A SYSTEMS APPROACH TO IDENTIFYING PATIENT SAFETY PROBLEMS IN ARTERIAL SURGERY

Thesis submitted to Imperial College London
for the degree of Doctor of Philosophy

Rachael Lear

Department of Surgery & Cancer
Imperial College London

SUPERVISORS

Mr Colin Bicknell
Department of Surgery & Cancer
Imperial College London

Professor Christine Norton
Florence Nightingale Faculty of Nursing & Palliative Care
King's College London

Professor Charles Vincent
Department of Experimental Psychology
University of Oxford

3rd March 2018

“Medicine used to be simple, ineffective and relatively safe.
Now it is complex, effective and potentially dangerous.”

Sir Cyril Chantler (1) (p.1181)

ABSTRACT

In the face of the oft-quoted dictum 'primum non nocere', it is now widely recognised that a significant number of patients come to harm whilst in hospital. A large body of evidence demonstrates that half of all harm events are preventable and the operating theatre appears to be the most common site for adverse events to occur. For patients undergoing arterial intervention, technical expertise and risk-factor management are clearly important in achieving excellent outcomes. Recent research in vascular surgery has focussed on volume-outcome relationships and the impact of advancements in endovascular intervention. By contrast, there is a relative lack of research examining the extraordinarily complex system within which patients with arterial disease are treated. This thesis aims to develop a broad understanding of system failures and their relationship with patient safety and outcomes in arterial surgery in the British NHS. In section I (chapter 1 and 2) the systems approach is outlined and discussed and the rationale for adopting this approach in arterial surgery is provided. Section II consists of three exploratory studies: chapter 3 presents a systematic review of the literature examining the impact of system factors on safety in arterial surgery; chapter 4 reports a mixed-methods study exploring surgeons' perceptions of the causes of adverse events in arterial surgery; and chapter 5 presents a multi-centre study of safety culture in vascular operating departments in England. Section III provides an account of the LEAP study: a multi-centre study of system failures occurring during aortic intervention. The methods and main findings of the LEAP study are presented in chapters 6 and 7. Chapter 8 reports on the determinants of intraoperative system failures and the relationship between intraoperative failure and patient outcome. Chapter 9 summarises the main findings and limitations of this thesis, and discusses recommendations for practice and future research.

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ABBREVIATIONS

AAA	Abdominal Aortic Aneurysm
AE	Adverse Event
ASA	American Society of Anesthesiologists
ASGBI	Association of Surgeons of Great Britain and Ireland
CEA	Carotid Endarterectomy
CI	Confidence Interval
COPD	Chronic Obstructive Pulmonary Disease
CORESS	Confidential Reporting System in Surgery
CABG	Coronary Artery Bypass Graft
Endo-OTAS	Endovascular Observational Teamwork Assessment for Surgery
EVAR	EndoVascular Aneurysm Repair
FEVAR	Fenestrated Endovascular Aneurysm Repair
GMC	General Medical Council
GRITS	Global Rating Index for Technical Skills
HSOPSC	Hospital Survey On Patient Safety Culture
ICECAP	Imperial College Error CAPture
IHD	Ischaemic Heart Disease
IQR	Inter-quartile range
IRR	Incidence Rate Ration
LEAP	Landscape of Error in Aortic Procedures
MaPSaF	Manchester Patient Safety Assessment Framework
N/A	Not Applicable
NHS	National Health Service
NIHR	National Institute for Health Research
NOTECHS	Non-TECHnical Skills
NQF	National Quality Forum
NRLS	National Reporting and Learning System
ODP	Operating Department Practitioner
OPRS	Operative Performance Rating Scale
OSATS	Objective Structured Assessment of Technical Skills
PAC	Preoperative Assessment Clinic
PAD	Peripheral Arterial Disease
PRISMA	Prerferred Reporting Items for Systematic reviews and Meta-Analyses
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SD	Standard Deviation
SAQ	Safety Attitudes Questionnaire
SQUIRE	Standards for Quality Improvement Reporting Excellence
STROBE	Strengthening The Reporting of Observational studies in Epidemiology
TAAA	Thoraco-Abdominak Aortic Aneurysm
TAVI	Transcatheter Aortic Valve Implantation
TEVAR	Thoracic Endovascular Aneurysm Repair
VTE	Venous Thrombo-Embolism
WHO	World Health Organisation

STATEMENT OF ORIGINALITY

The material presented in this report is the original work of the author. Where figures or tables have been reproduced from the work of others, the source is clearly stated.

THESIS OUTPUTS

Publications

Peer-reviewed Papers

- Lear R, Godrey AD, Riga C, Norton C, Vincent C, Bicknell CD. The Impact of System Factors on Quality and Safety in Arterial Surgery: A Systematic Review. *Eur J Vasc Endovasc Surg.* 2017; 54(1):79-93.

- Lear R, Godrey AD, Riga C, Norton C, Vincent C, Bicknell CD. Surgeons' Perceptions of the Causes of Preventable Harm in Arterial Surgery: A Mixed-Methods Study. *Eur J Vasc Endovasc Surg.* 2017; 54(6): 778-786.

- Lear R, Riga C, Godrey AD, Falaschetti E, Cheshire NJ, Van Herzeele I, et al. Multicentre observational study of surgical system failures in aortic procedures and their effect on patient outcomes. *Br J Surg.* 2016; 103(11): 1467-75.

Presentations

Oral

- Lear R. Patient Safety in Vascular Surgery. *European Society for Vascular Surgery Annual Meeting*, Copenhagen: 2016. [Invited Speaker].

- Lear R, Riga C, Godfrey AD, Falaschetti E, Cheshire N, Van-Herzeele I, Norton C, Vincent C, Darzi AW, Bicknell CD. A multi-disciplinary, nurse-led study identifies obstacles to safer aortic surgery. *Vascular Societies' Annual Scientific Meeting*, Bournemouth: 2015

- Lear R, Riga C, Godfrey AD, Falaschetti E, Cheshire N, Van-Herzeele I, Norton C, Vincent C, Darzi AW, Bicknell CD. A multi-disciplinary, nurse-led study identifies obstacles to safer aortic surgery. *Society of Vascular Nurses Annual Meeting*, Bournemouth: 2015 [Awarded the James Purdie Prize for Best Oral Presentation].

- Lear R. Identifying Safety Failure in Vascular Surgery. *European Society for Vascular Surgery Annual Meeting*, Stockholm: 2014 [Invited Speaker].

- Lear R, Cheshire NC, Norton C, Vincent C, Bicknell CD. Adverse events in arterial surgery are caused by failures at individual, team and systems levels: Identification of targets for improvement. *British Society for Endovascular Therapy Annual Meeting*, Nr Stratford Upon Avon, 2013.

- Lear R, Norton C, Bicknell CD. Identifying safety failures in vascular surgery: a multi-disciplinary approach. *Society of Vascular Nurses Annual Meeting*, Manchester: 2012 [Awarded the James Purdie Prize for Best Oral Presentation].

Presentations

Poster

- Lear R, Van Herzeele I, Bicknell CD. Adverse events in arterial surgery are caused by individual, team and organisational factors: impetus for multi-discplinary team training to improve patient outcomes. *International Surgical Congress of the Association of Surgeons of Great Britain and Ireland*, Harrogate: 2014.

ACKNOWLEDGEMENTS

It was to my good fortune that a clinical academic post was created at Imperial Vascular Unit just two years into my nursing career at St Mary's Hospital, Paddington. Game for a challenge although somewhat naïve to the demands of postgraduate research, I applied for the post and attended the interview at 9am one Thursday morning, just an hour or so after finishing four busy nightshifts in the high dependency unit. I cannot thank my interviewers - Mr Colin Bicknell and Professor Christine Norton - enough for giving me the opportunity to take up this new post within the Trust – it has opened so many doors. With Colin Bicknell's unfailing enthusiasm and dedication to the patient safety research agenda and Chris Norton's constant support as a mentor and role model, I was introduced to an exceptional supervisory team, later joined by Professor Charles Vincent who has provided sage advice and guidance throughout this process.

Particular thanks must go to my clinical colleagues at the Imperial Vascular Unit who supported and encouraged me throughout. Of note, I'd like to thank my office buddies Alex Rolls and Dean Godfrey who I worked alongside on the 10th floor - sharing a celebratory drink when we'd conquered a particulary tricky statistical test in SPSS and commiserating when the going was tough. Thanks also to Celia Riga, who provided ongoing support for the research and taught me how how to give oral presentations with confidence and clarity.

Thanks must also go to the Circulation Foundation and NIHR for providing funding for this research. I am also incredibly grateful to all the vascular operating teams and research staff who participated in the research - without whom this thesis would not have been possible. I am particularly grateful to Andy Gibson and Zoe Coleman for their gentle guidance in the early days of the LEAP study. Thanks must also go to Emanuela Falaschetti for contributing her excellent statistical expertise.

Finally, my Mum and my husband Patrick deserve special mentions for their unfailing support during this process. Through all of life's adventures over the past four years, my husband Patrick has helped me to focus to get this thesis finished – I am eternally grateful for his encouragement.

Section I:

Introduction

Section Overview

The original work presented in this thesis takes a broad look at factors influencing the safety of patients undergoing arterial operations. Chapters one and two present the background and context for this work. Chapter one explores important theoretical concepts that underpin the later studies. In chapter two, the focus is on safety in surgery. Drawing on surgical safety literature, chapter two explores the system approach to explaining surgical outcomes and presents the rationale for adopting this approach to understanding safety in arterial surgery.

1 An Introduction to Patient Safety

1.1 CHAPTER OVERVIEW

The concept of patient safety is explored from a broad perspective by way of an introduction to the subject of this thesis. The chapter explores why the issue of patient safety attracts so much attention and considers the issue of safety in relation to other important concepts such as quality. The nature and incidence of adverse events and medical errors are reviewed. The focus of the chapter is the systems approach to understanding why safety incidents occur in healthcare. It is this systems approach to explaining patient safety that underpins the original work presented in this thesis.

1.2 A SPOTLIGHT ON PATIENT SAFETY

High-profile events over the past three decades have prompted a great deal of interest in and reflection on patient safety and have created opportunities for change. In the late 1980s and early 1990s, tragic events at the Bristol Royal Infirmary were the subject of a major public inquiry (2). Staff raised concerns about the quality of paediatric cardiac surgery in the hospital as mortality rates were higher than at other comparable units. Surgery was halted, and under the spotlight of attention from the media, the General Medical Council (GMC) carried out an inquiry into the cases of 53 children, of whom 29 had died. A full public inquiry was launched by the Secretary State for Health, its findings and recommendations published in 2001. The inquiry stimulated a paradigm shift in the way in which medical errors and adverse events were investigated – moving away from the medical model of blaming and shaming. Of note, the inquiry adopted a so-called 'systems approach' to understanding what had happened. The outcome of the inquiry was not to pinpoint the errors of individuals – instead, it surfaced failures relating to leadership, teamwork, culture and the organisation of care (3). The tragic events in Bristol came to represent wider problems within the National Health Service (NHS), and the Bristol inquiry was the trigger for much more open scrutiny of healthcare outcomes.

Around the same time, patient safety was also hitting the headlines in the United States (US). In the 1990s, two large studies of patient harm events in hospitals in New York and in Utah and Colorado were published (4,5). These studies estimated that adverse events affected around three percent of hospitalised patients. Adverse events were defined as injuries caused by medical management (rather than a patient's underlying disease) that either prolonged hospitalisation or resulted in disability at the time of discharge, or both (4). In the study

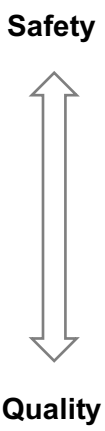
conducted in New York, 13.6% of patients who suffered an adverse event were thought to have died as a result (4). In both studies, half of all the adverse events identified from patients' medical records were deemed to be preventable. Following these studies, it was the Institute of Medicine's report 'To Err is Human', published later in 1999, that grabbed the attention of the public and government. The report suggested that when the results of the New York and Utah and Colorado studies were extrapolated to all US hospital admissions, medical error was the likely cause of the death of an estimated 44,000 – 98,000 Americans each year (6). President Clinton immediately ordered a study into the feasibility of implementing the report's recommendations to improve safety of hospitalised patients. The Institute of Medicine subsequently called for more emphasis on error and adverse event reporting and the creation of safety improvement programmes in healthcare organisations.

1.3 SAFETY AS A DIMENSION OF QUALITY

In 'To Err is Human' (6), the Institute of Medicine define safety as "freedom from accidental injury", which is a "critical component of quality" (p.4). In a separate report 'Crossing the Quality Chasm' (7), the Institute of Medicine set out six domains of quality to guide improvement in healthcare systems. These six domains state that healthcare should be safe, effective, patient-centred, timely, efficient and equitable. According to this report, safe care means "avoiding injuries to patients from the care that is intended to help them" (p.5). In the UK Department of Health report 'High Quality Care For All' (8), Lord Darzi asserts that "the first dimension of quality must be that we do no harm to patients" (p.47). In this 2008 report, safety sits alongside two further dimensions of quality: clinical effectiveness and the experience of patients. But when does a quality issue manifest as a safety issue? Brown and colleagues suggest that two measures are important in differentiating quality and safety issues: how soon harm occurs after a given event (immediacy) and whether or not the event can be clearly identified as the cause of harm (causality) (9). The two concepts are best considered on a continuum, as demonstrated in Table 1.1 below.

Table 1.1: The Safety-Quality Continuum

Failure	Causality	Immediacy
Transection of iliac vein during open abdominal aortic aneurysm repair resulting in massive haemorrhage and haemodynamic instability	High	High
Failure to prescribe heparin following a lower limb bypass graft. Two days later the patient develops an ischaemic limb and requires unplanned return to theatre to open up the graft.	High	Low
Failure to prescribe best medical therapy and antihypertensive medication for a patient under aortic aneurysm surveillance. Patients presents with a ruptured aneurysm.	Low	Low



Adapted from Brown et al. (2008) (9). Vascular examples have been added by the author of this thesis.

Accidental transection of a major vessel during surgery may obviously relate to the torrential haemorrhage and hypotension that immediately follows (a safety issue). The provision of high-quality care to a patient under aneurysm surveillance would generally involve prescribing best medical therapy, yet failure to do so is unlikely to be the obvious cause of the subsequent aneurysm rupture – therefore, the ruptured aneurysm cannot be clearly identified as preventable harm in this case. Admittedly, there are problems with Brown and colleagues' model. In clinical practice, there are many examples of safety issues that do not necessarily lead to harm in every patient. For example, forgotten administration of venous thrombo-embolism (VTE) prophylaxis may be associated with the development of deep venous thrombo-embolism/pulmonary embolism in some patients but not in others – yet most clinicians would agree that failing to give VTE prophylaxis is a safety issue. There are also a number of 'hidden' safety issues that may not actually result in harm on every occasion, but most certainly increase the risk of harm to patients and negatively influence the quality of their care – for example, inadequate staffing levels, lack of training, and failure to maintain equipment. Thus, there is no clear distinction between quality and safety.

1.4 THE NATURE AND SCALE OF PATIENT HARM

Over the past three decades, high-profile incidences of patient harm have sparked public and professional interest in patient safety. However, various systematic investigations into the incidence of adverse events in healthcare have revealed much higher rates of patient safety incidents than anyone had imagined. Mostly conducted in the 1990s and early 2000s, these studies from around the world have reported adverse events rates of between 8 and 12% of

hospitalised patients – the results of these studies conducted in eleven counties are summarised in Table 1.2. Estimated adverse events rates vary between countries - differences in definitions of patient harm and in the methodologies used to retrospectively review patient records are likely to account for some of this variation. There are also limitations with the retrospective record review methodology: close scrutiny of these studies reveals that the inter-rater reliability of independent reviewers for the occurrence of adverse events is generally low to moderate and therefore the reported adverse events rates may not be entirely accurate (4,5,10,11). Despite the concerns over inter-rater reliability and differences in methodology, the collective results of these studies do provide the sense that significant numbers of patients come to harm whilst in hospital, and various analyses of healthcare malpractice claims support this notion (12–15).

Table 1.2: Adverse events in acute hospitals in eleven countries

Study	Authors	Date of admissions	Number of hospital admissions	Adverse event rate (% of hospital admissions)
Harvard Medical Practice Study	Brennan *et al.*, 1991 (4); Leape *et al.*, 1991 (16)	1984	30,195	3.7
Utah-Colorado Study	Thomas *et al.*, 2000 (17)	1992	14,052	2.9
Quality in Australian Health Care Study	Wilson *et al.*, 1995 (10)	1992	14,179	16.6
United Kingdom	Vincent *et al.*, 2001 (18)	1999	1014	10.8
Denmark	Schioler *et al.*, 2001 (19)	1998	1097	9.0
New Zealand	Davis *et al.*, 2002 (20)	1998	6579	11.2
Canada	Baker *et al.,* 2004 (21)	Not stated	3745	7.5
France	Michel *et al.,* 2007 (22)	2004	8754	6.6 per 1000 days of hospitalisation
United Kingdom	Sari *et al.*, 2007 (23)	2004	1006	8.7
Spain	Aranaz-Andres *et al.*, 2008 (24)	2005	5624	8.4
The Netherlands	Zegers *et al.*, 2009 (11)	2006	7926	5.7
Sweden	Soop *et al.*, 2009 (25)	2006	1967	12.3
Republic of Ireland	Rafter *et al.*, 2017 (26)	2009	1574	12.2

Adapted from Vincent (2010) (27)

High-profile events reported in the media homed in on incidents of severe harm or death. However, the international adverse events studies and studies reviewing malpractice claims revealed that many safety incidents lead to less serious kinds of harm. In a systematic review of the incidence and nature of in-hospital adverse events, 56.3% (Inter-quartile range (IQR) 51.4 - 62.8%) of patients suffered no harm or only minor disability (28). However, the pooled results of six studies from five countries estimate 7.4% (IQR 4.7 – 14.2%) of adverse events lead to the patient's death – an alarmingly high figure (28).

1.5 THE NATURE AND SCALE OF MEDICAL ERROR

Patient safety is often equated with the prevention of medical error. Whereas adverse events studies focus on the outcome of care, studies of medical error generally assess whether given care processes meets pre-defined standards (27). Studies of medical error have been undertaken in various areas of clinical practice. First and foremost, there is a large body of evidence examining the issue of drug errors. Medication errors may occur at any point during the process of prescribing, preparing or administering a drug. A recent systematic review of 46 studies on drug errors demonstrated that around 1 in 10 drug orders are not administered as prescribed. However, the same review reported that most medication errors had minimal impact on the patient and none were fatal (29). On the other hand, studies of adverse drug events focus on medication-related harm to patients, which may or may not have been caused by an error.

While medication errors may rarely have any clinical significance, diagnostic errors are potentially more serious in terms of patient harm. In a study of 190 diagnostic errors in the primary care setting in the US, 98.4% of errors were thought to have some kind of clinical impact. In this study, the potential severity of delayed or missed diagnoses was considered to be moderate or severe in 86.8% of cases, with 14.2% of diagnostic errors likely to result in immediate or inevitable patient death (30).

Surgery is a high-risk area, involving a combination of technical skill, clinical decision-making and collaboration between operating team members. Errors in this arena may have catastrophic consequences due to the high-risk nature of the specialty. Studies of error in surgery have tended to focus on technical errors. For example, Regenbogen and colleagues studied technical errors in 444 randomly sampled surgical malpractice claims and reported that 49% of errors caused permanent disability with a further 16% resulting in a patients' deaths (12). Of note, Regenbogen and colleagues found that technical errors commonly occurred within the context of increased procedural complexity or in relation to failures in the 'system': equipment-use problems, ambiguity of responsibility and ineffective patient handovers were all associated with the technical errors made by surgeons. In their study of errors in paediatric cardiac surgery, Catchpole and colleagues clearly differentiate between technical and non-technical errors in the operating theatre (31). The researchers defined technical errors as those relating to knowledge, technical skill or expertise, while non-technical errors included a range of teamworking or cognitive failures – communication failures, team conflict, equipment problems, decision-making errors, planning failures and failures of

vigilance were all categorised as 'non-technical' errors. Interestingly, Catchpole and colleagues found that non-technical errors occurred more frequently than technical errors in paediatric cardiac surgical procedures. The researchers also identified a large number of intraoperative failures that were not associated with human error but were precipitated by so-called 'threats in the system'. These system threats related to issues such as poor safety culture or difficulties arising from complicated processes (31).

1.6 HUMAN ERROR

Human error can be divided into two broad categories : slips or lapses, and mistakes (18). Slips or lapses are errors of action that may occur when a person is distracted during largely automated, routine tasks, leading to outcomes that are unintentional. Slips occur when a person fails to pay attention to their actions (picking up the wrong syringe, for example) while lapses are the result of memory failure (such as forgetting to prescribe a medication). Mistakes, on the other hand, are errors in complex mental functioning, and may include failures in planning, problem solving or formulating intentions. Essentially, when a mistake is made, a person's actions match their intentions, but the plan was wrong in the first place. A patient receiving treatment for the wrong diagnosis is likely to be linked to a mistake rather than a slip or lapse.

Whatever their mechanism, errors can be viewed from different perspectives, with each approach offering a different solution to the problem of error (33). One such approach concentrates on the unsafe acts of individuals. This approach considers that human error results from inattention, forgetfulness, lack of motivation or even negligence. On the other hand, the systems approach asserts that human error cannot be separated from context in which it occurs. Many factors influence human behaviour in high-risk industries (including healthcare). These factors could relate to the nature of a given task, the team performing the task, the work environment and the wider organisational context. The systems approach acknowledges that failures transpire at all levels of the system, not only at the interface between operators and the task at hand. Thus, from the systems perspective, efforts to reduce the incidence of error should consider how to optimise the conditions in which humans work because the human propensity to err cannot be changed, but the system can.

In medicine, efforts to improve patient safety have traditionally focussed on achieving error-free performance from healthcare staff. The 'blame, shame and re-train' approach is

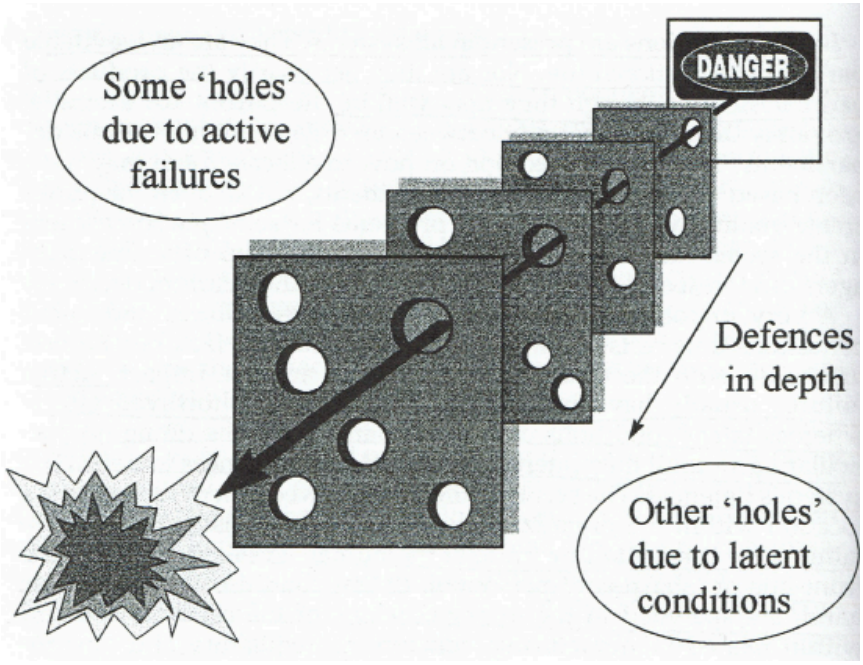
ineffective because it does not address the conditions that create 'accidents waiting to happen' at the interface between healthcare staff and patients (34).

1.7 UNDERSTANDING HOW THINGS GO WRONG IN HIGH-RISK INDUSTRIES

In attempting to understand the aetiology of organisational accidents, it is necessary to distinguish between 'active failures' and 'latent conditions' (35). Active failures encompass the errors and violations of individuals working at the 'sharp end' of the system. Examples of active failures include the pilot who shuts down the wrong engine on an aircraft or the surgeon who inadvertently nicks an artery. These unsafe acts are likely to have direct consequences for the safety of the system/patient, and their effects may be felt immediately. However, the system perspective considers that the errors of individuals always occur within a particular context, and various 'latent conditions' inherent in all organisations may precipitate the unsafe acts of individuals. Poor equipment design, undetected manufacturing defects, inadequate training or supervision, unmanageable workload, lack of staff or resources – these are examples of system factors that may make it more likely for humans to make errors. Some latent conditions arise as a result of flawed, top-level decision-making by organisational managers, designers or regulators, with the impact of these decisions being felt throughout the organisation. Latent conditions may lie dormant for a long period before interacting with a particular set of circumstances to cause harm to a patient (35). These conditions may also precipitate many seemingly inconsequential events before an incident with serious consequences occurs.

In order to minimise the risk of an organisational accident, high-risk industries such as aviation or the nuclear industry generally construct a variety of defences designed to increase the reliability of the system. These layers of defence include creating an understanding and awareness of local hazards, providing clear guidance on how to avoid accidents, and installing alerts to warn operators of imminent danger (35). These defences are designed to halt potential accident trajectories. However, in reality there is likely to be a number of weaknesses or gaps in the defensive layers that can allow hazards to come into contact with people or assets, often with harmful consequences. Reason uses the 'Swiss cheese' metaphor to illustrate this concept (see Figure 1.1) (35).

Figure 1.1: The Swiss Cheese Model



Source: Reason J. *Managing the Risks of Organizational Accidents*. Farnham: Ashgate Publishing; 1997 (p.12)
[No permissions needed]

1.7.1 *Organisational accidents: a case study*

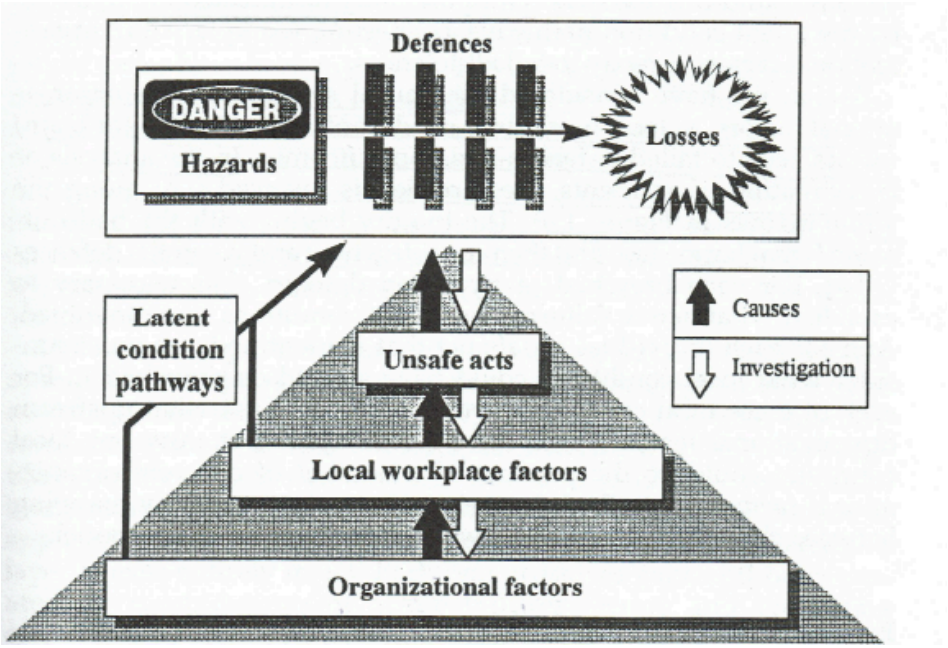
High-profile, organisational accidents in a high-risk industry can be used to illustrate how the combination of active failures and latent conditions have resulted in disaster. For example, on the morning of 26th April 1986, one of the worst accidents in the history of nuclear power occurred in Chernobyl, Ukraine. A power surge at the Chernobyl nuclear power caused two enormous explosions, exposing the reactor core to the environment and releasing a huge amount of radiation into the atmosphere. Twenty-eight highly exposed reactor staff and emergency workers subsequently died from radiation and thermal burns, and in the aftermath of the accident, there was an increased incidence of leukaemia and cataracts among plant workers and local residents (36). The accident happened when operators ran the plant at very lower power making the reactors highly unstable; they also switched off various engineered safety systems in order to complete this process – these unsafe acts were in violation of the plant's operating procedures and the immediate cause of the accident (35,36). A number of latent conditions were identified as precipitating the disaster: crucially, the plant had not been designed to contain an explosive leak of radiative material - it did not have the substantial containment structure that was a safety feature of most other nuclear plants (36). There were also concerns about safety culture at the plant – not only did the plant operators disable a number of safety systems, they also concealed the accident from the authorities, which

delayed evacuation of local residents. This case demonstrated that latent conditions may be present in the system for many years before interacting with the active failures of individuals to produce catastrophic effects.

1.7.2 *Reason's model of organisational accidents*

In his model of organisational accidents, James Reason outlines the principal stages in the development and investigation of major incidents (Figure 1.2).

Figure 1.2: Stages in the Development & Investigation of an Organisational Accident



Source: Reason J. *Managing the Risks of Organizational Accidents*. Farnham: Ashgate Publishing; 1997 (p.17)
[No permissions needed]

The model links the various factors contributing to an organisational accident with causation running from bottom-to-top and investigation running from top-to-bottom. It contains three primary levels: organisational factors, local workplace factors and unsafe acts. The trajectory of an accident starts with failures within the upper echelons of an organisation. These failures can be associated with processes such as budgeting, allocating resources, auditing, communicating and managing. The outcomes of these processes are transmitted via latent condition pathways to local workplaces – flight decks, power plant control rooms, hospital wards etc, where they are noticeable as the factors that may precipitate unsafe acts. These factors include equipment problems, time pressures, short-staffing, insufficient training, unrealistic workload, ineffective communication and poor safety culture. These local workplace factors create the conditions of 'accidents waiting to happen' by increasing the risk

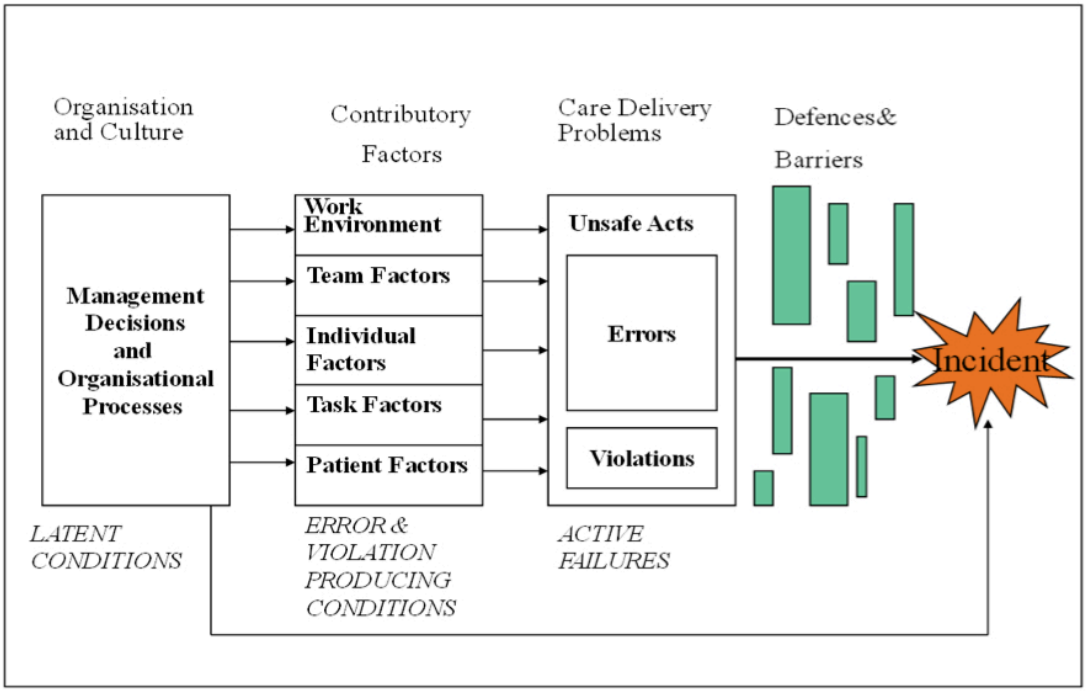
of human error. In contrast, when the causes of accidents are investigated, the sequence is reversed: the inquiry starts with the adverse outcome, before considering the failed defences, unsafe acts and contributory factors further up the chain.

1.8 APPLICATION IN MEDICINE

1.8.1 *Vincent's Systems Approach to Patient Safety*

Vincent and colleagues have adapted Reason's model to explain the stages in the development of a patient safety incident in healthcare and they have produced a framework for analysing risk and safety in clinical medicine (37) (Figure 1.3).

Figure 1.3: Stages in the Development of a Patient Safety Incident



Source: Vincent C. *The Essentials of Patient Safety* [Online] 2011 (p.24) Available from: https://www1.imperial.ac.uk/resources/5D671B2E-1742-454E-9930-ABE7E4178561/vincentessentialsofpatientsafety2012.pdf [Accessed 23rd Janaury 2018]

To improve its relevance to adverse events that occur in healthcare, Vincent's framework further classifies Reason's latent conditions into seven distinct categories which reflect a variety of aspects of the healthcare system (27,37):

Patient factors include the patient's co-morbidities and their condition, as well as their personality, cognitive state and language used, as these factors can influence how patients communicate. Patient risk factors are included in the framework because they are generally

held to be the most important determinant of outcome. This is particularly true of certain specialties such as vascular surgery - most patients presenting for major arterial procedures are elderly with a high incidence of cardiovascular and respiratory disease (38).

Task factors take into consideration the design of a task, the availability and use of protocols, test results and other factors that may have an impact of the processes of care. Care pathways, for example, may reduce the incidence of adverse events by prioritizing and protocolising care processes that are known to improve patient outcomes. In colorectal surgery, enhanced recovery pathways that include elements such as non-opioid analgesia, early postoperative feeding and mobilization have been shown to reduce length of stay and complications compared to standard perioperative care (39).

Individual factors reflect the knowledge, skills and experience of healthcare professionals involved in the patient's care. In a retrospective study of the causes of adverse events in NHS hospital practice, Neale and colleagues identified a variety of contributory factors, including inadequate input by consultants and a reliance on diagnoses made by inexperienced clinicians (40).

Team factors includes issues such as communication and teamwork – these issues been associated with harmful errors and adverse events across all domains of healthcare.

Working conditions describe the environment in which the patient is treated by healthcare professionals, which may include considerations such as lighting, temperature, noise or distractions, availability and maintenance of equipment.

Institutional context. Healthcare organizations do not function in isolation, and are influenced by a range of factors such the prevailing political and economic climate, external regulatory organisations and tight budgets.

Organisation and culture. Organisational factors include the decisions and actions of managers at a higher level of an organisation. Examples include the provision of training and equipment, and strategies to cover clinical areas that are short-staffed. The concept of safety culture is discussed in more detail below.

1.8.2 *Safety culture*

Since the investigation into the Chernobyl disaster identified poor safety culture as an important factor contributing to this tragic accident, many high-reliability organisations around

the world have attempted to better understand their own organisational culture and its impact on safety. Safety culture may be defined as the way in which patient safety is implemented and prioritised within a healthcare organisation. Various dimensions, such as leadership commitment to safety and teamwork, have been used to conceptualise safety culture (41). Consensus on the relative significance of safety culture dimensions has not yet been reached - the most frequently cited of these dimensions are outlined in Table 1.3. A strong culture of safety is likely to be a reflection of effective leadership and teamwork, with emphasis on delivering safe care and transparency with regards to medical error (42). Safety culture is thought to be evident in the shared attitudes, values and behaviors of frontline staff (43). In 2012, it was estimated that around one third of NHS organisations were using surveys to measure safety culture in their organisations in order to identify where safety improvements could be made (42). The term 'safety *climate*' was coined to describe the insight into safety culture that can be obtained by assessing staff perceptions, attitudes and beliefs; other aspects of safety culture, such as actions and behaviours, cannot generally be measured using survey tools (43). Safety climate should be considered a measurable window on safety culture, but the terms 'culture' and 'climate' are often used interchangeably in the literature (43).

Table 1.3: Dimensions of Safety Culture

- Leadership commitment to safety
- Open communication founded on trust
- Organisation learning
- A non-punitive approach to adverse event reporting and analysis
- Teamwork
- Shared belief in the importance of safety

The table outlines the dimensions that were most frequently cited in 113 articles on safety culture.
Source: Halligan M, Zecevic A. Safety culture in healthcare: a review of concepts, dimensions, measures and progress. *BMJ Qual Saf.* 2011; 20: 338-343.

Over the past two decades, there has been a paradigm shift in our understanding of the causes of patient harm in healthcare. Research has moved away from the traditional medical model towards a more holistic approach to investigating patient outcomes using a systems approach. Vincent's framework provides the conceptual basis for analysing errors and adverse events in healthcare using this approach. As such, it underpins much of the original work presented in later chapters of this thesis. The studies that follow these introductory chapters will attempt to characterise the landscape of system failures in arterial surgery. Within the conceptual framework of the systems approach, each study will elicit specific failures or problems that may threaten the safety of patients undergoing arterial procedures.

1.9 MEASURING PATIENT SAFETY FROM A SYSTEMS PERSPECTIVE

In considering patient safety from a systems perspective, it seems pertinent to consider how the safety of a system can be measured. Various methods and their relative advantages and disadvantages are summarised in Table 1.4 and these are discussed in more detail below.

1.9.1 *Retrospective record review*

Retrospective record review has been at the forefront of research into adverse events in healthcare. The international adverse events studies that were referred to earlier in this chapter all used retrospective record review to extract data on the incidence and nature of adverse events in hospitalised patients (4,5,10,11,16,18,20,44). Chart review relies on complete and accurate documentation in patients' medical records, meaning that events such as near-misses and failures in the systems of care are less likely to be reported. Kable and colleagues encountered this issue in their study of adverse events in hospitalised patients in Australia. These researchers reported that 11.5% of adverse events reviewed in the study were attributable to failures in the system, rather than to the errors of healthcare professionals. However, they emphasised that this figure was likely to under-represent the true rate of adverse events due to system failures because it is not common practice to document issues such as staff shortages, overwhelming caseloads, and communication failures in patients' medical records (44). While retrospective review of medical records can provide valuable insights into the incidence and severity of adverse events, they may be of limited use in uncovering possible system failures.

1.9.2 *Review of malpractice claims*

In contrast with retrospective review of patient medical records, analysis of detailed malpractice claims files can reveal a variety of latent conditions that have led indirectly to patient harm. For example, review of surgical errors relating to 444 malpractice claims made in the US revealed that system factors contributed in 82% of incidents – these precipitating factors included communication breakdown, lack of supervision, and technology failure (14). However, malpractice claims cannot be used to estimate the incidence of errors or adverse events. Claims are more likely to be made when in cases where serious harm was made, they may be heavily influenced by hindsight bias and their highly selective nature limits the generalisability of their findings (45).

Table 1.4: Methods to Assess Patient Safety: Advanatges and Disadvantages

Method to measure safety	Advantages	Disadvantages
Retrospective record review	Data is readily available Can be used to roughly estimate the incidence of adverse events	Patients medical records do not generally contain information about system factors
Review of malpractice claims	Claim files are generally detailed Can be used to reveal system factors	Hindsight bias Highly selective cases – lack of generalisability
Patient registries	Large samples increase confidence in findings Can be used as a benchmarking/monitoring tool	Data may be inaccurate or incomplete Not generally used to collect data on errors or adverse events
Incident reporting systems	Institutions can gain insights into their own failings May include data on system factors as well as medical errors	Reports may be incomplete or lacking in detail Cannot be used to reliably measure the incidence of safety incidents
Prompted reporting and interviews with clinical staff	A broad range of detailed reports can be obtained Can be used to obtain data on active failures and latent conditions/system factors Clinical staff can give contextual information to better understand the aetiology of errors and adverse events	Hindsight bias Reporting bias
Direct observation of patient care	Can be used to obtain data on active and latent failures	Time- and resource-intensive Possible Hawthorne effect

1.9.3 *Patient registries*

Large patient registries are commonly used to measure and monitor the safety and efficacy of healthcare and patient outcomes. Comparative data from large registries allows institutions to benchmark their surgical outcomes against similar centres in order to identify targets for improvement. Registries are particularly important in monitoring the safety of new medical devices and technologies (46). The previous UK Heart Valve Registry was created in response to difficulties identifying patients who had been implanted with faulty heart valves (47) and since 2007 the transcatheter aortic valve implantation (TAVI) registry has recorded all TAVI procedures performed in the UK. Although the data collected by large registries tends to have a strong focus on the outcomes of healthcare, many registries also use process measures, which can be useful for gaining insights into patient safety from a systems perspective. For example, the National Vascular Registry monitors the number of days between the onset of stroke or TIA symptoms and carotid intervention in eligible patients (48); the NICE guidelines state that this period should be less than two weeks (49). Centres not meeting this target are able to examine where the delays are in the system and put in place strategies for improvement. Most registries do not collect information on errors and adverse events, and where poor outcomes have been identified, registry data usually lacks the detailed contextual information that would enable the identification of causal factors.

1.9.4 *Incident reporting systems*

Voluntary reporting of patient safety incidents is now routine in many healthcare systems. In the UK, the National Reporting and Learning System (NRLS) has received over four million patient safety incident reports since it was set up in 2003 (50). NHS Improvement now publishes monthly reports detailing the prevalence and characteristics of reported adverse events at an organisational level (50). In additional to feeding back to NHS organisations, the data collected by NRLS has been used by clinicians and researchers wishing to develop a better understanding of safety incidents in their own specialties. For example, Catchpole and colleagues analysed more than 12,000 reported incidents in anaesthesia but the incident reports did not provide sufficiently detailed information to develop a persuasive understanding of the aetiology of the safety incidents upon which safety improvement interventions could be based. On the other hand, Martinez and colleagues assert that voluntary incident reports do provide insights into the types of incidents occurring in the operating room – they demonstrated that errors related to medical devices and equipment require attention to improve safety in cardiac surgery (51).

The Confidential Reporting System in Surgery (CORESS) is a system for collating and analysing adverse events that occur specifically in surgery. It was set up by the Association

of Surgeons of Great Britain and Ireland (ASGBI) in 2005 and it receives incident reports from surgeons and theatre staff. The incidents are analysed for important themes and the lessons learned are published in regular reports and fed back - both to the reporters themselves and to the surgical community via the ASGBI newsletter and the Annals of the Royal College of Surgeons of England journal (52). Although CORESS cannot be used to estimate the incidence of adverse events in surgery, the significance of CORESS is its systems approach and emphasis on sharing lessons in patient safety.

1.9.5 *Prompted reporting and interviews with clinical staff*

Some researchers have found that traditional voluntary reporting by clinical staff can be improved upon through the use of facilitated survey instruments administered to theatre staff at the time of surgical procedures (53–55). Oken and colleagues developed a survey consisting of brief open-ended questions to elicit information about non-routine events in anaesthesia (53). The survey was administered to anaesthetists in the post-anaesthesia care unit, and the results compared with data on adverse events collected through the hospital's voluntary reporting system. Although the traditional voluntary reporting system was useful for identifying events with severely harmful consequences, the active surveillance methodology captured a broader range of incidents including adverse events with minor sequelae and near misses, and was associated with better clinician compliance (53). Similarly, Bandari and colleagues were able to capture information on a wide range of intraoperative system failures using briefing and debriefing tools with all surgical team members peri-operatively (54). Equipment and communication problems were the most frequently reported system failures, however, the authors of this study did not report the clinical consequences of the failures identified (54). In other studies, researchers have conducted interviews with clinical staff to obtain detailed accounts of adverse events and to understand their aetiology. Gawande and colleagues interviewed 38 surgeons from three large Massachusetts teaching hospitals to elicit reports on surgical incidents (56). The study revealed that inexperience, communication breakdown and excessive workload were common factors contributing to surgical error. Detailed accounts of adverse events can provide a wealth of information about safety problems in healthcare, but the small sample sizes characteristic of most qualitative studies make it difficult to generalise their findings and interviews with clinical staff after an incident may be subject to hindsight bias and reporting bias.

1.9.6 *Direct observation of patient care*

Various studies have used a direct observational methodology to identify safety issues, with both active and latent failures being identified by observers present in the operating theatre (31,57,58). A key limitation of the observational approach is the Hawthorne effect – the notion

that individuals change their behaviour when they are aware that they are being watched (45). To ensure that observations are reliable, the approach may also be resource- and time-intensive – for example, Morgan and colleagues implemented a study of 'glitches' occurring in the operating room utilising the observational skills of experienced clinical operating staff and observers who held formal undergraduate or postgraduate qualifications in human factors (58). Human factors experts specialise in optimising safety and effectiveness through improvements in the design of equipment, processes and work systems (59).

1.10 CHAPTER 1: KEY POINTS

Large studies from around the world demonstrate that a significant proportion of patients come to harm while in hospital. There is a huge amount of public and professional interest in understanding the causes of preventable harm. Patient harm is often equated with medical error, but error is really only the tip of the iceberg when it comes to the multiplicity of factors that are likely to contribute to adverse events in healthcare. In order to develop a comprehensive understanding of the problem, patient safety needs to be analysed from a broad systems approach using methodologies that are suited to capturing information on system failures. This chapter has outlined the theoretical framework that underpins the original work presented in this thesis, which aims to develop a better understanding of the factors influencing patient safety in arterial surgery. The next chapter will explore how the systems approach can help to explain surgical outcomes, and the rationale for applying this approach in *arterial* surgery will be discussed.

2 Application of the Systems Approach to Understanding Patient Safety in Surgery

2.1 CHAPTER OVERVIEW

This chapter focuses on patient safety in surgery. It begins by reviewing estimated rates of surgical adverse events and complications due to error. The chapter goes onto explore determinants of surgical outcome, moving from the traditional focus on patient risk-factors and surgical expertise towards a systems approach to explaining surgical outcomes. Attention will then focus on safety in arterial surgery. The final part of this chapter will review current understanding of key determinants of outcome in patients undergoing arterial procedures. Subsequently, the rationale for adopting a systems approach to safety in this patient group will be outlined and the aims of the original work in this thesis will be presented.

2.2 THE INCIDENCE OF ADVERSE EVENTS & ERRORS IN SURGERY

In 1991, the seminal Harvard Medical Practice Study demonstrated that, of all the clinical areas that exist in hospitals, the operating room is the most common site for adverse events to occur (16). The study further demonstrated that rates of adverse events vary significantly between clinical specialties. Of ten specialties, vascular surgery was identified as the specialty carrying the highest risk of adverse events (4). In the Utah and Colorado adverse events study, abdominal aortic aneurysm repair and lower limb bypass graft operations carried the highest rates of *preventable* adverse events among fifteen common operations (5). These two ground-breaking studies were conducted two decades ago and there may be doubts over the relevance of their findings today. And yet, rates of adverse events in surgery have remained alarmingly high. A recent systematic review by Anderson and colleagues assessed the frequency, severity and preventability of adverse events occurring in surgery, drawing on evidence from studies conducted in nine countries (60). The authors of the review found that adverse events occurred in around 14% of surgical patients – higher than previous estimates. More than one third of these adverse events were deemed preventable (60). The review was not able to differentiate between different surgical specialties as case mix was not reported in sufficient detail in most of the collated studies. However, the review reported that an estimated 3.6% of patients who suffered an adverse event died as a result (60).

Other studies of safety in surgery have taken a different approach by investigating surgical complications specifically caused by the errors of medical professionals. Two recent studies found that between six and seven percent of surgical patients experience a complication caused by human error (61,62). In both studies, less than one percent of patients suffered fatal complications (61,62). However, one quarter of patients required treatment to counteract the deleterious effects of the errors, and nearly five percent suffered permanent disability (61). Of note, the proportion of surgical patients suffering complications due to error was found to be highest in thoracic surgery (9.9%) and vascular surgery (9.2%).

2.3 EXPLAINING SURGICAL OUTCOMES

A pioneer in surgical outcomes research, Ernest Codman was a surgeon working in Boston in the early 1900s. Codman followed up patients so that he could endeavour to understand the most important determinants of surgical outcome. The taxonomy of medical errors leading to unsuccessful treatment developed by Codman is outlined in Table 2.1.

Table 2.1: Codman's taxonomy of errors leading to unsuccessful treatment

- Errors due to lack of technical knowledge or skill
- Errors due to lack of surgical judgement
- Errors due to lack of care or equipment
- Errors due to lack of diagnostic skill
- The patient's unconquerable disease
- The patient's refusal of treatment
- The calamities of surgery or those accidents and complications over which we have no control.

Source: Sharpe V, Faden A. *Medical Harm: Historical, Conceptual and Ethical Dimensions of Iatrogenic Illness.* Cambridge: Cambridge University Press; 1998. (p.29)

Codman's taxonomy focuses on the physician error and patient factors and these factors are still held to be primary determinants of outcome today.

2.3.1 *Patient risk-factors*

Patient risk-factors are a particular concern in surgery because they influence both the decision to offer surgery and outcome. In aortic aneurysm surgery, for example, evidence from multivariable analyses of data from two large randomised controlled trials demonstrates that patients who are older or who have a larger aortic aneurysm diameter are more likely to experience graft-related complications (63). Patient factors that are widely accepted to increase the risk of complications following an invasive procedure are age, comorbidities,

major surgery and urgent/emergency surgery. Pre-operative anaemia is also associated with poorer post-operative outcomes, particularly in patients with a cardiac history (64). Some of these predictors of poor outcome can be mitigated through careful patient selection and strategies such as treatment of anaemia and chest physiotherapy to optimise the patient's condition pre-operatively.

2.3.2 *Surgical expertise*

The technical skills and experience of the surgeon are generally held to be key determinants of surgical outcome. Assessing the relationship between individual technical skill and surgical outcome is difficult and is rarely evaluated in research studies, yet this relationship underpins the development of league tables ranking individual surgical performance (40). In one of only a handful of studies assessing the association between technical skill and surgical outcome, Birkmeyer and colleagues found that bariatric surgeons with more advanced technical skills had lower rates of risk-adjusted complications, reoperation and readmission for laparoscopic gastric bypass operations (65). However, these findings were based on evaluation of only twenty surgeons working in Michigan hospitals who each submitted a self-selected videotaped recording of a single gastric bypass procedure for peer review and subjective assessment of technical skill. Surgeon case volume is sometimes used as a marker of surgical skill – the assumption is that higher volume surgeons achieve better outcomes. However, evidence suggests that the relative importance of surgical case volume is intimately related to both hospital case volume and procedure type (66). In a large study of 474,108 patients undertaken in the US, surgeon case volume accounted for the entire effect of hospital-level case volume for some procedures including aortic valve replacement and carotid endarterectomy - suggesting that technical skill is of primary importance in predicting the outcome of these procedures (66). However, for other cardiovascular operations, including coronary artery bypass grafting (CABG) and elective AAA repair, surgeon volume accounted for only a proportion of the effect of hospital volume, which may be explained by the importance of critical care provision for these patients and the longer duration of hospital stay compared to patients undergoing carotid endarterectomy. In further studies conducted by Dimick and colleagues in the US, operative mortality rates for AAA repair were shown to be significantly lower when these procedures are conducted in high-volume hospitals by high-volume vascular specialists; the relative risk reduction was 40% for surgery by a high-volume surgeon and 30% for high-volume hospitals (67). The hospital volume-outcome relationship was partly explained by the greater uptake of endovascular technology in higher-volume centres (68). Thus, while individual surgeon expertise are clearly essential, procedural and organisational characteristics also play a role in surgical outcome (66–68).

2.3.3 *Human Factors*

Clinicians and researchers working in some areas of surgery (most notably in the fields of cardiac surgery and anaesthesia) have drawn on the discipline of human factors to take their understanding of the determinants of outcome beyond patient risk factors and surgical expertise. In a seminal study published in 2000, de Leval and colleagues explored the role of human factors on adverse outcomes in paediatric cardiac surgery (69). This study demonstrated that human errors are often precipitated by cultural, organisational or environmental 'threats' inherent in the system. Examples included distractions, external pressures, lack of safety consciousness, equipment failures and workspace problems. In this study, a large number of seemingly minor non-technical errors were observed – these included communication/coordination failures and failures relating to cognitive skills. Although these minor errors appeared to have inconsequential effects in isolation, the total number of minor errors made during arterial switch operations was significantly associated with patient death. The authors suggested that because minor errors are more insidious, they may go unnoticed by operating teams and subsequently exert a multiplicative effect that can be severely detrimental to patient safety (69). Human factors engineering seeks to understand the factors precipitating human error in complex systems with the aim of improving performance and reliability (70). For example, in a qualitative study investigating the aetiology of anaesthetic errors, Cooper and colleagues found that factors commonly precipitating human error were associated with problematic equipment design, inadequate training or supervision, unmanageable workload and fatigue (55). The findings of this study were used to inform the human factors design of a new anaesthesia delivery system (55).

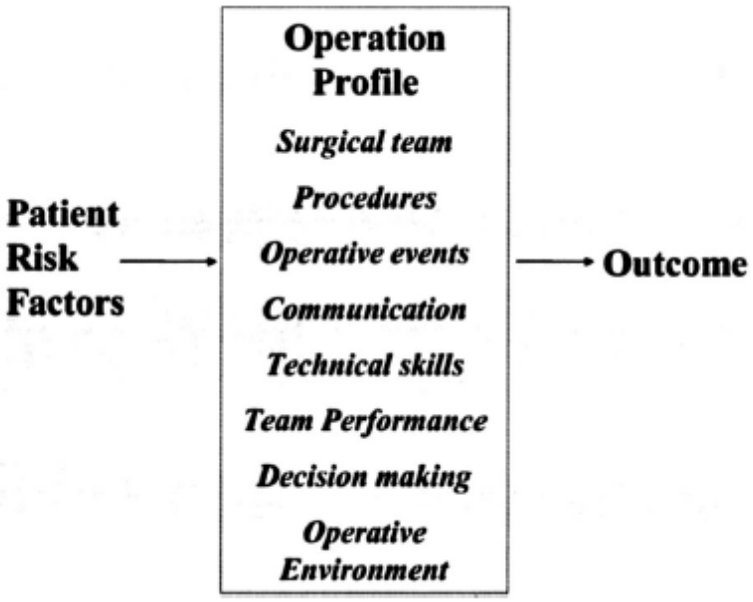
2.3.4 *Explaining surgical outcomes using 'the operation profile'*

While few would argue that patient risk factors and surgical skill are key determinants of surgical outcome, the best results are likely to be achieved when there is a broad understanding of factors that contribute to outcome (71–73). The ability to address additional contributory factors may make the difference between good performance and truly optimal performance.

Surgical outcomes are influenced by healthcare processes as well as structural aspects of the system (human and physical resources and infrastructure). Procedural volume is a common structural measure, which is known to predict surgical outcomes in a variety of specialties (74–79). Other structural variables that influence surgical outcome include hospital academic status and the provision of critical care facilities (80). Since these structural variables are likely to be relatively standardised, attention is drawn to the range of process variables that are potentially relevant in the operating room. Vincent's 'operation profile', shown in Figure

2.1, illustrates key process variables that influence outcomes in surgery. The model does not include events occurring before or after operations, but acknowledges that these factors also play a role in surgical outcomes. The operation profile summarises various components of Vincent's framework of factors influencing clinical practice from a surgical perspective, and includes factors such as team performance and the operative environment. It is underpinned by the systems approach to safety and the work of James Reason, outlined in full in chapter one of this thesis. For clarity and ease of interpretation, Vincent's framework of factors influencing clinical practice is provided in Table 2.2 overleaf and the table provides example of these factors in surgery.

Figure 2.1: The Operation Profile



Source: Vincent C, Moorthy K, Sarker SK, Chang A, Darzi AW. Systems Approaches to Surgical Quality and Safety: From Concept to Measurement. *Ann Surg.* 2004; 239: 475-485 (p.476).
The Operation Profile focusses on aspects of the systems approach to patient safety that are highly relevant to surgery. The Operation Profile is underpinned by the broad systems approach to patient safety outlined in table 2.2 overleaf.

Table 2.2: Framework of factors influencing clinical practice

Framework	Contributory Factors	Examples of Problems That Contribute to Errors in Surgery
Organisation & culture	Financial resources & constraints Policy standards & goals Safety culture & priorities	Lack of senior management commitment to safety in the operating theatre
Work environment	Staffing levels & mix of skills Patterns in workload & shift Design, availability, & maintenance of equipment Administrative & managerial support	Shortage of nursing staff in the operating theatres Lack of appropriately skilled surgical assistants Pressure to turn around cases quickly/production pressure Lack of access to specialist equipment Surgical instruments poorly maintained Poor scheduling
Team	Verbal communication Written communication Supervision & willingness to seek help Team leadership	Poor communication between different professions within multi-disciplinary operating teams Operating list containing inaccurate details Patients' medical notes missing Trainees not appropriately supervised Poor leadership skills of lead surgeon
Individual staff member	Knowledge & skills Motivation & attitude Physical & mental health	Lack of knowledge or technical skills Fatigue/stress due to being overworked
Task	Availability & use of protocols Availability & accuracy of test results	Failure to complete WHO Surgical Safety Checklist Delays in obtaining cross-match/ biopsy/ tissue culture results
Patient	Complexity & seriousness of condition Language & communication Personality & social factors	Patient's baseline characteristics including pre-operative respiratory, cardiac and renal function. Patient's refusal to comply with pre-operative guidelines for diet, exercise, smoking cessation, weight loss etc.

Adapted from: Vincent C. Understanding and Responding to Adverse Events. *N Engl J Med.* 2003; 348(11): 1051-56 (p.1052).
This table outlines factors from Vincent's broad systems approach to safety in healthcare and provides examples that are relevant to surgery.

2.4 APPLICATION OF THE SYSTEMS APPROACH IN SURGERY

Drawing on the wider surgical literature, this section adopts a systems approach to develop a better understanding of the sources of safety failure in surgery. Some examples of the systems approach, including the notion that 'threats' in the system precipitate human errors and that hospital-level characteristics have an impact on safety in in surgery, were alluded to earlier in this chapter – these will be discussed in more depth. Drawing on the operation profile presented above, various mechanisms underlying surgical safety failures are outlined and discussed below.

2.4.1 *Patient risk-factors*

The operation profile and framework of factors influencing clinical practice explicitly include patient risk factors. For example - for major non-cardiac operations, cardiovascular events are known to be the leading cause of death within thirty days of the procedure (81). Preoperative risk prediction using tools such as stress echocardiography can aid in patient selection and guide strategies for optimisation of the patient's condition prior to surgery. Post-operatively, monitoring for hypoxemia, haemodynamic compromise and myocardial ischaemia are essential to recognise and manage cardiovascular complications.

2.4.2 *Surgical/technical skill*

Few studies have directly assessed technical skills in surgery, though a number of studies report a relationship between technical errors and adverse events (44,61,62,82). A variety of tools may be used to assess technical competency of surgeons, including a tool for Objective Structured Assessment of Technical Skills (OSATS), the Global Rating Index for Technical Skills (GRITS), the Operative Performance Rating Scale (OPRS), and the Hopkins assessment of surgical competency (83). In practice, however, technical rating scales are rarely used. This may be due to concerns over validity and reliability of some assessment tools and the need for objective measures of surgical skill (84). A recent study of surgical skill and complications after bariatric surgery demonstrated that peer ratings of operative skill correlated with complication and mortality rates, though this study included a sample of only twenty bariatric surgeons in the US (65). Of note, a recent systematic review demonstrated that the non-technical skills of operating teams influence the technical performance of surgeons: in six studies, there was a strong relationship between teamwork failure and technical error, though the clinical significance of these errors was unclear (85). The findings of this review support the argument proposed by Reason and Leape that latent conditions frequently underlie the errors of individuals and that medical errors should not be considered in isolation (32,34,35).

2.4.3 *Team factors & communication*

Communication failures are frequently implicated in all domains of healthcare when patients have come to harm (4,10). In the operating room, a large amount of information is communicated, often between professionals from different disciplines and under highly pressurised circumstances. A systematic review of information transfer in surgery found that communication failures were frequently underpinned by assumptions (the assumption that all necessary equipment will be available, for example) and by the need for handovers of care (86). In a study of the impact of handovers in cardiac surgery, Hudson and colleagues found that the need for at least one handover of anaesthetic care during cardiac procedures was

associated with a 43% greater risk of in-hospital mortality and a 27% greater risk of major postoperative complications (87). Poor teamwork has also been associated with intraoperative errors (85,88) and postoperative morbidity and mortality (after adjustment for patient risk factors) (89). Kurmann and colleagues evaluated the impact of team familiarity on team performance and outcomes in patients undergoing abdominal surgery (90). Team familiarity was defined as how familiar team members were with each other. Following a period of continuous teamwork with stable teams of one senior and one junior surgeon, surgeon concentration scores improved and postoperative complications occurred less frequently (90). Similarly, a study performed in the US found that the safety and efficiency of CABG procedures, measured in terms of cardiopulmonary bypass and cross clamp times, is primarily driven by the cumulative experience of the attending surgeon and the cardiothoracic fellow rather than by the individual experience of the attending surgeon (91). These examples from the literature demonstrate that team factors are important considerations when attempting to develop a better understanding of safety in surgery.

2.4.4 *Work/operative environment*

Various studies have assessed the impact of noise levels, distractions and disruptions in procedural work flow in the operating room (92–94). Noise levels in the operating theatre have been recorded as high as 90 decibels – the equivalent of a lawn mower or subway train passing through an underground tunnel (94), making concentration difficult and communication sometimes impossible (92). A systematic review of surgical technology found specialties that rely heavily on advanced equipment in the operating room, such as cardiac and vascular surgery, bore a greater burden of equipment-related error than general surgery (95). To give an example, Wiegmann and colleagues conducted a human factors study of cardiopulmonary bypass machines, and demonstrated issues with the design and usability of the machines that provoked perfusion-related and technical errors that endangered the patient (94).

2.4.5 *Organisation & culture*

The way in which hospitals and healthcare systems organise service provision is an important determinant of patient safety. Service provision is likely to be influenced by policies, standards and goals, financial resources and constraints and wider regulatory and governmental bodies (96). The relative impact of these organisational and management factors can be challenging to assess. However, certain structural variables can be measured relatively easily from administrative data. Case volume, hospital teaching status and the provision and characteristics of intensive care facilities have been shown to improve surgical outcomes (75,80). Outcomes for open and endovascular AAA repair have been shown to depend on

hospital-level factors. A US study demonstrated that academic institutions seemed to achieve superior outcomes after elective AAA repair compared to community centres and this effect is particularly true for EVAR (80). Although the precise mechanisms underlying this relationship remain to be understood, the authors surmised that differences in the provision of training, resource availability and multidisciplinary care were likely to be significant. Other studies have demonstrated an association between staffing levels and skill mix and outcomes for surgical patients. For example, a retrospective, observational study conducted in nine European countries demonstrated that improving nurse-to-patient ratios in post-surgical care units and increasing the proportion of the nursing workforce with Bachelor's degrees was associated with improvements in post-operative 30-day mortality (80).

It has been argued that the creation of a positive safety culture is a fundamental aspect of the systems approach safety in healthcare (97). A key dimension of safety culture is leadership commitment to safety – an important aspect of leadership is promoting a culture of learning from error (98). Given the potentially catastrophic effects of error in the operating room (wrong-site/wrong-surgery procedures, for example), it is essential that operating team members feel empowered to surface and discuss errors. Many policy makers and clinical leaders have championed the 'Five Steps to Safety Surgery', not solely because it includes a checklist of evidence-based interventions, but also because team briefings and debriefings help to foster improved communication and collaboration, which are key aspects of a positive safety culture (99). Many authors postulate an association between safety culture and surgical outcomes. Of note, in a study conducted in seven surgical units in Minnesota, Fan and colleagues demonstrated that after adjusting for case volume and patient ASA grade, nine dimensions of safety culture (including communication openness and management support for safety) were associated with colon surgical site infections rates (100). However, this study was unique in its findings as two reviews of the literature investigating the potential association between safety culture and patient outcomes concluded that in general there is very little empirical evidence to support this relationship (101,102). Of note, improvements in safety culture have been linked to increased errors, but these results are likely due to improved reporting rates in units with better safety culture (102).

2.5 SAFETY INTERVENTION IN SURGERY

There is growing interest in human factors and the systems approach to safety in surgery, and a number of studies have adopted the systems approach to better understand safety in the operating room, most notably in the field of cardiac surgery. A number of strategies have been

developed to mitigate the impact of system failures during surgical procedures. Some of these interventions will be discussed briefly here.

2.5.1 *Team factors & communication*

A large cohort study involving 108 US hospitals demonstrated that implementation of a team training programme, based on the principles of crew resource management from aviation, is associated with lower surgical mortality (103). Crew resource management training focuses on improving operating team members' knowledge of safety, situational awareness, communication skills, decision-making, and briefing and debriefing (104). Similar results have been demonstrated in smaller single-centre studies evaluating surgical team training programmes in the UK (104,105). Simulation-based training is gaining popularity to train and assess operating teams in both the technical and non-technical skills required to perform surgery (106). Simulation-based training may improve teamwork by exposing teams to real-life clinical scenarios in high fidelity environments during which team members must react to emerging events and learn together (107). Despite the inherent practical and financial challenges of implementing a simulation-based curriculum, simulation-based training is rapidly becoming a core component of education in cardiovascular surgery (107).

In 2009, the New England Journal of Medicine published a seminal study suggesting that implementation of a Surgical Safety checklist was responsible for a reduction in surgical mortality from 1.5% to 0.8% and a reduction in surgical complications from 11.0% to 7.0% (108). It was suggested that the impact of the checklist lay not only in routine checks of safety issues, but also in its ability to foster teamwork and improve communication among operating team members (109). In February 2010, the checklist became a mandatory preoperative requirement for all invasive procedures performed in the UK. However, subsequent studies evaluating the impact of the checklist have not replicated the magnitude of improvement reported in the original publication (110). Several reasons for this have been put forward. The success of the checklist appears to rely on leadership and a willingness to adopt to new ideas and, in this regard, the effect of the checklist may lie in association rather than in causation, as safety conscious teams are more likely to be motivated by the adoption of safety interventions (109). One of the criticisms of checklists is that they remove flexibility and autonomy. By standardising key processes, checklists reduce reliance on memory for completion of tasks that may be vital to prevent adverse events (109). In certain situations, the ability to resort to controlled algorithms is likely to be of benefit. For example, in a simulation-based study, Arriaga and colleagues demonstrated that checklist use during surgical crisis scenarios significantly improved team performance and management of a range of intraoperative emergencies (111).

2.5.2 *Work/operative environment*

Noise and distractions in the operating theatre can be minimised through implementation of policies that minimise the number of observers and non-essential staff in theatre, limit the use of telephones and pagers, and discourage conversations unrelated to the case being performed (94). Similar policies exist in aviation and are applied during critical stages of a flight when cognitive workload is highest for the pilots – during take-off and landing and while flying at less than 10,000 feet. Known as the 'sterile cockpit rule' – this policy was implemented in 1981 by the Federal Aviation Administration following a number of incidents which happened when pilots were distracted during critical phases of the flight. Application of the sterile cockpit rule has also been proposed as a means to improve patient safety in surgery. One particular study evaluated this concept for use during cardiopulmonary bypass procedures, concluding that instituting similar rules at defined intervals during cardiac surgery would be challenging due to the wide variation in mental workload among different professional groups at different stages of cardiac operations (112). However, other studies have suggested that the sterile cockpit rule would be a useful addition to anaesthetic practice to improve safety during induction and emergence from anaesthesia (113).

