Colorectal cancer	30 day mortality	20%	0.65 (0.57-0.73)	<0.001	
mP-POSSUM (local modification)											
	90	China	Ren (2009)	90	General Surgery	Colorectal cancer	Inpatient mortality	3%	0.66	0.8	4.99
SAPS II											
	177	Turkey	Ertan (2008)	102	General Surgery	Colorectal cancer	30 day mortality	17%	0.83	0.98	1.079
		Turkey	Koc (2007)	75	PPU Repair	PPU	30 day mortality	11%	0.86	0.085	8.2
Sepsis score											
	117	Denmark	Buck (2012)	117	PPU Repair	PPU	30 day mortality	17%	0.69		
Surgical Risk Scale											
	2721	USA	Kwok (2011)	372	General Surgery	>80 years: colectomy	30 day mortality	26%	0.66	0.14	Residual GOF

Table 35 Discrimination and calibration of general tools

GOF: goodness of fit. PPU: perforated peptic ulcer. * indicates tools scored using preoperative data

Subpopulation-specific tools

A variety of indication-specific and comorbidity-specific tools were identified (Table 36).

Colorectal surgery

Of six tools specific to colorectal surgery, CR-POSSUM alone was assessed in multiple studies. Discrimination of 30 day outcome after unplanned surgery for colorectal cancer by *CR-POSSUM* was moderate or poor (AUC 0.65, 0.72).^{131, 134}

Peritonitis

Of four identified studies of tools specific to peritonitis, the Mannheim Peritonitis Index (MPI) and Peritonitis Index of Altona II (PIA II) underwent multiple assessments of external validity. Discrimination of short-term outcome by *MPI* and *PIA II* was inconsistent for patients undergoing general surgery for peritonitis (AUC 0.73, 0.97 and 0.69, 0.95 respectively).^{118,}

127, 135, 136

Perforated peptic ulcer (PPU)

Of 2 tools specific to PPU, the *Boey score* alone was assessed in multiple studies. Discrimination of outcome at 30 days by the *Boey score* was moderate or poor (AUC 0.63-0.86), but in discrimination of development of postoperative septic shock and complications, performance was moderate or good (AUC 0.72, 0.80 respectively) (Table 36 and Table 37).

119, 120, 132

Sub-population	Tool	Region	First Author (Year)	Cohort size	Surgical subtype	Cohort	Primary endpoint	Incidence of primary endpoint	AUC (95%CI)	Calibration p value	H-L value (unless stated)
Colorectal surgery											
	ACPGBI	UK	Ferjani (2008)	158	General Surgery	Colorectal cancer	30 day mortality	20%	0.61 (0.53-0.69)	<0.001	
	ACS Colorectal Surgery Risk Calculator	USA	Kwok (2011)	372	Colectomy	>80 years	30 day mortality	26%	0.71	0.68	Residual GOF
	CR-POSSUM	Turkey	Ertan (2008)	102	General Surgery	Colorectal cancer	30 day mortality	17%	0.72	0.037	16.38
		UK	Ferjani (2008)	158	General Surgery	Colorectal cancer	30 day mortality	20%	0.65 (0.57-0.73)	<0.001	
	modified CR-POSSUM	China	Ren (2009)	90	Colorectal	Colorectal cancer	Inpatient mortality	3%	0.99	0.8	0.45
	Practical mortality risk score for emergent colectomy	USA	Kermani (2013)	68344	Colectomy	Mixed	Inpatient mortality	9%	0.81 (0.81-0.82)		
	Targeted risk prediction score	USA	Kwok (2011)	372	Colectomy	>80 years	30 day mortality	26%	0.77	0.51	Residual GOF
Perforated peptic ulcer											
	Boey score	Denmark	Buck (2012)	117	PPU Repair	PPU	30 day mortality	17%	0.63		
		Denmark	Moller (2012)	2668	PPU Repair	PPU	30 day mortality	27%	0.7 (0.67-0.72)		
		Thailand	Lohsiriwat (2008)	152	PPU Repair	PPU	30 day mortality	9%	0.86 (0.79–0.91)		

	Peptic ulcer prediction score (PULP)	Denmark	Moller (2012)	2668	PPU Repair	PPU	30 day mortality	27%	0.83(0.82-0.85)		
Peritonitis											
	Colonic peritonitis severity score	Spain	Biondo (2000)	55	General Surgery	Peritonitis	Inpatient mortality	22%	0.89	0.16	
		Spain	Biondo (2006)	156	General Surgery	Peritonitis	Inpatient mortality	26%	0.79 (0.72-0.85)	<0.001	
	Combined Peritonitis Score	Turkey	Kologlu (2001)	473	General Surgery	Peritonitis	Inpatient mortality	20%	0.96*		
	Mannheim Peritonitis Index	Spain	Biondo (2006)	156	General Surgery	Peritonitis	Inpatient mortality	26%	0.73 (0.65-0.79)	<0.001	
		Europe	Ohmann (1993)	271	General Surgery	Peritonitis	30 day mortality	21%	0.79	<0.05	
		Turkey	Kologlu (2001)	473	General Surgery	Peritonitis	Inpatient mortality	20%	0.91*		
		Thailand	Lohsiriwat (2008)	152	PPU Repair	PPU	30 day mortality	9%	0.64 (0.56–0.72)		
		Iran	Notash (2005)	80	General Surgery	Peritonitis	Inpatient mortality	18%	0.97		
	Peritonitis Index of Altona	Europe	Ohmann (1993)	271	General Surgery	Peritonitis	30 day mortality	21%	0.69	<0.05	
		Turkey	Kologlu (2001)	473	General Surgery	Peritonitis	Inpatient mortality	20%	0.95*		

Table 36 Discrimination and calibration of tools assessed only in subpopulations or applicable only to subpopulations
GOF: goodness of fit. PPU: PPU. * AUC differences did not reach statistical significance.

Risk assessment tool	Region	First Author (Year)	Cohort size	Surgical subtype	Secondary endpoint	Incidence of secondary endpoint	AUC (95%CI)	Calibration
APACHE II	Denmark	Buck (2012)	117	Repair of Peptic Ulcer	Septic shock	26%	0.78	N/A
ASA-APS	Denmark	Buck (2012)	117	Repair of Peptic Ulcer	Septic shock	26%	0.57	N/A
	Thailand	Lohsiriwat (2008)	152	Repair of Peptic Ulcer	Complications	30%	0.80 (0.73–0.86)	N/A
Boey score	Denmark	Buck 2012	117	Repair of peptic ulcer	Septic shock	26%	0.72	N/A
	Thailand	Lohsiriwat 2008	152	Repair of peptic ulcer	Complications	30%	0.80 (0.73–0.86)	N/A
Sepsis score	Denmark	Buck (2012)	117	Repair of Peptic Ulcer	Septic shock	26%	0.74	N/A

Table 37 Tool performance against secondary endpoints

4.4 Discussion

Key points

- Postoperative mortality was considerable, but was observed to vary substantially between patient subgroups
- Methodological, population and endpoint heterogeneity precluded pooling of data to directly compare the performance of the identified risk assessment tools
- APACHE II demonstrated the most consistent discrimination across heterogeneous emergency laparotomy cohorts; and the performance of preoperative APACHE II risk estimates compared favourably with estimates using perioperative or postoperative data
- The ASA-PS demonstrated weak performance in cohorts of older patients and cannot be used to estimate percentage predicted risk
- P-POSSUM demonstrated weak performance in colorectal cohorts and its reliability may be compromised by subjective interpretation of data items. However, POSSUM systems have gained widespread acceptance by clinicians, and surgeons in particular in the United Kingdom
- Because reporting of calibration was inconsistent for all tools assessed in the identified studies, suitability as potential casemix adjustment tools cannot be assessed

4.4.1 Overview

Emergency laparotomies are performed commonly throughout the world, but one in six patients die within a month of surgery. Current international initiatives to reduce the considerable associated morbidity and mortality are founded upon the delivery of individualised perioperative care and analysis of associations with variation in casemix adjustment hospital outcomes. However, while the identification of high-risk patients requires the routine assessment of individual risk, no method of doing so has been demonstrated to be practical and reliable across the commonly encountered spectrum of presentations, co-morbidities and operative procedures

A systematic review of Embase and Medline identified 20 validation studies assessing 25 risk assessment tools in patients undergoing emergency laparotomy. The most frequently studied general tools were APACHE II, ASA-PS and P-POSSUM. Comparative, quantitative analysis of tool performance was not feasible due to the heterogeneity of study design, poor reporting and infrequent within-study statistical comparison of tool performance. Reporting of calibration was notably absent in many prognostic tool validation studies.

APACHE II demonstrated the most consistent discrimination of individual outcome across a variety of patient groups undergoing emergency laparotomy when used either preoperatively or postoperatively (area under the curve 0.76–0.98). P-POSSUM performance was demonstrated to be deficient in patients with colorectal cancer.

APACHE systems are used infrequently outside critical care units in the UK whereas POSSUM systems have gained widespread acceptance in the surgical community and POSSUM data items were therefore incorporated into the NELA year 1 patient audit dataset. These analyses have enhanced understanding of the populations in which P-POSSUM performance may be unreliable.

4.4.2 Performance

Because patients who require an emergency laparotomy are markedly heterogeneous, the capacity to tolerate a cascade of acute surgical pathology, massive surgical insult and resulting postoperative organ dysfunction varies between individuals. Furthermore, underlying surgical pathologies may not be apparent prior to surgery. For a tool to be useful in this context it should therefore be both applicable to and accurate across the spectrum of patient characteristics, surgical pathologies and operative procedures encountered in clinical practice. If performance is not substantially inferior, one general tool may therefore be preferable to multiple subpopulation specific tools.

When considering which tool may be best for assessing risk in patients undergoing emergency laparotomy, demonstration of satisfactory and consistent performance is essential and precedes other such considerations.^{104, 105, 113}

Comparisons of performance

Assessment of external validity provides the best measure of a tool's generalisability; and the performance of tools that are validated only internally may not be replicable in external patient populations due to factors including overfitting.^{113, 137} Of the identified general risk assessment tools, only seven were assessed in multiple external cohorts (Table 35). Performance of the two identified tools specific to emergency laparotomy was assessed only internally.¹⁰

For those tools that were assessed in multiple cohorts, pooling of data for head-to-head comparisons of tool performance was not feasible due to substantial heterogeneity of both study design and patient cohorts and the infrequent reporting of AUC confidence intervals, calibration and within-study statistical comparisons of performance.

Disparities were evident in the discriminatory performance (APACHE II: 0.76-0.98, ASA-PS: 0.66-0.91, P-POSSUM: 0.65-0.82) and calibration of the most frequently assessed tools. This variation most likely reflects differences in study cohorts and methodologies, poor generalisability of performance to some patient subgroups and poor reliability of subjectively scored tools. However, no identified tool incorporates measures of organisational structure and processes or of geographical variations in patient level risk, which could account for some of the variation observed.^{41, 48}

APACHE II was created for the assessment of risk in critical care admissions,¹²³ incorporating physiological parameters, markers of chronic disease and age. The comparatively good performance of APACHE II in these patients undergoing emergency

laparotomy may therefore reflect the associations of age, magnitude of systemic insult and relevant comorbidities with adverse postoperative outcomes in such cohorts of patients.

Performance in core subgroups

Complications of intra-abdominal malignancy are a common indication for emergency laparotomy;²³ up to a third of colorectal cancer diagnoses are made in the emergency setting;²⁰ the incidence of colorectal cancer in older people is increasing;²⁴ and outcomes after emergency laparotomy vary with age and timing of presentation with malignancy.^{25, 26} Because elderly patients and individuals with colorectal malignancy therefore represent core subgroups of patients undergoing emergency laparotomy, it is essential that the performance of tools for emergency laparotomy is generalisable to these patients.

While the observation represents the findings of only a handful of studies, it is therefore notable that whereas discrimination by APACHE II was not evidently reduced in a cohort of patients with colorectal cancer (AUC 0.78); P-POSSUM and CR-POSSUM discriminated less well in patients with colorectal cancer than in heterogeneous populations; and discrimination by the ASA-PS was reduced in a cohort of older patients (Table 35). The performance of the ASA-PS and P-POSSUM may therefore not be generalisable to these subgroups of patients.

It has been suggested that existing scoring systems are inaccurate and unreliable in elderly cohorts undergoing emergency surgery and that treatment decisions should not be made solely on generated estimates of risk.¹³⁸ It is therefore notable that in a cohort of older patients undergoing emergency colectomy, neither age-specific nor general tools demonstrated adequate discrimination.^{29, 30}

Calibration

Quantification of individual risk may be used to direct clinical decisions, including consent for surgery, appropriate seniority of clinicians in theatre and the location of postoperative care.^{21, 70-75} However, existing models should not be used to justify withholding or the withdrawal of treatment.

Reporting of the calibration of prognostic tools was found to be inconsistent and, where reported, performance was variable. Because percentage predicted risk may be used to justify a variety of treatment decisions, neither APACHE II nor P-POSSUM can be recommended for this purpose based on the evidence synthesised in this systematic review.

4.4.3 Tool characteristics and utility

Even if consistent and generalisable performance can be demonstrated, a tool is unlikely to be adopted into routine clinical practice if it is unwieldy. This may be true of tools requiring numerous datapoints, exacting a high burden of data collection or due to complexity of required calculation.

Subjectivity and application

The consistency of a tool's estimation or scoring of risk (reliability) may be reduced if interpretation of data items is required, or if the tool is applied variably. Inconsistencies may be evident at the level of individual clinicians, between centres or internationally.

Both the ASA-PS and P-POSSUM require the interpretation and scoring of clinical data items (including chest X-ray and ECG);¹²² the POSSUM system 'multiple procedures' item is variably interpreted by clinicians (Appendix 4.4); and linear and exponential analyses are variably used in the calculation of percentage predicted risk with POSSUM systems.¹³⁹ These factors may account for some of the variation observed in the performance of these tools (Table 35).

Number of required datapoints

The ASA-PS requires only one composite variable; APACHE II requires 12 routinely available data items; P-POSSUM requires 18 datapoints; whereas the perioperative NSQIP emergency laparotomy model requires 41 items (Appendix 4.3).

Tools that require numerous data items might be assumed to better capture all relevant risk factors and thus to more accurately discriminate between survivors and decedents 30-days after surgery or at discharge from hospital. However, data from the identified studies did not indicate a clear relationship between more numerous data items and better discrimination (Appendix 4.3 and Table 35) and parsimonious tools may impose fewer burdens on clinicians.

Complexity of risk calculation

Estimated risk may be quantified using prognostic tools and used to inform a variety of shared and clinical decisions. The ASA-PS lacks this capability, but percentage predicted mortality may be estimated with P-POSSUM and APACHE II. While logarithmic equations are required, the widespread availability of online and 'app'-based calculators mean that bedside estimations of individual risk are feasible and could be incorporated into routine clinical practice.

Timing of assessment of risk

Intraoperative variables including procedural factors, surgical findings and arising complications may independently predict postoperative mortality^{2, 6, 9, 10, 23, 26, 28-33} and their inclusion may therefore be expected to improve the accuracy of a predictive model which includes only preoperative variables. However, evaluation of individual risk is most informative in shared and clinical decision-making the earlier it is available in the patient journey. The requirement for operative or postoperative data may therefore limit clinical usefulness. Several of the identified tools require data that is available only during or after surgery (Appendix 4.3).

There is no consensus over the optimum time to assess risk. The derivation of the two models in the ACS-NSQIP study¹⁰ reflects this uncertainty; the preoperative version including no intraoperative data and the perioperative model including operative variables for cases when these data are available.

In fact, discrimination of outcome by tools that require operative and postoperative data items may not be superior to tools that require only preoperative data.¹⁴⁰ The results of the Al-Temimi et al. study suggest that discrimination may be increased only negligibly on inclusion of intraoperative data (AUC 0.87, 0.88 respectively) (Table 35) and discrimination by APACHE II, when calculated using only preoperative data, compared favourably with studies using perioperatively or postoperatively collected data (AUC 0.76-0.98, 0.78-0.87 respectively) (Table 35).

In discussing the relative merits of preoperative assessment of risk, P-POSSUM must also be considered. P-POSSUM incorporates six operative severity variables, although several may be reasonably be available preoperatively, including degree of peritoneal soiling if an abdominal CT has been performed (Appendix 4.4).

P-POSSUM predicted risk was not calculated using preoperative data items in any of the studies identified.^{117, 119, 127-131} The performance of P-POSSUM, when used preoperatively, may therefore be overestimated by the findings of this review.

4.5 Limitations

These findings must be interpreted in light of several limitations. Firstly, few of the identified tools were assessed in multiple validation studies and many cohorts were small and drawn from single centres, limiting both statistical power and assessment of the generalisability of tool performance.

Secondly, only studies reporting tool discrimination as AUC were included in this Systematic Review. While the benefits of doing so are widely accepted, a small proportion of excluded studies used alternative methods of assessing and reporting tool performance in patient cohorts undergoing emergency laparotomy. Quantitative comparative analysis of tool performance (discrimination and calibration) was not feasible due to significant heterogeneity of study design and cohort characteristics, poor reporting and infrequent within-study statistical comparisons of tool performance.¹¹⁵

Thirdly, organisational factors in the delivery of healthcare have undergone considerable change over recent years. Because this review includes studies from the 1990's the reported accuracy and calibration of identified tools may therefore not describe performance in contemporary patient cohorts.¹⁴¹

Finally, bias identification and mitigation was limited by variable reporting of study methodology, potential for preferential publication of studies with positive findings and the predominance of English language papers in the accessed electronic databases.¹⁴²

4.6 Conclusions and direction of future research

The identification of high-risk patients for targeted perioperative interventions and augmented pathways of care is a key component of current initiatives to improve patient outcomes after emergency laparotomy.²⁷

Direct comparisons of the performance of risk assessment tools for emergency laparotomy was not possible with existing data, highlighting the need for consensus in the reporting of perioperative outcomes.¹⁹ However, due to consistent performance across patient subgroups and its capacity to generate individual preoperative risk estimates using routinely available objective data items, APACHE II is promoted as a practical means of estimating individual risk in patients undergoing emergency laparotomy.

Despite evidence that its preoperative performance was comparable with postoperative use, anecdotal evidence suggested that APACHE II is used infrequently outside critical care units in the UK. Perioperative use of P-POSSUM on the other hand has gained widespread acceptance, in particular in the surgical community.

Unfocussed efforts to derive novel tools are likely to achieve only marginal improvements in performance, increase uncertainty and struggle to gain greater acceptance than APACHE II and P-POSSUM. Future efforts in this field should therefore seek to update the performance (discrimination and calibration) of APACHE II and P-POSSUM in large, well-conducted contemporary studies in heterogeneous emergency general surgical cohorts; assess the implications of dynamic risk scores (e.g. preoperative and postoperative scores); develop the ability to accurately predict postoperative morbidity, due to associations with prolonged excess mortality; and assess the impact of adoption of these tools on patient outcomes and clinical practice.^{16, 104, 113}

As in other disciplines, machine learning and artificial neural networks (ANN's) increasingly look set to occupy a central role in clinical risk prediction.¹⁴³ Significant advantages over risk assessment tools or biomarkers in isolation include their ability to continually learn mathematical relationships between input variables and a variety of outcomes of interest.¹⁴⁴ It is evident that substantial computational resources are required to establish and maintain ANNs, but it would seem opportune to do so alongside the implementation of large clinical databases.

Finally, the implementation of nationally co-ordinated methods for real-time evaluation of individual risk, as with the National Emergency Laparotomy Audit (NELA) and the American College of Surgeons (ACS) NSQIP underpins quality improvement and the delivery of best-practice to patients.

Appendix 4.1: Search strategy

Medline®

Search terms

1. exp Health Care Reform/ or exp Risk Adjustment/ or exp "Outcome Assessment (Health Care)"/ or exp Models, Statistical/ or exp Risk/ or risk predict\$.mp. or exp Risk Factors/ or exp Risk Assessment/ or exp "Predictive Value of Tests"/ or predict\$.mp. or exp Prognosis/ or risk stratification.mp. or case mix adjustment.mp. or scoring system.mp. or exp Postoperative Complications/ or cardiovascular risk.mp. or exp "Severity of Illness Index"/ or classification-system.mp. or physical status classification.mp. or logistic regression.mp. or exp Logistic Models/ or quality indicat\$.mp.
2. (emergen\$ or urgen\$ or acute or imminen\$).mp. or exp Emergencies/ or non-elective.mp. or expedite\$.mp.
3. surg\$.mp. or exp General Surgery/ or operat\$.mp. or exp Postoperative Complications/ or intraop\$.mp. or intra-op\$.mp. or exp Intraoperative Care/ or exp Perioperative Care/ or periop\$.mp. or peri-op\$.mp. or perop\$.mp. or per-op\$.mp. or celiotomy.mp. or exp Laparotomy/ or exp Digestive System Surgical Procedures/

Limits

limit to (humans and yr="1980 -Current" and ("young adult (19 to 24 years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)"))

Exclusions

1. Pregnancy Outcome/ or Cervix Uteri/ or Suture Techniques/ or Obstetric Labor, Premature/ or Pregnancy/ or Adult/ or Uterine Cervical Incompetence/ or Cerclage, Cervical/ or cerclage.mp. or Premature Birth/
2. cesarean section/ or vaginal delivery/ or cesarean.mp. or obstetric anesthesia.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
3. Bulimia/ or Mental Disorders/ or Binge-Eating Disorder/ or Nursing Staff, Hospital/ or Child Behavior Disorders/ or Psychiatric Nursing/ or Psychiatric Department, Hospital/ or Hospitals, Psychiatric/ or psych\$.mp. or Mental Health Services/
4. transluminal coronary angioplasty/ or carotid angioplasty/ or percutaneous transluminal angioplasty/ or angioplasty/ or patch angioplasty/ or angioplasty.mp. or laser angioplasty/ or percutaneous transluminal angioplasty balloon/

5. eye inflammation/ or eye injury/ or eye discharge/ or smooth pursuit eye movement/
or "neoplasms of the eye, lacrimal gland and orbit"/ or blood eye barrier/ or eye
edema/ or eye care/ or eye.mp. or eye burning/ or eye position/ or eye tumor/ or eye
examination/ or fungal eye infection/ or posterior eye segment/ or eye development/
or eye/ or eye infection/ or eye jaundice/ or eye allergy/ or eye redness/ or viral eye
infection/ or eye fundus/ or eye surgery/ or eye movement control/ or supplementary
eye field/ or National Eye Institute Visual Function Questionnaire/ or eye ointment/ or
eye axis length/ or eye burn/ or eye synechia/ or posterior eye chamber/ or frontal
eye field/ or eye chamber disease/ or eye protection/ or eye color/ or saccadic eye
movement/ or eye tracking/ or eye contusion/ or muscle eye brain disease/ or eye
fundus albipunctatus/ or anterior eye chamber angle/ or eye cancer/ or anterior eye
chamber/ or eye hand coordination/ or eye drops/ or eye fixation/ or eye movement
disorder/ or eye blood flow/ or "inflammation of the eye and surrounding structures"/
or perforating eye injury/ or eye refraction/ or eye dominance/ or eye toxicity/ or eye
discomfort/ or eye pain/ or agents acting on the eye/ or eye protective device/ or eye
disease/ or eye biopsy/ or bacterial eye infection/ or anterior eye chamber depth/ or
eye lavage/ or dry eye/ or eye swelling/ or eye protein/ or eye movement/ or
compound eye/ or anterior eye chamber disease/ or eye irritation/ or eye
malformation/ or eye photography/ or anterior eye segment/
6. cardiac surgery.mp. or heart surgery/
7. coronary surgery.mp. or coronary artery surgery/
8. coronary artery bypass.mp. or coronary artery bypass graft/
9. Stroke/ or Stroke, Lacunar/ or Heat Stroke/ or "National Institute of Neurological
Disorders and Stroke"/ or stroke.mp.
10. transplant.mp. or Transplants/

Appendix 4.2: Screening flow diagram

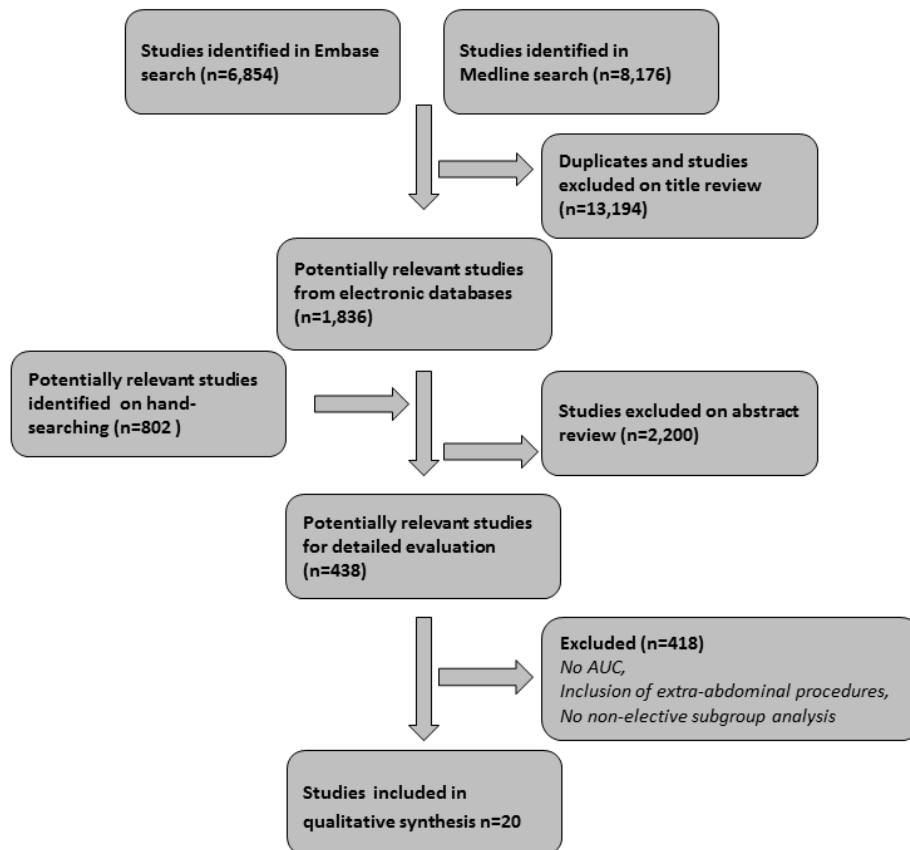


Figure 8 Screening flow diagram

Appendix 4.3: Characteristics of identified tools

Risk assessment tool	Number of data items	Subjectivity in interpretation of data item(s)	Intraoperative data items required
Association of coloproctology of Great Britain and Ireland (ACPGBI)	5	Yes	Yes
ACS Colorectal Surgery Risk Calculator	15	Yes	No
Acute physiology and Chronic health evaluation II (APACHE II)	14	No	No
Acute physiology and Chronic health evaluation III (APACHE III)	16	No	No
ASA physical status classification (ASA-PS)	1	Yes	No
Boey score	3	No	No
Colonic peritonitis severity score	6	Yes	Yes
Colorectal POSSUM (CR-POSSUM)	10	Yes	Yes
Modified Colorectal POSSUM (mCR-POSSUM)	10	Yes	Yes
Combined peritonitis severity score	Unknown		
Early warning score	6	No	No
Emergency Laparotomy perioperative model (NSQIP)	41	Yes	No
Emergency Laparotomy preoperative model (NSQIP)	39	Yes	Yes
Mannheim Peritonitis Index (MPI)	8	No	Yes
Mortality Probability Model II (MPM II)	14	No	No
Peptic ulcer prediction score (PULP)	8	Yes	No
Physiological and Operative Severity Score for the enumeration of Mortality and morbidity (POSSUM)	18	Yes	Yes
Portsmouth POSSUM (P-POSSUM)	18	Yes	Yes
modified P-POSSUM (mP-POSSUM)	18	Yes	Yes
Peritonitis index of Altona (PIA)	Unknown		
Practical mortality risk score for emergent colectomy	8	No	No
Simplified acute physiology score (SAPS II)	17	No	No
Sepsis score	5	No	No
Surgical Risk Scale	3	Yes	No
Targeted risk prediction score	8	No	No

Table 38 Characteristics of identified risk assessment tools

Appendix 4.4: POSSUM categorisation of data items

	Category score			
	1	2	4	8
The Physiological Severity Score (PSS)				
Age (years)	≤60	61-70	≥71	-
Cardiac signs (Chest radiograph)	No failure	Diuretic/digoxin/ anti-anginal/ anti- hypertensive	Peripheral oedema, warfarin therapy (Borderline cardiomegaly)	Raised JVP (Cardiomegaly)
Respiratory history (Chest radiograph)	No dyspnoea	Dyspnoea on exertion	Limiting dyspnoea (Moderate COPD)	Dyspnoea at rest (Fibrosis or consolidation)
Systolic Blood pressure (mmHg)	110-130	131-170 100-109	≥ 171 90-99	- ≤ 89
Pulse (beats/min)	50-80	81-100 40-49	101-120	≥ 121 ≤ 39
Glasgow coma score	15	12-14	9-11	≤ 8
Haemoglobin (g/dl)	13-16	11.5-12.9 16.1-17.0	10.0-11.4 17.1-18.0	≤ 9.9 ≥ 18.1
White cell count (10 ¹² /l)	4-10*	10.1-20.0 3.1-4.0	≥20.1 ≤ 3.0	-
Urea (mmol/l)	≤ 7.5	7.6-10	10.1-15.0	≥15.1
Sodium (mmol/l)	≥ 136	131-135	126-130	≤ 125
Potassium (mmol/l)	3.5-5.0	3.2-3.4 5.1-5.3	2.9-3.1 5.4-5.9	≤ 2.8 ≥ 6.0
Electrocardiogram	Normal	-	Atrial fibrillation (rate 60-90)	Other arrhythmia, ≥ 5 ectopics/ min, Q waves or ST/T wave changes
The operative severity score				
Operative severity	Minor	Moderate	Major	Major+
Multiple procedures	1	-	2	>2
Total blood loss (ml)	≤100	101-500	501-999	≥1000
Peritoneal soiling	None	Minor (serous fluid)	Local pus	Free bowel content. pus or blood
Presence of malignancy	None	Primary only	Nodal metastases	Distant metastases
Mode of surgery	Elective	-	Emergency resuscitation of >2h possible Operation <24 h after admission	Emergency (immediate surgery <2h needed)

Figure 9 The Physiological and Operative Severity Score for the enUmeration of mortality and morbidity (POSSUM) From: Copeland GP, Jones D, Walters M. POSSUM: a scoring system for surgical audit. Brit J Surg 1991; 78: 355-60¹²² (*: due to overlap between categories, these data were re-classified to include values 4.1-10)

5. EMERGENCY LAPAROTOMIES IN ENGLAND AND WALES: COHORT CHARACTERISTICS, PROCESSES OF CARE AND ASSOCIATIONS WITH HOSPITAL STRUCTURES

5.1 Introduction

Background

Emergency laparotomies are commonly performed operations associated with a high (overall) incidence of postoperative morbidity and mortality.^{2, 9-13} However, substantial variation in the incidence of postoperative adverse events has been observed both between patient subgroups and between the hospitals at which these operations are performed.^{2, 9, 36}

Donabedian and Iezzoni's models propose that some of the observed between-hospital variation in patient outcomes can be explained by differences in the provision of organisational structures and delivery of processes of care.^{40, 44} In support of these models, associations between organisational factors and patient outcomes have been indicated in a variety of clinical contexts.^{2, 6, 9-11, 23, 26, 28-33, 43, 46-62}

However, relationships are complex; because organisational factors do not exert an influence in isolation of one another, associations with patient outcomes may be modified by other organisational variables (Figure 4).

Furthermore some processes are applicable only to subgroups of patients (MCOP input in patients over the age of 70) and the indications and evidence for other processes restricted to subgroups (timing of antibiotics and surgery in intra-abdominal sepsis). Interactions between organisational and patient factors are therefore also expected.

Standards of care for emergency general surgical patients have been published in the United Kingdom, specifying minimum structural provisions and processes of care, with the intention of safeguarding the quality of care received by these patients.^{21, 70-75}

However, until the National Emergency Laparotomy Audit (NELA) was established in 2012, the approach to the collection of baseline organisational data relating directly to the care of emergency laparotomy patients was not systematic and, due primarily to methodological and inclusion criteria differences, exploration of these complex associations was limited.

In *Chapter 3* I reported my analysis of the first NELA organisational audit, demonstrating substantial between-hospital variation in the provision of organisational structures for emergency general surgical patients.

In 2013 NELA commenced an annual cycle of patient-level audits, collecting perioperative process, casemix and inpatient outcome data in order to describe between-hospital variation in the delivery of recommended processes of care and to report between-hospital variation in postoperative mortality rates (*Chapter 2*). In this Chapter I report my baseline analyses of the NELA year 1 patient audit dataset.

Aims

1. To identify and characterise variation in the delivery of recommended processes of care to patients undergoing emergency laparotomies at hospitals in England and Wales
2. To provide a contemporary estimate of the incidence of 30-day postoperative mortality after emergency laparotomy in the UK
3. To identify associations between aggregated (hospital-level) delivery of processes of care and organisational structural provisions for emergency laparotomy

Objectives

1. To characterise the patients comprising the NELA year 1 patient audit cohort
2. To identify key processes of care in emergency laparotomy from contemporary publications
3. To assess how comprehensively these processes of care were delivered to the patients comprising the NELA year 1 patient audit cohort
4. To report variation in the delivery of key processes of care by selected patient characteristics
5. To report between-hospital variation in the delivery of key processes of care
6. To report postoperative mortality in the NELA year 1 patient audit cohort
7. To test whether processes of care were more comprehensively delivered at hospitals that were reported to provide organisational structures for emergency general surgery

5.2 Materials and methods

5.2.1 The first NELA patient audit

A purpose-built webtool was constructed for the first year NELA patient audit, through which clinicians and audit staff at 195 participating hospitals submitted pseudoanonymised patient-level data (process of care, descriptive, administrative and outcome) for patients undergoing emergency laparotomies between 1st December 2013 and 30th November 2014.

Methods for the identification of participating hospitals, construction of the audit dataset and delivery of the audit are reported in *Chapter 2*.

5.2.2 Definitions

Inclusion criteria:

- Locked cases downloaded from the NELA webtool at 08.00 on 15th January 2015
- Index emergency laparotomy performed at an English or Welsh hospital
- Entry into an operating theatre for an emergency laparotomy between 1st December 2013 and 30th November 2014
- Primary operative procedure meeting published inclusion criteria (Appendix 5.1)
- Age \geq 18 years on entry into an operating theatre for index emergency laparotomy

Primary endpoint

In the absence of timely provision of externally collected mortality data by the ONS, inpatient death within 30-days of the index laparotomy (inpatient 30-day mortality) was selected as the primary endpoint

Operative urgency

Operative urgency was categorised for the first four months by POSSUM definitions:¹²²

- Emergency (immediate surgery <2 hours needed)
- Emergency resuscitation of >2 hours possible. Operation within 24 hours of admission

From 4th April 2014, operative urgency data was submitted as the following (in order to permit sufficient granularity of analyses):

- 1 Surgery indicated immediately, with minimal resuscitation (<2 hours)
- 2A Surgery indicated urgently (2-6 hours)
- 2B Surgery indicated urgently (6-18 hours)
- 3 Expedited (>18 hours)

P-POSSUM predicted risk of death

Preoperative and postoperative POSSUM data items were submitted. No detailed method for the application of the constituent physiological and operative severity scores has been published.¹⁴⁵ Constituent physiological severity scores were therefore calculated from preoperative data items and operative severity scores from postoperative data items and the NELA webtool equipped with functionality to estimate P-POSSUM predicted risk to inform clinical decisions.

5.2.3 Selection of variables

The construction of the NELA year 1 patient audit questionnaire is detailed in *Chapter 2*. In brief, candidate data items (including processes of care and surgical factors) were identified from existing research and standards of care documents (Appendix 2.2),^{21, 70-75} patient risk factors (POSSUM data items) from the findings of the systematic review of risk assessment tools (*Chapter 4*); and additional data items guided by the clinical and statistical expertise of the NELA project team. Expert multidisciplinary members of NELA stakeholder groups guided the final selection of data items and construction of the questionnaire and piloted the webtool questionnaire (Appendix 5.2).

Data items were imported from the first NELA organisational audit coding the organisational characteristics and structural provisions reported in *Chapter 3*:

- quartile of size,
- tertiary GI surgical referral centre status and
- configuration to admit EGS patients

5.2.4 Data management

An extract of the dataset was downloaded from the NELA webtool at 08.00 on 15th January 2015 as a Microsoft Excel comma separated values (CSV) spreadsheet and imported into and subsequently managed in Microsoft Excel (2010).

Cleaning and validation

- Ineligible cases were identified (including assessment of operative procedures coded as ‘other’ by Miss Emma Barrow) and excluded
- Variables were renamed in order to be compatible with Stata® (version 12, StataCorp LP, College Station, Texas USA) statistical software
- Hospitals were assigned the three letter identifier codes used in the first NELA organisational audit dataset
- Completeness of non-mandatory fields was assessed
- Binary variables recorded as words (including: yes/no, false/true, male/female) were converted to binary numerical data items
- Summary binary variables were constructed for provisions that were reported as multiple data items
- Summary categorical variables were constructed (including operative procedure and seniority of surgeon performing emergency laparotomy) for processes recorded as multiple binary variables
- Binary conditional fields were generated (summarising multiple submitted fields) coding variables including inpatient deaths within 30-days of surgery, preoperative consultant review and intraoperative consultant presence and timeliness of arrival in theatre for surgery

Imported data

Hospital characteristics and structures recorded in the first NELA organisational audit (*Chapter 3*) were matched to the NELA year 1 patient audit dataset and disaggregated to the level of individual patients.

5.2.5 Statistical Analyses

Analyses were performed in Stata® version 12 (StataCorp LP, College Station, Texas USA) and Microsoft Excel (2010).

In order to minimise bias, data items were analysed if collected comprehensively ($\geq 90\%$ of patients) in the NELA patient audit dataset.

Descriptive data

Parametrically distributed continuous data were reported as mean and standard deviation and non-parametrically distributed data as median and interquartile range.

Binary format variables were reported as percentages and categorical and ordinal variables reported as within-group percentages.

Variation in the delivery of processes of care was reported by patient characteristics and hospitals.

Crude mortality was reported by patient characteristics and operative factors.

P-POSSUM estimates

Estimation of likelihood of 30-day mortality using POSSUM systems requires the calculation of component physiological and operative severity scores (PSS and OSS). Because precedent exists for missing data items to be assigned the least deviant score,¹⁴⁶ missing POSSUM items in the NELA year 1 patient audit dataset were assigned a score of one in order to estimate individual P-POSSUM risk.

Individual estimates of P-POSSUM risk were then estimated using preoperative PSS and postoperative OSS data items. These estimates were then plotted as a frequency distribution to describe the NELA year 1 patient audit cohort; the proportion of patients in the upper quintile of P-POSSUM estimated risk plotted by hospital in order to ascertain between-hospital casemix variation; and median values used to describe and compare patient groups in subsequent analyses.

Day of the week and time of day data

Associations between temporal factors and structural provisions and processes of care have been indicated in emergency general surgical⁶⁸ and wider populations.^{66, 67} Day of hospital admission and arrival into an operating theatre for an emergency laparotomy data were therefore plotted.

Inpatient 30-day mortality

Mortality data were presented as the overall incidence of inpatient 30-day mortality and crude mortality by patient and surgical characteristics.

Processes of care

Delivery of the selected processes of care was reported as overall statistics, by patient subgroups and hospital-level delivery of processes of care are reported

Parametrically distributed continuous data were reported as mean and standard deviation, non-parametrically distributed data as median and interquartile range and binary, categorical and ordinal variables reported as within-group percentages.

Associations between hospital-level variables and process delivery

Hospital size

Differences in the delivery of processes of care across quartiles were assessed using the Wilcoxon matched pairs rank sum test for non-parametric continuous data and Pearson's χ^2 test for dichotomous data.

Tertiary gastrointestinal (GI) surgical referral centre status

Differences in the delivery of processes of care between tertiary referral centres and other hospitals were assessed using the Wilcoxon matched pairs rank sum (WRS) test for non-parametric continuous data and Pearson's χ^2 test for binary data.

Bonferroni corrections

Between-quartile testing requires multiple between-class analyses, p values were corrected using the Bonferroni method. Corrected p values are denoted as p'.⁸⁸

5.3 Results

Key findings

Cohort characteristics

- Following exclusions, 20183 patient records were included in the NELA year 1 patient audit dataset, submitted by participants at 192 hospitals across England and Wales
- Rates of data completeness were high overall, but poor reporting of time points precluded analysis of timeliness of surgery
- One or more POSSUM items was missing for every submitted case from 8% of hospitals, illustrating the rationale for missing items to be assigned the least deviant score rather than cases excluded
- Patients were markedly heterogeneous with respect to descriptive characteristics, markers of comorbidity, operative urgency and preoperative P-POSSUM predicted risk
- Peritonitis, perforation and intestinal obstruction were the most common precipitants for surgery and perforation and adhesions the most common surgical findings
- Estimates of preoperative P-POSSUM predicted risk indicated considerable between-hospital casemix variation
- More patients were admitted on Mondays than any other day, whereas more operations were begun on Thursdays than any other day. Only 8% of patients underwent surgery overnight
- Preoperative P-POSSUM predicted risk was significantly greater (17%) in patients who underwent surgery overnight than during 'daylight hours' (7%)

Postoperative mortality

- The overall incidence of inpatient 30-day mortality was 11.3%, but varied substantially between patient subgroups and by operative indication, surgical findings and primary procedure performed
- Stratification of mortality data by patient characteristics indicated that in excess of 40% of the population were at high (>10%) risk of inpatient 30-day mortality. These findings were supported by the distribution of preoperative P-POSSUM predicted risk (median 8.1%)

Processes of care

- A host of perioperative processes of care were assessed at patient-level of and at hospital-level. No process was delivered universally to all patients at all hospitals

and considerable variation was observed between patient groups and between hospitals

- At patient-level, variation in the delivery of many processes was associated with markers of risk (increasing age, ASA-PS,¹²⁶ documented risk and operative urgency)
- At hospital-level, variation in the delivery of many processes was associated with hospital characteristics (size, tertiary GI surgical referral centre status) and potential markers of high quality care (perioperative care pathways and operating theatres for exclusively for EGS)
- Small bowel resection, adhesiolysis and right hemicolectomy were the most frequently performed primary operative procedures

5.3.1 Data quality

Included cases

The extracted dataset comprised 22,391 patient records (Appendix 5.3) before exclusions.

Incomplete data

Data completeness was on the whole very high, thanks to the engagement of participants and mandatory designation of many data items.

Time of decision to operate was not submitted for 18% of patients and time of theatre booking absent for 22%. Neither time point was submitted for 12% of patients, precluding use of time of booking where time of decision was unavailable. Timeliness of arrival in theatre analysis was therefore not included in statistical analysis of the NELA year 1 patient audit dataset.

Individually, POSSUM items were missing in 0.2-1.5% of patient records and complete preoperative and postoperative POSSUM data items were submitted for 93% of all cases. However, one or more items were missing for every submitted case at 8% of hospitals. This illustrates the rationale for missing items to be assigned the least deviant score (i.e. 1) in order that P-POSSUM predicted risk might be calculated.¹⁴⁶

As a result of the re-classification of operative urgency categories (S5.2), two categories were available for 31% of the dataset and four categories for 69%. Analyses by operative urgency therefore include only 69% of the dataset.

5.3.2 Population characteristics

Patient characteristics

Characteristic	Group	Number of patients	Frequency
Gender	Female	10,375	51
	Male	9,808	49
Admission type	Emergency	18,693	93
	Elective	1,490	7
ASA-PS grade*	1	2,097	10
	2	6,793	34
	3	7,108	35
	4	3,747	19
	5	438	2

Table 39 Characteristics of the NELA Patient Audit cohort

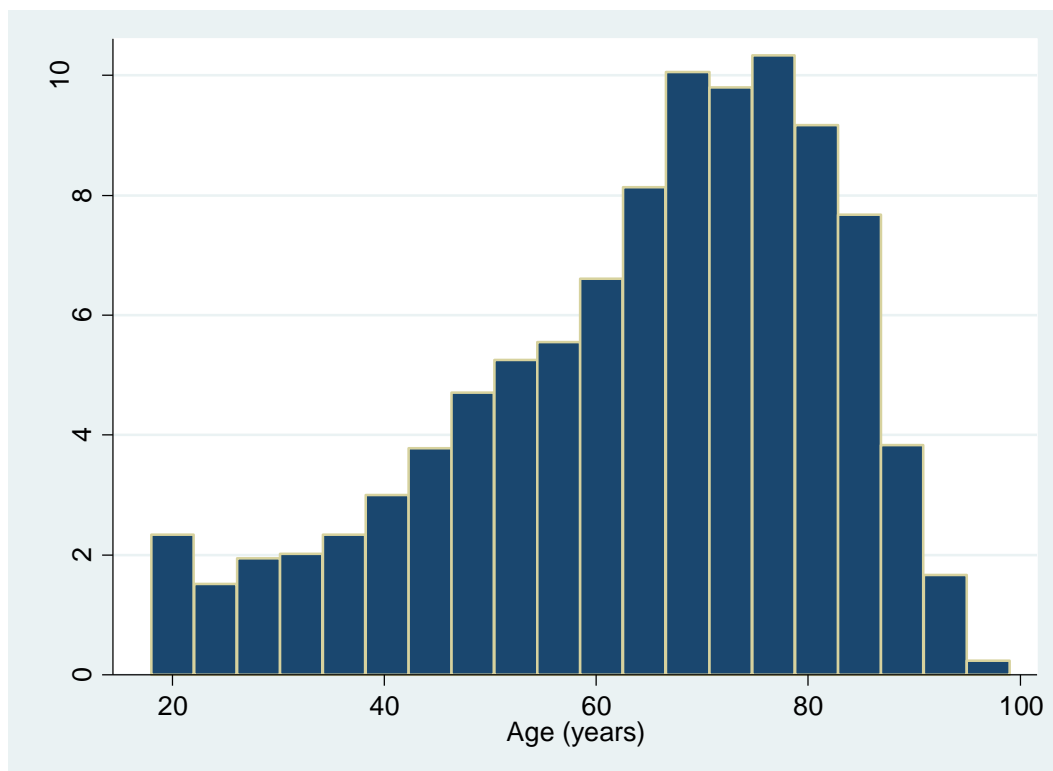


Figure 10 Density distribution plot of patient age on admission to hospital (Median age 67 years (IQR: 53-78))

* The American Society of Anaesthesiologists Physical status classification (commonly referred to as ASA grade) is a commonly used subjective score used to classify a patient's disease-status. The score ranges from 1-5; where 1 indicates the absence of systemic disease; and 5 the presence of severe and life-threatening disease

P-POSSUM estimated risk of postoperative 30-day mortality

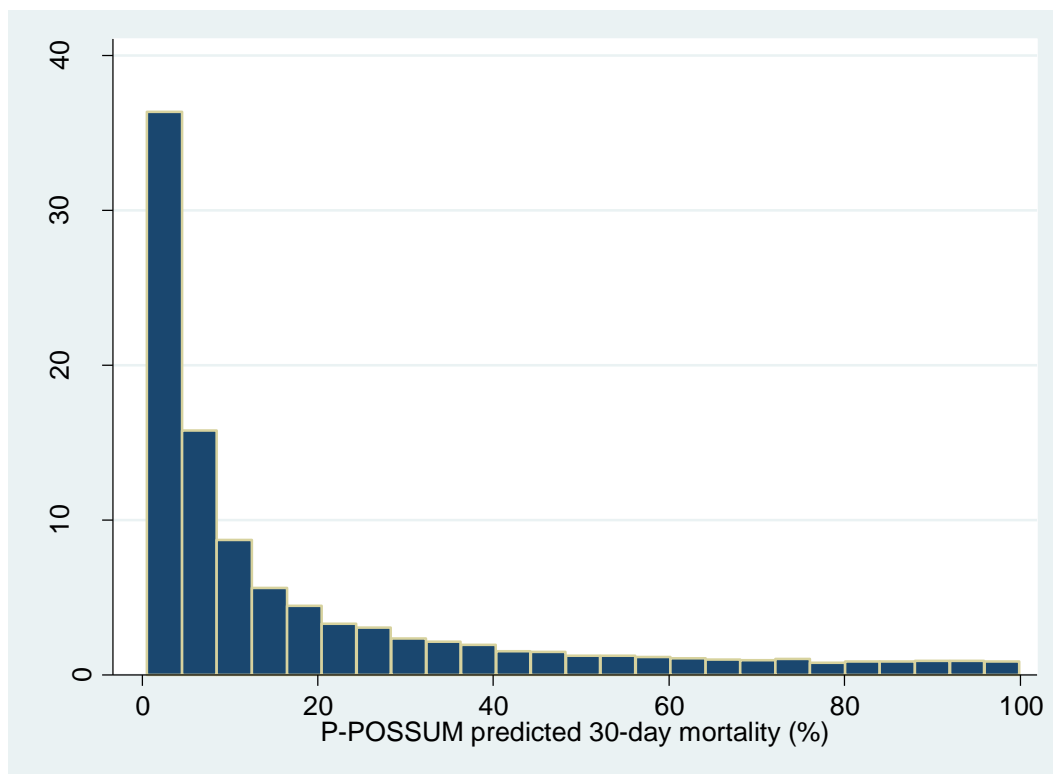


Figure 11 Distribution of preoperative P-POSSUM predicted risk of 30-day mortality (Median 8.1%: IQR 2.9-27.1)

Quintile	Range (%)	Patients
1	≤2.4	4030
2	2.5-5.4	4034
3	5.5-12.8	4027
4	12.9-35.3	4054
5	35.4-100	4038

Table 40 Quintiles of preoperative P-POSSUM predicted risk of 30-day mortality

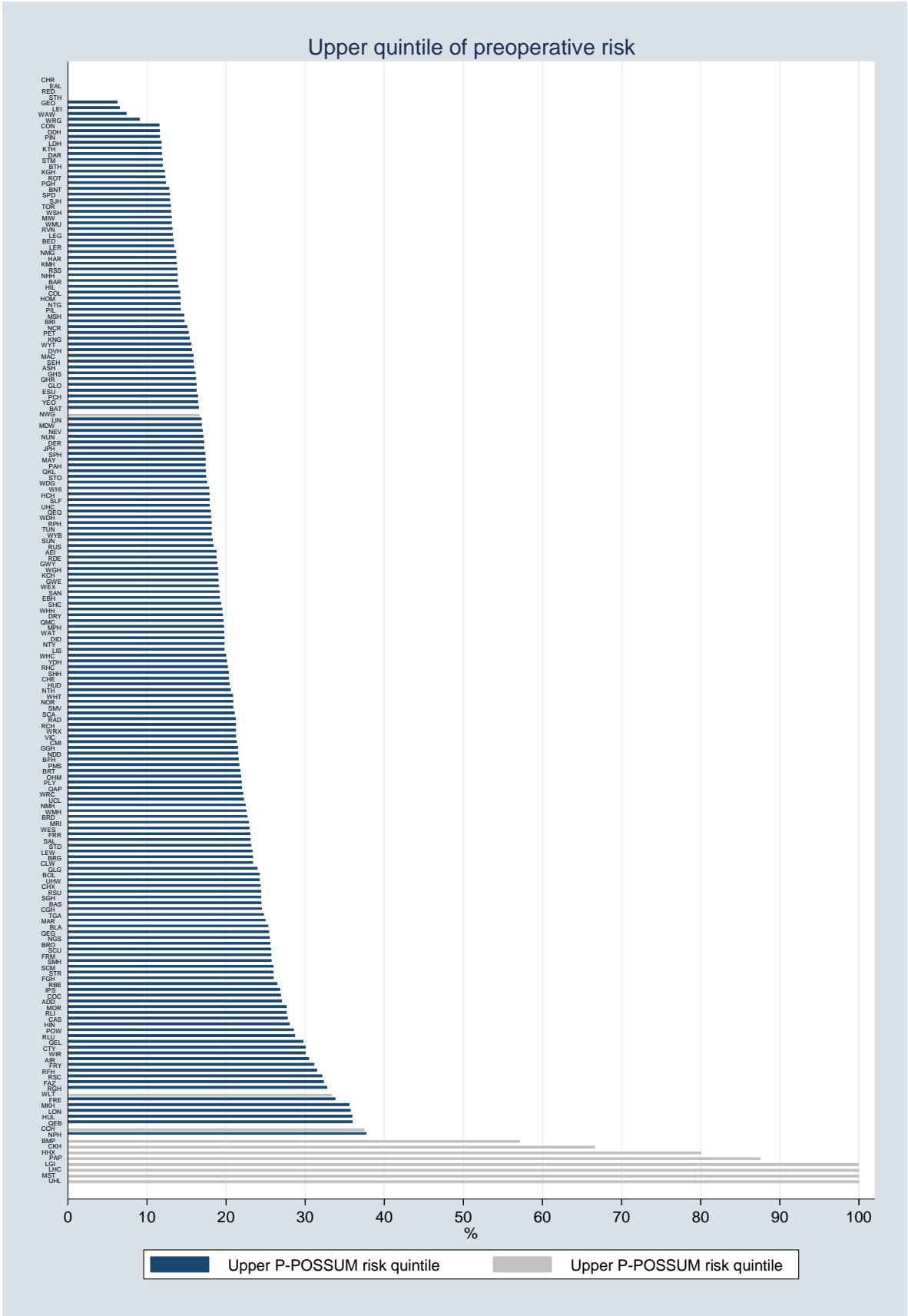


Figure 12 Proportion of upper quintile preoperative P-POSSUM risk patients by hospital (Grey bars indicate hospitals submitting fewer than ten cases)

Surgical characteristics

<i>Operative urgency</i>	Number of patients	Frequency (%)
<i>≤2 hours</i>	3,001	15
<i>>2 hours</i>	17,064	84
<i>Not recorded</i>	118	0.6
<i>Total</i>	20,183	100

Table 41 Distribution of operative urgency categories for all patients

<i>Operative urgency[†]</i>	Number of patients	Frequency (%)
<i>≤2 hours</i>	1,976	14
<i>2-6 hours</i>	5,498	39
<i>6-18 hours</i>	4,213	30
<i>18-24 hours</i>	2,247	16
<i>Not recorded</i>	58	0.4
<i>Total</i>	13,992	100

Table 42 Re-categorisation of operative urgency

<i>Index Emergency laparotomy</i>	Number of patients	Frequency (%)
<i>Primary procedure</i>	18,034	89
<i>Surgery for complication of a recent procedure</i>	2,149	11

Table 43 Incidence of emergency laparotomies performed as a primary procedure or secondary to recent surgery

[†] Following modification of the dataset, 31% of patients were excluded from analyses of operative urgency

5.3.3 Day of the week and time of day

Day of the week	Admissions to hospital (%)	Arrival in theatre for an emergency laparotomy (%)
Monday	3449 (17.1)	2510 (12.4)
Tuesday	3098 (15.4)	3027 (15.0)
Wednesday	2997 (14.9)	3154 (15.6)
Thursday	3069 (15.2)	3396 (16.8)
Friday	2969 (14.7)	3078 (15.3)
Saturday	2211 (11.0)	2565 (12.7)
Sunday	2390 (11.8)	2453 (12.2)

Table 44 Distribution of admissions to hospital and arrivals in theatre for emergency laparotomy by day of the week in the NELA year 1 patient audit

Time of day	Patients (%)	Preoperative P-POSSUM predicted risk of 30-day mortality (%)
0800-1159	4606 (22.8)	7***
1200-1759	8091 (40.1)	7
1800-2359	4995 (24.7)	10
0000-0759	1660 (8.2)	17
(missing)	(831) (4.1)	(9)
Overall	20183	8

Table 45 Median (IQR) preoperative P-POSSUM predicted 30-day mortality by time of day of admission and time of day of arrival in theatre for emergency laparotomy

(* p≤0.05, **p≤0.005, ***p≤0.001)

5.3.4 Mortality

	Decedents	Incidence (%)	Estimated overall variance
Inpatient deaths within 30 days of surgery	2,273	11.3	10.0
Inpatient deaths	2,570	12.7	11.1

Table 46 mortality in the NELA year 1 patient cohort

	Patients	Inpatient 30-day mortality (%)
Age (years)		
18–39	2,188	3***
40–49	1,939	3
50–59	2,707	6
60–69	4,197	9
70–79	5,084	15
80–89	3,537	20
≥90	531	24
ASA		
1	2,097	1 ***
2	6,793	3
3	7,108	9
4	3,747	30
5	438	58
Admission type		
Emergency	18,693	11 NS
Elective	1,490	10
Documented risk		
Lower	3,826	2 ***
High	2,386	6
Highest	5,059	28
Not documented	8,912	7
	20,183	11%

Table 47 Inpatient 30 day mortality by patient characteristics

(* p<0.05, **p≤0.005, ***p≤0.001, NS: not significant)

	Patients	Inpatient 30-day mortality (%)
Urgency of surgery		
<2hrs	1,976	26%***
2–6hrs	5,498	12%
6–18 hrs	4,213	7%
18–24 hrs	2,247	6%
	13,934	11%

Table 48 Inpatient 30-day mortality by operative urgency
(* p<0.05, **p≤0.005, ***p≤0.001)

Primary operative procedure	Patients (%)	Inpatient 30-day mortality (%)
Small bowel resection	3,420 (17)	12
Adhesiolysis	3,379 (17)	7
Colectomy: right	2,573 (13)	10
Hartmann's procedure	2,562 (13)	12
Stoma formation	1,148 (6)	10
Peptic ulcer - suture or repair of perforation	1,138 (6)	10
Colectomy: subtotal	1,113 (6)	15
Drainage of abscess/collection	588 (3)	8
Colectomy: left (including anterior resection)	578 (3)	8
Washout only	532 (3)	11
Repair of intestinal perforation	454 (2)	11
Colorectal resection - other	440 (2)	11
Exploratory/relook laparotomy only	408 (2)	26
Gastric surgery - other	327 (2)	14
Intestinal bypass	302 (2)	14
Haemostasis	245 (1)	7
Peptic ulcer oversew of bleed	210 (1)	19
Not amenable to surgery	185 (1)	73
Enterotomy	159 (1)	4
Stoma revision	161 (1)	7
Abdominal wall closure	121 (<1)	9
Laparostomy formation	77 (<1)	26
Resection of other intra-abdominal tumour(s)	63 (<1)	11

Table 49 Percentage inpatient 30-day mortality by primary operative procedure performed at emergency laparotomy

Indication for surgery	Patients	Inpatient 30-day mortality (%)
Abdominal abscess	1,332	8
Abdominal compartment syndrome	55	42
Abdominal wound dehiscence	116	9
Anastomotic leak	618	7
Colitis	748	7
Haemorrhage	819	14
Intestinal fistula	326	8
Intestinal obstruction	9,811	9
Ischaemia	1,720	29
Other	1,758	9
Perforation	4,744	15
Peritonitis	4,116	16
Planned relook	51	4
Sepsis: other	1,474	20

Table 50 Inpatient 30-day mortality by indication for surgery

Surgical findings	Patients	Inpatient 30-day mortality (%)
Abdominal compartment syndrome	45	38
Abscess	2,332	9
Adhesions	5,592	9
Anastomotic leak	591	9
Colitis	654	8
Crohn's disease	658	3
Diverticulitis	1,158	8
Haemorrhage: intestinal	207	11
Haemorrhage: peptic ulcer	228	21
Haemorrhage: postoperative	300	8
Incarcerated hernia	1,224	12
Intestinal ischaemia	2,543	25
Malignancy: disseminated	1,443	15
Malignancy: localised	2,480	9
Normal intra-abdominal findings	215	10
Other	3,375	11
Perforation: peptic ulcer	1,212	10
Perforation: small bowel/colonic	3,893	17
Volvulus	715	11

Table 51 Inpatient 30-day mortality by surgical findings

5.3.5 Processes of care

Consultant surgeon review within 12 hours of admission to hospital

	Patients	Proportion reviewed by a consultant surgeon within 12 hours of emergency admission to hospital (%)
Age (years)		
18-39	1,567	46*
40-49	1,331	51
50-59	1,883	51
60-69	2,889	48
70-79	3,550	47
80-89	2,610	46
≥90	409	44
ASA		
1	1565	55***
2	4851	48
3	4974	45
4	2563	48
5	286	47
Documented risk		
Lower	2905	50***
High	1746	50
Highest	3558	49
Not documented	6030	45
Overall	14239	48%

Table 52 Patients reviewed by a consultant surgeon within 12 hours of emergency admission to hospital. Data presented for patients admitted as an emergency and for whom the time of consultant review had been entered into the NELA webtool (* p<0.05, **p≤0.005, ***p≤0.001)

Operative urgency	Patients	Proportion reviewed by a consultant surgeon within 12 hours of emergency admission to hospital
<2hrs	1253	60%***
2-6hrs	3802	53%
6-18 hrs	3045	42%
18-24 hrs	1651	36%
Overall	9751	47%

Table 53 Proportion of patients reviewed by a consultant surgeon within 12 hours of admission to hospital by operative urgency
(* p<0.05, **p≤0.005, ***p≤0.001)

Time of emergency admission to hospital	Proportion of patients reviewed by a consultant surgeon within 12 hours of emergency admission to hospital	
	Monday-Friday	Saturday-Sunday
0800-1159	55%***	46%***
1200-1759	34%	31%
1800-2359	43%	48%
0000-0759	68%	64%
Overall	48%	46%

Table 54 Proportion of patients reviewed by a consultant surgeon within 12 hours of admission to hospital by time of day and day of week of emergency hospital admission
(* p<0.05, **p≤0.005, ***p≤0.001)

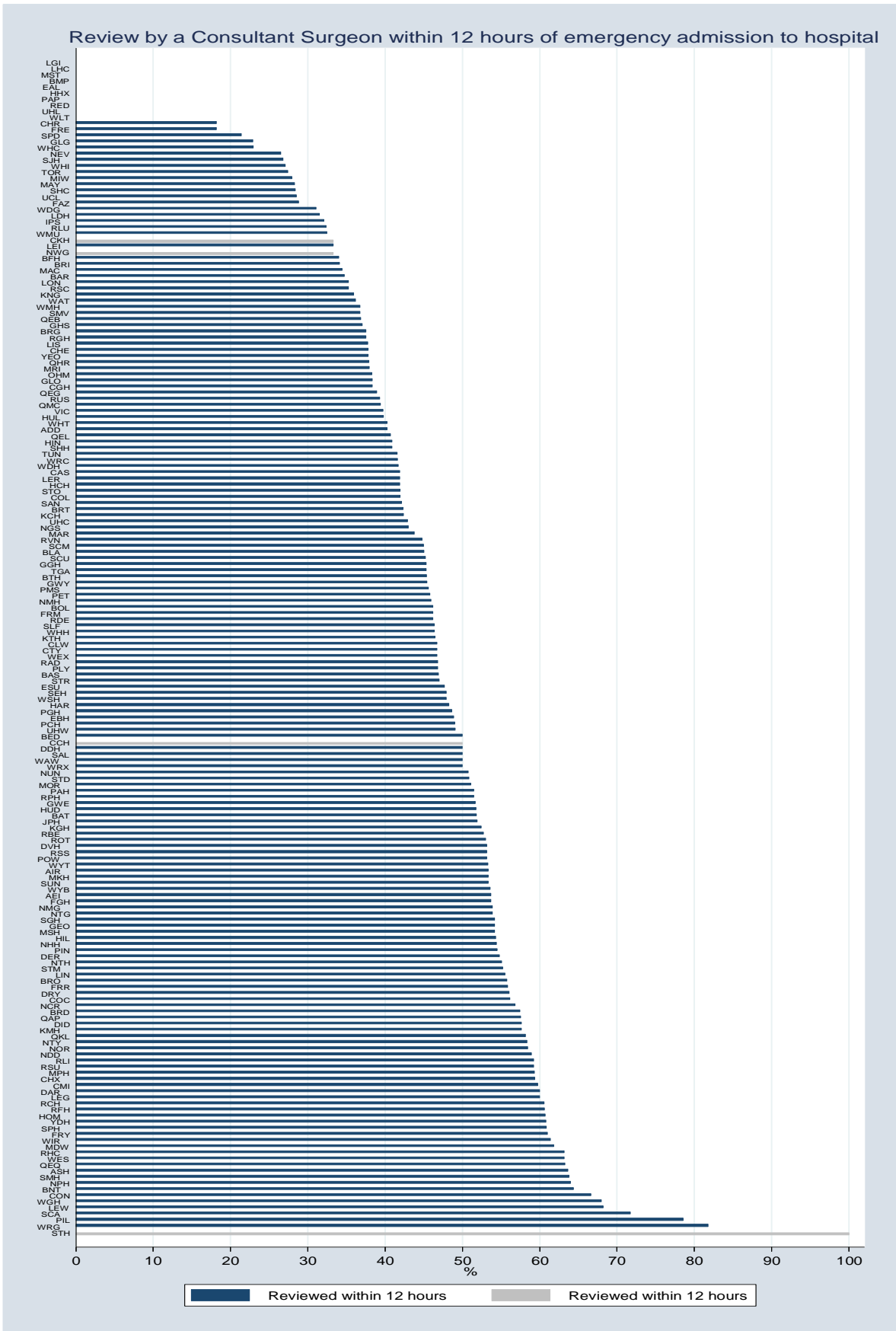


Figure 13 Patients reviewed by a consultant surgeon within 12 hours of emergency admission by participating hospital.
 (Grey bars indicate hospitals submitting fewer than ten cases)

Preoperative imaging

	Patients	Proportion who had a CT scan before surgery (%)	Proportion who had a CT scan reported by a consultant radiologist before surgery (%)
Age (years)			
18–39	2,188	69 ***	56 ***
40–49	1,939	77	64
50–59	2,707	81	67
60–69	4,197	82	70
70–79	5,084	81	69
80–89	3,537	83	71
≥90	531	83	71
ASA			
1	2,097	77 ***	65 ***
2	6,793	81	68
3	7,108	81	69
4	3,747	80	66
5	438	71	58
Admission type			
Emergency	18,693	81 ***	68 ***
Elective	14,90	70	60
Documented risk			
Lower	3,826	79 ***	69 ***
High	2,386	84	72
Highest	5,059	81	68
ND	8,912	79	66
Overall	20,183	16,169 (80%)	13,624 (68%)

Table 55 Preoperative CT scanning and reporting by descriptive patient characteristics
 (* p<0.05, **p≤0.005, ***p≤0.001, ND: not documented)

	Patients	Proportion who had a CT scan before surgery (%)	Proportion who had a CT scan reported by a consultant radiologist before surgery (%)
Urgency of surgery			
<2hrs	1976	70***	53***
2-6hrs	5498	81	67
6-18 hrs	4213	86	74
18-24 hrs	2247	80	73
Overall	13934	11246 (81%)	9530 (68%)

Table 56 Preoperative CT scanning and reporting by a Consultant Radiologist by documented urgency of surgery (* p<0.05, **p≤0.005, ***p≤0.001)

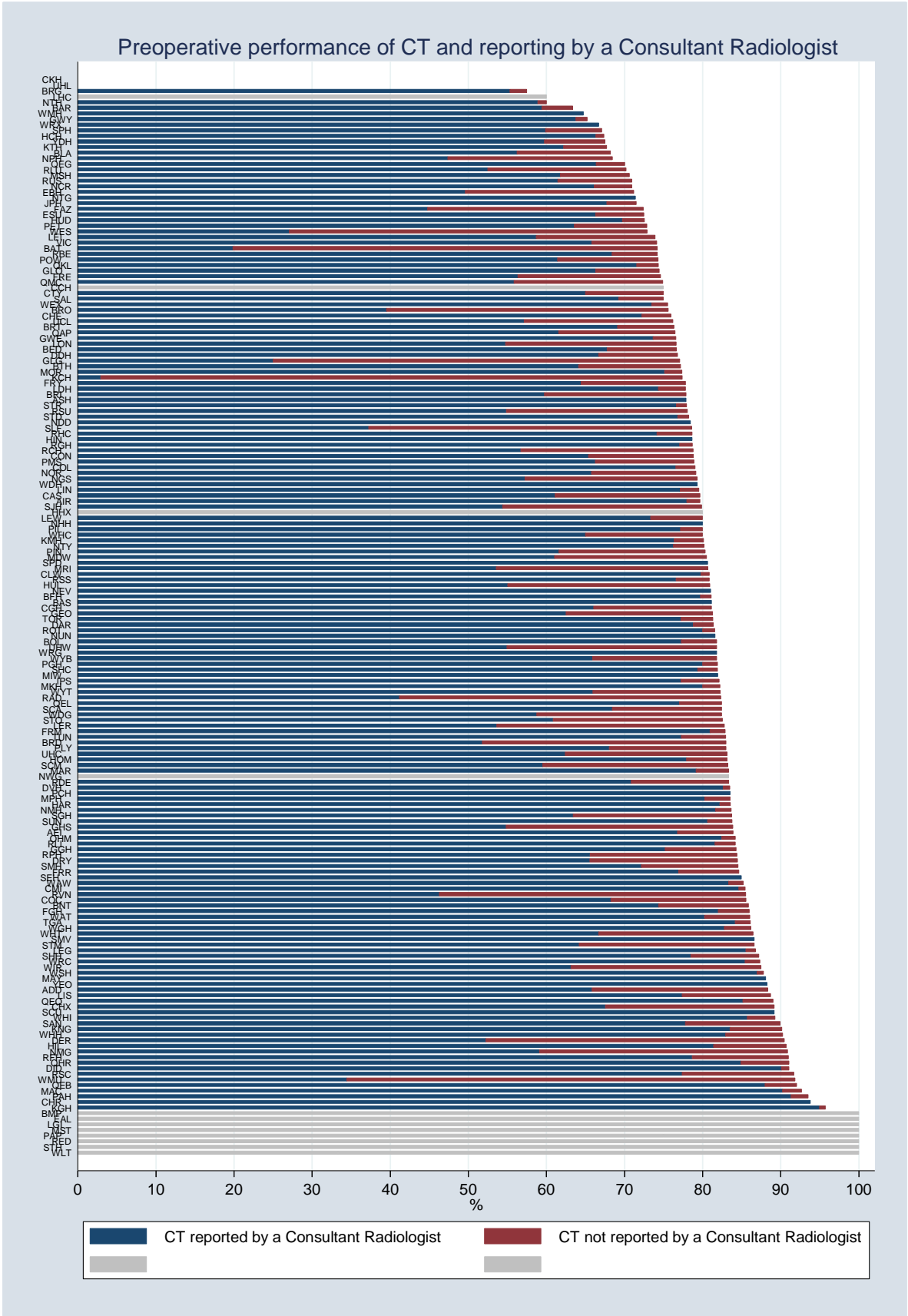


Figure 14 CT scanning and reporting by a consultant radiologist before emergency laparotomy. (Grey bars indicate hospitals submitting fewer than ten cases)

Preoperative documentation of risk

	Number of patients	Proportion of patients who had risk documented before surgery (%)
Age (years)		
18-39	2,188	52***
40-49	1,939	50
50-59	2,707	53
60-69	4,197	54
70-79	5,084	57
80-89	3,537	63
≥90	531	70
ASA		
1	2097	51***
2	6793	50
3	7108	53
4	3747	72
5	438	78
Admission type		
Emergency	18693	56 NS
Elective	1490	54
Overall	20183	11271 (56%)

Table 57 Proportion of patients for whom risk was documented before surgery by patient characteristics (* p<0.05, **p≤0.005, ***p≤0.001, NS: not significant)

	Number of patients	Proportion of patients who had risk documented before surgery (%)
Urgency of surgery		
<2hrs	1976	67 ***
2-6hrs	5498	60
6-18 hrs	4213	51
18-24 hrs	2247	52
Overall	13934	7932 (57%)

Table 58 Proportion of patients for whom risk was documented preoperatively by documented urgency of surgery (* p<0.05, **p≤0.005, ***p≤0.001)

Documented risk	Patients (%)	Median preoperative P-POSSUM predicted risk of death (%)
Lower (<5%)	3,826 (19)	3***
High (5-10%)	2,386 (12)	8
Highest (>10%)	5,059 (25)	33
Not documented	8,912 (44)	7
Overall	20,183	8

Table 59 P-POSSUM risk distribution in categories of preoperatively documented risk
(* p<0.05, **p≤0.005, ***p≤0.001)

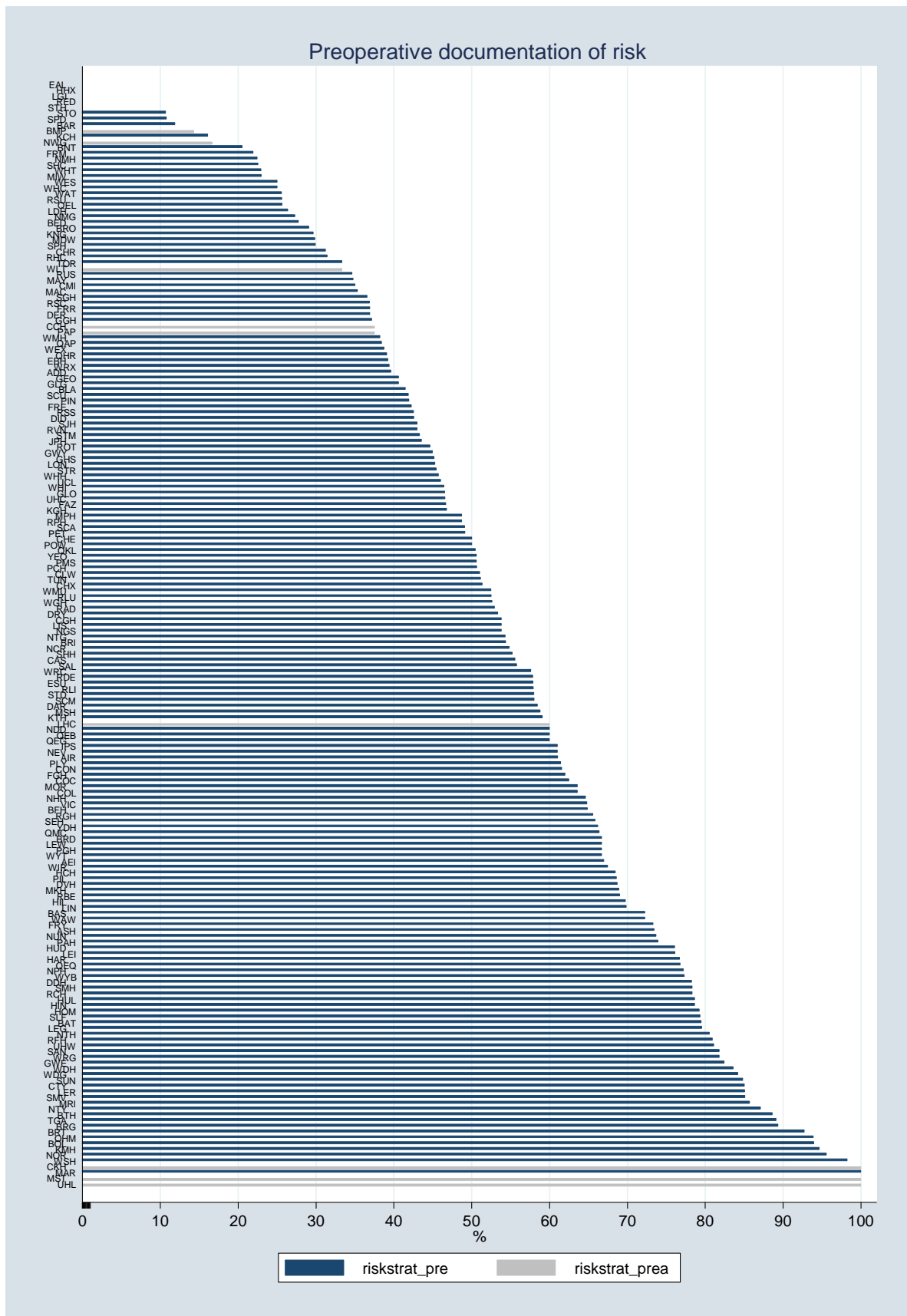


Figure 15 Proportion of patients who had risk documented preoperatively. (Grey bars indicate hospitals submitting fewer than ten cases)

Operation performed

Primary operative procedure	Number of patients	Frequency (%)
Small bowel resection	3,420	17
Adhesiolysis	3,379	17
Colectomy: right	2,573	13
Hartmann's procedure	2,562	13
Stoma formation	1,148	6
Peptic ulcer - suture or repair of perforation	1,138	6
Colectomy: subtotal	1,113	6
Drainage of abscess/collection	588	3
Colectomy: left (including anterior resection)	578	3
Washout only	532	3
Repair of intestinal perforation	454	2
Colorectal resection - other	440	2
Exploratory/relook laparotomy only	408	2
Gastric surgery - other	327	2
Intestinal bypass	302	2
Haemostasis	245	1
Peptic ulcer oversew of bleed	210	1
Not amenable to surgery	185	1
Enterotomy	159	1
Stoma revision	161	1
Abdominal wall closure	121	<1
Laparostomy formation	77	<1
Resection of other intra-abdominal tumour(s)	63	<1

Table 60 Recorded primary surgical procedure at emergency laparotomy

Operative approach	Number of patients	Frequency (%)
Open	17,573	87
Laparoscopic	1,208	6
Laparoscopic converted to open	1,215	6
Laparoscopic-assisted	187	1

Table 61 Operative approach at emergency laparotomy

Consultant delivered perioperative care

Preoperative care

	Patients	Review by both consultants (%)	Review by consultant surgeon (%)	Review by consultant anaesthetist (%)	Not reviewed by either consultant (%)
Age (years)					
18–39	2,188	55***	71***	72***	12***
40–49	1,939	55	70	74	10
50–59	2,707	57	73	75	10
60–69	4,197	59	72	78	8
70–79	5,084	60	72	79	8
80–89	3,537	61	74	80	8
≥90	531	65	75	83	7
ASA					
1	2,097	51***	70***	69***	13***
2	6,793	57	74	74	10
3	7,108	59	73	78	8
4	3,747	63	71	85	7
5	438	61	65	89	6
Admission type					
Emergency	18,693	58*	72 NS	77**	9*
Elective	1,490	61	73	81	7
Overall	20,183	58%	72%	77%	8%

Table 62 Proportions of patients receiving preoperative input by consultant surgeons and consultant anaesthetists by patient characteristics
(* p<0.05, **p≤0.005, ***p≤0.001, NS: not significant)

	Patients	Review by both consultants (%)	Review by consultant surgeon (%)	Review by consultant anaesthetist (%)	Not reviewed by either consultant (%)
Lower	3826	61%***	77%***	76%***	8%***
High	2386	65%	77%	81%	8%
Highest	5059	63%	72%	84%	7%
ND	8912	53%	69%	73%	11%
Overall	20183	58%	72%	77%	8%

Table 63 Proportion of patients receiving input before surgery by consultant surgeons and consultant anaesthetists by category of documented risk
(* p<0.05, **p≤0.005, ***p≤0.001, ND: not documented)

Preoperative care

	Patients	Both consultants present (%)	Consultant surgeon present (%)	Consultant anaesthetist present (%)	Neither consultant present (%)
Age (years)					
18–39	2,188	62**	84 NS	70***	8*
40–49	1,939	63	85	71	7
50–59	2,707	62	84	71	8
60–69	4,197	66	85	75	7
70–79	5,084	68	85	77	6
80–89	3,537	67	83	77	6
≥90	531	70	85	81	5
ASA					
1	2,097	54***	78***	64***	11***
2	6,793	62	83	71	8
3	7,108	66	85	75	6
4	3,747	74	89	81	4
5	438	80	90	88	3
Admission type					
Emergency	18,693	65***	84 NS	74***	7***
Elective	1,490	72	82	78	3
Overall	20,183	65%	85%	74%	7%

Table 64 Proportions of patients whose intraoperative care was directly supervised by consultant surgeons and consultant anaesthetists by patient characteristics

(* p<0.05, **p≤0.005, ***p≤0.001, NS: not significant)

	Patients	Both consultants present (%)	Consultant surgeon present (%)	Consultant anaesthetist present (%)	Neither consultant present (%)
Lower	3826	61***	82***	71***	9***
High	2386	67	85	76	6
Highest	5059	73	89	81	4
ND	8912	62	83	71	8
Overall	20183	65%	85%	74%	7%

Table 65 Proportion of patients whose care during surgery was directly supervised by consultant surgeons and consultant anaesthetists by patient characteristics

(* p<0.05, **p≤0.005, ***p≤0.001, ND: not documented)