2.5.3 *Tools & technology*

Performing surgical procedures requires continuous interface with equipment and advanced technologies. The design, implementation and utilisation of new technologies all require careful consideration to prevent device-related problems and end-user error. Human factors engineering is a science that can be used to evaluate and improve medical device-related issues. Even when a device has been carefully designed to be user-friendly, the success of the new technology is likely to rely on successful engagement with end-users to foster 'psychological ownership'. The introduction of a new technology has an impact on the task itself but it may also change the dynamic of the operating team and introduce new sources of error (94). To mitigate the potential negative effects of new technology, it is important to ensure that the introduction of new technologies is accompanied by process innovation (114) – this may require adapting team member roles and finding new ways to coordinate staff during the procedure. This phenomenon has been observed during the introduction of minimally invasive endovascular techniques, which has not only required surgeons to learn new skills, but has also prompted much higher levels of communication and collaboration between surgical and radiology staff.

2.5.4 *Organisation & culture*

The way healthcare services are organised plays an important role in improving patient safety. The findings of a number of recent systematic reviews and meta-analyses support a positive hospital-level volume-outcome relationship for a range of surgical specialties (115–118) and this evidence is shaping the reconfiguration and centralisation of a range of healthcare services. However, rather than simply encouraging all surgical units to achieve minimum threshold case volumes, many researchers have attempted to understand the precise mechanisms underlying this hospital-level volume-outcome relationship. A systematic review in paediatric surgery found that surgeon-level factors were associated with outcomes for minor procedures, whereas hospital-level factors were more strongly associated with patient outcomes for highly complex operations (117). Thus, for complex operations – the important exposure may not be the higher hospital case-volume, rather - the concentration of expertise, pooling of resources and appropriate critical care infrastructure characteristic of high-volume centres (117).

The organisation of surgical care may be optimised through implementation of care pathways that define the sequencing and timing of health interventions. Care pathways are designed to increase the reliability of core clinical processes and can require organisational changes to optimise allocation of resources (119). However, the evidence supporting their use is mixed. In a 2014 systematic review performed by Howell and colleagues, 38 studies had examined the relationship between care pathways and surgical adverse events. However, only twenty of these studies were medium- to high-quality. Of these higher quality studies, nine studies had focussed solely on care pathways in colorectal surgery and only six studies had demonstrated a significant decrease in adverse events (120).

Alongside interventions to improve the organisation and provision of surgical care, many healthcare organisations have become interested in how to improve the culture of safety within their organisations. Two popular strategies involve improving leadership engagement and accountability (94). There is some evidence that leadership/hospital executive walk rounds improve safety climate as perceived by frontline clinical staff (121). However, it may be more challenging to implement leadership walk rounds in theatres because active engagement by hospital executives with clinical staff is unlikely to be feasible during surgical procedures.

Safety culture may also be improved by encouraging units to take ownership of their results by submitting surgical outcomes data to national or international audits (120). In vascular surgery, submission of data to European audit enabled the UK to be identified as an outlier for in-hospital mortality after elective AAA repair (122). This stimulated a national AAA Quality

Improvement Programme in the UK, which provided standards, protocols and care bundles to promote best practice – this included standardising pre-operative anaesthetic assessment for all patient requiring AAA repair (123). Although the in-hospital mortality rate for AAA repair fell significantly following implementation of the Quality Improvement Programme, the results must be interpreted with caution due to the inherently flawed nature of quasi-experimental pre-post-intervention research – for example, the potential for biased case selection.

Finally, it should be noted that there is actually no good evidence that improving patient safety culture improves patient outcomes (102). This does not mean that safety culture has no influence, rather – there is a paucity of evidence on this subject and instead of a linear relationship in which culture directly affects surgical outcome, the relationship is likely to be much more complex (102).

2.6 EXPLAINING OUTCOMES IN ARTERIAL SURGERY: WHAT IS ALREADY KNOWN?

Vascular patients are generally elderly with complex cardiovascular and respiratory comorbidities (38). In this patient group, appropriate patient selection for high-risk arterial operations is of utmost importance in achieving satisfactory results. The ability to predict survival after high-risk arterial procedures is vital to inform clinical decision-making. Common risk factors in this cohort include ischaemic heart disease (IHD), heart failure, hypertension, chronic obstructive pulmonary disease (COPD), renal impairment, cerebrovascular disease and diabetes, and these risk-factors are associated with poorer post-operative outcomes (124). Many patient risk-factors are not modifiable and these must be taken into account when decisions are made to offer surgery to patients.

Surgical expertise is clearly essential. Underpinning this assumption, the volume-outcome relationship is now well-established for many arterial operations: higher annual caseload is consistently associated with lower mortality rates in this patient population (75–77,79,125), with the relative importance of surgeon volume and hospital-level volume varying depending on the arterial procedure studied (66). Subspecialisation has also been shown to be important with the best outcomes being delivered by high volume vascular specialists in high volume centres (126). Some vascular surgeons have cautioned that designing services based on threshold volumes for arterial operations is an oversimplification of the problem of patient safety and that the vascular community must seek to understand the precise mechanisms underlying the volume-outcome relationship (126). There is evidence that provision of intensive care facilities and input of specialist vascular anaesthetists improve patient outcomes

in this specialty (80,126,127). In recent years, the Vascular Society of Great Britain and Ireland have endeavoured to broaden the assessment of quality and safety for major vascular procedures and a range of process measures are now documented alongside post-operative outcomes in their annual reports of data from the National Vascular Registry (see Table 2.3) (128). Certain process measures reflect recommendations outlined in key guidelines, including the NICE guidelines on stroke and peripheral arterial disease (PAD), the Quality Improvement Framework and the Provision of Vascular Services documents published by the Vascular Society, and recent NICE guidance (draft for consultation) on the diagnosis and management of AAA (49,129,130). There have been significant and widespread efforts to understand and improve outcomes in patients undergoing arterial surgery. A great many studies have investigated patient-related determinants of outcome in arterial surgery. There has been widespread service reconfiguration in the UK and the National Vascular Registry has been instrumental in providing evidence underpinning many of these changes in service provision. However, there appears to be little evidence exploring the latent causes of preventable harm in patients undergoing arterial surgery.

Table 2.3: Process measures reported by the National Vascular Registry

Procedure	Process Measures
Carotid Endarterectomy	Time from index symptom to operation Anaesthetic technique Operative technique Post-operative care setting
Infra-renal AAA repair	Proportion of cases meeting VSGBI AAA Quality Improvement standards (e.g. anaesthetic review by consultant vascular anaesthetist) Operative technique Time from vascular assessment to surgery Post-operative care setting
Repair of ruptured AAA	Operative technique Post-operative care setting
Repair of complex aortic conditions	Operative technique Post-operative care setting
Lower limb revascularisation for peripheral arterial disease (PAD)	Ankle-brachial pressure index measurement Anaesthetic technique Operative technique
Lower limb amputation for PAD	Time from vascular assessment to surgery Anaesthetic technique Operative technique Consultant surgeon presence during surgery

Source: Waton S, Johal A, Heikkila K, Cromwell D, Loftus I. *National Vascular Registry: 2016 Annual Report*. London: The Royal College of Surgeons of England, November 2016.

2.7 JUSTIFICATION FOR THE ORIGINAL WORK PRESENTED IN THIS THESIS

Large studies of adverse events in hospitalised patients suggest that the rate of preventable safety incidents is particularly high in vascular surgery compared to other surgical specialties (4,5,10,11,61,82). It seems imperative, therefore, that consideration is given to the factors contributing to preventable patient harm in this specialty. Unlike registration of process and outcome measures, safety (in terms of preventable harm) is not measured as part of the national vascular audit in the UK. While it may be impractical to document seemingly inconsequential errors or near-misses on a national scale, there are a number of different approaches that could be taken to investigating these patient safety issues in vascular surgery – each with unique advantages and limitations. The original research presented in this thesis will utilise a range of methods in order to develop a better understanding of intraoperative safety failure in arterial procedures.

Some post-operative complications experienced by vascular patients are likely to be avoidable if closer attention is paid to identifying failures in the surgical system. In some cases, the relationship between a major error and a catastrophic adverse outcome may be obvious, but these incidents are thankfully rare. It is essential that attention is given to the more insidious causal trajectories leading to preventable harm. As demonstrated in cardiac surgery, minor errors may be seemingly inconsequential in isolation, but may have a multiplicative effect that is equally as hazardous as when a major error occurs (69). The study of errors and near misses might of value to better understand the latent failure pathways leading to adverse outcomes in patients undergoing arterial operations.

2.8 THESIS AIMS

The overarching aim of the original work presented in this thesis is to deepen our understanding of the causes of preventable harm in patients undergoing arterial intervention. Each of the studies presented in the following chapters will adopt a systems approach to identifying patient safety problems.

The aims of the original work presented in this thesis are:

1. **To explore what is already known about system factors and their relationship with patient safety in arterial surgery**
2. **To develop a broad understanding of the nature and relative importance of system factors in relation to patient safety in arterial surgery**
3. **To investigate the relationship between system failures and clinical outcomes in patients undergoing arterial intervention**

2.9 THESIS OUTLINE

The table below provides an outline of the chapters and studies presented in this thesis.

Section 1: Introduction		
Chapter 1 Patient safety: towards a systems approach	Chapter 2 A system approach to safety in surgery	
Section 2: Scoping exercises		
Chapter 3 What is known about the relationship between system factors and patient safety in arterial surgery: a systematic review of the literature	Chapter 4 Surgeons' perceptions of the causes of adverse events in arterial surgery: a mixed methods study	Chapter 5 Multicentre survey study of safety culture dimensions in vascular surgery: operating teams' perceptions of teamwork, working conditions, management and safety
Section 3: Defining the landscape of intraoperative safety failures in aortic surgery		
Chapter 6 Establishing the reliability of a structured, self-report method to capture intraoperative safety failures in vascular surgery	Chapter 7 Multicentre study of intraoperative system failures in aortic procedures	Chapter 8 Determinants of system failures in aortic procedures, and their relationship with patient outcomes
Section 4: Discussion & conclusions		
Chapter 9 Discussion & conclusions Implications for clinical practice & further research		

Section II:

Scoping Exercises

3 What is Known About the Relationship Between System Factors and Patient Safety in Arterial Surgery? A Systematic Review of the Literature

3.1 CHAPTER OVERVIEW

An important aim of this thesis is to develop a better understanding of how system factors affect patient safety in arterial surgery, so that recommendations can be made for future safety improvement interventions. To begin to address this aim, it is necessary to examine the existing literature on this topic. This chapter presents the methods and results of a systematic review of the literature. The review includes a broad range of original research papers that postulate a link between system factors and patient safety in the field of arterial surgery. The review presented in this chapter provides a summary of the existing evidence on the subject; the studies in the following chapters will build on this evidence-base. The review also informed the design of subsequent studies presented in this thesis.

An updated version of the review presented in this chapter was published in the European Journal of Vascular and Endovascular Surgery in 2017. A copy of this publication can be found in appendix 17, page 260.

3.2 INTRODUCTION

Chapters one and two outlined and discussed the systems approach to developing a comprehensive understanding of patient safety. This approach argues that investigation of factors influencing surgical outcome should be taken beyond assessment of patient risk-factors and surgical expertise. In arterial surgery, much of the literature on the determinants of patient outcomes has focussed on patient risk-factors and surgical techniques. For example, mortality rates after suprarenal aneurysm repair are known to be higher in patients with pre-operative renal impairment and in whom there is prolonged visceral ischaemia intraoperatively (131). However, it is important to consider that there is now robust evidence of a relationship between hospital case-load volume and outcome for a range of arterial procedures (75,77,78,126,127,132). Individual surgeon volume does not fully account for this relationship (66) so it follows that additional hospital-level or system factors must play a role in determining patient outcomes. The precise nature of these additional contributory factors

is not yet known. However, particular structural characteristics of healthcare organisations (such as the provision of intensive care facilities), as well as certain care processes (such as having targets for the time from diagnosis to surgical intervention) are known to be important.

Healthcare systems consist of complex sets of interrelated structures, people, processes and activities that must function successfully to provide care and treatment that is safe and effective for patients. The system in which patients with arterial disease are treated is particularly complex. Arterial patients are seen throughout the patient pathway, as inpatients and outpatients, by multi-disciplinary teams composed of professionals from different disciplines and specialties. Patients may be seen in arterial 'hubs' or in local 'spoke' centres, or they may be referred to tertiary centres for specialised treatment. Their treatment may involve traditional surgical techniques or minimally-invasive endovascular techniques, which are developing rapidly and rely heavily on advanced technologies. In addition to these complicated system factors, patients are usually elderly, with a range of comorbidities that can make them less physiologically resilient during operations, and arterial operations are frequently life- or limb-saving procedures. It is entirely conceivable that failures in the various dimensions of this complex system could lead either to poorer post-operative outcomes or even to patient harm. Hence, it is important to amalgamate the evidence that investigates this hypothesis - a systematic review of the literature that addresses the relationship between system factors and patient safety in arterial surgery is needed.

3.3 AIM

The systematic review outlined in this chapter was conducted to develop a comprehensive overview of relevant existing literature to guide the studies presented in this thesis. The aim of the review was to summarise evidence examining the relationship between specific system factors and patient safety in elective arterial surgery. The factors selected for investigation in this review encompass three levels of the healthcare system: team factors, work environment factors and organisational factors.

3.4 METHODS

3.4.1 *Protocol*

A summary of available evidence is only of use to clinicians if the evidence is collated and reported systematically and accurately (81). To this end, the PRISMA statement (Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocols) (81) was used to guide

protocol development before the review took place. The PRISMA checklist outlines important steps that authors should take when reporting a systematic review to ensure that the methods used are transparent and reproducible. A preliminary search of the literature also guided protocol development. The preliminary search revealed that literature on this subject was sparse, and therefore the protocol adopted a broad approach to the topic area to capture any potentially relevant evidence. The protocol was reviewed and agreed by vascular and patient safety experts within the local research group before the review was undertaken; this prevented any subjective decision-making during the conduct of the review.

3.4.2 *Definitions*

Elective arterial surgery

For the purposes of this review, elective arterial surgery refers to the planned open surgical or endovascular treatment of aneurysmal or occlusive arterial disease. The evaluation of factors influencing safety in emergency surgery was deemed beyond the scope of this review.

Measures of quality and safety

The principal outcome measures were mortality, complications, length of stay and readmission rates. These were complemented by other process measures including errors, failures or procedural problems, and unnecessary procedural delays. These process measures may provide important insights into quality and safety because they are frequently defined by their consequences (i.e. harm to patient or delays to an operation).

Factors influencing surgical quality and safety

A systems approach was adopted for the purposes of this review to take evaluation of factors influencing surgical quality and safety beyond patient risk factors and surgical skill. This approach, which was discussed in detail in chapter one, encourages consideration of all potentially relevant factors implicated in surgical quality and safety in the perioperative period (96,133). This review considers three overarching themes informed by a previously published framework of factors influencing clinical practice: team factors, work environment, and organisation and management factors (37). These three themes were chosen as they provide a broad overview of different aspects of the healthcare system that may influence the safety of patients undergoing arterial procedures. Further details of these themes are provided in Table 3.1.

Table 3.1: Factors Influencing Surgical Quality and Safety

Organisation and management factors	Work environment factors	Team factors
Financial resources & constraints Organisational structure Policy standards & goals Safety culture & priorities	Staffing levels & skill mix Workload & shift patterns Availability & maintenance of equipment Administrative & managerial support	Verbal communication Written communication Supervision & seeking help Team structure (consistency, leadership etc)

3.4.3 *Information Sources*

The following databases were systematically searched: Medline [Ovid Medline 1946 to 1st June 2015], Embase [Embase 1947 to 1st June 2015], PsycINFO [PsycINFO 1967 to May Week 4 2015], and the Cochrane Library. These databases were selected because they hold the largest and most comprehensive collections of biomedical journal articles. Reference lists of key papers were hand-searched for additional citations. The last search was performed on 1st June 2015.

3.4.4 *Search Strategy*

The search strategy was developed following a training session with a university librarian. A comprehensive list of search terms was devised in consultation with vascular and patient safety experts, identification of commonly used terms in the literature and synonyms of relevant terms (these search terms, with details of how they were combined using Boolean operators for can be reviewed in appendix 1, page 227). It was anticipated that few papers would specifically focus on investigation of team, work environment or organisational factors, therefore, the search was deliberately broad to capture papers that may include an assessment of such factors as an aspect of a wider study. Search terms were categorised into three groups: arterial disease; surgical intervention; measures of quality and safety. Within groups, search terms were linked by the Boolean operator 'OR'. Each group of search terms was linked using the Boolean operator 'AND'. The Boolean operator 'NOT' was used to exclude certain irrelevant articles from the search (papers on aortic valve repair, coronary artery bypass or gastric bypass, for example). Truncation and wildcard symbols were used in order to account for variations in spelling and word endings. MeSH (Medical Subject Headings) were used to ensure that the search was comprehensive. Limits were applied for humans, abstracts and papers in the English language.

3.4.5 *Study Selection*

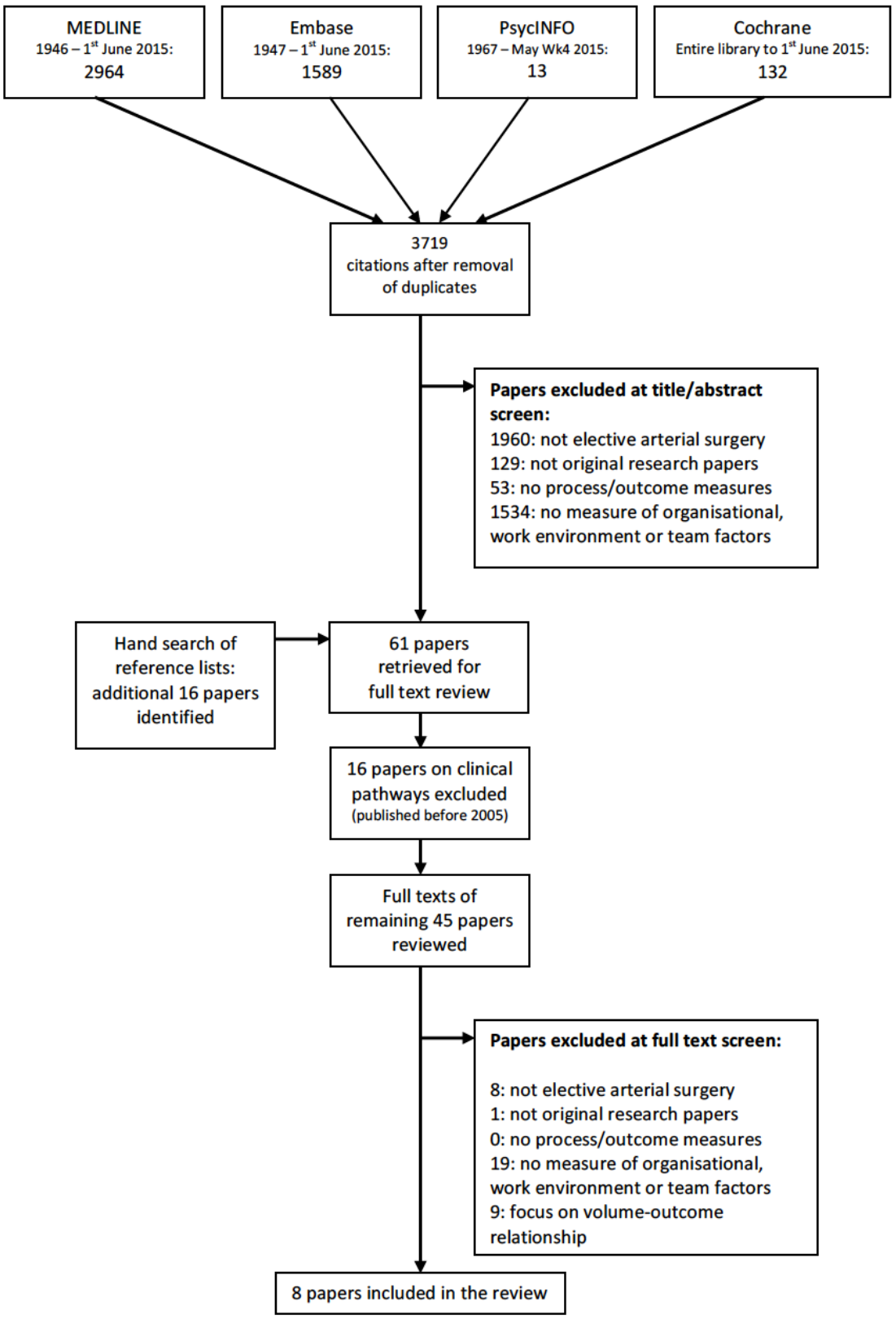
The primary reviewer (RL: author of this thesis) screened all titles and abstracts according to predefined inclusion and exclusion criteria, with a second reviewer (ADG: a clinical research fellow in vascular surgery) screening ten percent of citations. Cohen's kappa demonstrated good agreement between reviewers (κ = .86, p<.001). Both reviewers screened all papers selected for full text review to select included papers (κ = .78, p<.001). Any disagreements between reviewers at each stage of selection were resolved by consensus. A PRISMA flow diagram for study selection is presented in Figure 3.1 overleaf.

3.4.6 *Inclusion and exclusion criteria*

Studies were eligible for inclusion if they were original research papers published in a peer-reviewed journal, which addressed the relationship between team, work environment, and/or organisational factors, and selected process or outcome measures in elective arterial surgery during the perioperative period. The evaluation of factors influencing safety in emergency surgery was deemed beyond the scope of this review. Original research papers investigating interventions to optimise team, work environment and/or organisational factors, that also measured process/outcome measures, were additionally included.

Studies only investigating the impact of patient risk factors, surgical techniques, or pharmacological interventions (e.g. cardio protective medication) were excluded. Studies solely describing the following operation types were also excluded: emergency arterial surgery; iatrogenic arterial injury; cardiac or ascending aortic surgery; arterial closure devices. Case volume, whether at a surgeon-level or unit-level, is now frequently used as a surrogate marker of quality and safety in arterial surgery; this reflects the large body of evidence confirming a relationship between volume and outcome for a wide range of arterial procedures (75). Though it could be considered an important system factor, case volume has already been examined exhaustively and it was therefore not considered necessary to include case volume within scope of this review. Only papers evaluating care pathways published between 2005 and 2015 were considered to be relevant at the time the review was conducted, because vascular treatment and service provision has changed significantly in recent years. Therefore, any papers published earlier than 2005 that examined interventions along the clinical pathway were excluded. Reviews, case reports, editorials, opinions and conference proceedings were also excluded.

Figure 3.1: PRISMA Flow Diagram for Study Selection



3.4.7 *Data collection process and data items*

For each paper, details of the design, aim, study period, sample size, type of surgical intervention, aspect of team, work environment, or organisational factor(s) investigated, and measure(s) of quality or safety used, and details of intervention if applicable, were extracted using a standardised data extraction form. The primary reviewer (RL) extracted all of these details and the information was subsequently checked and verified by the second reviewer (ADG).

3.4.8 *Risk of bias of individual studies*

In order to come to reliable conclusions, authors should consider the possible limitations of studies included in a review. Design, conduct, analysis and reporting of findings are all aspects of a study that should be appraised in an assessment of study 'quality' (134). Various tools are available to ensure a systematic approach to critical appraisal; these tools are tailored to particular study designs. Due to the heterogeneity of study designs included in this review, a variety of tools and methods were used to assess risk of bias. Cross-sectional and case-control studies were quality assessed using two versions of the Newcastle-Ottawa Scale, a tool designed for the assessment of non-randomised studies, which assesses three aspects of study quality: selection of study groups; comparability or study groups; outcome measurement and analysis (135). The Newcastle Ottawa Scale facilitates independent assessment of study quality because it generates a quantitative score. High quality case-control and cross-sectional studies attained the maximum score of 9 stars; medium quality studies obtained a score of 7 or 8 stars, while a score of 6 stars or less indicated poor quality. Two reviewers (RL and ADG) independently scored case-control and cross-sectional papers, with satisfactory agreement between assessors for quality scoring (κ = .54, p=.01). To complement the quantitative scoring of study quality, the authors of the review felt it was important to make explicit particular strengths and weaknesses of included studies that may influence the conclusions of the review. To this end, the STROBE checklist (136) (Strengthening the Reporting of Observational studies in Epidemiology) guided a qualitative assessment of bias in the included studies. The only randomised controlled trial (RCT) included in this review was appraised using the Cochrane Collaboration's tool for assessment of risk of bias; this tool was selected because it is well-recognised and widely accepted having gone through an extensive evaluation process (134). Due to the small number of papers retrieved from the search, low quality papers were included in the review.

3.5 RESULTS

3.5.1 *Study designs and quality*

Eight studies(57,88,137–142) met selection criteria. Details of quality assessments are outlined in Table 3.2 and Table 3.3. The characteristics of these studies are outlined in Table 3.4. Half of the included studies (n=4) were observational and explored the relationship between various system factors and patient safety. The other half (n=4) evaluated an intervention designed to improve the safety of patients undergoing arterial procedures. Study designs were heterogeneous and of those with an experimental design, only one was a randomised control trial (RCT) (139). Seven of eight papers reported single-centre studies (57,88,138–142) and two studies had sample small sizes of less than 20 cases (141,142). Of the case-control and cross-sectional studies scored using the Newcastle-Ottawa Scale, only one paper was scored as high quality (137) and three papers were deemed to be of low quality (88,138,140). Thus, this review brings together a small number of largely poor quality studies on the subject – this has implications for the strength of the conclusions that can be inferred from the collated literature, which are discussed in more detail below.

3.5.2 *Measures of safety*

Measures of safety varied hugely between studies: only half of the included studies measured the clinical significance of study endpoints in terms of patient outcomes (137–140); these four studies measured in-hospital morbidity and mortality, and one study measured failure-to-rescue rates. Four papers measured 'surrogate markers' of surgical quality and safety – these surrogate markers included intraoperative errors, failures or procedural problems (57,88,141,142). Two studies measured the impact of intraoperative errors in terms of 'danger' and 'delay' scores – these were defined as the potential for patient harm and the level of procedure flow disruption (57,141).

Table 3.2: Quality assessments for cross-sectional and case-control studies

First Author Year	Study setting	Sample size	Study design	Selection (max 5 stars)	Comparability (max 2 stars)	Outcome (max 3 stars)	Overall quality score	Critical appraisal of factors likely to influence interpretation of findings
Brooke 2012	658 nationwide hospitals, US	16,732	Cross-sectional	****	**	***	High (9)	Multi-centre study with large sample size. Patient- & hospital-level variables controlled for in regression model. Self-report method, 50% response rate
Cantlay 2006	Single centre regional vascular unit, UK	234	Cross-sectional	****	0	0	Low (4)	Single-centre study. Comparison of mortality rates pre- & post-intervention provided for AAA repairs only. Patient risk factors/other confounders not controlled for.
Catchpole 2008	Single centre regional vascular unit, UK	22	Cross-sectional	***	*	**	Low (6)	Small sample size. Single-centre study. Tools used to evaluate teamwork & surgical errors were previously validated.
Murphy 2007	Single centre regional vascular unit, UK	60	Cross-sectional	***	0	***	Low (6)	Single-centre study. Demographics briefly described for each group though not controlled for with statistical methods.
Patel 2012	Single centre regional vascular unit, UK	15	Case-control	****	0	***	Medium (7)	Small sample size. Single-centre study. Descriptions of demographics for each group not sufficiently detailed to judge comparability. Observer & assessors not blinded to whether case was pre- or post-intervention.

Table 3.3: Quality assessments for descriptive studies and RCT

First Author Year	Study setting	Sample size	Study design	Critical appraisal of factors likely to influence interpretation of findings
Albayati 2012	Single centre regional vascular unit, UK	66	Descriptive	Single-centre study. Observational method: unstructured observations undertaken by medical students. Two blinded assessors with significant vascular surgical experienced judged intraoperative failures. Non-significant correlations between patient age & ASA grade, & failure rate (as potential confounders) are described.
Soane 2014	Single centre regional vascular unit, UK	12	Descriptive pilot study	Small sample size. Single-centre study. Observational method to capture intraoperative errors: previously validated, structured approach with independent verification by two vascular surgical experts. Self-report method to evaluate the role of teamworking. Attempts made to reduce Hawthorne effect prior to study. Data analysed to examine trends – statistical analysis not performed due to small sample size.
Muehling 2009	Single centre, Germany	101	Randomized controlled trial	Single-centre study *Selection bias:* patients were randomly assigned to either the traditional or the fast-track treatment arm but further description of allocation not provided. *Performance & detection bias:* blinding not feasible due to nature of intervention. *Attrition bias:* Intention-to-treat analysis performed. Five excluded (2 withdrew consent, 2 suprarenal clamping, 1 EDA dysfunction) Attrition not expected to affect results. *Reporting bias:* All pre-specified outcomes were reported.

Table 3.4: Characteristics of included studies

First Author Year	Operation type(s)	Intervention	Organisational Factors assessed	Work Environment Factors assessed	Team Factors assessed	Measures of quality & safety assessed	Findings
Albayati 2012 (UK)	TAAA repair AAA repair (open & endovascular) CEA LL BG	N/A	N/A	1. Team member absence 2. Equipment unavailability/ configuration/ malfunction 3. Fatigue	1. Communication 2. Team conflict	Intra-operative failure distribution	Most frequent failures related to equipment or communication. Failures were significantly higher in the endovascular phase.
Brooke 2012 (US)	Open AAA repair	Implementation of National Quality Forum (NQF) safety practices	1. Creation of safety culture 2. Pharmacy involvement with medication-use process 3. Specialist anti-coagulation service involvement 4. Protocols for prevention of complications	1. Nursing staffing levels 2. Workspaces where medications are prepared free from clutter, distraction, noise	N/A	In-hospital complications Failure to rescue (FTR) All-cause 30-day mortality	Hospitals that fully implemented safe practices were more likely to diagnose complications, had lower FTR rates, and had lower in-hospital mortality rates for most high-risk procedures, but not for AAA repair, compared to hospitals with partial safe practice compliance.

N/A: not applicable, TAAA: thoraco-abdominal aortic aneurysm, AAA: abdominal aortic aneurysm, CEA: carotid endarterectomy, LL BG: lower limb bypass graft

Table 3.4 continued:

First Author Year	Operation type(s)	Intervention	Organisational Factors assessed	Work Environment Factors assessed	Team Factors assessed	Measures of quality & safety assessed	Findings
Cantlay 2006	AAA repair-open & EVAR LL BG CEA	Implementation of vascular consultant anaesthetist-led pre-operative assessment clinic (PAC)	1. Multi-component intervention along clinical pathway (pre-operative)	N/A	N/A	In-hospital morbidity & mortality	In-hospital mortality for AAA repair fell from 14.5% in 2-year period before PAC to 4.8% in 2 years after introduction of PAC. Improvement likely multi-factorial but implementation of PAC played major role.
Catchpole 2008 (UK)	CEA	N/A	N/A	N/A	1. leadership & management 2. teamwork & cooperation 3. problem solving & decision-making 4. situational awareness	Operating time Errors in surgical technique Other procedural problems	Aspects of team performance strongly correlated with errors & procedural problems. Teamwork interventions could improve technical performance and patient outcomes.
Muehling 2009	Open AAA repair	Implementation of fast-track recovery program	1. Multi-component intervention along clinical pathway (post-operative)	N/A	N/A	In-hospital morbidity & mortality Length of stay & readmissions	Postoperative complications and hospital stay significantly reduced in fast-track group compared traditional treatment group.
Murphy 2007	Open AAA repair	Implementation of fast-track goal-directed pathway	1. Multi-component intervention along clinical pathway (post-operative)	N/A	N/A	In-hospital morbidity & mortality Length of stay & readmissions	Median hospital stay reduced from 9 to 5 days following implementation of the pathway without any associated complications.

N/A: not applicable, TAAA: thoraco-abdominal aortic aneurysm, AAA: abdominal aortic aneurysm, CEA: carotid endarterectomy, LL BG: lower limb bypass graft.

Table 3.4 continued:

First Author Year	Operation type(s)	Intervention	Organisational Factors assessed	Work Environment Factors assessed	Team Factors assessed	Measures of quality & safety assessed	Findings
Patel 2012 (UK)	Combined open & endovascular TAAA & AAA procedures	Implementation of a structured, mental rehearsal before the endovascular phase		1. Intervention designed to increase efficiency in equipment use	1. Intervention designed to improve team dynamics	Intraoperative error rates Delay scores Danger scores	Errors rates were significantly higher during the endovascular phase compared to open. Error rates, danger & delay scores were significantly lower after the intervention.
Soane 2014 (UK)	CEA LL BG	N/A	N/A	N/A	1. team orientation 2. coordination & leadership style 3.communication 4.error management 5.task distribution	Intraoperative error rates	Error rates were lower when there were effective teamwork measures in place. Teamwork training for vascular teams may help to prevent or mitigate errors.

N/A: not applicable, TAAA: thoraco-abdominal aortic aneurysm, AAA: abdominal aortic aneurysm, CEA: carotid endarterectomy, LL BG: lower limb bypass graft

3.5.3 *Team factors*

Four papers addressed team factors (57,88,141,142). Two studies found that levels of team skills (including teamwork, leadership and situational awareness) correlated with the frequency of errors or procedural problems in carotid endarterectomy and lower limb bypass operations. An example provided in the Catchpole study was a lapse in teamwork and communication which led to delayed heparin administration for arterial cross clamping, thus increasing the risk of embolisation (88). The tools used to assess teamwork were different in each study. Catchpole and colleagues used the Oxford NOTECHS (NON-TECHnical Skills) tool, which is well-validated and widely used in the surgical literature (31,143,144). Soane and colleagues developed their own assessment tool for the purposes of the study (142) – this was based on a tool that has been used to measure teamwork in air traffic control (145). The studies by Catchpole and Soane were both small (sample sizes of 22 and 12, respectively), and neither tested associations between the observed errors and clinical outcomes. In two further studies investigating the relationship between team factors and patient safety, two blinded experts assigned 'danger' and 'delay' scores to failures observed during a variety of arterial operations including AAA repair (57,142). Albayati and colleagues found that communication failures occurred more frequently than technical errors, but relatively fewer communication failures were perceived to have a major impact on procedural duration or patient safety (57). Patel and colleagues demonstrated a non-significant reduction in the number of communication errors occurring in combined open/endovascular arterial procedures following implementation of a structured, mental rehearsal before the endovascular phase but they did not control for any confounders, such as patient risk-factors or procedural variables (141).

All four studies examining team factors were small, single-centre studies that took place in the UK, which clearly limits the generalisability of their findings. These studies indicate that there may be a relationship between team factors and intraoperative errors and procedural efficiency, but they do not enable any conclusions to be inferred regarding the relationship between team factors and patient outcomes.

3.5.4 *Work environment factors*

Three papers addressed the relationship between work environment factors and patient safety (57,137,141). A large, multi-centre cross-sectional study in the US investigated associations between healthcare organisations' adherence to 27 hospital safety measures and outcomes after open AAA repair and other high-risk operations. The hospital safety measures consisted of a comprehensive set of evidenced-based hospital process measures and standardised practices endorsed by the National Quality Forum (NQF) (137); these include standards

relating to the work environment, such as safe nursing staffing levels and clinical areas conducive to safety medicine administration. In this study, the risk-adjusted mortality benefit conferred by full compliance with NQF safety practices was significant for most other high-risk procedures investigated in this study, but not for open AAA repair (Odds Ratio, 0.85; 95% CI, 0.71-1.03) – a finding that the authors do not comment on in their discussion. Unfortunately, the findings of this study were not presented in sufficient depth to ascertain the relative importance of work environment factors in relation to patient safety. The study authors suggest that compliance with NQF safe practices may foster a 'culture of safety' within participating organisations, which may in part explain the relatively superior outcomes seen in these organisations.

In Albayati's observational study of intraoperative failures, equipment and workspace failures constituted 13% (n=8/59) of all major failures that delayed the arterial operations or endangered the patient, and overall equipment failure was the most common intraoperative failure type (57). Two examples given were imaging equipment malfunction and stent graft deployment failure due to snapping of deployment mechanism. In this study, failure rates were found to be significantly higher in procedures with an endovascular component than in open surgical procedures. Although the authors of this study assessed the immediate consequences of intraoperative failures in terms of risk of harm and procedural delay, they did not investigate the relationship between intraoperative failures and actual patient harm or patient outcomes. In a further study, Patel and colleagues piloted a structured, team rehearsal of the endovascular phase of complex aortic aneurysm repairs that was designed to improve team communication and efficiency of equipment-use (141). In this study, rates of intraoperative error decreased and the perceived risk to patient safety and procedural efficiency associated with these errors improved following implementation of the structured, mental rehearsal intervention. These studies document equipment and workspace failures occurring during arterial operations. However, these two studies were performed at the same institution, which limits the generalisability of their findings. Furthermore, neither study investigated the relationship between work environment factors and patient outcomes.

3.5.5 *Organisational factors*

Four papers addressed the relationship between organisational factors and patient safety (137–140). In Brooke's large US study evaluating the impact of NQF safety practices on patient outcomes after AAA repair, many of the safety practices relate to organisational factors, such as establishing an organisational safety culture and organisational protocols to prevent surgical complications. As already discussed, the relative importance of these individual safety practices in determining patient outcomes was not reported in the paper.

Three studies described the impact of multi-component interventions along the entire clinical pathway: one pre-operative intervention (138) and two post-operative (139,140) interventions. In a well-conducted randomised controlled trial, Muehling et al. piloted the safety and efficacy of a fast-track recovery pathway for patients undergoing open AAA repair as compared with traditional patient care (139). Patient characteristics, surgical procedure and clamping time were comparable between the two groups ($p>0.05$ for all characteristics) and outcomes were assessed on an intention-to-treat basis with a low attrition rate (5 of 101 patients excluded). The rate of post-operative medical complications was significantly lower (16% versus 36%; $p=.039$), and length of stay was significantly shorter (10 days versus 11 days; $p=.016$) with no readmissions within 30 days in patients entered into the fast-track program compared to the traditional care group. In a similar study of a fast-track, goal directed clinical pathway for elective open AAA repair, Murphy et al., demonstrated shorter length of stay following implementation of the pathway (from median of 9 days (range 4-17) to 5 days (range 2-12), $p<.001$) with one readmission in the fast-track group and no complications attributable to pathway implementation (140). However, this was a cross-sectional study using historical controls, and although the two groups appeared similar in terms of patient demographics, these characteristics were not subject to statistical enquiry. In the third and final study evaluating clinical pathways, Cantlay et al., describe their experiences of introducing a pre-operative assessment clinic (PAC) led by vascular consultant anaesthetists designed to evaluate and manage pre-operative risk for patients undergoing major vascular procedures (138). While patients scheduled for a variety of arterial operations were reported to have attended the clinic, the authors report unadjusted mortality rates pre- and post-intervention for open infrarenal aneurysm repair only (14.5% and 4.8%, respectively) but patient risk factors and other confounding variables were not accounted for. Clinical pathways such as those described here define the sequencing and timing of health interventions and include efforts to increase the reliability of core clinical processes as well as organisational changes to optimise allocation of resources (119). Taken together, the results of these three studies suggest that there is a relationship between organisational factors and patient outcomes after AAA repair, though if considered individually, the only convincing evidence of this relationship comes from the RCT.

3.6 DISCUSSION

Research into the determinants of surgical outcome after arterial operations has primarily focussed on trying to understand the role of patient risk-factors and surgical techniques. This is the first systematic review to adopt a systems approach to understanding safety in arterial

surgery. Team, work environment, and organisational factors were evaluated with respect to patient outcomes and other markers of surgical quality and safety.

3.6.1 *Summary of findings*

This review demonstrates that only a small number of heterogeneous and largely poor-quality studies have investigated system factors in arterial surgery. The evidence collated in this review has identified various deficiencies in the systems in which arterial procedures are performed. Failures relating to teamwork and communication were consistently associated with high rates of intraoperative errors and procedural problems. Equipment-related problems also appear to have a significant impact on patient safety and operative efficiency. Of note, most of the studies included in the review failed to report the clinical significance of observed system failures. Finally, the findings of three studies suggest that care pathways that define the sequence and timing of specific healthcare interventions may be safely introduced for patients undergoing AAA repair, but the methodological quality of two of these studies was not sufficient to recommend that these pathways be introduced into clinical practice.

3.6.2 *Interpretation*

The heterogeneity and poor quality of the small number of studies collated in this review makes it difficult to draw meaningful conclusions. Designing studies that are capable of measuring all potentially relevant determinants of patient harm in a healthcare system is inherently challenging and this could be one reason for the paucity of literature examining system factors and patient safety in arterial surgery. Outcomes such as in-hospital mortality or readmission within 30 days are relatively rare. For studies to establish any associations between system factors and patient outcomes, sample sizes would need to be large, and likely to be resource- and time-intensive. While the utility of endpoints holding no clinical significance may seem questionable, there is an argument for identifying deficiencies that can be pinpointed as targets for building resilience in the system.

In the literature collated for this review, failures relating to teamwork and communication were associated with high rates of intraoperative errors and procedural problems. However, measures of teamwork differed between studies making it difficult to compare their findings. Research into team skills in arterial surgery is likely to benefit from the use of standardised assessment tools which are well-validated in terms of psychometric properties and content validity. For example, Endo-OTAS (Endovascular Observational Teamwork Assessment for Surgery) is a robust tool to assess teamwork skills in endovascular procedures and includes assessment of the teamwork skills of radiology staff (146). Additional assessment tools – such as OTAS (Observational Teamwork Assessment for Surgery) (147) and NOTECHS (the

Oxford Non-Technical Skills scale) (143,148) are well-validated and can be used to assess the non-technical skills of surgeons, anesthetists and nurses in open surgical procedures. Although further research is needed to understand the clinical impact of teamwork and communication failure during arterial procedures, it is highly likely that these non-technical errors have a negative impact of patient safety given the wealth of evidence that communication failures are associated with adverse events in other surgical specialties (86,149). For example, in a study of the impact of handovers in cardiac surgery, Hudson and colleagues found that communication failures occurred during handover of anaesthetic care during cardiac intervention and these were associated with a 43% greater risk of in-hospital mortality and a 27% greater risk of major postoperative complications following cardiac procedures (87). Arterial intervention is similar to cardiac surgery in that operations tend to be high-risk, long and complex and rely on multi-disciplinary teams and sophisticated technology – thus an equivalent study in arterial surgery may produce similar findings. Current training programmes in vascular surgery do not routinely include training in non-technical skills. To ascertain whether non-technical skills training needs to be introduced into vascular curricula to improve patient safety, further research is required to understand the nature and impact of non-technical errors during arterial intervention.

The evidence collated here suggests that equipment-related failure is common during arterial operations, having a significant impact on efficiency as well as patient safety. Cardiac surgery, which also relies heavily on technology, has been shown to bear a greater burden of equipment-related errors compared to general surgery (95). The relatively high rate of equipment-related problems may not be surprising given the rapid uptake and evolution of endovascular technology over the last two decades. Former health minister, professor Lord Ara Darzi cautioned that the introduction of new technologies must be accompanied by process innovation (114). A good example is the World Health Organisation's (WHO) Surgical Safety checklist, which includes an equipment check prior to knife-to-skin (108). The WHO checklist may be more readily accepted and utilised more effectively if vascular operating teams were to tailor the checklist to specific arterial operations to further improve equipment use during these procedures. Further research is needed to evaluate the clinical impact of the 'structured mental rehearsal' implemented by Patel and colleagues, which was designed to complement the WHO checklist by improving preparation and utilisation of equipment during the endovascular phase of arterial operations (141).

Three studies included in this review evaluated the safety of care pathways for patients undergoing AAA repair (138–140). Studies evaluating these improvement strategies were included in the review because the aim of implementing a care pathway is to optimise both

the organisation of specific healthcare interventions and the allocation of specific staff/resources. Thus, the underlying principles of care pathways align well with the systems approach to patient safety and service quality. In order to properly evaluate the impact of healthcare interventions, the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines should be adhered to (150). However, in this review, two of the three studies evaluating care pathways failed to control for patient, hospital and other confounding factors, making it difficult to understand the nature of the association between the intervention and the reported outcomes. Therefore, no recommendations can be made regarding their use in clinical practice.

3.6.3 *Generalisability*

Six studies of the eight studies included in this review were conducted in the UK, which limits their findings to the British NHS (none of the studies were performed in private healthcare facilities). Seven of the eight papers examined in this review reported on single-centre studies with small sample sizes. All the studies that observed teamwork, communication and equipment failures were single-centric and therefore larger, multi-centre studies are needed increase the validity of these findings.

3.6.4 *Limitations and recommendations for future research*

The heterogeneity and poor quality of the small number of studies collated in this review makes it difficult to draw meaningful conclusions. This review has highlighted a paucity of literature examining the relationship between system factors and patient safety in arterial surgery. The limitations of the collated evidence may reflect the inherently challenging nature of studying system factors and their relationship with patient safety. Healthcare systems consist of complex sets of interrelated structures, people, processes and activities that together provide treatment for patients. It is relatively straightforward to study isolated aspects of this system (teamwork in the operating theatre, for example). However, failures of isolated aspects of these complex systems may not hold any clinical relevance. Patient harm is more likely to result from the complex interplay of multiple failures at many levels of the system (151). Therefore, rather than focussing on a single dimension of the system, further research into the causes of preventable harm in arterial surgery should aim to investigate a broad range of potentially relevant system factors, as well as the relationships between these factors and patient outcomes. It is likely that qualitative research methods, such as interviews with vascular operating staff, would be suited to the exploration of complex system factors associated with patient harm. Given the exploratory nature of future studies in this field, preliminary studies are likely to benefit from a retrospective approach investigating the causes of adverse events, with the findings of these preliminary studies informing larger, multi-centre

trials. Large sample sizes will be needed to power studies capable of identifying associations between system factors and rare outcomes such as major complications or death.

3.7 CHAPTER SUMMARY

This chapter reported a systematic review of the relationship between system factors and safety in arterial surgery. This review has highlighted a paucity of literature examining the relationship between system factors and patient safety in arterial surgery. The heterogeneity and poor quality of the small number of studies collated in this review makes it difficult to draw meaningful conclusions. There is considerable scope more detailed and rigorous examination of patient safety in arterial intervention. Further research is required in several areas: firstly, the landscape of system failures in arterial surgery needs to be defined. Secondly, there should be an examination of the precise relationship between these system failures and actual patient harm. Finally, more work is needed to understand which interventions hold the most promise with regards to improving the safety of patients undergoing arterial procedures. However, to identify the most effective interventions, we must first study where the problems lie. Identifying and testing safety improvement interventions is beyond the scope of this thesis, which will focus on system failure and their relationship with patient harm.

4 Surgeons' Perceptions of the Causes of Adverse Events in Arterial Surgery: a Mixed-Methods Study

4.1 CHAPTER OVERVIEW

Chapter 4 presents an exploratory study that was designed to investigate vascular surgeons' perceptions of the causes of adverse events in patients undergoing arterial operations in the British NHS.

This mixed-methods study was published in the European Journal of Vascular and Endovascular Surgery in 2017. A copy of this publication can be found in appendix 17, page 260.

4.2 INTRODUCTION

The systematic review reported in the preceding chapter demonstrated that there is a paucity of literature examining system factors and their relationship with patient safety in arterial surgery. In cardiac surgery, human factors researchers have demonstrated that aspects of operating team performance (such as poor communication or situational awareness) are associated with poorer outcomes following arterial switch operations and adverse events can occur as a result of inherent threats in the system (31,69). Compared to other specialties, research into human factors and the investigation of patient safety using a systems approach is still in its infancy in vascular surgery. The systematic review identified a small number studies reporting intraoperative errors and procedural problems that were precipitated by system failures, but as these were single-centre studies, their findings could not be generalised across the specialty, Of note, the precise nature of the relationship between these system failures and patient harm or poor outcomes has not yet been established in arterial surgery.

The exploratory study presented in this chapter takes patient harm in arterial surgery as its starting point. Vascular surgeons were asked to consider adverse events that they had witnessed in patients undergoing arterial operations, and they were invited to consider the factors contributing to these harm events. Because vascular surgeons see patients throughout the patient pathway, they are ideally placed to comment on factors leading

preventable harm in their patients, yet the views of vascular surgeons in relation to the aetiology of adverse events have not been formally reported in previous studies.

4.3 AIM

This study aimed to investigate vascular surgeons' perceptions of the causes of peri-operative adverse events in patients undergoing arterial operations. The study aims to answer the following questions:

- What do vascular surgeons believe are the causes of peri-operative adverse events in patients undergoing arterial procedures?
- Do vascular consultants and registrars have different perceptions of the causes of peri-operative adverse events in arterial procedures?
- Is there a difference in the perceived profiles of contributory factors for peri-operative adverse events occurring in i) open versus endovascular procedures and in ii) elective versus emergency procedures?
- What strategies do vascular surgeons consider important to improve the safety of patients undergoing arterial procedures?

4.4 METHODS

4.4.1 *Study overview and definitions*

Research Ethics Committee (REC) approvals were obtained for this and other studies reported in this thesis (REC reference 12-LO-0710) (the REC approval letter can be found in appendix 2, page 228). In this exploratory, mixed-methods study, both quantitative and qualitative methodologies were used: surveys and semi-structured interviews were used to elicit vascular surgeons' perceptions of the causes of adverse events in patients undergoing arterial surgery. Additionally, interviewees were asked to provide recommendations for improving the safety of these patients. 'Adverse events' were defined according to the definition commonly used in the safety literature: unintended injuries to patients caused by medical management rather than the patient's underlying condition, leading to prolonged hospital stay, temporary or permanent disability, or death (27).

A mixed-methods approach was selected for this study for several reasons. A survey consisting of closed-ended questions was administered to quantify the relative importance of a range of contributory factors and to test for differences in patterns of contributory factors between various groups (procedure type, urgency, surgeons' level of training). Interviews with vascular surgeons were conducted to provide detailed accounts of factors leading to adverse

events. Whereas quantitative research measures frequency, prevalence and incidence, qualitative research seeks to understand the breadth and complexity of a given topic and is therefore suited to investigating various aspects of healthcare systems that are multi-faceted (152). Adverse events are good examples of complex phenomena in healthcare: there are a broad range of potentially relevant contributory factors. These factors are not fixed in time and space, which makes them difficult to measure empirically. For this reason, it may be useful to seek the perceptions of individuals who have witnessed adverse events and who are able to reflect on the entire patient pathway to identify the causes of these incidents. As previously stated, vascular surgeons are ideally placed to for this because they see patients in both the outpatient and hospital settings, in the operating theatre, critical care and ward settings. Semi-structured interviews are particularly useful in revealing beliefs, values and attitudes towards a given issue (152) and therefore it was deemed appropriate to conduct semi-structured interviews in addition to gathering data through quantitative surveys in this study. Pairing of quantitative and qualitative methods in this way can aid in a better understanding of causes of adverse events and can improve the validity of the findings through triangulation of the results of each methodology (153).

4.4.2 *Participants and inclusion criteria*

Surgeons were eligible to participate in this study if they regularly performed open and endovascular arterial operations in the British National Health Service (NHS) and were vascular consultants, vascular registrars, or general surgery registrars with a sub-specialty interest in vascular surgery. A power calculation to determine sample size was not performed because no previous studies have measured factors contributing to adverse events in arterial surgery in this way - this study was intended to be a scoping exercise. We aimed to obtain at least 50 survey responses and thus - with an estimated response rate of 50% - 100 surgeons were approached for survey completion. Potential interviewees were identified via two routes through existing clinical contacts using a convenience sampling technique. A pragmatic approach was taken to determining the number of surgeons to be interviewed – the aim was to achieve a sample that was diverse in terms of surgeons' geographical work location, case load and level of training, and interviews continued until a diverse sample was obtained. Survey administration and interviews took place between November 2012 and September 2013.

4.4.3 *Materials and methods*

A well-designed survey should be simple, acceptable to respondents, and should have a clear scoring system (154). The questions should clearly relate to the aims and objectives of the

study and they should accurately measure the concept of interest (154). Therefore, in consultation with a patient safety expert, the decision was taken to use Vincent's framework of factors known to contribute to adverse events in healthcare to devise the study survey (71). The framework is a widely accepted tool to guide analysis of clinical incidents having been published in both the *British Medical Journal* and the *New England Journal of Medicine* (37,133). As described in detail in chapter 3, this framework lists 25 contributory factors organised under the following headings: patient, staff, teams, the work environment, organisation and management, and institutional context. The survey was designed by taking each item from Vincent's framework of contributory factors and using it as a survey item. The framework items were not changed in any way, and they were listed on the survey within the same broad categories as in Vincent's framework. This led to the development of a survey containing 25 items that fit on a single side of A4 paper; it was anticipated that this would be acceptable to respondents. A 5-point Likert scale was added for all survey items, together with concise instructions on how to complete the survey. Further details regarding survey completion are provided below. A blank survey is presented in appendix 3, page 230.

To obtain a high response rate, surgeons were approached face-to-face during three vascular conferences and they were invited to complete the survey. Respondents were asked to consider each contributory factor listed on the survey in relation to a recent adverse event: (1) that they had personally witnessed and could recall the circumstances of, (2) that had occurred during or within 24 hours of an open or endovascular arterial procedure, and (3) that was caused by medical management rather than underlying disease, and resulted in prolonged hospital stay, disability or death. Respondents scored all factors in relation to the adverse event they had in mind on a Likert Scale; a score of 5 was 'highly likely' to have contributed, a score of 1 was 'highly unlikely' to have contributed and a score of 3 was neutral. A Likert scale was used for the study survey for two reasons: they are commonly used to provide an unambiguous measure of attitudes or views on a given topic and a Likert scale is an approach to answering surveys that healthcare professionals are familiar with (155). Respondents were asked to indicate their level of training (consultant or registrar), the type of procedure that the adverse event related to (open or endovascular surgery), the procedure setting (elective or emergency), and the consequences of the adverse event (temporary disability, prolonged hospital stay, permanent disability or death). Further details regarding the adverse events were not sought in order to preserve acceptability of the survey to potential respondents. To preserve anonymity and acceptability, survey respondents were not required to document their name or work location on the survey and, following completion, surveys were placed in a sealed envelope and returned to the researcher. Prior to survey administration, the survey was piloted with eight vascular trainees during an unrelated training course with subsequent

minor changes to the syntax of instructions. Survey administration was paper-based, and was undertaken by a single researcher (RL: author of this thesis).

When undertaking semi-structured interviews, the researcher must prepare a series of well thought out questions that are generally open-ended (154). To this end, the interview schedule was designed to elicit detailed accounts of perceived factors leading to adverse events, as well as recommendations to improve patient safety in arterial surgery. The interview schedule broadly consisted of three stages: firstly, open-ended questions invited the interviewee to consider factors that commonly contribute to adverse events in arterial surgery. Then, the interviewee was invited to consider a recent adverse event and further open-ended questions elicited the contributory factors and sequence of events leading to the incident. Secondly, the interviewees were invited to complete the survey in relation to the adverse event they had described. Interviewees were prompted to elaborate on their survey responses to further explain how each factor contributed towards the adverse event they had in mind. Finally, interviewees were asked to describe strategies that they considered could prevent harm to patients undergoing arterial surgery. If time permitted, interviewees were then invited to describe a second adverse event using the same process described above. The interview schedule was piloted with two vascular surgeons and an introductory 'warm-up' question was subsequently added to put the interviewee at ease and to facilitate natural conversation. The final interview schedule can be found in appendix 4, page 231. Potential interviewees were identified through existing clinical contacts using a convenience sampling technique. Invitations to interview were sent to potential participants via email, together with information about the study and a written consent form (see appendices 5 and 6, pages 233 and 234). All interviews were undertaken and recorded on a digital voice recorder by a single researcher (RL: author of this thesis). All interviews were transcribed verbatim by an independent professional transcriber and were anonymised and assigned a study identification number by the researcher.

4.4.4 *Analysis*

Quantitative analysis

The relative importance of contributory factors was established by calculating how frequently each factor was cited by study participants as leading to an adverse event. It was hypothesised that the following characteristics could influence perceptions of the profile of factors contributing towards an adverse event: (a) respondent's level of training (consultant versus trainee), (b) procedure type (open versus endovascular) and (c) setting (elective versus emergency). Level of training (consultant versus registrar), surgery type (open versus

endovascular) and setting (elective versus emergency) were coded as binary variables. To facilitate comparison of contributory factors between groups, Likert-scale survey responses were converted to binary variables, where factors judged as at least 'somewhat likely' to have contributed to adverse events were coded as 1, and the remainder were coded as 0. The chi-square test of independence was used to compare groups because this test establishes whether there is a statistically significant association between two nominal variables by comparing the observed frequencies to the frequencies that would be expected if there was no association between the two variables (156). Although the analysis involved multiple comparisons, the Bonferroni correction was not deemed appropriate due to the exploratory nature of the study. Armstrong argues that in the exploratory context, researchers may be concerned about missing a possible effect meriting further study and therefore a correction would be inappropriate (157). Surveys completed during interviews were not included in the quantitative analysis.

Qualitative analysis

To ensure a systematic approach to the management of qualitative data, analysis of transcripts adhered to the principles of the 'framework method'. 'Framework' is a method for managing qualitative data, which guides key steps in the process of thematic analysis (158). These steps are outlined below.

Step 1: familiarisation with transcripts to identify data relevant to the research question
Step 2: construction of a thematic framework from the data itself through identification of headings under which relevant data can be organized
Step 3: indexing and sorting: transcripts are coded using the headings from the thematic framework to identify parts of the data that can be grouped together
Step 4: charting: data is lifted from the transcripts and arranged in a preliminary theme/case matrix
Step 5: reviewing data extracts to organize data to create more coherent groupings
Step 6: data summary and display to summarize each interviewee's contribution to a theme

The framework approach to the analysis of transcript data was selected because it enables the researcher to navigate from the descriptive accounts provided by interviewees to a conceptual explanation of the data, using methods that are both rigorous and transparent (159). The framework approach was applied to transcript data to explore common factors contributing to adverse events and strategies that interviewees believed could improve patient safety. The author of this thesis received formal training in the application of the framework method prior to transcript analysis by attending a two-day course on the analysis of qualitative data, which focussed on the framework approach. The course was convened by a large

independent social research agency in the UK. In line with the framework method, all transcripts were reviewed in detail, searching for common themes. Themes that were specified a priori (common contributory factors identified through analysis of survey data) and new themes emerging from the data were combined to form a preliminary analytical framework. This initial thematic framework was applied to the transcripts, and coded data were arranged in a theme/case matrix in Microsoft Excel; a screenshot of this matrix is provided in appendix 7 (page 235) for illustrative purposes. The coded transcript data were then reviewed again and the data organised into more coherent groupings. A summary of the data with each interviewee's contribution to a given theme was documented in Microsoft Excel (a screenshot of the transcript data summary is provided in appendices 8 (page 236) for illustrative purposes).

4.5 RESULTS

Of 100 vascular surgeons approached, 77 completed the survey (response rate 77%) and reported on 77 separate adverse events. Survey respondents were consultants (n=37) and registrars (n=40), working in the British NHS who regularly perform open and endovascular arterial procedures. Twelve vascular surgeons were invited to be interviewed, and ten agreed to participate (response rate 83%). Ten interviewees provide detailed reports of fifteen adverse events in total – each interviewee described one or two adverse events depending on the time available. Interviewees were consultants (n=5) and registrars (n=5) from six different hospitals across England. Four interviewees worked in central London hospitals and six worked in other regions across England. All interviewees regularly performed open and endovascular procedures in arterial 'hubs' (centres where arterial expertise were concentrated following the process of centralisation in the UK).

Table 4.1 presents an overview of the procedures types, settings and consequences of the adverse events reported by the survey respondents and interviewees. For illustrative purposes, the details of three adverse events reported by interviewees, including the sequence of events and perceived contributory factors, are presented in Table 4.2.

Table 4.1: Procedures types and adverse event consequences

Procedure type	Surveys (77 adverse events reported by 77 survey respondents)	Interviews (15 adverse events reported during 10 interviews)
Open surgical procedures	**41**	**11**
Aortic aneurysm repair	20	2
Carotid endarterectomy	10	6
Lower limb bypass graft	8	2
Other	1	1
Missing data	2	-
Endovascular procedures	**36**	**4**
Aortic aneurysm repair (EVAR)	34	3
Iliac stent	2	-
Setting		
Elective	31	13
Emergency	21	2
Missing data	25	-
Consequences of adverse event		
Temporary disability/prolonged hospital stay	36	5
Permanent disability	16	1
Death	18	5
Missing data	7	-

Table 4.2: Details of three adverse events reported by interviewees

Details of adverse event	Contributory factors as perceived by the interviewee
Patient with large pseudoaneurysm in groin & history of aortobifemoral bypass graft. While dissecting out the iliac arteries there was an injury to the iliac vein. Balloon catheter inserted to try to get control. Balloon ruptured the iliac vein resulting in massive haemorrhage. Patient died.	• Complex re-do operation and situation escalated into an emergency • Scrub nurse was inexperienced and a more experienced scrub nurse refused to scrub in • Balloon catheter of appropriate size not immediately available - Foley catheter used instead • Surgeon did not check that the catheter before placing it into the iliac vein and scrub nurse was too afraid to challenge the surgeon
Patient with large thoracic aneurysm anaesthetised and spinal drain placed. Operating team then realised that the custom-made thoracic stent had not been delivered to the hospital - operation could not proceed as planned. Patient underwent unnecessary invasive procedures and required additional hospital stay to complete stenting procedure.	• Industry representative was new and unfamiliar with the system • Operations are scheduled according to the shipping/delivery date for custom-made stents, but the industry representative did not communicate change of stent delivery date to surgical team • Nobody in the operating team checked to see if the stent had actually been delivered • All team members wrongly assumed that someone else had checked that the stent was available
Large man with ruptured AAA transferred from the emergency department to the interventional radiology department without proper anaesthetic support or emergency equipment. Patient died.	• Ruptured aneurysm/emergency case • Heavy workload - lots of emergencies happening at the same time • Skeleton staff at night time – no-one available to cover • Financial constraints preclude having a anaesthetist on call dedicated only for vascular emergencies • Delays in starting the procedure because intubation equipment and intravenous access was not immediately available

4.5.1 *Overview of contributory factors reported by survey respondents*

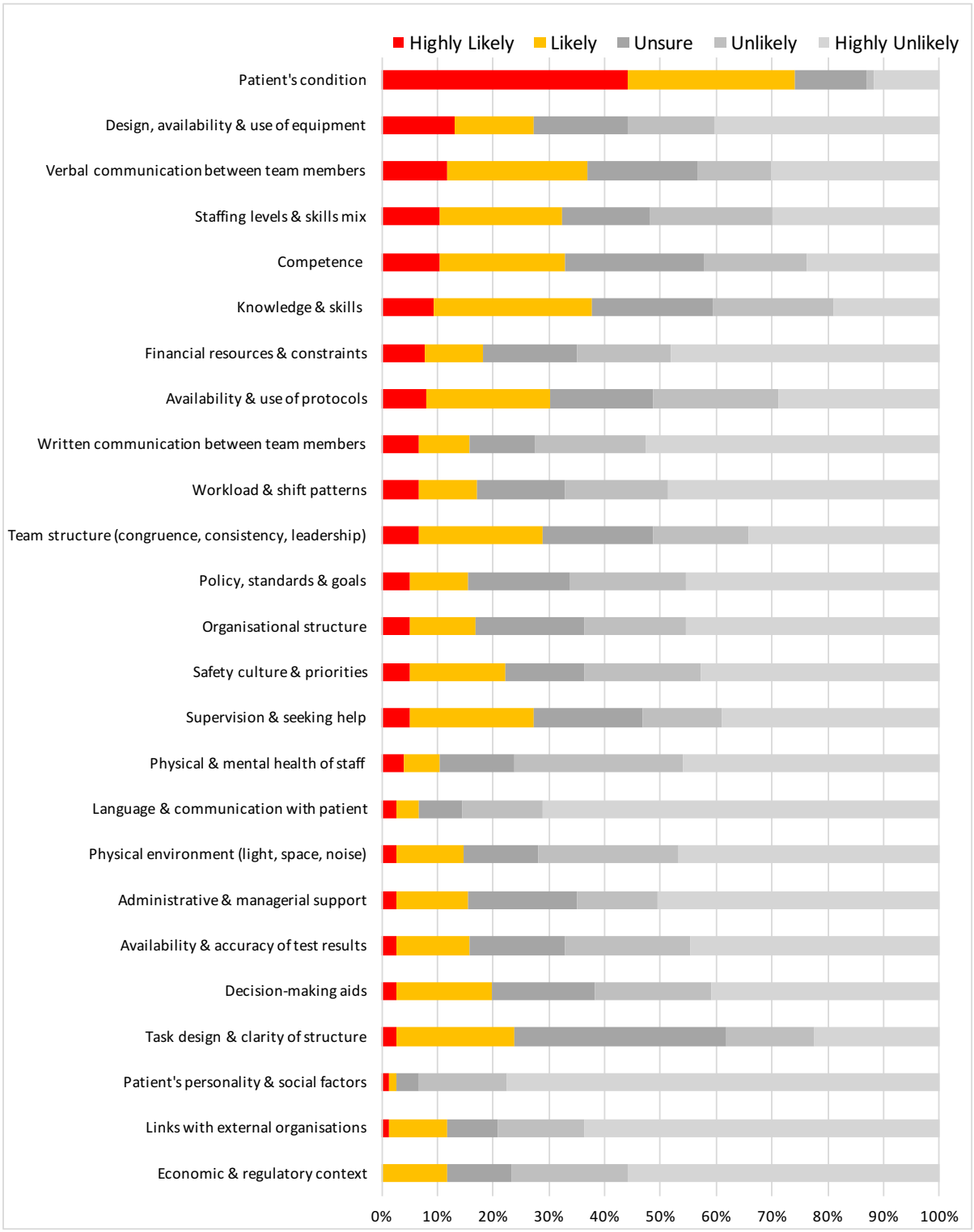
Eighty-three percent of survey respondents reported that multiple factors contributed to the adverse event they had witnessed (median number of factors = 5, interquartile range (IQR) 2-9, range 0-25). Aside from the patient's condition, the most frequently reported contributory factors for all adverse events were failures in verbal communication between operating team members (perceived to have contributed to 36.4% of reported adverse events: n=28/77), inadequate staffing levels or skill mix (32.5%; n=25/77), and a lack of knowledge/skills (37.3%; n=28/75) or competence (32.9% (25/76). Table 4.3 outlines the profile of contributory factors perceived to have contributed to the 77 separate adverse events reported. The most frequently cited factors considered 'highly likely' to have contributed towards an adverse event were: the patient's condition (44.2%: n=34/77), equipment problems (13.0%: n=10/77), communication failures (11.7%: n=9/77) and inadequate staffing levels or skill mix (10.4%: n=8/77). Figure 4.1 presents the Likert scale responses of survey respondents.