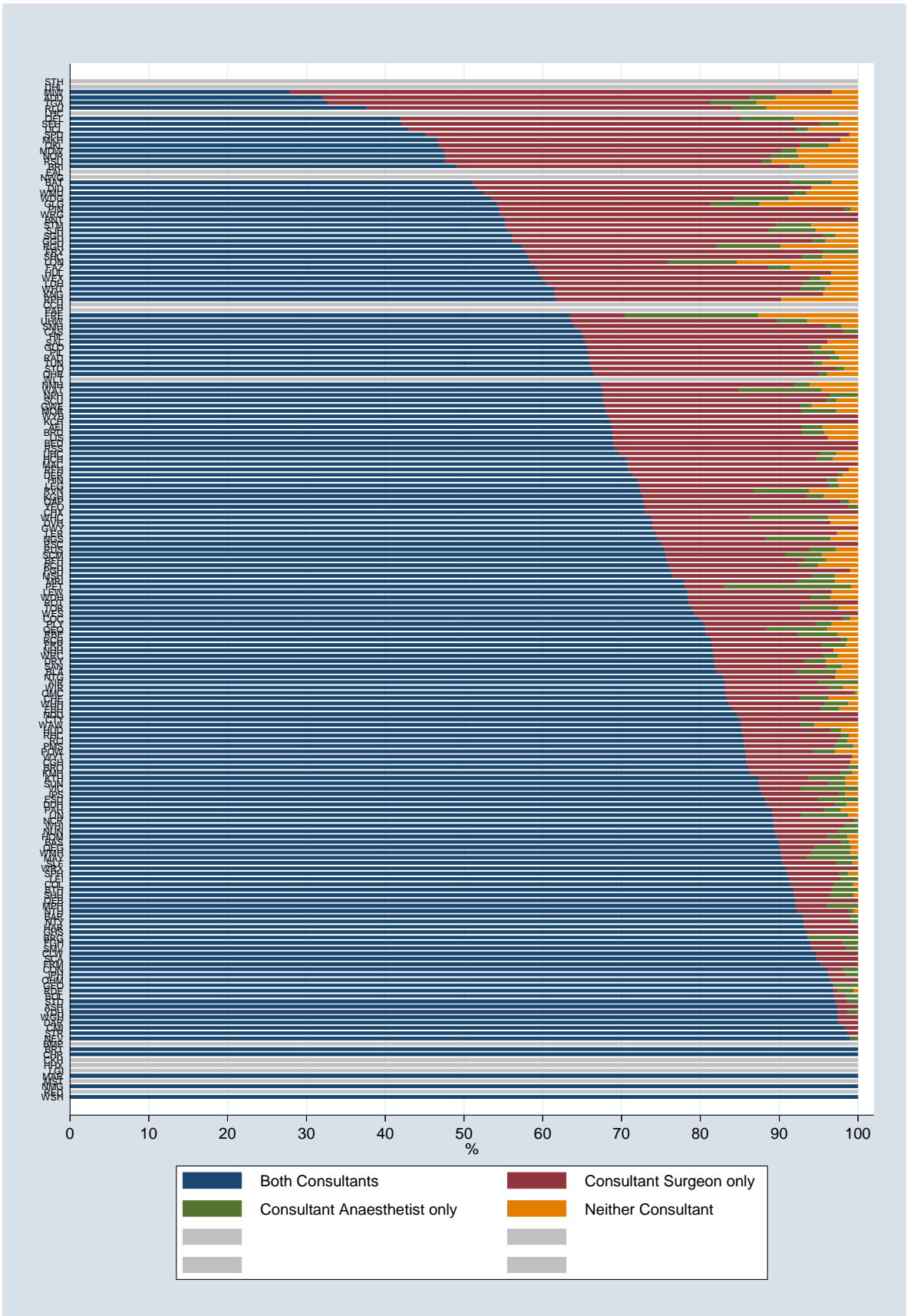


Figure 16 Patients reviewed preoperatively by a consultant surgeon and anaesthetist (Grey bars indicate hospitals submitting fewer than ten cases)

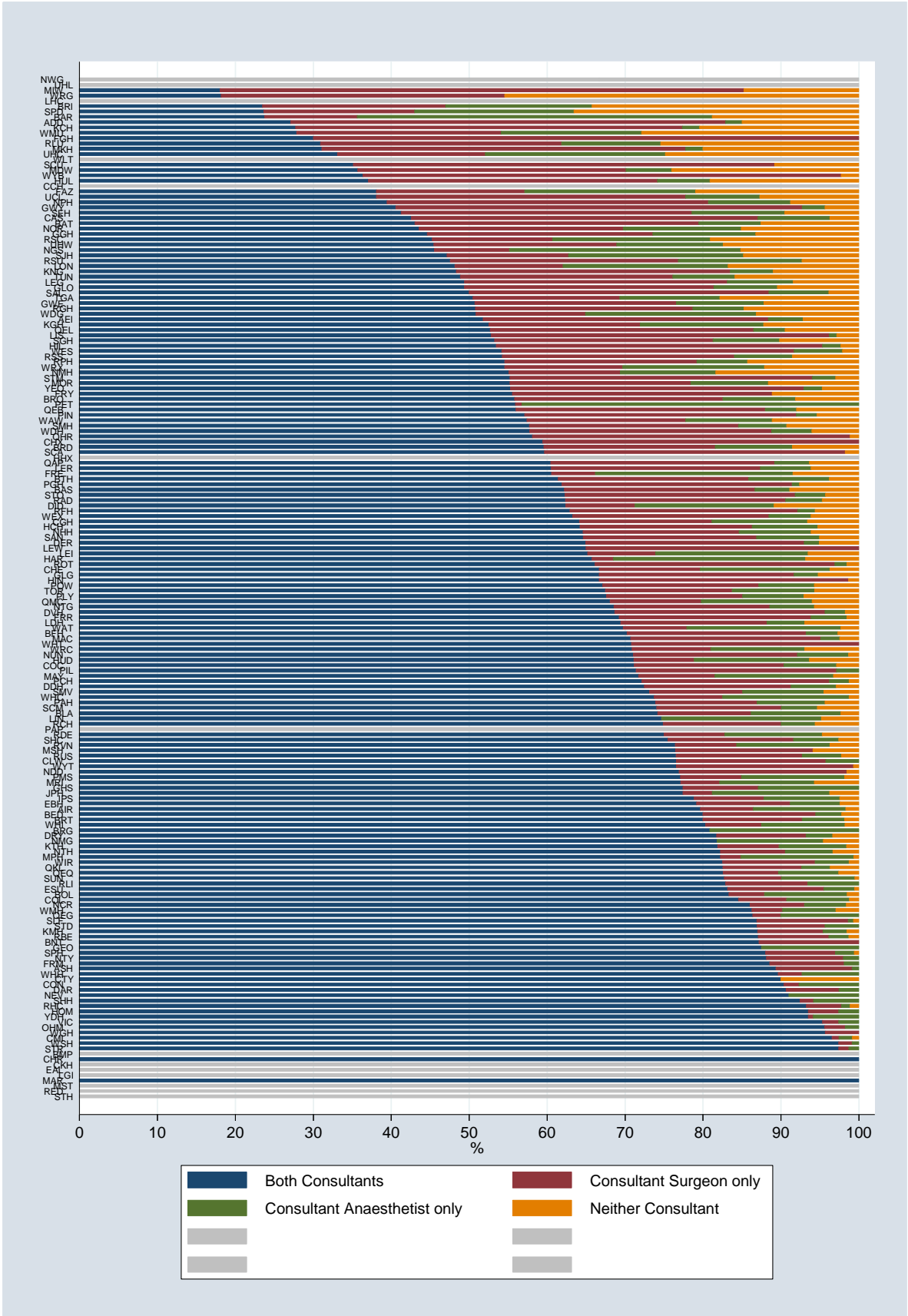


Figure 17 Patients for whom surgery was directly supervised by a consultant surgeon anaesthetist. (Grey bars indicate hospitals submitting fewer than ten cases)

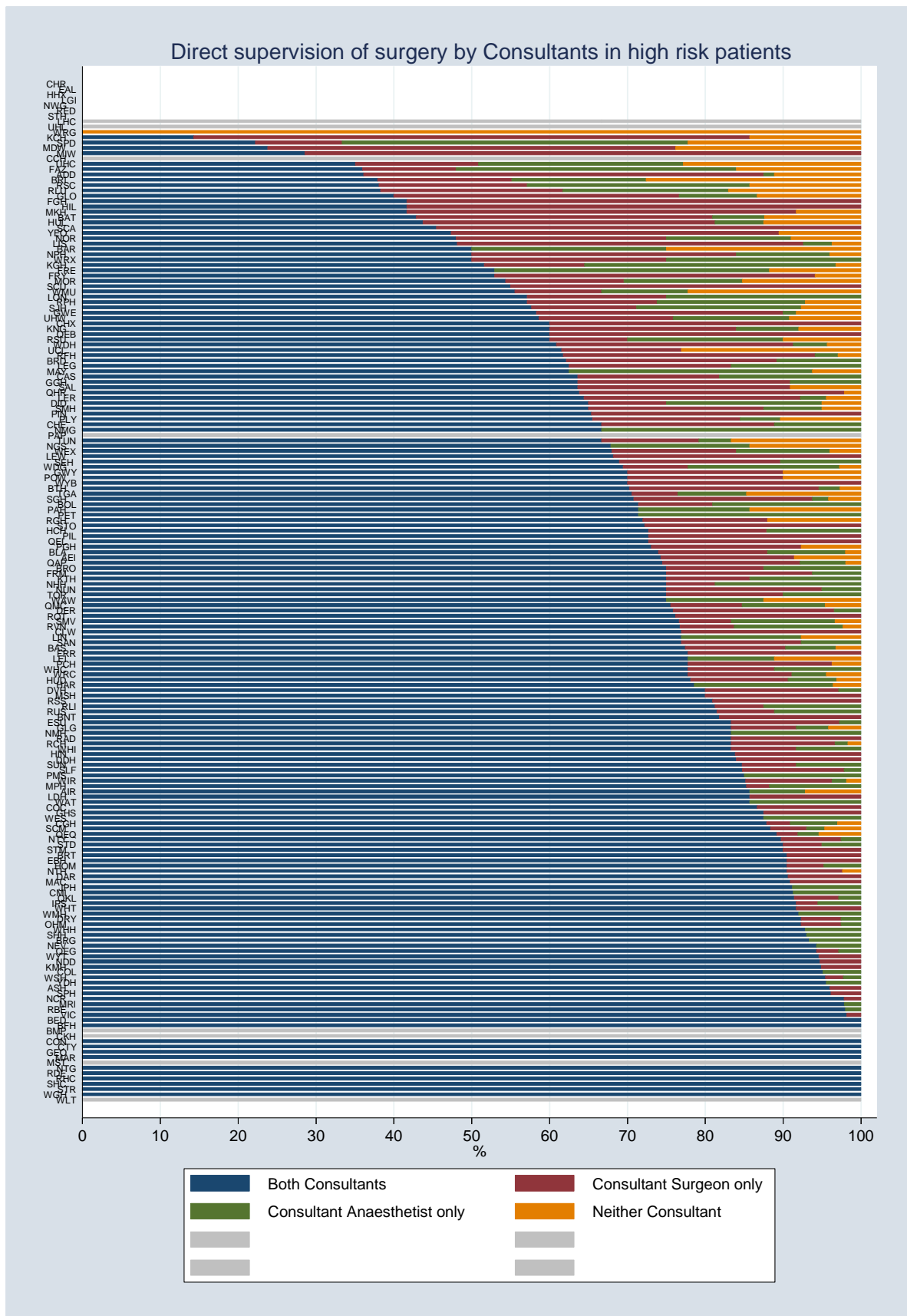


Figure 18 Highest (>10%) risk patients for whom surgery was directly supervised by a consultant surgeon and anaesthetist.
 (Grey bars indicate hospitals submitting fewer than ten cases)

Time of arrival in operating theatre	Monday-Friday			Saturday-Sunday		
	Both	Consultant surgeon	Consultant anaesthetist	Both	Consultant surgeon	Consultant anaesthetist
0800-1159	66%***	77%***	85%***	55%***	76%***	70%***
1200-1759	69%	80%	85%	57%	78%	72%
1800-2359	55%	70%	76%	43%	62%	66%
0000-0759	26%	39%	55%	26%	38%	54%
Overall	61%	73%	80%	50%	69%	68%

Table 66 Proportion of patients receiving input before surgery by consultant surgeons and consultant anaesthetists by time of day of arrival in theatre for emergency laparotomy (* p<0.05, **p≤0.005, ***p≤0.001)

	Patients	Both consultants present (%)	Consultant surgeon present (%)	Consultant anaesthetist present (%)	Neither consultant present (%)
Monday	2,510	67***	86***	75***	6***
Tuesday	3,027	70	87	78	6
Wednesday	3,154	68	83	78	7
Thursday	3,396	69	85	79	5
Friday	3,078	68	85	77	6
Saturday	2,565	56	83	64	9
Sunday	2,454	57	84	64	9
Overall	20,183	65%	84%	74%	7%

Table 67 Proportions of patients whose intraoperative care was directly supervised by consultant surgeons and consultant anaesthetists by day that surgery was commenced (* p<0.05, **p≤0.005, ***p≤0.001)

Time of arrival in operating theatre	Monday-Friday			Saturday-Sunday		
	Both	Consultant surgeon	Consultant anaesthetist	Both	Consultant surgeon	Consultant anaesthetist
0800-1159	76%***	87%***	86%***	62%***	89%***	67%***
1200-1759	75%	88%	84%	60%	85%	68%
1800-2359	61%	83%	70%	52%	80%	61%
0000-0759	41%	69%	49%	41%	71%	50%
Overall	69%	85%	78%	57%	83%	64%

Table 68 Proportion of patients whose care during surgery was directly supervised by consultant surgeons and consultant anaesthetists by time of day of arrival in operating theatre (* p<0.05, **p≤0.005, ***p≤0.001)

Goal directed fluid therapy

	Number of patients	Proportion of patients (%)		
		Cardiac output monitor	Other method	Overall
Overall	20183	37%	15%	52%
Age (years)				
18–39	2,188	27***	13***	40
40–49	1,939	33	15	48
50–59	2,707	35	13	48
60–69	4,197	37	15	52
70–79	5,084	40	15	55
80–89	3,537	40	16	56
≥90	531	37	19	56
ASA				
1	2,097	28 ***	11***	39
2	6,793	32	13	45
3	7,108	38	16	54
4	3,747	45	18	63
5	438	43	16	59
Admission type				
Emergency	18,693	36 NS	15 NS	51
Elective	1,490	37	15	52
Documented risk				
Lower	3,826	33***	12***	45
High	2,386	40	17	57
Highest	5,059	45	17	62
ND	8,912	32	14	46
Overall	20,183	37%	15%	52%

Table 69 Proportions of patients receiving goal directed fluid therapy and method of provision by descriptive patient characteristics

(* p<0.05, **p≤0.005, ***p≤0.001, ND: not documented, NS: not significant)

	Number of patients	Proportion of patients (%)		
		Cardiac output monitoring	Other method	Overall
<2hrs	1,976	41***	19***	60
2–6hrs	5,498	39	15	54
6–18 hrs	4,213	34	14	48
18–24 hrs	2,247	31	13	44
Overall	13,934	36%	15%	51%

Table 70 Proportions of patients receiving goal directed fluid therapy and method of provision by documented urgency of surgery

(* p<0.05, **p≤0.005, ***p≤0.001)

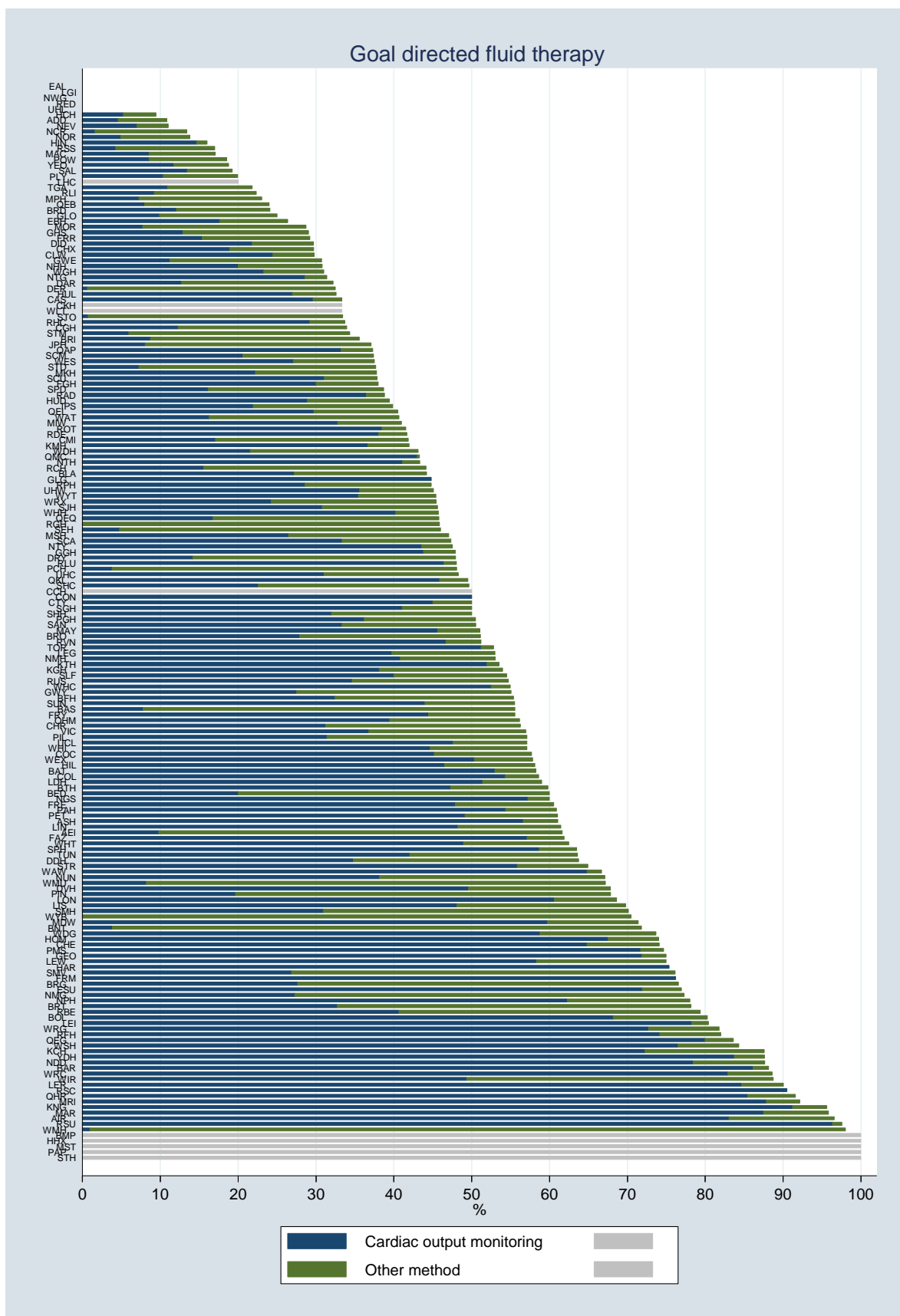


Figure 19 Patients for whom goal directed fluid therapy was used in theatre by hospital. (Grey bars indicate hospitals submitting fewer than ten cases)

Direct postoperative admission to critical care

	Number of patients	Proportion of patients directly admitted to a high dependency or intensive care bed after surgery (%)
Age (years)		
18–39	2,188	38***
40–49	1,939	47
50–59	2,707	51
60–69	4,197	61
70–79	5,084	68
80–89	3,537	72
≥90	531	70
ASA		
1	2,097	29***
2	6,793	43
3	7,108	67
4	3,747	90
5	438	97
Admission type		
Emergency	18,693	59 ***
Elective	1,490	72
Overall	20,183	60%

Table 71 Proportion of patients directly admitted to a high dependency or intensive care bed after surgery by patient characteristics
(* p<0.05, **p≤0.005, ***p≤0.001)

	Number of patients	Proportion of patients directly admitted to a high dependency or intensive care bed after surgery (%)
<2hrs	1,976	84 ***
2–6hrs	5,498	66
6–18 hrs	4,213	50
18–24 hrs	2,247	44
Overall	13,934	60%

Table 72 Proportion of patients directly admitted to a high dependency or intensive care bed after surgery by operative urgency
(* p<0.05, **p≤0.005, ***p≤0.001)

	Number of patients	Frequency (%)	Proportion of patients admitted directly to a high dependency or intensive care unit after surgery (%)
Preoperative documentation of risk			
Lower	3826	19	34 ***
High	2386	12	64
Highest	5059	25	89
Not documented	8912	44	53
Postoperative classification of risk			
Lower risk	8592	43	21 ***
Highest risk	11591	57	88
Overall	20183	100	60%

Table 73 Proportion of patients admitted directly to a critical care unit after surgery by assessment of risk (* p<0.05, **p≤0.005, ***p≤0.001)

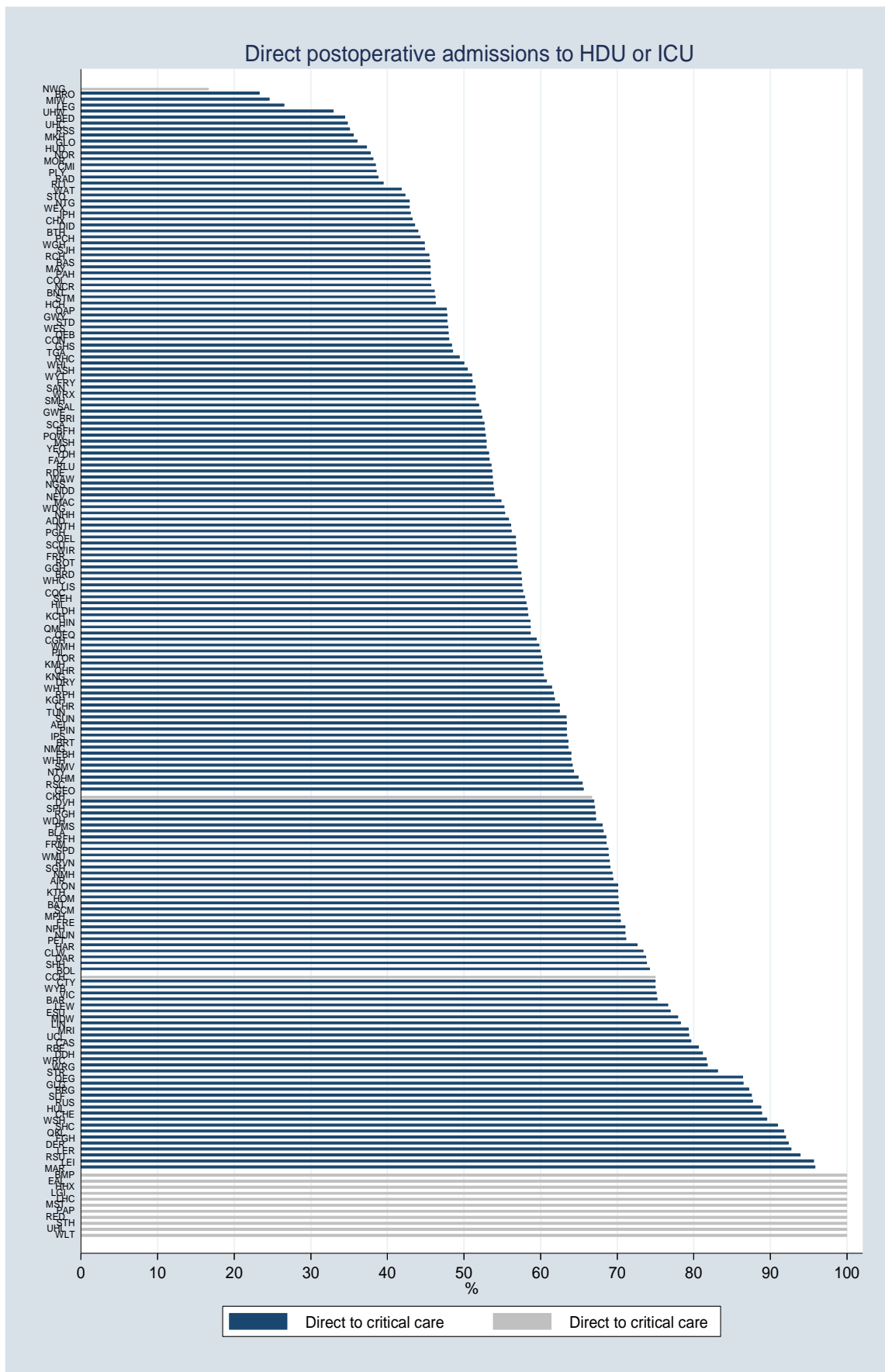


Figure 20 Patients admitted directly to a critical care unit following emergency laparotomy. (Grey bars indicate hospitals submitting fewer than ten cases)

Assessment by a medicine for the care of the older person

	Number of patients	Proportion of patients assessed after surgery by a MCOP Specialist (%)
ASA		
1	178	5 ***
2	2,380	6
3	3,998	11
4	2,325	13
5	215	6
Admission type		
Emergency	8,454	10*
Elective	642	8
Documented risk		
Lower	1,022	8***
High	1,254	11
Highest	3,154	13
Not documented	3,666	7
Overall	9,096	10%

Table 74 Proportion of patients over the age of 70 who were assessed after surgery by a Medicine for Care of the Older Person (MCOP) Specialist following emergency laparotomy by patient characteristics
(* p<0.05, **p≤0.005, ***p≤0.001)

	Number of patients	Proportion of patients assessed after surgery by a MCOP Specialist (%)
50-59	2,707	1***
60-69	4,197	3
70-79	5,084	7
80-89	3,537	13
≥90	531	21
Overall	15812	7%

Table 75 Proportion of patients assessed after surgery by a Medicine for Care of the Older Person (MCOP) Specialist following emergency laparotomy by patient age
(* p<0.05, **p≤0.005, ***p≤0.001)

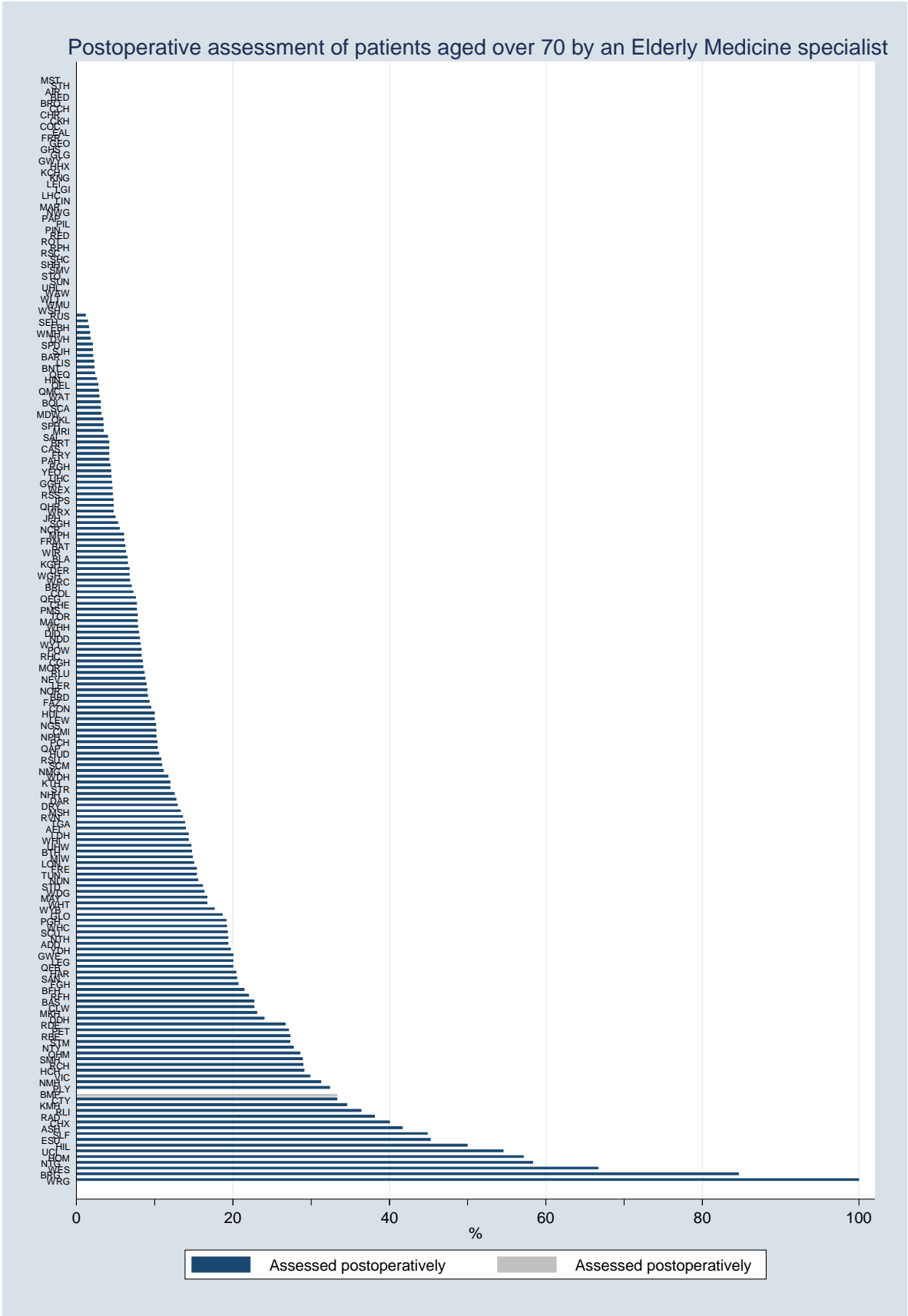


Figure 22 Older patients (>70 years) assessed by an MCOP physician after surgery, by hospital. (Grey bars indicate hospitals submitting fewer than ten cases)

5.3.6 Associations between the delivery of processes of care and hospital characteristics and structural provisions

Hospital size (quartile of bed number)

Process	Quartile 1	Quartile 2	Quartile 3	Quartile 4
Reviewed within 12 hours of admission by a consultant surgeon	45 (38-54)	50 (36-59)	47 (38-54)	46 (41-55) NS
CT performed preoperatively	83 (77-87)	81 (76-84)	81 (74-86)	82 (77-84) NS
CT reported preoperatively by a consultant radiologist	78 (66-82)	72 (61-80)	75 (65-80)	62 (55-70)*
Preoperative documentation of risk	59 (38-77)	49 (30-65)	60 (45-79)	54 (42-67) NS
Decision to operate was made in person by a consultant surgeon	75 (55-88)	74 (65-81)	76 (67-81)	72 (64-81) NS
Patients reviewed before surgery by a consultant anaesthetist	85 (69-97)	78 (61-89)	83 (67-94)	80 (67-90) NS
Intraoperative care directly supervised by consultant surgeon and consultant anaesthetist	71 (53-82)	65 (50-77)	67 (51-82)	66 (56-82) NS
Patients for whom GDFT was used	53 (38-70)	48 (34-70)	56 (42-69)	49 (37-61) NS
Direct postoperative critical care admission	67 (57-81)	56 (48-75)	60 (51-70)	57 (47-70) NS
Direct postoperative critical care admission of highest risk patients	91 (85-96)	88 (84-96)	91 (81-95)	88 (80-94) NS
Postoperative review by MCOP physician for older (>70 years) patients	12 (0-20)	7 (2-12)	8 (4-20)	9 (3-15) NS

Table 76 Process delivery by hospital size

Reported as median (IQR) hospital-level delivery of process. Quartile 1: fewest beds, Quartile 4: most beds, highest risk: preoperatively documented $\geq 10\%$ risk of death. * $p' < 0.05$, ** $p' \leq 0.005$, *** $p' \leq 0.001$, NS: non-significant. CT: computed tomography, GDFT: goal directed fluid therapy, MCOP: medicine for the care of the older person

Tertiary GI surgical referral centre status

Processes of care	Tertiary GI surgical referral centre	Other hospitals
Reviewed within 12 hours of admission by a consultant surgeon	45 (37-54)	48 (39-56) NS
CT performed preoperatively	81 (77-84)	81 (77-86) NS
CT reported preoperatively by a consultant radiologist	63 (55-73)	77 (66-82)***
Preoperative documentation of risk	52 (39-67)	58 (39-73) NS
Decision to operate was made in person by a consultant surgeon	69 (60-79)	76 (69-83) NS
Patients reviewed before surgery by a consultant anaesthetist	76 (67-89)	85 (69-94) NS
Intraoperative care directly supervised by consultant surgeon and consultant anaesthetist	61 (47-74)	71 (55-83) NS
Patients for whom GDFT was used	48 (34-68)	53 (39-68) NS
Direct postoperative critical care admission	59 (51-70)	60 (50-73) NS
Direct postoperative critical care admission of highest risk patients	88 (83-95)	91 (84-95) NS
Postoperative review by MCOP physician for older (>70 years) patients	9 (2-15)	8 (2-19) NS

Table 77 Process delivery by referral centre status

Reported as median (IQR) hospital-level delivery of process. Highest risk: preoperatively documented $\geq 10\%$ risk of death, * $p < 0.05$, ** $p \leq 0.005$, *** $p \leq 0.001$, NS: non-significant. GI: gastrointestinal, CT: computed tomography, GDFT: goal directed fluid therapy, MCOP: medicine for the care of the older person

Hospital configuration to admit EGS patients

Processes of care	Hospitals configured to admit EGS patients	Hospitals not configured to admit EGS patients
Reviewed within 12 hours of admission by a consultant surgeon	47 (39-55)	18 (0-43)*
CT performed preoperatively	81 (77-100)	81 (75-100) NS
CT reported preoperatively by a consultant radiologist	71 (62-80)	67 (40-80) NS
Preoperative documentation of risk	54 (41-70)	49 (33-100) NS
Decision to operate was made in person by a consultant surgeon	75 (66-82)	50 (40-78) NS
Patients reviewed before surgery by a consultant anaesthetist	81 (67-92)	100 (67-100) NS
Intraoperative care directly supervised by consultant surgeon and consultant anaesthetist	67 (53-81)	60 (38-100) NS
Patients for whom GDFT was used	50 (38-67)	58 (33-100) NS
Direct postoperative critical care admission	56 (48-70)	98 (70-100)***
Direct postoperative critical care admission of highest risk patients	90 (83-95)	100 (93-100)**
Postoperative review by MCOP physician for older (>70 years) patients	8 (3-19)	0 (0-4) NS

Table 78 Process delivery by configuration to admit patients

Reported as median (IQR) hospital-level delivery of process. Highest risk: preoperatively documented $\geq 10\%$ risk of death, * $p < 0.05$, ** $p \leq 0.005$, *** $p \leq 0.001$, NS: non-significant. EGS: emergency general surgery, CT: computed tomography, GDFT: goal directed fluid therapy, MCOP: medicine for the care of the older person

5.4 Discussion

Key points

- This cohort of 20,183 patients represents the largest prospectively identified population of emergency laparotomy patients to date
- The patients comprising this cohort were markedly heterogeneous and large high-risk subpopulations were identified
- Risk profiling using P-POSSUM suggested considerable between-hospital casemix variation
- Markedly fewer patients underwent surgery overnight than during 'daylight hours'. These patients were at significantly higher risk of death than their counterparts
- The overall incidence of inpatient 30-day mortality was 11.3%. This incidence may be lower than in previously reported series due to methodological differences, or may represent a genuine reduction in overall mortality after emergency laparotomy
- As in previous studies, substantial variation in postoperative mortality rates was observed between patient groups, when defined by patient characteristics and surgical pathologies
- Marked variation was observed in the delivery of processes of care; characterised by markers of preoperative patient-level risk; but not characterised by hospital characteristics
- Crude mortality was substantially increased in older patients (>70 years), who comprised almost half of the cohort. However, involvement of MCOP physicians in the care of these patients was universally poor. The findings of the Organisational Audit indicate that structural provisions may currently be inadequate

5.4.1 Overview

Emergency laparotomies are frequently performed for potentially life-threatening pathologies and while postoperative mortality and morbidity within a month of surgery are common overall,^{2, 9-13, 89} substantial variation has been indicated between patient groups^{2, 6, 9, 10, 23, 26, 28-33} and between healthcare providers.^{2, 9, 36}

These observations of variation offer opportunities for improving patient outcomes and standards of care received by patients undergoing emergency laparotomies. Modelling of between-hospital outcome variation suggests that, having modelled patient-level risk, residual variation may be explained by differences in hospital-level factors and chance.^{40, 44} It is therefore anticipated that the identification of associations may provide targets for quality improvement strategies in emergency laparotomy populations.²⁷

However, relationships between organisational factors and patient outcomes represent multiple simultaneous exposures across multiple hierarchical levels and remain poorly defined in emergency general surgical (EGS) populations. The National Emergency Laparotomy Audit (NELA) was established to address the lack of systematically collected hospital-level and patient-level data in emergency laparotomy cohorts.

My analysis of the first NELA organisational audit dataset in *Chapter 3* identified substantial between-hospital variation in the provision of organisational EGS structures. In this Chapter I report baseline patient characteristics, crude mortality rates, the delivery of key processes of care and temporal variations in surgery in the NELA year 1 patient audit cohort, before identifying associations between variations in the delivery of processes of care and hospital-level (characteristics and structural provisions) factors.

In subsequent Chapters I will go on to evaluate the evidence for between-hospital variation in postoperative mortality and identify processes of care associated with variation in mortality in this cohort of patients.

5.4.2 Population characteristics

Marked heterogeneity was observed among the patients comprising the NELA year 1 patient audit cohort with regard to markers of risk, pathologies and surgical events precipitating surgery and procedures performed (Appendix 5.4).

The cohort comprised roughly equal proportions of males and females and most patients were admitted emergently (93%) and underwent a primary surgical procedure (89%), rather than for the complications of recent surgery (Table 39).

Several markers indicated that a substantial proportion of this population were at high risk of postoperative mortality:

- ASA-PS 3-5: 56%. The ASA-PS has been consistently validated as a marker of preoperative health status,¹⁴⁷ incorporating measures of comorbidity and frailty, both of which are associated with increased morbidity and mortality
- Surgery within 2-6 hours: 53%. Operative urgency is a subjective marker of the severity of the pathology and resulting systemic compromise precipitating the need for an emergency laparotomy
- Median age: 67 years. Increasing age may be associated with reduction in physiological reserve and increased prevalence of multi-morbidity and frailty syndromes,¹⁴⁸ resulting in reduced ability to compensate for the physiological stresses of surgery and anaesthesia, and increased overall incidence of postoperative morbidity and mortality^{25, 149}
- >10% P-POSSUM predicted 30-day mortality risk: 44%. More conservative Standards of care identify high risk patients as those at greater than 10% risk of death.⁷⁴ P-POSSUM was identified as one of the better validated risk assessment tools in the systematic review (*Chapter 4*)¹⁵⁰

Furthermore, plotting of the distribution of high risk patients (in the highest quintile (>35%) of P-POSSUM predicted risk) by hospital indicated that casemix varied substantially between participating hospitals (Figure 11).

5.4.3 Mortality after emergency laparotomy

Inpatient 30-day mortality following emergency laparotomy was 11.3% in this heterogeneous cohort, supporting other observations of high short-term postoperative mortality in contemporary series.^{2, 9-13} However, 30-day mortality estimates were somewhat higher (13-18%) in these studies than in the NELA year 1 patient cohort. These apparent disparities may represent genuine improvements in quality of care and postoperative survival, but heterogeneity of study design, endpoint selection or patient populations and healthcare systems should be considered.

However, while overall mortality rates compare favourably, it should be noted that crude mortality rates remain substantially elevated in older patients and these findings indicate that they have not reduced appreciably in recent decades.^{69, 149, 151}

5.4.4 Delivery of processes of care

In total, eight perioperative process domains are reported in these analyses, including; preoperative review, imaging and risk assessment; operative procedure, intraoperative consultant supervision and use of cardiac output monitoring; and postoperative admission to critical care and review by a medicine for the care of the older person (MCOP) physician.

No process was delivered universally, to every patient at every hospital, instead marked variation was observed; firstly, between processes of care, some were delivered far more comprehensively than others (86% of all patients arrived in theatre in a timely manner, whereas only 10% of older patients were reviewed postoperatively by an MCOP physician); secondly, between patient groups; thirdly, between hospitals there was substantial variation in the delivery of many processes of care; and finally, temporal variations were observed in some processes of care.

Variation by patient characteristics

The delivery of many processes of care was observed to vary between patient subgroups, defined by category of preoperative risk, patient age and operative urgency in the NELA year 1 patient audit dataset.

Older patients

Increasing age is associated with reduction in physiological reserve and increased prevalence of multi-morbidity and frailty syndromes.¹⁴⁸ These factors may result in reduced ability to compensate for the physiological stresses of surgery and anaesthesia, increasing the likelihood of postoperative morbidity and mortality.^{25, 149}

Almost half of the patients comprising the NELA year 1 patient audit cohort were over-70 years of age (Figure 10) and while overall rates in the NELA year 1 patient audit cohort compared favourably with contemporary series, mortality remained substantially elevated in older patients (Table 47) indicating that it may not have decreased appreciably in recent decades.^{69, 149, 151}

However, while there is accumulating evidence that perioperative MCOP input is associated with improved outcomes in frail and older patients in other surgical settings,^{152, 153} in this cohort only 10% of patients over-70 years of age and 21% of patients over-90 years of age were reviewed by MCOP in the postoperative period (Table 75) and variation was observed at hospital level (Figure 22).

More comprehensive delivery of MCOP input into the care of older and frail patients therefore has the potential to realise substantial quality, outcome and financial gains. Analysis of the first NELA organisational audit dataset (*Chapter 3*) suggests that provisions were insufficient and delivery of this process might be improved by formalisation of multidisciplinary teams incorporating MCOP staff.

Preoperative categorisation of risk

The delivery of perioperative consultant-led care, intraoperative goal directed fluid therapy (GDFT) and postoperative critical care admission were observed to be most comprehensive in the highest risk patients, whether defined by age, operative urgency, ASA-PS grade or documented risk (Table 62, Table 64, Table 69, Table 71 and Table 72).