Table 4.3: Profile of contributory factors for 77 adverse events reported by survey respondents

Factors contributing to adverse events (organised by most cited to least cited by survey respondents)	**All adverse events reported by survey respondents*** (n=77)
Patient's condition	74.0% (57/77)
Knowledge & skills	37.3% (28/75)
Verbal communication between team members	36.4% (28/77)
Competence	32.9% (25/76)
Staffing levels & skills mix	32.5% (25/77)
Availability & use of protocols	29.9% (23/77)
Team structure (congruence, consistency, leadership)	28.9% (22/76)
Supervision & seeking help	28.6% (22/77)
Design, availability & use of equipment	27.3% (21/77)
Task design & clarity of structure	23.7% (18/76)
Safety culture & priorities	22.1% (17/77)
Workload & shift patterns	19.7% (15/76)
Decision-making aids	19.7% (15/76)
Financial resources & constraints	16.9% (13/77)
Organisational structure	16.9% (13/77)
Written communication between team members	15.8% (12/76)
Availability & accuracy of test results	15.8% (12/76)
Administrative & managerial support	15.6% (12/77)
Policy, standards & goals	15.6% (12/77)
Physical environment (light, space, noise)	14.5% (11/76)
Physical & mental health of staff	11.8% (9/76)
Economic & regulatory context	11.7% (9/77)
Links with external organisations	11.7% (9/77)
Patient's personality & social factors	6.6% (5/76)
Language & communication with patient	2.6% (2/76)

*This table reflects the views of survey respondents, who scored contributory factors as either 4 or 5 – i.e. they either agreed or strongly agreed that a given contributed towards the adverse event that they had in mind when completing the survey.

Figure 4.1: Survey respondents' likert scale scores for the likelihood that factors contributed to 77 adverse events



Factors are arranged from most frequently to least frequently cited as 'highly likely' to have contributed towards an adverse event. Percentages indicate the proportion of survey respondents citing each contributory factor for a total of 77 survey respondents.

4.5.2 *Differences between groups for factors contributing to adverse events*

These results are presented in Table 4.4 overleaf. There were no significant differences between consultants and registrars for the pattern of contributory factors reported. There were no significant differences between elective and emergency procedures for any of the contributory factors but, of note, data for the urgency of the procedure was missing in 32.5% (25/77) of survey responses. A lack of knowledge or skill was more frequently cited as contributing to adverse events (AEs) in open procedures compared with endovascular procedures (19 AEs versus 9 AEs, $p = 0.034$), as were failures relating to competence (18 AEs versus 7 AEs, $p = 0.018$). Issues relating to organisational structure were more frequently reported as contributing to adverse events in endovascular procedures than in open procedures (10 AEs versus 3 AEs, $p = 0.017$).

4.5.3 *Key themes arising from interview transcripts*

The main themes arising from interview transcripts are derived from the proportion of interviewees who provided reports related to a given theme. Nine of ten interviewees described contributory factors that resulted in the theme 'team factors' – these reports included communication failures (described by 8 interviewees), lack of team continuity (4 interviewees) and a lack of clarity over the roles and responsibilities of team members (3 interviewees). All ten interviewees provided reports that resulted in the theme 'work environment factors' – these reports included equipment issues (8 interviewees), inadequate staffing levels or skill mix (7 interviewees) and distractions or external pressures (6 interviewees). All ten interviewees also described reports that resulted in the theme 'training and supervision' – these reports related to failures in training or supervision for the technical aspects of arterial surgery (9 interviewees) as well as for developing the ability to manage the operating environment (4 interviewees). These data, together with illustrative quotes for each sub-theme are provided in Table 4.5. The themes 'team factors', 'work environment factors' and 'training/supervision' are described in more detail next – data obtained from survey responses and interview transcripts are provided in relation to each theme.

Table 4.4: Comparison between groups for factors contributing to adverse events

Factors contributing to adverse events (organised as per Vincent's framework for analysing risk and safety in clinical medicine, 1998)	**Adverse events reported by:**			**Adverse events occurring in:**		
	Consultants (n=37)	**Registrars** (n=40)	**P value**	**Open surgical procedures** (n=41)	**Endovascular procedures** (n=36)	**P value**
TEAM FACTORS						
Verbal communication between team members	29.7% (11/37)	42.5% (17/40)	NS	39.0% (16/41)	33.3% (12/36)	NS
Team structure (congruence, consistency, leadership)	27% (10/37)	30.8% (12/39)	NS	29.2% (12/41)	28.6% (10/36)	NS
Supervision & seeking help	24.3% (9/37)	32.5% (13/40)	NS	36.6% (15/41)	19.4% (7/36)	NS
Written communication between team members	13.9% (5/36)	17.5% (7/40)	NS	17.1% (7/41)	14.2% (5/35)	NS
WORK ENVIRONMENT FACTORS						
Staffing levels & skills mix	37.8% (14/37)	27.5% (11/40)	NS	39.0% (16/41)	25.0% (9/36)	NS
Design, availability & use of equipment	27.0% (10/37)	27.5% (11/40)	NS	22.0% (9/41)	33.3% (12/36)	NS
Workload & shift patterns	19.4% (7/36)	20% (8/40)	NS	25.0% (10/40)	13.9% (5/36)	NS
Administrative & managerial support	18.9% (7/37)	12.5% (5/40)	NS	12.2% (5/41)	19.4% (7/36)	NS
Physical environment (light, space, noise)	11.1% (4/36)	17.5% (7/40)	NS	12.2% (5/41)	17.1% (6/35)	NS
STAFF FACTORS						
Knowledge & skills	37.8% (14/37)	36.8% (14/38)	NS	48.7% (19/39)	25.0% (9/36)	**0.034**
Competence	37.8% (14/37)	28.2% (11/39)	NS	45.0% (18/40)	19.4% (7/36)	**0.018**
Physical & mental health	8.1% (3/37)	15.4% (6/39)	NS	10.0% (4/40)	13.9% (5/36)	NS
TASK FACTORS						
Availability & use of protocols	27.0% (10/37)	32.5% (13/40)	NS	26.8% (11/41)	33.3% (12/36)	NS
Task design & clarity of structure	16.7% (6/36)	30.0% (12/40)	NS	26.8% (11/41)	20.0% (7/35)	NS
Decision-making aids	16.7% (6/36)	22.5% (9/40)	NS	22.0% (9/41)	17.1% (6/35)	NS
Availability & accuracy of test results	13.9% (5/36)	17.5% (7/40)	NS	17.5% (7/40)	13.9% (5/36)	NS
ORGANISATIONAL FACTORS						
Safety culture & priorities	18.9% (7/37)	25.0% (10/40)	NS	22.0% (9/41)	22.2% (8/36)	NS
Financial resources & constraints	16.2% (6/37)	22.5% (9/40)	NS	12.2% (5/41)	22.2% (8/36)	NS
Organisational structure	10.8% (4/37)	17.5% (7/40)	NS	7.3% (3/41)	27.8% (10/36)	**0.017**
Policy, standards & goals	13.5% (5/37)	17.5% (7/40)	NS	14.6% (6/41)	16.7% (6/36)	NS
INSTITUTIONAL CONTEXT FACTORS						
Economic & regulatory context	13.5% (5/37)	10.0% (4/40)	NS	12.2% (5/41)	11.1% (4/36)	NS
Links with external organisations	16.2% (6/37)	7.5% (3/40)	NS	7.3% (3/41)	16.7% (6/36)	NS
PATIENT FACTORS						
Patient's condition	73.0% (27/37)	75.0% (30/40)	NS	75.6% (31/41)	72.2% (26/36)	NS
Patient's personality & social factors	8.3% (3/36)	5.0% (2/40)	NS	4.9% (2/41)	8.6% (3/35)	NS
Language & communication with patient	0% (0/36)	5.0% (2/40)	NS	2.4% (1/41)	2.9% (1/35)	NS

Table 4.5: Key themes emerging from interview transcripts

Key themes that emerged from analysis of interview transcripts	Number of interviewees	Illustrative quote (participant ID number, level of training)
TEAM FACTORS		
Communication failure	8	*"so having, you know, staff in theatre, who you had spoken to preoperatively about how you exactly wanted things done very simply. But then they left without handing over to the people who took over"* (interviewee 8, registrar)
Lack of operating team continuity	4	*"it is not uncommon in the very complex cases to have changes of staffing [...] the only one who tends to be constant is the operating surgeon and it is easy to see how things can be forgotten like an extra clamp that has been left on too long, a swab that has been placed under the pelvis, and whilst there are mechanisms in place to try to capture those errors, things fall through the net"* (interviewee 10, registrar)
Lack of clarity over roles & responsibilties	3	*"it was also the fact that the roles are not clearly defined, in terms of who's responsible for what part of the operation when you've got two different teams -radiology and scrub teams- merging or joining to perform one task"* (interviewee 4, registrar)
WORK ENVIRONMENT FACTORS		
Inadequate staffing levels or skill mix	7	*"Now we work with nurses who it might be their second day doing vascular and then, you know, in big cases it's not appropriate"* (interviewee 6, registrar)
Distractions and external pressures	6	*"I was getting stressed because people were continually interrupting me, 'What do we do with this patient, what shall we do about this patient' […] it was noisy, it was unbearable, people were going in and out, it was awful"* (interviewee 5, consultant)
Equipment issues	8	*"things that we're seeing more and more often are sort of technology failures if you like. And whether you work in laparoscopic surgery or in endovascular intervention, if the machine isn't working properly you can sort of, you know, cause signficant injury to the patient"* (interviewee 4, registrar)
TRAINING & SUPERVISION		
Technical aspects	9	*"And in the end I felt I had to descrub and go and do the ruptured aneurysm and leave the senior registrar to finish the case, with an assistant. He was doing the case and I was supervising. But then he broke a stitch and the patient was clamped for longer than they should have been and he had a TIA."* (interviewee 5, consultant)
Management of operating environment	4	*"You're a new consultant, you're not going through a learning phase with the operating, but with managing the world outside of our immediate zone […] you're taking responsibility for what other people are doing around you. Your training has been very focussed on doing one aspect of a wider job. Such that you were never trained in particularly how to organise the theatre the way you like."* (interviewee 1, consultant)

4.5.4 *Team factors*

More than one third of survey respondents (36.4%) and eight of ten interviewees indicated that verbal communication failures had contributed towards an adverse event that they had witnessed. Intrinsic factors leading to poor communication were reported as a reluctance to challenge perceived authority *"I didn't feel I could speak up being a more junior member of the team"* (interviewee 9, registrar), or a desire to demonstrates one's own capabilities without senior help: *"Knowing when to ask for help, that element of communication is difficult. I think it goes back to the hierarchy, and almost proof of self-worth"* (interviewee 10, registrar). Long cases requiring staff changeover intra-operatively were viewed as particularly vulnerable to communication failure: *"…the only one who tends to be constant is the operating surgeon and if there is a complex case which takes many hours and requires shift changes, it is easy to see how things can be forgotten like an extra clamp that has been left on too long, a swab that has been placed under the pelvis"* (interviewee 10, registrar). Problems relating to team structure (congruence, consistency, leadership) were reported by 28.9% of survey respondents and by four of ten interviewees. Unfamiliarity with other team members made it more challenging to operate safely, and this was particularly problematic during emergency cases occurring out-of-hours: *"the scrub teams, the emergency scrub team, which is very incongruent, just sort of thrown together […] I'd never met my assistant before, never mind worked with her"* (interviewee 7, consultant). Poorly defined roles and responsibilities within the operating team were described by three interviewees. In one case, it was not clear who was responsible for confirming delivery of an essential piece of kit – failure to check that the equipment had been received led to the planned operation being cancelled after the patient had been put under general anaesthesia (interviewee 3, consultant).

4.5.5 *Work environment factors*

Nearly half of survey respondents (48.1%) reported that work environment factors contributed to adverse events. Staffing levels or skill mix are designated as 'work environment factors' according to Vincent's framework (37). Inadequate staffing levels or skill mix were cited by 32.5% of all survey respondents and by seven out of ten interviewees. Two new consultants felt that having to rely on inexperienced team members impeded their ability to concentrate on operating, and six of ten interviewees cited distractions and external pressures - such as concurrent emergencies- as factors contributing towards adverse events. Other distractions in the work environment (light, space, noise) were reported by 14.5% of survey respondents.

27.3% of survey respondents and eight of ten interviewees reported issues relating to the design, availability and use of equipment. Half of interviewees (5/10) described failures in planning or preparing essential equipment: two interviewees felt that adverse events had

occurred because appropriate rescue equipment was not available when required. Three interviewees reported that unfamiliarity with equipment contributed towards adverse events they had witnessed.

4.5.6 *Supervision/training factors*

28.7% of survey respondents and nine of ten interviewees indicated that failures in supervision or failing to seek help were important determinants of adverse events: *"the surgical consultant saw that I was struggling and I kept asking for advice on what to do for surgical components but I never said I need you to scrub. Without that direct demand and I guess in part my own inexperience the patient lost a reasonable amount of blood"* (interviewee 10, registrar). Four interviewees described difficulty in managing the operating environment and the team due to a lack of training in 'soft skills': *"…for the relatively inexperienced consultant's level, it takes up a lot of, you know, thinking part of the brain, to have it concentrate on reminding the assistant as well as concentrating on what's a very technically demanding procedure"* (interviewee 7, consultant).

4.5.7 *Strategies to improve patient safety*

Interviewees suggested a variety of strategies to improve patient safety in arterial surgery (Table 4.6). Half of interviewees (5/10) would like to implement training programmes enabling the entire multi-disciplinary operating team to train together. One interviewee emphasised that team training would be particularly important to rehearse crisis scenarios. Four interviewees suggested implementing further protocols or checklists to standardise processes such as mid-procedure handovers between staff. Two interviewees believed that high-risk procedures are safest when performed by experienced operating team members who have worked together for many years. Current issues with staff retention or rotation were acknowledged as barriers to this "old fashioned' way of working. It was argued that: "…*if you can't have a blanket policy where the safety is always number one, because, it's impossible to have this level of expertise all the time – then you've got to make sure you have it there for cases where things start to become emergent"* (interviewee 6, registrar). Accordingly, three interviewees would like to implement further escalation algorithms to facilitate adequate staffing levels or skill mix during emergencies.

Table 4.6: Strategies that interviewees perceived could improve patient safety in arterial surgery

Key themes that emerged from interview transcripts	**Number of interviewees**	**Illustrative quote** (participant ID number, level of training)
Team training	5	*"I think we need to do crisis management training. So it's greater awareness of what you do in a crisis, you know, we give people routines. Once in crisis, this is first step, second step, third step, these are the things you should be looking out for, because otherwise we reinvent the wheel each time when it harms patients."* (interviewee 6, regiatrar)
Further protocols or checklists to standardise & facilitate key processes	4	*"The thing to stop it happening to the next person is to have it on our checklist of, of things to check before the operation. If you read that WHO checklist, the equipment check is a bit late once the patient is asleep. I think we need to bring the processes of checking and discussing the case earlier rather than later"* (interviewee 3, consultant)
Better escalation procedures to ensure experienced staff available when required	3	*"You need to have mechanisms in place where you can recruit another member of staff if there aren't enough people available...the ability to recruit people to tend to the patient if the situations becomes uncontrollable"* (interviewee 2, consultant)

4.6 DISCUSSION

In the context of a dearth of literature on the relationship between system factors and patient safety, this mixed-methods study was to designed to provide an account of vascular surgeons' perceptions of factors contributing to peri-operative adverse events in arterial surgery. Quantitative and qualitative analysis of data from 77 survey respondents and 10 interviewees yielded important insights into the factors that are perceived to contribute to incidents of harm in patients undergoing arterial procedures, as well as into strategies that could improve patient safety. The paragraph below outlines a summary of the findings and the relative strengths and weaknesses of this study are subsequently discussed. The findings of this study are further considered in the final discussion chapter.

4.6.1 *Summary of findings*

Most survey respondents and all interviewees reported that the complexity and seriousness of the patient's condition contributed to the adverse event they had in mind when participating in the study. However, a number of additional contributory factors were reported, and most adverse events resulted from combination of factors rather from than a single, direct cause – this fits with the systems approach to understanding patient safety outlined in chapter one. Alongside patient factors, vascular surgeons indicated that communication failures between operating team members are common precipitants of adverse events. Vascular surgeons emphasised that the problem of communication failure is exacerbated by a lack of operating team continuity, underpinned by problems with staff retention and the current structure of training programmes that requires surgeons (and often nurses) to rotate between specialties. Long arterial operations may be more vulnerable to communication failures due to anaesthetic and nursing handovers at shift changes and it was suggested that these communication failures could be addressed through strategies to standardise these vulnerable processes such as checklists. In addition to team factors, vascular surgeons' reports provided an insight into 'latent failures' in the work environment that have led to the adverse events witnessed by study participants. Staffing levels and skill mix were a common concern, and these issues were usually amplified in arterial operations taking place out of normal working hours. Failures relating to equipment, interruptions and distractions, and external pressures (such as concurrent emergencies) were all cited as factors that not only predisposed the patient to harm but also diverted the attention of the operating team away from dealing with the task at hand. Lack of supervision of trainees and difficulty managing the operating environment while concentrating on the technical aspects of the operation were also cited as factors contributing to adverse events. Vascular surgeons suggested that providing healthcare professionals with

the opportunity to train as teams would improve the safety of many of the technical and non-technical aspects of arterial operations, and would be particularly useful to rehearse emergency procedures.

4.6.2 *Interpretation*

The findings of this mixed methods study of factors contributing to peri-operative adverse events in arterial surgery echo the results of a previous interview study performed in the US, which aimed to understand factors contributing to surgical errors across six surgical specialties. In line with the US study, we found that communication failures and a lack of knowledge, skill or competence were the most frequent factors cited by surgeons. This suggests that knowledge, skill, competence and good communication are pre-requisites for preventing errors and adverse events across all surgical specialties. In contrast with the previous study, our study revealed a more nuanced understanding of the causes of communication failure during arterial intervention. A lack of clarity over roles and responsibilities among team members and lack of team continuity were both issues that exacerbated the problem of communication errors. This issue of team continuity has been highlighted previously in an observational study of anaesthetic handovers during cardiac surgery (87). In this study, the need to handover care from one anaesthetist to another during complex cardiac operations was associated with poorer post-operative outcomes. In contrast with the US study (56), we found no significant differences in the profile of contributory factors between elective and emergency procedures. However, our dataset was incomplete (33% of respondents did not answer this question) and a larger sample size may yield different results.

Our study raises some concerns that are unique to the field of vascular surgery, particularly in relation to the organisation of endovascular services in the UK (and in some other European countries where practices are similar). Interviewees described errors in communication as a result of the involvement of two teams in the same procedure (surgical and interventional radiology – see example in Table 4.5). Organisational structure was also associated with a higher incidence of adverse events in endovascular procedures than in open procedures. These findings may be interpreted to suggest that the organisation of staff and resources is yet to be optimised to support the practice of endovascular surgery in many institutions – in contrast with open surgery for which systems and procedures are well established.

4.6.3 *Strengths and limitations*

The work contained within this chapter has a number of strengths and weaknesses. The key concepts of credibility, dependability and transferability in qualitative research are analogous to the principles of validity, reliability and generalisability in quantitative research, and all must

be considered in an assessment of this study's rigor. A notable strength of the study was the use of both quantitative and qualitative methods to explore factors contributing to adverse events in arterial surgery. The two methodologies produced remarkably similar results, providing cross-validation of results through the process of triangulation - thus increasing the credibility or validity of the study's findings. Furthermore, the findings of this study align with the theoretical basis for how and why adverse events occur in healthcare outlined in chapter one – although study participants clearly highlighted the importance of knowledge, skills and competence, the study has identified a variety of latent failures that appear to create the conditions that lead to adverse events.

Dependability in qualitative research can be enhanced through the use of multi-coders and multi-coder agreement in transcript analysis; this was not possible for the present study, thus the 'framework approach' was used as a rigorous and methodical alternative approach to transcript analysis by a single coder. Case selection was based on convenience sampling and study participation was voluntary, therefore surgeons with a particular interest in patient safety may have been more likely to participate. This study relied on accurate reporting of events by surgeons and may be vulnerable to the limitations of recall bias and selective reporting. Recall bias was minimised through the use of Vincent's framework of contributory factors, which provided structured prompts to improve surgeons' recall of events while interviews allowed for additional themes to emerge.

4.6.4 *Generalisibility*

This study is limited in terms of generalisability. The sample size was small and the reports only reflect practice within the British NHS. Survey respondents and interviewees were identified through convenience sampling, therefore, vascular surgeons with a particular interest in patient safety may have been more likely to participate. Of note, recommendations to improve safety were based on interviews with only ten vascular surgeons and larger studies are needed to establish whether these views are representative. Surveys of and interviews with other healthcare professionals involved in arterial surgery are likely to provide further insights into the problem. Furthermore, research in this area would also benefit from larger studies investigating team and work environment factors as well as research involving direct observation of operating room safety failures to provide further validation of the findings presented in this chapter. This study has specifically examined the causes of harm to patients undergoing arterial intervention. Further research should also explore latent failures in healthcare systems. Latent failures may not be obviously related to patient harm, but they may contribute to poorer patient outcomes.

4.7 CHAPTER SUMMARY

The purpose of the mixed-methods study presented in this chapter was to describe vascular surgeons' perceptions of factors contributing to peri-operative adverse events in arterial surgery. The findings demonstrate that it is essential to look beyond patient risk factors and procedural complexity to understand the causes of harm to patients undergoing arterial operations. Team factors, work environment factors and issues around training and supervision are likely to require attention to improve the safety of patients undergoing arterial intervention. However, more work is needed to establish the validity of these findings. Future studies should explore latent failures in healthcare organisations where arterial surgery is performed. These studies would benefit from multi-centre involvement to produce findings that can be generalised to arterial centres across the UK. The study reported in the next chapter attempts to address some of these issues.

5 Safety culture in the vascular operating theatre: a multi-centre study of operating teams' perceptions of teamwork, working conditions, management and safety.

5.1 CHAPTER OVERVIEW

This chapter describes a multi-centre, survey study of safety culture in the vascular operating theatre. The study was designed to investigate operating team members' perceptions of teamwork, working conditions, management and safety in vascular operating departments in England.

5.2 INTRODUCTION

The previous chapter reported a retrospective study of vascular surgeons' perceptions of factors contributing towards peri-operative adverse events in patients undergoing arterial intervention in the NHS. Key themes that emerged from this exploratory study related to team factors, work environment factors and problems related to training or supervision. However, these themes emerges from surveys of and interviews with a small sample of vascular surgeons only – more work was needed to understand the culture within the vascular operating theatre as perceived by all members of the multi-disciplinary team at multiple arterial centres.

Multidisciplinary vascular operating staff working in vascular operating departments can shed light on local cultural norms with regards to patient safety and they can provide valuable insights into the way systems function. The original work presented in this chapter provides a snapshot of safety culture in various vascular operating departments in England where arterial operations are regularly performed. Safety culture is a reflection of the way in which healthcare organisations organise and prioritise patient safety (160). Safety culture is thought to be reflected in the values, attitudes, perceptions and behaviours of healthcare staff. These attitudes or perceptions can be captured using purposively designed and psychometrically tested surveys (43,161,162). When safety culture is measured in this way, it is referred to in the safety literature as 'safety *climate*'. The term 'safety *climate*' was coined to describe the insight into safety culture that can be obtained by assessing staff perceptions, attitudes and beliefs; other aspects of safety culture, such as actions and behaviours, cannot generally be measured using survey tools (43). A strong culture of safety is likely to reflect effective

leadership and teamwork, with emphasis on transparency and learning from medical error (42). However, there is no consensus on the precise dimensions of safety culture in the safety literature (41).

5.3 AIM

The study presented in this chapter aims to explore the dimensions of teamwork, working conditions, management and safety in order to build upon the findings of the previous study reported in chapter 4.

The present study aims to answer the following questions:

- What are the perceptions of staff working in vascular operating departments in England with respect to teamwork, working conditions, management and safety?
- Are there differences in perceptions of teamwork, working conditions, management and safety between vascular operating departments?
- Are there differences in perceptions of teamwork, working conditions, management and safety between professional groups?
- What do staff perceptions of these safety culture dimensions reveal about targets for safety improvement in vascular operating departments in England?

5.4 METHODS

5.4.1 *Study overview and definitions*

In this cross-sectional study, a previously validated survey was administered to staff working in vascular operating theatres at ten NHS hospitals in England to elicit perceptions of teamwork, working conditions, management and safety. Survey administration took place over a six-week period at each site between September 2012 and September 2013. Full Research Ethics Committee (12-LO-0710) and local approvals were obtained for this study (see approval letter in appendix 2).

Survey administration provides an insight into the culture of safety within organisations by capturing the views of healthcare staff working on the frontline. Sexton and colleagues argue that when using surveys to measure the attitudes of groups of healthcare staff, it is more appropriate to use the term climate rather than culture (i.e. safety climate, teamwork climate etc.) (43). However, in the safety literature, the terms culture and climate are used interchangeably (42). For the purposes of this chapter, the term ‘climate’ is used to describe a measurable dimension of safety culture, while ‘safety culture’ is defined as, ‘the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour

that determine the commitment to, and the style and proficiency of, an organisation's health and safety management' (43). The dimensions of safety culture that are measured in this study are outlined in the table below:

Table 5.1: Dimensions of safety culture

Teamwork Climate	Perceived quality of collaboration between operating team members
Working Conditions	Perceived quality of the work environment and logistical support (staffing, equipment, etc.)
Perceptions of Management	Operating team members' approval of managerial action
Safety Climate	Perceptions of strong and pro-active organisational commitment to safety

Adapted from Halligan and Zecevic (2011) (41)

5.4.2 *Participants*

Ten hospitals with diverse characteristics in terms of geographical location, bed capacity, and arterial case volume were recruited as part of another patient safety study (this study is presented in chapters seven and eight). Sites were identified through clinical contacts and through the National Institute for Health Research (NIHR) Clinical Research Network Portfolio. To meet the criteria for participation, sites had to have operating departments in which arterial procedures were routinely performed: i.e. sites were included if they were arterial 'hubs' in the hub and spoke model of vascular service provision in the UK. Site recruitment was capped at ten centres due to practical reasons/funding constraints. No site volunteering participation was excluded during the recruitment phase. However, the author of this thesis reviewed each site's geographical location, size and arterial caseload at the point that participation was volunteered, in order to ensure that a diverse sample of participating centres was achieved. A principal investigator (PI) was identified at each site in order to promote the studies locally and to lead implementation at each site with the support of the team conducting the research. All PIs were consultant vascular surgeons. Members of staff working in vascular operating teams at each site were provided with a study information sheet and consent form – voluntary, written consent was sought from all staff prior to study participation. Copies of the participant information sheet and consent form used for studies presented in chapters 5-8 are provided in appendix 9 (page 237).

5.4.3 *Inclusion criteria*

Potential participants included all professionals working in vascular operating teams who regularly performed arterial procedures – including surgeons, anaesthetists, nurses, radiologists, radiographers, operating department practitioners (ODPs) and healthcare

support workers. Vascular operating team members were to have worked in the local vascular operating department for a minimum period of two months – this included staff who were based in the unit and others who were not based in the unit but regularly contributed to the arterial caseload there. A work commitment of two months was deemed necessary for participants to have had sufficient exposure to the cultural norms of the department. Participants of any grade/level of training were eligible to complete the survey, as long as they had worked in the department for the minimum period.

5.4.4 *Materials and methods*

To be considered appropriate for use in this study, the designated survey had to meet several important criteria:

- As a minimum, the survey should measure staff perceptions of the main themes emerging from the previous study: team factors, work environment factors and issues relating to training/supervision. Other system factors could also be included.
- The survey should demonstrate sound psychometric properties. It should possess high face validity, high content validity (the way in which the survey was developed should be clear) and good scale reliability (internal consistency between items in a scale) (163).
- As the survey is intended for completion by busy operating staff with clinical priorities, the survey should not be time-consuming or convoluted.

Three pre-existing surveys were reviewed in order to select the most appropriate survey for this study – these were the Manchester Patient Safety Culture Assessment Framework (MaPSaF) (161), the Hospital Survey on Patient Safety Culture (HSOPSC) (164), and the Safety Attitudes Questionnaire (SAQ) (43). A table outlining the key characteristics of each survey reviewed is presented in appendix 10 (page 240). After reviewing the key characteristics and psychometric properties of all three surveys, the Safety Attitudes Questionnaire was selected for the purposes of this study for several reasons. Firstly, it can be used to measure six dimensions of safety culture – these include teamwork, working conditions, safety, perceptions of management, stress recognition and job satisfaction. Secondly, the safety attitudes questionnaire was validated in a sample of 10,843 healthcare professionals in 203 clinical areas – including in operating rooms in the UK. The ρ value for composite scale reliability in this large sample was 0.90 (assessed using Raykov's ρ coefficient), though the authors of the questionnaire do not provide reliability scores for individual scales (43). Finally, unlike the MaPSaF survey that involves the need for respondents to refer to a detailed framework document to complete the survey, the Safety Attitudes Questionnaire is straightforward to complete. Permissions were granted by the

authors of the Safety Attitudes Questionnaire for its use in this study (see appendix 11, page 242).

The authors of the Safety Attitudes Questionnaire recommend the use of the short-form version to facilitate a higher response rate, and typically they only measure two of the six constructs - teamwork and safety climate (165). The author of this thesis opted to use four of the six constructs that can be measured using the Safety Attitudes Questionnaire: teamwork, working conditions, perceptions of management and safety. The constructs 'teamwork', 'working conditions', 'perceptions of management' and 'safety' contain survey items that best reflect the themes that emerged as important in the previous study. The constructs 'stress recognition' and 'job satisfaction' did not emerge as themes in the previous study and were therefore not included in the survey for the current study.

The final single-sided, paper-based survey consisted of 21 items (see appendix 12, page 243). Each survey item pertains to one of the four constructs (teamwork, working conditions, perceptions of management, safety) and a 5-point Likert scale is used to score each of the survey items (1 = 'strongly disagree' and 5 = 'strongly agree'). Survey respondents were requested to indicate their professional group and how long they had been working in their role in their current unit. Respondents were not required to provide their name and completed surveys were placed in a sealed envelope to preserve anonymity. Each vascular unit was allocated a study identification code, which was subsequently recorded on completed surveys to identify each survey to a particular unit. In order to achieve a high response rate, paper surveys were administered face-to-face during site visits by the researcher. A purposive sampling technique was adopted to achieve a sample that was representative of all professions working in vascular operating teams in England. The author of this thesis monitored which professions had completed the survey at each site, and where a particular profession was under-represented the author of the thesis actively sought members of that particular profession to invite them to complete the survey. Survey administration was undertaken during a six-week initiation phase of the study described in the following chapters – this took place between September 2012 and September 2013. The author of this thesis visited each site four times on average during the six-week period, and the survey was administered to all available vascular operating staff during each visit.

5.4.5 *Analyses*

A number of surveys were completed by staff who were not regularly involved in performing arterial procedures and by staff who had worked in their local unit for less than two months. In accordance with the inclusion criteria, these surveys were excluded from analyses.

Response rates at each site were calculated as the proportion of surveys administered that were subsequently completed and returned. The characteristics of survey respondents were summarised using descriptive statistics. Preliminary analyses treated individual item-level Likert responses as ordinal data. For each survey item, the total number and percentage of respondents scoring 'disagree strongly', 'disagree slightly', 'neutral', 'slightly agree', 'agree strongly' was calculated and reported in a frequency table. The number of missing responses, the median and interquartile range (IQR) were calculated for each item. As the number of responses in the categories 'disagree strongly' and 'disagree slightly' were small, the responses were also treated as binary variables – i.e. 'agree or disagree' to aid in understanding of the findings.

Scale-scores were then calculated using the individual item-level responses. For surveys employing a number of Likert-type items to measure a given concept, it is arguably more informative to calculate a scale-score because individual survey items do not adequately capture the concept being assessed (166). For example, a response to the survey item "Nurse input about patient care is well received in the operating theatre" does not adequately express the concept of teamwork, but taken together the six items in the teamwork scale provide a better understanding of the teamwork construct. To assess whether calculation of scale-scores was appropriate, Cronbach's alpha was used to assess the internal consistency of items within each scale (167). In the literature, there is debate regarding how to derive scale-scores from ordinal item-level data. Summating the item-level scores to produce an overall scale-score is problematic because each scale contains a different number of items and missing data affect the summated scores. Another option is to calculate the mean of item-level scores within the given scale. Other authors derive a 100-point score from the means of item-level responses (43). However, there is much controversy in the literature about whether it is appropriate to calculate the mean of ordinal-level data (155,166,168). Although various authors report scale-scores based on the means of item-level responses for the Safety Attitudes Questionnaire (169), the author of this thesis agrees with Jamieson (155) that calculation of means/standard deviations is inappropriate for ordinal data. Therefore, the following calculations were used to derive scale-scores from item-level responses:

- For each respondent, individual item-level responses were summated.
- The summated scores were divided by the maximum possible scores for each scale. (For example, the 'working conditions' scale contains four items, therefore the maximum possible score was 4 x 5 = 20). To account for missing data, the maximum possible score was based on the number of items answered by individual respondents

(therefore, if a respondent only answered three of the four items in the 'working conditions' scale, the maximum possible score was 3 x 5 = 15).

- These scores were multiplied by 100 to give the final scale-score. Calculation of the 100-point score derives a comparative score for all scales as each scale contains a different number of items.

A higher scale-score suggests that a respondent has a more positive perception of the dimension of safety culture being assessed, while a lower scale-score indicates a more negative perception of the dimension being assessed. Because scale-scores are continuous in nature (rather than ordinal), it is not possible to state that a scale-score above or below a given value *reliably* represents a positive or negative perception of the dimension being assessed. However, researchers wishing to highlight differences between groups have reported the 'percent positive' – i.e. the number of respondents within each group with scale-scores above an arbitrary cut-off point (43,170). For the purposes of this study, a scale-score of 75-100 is considered to reflect a positive perception of a given dimension of safety culture. The proportion of respondents at each site with scale-scores of 75-100 was calculated as the 'percent positive' to facilitate comparison of safety culture dimensions between groups. The author of this thesis acknowledges that the legitimacy of converting continuous data into categorical variables in this way is questionable. In order to establish whether there are statistically significant differences in perceptions of safety culture dimensions between different professional groups and between different vascular units, tests were performed on continuous 100-point scale-scores. Scale-scores were assessed for normality using the Shapiro-Wilk test, and differences between groups were subsequently tested for using the non-parametric one-way ANOVA on ranks test (also known as the Kruskal-Wallis test) with professional group and site as the independent variables.

5.5 RESULTS

5.5.1 *Overview*

Of 299 surveys administered, 275 respondents completed and returned the Safety Attitudes Questionnaire for an overall response rate of 92.0% (range 89.8-95.0%) across ten participating sites. The sites were diverse in terms of geographical location, bed capacity, and arterial case load (see Table 5.2). A total of 14 surveys were excluded from analyses because respondents indicated that they had worked in the vascular unit for less than two months

(n=12) or worked there infrequently (n=2), giving rise to a final sample size of 261 respondents (mean site-level sample size = 26, range = 16-52).

Table 5.2: Site characteristics

Site	Location	Size (Trust bed capacity*)	CEA case volume**	AAA repair case volume***	Surveys administered	Surveys completed and returned	Response rate (%)	Excluded from analysis	Final sample size (n)
A	Greater London	750-1000	200-300	200-300	36	33	91.7	0	33
B	Yorkshire & the Humber	750-1000	>300	200-300	17	16	94.1	0	16
C	East Anglia	750-1000	200-300	400-500	20	19	95.0	0	19
D	East Midlands	>1000	>300	400-500	49	44	89.8	0	44
E	South East	>1000	200-300	300-400	26	24	92.3	1	23
F	North West	500-750	<100	100-200	25	23	92.0	0	23
G	Greater London	750-1000	<100	>500	19	17	89.5	1	16
H	East Anglia	500-750	100-200	300-400	64	60	93.8	8	52
I	South East	500-750	100-200	100-200	20	18	90.0	1	17
J	Greater London	750-1000	200-300	>500	23	21	91.3	3	18
Overall	**-**	**-**	**-**	**-**	**299**	**275**	**92.0**	**14**	**261**

CEA: carotid endarterectomy AAA: abdominal aortic aneurysm
*Data from NHS England for period July-September 2013. **Data from the National Vascular Registry for the period 2011-2014. ***Data from the national vascular registry for the period 2010-2014.

The characteristics of survey respondents are presented in Table 5.3. Respondents were vascular surgeons (n=45); nurses (n=65); anaesthetists (n=54); radiologists (n=13); radiographers (n=19); healthcare assistants (n=18); operating department practitioners (n=37); and other healthcare professionals including junior doctors and research fellows (n=10). On average, respondents had worked in their vascular operating department for 7.9 years (standard deviation (SD): 8.4 years, range (0.17 – 35 years).

Table 5.3: Characteristics of survey respondents

Professional Group	Number of respondents	% of sample	Mean age (SD)	% Female	Mean length of service in current department (years) (SD)
Surgeon	45	17.2	38 (7.5)	13.9	8.5 (6.9)
Nurse	65	24.9	40 (9.4)	84.6	8.2 (8.7)
Anaesthetist	54	20.1	40 (10.0)	33.3	11.0 (10.7)
Radiologist	13	5.0	43 (8.1)	7.7	11.3 (8.2)
Radiographer	19	7.3	38 (12.8)	63.2	7.5 (7.2)
Healthcare assistant	18	6.9	39 (14.5)	61.1	5.6 (9.8)
Operating department practitioner	37	14.2	37 (10.9)	53.0	7.7 (6.5)
Other	10	3.8	31 (8.0)	60.0	3.9 (2.4)
Overall	**261**	**100**	**38 (10.6)**	**49.0**	**7.9 (8.4)**

Table 5.4 presents the number of missing responses and the number/percentage of Likert responses for each item in the survey. Of a total of 5481 possible responses, data were missing for 45 responses (0.8%). Healthcare assistants (n=13/45) and surgeons (n=10/45) were most likely to omit a response. However, the small amount of missing data was not expected to affect interpretation of the findings.

The individual item that received most negative response was “The levels of staffing in our operating theatres are sufficient to handle the number of patients” – 30.0% (78/260) of respondents disagreed with this survey item. The individual item that received the most positive response was “Nurse input about patient care is well received in the operating theatre” – 84.5% (218/258) of respondents agreed with this survey item.

Table 5.4: Likert scale responses of vascular operating staff

		Responses of staff (n=261) across vascular operating departments (n=10)									
Survey items (each item relates to a given contruct)	**Missing responses**	**Disagree strongly**		**Disagree slightly**		**Neutral**		**Slightly agree**		**Strongly agree**	
TEAMWORK											
Nurse input about patient care is well received in the operating theatre.	3	0.0%	(0/258)	2.7%	(7/258)	12.8%	(33/258)	46.1%	(119/258)	38.4%	(99/258)
It is difficult to speak up if I perceive a problem with patient care.	1	23.1%	(60/260)	38.5%	(100/260)	20.0%	(52/260)	15.8%	(41/260)	2.7%	(7/260)
Disagreements in my operating theatres are resolved appropriately	2	0.8%	(2/259)	6.9%	(18/259)	25.9%	(57/259)	44.8%	(116/259)	21.6%	(56/259)
I have the support I need from other staff to treat my patients.	1	0.0%	(0/260)	3.8%	(10/260)	14.2%	(37/260)	45.8%	(119/260)	36.2%	(94/260)
It is easy for staff in my operating theatres to ask questions when there is something that they do not understand.	1	0.4%	(1/260)	3.5%	(9/260)	5.4%	(40/260)	46.5%	(121/260)	34.2%	(89/260)
The clinicians and nurses here work together as a well-coordinated team.	1	1.2%	(3/260)	3.8%	(10/260)	16.2%	(42/260)	46.9%	(122/260)	31.9%	(83/260)
WORKING CONDITIONS											
This hospital does a good job of training new personnel.	4	1.9%	(5/257)	8.2%	(21/257)	23.7%	(61/257)	42.4%	(109/257)	23.7%	(61/257)
All the necessary information is available before the start of a procedure.	1	1.2%	(3/260)	10.0%	(26/260)	18.8%	(49/260)	45.8%	(119/260)	24.2%	(63/260)
My hospital deals constructively with problem clinicians and employees.	5	4.3%	(11/256)	16.4%	(42/256)	43.8%	(112/256)	24.2%	(62/256)	11.3%	(26/256)
Trainees in my discipline are adequately supervised.	2	0.4%	(1/259)	3.5%	(9/259)	16.2%	(42/259)	40.9%	(106/259)	39.0%	(101/259)
PERCEPTIONS OF MANAGEMENT											
The administration of my hospital is doing a good job.	0	10.7%	(28/261)	16.5%	(43/261)	37.5%	(98/261)	26.4%	(69/261)	8.8%	(23/261)
Hospital management does not knowingly compromise the safety of patients.	2	5.4%	(14/259)	12.7%	(33/259)	25.1%	(65/259)	35.1%	(91/259)	20.8%	(54/259)
The levels of staffing in our operating theatres are sufficient to handle the number of patients.	1	13.8%	(36/260)	16.2%	(42/260)	20.0%	(52/260)	34.2%	(89/260)	15.8%	(41/260)
I am provided with adequate, timely information about events in my hospital that might affect my work.	0	6.9%	(18/261)	18.0%	(47/261)	29.5%	(77/261)	35.2%	(92/261)	10.3%	(27/261)
SAFETY CLIMATE											
I would feel safe being treated in my hospital as a patient.	4	0%	(0/257)	5.1%	(13/257)	11.7%	(30/257)	39.3%	(101/257)	44.0%	(113/257)
Medical errors are handled appropriately in my hospital.	7	1.6%	(4/254)	5.5%	(14/254)	28.7%	(73/254)	37.4%	(95/254)	26.8%	(68/254)
I receive appropriate feedback about my performance.	2	5.4%	(14/259)	12.7%	(33/259)	29.3%	(76/259)	39.8%	(103/259)	12.7%	(33/259)
In the operating theatre, it is difficult to discuss errors.	4	15.6%	(40/257)	34.2%	(8/257)	28.8%	(74/257)	16.3%	(42/257)	5.1%	(13/257)
I am encouraged by my colleagues to report any patient safety concerns I may have.	0	0.0%	(0/261)	5.4%	(14/261)	13.4%	(35/261)	39.5%	(103/261)	41.8%	(109/261)
The culture in the operating theatres here makes it easy to learn from the errors of others.	1	1.2%	(3/260)	8.5%	(22/260)	23.5%	(61/260)	47.3%	(123/260)	19.6%	(51/260)
I know the proper channels to direct questions regarding patient safety in my operating theatres.	3	1.2%	(3/258)	3.9%	(10/258)	16.7%	(43/258)	44.2%	(114/258)	34.1%	(88/258)

5.5.2 *Scale reliability and distribution of scale scores*

All four scales had acceptable levels of internal consistency, as determined by a Cronbach's alpha of 0.65 or higher (see Table 5.5).

Table 5.5: Scale reliability

	Survey items	Scale reliability (Cronbach's alpha)
Teamwork	Nurse input about patient care is well received in the operating theatre.	**.72**
	It is difficult to speak up if I perceive a problem with patient care.	
	Disagreements in my operating theatres are resolved appropriately	
	I have the support I need from other staff to treat my patients.	
	It is easy for staff in my operating theatres to ask questions when there is something that they do not understand.	
	The clinicians and nurses here work together as a well-coordinated team.	
Working Conditions	This hospital does a good job of training new personnel.	**.65**
	All the necessary information is available before the start of a procedure.	
	My hospital deals constructively with problem clinicians and employees.	
	Trainees in my discipline are adequately supervised.	
Perceptions of Management	The administration of my hospital is doing a good job.	**.65**
	Hospital management does not knowingly compromise the safety of patients.	
	The levels of staffing in our operating theatres are sufficient to handle the number of patients.	
	I am provided with adequate, timely information about events in my hospital that might affect my work.	
Safety Climate	I would feel safe being treated in my hospital as a patient.	**.75**
	Medical errors are handled appropriately in my hospital.	
	I receive appropriate feedback about my performance.	
	*In the operating theatre, it is difficult to discuss errors.	
	I am encouraged by my colleagues to report any patient safety concerns I may have.	
	The culture in the operating theatres here makes it easy to learn from the errors of others.	
	I know the proper channels to direct questions regarding patient safety in my operating theatres.	

The Shapiro-Wilk test demonstrated that scale-scores of teamwork climate, working conditions, perceptions of management and safety climate were not normally distributed. The distribution of scale scores for all survey respondents for each dimension of safety culture are presented in Table 5.6.

Table 5.6: Distribution of scale scores

Scale	Test for normality	Scale Scores for survey respondents (n=261) across vascular operating departments (n=10) Mean (standard deviation)	Median (interquartile range)	Minimum Score	Maximum Score
Teamwork	<.001	79.7 (11.5)	80.0 (16.7)	40.0	100.0
Working Conditions	.001	74.9 (13.2)	75.0 (20.0)	35.0	100.0
Perceptions of Management	.003	65.3 (16.0)	65.0 (20.0)	20.0	100.0
Safety	.003	76.7 (12.2)	77.1 (17.1)	40.0	100.0

The results related to each dimension of safety culture will now be presented in more detail.

5.5.3 *Teamwork*

More than 75% of survey respondents (n=261) reported that nurse input about patient care in well-received in the operating theatre, that they have the support they need from other staff to treat their patients and that the clinicians and nurses work as a well-coordinated team (see Figure 5.1 overleaf). However, 18.5% (48/260) of respondents believe that it is difficult to speak up if they perceive a problem with patient care. One quarter (n=12/48) of these respondents worked in the operating department with the worst teamwork scale-scores overall. Nurses (38%; 17/65) and operating department practitioner (ODPs) (24%; 11/37) reported more difficulty speaking up than surgeons (18%; 8/45), anaesthetists (9%; 4/54) or radiologists (2%; 1/13). Of the respondents who disagreed that the clinicians and nurses work together as a well-coordinated team, 57.1% (n=4/7) worked in the same operating department.

Figure 5.2 demonstrates the distribution of teamwork scale-scores for survey respondents in vascular operating departments at ten hospitals. Median teamwork scale-score for all survey respondents (n=261) was 80.0 (IQR 16.7; range 40.0-100.0). The distribution of teamwork scale-scores differed significantly between operating departments (p<.001) but not between professional groups (p=.490), suggesting that cultural norms within the respondents' place of work influenced their perceptions of teamwork more than teamwork practices within their professional group.

Figure 5.1: Proportion of all survey respondents (n=261) agreeing/disagreeing with survey items in the teamwork scale

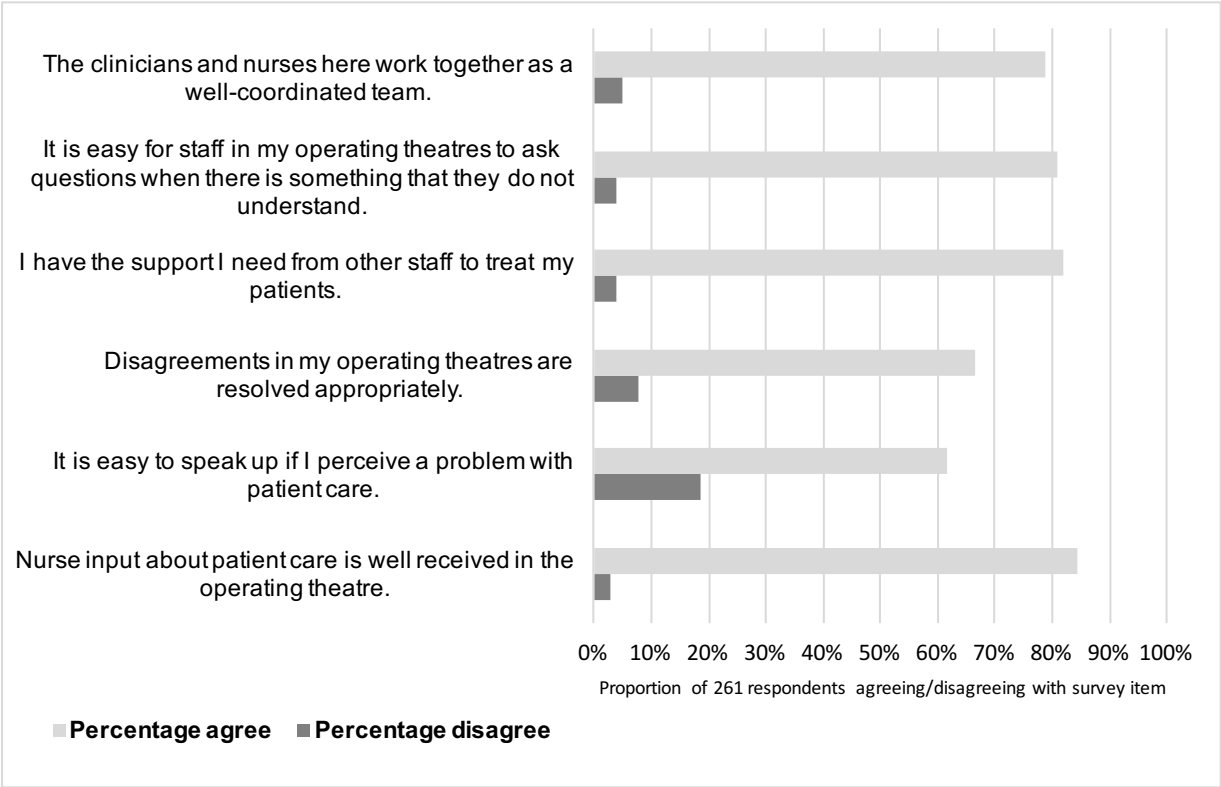
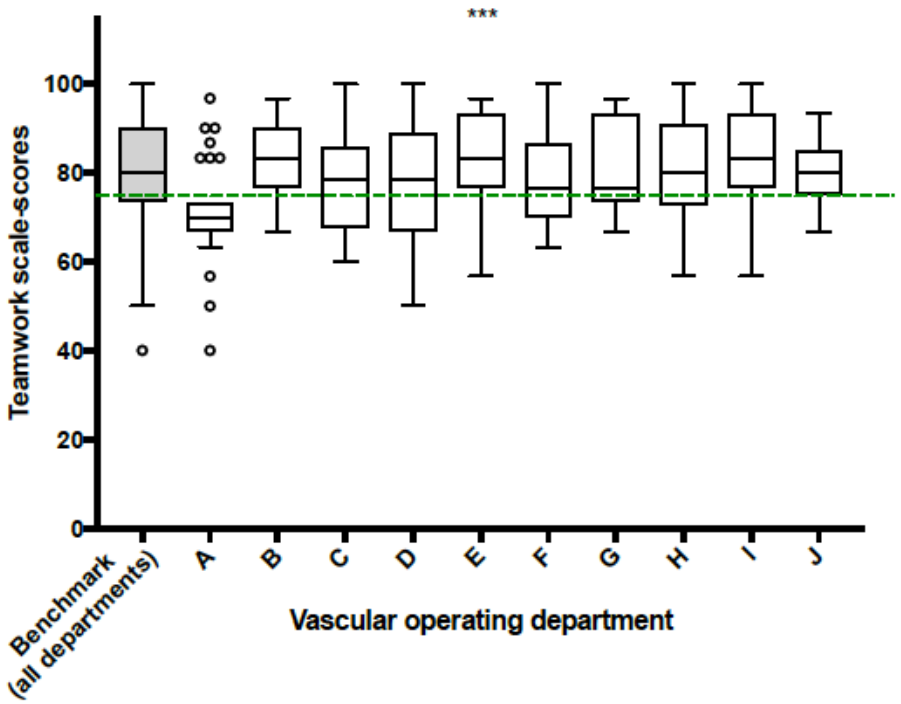


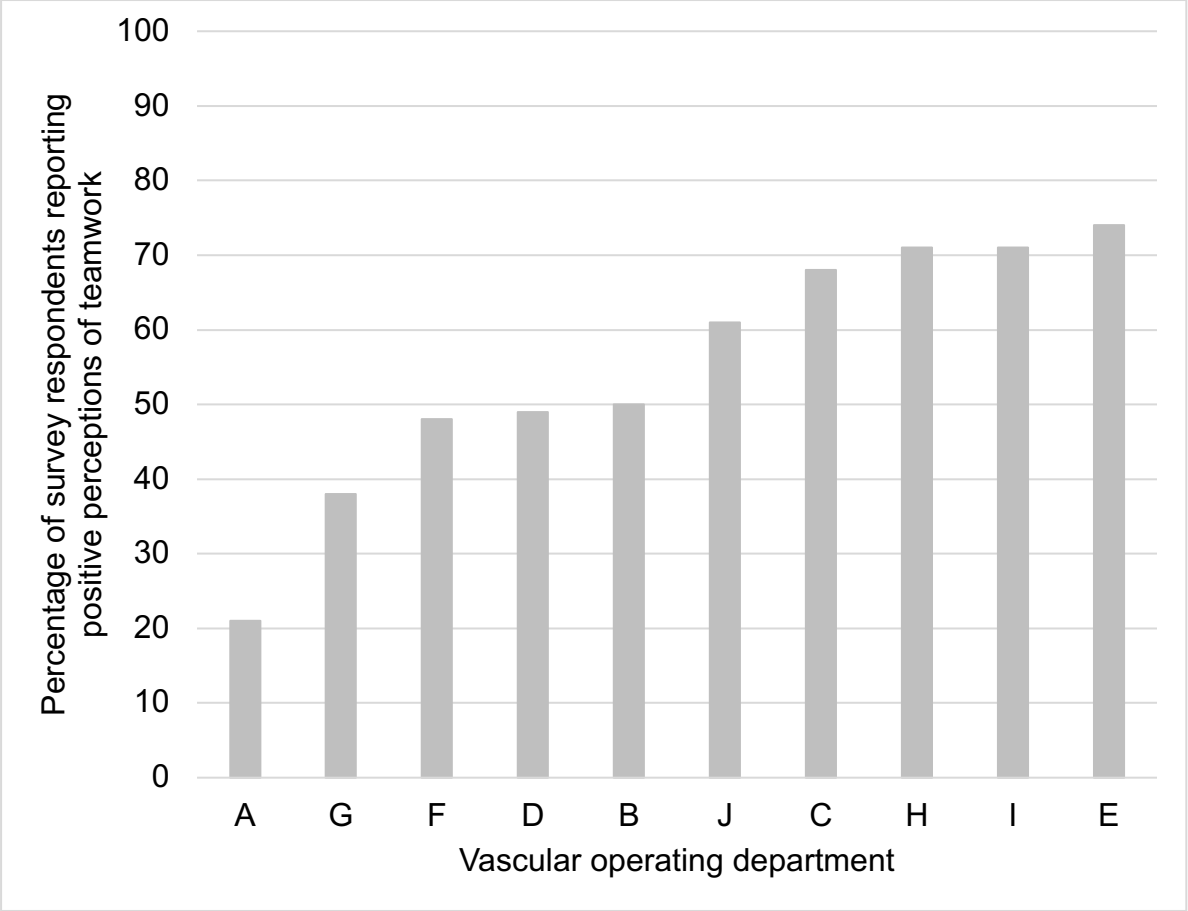
Figure 5.2: Distribution of teamwork scale-scores across vascular operating departments at ten different hospitals



*** p<.001. Figure shows the distribution of scales scores based on team survey responses at each site. Scale-scores greater than 75 (indicated by the dashed green line) are considered to reflect positive perceptions of teamwork.

Across all sites 64.6% (n=169) of 261 respondents had teamwork scale-scores greater than 75, suggesting that a majority of respondents had positive perceptions of teamwork. Respondents working in the vascular operating department at site A held the least positive perceptions of teamwork; only 21% (n=7/33) of respondents had scale scores greater then 75) (see Figure 5.3).

Figure 5.3: Proportion of individual respondents with positive perceptions of teamwork by vascular operating department



Scale-scores greater than 75 were considered to reflect positive perceptions of teamwork.

5.5.4 *Working conditions*

Figure 5.4 demonstrates the proportion of respondents agreeing/disagreeing with each item in the working conditions scale. The majority (79.9%; n=207/259) of respondents reported that trainees in their discipline are adequately supervised. However, 10.1% (n=26/257) disagreed that their hospital does a good job of training new staff and of these respondents, 53.9% (n=14/26) worked in two of the ten operating departments. Of all respondents, 11.2%; n=29/260) disagreed that all necessary information is available before the start of the

procedure; 37.9% (n=11/29) of these respondents worked in one of the ten operating departments.

Figure 5.4: Proportion of all survey respondents (n=261) agreeing/disagreeing with survey items in the working conditions scale

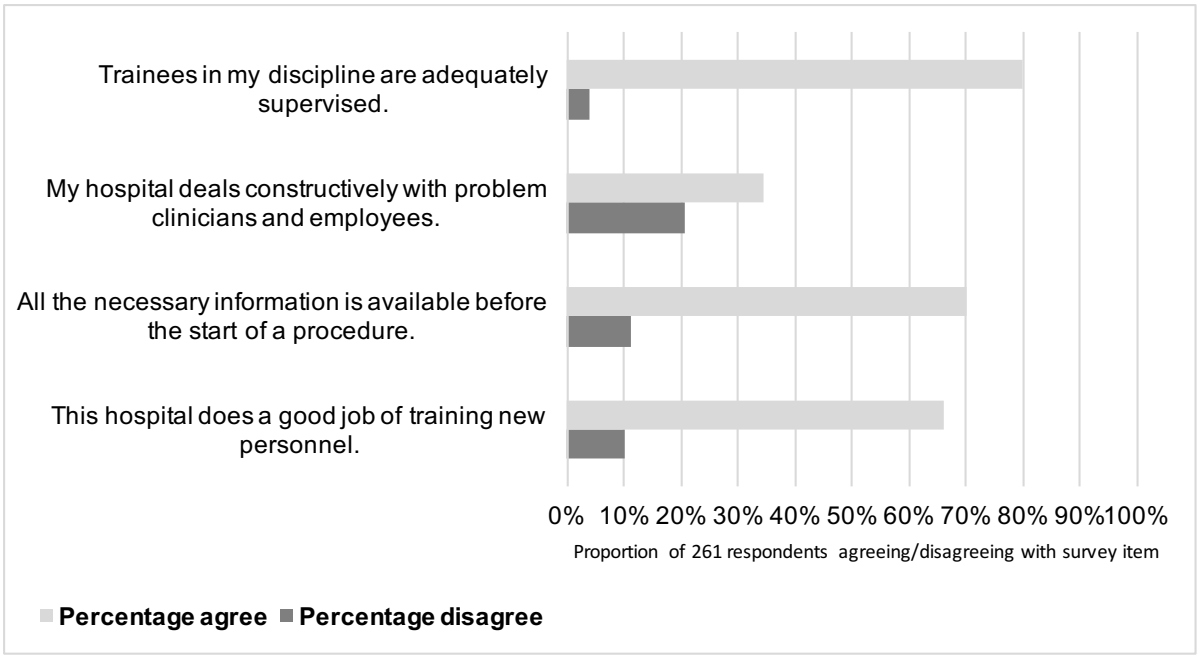
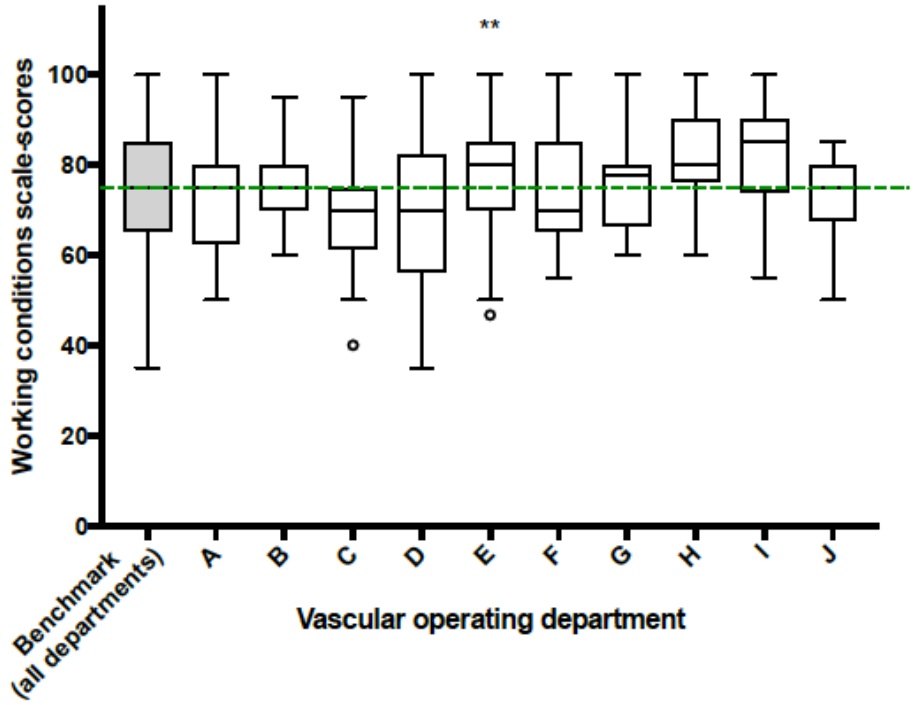


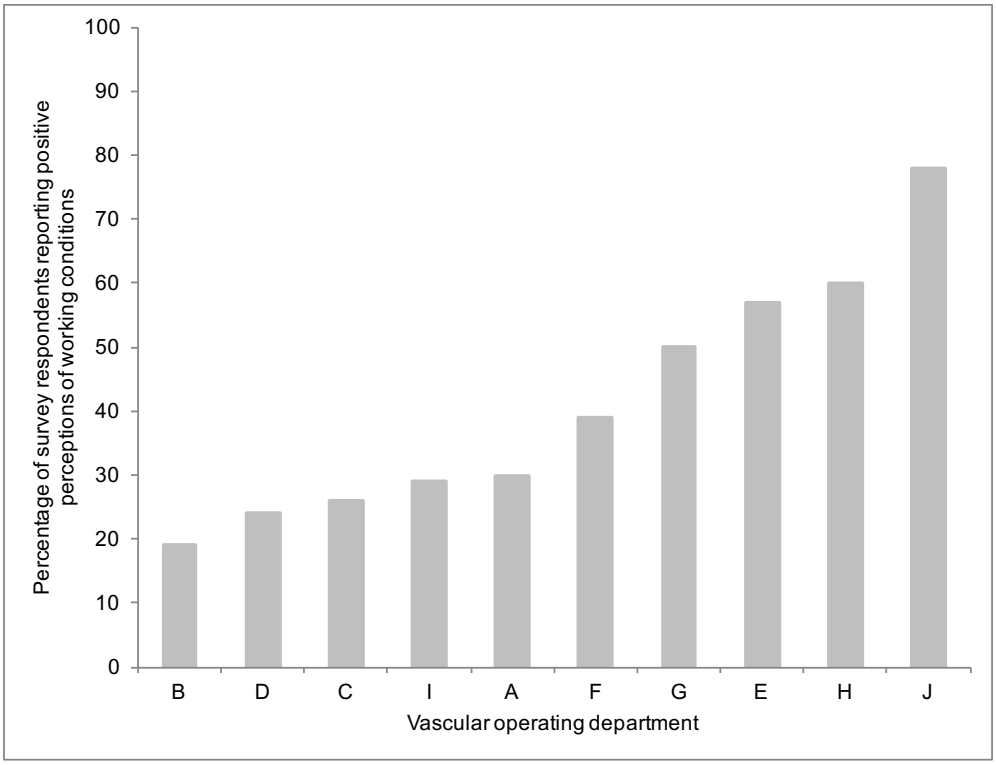
Figure 5.5: Distribution of working conditions scale-scores across vascular operating departments at ten different hospitals



** p=.002. Figure shows the distribution of scales scores based on team survey responses at each site. Scale-scores greater than 75 (indicated by the dashed green line) are considered to reflect positive perceptions of working conditions.

Figure 5.5 demonstrates the distribution of working conditions scale-scores for survey respondents in vascular operating departments at ten hospitals. Median working conditions scale-score for all respondents was 75.0 (IQR 20.0; range 35.0-100.0). Less than 20% of respondents working at site B held positive perceptions of working conditions while 78% of respondents working at site J had positive perceptions of working conditions. The distribution of working conditions scale-scores differed significantly between operating departments (p=.002) and between professional groups (p=.044). Of note, staff working in anaesthesia had the least positive perceptions of working conditions, while interventional radiology staff had the most positive perceptions of working conditions.

Figure 5.6: Proportion of individual respondents with positive perceptions of working conditions by vascular operating department

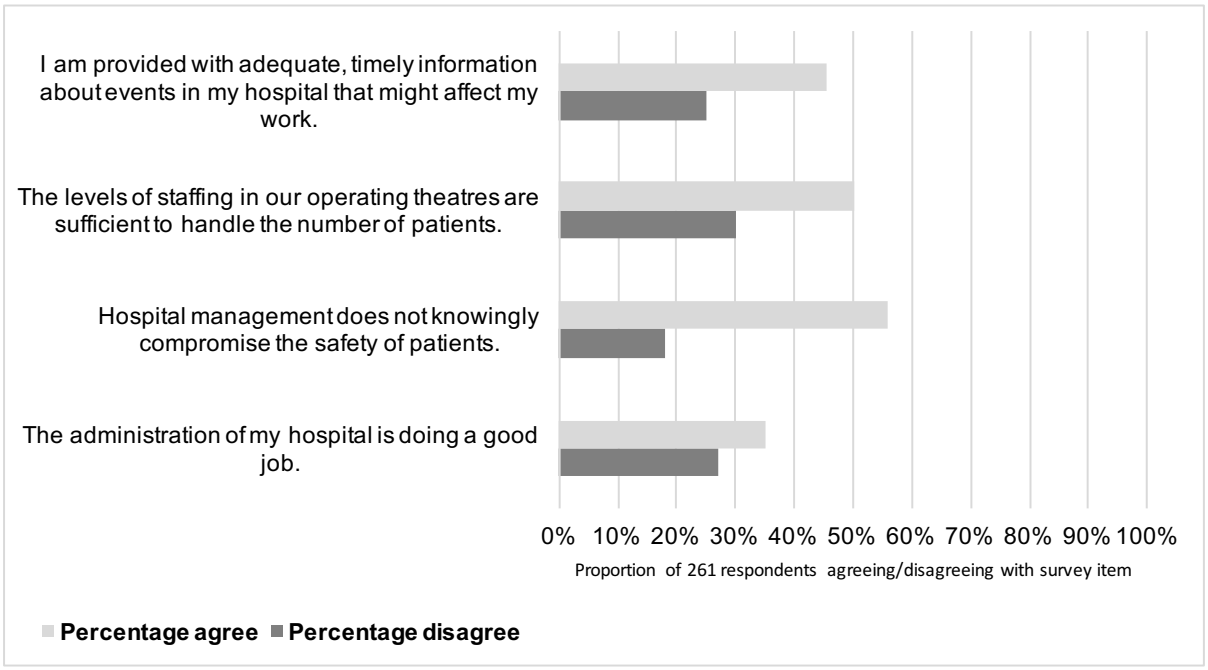


Scale-scores greater than 75 were considered to reflect positive perceptions of teamwork.

5.5.5 *Perceptions of management*

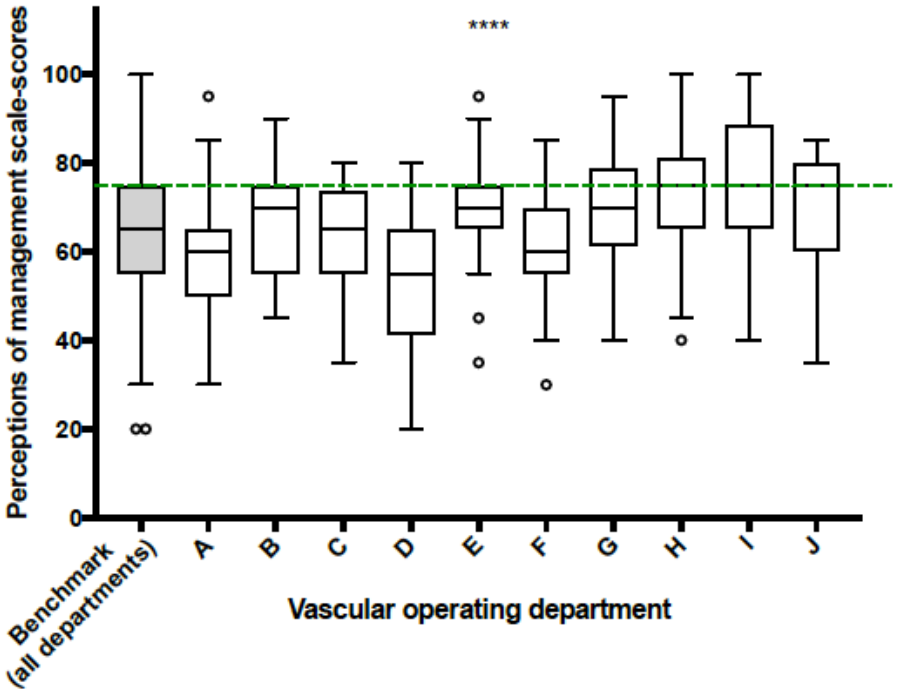
Nearly a third of survey respondents (30.0%; n=78/260) disagreed that staffing levels in their operating department were sufficient to handle the number of patients (Figure 5.7). More than one quarter of respondents (27.2%; n=71/261) did not believe that the administration of their hospital was doing a good job and 24.9% (n=65/261) felt that they were not given timely information about events in their hospital that might affect their work.

Figure 5.7: Proportion of all survey respondents (n=261) agreeing/disagreeing with survey items in the management climate scale



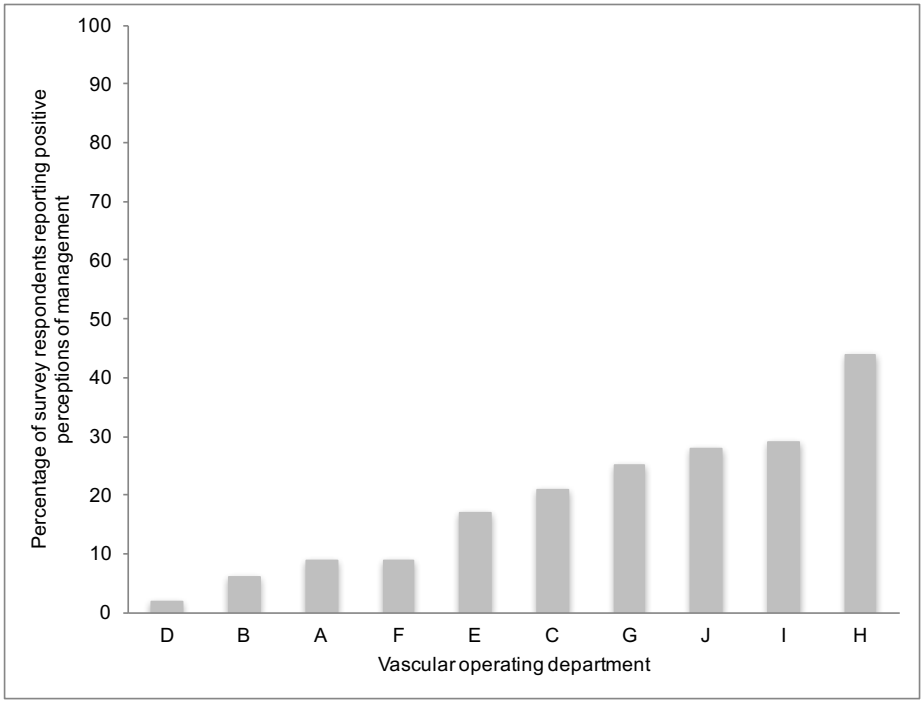
Only 33.7% (n=88/261) of all respondents had management climate scale-scores of greater than 75, suggesting that the majority of respondents do not have positive perceptions of management. Figure 5.8 demonstrates the distribution of scale-scores for perceptions of management for all survey respondents in vascular operating departments at ten hospitals. Median management climate scale-scores for all respondents was 65.3 (IQR 16.0; range 20.0-100.0). The distribution of scale-scores for perceptions of management differed significantly between operating departments ($p<.001$) and between professional groups ($p=.048$). Only 2% of survey respondents working at site D held positive perceptions of management. (Figure 5.9).

Figure 5.8: Distribution of management climate scale-scores across vascular operating departments at ten different hospitals



**** p<0.0001. Figure shows the distribution of scales scores based on team survey responses at each site. Scale-scores greater than 75 (indicated by the dashed green line) are considered to reflect positive perceptions of management.

Figure 5.9: Proportion of individual respondents with positive perceptions of management by vascular operating department

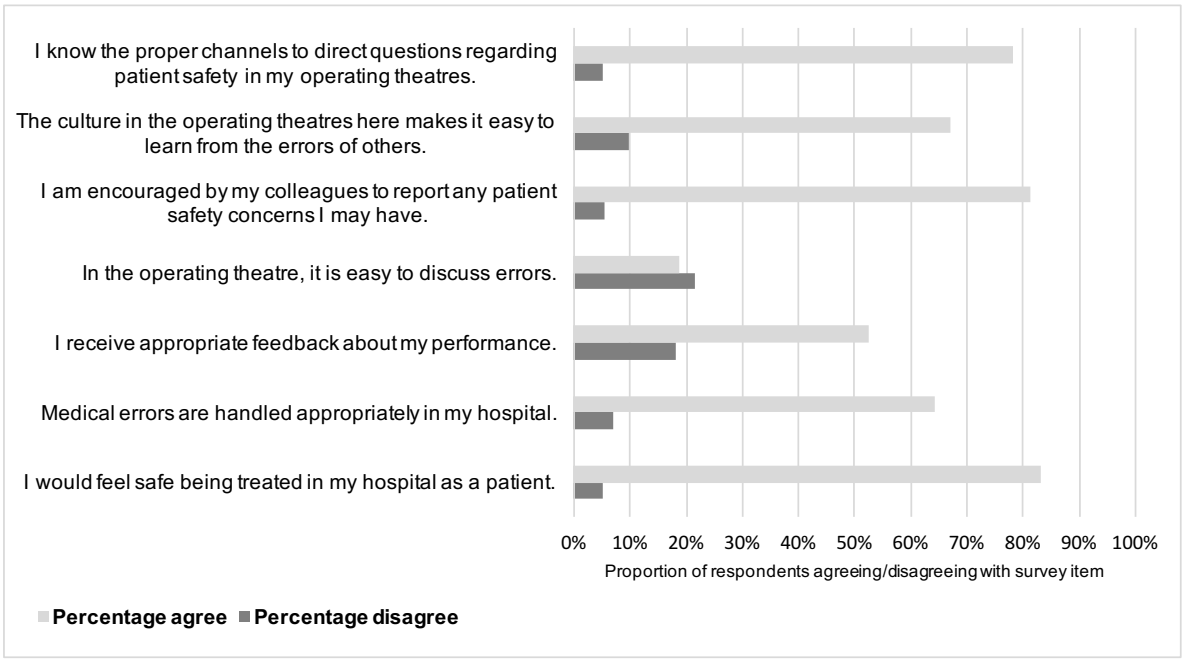


Scale-scores greater than 75 were considered to reflect positive perceptions of management.

5.5.6 *Perceptions of safety*

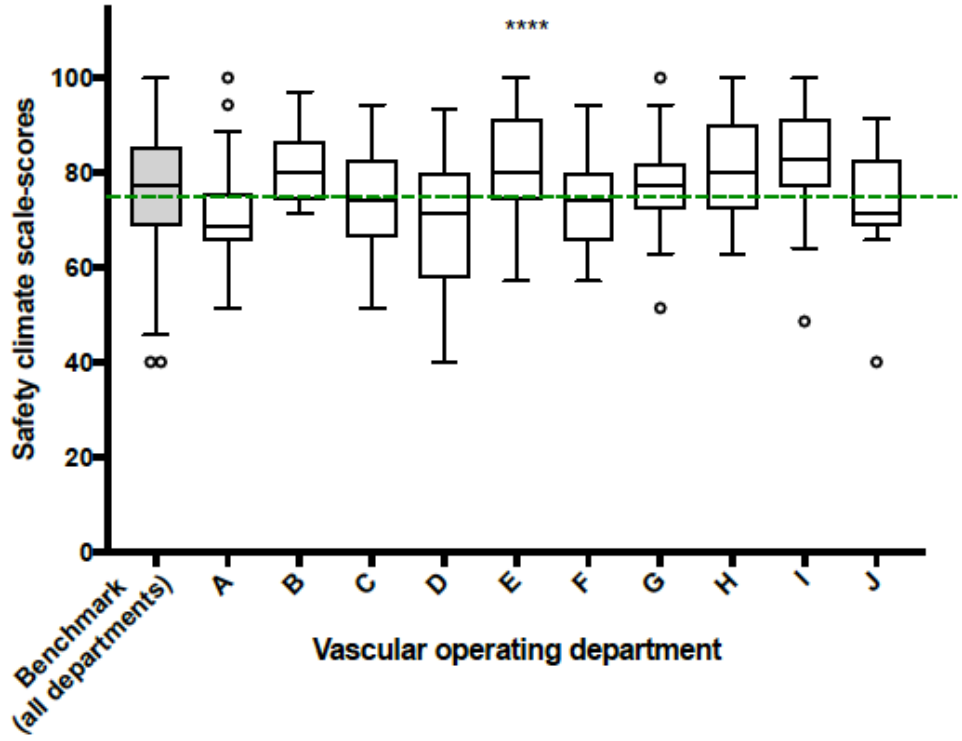
Of 261 survey respondents, 21.4% (n=55/257) reported that it is difficult to discuss errors and 9.6% (n=25/260) disagreed that the culture in the operating theatre makes it easy to learn from the errors of others (Figure 5.10). Although only 64.2% (n=163/254) of respondents believed that medical errors are handled appropriately in their hospital, 83.3% (n=214/257) reported that they would feel safe being treated as a patient there.

Figure 5.10: Proportion of all survey respondents (n=261) agreeing/disagreeing with survey items in the safety climate scale



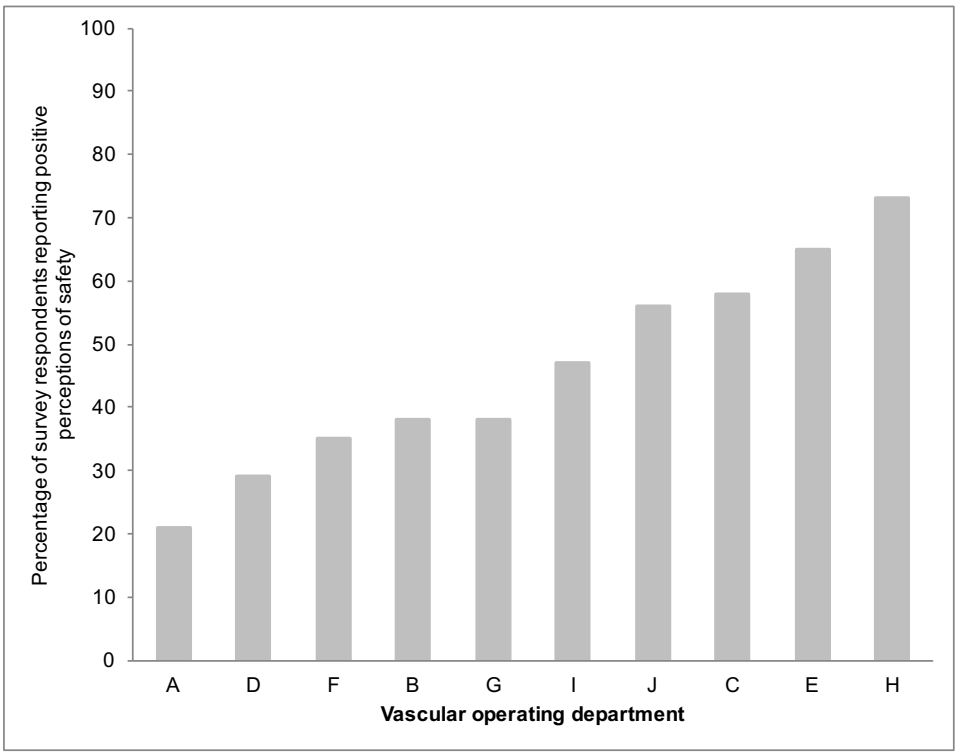
Overall, 64.4% (n=168/261) of respondents had safety climate scale-scores greater than 75, therefore a majority of respondents hold positive perceptions of safety. Figure 5.11 demonstrates the distribution of scale-scores for perceptions of safety for all survey respondents in vascular operating departments at ten hospitals. The median safety climate scale-score for all respondents was 76.7 (IQR 12.2; range 40.0-100.0). The distribution of scale-scores for safety climate did not differ between professional groups (p=.187) but differed significantly between operating departments (p<.0001). Only 21% of survey respondents held positive perceptions of safety at site A, while 74% of respondents working at site H held positive perceptions of safety. Perceptions of safety appear to be strongly influenced by the cultural norms of individual operating departments.

Figure 5.11: Distribution of safety climate scale-scores across vascular operating departments at ten different hospitals



**** p<0.0001. Figure shows the distribution of scales scores based on team survey responses at each site. Scale-scores greater than 75 (indicated by the dashed green line) are considered to reflect positive perceptions of safety.

Figure 5.12: Proportion of individual respondents with positive perceptions of management by vascular operating department



Scale-scores greater than 75 were considered to reflect positive perceptions of safety.

5.6 DISCUSSION

This multi-centre, survey study aimed to investigate the perceptions of operating staff with regards to teamwork, working conditions, management and safety in vascular operating departments across England. A previously validated and psychometrically sound questionnaire was administered to vascular operating teams at ten sites across England. This resulted in site-level scores representing perceptions of teamwork, working conditions, management and safety for each vascular operating department.

5.6.1 *Summary of findings*

Although most vascular operating staff in this sample reported that clinicians and nurses work together as a well-coordinated team, there was significant variation between sites for perceptions of teamwork. At one centre, only 21% of vascular operating staff viewed teamwork positively in their operating department. Furthermore, nearly 20% of all operating team members in this sample reported difficulty speaking up if they perceived a problem with patient care. Perceptions of working conditions varied significantly between sites and between professional groups. Staff working in anaesthetics reported the least positive views of working conditions. Around one in ten vascular operating team members in this sample reported that the provision of training was poor, and that relevant information was not always available before the start of operations. In general, perceptions of management were poor across all ten participating sites. Around one third of respondents reported that staffing levels were not sufficient to handle the number of patients in their operating departments. Perceptions of patient safety varied significantly between sites, but overall more than 20% of vascular operating team members reported difficulty discussing errors.

5.6.2 *Interpretation*

The crux of the findings of this survey study is that perceptions of teamwork, working conditions, management and safety vary significantly between different vascular operating departments. This variability in staff perceptions at the unit level has been observed in similar studies of safety culture in surgical departments (43,171). Cultural norms with regards to patient safety may depend heavily on local factors rather than on national standards, and thus strategies to improve patient safety should be tailored to the needs of individual units. Of note, a vascular team-training programme has been implemented at the site with the worst perceptions of teamwork as a direct result of this study.

The findings of this study suggest that a significant proportion of vascular operating team members find it difficult to discuss errors or to speak up if there is a problem with patient care. Most of the respondents reporting these concerns were either nurses or operating department practitioners. Traditionally, clinicians and nurses exhibit different communication styles. Whereas clinicians are trained to communicate clearly and concisely, nurses are taught to communicate more holistically (171) and these differences in communication styles may contribute to the difficulty of some vascular operating team members in speaking up. A recent systematic review of communication failure in the operating theatre found that power relationships – particularly the position of surgeons and anaesthetists at the top of an unhealthy hierarchical structure - contributed to team members feeling unable to voice their concerns, which ultimately led to unsafe practices (172). In the previous study presented in this thesis, trainees reported similar concerns regarding hierarchy in the vascular operating environment (173). There may need to be a shift from a traditional hierarchical environment to one in which effective leadership fosters cultural and behavioural norms that encourage team members to speak out when patient safety is at risk (98).

In this study, perceptions of hospital-level management were generally poor. The greatest concern – reported by 30% of all respondents in this sample - was that staffing levels in the vascular theatres were not sufficient to handle the number of patients. Given the current state of staffing levels in the NHS, this finding is likely to reflect much broader problems within the health service, rather than failings at the hospital-management level. In the UK, theatre nurse shortages have forced some NHS Trusts to cancel routine operations in recent years, and most Trusts are struggling with recruitment (174). Furthermore, a recent vascular workforce survey suggested that a number of pressures, including current over-stretched job-plans and the move to a seven-day service, will necessitate the creation of additional vascular consultant posts in the UK to maintain the current level of service provision (175). In the previous study presented in this thesis, one third of surgeons believed that poor staffing levels and skill mix contributed to perioperative adverse events in patients undergoing arterial intervention. While more work is needed to understand the precise impact of poor staffing levels and skill mix on patient safety in the vascular operating theatre, these preliminary studies are a step towards making these concerns more visible to hospital managers and policy makers.

5.6.3 *Strengths and limitations*

The survey used to capture vascular operating team members' perceptions of teamwork, working conditions, management and safety was a psychometrically sound questionnaire that has been well-validated and previously administered in many clinical areas, including the operating theatre, in the UK (43).

Vascular operating departments volunteered their participation for this and other patient safety studies contained in this thesis. Centres with a particular interest in patient safety may have been more likely to participate. Due to the fluid nature of operating teams with staff rotating in and out of surgical specialties, it was impossible to ascertain the total number of staff who would be eligible to complete the survey at each site. It is possible that some potentially eligible participants were not captured in the sample. To try to overcome this potential sample bias, the author of this thesis made several visits to the departments on different days to capture as many eligible participants as possible. Although considered to be a non-probability sampling method that can be vulnerable to judgement errors, the purposive sampling technique enabled the author of this thesis to actively seek potential survey respondents representing all professional groups involved in arterial operations. Some of the site-level sample sizes were small and this precluded more sophisticated between-group analyses using regression models.

Of note, this study did not measure the relationship between dimensions of safety culture and clinical outcomes. Measuring this relationship is challenging because the methodologies used to measure culture can only provide a snapshot of safety climate at a given point in time and a large number of confounding variables, including local structure and process variables that may be difficult to control for, are likely to interfere with the findings.

5.6.4 *Generalisability*

Of note, this was a cross-sectional study providing a snapshot of safety climate within vascular operating departments at the point of survey administration. To gain a more comprehensive understanding of safety culture within vascular operating departments, longitudinal studies are needed to track the nature of safety climate over time. The survey results reported here represent the views of vascular operating team members at ten NHS sites across England. From this multi-centre sample, we were able to observe significant variation between sites for perceptions of teamwork, working conditions, management and safety. These findings emphasise the need for individual units to evaluate safety culture locally.

5.7 CHAPTER SUMMARY

The purpose of the study presented in this chapter was to explore the perceptions of vascular operating staff with regards to teamwork, working conditions, management and safety. This study has demonstrated that perceptions of these safety culture dimensions vary significantly between centres; safety improvement strategies are likely to be most effective when tailored

to the needs of individual operating departments. More work is needed to establish whether these aspects of safety culture are associated with patient outcomes.

Section III:

Defining the Landscape of Intraoperative Safety Failure In Aortic Intervention

Section Overview

The three chapters presented in section 3 present a report on the LEAP study (Landscape of Error in Aortic Procedures). The LEAP study was a multi-centre, observational, collaborative effort to investigate system failures occurring during aortic procedures. The primary aim of the LEAP study was to use a systems approach to develop a comprehensive understanding of intraoperative safety failure in aortic procedures. Secondary aims were to investigate potential determinants of intraoperative failure and the relationship between intraoperative failure and post-operative outcome. The LEAP study comprised two phases: phase I was a training phase to familiarise operating teams with the study protocol and to establish the feasibility and reliability of a structured debrief approach for use by vascular operating teams to self-report intraoperative failures. In phase II, teams self-reported failures occurring in aortic procedures. They also reported the immediate impact of these failures in terms of patient harm and procedural delay, and 30-day post-operative outcomes.

The table overleaf provides an overview of the next three chapters. In chapter 6 the methods used to conduct phases I and II of the LEAP study are presented and the chapter goes on to address the feasibility and reliability of a structured, team debrief approach to capture intraoperative system failures. Chapter 7 investigates the frequency and type of failures occurring during aortic procedures as well as their immediate impact in terms of intraoperative delays and patient harm. Chapter 8 presents exploratory analyses to investigate patient, procedure and team predictors of intraoperative failure and the relationship between intraoperative failure and postoperative outcomes.

CHAPTER 6		
LEAP Study Phase I (training phase)		
Objectives To train operating teams to self-report intraoperative failures using the Imperial College Error CAPture (ICECAP) debriefing tool To establish the feasibility and reliability of this approach	**Outcome Measures** Proportion of operating team members participating in the ICECAP debrief Correlation between trainer and teams for the number of intraoperative failures identified within different categories of failure type/severity	**Setting & Participants** Vascular operating departments in 10 different hospitals in England *Staff:* all vascular operating team members *Patients:* adults undergoing **any** elective procedure on vascular operating lists
CHAPTER 7		
LEAP Study Phase II		
Objectives To use a system approach to develop a better understanding of the landscape of failure in aortic procedures	**Outcome Measures** Frequency, type and severity of intraoperative failures Immediate consequences of failure in terms of patient harm and procedural delay	**Setting & Participants** Vascular operating departments in 10 different hospitals in England *Staff:* all vascular operating team members *Patients:* adults undergoing **aortic** procedures
CHAPTER 8		
LEAP Study Phase II		
Objectives To establish patient, procedure and team predictors of intraoperative failure To investigate the relationship between intraoperative failure and patient outcomes	**Outcome Measures** Associations between patient, procedure and team variables and failure rate Associations between failure rate and patient outcomes	**Setting & Participants** Vascular operating departments in 10 different hospitals in England *Staff:* all vascular operating team members *Patients:* adults undergoing **aortic** procedures

6 The LEAP Study: (i) Methods; (ii) Testing the feasibility and reliability of a structured, debriefing tool for use by vascular operating teams to self-report intra-operative system failures in arterial operations

6.1 CHAPTER OVERVIEW

The first part of this chapter outlines the methods used to undertake the LEAP study (phases I and II). The study design, setting, participants, materials, and methods of data collection are presented. The chapter goes on to present the results of phase I of the study, during which vascular operating teams at multiple sites were trained in the study protocol and the use of a structured debriefing approach to self-report intraoperative system failures. The feasibility and reliability of this approach is outlined and discussed.

6.2 INTRODUCTION

Retrospective consideration of adverse events in arterial surgery by vascular surgeons during the study outlined in chapter 4 suggested that system failures are related to patient harm and poor outcomes. Other single-centre observational studies of 'error' indicate that a range of procedural problems occur during arterial intervention (57,141). Many of the important issues reported in these publications and in the study presented in chapter 4 appear to relate to latent system failures rather than to the errors of individuals. However, the findings reported in previous single-centre studies lack external validity and require further investigation in larger, multi-centre patient safety studies. To this end, the study presented in this and the following two chapters was designed to elicit prospective reports of safety failure events occurring during aortic intervention at multiple centres.

6.3 AIM AND OBJECTIVES

6.3.1 *Aim*

The overarching aim of the LEAP study was to use a systems approach to develop a comprehensive understanding of intraoperative safety failure in aortic procedures. To address

this aim, the study protocol was implemented in multiple vascular operating departments and operating teams were trained in the use of a structured debriefing approach to self-report intraoperative system failures (LEAP study phase I).

6.3.2 *LEAP study phase I - objectives*

The specific objectives of phase I of the LEAP study were:

- To train operating teams in ten vascular operating departments to use the Imperial College Error CAPture (ICECAP) debriefing tool to self-report intraoperative failures.

- To establish the feasibility and reliability of the ICECAP debriefing approach.

6.4 METHODS

6.4.1 *Ethical approvals & sources of funding*

Full Research Ethics Committee (REC) (12-LO-0710) and local site-specific approvals were obtained for this study (the REC approval letter can be found in appendix 2 on page 228). This study was funded through grants awarded by the Circulation Foundation (President's Early Career Award – Mr Colin Bicknell) and by NIHR (Clinical Academic Training Fellowship – Rachael Lear).

6.4.2 *Study design*

The LEAP study was a multi-centre, observational cohort study. The study comprised two phases: phase I was a training phase to familiarise operating teams with the study protocol and to establish the feasibility and reliability of a structured debriefing approach for use by vascular operating teams to self-report intraoperative failures. The author of this thesis made several visits to each participating site during this phase to provide information and training to participating operating teams. In phase II, vascular operating teams used the ICECAP debriefing tool to self-report failures occurring in aortic procedures. The immediate impact of these failures in terms of patient harm and procedural delays, and 30-day post-operative patient outcomes were also reported.

6.4.3 *Key definitions*

We sought terms that (i) reflected a range of intraoperative safety problems – including technical and non-technical errors as well as system failures, (ii) described the immediate impact of the problem on the patient while still on the operating table, and (iii) were accessible

in terms of being easily understood and operationalised by participating operating teams. Recognised terminology and definitions found in the safety literature were not appropriate for this study. For example, in the safety literature, the term 'error' is defined as "an unintended act (either of omission or commission) or one that does not achieve its intended outcome" (p.1851) (34), while adverse events have been defined as injuries caused by medical management rather than a patient's underlying disease that either prolong hospitalisation or resulted in temporary or permanent disability at the time of discharge (4). These terms from the safety literature are rather convoluted, do not reflect the variety of safety problems we aimed to capture, and do not focus on the immediate impact on the patient. Therefore, we developed key definitions for the specific purposes of this study; these terms are outlined below.

Intraoperative failure: For the purposes of this study, a failure was defined as any event that prevented the operation from progressing in an ideal manner. This definition was deliberately broad to capture all potentially relevant safety events, including failures in the surgical system (system factors), human errors and sources of intraoperative delays (including patient-related difficulties). Failures were to be reported by the trainer and by the operating teams if they occurred between the patient being transferred into the operating theatre and final closure of the wound. This definition requires a subjective assessment of deviations from the 'perfect' operative course by the operating teams reporting who participated in the study. However, we felt that it would be easy for teams to operationalise this definition and it encouraged teams to report all potentially relevant safety problems.

Harm: Harm was defined as injury to the patient evidenced by either a physiological response to the injury (such as cardiovascular instability), or by the need for further invasive intervention to mitigate the injury. This definition of harm was developed to provide a measure of the immediate impact of a failure on the patient while he/she was still on the operating table.

Procedural delay: Procedural delay was defined as an unnecessary pause during a procedure as a result of intraoperative failure.

6.4.4 *Study setting*

The LEAP study recruited staff and patients from ten NHS hospitals across England between September 2012 and July 2014. Eligible study sites were arterial centres where open and endovascular aortic procedures are routinely performed. Within the scope of practical and funding constraints, the research team at the lead site aimed to recruit nine additional arterial

centres with diverse characteristics in terms of size, geographical location, and aortic case volume/complexity. Study sites were identified via two means. Firstly, the research team approached known clinical contacts and invited them to volunteer their participation. Secondly the study was listed on the NIHR Clinical Research Network Portfolio and the research team were approach by sites wishing to volunteer study participation. System failures occurring during aortic procedures were recorded by vascular operating teams and patients were followed up for a period of 30 days from the day of aortic intervention. Recording of intraoperative system failures took place in the immediate post-operative period in vascular operating departments or in interventional radiology suites at participating sites.

6.4.5 *Participants*

Staff: Two consultant vascular surgeons were identified to lead the study at each participating site. Surgeons were not selected at random – their participation was voluntary. All vascular operating team members who were involved in operations taking place on these consultant vascular surgeons' vascular operating lists were then eligible to participate in the study. This included any surgeon, anaesthetist, nurse, radiologist, radiographer, operating department practitioner or healthcare assistant who was involved in operations performed by the participating consultant vascular surgeons. In order to recruit vascular operating team members into the study, the study coordinator (the author of this thesis) made several visits to each participating site. Participating consultant vascular surgeons and the study coordinator provided vascular operating team members with verbal and written information about the study during morning team briefings and staff had the opportunity to ask questions before deciding whether or not to participate. Study participation was voluntary and informed written consent was obtained from all participating team members (see staff information sheets and consent form for study participation in appendix 9, page 237).

Patients: In phase I of the LEAP study (the training phase), patients were eligible for study participation if they were over the age of 18, had capacity to consent to study participation and were scheduled to undergo any operation on participating consultant vascular surgeons' operating list on the day of a site visit by the trainer. In phase I of the study, eligibility was not restricted to patients undergoing aortic intervention because the primary purpose of this phase was to train operating staff to undertake the Imperial College Error CAPture debrief. In phase II of the study, patients were eligible for study participation if they were over the age of 18, had capacity to consent to study participation and were scheduled to undergo an elective or an emergency, open, endovascular, or hybrid aortic intervention on participating consultant vascular surgeons' operating lists. No patient was excluded on the basis of age, gender, aortic pathology or co-morbid conditions. To be invited to participate, patients were approached by

a member of the vascular team or by a designated research nurse on presentation to the outpatient department prior to admission, or on admission to hospital 24 hours prior to the procedure. Patients were provided with verbal and written information about the study and they were given the opportunity to ask questions before they decided whether or not to participate. Participation was voluntary and informed written consent was obtained (see patient information sheets and consent form for study participation in appendix 13, page 244).

6.4.6 *Sampling strategy*

In phase I of the LEAP study (the training phase), a purposive sampling technique was used to recruit patients scheduled to undergo any operation on participating consultant vascular surgeons' operating list on the day of a site visit by the trainer. A representative sample of patients was not required because the main purpose of phase I was to familiarise operating teams with the study protocol. In phase II, patients were consecutively recruited in order of presentation to participating sites during the study period. Two strategies were implemented to enable the research team to retrospectively assess whether the sample members were representative of the adult population undergoing aortic intervention. Firstly, demographic information about each patient was recorded on designated study case report forms. Demographic information included the patient's age, gender, ASA grade, aortic pathology and planned procedure. Secondly, participating consultant vascular surgeons were asked to maintain a log of all aortic procedures that they performed during the study period, indicating any patients who were not included in the study and reasons for exclusion (see aortic case log in appendix 14, page 248).

6.4.7 *Sample size*

In phase I, a pragmatic approach was taken to patient recruitment. Based on previous experience with the Imperial College Error CAPture tool (176), the research team estimated that five cases per consultant-led vascular operating team would provide the sufficient opportunity for teams to be familiarised with the study protocol and trained in the use of the Imperial College Error CAPture debriefing tool. With two consultants identified to lead the study at each site, a recruitment target of 100 patients in phase 1 (10 patients per participating site) was set. Recruitment was also guided by the training needs of participating vascular operating teams at each site and the availability of the study coordinator who provided the training. Training needs were largely shaped by the size of the department (i.e. the number of vascular operating team members requiring training) and the number of patients scheduled for intervention during site visits by the trainer (as this dictated the number of Imperial College Error CAPture debriefs that could be performed during a site training visit).

In phase II, each site was given a recruitment target of twenty patients in order to achieve a total phase II sample size of 200 patients undergoing aortic intervention. The recruitment target was not determined through the use of a power calculation as the failure rates and the association between failure rate and outcome was not known. The sample size was as large as the available funding and time constraints allowed.

6.4.8 *The Imperial College Error CAPture (ICECAP) tool*

This study was designed to prospectively elicit clinicians' reports of intraoperative safety failure. Previous single-centre studies analysing the occurrence of procedural failures and errors during surgical procedures utilised direct observational methods that are labour-intensive and impractical for widespread application (57,58,141). As a result, researchers in vascular surgery developed the Imperial College Error CAPture (ICECAP) tool (176). The tool consists of a series of questions/prompts organised into six primary categories (communication, equipment, procedure-independent pressures, technical, safety awareness and patient-related) and twenty subcategories (see Table 6.1).

Table 6.1: The Imperial College Error CAPture tool: categories and questions/prompts

Primary failure categories	Failure subcategories
1. Equipment Issues	- Any equipment unavailable? - Any equipment faulty? - Any equipment not configured correctly? - Any equipment desterilised? - Were there any drugs or medication-related issues?
2. Communication issues	Were there any problems caused by poor communication? If so, was the problem caused by: - Misleading communication - Lack of communication - Discord between staff - Information not heard/misheard
3.Procedure-independent pressures	- Were any team members absent who should have been here or did any team member need to leave during the procedure? - Were there any distractions/interruptions? - Were there any external pressures?
4. Technical issues	Were there any technical errors or issues? If so, was the technical error/issue related to: - a psychomotor error - unfamiliarity with the procedure - unfamiliarity with equipment - unfamiliarity with a technique?"
5. Safety awareness issues	- Were any safety checks omitted? - Were there any active violations of safety regulations?
6. Patient-related issues	- Were there any unanticipated difficulties caused by this patient's anatomy? - Were there any unanticipated problems relating to this patient's physiology?
7. Other issues	- Were there any other errors/inefficiencies/safety failures that have not already been mentioned?"

Questions regarding the immediate consequences of each failure in terms of patient harm and procedural delay are also included on the tool (see

Table 6.2 overleaf). The ICECAP tool can be used by observers in theatre to record failures occurring in real time or by operating teams to structure post-operative debriefs during which failures are recalled and discussed. When completed, the ICECAP tool provides a paper-based record of failures occurring during vascular operations and their immediate consequences in terms of patient harm and procedural delay (the completed Imperial College Error CAPture record in appendix 15, page 249, has been anonymised and is provided as an example).

Table 6.2: Questions about the immediate consequences of intraoperative failures

Patient harm	Procedural delay
Did this issue cause visible injury or impact on the patient's physiological condition intra-operatively?	**What was the estimated delay caused by this issue?**
- Yes, actual harm occurred as a direct consequence of this issue - Corrective measures needed to prevent harm. - No harm	- No delay - < 1 minute - < 15 minutes - < 1 hour - > 1 hour

6.4.9 *Previous validation work and reasons for selection*

The design and validation of the Imperial College Error CAPture tool is described in full in the related publication (176). It was developed by a group of twelve vascular experts using data from previously collected ethnographic field notes - the six primary failure categories are based on the most significant intraoperative failures that were deemed to have occurred during 250 hours of arterial intervention.

In a study unrelated to the work presented in this thesis (176), the tool was piloted for use by (i) observers recording failures in real time, and for use by (ii) operating teams to structure post-operative debriefs during which failures are recalled and discussed. When tested by independent observers in theatre, good inter-observer agreement was demonstrated for the number of intraoperative failures per case, for failure categorisation and for the identification of moderate to severe failures. For minor failures, inter-observer agreement was < 0.5 (Cohen's Kappa). Compared to an observer recording intraoperative failures in real-time, operating teams were able to recall 24.4% of recorded failures without the use of the Imperial College Error CAPture tool as a prompt, and 69.7% of failures when the tool was used. Teams were able to recall 79.0% of moderate to severe failures using the Imperial College Error CAPture tool. These findings suggest that it is feasible for the Imperial College Error CAPture tool to be used by observers and by operating teams to aid in the identification and categorisation of intraoperative failures. The findings may also be interpreted to suggest that precise failure rates cannot be determined using the tool. Furthermore, minor failures may be particularly vulnerable to under-reporting by operating teams, possibly due to the influence of post-event cognitive shaping – for example, some intraoperative failures (such as inadvertent desterilisation of a piece of equipment) might be rationalised as routine events. However, the

tool appears to be useful for evaluation and categorisation of intraoperative failures, and for reliably identifying major failure. In addition, the use of the tool as a prompt for structuring debriefs immediately after a case is likely to reduce recall bias and reporting bias, and this type of methodology has been shown to uncover significantly more intraoperative safety concerns than traditional hospital incident reporting systems (53). The tool does not simply focus on technical error or patient-related problems; it prompts consideration of a wide range of intraoperative failures, including problems related to equipment, communication issues, and pressures on operating staff and resources that originate from outside the operating theatre. Consideration of these failure categories aligns with the systems approach to understanding patient safety. Thus, the Imperial College Error CAPture tool was deemed to be suitable for use in the LEAP study.

6.4.10 *Training in the use of the Imperial College Error CAPture tool*

Prior to the LEAP study, the author of this thesis received formal training in the application of the Imperial College Error CAPture tool during a two-week training period in theatre.

During phase I of the study, the author of this thesis (the 'trainer') undertook multiple visits to each participating site to familiarise participating operating teams with the study protocol and to train them to use the Imperial College Error CAPture tool to self-report intraoperative failures. Multiple site visits were necessary because shift patterns and staff rotation meant that team composition was not consistent, and the trainer endeavoured to train all key operating team members prior to phase II of the study. Visits were negotiated and planned with participating consultant vascular surgeons and research nurses to try to capture all key team members.

The trainer attended the consultant vascular surgeons' operating lists and provided all participating team members with verbal and written information about the study. At the beginning of each operating list, the trainer outlined the aims of the study, briefly ran through the study protocol, and pointed out key study definitions. The operating list then began as normal. At the end of the first operation, the trainer led the operating team through the ICECAP debrief and guided completion of the written ICECAP record. Thereafter, a member of the operating team was allocated to lead the debrief, which took place in the same structured manner on each occasion. The trainer/operating team member read aloud the questions/prompts on the ICECAP tool to structure the debrief and a member of the operating team or a research nurse was allocated to complete the paper-based ICECAP record. The trainer remained in theatre during each operation – she observed events intraoperatively and recorded failures in a prospective manner. At the end of the team debrief, the trainer

highlighted any additional intraoperative failures that had not been recalled by the operating team. This discussion between the trainer and the teams was undertaken to highlight that "all events preventing the operation from proceeding in an ideal manner" should be recorded on the ICECAP tool.

The trainer encouraged reflection and open discussion between operating team members and team members were advised to come to a consensus on the failures to be documented on the ICECAP record. Typically, the debrief took place during skin closure or after the patient had been safely transferred to the recovery room – the trainer advised team members that they should negotiate between each other a suitably safe and convenient time to perform the debrief before the next case began; the timing of the debrief usually depended on the stability of the patient and the procedure type.

6.4.11 *Data collection & management*

Phase I: During phase I of the LEAP study, intraoperative failures were recorded by the trainer and by operating teams. Team member participation in the debrief was recorded to establish whether the ICECAP debrief was feasible/acceptable to all professional groups. A case report form containing patient and procedure demographic information was also completed for each case.

Phase II: During phase II of the LEAP study, intraoperative failures were recorded by operating teams only, with no trainer present. Team member participation in the debrief was also recorded at the time of the debrief. Case report forms elicited demographic information about the patient, the procedure, operating team composition, team member experience, operator unfamiliarity with any equipment, procedural success, and 30-day post-operative outcomes. These case report forms were completed by the vascular consultant in charge of the case or by research nurses at sites where this support was available.

Phases I and II: All patients recruited into the study were assigned unique study identification numbers, which were recorded on the ICECAP records and case reports forms; no identifiable patient information was documented on the study paperwork. Completed ICECAP records and case report forms were collated by the trainer and checked for patient/centre anonymity before being transferred to the lead site. Raw data were entered onto a purpose-built Filemaker© database by an independent research assistant. The author of this thesis then reviewed the data contained in the database against the case report forms to ensure accuracy.

6.4.12 *Data analyses*

Initial analyses: Before analysing the intraoperative failure data to address the study aims and objectives, the data underwent evaluation by two independent reviewers (two experienced consultant vascular surgeons). If a failure did not meet the pre-agreed definition (for example, it occurred prior to the patient being transferred into the operating theatre) it was removed from the database and excluded from further analyses. Independent assessors categorised the remaining failures as either 'major' or 'minor' according to pre-agreed definitions. Major and minor failures were defined by their immediate consequences during surgery –Table 6.3 presents an overview of their definitions and severity with examples.

Table 6.3: Major & minor failures: table of definitions and examples

Failure Type	Definition	Example	Severity
Minor failures	- Cause minimal or no disruption to the operation (less than 15 mins delay) - Do not directly cause harm to patients - Do not have the potential to harm in the majority of circumstances.	"On call phone caused distraction"	Seemingly inconsequential
Major failures	- Cause major disruption to the operation (more than 15 mins delay) - Directly cause patient harm - Have the potential to cause harm in the majority of circumstances.	"Surgeon anastomosed the graft to the origin of internal & external iliac artery but did not include the true & false lumen. There was two litres blood loss & subsequent hypotension during attempted a repair."	Potentially dangerous or harm-producing Very disruptive

Where there were disagreements between independent assessors, these were resolved with input from a third assessor (an experienced vascular registrar/ research fellow). Agreement between independent assessors was assessed using Cohen's kappa (κ).

6.4.13 *Analyses to meet the objectives of phase I*

Patient and procedural demographic information for all cases included in phase I of the LEAP study were summarised using descriptive statistics. To assess feasibility and acceptability of the ICECAP debrief approach, debrief participation was calculated for all professional groups, based on the presence or absence of key team members at the debrief (lead surgeon,

anaesthetist, scrub nurse, circulating nurse, and radiologist/radiographer if present during the procedure). In order to establish the reliability of team self-report in terms of the number of failures reported, a Spearman's rank-order correlation (r_s) was run to test agreement between the trainer and the operating teams for the number of failures recorded per operation and per failure category. The details of all reported failures were reviewed to try to determine whether the same failures were reported by the trainer and by the operating teams. This was not possible for the minor failures because they were not easily distinguished as unique events. However, it was possible to track whether the trainer and teams reported the same major failures. The proportion of major failures captured by both the trainer and teams was then calculated to further establish the reliability of the team self-report approach. Statistical analyses were performed using Stata® version 12 and SPSS® version 23. Reported P values are two-sided and P <.05 was deemed to indicate statistical significance.

6.4.14 *Analyses to meet the objectives of phase II*

Further analyses were conducted to address the objectives of phase II of the LEAP study are outlined in subsequent chapters of this thesis.

6.5 RESULTS: PHASE I

6.5.1 *Site participation*

Ten sites were recruited with diverse characteristics in terms of geographical location, Trust size and arterial/aortic case volume (see Table 6.4). Two consultant vascular surgeons were identified at each site. The trainer attended a median of 5 (range 4-6) procedures with each participating consultant vascular surgeon and their operating teams in phase I of the LEAP study.

6.5.2 *Patients & procedures*

Eighty-eight patients consented to participate in phase I of the study. Patients were generally male (72.4%; n=63/87, missing data n=1/88), older (mean age = 66, standard deviation (SD) = 15.6, range = 24 -90) and suffering from severe systemic disease (54.0%; n=47/87 of patients were assigned an ASA (American Society of Anaesthesiologists) grade of III) (see Table 6.5). Intraoperative failures were recorded by the trainer and by operating teams during 34 aortic repairs, 9 carotid endarterectomies, 22 lower limb arterial interventions, and during a range of other procedures performed on participating vascular consultants' lists (n=27/88) (see Table 6.6).

Table 6.4: Characteristics of participating sites (n=10)

Site	Location	Size* (Trust bed capacity)	Case volume: CEA**	Case volume: AAA repair***
A	Greater London	>1000	200-300	200-300
B	East Anglia	750-1000	200-300	400-500
C	Yorkshire & the Humber	>1000	>300	200-300
D	East Midlands	>1000	>300	400-500
E	South East	>1000	200-300	300-400
F	North West	500-750	<100	100-200
G	Greater London	750-1000	<100	>500
H	South East	750-1000	200-300	>500
I	East Anglia	500-750	100-200	300-400
J	Greater London	500-750	100-200	100-200

CEA: carotid endarterectomy AAA: abdominal aortic aneurysm
*Figures reflect the average number of general and acute overnight beds available for occupancy for the entire Trust for the period October - December 2012 ; source - NHS England https://www.england.nhs.uk/statistics/statistical-work-areas/bed-availability-and-occupancy/bed-data-overnight/. **Figures reflect the number of carotid endarterectomy procedures performed between 1 October 2009 - 30 September 2012; source - National Vascular Registry 2013 Report on Surgical Outcomes.
***Figures reflect the number of elective AAA repairs performed between 1 January 2008 - 31 December 2012; source - National Vascular Registry 2013 Report on Surgical Outcomes.

Table 6.5: Patient (n=88) characteristics

Mean age in years (SD, min-max)	**66 (15.6, 24-90)**
Male gender	72.4% (n=63/87)
ASA grade	
I (a normal healthy patient)	13.8% (n=12/87)
II (a patient with mild systemic disease)	25.3% (n=22/87)
III (a patient with severe systemic disease)	54.0% (n=47/87)
IV (a patient with severe systemic disease that is a constant threat to life)	6.9% (n=6/87)

SD: standard deviation ASA: American Society of Anesthesiologists
Missing data for gender and ASA grade: n=1.

Table 6.6: Procedural (n=88) characteristics

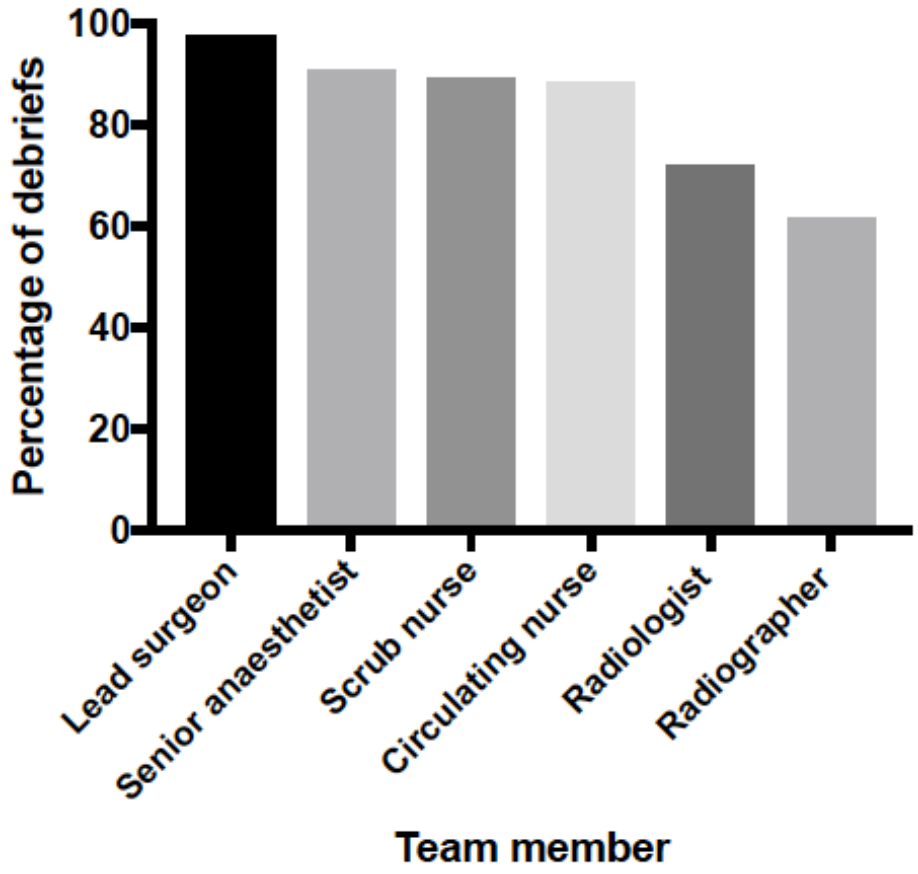
Procedure type	Percentage of cases in sample (n)	Procedure sub-category	(n)
Carotid endarterectomy	10.2% (9/88)	-	-
Lower limb arterial	25.0% (22/88)	-	-
Aortic	34.1% (30/88)	Open infrarenal AA repair	4/30
		Open aortoiliac bypass	1/30
		TEVAR +/- adjunct procedure	5/30
		FEVAR +/- adjunct procedure	6/30
		EVAR +/- adjunct procedure	13/30
		Visceral hybrid repair	1/30
Other	30.7% (27/88)	Varicose veins surgery	9/27
		Hernia repair	6/27
		Amputation	4/27
		Arterio-venous fistula formation	2/27
		Surgical wound debridement	2/27
		Temporal artery aneurysm ligation	1/27
		Brachial artery aneurysm repair	1/27
		Scalenectomy	1/27
		Laparoscopic cholecystectomy	1/27

AA: aortic aneurysm TEVAR: thoracic endovascular aneurysm repair FEVAR: fenestrated endovascular aneurysm repair EVAR: endovascular aneurysm repair

6.5.3 *Debrief participation*

Lead surgeons, senior anaesthetists, scrub and circulating nurses all participated in at least 90% of the ICECAP debriefs for the operations that they were involved in (see Figure 6.1). Radiologists participated in 72.0% of the ICECAP debriefs for the procedures they were involved in. Radiographers participated in 61.5% of the ICECAP debriefs for the procedures they were involved in. Anecdotally, reasons for non-attendance in the study debrief generally related to external commitments, particularly for interventional radiology staff, and production pressure/pressure to turn the theatre around for the next case.

Figure 6.1: Operating team member participation in ICECAP debriefs



Percentages account for missing data and reflect debrief participation for the procedures that team members were involved in.

6.5.4 *Independent assessment of intraoperative failures*

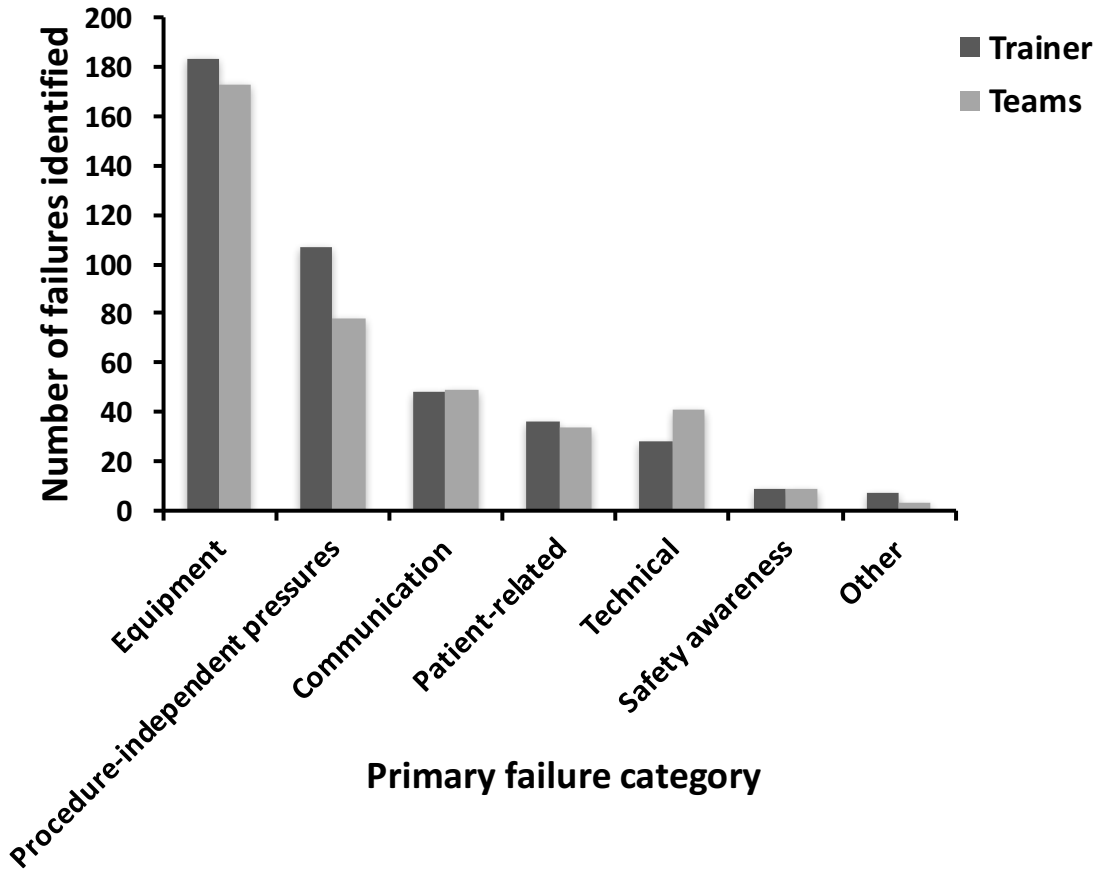
A total of 825 failures were recorded during 88 cases included in phase I of the study by operating teams and the observer. Independent assessors excluded 20 failures that did not meet the pre-agreed study definition of the term 'failure'. Reasons for exclusion were: failure occurred prior to the patient being transferred into the operating theatre (n=7/20); same failure recorded twice on a single ICECAP record by either the trainer or by the teams (n=5); patient-related problems that were clearly anticipated pre-operatively (n=7); event that did not influence the procedure in any way (n=1). Inter-rater agreement for failure severity (major/minor/exclude failure) was good (κ = .747 (95% confidence interval (CI) 0.653-0.841, p <.001). A total of 805 failures were subject to further analyses.

6.5.5 *Comparison of failures reported by the trainer and teams*

During 88 procedures on consultant vascular surgeons' operating lists, the trainer recorded 418 failures (median failures per procedure = 4, IQR = 5, range = 0-16) and the operating

teams recorded 387 failures (median = 4, IQR = 4, range = 0-14). There was a strong positive correlation between the trainer and operating teams for the total number of failures captured per operation, r_s = .766, p<.0001. Figure 6.2 demonstrates the total number of failures recorded by the trainer and by operating teams for each primary failure category. Overall, the trainer and the teams reported a similar pattern of failures across all failure categories. There were strong positive correlations between the trainer and the operating teams for the number of equipment failures recorded per procedure (r_s = .788, p>.0001) and communication failures recorded per procedure (r_s = .625, p<.0001). There were moderate positive correlations for procedure-independent pressures (r_s = .572, p<.0001) and patient-related issues (r_s = .567, p<.0001. Operating teams reported more technical failures per procedure than the trainer (r_s = .519, p<.0001). The correlation between the trainer and the operating teams for the number of safety awareness failures per procedure was low (r_s = .380, p<.0001) although the number of failures reported in this category was also low (n=18/805).

Figure 6.2: Comparison of failures reported by the trainer and teams



6.5.6 *Comparison of major failures reported by the trainer and teams*

During 88 cases, the trainer and operating teams identified a total of 19 major intraoperative failures (see Table 6.7). The trainer identified 68.4% (n=13/19) of these major failures while the operating teams identified 94.7% (n=18/19). Compared to the observer, operating teams were more likely to identify major failures caused by a lack of communication between team members (n=3) or by unanticipated patient-related issues (n=5). Of the 11 major failures identified by both the trainer and the operating teams, estimates for the duration of procedural delay were the same for 8 failures.

Table 6.7: Major failures identified by the trainer and teams

Failure details	Delay estimated by trainer	Delay estimated by operating teams
Equipment failures		
Fenestrated stent unavailable for second part of procedure though this was not realised until after spinal drain had been inserted	> 1 hour	> 1hour
Robotic catheters not immediately available	< 1 hour	< 1hour
Wire snapped off stent delivery device making removal difficult	< 1 hour	< 1 hour
Patient was receiving IV sedation – cannula fell out. Patient became agitated/started moving around.	< 1 hour	< 1 hour
Communication failures		
Arterial line inserted on wrong side due to poor planning/communication – required additional invasive procedure to reposition	Not identified	< 1 hour
Radiologist did not communicate to anaesthetist when stent was about to be deployed – patient's BP high at the time	Not identified	Data missing
Surgeon did not warn anaesthetist that clamp was being removed from artery	Not identified	No delay
Miscommunication between surgical team and interventional radiology regarding start time for endovascular component – delays while waiting for IR team to arrive	< 1 hour	Not identified
Procedure-independent pressures		
Patient anaesthetised and transferred into the OR, but start of case was delayed due to external emergency. Patient under GA for an extra 1.5 hours.	> 1 hour	> 1 hour
No juniors available to assist - delayed procedure	Not identified	< 1 hour
Technical failures		
Injury to vein during dissection – required repair x 3	< 1 hour	< 1 hour
Slipped ligature resulted in approx. 500mls blood loss –required blood transfusion and returned to theatre	> 1 hour	> 1 hour
Vessel injury during dissection requiring repair and blood transfusion	< 15 mins	< 1 hour
Injury to vessel – delay while waiting for radiology staff to attend for on-table angiogram	< 1 hour	< 15 mins
Unanticipated patient-related issues		
Renal artery angulation causing difficulty/delay – required change of operative plan to brachial approach	Not identified	< 1 hour
Anatomy of iliac arteries led to stent collapsing down/poor seal – required ballooning and wall stent	< 1 hour	< 1 hour
CT scan underplayed severity of iliac disease. Vessel dissected during wire insertion – required extra uncovered stent	< 15 mins	< 1 hour
Patient developed acidosis during procedure due to distal embolisation. Patient kept intubated post-operatively.	Not identified	No delay
Patient developed laryngospasm – propofol given	Not identified	No delay

6.6 DISCUSSION

6.6.1 *Summary of findings*

Review of objectives

- To train operating teams in ten vascular operating departments to use the Imperial College Error CAPture (ICECAP) debriefing tool to self-report intraoperative failures.

- To establish the feasibility and reliability of the ICECAP debriefing approach.

A standardised approach was used to train operating teams in ten vascular operating departments at different sites to use the Imperial College Error CAPture debriefing tool to self-report intraoperative failures. The findings of phase I of the LEAP study suggest that it is feasible for vascular operating teams at multiple sites to use the Imperial College Error CAPture tool to identify and categorise intraoperative failures. Surgeons, anaesthetists and nurses participated in Imperial College Error CAPture debriefs for more than 90% of operations they were involved in. Relatively fewer radiologists and radiographers attended the study debriefs for procedures they were involved in, but the interventional radiology staff who did participate still constituted the majority. In general, the level of participation in the Imperial College Error CAPture debrief suggests that this method of identifying and discussing intraoperative failures is acceptable to vascular operating teams. Compared to the trainer who documented intraoperative failures in a prospective fashion, vascular operating teams identified a similar number and pattern of intraoperative failures. There was good agreement between the trainer and the teams for the number of equipment and communication failures recorded per procedure, and moderate agreement for the remaining failure categories. Operating teams were less likely to report procedure-independent pressures and more likely to report technical errors compared with an observer. Teams reported a greater number of major communication failures and technical problems than the observer.

6.6.2 *Interpretation*

There is increasing recognition that patients are at risk of preventable harm during invasive procedures and efforts are being made to identify aspects of surgical safety that can be improved. To date, there is no consensus on the most effective and reliable methods for investigating the problem of surgical safety. Traditional methods, such as retrospective record review or the review of records held by hospital incident reporting systems, are limited by

selective reporting and the accuracy of the data that has been entered into the record. System issues, which are of primary interest here, are not generally documented in patients' medical notes. Oken and colleagues compared a novel facilitated survey method with records submitted to the hospital's traditional voluntary reporting system for the pattern of non-routine events occurring during anaesthesia (53). The prospective survey method identified a large number of anaesthesia events that were not captured by the hospital's reporting system. Several other studies have used a facilitated survey instrument administered to theatre staff to collect data on intraoperative safety issues (53–55). However, to our knowledge, the study reported here is the first to assess safety failures during arterial intervention.

We asked vascular operating teams to undertake structured debriefs to elicit data on intraoperative failures. The majority of team members participated in this debriefs, although participation by interventional radiology staff was less frequent. In a similar study conducted at a single centre in Michigan, 76% of participating operating staff (n=78) agreed that debriefings were a good opportunity to surface intraoperative safety failures (54). These data support the notion that the structured team debrief approach is feasible and acceptable to operating staff. Barriers to successful implementation of this approach have been previously identified as production pressure and clinical commitments (53). This was also the anecdotal experience of the author of thesis with regards to the present study. In the present study, patterns of intraoperative failure identified by the observer and teams were similar, although the teams identified a greater number of major communication failures and technical errors compared to the observer. In a similar observational study of 'glitches' occurring during surgical procedures undertaken by four different specialties, frontline healthcare professionals identified consistently more intraoperative glitches than an observer trained in human factors research (54). The findings of these studies support the notion that clinical staff are ideally placed to identify and report safety concerns in the operating theatre.

In line with the findings of the present study, Bandari and colleagues found that equipment and communication issues were the most frequent types of failures occurring during surgical procedures at a single centre in Michigan (54). Problems relating to the design and malfunction of equipment were also frequently observed in two studies examining safety failures occurring in the anaesthetic room (53,55). It would be interesting to compare failure rates documented in this study with those of similar studies, but this was not possible due to variation in the units of measurement used for failure rates. Of note, in a recent systematic review of quantitative studies, Weerakkody and colleagues demonstrated that surgical specialties relying on sophisticated technology bear a greater burden of equipment-related

error (95). More work is needed to establish whether vascular surgery, with its rapid uptake of minimally invasive endovascular techniques, exhibits a similar pattern of error.

6.6.3 *Limitations*

The findings of the present study suggest that certain types of intraoperative failure may be vulnerable to under-reporting by operating teams. In particular, procedure-independent pressures were less frequently reported by teams compared to the trainer – perhaps some of these issues, including telephone calls/pagers going off/external staff entering the operating theatre, were rationalised by operating teams as routine events. It is also possible that teams who were focussed on the task at hand did not consider these events to be distracting. Evidence from the original study conducted to investigate the validity of the Imperial College Error CAPture tool suggested that operating teams are less likely to report minor failures compared to a trainer observer (176). As the minor failures documented in this study were not easily distinguishable as unique events, it was not possible to determine whether the trainer and teams had reported the exact same failures. Nonetheless, it is reasonable to assume the minor failures are particularly vulnerable to under-reporting by operating teams because the debrief method requires teams to recall intraoperative events and minor failures are likely to be less memorable than major ones. The use of a structured debriefing tool as a prompt for team-recall of events and the stipulation that the study debrief should take place immediately after the operation are two strategies to minimise recall bias. The disadvantage of using a structured debriefing tool is the potential for selective reporting by focussing the teams' attention of the categories of failure listed on the tool. On the other hand, debriefing with the Imperial College Error CAPture tool has been shown to aid teams to identify significantly more intraoperative failures compared to unstructured team self-report without prompts (176). Accurate and reliable reporting of intraoperative failures by operating teams requires input from all members of the team performing the procedure; it is reasonable to suggest that failures related to anaesthetic equipment, for example, are more likely to be reporting by anaesthetic staff, while technical errors, for example, or more likely to be reported by surgeons. The results of a study such as this are likely to be limited by the level of participation of team members in the Imperial College Error CAPture debrief. As interventional radiology staff only attended two thirds of the debriefs for procedures they were involved in, it could be that certain 'radiology-related' failures are under-reported.

6.6.4 *Generalisibilty*

The data reported here are derived from a large, multi-centre study involving ten centres with diverse characteristics in terms of geographical location arterial case volume. These data support the findings of the original study on the development of the Imperial College Error

CAPture record: the structured team debrief approach is a method that is feasible and acceptable to vascular operating teams to identify a range of intraoperative safety failures. However, it is worth noting that most participating teams were self-selected and these teams may hold a particular interest in patient safety in the vascular operating theatre.

6.7 CHAPTER SUMMARY

This chapter has presented the aims and methods of the LEAP study, which was a multi-centre collaborative effort to better understand intraoperative failures occurring in aortic surgery.

The findings of this 'training phase' of the study suggest that it is feasible for operating teams to use the Imperial College Error CAPture tool to report intraoperative failures. These failure reports are likely to provide valuable insights into the nature of intraoperative system failures that impact upon patient safety during aortic intervention. One caution is that under-reporting of certain categories of failure is likely to be a limitation of this approach.

7 Multi-centre Study of Intraoperative System Failures in Aortic Procedures

7.1 CHAPTER OVERVIEW

The previous chapter presented the methods of the LEAP study and the findings of phase I. This chapter presents the findings of phase II of the LEAP study. The primary aim of the LEAP study was to use a systems approach to develop a better understanding of the landscape of failures occurring in aortic procedures. This chapter presents the frequency and type of intraoperative failures occurring during aortic intervention, as reported by vascular operating teams at ten hospitals in England. The chapter also explores the immediate impact of these failures in terms of patient harm and intraoperative delays.

The original work presented in chapters 7 and 8 was published in the British Journal of Surgery in 2016. A copy of this publication can be found in appendix 17, page 260.

7.2 INTRODUCTION

The model of patient safety underpinning the work presented in this thesis distinguishes between active failures (errors made by frontline healthcare staff) and latent conditions (failures in the system of healthcare). Adverse events are believed to result from a combination of latent system issues and more readily apparent human errors. Identification and correction of system failures is vital to reduce the incidence of preventable patient harm. However, there is no clear gold standard methodology for investigating the pathways that lead to adverse events in healthcare. Retrospective review of patients' medical records and interviews with clinical staff after a harm event has occurred are methods commonly used to try to define the sequence of events leading to a poor outcome. Retrospective methodologies such as these are limited by the nature of information that is documented in medical records and by the ability of clinical staff to accurately recall events. Therefore, although traditional incident investigations play an important role in organisational patient safety agendas, these processes are subject to a number of limitations. In the previous chapter, the use of a structured, debriefing tool by operating teams (the Imperial College Error CAPture tool) was shown to be a feasible method to uncover system failures occurring during vascular

intervention. The key differences between the structured debriefing tool and retrospective methodologies are:

- The debriefing tool enables intraoperative failures to be identified and evaluated in a prospective manner, thereby reducing recall bias compared to post-event interviews with clinical staff
- The debriefing tool prompts reflection on potential system issues that are unlikely to be documented in patients' medical records

In the original work reported in this chapter, the Imperial College Error Capture tool was used by vascular operating teams to self-report intraoperative failures occurring during aortic procedures. Aortic intervention was selected because of its high-risk and complex nature, and because of the significant risk of morbidity and mortality associated with this type of invasive procedure. In this arena, identification of safety issues and implementation of improvement strategies is likely to be of significant benefit to patients.

7.3 AIM AND OBJECTIVES

The overarching aim of the LEAP study was to use a systems approach to develop a better understanding of the landscape of intraoperative failure in open and endovascular aortic procedures.

The specific objectives addressed in this chapter are:

1) To establish the frequency, type and severity of failures occurring during aortic procedures
2) To explore the immediate impact of intraoperative failures in terms of patient harm and procedural delay

7.4 METHODS

The study design, setting, participants and methods used to collect the data for the present analysis were described in the previous chapter.

7.4.1 *Grouping of quantitative variables*

For the purposes of most analyses in presented in this chapter, intraoperative failures are grouped by primary failure category (communication, equipment, procedure-independent pressures, technical, safety awareness and patient-related) and by failure severity (major or minor).

7.4.2 *Analyses*

To address objective 1, descriptive statistics were used to explore the frequency, type and severity of intraoperative failures occurring during aortic procedures. Assessment of failure severity was conducted by independent assessors as per the methods outlined in chapter 6. The relationship between minor and major intraoperative failures was explored using Spearmann's correlation coefficient and univariate Poisson regression.

To address objective 2, the frequency and type of failures causing intraoperative delays and direct harm to patients was calculated. For failures that were considered to be directly associated with patient harm, case report forms were reviewed to identify any additional contributory factors. For illustrative purposes, the precise events leading to two specific incidents of patient harm were sought from the consultant vascular surgeons involved, and these incidents are presented as case studies in the results section.