Standards for consultant-led care and critical care bed utilisation are informed by consensus opinion that higher risk patients benefit from these processes of care,^{21, 70-75} and clinical trial data indicate that GDFT may confer the greatest benefit in higher risk patients.^{154, 155}

Risk of death should be estimated and documented for all patients and used to inform shared decision making and treatment decisions,⁷⁵ however it was not documented for 44% of patients (Table 57). Assessment against other indices indicate that risk was more comprehensively documented in higher risk patient subgroups (Table 57 and Table 58), but comparison of P-POSSUM estimated 30-day mortality estimates demonstrated that the risk

profile of patients for whom risk had not been documented was not statistically different to the group of high risk patients (Table 59). It is therefore notable that many processes were least comprehensively delivered to the large minority (44%) of moderate-risk patients (median P-POSSUM predicted risk of 30-day mortality 7%) for whom risk was not documented preoperatively.

Prompt decision making and delivery of treatment

Prompt diagnosis, decision making and treatment are fundamental to high quality care in emergency laparotomy and survival may be improved if delays can be minimised.⁴⁷ It is therefore notable that preoperative CT reporting was least comprehensive in the group of patients requiring surgery within 2 hours (Table 56). Patients are rarely so clinically unstable that the risks of temporarily delaying surgery outweigh the benefits of greater information.⁸⁹

Hospital-level variation

Of the eight assessed domains, no process of care was delivered to every patient at every hospital and substantial between-hospital variation was observed in the proportion of patients receiving each process.

As reported above, delivery of processes of care varied between patient groups and substantial between-hospital casemix variation was observed (Figure 11). Some of the observed variation in the comprehensiveness of the delivery of processes of care may therefore be attributable to population differences between hospitals; however, many processes should be delivered to every patient and systematic differences are assumed to underlie some of this variation. This is explored further in the next section.

5.4.5 Associations between hospital-level delivery of processes of care and organisational characteristics

Structural provisions underpin the delivery of processes of care⁴⁰ and the comprehensiveness with which structures were provided was demonstrated to be associated with hospital characteristics in *Chapter 3*. However, the influence of competition for resources on the availability of these structures for individual patients is uncertain. Associations between hospital-level delivery of the identified processes of care was therefore assessed against hospital characteristics in order to test these associations.

The findings of the organisational audit indicated that emergency general surgery (EGS) provisions were more comprehensive at large hospitals and tertiary GI surgical referral centres and less comprehensive at hospitals that were not configured to admit EGS patients.

The analyses presented in this Chapter indicate that many processes were less comprehensively delivered at the largest hospitals and at tertiary GI surgical referral centres and no less comprehensively delivered to the small number of patients at hospitals that were not configured to admit EGS patients.

Taken together, these analyses therefore suggest that the delivery of these processes of care is not predicted by the provision of the various structures assessed in the organisational audit. As I discussed in *Chapter 3*, the potential for greater competition for resources at large hospitals may therefore mean that more comprehensive provision of EGS structures does not translate into more comprehensive delivery of these processes of care.

With regard to structural provisions, the analyses reported in this Chapter indicate that the delivery of individual processes of care was associated with the provision of structures that directly underpin them.

Hospital size

Delivery of many of the assessed processes of care varied by hospital size: and where variation was observed, many processes were least comprehensively delivered at the largest hospitals.

Perioperative processes of care were less frequently led by a consultant surgeon at the largest hospitals, fewer CT scans were reported contemporaneously and a lower proportion of patients were admitted directly to a critical care unit postoperatively. Conversely, only cardiac output monitoring (COM) to guide goal-directed fluid therapy (GDFT) was less comprehensively delivered at the smallest hospitals.

Notably, in patients identified by participants as being at high risk of death, direct postoperative admission to a critical care unit did not vary by hospital size.

These findings suggest that at larger hospitals, where competition for resources is greatest, provision of key processes of care to emergency laparotomy patients may be least comprehensive. However, where individual risk of death at the end of surgery is used to inform postoperative clinical decisions, high-risk patients are prioritised at all hospitals.

Supervision of surgery in high-risk patients by a consultant surgeon was high overall (89%), but in the context of these findings, it is notable that variation by hospital size was also observed in the high-risk patient group, suggesting that the care of these patients may not be prioritised in the same way as allocation of critical care beds. There are of course many possible explanations for this observed variation, including greater provision of higher surgical trainees at larger hospitals; however the observation of infrequent documentation of preoperative risk suggests that risk may be used less frequently to inform perioperative processes of care.

Configuration to admit emergency general surgical patients

Little variation in the delivery of key processes of care was observed on the basis of configuration to admit EGS patients Table 78 and statistical testing was limited by the small sample size.

It is notable that while no significant variation was observed across the spectrum of preoperatively documented risk, supervision of surgery in high-risk patients by a consultant surgeon was substantially less frequent at hospitals not configured to admit EGS patients. These are predominantly small, subspecialty hospitals (*Chapter 3*) and the causes underlying this variation may be expected to differ from those observed by hospital size. If the absence of a consultant surgeon is determined to be associated with greater mortality risk, this finding will warrant further exploration.

While GDFT was more frequently provided at hospitals not configured to admit EGS patients, the use of COM to guide GDFT was significantly less comprehensive. This may reflect greater use of other techniques to guide perioperative fluid therapy at these subspecialty hospitals.

Tertiary Gastrointestinal surgical referral centres

The findings of the Organisational Audit suggested that the provision of some hospital structures for emergency laparotomy was more comprehensive at hospitals that were identified as tertiary gastrointestinal (GI) surgical referral centres.

The findings that almost of the assessed processes of care were substantially less comprehensively delivered at these centres (Table 77) is therefore significant, challenging assumptions that services are better configured for the care of EGS patients at these centres.

Tertiary GI surgical referral centres were determined to be large hospitals in the Organisational Audit and it may therefore be that problems of increased competition for resources at these hospitals underlie these observed variations in the delivery of key processes of care. However, the findings of the Organisational Audit also indicated that the provision of an emergency surgical unit (ESU) was not associated with Tertiary GI surgical referral centre status, suggesting that while these centres are configured for complex elective GI surgical patients, structures for EGS patients are not more comprehensively provided.

5.5 Limitations

The findings of the analyses reported in this Chapter should be interpreted in the context of the following limitations of the NELA datasets.

While levels of engagement were extremely high, three of the 195 identified hospitals submitted no data to the audit. Analyses of postoperative mortality and provisions for EGS may therefore not be generalisable to these hospitals.

Overall levels of completeness were high; however it is notable that some non-mandatory items (including time of decision to operate, time of booking for theatre and preoperative serum lactate concentration) were missing in a large proportion of cases, precluding analysis of these data.

Assessments of provisions by operative urgency category were limited by the exclusion of 31% from subgroup analyses as a result of changes to operative urgency definitions during the course of data collection.

Several potential limitations of the data acquisition process may have consequences for the preoperative estimates of patient-level risk reported throughout this Chapter.

Firstly, individual POSSUM items were missing in 0.2-1.5% of submitted records. It is not known whether these items were missing completely at random (MCAR) or due to systematic causes. Furthermore, while the assigning of scores to missing POSSUM items has been reported previously, this approach may have substantially underestimated risk in these patients.

Secondly, time (relative to surgery) was not specified for many data items. This is of particular relevance to preoperative variables used to assess patient-level risk, since data within normal physiological and biochemical parameters might equally reflect either lower risk or the consequences of good preoperative care. These distinctions may have considerable implications for identification of casemix variation, comparisons of casemix adjusted outcomes and assessments of quality of care.

Finally, retrospective entry of data items has the potential to have introduced bias, again of particular relevance to preoperative risk estimation, since data entry may have been influenced by knowledge of a patient's perioperative and postoperative course and outcome.

Finally, analyses of associations between organisational (hospital characteristics and structures) variables and patient-level (processes of care and patient outcomes) variables should be interpreted with a degree of caution; firstly, since reconfiguration of services may

have occurred in the intervening period between the NELA organisational audit and the NELA patient audit; and secondly, because no organisational data were available for two hospitals participating in the patient audit.

5.6 Conclusions

Baseline analysis of population characteristics, delivery of processes of care and inpatient 30-day mortality in the largest prospectively identified population of emergency laparotomy patients reveal interesting new insights.

While overall inpatient 30-day mortality was lower than in other recent series, variation in crude mortality rates was observed between patient groups, consistent with previous findings, with substantially increased mortality in older patients, those with limiting comorbidities and individuals requiring urgent surgery.

The cohort was observed to be markedly heterogeneous with respect to patient characteristics, underlying pathologies and markers of preoperative risk. Furthermore, P-POSSUM risk profiling indicated substantial between-hospital casemix heterogeneity.

And while delivery of perioperative processes of care varied markedly between patient groups and between participating hospitals, in contrast with structural provisions (*Chapter 3*) variation was not characterised by hospital size, tertiary GI surgical referral centre status or configuration to admit EGS patients.

In subsequent Chapters I will develop the themes of this and preceding Chapters in order to; determine the magnitude of casemix adjusted hospital mortality rates; and identify potentially modifiable processes of care associated with variation in postoperative mortality in the NELA year 1 patient audit; before incorporating the findings of the first NELA organisational audit in order to identify principal determinants of variation in patient outcomes after emergency laparotomy.

Appendix 5.1 NELA year 1 patient audit inclusion criteria

Inclusion Criteria[‡]

NELA will enrol the patients treated in England or Wales who meet the following criteria:

aged 18 years and over,
have an NHS number
who undergo an expedited, urgent or emergency (NCEPOD definitions) abdominal procedure on the gastrointestinal tract.

This will include:

Open, laparoscopic, or laparoscopically-assisted procedures
Procedures involving the stomach, small or large bowel, or rectum for conditions such as perforation, ischaemia, abdominal abscess, bleeding or obstruction
Washout/evacuation of intra-peritoneal abscess (unless due to appendicitis or cholecystitis - excluded, see below)
Washout/evacuation of intra-peritoneal haematoma
Bowel resection/repair due to incarcerated umbilical, inguinal and femoral hernias (but not hernia repair without bowel resection/repair)
Bowel resection/repair due to obstructing/incarcerated incisional hernias provided the presentation and findings were acute
Laparotomy/laparoscopy with inoperable pathology (e.g. peritoneal/hepatic metastases)
Laparoscopic/Open Adhesiolysis
Return to theatre for repair of substantial dehiscence of major abdominal wound (i.e. "burst abdomen")
Any reoperation/return to theatre meeting the criteria above is included, such as;

- patients returning to theatre for ischaemic bowel following elective or emergency aortic aneurysm surgery, or for ischaemic bowel following cardiac surgery
- patients requiring non-elective GI surgery following prior gynaecological surgery

If multiple procedures are performed on different anatomical sites within the abdominal/pelvic cavity, the patient would be included if the major procedure is general surgical. E.g.

Non-elective colonic resection with hysterectomy for a fistulating colonic cancer would be included as the bowel resection is the major procedure

However bowel resection at the same time as emergency abdominal aortic aneurysm repair would not be included as the aneurysm repair is the major procedure

Any reoperation/return to theatre meeting the criteria above is included, such as;

- patients returning to theatre for ischaemic bowel following elective or emergency aortic aneurysm surgery, or for ischaemic bowel following cardiac surgery

[‡] Downloaded from <http://www.nela.org.uk/Criteria> on 14th October 2015

- patients requiring any of the above non-elective GI procedures following prior gynaecological surgery
- patients returning to theatre for post-operative complications (e.g. bleeding, sepsis) following prior urological/renal surgery (except transplant)
- patients requiring any of the above non-elective GI procedures as a return to theatre following any other elective or emergency procedure (even if the original procedure would have been excluded)

NELA Exclusion Criteria

Patients with the following characteristics will be excluded from NELA:

1. Patients under 18
2. Do not have an NHS number
3. Elective laparotomy / laparoscopy
4. Diagnostic laparotomy/laparoscopy where no subsequent procedure is performed (NB, if no procedure is performed because of inoperable pathology, then include)
5. Appendicectomy +/- drainage of localised collection unless the procedure is incidental to a non-elective procedure on the GI tract
6. Cholecystectomy +/- drainage of localised collection unless the procedure is incidental to a non-elective procedure on the GI tract (All surgery involving the appendix or gallbladder, including any surgery relating to complications such as abscess or bile leak is excluded. The only exception to this is if carried out as an incidental procedure to a more major procedure. We acknowledge that there might be extreme cases of peritoneal contamination, but total exclusion avoids subjective judgement calls about severity of contamination.)
7. Non-elective hernia repair without bowel resection
8. Minor abdominal wound dehiscence unless this causes bowel complications requiring resection
9. Vascular surgery, including abdominal aortic aneurysm repair (NB: resection of ischaemic bowel as a separate visit to theatre following abdominal aortic aneurysm repair is included)
10. Caesarean section or obstetric laparotomies
11. Gynaecological laparotomy (However bowel resection performed as a non-elective procedure for obstruction due to gynaecological cancer would be included)
12. Ruptured ectopic pregnancy, or pelvic abscesses due to pelvic inflammatory disease
13. Laparotomy/laparoscopy for pathology caused by blunt or penetrating trauma
14. All surgery relating to organ transplantation (including returns to theatre for any reason following transplant surgery)
15. Surgery relating to sclerosing peritonitis
16. Surgery for removal of dialysis catheters
17. Laparotomy/laparoscopy for oesophageal pathology
18. Laparotomy/laparoscopy for pathology of the spleen, renal tract, kidneys, liver, gall bladder and biliary tree, pancreas or urinary tract

Appendix 5.2: The NELA patient audit questionnaire

1.	Demographics and Admission	
1.1	NHS Number	
1.2	Pseudo-anonymisation	
1.3	Local patient id/hospital number	
1.4	Date of birth	
1.4	Age on arrival	
1.5	Gender	
1.6	Forename	
1.7	Surname	
1.8	Postcode	
1.9	Date and time patient admitted to this hospital	
1.10	What was the nature of this admission?	
2	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/referral	Date _____(DD/MM/YYYY) Date not known Time _____(HH:MM) Time not known Not Seen
2.2	Date and time that the decision was made to operate If this is unavailable please enter date and time that this patient was first booked for theatre for emergency laparotomy	Date _____(DD/MM/YYYY) Date not known Time _____(HH:MM) Time not known
2.2i	Which date and time is recorded?	Decision to operate First booked for theatre
2.3	Consultant responsible for surgical care at the time the decision was made to operate (this may be different to the operating consultant)	
2.4	What was the grade of the most senior person making the decision to operate?	Consultant Post-CCT non consultant SAS grade Research Fellow / Clinical Fellow Specialty trainee / registrar Core trainee / SHO Other _____ Unknown
2.5	Did this clinician personally review the patient at the time of this decision?	No Yes Unknown
2.6	What was the date and time that the patient was first booked for theatre? NOT REQUIRED FOR ADMISSIONS AFTER 1/12/14	Date _____(DD/MM/YYYY) Date not known Time _____(HH:MM) Time not known

2.7	Was an abdominal CT scan performed in the pre-operative period as part of the diagnostic work-up?	No Yes Unknown
2.8	If performed, was this CT reported pre-operatively by a consultant radiologist?	No Yes Unknown
2.9	Date and time first seen by consultant anaesthetist prior to entry into operating theatre/anaesthetic room (not theatre suite)	Date _____ (DD/MM/YYYY) Date not known Time _____ (HH:MM) Time not known Not Seen
2.10	What was the date and time of the first dose of antibiotics following admission?	Date _____ (DD/MM/YYYY) Date not known Time _____ (HH:MM) Time not known Not Administered
3	Pre-op Risk stratification	
3.1	What risk of death was the patient documented as having?	low (<5%) medium (5-10%) high (>10%) Not documented
3.2	If documented, how was this assessment of risk made? (Please select all that apply)	<input type="checkbox"/> Risk prediction tool (e.g. P-POSSUM) <input type="checkbox"/> Clinical Judgement <input type="checkbox"/> Surgical APGAR <input type="checkbox"/> Physiological criteria <input type="checkbox"/> Other e.g. hospital policy
3.3	What was the ASA score?	1: No systemic disease 2: Mild systemic disease 3: Severe systemic disease, not life-threatening 4: Severe, life-threatening 5: Moribund patient
3.4	What was the pre-operative Serum Creatinine micromol/l	performed <input type="radio"/> Not
3.5	What was the pre-operative Blood lactate – may be arterial or venous (mmol/l)	performed <input type="radio"/> Not
	P-POSSUM calculation	
	For questions 3.6 to 3.22 please enter values closest to time of booking for theatre in order to calculate P-POSSUM. Answers should reflect chronic and acute pathophysiology.	
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 ($\times 10^9 / l$)	
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 AF rate 60-90 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 Diuretic, digoxin, antianginal or antihypertensive therapy
		Peripheral oedema, warfarin Therapy or CXR: borderline cardiomegaly 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 Dyspnoea on exertion or CXR: mild COAD Dyspnoea limiting exertion to < 1 Flight or CXR: moderate COAD Dyspnoea at rest/rate > 30 at rest or CXR: fibrosis or consolidation
3.17	Select the operative severity of the intended surgical intervention (see help box for examples)	Major Major+
3.18	Including this operation, how many operations has the patient had in the 30 day period prior to this procedure?	1 2 >2
3.19	Based on your clinical experience of the intended surgery, please estimate the likely intraoperative blood loss (ml)	<100 ○101-500 501-999 ≥1000
3.20	Please select a value that best describes the likely degree of peritoneal soiling	None Serous fluid Localised pus Free bowel content, pus or blood
3.21	What severity of malignancy is anticipated to be present?	None Primary only Nodal metastases Distant metastases
3.22	Please select urgency of surgical intervention (see help notes for additional information, including equivalent Possum categories)	3. Expedited (>18 hours) 2B. Urgent (6-18 hours) 2A. Urgent (2-6 hours) 1. Immediate (<2 hours)
3.23	Pre-op P-POSSUM predicted mortality	Calculated
3.24	Pre-op POSSUM predicted morbidity	Calculated
3.25	Not all P-POSSUM investigations available	
4	Intra-op	
4.1	Date and time of entry in to operating theatre/anaesthetic room (not theatre suite)	Date _____ (DD/MM/YYYY) Time _____ (HH:MM) <input type="checkbox"/> Time not known
4.2	Senior surgeon grade	Consultant Post-CCT fellow SAS grade

		Research Fellow / Clinical Fellow Specialty trainee / registrar Core trainee / SHO Other
4.3	Senior anaesthetist grade	Consultant Post-CCT fellow SAS grade Research Fellow / Clinical Fellow Specialty trainee / registrar Core trainee / SHO Other
4.4	How did you provide goal directed fluid therapy?	Not provided Cardiac output monitor 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 Surgery for complication of 0 previous surgical procedure within the same admission
5.2	What is the indication for surgery? (Please select all that apply)	Peritonitis Perforation Abdominal abscess Anastomotic leak Intestinal fistula Sepsis (other) Intestinal obstruction Haemorrhage Ischaemia Colitis Abdominal wound dehiscence Abdominal compartment syndrome Planned relook Other (Please give details)
5.3.a	Main procedure	Peptic ulcer – suture or repair of perforation
5.3.b	Second procedure (at same laparotomy)	Peptic ulcer – oversew of bleed Gastric surgery - other Small bowel resection
5.3.c	Third procedure (at same laparotomy)	Colectomy: left (including anterior resection)
5.3.d	Fourth procedure (at same laparotomy)	Colectomy: right Colectomy: subtotal Hartmann's procedure Colorectal resection - other Abdominal wall closure Adhesiolysis Drainage of abscess/collection Exploratory/relook laparotomy only Haemostasis Intestinal bypass Laparostomy formation Repair of intestinal perforation Resection of other intra-abdominal tumour(s) Stoma formation

		Stoma revision Washout only Not amenable to surgery Other (please specify)
5.4	Procedure approach	<input type="radio"/> Open <input type="radio"/> Laparoscopic
		Laparoscopic assisted Laparoscopic converted to open
5.5	Operative findings: (Please select all that apply) If unsure whether this patient is eligible for NELA please refer to help box	Abscess Adhesions Anastomotic leak Colitis Crohn's disease Abdominal compartment syndrome Diverticulitis Haemorrhage – peptic ulcer Haemorrhage – intestinal Haemorrhage – postoperative Incarcerated hernia Intestinal ischaemia Malignancy – localised Malignancy – disseminated Perforation – peptic ulcer Perforation – small bowel/colonic Volvulus Normal intra-abdominal findings Other (please specify)
5.6	Please describe the peritoneal contamination present (select all that apply)	None or reactive serous fluid only <input type="radio"/> Free gas from perforation +/- minimal contamination Pus Bile Gastro-duodenal contents Small bowel contents Faeculent fluid Faeces Blood/haematoma
5.7	Please indicate if the contamination was;	Localised to a single quadrant of the abdomen More extensive / generalised
6	Post-op Risk stratification	
6.1	Was the patient classified as high risk at the end of surgery?	<input type="radio"/> No <input type="radio"/> Yes
6.2	How was this assessment of risk made? (Please select all that apply)	<input type="checkbox"/> Risk prediction tool (e.g. P-POSSUM) <input type="checkbox"/> Clinical Judgement <input type="checkbox"/> Surgical APGAR score <input type="checkbox"/> Physiological criteria <input type="checkbox"/> Other, e.g. hospital policy
6.3	Blood lactate – may be arterial or venous (mmol/l)	<input type="checkbox"/> Not performed
6.4	Serum Sodium concentration (mmol/l)	
6.5	Serum Potassium (mmol/l)	
6.6	Serum Urea (mmol/l)	

6.7	Haemoglobin concentration in g/dl	
6.8	White cell count (x10 ⁹ /l)	
6.9	Pulse rate (bpm)	
6.10	Systolic BP (mmHg)	
6.11	Glasgow coma score	
6.12	Describe ECG findings	No abnormalities AF rate 60-90 'AF rate >90/ any other abnormal rhythm/paced rhythm/ >5VE/min/ Q, ST or T wave abnormalities'
6.13	Describe Cardiac history / CXR appearance	No failure Diuretic, digoxin, antianginal, antihypertensive therapy Peripheral oedema, warfarin Therapy or CXR: borderline cardiomegaly Raised jugular venous pressure or CXR: cardiomegaly
6.14	Describe Respiratory history / CXR appearance	No dyspnoea Dyspnoea on exertion or CXR:mild COAD Dyspnoea limiting exertion to <1 Flight or CXR: moderate COAD Dyspnoea at rest/rate >30 at rest or CXR: fibrosis or consolidation
6.15	What was the operative severity? (see help box for examples)	Major Major+
6.16	Including this operation, how many operations has the patient had in the 30 day period prior to this procedure?	1 2 >2
6.17	Please select this patient's measured intraoperative blood loss (ml)	<100 101-500 501-1000 >1000
6.18	Please select the option that best describes this patient's degree of peritoneal soiling	None Serious fluid Local pus Free bowel content, pus or blood
6.19	What was the level of malignancy based on surgical findings	None Primary only Nodal metastases Distant metastases
6.20	What is the NCEPOD urgency? (see help notes for additional information, including equivalent Possum categories)	3. Expedited (>18 hours) 2B. Urgent (6-18 hours) 2A. Urgent (2-6 hours) 1. Immediate (<2 hours)
6.21	Post-op P-POSSUM predicted mortality:	Calculated
6.22	Post-op POSSUM predicted morbidity:	Calculated
6.23	Not all P-POSSUM investigations available	○

6.24	Where did the patient go for continued post-operative care following surgery?	Ward Level 2 HDU Level 3 ICU Died prior to discharge from theatre complex
6.24 a	At the end of surgery, was the decision made to place the patient on an end of life pathway?	Yes No
6.25	Is the patient on a vasopressor/ inotrope?	<input type="radio"/> No <input type="radio"/> Yes
7	Post-op	
7.1	Total length of post-operative ITU stay (days) see help box for additional information'	Number required
7.2	Total length of post-operative HDU stay (days) see help box for additional information	Number required
7.3	Was the patient assessed by a specialist from Elderly Medicine in the post-operative period?	No <input type="radio"/> Yes Unknown <input type="radio"/> Not applicable
7.4	Within this admission, did the patient return to theatre in the post-operative period following their initial emergency laparotomy?	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
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)	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
7.6	Histology	Crohn's disease Diverticulitis Ischaemia Malignancy Peptic ulcer disease Ulcerative colitis Not applicable/Not available at time of discharge <input type="radio"/> Other
7.7	Status at discharge	Dead <input type="radio"/> Alive Still in hospital at 60 days
7.8	Date discharged from hospital	(DD/MM/YYYY) Date required

Appendix 5.3: Excluded cases

Exclusion criterion	Cases
Admitted to Scottish hospitals	427
Under 18 at time of hospital admission	2
Arrival in theatre after data collection period	1,015
Arrival in theatre before data collection period	9
Primary surgical procedure ineligible for inclusion	755
Total	2208

Table 79 Cases ineligible for inclusion in analysis of the Year 1 NELA patient dataset

Appendix 5.4: Indications for surgery and operative findings

Indication for surgery	Number of patients	Frequency (%)
Intestinal obstruction	9,811	49
Perforation	4,744	24
Peritonitis	4,116	20
Ischaemia	1,720	9
Abdominal abscess	1,332	7
Sepsis: other	1,474	7
Haemorrhage	819	4
Colitis	748	4
Anastomotic leak	618	3
Intestinal fistula	326	2
Abdominal wound dehiscence	116	0.6
Abdominal compartment syndrome	55	0.3
Planned relook	51	0.3
Other	1,758	9

Table 80 Recorded indications for performing emergency laparotomy

Surgical findings	Number of patients	Frequency (%)
Adhesions	5,592	28
Perforation: small bowel/colonic	3,893	19
Intestinal ischaemia	2,543	13
Malignancy: localised	2,480	12
Abscess	2,332	12
Malignancy: disseminated	1,443	7
Incarcerated hernia	1,224	6
Perforation: peptic ulcer	1,212	6
Diverticulitis	1,158	6
Volvulus	715	4
Crohn's disease	658	3
Colitis	654	3
Anastomotic leak	591	3
Haemorrhage: postoperative	300	1
Haemorrhage: peptic ulcer	228	1
Normal intra-abdominal findings	215	1
Haemorrhage: intestinal	207	1
Abdominal compartment syndrome	45	0.2
Other	3,375	17

Table 81 Surgical findings at emergency laparotomy

6. BETWEEN HOSPITAL VARIATION IN MORTALITY AFTER EMERGENCY LAPAROTOMY IN THE NELA YEAR 1 PATIENT AUDIT POPULATION: RISK ADJUSTED OUTCOMES ANALYSIS

6.1 Introduction

Background

Emergency laparotomies are commonly performed operations associated with high overall incidences of postoperative morbidity and mortality.^{2, 9-13} However, substantial variation in mortality rates has been observed between patient subgroups and between hospitals.^{2, 9, 36}

Associations have been indicated with a host of individual patient-level and hospital-level factors,^{2, 6, 9-11, 23, 26, 28-33, 43, 46-62} but relationships are complex (Figure 4)⁴⁰ and the mechanisms underlying inter-institutional variations in postoperative mortality after emergency laparotomy remain poorly understood.

In intervention studies, the randomised control trial (RCT) is the gold standard method for testing the impact of an exposure on an identified patient-level outcome. However, there are circumstances in which it is desirable to assess the impact of multiple simultaneous exposures at multiple hierarchical levels and it may be impractical or unethical to randomise exposures. Epidemiological methods are used in these circumstances and because patients are not randomised to identified exposures (and because key exposures may only be subsequently identified), it is necessary to measure and control for potential confounders.

In this context, the national emergency laparotomy audit (NELA) was commissioned in 2012 to collect high quality organisational and patient-level data. The cohort of 20,183 patients comprising the first year NELA patient dataset currently represents the largest prospectively identified population undergoing emergency laparotomies worldwide.

Because some patient characteristics are associated with variation in postoperative mortality rates,^{2, 6, 9, 10, 23, 26, 28-33} differences in the distribution of these characteristics (casemix) between hospitals may confound between-hospital comparisons. Casemix adjustment is a family of techniques in which aggregated patient outcomes (for example hospital-level) are adjusted to account for variations in patient risk factors in order to enable meaningful comparisons. Age and administrative (HES) data were used to calculate previous estimates of hospital-level 30-day mortality after emergency laparotomy.^{2, 9}

In *Chapter 3 and Chapter 5* I reported evidence of variations in hospital characteristics, structural provisions and the delivery of standards of care for emergency general surgery

(EGS). In this Chapter I will use indirect casemix adjustment techniques to explore between-hospital variation in postoperative mortality rates in the National Emergency Laparotomy Audit year 1 patient dataset.

The case for reporting patient outcomes

National reporting of adjusted hospital-level patient outcomes and the identification of statistical outliers has become common practice over recent decades. Proponents argue that these efforts inform patient choice, improve accountability and drive quality improvement and have been associated with improvements in patient outcomes in other surgical specialties.^{156, 157}

There is however debate over the appropriate hierarchical level at which to measure and investigate the causes of variation in patient outcomes and while casemix adjustment techniques continue to evolve, the robustness of comparisons is routinely called into question.

With regard to hierarchical levels; while mortality rates are currently published by NHS Choices for individual surgeons across multiple subspecialties in the UK,[§] adequate statistical power to correctly identify outlying individual surgeon performance is prevented by insufficient case volumes and a low incidence of the outcome of interest in many specialties,¹⁵⁸ and in an era of increasing responsibility by multiple clinicians and allied healthcare professionals for aspects of care across patient episodes, the fairness of sole accountability is being increasingly questioned and clinical teams have been suggested as a more appropriate hierarchical level at which to assess variation.

However, defining clinical teams is problematic and with evidence of between-hospital variation in mortality rates after emergency laparotomies, the NELA year 1 patient audit was designed to identify hospital-level variation.

[§] <https://www.nhs.uk/service-search/performance/Consultants>. Last accessed 25th March 2016

Casemix adjustment modelling

Casemix adjustment methods may be classified as either direct or indirect. While there are limitations to indirect techniques, recent modelling indicates that direct standardisation may be impractical when multiple predictors are modelled.¹⁵⁹ Provided the results are interpreted with caution, indirect standardisation may therefore represent the most feasible means of calculating and comparing between-hospital variation in patient outcomes.¹⁶⁰

Indirect adjustment of hospital-level mortality rates requires the predicted likelihood of death to be calculated for every patient. However, if the tool used to model patient outcomes is poorly calibrated; over-estimation of individual risk may mask greater-than-expected hospital-level mortality rates; and underestimation may lead to the failure to identify low mortality outliers. It is therefore essential that a well-calibrated tool is used for casemix adjusted comparisons.

The Physiological and Operative Severity Score for the enUmeration of mortality and morbidity (POSSUM) was developed for the estimation of individual likelihood of inpatient mortality, in order that casemix-adjusted provider-level outcomes might be more fairly compared.¹²²

Informed by the analysis of the findings of the systematic review (*Chapter 4*)¹⁵⁰ and the expert opinion of the NELA Project Board (*Chapter 2*), POSSUM data items were incorporated into the NELA Patient Audit dataset in order that Portsmouth POSSUM (P-POSSUM)¹⁴⁵ predicted inpatient mortality might be calculated and for consideration as a candidate risk adjustment model.

However, data identified in the systematic review of risk tools validated for emergency laparotomy (*Chapter 4*) indicate that P-POSSUM may be inadequately calibrated for contemporary populations. Furthermore, in studies ineligible for inclusion in the systematic review, P-POSSUM was poorly calibrated at extremes of age, above a predicted risk of 11% and in populations undergoing non-elective surgery.^{161, 162}

Aims

1. To assess for and quantify between-hospital variation in short-term mortality after emergency laparotomy

Objectives

1. Derivation of candidate risk adjustment tools
2. Assessment of the calibration (and discrimination) of P-POSSUM and the novel tools within the NELA year 1 patient dataset
3. Estimation of risk-adjusted institutional incidences of mortality after emergency laparotomy

6.2 Materials and methods

Patient-level data were drawn from the year 1 National Emergency Laparotomy Audit (NELA) patient Audit cohort, comprising 20,183 cases submitted by 192 hospitals.

The structure of NELA is reported in *Chapter 2* and the methods and findings of the Patient audit reported in *Chapter 5*. No further exclusion criteria were imposed at patient- or at hospital-level.

Indirect casemix adjusted hospital-level postoperative mortality rates were derived as detailed below. P-POSSUM was identified as one of the better validated risk assessment models (*Chapter 4*) and subsequently included in the NELA patient audit webtool for consideration as a candidate adjustment model. However, because there is evidence that P-POSSUM is poorly calibrated in key emergency laparotomy demographics (elderly, high-risk and non-elective surgical populations),^{161, 162} POSSUM categories were re-classified, the tool re-calibrated and novel models derived in order to identify a model for casemix adjustment.

6.2.1 Definitions

Study endpoints

The endpoint selected for modelling in this Chapter was inpatient death within 30-days of the index laparotomy (inpatient 30-day mortality).

Casemix adjustment

By controlling for patient risk factors, casemix adjustment may be used to estimate and compare standardised hospital-level mortality rates.^{44, 163} Identification of statistical outliers may then facilitate the exploration of associations between processes of care and structural provisions with patient outcomes.

Variables

Methods used to identify the variables entered into risk adjustment models are reported in the following section and variables defined in Appendix 6.1.

Calibration

How closely a prognostic model's estimations match the observed incidence of a specified outcome across a study population. Calibration is most commonly assessed using χ^2 techniques. $p > 0.05$ indicates that observed and expected outcomes are similar and $p < 0.05$ differences are statistically significant.

Discrimination

How well a tool is able to discriminate between dichotomous outcomes (e.g. death and survival at 30 days) across a spectrum of risk profiles within a population of patients. Presentation as area under the receiver operator characteristic curve (AUC) provides a single, quantitative measure of the accuracy of a prognostic tool and also facilitates the comparison of dissimilar systems.¹⁰⁵ In interpreting AUC values: >0.9 good discrimination; 0.7-0.9 moderate; and <0.7 poor.¹⁰⁵

Funnel plot

An estimate of an underlying quantity (incidence of postoperative mortality) is plotted against a measure of the estimates' precision. Standard error 'control limits' form a funnel around the target outcome, analogous to standard Shewhart control charts in order to permit identification of common cause and special cause variation.¹⁶³

6.2.2 Selection of variables

POSSUM variables

POSSUM comprises a physiological severity score (PSS) and an operative severity score (OSS).¹²² The PSS comprises 12 variables and the OSS is made up of 6 variables (Appendix 4.4). Component variables are scored and the PSS and OSS calculated. The PSS and OSS are then entered into a logarithmic equation to quantify patient-level risk. Multiple modifications of the POSSUM equation have been published, including surgery- and population-specific models (Appendix 6.2).

Almost twenty five years after its publication, no detailed method of the application of POSSUM has been published.¹⁴⁵ And because the timing of collection of data items (relative to surgery) has not been specified, POSSUM data items are submitted both preoperatively and postoperatively into the NELA webtool (Appendix 5.2).

Preoperatively measured physiological parameters may be less prone to the influences of hospital-level factors than postoperative values. Preoperative PSS variables were therefore selected for modelling. Furthermore, because preoperative scoring of intraoperative variables (including degree of soiling and extent of blood loss) is subjective, postoperative OSS values were selected for modelling.

The twelve preoperative PSS variables and six postoperative OSS variables (Appendix 4.4) were therefore used in the calculation of P-POSSUM predicted inpatient mortality and the derivation of the three novel models (Figure 23).

Because multiple data ranges may be assigned the same category in POSSUM (Appendix 4.4), systolic blood pressure, pulse, haemoglobin, white cell count and potassium categories were re-classified prior to entry into the model (Appendix 6.1) to better explain associations between these continuous variables and inpatient 30-day mortality.

Modified POSSUM categories and additional variables

The three age categories defined by Copeland et al. provide insufficient discrimination of patient risk in contemporary cohorts whose life expectancy is longer, but in whom the incidence of multimorbidity increases substantially with increasing age.¹⁴⁸ Validation of the elderly POSSUM (E-POSSUM) incorporating a fourth, ‘advanced age’ category, demonstrated good discrimination and calibration in a cohort of older patients undergoing colorectal surgery.¹⁶⁴ Logistic regression modelling of the association of decades of age with inpatient 30-day mortality therefore informed the re-categorisation of age for inclusion in the novel model.

Model 1	Log (odds) = $-9.065 + (0.1692 \times \text{PSS}) + (0.155 \times \text{OSS})$
Model 2	POSSUM physiological severity score
	POSSUM operative severity score

Table 82 Variables included in Model 1 and model 2, the recalibrated POSSUM models (PSS: physiological severity score, OSS: operative severity score)

Additional candidate patient risk factors for inclusion in Model 3 were identified from those collected in the NELA year 1 patient dataset. Variables were selected for inclusion where an evidence base existed of an association with short-term outcome in emergency general surgical or gastrointestinal populations^{8, 165, 166} and if the following criteria were fulfilled:

- collected comprehensively ($\geq 90\%$ of patients) in the NELA patient audit dataset
- reflect patient risk immediately before surgery
- unlikely to be influenced by organisational structures or processes of care

Preoperative serum creatinine concentration was categorised first into twenty equal quantiles. The association of these categories with inpatient 30-day mortality was then modelled using logistic regression and the data re-categorised for inclusion in the model.

All variables were included in the construction of Model 3 regardless of significance of association with inpatient 30-day mortality on univariate analysis (Appendix 6.1).¹⁶⁷

6.2.3 Data management

Cleaning and validation of the NELA year 1 patient audit dataset is reported in *Chapter 5*. New variables constructed in the refitting of POSSUM systems and derivation of a novel model were managed within Stata® (version 12, StataCorp LP, College Station, Texas, USA) statistical software.

6.2.4 Statistical analysis and modelling

Analyses were performed in Stata® version 12 (StataCorp LP, College Station, Texas, USA) and Microsoft Excel (2010).

Three stages were required in the calculation of risk adjusted mortality rates:

- the identification of a candidate prognostic tool (P-POSSUM), its recalibration and the derivation of novel tools (Figure 23)
- assessment of the calibration of these prognostic tools to the NELA year 1 patient cohort, and
- use of the best calibrated tool to generate ratios of observed to expected deaths in order to calculate risk adjusted mortality rates.

<u>P-POSSUM</u>	predicted risk of inpatient mortality
<u>Model 1</u>	Estimation of a novel intercept and coefficient for P-POSSUM estimated risk of death (using Equation 3 <i>in toto</i>)
<u>Model 2</u>	Re-estimation of an intercept and coefficients for the POSSUM (and P-POSSUM) component physiological and operative severity scores (PSS and OSS)
<u>Model 3</u>	Construction and backward elimination of a multiple logistic regression model incorporating POSSUM variables and other identified patient risk factors

Figure 23 The four candidate prognostic models

P-POSSUM estimates

Estimation of risk using POSSUM systems requires data items to be assigned scores for the calculation of component physiological and operative severity scores (PSS and OSS). Missing continuous and categorical data items therefore pose a problem. However, precedent exists for missing data items to be assigned the least deviant score.¹⁴⁶ Missing POSSUM items were therefore assigned the lowest score (1) in order to estimate individual

P-POSSUM risk and in the derivation of Model 2, in which the component scores were calculated.

Individual POSSUM items were missing in 0.2-1.5% of all submitted records, but the proportion of cases submitted with missing POSSUM items was observed to vary between hospitals (*Chapter 5*). The above approach risks substantially inflating hospital-level adjusted mortality rates (by underestimating expected deaths) at hospitals with high rates of missing items. In deriving the novel tool, associations with missing items were therefore modelled as distinct categories.

Recalibration of P-POSSUM and Model building

Model 1 logistic regression was performed modelling P-POSSUM predicted 30-day mortality (Equation 3) as a continuous input variable against inpatient 30-day mortality, entered as a dichotomous variable

The derived intercept and coefficient were applied to P-POSSUM predicted inpatient mortality for each patient to estimate likelihood of inpatient 30-day mortality

Model 2 multiple logistic regression was performed modelling preoperative physiological severity score (PSS) and postoperative operative severity score (OSS), entered as continuous variables, against inpatient 30-day mortality, entered as a dichotomous variable

The derived intercept and coefficients were applied to PSS and OSS for each patient to estimate likelihood of inpatient 30-day mortality

Model 3 variables were entered into a multiple logistic regression model (Appendix 6.1). Categorical variables were entered as indicator variables and inpatient 30-day mortality was entered as a dichotomous variable. Correlation matrices were generated for each block of variables to assess for multi-collinearity between variables (>0.8)¹⁶⁸

Stepwise backward elimination of non-significant variables was performed. On sequential analysis the criterion for inclusion was $p<0.2$, $p<0.1$, $p<0.05$, such that the final model included only variables associated with the outcome to $p<0.05$ and categorical variables in which one or more categories was associated with the outcome to $p<0.05$.

The derived intercept and coefficients** were applied to variable categories for each patient to estimate likelihood of inpatient 30-day mortality.

Assessment of model performance

Percentage predicted risk of 30-day mortality was calculated for P-POSSUM and percentage predicted risk of inpatient 30-day mortality was calculated for models 1, 2 and 3 (Figure 24).

Model	Calculation
P-POSSUM	Equation 3 applied to PSS and OSS
Model 1	Derived intercept and coefficient applied to P-POSSUM predicted 30-day mortality
Model 2	Derived intercept and coefficients applied to OSS and PSS
Model 3	Derived intercept and coefficients applied to individual variables (Appendix 6.2)

Figure 24 Methods of calculating percentage predicted risk of death for each patient (PSS: physiological severity score, OSS: operative severity score).

The calibration of these four models was then assessed using Hosmer-Lemeshow χ^2 analysis.

In common with other χ^2 techniques, a non-significant p value (≥ 0.05) indicates no significant difference between observed and expected event counts and thus no lack-of-fit by the model in the patient cohort. If event counts are significantly different ($p < 0.05$), the Hosmer-Lemeshow statistic reports the magnitude of discordance.

However, in very large patient cohorts, differences between observed and expected event counts become magnified, reflected by a significant 'p' value.^{10, 109} Adequacy of calibration was therefore assessed both within patient subgroups and across the cohort of 20183 patients with reference to the Hosmer-Lemeshow statistic. No cut-off value has been reported in the literature to guide determination of model fit in large patient cohorts.

In the original description of the goodness of fit test, Lemeshow and Hosmer divided the cohort into deciles of risk to assess model fit.¹⁰⁷ This approach may however lack sensitivity across the profile of population risk (the tail of skewed data). In order to better identify any

** Coefficients were applied only to variable categories where the association with inpatient 30-day mortality was demonstrated to differ significantly ($p < 0.05$) from the reference variable.

lack of fit and to compare calibration of the assessed models, Hosmer-Lemeshow χ^2 analyses were therefore also performed using 20 equally sized quantiles of predicted risk.

Hosmer-Lemeshow statistics were then compared to identify which of the four tools was best calibrated to the dataset.

Calibration of POSSUM-based systems has previously been shown to be deficient in older people. Calibration of the models was therefore also assessed in a subgroup of older patients (>70 years).

Discrimination of patient outcome at 30 days in hospital was assessed for each of the assessed models by calculation and graphing of AUC and relative performances assessed by comparison of estimated AUC.

Calculation of hospital-level risk adjusted inpatient 30-day mortality

Risk adjustment may be used to quantify and graph hospital-, team- or clinician-level mortality rates, controlling for patient factors to attempt to make comparisons equitable. Indirect risk adjustment was used to estimate and compare hospital-level inpatient 30-day mortality rates.^{44, 163}

The sum of the observed inpatient deaths within 30 days of surgery was then compared with the sum of the expected number of deaths, using the best-calibrated prognostic model, for each hospital. This was then used to calculate the ratio of observed to expected events for each hospital.

This ratio was then applied to the overall inpatient 30-day mortality rate in the entire cohort. A greater-than-expected number of deaths would therefore result in a hospital mortality rate exceeding the overall mortality rate whereas a lower-than-expected number of deaths would result in a hospital mortality rate less than the overall average.

These data were then used to create a funnel plot of adjusted hospital-level inpatient 30-day mortality rates by volume of cases submitted to the Audit.¹¹² Two pairs of upper and lower control limits (2 standard error (SE) and 3 SE control limits respectively) were then constructed about the centre line to aid identification of incidences of 'special cause variation' which might merit further investigation.¹⁶⁹

Observed deaths: Patient who died in hospital within 30 days of the index emergency laparotomy

Expected deaths: The sum of the estimated individual likelihoods of death within 30 days of the index emergency laparotomy

Centre line: the overall inpatient 30-day mortality across the entire patient cohort

6.3 Results

Key findings

- Following exclusions, 20,183 patient records were included in the NELA year 1 patient audit dataset, submitted by participants at 192 hospitals across England and Wales
- With the exception of preoperative serum lactate levels, rates of completeness of candidate casemix adjustment model variables were high overall
- P-POSSUM was poorly calibrated for predictions of inpatient 30-day mortality risk in the NELA year 1 patient audit (Hosmer-Lemeshow (H-L): 2943), progressively overestimating risk above a predicted risk of 10%
- Recalibrated POSSUM models (Model 1 and Model 2) were better calibrated than P-POSSUM for predictions of inpatient 30-day mortality (H-L: 128 and 155 respectively)
- No inter-correlation (>0.8) was observed between novel model candidate variables when entered into a correlation matrix
- The novel model demonstrated superior calibration (H-L: 52) over the other assessed models and was well calibrated in a subgroup of patients over the age of 70 on hospital admission (H-L: 15)
- Discrimination of inpatient 30-day mortality was also superior with the novel model (AUC: 0.85)
- Overall inpatient 30-day mortality was 11.3%, but casemix adjusted hospital mortality rates varied substantially (0-33%)
- A funnel plot of procedural volumes against casemix adjusted inpatient 30-day mortality indicates the presence of 13 potential high mortality hospitals (mortality exceeding two standard errors above the mean) and two potential high mortality outlier hospitals (exceeding three standard errors above the mean)

6.3.1 Data quality

Incomplete data

Preoperative serum lactate levels were submitted for 52% of submitted cases, precluding its inclusion in the casemix adjustment model.

Other additional candidate variables (Sex, ASA-PS, admission type and reoperation) were 100% complete.

Data completeness and excluded cases are reported in full in *Chapter 5*.

6.3.2 Recalibration of P-POSSUM and construction of a novel risk adjustment model

Model 1: Derivation of a novel intercept and coefficient for P-POSSUM predicted 30-day mortality

Variable	Coefficient	Standard error	p value	95% Confidence interval
P-POSSUM predicted 30-day mortality	0.55	0.01	<0.001	0.53 - 0.57
Constant	-1.32993	0.04	<0.001	-1.38 - -1.28

Table 83 Results of the logistic regression analysis of P-POSSUM predicted 30-day mortality against inpatient 30-day mortality ($p < 0.001$)

Model 2: Derivation of a novel intercept and individual coefficients for the component POSSUM severity scores

Variable	Coefficient	Standard error	p value	95% Confidence interval
Preoperative physiological severity score (PSS)	0.11	0.00	<0.001	0.10 - 0.11
Postoperative operative severity score (OSS)	0.06	0.00	<0.001	0.05 - 0.06
Constant	-6.06818	0.11	<0.001	-6.28 - -5.86

Table 84 Results of the multiple logistic regression analysis of the POSSUM preoperative physiological and postoperative operative severity scores against inpatient 30-day mortality ($p < 0.001$)

Model 3: Derivation of a novel model

Remodelling age on admission

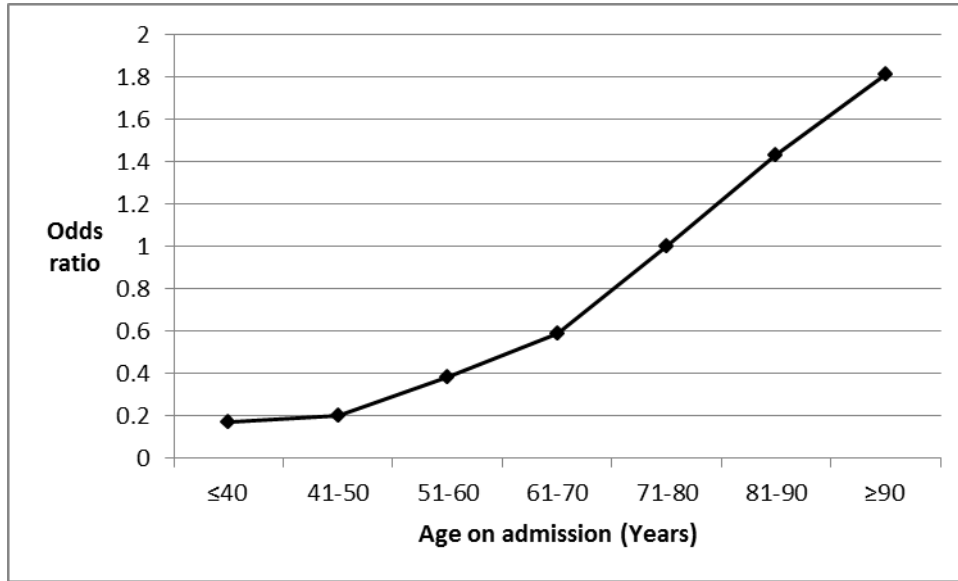


Figure 25 Association between deciles of age and inpatient 30-day mortality

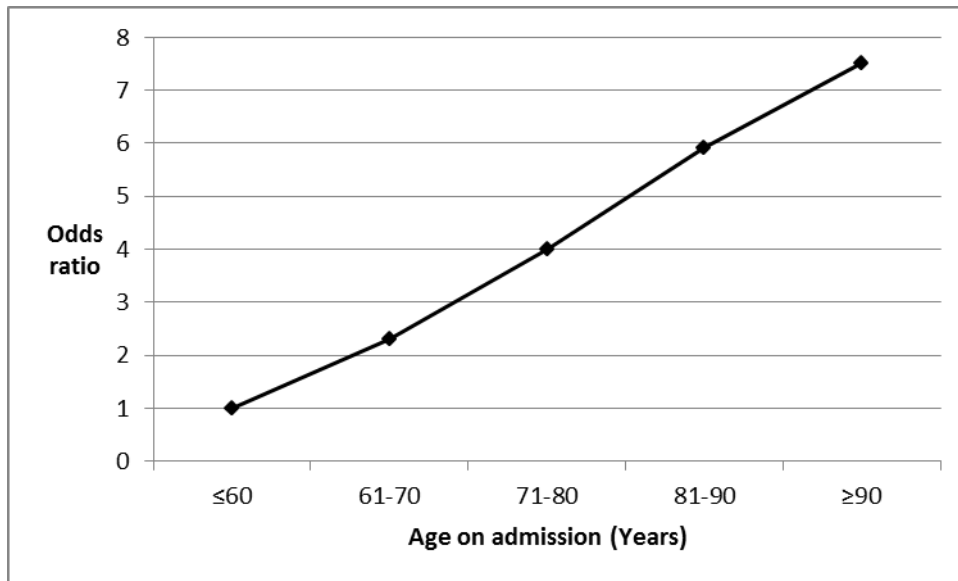


Figure 26 Remodelled age categories

Modelling additional continuous variables: Preoperative serum creatinine concentration

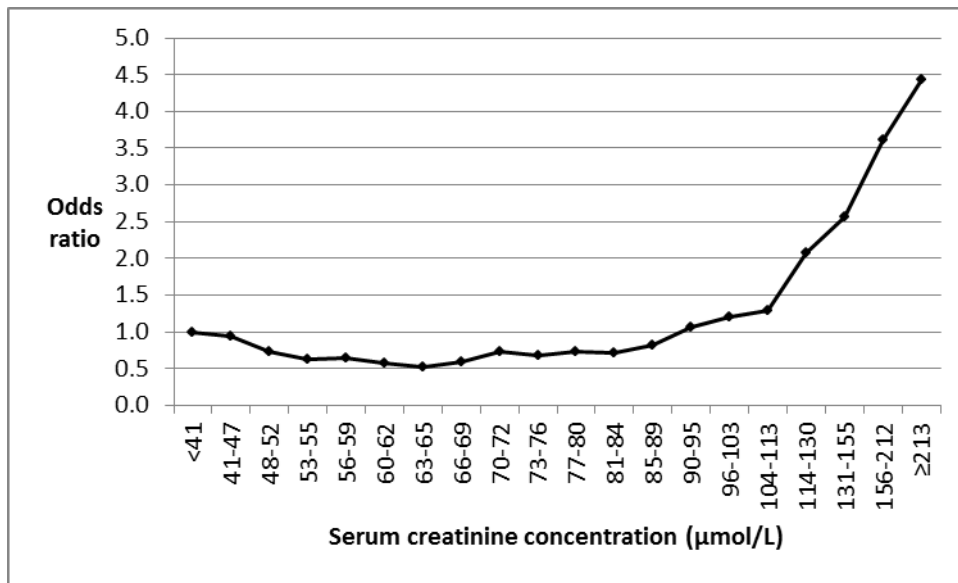


Figure 27 Association between quantiles of serum creatinine concentration and inpatient 30-day mortality

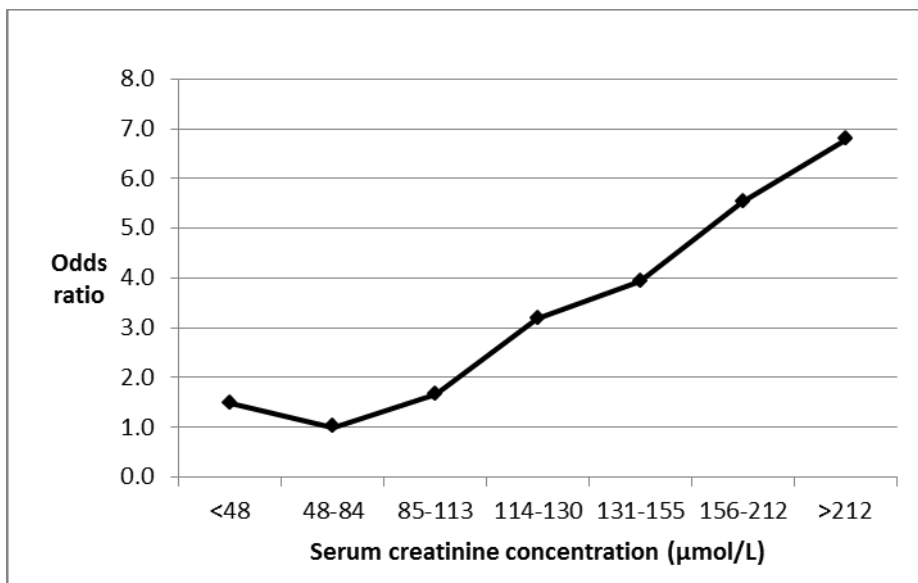


Figure 28 Re-modelled preoperative serum creatinine concentration categories

Variable	Range	Coefficient	Standard error	p value	95% Confidence interval	
Age (years)						
	≤60	0	Ref	-	-	-
	61-70	0.48	0.09	<0.001	0.30	0.66
	71-80	0.96	0.09	<0.001	0.79	1.13
	81-90	1.33	0.09	<0.001	1.14	1.51
	≥91	1.58	0.14	<0.001	1.30	1.85
Cardiac signs*						
	No failure	0	Ref	-	-	-
	Diuretic/ digoxin/ anti-anginal/ anti-hypertensive medication	0.08	0.06	NS	-0.04	0.21
	Peripheral oedema or warfarin therapy	0.32	0.10	<0.001	0.13	0.51
	Raised JVP	0.35	0.17	0.03	0.03	0.67
Respiratory history						
	No dyspnoea	0	Ref	-	-	-
	Dyspnoea on exertion	0.29	0.07	<0.001	0.16	0.42
	Limiting dyspnoea	0.47	0.08	<0.001	0.32	0.63
	Dyspnoea at rest	0.72	0.10	<0.001	0.53	0.92
Systolic blood pressure						
	MD	-0.09	0.59	NS	-1.25	1.08
	≤ 89	0.46	0.10	<0.001	0.27	0.65
	90-99	0.40	0.09	<0.001	0.21	0.58
	100-109	0.19	0.09	0.03	0.02	0.35
	110-130	0	Ref	-	-	-
	131-170	-0.12	0.07	NS	-0.25	0.01
	≥ 171	-0.05	0.14	NS	-0.33	0.23
Heart rate						
	MD	0.27	0.61	NS	-0.93	1.47
	≤ 39	0.08	0.84	NS	-1.58	1.73
	40-49	0.36	0.48	NS	-0.58	1.30
	50-80	-0.25	0.07	<0.001	-0.38	-0.12
	81-100	0	Ref	-	-	-
	101-120	0.16	0.07	0.02	0.03	0.29
	≥ 121	0.14	0.09	NS	-0.05	0.32
Glasgow Coma Score						
	15	0	Ref	-	-	-
	12-14	0.40	0.08	<0.001	0.25	0.56
	9-11	0.77	0.25	<0.001	0.29	1.25
	≤ 8	0.98	0.13	<0.001	0.72	1.23

White cell count						
	MD	-0.12	0.42	NS	-0.94	0.71
	≤ 3.0	0.71	0.13	<0.001	0.46	0.96
	3.1-4.0	0.20	0.16	NS	-0.12	0.52
	4.1-10	0.01	0.06	NS	-0.10	0.13
	10.1-20.0	0	Ref	-	-	-
	≥20.1	0.49	0.07	<0.001	0.34	0.63
Urea						
	≤ 7.5	0	Ref	-	-	-
	7.6-10	0.24	0.08	<0.001	0.09	0.39
	10.1-15.0	0.36	0.08	<0.001	0.20	0.51
	≥15.1	0.42	0.09	<0.001	0.24	0.61
Sodium						
	≥ 136	0	Ref	-	-	-
	131-135	0.19	0.06	<0.001	0.07	0.30
	126-130	0.27	0.09	<0.001	0.10	0.45
	≤ 125	0.31	0.16	NS	<0.001	0.61
Potassium						
	MD	0.57	0.35	NS	-0.12	1.26
	≤ 2.8	0.80	0.17	<0.001	0.46	1.14
	2.9-3.1	0.31	0.14	0.03	0.04	0.58
	3.2-3.4	0.15	0.10	NS	-0.05	0.34
	3.5-5.0	0	Ref	-	-	-
	5.1-5.3	0.23	0.12	NS	<0.001	0.46
	5.4-5.9	0.40	0.13	<0.001	0.14	0.65
	≥ 6.0	0.32	0.22	NS	-0.11	0.74
ECG						
	Normal	0	Ref	-	-	-
	Atrial fibrillation (rate 60-90)	0.10	0.11	NS	-0.11	0.31
	Other arrhythmia, ≥ 5 ectopics/ min, Q waves or ST/T wave changes	0.16	0.06	0.01	0.04	0.28
Operative severity						
	Major	0	Ref	-	-	-
	Major+	0.16	0.05	<0.001	0.05	0.26
Peritoneal soiling						
	None	0	Ref	-	-	-
	Minor (serous fluid)	0.25	0.07	<0.001	0.12	0.38
	Local pus	0.02	0.10	NS	-0.18	0.23
	Free bowel content, pus or blood	0.39	0.07	<0.001	0.26	0.53
Presence of malignancy						
	None	0	Ref	-	-	-
	Primary only	0.10	0.09	NS	-0.07	0.27
	Nodal metastases	0.28	0.13	0.02	0.04	0.53

	Distant metastases	0.72	0.09	<0.001	0.54	0.89
Mode of surgery						
	Emergency resuscitation of >2h possible	0	Ref	-	-	-
	Emergency (immediate surgery <2h needed)	0.43	0.06	<0.001	0.30	0.55
Sex						
	Male	-0.13	0.05	0.01	-0.24	-0.03
	Female	0	Ref	-	-	-
ASA-PS						
	1	-0.95	0.21	<0.001	-1.36	-0.54
	2	-0.62	0.09	<0.001	-0.79	-0.45
	3	0	Ref	-	-	-
	4	0.77	0.06	<0.001	0.64	0.89
	5	1.46	0.13	<0.001	1.21	1.71
Admission type						
	Elective	-0.45	0.14	<0.001	-0.71	-0.18
	Emergency	0	Ref	-	-	-
Reoperation						
	No	0	Ref	-	-	-
	Yes	-0.25	0.11	0.03	-0.46	-0.03
Preoperative serum creatinine concentration						
	MD	0.00	0.27	NS	-0.53	0.53
	<48	0.29	0.10	<0.001	0.09	0.48
	48-84	0	Ref	-	-	-
	85-113	0.02	0.08	NS	-0.13	0.17
	114-130	0.23	0.11	0.03	0.02	0.44
	131-155	0.24	0.11	0.03	0.03	0.45
	156-212	0.21	0.11	NS	-0.01	0.42
	>212	0.39	0.12	<0.001	0.16	0.61
Constant						
		-4.20074	0.12	<0.001	-4.44	-3.96

Table 85 The final multiple logistic regression model following backward elimination of non-significant variables. Most prevalent categories used as reference variables (p<0.001) (MD: missing data, NS: non-significant)

6.3.3 Calibration of the candidate risk adjustment models

P-POSSUM

Group	Patients	Observed deaths (%)	Expected deaths (%)	Minimum predicted risk (%)	Maximum predicted risk (%)	Hosmer-Lemeshow statistic
1	980	6 (0.6)	8.2 (0.8)	0.6	1.1	0.6
2	985	5 (0.5)	12.1 (1.2)	1.1	1.5	4.23
3	948	11 (1.2)	15.4 (1.6)	1.5	1.8	1.3
4	1028	17 (1.7)	21.4 (2.1)	1.8	2.3	0.91
5	1080	24 (2.2)	28.0 (2.6)	2.4	2.9	0.58
6	1012	37 (3.7)	32.3 (3.2)	2.9	3.5	0.7
7	1000	41 (4.1)	38.8 (3.9)	3.5	4.2	0.13
8	974	49 (5.0)	45.6 (4.7)	4.3	5.1	0.26
9	1061	61 (5.7)	60.8 (5.7)	5.2	6.4	0
10	975	51 (5.2)	68.7 (7.0)	6.4	7.7	4.92
11	1009	74 (7.3)	86.3 (8.6)	7.8	9.5	1.93
12	1057	83 (7.9)	113.0 (10.7)	9.6	12	8.92
13	1007	120 (11.9)	135.7 (13.5)	12.2	15	2.11
14	1006	113 (11.2)	172.7 (17.2)	15.2	19.2	24.92
15	1010	141 (14.0)	222.3 (22.0)	19.4	24.7	38.14
16	1005	168 (16.7)	287.7 (28.6)	25	32.7	69.73
17	1012	243 (24.0)	377.7 (37.3)	32.7	42.9	76.67
18	1006	245 (24.4)	502.4 (49.9)	43	57.6	263.53
19	1004	323 (32.2)	672.4 (67.0)	57.7	76.8	549.77
20	1024	461 (45.0)	905.9 (88.5)	77.1	99.9	1894.28
Total	20183	2273 (11.3)	3807.6 (18.9)	0.6	99.9	2943.63

Table 86 Hosmer-Lemeshow χ^2 analysis of the calibration of P-POSSUM ($p < 0.001$)

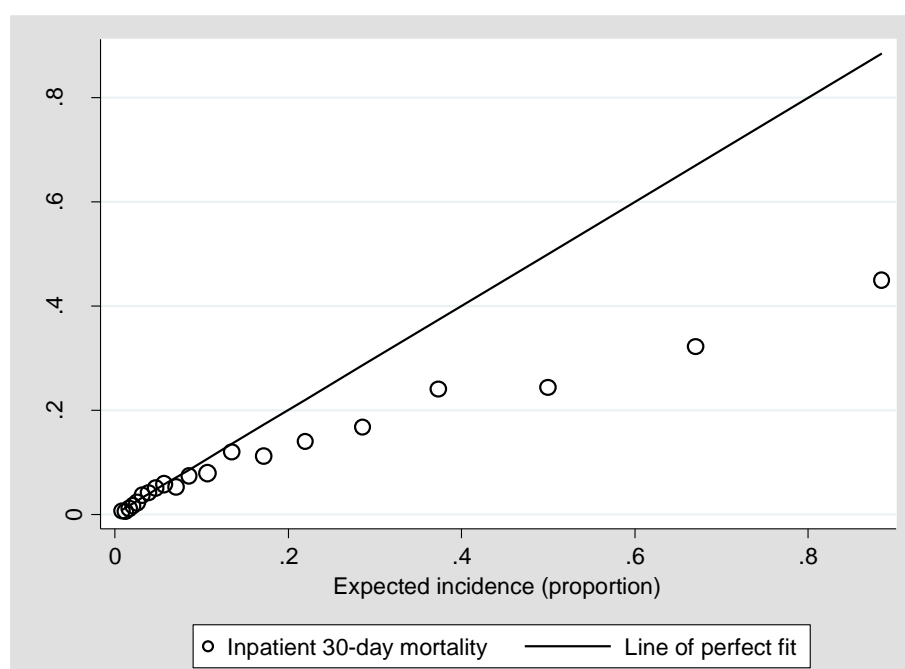


Figure 29 Hosmer-Lemeshow χ^2 plot of the calibration of P-POSSUM

Model 1: Refitted P-POSSUM predicted 30-day mortality

Group	Patients	Observed deaths (%)	Expected deaths (%)	Minimum predicted risk (%)	Maximum predicted risk (%)	Hosmer-Lemeshow statistic
1	998	5 (0.5)	18.5 (1.9)	1.5	2.1	10.07
2	1094	6 (0.5)	25.2 (2.3)	2.1	2.5	14.95
3	979	8 (0.8)	26.4 (2.7)	2.6	2.8	13.22
4	1094	19 (1.7)	33.9 (3.1)	2.9	3.3	6.76
5	1004	21 (2.1)	35.2 (3.5)	3.3	3.7	5.93
6	1077	35 (3.2)	42.4 (3.9)	3.7	4.2	1.33
7	1025	43 (4.2)	45.1 (4.4)	4.2	4.6	0.1
8	1074	41 (3.8)	52.7 (4.9)	4.6	5.2	2.74
9	1061	52 (4.9)	58.9 (5.5)	5.2	5.8	0.85
10	1006	63 (6.3)	62.6 (6.2)	5.9	6.6	0
11	1103	78 (7.1)	77.4 (7.0)	6.6	7.5	0
12	1048	91 (8.7)	83.6 (8.0)	7.5	8.5	0.71
13	1039	110 (10.6)	94.8 (9.1)	8.5	9.8	2.67
14	1039	115 (11.1)	109.8 (10.6)	9.8	11.4	0.27
15	1052	170 (16.2)	129.9 (12.3)	11.5	13.4	14.13
16	1046	185 (17.7)	153.4 (14.7)	13.5	16	7.65
17	1041	223 (21.4)	185.6 (17.8)	16	19.9	9.18
18	1059	281 (26.5)	238.3 (22.5)	20	25.6	9.89
19	1041	325 (31.2)	313.1 (30.1)	25.6	36.5	0.65
20	1058	461 (43.6)	545.3 (51.5)	36.6	97.1	26.89
Total	20183	2332 (11.1)	2332.0 (11.1)	1.5	97.1	128.02

Table 87 Hosmer-Lemeshow χ^2 analysis of the calibration of Model 1 ($p < 0.001$)

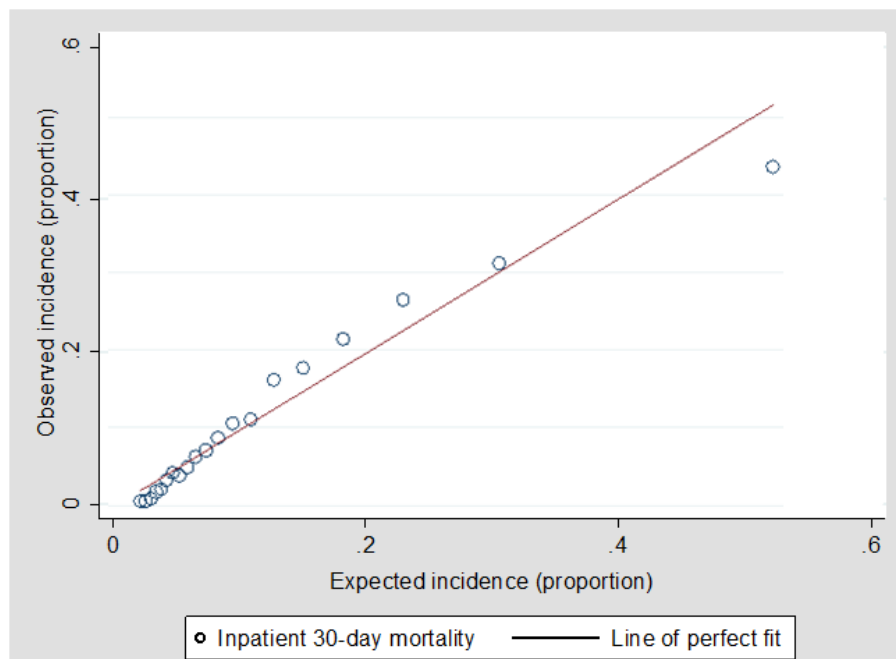


Figure 30 Hosmer-Lemeshow χ^2 plot of the calibration of Model 1

Model 2: Refitted POSSUM physiological and operative severity scores

Group	Patients	Observed deaths (%)	Expected deaths (%)	Minimum predicted risk %	Maximum predicted risk %	Hosmer-Lemeshow statistic
1	1014	5 (0.5)	19.6 (1.9)	1.6	2.1	11.13
2	1041	6 (0.6)	24.5 (2.4)	2.2	2.5	14.31
3	1021	6 (0.6)	27.6 (2.7)	2.5	2.9	17.37
4	1058	16 (1.5)	32.4 (3.1)	2.9	3.2	8.57
5	1067	21 (2.0)	36.7 (3.4)	3.3	3.6	6.98
6	992	27 (2.7)	38.0 (3.8)	3.6	4	3.33
7	1134	34 (3.0)	48.7 (4.3)	4	4.5	4.64
8	975	43 (4.4)	46.8 (4.8)	4.6	5.1	0.32
9	1107	59 (5.3)	59.7 (5.4)	5.1	5.7	0.01
10	1048	52 (5.0)	63.6 (6.1)	5.7	6.4	2.24
11	1033	81 (7.8)	70.7 (6.8)	6.4	7.3	1.6
12	1005	94 (9.4)	78.1 (7.8)	7.3	8.3	3.49
13	1110	112 (10.1)	98.8 (8.9)	8.4	9.6	1.95
14	1038	129 (12.4)	107.7 (10.4)	9.6	11.2	4.72
15	1035	149 (14.4)	126.6 (12.2)	11.3	13.3	4.52
16	1060	192 (18.1)	155.5 (14.7)	13.4	16.2	10.05
17	1046	213 (20.4)	187.3 (17.9)	16.2	20	4.28
18	1060	312 (29.4)	239.2 (22.6)	20	25.7	28.63
19	1040	312 (30.0)	316.9 (30.5)	25.8	36.5	0.11
20	1054	469 (44.5)	553.5 (52.5)	36.5	98.1	27.19
Total	20183	2332 (11.1)	2332.0 (11.1)	1.6	98.1	155.42

Table 88 Hosmer-Lemeshow χ^2 analysis of the of the calibration of Model 2 ($p < 0.001$)

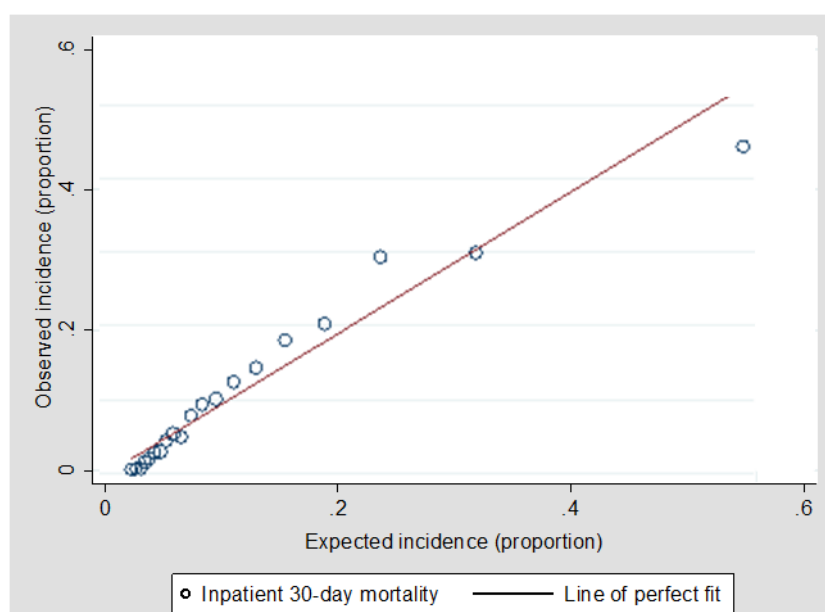


Figure 31 Hosmer-Lemeshow χ^2 plot of the of the calibration of Model 2

Model 3: Novel model

Group	Patients	Observed deaths (%)	Expected deaths (%)	Minimum predicted risk %	Maximum predicted risk %	Hosmer-Lemeshow statistic
1	1001	4 (0.4)	5.5 (0.6)	0.2	0.7	0.43
2	1018	3 (0.3)	7.9 (0.8)	0.7	0.9	3.05
3	1009	7 (0.7)	10.0 (1.0)	0.9	1.1	0.9
4	1009	7 (0.7)	12.5 (1.2)	1.1	1.4	2.43
5	1009	9 (0.9)	15.4 (1.5)	1.4	1.7	2.73
6	1009	12 (1.2)	19.0 (1.9)	1.7	2.1	2.65
7	1009	20 (2.0)	23.4 (2.3)	2.1	2.6	0.52
8	1009	20 (2.0)	28.9 (2.9)	2.6	3.1	2.83
9	1009	34 (3.4)	35.2 (3.5)	3.1	3.9	0.05
10	1008	40 (4.0)	42.8 (4.2)	3.9	4.7	0.19
11	1011	56 (5.5)	52.3 (5.2)	4.7	5.7	0.27
12	1009	69 (6.8)	63.0 (6.2)	5.7	6.9	0.6
13	1009	95 (9.4)	77.2 (7.6)	6.9	8.5	4.46
14	1009	114 (11.3)	95.2 (9.4)	8.5	10.4	4.09
15	1009	116 (11.5)	118.0 (11.7)	10.4	13.1	0.04
16	1009	192 (19.0)	150.5 (14.9)	13.1	16.9	13.44
17	1009	228 (22.6)	196.2 (19.4)	16.9	22.4	6.38
18	1009	289 (28.6)	264.7 (26.2)	22.4	30.5	3.03
19	1009	385 (38.2)	369.8 (36.7)	30.5	44.2	0.99
20	1010	573 (56.7)	599.9 (59.4)	44.2	93.3	2.97
Total	20183	2273 (11.3)	2187.6 (10.8)	0.2	93.3	52.04

Table 89 Hosmer-Lemeshow χ^2 analysis of the calibration of Model 3 ($p < 0.001$)

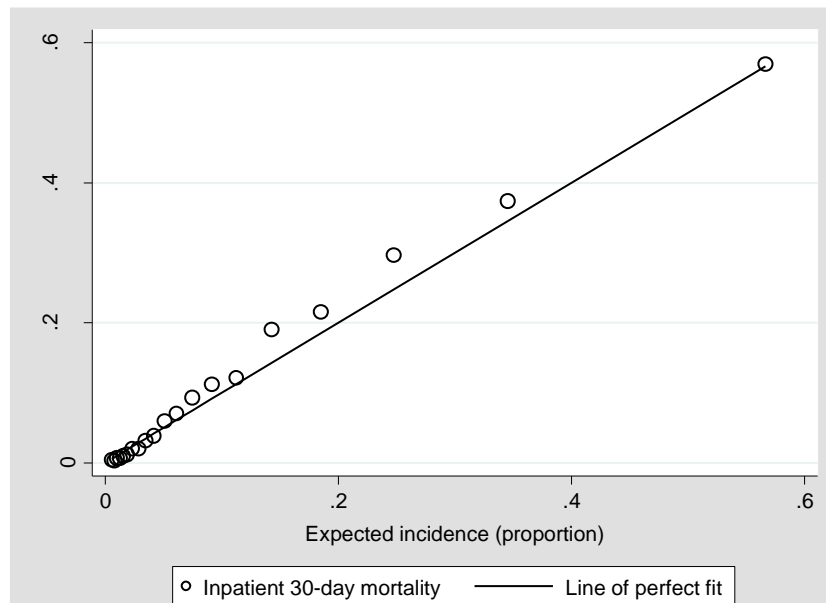


Figure 32 Hosmer-Lemeshow χ^2 plot of the calibration of Model 3

Group	Patients	Observed deaths (%)	Expected deaths (%)	Minimum predicted risk %	Maximum predicted risk %	Hosmer-Lemeshow statistic
1	916	18 (2.0)	20.7 (2.3)	0.7	3	0.35
2	919	33 (3.6)	34.0 (3.7)	3	4.4	0.03
3	911	54 (5.9)	47.5 (5.2)	4.4	6	0.93
4	915	76 (8.3)	62.8 (6.9)	6	7.9	2.98
5	915	84 (9.2)	82.8 (9.0)	7.9	10.3	0.02
6	916	118 (12.9)	108.9 (11.9)	10.3	13.8	0.86
7	915	168 (18.4)	148.3 (16.2)	13.8	19	3.12
8	915	240 (26.2)	210.1 (23.0)	19	27.6	5.53
9	915	305 (33.3)	307.1 (33.6)	27.6	41.1	0.02
10	915	507 (55.4)	522.1 (57.1)	41.1	93.3	1.01
Total	9152	1603 (17.5)	1544.2 (16.9)	0.7	93.3	14.85

Table 90 Hosmer-Lemeshow χ^2 analysis of the calibration of Model 3 in patients over 70 years ($p=0.14$)

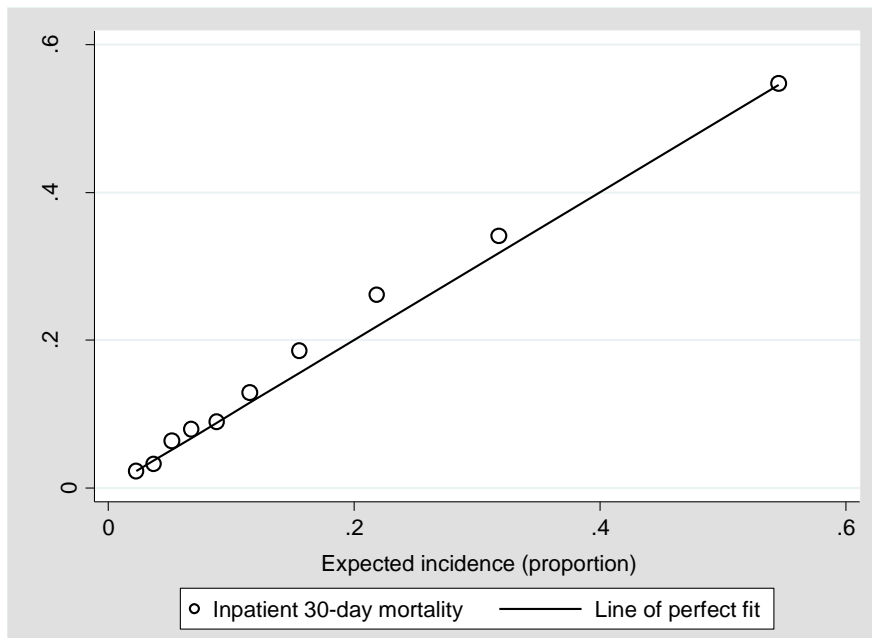


Figure 33 Hosmer-Lemeshow χ^2 plot of the calibration of Model 3 in patients over 70 years on admission

6.3.4 Discrimination of postoperative patient outcome at 30-days

Model	Area under the receiver operator characteristic curve (95% Confidence Interval)
P-POSSUM	0.80 (0.79-0.81)
Model 1.	0.80 (0.79-0.81)
Model 2.	0.81 (0.80-0.81)
Model 3.	0.85 (0.85-0.86)***

Table 91 Discrimination of outcome at 30 days after surgery in inpatients by P-POSSUM (χ^2 comparison of performance against P-POSSUM: *: $p<0.05$, ** $p<0.005$, *** $p<0.001$)

6.3.5 Hospital-level risk-adjusted inpatient 30-day mortality

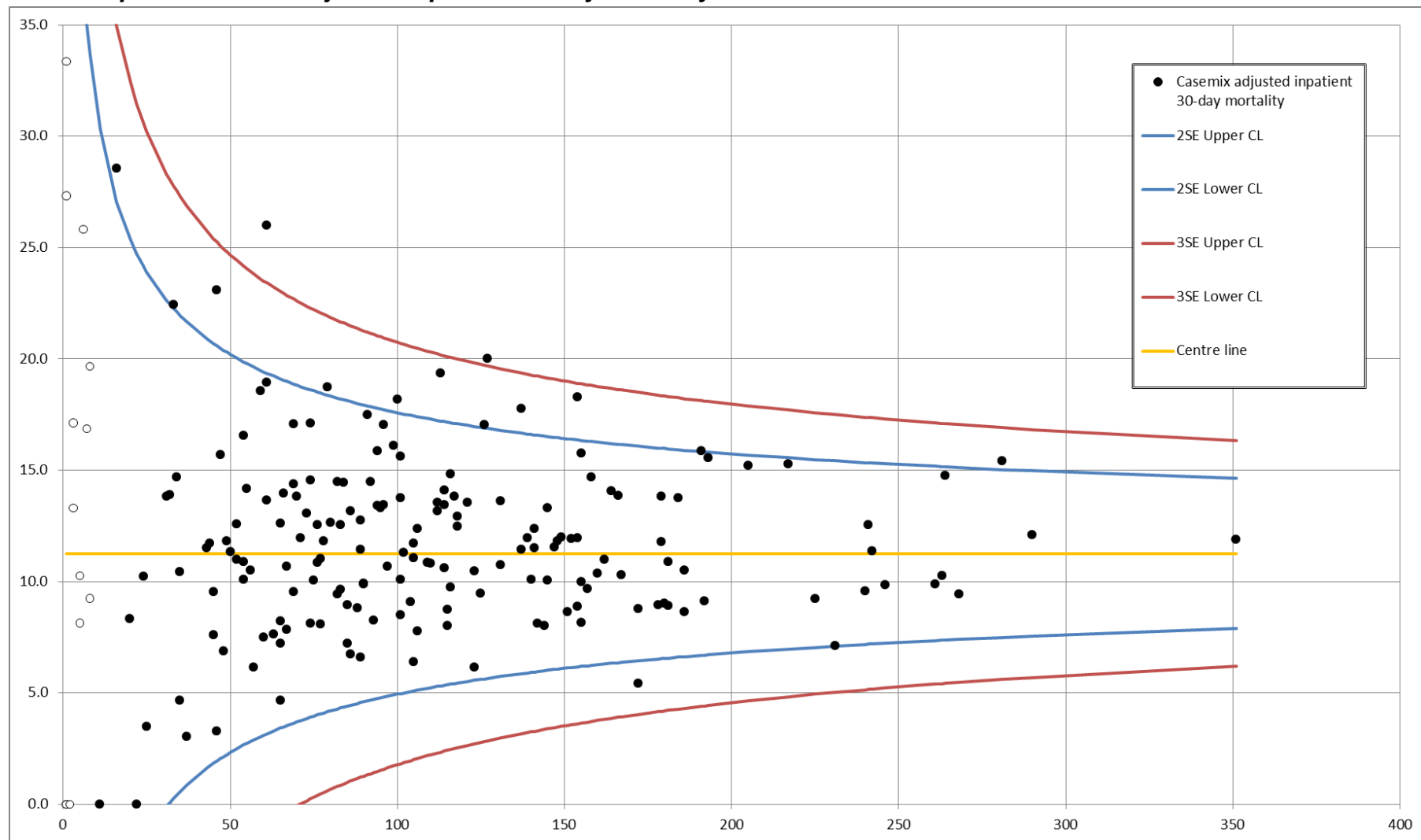


Figure 34 Funnel plot of casemix adjusted hospital-level inpatient 30-day mortality by volume of cases submitted to the NELA year 1 patient audit: Indirect adjustment using the novel model (Hospitals submitting fewer than 10 cases are denoted by open circles, SE: standard error, CL: control limit)

6.4 Discussion

Key points

- This cohort of 20,183 patients represents the largest prospectively identified population of emergency laparotomy patients to date
- Substantial between-hospital variation in casemix adjusted postoperative mortality rates was demonstrated, supporting previous indications of between-hospital variation in outcomes after emergency laparotomies
- Plotting adjusted hospital mortality rates against case volumes suggested higher mortality rates than would be expected due to chance alone at 13 hospitals
- The magnitude of between-hospital variation in casemix adjusted mortality rates may have been inflated by casemix variation, geographical variation in the weighting of patient-level risk factors and variation in casemix selection
- Some of the between-hospital variation after modelling of patient-level risk factors may be explained by differences in organisational factors and chance, but should not be attributed solely to variation in structural provisions and the delivery of processes of care
- A novel casemix adjustment model demonstrated superior calibration for inpatient 30-day mortality across risk profiles
- P-POSSUM was sufficiently well calibrated over the clinical decision range (predicted risk 0-10%) to inform treatment decisions in emergency laparotomy populations

6.4.1 Overview

Emergency laparotomies are frequently performed for potentially life-threatening pathologies and while postoperative mortality and morbidity within a month of surgery are common overall,^{2, 9-13, 89} substantial variation has been indicated between patient groups (*Chapter 5*).^{2, 6, 9, 10, 23, 26, 28-33} And while between-hospital variation has also been indicated,^{2, 9, 36} because the robustness of casemix adjustment was limited by dataset constraints in these studies, it was necessary to first identify between-hospital variation in this cohort of 20,183 patients.