7.5 RESULTS

7.5.1 *Participating sites*

The same ten sites that were described in the results section of chapter 6 constituted the setting for the study presented in this chapter.

7.5.2 *Patients & procedures*

Twenty consultant vascular surgeons and their operating teams reported failures occurring during 187 aortic procedures during the study period. Only two emergency cases were recruited and were therefore excluded from analyses. Patients and procedures were highly reflective of the population being studied (see Table 7.1 and Table 7.2). Patients were generally older (mean age = 73, SD = 10, range 37-100), male (85%; n=153/180; missing data for gender: n=5), with severe systemic disease (66.5% had an ASA grade of III; n=119/179; missing data for ASA grade: n=6). Most patients were treated for an infra-renal AAA (61.0%; n=111/182; missing data n=3). Patients with juxta-renal aortic aneurysms (n=30), thoracic/arch aneuryms (n= 8); thoraco-abdominal aortic aneurysms (n=15) and aorto-iliac

occlusive disease (n=9) were also recruited into the study. Forty-seven open surgical repairs and 138 endovascular repairs were performed during the study period. Conventional EVAR was the most common procedure type (37.3%; n=69/185), followed by branched/fenestrated EVAR (12.4%; n=23/185) and open infra-renal AAA repair (11.4%; n=21/185). A small number of interventions involving the thoracic and visceral segments were also undertaken during the study period.

Table 7.1: Patient (n=185) characteristics

Mean age (SD, min-max)	**73 (9.9, 37-100)**
Male gender	85.0% (n=153/180)
ASA grade	
I (a normal healthy patient)	1.1% (n=2/179)
II (a patient with mild systemic disease)	24.6% (n=44/179)
III (a patient with severe systemic disease)	66.5% (n=119/179)
IV (a patient with severe systemic disease that is a constant threat to life)	7.8% (n=14/179)
Primary aortic pathology	
Infrarenal AAA	61.0% (n=111/182)
Juxtarenal AAA	16.5% (n=30/182)
Isolated thoracic AA	4.4% (n=8/182)
Thoraco-abdominal AA	8.2% (n=9/182)
Aorto-iliac occlusive disease	4.9% (n=9/182)
Other	4.9% (n=9/182)

SD: standard deviation ASA: American Society of Anesthesiology AAA abdominal aortic aneurysm AA: aortic aneurysm
Percentages account for missing data.

Table 7.2: Procedural (n=185) characteristics

Procedure type	Percentage of cases in sample (n)
Open infrarenal AAA repair	11.4% (n=21/185)
Open juxtarenal AAA repair/ type IV TAAA repair	4.9% (n=9/185)
Open aortoiliac bypass	3.8% (n=7/185)
Open aortofemoral bypass	3.8% (n=7/185)
EVAR (conventional)	37.3% (n=69/185)
EVAR (additional complexity*)	9.7% (n=18/185)
Branched/ fenestrated EVAR (conventional)	12.4% (n=23/185)
Branched/ fenestrated EVAR (additional complexity*)	2.2% (n=4/185)
TEVAR (conventional)	4.3% (n=8/185)
TEVAR (additional complexity*)	3.8% (n=7/185)
Visceral hybrid repair	1.1% (n=2/185)
Other	5.4% (n=10/185)

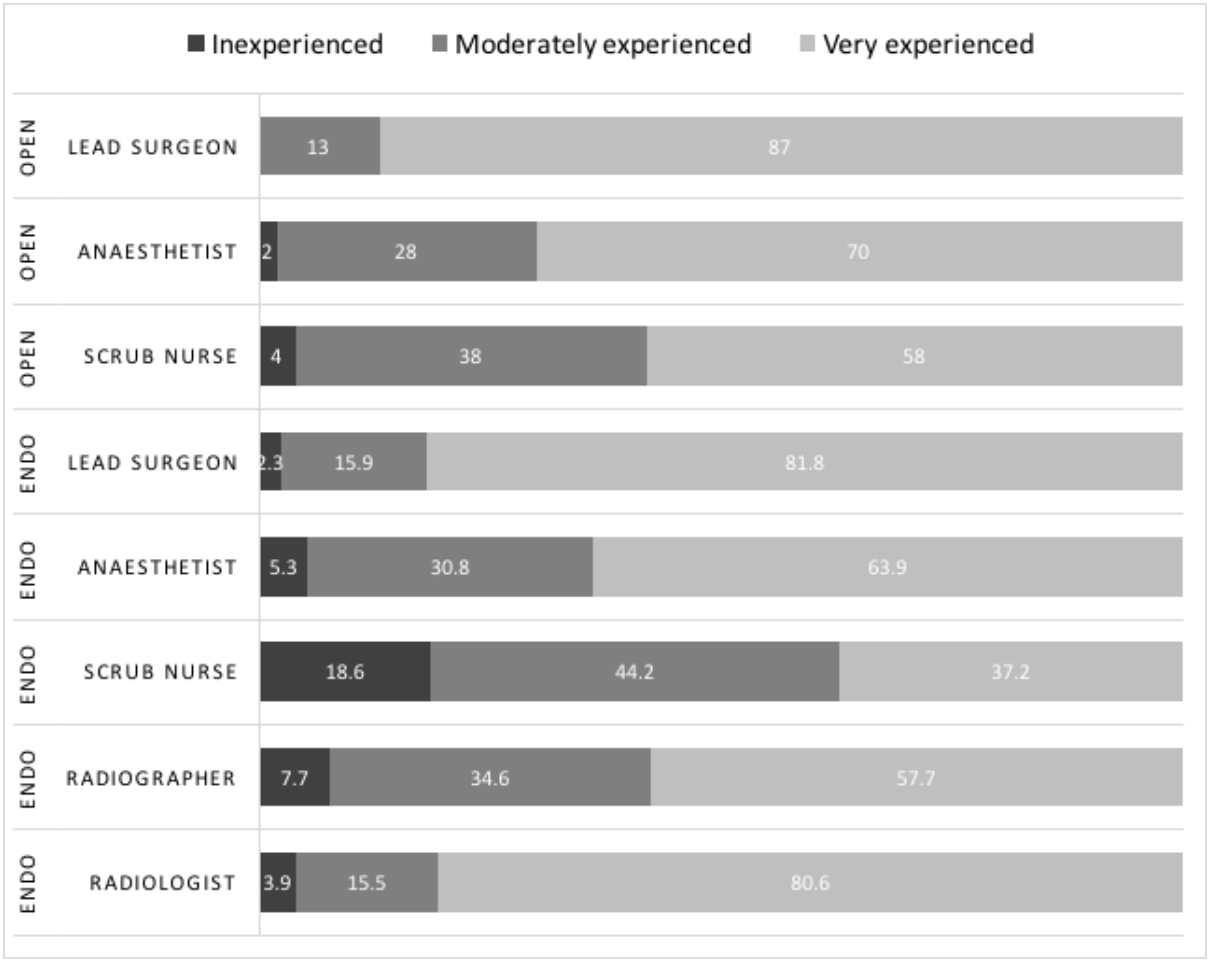
AAA: abdominal aortic aneurysm TAAA: thoraco-abdominal aortic aneurysm EVAR: endovascular aneurysm repair TEVAR: thoracic endovascular aneurysm repair

The aortic procedure log was poorly completed across the ten sites and was therefore unhelpful with regards to assessing selective reporting bias.

7.5.3 *Operating teams*

Team composition and team member experience was reported for 93.6% of open surgical cases (n=44/47) and for 72.5% of endovascular cases (n=100/138). Interventional radiology (IR) staff were involved in all endovascular cases during the study period. All principal operating team members (lead surgeon, senior anaesthetist, scrub nurse, and IR staff where applicable) had performed more than fifty similar cases for 47.7% (n=21/44) of open surgical repairs, compared to 28.0% (n=28/100) of endovascular repairs during the study period (p=0.021, Pearson's chi-square). For 19% (n=19) of endovascular procedures, at least one principal operating team member had performed less than five similar procedures, compared to 6.8% (n=3) of open surgical repairs (p=0.079; Fisher's exact). The most experienced team members tended to be the lead surgeon and the radiologist; the least experienced team members tended to be the nurses – scrub nurses were particularly inexperienced with regards to endovascular intervention (see Figure 7.1).

Figure 7.1: Team member experience across professional groups



Endo: endovascular
Inexperienced: team member had performed < 5 similar cases; moderately experienced: team member had performed 6-50 similar cases; very experienced: team member had performed > 50 similar cases.
Figures represent the proportion (%) of team members performing open surgical procedures (n=45) and endovascular procedures (n=100) within each category of experience.

7.5.4 *Staff participation in the ICECAP debriefs*

Staff participation was recorded for 170 ICECAP debriefs (missing data: n=15). For 44 open surgical procedures, all principal team members (lead surgeon, senior anaesthetist, scrub nurse) were present and participated in more than 90% of ICECAP debriefs (see Figure 7.2). For 141 endovascular procedures, radiologists participated in 69% and radiographers participated in 61% of ICECAP debriefs for the cases they were involved in (see Figure 7.3).

Figure 7.2: ICECAP debrief participation after open surgical cases (n=44)

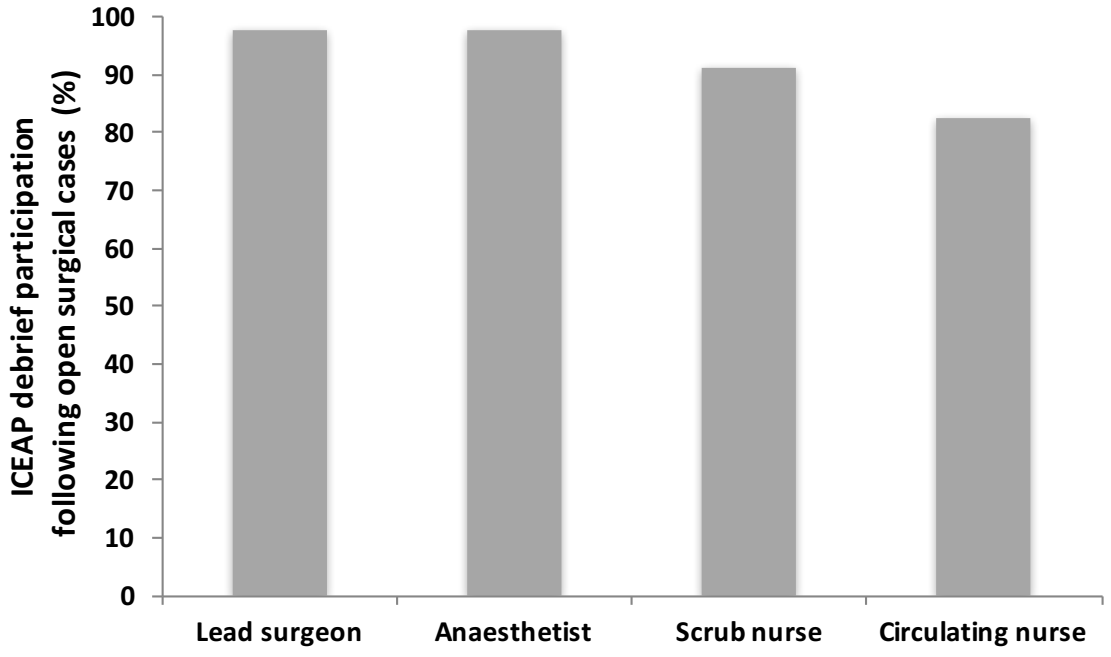
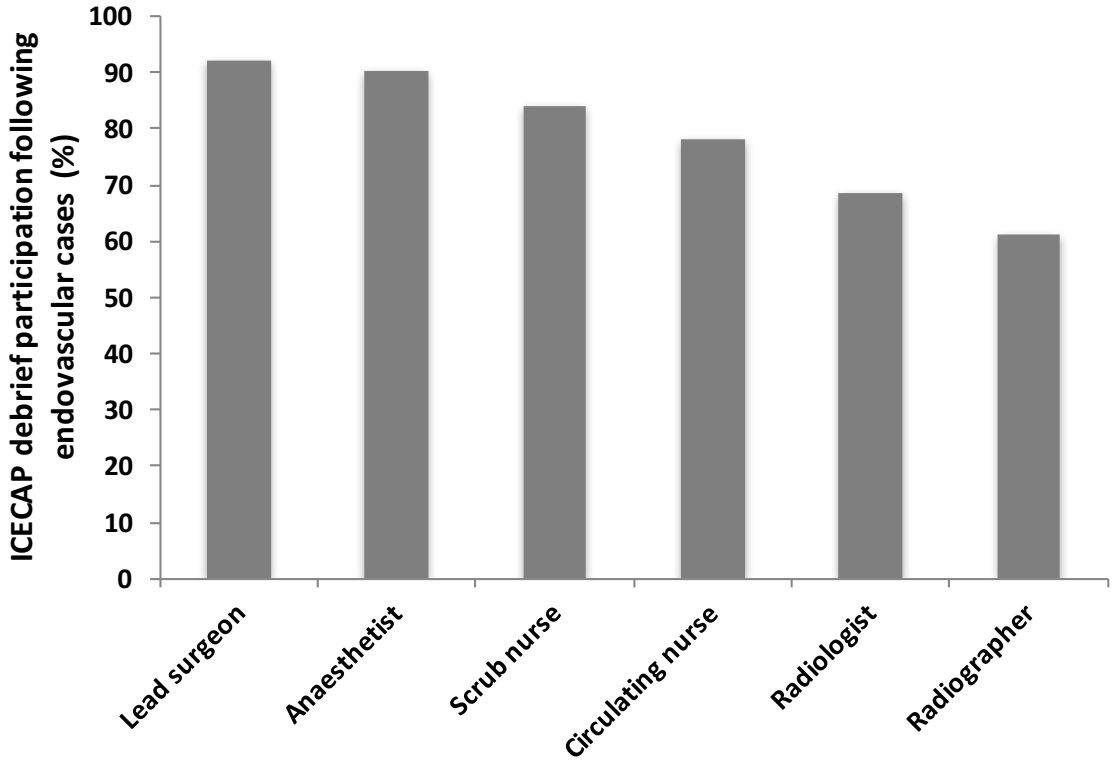


Figure 7.3: ICECAP debrief participation after endovascular cases (n=141)



7.5.5 *Overview of intraoperative failures*

Operating teams reported 930 failure events during 185 aortic procedures. Independent assessors excluded 131 failures that did not meet the study definition of 'failure'. Reasons for exclusion were: event did not occur between the patient entering the operating theatre and the final suture (n=43; example: delayed start due to intensive care bed unavailability); patient-related issue that was likely to have been anticipated prior to the procedure (n=72; example: tortuous iliac arteries identified on pre-operative imaging); other (n=16). The remaining 799 failures occurring during 185 elective cases are presented in further detail below.

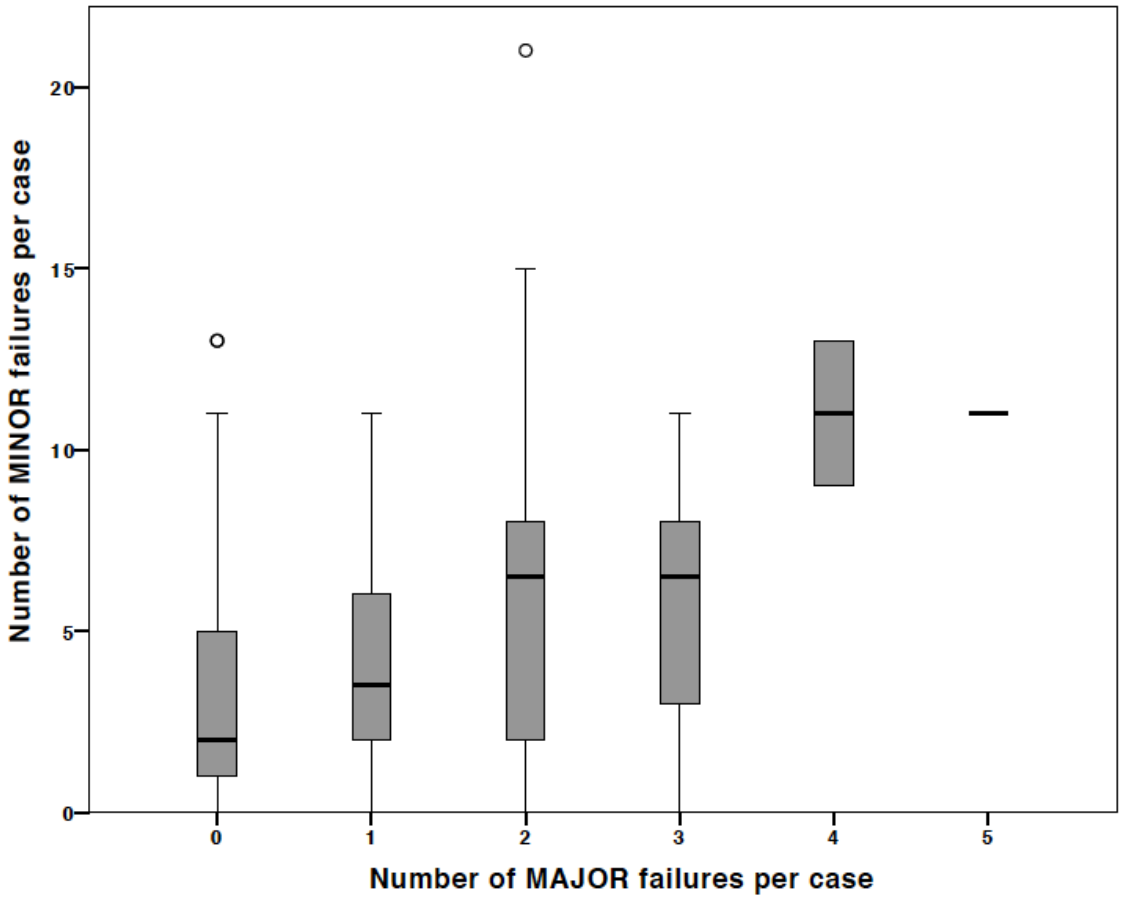
7.5.6 *Frequency of intraoperative failures*

Intraoperative failures occurred during 170 of 185 aortic procedures during the study period (91.9%). Teams reported a median of 3 failures per procedure (IQR = 2-6, range = 0-23). Median failure rate per hour was 1 (IQR = 0.6-2, range 0-6). The correlation between the number of failures occurring intra-operatively and the duration of the procedure was 0.300, p<.001.

7.5.7 *Severity of intraoperative failures*

The majority of failures were considered to be minor (88.4%; n=706/799). These minor failures were considered to have limited potential to directly harm patients and caused minimal or no disruption to procedural workflow. However, major failures occurred during 29.7% of procedures during the study period (n=55/185). Major failures either directly harmed patients, put patients at serious risk of harm, or caused significant disruption to procedural workflow. Median number of *minor* failures per case was 3 (interquartile range (IQR) = 5, range = 0-21). Median number of *major* failures per case was 0 (IQR = 1, range 0-5). There was a moderately positive correlation between the number of major and minor failures per case (r_s = 0.308, p<0.001) (see Figure 7.4). Further investigation into this relationship revealed that for every one unit increase in minor intraoperative failure, major failure count increased by 29% (incidence rate ratio (IRR) = 1.29; 95% confidence interval (CI) = 1.24-1.36, p<0.001).

Figure 7.4: Association between major and minor intraoperative failures



Box plots demonstrate the median values, IQR (box) and Tukey-style 1.5 IQR (whiskers); outliers are represented by dots.

7.5.8 *Types of intraoperative failure*

Figure 7.5 demonstrates the pattern of failures reported during 185 aortic interventions - in this figure, all 799 failures are organised into seven categories (equipment, communication, procedure-independent pressures, technical, patient-related, safety awareness, other) and twenty sub-types.

Figure 7.6 organises the 799 failures by type and severity. Table 7.3 presents illustrative examples of major and minor failures taken from the completed ICECAP records.

Each category of failure is discussed in further detail below.

Figure 7.5: Types of failure occurring during 185 aortic procedures

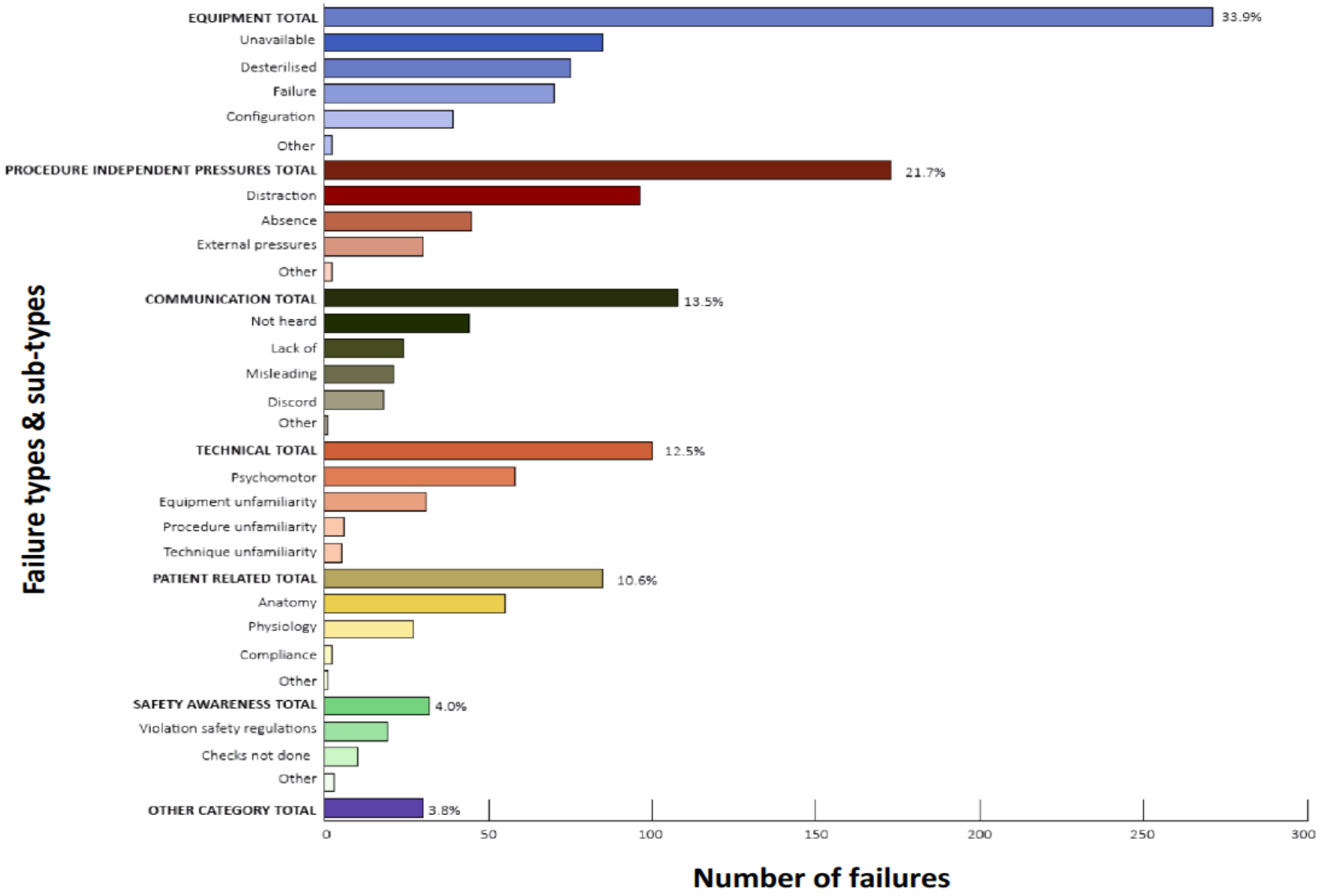


Figure 7.6: Type and severity of failures occurring during 185 aortic procedures

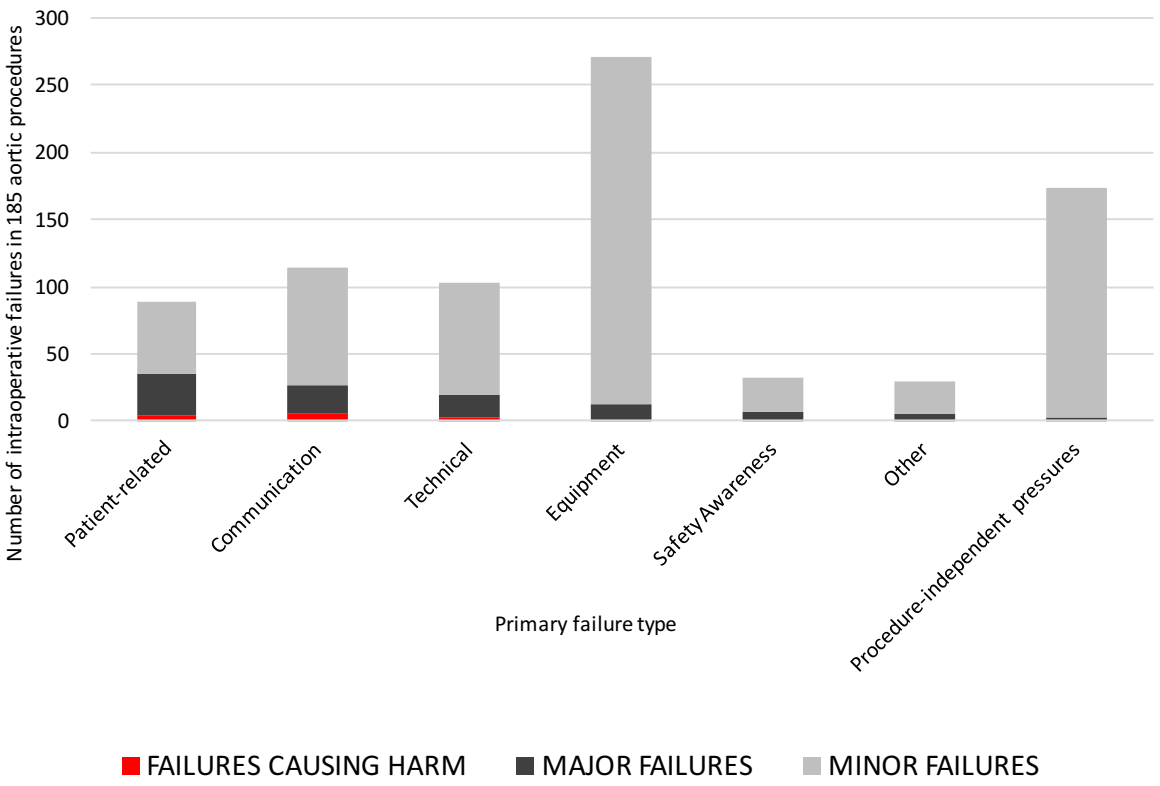


Table 7.3: Illustrative examples of major and minor failures

	Minor Failures		Major Failures	
	n	Example from completed ICECAP records	n	Example from completed ICECAP records
Equipment	**259**		**12**	
Unavailable	78	Ultrasound machine not available	7	Contra-lateral limb not available therefore change in operative plan required
Faulty	65	Contrast pump not working - contrast inject manually	5	C-arm overheated leading to significant delays
Not configured correctly	39	C arm positioning restricted access to the patient	0	-
Desterilised	75	Wire deterilised - clean with betadine	0	-
Other	2	Needle lost	0	-
Communication	**88**		**20**	
Misleading	13	Blood requested urgently as a 'crash bloods' when should be a 'code red'	8	Stent deployed in the wrong position due to miscommunication between radiologist and radiographer regarding which angio run to display
Lack of	16	Surgeons did not inform anaesthetist that clamp was about to be released	8	Wrong incision performed due to lack of communciation between radiologist and surgical team regarding operative plan
Discord	15	Friction between team members due to poor communication about the operating list	3	Conflict between surgeons and nurses while patient bleeding - difficulty in placing pledgeted sutures. Patient became unstable.
Not heard/misheard	43	Anaesthetist did not hear request for heparin administration	1	Instruction from lead surgeon misheard - wrong clamp taken off graft leading to bleeding and haemodynamic instability.
Other	1	Change of staff mid-procedure - handover suboptimal	0	-
Procedure-indepependent pressures	**171**		**2**	
Team member absence	44	Radiologist not available for start of internal iliac artery embolisation	1	Surgical assistant absent therefore procedure took much longer than it should have done.
Distractions/interruptions	96	Theatre phone constantly ringing	0	-
External pressures	29	Needed to vacate angiography suite for a trauma case - pressure to finish procedure urgently	1	Carotid-subclavian bypass completed in theatre but could not transfer patient to angiography suite as room was in use - significant intraoperative delays while waiting for angio suite to become available
Other	2	Bleeding from groin during endovascular phase - radiology nurse not trained to manage open surgical repair. Short delay while waiting for scrub nurse to come from main theatres.	0	-

Table 7.3 continued: Illustrative examples of major and minor failures

	Minor Failures		Major Failures	
	n	Example from completed ICECAP records	n	Example from completed ICECAP records
Technical	**84**		**16**	
Psychomotor error	46	Valve on sheath left open leading to a small amount of bleeding	12	Balloon inflated outside stent in right external iliac leading to rupture of the vessel
Unfamiliarity with the procedure	30	Anaesthetist not familiar with procedure (usual vascular anaesthetist not available)	1	No available assistants with sufficient knowledge/experience of the procedure therefore lead surgeon performed all aspects - procedure significantly longer than necessary
Unfamiliarity with equipment	5	Theatre nurses unfamilar with use of the cell saver machine (do not usually work in vascular theatres)	1	Team not familiar with nellix kit - long delays intraoperatively
Unfamiliarity with a technique	3	Assistant not familiar with endovascular techniques - both sheaths came out	2	Scrub nurse not familiar with how pledgeted sutures are used - increased pressure while patient bleeding and unstable
Safety awareness	**25**		**7**	
Safety checks omitted	17	'Time out' not performed	2	WHO surgical safety checklist completely omitted
Violations of safety regulations	7	Staff entered theatre without lead on during screening	3	Circulating nurse not scrubbed - pressed on groin while groin open
Other	2	Radiologist not present for WHO checklist	1	Proper checks for blood transfusion not done
Patient-related	**54**		**31**	
Anatomy	31	Small iliacs - unable to pass 24fr sheath	24	Dissection (unanticipated) in left common iliac artery - took 1.5 hours to repair
Physiology	21	Difficult to control hypertension	7	Patient developed ST depression/washout acidosis after removal of clamp
Other	2	Patient did not tolerate LA - conversion to GA	0	-

7.5.9 *Equipment failures*

The most frequently reported failures related to equipment problems (33.9%; n=271/799). Equipment unavailability (items not available at the time they were needed) was the most common equipment-related issue (n=85/271). Most equipment issues (95.6%; n=259/271) were considered to be minor issues; these were generally compensated for by retrieving stock from a different department or by using an alternative item (e.g: "straight 7 french sheath not available - curved sheath used instead"). However, 66.7% (n=181/271) of equipment issues caused procedural delays. Most *major* equipment failures (n=11/12) occurred during endovascular procedures and either related to direct malfunction of the stent or delivery device (n=5) or to unavailability of the desired type/size of stent (n=6). The primary operator reported being unfamiliar with one or more items of equipment in one open surgical procedure and in seventeen endovascular procedures. Unfamiliarity with stent-graft devices was the most commonly reported issue (n=11/18).

7.5.10 *Procedure-independent pressures*

Procedure-independent pressures occurred frequently (n=173/799), but were not directly associated with any instances of patient harm intraoperatively. Distractions accounted for more than half of these failures (n=96/173) and these were primarily due to telephones/pagers ringing or noise due to conversations unrelated to the operation. Teams also reported being affected by external pressures (n=30/173). External pressures were sometimes the result of external emergencies (n=6/30), but staff also described production pressure related to elective cases (n=6/30) and pressure to answer queries/organise care for other patients (n=8) - for example, during one case, the anaesthetist had to leave to find a post-operative bed for another patient.

7.5.11 *Communication failures*

Communication failures accounted for 13.5% (n=108/799) of all intraoperative failures, but they were the most severe in terms of the direct association with patient harm intraoperatively. They also accounted for 21.5% (n=20/93) of all major errors, which either caused significant intraoperative delays or put the patient at serious risk of harm. Although teams frequently reported not hearing instructions/information (n=44/108 communication failures), the most serious communication failures were caused by either a lack of communication or by misleading communication between different members of the multi-disciplinary team (n=16/20 major communication failures). For example, a lack of communication between the surgical and interventional radiology staff regarding the procedure resulted in the wrong incision being performed on one occasion. On another occasion, miscommunication between the lead

operator and the radiographer led to incorrect placement of the stent as a result of the wrong angiography run being displayed and marked.

7.5.12 *Technical failures*

Technical failures were reported less frequently overall (n=100/799). Most technical failures were either considered to be 'psychomotor errors' (n=58/100) or technical errors related to unfamiliarity with equipment (n=31/100). Technical errors were directly associated with four instances of patient harm intraoperatively (see Figure 7.6).

7.5.13 *Patient-related issues*

Unanticipated patient-related problems account for 10.6% (n=85/799) of all intraoperative failures. More than a third of patient-related issues (n=31/85) were deemed to be 'major' because they caused long intraoperative delays while teams tried to mitigate the challenges posed by unanticipated difficulties related to the patient's anatomy (n=24/31) or physiology (n=6/31).

7.5.14 *Safety-awareness failures*

Safety awareness failures accounted for only 4.0% (n=32/799) of all reported failures. Eleven of these failures related to omission of aspects of WHO Surgical Safety checklist or team member absence for the 'time-out' procedure. Eight failures related to staff entering theatre during screening without wearing protective lead clothing.

7.5.15 *Immediate impact of intraoperative failures*

Nearly two thirds of all failures (62.9%; n=503/799) caused intraoperative delays and 9.8% (n=78/799) of failures led to significant and unnecessary intraoperative delays (pauses longer than fifteen minutes preventing the procedure from progressing).

More than one third (33.8%; n=270/799) of failures required corrective action by operating teams. In most cases, teams were able to mitigate the effects of intraoperative failure to prevent any impact on the patient. However, fourteen failures were directly associated with harm (cardiovascular instability and/or the need for further invasive procedures) in twelve patients (6.5% of the study cohort) (see Table 7.4).

Table 7.4: Failures directly associated with harm (n=14) in 12 patients

Failures details	Failure type as categorised by the reporting team	Contributory factors (inferred from review details reported on ICECAP records)
"Wrong incision. Team in theatre were not aware that operation was aortouniliac and fem fem crossover - only radiologist was aware, wrong incision done but able to complete aorto uni iliac procedure without further incision." (EVAR & fem-fem crossover)	Lack of communication between team members	Involvement of two sub-teams: surgical & interventional radiology
"Bleeding from a branch of the internal iliac vein - suture with pledgets placed. Scrub nurse did not know or understand the sequence of events for placing this type of suture. The sutures were placed accurately but were pulled out, tearing the main internal iliac vein trunk. Next suture knotted. There was substantial discord between the surgeons and nursing staff during this period in which the patient was acutely unstable due to significant blood loss with hypotension and need for rapid transfusion." (EVAR with iliac conduit & surgical ligation of IIA)	Discord between team members	Inexperience of scrub nurse Experienced nursing staff not available Lack of training
"Wrong sized limb was placed during EVAR necessitating subsequent embolisation of the internal iliac artery and placement of an extra limb extending down to external iliac artery. Unclear whether wrong graft ordered or wrong size selected from stock. There was miscommunication between consultant and registrar, lack of clarity over roles during the procedure and registrar had not attended the morning briefing." (EVAR & fem-fem crossover)	Lack of communication between team members	Inexperience of registrar Registrar absent from safety briefing Lack of clarity over roles and responsibilities during the procedure Lack of vigilance/safety awareness
"Anaesthetic consultant changed intraoperatively. No blood transfused after initial 2 units. Patient suffered cardiac arrest in angio suite immediately post procedure and required re-intubation." (TEVAR)	Lack of communication between team members	Shift changes and the need to handover care intraoperatively Patient with severe systemic disease
"Patient bleeding. Delays obtaining blood units- blood transfusion department claims blood was not cross-matched, yet surgical team was informed that cross-matched blood was available prior to the procedure." (TEVAR)	Misleading communication between departments	Involvement of different staff and different departments at various stages of the patient pathway
"Miscommunication between lead surgeon and assistant. Wrong clamps taken off the graft leading to significant blood loss and hypotension." (Visceral Hybrid Repair)	Misleading communication between team members	Inexperience of surgical assistant Highly complex procedure
"Theatre staff unfamiliar with how to use the cell salvage machine. Consequently, there was confusion about how much blood had been collected, and the team were unable to reliably communicate the degree of blood loss to the anaesthetist. Patient cardiovascularly unstable." (Open AAA repair)	Misleading communication between team members	Inexperience of team members Experienced staff not available Lack of training

Table 7.4 continued: Failures directly associated with harm (n=14) in 12 patients

Failures details	Failure type as categorised by the reporting team	Contributory factors (inferred from review details reported on ICECAP records)
"Iliac sheath removal led to rupture of vessel – massive blood loss. Patient became acutely unstable and required immediate stenting and laparotomy" (TEVAR extension for type 1A endoleak)	Technical: psychomotor error	Poor quality vessel High-risk patient: ASA grade III
"Injury to iliac vein leading to massive blood loss and haemodynamic instability" (Open AAA repair)	Technical: psychomotor error	No contributory factors could be inferred
"Balloon blown up outside of stent in right external iliac leading to rupture of the vessel, significant blood loss and hypotension. Stent extended with aortic balloon control." (EVAR)	Technical: psychomotor error	No contributory factors could be inferred
"Injury to inferior vena cava on closing requiring repair – blood loss +++" (Aorto-bi-iliac bypass)	Technical: psychomotor error	No contributory factors could be inferred
"Difficult top end. Anastomosis performed and tested- split due to plaque posteriorly leading to significant blood loss and hypotension." (Open AAA repair)	Patient-related	No contributory factors could be inferred
"Difficult anatomy (unanticipated dissection in left common iliac artery) led to need for further anastomosis (jump graft). Hypotension caused by blood loss & reperfusion during this additional procedure." (Open AAA repair)	Patient-related	No contributory factors could be inferred
"Left renal artery thrombosed. Attempted thrombectomy." (FEVAR)	Patient-related	Procedural delays caused by equipment problems: stent delivery catheter was not adequate (operative plan had to be changed); C-arm overheated during the procedure. Unfolded arch of aorta – brachial access difficult – femoral access adopted.

Teams categorised half of these harm-producing failures as 'communication' problems (n=7). However, review of case report forms revealed several additional factors that likely contributed towards the harm incidents – these factors included:

- inexperience of team members
- inadequate training
- the involvement of different staff and departments along the patient pathway
- the involvement of different sub-teams in the procedure
- the complexity of the procedure and the severity of the patient's disease.

The two case studies presented below are included to illustrate the multi-factorial nature of the causal pathways leading to harm events. Although the incident in case study 1 was primarily categorised as a communication failure, factors that additionally contributed to placement of the wrong-sized stent included team member inexperience, lack of vigilance, and a lack of clarity over roles and responsibilities. Similarly, in case study 2, the episode of uncontrolled bleeding was primarily considered as a result of discord between the surgeons and the nursing staff, yet it is clear that inexperience and a lack of training contributed to this incident.

Case study 1

An 82-year-old male, with an ASA of III, was an elective admission for an EVAR & left to right fem fem cross over.

During the procedure, the wrong sized limb was placed. This error necessitated subsequent embolisation of the internal iliac artery and placement of an extra limb extending down to external iliac artery. After a delay of 35 minutes, the procedure was completed without further sequelae. The patient was discharged 4 days following the procedure with no complications.

Immediately after the procedure, the vascular consultant led the team debrief. It remained unclear whether the wrong limb had been asked for or whether the wrong limb was given. However, the limb size was not checked by the operator, who was the registrar performing the procedure, prior to it being placed.

Confounding factors were a new vascular registrar performing the EVAR, without this being discussed beforehand. There was a lack of clarity over the registrar's experience and over the roles of the registrar and the consultant as the two operators. The registrar had also been absent from the morning safety briefing.

The following changes in practice were implemented following this event:

- More vigilance in checking equipment.
- Grafts are checked with radiology staff before the start of the procedure.
- During the pre-operative safety briefing, the consultant asks for vigilance in checking sizes when opening grafts.
- The radiology staff now attend the pre-operative safety briefing, and this has been rolled out across the entire unit.

Case study 2

A 75 year old male (ASA grade of III) with an infrarenal AAA was scheduled to undergo an EVAR & internal iliac artery (IIA) embolisation.

During the procedure the IIA could not be embolised and after stent graft insertion the IIA was suture ligated through a flank incision and retroperitoneal dissection. There was bleeding from a branch of the internal iliac vein. A suture with pledgets was placed. The (non-vascular, inexperienced) scrub nurse did not know or understand the sequence of events for placing this type of suture. The sutures were placed accurately but were pulled out, tearing the main internal iliac vein trunk. The next suture knotted.

There was substantial discord between the surgeons and nursing staff during this period in which the patient became acutely unstable due to significant blood loss with hypotension and need for rapid transfusion.

Post-operatively, the patient developed respiratory complications and died in hospital.

This event resulted from failures in planning, training and communication, and may have been prevented if better explanations of the task had been given.

The surgeon acknowledges that he is responsible for mentally preparing and training the team for these situations. Since these patient safety studies were conducted, a weekly programme of multidisciplinary team training has been implemented at this site for all staff involved in vascular intervention.

7.6 DISCUSSION

7.6.1 *Summary of findings*

The study presented in this chapter aimed to develop a better understanding of intraoperative safety failure during aortic intervention. Intraoperative safety failures seem to occur during the majority of aortic procedures. While most intraoperative failures appear to have little or no immediate impact, the findings of this study suggest that there is a relationship between minor failures and the occurrence of major failures that harm or endanger the patient. Interruptions, distractions and equipment-related problems seem to occur frequently during aortic interventions. However, events that culminate in haemodynamic instability and/or the need for invasive corrective action are generally the result of poor communication between team members or technical error. Related to these harmful events are latent failures such as inadequate training and inexperience. Unfamiliarity with equipment appears to be related to major failures primarily during endovascular intervention.

7.6.2 *Interpretation*

In line with similar studies conducted in other surgical specialties (31,54,58), the present work demonstrates that many failures leading to patient harm during surgery stem from failures in the system. Team factors, problems in the operating environment, and external pressures have all been documented in previous safety studies in the operating theatre (31,54,56,58).

However, this is the first large-scale study to adopt a systems approach to understanding safety in aortic intervention.

Of note, participating teams reported a slightly lower failure rate in phase II of the LEAP study (median of 3 failures per procedure (IQR = 2-6, range = 0-23) compared to phase I (median of 4 failures per procedures (IQR = 4, range = 0 – 14) despite the fact that the aortic procedures in phase II were likely to be longer and more complex than the phase I arterial procedures. While this observation may reflect a reporting bias - influenced by the presence of the trainer in theatre in phase I and the absence of the trainer in theatre in phase II - the reduction in failure rate may also reflect learning and safety improvement as a result of safety-conscious teams' participation in phase I of the study. Compared to a similar study of intraoperative 'glitches' in orthopaedic, vascular, trauma and plastics procedures, the rate of intraoperative failures was lower in the present study (median number of failures per procedure = 5, compared to a median number of failures per procedure = 14 in Morgan's study (58)). In their study, Morgan and colleagues found no significant difference in glitch rates between surgical specialties. Given the complex nature of aortic intervention, the lower intraoperative failure rate reported in the present study seems counter-intuitive. The discrepancy in failure rates is likely to be explained by difference in methodology. Morgan's study used a method in which two observers, one with human factors expertise and one with a surgical background, observed surgical procedures and documented intraoperative glitches in real time (58). Prospective reporting using direct observational methods with multiple observers in theatre is likely to provide estimated failure rates closer to the true incidence of failures in surgery. However, such methods are time-intensive and not suitable for widespread application. Of note, Morgan and colleagues did not report the clinical impact of intraoperative glitches (58). The benefits of team self-report of intraoperative failure – the method used in the present study - is the ability of the clinical team to assess the immediate impact of the failure in terms of procedural efficiency and patient harm; these direct consequences may not be immediately apparent to an observer.

Despite the potential for under-reporting intraoperative failures, this study found that for every additional minor failure that occurred, the risk of major failure increased by 29%. Therefore, seemingly inconsequential failures may accumulate to cause major intraoperative failures that put the patient at serious risk of harm. This 'snowball effect' has been documented in previous studies of safety in anaesthesia and in paediatric cardiac surgery (31,53), and its finding in this study highlights the need to pay attention to intraoperative events that are non-injurious and not generally considered worthy of investigation.

This study identified a number of system failures and latent conditions that are likely to negatively impact on the safety of patients undergoing aortic intervention. In this study, teams at all ten participating sites frequently experienced procedure-independent pressures (interruptions/distractions and team member absence). These issues are likely to reflect wider institutional problems related to staffing levels and the organisation of medical-surgical cover for clinical areas outside the operating theatre. Although external pressures were not considered to have a direct impact on the safety of the patient on the operating table, these external issues may place demands on the teams' time and attention that consequently reduce their capacity to compensate for more serious events when they arise. This may explain why the risk of major failure increased as the rate of minor failure increased. This phenomenon has also been observed when failures occur during complex paediatric cardiac operations and the authors of that study provide a similar explanation for this observation in their discussion (144).

In this study, communication failure was identified as the root cause of several incidents of patient harm. This is not surprising given the wealth of literature providing evidence to support this relationship in other surgical specialties (86,99,177). However, the problem of communication failure is exacerbated in aortic intervention. Some of the illustrative examples of communication failure presented in this study highlight the particular features of aortic intervention that make this type of surgery particularly prone to communication failure – namely: the involvement of two primary sub-teams (surgical and interventional radiology, as is common practice for endovascular intervention in the UK), and the need to handover care from one team member to another during lengthy aortic procedures. These features of aortic intervention require further attention as intraoperative handover of anaesthetic care during cardiac procedures has been associated with poorer patient outcomes compared to operations where the consultant anaesthetist was consistent throughout (87). Aortic intervention is also characterised by the use of rapidly evolving endovascular techniques. This study has highlighted that endovascular intervention often involves team members (particularly scrub nurses) who are inexperienced; unfamiliarity with stent-graft devices also appears to be common. Vascular operating teams are using an increasingly wide range of stent-graft devices to treat a broad range of anatomical configurations, and it is challenging for all members of the operating team to stay abreast of emerging technology. Cumulative team experience iikely to be important - a study conducted in cardiac surgery demonstrated that cumulative team experience had a greater effect on cardiopulmonary bypass and crossclamp times than the individual experience of the lead surgeon (91).

7.6.3 *Limitations*

As discussed in the previous chapter, under-reporting is likely to be a limitation of the approach used to collect data in this study; various strategies were implemented to minimise this risk as previously described and we did not seek to accurately define intraoperative failure rates. Of note, around a third of interventional radiology staff did not attend the ICECAP debriefs for the procedures they were involved in in phase II of the study – therefore, radiology-related failures may have been under-reported. As the aortic procedure logs were completed poorly, it is not possible to establish whether consecutive patients were included in the study. However, the demographic of this cohort reflects a broad spectrum of procedural complexity suggesting that selection bias is likely to be minimal. In this study, unanticipated patient-related issues were recorded and documented as failures. While some of these patient-related problems may point to failures in planning or preparation, a more appropriate measure of safety may focus on how successfully operating teams mitigate these unexpected patient issues – this point should be considered in the design of future studies.

7.6.4 *Generalisability*

This was a multi-centre study involving ten vascular operating departments with diverse characteristics in terms in terms of geographical location and aortic case load, and the patients and procedures studied are typical of the population of vascular patients undergoing elective aortic intervention in NHS hospitals in England. However, study participation was voluntary and therefore these findings are likely to reflect practice within centres with a particular interest in patient safety.

7.7 CHAPTER SUMMARY

The work presented in this chapter has led to a greater understanding of the nature of intraoperative safety failure in aortic intervention. A number of safety improvement targets have been identified and this study has highlighted the potential importance of events that are seemingly inconsequential in isolation. To provide further insights into the nature of safety failure during aortic intervention, the next chapter will explore determinants of intraoperative failure, and the relationship between intraoperative failure and post-operative outcome.

8 Determinants of Intraoperative Failure and the Relationship Between Intraoperative Failure and Postoperative Outcomes

8.1 CHAPTER OVERVIEW

This chapter presents a quantitative analysis of the data collected in phase II of the LEAP study in order to address the secondary aims of the study, which were to establish patient, procedure and team predictors of intraoperative failure and to explore the relationship between intraoperative failures and post-operative outcomes.

8.2 INTRODUCTION

The previous chapter outlined a range of system failures and latent conditions that may endanger the patient during aortic intervention. A minority of failures appear to be directly associated with haemodynamic instability or the need for additional invasive intervention and while most failures appear to be relatively minor - even these may combine to cause harm. To develop a greater understanding of safety during aortic intervention, it is important to establish whether certain patient, procedure or team characteristics influence intraoperative failure rates. It is also important to establish whether intraoperative failures translate into poorer post-operative outcomes.

8.3 OBJECTIVES

This chapter addresses the secondary objectives of the LEAP study, which were:

1) To establish patient, procedure and team predictors of intraoperative failure

2) To explore the relationship between intraoperative failures and post-operative outcomes.

8.4 METHODS

The study design, setting, participants and methods used to collect the data for the present analysis were described in the previous chapter.

8.4.1 *Handling of quantitative variables*

To address objective 1, various patient, procedure and team groupings were considered as possible explanatory variables – these are outlined in Table 8.1. In these analyses, dependent variables were intraoperative failure rate (failures per hour) and major intraoperative failure rate (major failures per hour). To account for differences in operative duration between different groups of patient, procedure and team variables, the number of intraoperative failures was presented as the failure rate (failures per hour).

Table 8.1: Predictive variables considered in the regression model

Patient variables	Procedure variables	Team variables
Age Gender ASA grade Aortic pathology	*Type*: Open surgical/ endovascular *Site of repair:* thoracic aorta/abdominal aorta/involving the visceral segment	Team experience Team profile (composition of staff) Familiarity with equipment

To address objective 2, outcome measures were unplanned return to theatre, post-operative complications, length of stay and in-hospital mortality within 30 days of the procedure. The independent variable was the number of failures (total, minor, major) occurring during a procedure. A poor post-operative outcome may relate (directly or indirectly) to one or more intraoperative failures yet be unrelated to the overall failures rate (failures per hour), thus it was not deemed necessary to account for operative duration in the tests of association between intraoperative failure and post-operative outcome.

8.4.2 *Grouping of quantitative variables*

In order to facilitate statistical analyses, certain variables were grouped as described below.

Patient variables: ASA grade I and II were treated as a single categorical variable due to the small number of patients in each sub-category. The variable 'aortic pathology' reflected the anatomical location of disease and contained four groupings: (i) thoraco-abdominal aortic aneurysms; (ii) isolated thoracic/arch aortic aneurysms; (iii) infra-/juxta-renal aortic aneurysms and aorto-iliac occlusive disease; (iv) other (e.g. type 1 endoleak, false aneurysm at site of previous repair).

Procedure variables: similar to 'aortic pathology', the variable 'procedure type' contained four groupings: (i) repair involving the visceral segment; (ii) TEVAR; (iii) open infra-/juxta-renal repair/ EVAR/ open aorto-iliac/femoral bypass graft; (iv) other (e.g. stent relining, extension of previous endovascular repair). Procedures were also considered as either 'open surgical' or 'endovascular' repairs in order to reflect the nature of the equipment/technology used during the procedure as well as the clinical staff involved. Procedures were grouped under the heading 'endovascular' repair if they involved an endovascular component even if open surgical techniques were required for arterial access or for extra-anatomical bypass grafting.

Team variables: the variable 'team member experience' contained two groupings – 'experienced' and 'less experienced'. Each profession within the team was considered separately. Each healthcare professional was considered to be experienced if they had performed greater than fifty similar cases – this figure was chosen pragmatically because the learning curve is likely to differ between different groups of procedure type and professional background. Team profile was based on team composition and contained two groupings: operating teams with and without the involvement of interventional radiology staff. The variable 'familiarity with equipment' was also a binary variable, and reflected the familiarity/unfamiliarity of the lead operator with any item of equipment. This was a subjective assessment of familiarity made by the lead operator and was not based on a quantitative measure of the number of times the operator had used the equipment item.

Post-operative complications: due to the relatively small number of patients developing serious post-operative complications, complications were grouped into two categorical variables. Complications assigned a Clavien-Dindo score of III, IV or V were classed as 'major complications' and complications assigned a Clavien-Dindo score of I or II were considered to be 'minor complications' (178).

8.4.3 *Statistical methods*

Objective 1: Univariate and multivariable Poisson regression analyses were used to compare intraoperative failure rates (failures per hour) for different groups of patient, procedure and team variables described above. Poisson regression can be used to model the count of events occurring within a specific time period while controlling for confounding variables (179,180). Poisson regression was therefore appropriate for this analysis, which aimed to understand the relative independent effects of patient, procedure and team variables on the number of intraoperative failures per hour. An important assumption of the Poisson model is that the dependent variable is not over-dispersed (181) - the variable 'failures per hour' followed a Poisson-like distribution (i.e. the mean and the variance were approximately equal and it was assumed that intraoperative failures occur infrequently and in a random fashion). For both univariate and multivariable analyses, an incidence rate ratio (IRR) with 95% confidence intervals (95% CI) was calculated for each group of a predictive variable. IRRs can be interpreted in a similar manner to relative risk ratios (180); the IRR provides a relative measure of the effect of different groups of a given predictive variable on a dependent variable. Where the 95% CI for the IRR excludes 1.0, this indicates a statistically significant difference between intraoperative failure rates for different groups of a given variable. The Poisson regression model calculates the IRR of intraoperative failures for each of the predictive variables, adjusted for the other variables included in the regression (180). Cut-off for inclusion in the multi-variable model was a significance level of .01 in univariate analyses. The variables 'site of aortic repair' and 'team profile' were not included in the multivariable model due to multicollinearity with the variables 'aortic pathology' and 'procedure type (open vs. endovascular)', respectively. Collinearity is a term that is used to depict non-independence of predictive variables - it is problematic because it overinflates standard errors, potentially leading to incorrect identification of predictors in a regression model (182,183). Although all operating teams were trained to report intraoperative failures in the same structured manner, the clustering effect due to potential variability in reporting across the 10 hospitals was taken into account in the regression using cluster robust standard errors.

Objective 2: The Wilcoxon rank sum test was used to test whether patient outcomes were associated with intraoperative failures. The Bonferroni correction was not deemed appropriate for this exploratory analysis. All reported P values are two-sided. P <.05 was deemed to indicate statistical significance.

8.5 RESULTS

8.5.1 *Determinants of intraoperative failure*

Patient variables: In univariate analyses, patient age, gender and ASA grade were not associated with increased failure rates (see Table 8.2). However, compared to other aortic pathologies, isolated thoracic/arch aneurysms (n=9) predicted a significantly higher failure rate (incidence rate ratio (IRR) = 2.30 (95% CI: 1.45-3.63), p<.001) and isolated thoracic/arch aneurysms remained a significant predictor of increased intraoperative failure rate in multivariable analyses (IRR=2.07 (95% CI: 1.39-3.08), p<.001) (see Figure 8.1).

Procedural variables: Repairs involving the visceral segment (open juxtarenal/type IV repairs, FEVAR, visceral hybrid procedures) were associated with lower intraoperative failure rates (IRR = 0.65 (95% CI: 0.54-0.79), p<.001) in univariate analyses. Site of aortic repair was not considered in the multivariable model due to collinearity with aortic pathology. In univariate analyses, open surgical procedures were associated with lower intraoperative failures rates compared to endovascular procedures (IRR = 0.64 (95% CI 0.49-0.86), p=.003). Endovascular repair remained a significant predictor of increased failure rate compared to open repair in the multivariable model (IRR for open surgical procedures = 0.71 (95% CI 0.57-0.88), p=.002).

Team variables: In univariate analyses, level of experience was not associated with intraoperative failure rate for most professional groups in the vascular operating team. The presence of an experienced radiographer appeared to be associated with a higher intraoperative failure rate (IRR = 1.49 (95% CI 1.04-2.13), p=.03). As this association did not reach a significance of <.01, it was not included in the multivariable model. Teams composed of surgical and interventional radiology (IR) staff were associated with higher intraoperative failure rates compared to teams composed of only of surgical staff (IRR = 1.54 (95% CI 1.16-2.05), p=.003) in univariate analyses. Team profile was not included in the regression model due to collinearity with procedure type (open vs. endovascular repair).

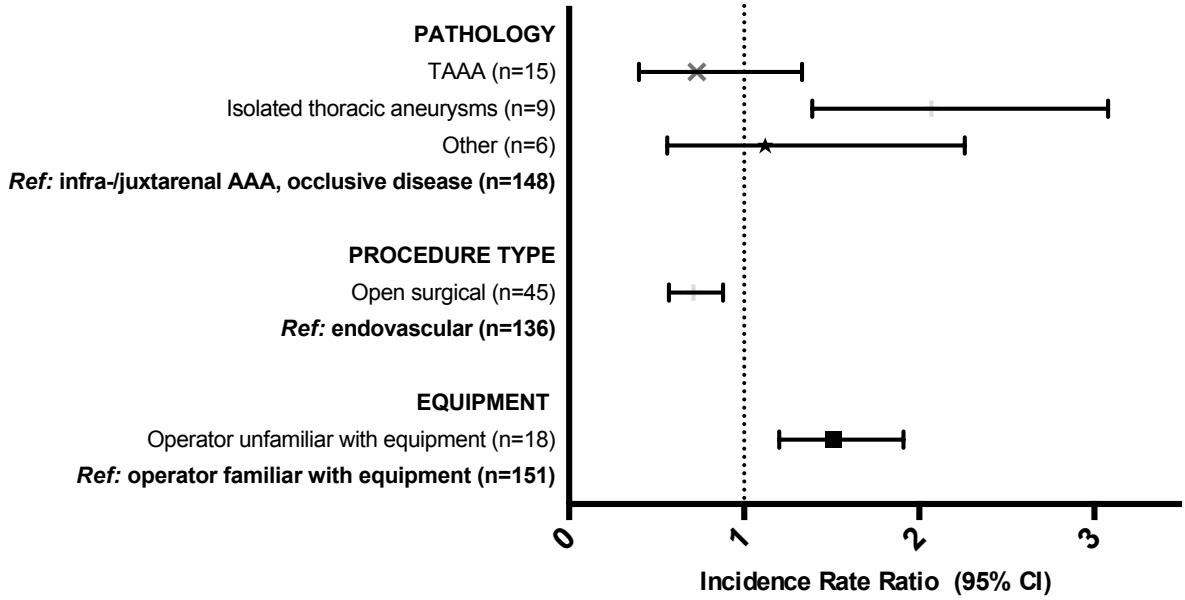
Operator unfamiliarity with equipment demonstrated an association with increased failure rate in univariate analyses (IRR = 1.63 (95% CI 1.35-1.96), p<.001) and this association remained significant in multivariable analyses (IRR = 1.52 (95% CI 1.20-1.91), p<.001). Of note, the primary operator reported being unfamiliar with one or more items of equipment during one open surgical procedure and in seventeen endovascular procedures. Unfamiliarity with stent-graft devices was the most commonly reported issue (n=11/18).

Table 8.2: Univariate analyses for intraoperative failures per hour

Variable	Incidence Rate Ratio (95% CI)	P-value
PATIENT VARIABLES		
Age	0.99 (0.96-1.02)	0.652
Gender:		
Male (n=150)	(ref)	
Female (n=27)	0.81 (0.53-1.24)	0.336
ASA grade:		
ASA I & II (n=45)	(ref)	
ASA III (n=117)	1.09 (0.76-1.59)	0.619
ASA IV (n=13)	1.48 (0.91-2.40)	0.11
Aortic pathology:		
Infra-/juxtarenal AAA, occlusive disease (n=148)	(ref)	
TAAA (Types I, II, III, IV) (n=15)	0.79 (0.39-1.60)	0.514
Isolated thoracic AA, arch aneurysm (n=9)	2.30 (1.45-3.63)	<0.001
Other (n=6)	1.35 (0.66-2.77)	0.408
PROCEDURE VARIABLES		
Primary approach:		
Endovascular (n=136)	(ref)	
Open surgical (n=45)	0.64 (0.49-0.86)	0.003
Site of repair:		
Open infrarenal AAA repair, open aortoiliac & aortofemoral bypass, EVAR (n=120)	(ref)	
Open juxtarenal/Type IV TAAA repair, FEVAR, Visceral Hybrid (n=36)	0.65 (0.54-0.79)	<0.001
TEVAR (n=15)	1.52 (0.74-3.12)	0.251
Other (n=10)	0.95 (0.54-1.66)	0.855
TEAM VARIABLES		
Team experience:		
Less experienced equivalent professionals	(ref)	
Experienced lead surgeons (n=147)	1.05 (0.77-1.43)	0.774
Experienced anaesthetists (n=117)	1.23 (0.92-1.64)	0.163
Experienced scrub nurses (n=73)	0.99 (0.82-1.20)	0.927
Experienced radiologists (n=103)	1.24 (0.80-1.93)	0.332
Experienced radiographers (n=61)	1.49 (1.04-2.13)	0.030
Team profile:		
Surgical team only (n=45)	(ref)	
Surgical & radiological input (n=136)	1.54 (1.16-2.05)	0.003
Familiarity with equipment:		
Operator familiar with all equipment (n=151)	(ref)	
Operator unfamiliar with one or more items of equipment (n=18)	1.63 (1.35-1.96)	<0.001

ref: reference variable ASA: American Society of Anesthesiologists; AAA: abdominal aortic aneurysm; TAAA: thoraco-abdominal aortic aneurysm; EVAR: endovascular aneurysm repair; TEVAR: thoracic endovascular aneurysm repair. 'Experienced' was defined as having performed more than 50 similar cases. Equipment familiarity was determined by the subjective assessment of the lead operator.
Cut-off for inclusion in the multi-variable model was a significance level of 0.01 in univariate analyses.

Figure 8.1: Forest plot of multivariable incidence rate ratio (95% CI) for predictors of intraoperative failure rate.



TAAA: thoraco-abdominal aortic aneurysm AAA=abdominal aortic aneurysm
Cut-off for inclusion in the multivariable regression model was a significance level of 0.01 in the univariate model. Regression analyses used the dependent variable 'errors per hour' to control for differences in operative duration. The clustering effect at the institution level (10 clusters) was taken into account in the model. N indicates the sample size for each group. Data points indicate the incidence rate ratio (IRR) with 95% confidence intervals (CIs).

8.5.2 *Determinants of major intraoperative failure*

In univariate analyses the only significant predictor of major intraoperative failure was unfamiliarity with equipment (IRR = 2.59 (95% CI 1.51-4.48), p=.001) (see Table 8.3).

Table 8.3: Univariate analyses for major intraoperative failures per hour

Variable	Incidence Rate Ratio (95% CI)	P-value
PATIENT VARIABLES		
Age	1.00 (0.97-1.05)	0.755
Gender:		
Male (n=150)	(ref)	
Female (n=27)	1.24 (0.61-2.53)	0.545
ASA grade:		
ASA I & II (n=45)	(ref)	
ASA III (n=117)	1.28 (0.56-2.91)	0.555
ASA IV (n=13)	1.16 (0.25-5.47)	0.852
Aortic pathology:		
Infra-/juxtarenal AAA, occlusive disease (n=148)	(ref)	
TAAA (Types I, II, III, IV) (n=15)	1.22 (0.35-4.28)	0.754
Isolated thoracic AA, arch aneurysm (n=9)	1.34 (0.85-2.12)	0.205
Other (n=6)	1.78 (0.87-3.66)	0.114
PROCEDURE VARIABLES		
Primary approach:		
Endovascular (n=136)	(ref)	
Open surgical (n=45)	0.73 (0.36-1.51)	0.403
Site of repair:		
Open infrarenal AAA repair, open aortoiliac & aortofemoral bypass, EVAR (n=120)	(ref)	
Open juxtarenal/Type IV TAAA repair, FEVAR, Visceral Hybrid (n=36)	0.99 (0.41-2.39)	0.977
TEVAR (n=15)	0.94 (0.39-2.29)	0.899
Other (n=10)	1.34 (0.47-3.81)	0.580
TEAM VARIABLES		
Team experience:		
Less experienced equivalent professionals	(ref)	
Experienced lead surgeons (n=147)	0.90 (0.61-1.33)	0.590
Experienced anaesthetists (n=117)	1.25 (0.79-2.00)	0.341
Experienced scrub nurses (n=73)	1.19 (0.61-2.30)	0.605
Experienced radiologists (n=103)	0.64 (0.22-1.85)	0.412
Experienced radiographers (n=61)	1.22 (0.70-2.14)	0.479
Team profile:		
Surgical team only (n=45)	(ref)	
Surgical & radiological input (n=136)	1.36 (0.66-2.78)	0.403
Familiarity with equipment:		
Operator familiar with all equipment (n=151)	(ref)	
Operator unfamiliar with one or more items of equipment (n=18)	2.60 (1.51-4.48)	0.001

ref: reference variable ASA: American Society of Anesthesiologists; AAA: abdominal aortic aneurysm; TAAA: thoraco-abdominal aortic aneurysm; EVAR: endovascular aneurysm repair; TEVAR: thoracic endovascular aneurysm repair. 'Experienced' was defined as having performed more than 50 similar cases. Equipment familiarity was determined by the subjective assessment of the lead operator.

8.5.3 *Relationship between intraoperative failures and postoperative outcomes*

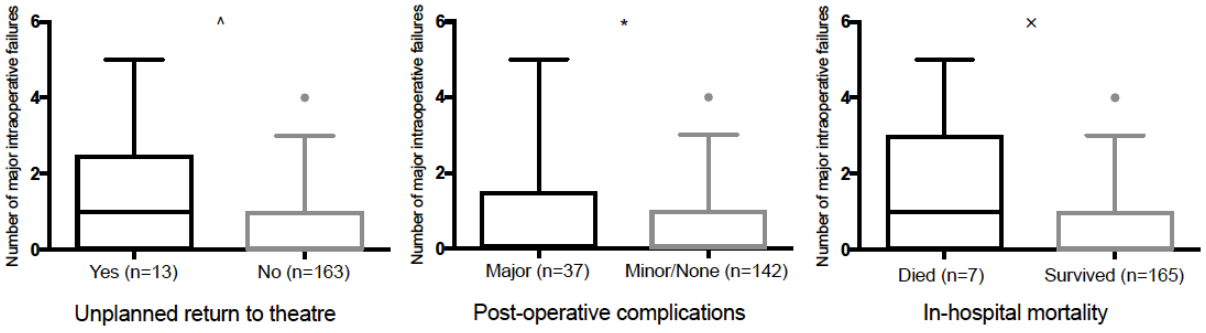
Some 152 of 171 procedures were successful technically with no adverse events at 24 hours after surgery (data missing for 14 procedures). Thirteen patients required reoperation (7.4% n=13/176; data missing n=9/185), 37 patients developed major complications (20.7% n=37/179; data missing n=6/185), four patients had a prolonged hospital stay (over 30 days) (2.4% n=4/168; missing data n=17/185) and seven patients died (4.1% n=7/172; missing data n=13/185). There were no differences in the number of intraoperative failures occurring during successful *versus* unsuccessful procedures (median 3 (IQR: 2–6) *versus* 5 (2–6); $P = 0.147$) or between regular and prolonged (over 30 days) hospital stay (3 (2–6) *versus* 4 (3–5); $P = 0.837$) (see Table 8.4). The *total number* of intraoperative failures was significantly higher in procedures subsequently requiring unplanned return to theatre: median 5 (IQR 4–10) *versus* 3 (2–6) for procedures with no further operation ($P = 0.037$). The number of *major* intraoperative failures was also significantly higher in procedures subsequently requiring unplanned return to theatre: median 1 (0–2.5) *versus* 0 (0–1) ($P = 0.011$). Significantly greater numbers of major failures were reported during procedures after which the patient developed a major complication: median 0 (0–1.5) *versus* 0 (0–1) than for procedures followed by minor or no complications ($P = 0.029$). Similarly, the number of major failures was associated with 30-day in-hospital mortality: median 1 (0–3) for procedures after which the patient died within 30 days *versus* 0 (0–1) where the patient survived to discharge ($P = 0.027$) (see figure 8.2).