These observations of variation offer opportunities for improving patient outcomes and standards of care received by patients undergoing emergency laparotomies. Modelling of between-hospital outcome variation suggests that, having modelled patient-level risk, residual variation may be explained by differences in hospital-level factors and chance.^{40, 44} It is therefore anticipated that the identification of associations may provide targets for quality improvement strategies in emergency laparotomy populations.²⁷

The findings of the analyses reported in this Chapter support previous observations by confirming that between-hospital variation in casemix adjusted short-term postoperative mortality was substantial in this cohort of 20,183 patients, the largest population of prospectively identified patients undergoing emergency laparotomy worldwide to date.

It should be noted however, that because the magnitude of casemix adjusted variation may be inflated by between-hospital casemix differences, as were observed in *Chapter 5*, and because the weighting of risk factors may not be constant geographically, further analysis is required to determine the magnitude of hospital-level variance.

6.4.2 Between hospital variation in inpatient 30-day mortality after emergency laparotomy

While the overall incidence of inpatient 30-day mortality after emergency laparotomy was 11.3% (*Chapter 5*), adjustment for patient-level risk indicated that postoperative mortality varied substantially (0 - 33%) between the 192 hospitals participating in the year 1 NELA patient audit (Figure 34).

Interpretation of these findings differs somewhat if a quality control approach¹⁶³ or a more conventional statistical approach⁴¹ is taken.

A quality control approach

When casemix adjusted hospital-level mortality data were represented as a funnel plot against volume of submitted cases (Figure 34), the adjusted hospital-level mortality rate exceeded two standard errors above the mean at 13 hospitals and exceeded three standard errors above the mean at two high mortality outlier (HMO) hospitals. In contrast, only one hospital was identified with an adjusted mortality rate under two standard errors below the mean.

Due to chance alone, four hospitals (2.2%) would be expected to lie more than two standard errors above the mean and a further four more than two standard errors below the mean, whereas 0.2% would be expected to lie outside three standard errors (0.1% above and 0.1% below).

These findings therefore indicate *special cause variation*¹⁶³ at the thirteen identified high outlier hospitals and further investigation of the quality of care delivered to patients undergoing emergency laparotomies at HMO hospitals is merited.*

Statistical considerations

The findings of the casemix adjusted outcomes analyses and the above discussion should be interpreted in the context of discussions of the weaknesses of standardisation techniques.

Hospital-level mortality rates are adjusted only for those patient risk factors that are modelled, and the validity of casemix adjustment models is determined by the accuracy and reliability of these data. Furthermore, differences in quality of care may explain as little as half of observed variance⁴² and a substantial proportion of between-hospital variance may result from chance alone.⁴⁵ The findings reported in this Chapter should therefore not be

* The NELA outlier policy was followed by NELA when ONS mortality data was received

interpreted as evidence that hospital factors (structures, processes and characteristics) alone are responsible for between-hospital variation in mortality after emergency laparotomy. This is *the casemix adjustment fallacy*.¹⁷⁰

Moreover, indirect standardisation makes no allowance for the likelihood of death associated with individual patient risk factors to vary between the geographical populations (*the constant risk fallacy*),¹⁷¹ or for interactions between hospital and casemix. The magnitude of the observed variation in hospital-level mortality rates may therefore be explained in part by population and casemix selection differences, as might be observed at tertiary referral or cancer centres. Interpretation must therefore be made in the context of interactions with hospital-level variables.¹⁵⁹

Finally, the estimation of a hospital's expected number of deaths is influenced by casemix makeup. Therefore, even if the quality of care delivered by two different hospitals is equivalent for every measured patient characteristic, if the casemix makeup varies sufficiently between the hospitals, adjusted mortality rates may differ (*Simpson's paradox*).¹⁷² Interpretation of the results of casemix adjusted provider-level outcomes should therefore include contextualisation with casemix differences.¹⁵⁹

With regard to assessment of casemix differences between participating hospitals, accepting the propensity for overestimation at higher risk, P-POSSUM risk profiles were observed to vary widely between participating hospitals (Figure 11).

Therefore, in summary, contextualisation with casemix data suggests that the magnitude of variation in casemix adjusted hospital mortality rates may have been inflated by the effects of Simpson's paradox, variation in the effects of risk factors between hospitals and variation in casemix selection; and that having modelled some patient-level variables, residual between-hospital variation should not be attributed solely to organisational factors. These factors are explored further in *Chapter 8*.

6.4.3 The volume effect

Existing data evaluating associations between hospital-level case volumes and variation in patient outcomes is markedly conflicting in surgical and non-surgical cohorts.^{54, 56-62} While multilevel modelling is required to definitively assess for the presence of a volume effect (*Chapter 8*), it is therefore notable that a trend toward low mortality outlier status at higher volume centres was not observed in the analyses reported in this Chapter (Figure 34).

6.4.4 Risk adjustment models

A novel, purpose built tool was demonstrated to be better calibrated to the year 1 NELA patient Audit cohort than other candidate tools (Figure 32). In contrast with P-POSSUM and recalibrated POSSUM tools (Figure 30 and Figure 31), the calibration of the novel tool did not deteriorate with increasing predicted risk of death (Figure 32), nor was it inferior in a subgroup of patients over the age of 70 years (Figure 33).

The calibration of P-POSSUM was infrequently reported in the papers identified in the systematic review in emergency laparotomy cohorts (*Chapter 4*), but in support of previous findings, the calibration of P-POSSUM was observed to progressively deteriorate above a 15% predicted risk of death in the NELA year 1 patient audit and calibration was poor in older patients (Figure 29).^{161, 162} However, it is notable firstly that P-POSSUM was derived to predict for 30-day mortality, rather than inpatient 30-day mortality and secondly that because calibration was adequate across the risk range specified in contemporary standards of care to categorise risk, these findings support the current use of P-POSSUM for this purpose in emergency laparotomy cohorts.

A non-significant ($p \geq 0.05$) Hosmer-Lemeshow (H-L) statistic indicates that observed and expected outcomes are similar across subgroups and that there is good fit by the model to the population.¹⁰⁶⁻¹⁰⁸ However, significant results are frequently encountered in large populations, since the effects of small differences may be magnified.^{10, 109} The significant H-L statistics observed in all but subgroup analyses reported in this Chapter should therefore not be assumed to imply poor fit of the models.

Finally, formal validation in an external population would be required prior to use of the novel tool to predict individual risk of death in clinical practice.^{104, 113}

6.5 Limitations

Limitations of data acquisition processes in the NELA year 1 patient audit dataset are reported in *Chapter 5*. There are however limitations of particular relevance to the casemix adjustment modelling and comparisons of hospital-level outcomes reported in this Chapter.

Firstly, time (relative to surgery) was not specified for many data items. This is of particular relevance to preoperative variables used to assess patient-level risk, since data within normal physiological and biochemical parameters might equally reflect either lower risk or the consequences of good preoperative care. Between-hospital comparisons of casemix adjusted outcomes and quality of care may therefore be confounded by processes of care delivered before those assessed in the audit.

Secondly, variables available for deriving a novel casemix adjustment model were limited to those selected for inclusion in the NELA year 1 patient audit questionnaire and, in the case of serum lactate concentration, by data completeness.

Thirdly, retrospective entry of data items has the potential to have introduced bias, since values may have been influenced by knowledge of a patient's perioperative and postoperative course and outcome.

Finally, assessments of normal cause and special cause variation in hospital-level mortality rates are reliant upon a measure of case volume. In the analyses reported in this Chapter, the volume of cases submitted to the audit was used in the identification of potential mortality outlier hospitals, however levels of case ascertainment are unknown and identification of outlier status may therefore have been subject to systematic or unconscious bias at the hospitals participating in the NELA year 1 patient audit.

6.6 Conclusions

The findings of the analyses reported in this Chapter support previous observations by confirming that between-hospital variation in casemix adjusted short-term postoperative mortality was substantial in this cohort of 20,183 patients, the largest population of prospectively identified patients undergoing emergency laparotomy worldwide to date. However, the magnitude of between-hospital variation is anticipated to have been inflated in the estimates reported in this Chapter.

Modelling between-hospital outcome variation suggests that, accounting for patient-level risk, residual variation may be explained by chance and differences in hospital-level factors. In subsequent Chapters I will therefore develop the themes of this and preceding Chapters in order to; identify potentially modifiable processes of care associated with variation in postoperative mortality in the NELA year 1 patient audit; and compare the relative influences of patient-level and hospital-level differences on patient outcomes after emergency laparotomy.

Appendix 6.1: Categorisation of modelled data items

Variable	Category							
	0	1	2	3	4	5	6	7
Cardiac*	MD	No failure	Meds	Oedema/ warfarin	Raised JVP	-	-	-
Respiratory (dyspnoea)*	MD	None	On exertion	Limiting	At rest	-	-	-
Systolic Blood pressure (mmHg) §	MD	≤ 89	90-99	100-109	110-130	131-170	≥ 171	-
Pulse (beats/min) §	MD	≤ 39	40-49	50-80	81-100	101-120	≥ 121	-
Glasgow coma score*	MD	15	12-14	9-11	≤ 8	-	-	-
Haemoglobin (g/dl) §	MD	≤ 9.9	10.0-11.4	11.5-12.9	13.0- 16.0	16.1- 17.0	17.1- 18.0	≥ 18.1
White cell count (10 ¹² /l) §	MD	≤ 3.0	3.1-4.0	4.1-10	10.1- 20.0	≥20.1	-	-
Urea (mmol/l)*	MD	≤ 7.5	7.6-10	10.1-15.0	≥15.1	-	-	-
Sodium (mmol/l)*	MD	≥ 136	131-135	126-130	≤ 125	-	-	-
Potassium (mmol/l) §	MD	≤ 2.8	2.9-3.1	3.2-3.4	3.5-5.0	5.1-5.3	5.4- 5.9	≥ 6.0
ECG*	MD	Normal	-	AF	Other	-	-	-
Operative severity*	MD	Minor	Moderate	Major	Major+	-	-	-
Multiple procedures*	MD	1	-	2	>2	-	-	-
Total blood loss (ml)*	MD	≤100	101-500	501-999	≥1000	-	-	-
Peritoneal soiling*	MD	None	Minor (serous fluid)	Local pus	Free bowel content	-	-	-
Presence of malignancy*	MD	None	Primary only	Nodal mets	-	-	-	-
Mode of surgery‡	MD	Elective	-	>2hr, <24hr	<2hr	-	-	-
sex	MD	Male	Female	-	-	-	-	-
ASA-PS	MD	1	2	3	4	5	-	-
admission type	MD	Elective	Emergent	-	-	-	-	-
reoperation	MD	Yes	No	-	-	-	-	-

Table 92 Variables included in construction of model 3

Additionally age and serum creatinine concentration were reclassified following modelling (MD: missing data, *: Variables classified according to POSSUM categories, §: Variables reclassified for model construction, ‡: re-categorised in NELA webtool)

Appendix 6.2: POSSUM and P-POSSUM mortality estimation equations

$$\text{Log (odds)} = -7.04 + (0.13 \times \text{PSS}) + (0.16 \times \text{OSS})$$

Equation 1 The original POSSUM (Copeland et al.) equation for the estimation of 30-day postoperative mortality (PSS: physiological severity score, OSS: operative severity score)¹²²

$$\text{Log (odds)} = -9.37 + (0.19 \times \text{PSS}) + (0.15 \times \text{OSS})$$

Equation 2 The Whiteley et al. Portsmouth equation for the estimation of 30-day postoperative mortality using POSSUM variable categories (PSS: physiological severity score, OSS: operative severity score)¹⁷³

$$\text{Log (odds)} = -9.065 + (0.1692 \times \text{PSS}) + (0.155 \times \text{OSS})$$

Equation 3 The updated (Prytherch et al.) Portsmouth equation for the estimation of 30-day postoperative mortality using POSSUM variable categories (PSS: physiological severity score, OSS: operative severity score)¹⁴⁵

Appendix 6.3: Casemix adjusted hospital mortality estimates

Hospital code	Cases	Observed deaths	Expected deaths	O:E ratio	Raw inpatient 30-day mortality (%)	Adjusted inpatient 30-day mortality (%)
LGI	1	0	0.18	0.0	0.0	0.0
UHL	1	1	0.34	3.0	100.0	33.4
STH	1	0	0.02	0.0	0.0	0.0
MST	1	1	0.41	2.4	100.0	27.3
RED	1	0	0.03	0.0	0.0	0.0
EAL	2	0	0.19	0.0	0.0	0.0
WLT	3	1	0.85	1.2	33.3	13.3
CKH	3	1	0.66	1.5	33.3	17.1
LHC	5	2	2.77	0.7	40.0	8.1
HHX	5	1	1.10	0.9	20.0	10.3
NWG	6	1	0.44	2.3	16.7	25.8
BMP	7	2	1.34	1.5	28.6	16.9
PAP	8	3	1.72	1.7	37.5	19.7
CCH	8	1	1.22	0.8	12.5	9.2
WRG	11	0	0.62	0.0	0.0	0.0
CHR	16	2	0.79	2.5	12.5	28.6
CTY	20	3	4.06	0.7	15.0	8.3
NMG	22	0	2.27	0.0	0.0	0.0
MAR	24	2	2.20	0.9	8.3	10.2
QEB	25	1	3.23	0.3	4.0	3.5
GHS	31	4	3.26	1.2	12.9	13.8
GEO	32	4	3.24	1.2	12.5	13.9
WRX	33	9	4.52	2.0	27.3	22.4
MSH	34	5	3.84	1.3	14.7	14.7
NTG	35	1	2.41	0.4	2.9	4.7
PIL	35	3	3.23	0.9	8.6	10.5
CHX	37	1	3.73	0.3	2.7	3.0
HIL	43	4	3.91	1.0	9.3	11.5
WYB	44	4	3.85	1.0	9.1	11.7
FRY	45	6	7.09	0.8	13.3	9.5
MKH	45	3	4.45	0.7	6.7	7.6
PAH	46	7	3.42	2.0	15.2	23.1
LEI	46	1	3.45	0.3	2.2	3.3
BRG	47	9	6.46	1.4	19.1	15.7
WES	48	4	6.55	0.6	8.3	6.9
NMH	49	4	3.82	1.0	8.2	11.8
FGH	50	6	5.95	1.0	12.0	11.3
SAL	52	7	6.26	1.1	13.5	12.6
CON	52	4	4.10	1.0	7.7	11.0
WAW	54	5	5.59	0.9	9.3	10.1
CHE	54	9	6.12	1.5	16.7	16.6

CAS	54	7	7.25	1.0	13.0	10.9
BRT	55	8	6.36	1.3	14.5	14.2
WHI	56	6	6.42	0.9	10.7	10.5
SCA	57	4	7.34	0.5	7.0	6.1
AIR	59	12	7.28	1.6	20.3	18.6
LEW	60	5	7.51	0.7	8.3	7.5
MIW	61	10	5.94	1.7	16.4	18.9
RGH	61	16	6.93	2.3	26.2	26.0
WMU	61	7	5.77	1.2	11.5	13.7
UCL	63	4	5.89	0.7	6.3	7.6
NHH	65	3	7.26	0.4	4.6	4.7
FRR	65	4	5.48	0.7	6.2	8.2
ROT	65	2	3.12	0.6	3.1	7.2
NDD	65	11	9.83	1.1	16.9	12.6
BOL	66	9	7.26	1.2	13.6	14.0
SMV	67	6	8.62	0.7	9.0	7.8
STM	67	4	4.22	0.9	6.0	10.7
DDH	69	8	5.28	1.5	11.6	17.1
STD	69	11	8.61	1.3	15.9	14.4
GWY	69	6	7.08	0.8	8.7	9.5
POW	70	13	10.60	1.2	18.6	13.8
FRE	71	9	8.48	1.1	12.7	12.0
HAR	73	12	10.34	1.2	16.4	13.1
QEL	74	17	11.19	1.5	23.0	17.1
BFH	74	8	6.20	1.3	10.8	14.5
SCU	74	7	9.72	0.7	9.5	8.1
HIN	75	7	7.83	0.9	9.3	10.1
RLI	76	8	8.29	1.0	10.5	10.9
NUN	76	9	8.09	1.1	11.8	12.5
STR	77	12	12.27	1.0	15.6	11.0
HOM	77	4	5.57	0.7	5.2	8.1
BNT	78	8	7.63	1.0	10.3	11.8
PCH	79	14	8.41	1.7	17.7	18.7
WHC	80	9	8.00	1.1	11.3	12.7
RSU	82	9	10.75	0.8	11.0	9.4
MAC	82	9	7.00	1.3	11.0	14.5
LEG	83	6	7.01	0.9	7.2	9.6
LIN	83	8	7.17	1.1	9.6	12.6
RSC	84	13	10.14	1.3	15.5	14.4
YEO	85	6	9.35	0.6	7.1	7.2
RAD	85	7	8.81	0.8	8.2	8.9
BRO	86	5	8.34	0.6	5.8	6.8
WAT	86	12	10.25	1.2	14.0	13.2
TUN	88	9	11.53	0.8	10.2	8.8

RHC	89	6	10.26	0.6	6.7	6.6
HUL	89	16	14.14	1.1	18.0	12.7
RFH	89	13	12.79	1.0	14.6	11.4
BAS	90	9	10.21	0.9	10.0	9.9
BED	90	7	7.98	0.9	7.8	9.9
KNG	91	16	10.30	1.6	17.6	17.5
MAY	92	10	7.77	1.3	10.9	14.5
SPD	93	5	6.82	0.7	5.4	8.3
RSS	94	12	8.52	1.4	12.8	15.9
CLW	94	14	11.75	1.2	14.9	13.4
HCH	95	11	9.32	1.2	11.6	13.3
GLG	96	15	12.58	1.2	15.6	13.4
WHT	96	14	9.25	1.5	14.6	17.0
SMH	97	12	12.64	0.9	12.4	10.7
SAN	99	15	10.48	1.4	15.2	16.1
NEV	100	17	10.53	1.6	17.0	18.2
TGA	101	17	12.25	1.4	16.8	15.6
NTY	101	18	14.73	1.2	17.8	13.8
DID	101	8	10.60	0.8	7.9	8.5
BAR	101	7	7.83	0.9	6.9	10.1
WMH	102	12	11.95	1.0	11.8	11.3
COC	104	10	12.37	0.8	9.6	9.1
PGH	105	9	9.16	1.0	8.6	11.1
FAZ	105	7	12.33	0.6	6.7	6.4
FRM	105	11	10.58	1.0	10.5	11.7
LIS	106	10	9.11	1.1	9.4	12.4
CGH	106	10	14.51	0.7	9.4	7.8
QKL	109	13	13.51	1.0	11.9	10.8
QEG	110	15	15.61	1.0	13.6	10.8
PIN	112	12	9.98	1.2	10.7	13.5
AEI	112	15	12.84	1.2	13.4	13.2
ASH	113	18	10.48	1.7	15.9	19.3
NPH	114	18	14.36	1.3	15.8	14.1
WDG	114	15	12.55	1.2	13.2	13.5
OHM	114	12	12.76	0.9	10.5	10.6
DVH	115	7	9.85	0.7	6.1	8.0
WSH	115	9	11.59	0.8	7.8	8.7
WDH	116	12	13.89	0.9	10.3	9.7
WGH	116	15	11.38	1.3	12.9	14.8
CMI	117	16	13.03	1.2	13.7	13.8
DAR	118	15	13.06	1.1	12.7	12.9
PET	118	15	13.53	1.1	12.7	12.5
GGH	121	19	15.79	1.2	15.7	13.5
TOR	123	11	11.82	0.9	8.9	10.5

IPS	123	10	18.37	0.5	8.1	6.1
EBH	125	11	13.09	0.8	8.8	9.5
SEH	126	16	10.57	1.5	12.7	17.1
KTH	127	22	12.39	1.8	17.3	20.0
SCM	131	18	18.89	1.0	13.7	10.7
KMH	131	12	9.92	1.2	9.2	13.6
KCH	137	16	10.15	1.6	11.7	17.8
LON	137	23	22.63	1.0	16.8	11.4
KGH	139	14	13.19	1.1	10.1	12.0
MRI	140	15	16.75	0.9	10.7	10.1
BRD	141	16	15.67	1.0	11.3	11.5
WYT	141	15	13.67	1.1	10.6	12.4
HUD	142	12	16.66	0.7	8.5	8.1
LDH	144	8	11.22	0.7	5.6	8.0
SLF	145	14	15.67	0.9	9.7	10.1
NGS	145	14	11.84	1.2	9.7	13.3
WEX	147	17	16.59	1.0	11.6	11.5
DRY	148	18	17.18	1.0	12.2	11.8
BRI	149	17	15.95	1.1	11.4	12.0
BAT	151	13	16.93	0.8	8.6	8.6
MPH	152	18	17.01	1.1	11.8	11.9
MDW	154	26	16.01	1.6	16.9	18.3
YDH	154	15	19.05	0.8	9.7	8.9
RPH	154	20	18.82	1.1	13.0	12.0
RBE	155	24	17.14	1.4	15.5	15.8
SHC	155	13	14.64	0.9	8.4	10.0
QEQ	155	10	13.81	0.7	6.5	8.2
DER	157	9	10.48	0.9	5.7	9.7
WRC	158	21	16.11	1.3	13.3	14.7
WIR	160	22	23.92	0.9	13.8	10.4
COL	162	14	14.34	1.0	8.6	11.0
WHH	164	20	16.02	1.2	12.2	14.1
PMS	166	25	20.29	1.2	15.1	13.9
SPH	167	14	15.32	0.9	8.4	10.3
SHH	172	9	18.71	0.5	5.2	5.4
GLO	172	14	17.97	0.8	8.1	8.8
ESU	178	13	16.34	0.8	7.3	9.0
QHR	179	24	19.54	1.2	13.4	13.8
RUS	179	21	20.05	1.0	11.7	11.8
NTH	180	15	18.71	0.8	8.3	9.0
RLU	181	22	27.79	0.8	12.2	8.9
MOR	181	18	18.65	1.0	9.9	10.9
BTH	184	18	14.73	1.2	9.8	13.8
JPH	186	17	18.25	0.9	9.1	10.5

NCR	186	14	18.29	0.8	7.5	8.6
SUN	191	31	22.01	1.4	16.2	15.9
RDE	192	16	19.73	0.8	8.3	9.1
VIC	193	32	23.17	1.4	16.6	15.6
GWE	205	28	20.75	1.3	13.7	15.2
BLA	217	36	26.55	1.4	16.6	15.3
NOR	225	20	24.41	0.8	8.9	9.2
RCH	231	17	26.95	0.6	7.4	7.1
ADD	240	21	24.74	0.8	8.8	9.6
PLY	241	31	27.85	1.1	12.9	12.5
RVN	242	20	19.83	1.0	8.3	11.4
SGH	246	29	33.14	0.9	11.8	9.9
LER	261	25	28.54	0.9	9.6	9.9
SJH	263	19	20.85	0.9	7.2	10.3
UHW	264	42	32.03	1.3	15.9	14.8
QAP	268	26	31.02	0.8	9.7	9.4
STO	281	41	29.98	1.4	14.6	15.4
UHC	290	33	30.73	1.1	11.4	12.1
QMC	351	35	33.14	1.1	10.0	11.9
Total	20183	2273	2273	1.0	11.3	-

Table 93 Inpatient deaths within 30 days of surgery and raw and adjusted incidence by hospital

7. PATIENT-LEVEL VARIABLES ASSOCIATED WITH VARIATION IN MORTALITY AFTER EMERGENCY LAPAROTOMY IN THE NELA YEAR 1 PATIENT AUDIT DATASET: MULTIVARIABLE ANALYSES

7.1 Introduction

Background

Emergency laparotomies are commonly performed operations associated with high overall incidences of postoperative morbidity and mortality.^{2, 9-13} However, substantial variation in the incidence of postoperative adverse events has been observed both between patient subgroups and between the hospitals at which these operations are performed.^{2, 9, 36} Furthermore, temporal factors have been shown to be associated with structural provisions and the delivery of processes of care in emergency general surgery (EGS)⁶⁸ and with patient outcomes in other clinical contexts.^{66, 67}

Associations between variations in patient outcomes and a variety of individual structure, process and patient factors have been indicated.^{2, 6, 9-11, 23, 26, 28-33, 43, 46-62} However, relationships between these factors are complex (Figure 4)⁴⁰ and mechanisms underlying inter-institutional variations in postoperative mortality after emergency laparotomy remain poorly understood.

The analysis of the NELA year 1 patient cohort reported in *Chapter 6* indicates substantial between-hospital variation in mortality after emergency laparotomy at participating hospitals, after adjustment for patient-level risk. And in *Chapter 5* I reported evidence of variation in the delivery of perioperative processes of care, operative procedures performed, timing of emergency laparotomy and patient characteristics in this population of patients.

Multivariable analysis is a family of versatile statistical techniques which can be used to identify multiple independent predictors (at a single hierarchical level) of the outcome of interest and to determine the relative strengths of associations with the outcome of interest. Multivariable modelling techniques are therefore well suited to the identification of associations between perioperative processes of care and temporal factors (measurable at the level of individual patients) and variations in postoperative mortality in the NELA year 1 patient cohort.

Aim

1. To determine the contribution of perioperative processes of care to variation in mortality after emergency laparotomy

Objectives

1. To construct multiple logistic regression models incorporating patient-level variables (including perioperative surgical and temporal variables) which might plausibly be associated with postoperative mortality in the NELA year 1 patient cohort and relevant subgroups
2. In contrast with the approach taken in *Chapter 6*, to model markers of surgical pathology that precipitate emergency laparotomy
3. To identify perioperative processes of care independently associated with mortality after emergency laparotomy in the NELA year 1 patient cohort and relevant subgroups
4. Stepwise construction of multivariable models, introducing patient, process and temporal variables en-bloc to quantify the contribution by these groups of variables to the observed variance in postoperative mortality

7.2 Materials and methods

Patient-level data were drawn from the year 1 National Emergency Laparotomy Audit (NELA) patient Audit cohort, comprising 20,183 cases submitted by 192 hospitals. Methods and findings of the Patient audit are reported in *Chapter 5*. No further exclusion criteria were imposed at patient- or at hospital-level prior to these analyses.

7.2.1 Definitions

Study endpoints

The endpoint selected for multivariable modelling in this Chapter was inpatient death within 30-days of the index laparotomy (inpatient 30-day mortality).

Multivariable analysis

Multivariable analysis is a versatile technique which can be used to assess and quantify the relative strengths of complex associations between multiple variables, or groups of variables and postoperative mortality.^{168, 174-176}

Variables

Methods used to identify the variables entered into multivariable models are outlined in the following sections.

Squared multiple correlation (R^2)

The R^2 statistic estimates the proportion of the variance observed in an outcome variable that is modelled by explanatory variables included in the model. Values of 0.1-0.2 indicate moderate fit and values exceeding 0.3 strong fit.¹⁷⁷ Results should be interpreted acknowledging the limitations of this technique for binary outcome data.

Variance

If outcome data are binary, as is the case with inpatient 30-day mortality, the overall sample variance may be estimated using a simplified equation:

$$s^2 = \hat{\pi}(1 - \hat{\pi})$$

Equation 4 Estimate of the sample variance (s^2 : sample variance, $\hat{\pi}$: inpatient 30-day mortality as a proportion of the sample population)

7.2.2 Selection of variables

In constructing a casemix adjustment model in *Chapter 6*, variables were restricted to preoperative patient data items that were unlikely to have been influenced by hospital structures and processes in order to quantify between-hospital variation in postoperative mortality. However, in order to identify perioperative processes of care and temporal factors associated with variation in mortality after emergency laparotomy, it was necessary to also consider the effects of other patient-level variables that might affect the relationships of interest.

Within the confines of the collected dataset, a greater diversity of patient risk factors and indicators of surgical pathology were therefore considered in the construction of the multivariable models. Furthermore, candidate variables were not restricted to those demonstrated to be significantly associated with inpatient 30-day mortality on univariate analysis.¹⁶⁷

P-POSSUM was identified as one of the best validated perioperative risk assessment tools for emergency laparotomy in the systematic review reported in *Chapter 4* and subsequently incorporated into the NELA webtool following assessment by the NELA Project Board (*Chapter 2*). POSSUM data items were entered as categorised in the construction of the novel casemix adjustment model (Appendix 6.1).

Additional candidate patient risk factors for inclusion in model building were identified from those collected in the NELA year 1 patient dataset. Variables were selected for inclusion, as Block 2 (Appendix 7.1), where an evidence base existed supporting an association with short-term outcome in emergency general surgical and gastrointestinal populations,^{8, 165-167} and if the following criteria were fulfilled:

- collected comprehensively ($\geq 90\%$ of patients) in the year 1 NELA patient audit dataset
- reflecting patient risk immediately before surgery
- unlikely to be influenced by organisational structures and culture or processes of care

Age and serum creatinine concentration were modelled as categorised in the derivation of the novel casemix adjustment model (Figure 26 and Figure 28).

Temporal factors have been shown to be associated with structural provisions and the delivery of processes of care in emergency general surgery (EGS)⁶⁸ and with patient outcomes in other clinical contexts.^{66, 67} Day of the week and time of day of surgery, modelled as reported in Table 94, were therefore entered into the model (Appendix 7.1).

Category	Time of arrival in operating theatre for emergency laparotomy
0	Data not submitted
1	0800-1159
2	1200-1759
3	1800-2359
4	0000-0759

Table 94 Time of day of surgery categories

Operative indications and surgical findings were selected as indicators of surgical pathology and entered as multiple binary items, since multiple responses could be selected.

While there is a relative wealth of data regarding patient risk factors, evidence of associations between processes of care and postoperative outcome after emergency laparotomy is extremely sparse. Limited associations have however been demonstrated in other clinical contexts and several Standards documents have made recommendations regarding the delivery of processes of care for emergency general surgical patients, informed largely by expert opinion (Appendix 2.1).^{21, 70-75}

Data items relating to a large number of these processes of care were collected in the NELA year 1 patient dataset (*Chapter 2*). Candidate variables for inclusion in the construction of the multivariable model were identified from this pool of data items and selected for inclusion on the basis of the following criteria:

- collected comprehensively (≥90% of patients) in the NELA patient audit dataset
- reflect patient risk immediately before surgery
- unlikely to be influenced by organisational structures or processes of care

Postoperative review by a medicine for care of the older person (MCOP) physician is not appropriate for all patients undergoing an emergency laparotomy. Review by an MCOP physician was therefore included within the perioperative processes of care block of variables (Appendix 7.1) in a subgroup analysis of older patients (>70 years).

Patient outcomes after emergency laparotomy vary with the precipitating pathology and the operation performed (Table 50, Table 51 and Table 49). However, because the choice of operative procedure[†] may be influenced by hospital-level structural and cultural determinants, primary procedure and surgical approach were included in assessment of the squared multiple correlation (R^2) analyses (Appendix 7.1), but removed prior to backward elimination of variables to determine independent predictors of mortality. Primary operative

[†] Including not only the procedure performed, but also the operative approach, invasiveness and extent of surgery

procedure was entered as a single categorical variable since only a single response could be recorded for each patient (Appendix 7.2).

The association of an independent variable with the outcome may be influenced by other independent variables. *A priori* it was considered clinically plausible that interactions might exist between patient risk factors (e.g. ASA-PS grade and age and cardiac and respiratory comorbidity categories) and between patient risk factors and surgical pathologies (e.g. preoperative systolic blood pressure and precipitants of intra-abdominal sepsis). Potential interactions were identified and factor terms entered alongside relevant blocks in construction of the models (Appendix 7.1).^{167, 168, 178}

7.2.3 Data management

Procedures for the cleaning and validation of the NELA year 1 patient audit dataset are reported in *Chapter 5*.

Additional variables constructed in the derivation of the novel casemix adjustment model (informing selection of variables for multivariable modelling) are described in *Chapter 6*.

7.2.4 Statistical analysis and modelling

Multiple logistic regression analyses were performed in Stata® version 12 (StataCorp LP, College Station, Texas, USA) using the 'xi:' command structure, allowing the user to specify reference variables. Database management was performed in Microsoft Excel (2010).

In total, four multivariable models were constructed due to; the likelihood of interactions between operative indications and surgical findings; the potential for hospital-level variations in selection of operative procedures; and the need for age-defined subgroup analysis of postoperative review by medicine for the care of older persons (MCOP) physicians

General models

Outcomes after emergency laparotomies vary by precipitating events and pathologies. Operative indications and surgical findings were both recorded in the NELA year 1 patient audit dataset and might equally be used as indicators of these surgical events (Table 50 and Table 51). However, because it was not apparent which field would better capture risk associated with surgical pathology and furthermore, because a high degree of correlation was anticipated between operative indications and findings, two distinct multivariable models were created (Appendix 7.1).

Models were constructed in a stepwise fashion, introducing groups of related variables as blocks (Appendix 7.1). By sequentially introducing blocks of variables, changes in the squared multiple correlation (R^2) statistic was tracked to evaluate how much of the observed variation in mortality could be explained by related groups of variables.¹⁶⁸

Because it was anticipated that institutional structural and cultural factors might inform the selection of surgical procedure, primary operative procedure and surgical approach were then removed from the models.

Correlation matrices were generated for the models to identify multi-collinearity and variables excluded where correlation coefficients exceeded 0.8. Stepwise backward elimination of non-significant variables and interaction terms was then performed. Variables that were not significantly associated with inpatient 30-day mortality ($p>0.2$) were removed from the model. Ordinal variables were removed only if no category was associated with inpatient 30-day mortality at this level of significance.

On sequential analysis the criterion for inclusion was $p<0.1$ and $p<0.05$, such that the final model included only variables associated with the outcome to $p<0.05$ and categorical variables in which one or more categories was associated with the outcome to $p<0.05$.

Modelling of processes of care in older patients

Definitions of the 'older person' are not universal[‡] and methods for identifying patients who may benefit from perioperative input by medicine for care of the older person (MCOP) physicians vary. Due to both the size of the population and evidence of an inpatient 30-day mortality rate exceeding 10%, construction of both multivariable models (operative indications and surgical findings models) was repeated in a subgroup of patients over the age of 70, including postoperative review by an MCOP physician within the perioperative processes of care block of variables (Appendix 7.1).

[‡] In its "Age Old Problem" publication, NCEPOD highlights the increased incidence of mortality after emergency abdominal surgery in two groups of patients: those over the age of 65 and in patients over the age of 80 years.

7.3 Results

Key findings

- Following exclusions, 20,183 patient records were included in the NELA year 1 patient audit dataset, submitted by participants at 192 hospitals across England and Wales
- Rates of data completeness were high overall

Final multivariable models

- Two processes of care independently predicted inpatient 30-day mortality in the general models:
 - direct postoperative critical care admission (Odds ratio (OR) 1.50-1.51)
 - preoperative documentation of risk (OR 1.14-1.16)
- In patients over the age of 70 years, postoperative review by an MCOP physician was associated with substantial risk reduction (OR 0.29)
- Interaction terms common across the four models included:
 - Surgery on a Monday evening (1800-2359) was associated with increased risk of death (OR 1.69-1.86) with reference to surgery on a Thursday afternoon (1200-1759)
 - Multiple interactions between respiratory history and ASA-PS classes were observed
- 11 of the 18 POSSUM variables were retained in the final models following backward elimination. Additionally, ASA-PS, admission type and serum creatinine were retained across all models

R² values associated with model construction and backward variable elimination

- Block-wise model construction of the general (operative indication and surgical findings) models indicated that POSSUM variables and additional patient risk factors modelled up to 27% of the estimated total variance in inpatient 30-day mortality
- In contrast, processes of care, operative, procedural and temporal factors modelled only 3-4%
- In patients over the age of 70 years on hospital admission, POSSUM variables and additional risk factors modelled up to 19% of the variance, but again processes of care, operative, procedural and temporal factors modelled less than 3-4%
- Following backward elimination, the general models could explain 28% and the older patient models 22% of the estimated total variance

7.3.1 Data quality

Incomplete data

Preoperative serum lactate levels were submitted for 52% of submitted cases, precluding its inclusion in multivariable models.

Other additional candidate variables (Sex, ASA-PS, admission type and reoperation) were 100% complete.

Data completeness and excluded cases are reported in full in *Chapter 5*.

7.3.2 Final multivariable models

1. Operative indications model

Variable	Categories	Patients (%)	Odds Ratio	p value	95% Confidence Interval	
Age (years)						
	≤60	6,834 (33.9)	1.00 (Ref)	-	-	-
	61-70	4,197 (20.8)	1.61	<0.001	1.34	1.93
	71-80	5,084 (25.2)	2.52	<0.001	2.12	2.99
	81-90	3,537 (17.5)	3.65	<0.001	3.03	4.39
	≥91	531 (2.6)	4.95	<0.001	3.75	6.55
Cardiac signs						
	No failure	14,970 (74.2)	1.00 (Ref)	-	-	-
	Diuretic/ digoxin/ anti-anginal/ anti- hypertensive	4,031 (20.0)	1.07	NS	0.94	1.21
	Peripheral oedema, warfarin therapy	946 (4.7)	1.36	<0.001	1.13	1.64
	Raised JVP	236 (1.2)	1.36	NS	0.98	1.88
Respiratory history ^(†)						
	No dyspnoea	14,703 (72.9)	1.00 (Ref)	-	-	-
	Dyspnoea on exertion	3,068 (15.2)	1.48	<0.001	1.21	1.81
	Limiting dyspnoea	1,648 (8.2)	1.77	<0.001	1.38	2.26
	Dyspnoea at rest	764 (3.8)	3.00	<0.001	2.00	4.50
Systolic blood pressure						
	≤ 89	902 (4.5)	1.54	<0.001	1.27	1.87
	90-99	1,153 (5.7)	1.41	<0.001	1.17	1.70
	100-109	1,981 (9.8)	1.16	NS	0.98	1.37
	110-130	8,210 (40.7)	1.00 (Ref)	-	-	-
	131-170	6,922 (34.3)	0.91	NS	0.80	1.03
	≥ 171	711 (3.5)	0.94	NS	0.71	1.25
Heart rate						
	≤ 39	11 (0.1)	1.11	NS	0.20	6.12
	40-49	47 (0.2)	1.40	NS	0.54	3.62
	50-80	6,584 (32.6)	0.80	<0.001	0.70	0.92
	81-100	7,977 (39.5)	1.00 (Ref)	-	-	-
	101-120	3,998 (19.8)	1.14	NS	1.00	1.30
	≥ 121	1,274 (6.3)	1.12	NS	0.93	1.34
Glasgow Coma Score						
	15	18,300 (90.7)	1.00 (Ref)	-	-	-
	12-14	1,195 (5.9)	1.44	<0.001	1.23	1.68
	9-11	96 (0.5)	2.06	<0.001	1.26	3.34
	≤ 8	592 (2.9)	2.28	<0.001	1.77	2.95
White cell count						
	≤ 3.0	478 (2.4)	2.05	<0.001	1.59	2.64
	3.1-4.0	455 (2.3)	1.23	NS	0.89	1.70
	4.1-10	7,630 (37.8)	1.03	NS	0.92	1.16
	10.1-20.0	9,342 (46.3)	1.00 (Ref)	-	-	-
	≥20.1	2,171 (10.8)	1.53	<0.001	1.32	1.77
Urea						
	≤ 7.5	12,472 (61.8)	1.00 (Ref)	-	-	-
	7.6-10	2,991 (14.8)	1.25	<0.001	1.07	1.45
	10.1-15.0	2,540 (12.6)	1.42	<0.001	1.21	1.67
	≥15.1	2,180 (10.8)	1.58	<0.001	1.31	1.90

Sodium						
	≥ 136	12,790 (63.4)	1.00 (Ref)	-	-	-
	131-135	5,493 (27.2)	1.22	<0.001	1.08	1.36
	126-130	1,471 (7.3)	1.34	<0.001	1.13	1.60
	≤ 125	429 (2.1)	1.40	0.03	1.03	1.91
Potassium						
	≤ 2.8	251 (1.2)	2.25	<0.001	1.60	3.16
	2.9-3.1	601 (3.0)	1.38	0.02	1.04	1.81
	3.2-3.4	1,447 (7.2)	1.16	NS	0.96	1.41
	3.5-5.0	16,463 (81.6)	1.00 (Ref)	-	-	-
	5.1-5.3	687 (3.4)	1.21	NS	0.97	1.53
	5.4-5.9	448 (2.2)	1.45	<0.001	1.13	1.88
	≥ 6.0	141 (0.7)	1.40	NS	0.91	2.16
ECG						
	Normal	16,028 (79.4)	1.00 (Ref)	-	-	-
	Atrial fibrillation (rate 60-90)	850 (4.2)	1.09	NS	0.88	1.35
	Other arrhythmia	3,305 (16.4)	1.15	0.03	1.02	1.31
Peritoneal soiling						
	None	7,560 (37.5)	1.00 (Ref)	-	-	-
	Minor (serous fluid)	5,227 (25.9)	1.20	0.01	1.05	1.38
	Local pus	2,126 (10.5)	1.05	NS	0.85	1.30
	Free bowel content, pus or blood	5,270 (26.1)	1.48	<0.001	1.28	1.70
Presence of malignancy						
	None	15,557 (77.1)	1.00 (Ref)	-	-	-
	Primary only	2317 (11.5)	1.22	0.02	1.03	1.45
	Nodal metastases	861 (4.3)	1.49	<0.001	1.16	1.91
	Distant metastases	1,448 (7.2)	2.44	<0.001	2.04	2.93
Mode of surgery						
	Emergency resuscitation of >2h possible	17,157 (85)	1.00 (Ref)	-	-	-
	Emergency (immediate surgery <2h needed)	3,026 (15)	1.37	<0.001	1.21	1.57
Sex						
	Male	9,808 (48.6)	0.89	0.03	0.80	0.99
	Female	10,375 (51.4)	1.00 (Ref)	-	-	-
ASA-PS ^(†)						
	1	2,097 (10.4)	0.44	<0.001	0.29	0.68
	2	6,793 (33.7)	0.58	<0.001	0.47	0.71
	3	7,108 (35.2)	1.00 (Ref)	-	-	-
	4	3,747 (18.6)	2.32	<0.001	1.96	2.76
	5	438 (2.2)	5.09	<0.001	3.56	7.27
Admission type						
	Elective	1,490 (7.4)	1.00 (Ref)	-	-	-
	Emergency*	18,693 (92.6)	2.00	<0.001	1.62	2.47
Preoperative serum creatinine concentration						
	<48	1,874 (9.3)	1.30	0.01	1.07	1.58
	48-84	9,986 (49.5)	1.00 (Ref)	-	-	-
	85-113	4,041 (20.0)	1.01	NS	0.86	1.17
	114-130	1,025 (5.1)	1.19	NS	0.96	1.47
	131-155	1,020 (5.1)	1.22	NS	0.99	1.51
	156-212	1,003 (5.0)	1.14	NS	0.92	1.42
	>212	1,000 (5.0)	1.31	0.02	1.04	1.65

Operative indications						
	Abdominal Abscess	1,332 (6.6)	0.77	0.04	0.60	0.98
	Intestinal Obstruction	9,811 (48.6)	0.87	0.04	0.77	0.99
	Ischaemia	1,720 (8.5)	1.83	<0.001	1.58	2.13
Perioperative processes of care						
	Risk documented preoperatively*	11,271 (55.8)	1.14	0.02	1.08	1.28
	Direct postoperative critical care admission*	12,041 (59.7)	1.50	<0.001	1.29	1.74
Constant			0.02	<0.001	0.01	0.03

Table 95 Final operative indications model. Reference categories were the most prevalent category in the cohort, except where denoted by an asterisk. Values in parentheses are percentages unless otherwise stated (NS: not significant, ^(†): Significant interactions observed)

Variable 1	Variable 2	Odds Ratio	p value	95% Confidence Interval	
Day of surgery: Monday (Thursday)	Time of day of surgery: 1800-0000 (1200-1759)	1.72	0.02	1.08	2.72
Respiratory history: Dyspnoea at rest (none)	ASA-PS: 4 (3)	0.57	0.02	0.35	0.91
Respiratory history: Dyspnoea at rest (none)	ASA-PS: 5 (3)	0.49	0.04	0.25	0.96

Table 96 Significant interaction terms in the final operative indications model (Reference terms are provided in parentheses)

2. Surgical findings model

Variable	Categories	Patients (%)	Odds Ratio	p value	95% Confidence Interval	
Age (years)						
	≤60	6,834 (33.9)	1.00 (Ref)	-	-	-
	61-70	4,197 (20.8)	1.60	<0.001	1.33	1.93
	71-80	5,084 (25.2)	2.55	<0.001	2.15	3.04
	81-90	3,537 (17.5)	3.65	<0.001	3.03	4.39
	≥91	531 (2.6)	4.97	<0.001	3.76	6.56
Cardiac signs						
	No failure	14,970 (74.2)	1.00 (Ref)	-	-	-
	Diuretic/ digoxin/ anti-anginal/ anti-hypertensive	4,031 (20.0)	1.05	NS	0.92	1.19
	Peripheral oedema, warfarin therapy	946 (4.7)	1.35	<0.001	1.11	1.63
	Raised JVP	236 (1.2)	1.32	NS	0.95	1.84
Respiratory history^(†)						
	No dyspnoea	14,703 (72.9)	1.00 (Ref)	-	-	-
	Dyspnoea on exertion	3,068 (15.2)	1.48	<0.001	1.21	1.81
	Limiting dyspnoea	1,648 (8.2)	1.74	<0.001	1.36	2.23
	Dyspnoea at rest	764 (3.8)	2.99	<0.001	1.99	4.47
Systolic blood pressure						
	≤ 89	902 (4.5)	1.58	<0.001	1.29	1.93
	90-99	1,153 (5.7)	1.49	<0.001	1.23	1.80
	100-109	1,981 (9.8)	1.20	0.04	1.01	1.43
	110-130	8,210 (40.7)	1.00 (Ref)	-	-	-
	131-170	6,922 (34.3)	0.95	NS	0.83	1.08
	≥ 171	711 (3.5)	0.97	NS	0.72	1.29
Heart rate						
	≤ 39	11 (0.1)	1.00	NS	0.18	5.75
	40-49	47 (0.2)	1.51	NS	0.58	3.91
	50-80	6,584 (32.6)	0.81	<0.001	0.71	0.93
	81-100	7,977 (39.5)	1.00 (Ref)	-	-	-
	101-120	3,998 (19.8)	1.15	0.04	1.00	1.31
	≥ 121	1,274 (6.3)	1.12	NS	0.93	1.35
Glasgow Coma Score						
	15	18,300 (90.7)	1.00 (Ref)	-	-	-
	12-14	1,195 (5.9)	1.46	<0.001	1.25	1.71
	9-11	96 (0.5)	2.25	<0.001	1.38	3.68
	≤ 8	592 (2.9)	2.37	<0.001	1.84	3.07
Haemoglobin						
	≤ 9.9	3,171 (15.7)	1.21	0.01	1.04	1.41
	10.0-11.4	3,421 (17.0)	1.10	NS	0.94	1.28
	11.5-12.9	4,467 (22.1)	1.03	NS	0.89	1.19
	13.0-16.0	7,504 (37.2)	1.00 (Ref)	-	-	-
	16.1-17.0	900 (4.5)	1.01	NS	0.77	1.31
	17.1-18.0	396 (2.0)	0.65	NS	0.43	0.99
	≥ 18.1	250 (1.2)	0.82	NS	0.53	1.26
White cell count						
	≤ 3.0	478 (2.4)	1.96	<0.001	1.52	2.54
	3.1-4.0	455 (2.3)	1.25	NS	0.91	1.73
	4.1-10	7,630 (37.8)	1.03	NS	0.92	1.16
	10.1-20.0	9,342 (46.3)	1.00 (Ref)	-	-	-
	≥20.1	2,171 (10.8)	1.56	<0.001	1.34	1.81

Urea						
	≤ 7.5	12,472 (61.8)	1.00 (Ref)	-	-	-
	7.6-10	2,991 (14.8)	1.23	0.01	1.06	1.43
	10.1-15.0	2,540 (12.6)	1.40	<0.001	1.19	1.64
	≥15.1	2,180 (10.8)	1.49	<0.001	1.24	1.80
Sodium						
	≥ 136	12,790 (63.4)	1.00 (Ref)	-	-	-
	131-135	5,493 (27.2)	1.21	<0.001	1.07	1.35
	126-130	1,471 (7.3)	1.31	<0.001	1.09	1.56
	≤ 125	429 (2.1)	1.43	0.02	1.05	1.95
Potassium						
	≤ 2.8	251 (1.2)	2.23	<0.001	1.58	3.15
	2.9-3.1	601 (3.0)	1.36	0.03	1.03	1.80
	3.2-3.4	1,447 (7.2)	1.18	NS	0.97	1.43
	3.5-5.0	16,463 (81.6)	1.00 (Ref)	-	-	-
	5.1-5.3	687 (3.4)	1.21	NS	0.96	1.52
	5.4-5.9	448 (2.2)	1.49	<0.001	1.16	1.92
	≥ 6.0	141 (0.7)	1.41	NS	0.92	2.18
ECG						
	Normal	16,028 (79.4)	1.00 (Ref)	-	-	-
	Atrial fibrillation (rate 60-90)	850 (4.2)	1.10	NS	0.88	1.36
	Other arrhythmia	3,305 (16.4)	1.14	0.04	1.01	1.29
Peritoneal soiling						
	None	7,560 (37.5)	1.00 (Ref)	-	-	-
	Minor (serous fluid)	5,227 (25.9)	1.17	0.02	1.02	1.34
	Local pus	2,126 (10.5)	1.04	NS	0.83	1.30
	Free bowel content, pus or blood	5,270 (26.1)	1.38	<0.001	1.18	1.62
Presence of malignancy						
	None	15,557 (77.1)	1.00 (Ref)	-	-	-
	Primary only	2317 (11.5)	1.16	NS	0.98	1.38
	Nodal metastases	861 (4.3)	1.21	NS	0.92	1.58
	Distant metastases	1,448 (7.2)	1.64	<0.001	1.25	2.16
Mode of surgery						
	Emergency resuscitation of >2h possible	17,157 (85)	1.00 (Ref)	-	-	-
	Emergency (immediate surgery <2h needed)	3,026 (15)	1.43	<0.001	1.26	1.63
ASA-PS ^(†)						
	1	2,097 (10.4)	0.45	<0.001	0.29	0.70
	2	6,793 (33.7)	0.58	<0.001	0.47	0.71
	3	7,108 (35.2)	1.00 (Ref)	-	-	-
	4	3,747 (18.6)	2.33	<0.001	1.97	2.77
	5	438 (2.2)	5.09	<0.001	3.55	7.29
Admission type						
	Elective	1,490 (7.4)	1.00 (Ref)	-	-	-
	Emergency*	18,693 (92.6)	1.91	<0.001	1.54	2.36
Preoperative serum creatinine concentration						
	<48	1,874 (9.3)	1.35	<0.001	1.11	1.64
	48-84	9,986 (49.5)	1.00 (Ref)	-	-	-
	85-113	4,041 (20.0)	1.00	NS	0.86	1.16
	114-130	1,025 (5.1)	1.19	NS	0.96	1.47
	131-155	1,020 (5.1)	1.20	NS	0.97	1.48
	156-212	1,003 (5.0)	1.14	NS	0.92	1.41
	>212	1,000 (5.0)	1.31	0.02	1.04	1.64

Surgical findings						
	Abscess	2,332 (11.6)	0.82	0.04	0.68	0.99
	Diverticulitis	1,158 (5.7)	0.73	0.02	0.57	0.94
	Haemorrhage: intestinal	207 (1.0)	0.50	0.01	0.30	0.82
	Intestinal Ischaemia	2,543 (12.6)	1.80	<0.001	1.57	2.06
	Malignancy: disseminated	1,443 (7.2)	1.63	<0.001	1.24	2.14
	Perforation of small bowel/colon	3,893 (19.3)	1.39	<0.001	1.20	1.61
Perioperative processes of care						
	Risk documented preoperatively*	11,271 (55.8)	1.16	0.01	1.08	1.28
	Direct postoperative critical care admission*	12,041 (59.7)	1.51	<0.001	0.90	1.66
Constant			0.02	<0.001	0.01	0.02

Table 97 Final surgical findings model. Reference categories were the most prevalent category in the cohort, except where denoted by an asterisk. Values in parentheses are percentages unless otherwise stated (NS: not significant, ^(†): Significant interactions observed)

Variable 1	Variable 2	Odds Ratio	p value	95% Confidence Interval	
Day of surgery: Monday (Thursday)	Time of day of surgery: 1800-0000 (1200-1759)	1.69	0.03	1.07	2.69
Respiratory history: Dyspnoea at rest (none)	ASA-PS: 4 (3)	0.56	0.02	0.35	0.89
Respiratory history: Dyspnoea at rest (none)	ASA-PS: 5 (3)	0.49	0.04	0.25	0.97

Table 98 Significant interaction terms in the final surgical findings model (Reference terms are reported in parentheses)

3. Operative indications model in patients over the age of 70

Variable	Categories	Patients (%)	Odds Ratio	p value	95% Confidence Interval	
Age (years)						
	71-80	5,084 (55.6)	1.00 (Ref)	-	-	-
	81-90	3,537 (38.7)	1.55	<0.001	1.36	1.77
	≥91	531 (5.8)	2.31	<0.001	1.80	2.96
Respiratory history ^(†)						
	No dyspnoea	5,654 (61.8)	1.00 (Ref)	-	-	-
	Dyspnoea on exertion	1,951 (21.3)	1.42	<0.001	1.12	1.81
	Limiting dyspnoea	1,125 (12.3)	1.69	<0.001	1.26	2.26
	Dyspnoea at rest	422 (4.6)	2.65	<0.001	1.55	4.52
Systolic blood pressure						
	≤ 89	457 (5.0)	1.76	<0.001	1.38	2.26
	90-99	551 (6.0)	1.61	<0.001	1.27	2.03
	100-109	778 (8.5)	1.20	NS	0.97	1.49
	110-130	3,342 (36.5)	1.00 (Ref)	-	-	-
	131-170	3,438 (37.6)	0.87	NS	0.74	1.01
	≥ 171	466 (5.1)	0.89	NS	0.65	1.23
Heart rate						
	≤ 39	8 (0.1)	1.66	NS	0.28	9.66
	40-49	27 (0.3)	1.49	NS	0.54	4.08
	50-80	3,143 (34.3)	0.81	0.01	0.69	0.95
	81-100	3,731 (40.8)	1.00 (Ref)	-	-	-
	101-120	1,596 (17.4)	1.08	NS	0.91	1.27
	≥ 121	537 (5.9)	0.93	NS	0.73	1.19
Glasgow Coma Score						
	15	8,171 (89.3)	1.00 (Ref)	-	-	-
	12-14	763 (8.3)	1.69	<0.001	1.40	2.04
	9-11	47 (0.5)	3.03	<0.001	1.49	6.15
	≤ 8	171 (1.9)	1.79	<0.001	1.23	2.60
White cell count						
	≤ 3.0	207 (2.3)	1.99	<0.001	1.41	2.81
	3.1-4.0	190 (2.1)	1.00	NS	0.65	1.54
	4.1-10	3,531 (38.6)	0.97	NS	0.84	1.12
	10.1-20.0	4,218 (46.1)	1.00 (Ref)	-	-	-
	≥20.1	960 (10.5)	1.46	<0.001	1.21	1.76
Urea						
	≤ 7.5	4,258 (46.5)	1.00 (Ref)	-	-	-
	7.6-10	1,788 (19.5)	1.14	NS	0.95	1.37
	10.1-15.0	1,677 (18.3)	1.33	<0.001	1.10	1.60
	≥15.1	1,429 (15.6)	1.55	<0.001	1.24	1.94
Potassium						
	≤ 2.8	130 (1.4)	2.49	<0.001	1.62	3.83
	2.9-3.1	303 (3.3)	1.49	0.02	1.07	2.06
	3.2-3.4	751 (8.2)	1.05	NS	0.83	1.32
	3.5-5.0	7,279 (79.5)	1.00 (Ref)	-	-	-
	5.1-5.3	355 (3.9)	1.18	NS	0.88	1.57
	5.4-5.9	222 (2.4)	1.09	NS	0.77	1.55
	≥ 6.0	57 (0.6)	1.12	NS	0.57	2.20
ECG						
	Normal	6,125 (66.9)	1.00 (Ref)	-	-	-
	Atrial fibrillation (rate 60-90)	724 (7.9)	1.12	NS	0.89	1.41
	Other arrhythmia	2,303 (25.2)	1.21	0.01	1.04	1.40

Operative severity						
	Major	5,717 (62.5)	1.00 (Ref)	-	-	-
	Major +	3,435 (37.5)	1.16	0.03	1.02	1.32
Peritoneal soiling						
	None	3,575 (39.1)	1.00 (Ref)	-	-	-
	Minor (serous fluid)	2,548 (27.8)	1.13	NS	0.96	1.34
	Local pus	782 (8.5)	0.99	NS	0.77	1.28
	Free bowel content, pus or blood	2,247 (24.6)	1.50	<0.001	1.27	1.77
Presence of malignancy						
	None	6,710 (73.3)	1.00 (Ref)	-	-	-
	Primary only	1,287 (14.1)	1.36	0.04	1.02	1.81
	Nodal metastases	480 (5.2)	0.96	NS	0.60	1.54
	Distant metastases	675 (7.4)	2.07	<0.001	1.47	2.93
Sex						
	Male	4,097 (44.8)	0.79	<0.001	0.69	0.90
	Female	5,055 (55.2)	1.00 (Ref)	-	-	-
ASA-PS ^(†)						
	1	178 (1.9)	0.41	NS	0.13	1.25
	2	2,384 (26.1)	0.51	<0.001	0.37	0.71
	3	4,007 (43.8)	1.00 (Ref)	-	-	-
	4	2,351 (25.7)	1.98	<0.001	1.52	2.58
	5	232 (2.5)	4.01	<0.001	1.93	8.32
Admission type						
	Elective	644 (7.0)	1.00	-	-	-
	Emergency *	8,508 (93.0)	1.73	<0.001	1.34	2.24
Preoperative serum creatinine concentration						
	<48	637 (7.0)	1.37	0.02	1.06	1.77
	48-84	3,770 (41.2)	1.00 (Ref)	-	-	-
	85-113	2,103 (23.0)	1.03	NS	0.86	1.23
	114-130	673 (7.4)	1.33	0.02	1.04	1.70
	131-155	668 (7.3)	1.26	NS	0.98	1.62
	156-212	651 (7.1)	1.24	NS	0.95	1.61
	>212	562 (6.1)	1.38	0.03	1.03	1.85
Operative indications						
	Intestinal ischaemia	983 (10.7)	1.87	<0.001	1.56	2.24
Perioperative processes of care						
	preoperative documentation of risk*	5,476 (59.8)	1.17	0.02	1.02	1.34
	direct postoperative admission to critical care*	6,370 (69.6)	1.44	<0.001	1.20	1.73
	reviewed postoperatively by MCOP	906 (9.9)	0.29	<0.001	0.23	0.37
Constant			0.06	<0.001	0.04	0.09

Table 99 Final operative indications model in older patients (70)

Reference categories were the most prevalent category in the cohort, except where denoted by an asterisk. Values in parentheses are percentages unless otherwise stated (NS: not significant, ^(†): Significant interactions observed)

Variable 1	Variable 2	Odds Ratio	p value	95% Confidence Interval	
Day of surgery: Monday (Thursday)	Time of day of surgery: 1800-0000 (1200-1759)	1.82	0.04	1.04	3.17
ASA-PS: 2 (3)	Limiting dyspnoea (none)	2.47	0.03	1.08	5.61
ASA-PS: 2 (3)	Mode of surgery: required within 2 hours (>2 hours)	2.23	0.00	1.29	3.87
ASA-PS: 5 (3)	Diuretic/ digoxin/ anti-anginal/ anti- hypertensive (no failure)	2.51	0.02	1.19	5.27
ASA-PS: 5 (3)	Dyspnoea at rest (none)	0.33	0.03	0.12	0.88

Table 100 Significant interaction terms in the final operative indications model in patients over the age of 70 (Reference terms are reported in parentheses)

4. Surgical findings model in patients over the age of 70

Variable	Categories	Patients (%)	Odds Ratio	p value	95% Confidence Interval	
Age (years)						
	71-80	5,084 (55.6)	1.00 (Ref)	-	-	-
	81-90	3,537 (38.7)	1.51	<0.001	1.32	1.73
	≥91	531 (5.8)	2.25	<0.001	1.75	2.88
Respiratory history ^(†)						
	No dyspnoea	5,654 (61.8)	1.00 (Ref)	-	-	-
	Dyspnoea on exertion	1,951 (21.3)	1.43	<0.001	1.12	1.81
	Limiting dyspnoea	1,125 (12.3)	1.70	<0.001	1.27	2.28
	Dyspnoea at rest	422 (4.6)	2.61	<0.001	1.53	4.46
Systolic blood pressure						
	≤ 89	457 (5.0)	1.81	<0.001	1.41	2.32
	90-99	551 (6.0)	1.60	<0.001	1.27	2.02
	100-109	778 (8.5)	1.21	NS	0.98	1.50
	110-130	3,342 (36.5)	1.00 (Ref)	-	-	-
	131-170	3,438 (37.6)	0.89	NS	0.76	1.04
	≥ 171	466 (5.1)	0.90	NS	0.66	1.25
Heart rate						
	≤ 39	8 (0.1)	1.55	NS	0.25	9.50
	40-49	27 (0.3)	1.64	NS	0.60	4.51
	50-80	3,143 (34.3)	0.83	0.02	0.71	0.97
	81-100	3,731 (40.8)	1.00 (Ref)	-	-	-
	101-120	1,596 (17.4)	1.08	NS	0.91	1.27
	≥ 121	537 (5.9)	0.94	NS	0.74	1.20
Glasgow Coma Score						
	15	8,171 (89.3)	1.00 (Ref)	-	-	-
	12-14	763 (8.3)	1.70	<0.001	1.41	2.06
	9-11	47 (0.5)	3.18	<0.001	1.58	6.37
	≤ 8	171 (1.9)	1.94	<0.001	1.34	2.81
White cell count						
	≤ 3.0	207 (2.3)	1.91	<0.001	1.35	2.70
	3.1-4.0	190 (2.1)	0.99	NS	0.64	1.52
	4.1-10	3,531 (38.6)	0.98	NS	0.85	1.13
	10.1-20.0	4,218 (46.1)	1.00 (Ref)	-	-	-
	≥20.1	960 (10.5)	1.49	<0.001	1.23	1.79
Urea						
	≤ 7.5	4,258 (46.5)	1.00 (Ref)	-	-	-
	7.6-10	1,788 (19.5)	1.14	NS	0.95	1.36
	10.1-15.0	1,677 (18.3)	1.32	<0.001	1.09	1.59
	≥15.1	1,429 (15.6)	1.50	<0.001	1.20	1.88

Potassium						
	≤ 2.8	130 (1.4)	2.49	<0.001	1.62	3.83
	2.9-3.1	303 (3.3)	1.47	0.02	1.06	2.04
	3.2-3.4	751 (8.2)	1.10	NS	0.87	1.38
	3.5-5.0	7,279 (79.5)	1.00 (Ref)	-	-	-
	5.1-5.3	355 (3.9)	1.20	NS	0.90	1.59
	5.4-5.9	222 (2.4)	1.10	NS	0.78	1.56
	≥ 6.0	57 (0.6)	1.14	NS	0.59	2.23
ECG						
	Normal	6,125 (66.9)	1.00 (Ref)	-	-	-
	Atrial fibrillation (rate 60-90)	724 (7.9)	1.12	NS	0.89	1.41
	Other arrhythmia	2,303 (25.2)	1.20	0.01	1.04	1.40
Peritoneal soiling						
	None	3,575 (39.1)	1.00 (Ref)	-	-	-
	Minor (serous fluid)	2,548 (27.8)	1.11	NS	0.94	1.3
	Local pus	782 (8.5)	0.92	NS	0.71	1.19
	Free bowel content, pus or blood	2,247 (24.6)	1.31	<0.001	1.09	1.58
Presence of malignancy						
	None	6,710 (73.3)	1.00 (Ref)	-	-	-
	Primary only	1,287 (14.1)	1.23	0.04	1.01	1.49
	Nodal metastases	480 (5.2)	1.18	NS	0.86	1.63
	Distant metastases	675 (7.4)	1.69	<0.001	1.20	2.38
Sex						
	Male	4,097 (44.8)	0.81	<0.001	0.71	0.92
	Female	5,055 (55.2)	1.00 (Ref)	-	-	-
ASA-PS ^(†)						
	1	178 (1.9)	0.78	NS	0.38	1.58
	2	2,384 (26.1)	0.50	<0.001	0.38	0.68
	3	4,007 (43.8)	1.00 (Ref)	-	-	-
	4	2,351 (25.7)	2.00	<0.001	1.57	2.56
	5	232 (2.5)	4.65	<0.001	2.32	9.33
Admission type						
	Elective	644 (7.0)	1.00 (Ref)	-	-	-
	Emergency *	8,508 (93.0)	1.61	0.00	2.09	1.24
Preoperative serum creatinine concentration						
	<48	637 (7.0)	1.37	0.02	1.06	1.77
	48-84	3,770 (41.2)	1.00 (Ref)	-	-	-
	85-113	2,103 (23.0)	1.02	NS	0.85	1.23
	114-130	673 (7.4)	1.30	0.04	1.02	1.67
	131-155	668 (7.3)	1.24	NS	0.97	1.61
	156-212	651 (7.1)	1.24	NS	0.95	1.61
	>212	562 (6.1)	1.43	0.02	1.07	1.91
Surgical findings						
	Intestinal ischaemia	1,484 (16.2)	1.74	<0.001	1.49	2.05
	Malignancy: disseminated	704 (7.7)	1.57	0.01	1.12	2.20
	Perforation: small bowel/ colon	1,749 (19.1)	1.36	<0.001	1.15	1.62

Perioperative processes of care						
	preoperative documentation of risk*	5,476 (59.8)	1.20	0.01	1.04	1.37
	direct postoperative admission to critical care*	6,370 (69.6)	1.48	<0.001	1.77	1.24
	reviewed postoperatively by MCOP	906 (9.9)	0.29	<0.001	0.23	0.38
Constant			0.07	<0.001	0.05	0.09

Table 101 Final surgical findings model in older patients (>70 years)

Reference categories were the most prevalent category in the cohort, except where denoted by an asterisk. Values in parentheses are percentages unless otherwise stated (NS: not significant, ^(†): Significant interactions observed)

Variable 1	Variable 2	Odds Ratio	p value	95% Confidence Interval	
Day of surgery: Monday (Thursday)	Time of day of surgery: 1800-0000 (1200-1759)	1.86	0.03	1.07	3.24
ASA-PS: 2 (3)	Limiting dyspnoea (none)	2.46	0.03	1.09	5.57
ASA-PS: 2 (3)	Mode of surgery: required within 2 hours (>2hours)	2.19	0.01	1.27	3.78
ASA-PS: 5 (3)	Diuretic/ digoxin/ anti-anginal/ anti-hypertensive (no failure)	2.15	0.04	1.04	4.43
ASA-PS: 5 (3)	Dyspnoea at rest (none)	0.35	0.03	0.13	0.91

Table 102 Significant interaction terms in the final surgical findings model in patients over the age of 70 (Reference terms are provided in parentheses)

7.3.3 Block-wise model construction

Variables	Model			
	Operative indication	Surgical findings	Operative indication (>70yrs)	Surgical findings (>70yrs)
POSSUM variables	0.23	0.23	0.16	0.16
Additional patient factors*	0.27	0.27	0.19	0.19
Operative indication*	0.28	-	0.21	-
Surgical findings*	-	0.28	-	0.21
Processes of care*	0.28	0.29	0.22	0.22
Temporal*	0.28	0.29	0.23	0.23
Procedural factors †	0.30	0.31	-	-
FINAL MODELS	0.28	0.28	0.22	0.22

Table 103 Pseudo R² values associated with inclusion of groups of variables on block-wise model construction and final models following backward elimination of non-significant variables (*: interaction terms included in block, †: not included in final models)

7.4 Discussion

Key points

- This cohort of 20,183 patients represents the largest prospectively identified population of emergency laparotomy patients to date
- Patient risk factors modelled a substantial proportion of the estimated overall variation in postoperative inpatient 30-day mortality
- In contrast, delivery of perioperative processes of care modelled only a small fraction of the estimated overall variation
- Only two processes of care (direct postoperative critical care admission and preoperative documentation of risk) independently predicted inpatient 30-day mortality across the cohort. The apparent increase in risk associated with these processes is anticipated to reflect unmeasured confounding in the dataset
- The observation that postoperative review by an MCOP physician was associated with substantial risk reduction in a subgroup of patients over the age of 70 years merits further investigation

7.4.1 Overview

Emergency laparotomies are frequently performed for potentially life-threatening pathologies and while postoperative mortality and morbidity within a month of surgery are common overall,^{2, 9-13, 89} the analyses reported in *Chapter 5 and Chapter 6* support previous findings demonstrating substantial variation between patient groups^{2, 6, 9, 10, 23, 26, 28-33} and between hospitals respectively.^{2, 9, 36}

These observations offer opportunities for improving patient outcomes and standards of care received by patients undergoing emergency laparotomies. Therefore, because hospital structures and processes of care may account for some of the observed between-hospital variation,^{40, 44} it is anticipated that the identification of associations will provide targets for quality improvement strategies in emergency laparotomy populations.²⁷

Associations between variations in patient outcomes and organisational and temporal factors have been reported in wider contexts,^{2, 6, 9-11, 23, 26, 28-33, 43, 46-55} and in *Chapter 3 and Chapter 5* I reported marked variations in structural provisions and the delivery of processes of care for emergency laparotomy. The analyses reported in this Chapter build upon these findings to firstly identify processes of care independently associated with variation in mortality after emergency laparotomy; and to then estimate the contribution of these processes to overall variation in postoperative mortality.

Three processes of care were identified as independent predictors of mortality, however, while these processes explained only a small fraction, patient risk factors explained a substantial proportion of variation in inpatient 30-day mortality, supporting previous findings.⁴⁶

7.4.2 Independent patient-level predictors of inpatient 30-day mortality

Processes of care were modelled alongside potential confounding variables (patient factors, surgical pathologies and temporal factors) in order to identify independent predictors of inpatient 30-day mortality after emergency laparotomy. Because multivariable analysis cannot accommodate variables across hierarchical levels, variables measured at or anticipated to be influenced at hospital level were not modelled.

Perioperative processes of care

Of the eleven processes of care modelled (Appendix 7.1), only two (direct postoperative critical care admission and preoperative documentation of risk) were determined to be significantly associated with variation in inpatient 30-day mortality across the models (Table 95, Table 97, Table 99 and Table 101). Postoperative review by an MCOP physician was additionally identified as being significantly associated with variation in patient outcome in patients over the age of 70 (Table 99 and Table 101).

Direct postoperative admission to critical care was consistently observed to be associated with increased incidence of inpatient 30-day mortality across the four multivariable models. These findings indicate firstly that this association was not substantially influenced by the inclusion of patient age or by selection of operative indication or surgical findings; and secondly that, when the modelled measures of patient risk and surgical pathology were accounted for, direct admission to critical care following emergency laparotomy was associated with excess inpatient 30-day mortality.

These findings appear to contradict widespread perceptions that postoperative outcomes are improved with the early recognition and 'rescue' of deteriorating patients that characterise critical care environments.^{49, 179} However, similar associations have been identified previously in observational studies of EGS cohorts,¹¹ and this finding should be interpreted in light of the limitations of observational studies.

In previous chapters I discussed the need to adjust for confounding variables in observational studies and the consequences of residual confounding when interpreting

associations. When evaluating associations between interventions and patient outcomes in observational studies, it is also necessary to consider a special type of confounding, confounding by indication.

In well conducted randomised studies of sufficient size, the distribution of potential confounding variables should be sufficiently similar in intervention and control arms to not require adjustment. In contrast, patients are not exposed to processes of care at random in observational studies; rather the treatment received should be indicated by their clinical condition. Therefore, if confounding variables are not adequately quantified in intervention (patients admitted directly to critical care) and non-intervention (patients admitted directly to a general ward) groups, or if methods to control for these variables are inadequate, associations may be confounded by differences between the groups.

Therefore, while a large number of patient risk factors, temporal variables and other processes of care were modelled in these multivariable analyses, there is significant potential that the identified association between postoperative critical care unit admission and inpatient 30-day mortality was confounded by indication.

Preoperative documentation of risk of death was also observed to be consistently associated with increased incidence of inpatient 30-day mortality across the four multivariable models. Preoperative assessment of risk is widely perceived as an essential component of good clinical practice,⁷⁵ informing not only consent but also targeting the delivery of augmented processes of care to patients at increased risk of adverse postoperative events.

Analysis of associations with patient characteristics in *Chapter 5* indicated that the preoperative documentation of patient risk was more comprehensive in higher risk patient groups (Table 57, Table 58 and Table 59). Therefore, when viewed in the context of prevailing opinion and the observations reported in *Chapter 5*, this association may have been confounded by unmeasured differences between the groups.

Postoperative review by an MCOP physician was identified as being significantly associated with reduced incidence of inpatient 30-day mortality when modelled in a subset of patients over the age of 70.

These findings indicate firstly that this association was not substantially influenced by the selection of operative indication or surgical findings; and secondly that, when the modelled measures of patient risk and surgical pathology were accounted for, postoperative mortality was substantially reduced in the minority of patients over the age of 70 who were reviewed postoperatively by an MCOP physician.

Interpretation of the associations with postoperative mortality discussed above indicated that unmeasured patient variables may have confounded these associations. The potential of unmeasured variables to confound the association between MCOP review and postoperative mortality should therefore also be considered. However, in a large and increasing population at substantially increased risk of death within a month of surgery, this association may have considerable consequences for patient care and outcomes following emergency laparotomy.

Temporal factors

Data regarding temporal variations in patient outcomes over the course of the week are conflicting,⁶⁶⁻⁶⁸ and day and time of day of surgery were not demonstrated to be independent predictors of postoperative mortality in these analyses. It is however notable that postoperative mortality was consistently increased across all four models in patients undergoing surgery on Monday evenings (1800-0000) with reference to Thursday afternoons (Table 96, Table 98, Table 100 and Table 102).

Analyses in *Chapter 5* indicated a discrepancy between admissions to hospital and cases arriving in theatre, with admissions being most numerous on Mondays, while the most operations were performed on Thursdays (Table 44). While postoperative mortality varies by surgical pathology (Table 50 and Table 51) and appropriate delay to surgery varies between pathologies, this apparent discrepancy is most likely to represent variation in structural provisions and the delivery of processes of care by day of the week.

7.4.3 Squared multiple correlation (R^2)

Variance in inpatient 30-day mortality was estimated in *Chapter 5* to be 0.1 (equating to a standard deviation of 31% about the mean of 11.3%). Families of variables were introduced as blocks into multivariable models and changes in the R^2 statistic tracked in order to estimate the proportion of the overall estimated variance that could be explained by modelled variables including processes of care, temporal factors and markers of patient-level risk.¹⁶⁸

Patient risk factors (POSSUM variables and additional factors) modelled up to 27% of variance in inpatient 30-day mortality after emergency laparotomy (Table 103), whereas processes of care, surgical pathology, temporal factors and operative procedure together explained 3 - 4% of the variance and their inclusion increased the explanatory power of the models only modestly.

Squared multiple correlation analyses should be interpreted with a degree of caution for binary outcome data. However, while there is little precedent of direct comparisons of the strengths of associations of patient and process factors with which to contextualise these findings, there are data indicating that patient factors may explain the majority of observed variation in mortality,⁶⁰ and that a in excess of half of observed between-hospital variance may result from chance alone.^{42, 45} The findings of this R^2 analysis therefore indicate that patient factors modelled a substantial proportion of the overall variance in postoperative mortality and that, in contrast, the modelled processes of care explained only a small fraction.

In *Chapter 3 and Chapter 5* I reported substantial variation in the delivery of processes of care and underpinning structural provisions. Theoretical modelling indicates that such variations in organisational factors may contribute to between-hospital variation in patient outcomes.^{40, 44} However, modelling of perioperative processes of care in the analyses reported in this Chapter suggest that the influence of patient risk factors on variation in mortality after emergency laparotomy may be considerably greater.

7.5 Limitations

Limitations of data acquisition processes in the NELA year 1 patient audit dataset are reported in *Chapter 5*. There are however limitations of particular relevance to the multivariable modelling reported in this Chapter.

In common with the derivation of a novel casemix adjustment model (*Chapter 6*); variable selection was limited to those variables collected in the NELA year 1 patient audit and by data completeness; because time (relative to surgery) was not specified for many data items, associations between items used to estimate patient-level risk and postoperative mortality may have been confounded by good preoperative care; and retrospective data collection may have been biased by knowledge of a patient's perioperative course and postoperative outcome.

Finally, analyses of associations between organisational (hospital characteristics and structures) variables and patient-level (processes of care and patient outcomes) variables should be interpreted with caution; firstly, since reconfiguration of services may have occurred in the intervening period between the NELA organisational audit and the NELA patient audit; and secondly, because no organisational data were available for two hospitals participating in the patient audit.

7.6 Conclusions

Multivariable analysis of patient-level variables in the largest prospectively identified cohort of patients undergoing emergency laparotomy identified only three processes of care that were independent predictors of inpatient 30-day mortality; and indicated that patient factors explained considerably more variation in mortality than the delivery of modelled processes of care or temporal factors.

Older patients (>70 years) comprised almost half of the NELA year 1 patient audit cohort and inpatient 30-day mortality was considerably increased in this subgroup, however MCOP input was infrequent (*Chapter 5 and Chapter 7*). The observed reduction in mortality associated with postoperative review of these patients by an MCOP physician therefore warrants further investigation.