Table 8.4: Associations between intraoperative failures and postoperative outcomes

Operative success	**Unsuccessful** (n=19)		**Successful** (n=152)		
	Median	IQR	Median	IQR	p value
Errors per procedure	5	2-6	3	2-6	0.147
Minor errors per procedure	4	1-6	3	2-6	0.480
Major errors per procedure	0	0-3	0	0-1	0.066
Unplanned return to theatre	**Yes** (n=13)		**No** (n=163)		
	Median	IQR	Median	IQR	p value
Errors per procedure	5	4-10	3	2-6	**0.037**
Minor errors per procedure	5	4-7	3	2-6	0.073
Major errors per procedure	1	0-2.5	0	0-1	**0.011**
Post-operative complications	**Major complications** (n=37)		**None/minor complications** (n=142)		
	Median	IQR	Median	IQR	p value
Errors per procedure	3	2-6	4	1-5	0.860
Minor errors per procedure	3	2-6	3	1-5	0.620
Major errors per procedure	0	0-1.5	0	0-1	**0.029**
Length of stay >30 days	**Yes** (n=5)		**No** (n=164)		
	Median	IQR	Median	IQR	p value
Errors per procedure	4	3-5	3	2-6	0.837
Minor errors per procedure	3	3-5	3	1-5.5	0.790
Major errors per procedure	0	0-0	0	0-1	0.640
In-hospital mortality	**Yes** (n=7)		**No** (n=165)		
	Median	IQR	Median	IQR	p value
Errors per procedure	5	4-14	4	2-6	0.056
Minor errors per procedure	5	3-11	3	1-5	0.067
Major errors per procedure	1	0-3	0	0-1	**0.027**

IQR: interquartile range
Operative success was defined as a technically successful procedure with no adverse events at 24 hours post-operatively.

Figure 8.2: Significant associations between major intraoperative failure and postoperative outcomes



Box plots demonstrate the median values, IQR (box) and Tukey-style 1.5 IQR (whiskers); outliers are represented by dots.
^ P= 0.011; *P=0.029; x P=0.027 (Wilcoxon rank sum test, unadjusted for multiple comparisons)

8.6 DISCUSSION

8.6.1 *Summary of findings*

The analyses presented in this chapter suggest that there is a relationship between intraoperative safety failures and postoperative patient outcomes. Total intraoperative failure rate predicted unplanned return to theatre, and major intraoperative failures were additionally associated with severe postoperative complications and 30-day in-hospital mortality. Patient age, gender and ASA grade did not predict intraoperative failure rate, thus highlighting that many safety events are not attributable to patient risk-factors in this specific patient group. Interestingly, while isolated thoracic aneurysms were independently associated with higher failure rates compared to infra-renal pathologies, thoraco-abdominal aortic aneurysms did not predict higher failure rates. In univariate analyses, repairs involving the visceral segment were even associated with lower failure rates compared to infra-renal repairs. Overall, endovascular repair was independently associated with higher failure rates than open repair. Surprisingly, team experience with the intervention did not predict intraoperative failure rates, yet unfamiliarity with specific items of equipment did – most of these cases of unfamiliarity with equipment related to stent-graft devices. In addition, unfamiliarity with equipment was the single predictor of *major* failure in this analysis.

8.6.2 *Interpretation*

Despite some limitations that are discussed below, this study implies a credible relationship between intraoperative safety failure and postoperative outcomes. In this cohort, major intraoperative failures were associated with post-operative complications and patient death. A previous study of intraoperative adverse events in complex endovascular aortic repair has also reported similar results (184). Although the precise nature of this relationship remains to be fully understood, it is reasonable to suggest that major intraoperative failures trigger a cascade of events culminating in the death of the patient. As reported in the previous chapter of this thesis, intraoperative failures were observed to cause significant intraoperative delays during many cases. Lengthy procedures can lead to compartment syndrome, systemic reperfusion injury, cardiovascular instability and multi-organ failure – thus any preventable delays should be avoided. A further possibility is operating on complex patients generates more serious intraoperative failures. However, our analyses do not support this hypothesis: ASA grade did not predict intraoperative failure rate, and complex repairs (those involving the visceral segment) were independently associated with lower rates of intraoperative failures – a finding that is counterintuitive, but which may be explained by the greater intensity of preparation and planning for these complex cases.

The finding of an association between total intraoperative failure rate and unplanned return to theatre does make sense clinically. Given that return to theatre was reported for 7% of 1316 open repairs and 2.1% of 2882 endovascular repairs in 2015 in the UK (128), significant improvements could be made if more attention is paid to the systems and processes in place during aortic intervention. The findings of this study suggest that particular attention must be given to preventing failures during intervention for arch/isolated thoracic repairs. In contrast, repairs involving the visceral segment appear to be associated with fewer failures. Operating teams are likely to plan for procedures involving the visceral segment in greater detail compared to standard infra-renal or isolated thoracic repairs, and this may explain the relatively fewer intraoperative failures associated with this type of repair. In a study of safety in complex paediatric cardiac operations, a large number of threats in the system were thought to have existed prior to the operation, yet these threats were mitigated by teams to produce a successful outcome (31). In a similar fashion, the in-depth planning that is required for the most complex aortic repairs is likely to address potential risks to patient safety, thereby minimising the number of intraoperative failures that occur. However, research into pre-operative system factors is required to investigate this assumption in complex vascular surgery.

Endovascular repair was independently associated with a higher rate of intraoperative failure compared to open repair. This result validates the findings of previous single-centre studies that have compared rates of failure occurring in open and endovascular arterial procedures (57,141). The precise reasons for the increased incidence of failures during endovascular repair remains to be understood. However, previous research has demonstrated that variation in intraoperative error rates may be explained by the relative uptake of surgical technology, with specialties relying heavily on advanced equipment bearing a greater incidence of equipment-related error (95). Another source of intraoperative failures during endovascular repair may relate to the performance of these procedures by large, multidisciplinary teams. In the UK and in other European countries, it is common practice for interventional radiology staff to be involved in endovascular procedures alongside the surgical, anaesthetic and nursing teams. The increased size and complexity of the teams may make communication and accurate information transfer more challenging, and may explain, at least in part, the increased number of failures occurring during endovascular intervention.

In the present study, perceived unfamiliarity with equipment was independently associated with increased rates of intraoperative failure, whereas actual experience (in terms of the number of similar operations performed) was not. Most reports of unfamiliarity with equipment

related to new stent-graft devices rather than with traditional surgical instruments. Vascular operating teams are using an increasingly wide range of stent-graft devices to treat patients with a broad range of anatomical configurations and equipment unfamiliarity will continue to be a safety concern. Previous research into adverse events associated with branched and fenestrated stent grafting has highlighted the significant learning curve associated with these complex procedures and the need for them to be performed in high-volume centres (184) – the findings presented in this chapter support this.

8.6.3 *Limitations*

As discussed in previous chapters, the methods used to collect data on intraoperative failures relied on accurate recall and reporting by operating teams. In this analysis, the regression models would be affected by the potential reporting biases (under-reporting, selective-reporting, recall bias) that have been outlined previously. Of note, the variable 'unfamiliarity with equipment' may have been influenced by hindsight bias – i.e. lead operators may have been more likely to indicate that he/she was unfamiliar with an item of equipment if there was an adverse event intraoperatively. Team profile (with/without input from interventional radiology staff) was omitted from the multivariable model due to multi-collinearity with procedure type (open versus endovascular). This was necessary to prevent over-inflation of standard errors. From this regression, it is not possible to ascertain whether the increased failure rates seen during endovascular intervention are a result of procedural variables or variability in the team profile. Further research is needed to illuminate this issue. The tests of association between intraoperative failure and postoperative outcomes were not adjusted for multiple comparisons or patient risk-factors due to the exploratory nature of this analysis and the small number of poor outcomes documented in this study, therefore evidence of this relationship should be interpreted with caution.

8.6.4 *Generalisability*

These analyses were performed on data collected during a multi-centre study involving ten vascular operating departments with diverse characteristics in terms in terms of geographical location and aortic case load. As previously stated, the patients and procedures studied are typical of the population of vascular patients undergoing elective aortic intervention in NHS hospitals in England. However, these results should be interpreted with caution due to the limitations outlined above and further research is required to validate the evidence of a relationship between intraoperative safety failures and postoperative outcomes.

8.7 CHAPTER SUMMARY

The work presented in this chapter has led to a greater understanding of the determinants of intraoperative safety failure. Furthermore, the findings reported in this chapter are indicative of a relationship between intraoperative failures and postoperative outcomes. The implications of these findings - and those of the studies reported in previous chapters - will now be discussed in more detail in the final discussion chapter.

Section IV:

Discussion

9 Discussion Chapter

9.1 CHAPTER OVERVIEW

This final chapter summarises and discusses the key findings, methodological issues and limitations of the original work presented in this thesis. The implications of this work with regards to future research, clinical practice and healthcare organisation and policy are also discussed.

9.2 SUMMARY AND INTERPRETATION OF FINDINGS

The work presented in this thesis has combined a range of methodologies, including questionnaires, interviews and structured post-operative debriefs with vascular operating teams to further the current understanding of the incidence and impact of preventable harm in patients undergoing arterial intervention. This thesis has presented the first series of studies to adopt a systems approach to understanding threats to patient safety in vascular surgery – the work is unique in this respect.

The paragraph below briefly reviews the studies conducted to achieve the aims of this thesis, which were:

1. **To explore what is already known about system factors and their relationship with patient safety in arterial surgery**
2. **To develop a broad understanding of the nature and relative importance of system factors in relation to patient safety in arterial surgery**
3. **To investigate the relationship between system failures and clinical outcomes in patients undergoing arterial intervention**

After briefly summarising the studies presented in this thesis, a summary of the findings relevant to each aim will be presented.

9.3 OVERVIEW OF CHAPTERS AND STUDIES

After introducing relevant concepts and theoretical frameworks in chapters 1 and 2, three exploratory studies were reported in section 2: a systematic review of the literature summarised existing evidence examining the relationship between system factors and patient safety in elective arterial surgery (chapter 3); a mixed-methods study investigated vascular surgeons' perceptions of the causes of peri-operative adverse events in patients undergoing arterial operations (chapter 4); and a multi-centre survey study measured vascular operating team members' perceptions of four dimensions of safety culture - teamwork, working conditions, management and safety (chapter 5). In section 3, three chapters presented the findings of the LEAP study (the Landscape of Error in Aortic Procedures). In phase I of the LEAP study vascular operating teams at sites were trained to use the Imperial College Error CAPture (ICECAP) debriefing tool to self-report intraoperative failures. The purpose of the study presented in chapter 6 was to establish the feasibility and reliability of the ICECAP debriefing approach. The structured team debrief was used in phase II of the LEAP study to develop a better understanding of the landscape of intraoperative system failures in aortic intervention (chapter 7). In chapter 8, multivariable regression analyses investigated the patient, procedure and team predictors of intraoperative failure, and the relationship between intraoperative failure and patient outcome was explored.

9.4 REVIEW OF FINDINGS WITH RESPECT TO THE AIMS OF THIS THESIS

9.4.1 *Findings in relation to aim 1*

Aim 1: To explore what is already known about system factors and their relationship with patient safety in arterial surgery

The first piece of work presented in chapter three was a systematic review, which found that there was a lack of research that had previously investigated system factors and their relationship with patient safety in arterial surgery. A small number of studies suggested that a range of system problems may exist in arterial surgery, including failures relating to teamwork, communication and equipment. The collated evidence mainly consisted of small, single-centre studies that evaluated specific dimensions of the surgical system. As such, no meaningful conclusions could be drawn from the review and the need for research in this area was highlighted. The paucity of literature on system factors and patient safety in vascular surgery compared unfavourably to other surgical specialties, where there appeared to be a

great deal of interest in human factors and the systems approach to understanding patient safety (51,53,55,69,87,94,144,185–188). In particular, cardiac surgery and anaesthesia had embraced this broad systems approach resulting in a much greater understanding of potential strategies to improve patient safety. For example, studies in cardiac surgery found that the incidence of technical errors could be reduced by improving the design and usability of cardiopulmonary bypass machines. Furthermore, the performance of cardiac surgeons during aortic switch operations could be improved by ensuring stability and consistency of the operating team (94). It was anticipated that, by adopting a systems approach, similar studies in arterial surgery could identify targets for safety improvement to further improve patient outcomes.

9.4.2 *Findings in relation to aim 2*

Aim 2: To develop a broad understanding of the nature and relative importance of system factors in relation to patient safety in arterial surgery

The findings of the original work presented in this thesis will now be considered under the broad headings from Vincent's framework of factors influencing clinical practice (71). The headings from Vincent's framework are considered to be useful here as they can be used to structure reflection on the main sources of patient safety problems in healthcare.

Patient factors

In the mixed-methods study presented in chapter 4, the most common factor cited by vascular surgeons as contributing towards perioperative adverse events in arterial surgery was the complexity or seriousness of the patient's condition. This result is unsurprising given that most patients presenting for major arterial procedures are elderly with co-existing cardiovascular and respiratory disease (38), and these risk-factors are known to influence outcome. However, in the LEAP study (chapter 8), multivariable regression analyses revealed that the patient's age and ASA grade did not predict the rate of intraoperative safety failures. These findings may be interpreted to suggest that, while the patient's condition does not necessarily precipitate safety failures, these failures may be harder for the team to mitigate when they impact on a patient with severe systemic disease - these patients are also likely to be less resilient to withstand the impact of safety failures when they occur.

Task factors

While patient factors did not predict intraoperative failure rates in the LEAP study, procedural factors did. Compared to standard infrarenal aortic repairs, repairs of thoracic or arch

aneurysms were independently associated with higher intraoperative failure rates, which may be explained by the increased complexity of these procedures. Increased procedural complexity is likely to necessitate exceptional expertise, more precise communication and collaboration between team members, and may also place much greater mental and physical demands on the operating team. Yet, repairs involving the visceral segment were not associated with higher failure rates in multivariable analyses. The findings could be explained by the intensive preparation and planning that is required for these exceptionally complex procedures, which may mititgate some intraoperative problems, although more work is needed to investigate these assumptions.

In line with previous single-centre studies (57,141), endovascular repair was independently associated with higher failure rates compared to traditional open surgical repair. The precise reasons for the increased incidence of failures during endovascular repair remains to be understood. However, previous research has demonstrated that variation in intraoperative error rates may be explained by the relative uptake of surgical technology, with specialties relying heavily on advanced equipment bearing a greater incidence of equipment-related error (95). Another source of intraoperative failures during endovascular repair may relate to the performance of these procedures by large, multidisciplinary teams, with an increased potential for failures in communication and coordination – this hypothesis will be discussed in further depth under the heading 'team factors' below.

Unfamiliarity with equipment was an additional predictor of increased intraoperative failures rates. Furthermore, unfamiliarity with equipment was the single predictor of *major* failure. Of note, most reports of unfamiliarity with equipment related to new stent-graft devices. Vascular operating teams are using an increasingly wide range of stent-graft devices to treat patients with a broad range of anatomical configurations and equipment unfamiliarity will continue to be a safety concern. Previous research into adverse events associated with branched and fenestrated stent grafting has highlighted the significant learning curve associated with these complex procedures and the need for them to be performed in high-volume centres (184) – the findings of the LEAP study support this. However, more attention should be paid to how these devices are introduced when they are new to operators and are being used in patients.

Operators planning to introduce a new stent-graft have a responsibility to ensure that the introduction of new equipment is accompanied by adequate training and fulfils safety and financial regulations within their institution. This may include gaining approval from the divisional board and new procedures committee, ensuring that protocols are in place, and ensuring there is a robust structure for audit and evaluation. In reality, new devices and

equipment are regularly introduced into the operating environment without any clarity on who is ultimately responsible for training endovascular operators and their teams, whether industry or healthcare institutions.

Individual (staff) factors

In the mixed-methods study presented in this thesis, around a third of surgeons responding to the survey indicated that a lack of knowledge, skills or competence contributed to adverse events they had witnessed. In this study, these knowledge-based factors were more likely to have contributed to adverse events occurring in open surgical procedures than in endovascular procedures. This finding may reflect recent trends in the volume of open aneurysm repairs completed by trainees. A recent analysis of the shortfall in open aneurysm experience for vascular surgical trainees identified the expanding indications for EVAR and the increased uptake of FEVAR and BrEVAR as factors underlying this trend (189). Although this analysis was conducted using US data where the uptake of endovascular intervention is greater than in the UK, it is likely that current vascular trainees practising in the UK have less exposure to open surgical repair, and this may have a serious impact on patient safety. Technical errors accounted for a significant proportion of major intraoperative failures observed in the LEAP study, and they were the root cause of 28.5% (n=4/14) failures that directly harmed patients undergoing aortic intervention. While it has long been recognised that surgical skill is a pre-requisite for good surgical outcome, there is clearly a need to ensure that training programmes are sufficient despite the declining numbers of some index procedures.

Alongside vascular surgeons, the knowledge and skills of all vascular team members are likely to require attention. The results of the LEAP study demonstrated that for aortic intervention the most experienced team members are generally the lead surgeon and the interventional radiologist; the least experienced team members tend to be the nurses. It is alarming that in this cohort, scrub nurses who were experienced with the procedure being performed were involved in only 58% of open surgical cases and only 37.2% of endovascular cases. Although the experience of individual professionals within the multidisciplinary vascular operating team did not predict intraoperative failure rate in this study, it could be that cumulative team experience matters more than the experience of individuals in terms of patient safety, as has been found by researchers investigating the experience of operating teams in cardiac surgery. El Bardissi and colleagues found that cumulative team experience had a greater impact on cardiopulmonary bypass and cross-clamp times than the individual experience of the lead surgeon, although in that study, cumulative team experience was defined as the combined

experience of the attending surgeon and the cardiothoracic fellow – the experience of the scrub nurse was not included (91). Further work should assess the relationship between cumulative or combined team experience – nursing staff included – and measures of patient safety in arterial intervention.

Team factors

In the multi-centre LEAP study, communication failures accounted for nearly a quarter of major intraoperative failures during aortic intervention; they also constituted a root cause of half of the failures that led directly to patient harm. In the mixed-methods study, a small sample of vascular surgeons who were interviewed suggested that the problem of communication failure was exacerbated by a lack of team continuity. Team stability may be affected by institutional issues including difficulty with staff recruitment and retention, and influenced by organisational policies that require staff to rotate through different surgical specialties. Team continuity may also an issue during lengthy operations and typically during long and complex aortic interventions when sometimes the only constant operating team member is the lead surgeon. This problem has been highlighted previously in a study of anaesthetic handover in cardiac surgery (87). In propensity-matched groups, the need to hand over care from one anaesthetist to another during complex cardiac operations was associated with significantly higher rates of major complications and in-hospital mortality compared to operations during which no handover was required (87). A somewhat similar event was observed in the LEAP study (chapter 7) in relation to a patient with severe systemic disease who underwent TEVAR – the anaesthetic consultant changed intraoperatively without a thorough handover. No blood products were transfused after initial 2 units and the patient suffered a hypovolaemic cardiac arrest immediately after the procedure, requiring reintubation.

In the mixed-methods study, nearly a third of survey respondents (n= 22/77) cited poor team structure as a factor contributing to adverse events and four interviewees described lack of clarity over roles and responsibilities with the operating team – these reports all related to endovascular procedures. In the UK, it remains common practice for vascular and interventional radiology teams to collaborate during endovascular intervention. Although both teams benefit from the expertise of the other, the size and complexity of the operating team is ultimately greater. Consequently, effective communication between team members from different professional backgrounds may be more challenging intra-operatively. Below, two models of intra-operative communication are compared – one for communication during traditional open surgical repair and one during endovascular intervention reflecting common practice in the UK (see Figure 9.1 and Figure 9.2). The model of communication and information transfer for endovascular repair is visibly more complex. Of note, the input of

interventional radiology staff is usually required mid-procedure, and thus radiology staff may not be present for pre-operative briefings or for the WHO Surgical Safety checklist's 'time-out' procedure prior to knife-to-skin. This absence from safety briefings may further exacerbate the problem of communication failure between team members.

Figure 9.1: Model of communication & information transfer during open surgical procedures

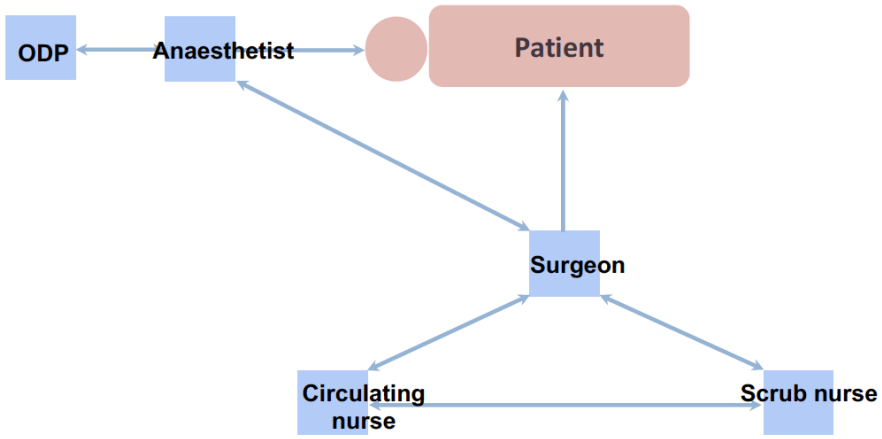
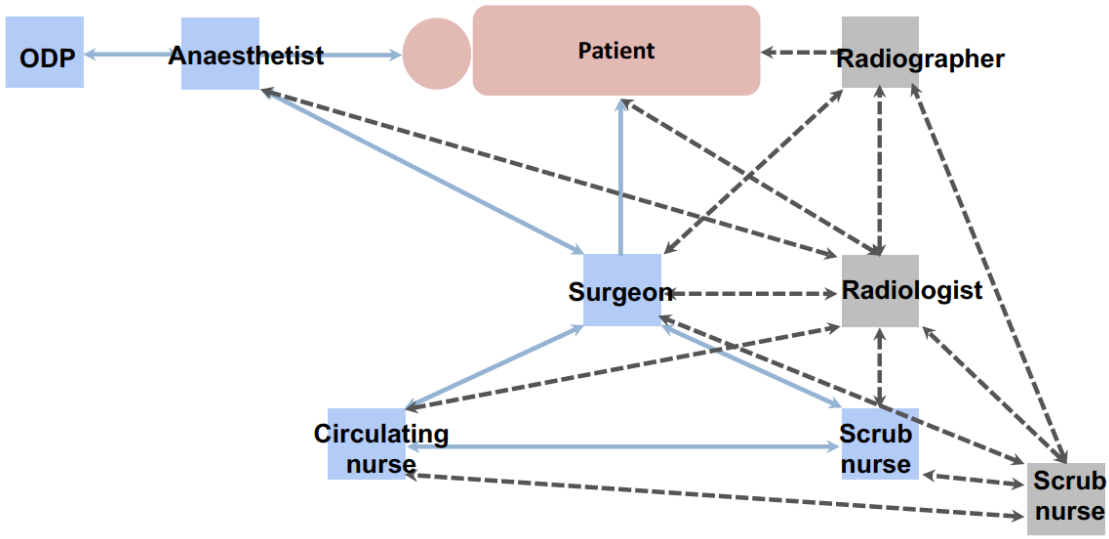


Figure 9.2: Model of communication & information transfer during endovascular procedures

This model reflects standard team composition in the UK with collaboration between radiological and surgical teams.



In the LEAP study (chapter 8), it was demonstrated that endovascular procedures are independently associated with higher rates of intraoperative failure compared to traditional open surgical procedures. The greater size and complexity of teams performing these procedures may be a factor underlying this finding.

Additional factors underpinning the problem of communication failure appear to relate to team dynamics and power relationships with vascular operating teams. In the mixed-methods study, trainees reported a reluctance to challenge perceived authority and in the survey study on safety culture (chapter 5), a significant proportion of operating team members indicated that they found it difficult to discuss errors or to speak up if there is a problem with patient care in the vascular operating theatre. In the latter study, most of the respondents reporting these concerns were either nurses or operating department practitioners. These findings are supported by a recent systematic review of communication failure in the operating theatre, which found that power relationships – particularly the position of surgeons and anaesthetists at the top of an unhealthy hierarchical structure - contributed to team members feeling unable to voice their concerns, which ultimately led to unsafe practices (172).

The safety culture study (chapter 5) demonstrated that perceptions of teamwork vary significantly between different vascular units. This study highlighted the need for vascular operating teams to examine local deficiencies in patient safety in order to develop tailor-made solutions. To illustrate this point, it is worthwhile noting that at the site where only 21% of vascular operating team members reported positive perceptions of teamwork, a programme of vascular team training has now been implemented.

Work environment factors

Problems relating to the operating environment (light, space, noise) were cited by 14.5% of vascular surgeons responding to the survey on the causes of adverse events in arterial procedures. Nearly one third of survey respondents also reported problems relating to the design, availability or use of equipment. In the LEAP study, the most frequently reported intraoperative failures related to equipment problems and 'procedure-independent pressures' – including noise, distractions, team member absence and external pressures. Only a small proportion of these work environment failures were considered to be 'major' and none were directly linked to incidents of patient harm. Vascular operating teams are used to dealing with these seemingly inconsequential work environment failures, which can generally be mitigated fairly easily. However, these 'minor' failures may not be as innocuous as they seem; in this study, for every additional minor failure that occurred, the risk of a major failure occurring increased by 29% - an important finding to note. Therefore, failures that appear to be minor

at first glance may accumulate to create the conditions in which a major failure can occur, thus placing the patient at risk of harm. This 'snowball effect' has been documented in previous studies of safety in anaesthesia and in paediatric cardiac surgery (31,53), and its finding in the work presented in this thesis emphasises the need to pay attention to latent failures that can create the conditions of 'accidents waiting to happen'.

Organisational factors

Inadequate staffing levels/skill mix were cited by one third of vascular surgeons responding to the survey on the causes of perioperative adverse events in arterial surgery and in the safety culture study 30% of multidisciplinary vascular operating team member reported that staffing levels were not sufficient to handle the number of patients in their operating theatres. In the UK, theatre nurse shortages have forced some NHS Trusts to cancel routine operations in recent years and many Trusts are struggling with staff recruitment into these posts (174). A recent vascular workforce survey suggested that a number of pressures, including current over-stretched job-plans and the move to a seven-day service, will necessitate the creation of additional vascular consultant posts in the UK to maintain the current level of service provision (175). At an organisational level, retention of existing staff in vascular posts will be of upmost importance to withstand shortcomings in patient safety and service quality.

One of the findings of the exploratory mixed-methods study was that problems related organisational structure contributed to a higher incidence of adverse events in endovascular procedures compared to open surgical procedures. This result was derived from quantitative questionnaire data and thus surgeons' views on the mechanisms underpinning organisational failings and adverse events in endovascular procedures were not captured. However, this finding may be interpreted to suggest that the organisation of staff and resources within hospitals with endovascular facilities requires attention. Whereas traditional open surgery has been in existence for many years, with well-established infrastructure and processes to support it, endovascular intervention is relatively in its infancy. It may be that the processes and protocols in place for endovascular intervention need to be examined in more detail and optimised to support the practice of endovascular surgery in some institutions. This notion is supported by Lord Darzi's recommendation that the introduction of surgical technology should be accompanied by process innovation (114).

Evidence from the survey study on safety culture (chapter 5) clearly demonstrates that perceptions of teamwork, working conditions, management and safety vary significantly between different centres. This unit-level variability in safety climate has been observed in similar studies of safety culture in surgery (43,171). Cultural and behavioural norms with

regards to patient safety may depend heavily on local factors rather than on national standards. More work is required to understand the relationship between safety culture and patient outcomes in vascular surgery, but strategies to improve patient safety are likely to be most effective when tailored to the problems inherent in individual operating departments and as well as to the wider problems of an NHS 'in crisis'.

9.4.3 *Findings in relation to aim 3*

Aim 3: To investigate the relationship between system failures and clinical outcomes in patients undergoing arterial intervention

Using data from the LEAP study, unadjusted analysis of between-group differences suggests that there is a relationship between intraoperative safety failures and postoperative patient outcomes. Total intraoperative failure rate predicted unplanned return to theatre, and major intraoperative failures were additionally associated with severe postoperative complications and 30-day in-hospital mortality. The finding that higher rates of intraoperative failures were associated with unplanned return to theatre makes sense clinically. However, the mechanism by which major intraoperative failures contribute to major post-operative complications and 30-day mortality is less clear. There is likely to be a tremendous number of possible ways in which the system failures discussed in the previous section combine to cause patient harm. For example, the complexity of an operation is likely to influence rates of intraoperative failure, which may escalate into a more serious set of circumstances if the operating team is unable to mitigate the effects of these failures. Furthermore, failures in communication between operating team members may not only precipitate error and intraoperative patient harm, poor teamwork may also mean that operating teams are less able to mitigate the effects of errors when they occur, thus allowing these errors to impact on the patient. In addition, although minor failures such as distractions and external pressures may generally be considered to be routine annoyances rather than the immediate causes of patient harm, but these, too, may reduce an operating team's capacity to deal with emerging crises by placing additional demands on the mental workload of operating team members, and this is likely to be additionally challenging for those who are technically inexperienced or new to leading the team or managing the operating environment. The findings of the LEAP study demonstrated that minor failures precipitate major failures and major failures were associated with episodes of patient harm intraoperatively. These major failures may reduce patients' resilience - leading them to being less likely to recover from minor post-operative complications, thus contributing

to major complications and even death. The initial trigger for this 'snowball effect' may relate to failures in the operating theatre.

9.5 METHODOLOGICAL ISSUES AND LIMITATIONS

The methodological issues and limitations unique to individual studies have been reported and discussed within each of the study chapters. However, there are a number of important limitations to the work as a whole. These limitations largely relate to the observational nature of the studies and the use of self-reported data. In observational studies, researchers attempt to provide a better understanding of a phenomenon by searching for associations between observed variables; these associations can be influenced sampling bias and other confounding variables. The studies presented in this thesis all used non-probability purposive or convenience sampling techniques. Self-selected participants may have held a particular interest in patient safety and their responses may have differed to those of participants identified through random sampling. However, the work presented in this thesis relied on honest reporting of safety problems in arterial surgery and participants with an interest in patient safety may be more likely to provide open, honest accounts of errors and adverse events in order to illuminate the problem of patient safety.

Studies reliant on self-report by frontline operating staff are likely to be influenced by recall bias, hindsight bias, production pressure and other clinical commitments. These biases may have influenced the data reported in each of the studies presented in this thesis. However, various strategies were implemented to minimise the effect of these potential biases. For example, the questionnaire for the mixed-methods study was administered during breaks at vascular conferences - away from the pressures of the clinical environment. In the LEAP study presented in chapter 6-8, recall bias was minimised by asking operating teams to undertake the study debrief (to discuss and record intraoperative failures) immediately after each case, and a structured debriefing tool was used to prompt recall of intraoperative failures. As this was a prospective study, the effects of hindsight bias were minimal as the operating teams were unaware of the post-operative outcome as the time the study debrief was undertaken.

The work presented in this thesis adopted a systems approach to understanding patient safety in arterial surgery – by its very nature, this type of research addresses a tremendous range of variables and it may be impossible to evaluate all relevant factors contributing to patient safety within the scope of this thesis. Unmeasured confounding variables may have had an impact on the findings. However, attempts were made to minimise the effects of confounding

variables – firstly, by adopting a broad systems approach in order to address a wide spectrum of potential safety problems. In the LEAP study, potential confounders were addressed by taking patient risk-factors (age, gender, severity of condition) procedural factors (site/ type of repair) and team factors (individual experience with the procedure, familiarity with equipment) into account in the regression models to identify predictors in intra-operative failure rates.

9.6 GENERALISABILITY

The work presented in this thesis has focussed exclusively on arterial intervention in the British NHS. Ten centres in England with diverse characteristics in terms of geographical location and arterial caseload participated in the multi-centre studies in this thesis and, despite some limitations described above, we believe that these findings are generalisable to other arterial centres in England. A number of parallels have been made between the findings of this work and evidence from other surgical specialties and other countries – particularly with regards to the incidence of communication failure and equipment-related issues. However, there are several features of arterial intervention in the UK that may limit the relevance of these findings to other areas of surgical practice and vascular surgical practice internationally. As discussed previously, current practice in the UK is for collaboration between surgical teams and interventional radiology teams to perform arterial operations using endovascular techniques. Some centres in the UK, and many centres in other countries have moved away from this model, and in those centres endovascular procedures are being performed by one primary surgical team, which may impact on the nature and incidence of intraoperative failure.

Furthermore, dual-consultant operating is now common practice for more complex arterial operations, and the evolution and uptake of endovascular technology has proceeded in an exceptionally rapid manner in this specialty. These factors may influence the types of failure occurring during arterial intervention compared with other surgical specialties. The types of failure that have been observed in the studies presented here may be slightly different from those occurring in another ten years' time as team dynamics change and technology continues to advance at pace. However, although the balance of failure types may change, it is likely that the same general findings will apply. The importance of efforts to understand safety problems in arterial surgery and the need to involve frontline staff in identifying solutions to these problems will still remain.

9.7 RECOMMENDATIONS

Reflecting on efforts to improve patient safety and surgical outcomes in arterial intervention, there have been tremendous technical and structural advancements over the past two decades (see
Figure 9.3). Technological innovations have provided the means to treat the elderly and the frail as well as an increasing range of anatomical configurations, with known improvements in short-term survival. The use of simulators is now commonplace and they provide surgeons with the opportunity to rehearse technical skills outside the operating theatre. In the UK, there have been major structural changes to improve vascular service provision. The move to the 'hub and spoke' model has enables the concentration of expertise and resources to ensure that patients undergoing arterial intervention receive the best operative treatment available. There has also been investment to build hybrid operating theatres so that vascular operating teams can transition seamlessly between open surgical and endovascular techniques. These are all examples of incredibly valuable progress, but reflecting on these developments raises the question: what next to further improve patient safety and surgical outcomes?

9.7.1 *A human factors approach to improving patient safety in arterial surgery*

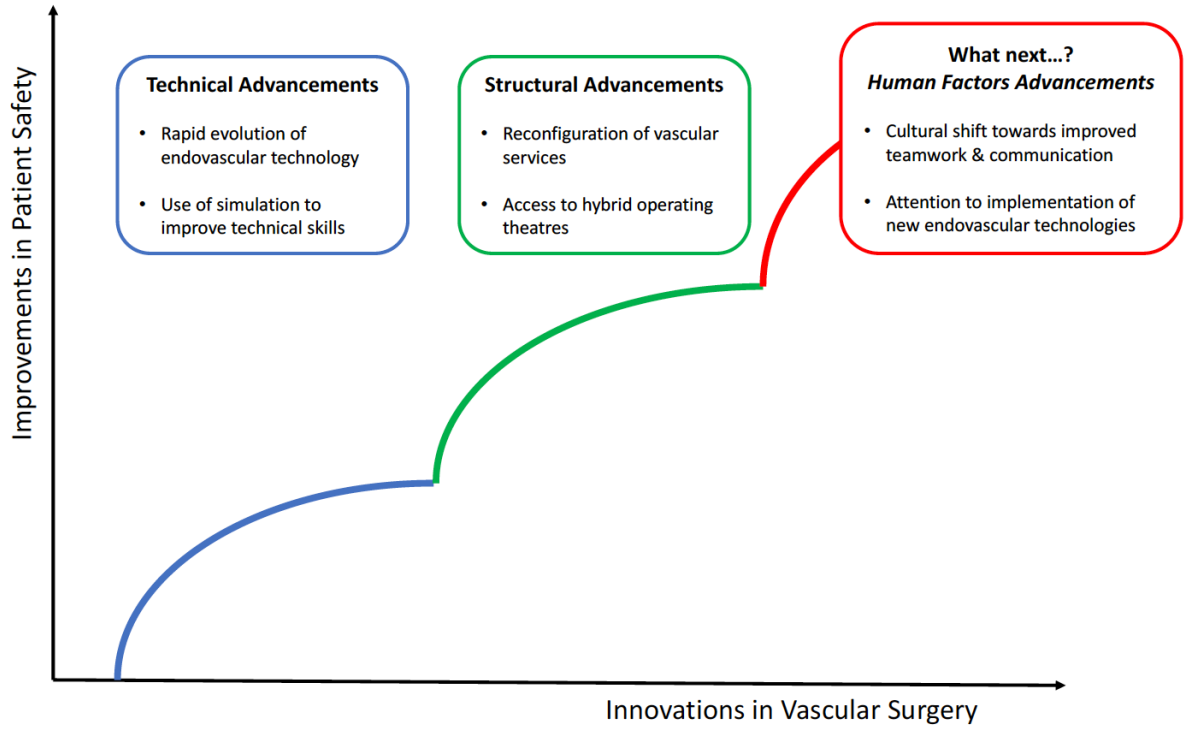
The findings of the original work presented in this thesis support the notion that future innovation should incorporate human factors science. The work presented here has demonstrated that intraoperative system failures are common and are likely to influence patient outcomes in arterial surgery. The human factors approach acknowledges that errors and adverse events may be caused by both individual surgeon factors and work system factors (190). The main aim of a human factors approach is to "promote efficiency, safety and effectiveness by improving the design of technologies, processes and work systems" (59).

Recent trends in vascular surgical innovation to improve patient safety demonstrate significant technological advancements and structural improvements (including the reconfiguration of vascular services and improved access to hybrid operating theatres) (see
Figure **9.3**). Attention must now turn to how vascular operating team member interact, how they organise and enact their work and how they set up the operating environment for reliable, failure-free performance. To illustrate this point, Ghaferi and colleagues provide this excellent analogy (191) (p.2):

> "Similar to how improvements in smartphones have shifted from increasing processor speed or screen resolution to focussing on better user experience,

innovation in surgery has to shift from the technical or structural aspects to emphasising how people, processes, and practices come together in the pursuit of patient safety."

Figure 9.3: Trends in vascular surgical innovation to improve safety and outcomes



Adapted from Ghaferi et al. (2016) (191)

To achieve reliable performance with minimal intraoperative failures, improvement strategies should address the culture within operating departments and the interactions, practices and behaviours of vascular operating team members. Informed by the findings of the work presented in this thesis, the final section of this chapter will recommend relevant strategies that may improve patient safety and surgical outcomes in arterial intervention.

9.7.2 *For vascular operating teams*

Vascular operating teams should be aware that the quality of teamwork and communication, and the organisation of the operating environment, appear to influence the safety of patient undergoing arterial intervention. To improve team communication and collaboration, it is recommended that vascular operating team members take the opportunity to train together as

multi-professional teams rather than within their separate disciplines. This suggestion is supported by the recently published National Safety Standards for Invasive Procedures (192). Team training programmes in healthcare are generally based on principles of crew resource management theory from aviation. Crew resource management training aims to encourage team members to challenge each other when there is a risk to patient safety and to take a step back to improve situational awareness (103). The importance of briefings and debriefings, the use of communication strategies (such as 'close the loop'), and emphasis on a culture of transparency and open discussion of errors, are also incorporated into this style of training. However, rather than simply training vascular teams 'best practice' in terms of teamwork and communication, we believe that high-fidelity simulation should play an integral role in providing operating teams with the opportunity to rehearse arterial interventions in realistic environments where there is no risk to staff in terms of radiation and, of course - no risk to patients. Team simulations have been shown to improve both the technical and non-technical skills of vascular operating staff, and may be particularly useful to rehearse crisis scenarios or exceptionally complex arterial procedures (193,194). Patient-specific rehearsal uses computed tomography angiography data to create a virtual three-dimensional model of a patient's anatomy, which is upload to a virtual reality simulator. A recent multi-centre trial of this technology found that patient-specific rehearsal prior to EVAR positively influences the operative plan and operating teams who participated in the trial believed that this technology could also improve the non-technical skills of team members intraoperatively (195). Patient specific rehearsal places a number of demands in terms of time, cost and expertise, but this intervention may hold promise in terms of reducing the incidence of intraoperative failures. In the current climate, overstretched operating lists, short-staffing and tight budgets may mean that implementing simulation-based team-training programmes is challenging, and undoubtedly, support from senior management and strong leadership from within local vascular teams will be required.

9.7.3 *For medical directors of NHS trusts and NHS commissioners*

Medical Directors should be aware that arterial interventions are generally high-risk and frequently lengthy and complex procedures. They should ensure that resources in terms of staffing and equipment reflect the complexity and seriousness of the procedures being carried out. Team stability and consistency is likely to be important to minimise the problem of intraoperative communication failure. However, this may be difficult from a logistical standpoint. Strategies that improve staff retention as well as policies that ensure that staff are not rotated between surgical specialties too frequently are likely to beneficial with regards to team stability. To avoid handovers at shift changes during lengthy procedures, organisational support is likely to be required to ensure that long and complex operations start early in the

day – such support may include assistance to identify a post-operative bed in an appropriate level of care on the morning of the operation so that the procedure can go ahead without delay.

The NHS Commissioning Board specifies that providers of complex endovascular stent graft services must make provision for training and developing the skills of core personnel involved in endovascular procedures (196). Currently, there is a lack of clarity over which organisations are best placed to deliver this training, which in practice is provided by a combination of individual healthcare organisations, industry, the Vascular Society of Great Britain and Ireland (VSGBI) and the European Society for Vascular Surgery (ESVS). Clearly, consideration has to be given to how training programmes are developed and how new stent graft devices are introduced when they are new and being used in patients for the first time. Of note, the international trend of developing "hybrid scrub nurses" who are trained in both open and endovascular skills, working in hybrid theatres alongside vascular surgeons who can switch between open and endovascular techniques depending on the patient's pathology, is model that requires more attention in the UK.

Medical directors should also be encouraged to review in-house systems for the reporting of surgical errors and adverse events. Alongside submission of patient safety incidents to the National Reporting and Learning System, it may be appropriate to institute more granular in-house reporting systems, which permit operating teams to feedback safety concerns immediately following invasive procedures - with time allocated for discussion of intraoperative system failures and consideration of safety improvement strategies. While such a system would likely have a positive impact on surgical safety culture, over-stretched operating lists and the current backlog of patients waiting for operations on the NHS would undoubtedly pose difficulties in implementing such a system.

9.7.4 *For the Vascular Society of Great Britain & Ireland*

It is important that the VSGBI fosters a culture of openness and transparency with regards to errors and adverse events during arterial intervention among its members. There may be scope for collecting data on the causes of perioperative adverse events as part of the National Vascular Registry in the future. The Confidential Reporting System in Surgery (CORESS) could provide the model for this: CORESS receives anonymised incident reports from surgeons and theatre staff, which are reviewed by its advisory committee – comments and lessons to be learned from the incidents are then circulated in the surgical literature. CORESS' ethos focuses on encouraging learning from incidents rather than assigning blame to individuals.

9.7.5 *For future research*

Future research into patient safety during arterial intervention should further investigate the relationship between system failures and patient outcomes to validate the findings presented in this thesis. Such studies will need to be properly powered to test for associations between intraoperative failure rates and rare outcomes such as in-hospital mortality - outcomes should also be carefully risk-adjusted to provide credible results.

The original work presented in this thesis demonstrated that endovascular procedures are independently associated with higher rates of intraoperative safety failures compared to open surgical procedures. Future work should endeavour to understand the underlying reasons for this observation. It has been suggested that the increased size and complexity of the operating team due to collaboration between surgical and interventional radiology (IR) staff play a role. It would be interesting to compare intraoperative failure rates and patient outcomes for endovascular procedures performed by one primary team consisting of a leader operator and 'hybrid' scrub nurses, versus teams reliant on collaboration between surgery and IR. This work would enable vascular teams to understand which model of team composition is best for patients and could guide the requirements for future team-training programmes.

There is much work to be done to assess the efficacy of interventions designed to minimise intraoperative failures to improve patient safety in arterial intervention. Based on the findings of the work presented in this thesis, an obvious target for evaluation at present is the implementation of fully-immersive, simulated, team-training programmes. Simulation-based team training programmes have the potential to reduce the number of communication and equipment-related failures by enabling different professional groups to train together in an environment very similar to the real-life operating theatre - using equipment normally employed during actual arterial procedures. Given the emerging evidence in other specialties that surgical team training confers a significant benefit in terms of patient outcomes (103), this strategy is certainly worthy of investigation in arterial surgery. There is likely to be benefit in the development of a local systems for operating teams to feedback intraoperative safety concerns and system failures (in a similar manner to the ICECAP debriefs conducted as part of the LEAP study) to identify targets for safety improvement in-house. Alongside local learning and safety improvement, there may also be scope for audits of safety in arterial surgery to be conducted via the National Vascular Registry to enable learning from safety issues at a national level.

9.7.6 *For the benefit of patients and their families*

In the current era, patients undergoing arterial intervention, and their families, should be reassured by the tremendous progress that have been made in this specialty over the past

two decades. Significant improvements in outcome have been possible because of the incredible expertise and dedication of the vascular teams involved, as well as tremendous advancements in technology and the careful reorganisation of services in the UK to concentrate expertise and technologies in specialist centres of excellence. The work presented in this thesis points to a new era in which attention to human factors will underpin further improvements in safety and outcomes for patients undergoing arterial intervention.

9.8 CONCLUDING REMARKS

The work presented in this thesis has utilised a variety of methods to explore the causes of preventable harm to patients undergoing arterial intervention. By adopting of a systems approach to understanding safety in this high-risk patient group, a broad range of important factors have been considered. At the outset, this thesis highlighted that there is little research addressing the relationship between system factors and patient outcome in arterial surgery. Despite some methodological limitations, the original work presented here has provided a broad understanding of important system factors and has shown that intraoperative safety failures are likely to influence patient outcome. Thus, there is a real need for practical strategies to minimise the incidence of intraoperative safety failure and for further research in this arena. This thesis has demonstrated the need for greater focus on how teams, their tools and the environment interact for reliable performance, in the pursuit of patient safety in arterial surgery.

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APPENDICES

APPENDIX 1: SEARCH STRATGEY

1. (adverse adj2 event$).ab,ti.
2. Postoperative Complications/ep, mo [Epidemiology, Mortality]
3. patient safety indicator$.ab,ti.
4. harm.ab,ti.
5. error$.ab,ti.
6. morbidity/ or incidence/ or prevalence/ or mortality/ or "cause of death"/ or fatal outcome/ or hospital mortality/ or survival rate/
7. frequency.ab,ti.
8. rate.ab,ti.
9. severity.ab,ti.
10. Treatment Outcome/
11. consequence$.ab,ti.
12. avoidable.ab,ti.
13. prevent$.ab,ti.
14. operation.ab,ti.
15. intervention$.ab,ti.
16. surg$.ab,ti.
17. Arterial Occlusive Diseases/ or Peripheral Arterial Disease/
18. Vascular Surgical Procedures/ or vascular surgery.mp.
19. endovascular.ab,ti.
20. bypass.ab,ti.
21. aort$.ab,ti.
22. carotid.ab,ti.
23. Aortic Aneurysm, Abdominal/ or Aneurysm, Dissecting/ or Aneurysm, Ruptured/ or Aortic Aneurysm, Thoracic/ or Iliac Aneurysm/ or Aortic Aneurysm/
24. Limb Salvage/ae, mo [Adverse Effects, Mortality]
25. 1 or 2 or 3 or 4 or 5
26. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
27. 14 or 15 or 16
28. 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
29. 25 and 26 and 27 and 28
30. "gastric bypass".ab,ti.
31. "cardiopulmonary bypass".ab,ti.
32. "heart bypass".ab,ti.
33. "coronary artery bypass".ab,ti.
34. "coronary bypass".ab,ti.
35. "coronary intervention".ab,ti.
36. "aortic valve".ab,ti.
37. "coronary artery stenting".ab,ti.
38. (cerebral adj3 aneurysm).ab,ti.
39. 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38
40. 29 not 39
41. limit 40 to abstracts
42. limit 41 to humans
43. limit 42 to english language

APPENDIX 2: ETHICAL APPROVAL LETTER

NRES Committee London - City Road & Hampstead
Bristol Research Ethics Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1339
Facsimile: 0117 342 0445

26 June 2012

Mr Colin D Bicknell
Clinical Senior Lecturer and Hon Consultant Surgeon
Imperial College London
Vascular Secretaries Office St Mary
Waller Cardiac Building
St Mary's Hospital, Praed Street
W2 1NY

Dear Mr Bicknell

Study title:	**A national evaluation of error during aortic procedures in the open and endovascular operating environment.**
REC reference:	**12/LO/0710**

Thank you for your letter of 20 June 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Alternative Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

12/LO/0710:	**Please quote this number on all correspondence**

Yours sincerely

Dr David Slovick
Chair

APPENDIX 3: QUESTIONNAIRE

THE CAUSES OF ADVERSE EVENTS IN ARTERIAL SURGERY

Investigator: Rachael Lear
Academic supervisors: Mr. Colin Bicknell, Professor Charles Vincent, Professor Nicholas Cheshire, Professor Christine Norton

Imperial College London

This survey is designed to understand your perception of factors leading to adverse events in arterial surgery.

Profession:	Grade:	Gender:	Age:
☐ Surgeon ☐ Radiologist ☐ Other	☐ Registrar ☐ Fellow ☐ Consultant ☐ Other	☐ Male ☐ Female	

Please answer this questionnaire using the following definition of an adverse event:

'unintended injury to a patient caused by medical management rather than by the patient's disease process'

Think about a *recent* adverse event that you witnessed during or within 24 hours of an *arterial* operation – please indicate the details below:

Procedure: (e.g. EVAR):		How long ago did this adverse event occur?	What was the outcome for the patient?
_____	☐ open ☐ endovascular ☐ elective ☐ emergency	☐ < 2 months ☐ < 1 year ☐ < 2 years	☐ Temporary disability/prolonged hospital stay ☐ Permanent disability ☐ Death

Please use the scale to comment on the extent to which you feel each factor contributed towards the adverse event you have in mind.

1	2	3	4	5
High unlikely	Unlikely	Neutral	Likely	Highly likely

PATIENT FACTORS					
1. Condition (complexity & seriousness)	1	2	3	4	5
2. Language and communication (with the *patient*)	1	2	3	4	5
3. Personality and social factors (patient)	1	2	3	4	5
TASK AND TECHNOLOGY FACTORS					
4. Task design & clarity of structure	1	2	3	4	5
5. Availability & use of protocols/ inappropriate protocols	1	2	3	4	5
6. Availability & accuracy of test results	1	2	3	4	5
7. Decision-making aids	1	2	3	4	5
INDIVIDUAL (STAFF) FACTORS					
8. Knowledge & skills	1	2	3	4	5
9. Competence/ experience	1	2	3	4	5
10. Physical and mental health, including fatigue	1	2	3	4	5
TEAM FACTORS					
11. Verbal communication	1	2	3	4	5
12. Written communication	1	2	3	4	5
13. Supervision & seeking help, including lack of supervision of trainees	1	2	3	4	5
14. Team structure (congruence, consistency, leadership, etc.)	1	2	3	4	5
WORK ENVIRONMENTAL FACTORS					
15. Staffing levels & skills mix	1	2	3	4	5
16. Workload & shift patterns	1	2	3	4	5
17. Design, availability and maintenance of equipment	1	2	3	4	5
18. Administrative and managerial support	1	2	3	4	5
19. Physical environment (light, space, noise, etc)	1	2	3	4	5
ORGANISATIONAL & MANAGEMENT FACTORS					
20. Financial resources & constraints	1	2	3	4	5
21. Organisational structure	1	2	3	4	5
22. Policy, standards, goals	1	2	3	4	5
23. Safety culture & priorities	1	2	3	4	5
INSTITUTIONAL CONTEXT FACTORS					
24. Economic & regulatory context	1	2	3	4	5
25. Links with external organisations	1	2	3	4	5

Adapted from Vincent, C, Taylor-Adams, S, Stanhope, S. Framework for analyzing risk and safety in clinical medicine. *BMJ*. 1998; 316: 1154-7, & Gawande AA, Zinner MJ, Studdert, DM, Brennan TA. Analysis of errors reported by surgeons at three teaching hospitals. *Surgery*, 2003: 133: 614-21.

APPENDIX 4: INTERVIEW SCHEDULE

Opening the interview:

"Thank you very much for your time – this interview should last approximately 30 minutes. The aim of this interview study is to explore vascular surgeons' perceptions of how and why adverse events occur in arterial surgery. We'll start by talking broadly about adverse events before going onto to discuss your own personal experiences. You will not be identified in the final report. Do you have any questions? Are you happy to proceed?"

[Complete written consent form if not already completed]

Introductory warm-up question:

1. "*First of all, please tell me about your current role and how long you have been working in vascular surgery."*

Question to introduce the concept of an adverse event and to ensure that definitions are aligned:

2. "*What is your understanding of the term 'adverse event'?"*

   "For the rest of this interview, the definition of an adverse event that we will use is 'injury to the patient caused by medical management, rather than the patient's underlying disease process'".

Open-ended questions about the interviewee's experiences of adverse events:

3. *"Think about you experience in arterial surgery over the last 2 years. Are there any factors that you feel have often lead to adverse events?"*

   Please consider one recent adverse event in particular. Can you briefly outline the adverse event, and why you think it happened?"

Questions related to interviewee's survey responses:

5. "*Please look at this survey. Could you score each factor on the Likert scale according to the extent to which you feel it contributed towards the adverse event you have described.*

"*Are there any factors that you have scored 4 or 5 here, which we haven't already discussed? Can you expand on your answer?"*

Question to elicit safety improvement recommendations:

10. "Finally, reflecting on your experiences of adverse events in arterial surgery, what realistic recommendations can you make to prevent future adverse events from occurring?"

APPENDIX 5: INVITATION TO INTERVIEW

Dear …

I am writing to you in my capacity as a PhD student undertaking research in the field of patient safety in vascular surgery.

The overriding aim of my research is to establish the nature of safety failures in vascular surgery, in order to inform future initiatives to improve safety in this specialty.

I am writing to invite you to kindly participate in an interview study that would require approximately 30 minutes of your time.

The aim of this interview study is to identify surgeons' perceptions of important factors that have contributed towards adverse events in arterial surgery in recent years. This study is the qualitative component of a wider safety agenda that investigates error and adverse events in vascular surgery to inform future safety improvement strategies.

Please be reassured that, while interviews will be recorded, any identifiable information will be removed during the transcription process, and findings of the study will be reported anonymously.

I would be very grateful if you would consider participating; your contribution would be extremely valuable.

Kind Regards

Rachael Lear

Clinical Academic Staff Nurse
Vascular Surgery
Imperial College NHS Healthcare Trust

APPENDIX 6: INTERVIEW CONSENT FORM

UK LEAP study:
The Landscape of Error in Aortic Procedures

Chief Investigator: Mr Colin Bicknell

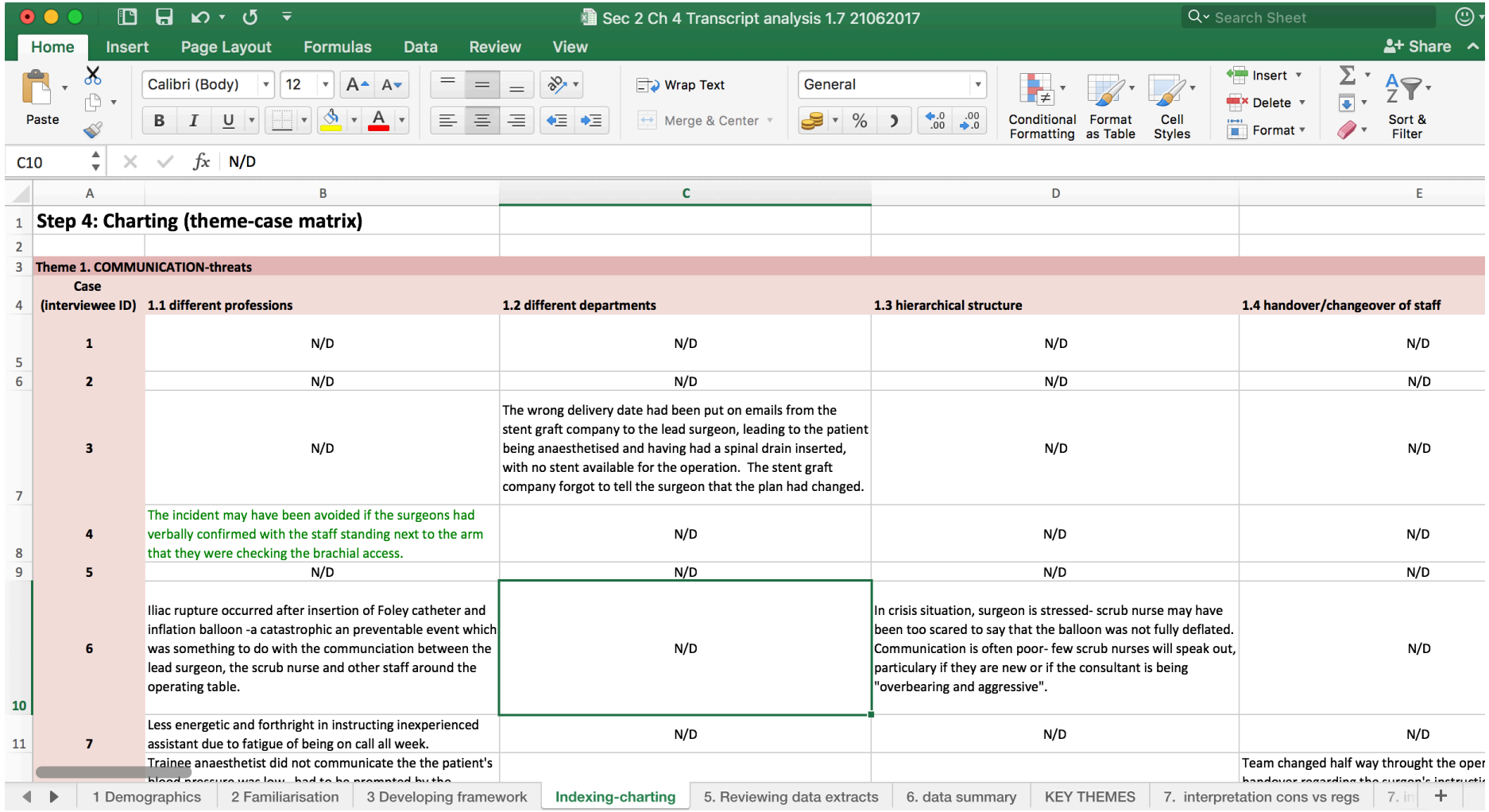
Adverse events in Vascular Surgery

INTERVIEW CONSENT FORM FOR OPERATING STAFF

	Please initial boxes
1. I confirm that I have read and understand the research information sheet for the above study and have had the opportunity to ask questions which have been answered fully.	☐
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my legal rights being affected.	☐
3. I understand that any identifiable data expressed in this interview will be anonymised.	☐
4. I agree to take part in the interview study.	☐

Name of Participant	Signature	Date
Name of Person taking consent (if different from the principal investigator)	Signature	Date
Name of Principal Investigator	Signature	Date

APPENDIX 7: SCREENSHOT TO ILLUSTRATE THEME-CASE MATRIX



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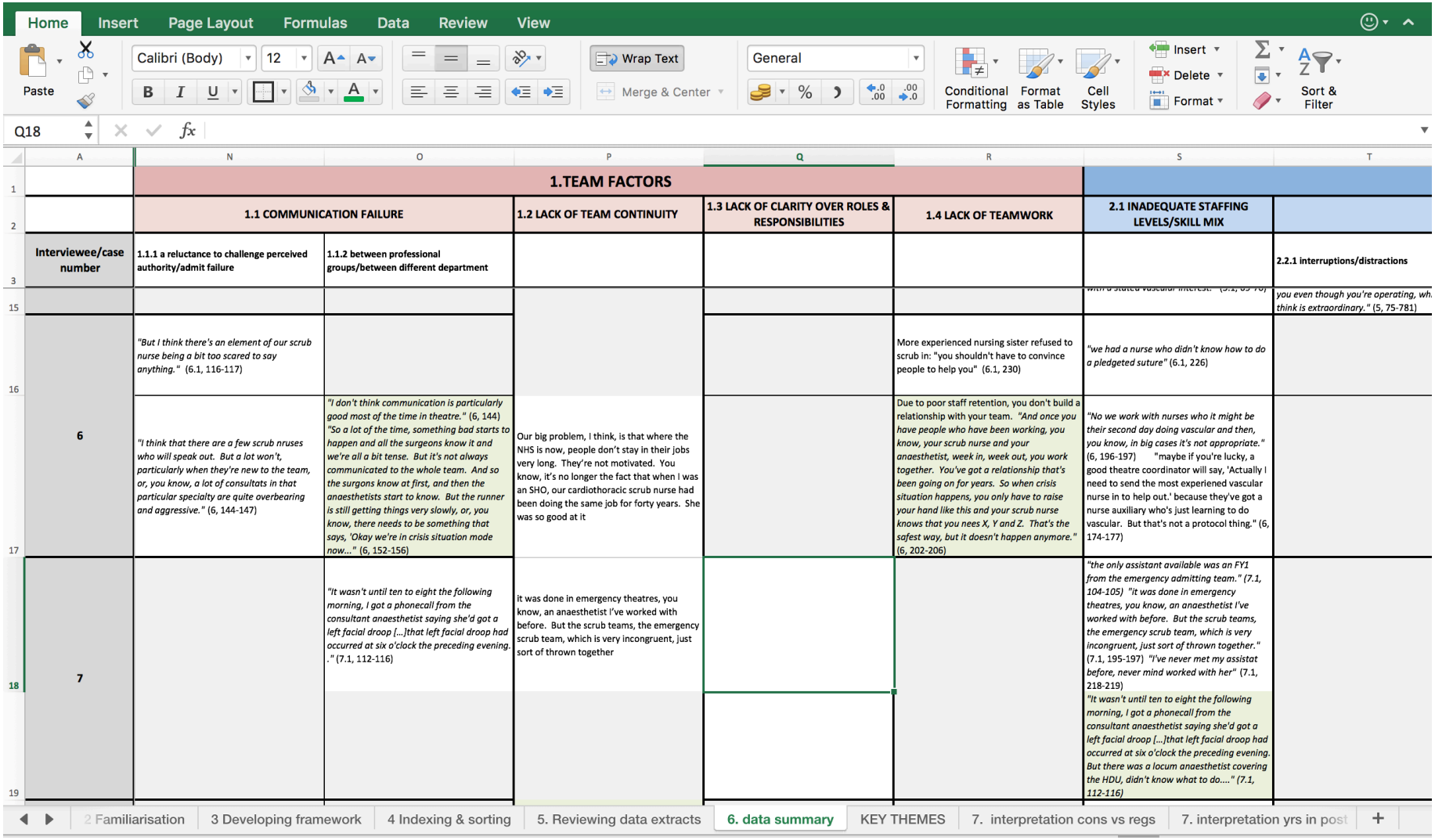
	A	B	C	D	E
1	**Step 4: Charting (theme-case matrix)**				
2					
3	**Theme 1. COMMUNICATION-threats**				
4	**Case (interviewee ID)**	**1.1 different professions**	**1.2 different departments**	**1.3 hierarchical structure**	**1.4 handover/changeover of staff**
5	**1**	N/D	N/D	N/D	N/D
6	**2**	N/D	N/D	N/D	N/D
7	**3**	N/D	The wrong delivery date had been put on emails from the stent graft company to the lead surgeon, leading to the patient being anaesthetised and having had a spinal drain inserted, with no stent available for the operation. The stent graft company forgot to tell the surgeon that the plan had changed.	N/D	N/D
8	**4**	The incident may have been avoided if the surgeons had verbally confirmed with the staff standing next to the arm that they were checking the brachial access.	N/D	N/D	N/D
9	**5**	N/D	N/D	N/D	N/D
10	**6**	Iliac rupture occurred after insertion of Foley catheter and inflation balloon -a catastrophic an preventable event which was something to do with the communciation between the lead surgeon, the scrub nurse and other staff around the operating table.	N/D	In crisis situation, surgeon is stressed- scrub nurse may have been too scared to say that the balloon was not fully deflated. Communication is often poor- few scrub nurses will speak out, particulary if they are new or if the consultant is being "overbearing and aggressive".	N/D
11	**7**	Less energetic and forthright in instructing inexperienced assistant due to fatigue of being on call all week.	N/D	N/D	N/D
		Trainee anaesthetist did not communicate the the patient's			Team changed half way throught the oper

1 Demographics | 2 Familiarisation | 3 Developing framework | Indexing-charting | 5. Reviewing data extracts | 6. data summary | KEY THEMES | 7. interpretation cons vs regs

N/D = Not Discussed during interview

APPENDIX 8: SCREENSHOT TO ILLUSTRATE TRANSCIPT DATA SUMMARY



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	A	N	O	P	Q	R	S	T
1		1.TEAM FACTORS						
2		1.1 COMMUNICATION FAILURE		1.2 LACK OF TEAM CONTINUITY	1.3 LACK OF CLARITY OVER ROLES & RESPONSIBILITIES	1.4 LACK OF TEAMWORK	2.1 INADEQUATE STAFFING LEVELS/SKILL MIX	
3	Interviewee/case number	1.1.1 a reluctance to challenge perceived authority/admit failure	1.1.2 between professional groups/between different department					2.2.1 interruptions/distractions
15								*you even though you're operating, wh think is extraordinary."* (5, 75-781)
16		*"But I think there's an element of our scrub nurse being a bit too scared to say anything."* (6.1, 116-117)				More experienced nursing sister refused to scrub in: "you shouldn't have to convince people to help you" (6.1, 230)	*"we had a nurse who didn't know how to do a pledgeted suture"* (6.1, 226)	
17	6	*"I think that there are a few scrub nruses who will speak out. But a lot won't, particularly when they're new to the team, or, you know, a lot of consultats in that particular specialty are quite overbearing and aggressive."* (6, 144-147)	*"I don't think communication is particularly good most of the time in theatre."* (6, 144) *"So a lot of the time, something bad starts to happen and all the surgeons know it and we're all a bit tense. But it's not always communicated to the whole team. And so the surgons know at first, and then the anaesthetists start to know. But the runner is still getting things very slowly, or, you know, there needs to be something that says, 'Okay we're in crisis situation mode now..."* (6, 152-156)	Our big problem, I think, is that where the NHS is now, people don't stay in their jobs very long. They're not motivated. You know, it's no longer the fact that when I was an SHO, our cardiothoracic scrub nurse had been doing the same job for forty years. She was so good at it		Due to poor staff retention, you don't build a relationship with your team. *"And once you have people who have been working, you know, your scrub nurse and your anaesthetist, week in, week out, you work together. You've got a relationship that's been going on for years. So when crisis situation happens, you only have to raise your hand like this and your scrub nurse knows that you nees X, Y and Z. That's the safest way, but it doesn't happen anymore."* (6, 202-206)	*"No we work with nurses who it might be their second day doing vascular and then, you know, in big cases it's not appropriate."* (6, 196-197) "maybe if you're lucky, a good theatre coordinator will say, 'Actually I need to send the most experiened vascular nurse in to help out.' because they've got a nurse auxiliary who's just learning to do vascular. But that's not a protocol thing." (6, 174-177)	
18	7		*"It wasn't until ten to eight the following morning, I got a phonecall from the consultant anaesthetist saying she'd got a left facial droop [...]that left facial droop had occurred at six o'clock the preceding evening. ."* (7.1, 112-116)	it was done in emergency theatres, you know, an anaesthetist I've worked with before. But the scrub teams, the emergency scrub team, which is very incongruent, just sort of thrown together			*"the only assistant available was an FY1 from the emergency admitting team."* (7.1, 104-105) *"it was done in emergency theatres, you know, an anaesthetist I've worked with before. But the scrub teams, the emergency scrub team, which is very incongruent, just sort of thrown together."* (7.1, 195-197) *"I've never met my assistat before, never mind worked with her"* (7.1, 218-219)	
19							*"It wasn't until ten to eight the following morning, I got a phonecall from the consultant anaesthetist saying she'd got a left facial droop [...]that left facial droop had occurred at six o'clock the preceding evening. But there was a locum anaesthetist covering the HDU, didn't know what to do...."* (7.1, 112-116)	

2 Familiarisation | 3 Developing framework | 4 Indexing & sorting | 5. Reviewing data extracts | 6. data summary | KEY THEMES | 7. interpretation cons vs regs | 7. interpretation yrs in post

APPENDIX 9: PARTICIPANT INFORMATION SHEET AND CONSENT FORM

This participant information sheet and consent form was used for the studies presented in chapters 5-8.