In the final Chapter I will develop the themes of the preceding Chapters in order to compare the relative influences of patient-level and hospital-level differences on patient outcomes after emergency laparotomy using mixed effects analysis.

Appendix 7.1: Multivariable modelling covariates

	Model 1: Operative indications	Model 2: Surgical findings
<i>Block 1: POSSUM variables[†]</i>		
	Age	
	Cardiac signs and Chest radiograph	
	Respiratory history and Chest radiograph	
	Systolic Blood pressure	
	Heart rate	
	Glasgow coma score	
	Haemoglobin	
	White cell count	
	Urea	
	Sodium	
	Potassium	
	Electrocardiogram	
	Operative severity	
	Multiple procedures	
	Total blood loss	
	Peritoneal soiling	
	Presence of malignancy	
	Mode of surgery	
<i>Block 2: Additional patient-level risk factors[†]</i>		
	Sex	
	ASA-PS	
	Admission type	
	Reoperation	
	Preoperative serum urea concentration [‡]	
<i>Block 2: Interaction terms</i>		
	ASA-PS*Cardiac signs	
	ASA-PS*Respiratory history	
	ASA-PS*GCS	
	ASA-PS*Presence of malignancy	
	ASA-PS*Mode of surgery	
	Admission type *Mode of surgery	
<i>Block 3</i>	<i>Operative indications</i>	<i>Surgical findings</i>
	Peritonitis	Abscess
	Perforation	Adhesions
	Abdominal Abscess	Anastomotic Leak
	Anastomotic Leak	Colitis
	Intestinal Fistula	Crohn's Disease
	Sepsis Other	Abdominal Compartment Syndrome
	Intestinal Obstruction	Diverticulitis
	Haemorrhage	Haemorrhage (Peptic Ulcer)
	Ischaemia	Haemorrhage (Intestinal)
	Colitis	Haemorrhage (Postoperative)
	Abdominal Wound Dehiscence	Incarcerated Hernia
	Abdominal Compartment Syndrome	Intestinal Ischaemia
	Planned Relook	Malignancy (Localised)
	-	Malignancy (Disseminated)
	-	Perforation (Peptic Ulcer)
	-	Perforation (Small Bowel Colonic)
	-	Volvulus
	-	Normal Intra-Abdominal Findings
<i>Block 3: Interaction terms</i>		
	SBP score * Perforation	SBP score* Abscess
	SBP score * Abdominal Abscess	SBP score* Perforation (Peptic Ulcer)
	SBP score * Sepsis Other	SBP score* Perforation (Small Bowel

		Colonic)
	Haemoglobin score* Haemorrhage	Haemoglobin score* Haemorrhage (Peptic Ulcer)
	Peritoneal soiling score* Perforation (Small Bowel Colonic)	Haemoglobin score* Haemorrhage (Intestinal)
	Peritoneal soiling score* Anastomotic Leak	Haemoglobin score* Haemorrhage (Postoperative)
	-	Peritoneal soiling score *Anastomotic Leak
	-	Peritoneal soiling score *Perforation (Peptic Ulcer)
<i>Block 4: Perioperative processes of care</i>		
	Risk was documented preoperatively	
	Decision to operate made in person by a consultant surgeon	
	Preoperative review by a consultant anaesthetist	
	Operation performed under direct supervision of a consultant surgeon	
	Operation under direct supervision of Consultant Anaesthetist	
	Both consultants present in theatre	
	Direct critical care admission	
	Preoperative documentation of risk	
	CT reported before emergency laparotomy	
	Goal directed fluid therapy	
	Postoperative review by an MCOP specialist in patients over 70 years of age [§]	
<i>Block 4: Interaction terms</i>		
	Mode of surgery* Decision to operate made in person by a consultant surgeon	
	Mode of surgery* Preoperative review by a consultant anaesthetist	
	Admission type* Mode of surgery	
<i>Block 5: Day of week and time of day of surgery</i>		
	Day of surgery ^ε	
	Time of day of surgery ^ε	
	Day of the week of surgery* Time of day of surgery	
<i>Block 6: Operative factors and interaction terms</i>		
	Primary operative procedure	
	Procedural approach	

Table 104 Covariates modelled in multivariable analysis

(†: Variables comprising blocks 1 and 2 were entered as categorised in Table 148, ‡ Continuous variable entered into the models as categories *: factor interaction terms, §: assessed only in a subpopulation of older patients (>70 years), SBP: systolic blood pressure, ε: defined as arrival into operating theatre for index emergency laparotomy

Appendix 7.2: Primary operative procedure

Peptic ulcer - suture or repair of perforation
Peptic ulcer over-sew of bleed
Gastric surgery - other
Small bowel resection
Colectomy: left (including anterior resection)
Colectomy: right
Colectomy: subtotal
Hartmann's procedure
Colorectal resection - other
Abdominal wall closure
Adhesiolysis
Drainage of abscess/collection
Exploratory/relook laparotomy only
Haemostasis
Intestinal bypass
Laparostomy formation
Repair of intestinal perforation
Resection of other intra-abdominal tumour(s)
Stoma formation
Stoma revision
Washout only
Not amenable to surgery

Table 105 Primary operative procedure

8. HOSPITAL-LEVEL AND PATIENT-LEVEL VARIABLES ASSOCIATED WITH VARIATION IN MORTALITY AFTER EMERGENCY LAPAROTOMY IN THE NELA YEAR 1 PATIENT AUDIT DATASET: MIXED EFFECTS ANALYSIS

8.1 Introduction

Background

Emergency laparotomies are commonly performed operations associated with high overall incidences of postoperative morbidity and mortality.^{2, 9-13} However, substantial variation in the incidence of postoperative adverse events has been observed both between patient subgroups and between the hospitals at which these operations are performed.^{2, 9, 36} Associations with a wide array of individual variables have been observed,^{2, 6, 9-11, 23, 26, 28-33, 43, 46-55} but relationships between variables are complex (Figure 4)⁴⁰ and the mechanisms underlying between-hospital variations in postoperative mortality after emergency laparotomy poorly described.

Candidate variables may be categorised into hierarchical levels, with for example individual patients forming the first level, hospitals the second, healthcare trusts the third and so on. Associations between postoperative mortality and patient-level variables were demonstrated in the analyses presented in *Chapter 7*; and with hospital-level variables, including hospital characteristics, structures, processes of care and procedure volumes.^{2, 6, 9-11, 23, 26, 28-33, 43, 46-62}

Disaggregation of hospital-level (level 2) variables to the level of individual patients (level 1) violates assumptions of the independence of variables that are fundamental to many statistical techniques. Doing so may therefore overestimate the significance of associations between level 2 variables and patient-level outcomes, leading to the false rejection of null hypotheses.¹⁸⁰ Classical techniques, including multivariable analysis (*Chapter 7*), are therefore inappropriate for analysis of the associations across hierarchical levels.

Mixed effects modelling is a group of multi-level techniques that is characterised by the derivation of fixed slope and random intercept regression models.[§] In order to quantify and investigate between-hospital differences, the mean effect (the model intercept) of individual hospitals on mortality is allowed to vary within the model; while the fixed part of the model (comprising patient-level predictor variables, akin to the multivariable models in *Chapter 7*) is held constant across participating hospitals.¹⁸⁰

[§] Random slopes may also be derived using mixed effects modelling, but for the purposes of these analyses logarithmic regression slopes are held constant and only the intercept allowed to vary.

Mixed effects modelling techniques are versatile and may be used in health services research for a variety of purposes: firstly, to quantify the effect of hospitals on variance in patient outcomes;^{180, 181} secondly, to quantify associations between hospital-level variables and patient outcomes; thirdly, to assess for the 'clustering' of patient-level variables at hospitals; and finally, by allowing the intercept to vary randomly, hospital-specific estimates of patient risk may be incorporated into clinical prediction tools.¹⁸²

In *Chapter 6*, I demonstrated between-hospital variation in casemix-adjusted inpatient 30-day mortality at hospitals participating in the NELA year 1 patient audit; in *Chapter 7*, I reported associations between patient-level variables and postoperative mortality and the degree to which patient-level variable models explain variance in postoperative mortality in this cohort of patients; and in *Chapter 3 and Chapter 5* I reported evidence of variation in hospital characteristics, structural provisions, procedure volumes and process delivery.

In this final analysis Chapter, I build on the analyses reported in the preceding 5 Chapters, using mixed effects techniques to confirm the existence of the hospital-level variation in mortality identified in *Chapter 6* and to quantify the effects of key hospital-level variables on variation in mortality after emergency laparotomy in the NELA year 1 patient dataset.

Aims

1. To quantify between-hospital variation in postoperative mortality, controlling for patient-level and hospital-level covariates
2. To identify hospital characteristics, structures and processes that model between-hospital variation in postoperative mortality

Objectives

1. Construct a variance component model (VCM)
2. Identify patient-level predictors of postoperative mortality within the NELA year 1 patient audit dataset
3. Construct a mixed effects model incorporating patient-level explanatory covariates
4. Sequentially test and quantify the effects of pre-specified hospital-level covariates on between-hospital variation in postoperative mortality

8.2 Materials and methods

Patient-level data were drawn from the year 1 National Emergency Laparotomy Audit (NELA) patient Audit cohort, comprising 20,183 cases submitted by 192 hospitals (*Chapter 5*) and organisational data from the first NELA Organisational Audit dataset, comprising datasets submitted by 190 hospitals (*Chapter 3*).

Data items are reported in Appendix 3.1 and Appendix 5.2. Organisational audit data were disaggregated and the datasets of the two Audits combined in Microsoft Excel (2010). Methods of the organisational and patient audits are reported in *Chapter 3 and Chapter 5* respectively. No additional exclusion criteria were imposed at patient-level or at hospital-level.

8.2.1 Definitions

Study endpoints

Inpatient death within 30-days of the index laparotomy (inpatient 30-day mortality) was used as the response variable in mixed effects modelling.

Mixed effects analysis

Mixed effects modelling may be used to assess and quantify the degree of variation in outcome that can be explained by hierarchical levels. Individual patients might form the first level, clinicians the second, hospitals the third, healthcare trusts the fourth and so on.

Logistic regression models may comprise a fixed slope (level 1 predictor variables determine the gradient of the slope), which is held constant at the highest hierarchical level; while the intercept of the model is allowed to vary (the variable component) in order to determine the effect of this hierarchical level (individual hospitals) on the study endpoint.

Variance component model (VCM)

In the stepwise construction of a mixed effects model, a VCM represents only the random effects component of the model, prior to the introduction of explanatory variables.¹⁷⁷ This may be used to calculate the variance^{**} in the level 1 (patient) outcome associated with level 2 (hospital) identifiers (incidence of inpatient 30-day mortality measured at hospital-level).^{††} VCMs are also referred to as null 2-level model models.

Explanatory and contextual variables may model some of the variance in hospital mortality rates.

^{**} Statistical models may also be configured to calculate standard deviation, deviance or other outputs

^{††} Or other identifiers at higher hierarchical levels

Variance

Variance (σ^2) provides a summary estimate of individual deviations from a population mean (hospital inpatient 30-day mortality rates).

Overall σ^2 can be divided into that which can be explained by modelled covariates and residual variance that is not explained by statistical modelling.

Explained variance: Statistical modelling of variables (individually or as groups) or hierarchical levels may explain some of the variance observed in a sample population

Residual variance: Also referred to as unexplained variance. Remaining variance that is not explained by statistical modelling

The associated p value is the probability that the null hypothesis (that there are no hospital-level differences in inpatient 30-day mortality) is due to chance.

Variance may be converted into other descriptions of data spread including standard deviations (or coverage intervals). Two standard deviations above and below the mean (representing ~95% of observations) may be calculated using the following transformation:

$$\mu \mp (2 \sqrt{\sigma^2})$$

Median Odds Ratio (MOR)

Comparisons of variances and standard deviations (even when transformed) are not intuitive. Models may instead be configured to report variance as median odds ratios and accompanying p values (the probability that the null hypothesis is due to chance).¹⁸³

An MOR of 1 (or non-significant p value) indicates that there is no variation in the incidence of postoperative mortality between hospitals, whereas increasingly large MORs indicate considerable variation.

Variables

Methods used to identify the variables entered into the mixed effects model are reported in the following section and individual variables reported.

8.2.2 Variable selection

Patient-level (level 1) variables were used to construct the mixed effects model and to test the effects of hospital-level (level 2) variables.

Patient-level (level 1) variables

The patient-level variables comprising the final general multivariable models constructed in *Chapter 7* (Table 95 and Table 97) were independent predictors of inpatient 30-day mortality. The level 1 (between-patient) variance modelled by these variables has been estimated (Table 103). These variables therefore represent strong candidates for inclusion in the fixed effects model.

Neither model was demonstrated to be superior in modelling the study endpoint (Table 103). The component variables of the final operative indications model (Table 95) were selected for inclusion in the construction of a single fixed effects model (Table 106), since it is proposed that operative indication represents an earlier marker of the event precipitating surgery and may be less influenced by hospital-level factors.

The processes of care (documentation of risk and direct critical care admission) modelled on multivariable analysis were retained when constructing the patient-level fixed effects model in order to test interactions between delivery at patient-level and hospital-level.^{180, 181}

Hospital-level (level 2) variables

Candidate variables were identified from the analyses of the NELA organisational audit dataset and NELA patient audit dataset (*Chapter 3 and Chapter 5* respectively). Variables were selected for modelling (Table 106) where precedent exists for the characterisation of hospital-level variation in patient outcomes,^{53, 56, 57, 68} and where associations were demonstrated in analyses of the organisational and patient audit datasets (*Chapter 3 and Chapter 5*).

Delivery of processes of care may be assessed as a predictor variable both at the level of individual patients (*Chapter 7*) and at provider-level, reflecting hospital-level structural and cultural determinants.⁴⁰ Hospital-level delivery of selected processes of care was therefore modelled by stratifying participating hospitals into quintiles, categorised by the proportion of patients who had received these processes of care (Table 106).

Three processes were identified as independent predictors of mortality at patient-level in the multivariable analyses presented in *Chapter 7*. Two of which, direct postoperative critical care admission and preoperative documentation of risk, were generalisable across the NELA year 1 patient cohort and were selected for modelling (Table 106). The third process,

postoperative review by an MCOP physician, was relevant only to older patients and was therefore not considered for modelling.

<i>Patient-level (level 1) variables</i>
Variables included in the final <i>operative indications</i> multivariable model
<i>Hospital-level (level 2) variables</i>
Hospital size (quartile of beds)
Tertiary GI surgical referral centre status
Configuration to admit EGS patients
24 hour provision of an operating theatre exclusively for ELs
EGS care pathway
Emergency surgical unit
Regular reviews of morbidity and mortality following EL
Volume of cases submitted (Quintiles)*
Preoperative documentation of risk (Quintiles)*
Direct postoperative critical care admission (Quintiles) *
Consultant surgeon and consultant anaesthetists supervising surgery (Quintiles) *

Table 106 Component variables of the mixed effects models (EGS: emergency general surgery, EL: emergency laparotomy) Level 2 variables were extracted from the organisational audit dataset, with the exception of data denoted by * which were obtained from the NELA patient audit

Finally, because the effect of the presence of consultant surgeons and consultant anaesthetists during emergency laparotomies is the subject of continued debate, their presence was modelled as a composite binary covariate (Table 106).

8.2.3 Data management

Procedures for the cleaning and validation of the NELA year 1 patient audit dataset are reported in *Chapter 5*.

Additional variables constructed in the derivation of the novel casemix adjustment model (informing selection of variables for multivariable modelling) are described in *Chapter 6*.

8.2.4 Statistical analysis and modelling

Mixed effects modelling was performed using Stata® version 12 (StataCorp LP, College Station, Texas, USA). NELA organisational and patient audit datasets were managed in Microsoft Excel (2010).

The Stata command for fitting multilevel models for binary response variables *xtmelogit* was used to construct mixed effects models. Model output was reported as median odds ratio (MOR) in the incidence of inpatient 30-day mortality.

Stepwise construction of the model was as follows:

1. *Variance component model (VCM) construction*: including only inpatient 30-day mortality and hospital identifier codes
2. *Construction of the mixed effects model*: The fixed effects (FE) model was constructed using patient-level variables (Table 95) and mixed effects analysis performed using *xtmelogit*. Non-significant variables and interaction terms ($p \geq 0.05$) were removed using a process of backward elimination. Categorical variables were retained if one or more categories was demonstrated to be significantly associated with inpatient 30-day mortality ($p < 0.05$)
3. *Modelling hospital-level explanatory variables*: Hospital-level variables (Table 106) were modelled individually as explanatory covariates (in the fixed effects model). Changes in the MOR were recorded

8.3 Results

Key findings

- Following exclusions, 20,183 patient records were included in the NELA year 1 patient audit dataset, submitted by participants at 192 hospitals across England and Wales
- Across the submitted data items, completeness was high
- After controlling for casemix, significant between-hospital variance in postoperative inpatient 30-day mortality was observed
- Hospital size and specialty status explained a small proportion of this variance
- In contrast, case volume, organisational structural provisions and hospital-level delivery of processes of care did not model the observed variance

8.3.1 Data quality

Preoperative serum lactate levels were submitted for 52% of submitted cases, precluding its inclusion in the fixed effects model. Data completeness and excluded cases in the NELA year 1 patient audit dataset are reported in full in *Chapter 5*.

8.3.2 Variance component and mixed effects models

Model	Median odds ratio (95% CI)
Variance component model	1.20*** (1.14-1.28)
Mixed effects model: patient-level explanatory variables [†]	1.24*** (1.17-1.34)

Table 107 Output of the variance component and mixed effects models
(* p<0.05, **p≤0.005, ***p≤0.001, [†] Non-significant variables (p≥0.05): Preoperative serum haemoglobin concentration, preoperative heart rate, operative indication: abdominal abscess, factor interaction term: day and time of surgery)

8.3.3 Modelling hospital-level explanatory variables

Variable	MOR (95% CI)	Change in MOR
<i>Hospital characteristics</i>		
Inpatient and overnight beds (Quartiles)	1.22*** (1.16-1.32)	-0.02
Tertiary GI surgical referral centre status	1.23*** (1.16-1.32)	-0.01
Configuration to admit EGS patients	1.24*** (1.17-1.34)	0
<i>Volume</i>		
Volume of submitted cases (Quintiles)	1.24*** (1.17-1.33)	0
<i>Structural provisions</i>		
24 hour provision of an operating theatre exclusively for ELs	1.24*** (1.17-1.33)	0
EGS care pathway	1.24*** (1.17-1.33)	0
Emergency surgical unit	1.24*** (1.17-1.34)	0
Regular reviews of morbidity and mortality following EL	1.24*** (1.17-1.33)	0
<i>Hospital-level delivery of processes of care</i>		
Preoperative documentation of risk (Quintiles)	1.24*** (1.17-1.33)	0
Direct postoperative critical care admission (Quintiles)	1.24*** (1.17-1.33)	0
Consultant surgeon and consultant anaesthetists supervising surgery (Quintiles)	1.24*** (1.17-1.34)	0

Table 108 Changes in the median odds ratio associated with modelling of hospital-level variables (* p<0.05, **p≤0.005, ***p≤0.001, ‡ from the 1.24 estimated by the patient-level-only mixed effects model)

Variable (categories)	Odds ratio (95% CI)
Inpatient and overnight beds (Quartiles)	
1	-Ref-
2	0.77 (0.63-0.94)*
3	0.82 (0.68-1.00) NS
4	0.76 (0.63-0.91)**
Tertiary GI surgical referral centre	0.83 (0.73-0.95)**
Configuration to admit EGS patients	1.01 (0.65-1.56) NS
Volume of submitted cases (Quintiles)	
1	-Ref-
2	1.07 (0.79-1.45) NS
3	1.02 (0.76-1.37) NS
4	1.01 (0.76-1.34) NS
5	0.99 (0.75-1.31) NS
24 hour provision of an operating theatre exclusively for ELs	0.91 (0.79-1.05) NS
EGS care pathway	0.92 (0.80-1.06) NS
Emergency surgical unit	0.92 (0.80-1.06) NS
Regular reviews of morbidity and mortality following EL	1.06 (0.90-1.24) NS
Preoperative documentation of risk (Quintiles)	
1	-Ref-
2	0.97 (0.79-1.19) NS
3	0.94 (0.76-1.15) NS
4	1.01 (0.82-1.25) NS
5	1.00 (0.81-1.23) NS
Direct postoperative critical care admission (Quintiles)	
1	-Ref-
2	0.94 (0.76-1.16) NS
3	0.90 (0.74-1.10) NS
4	0.93 (0.76-1.13) NS
5	0.85 (0.69-1.04) NS
Consultant surgeon and consultant anaesthetists supervising surgery (Quintiles)	
1	-Ref-
2	1.07 (0.87-1.31) NS
3	1.00 (0.81-1.23) NS
4	1.04 (0.85-1.28) NS
5	1.09 (0.89-1.33) NS

Table 109 Odds ratios associated with hospital level explanatory variable groups (* p<0.05, **p≤0.005, ***p≤0.001, NS: non significant)

8.4 Discussion

Key points

- This cohort of 20,183 patients represents the largest prospectively identified population of emergency laparotomy patients to date
- significant between-hospital variation in the incidence of short-term postoperative mortality was demonstrated
- This supports the findings of the casemix adjusted analyses reported in *Chapter 6* and previous indications of between hospital variation in postoperative mortality
- After controlling for casemix differences, significant between-hospital variance in postoperative inpatient 30-day mortality was observed to persist
- Hospital size and tertiary GI surgical referral centre status modelled a small proportion of the observed level 2 variance, but the other level 2 variables which were assessed were unable to explain any variance
- The increase in the MOR on the introduction of patient level explanatory variables (from 1.20 to 1.24) suggests variation in casemix composition between hospitals, variation in the weighting of level 1 risk factors between hospitals or perhaps variation in organisational responses to determinants of patient risk

8.4.1 Overview

Emergency laparotomies are frequently performed operations that have been consistently associated with high overall incidences of postoperative mortality (*Chapter 5*), morbidity and prolonged length of hospitalisation.^{2, 9-13} However, while average short-term mortality rates may exceed 15%, substantial variation has been observed between patient subgroups (*Chapter 5 and Chapter 7*)^{2, 6, 10, 23, 26, 28-33} and between hospitals (*Chapter 6*).^{2, 9, 27, 36}

Donabedian and Iezzoni proposed that, accounting for casemix, between-hospital variations may be explained by hospital-level variables and chance.^{40, 44} The identification of organisational factors (structures, processes and characteristics) that are associated with variation in mortality after emergency laparotomy might therefore inform the organisational change, quality improvement and targeted care initiatives that have been proposed for improving patient outcomes and quality of care in these high-risk populations.^{27, 69}

However, perioperative care is a multidimensional construct and relationships complex (Figure 4)⁴⁰ and, in contrast with patient-level variables, existing data regarding associations between organisational factors and patient outcomes are limited and conflicting.^{2, 9, 11, 43, 46-55}

In preceding Chapters I reported marked between-hospital variation in structural provisions (*Chapter 3*) and the delivery of perioperative processes of care (*Chapter 5*) for emergency laparotomies in England and Wales. However, multivariable modelling of patient-level variables in the 20,183 patients comprising the NELA year 1 patient cohort (*Chapter 7*) identified only 3 processes as independent predictors of postoperative inpatient 30-day mortality and, in contrast with patient risk factors, indicated that processes of care explained only a small fraction of the overall variation in mortality.

In this Chapter, associations between cross-level variables and factors with postoperative mortality were assessed using mixed effects modelling. These analyses demonstrated that significant between-hospital variation in the incidence of postoperative mortality persisted after controlling for patient-level factors, but that the hospital-level covariates selected for modelling explained little of this variation.

8.4.2 Model construction

The variance component model (VCM) demonstrated significant between-hospital variation in inpatient 30-day mortality (Table 107). This variation persisted after controlling for independent level 1 predictors of mortality (Table 107).

It is notable that the temporal factor variable was eliminated from the final mixed effects model due to non-significance.

The increase in the median odds ratio (MOR) observed on introducing level 1 variables to the VCM suggests that the effect of patient-level variables on hospital-level mortality may have varied between hospitals.¹⁷⁷ This could simply reflect casemix variation that was not described by the fixed effects (FE) model, variation in the weighting of risk factors (as discussed in *Chapter 6*) or variation in organisational responses to level 1 determinants of mortality.

The adopted approach to mixed effects modelling was to fix the gradient of the logistic regression slope, assuming that the coefficients of individual level 1 variables did not vary between hospitals. Allowing the gradient of the slopes to vary might better describe differences in the weighting of level 1 risk factors.

8.4.3 Hospital-level covariates

In total, 11 hospital-level covariates were modelled, including hospital characteristics, structural provisions for and delivery of processes of care to emergency general surgical patients and submitted case volumes (Table 106).

Of these variables, only hospital size and tertiary GI surgical referral centre status modelled small but appreciable proportions of the level 2 variance in inpatient 30-day mortality (Table 108). The findings of *Chapter 3* demonstrated that specialist GI centres were large hospitals and the association demonstrated by mixed effects modelling between specialty status and mortality may simply be a reflection of hospital size.

In earlier Chapters, structural provisions (including operating theatres, critical care beds; non-surgical interventional services and critical care consultant expertise) were demonstrated to be substantially more comprehensive at the largest hospitals. Provision of these resources could therefore account for the observed association.

The inability of the other level 2 variables to model level 2 variation in the incidence of postoperative mortality is notable. Firstly, and in contrast with some findings in other clinical settings, mortality rates did not vary by case volume in this population of emergency

laparotomy patients.^{54, 56-62} Secondly, the four structural provisions that were identified as potential markers of high quality EGS services (*Chapter 3*) did not model level 2 variation. Thirdly, hospital-level rates of direct critical care admission and documentation of risk, which modelled level 1 variation in mortality in *Chapter 7*, did not model level 2 mortality variation. And finally, hospital-level rates of consultant-led intraoperative care did not model level 2 variation.

8.5 Limitations

Limitations of data acquisition processes in the NELA year 1 patient audit dataset are reported in *Chapter 5*. There are however limitations of particular relevance to the mixed effects modelling reported in this Chapter.

Covariate selection was restricted to those variables collected in the NELA year 1 patient audit and by data completeness. Because time (relative to surgery) was not specified for many data items, associations between items used to estimate patient-level risk and postoperative mortality may have been confounded by good preoperative care. Retrospective data collection may have been biased by knowledge of a patient's perioperative course and postoperative outcome.

Finally, analyses of associations between organisational (hospital characteristics and structures) variables and patient-level (processes of care and patient outcomes) variables should be interpreted with caution; firstly, since reconfiguration of services may have occurred in the intervening period between the NELA organisational audit and the NELA patient audit; and secondly, because no organisational data were available for two hospitals participating in the patient audit.

8.6 Conclusions

Mixed effects modelling in the largest prospectively identified cohort of patients undergoing emergency laparotomy demonstrated significant variation in hospital-level mortality rates which persisted after controlling for patient risk factors and perioperative processes of care.

This variation was explained in part by hospital size and specialty (tertiary GI surgical referral centre) status. However, no volume effect was observed and differences between hospitals in the provision of EGS structures and the delivery of processes of care did not model the observed variation in postoperative mortality. The findings of these analyses are also notable for the absence of a temporal variation in postoperative mortality.

Findings of reduced mortality at the largest hospitals and specialist centres and indications that differences in organisational responses to patient risk factors may be associated with variation in mortality warrant further research

9. CONCLUSIONS AND DIRECTION OF FUTURE RESEARCH

9.1 Summary of this Thesis

Emergency laparotomies are performed commonly worldwide and postoperative morbidity and mortality represent sizable burdens to individual patients, healthcare providers and wider societies that may extend well beyond the immediate perioperative period. Furthermore, because contemporary cohorts comprise a high proportion of older patients, numbers of emergency laparotomies are forecast to increase dramatically over coming decades in the context of ageing global populations.

However, while many of the surgical events precipitating the need for an emergency laparotomy are potentially life-threatening, data from recent years have indicated that short-term postoperative survival varies substantially both between patient subgroups and between the hospitals at which these operations are performed.

These observations represent opportunities to improve the quality of care and disease-free survival in this large population of patients, and initiatives are underway internationally targeting high-risk subgroups. Modelling of between-hospital variation suggests that, having accounted for chance and variation in patient-level risk, residual variation can be explained by hospital-level differences in the delivery of processes of care (and underpinning structural provisions). Therefore, by identifying hospital-level factors associated with between-hospital variations in patient outcomes, targets for subsequent quality improvement projects might be identified. Existing data are limited by small sample sizes, retrospective data analysis and limited datasets.

The aims of the analyses presented in this thesis were; firstly to assess for the existence of between-hospital variation in short-term mortality after emergency laparotomy in the largest prospectively identified population of emergency laparotomy patients to date; secondly, to identify and characterise variation in structural provisions for and the delivery of perioperative processes of care to these patients; and thirdly, to identify potentially modifiable organisational factors (processes of care and hospital structures) associated with variation in postoperative mortality.

Analyses of the NELA year 1 patient audit (*Chapter 5*) confirmed a 30-day incidence of mortality exceeding 10% after emergency laparotomy and variation between patient groups consistent with previous findings.^{2, 9-13} Three processes of care were identified as independent predictors of mortality (*Chapter 7*) and significant between-hospital variation in mortality was demonstrated which persisted after controlling for casemix differences (*Chapter 6 and Chapter 8*). Tantalisingly, mixed effects analysis also indicated that hospital responses to patient risk factors might vary.

In *Chapter 3*, my analysis of the organisational data submitted by 190 hospitals to NELA demonstrated wide variation in the comprehensiveness of the provision of organisational structures for the care of emergency general surgical (EGS) patients; that participating hospitals were markedly heterogeneous; and that many structures were significantly more comprehensively provided at large and tertiary GI surgical centre hospitals and less comprehensively provided at hospitals not configured to routinely admit EGS patients.

In *Chapter 4*, a systematic review of risk assessment tools validated for perioperative use in adult emergency laparotomy cohorts identified APACHE II and P-POSSUM as the best validated clinical prediction tools. In the absence of sufficient data with which to compare performance and due to acceptance of P-POSSUM by the UK surgical community, POSSUM data items were incorporated into the NELA year 1 patient audit dataset.

In *Chapter 5*, my analysis of the largest prospectively identified population of emergency laparotomy patients demonstrated an overall inpatient 30-day mortality of 11.3%, substantial variation in crude mortality rates between patient groups and markedly increased mortality in older patients, those with limiting comorbidities and individuals requiring urgent surgery. Furthermore, considerable overall and between-hospital casemix heterogeneity was observed and the delivery of perioperative processes of care varied markedly, both between patient groups and between participating hospitals. In contrast with structural provisions, variation in the delivery of processes of care was not characterised by hospital size, tertiary GI surgical referral centre status or configuration to admit EGS patients.

In *Chapter 6*, casemix adjustment using a novel POSSUM-based model suggested wide between-hospital variation in the incidence of inpatient 30-day mortality, supporting the findings of recent studies. However, in the context of the casemix variation demonstrated in *Chapter 5* and potential between-hospital variation in the weighting of risk factors, the magnitude of between-hospital variation may have been overestimated.

Only three processes of care were identified as independent predictors of inpatient 30-day mortality in *Chapter 7*. The apparent positive associations of direct postoperative critical care admission and documentation of risk may be confounded by indication, but the magnitude of the association with postoperative MCOP review suggests that delivery of this complex intervention is likely to be of real benefit to older patients.

Significant between-hospital variation in inpatient 30-day mortality was demonstrated using mixed effects analysis in *Chapter 8*. Persistence of this variation after controlling for patient-level variables supported the casemix adjustment findings from *Chapter 6*. Hospital size and specialty (tertiary GI surgical referral centre) status were demonstrated to model a small but significant proportion of this variation.

The casemix variation observed in *Chapter 5* and variation in the effect of patient-level factors in *Chapter 8* indicates that the extent to which the delivery of processes of care is modified in response to patient risk factors varies between hospitals.

9.2 Implications of these findings

This thesis reports the findings of the most sophisticated analysis of two unparalleled datasets (the first systematic audit of hospital structures for the delivery of EGS care in the UK and the largest prospectively identified population of emergency laparotomy patients) and the first systematic review to identify and seek to compare risk assessment tools for emergency laparotomy. The findings of these analyses provide unique insights into perioperative care and postoperative outcomes that will inform the care of tomorrow's patients across the UK and perhaps beyond.

Firstly, substantial variation in structural provisions for and the delivery of perioperative processes of care to EGS patients was demonstrated between the hospitals in England and Wales at which emergency laparotomies are performed.

Secondly, between-hospital variation in 30-day mortality was confirmed in this large population of emergency laparotomy patients. This variation persisted after controlling for patient-level determinants of risk and perioperative processes of care.

Thirdly, three potentially modifiable processes of care (postoperative MCOP input, postoperative critical care admission and preoperative assessment of risk) were identified as independent predictors of mortality and there was an indication that organisational responses to patient risk factors might vary between hospitals.

And finally, 30-day mortality rates were demonstrated to be significantly lower at the largest hospitals and at tertiary GI surgical referral centres than at other hospitals, but not to vary by the volume of operations performed.

Taken together, these findings suggest that the routine preoperative estimation of risk of death (which might incorporate a hospital-level correction factor) for every patient undergoing an emergency laparotomy and the use of the resulting estimates to tailor individual perioperative care using structured multidisciplinary pathways may be associated with improved postoperative survival.

The associations between hospital size and specialist status with mortality rates merit further investigation not only with a view to improving quality of care and patient outcomes, but also in the context of ongoing policy discussions regarding the reconfiguration of EGS services.

9.3 Direction of subsequent work

9.3.1 Risk prediction

Accurate quantification of risk is the cornerstone of efforts to improve quality of care and disease-free survival after emergency laparotomy. It should inform discussions with patients, direct clinical decisions and be used to fairly compare between-hospital outcomes.

However, it is apparent from the analyses presented here that methods to quantify risk should incorporate hospital-level correction factors (to account for variation in the weighting of risk factors and response to patient risk); a wider spectrum of variables that might include socio-economic categories; and that more sophisticated tools may be required in order to circumvent the suspected confounding by indication. Furthermore, the reasons for the poor uptake of some prediction tools into clinical practice remain poorly understood.

With the advent of 'Big data' analytic techniques and systems with the capacity to compile multi-dimensional patient data profiles across time points, machine learning offers significant advantages, both in user experience and performance, due to its capacity to automatically acquire data items and to learn and continually update complex mathematical relationships between a vast array of input variables and outcomes of interest.^{143, 144}

9.3.2 Multidisciplinary pathways of care

Older patients are over-represented in emergency laparotomy populations and postoperative mortality rates are high. These analyses indicated that while MCOP input was infrequent, it may be associated with considerably decreased postoperative mortality rates and further investigation is therefore warranted.

Existing evidence for individual processes of care in emergency laparotomy is inconsistent and the adoption of emergency laparotomy pathways of care was poor when assessed in 2013. However, the use of bundles and pathways of care has been associated with improved patient outcomes in emergency laparotomy cohorts⁵⁰ and in wider contexts.^{51 52}

Implementation of evidence-based care pathways for emergency laparotomy (such as the ELPQuiC pathway) which additionally stratify risk and formalise the involvement of MCOP expertise may therefore have much to offer.

9.3.3 Prevention

Intra-abdominal malignancies commonly precipitate emergency laparotomies,²³ colorectal cancers are becoming increasingly common in older people²⁴ and postoperative outcomes vary with age and timing of presentation with malignancy.^{25, 26} The observation that up to a third of colorectal cancer diagnoses are made in the emergency setting²⁰ should therefore prompt investigations to determine the value of routine screening in reduce the burden of emergency laparotomies and improving postoperative outcomes.

9.3.4 Broader research questions

The burden of emergency laparotomies is likely to be underestimated since short-term mortality is currently the most widely reported outcome.¹⁶⁻¹⁸ The development of validated, reliable measures of postoperative morbidity, long-term survival and patient-reported outcomes in the context of a core outcomes framework would be welcomed.^{14, 15, 19}

Alternative statistical techniques are required to better model the effects of interactions between processes of care and patient factors (including critical care admission and patient risk factors). These might include allowing the slope of multilevel regression curves (fixed component) to vary; by expanding risk prediction modelling techniques, as discussed above; or through alternative techniques including instrumental variable analysis.

9.4 Principal limitations of these analyses

Interpretation of these analyses in the context of the existing literature and current trends in clinical practice necessitates a discussion of the limitations of the source data and statistical methods used.

9.4.1 Source data

The data analysed in this thesis were obtained from three sources: the first NELA organisational audit, the NELA year 1 patient audit and a systematic review of contemporary literature.

Common to both NELA audits is the issue of 'inter-rater' variability, particularly in the reduction of complex interventions^{††} to dichotomous variables (such as postoperative critical care admission). This poses a substantial potential limitation to the interpretation of the associations reported in *Chapter 6, Chapter 7 and Chapter 8*.

The first NELA organisational audit:

With the exception of reported number of beds, reported data were not externally validated and errors in reporting may therefore have gone undetected. Therefore in addition to potential for 'inter-rater' variability, reliability of data may have limited the ability to identify and quantify associations between hospital-level variables (*Chapter 3*) and between hospital-level and patient-level variables (*Chapter 7 and Chapter 8*).

The NELA year 1 patient audit:

Outcome analyses used a self-reported (inpatient 30-day mortality) endpoint as a surrogate for 30-day mortality in the absence of ONS data. Unreported inpatient deaths and deaths discharge from hospital within 30 days therefore limit analyses of associations with these data (*Chapter 6, Chapter 7 and Chapter 8*).^{§§}

The total number of included cases across England and Wales (20,183) was substantially smaller than the predicted annual caseload for England alone² and case ascertainment at English hospitals was estimated to be 83% in this cohort.⁸⁹ Potential causes of this discrepancy range from the methods used to model the denominator using HES data to the systematic failure of individual hospitals to enter high-risk cases. The generalisability of these findings across English and Welsh hospitals (and beyond) is therefore uncertain.

^{††} Both processes and structures

^{§§} ONS derived 30-day mortality in this cohort was reported to be 11.7% in the 2nd NELA patient Report, comparing favourably with the 11.3% inpatient 30-day mortality quoted in this thesis

Data completeness was on the whole remarkably good. The consequences of variable recording of some fields (most notably time points and POSSUM items) are outlined in the subsequent section.

The systematic review of contemporary literature:

The effects of bias in the identification of potential papers for inclusion in data synthesis are discussed in *Chapter 4*. Inclusion criteria, most notably only of papers reporting discrimination as AUC, methodological quality and heterogeneity of study design and patient populations may limit generalisability of the data synthesised in the systematic review within emergency laparotomy cohorts.

9.4.2 Statistical methods

A variety of statistical techniques were employed in order to achieve the aims of this thesis. The principal limitations of these techniques relate primarily to the quality and scope of source data.

In analyses of both the organisational and patient audits, the selection of modelled variables was limited by the available data. Modelling was therefore limited by the methods used to quantify these variables and perhaps also confounded by unmeasured variables.

The NELA year 1 patient audit:

Modelling of associations between timeliness of surgery and interval to antibiotics with postoperative outcome was not feasible, due to variable recording of time points, and may represent a source of residual confounding.

Over and above the limitations of indirect casemix adjustment (*Chapter 6*), two key factors limit the identification of casemix variation, comparisons of casemix adjusted outcomes and assessments of quality of care. Firstly, the substitution of missing P-POSSUM items with least deviant scores risks substantially underestimating risk in hospitals at which recording was poor. Secondly, the failure to capture the timing of recording of physiological variables relative to surgery resulted in an inability to differentiate between good preoperative care and lower risk populations.

Due to the intervening year between the closure of the organisational and patient audits, it should be noted that hospital- and patient-level data may not be contemporaneous. ***

*** In the second annual report of the NELA patient audit, few changes were observed at hospital-level.

The systematic review of contemporary literature:

Meta-analysis and direct comparisons of tool performance were precluded primarily by heterogeneity of study design and study populations.

APPENDIX A: PUBLICATIONS ASSOCIATED WITH THIS THESIS

Chapter 1.

Matt Oliver, Mike Grocott, Iain Anderson, Dave Murray. *The problem with emergency laparotomies*. British Journal of Hospital Medicine, September 2015, 76(9): 498-499 (doi:10.12968/hmed.2015.76.9.498)

Chapter 3.

NELA Project Team. First Organisational Audit Report of the National Emergency Laparotomy Audit. Royal College of Anaesthetists, London. 2014

Chapter 4.

Oliver CM, Walker EM, Giannaris S, Grocott MPW, Moonesinghe SR. *Risk assessment tools validated for patients undergoing emergency laparotomy: a systematic review*. British journal of anaesthesia 2015; 115: 849-60 (doi:10.1093/bja/aev350)

CM Oliver. *Risk tools for emergency laparotomy*. Br. J. Anaesth. (2016); 117 (5): 668. (doi: 10.1093/bja/aew346)

Chapter 5.

NELA Project Team. First Patient Audit Report of the National Emergency Laparotomy Audit. Royal College of Anaesthetists, London. 2015

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