RESEARCH INFORMATION SHEET FOR OPERATING STAFF

UK LEAP study:
The Landscape of Error in Aortic Procedures

Chief Investigator: Mr Colin Bicknell
Principal Investigator at this site:

UK LEAP Study
Landscape of Error in Aortic Procedures

What is the purpose of the research?

The purpose of this research is to establish the patterns of error, inefficiency and delay that occur in open and endovascular aortic procedures at multiple UK centres, and to determine the impact of these errors on our patients, in terms of adverse events intra-operatively and complications post-operatively. The findings of this research study will be used to identify and develop mechanisms to improve the safety of our patients.

What do we mean by 'error'? Is this a test?

No, this study is not about testing people's performance or abilities. We recognise that when errors occur, these are usually a result of the complex interplay between clinicians, their tools, and their working environment. In this study, we define error as any action or event prevented the operation from proceeding in an ideal fashion. In practice, this means an error could be anything from the diathermy machine not working, to a miscommunication of instructions, to a pager going off causing distraction. Should you decide to participate in this research, you will gain a greater understanding of what we mean when we use the term 'error', but for now, please be reassured that this study is not a test of your skills or performance.

What are the research methods?

Participating operating teams will be trained to use the Imperial College Error Capture record (ICECAP), which acts as a prompt to assist operating teams to recall errors, inefficiencies and delays occurring during aortic procedures. This error record is completed at the end of consecutive aortic cases. Errors that occurred during the procedure are assigned to various categories on the record, and are assessed for their potential to cause harm to the patient, or delay.

There will be a training phase with participating teams, during which the trainer will be in the operating theatre as an observer, recording errors that occur in real time. At the end of the case the trainer will facilitate the team to use the error record to recall errors. Observer and team recall records will be compared and discussed to ensure the team feel confident in completing the error record and understand what kinds of errors should be recorded. The training phase will usually consist of five arterial cases, and will take place in the team's usual operating theatre.

Following the training phase, operating teams will continue to complete the error record at the end of consecutive aortic cases. There will no longer be a trainer/observer in theatre. Data collection will therefore rely on teams self-reporting error with the error record.

Two further methodologies will help researchers to establish the nature of safety failure in vascular surgery. Operating staff will be asked to complete a questionnaire that enables assessment of collective attitudes towards various influences on patient safety. Staff will also be invited to take part in an interview to explore an adverse event or clinical incident that they were involved in or witnessed.

During the interview, staff will be asked to describe what they felt were the various factors that contributed towards the occurrence of the adverse event they describe. The questionnaires and interviews provide an opportunity for frontline workers to express their attitudes towards, and thoughts about, the nature of patient safety in this speciality.

How long does the research take?

The 'team recall' of error takes about 5-10 minutes at the end of a case. The lead surgeon directs it, but any unscrubbed team member may complete the written record.

The researchers would like each operating team to use the error record for at least 10 consecutive aortic cases. Together with error records from other UK centres, the data will allow us to identify what the most important and frequent errors are.

The questionnaires take about 5 minutes to complete, and the interviews are expected to last 20-30 minutes.

Where is the research taking place?

The study is being led by a team at Imperial College, London, and is taking place at number of hospitals across the UK where open and endovascular aortic surgery is performed.

What are the benefits to participating?

By participating in this study, you would contribute towards a body of knowledge regarding the nature of error, adverse events and safety failures in vascular surgery. This knowledge will be used to devise strategies to improve the safety of our patients.
Operating teams who have used the aforementioned error record in previous research found that it was an excellent method of debriefing with their colleagues. They also found that it was beneficial in highlighting some of the safety issues that needed to be addressed in their own departments.

Are there any drawbacks?

Some staff might be concerned that the team recall of error at the end of a case might delay the next case starting, or prevent them from leaving the operating theatre promptly. Previous research using this error record found that it did not delay the list in any way, and that the team recall could be performed whilst staff are undertaking their usual duties at the end of the case.

Anonymity

Please be reassured that all information in this study will be anonymised. The department in which you are working will be assigned a unique identifier number. Staff involved will not be named and will not be identifiable to the researchers or in the final report.

Confidentiality

All data will be stored securely either electronically on computer or in hard copy version in a locked office.

Research Dissemination

Data obtained through this research will be disseminated though presentation at conferences and though publication in peer-reviewed journals.

Queries

Please direct any queries regarding this research to the principal investigator at this centre Mr Bijan Modarai or to Rachael Lear, doctoral researcher at Imperial College, London, on behalf of the Chief Investigator, Mr Colin Bicknell.

Contact:
Rachael Lear
Room 1025, 10F QEQM building,St Marys' Hospital, Praed st, London, W2 1NY
Tel: 0203 312 1979 Email: r.lear12@imperial.ac.uk

UK LEAP study:
The Landscape of Error in Aortic Procedures

Chief Investigator: Mr Colin Bicknell
Principal Investigator:

CONSENT FORM FOR OPERATING STAFF

	Please initial boxes
1. I confirm that I have read and understand the research information sheet for the above study and have had the opportunity to ask questions which have been answered fully.	☐
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my legal rights being affected.	☐
3. I agree to take part in the above study.	☐

Name of Participant	Signature	Date
Name of Person taking consent (if different from the principal investigator)	Signature	Date
Name of Principal Investigator	Signature	Date

APPENDIX 10: SAFETY CULTURE SURVEYS

Tool and authors	References	Culture domains assessed	Reliability and validity evidence	Administration setting	Key strengths	Key weaknesses	Accept /reject?
Manchester Patient Safety Culture Assessment Framework (MaPSaF) (NPSA)	http://www.nrls.npsa.nhs.uk/resources/?entryid45=59796 Parker et al. 2005 Parker et al. 2006 Kirk et al. 2007	-continuous improvement -priority given to safety -system errors and individual responsibilities -recording incidents -evaluating incidents -learning and effective change -communication -personnel management -staff education -teamwork	High face validity (Kirk et al. 2007) No other psychometric properties reported in the literature.	Developed in the UK with NHS in mind, promoted by the NPSA. Originally developed for primary care, version available for 'acute setting'. No publication on use in the operating theatre.	Safety culture is measured at organizational and team levels.	Respondents refer to a detailed framework document to complete the survey-may be time-consuming to complete. Administration usually carried out in workshops which are facilitated- may not be feasible to gather all members for multi-disciplinary operating team together for a workshop. Comparatively little published on its use.	Reject
Hospital Survey on Patient Safety Culture (HSOPSC) (AHRQ)	http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html Waterson et al. 2010	12 culture domains/42 items -teamwork within units -supervisor/manager expectations & actions promoting patient safety -organisational learning-continuous improvement -management support for safety -overall perceptions of safety -feedback & communication about error -communication openness -frequency of events reported -teamwork across units -staffing -handoffs and transitions -nonpunitive response to error	Potential validity issues. UK version: more than half of scale items failed to achieve internal consistency/ poor fit compared to American model (Waterson et al. 2010)	Developed for use in the hospital setting in the US, widely used outside of the US. Previously administered in the operating room setting.	Safety culture can be measured at individual, unit and organizational levels. Benchmarking data available.	Caution advised for use in the UK due to validity issues (Waterson et al., 2010)	Reject

Tool and authors	References	Culture domains assessed	Reliability and validity evidence	Administration setting	Key strengths	Key weaknesses	Accept/ reject?
Safety Attitudes Questionnaire (Sexton et al. 2006)	https://med.uth.edu/chqs/surveys/safety-attitudes-and-safety-climate-questionnaire/ Sexton et al. 2006	6 domains (60 or 30 items) -teamwork climate -safety climate -perceptions of management -job satisfaction -working conditions -stress recognition	Scale reliability is 0.9 (Sexton et al. 2006)	Multiple healthcare setting including the operating room. Widely used outside the USA, including the UK.	Benchmarking data available. Short form (30 items) available. Measures safety culture at the unit level. Operating room version available. Relatively short & simple to complete. SAQ scores have been associated with staff and patient outcomes	Comparatively less culture domains than other tools.	Accept

APPENDIX 11: LETTER OF PERMISSION FOR USE OF THE SAFETY ATTITUDES QUESTIONNAIRE

On 1/28/12, Rachael Lear <lear_rachael@yahoo.co.uk> wrote:
> Dear authors,
>
> I am developing a PhD research proposal that will examine safety
> culture and the landscape of error in open and endovascular aortic
> surgery. The project will be undertaken by a team from Imperial
> College, London and will involve around 20 vascular teams across the UK.
>
> I
> am impressed with the validity of the Safety Attitudes Questionnaire,
> and am writing to ask how I might formally request permission to use
> the operating room version of it in our study?
>
> Many thanks for your time,
>
> Kind Regards,
>
> Rachael Lear
>
> Staff nurse/ PhD research student (vascular)
> St Mary's Hospital
> Praed Street
> Paddington
> London
> W2 1NY

You are most welcome to use the SAQ. No other permission needed. Good luck.

Bob
--
Robert L. Helmreich, PhD, FRAeS
Professor Emeritus of Psychology
The University of Texas at Austin
1534 Hill Circle South Dr
Granite Shoals, TX 78654

APPENDIX 12: SAFETY ATTITUDES QUESTIONNAIRE

SAFETY CULTURE IN VASCULAR SURGERY

Imperial College London

UK LEAP study
Chief Investigator: Mr. Colin Bicknell. Principal Investigator: X

This questionnaire is designed to understand safety-relevant issues in the operating theatre. The findings of this survey will be used to guide future safety improvement initiatives.

BACKGROUND INFORMATION		
☐ Surgeon ☐ Radiologist ☐ Radiographer ☐ Scrub/ circulating nurse ☐ Anaesthetist ☐ ODP/ODA ☐ HCA ☐ Other (please state) _____ GRADE: _____	How many years of experience do you have working in vascular surgery in your current unit? _____ (years)	Gender: ☐ Male ☐ Female Age (years): _____

Please answer the following with respect to your experiences in the vascular operating theatres and angiography/interventional radiology suite here.

1	2	3	4	5
Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly

1. Nurse input about patient care is well received in the operating theatre.	1	2	3	4	5
2. I would feel safe being treated in my hospital as a patient.	1	2	3	4	5
3. Medical errors* are handled appropriately in my hospital.	1	2	3	4	5
4. This hospital does a good job of training new personnel.	1	2	3	4	5
5. All the necessary information is available before the start of a procedure.	1	2	3	4	5
6. The administration of my hospital is doing a good job.	1	2	3	4	5
7. I receive appropriate feedback about my performance.	1	2	3	4	5
8. In the operating theatre, it is difficult to discuss errors*.	1	2	3	4	5
9. Hospital management does not knowingly compromise the safety of patients.	1	2	3	4	5
10. The levels of staffing in our operating theatres are sufficient to handle the number of patients.	1	2	3	4	5
11. I am encouraged by my colleagues to report any patient safety concerns I may have.	1	2	3	4	5
12. The culture in the operating theatres here makes it easy to learn from the errors of others.	1	2	3	4	5
13. My hospital deals constructively with problem clinicians and employees.	1	2	3	4	5
14. It is difficult to speak up if I perceive a problem with patient care.	1	2	3	4	5
15. I am provided with adequate, timely information about events in my hospital that might affect my work.	1	2	3	4	5
16. I know the proper channels to direct questions regarding patient safety in my operating theatres.	1	2	3	4	5
17. Disagreements in my operating theatres are resolved appropriately (i.e. not *who* is right but *what* is best for the patient)	1	2	3	4	5
18. I have the support I need from other staff to treat my patients.	1	2	3	4	5
19. It is easy for staff in my operating theatres to ask questions when there is something that they do not understand.	1	2	3	4	5
20. The clinicians and nurses here work together as a well-coordinated team.	1	2	3	4	5
21. Trainees in my discipline are adequately supervised.	1	2	3	4	5

*Medical error is defined as any mistake in the delivery of care, by any healthcare professional, regardless of the outcome.

Thank you for completing this questionnaire- your time and participation are greatly appreciated.

APPENDIX 13: PATIENT INFORMATION SHEET AND CONSENT FORM

TRUST LOGO HERE

The UK LEAP study

The Landscape of Error in Aortic Procedures
Chief Investigator: Mr. Colin Bicknell
Principal Investigator: XXX

Patient Information Sheet (Non-aortic cases)

You are being invited to take part in a research study. Before you decide whether or not to take part in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Do contact me if there is anything that is not clear or if you would like more information. It is important that you take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

Members of the vascular team are constantly striving to improve the service and care that they give in order to improve the quality of care patients receive. Patient safety in surgery is one of our top priorities. Although we do everything we can to make patient care and treatment as safe as possible, surgical procedures do entail some degree of risk, which your doctor will be happy to discuss with you. Consequently, the aims of this study are to identify and evaluate areas of risk during vascular operations. The study will record potential errors, inefficiencies and safety failures, primarily during aortic surgery. The results will be used to develop strategies to improve safety for our patients.

Why have I been chosen?

You have been selected because you are having surgery performed by the vascular operating team. The aim of this study is to investigate safety in the vascular operating department, primarily during operations on the aorta (the large blood vessel supplying blood and oxygen to the body from the heart). While the focus of this study is on aortic operations, the initial stage of this study involves all patients having surgery in the vascular operating department.

Do I have to take part?

No, you do not have to take part in this study; it is entirely up to you to decide whether or not to take part. Whether or not you decide to take part, you will be given this information sheet to keep.
If, after careful consideration, you do decide to take part, you will be asked to sign a consent form and return it to me. You will then be sent a copy of your signed consent from to keep with this information sheet. Even if you do decide to take part and

return the consent from, you are still free to withdraw from the study at any time and you do not need to give a reason. Please be assured that the decision not to take part or a decision to withdraw from the study at any time during the research will not affect the standard of care that you receive from the vascular team.

What will happen to me if I take part?

You will receive exactly the same care and treatment as you would have done if you were not taking part. This is an observational study, meaning that researchers will simply take note of events that happen during the course of your normal care and treatment. You will undergo your operation as planned; the only difference if you decide to take part is that the healthcare staff involved in your operation will also record data relevant to the study. There may be an observer in theatre during your operation but he or she will not have any impact on the course of your procedure. After your operation, your vascular operating team will meet together to record any potential errors or risks to safety that may have arisen during your operation. The team may also monitor you for any complications, as usual, following your procedure until the end of your hospital stay. Any complications that you might experience could be recorded as part of the data collection process. If, after giving informed consent to participate, you experience a complication that causes you to lose mental capacity (such as confusion after a general anaesthetic), your data would still be included in the study, as this information is very useful to providing us with a clear picture of post operative complications.

What are the possible disadvantages and risks of taking part?

Reading this information leaflet may prompt you to have concerns about safety and the risks of surgery. If this is the case, please feel free to discuss this with your healthcare team. If you would like to discuss any concerns you might have about safety following your operation, this can also be organised for you.

What are the possible benefits of taking part?

You, along with other people taking part in this research study, will be part of a project that aims to highlight potential safety issues with a view to improving safety in vascular surgery for all patients.

We aim to provide national guidance on potential safety improvement strategies.

Will my taking part in this study be kept confidential?

Only the researchers and members of the hospital team caring for you will have access to your medical records. Any information gathered about you will be anonymous (this means that no personal data, such as your name, address, date of birth will be recorded). No member of the vascular team, or anyone involved in your care, will be able to identify who or who has not taken part in the research from the final report. Your own names will not be used and no personal information about yourself will be given in the final report.

What will happen to the results of the research study?

The results of the research study will be collected together and a report written. The report will be presented to experts in the vascular field and vascular teams who were involved in this study, to help them to generate ideas to improve safety in vascular surgery.
Results from the research will be published in professional healthcare journals, and will also be presented at professional conferences, in order that other healthcare professionals and patients will learn and benefit from the results.

Who is organising and funding the research?

This research has been organised by representatives from the vascular team at St Mary's Hospital and Imperial College, London. Vascular teams at multiple hospitals are carrying out the research across the UK. Funding has been granted by the Circulation Foundation of Great Britain.

Who has reviewed the study?

This study has been reviewed by the City Road and Hampstead Research Ethics Committee and the Circulation Foundation of Great Britain.

Contact for further information

If you have any further questions or wish further information, then please contact the principal investigator at your hospital:

Name:
Address:
Phone number:
Email:

I would like to take this opportunity to thank you for taking the time to read this information sheet and, whether or not you decide to take part in the research, thank you for considering it.

TRUST LOGO HERE

INFORMED CONSENT FORM

The UK LEAP study

Name of Chief Investigator: Mr. Colin Bicknell
Name of Principal Investigator: XXX

Please initial box

1. I confirm that I have read and understand the participant information sheet dated 31/01/13, version 1.6 or 1.7, for the above study and have had the opportunity to ask questions which have been answered fully. ☐
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from York Teaching Hospital or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to access my records that are relevant to this research. ☐
4. I understand that, should I lose mental capacity after giving informed consent to take part,my data will still be included in the study, ☐
5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient/Participant	Signature	Date
_____	_____	_____
Name of Person taking consent (if different from Principal Investigator)	Signature	Date
_____	_____	_____
Principal Investigator	Signature	Date

1 copy for patient/participant; 1 copy for Principal Investigator; 1copy to be kept with hospital notes

Version 1.3 29/05/12

APPENDIX 14: AORTIC CASE LOG

UK LEAP

Centre #:

CI: Mr Colin Bicknell
PI: XXX

Aortic Case Log

Data collection period: From ___/___/___ to ___/___/___
Consultant initials: _____

Case #	Name of procedure	Date	Patient recruited? (If Yes- please give study ID #)	If not recruited, please give the reason:
1			☐ Yes ☐ No	☐ Refused consent ☐ Does not have mental capacity to consent ☐ Other: please give details:
2			☐ Yes ☐ No	☐ Refused consent ☐ Does not have mental capacity to consent ☐ Other: please give details:
3			☐ Yes ☐ No	☐ Refused consent ☐ Does not have mental capacity to consent ☐ Other: please give details:
4			☐ Yes ☐ No	☐ Refused consent ☐ Does not have mental capacity to consent ☐ Other: please give details:
5			☐ Yes ☐ No	☐ Refused consent ☐ Does not have mental capacity to consent ☐ Other: please give details:
6			☐ Yes ☐ No	☐ Refused consent ☐ Does not have mental capacity to consent ☐ Other: please give details:
7			☐ Yes ☐ No	☐ Refused consent ☐ Does not have mental capacity to consent ☐ Other: please give details:
8			☐ Yes ☐ No	☐ Refused consent ☐ Does not have mental capacity to consent ☐ Other: please give details:
9			☐ Yes ☐ No	☐ Refused consent ☐ Does not have mental capacity to consent ☐ Other: please give details:
10			☐ Yes ☐ No	☐ Refused consent ☐ Does not have mental capacity to consent ☐ Other: please give details:

APPENDIX 15: COMPLETED EXAMPLE OF THE IMPERIAL COLLEGE ERROR CAPTURE TOOL

UK LEAP
CI: Mr Colin Bicknell
Centre #:
Patient ID #:

Imperial College Error CAPture Record (ICECAP)

PATIENT IDENTIFIER NUMBER: [redacted]

Imperial College Error CAPture record (ICECAP)

To use ICECAP, follow these steps:

☐ **1. Allocate one member of team to be 'scribe'.**

(This team member will lead the team-recall during skin closure and record re-called errors in the ICECAP record.)

☐ **2. Scribe to read the following aloud before the start of the procedure:**

(We suggest doing this during "Time-Out" if using the WHO Surgical Safety Checklist)

"In an effort to improve patient safety in vascular surgery, we, as a team, are involved in a research study in collaboration with representatives of Imperial College, London, and the Circulation Foundation.
The research aims to identify errors, inefficiencies and safety failures that occur during aortic procedures. During this case, all team members should make a mental note of errors, inefficiencies and safety failures that occur. This is not a test of your technical abilities, and you should go about your duties in the usual manner. During skin closure, the team will collaborate to recall errors, inefficiencies and safety failures that occurred, and the scribe will record these on the Imperial College Error CAPture record. Definitions of error are given on page 2 of the ICECAP record."

☐ **3. Scribe to lead team-recall of error and complete ICECAP record during skin closure.**

Please use verbal prompts at the top of each error category on the ICECAP record and record as many errors as you can recall in the boxes given. There is no minimum or maximum number of errors that can be recorded.

UK LEAP
CI: Mr Colin Bicknell
Centre #:
Patient ID #:

Imperial College Error CAPture Record (ICECAP)

1. Equipment Issues

Scribe to read aloud:

1. (if applicable) "**Radiological equipment:** any equipment unavailable, faulty, not configured correctly or desterilised?"
2. "**Surgical equipment:** any equipment unavailable, faulty, not configured correctly or desterilised?"
3. "**Anaesthetic equipment:** any equipment unavailable, faulty, not configured correctly or desterilised?"
4. "Were there any **drugs or medication-related issues**?"
5. "Were there **any other** equipment-related issues that have not already been mentioned?"

Record errors/inefficiencies/safety failures below:

Error #	Equipment category:	Type of equipment problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☐ Radiological ☑ Surgical ☐ Drugs/medication ☐ Other	☑ Unavailable ☐ Failure/fault ☐ Configuration ☐ Desterilised	Sticky drapes not available at start.	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☐ No delay ☑ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2	☑ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☑ Unavailable ☐ Failure/fault ☐ Configuration ☐ Desterilised	Covered disc stents not immediately available → aortic balloon placed (FOR THE EMERGENCY THAT RESCUE)	☐ Yes, actual harm occurred as a direct consequence of this issue ☑ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☑ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ Radiological ☑ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☐ Configuration ☑ Desterilised	light handle desterilised	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ Radiological ☑ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☐ Configuration ☑ Desterilised	— " —	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☑ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
	☑ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☐ Configuration ☐ Desterilised	2nd Wire were not available	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☐ No delay ☑ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☑ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☑ Failure/fault ☐ Configuration ☐ Desterilised	Covered disc stent maldeployed. 2nd balloning needed	☐ Yes, actual harm occurred as a direct consequence of this issue ☑ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☑ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☑ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☑ Configuration ☐ Desterilised	Wire desterilization during emergency part. TABLE NOT LONG ENOUGH. *CONFINED ANGIO SPACE*	☐ Yes, actual harm occurred as a direct consequence of this issue ☑ Corrective measures needed to prevent harm. ☐ No harm	☑ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

UK LEAP
CI: Mr Colin Bicknell
Centre #:
Patient ID #:

Imperial College Error CAPture Record (ICECAP)

24/4/14

2. Communication

Scribe to read aloud:

☐ 1. "**Misleading.** Did anyone experience communication that was misleading or unclear?"
☐ 2. "**Lack of.** Did anyone experience a lack of communication?"
☐ 3. "**Discord.** Were there any significant disagreements between team members about the plan of action etc?"
☐ 4. "**Does not hear/misheard.** Was any information/instruction communicated that was not heard/ misheard by other team members?"

Record errors/inefficiencies/safety failures below:

Error #	Type of communication problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☐ Misleading ☐ Lack of ☑ Discord ☐ Does not hear/misheard	of team during case starting → stopped by Cons in charge	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☑ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2	☐ Misleading ☐ Lack of ☐ Discord ☑ Does not hear/misheard	Request for clamps	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☐ No delay ☑ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ Misleading ☐ Lack of ☐ Discord ☑ Does not hear/misheard	Request for swabs	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☐ No delay ☑ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ Misleading ☐ Lack of ☐ Discord ☑ Does not hear/misheard	— " —	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☑ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5	☐ Misleading ☐ Lack of ☐ Discord ☐ Does not hear/misheard		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☐ Misleading ☐ Lack of ☐ Discord ☐ Does not hear/misheard		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☐ Misleading ☐ Lack of ☐ Discord ☐ Does not hear/misheard		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

UK LEAP
CI: Mr Colin Bicknell
Centre #:
Patient ID #:

26/6/14 (88)

Imperial College Error CAPture Record (ICECAP)

3. Procedure-Independent Pressures

(ribe to read aloud:

☐ 1. **"Absence.** Were any team members absent who should have been here, or did any team member need to leave due to other pressures?"
☐ 2. **"Distraction.** Were there any distractions, e.g. from pagers or phones, interruptions etc?"
☐ 3. **"External pressures.** Were there external pressures, such as external emergencies, equipment or theatre needed for a different case?"

Record errors/inefficiencies/safety failures below:

Error #	Type of procedure-independent problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☐ Absence ☐ Distraction ☑ External pressures	delay pre op in waiting for IV bed	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☑ > 1 hour
2	☐ Absence ☑ Distraction ☑ External pressures	Medical teams entering room for unlabeled X-ray requests not recognizing emergent nature of procedure, obstructing access pathway	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☐ No delay ☑ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ Absence ☑ Distraction ☐ External pressures	Theatre staff having multiple conversations unrelating to the procedure	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☑ No delay ☐ < 1 minute ☑ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ Absence ☐ Distraction ☐ External pressures		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5	☐ Absence ☐ Distraction ☐ External pressures		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☐ Absence ☐ Distraction ☐ External pressures		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☐ Absence ☐ Distraction ☐ External pressures		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

UK LEAP
CI: Mr Colin Bicknell
Centre #:
Patient ID #:

26/6/1F (88)

Imperial College Error CAPture Record (ICECAP)

4. Technical Issues

Scribe to read aloud:

☐ 1. "**Psychomotor.** Did any team member experience a psychomotor issue, such as dropping an instrument or psychomotor difficulty with a particular technique?"
☐ 2. "Was anyone **unfamiliar** with:
☐ the **procedure**, ☐ any of the **equipment**, ☐ any of the **techniques** used?"

Record errors/inefficiencies/safety failures below:

Error #	Type of technical problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☑ Psychomotor ☐ Unfamiliarity with: ☐ procedure ☐ equipment ☐ technique	Wire destentured as dropped.	☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☑ No harm	☐ No delay ☑ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2	☑ Psychomotor ☐ Unfamiliarity with: ☐ procedure ☐ equipment ☐ technique	Dyspnoea & funeral during percutaneous puncture of vessel.	☐ Yes, actual harm occurred as a direct consequence of this issue ☑ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☑ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☑ Psychomotor ☐ Unfamiliarity with: ☐ procedure ☐ equipment ☐ technique	Iliac sheath removal led to iliac rupture. Aortic unstable req. moderate sedation + laparotomy	☑ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☑ > 1 hour
4	☐ Psychomotor ☐ Unfamiliarity with: ☐ procedure ☐ equipment ☐ technique		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5	☑ Psychomotor ☐ Unfamiliarity with: ☐ procedure ☐ equipment ☐ technique	Iliac stenting initially not sealing leak 2° to misplacement	☐ Yes, actual harm occurred as a direct consequence of this issue ☑ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☑ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☑ Psychomotor ☐ Unfamiliarity with: ☐ procedure ☐ equipment ☐ technique	Initial iliac graft ruptured into poor quality vessel + bleeding, needed stenting into femoral	☐ Yes, actual harm occurred as a direct consequence of this issue ☑ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☑ < 1 hour ☐ > 1 hour
7	☐ Psychomotor ☐ Unfamiliarity with: ☐ procedure ☐ equipment ☐ technique		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

5. Safety Issues

Scribe to read aloud:

☐ 1. **"Checks not done.** Were any safety checks omitted, such as checking patient identification, anesthetic equipment, WHO Surgical Safety checklist (if applicable)?"
☐ 2. **"Active violation of safety regulations.** Were there any active violations of safety regulations, such as not wearing protective clothing, violating infection control guidelines etc?"

Record errors/inefficiencies/safety failures below:

Error #	Type of safety problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☐ Checks not done ☐ Active violation of safety regulations		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2	☐ Checks not done ☐ Active violation of safety regulations		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ Checks not done ☐ Active violation of safety regulations		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ Checks not done ☐ Active violation of safety regulations		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
	☐ Checks not done ☐ Active violation of safety regulations		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☐ Checks not done ☐ Active violation of safety regulations		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☐ Checks not done ☐ Active violation of safety regulations		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

UK LEAP
CI: Mr Colin Bicknell
Centre #:
Patient ID #:

26/6/14 (8)

Imperial College Error CAPture Record (ICECAP)

6. Patient-related Issues

Scribe to read aloud:

☐ 1. "**Unusual anatomy.** Were any problems experienced due to this patient having unusual anatomy, e.g. location of vessels?"
☐ 2. "**Physiology problems.** Were there any problems relating to this patient's physiology, e.g. hypotension, severe COPD etc.?"
☐ (Only applicable if patient not under GA) 3. "**Compliance.** Were there any issues with patient compliance?"

Record errors/inefficiencies/safety failures below:

Error #	Type of patient-related problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☐ Unusual anatomy ☑ Physiology problems ☐ Compliance	thrombus formation in lower limb arteries during bypass grafting → needed thrombectomy	☐ Yes, actual harm occurred as a direct consequence of this issue ☑ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☑ > 1 hour
2	☐ Unusual anatomy ☐ Physiology problems ☐ Compliance		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ Unusual anatomy ☐ Physiology problems ☐ Compliance		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ Unusual anatomy ☐ Physiology problems ☐ Compliance		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5	☐ Unusual anatomy ☐ Physiology problems ☐ Compliance		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☐ Unusual anatomy ☐ Physiology problems ☐ Compliance		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☐ Unusual anatomy ☐ Physiology problems ☐ Compliance		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

7. Other Issues

Scribe to read aloud:

☐ 1. "Were there any other errors/inefficiencies/safety failures that have not already been mentioned?"

Record errors/inefficiencies/safety failures below:

Error #	If there were any other errors/delays/inefficiencies/safety failures that occurred, please note them here:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

End of Team-Recall.
Thank you for your time and cooperation.

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Title of your thesis / dissertation	A systems approach to patient safety in arterial surgery
Expected completion date	Jul 2018
Expected size (number of pages)	200
Requestor Location	Ms. Rachael Lear [redacted] Attn: Ms. Rachael Lear
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Total	0.00 GBP
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APPENDIX 17: PUBLICATIONS

The three publications listed below are included in the final pages of this thesis (see permissions in appendix 16):

- Lear R, Godrey AD, Riga C, Norton C, Vincent C, Bicknell CD. The Impact of System Factors on Quality and Safety in Arterial Surgery: A Systematic Review. *Eur J Vasc Endovasc Surg.* 2017; 54(1):79-93.

- Lear R, Godrey AD, Riga C, Norton C, Vincent C, Bicknell CD. Surgeons' Perceptions of the Causes of Preventable Harm in Arterial Surgery: A Mixed-Methods Study. *Eur J Vasc Endovasc Surg.* 2017; 54(6): 778-786.

- Lear R, Riga C, Godrey AD, Falaschetti E, Cheshire NJ, Van Herzeele I, et al. Multicentre observational study of surgical system failures in aortic procedures and their effect on patient outcomes. *Br J Surg.* 2016; 103(11): 1467-75.

Eur J Vasc Endovasc Surg (2017) 54, 79—93

REVIEW

The Impact of System Factors on Quality and Safety in Arterial Surgery: A Systematic Review

R. Lear [a,b,*], A.D. Godfrey [a], C. Riga [a,b], C. Norton [b,c], C. Vincent [d], C.D. Bicknell [a,b,e]

[a] Department of Surgery and Cancer, Imperial College London, London, UK
[b] Imperial College Healthcare NHS Trust, London, UK
[c] Faculty of Nursing and Midwifery, King's College London, London, UK
[d] Department of Experimental Psychology, Medical Sciences Division, Oxford University, Oxford, UK
[e] Centre for Health Policy, Imperial College London, London, UK

WHAT THIS STUDY ADDS

This review addresses an underexplored topic in vascular surgery: how system factors such as teamwork and the work environment influence quality and safety. The limited evidence collated in this review is heterogeneous in terms of definitions, methodologies, and outcome measures, which makes it difficult to draw meaningful conclusions from the existing body of literature. Research in this field would benefit from consistency in terminology, the use of validated assessment tools, measurement of clinically relevant endpoints, and adherence to national reporting guidelines.

Objective: A systems approach to patient safety proposes that a wide range of factors contribute to surgical outcome, yet the impact of team, work environment, and organisational factors, is not fully understood in arterial surgery. The aim of this systematic review is to summarize and discuss what is already known about the impact of system factors on quality and safety in arterial surgery.

Data sources: A systematic review of original research papers in English using MEDLINE, Embase, PsycINFO, and Cochrane databases, was performed according to PRISMA guidelines.

Review methods: Independent reviewers selected papers according to strict inclusion and exclusion criteria, and using predefined data fields, extracted relevant data on team, work environment, and organisational factors, and measures of quality and/or safety, in arterial procedures.

Results: Twelve papers met the selection criteria. Study endpoints were not consistent between papers, and most failed to report their clinical significance. A variety of tools were used to measure team skills in five papers; only one paper measured the relationship between team factors and patient outcomes. Two papers reported that equipment failures were common and had a significant impact on operating room efficiency. The influence of hospital characteristics on failure-to-rescue rates was tested in one large study, although their conclusions were limited to the American Medicare population. Five papers implemented changes in the patient pathway, but most studies failed to account for potential confounding variables.

Conclusions: A small number of heterogenous studies have evaluated the relationship between system factors and quality or safety in arterial surgery. There is some evidence of an association between system factors and patient outcomes, but there is more work to be done to fully understand this relationship. Future research would benefit from consistency in definitions, the use of validated assessment tools, measurement of clinically relevant endpoints, and adherence to national reporting guidelines.

Article history: Received 24 October 2016, Accepted 18 March 2017, Available online 11 May 2017

Keywords: Quality, Safety, Arterial surgery, System factors

INTRODUCTION

The outcomes of vascular surgery vary considerably between organisations and between countries but the reasons for this are not fully understood.[1—3] A relationship between annual caseload and patient outcome is now well established for many arterial procedures. Robust evidence

* Corresponding author. 10th Floor QEQM Building, St. Mary's Hospital, Praed Street, London W2 1NY, UK.
E-mail address: r.lear12@imperial.ac.uk (R. Lear).

http://dx.doi.org/10.1016/j.ejvs.2017.03.014

demonstrates that higher procedural volumes predict lower operative mortality for a range of arterial procedures including elective open abdominal aortic aneurysm (AAA) repair, endovascular aortic aneurysm repair (EVAR), carotid endarterectomy (CEA), and lower extremity bypass.[4–6] Such evidence has prompted major service reconfiguration (centralisation) in recent years. Individual surgeon volume does not account for the entire effect of institutional volume, with the relative importance of surgeon volume varying according to the operation performed.[7] Therefore, other determinants within a healthcare institution must also play a role. Alongside caseload volume and experience, emerging evidence suggests that hospital teaching status is important — with academic institutions having better outcomes, a finding which may be explained by variations in training.[8] The precise determinants of variation in outcome are yet to be established, although contributory factors are likely to include differences in formalised training programmes, resource availability, specialty teams, and provision of intensive care facilities.[8]

A systems approach to surgical quality and safety proposes that all aspects of the healthcare system should be considered when attempting to explain outcome.[9] A number of studies conducted in the surgical setting have implicated communication failures, fatigue, poor staffing levels, and equipment problems.[10–12] This systematic review aims to summarize and discuss what is known about the impact of team, work environment, and organisational factors on quality and safety in arterial surgery.

METHOD

Protocol

The protocol for this systematic review was specified in advance of the review taking place. The methodology and reporting of the review adheres to the Preferred Reporting Items for Systematic reviews and Meta-Analyses statement (PRISMA).[13]

Definitions

Elective arterial surgery. Elective arterial surgery refers to the planned open surgical or endovascular treatment of aneurysmal or occlusive arterial disease. The evaluation of factors influencing safety and quality in emergency surgery was deemed beyond the scope of this review.

Measures of quality and safety. The principal outcome measures were mortality, complications, length of stay, and readmission rates. These were complemented by other surrogate process measures, including intra-operative errors, failures or procedural problems, and unnecessary procedural delays. These surrogate process measures may provide important insights into quality and safety because they are often defined by their consequences (i.e. harm to patient or delays to an operation).

Factors influencing surgical quality and safety. A systems approach was adopted for the purposes of this review to take evaluation of factors influencing surgical quality and safety, beyond patient risk factors and surgical skill. This approach, which has been described in full elsewhere,[9] encourages consideration of all potentially relevant factors implicated in surgical quality and safety in the perioperative period. This review considers three overarching themes informed by a previously published framework of factors influencing clinical practice[14]: team factors, work environment, and organisation and management factors. Further details of these themes are provided in Table 1.

Information sources

The following databases were systematically searched: Medline (Ovid Medline 1946 to July 1, 2016), Embase (Embase 1947 to June 30, 2016), PsycINFO (PsycINFO 1967 to June Week 5 2016), and the Cochrane Library. Reference lists of key papers were hand searched for additional citations. The last search was performed on January 29, 2017.

Search

A comprehensive list of search terms was devised in consultation with vascular and patient safety experts, identification of commonly used terms in the literature, and synonyms of relevant terms (Appendix 1). It was anticipated that few papers would specifically focus on investigation of team, work environment or organisational factors, therefore the search was deliberately broad to capture papers that may include an assessment of such factors as an aspect of a wider study. Search terms were categorized into three groups: arterial disease; surgical intervention; measures of quality and safety. Within groups, search terms were linked by the Boolean operator 'OR'. Each group of search terms was linked using the Boolean operator 'AND'. MeSH (Medical Subject Headings) were used to ensure that the search was comprehensive. Limits were applied for humans, abstracts, and papers in the English language.

Study selection

The primary reviewer (RL, advanced vascular nurse practitioner) screened all titles and abstracts according to predefined inclusion and exclusion criteria, with a second reviewer (ADG, clinical research fellow) screening 10% of

Table 1. Factors influencing surgical quality and safety.

Organisation and management factors	Work environment factors	Team factors
Financial resources and constraints	Staffing levels and skill mix	Verbal communication
Organisational structure	Workload and shift patterns	Written communication
Policy standards and goals	Availability and maintenance of equipment	Supervision and seeking help
Safety culture and priorities	Administrative and managerial support	Team structure (consistency, leadership, etc.)

citations. Reviewers were blinded to each other's results. Cohen's kappa demonstrated good agreement between reviewers ($\kappa = .87$, $p < .001$). Both reviewers screened all papers selected for full text review to identify included papers ($\kappa = .84$, $p < .001$). Any disagreements between reviewers at each stage of selection were resolved by consensus.

Inclusion criteria

Studies were eligible for inclusion if they were original research papers published in a peer-reviewed journal, which addressed the relationship among team, work environment, and/or organisational factors, and quality or safety measures in elective arterial surgery during the peri-operative period. Original research papers investigating interventions to optimise team, work environment, and/or organisational factors, that also used safety or quality measures, were additionally included.

Exclusion criteria

Studies investigating the impact of patient risk factors, surgical techniques, or pharmacological interventions (e.g. cardioprotective medication) were excluded. Studies solely describing the following operation types were also excluded: emergency arterial surgery; iatrogenic arterial injury; the vasculature of the heart or the brain; type A aortic dissection; arterial closure devices.

Volume outcome relationships have already been examined exhaustively in arterial surgery, and such studies are therefore excluded from this review. Only clinical pathway papers published within the last decade were considered to be relevant to the current state of arterial service provision. Therefore, any papers published earlier than 2005 that examined interventions along the clinical pathway were excluded. Reviews, case reports, editorials, opinions, and conference proceedings were also excluded.

Data collection process and data items

For each paper, details of the design, aim, study period, sample size, type of surgical intervention, aspect of team, work environment, or organisational factor(s) investigated, and measure(s) of quality or safety used, and details of intervention if applicable, were extracted using a standardised data extraction form. The primary reviewer (RL) extracted all preset information, which was subsequently checked and verified by the second reviewer (ADG).

Risk of bias of individual studies

Case control studies were quality assessed using the Newcastle-Ottawa Scale, which has been described elsewhere.[15] A modified version of the Newcastle-Ottawa Scale[16] was used to assess the quality of cross sectional studies. Studies were assessed for risk of bias, based on case selection, comparability of groups, and outcome measurement and analysis. High quality case control and cross sectional studies attained the maximum score of 9; medium quality studies obtained a score of 7 or 8, while a score of 6 or less indicated that the study was of poor quality (Tables 2 and 3). Two reviewers (RL and ADG) independently scored case control and cross sectional papers, with satisfactory agreement between assessors for quality scoring ($\kappa = .56$, $p = .01$). As a small number of papers was retrieved from the search, low quality papers were included in the review. The only randomised controlled trial (RCT) identified thought the search strategy, was appraised using the Cochrane Collaboration's tool for assessment of risk of bias.[17] A critical appraisal of all included studies, guided by the STROBE checklist[18] (Strengthening the Reporting of Observational studies in Epidemiology) has been included in Tables 2 and 3 to make explicit particular strengths and weakness that may influence the findings.

RESULTS

Study characteristics

Twelve studies[19–30] met the selection criteria (PRISMA diagram, Fig. 1). Seven of these were undertaken in the UK.[19,21,22,24–26,29] There were four descriptive studies,[19,26,28,29] one case control,[25] one cohort,[27] five cross sectional studies,[20–22,24,30] and one randomised control trial (RCT).[23] Seven studies measured the impact of an intervention designed to improve surgical quality and safety.[20,21,23–25,27,28] The most common operation studied was aortic aneurysm (AAA) repair (10/12 studies[19–21,23–25,27–30]); five of these included endovascular aortic aneurysm repairs (EVARs).[19,21,25,28,29] Four papers addressed carotid endarterectomy (CEA)[19,21,22,26] and four papers included lower limb bypass graft (LL BG).[19,21,26,30] Seven papers addressed organisational factors,[20,21,23,24,27,28,30] five papers addressed work environment factors,[19,20,25,29,30] and five papers addressed team factors.[19,22,25,26,29] Eight papers measured patient outcomes[20,21,23,24,27–30] and four papers measured surrogate markers of surgical quality and safety (including intra-operative errors or procedural problems, and operating time).[19,22,25,26]

Quality assessment

Eight of twelve papers reported single centre studies,[19,21–27] and of these, two had sample sizes of less than 20 cases.[25,26] Two cross sectional studies, both undertaken in the USA had large sample sizes of more than 10,000 cases.[20,30] Only one of the studies was a randomised controlled trial,[23] which reported outcomes on an intention to treat basis, but researchers and patients could not be blinded to the allocation groups because of the nature of the intervention studied. Of the studies scored using the Newcastle-Ottawa Scale, three papers were scored as high quality[20,27,30] and three were deemed to be of low quality.[21,22,24] Details of the quality assessments for all papers are provided in Tables 2 and 3.

Factors influencing quality and safety in arterial surgery

Relevant findings from included papers are organised into the following three themes: team, work environment, and

Table 2. Quality assessments for studies evaluated using the (modified) Newcastle-Ottawa Scale.

First author year	Study setting	Sample size	Study design	Selection	Comparability	Outcome	Overall quality score	Critical appraisal of factors likely to influence interpretation of findings
Brooke 2012[20]	658 nationwide hospitals, USA	16,732	Cross sectional	4	2	3	High (9)	Multicentre study with large sample size Patient and hospital level variables controlled for in regression model Self report method, 50% response rate
Cantlay 2006[21]	Single centre regional vascular unit, UK	234	Cross sectional	4	0	0	Low (4)	Single centre study Comparison of mortality rates pre- and post-intervention provided for AAA repairs only. Patient risk factors/other confounders not controlled for
Catchpole 2008[22]	Single centre regional vascular unit, UK	22	Cross sectional	3	1	2	Low (6)	Small sample size Single centre study Tools used to evaluate teamwork and surgical errors were previously validated
Feo 2016[27]	Single centre, university hospital, Italy	221	Retrospective cohort	4	2	2	High (8)	Single centre study Patient and peri-operative variables controlled for in regression model Retrospective control group
Murphy 2007[24]	Single centre regional vascular unit, UK	60	Cross sectional	3	0	3	Low (6)	Single centre study Demographics briefly described for each group, although not controlled for with statistical methods
Patel 2012[25]	Single centre regional vascular unit, UK	15	Case control	4	0	3	Medium (7)	Small sample size Single centre study Descriptions of demographics for each group not sufficiently detailed to judge comparability Observer and assessors not blinded to whether case was pre- or post-intervention
Sheetz 2016[30]	National data from Medicare Provider Analysis and Review (MEDPAR) files, USA	188,849 AAA repairs 681,078 LL BG	Cross sectional	4	2	3	High (9)	Large sample size Multi-centre study Restricted to Medicare population Hospital characteristics were self reported Patient and operative variables controlled for in regression model

Selection assesses representativeness of the sample, sample size, description of cases not included, and measurement of the exposure. Comparability assesses the extent to which confounding factors are controlled for to ensure different outcome groups are comparable. Outcome assesses the quality of outcome assessment and statistical analyses.
High quality case control and cross sectional studies attained the maximum score of 9; medium quality studies obtained a score of 7 or 8, while a score of 6 or less indicated that the study was of poor quality.

Table 3. Quality assessments for four descriptive studies and one randomised controlled trial.

First author year	Study setting	Sample size	Study design	Critical appraisal of factors likely to influence interpretation of findings
Albayati 2012[19]	Single centre regional vascular unit, UK	66	Descriptive	Single centre study Observational method: unstructured observations undertaken by medical students Two blinded assessors with significant vascular surgical experience judged intra-operative failures Non-significant correlations between patient age and ASA grade, and failure rate (as potential confounders) are described
Soane 2014[26]	Single centre regional vascular unit, UK	12	Descriptive pilot study	Small sample size Single centre study Observational method to capture intra-operative errors: previously validated, structured approach with independent verification by two vascular surgical experts Self report method to evaluate the role of team working Attempts made to reduce Hawthorne effect prior to study Data analysed to examine trends — statistical analysis not performed because of small sample size
Muehling 2009[23]	Single centre, Germany	101	Randomised controlled trial[a]	Single centre study *Selection bias:* patients were randomly assigned to either the traditional or the fast track treatment arm but further description of allocation not provided *Performance and detection bias:* blinding not feasible because of nature of intervention *Attrition bias:* Intention to treat analysis performed. Five excluded (2 withdrew consent, 2 suprarenal clamping, 1 EDA dysfunction) Attrition not expected to affect results *Reporting bias:* All pre-specified outcomes were reported
Krajcer 2016[28]	Multicentre, USA	129	Descriptive	Post-market study of a single stent graft device Number of participating sites not stated Outcomes compared for completers and non-completers of fast track protocol (no true control group)
Lear 2016[29]	Multi-centre, UK	185	Descriptive	Multicentre study (10 sites) Structured, self report method to report intra-operative system failures Training period to standardize structured, self reporting method across sites Between group differences for patient outcomes not adjusted for multiple comparisons

[a] Quality of the RCT was assessed using the Cochrane Collaboration tool for assessment risk of bias in randomised trials.

organisational factors. Table 4 provides a summary of these study characteristics.

Team factors. Five papers — all from the UK - examined the relationship between team factors and quality and safety[19,22,25,26,29]; all five papers addressed team factors in the operating room. One study measured the impact of these factors on patient outcomes.[29] A multicentre study of system failures in 185 aortic procedures demonstrated that major intra-operative failures (defined as failures that caused significant intra-operative delay or endangered the patient) were associated with unplanned return to theatre ($p = .011$), major complications ($p = .029$), and in hospital mortality ($p = .027$), independent of patient age, gender, or ASA grade.[29] In this study, a significant proportion (22%) of major intra-operative failures were categorized as errors in communication. Smaller, single centre studies examining team factors used process measures to evaluate markers of quality or safety, including intra-operative errors and procedural problems[19,22,25,26] without measuring patient outcomes. Two studies found that levels of team skills (including teamwork, leadership, and situational awareness) correlated with the frequency of errors or procedural problems in arterial operations, although the tools that they

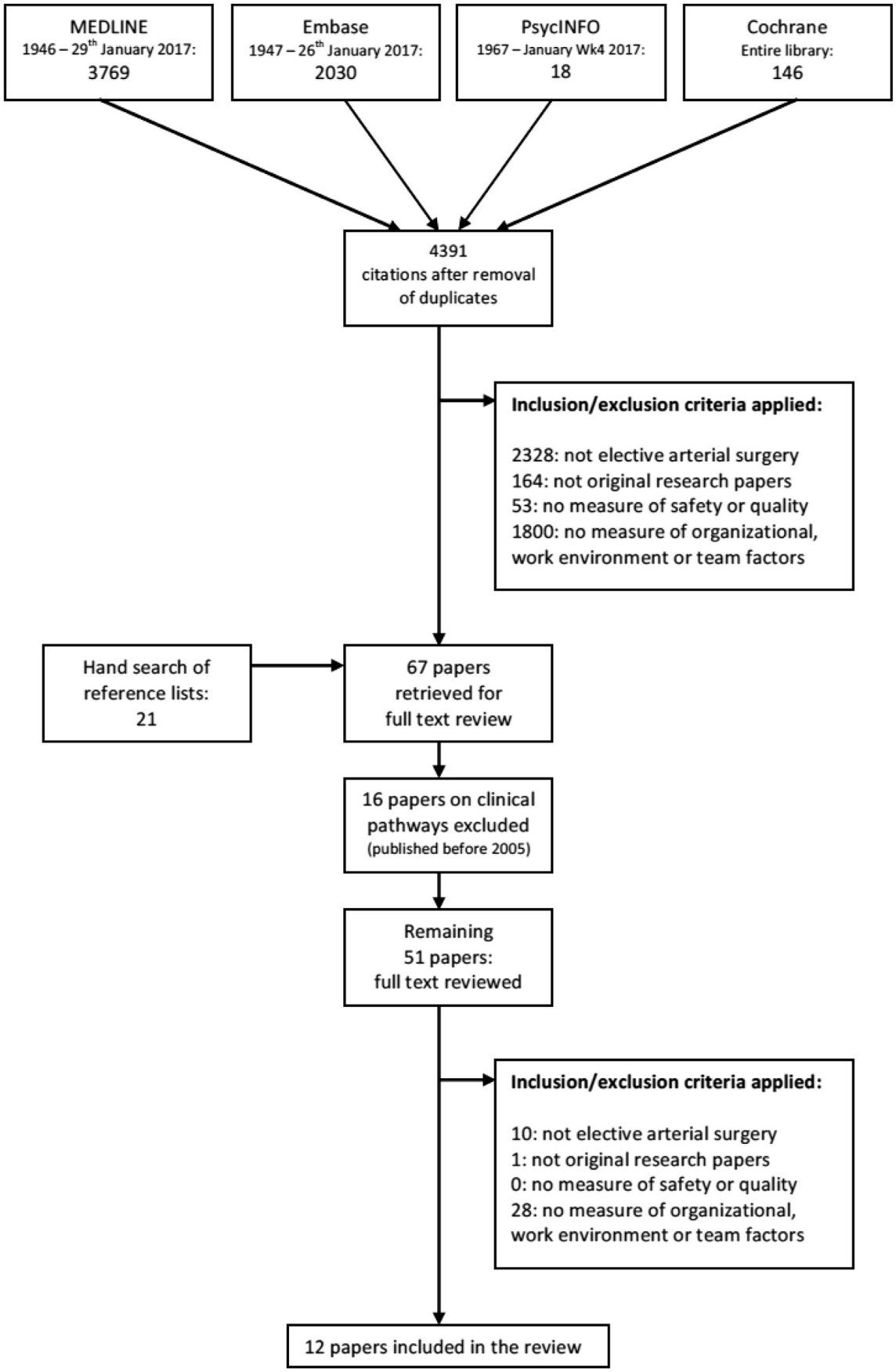

Figure 1. PRISMA diagram for study selection.

Table 4. Characteristics of included studies.

First author year	Operation type(s)	Intervention	Organisational factors assessed	Work environment factors assessed	Team factors assessed	Measures of quality and safety assessed	Findings
Albayati 2012[19]	TAAA repair AAA repair (open and endovascular) CEA LL BG	N/A	N/A	1. Team member absence 2. Equipment unavailability/ configuration/ malfunction 3. Fatigue	1. Communication 2. Team conflict	Intra-operative failure distribution	Most common failures related to equipment 5.2% of failures had high danger/delay scores
Brooke 2012[20]	Open AAA repair	Implementation of National Quality Forum (NQF) safety practices	1. Creation of safety culture 2. Pharmacy involvement with medication-use process 3. Specialist anticoagulation service involvement 4. Protocols for prevention of complications	1. Nursing staffing levels 2. Workspaces where medications are prepared free from clutter, distraction, noise	N/A	In hospital complications Failure to rescue (FTR) All-cause 30 day mortality	Hospitals that fully implemented safe practices were more likely to diagnose complications, had lower FTR rates, and had lower in hospital mortality rates for most high risk procedures, but not for AAA repair, compared with hospitals with partial safe practice compliance
Cantlay 2006[21]	AAA repair-open and EVAR LL BG CEA	Implementation of vascular consultant anaesthetist-led pre-operative assessment clinic (PAC)	1. Multi-component intervention along clinical pathway (pre-operative)	N/A	N/A	In hospital mortality	In hospital mortality for AAA repair fell from 14.5% in 2 year period before PAC to 4.8% in 2 years after introduction of PAC Improvement likely multi-factorial but implementation of PAC played major role

Continued

Table 4-*continued*

First author year	Operation type(s)	Intervention	Organisational factors assessed	Work environment factors assessed	Team factors assessed	Measures of quality and safety assessed	Findings
Catchpole 2008[22]	CEA	N/A	N/A	N/A	1. Leadership and management 2. Teamwork and cooperation 3. Problem solving and decision making 4. Situational awareness	Errors in surgical technique Other procedural problems	Aspects of team performance strongly correlated with errors and procedural problems Teamwork interventions could improve technical performance and patient outcomes
Feo 2016[27]	Open AAA repair via retroperitoneal approach	Implementation of an Enhanced Recovery Program (ERP)	1. Multi-component intervention along clinical pathway (peri-operative)	N/A	N/A	Morbidity and mortality ICU admission rate Time to functional recovery Length of stay Readmission rate	ERP had fewer complications and fewer ICU admissions than traditional care, although mortality was comparable between groups Functional recovery and discharge from hospital were achieved earlier in the ERP group, with no readmissions reported
Krajcer 2016[28]	EVAR	Implementation of fast track recovery protocol	1. Multi-component intervention along clinical pathway (peri-operative)	N/A	N/A	Major adverse events Health related quality of life measures	There was one major adverse event in the fast track group Completers of fast track protocol reported improved quality of life, whereas quality of life measures remained unchanged in non-completers group

Lear 2016[29]	Open and endovascular AAA repair	N/A	N/A	Equipment related failures Noise/distractions	Communication failures	Unplanned return to theatre Post-operative complications In hospital mortality	Major intra-operative system failures were associated with unplanned return to theatre, major complications, and death
Muehling 2009[23]	Open AAA repair	Implementation of fast track recovery program	1. Multi-component intervention along clinical pathway (post-operative)	N/A	N/A	Morbidity and mortality Length of stay and readmission rate	Post-operative complications and hospital stay significantly reduced in fast track group compared traditional treatment group, with no readmission within 30 days of discharge
Murphy 2007[24]	Open AAA repair	Implementation of fast track goal directed pathway	1. Multi-component intervention along clinical pathway (post-operative)	N/A	N/A	Length of stay and readmission rate	Median hospital stay reduced from 9 to 5 days following implementation of the pathway, with only one readmission
Patel 2012[25]	Combined open and endovascular TAAA and AAA procedures	Implementation of a structured, mental rehearsal before the endovascular phase		1. Intervention designed to increase efficiency in equipment use	1. Intervention designed to improve team dynamics	Intra-operative error rates Delay scores Danger scores	Error rates were significantly higher during the endovascular phase compared with open Error rates, danger and delay scores were significantly lower after the intervention

Continued

Table 4-*continued*

First author year	Operation type(s)	Intervention	Organisational factors assessed	Work environment factors assessed	Team factors assessed	Measures of quality and safety assessed	Findings
Sheetz 2016[30]	AAA repair LL BG	N/A	1. Hospital teaching status 2. Hospital occupancy 3. Number of ICU beds	1. Nurse to patient ratio 2. Technology	N/A	Failure-to-rescue (FtR)	Teaching status, occupancy, high hospital technology, nurse to patient ratio, and size of ICU significantly influenced FtR rates for AAA repair and LL BG. Hospital and patient characteristics accounted for 19% of variability in FtR rates for AAA repair, and 12% of variation for LL BG
Soane 2014[26]	CEA LL BG	N/A	N/A	N/A	1. Team orientation 2. Coordination and leadership style 3.Communication 4. Error management 5. Task distribution	Intra-operative error rates	Error rates were lower when there were effective teamwork measures in place Teamwork training for vascular teams may help to prevent or mitigate errors

N/A = not applicable; TAAA = thoraco-abdominal aortic aneurysm; AAA = abdominal aortic aneurysm; CEA = carotid endarterectomy; LL BG = lower limb bypass graft; ICU = intensive care unit.

used to assess team skills were not consistent. Catchpole and colleagues used the Oxford NOTECHS (NON-TECHnical Skills) tool, which is well validated and widely used in the surgical literature,[31–33] while Soane and colleagues developed their own assessment tool for the purposes of their study[26], based on T^{2}EAM tool approach used to assess team skills in air traffic control, which has been described elsewhere.[34] These two studies by Catchpole and Soane were small (sample sizes of 22 and 12, respectively), and neither tested associations between the observed errors and clinical outcomes. However, anecdotes were reported to provide insights into the impact of these errors, for example, Catchpole and colleagues describe a lapse in teamwork and communication which led to delayed heparin administration for arterial cross-clamping, thus increasing the risk of embolisation.[22,26] In two further studies, two blinded experts assigned "danger" and "delay" scores to failures observed during arterial operations, to provide an insight into the impact of these failures on the patient and the procedure.[19,26] Albayati and colleagues found that 21% (240/1145) of all observed failures related to communication.[19] Four of these communication failures were "major," that is were perceived to have a major effect on procedural duration or patient safety, these occurred during critical stages of the operation but their clinical consequences are not reported. In the only study evaluating a teamwork intervention, Patel and colleagues demonstrated a non-significant reduction in the number of communication errors occurring in combined open/endovascular arterial procedures following implementation of a structured, mental rehearsal before the endovascular phase.[25] The authors reported that no major errors occurred intra-operatively after implementation of the intervention but they did not control for any confounders, such as patient risk factors or procedural variables.[25]

Work environment factors. Five papers addressed work environment factors.[19,20,25,29,30] Two UK studies found that intra-operative failures relating to equipment were common during arterial operations.[19,29] Equipment failures (unavailability, configuration, workspace/equipment management, malfunction) were the most commonly observed category of intra-operative failures in both studies. Lear and colleagues reported that 17% of equipment failures occurring in aortic procedures either endangered the patient or caused long procedural delays, and these major failures were associated with poorer patient outcomes.[29] In the study evaluating a structured mental rehearsal intervention before the endovascular phases of combined open/endovascular procedures, the number of intra-operative equipment related failures fell after implementation of the intervention, but these findings were not statistically significant (2.40 equipment problems/hour (0—5.33) vs. 1.01/hour (0—4.0); $p = .140$) and not adjusted for potential confounders.[25]

The impact of staffing levels on patient outcomes following AAA repair was assessed in two American studies using data from large, national databases.[20,30] Sheetz and colleagues investigated the impact of hospital characteristics on failure-to-rescue following major vascular surgery in the American Medicare population. After properly adjusting for potential confounders, the authors reported that hospitals with increased nurse to patient ratios had lower failure-to-rescue rates in patients undergoing AAA repair and lower limb bypass graft.[30] Another large, multicentre cross sectional study investigated US healthcare organisations' adherence to 27 hospital safety measures comprising a comprehensive set of evidence based hospital process measures and standardised practices endorsed by the National Quality Forum (NQF).[20] Included in these safety measures were standards to ensure safe nurse staffing levels. Hospitals with full compliance had a lesser unadjusted rate of failure-to-rescue for open AAA repair compared with hospitals with partial compliance (11.71% vs. 12.96%). The risk adjusted mortality benefit conferred by full compliance with NQF safety practices was significant for most high risk procedures but not for open AAA repair (OR 0.85; 95% CI 0.71—1.03), and the findings were not presented in sufficient depth to ascertain the relative importance of individual safe practices. Of note, the level of compliance with NQF safety practices was calculated from self report data and the survey had a 50% response rate.

Organisational factors. A total of seven papers investigated organisational factors. In the large American Medicare study that evaluated the impact of particular hospital characteristics on properly risk adjusted patient outcomes — hospital teaching status, lower bed occupancy, and higher numbers of ICU beds were all associated with lower rates of failure-to-rescue for patients undergoing AAA repair and lower limb revascularisation.[30] Six further studies describe the impact of multi-component interventions along the entire clinical pathway.[20,21,23,24,27,28] Clinical pathways define the sequencing and timing of health interventions,[35] and include efforts to increase the reliability of core clinical processes as well as organisational changes to optimise allocation of resources. Four studies evaluated the implementation of a fast track or enhanced recovery programme for AAA repair.[23,24,27,28] However, only one of these studies was a randomised controlled trial (RCT) that adhered to SQUIRE guidelines.[36] In this RCT, Muehling et al. piloted the safety and efficacy of a fast track recovery pathway for patients undergoing open AAA repair, which included reduced pre-operative fasting, no bowel preparation, patient controlled epidural anaesthesia, enhanced post-operative feeding, and early mobilisation.[23] Patient characteristics, surgical procedure, and clamping time were comparable between the two groups ($p > .05$ for all characteristics). In this RCT, which assessed outcomes on an intention to treat basis with a low attrition rate (5 of 101 patients excluded), the rate of post-operative medical complications was significantly lower (16% vs. 36%; $p = .039$), and length of stay was significantly shorter with no readmissions within 30 days (10 days vs. 11 days; $p = .016$) in patients entered into the fast-track programme compared with the treatment group. Cantlay et al. describe their experiences of introducing a pre-operative assessment

clinic (PAC) led by vascular consultant anaesthetists, designed to evaluate and manage pre-operative risk for patients undergoing major vascular procedures.[21] While patients scheduled for a variety of arterial operations were reported to have attended the clinic, the authors report unadjusted mortality rates pre- and post-intervention for open infrarenal aneurysm repair only (14.5% and 4.8%, respectively). Patient risk factors and other confounding variables were not accounted for, although the authors reported that introduction of the PAC took place at the same time as centralisation of arterial services within this organisation.

DISCUSSION

This is the first systematic review to adopt a systems approach to understanding quality and safety in arterial surgery. Team, work environment, and organisational factors were evaluated with respect to patient outcomes and other markers of surgical quality and safety. The design and methodologies of the studies are varied and this heterogeneity makes it difficult to draw meaningful conclusions from the collected literature. Designing studies that are capable of measuring all potentially relevant determinants of patient harm in a given healthcare system is inherently challenging. When adverse events occur, these incidents are rarely the result of a single error with direct consequences - rather, patient harm is often the consequence of multiple failures at many levels of the system.[37] The evidence collected in this review identifies various deficiencies in the systems supporting arterial surgery, although the link between these deficiencies and patient outcomes is not entirely clear. Some of the collected studies failed to measure the clinical significance of reported system failures or procedural problems. Outcomes such as in hospital mortality or readmission within 30 days are relatively rare. For studies to establish any associations between system factors and patient outcomes, sample sizes would need to be large, and likely to be resource and time intensive. While the utility of endpoints holding no clinical significance may seem questionable, there is an argument for identifying deficiencies that can be pinpointed as targets for building resilience in the system. However, publication guidelines for quality improvement reporting excellence advocate assessment of a combination of process and outcome measures to evaluate quality interventions.[36]

In the literature collated for this review, failures relating to teamwork and communication were consistently associated with high rates of intra-operative errors and procedural problems, although one large study from the UK demonstrated an association between major intra-operative communication failures and patient outcomes for patients undergoing aortic procedures. In other surgical specialties, failures of communication and information transfer have been directly associated with patient harm.[11] However, there is more work to be done to confirm the relationship between team factors and clinical outcomes in patients undergoing arterial surgery. Research into team skills in vascular surgery is likely to benefit from the use of standardised assessment tools which are well validated in terms of psychometric properties and content validity. The authors advocate the use of Endo-OTAS (Endovascular Observational Teamwork Assessment for Surgery), which is a robust tool to assess teamwork skills in endovascular procedures[38]; other teamwork assessment tools — such as OTAS[39] and NOTECHS[31,40] are well validated and can be used to assess the non-technical skills of surgeons, anaesthetists, and nurses in open surgical procedures. Certainly in the UK, current training programmes in vascular surgery do not routinely include training in non-technical skills, although individual studies on the use of simulation to improve team performance in emergency arterial operations are encouraging.[41]

The evidence collated here suggests that equipment related failure is common during arterial operations, having a significant impact on efficiency as well as patient safety. Cardiac surgery, which also relies heavily on technology, has been shown to bear a greater burden of equipment related errors compared with general surgery.[12] The relatively high rate of equipment related problems may not be surprising given the rapid uptake and evolution of endovascular technology over the last two decades. Former health minister, professor Lord Ara Darzi cautioned that the introduction of new technologies must be accompanied by process innovation.[42] An example of process innovation is the implementation of the World Health Organisation's Surgical Safety checklist, which includes an equipment check prior to knife to skin.[43] We suggest that the WHO checklist could be tailored to specific arterial operations, to further improve preparation and use of equipment and associated technologies in these procedures.

Team factors and equipment failures appear to be a source of risk to patient safety and affect procedural efficiency in arterial surgery. Researchers seeking to address deficiencies should be aware of the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines[36] when designing studies to evaluate the impact of interventions. In this review, most of the studies that implemented a quality improvement intervention failed to control for patient, hospital, and other confounding factors, making it difficult to understand the nature of the association between the interventions and the reported outcomes. These studies were also largely small, single centre studies with limited generalisability, and some of the studies used methodologies, such as self reporting, which threatens the internal validity of the intervention being studied.

This review included a large, well conducted study that found significant associations between certain hospital characteristics — including hospital occupancy, number of ICU beds, and nurse to patient ratios and failure-to-rescue rates for AAA repair and lower limb revascularisation.[30] However, this study was limited to Medicare beneficiaries in the USA. Future research should replicate this study in other countries to further understand organisational factors that influence patient outcomes. Many further aspects of the work environment that might conceivably influence

surgical quality and safety have yet to be studied in vascular surgery. For example, the majority of vascular consultants work more than 50 h a week and provide emergency cover more often than is considered safe according to a recent workforce evaluation in the UK[44] and in the USA, vascular surgery has been ranked the highest of 41 specialties with regards to the number of hours worked annually, but the impact of working long hours on service quality and patient outcome is not known.

There is considerable scope for more detailed examination of a range of factors that may influence surgical outcomes, as well as to evaluate interventions to enhance teamwork, the working environment, and the wider organisation of vascular surgery. Research in this field would benefit from studies that are properly powered to understand the relationships between system factors and clinical outcomes, and which adhere to national guidelines for reporting standards. To produce generalisable results, large studies are likely to require collaborative efforts between institutions with use of validated assessment methods and consistent endpoints.

CONFLICT OF INTEREST

None.

FUNDING

This work was supported by the National Institute for Health Research (CDRF-2012-03-040 to RL); the Circulation Foundation (President's Early Career Award to CB); and the National Institute for Health Research Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London. The views expressed in this publication are those of the author(s) and not necessarily those of the funders, the NHS, the National Institute for Health Research or the Department of Health.

APPENDIX 1. SEARCH TERMS FOR MEDLINE, EMBASE AND PSYCINFO.

1. (adverse adj2 event$).ab,ti.
2. Post-operative Complications/ep, mo [Epidemiology, Mortality]
3. patient safety indicator$.ab,ti.
4. harm.ab,ti.
5. error$.ab,ti.
6. morbidity/ or incidence/ or prevalence/ or mortality/ or "cause of death"/ or fatal outcome/ or hospital mortality/ or survival rate/
7. frequency.ab,ti.
8. rate.ab,ti.
9. severity.ab,ti.
10. Treatment Outcome/
11. consequence$.ab,ti.
12. avoidable.ab,ti.
13. prevent$.ab,ti.
14. operation.ab,ti.
15. intervention$.ab,ti.
16. surg$.ab,ti.
17. Arterial Occlusive Diseases/ or Peripheral Arterial Disease/
18. Vascular Surgical Procedures/ or vascular surgery.mp.
19. endovascular.ab,ti.
20. bypass.ab,ti.
21. aort$.ab,ti.
22. carotid.ab,ti.
23. Aortic Aneurysm, Abdominal/ or Aneurysm, Dissecting/ or Aortic Aneurysm, Thoracic/ or Iliac Aneurysm/ or Aortic Aneurysm/
24. Limb Salvage/ae, mo [Adverse Effects, Mortality]
25. 1 or 2 or 3 or 4 or 5
26. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
27. 14 or 15 or 16
28. 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
29. 25 and 26 and 27 and 28
30. "gastric bypass".ab,ti.
31. "cardiopulmonary bypass".ab,ti.
32. "heart bypass".ab,ti.
33. "coronary artery bypass".ab,ti.
34. "coronary bypass".ab,ti.
35. "coronary intervention".ab,ti.
36. "aortic valve".ab,ti.
37. "coronary artery stenting".ab,ti.
38. (cerebral adj3 aneurysm).ab,ti.
39. 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38
40. 29 not 39
41. limit 40 to abstracts
42. limit 41 to humans
43. limit 42 to english language

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Eur J Vasc Endovasc Surg (2017) 54, 778–786

Surgeons' Perceptions of the Causes of Preventable Harm in Arterial Surgery: A Mixed-Methods Study

Rachael Lear [a,b,*,1], **Anthony D. Godfrey** [a], **Celia Riga** [a,c], **Christine Norton** [d], **Charles Vincent** [e], **Colin D. Bicknell** [a,c,f]

[a] Department of Surgery & Cancer, Imperial College London, UK
[b] Faculty of Health, Social Care and Education, Kingston University and St George's University of London, UK
[c] Imperial Vascular Unit, Imperial College Healthcare National Health Service Trust, London, UK
[d] Faculty of Nursing and Midwifery, King's College London, UK
[e] Department of Experimental Psychology, Medical Sciences Division, Oxford University, UK
[f] Centre for Health Policy, Imperial College London, UK

WHAT THIS PAPER ADDS

It is well established that patient risk factors and procedural volume/technique relate to patient outcome for a range of arterial procedures. This paper provides a summary of vascular surgeons' reports of broader 'system' factors influencing the safety of patients undergoing arterial surgery. Vascular surgeons perceive that adverse events are not solely related to inherent complexities in the procedure or the patient's condition, but are commonly caused by a combination of team, environment, and organisational failures, which may combine to cause harm.

Background: System factors contributing to preventable harm in vascular patients have not been previously reported in detail. The aim of this exploratory mixed-methods study was to describe vascular surgeons' perceptions of factors contributing to adverse events (AEs) in arterial surgery. A secondary aim was to report recommendations to improve patient safety.

Methods: Vascular consultants/registrars working in the British National Health Service were questioned about the causes of preventable AEs through survey and semi-structured interview (response rates 77% and 83%, respectively). Survey respondents considered a recent AE, indicating on a 5 point Likert scale the extent to which various factors from a validated framework contributed toward the incident. Semi-structured interviews were conducted to obtain detailed accounts of contributory factors, and to elicit recommendations to improve safety.

Results: Seventy-seven surgeons completed the survey on 77 separate AEs occurring during open surgery ($n = 41$) and in endovascular procedures ($n = 36$). Ten interviewees described 15 AEs. The causes of AEs were multifactorial (median number of factors/AE = 5, IQR 3-9, range 0–25). Factors frequently reported by survey respondents were communication failures (36.4%; $n = 28/77$); inadequate staffing levels/skill mix (32.5%; $n = 25/77$); lack of knowledge/skill (37.3%; $n = 28/75$). Themes emerging from interviews were team factors (communication failure, lack of team continuity, lack of clarity over roles/responsibilities); work environment factors (poor staffing levels, equipment problems, distractions); inadequate training/supervision. Knowledge/skill ($p = .034$) and competence ($p = .018$) appeared to be more prominent in causing AEs in open procedures compared with endovascular procedures; organisational structure was more frequently implicated in AEs occurring in endovascular procedures ($p = .017$). To improve safety, interviewees proposed team training programmes (5/10 interviewees); additional protocols/checklists (4/10); improved escalation procedures (3/10).

Conclusion: Vascular surgeons believe that AEs in arterial operations are caused by multiple, modifiable system factors. Larger studies are needed to establish the relative importance of these factors and to determine strategies that can effectively address system failures.

Article history: Received 17 May 2017, Accepted 2 October 2017, Available online 15 November 2017

Keywords: Patient safety, Communication, Endovascular procedures

INTRODUCTION

Some of the highest rates of preventable adverse events are in vascular patients undergoing surgical intervention,[1–5] yet relatively few studies have sought to identify the preventable causes of these incidents in vascular surgery. Operator and institution inexperience, deficiencies in technical skills,

[1] *Present address:* 6th Floor Hunter Wing, St. George's Hospital, Faculty of Health, Social Care and Education, Kingston University and St George's University of London, Cranmer Terrace, London SW17 ORE, UK.

* Corresponding author. Division of Surgery, Department of Surgery & Cancer, Imperial College London, St Mary's Campus, London, W2 1NY, UK.
E-mail address: r.lear12@imperial.ac.uk (Rachael Lear).

1078-5884/

https://doi.org/10.1016/j.ejvs.2017.10.003

and inappropriate patient selection are known to be associated with poorer outcomes.[6] In a small number of single centre studies, observers have reported failures relating to equipment, workspace configuration, communication, and teamwork.[7,8] These findings have been corroborated in a larger, multicentre observational study of 'system' failures in aortic surgery in the UK.[9] Non-technical failures have been linked to intra-operative errors, procedural problems, and longer operating times, but their direct relationship with patient harm is less clear.[7,8] To ensure the best outcomes, the vascular community must seek to understand the preventable causes of adverse events and target interventions to improve safety across the specialty. Vascular surgeons are ideally placed to comment on factors leading to adverse events, yet to date their views have not been formally reported. The aim of this exploratory, mixed-methods study was to describe vascular surgeons' perceptions of factors contributing towards adverse events in arterial surgery. A secondary aim was to report vascular surgeons' recommendations for improving the safety of these patients.

METHODS

Overview and definitions

In this exploratory, mixed-methods study, surveys and semi-structured interviews elicited vascular surgeons' perceptions of the causes of adverse events in patients undergoing arterial surgery, and interviewees were asked to provide recommendations for improving the safety of these patients. 'Adverse events' were defined as unintended injuries to patients caused by medical management rather than the patient's underlying condition, leading to prolonged hospital stay, temporary or permanent disability, or death.[10]

Inclusion criteria and recruitment of participants

To obtain a high response rate, a convenience sample of 100 surgeons were approached face to face during three vascular conferences between November 2012 and September 2013 and were invited to complete the survey. Interviewees were either survey respondents or clinical contacts invited to participate based on their geographical work location or level of training to ensure a diverse sample. Surgeons were eligible to participate in the study if they regularly performed open and endovascular arterial operations in the British National Health Service (NHS) and were vascular consultants, vascular registrars, or general surgery registrars with a sub-interest in vascular surgery. Interviews continued until a diverse sample was obtained in terms of interviewee level of training and geographical work location.

MATERIALS AND METHODS

A validated framework of factors known to contribute to adverse events in health care was used to devise the survey. The framework, which is described in full elsewhere,[11,12] lists 25 contributory factors organised under the following headings: patient, staff, teams, the work environment, organisation and management, and institutional context. Respondents were asked to consider each contributory factor in relation to an adverse event: (1) that they had personally witnessed and could recall the circumstances of, (2) that had occurred during or within 24 h of an open or endovascular arterial procedure, and (3) that was caused by medical management rather than underlying disease, and resulted in prolonged hospital stay, disability, or death. Respondents scored all factors in relation to the adverse event on a Likert scale; a score of 5 was 'highly likely' to have contributed, a score of 1 was 'highly unlikely' to have contributed, and a score of 3 was neutral. To facilitate comparison between groups (consultants versus registrars; emergency versus elective procedures) in a small sample, survey responses were later converted to binary variables, where factors judged as at least 'somewhat likely' to have contributed to adverse events were coded as 1, and the remainder were coded as 0. Respondents were asked to indicate their level of training (consultant or registrar), the type of procedure that the adverse event related to (open or endovascular surgery), the procedure setting (elective or emergency), and the consequences of the adverse event. To preserve anonymity and to encourage a higher response rate, survey respondents were not asked to give their name or work location. The survey was piloted with eight vascular trainees to ensure acceptability with subsequent minor changes to the syntax of instructions. Survey administration was paper based, and was undertaken by a single researcher (RL: clinical research fellow). The semi-structured interview schedule elicited detailed accounts of perceived factors leading to adverse events, as well as recommendations to improve patient safety in arterial surgery. All interviews were undertaken by a single researcher, recorded, transcribed verbatim by a professional independent transcriber, anonymised, and assigned a study identification number.

Analysis

The most frequently reported contributory factors were calculated from quantitative survey responses. It was hypothesised that the following characteristics could influence perceptions of the profile of factors contributing towards an adverse event: (1) respondent's level of training (consultant versus trainee), (2) procedure type (open versus endovascular) and (3) setting (elective versus emergency). These hypotheses were tested using Pearson's chi-square analysis. The Bonferroni correction was not deemed appropriate because of the exploratory nature of the study.

Analysis of interview transcripts adhered to the principles of the 'framework method', which outlines key steps in the process of thematic analysis[13] to ensure a systematic approach (Box 1). The researcher (RL), who had received formal training in the framework method through an

Box 1. Steps in qualitative data management using the Framework approach.[13]

Step 1 **familiarisation** with transcripts to identify data relevant to the research question
Step 2 **construction of a thematic framework** from the data itself through identification of headings under which relevant data can be organised
Step 3 **indexing and sorting** to identify parts of the data that can be grouped together
Step 5 **reviewing data extracts** to organise data to create more coherent groupings
Step 6 **data summary and display** to summarise each interviewee's contribution to a theme
Step 7 **abstraction and interpretation** to map the range and diversity of views and experiences, and to suggest explanations for the findings.

accredited centre, read all transcripts in detail, searching for common themes. Themes that were specified a priori (common contributory factors identified through analysis of survey data) and new themes emerging from the data were combined to form an analytical framework, comprising a number of themed headings. This thematic framework was applied to all transcripts. Coded transcript data and relevant illustrative quotes were arranged in a theme/case matrix in Microsoft Excel.

Ethical approval

The study obtained ethics approval from the North West London REC (12/LO/0710).

RESULTS

Of 100 vascular surgeons approached, 77 completed the survey (response rate 77%) and reported on 77 separate adverse events. Survey respondents were consultants ($n = 37$) and registrars ($n = 40$), working in the British NHS who regularly perform open and endovascular arterial procedures. Twelve vascular surgeons were invited to be interviewed, and 10 agreed to participate (response rate 83%). Interviewees were consultants ($n = 5$) and registrars ($n = 5$) from six different hospitals across England. All interviewees regularly performed open and endovascular procedures in arterial 'hubs' (centres where arterial expertise is concentrated following the process of centralisation in the UK). Four interviewees worked in central London hospitals and six worked in other regions. Table 1 presents an overview of the procedure types, settings, and consequences of the adverse events reported by the survey respondents and interviewees. For illustrative purposes, the details of three adverse events reported by interviewees, including the sequence of events and perceived contributory factors, are presented in Table 2.

Table 1. Procedure types and adverse event consequences reported by survey respondents and interviewees.

	Surveys (77 adverse events reported by 77 survey respondents)	**Interviews** (15 adverse events reported during 10 interviews)
Procedure type		
Open surgical procedures	**41**	**11**
Aortic aneurysm repair	20	2
Carotid endarterectomy	10	6
Lower limb bypass graft	8	2
Other	1	1
Missing data	2	—
Endovascular procedures	**36**	**4**
Aortic aneurysm repair (EVAR)	34	3
Iliac stent	2	—
Setting		
Elective	31	13
Emergency	21	2
Missing data	25	—
Consequences of adverse event		
Temporary disability/prolonged hospital stay	36	5
Permanent disability	16	1
Death	18	5
Missing data	7	—

Overview of contributory factors

Eighty-three per cent of survey respondents reported that multiple factors contributed to the adverse event they had witnessed (median number of factors = 5, interquartile range (IQR) 2—9, range 0—25). Table 3 outlines the profile of contributory factors reported by 77 survey respondents for 77 separate adverse events. Aside from the patient's condition, the most frequently reported contributory factors were failures in verbal communication between operating team members (36.4%: $n = 28/77$), inadequate staffing levels or skill mix (32.5%; $n = 25/77$), and a lack of knowledge/skills (37.3%; $n = 28/75$) or competence (32.9%; $n = 25/76$). There were no significant differences between consultants and registrars for the pattern of contributory factors reported. Although the pattern of contributory factors did not differ significantly between elective or emergency procedures, data for the urgency of the procedure were missing in 32.5% (25/77) of survey responses and therefore these results are not presented in further detail. Failures relating to knowledge or skill were more frequently cited as contributing to adverse events (AEs) in open procedures compared with endovascular procedures (19 AEs vs. 9 AEs, $p = .034$), as were failures relating to competence (18 AEs versus 7 AEs, $p = .018$). Issues relating to organisational structure were more frequently reported as contributing to adverse events in endovascular procedures than in open procedures (10 AEs vs. 3 AEs, $p = .017$).

The most commonly reported themes arising from survey responses and thematic analysis of interview transcripts are

Table 2. Details of three adverse events reported by interviewees (for illustrative purposes).

Details of adverse event	Contributory factors as perceived by the interviewee
Patient with large pseudoaneurysm in groin & history of aortobifemoral bypass graft. While dissecting out the iliac arteries there was an injury to the iliac vein. Balloon catheter inserted to try to get control. Balloon ruptured the iliac vein resulting in massive haemorrhage. Patient died.	• Complex re-do operation and situation escalated into an emergency • Scrub nurse was inexperienced and a more experienced scrub nurse refused to scrub in • Balloon catheter of appropriate size not immediately available - Foley catheter used instead • Surgeon did not check that the catheter before placing it into the iliac vein and scrub nurse was too afraid to challenge the surgeon
Patient with large thoraco-abdominal aneurysm anaesthetised and spinal drain placed. Operating team then realised that the fenstrated stent had not been delivered to the hospital - operation could not proceed as planned and only the extra-anatomical bypass grafts were completed. Patient underwent unecessary invasive procedures and required additional hospital stay to complete stenting procedure. Patient was fully informed of the error after awaking from the general anaesthetic.	• Industry representative was new and unfamiliar with the system • Operations are scheduled according to the shipping/ delivery date for custom-made stents, but the industry representative did not communicate change of stent delivery date to surgical team • All team members wrongly assumed that someone else had checked that the stent was availalble • Ruptured aneurysm/emergency case
Large man with ruptured AAA transferred from the emergency department to the interventional radiology department without proper anaesthetic support or emergency equipment. Patient died.	• Heavy workload - lots of emergencies happening at the same time • Skeleton staff at night time — no one was available to cover • Financial constraints preclude having a anaesthetist on call dedicated only for vascular emergencies • Delays in starting the procedure because intubation equipment and intravenous access was not immediately available

described in depth below. Verbatim quotes are given in italics. Table 4 provides a summary of key themes that emerged from analysis of interview transcripts.

Team factors

More than one third of survey respondents (36.4%) and eight of 10 interviewees indicated that verbal communication failures had contributed towards an adverse event that they had witnessed. Intrinsic factors leading to poor communication were reported as a reluctance to challenge perceived authority *"I didn't feel I could speak up being a more junior member of the team"* (interviewee 9, registrar), or a desire to demonstrates one's own capabilities without senior help: *"Knowing when to ask for help, that element of communication is difficult. I think it goes back to the hierarchy, and almost proof of self worth"* (interviewee 10, registrar). Long cases requiring staff changeover intra-operatively were viewed as particularly vulnerable to communication failure: *"… the only one who tends to be constant is the operating surgeon and if there is a complex case which takes many hours and requires shift changes, it is easy to see how things can be forgotten like an extra clamp that has been left on too long, a swab that has been placed under the pelvis"* (interviewee 10, registrar). Problems relating to team structure (congruence, consistency, leadership) were reported by 28.9% of survey respondents and by four of 10 interviewees. Unfamiliarity with other team members made it more challenging to operate safely, and this was particularly problematic during emergency cases occurring out of hours: *"the scrub teams, the emergency scrub team, which is very incongruent, just sort of thrown together […] I'd never met my assistant before, never mind worked with her"* (interviewee 7, consultant). Poorly defined roles and responsibilities within the operating team were described by three interviewees. In one case, it was not clear who

Table 3. Profile of factors contributing to 77 adverse events reported by survey respondent.

Factors contributing to adverse events (organised as per Vincent's framework for analysing risk and safety in clinical medicine, 1998)	All adverse events reported by survey respondents (n = 77)	Adverse events reported by: Consultants (n = 37)	Registrars (n = 40)	P value	Adverse events occurring in: Open surgical procedures (n = 41)	Endovascular procedures (n = 36)	P value
Team factors							
Verbal communication between team members	36.4% (28/77)	29.7% (11/37)	42.5% (17/40)	.244	39.0% (16/41)	33.3% (12/36)	.604
Team structure (congruence, consistency, leadership)	28.9% (22/76)	27% (10/37)	30.8% (12/39)	.719	29.2% (12/41)	28.6% (10/36)	.947
Supervision & seeking help	28.6% (22/77)	24.3% (9/37)	32.5% (13/40)	.428	36.6% (15/41)	19.4% (7/36)	.097
Written communication between team members	15.8% (12/76)	13.9% (5/36)	17.5% (7/40)	.630	17.1% (7/41)	14.2% (5/35)	.701
Work environment factors							
Staffing levels & skills mix	32.5% (25/77)	37.8% (14/37)	27.5% (11/40)	.333	39.0% (16/41)	25.0% (9/36)	.190
Design, availability & use of equipment	27.3% (21/77)	27.0% (10/37)	27.5% (11/40)	.963	22.0% (9/41)	33.3% (12/36)	.263
Workload & shift patterns	19.7% (15/76)	19.4% (7/36)	20% (8/40)	.952	25.0% (10/40)	13.9% (5/36)	.224
Administrative & managerial support	15.6% (12/77)	18.9% (7/37)	12.5% (5/40)	.438	12.2% (5/41)	19.4% (7/36)	.382
Physical environment (light, space, noise)	14.5% (11/76)	11.1% (4/36)	17.5% (7/40)	.429	12.2% (5/41)	17.1% (6/35)	.541
Staff factors							
Knowledge & skills	37.3% (28/75)	37.8% (14/37)	36.8% (14/38)	.929	**48.7% (19/39)**	**25.0% (9/36)**	**.034**
Competence	32.9% (25/76)	37.8% (14/37)	28.2% (11/39)	.372	**45.0% (18/40)**	**19.4% (7/36)**	**.018**
Physical & mental health	11.8% (9/76)	8.1% (3/37)	15.4% (6/39)	.326	10.0% (4/40)	13.9% (5/36)	.603
Task factors							
Availability & use of protocols	29.9% (23/77)	27.0% (10/37)	32.5% (13/40)	.600	26.8% (11/41)	33.3% (12/36)	.534
Task design & clarity of structure	23.7% (18/76)	16.7% (6/36)	30.0% (12/40)	.172	26.8% (11/41)	20.0% (7/35)	.485
Decision-making aids	19.7% (15/76)	16.7% (6/36)	22.5% (9/40)	.523	22.0% (9/41)	17.1% (6/35)	.600
Availability & accuracy of test results	15.8% (12/76)	13.9% (5/36)	17.5% (7/40)	.666	17.5% (7/40)	13.9% (5/36)	.666
Organisational factors							
Safety culture & priorities	22.1% (17/77)	18.9% (7/37)	25.0% (10/40)	.520	22.0% (9/41)	22.2% (8/36)	.977
Financial resources & constraints	16.9% (13/77)	16.2% (6/37)	22.5% (9/40)	.881	12.2% (5/41)	22.2% (8/36)	.241
Organisational structure	16.9% (13/77)	10.8% (4/37)	17.5% (7/40)	.171	**7.3% (3/41)**	**27.8% (10/36)**	**.017**
Policy, standards & goals	15.6% (12/77)	13.5% (5/37)	17.5% (7/40)	.630	14.6% (6/41)	16.7% (6/36)	.806
Institutional context factors							
Economic & regulatory context	11.7% (9/77)	13.5% (5/37)	10.0% (4/40)	.632	12.2% (5/41)	11.1% (4/36)	.883
Links with external organisations	11.7% (9/77)	16.2% (6/37)	7.5% (3/40)	.234	7.3% (3/41)	16.7% (6/36)	.203
Patient factors							
Patient's condition	74% (57/77)	73.0% (27/37)	75.0% (30/40)	.839	75.6% (31/41)	72.2% (26/36)	.735
Patient's personality & social factors	6.6% (5/76)	8.3% (3/36)	5.0% (2/40)	.558	4.9% (2/41)	8.6% (3/35)	.517
Language & communication with patient	2.6% (2/76)	0% (0/36)	5.0% (2/40)	.174	2.4% (1/41)	2.9% (1/35)	.910

was responsible for confirming delivery of an essential piece of kit — failure to check that the equipment had been received led to the planned operation being cancelled after the patient had been put under general anaesthesia (interviewee 3, consultant).

Work environment factors

Nearly half of survey respondents (48.1%) reported that work environment factors contributed to adverse events. Inappropriate staffing levels or skill mix were cited by 32.5%

Table 4. Factors contributing towards adverse events: key themes that emerged from analysis of interview transcripts.

Key themes that emerged from analysis of interview transcripts	Number of interviewees	Illustrative quote (participant ID number, level of training)
TEAM FACTORS		
Communication failure	8	*"so having, you know, staff in theatre, who you had spoken to preoperatively about how you exactly wanted things done very simply. But then they left without handing over to the people who took over"* (interviewee 8, registrar)
Lack of operating team continuity	4	*"it is not uncommon in the very complex cases to have changes of staffing […] the only one who tends to be constant is the operating surgeon and it is easy to see how things can be forgotten like an extra clamp that has been left on too long, a swab that has been placed under the pelvis, and whilst there are mechanisms in place to try to capture those errors, things fall through the net"* (Interviewee 10, registrar)
Lack of clarity over roles & responsibilties	3	*"it was also the fact that the roles are not clearly defined. In terms of who's responsible for what part of the operation when you've got two different teams -radiology and scrub terms - merging or joining to perform one task"* (interviewee 4, registrar)
WORK ENVIRONMENT		
Inadequate staffing levels or skill mix	7	"*Now we work with nurses who it might be their second day doing vascular and then, you know, in big cases it's not appropriate"* (interviewee 6, registrar)
Distractions and external pressures	6	*"I was getting stressed because people were continually interrupting me, what do we do with this patient, what shall we do about this patient(…) It was noisy. It was unbearable, people were going in and out. It was awful"* (interviewee 5, consultant)
Equipment issues	8	*"things that we're seeing more and more often are sort of technology failures if you like. And whether you work in laparoscopic surgery or in endovascular intervention, if the machine isn't working properly you can sort of, you know, cause significant injury to the patient"* (interviewee 4, registrar)
TRAINING & SUPERVISION		
Technical aspects	9	*"And in the end I felt I had to descrub and go and do the ruptured aneurysm and leave the senior registrar to finish the case, with on assistant. He was doing the case and I was supervising. But then he broke a stitch and the patient was clamped for longer than they should have been and he had a TIA."* (interviewee 5, consultant)
Management of operating environment	4	*"You're a new consultant, you're not going through a learning phase with the operating, but with managing the world outside of your immediate zone — you're taking responsibility for what other people are doing around you. Your training has been very focussed on doing one aspect of a wider job.* Such *that you were never trained in particularly how to organise the theatre the way you like."* (interviewee 1, consultant)

of all survey respondents and by seven out of 10 interviewees. Two new consultants felt that having to rely on inexperienced team members impeded their ability to concentrate on operating, and six of 10 interviewees cited distractions and external pressures, such as concurrent emergencies, as factors contributing towards adverse events. Other distractions in the work environment (light, space, noise) were reported by 14.5% of survey respondents.

27.3% of survey respondents and eight of 10 interviewees reported issues relating to the design, availability, and use of equipment. Half of interviewees (5/10) described failures in planning or preparing essential equipment: two interviewees felt that adverse events had occurred because appropriate rescue equipment was not available when required. Three interviewees reported that unfamiliarity with equipment contributed towards adverse events they had witnessed.

Lack of supervision/training

28.7% of survey respondents and nine of 10 interviewees indicated that failures in supervision or failing to seek help were important determinants of adverse events: *"the surgical consultant saw that I was struggling and I kept asking for advice on what to do for surgical components but I never said I need you to scrub. Without that direct demand and I guess in part my own inexperience the patient lost a reasonable amount of blood"* (interviewee 10, registrar). Four interviewees described difficulty in managing the operating environment and the team because of a lack of training in "soft skills": *"… for the relatively inexperienced consultant's level, it takes up a lot of, you know, thinking part of the brain, to have it concentrate on reminding the assistant as well as concentrating on what's a very technically demanding procedure"* (interviewee 7, consultant).

Strategies to improve patient safety

Interviewees suggested a variety of strategies to improve patient safety in arterial surgery (Table 5). Half of interviewees (5/10) would like to implement training programs enabling the entire multidisciplinary operating team to train together. One interviewee emphasised that team training would be particularly important to rehearse crisis scenarios. Four interviewees suggested implementing further protocols or checklists to standardise processes such as mid-procedure handovers between staff. Two interviewees believed that high risk procedures are safest when performed by experienced operating team members who have worked together for many years. Current issues with staff retention or rotation were acknowledged as barriers to this "old fashioned' way of working. It was argued that: "… *if you can't have a blanket policy where the safety is always number one, because, it's impossible to have this level of expertise all the time — then you've got to make sure you have it there for cases where things start to become emergent"* (interviewee 6, registrar). Accordingly, three interviewees would like to implement further escalation algorithms to facilitate adequate staffing levels or skill mix during emergencies.

DISCUSSION

The purpose of this study was to describe vascular surgeons' perceptions of factors contributing to adverse events in arterial surgery. Vascular surgeons report that adverse events are not solely related to inherent complexities in the procedure or the patient's condition, but are commonly caused by a combination of team, environment, and organisational failures.

A mixed-methods approach was adopted for this study. Surgeons' survey responses were reported using an existing framework, but searches of interview transcripts were conducted to identify additional themes. Direct quotations from interviews with surgeons are provided in this report. Although this qualitative approach might seem alien in a field that relies heavily on quantitative experimental designs, there are several advantages to using a qualitative or mixed-methods methodology when seeking to understand why adverse events occur. Whereas quantitative research measures frequency, prevalence, and incidence, qualitative research seeks to understand the breadth and complexity of a given topic.[14] Hence qualitative methodologies are appropriate when investigating the complex interplay of factors contributing towards adverse events, particularly as potentially relevant factors are not fixed in time and space. An advantage of pairing quantitative and qualitative methods is increased confidence in study findings through triangulation.[15] Indeed, in the present study, the independent responses of survey respondents and interviewees indicated that team and work environment factors are important determinants of adverse events. However, the interviews revealed a more nuanced interpretation of this relationship, for example, whereas analysis of survey results demonstrated that communication failures frequently resulted in adverse events, analysis of interview transcripts revealed some of the factors underpinning these communication failures, such as an unhealthy hierarchy, lack of team continuity or confusion over roles and responsibilities within multidisciplinary teams.

Looking at the findings of this study it is possible to infer that many of the problems leading to patient harm in arterial surgery are common across all surgical specialties. Communication failure, for example, is a widely recognised determinant of patient harm, particularly in the operating theatre.[16] Vascular surgeons in this study reported that communication failures may be exacerbated by the issue of operating team continuity. This issue has also been reported in other surgical specialties involving long and complex operations — for example, in a large retrospective cohort study of patients undergoing cardiac surgery, the need to handover anaesthetic care from one anaesthetist to another was associated with a 27% relative increase in risk adjusted, post-operative complications compared with cases in which the same anaesthetic team members were present throughout the operation.[17] In a further study of outcomes in patients undergoing abdominal surgery, surgeons reported higher levels of concentration when they

Table 5. Strategies to improve patient safety: key themes that emerged from analysis of interview transcripts.

Key themes that emerged from interview transcripts	Number of interviewees	Illustrative quot (participant ID number, level of training)
Team training	5	*"I think* we *need to do crisis management training. It's greater awareness of what you do in a crisis, you know, we give people routines. Once in crisis, this is first step, second step, third step, these are the things you should be looking out for, because otherwise we reinvent the wheel each time."* (interviewee 6, registrar)
Further protocols or checklists to standardise & facilitate key processes	4	*"The thing to stop it happening to the next person is to have it on our checklist of, of things to check before the operation. If you read* that *WHO checklist, the equipment check is a bit late once the patient is asleep. I think need to bring the processes of checking and discussing the case earlier rather than later"* (interviewee 3, consultant)
Better escalation procedures to ensure experienced staff available when required	3	*"You need to have mechanisms in place where you can recruit another member of staff if there aren't enough people available … the ability to recruit people to tend to the patient if the situations becomes uncontrollable"* (interviewee 2, consultant)

consistently worked with the same operating team members, and this study demonstrated that team familiarity was a significant predictor of post-operative complications.[18] Work environment factors including staffing levels or skill mix and equipment issues have also been widely reported in the safety literature. Nurse staffing and education level is strongly associated with outcomes in surgical patients.[19,20] Furthermore, cumulative operating team experience has been shown to be more important than the individual experience of the most senior surgeon in cardiac operations with regards to cardiopulmonary bypass and clamp times.[21] This is concerning because vascular surgeons in the present study pointed out that they frequently work with very junior assistants or scrub nurses with little experience of major arterial procedures. Vascular surgeons also reported that equipment issues are common contributory factors when adverse events occur. These reports echo the findings of several other studies of safety in surgery, which have demonstrated that equipment failures are common during arterial operations, occurring most frequently during procedures that use endovascular technology.[7–9,22] A systematic review of equipment failures in the operating theatre demonstrated that procedures relying more heavily on technology, such as those in vascular and cardiac specialties, carried a higher burden of equipment-related error than general surgical procedures.[23] In the context of the wider surgical literature, the issues identified in the present study are unlikely to come as a surprise to most vascular surgeons, but publishing this work within the vascular surgical literature is an important move towards increasing the visibility of these problems for policy makers.

This study raises some concerns that are unique to the field of vascular surgery, particularly in relation to the organisation of endovascular services in the UK and some other European countries. Organisational structure was associated with a higher incidence of adverse events in endovascular procedures than open procedures, and vascular surgeons described errors in communication as a result of the involvement of two teams (surgical and interventional radiology) in the same procedure, as is common practice in the UK. This finding has been echoed in a larger, multicentre study of intra-operative failures in aortic procedures in the UK, in which procedure type independently predicted intra-operative failure rate, with endovascular procedures associated with significantly higher rates of intra-operative equipment related and communication failures.[9] Further research could compare adverse events in patients undergoing endovascular procedures at centres where there is complete integration of vascular and interventional radiology teams versus centres where there is demarcation of territory. It is likely that, to improve patient safety in the UK, it is necessary to follow the international trend of developing "hybrid scrub nurses" who are trained in both open and endovascular skills - working in hybrid theatres alongside vascular surgeons who can switch between open and endovascular techniques depending on the patient's pathology. Greater integration of vascular surgery and interventional radiology departments is certainly encouraged to reduce failures in teamwork and communication. The feasibility of simulation based *team* training, in which different disciplines train together to facilitate the acquisition of both the technical and *non-technical* skills required for open and endovascular procedures, has been demonstrated in some preliminary studies,[24,25] but there is more work to be done in this arena. Tools that facilitate clinical decision making, such as the recently published European Society of Cardiology Guidelines on the Diagnosis and Treatment of Peripheral Arterial Disease in collaboration with the European Society of Vascular Surgery,[26] clearly play an important role in reducing the number of preventable adverse events in vascular patients.

Investigating the causes of adverse events in health care is challenging because of the broad range of potentially relevant contributing factors. There are a number of approaches that can be taken to address the problem and a mixed-methods approach has been used here to capitalise on the strengths of both quantitative and qualitative methodologies. However, the study has a number of important limitations that must be acknowledged. Firstly, this study relied on accurate reporting of retrospective events by participants. Clearly, the reports are subjective, vulnerable to selective reporting and recall bias. Furthermore, case selection was based on convenience sampling and study participation was voluntary, therefore surgeons with a particular interest in patient safety may have been more likely to participate; vascular surgeons' perceptions reported in this study may not be entirely representative. Of particular note, the sample size was small in this exploratory study and the reports only reflect practice within the British NHS - thus limiting the generalisability of the findings. In contrast with another similar study of adverse events in surgery,[27] no significant differences were found in the profile of contributory factors between elective and emergency procedures. However, the dataset was incomplete and a larger sample size may yield different results. Finally, recommendations to improve safety were based on interviews with 10 vascular surgeons and larger studies are needed to establish whether these views are representative.

CONCLUSION

Vascular surgeons believe that adverse events in arterial operations are frequently caused by multiple, modifiable system factors. This exploratory study has identified important system failures meriting further attention - including team and training issues, problems in the operating environment, and challenges in the organisation of endovascular services. Larger studies are needed to establish the relative significance of these contributory factors in arterial surgery and to determine strategies that can effectively address system failures to prevent future adverse events and further improve surgical outcomes.

CONFLICTS OF INTEREST

None.

FUNDING

This research was supported by the National Institute for Health Research (Rachael Lear, Clinical Doctoral Research Fellowship, CDRF-2012-03-040), the Circulation Foundation, and by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London. The views expressed in this publication are those of the author(s) and not necessarily those of the funders, the NHS, the National Institute for Health Research or the Department of Health.

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Original article

Multicentre observational study of surgical system failures in aortic procedures and their effect on patient outcomes

R. Lear[1,4], C. Riga[1,4], A. D. Godfrey[1], E. Falaschetti[2], N. J. Cheshire[1], I. Van Herzeele[7], C. Norton[4,5], C. Vincent[6], A. W. Darzi[1,3] and C. D. Bicknell[1,3,4], on behalf of the LEAP Study Collaborators*

[1]Department of Surgery and Cancer, [2]Clinical Trials Unit and [3]Centre for Health Policy, Imperial College London [4]Imperial College Healthcare NHS Trust, and [5]Faculty of Nursing and Midwifery, King's College London, London, and [6]Department of Experimental Psychology, Medical Sciences Division, Oxford University, Oxford, UK, and,[7]Department of Thoracic and Vascular Surgery, Ghent University Hospital, Ghent, Belgium

Correspondence to: Ms R. Lear, Division of Surgery, Department of Surgery and Cancer, Imperial College London, St Mary's Campus, London W2 1NY, UK (e-mail: r.lear12@imperial.ac.uk)

Background: **Vascular surgical care has changed dramatically in recent years with little knowledge of the impact of system failures on patient safety. The primary aim of this multicentre observational study was to define the landscape of surgical system failures, errors and inefficiency (collectively termed failures) in aortic surgery. Secondary aims were to investigate determinants of these failures and their relationship with patient outcomes.**

Methods: **Twenty vascular teams at ten English hospitals trained in structured self-reporting of intraoperative failures (phase I). Failures occurring in open and endovascular aortic procedures were reported in phase II. Failure details (category, delay, consequence), demographic information (patient, procedure, team experience) and outcomes were reported.**

Results: **There were strong correlations between the trainer and teams for the number and type of failures recorded during 88 procedures in phase I. In 185 aortic procedures, teams reported a median of 3 (i.q.r. 2–6) failures per procedure. Most frequent failures related to equipment (unavailability, failure, configuration, desterilization). Most major failures related to communication. Fourteen failures directly harmed 12 patients. Significant predictors of an increased failure rate were: endovascular compared with open repair (incidence rate ratio (IRR) for open repair 0·71, 95 per cent c.i. 0·57 to 0·88; $P = 0·002$), thoracic aneurysms compared with other aortic pathologies (IRR 2·07, 1·39 to 3·08; $P < 0·001$) and unfamiliarity with equipment (IRR 1·52, 1·20 to 1·91; $P < 0·001$). The major failure total was associated with reoperation ($P = 0·011$), major complications ($P = 0·029$) and death ($P = 0·027$).**

Conclusion: **Failure in aortic procedures is frequently caused by issues with team-working and equipment, and is associated with patient harm. Multidisciplinary team training, effective use of technology and new-device accreditation may improve patient outcomes.**

*The LEAP Study Collaborators are co-authors of this study and can be found under the heading Collaborators

Paper accepted 21 June 2016

Published online 25 August 2016 in Wiley Online Library (www.bjs.co.uk). **DOI:** 10.1002/bjs.10275

Introduction

It is well known that a significant number of patients come to harm while in hospital[1]. The highest rate of adverse events is in patients undergoing surgical intervention, most notably in those undergoing a major vascular procedure[2].

Medicine used to be simple, ineffective and relatively safe, whereas it is now complex, effective and potentially dangerous[3]. This is certainly true for major vascular surgery. Patient and technical factors are obvious determinants of outcome, but current thinking emphasizes the role of wider aspects of the surgical system in patient safety[1]. The high-risk nature of vascular procedures in elderly patients with complex co-morbidities and the importance of technical expertise are well recognized in vascular surgery. Investigation of wider system factors is now warranted, particularly as vascular surgery has undergone significant changes in recent years, with centralization of services in the UK and the rapid development of minimally invasive (endovascular) technologies. These novel strategies for

vascular patients have undoubtedly reduced major morbidity and mortality but, to achieve consistently optimal results, continuous emphasis must be placed on optimizing patient safety. Single-centre exploratory studies[4,5] in arterial surgery identified failures related to team communication, surgical equipment and planning, but whether these failures occur at vascular centres throughout the country and, most importantly, their impact on patient outcomes remain unknown. The mechanisms of harm, the determinants of increased failure rates and the impact of system failures on patient outcomes are important information to plan strategies for safety improvement.

The LEAP (Landscape of Error in Aortic Procedures) study is a multicentre, collaborative effort to explore patient safety in vascular surgery. The primary aim of the LEAP study was to define the landscape of surgical system failure, error and inefficiency in open and endovascular aortic surgery. Secondary aims were to investigate determinants of failure, and the relationship between intraoperative failure and patient outcomes.

Methods

Phase I was a training phase to train teams and establish the reliability of a self-reporting method. In phase II, teams self-reported failures occurring in aortic procedures, the impact of these failures, and patient outcomes. Full research ethics committee (12-LO-0710) and local approvals from the participating organizations were obtained.

Setting and participants

Participating operating teams were recruited in ten hospitals in England (September 2012 to July 2014). Operating teams consisted of a consultant vascular surgeon, anaesthetists, nurses and support staff, as well as radiology staff (radiologist and/or radiographer) for many procedures; team composition was not the same for all procedures owing to shift patterns and rotation of staff. For the training phase (phase I), all adult patients on participating vascular consultants' operating lists were eligible for inclusion. However, in phase II, only adult patients undergoing elective or urgent aortic surgery for aneurysm or aorto-occlusive disease were included. Staff and patients provided written informed consent to participate.

Materials

Twenty consultant vascular surgeons and their operating teams were trained by a single observer (a senior vascular nurse practitioner) to report intraoperative surgical system failures, errors and inefficiencies using a validated and structured, team-based approach. The Imperial College error capture record (ICECAP) is a paper-based tool consisting of several prompts read aloud to structure reporting of failures; its development and validation is described in full elsewhere[5]. Primary failure categories are: equipment, communication, procedure-independent pressures (distractions, team member absence, external pressures), technical, safety awareness and patient-related. Each of the primary categories has a number of secondary fields. For a failure to be recorded on ICECAP, the team had to come to a consensus on whether or not a failure had occurred, and on the category of failure.

Definitions

A failure was defined as any event that prevented the procedure from progressing in an ideal manner. This broad definition was a deliberate attempt to capture all relevant safety events. The term failure encompasses different types: failures in the surgical system (system factors), human errors and sources of inefficiency. Failures were to be reported if they occurred between the patient being transferred into the operating theatre and final closure of the wound.

Major and minor failures were defined by their immediate consequences during surgery. Failures that caused intraoperative delay of more than 15 min, caused harm, or placed the patient at significant risk of harm were referred to as major failures. Harm was defined as injury to the patient evidenced by a physiological response to the injury (such as cardiovascular instability), or by the need for further invasive intervention; harm may have occurred during the operation without further sequelae (lasting disability).

Procedure and data collection

Phase I

Shift patterns and staff rotation meant that the operating team composition was inconsistent; the trainer therefore undertook multiple visits to each site to capture as many operating staff as possible. The trainer attended a median of 5 (range 4–6) procedures with each consultant vascular surgeon and team, to provide training to all key participating staff. At the beginning of the operating list, the trainer outlined the aims of the study, important definitions and protocol to the operating team. During the procedure, the trainer recorded failures that occurred. At the end of the first procedure with the trainer present, the trainer led the team through the ICECAP debrief and completion of the written ICECAP record. Thereafter, a member of the

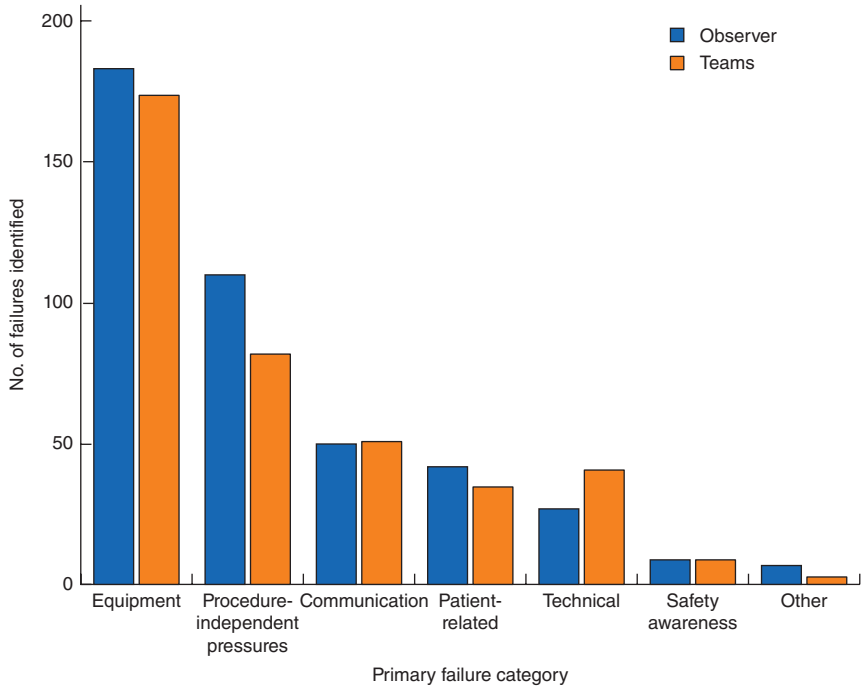

Fig. 1 Profile of failures identified through prospective observation by the trainer and structured team self-reporting during the training phase

team led the debrief, which took place in the same structured manner on each occasion. The trainer highlighted failures that she recorded to help teams develop an understanding of the types of failure that should be reported. The trainer encouraged reflection and discussion between team members to enable a consensus to be reached regarding failures to be documented on the ICECAP record.

Phase II

In the main study phase, each site aimed to collect data independently during 20 consecutive aortic procedures. Sites were asked to complete an aortic procedure log, indicating any interventions that were not recruited, with reasons. For each intervention, patient, procedure and team demographic data were collected, and the primary operator indicated whether he or she was unfamiliar with any of the equipment used. Details of each failure were recorded, including whether or not the patient was harmed, any corrective measures necessary to prevent harm, and the delay caused by the failure. Postoperative complications were recorded for 30 days or until hospital discharge, whichever was sooner.

Handling of data

Case report forms were collated and information was entered into a purpose-built database at the lead site. All failures were reviewed independently by two experienced clinical assessors, and categorized as major or minor, or excluded if they did not meet the study definition. Two independent assessors graded postoperative complications using the Clavien–Dindo system[6]. Grades III, IV and V are referred to as major complications.

Statistical analysis

Agreement between assessors was assessed by means of Cohen's κ. Univariable and multivariable Poisson regression analysis was used to compare failure rates (failures per hour) for different patient, procedure and team groups, and the clustering effect resulting from potential variability in reporting styles at the hospital-site level was taken into account by using cluster robust standard errors. The variables included in the regression were: age, sex, ASA fitness grade, aortic pathology, procedure type (open surgical or endovascular), team member experience based on the number of similar operations performed (over 50 *versus* fewer than 6 similar procedures), and familiarity with equipment. The Wilcoxon rank sum test was used to test for differences in the number of intraoperative failures and patient outcomes. All reported P values are two-sided. $P < 0{\cdot}050$ was deemed to indicate statistical significance. Data were analysed in Stata® version 12 (StataCorp, College Station, Texas, USA) by an independent statistician.

Results

Phase I

Eighty-eight procedures were included in phase I. The failure profiles reported by the trainer and in self-report by operating teams are summarized in *Fig. 1*. The correlation between the trainer and operating teams for the number of failures identified per procedure was good ($r_s = 0{\cdot}766$, $P < 0{\cdot}001$) and operating teams identified 95 per cent of major failures (18 of 19), indicating that they were able to follow study procedures and assess failure rates reliably.

Phase II

Following a period of training, 20 consultant vascular surgeons and their operating teams reported failures occurring in 185 elective aortic procedures. Only two urgent patients were recruited and were therefore excluded from analyses; only planned procedures were included. The aortic procedure log was completed poorly and was therefore unhelpful. Teams performing open surgical procedures consisted of the following core members: consultant vascular surgeon, consultant anaesthetist, scrub nurse and support staff. For endovascular interventions, core team members additionally included a consultant radiologist and a radiographer, as is common practice in the UK. All procedures started during daytime hours, although 16·2 per cent (30 of 185) finished after 17.00 hours. Patient, pathology and procedure characteristics are provided in *Table 1*.

Table 1 Patient and procedure data in phase II

	No. of patients ($n = 185$)
Patient demographics	
Mean age (years)*	73(10) (37–100)
Male sex	153 of 180 (85·0)
ASA fitness grade	
I	2 of 179 (1·1)
II	44 of 179 (24·6)
III	119 of 179 (66·5)
IV	14 of 179 (7·8)
Primary aortic pathology	
Infrarenal abdominal AAA	111 of 182 (61·0)
Juxtarenal abdominal AAA	30 of 182 (16·5)
Thoracic/arch aortic aneurysm	8 of 182 (4·4)
Thoracoabdominal aortic aneurysm	15 of 182 (8·2)
Occlusive disease	9 of 182 (4·9)
Other	9 of 182 (4·9)
Procedures	
Open infrarenal AAA repair	21 (11·4)
Open juxtarenal aortic aneurysm repair/type IV aortic aneurysm repair	9 (4·9)
Open aortoiliac bypass	7 (3·8)
Open aortofemoral bypass	7 (3·8)
EVAR – conventional	69 (37·3)
EVAR – additional complexity†	18 (9·7)
Branched EVAR/fenestrated EVAR – conventional	23 (12·4)
Fenestrated EVAR – additional complexity†	4 (2·2)
Thoracic EVAR – conventional	8 (4·3)
Thoracic EVAR – additional complexity†	7 (3·8)
Visceral hybrid repair	2 (1·1)
Other	10 (5·4)

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.) (range). †Endovascular procedure with additional intervention besides femoral cut down for arterial access. AAA, abdominal aortic aneurysm; EVAR, endovascular aneurysm repair.

Failure characteristics

The operating teams recalled 930 failure events in total. Independent assessment excluded 131 events that did not meet the study definition for the following reasons: event did not occur during surgery (43; such as lack of intensive care bed delayed start of procedure); likely anticipated patient-related issue (72; for example, tortuous iliac arteries identified on preoperative imaging); and other (16). Of 799 failures, operating teams identified a median of 3 (i.q.r. 2–6, range 0–23) per procedure. The median failure rate was 1·0 (i.q.r. 0·6–2·0, range 0–6) per h. There was a significant correlation between the number of failures per procedure and the duration of operation ($r_s = 0{\cdot}300$, $P < 0{\cdot}001$).

The details of failures are shown in *Fig. 2*. Overall, most frequent failures related to equipment (33·9 per cent), usually non-availability, ranging from minor issues, such as non-availability of the desired sheath size, to major failures, for example 'unavailability of the custom-made thoracic stent graft, which was believed to be on site but was found not to be available after spinal drain insertion and general anaesthesia'. The primary operator reported unfamiliarity with equipment in 18 procedures (open 1, endovascular 17), of which unfamiliarity with stent-graft devices was reported in 11. Procedure-independent pressures (interruptions and distractions, team member absence and external pressures) were also common (21·7 per cent of all failures).

Consequences of failure

The consequences of failure were varied. Nearly two-thirds of failures (62·9 per cent) caused intraoperative delays, and 9·8 per cent of failures led to significant delays (more than 15 min during the operation). In total, intraoperative delays accounted for more than 90 h of unproductive operating time over the 185 procedures. More than one-third of failures (33·8 per cent) necessitated corrective action by the operating teams.

Some 93 (11·6 per cent) of 799 failures were classified as major failures. Most frequent major failures were

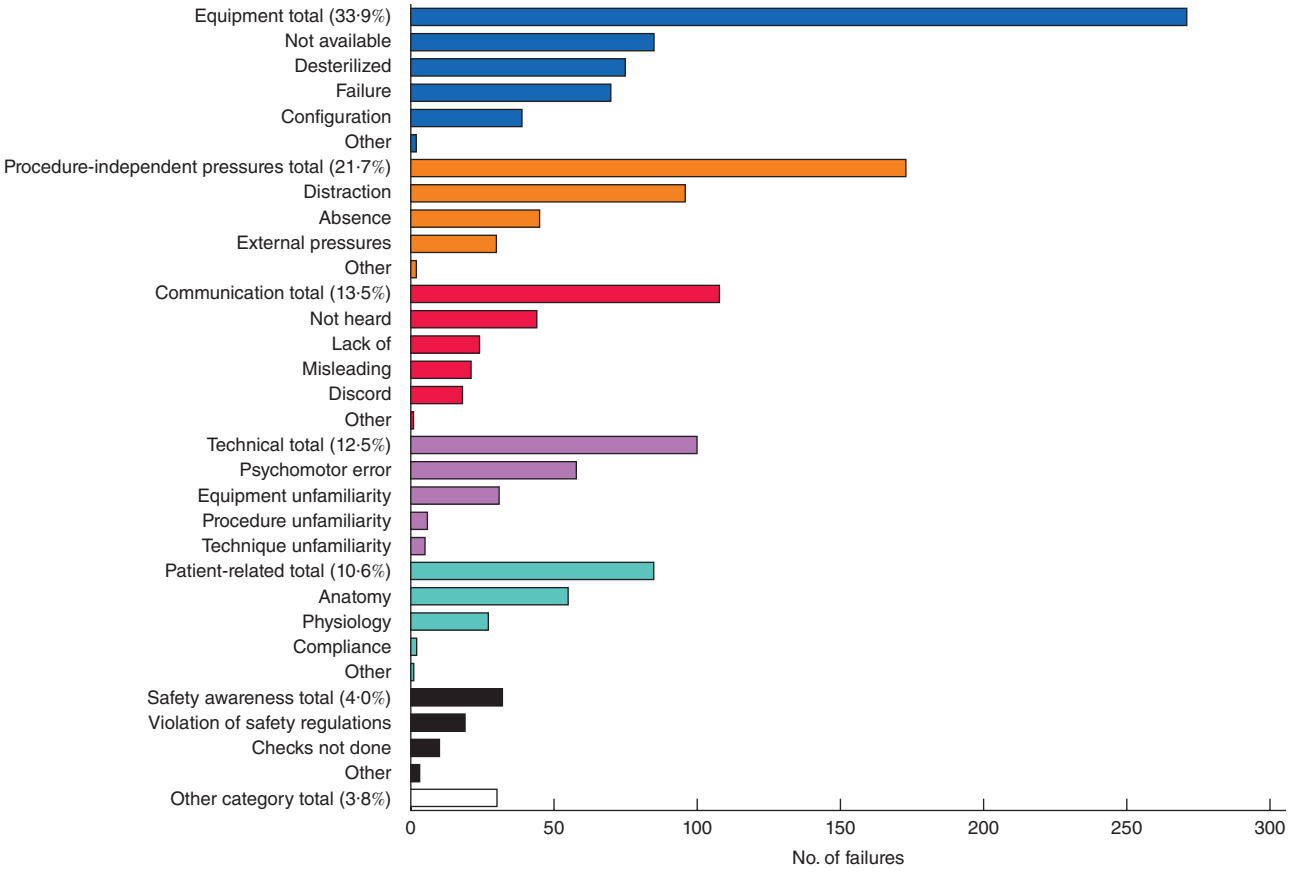

Fig. 2 Causes of failure in 185 aortic procedures by primary category and subcategory

unanticipated problems related to the patient's anatomy or physiology (33 per cent). Patient-related failures are therefore an important source of unanticipated delay (while the operating team address the problem), and could indicate failures in preoperative planning or preparation. Non-patient-related failures were most commonly communication failures (22 per cent of major failures), for example 'radiology staff not informed of start time – delay in starting endovascular phase (45 min) while patient under general anaesthesia'. Of the major communication failures, 65 per cent were due to communication problems between operating subteams: between the surgical and radiology teams (38 per cent); between the surgical and the anaesthetic teams (23 per cent); and between other team members including the nursing team (4 per cent). Of the remaining major failures, 17 per cent were technical failures, 13 per cent were equipment-related failures, 7 per cent were safety awareness failures (such as checks not done) and 5 per cent were procedure-independent pressures.

Most major failures (83 per cent) led to significant intraoperative delay. Fourteen major failures directly caused harm. Among the 17 per cent of failures that posed significant risk of harm without any associated delays, communication failures were the most common. Of the 14 major failures that led directly to intraoperative harm in 12 patients (6·5 per cent of study cohort), communication failures were reported by the team to have led to half of these harm-producing events (*Table 2*). There were four technical errors that harmed patients directly. Three events related to unanticipated difficulties with the patient's anatomy. Although not a primary aim of the study, review of these failures indicated that additional factors, such as inexperience or a lack of vigilance, may also have played a role; harm was rarely the direct result of a single identifiable cause.

Determinants of failure

Patient age, sex and ASA grade were not associated with increased failure rates in univariable analyses. There were also no significant differences in failures rates between levels of experience for all professions in the operating team. In multivariable regression, thoracic/arch aneurysms in comparison with other aortic pathologies (incidence

Table 2 Illustrative quotes from Imperial College error capture records for major failure leading to harm

'Misleading communication led to wrong clamps being taken off the graft … substantial blood loss, which was 'hidden' and went unnoticed leading to severe hypotension in a patient with significant co-morbidity' (hybrid open visceral artery retrograde revascularizsation and endovascular thoracoabdominal aneurysm repair)
'Communication failure and discord between surgeons and scrub nurse during bleeding. Scrub nurse unfamiliar with use of pledgeted sutures to repair internal iliac vein injury. Miscommunication led to a further tear in vein as sutures were pulled out. Patient became acutely unstable' (EVAR with surgical ligation of IIA)
'Wrong sized limb placed necessitating embolization of IIA' (EVAR and left to right femorofemoral artery crossover graft)
'Wrong incision due to lack of communication between radiology and surgical teams' (aortouni-iliac and femorofemoral artery crossover graft)
'Lack of communication between surgeons and anaesthetist regarding degree of blood loss. Change of consultant anaesthetist mid-procedure – patient not transfused after initial 2 units. Miscommunication with blood transfusion laboratory – delay in receiving cross-matched blood for hypovolaemic patient' (thoracic EVAR)

EVAR, endovascular aneurysm repair; IIA, internal iliac artery.

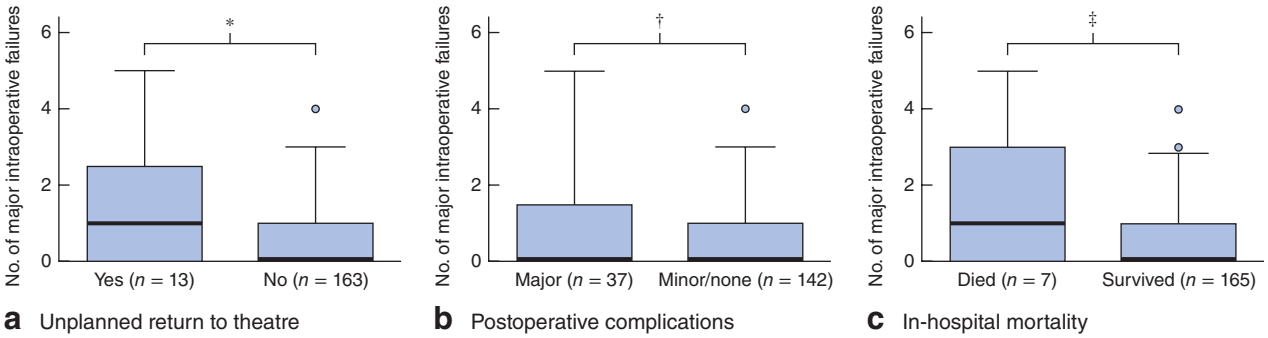

Fig. 3 Association between major failures per procedure and patient outcomes: **a** unplanned return to the operating theatre, **b** postoperative complications and **c** in-hospital mortality. Median values (bold line), i.q.r. (box) and 1·5 × i.q.r. (whiskers) are shown; outliers are represented by symbols. *$P = 0·011$, †$P = 0·029$, ‡$P = 0·027$ (Wilcoxon rank sum test, not adjusted for multiple comparisons)

rate ratio (IRR) 2·07, 95 per cent c.i. 1·39 to 3·08; $P < 0·001$) were significant predictors of increased failure rates. Of note, two-thirds of patients with thoracic/arch aneurysms in this cohort underwent either carotid subclavian bypass and thoracic endovascular repair (TEVAR) or custom-made TEVAR.

Unfamiliarity with equipment (IRR 1·52, 1·20 to 1·91; $P < 0·001$), and endovascular repair compared with open surgical approaches (IRR for open repair 0·71, 0·57 to 0·88; $P = 0·002$) were also significant predictors of failure. For major failure, only unfamiliarity with equipment was significantly associated with an increased failure rate (IRR 2·59, 1·51 to 4·28; $P = 0·001$).

Association between intraoperative failures and patient outcomes

Some 152 of 171 procedures were successful technically with no adverse events at 24 h after surgery (data missing for 14 procedures). Thirteen patients required reoperation, 37 developed major complications, four had a prolonged hospital stay (over 30 days) and seven patients died. The total number of intraoperative failures was significantly higher in procedures requiring an unplanned return to theatre: median 5 (i.q.r. 4–10) *versus* 3 (2–6) for procedures with no further operation ($P = 0·037$). The number of major intraoperative failures was also significantly higher in procedures subsequently requiring reoperation: median 1 (0–2·5) *versus* 0 (0–1) ($P = 0·011$). Significantly greater numbers of major failures were reported during procedures after which the patient developed a major complication: median 0 (0–1·5) *versus* 0 (0–1) for procedures followed by minor or no complications ($P = 0·029$). Similarly, number of major errors was associated with death: median 1 (0–3) for procedures followed by death *versus* 0 (0–1) where the patient survived to discharge ($P = 0·027$) (*Fig. 3*). There were no differences in the number of intraoperative failures occurring during successful *versus* unsuccessful procedures (3 (2–6) *versus* 5 (2–6); $P = 0·147$) or between regular and prolonged (over 30 days) hospital stay (3 (2–6) *versus* 4 (3–5); $P = 0·837$).

Discussion

This large study in vascular surgery demonstrates that many avoidable safety failures relate to aspects of the surgical system, in addition to patient factors and technical expertise. This study links intraoperative safety failure with

adverse outcomes in patients undergoing aortic surgery. In line with a smaller study of safety failures in cardiac surgery[7], the present work shows that many failures leading to patient harm stem from failures in the system. Operating teams must recognize potential failures in the surgical system and endeavour to mitigate them.

The National Reporting and Learning System (NRLS) is voluntary system for reporting adverse events and near misses that occur in healthcare. As such, it relies on the details submitted by the reporter and is inherently under-representative of the volume of events that occur[8]. The benefits of NRLS, in the same way as the LEAP study, come from analysing the report to identify themes, which can be targeted for improvement. A retrospective study of NRLS, aiming to identify the causes of patient harm in aortic surgery, demonstrated findings remarkably similar to those of the present study (A. D. Godfrey, R. Lear, N. Radcliffe, C. Riga, A. Darzi, C. D. Bicknell; unpublished data). There is a clear need to address communication and equipment-related failures. A benefit of the ICECAP debriefing approach to identifying intraoperative failures is that it enables learning to take place locally, so that improvement measures can be implemented immediately.

Intraoperative failures appear to have a significant effect on operating theatre efficiency, as well as patient safety. Nearly two-thirds of errors caused intraoperative delays in procedural workflow, with more than 90 h lost over 185 procedures. Since the average cost of running an operating theatre exceeds £1200 per h (€1443 per h; exchange rate 28 June 2016)[9], by avoiding these procedural delays the potential cost savings would be great for each institution.

It has been demonstrated that error rates vary between operation types, with procedures relying on technology, such as those in vascular or cardiac surgery[7], having the highest rates of total and equipment-related error. The present study has expanded on the findings of previous single-centre studies, demonstrating that endovascular procedures are consistently associated with more failures than open surgical operations. Although minimally invasive surgery has undoubtedly reduced surgical morbidity and mortality rates, to achieve optimal, safe and efficient outcomes avoidable error must be minimized. The increased rates of error during endovascular *versus* open surgical procedures may be explained by the rapidly evolving nature of the endovascular field, more challenging technology and the increased number of new devices on the market, resulting in an extensive and changing learning curve. Thoracic/arch aortic aneurysms predicted higher failure rates than infrarenal or juxtarenal aortic procedures, which may be explained by their relative technical difficulty.

In the present study, perceived unfamiliarity with equipment significantly predicted increased rates of intraoperative failure, whereas actual experience (in terms of the number of operations performed) did not. Vascular operating teams are using an increasingly wide range of stent-graft devices in order to treat patients with a broad range of anatomical configurations, and the large number of devices being used is a factor contributing to unfavourable results[10]. Operators planning to introduce a new interventional device have a responsibility to ensure that the introduction of new equipment is accompanied by adequate training, and fulfils safety and financial regulations within their institution. This may include gaining approval from the divisional board and new procedures committee, ensuring that protocols are in place, and ensuring there is a robust structure for audit and evaluation. In reality, however, new devices and equipment are regularly introduced into the operating environment. Currently, it is unclear who is ultimately responsible for training endovascular operators and their teams, whether industry or healthcare institutions, when new devices become available for use in patients. New-device training requires attention to improve patient safety.

Communication failures represented a significant proportion of major errors reported in the study, and contributed to half of all intraoperative harm events. Complex aortic procedures demand precise communication and collaboration from increasingly large and multidisciplinary operating teams. This study was undertaken in the UK, where, similar to many European institutions, surgeons and interventional radiologists commonly collaborate to perform endovascular procedures. Dual consultant operating has also become routine practice. Rotation of operating staff is commonplace and, as a result, team members may not work together regularly. Consequently, effective leadership and teamwork are challenging in this high-risk environment, yet training in these essential non-technical skills is not routine practice, despite the evidence of a relationship between teamwork and patient outcomes[11].

This study highlights the need to address human factor skills (such as communication, team-working, leadership) and system factors (equipment planning, provision and maintenance, pressures on the operating team and their environment, provision of training) that may influence patient outcomes in aortic surgery, while continuing to optimize the patient's preoperative condition and technical expertise among surgeons. A substantial proportion of equipment failures were due to non-availability, failure or

configuration, suggesting that there are clear advantages to implementing protocols to reduce equipment-related error. Procedure-specific equipment checks could be incorporated into the WHO surgical safety checklist[12], specially adapted for aortic repair.

The provision of teamwork and leadership training for vascular operating teams is crucial to improve patient outcomes. Team simulations have been shown to be a powerful tool for training and improving the technical and non-technical skills required to perform endovascular aortic aneurysm repair and complex cardiovascular procedures, and may be particularly useful for rehearsal of crisis scenarios[13].

A clear limitation of this study is self-reporting, which is likely to be influenced by cognitive biases, clinical processes (such as production pressure) and individual reporting styles[14]. To minimize the impact of this limitation, the ICECAP tool was used immediately after the procedure to structure postoperative team self-reporting of failures, which has been shown to reduce recall bias[5]. Although independent observation is not susceptible to primacy and recency bias effects, and is an alternative to collecting data on intraoperative failures, it is relatively time-consuming and expensive, and may influence operating team behaviours (Hawthorne effect). A further potential limitation of self-report is selective reporting. As the aortic procedure log was completed poorly across participating sites, it is not clear whether consecutive patients were recruited into the study. In an ideal study environment, consistent teams would have been necessary for data reporting. This study aimed to capture real-world intraoperative failures, so the fact that teams were inconsistent provided an honest report. Finally, the number of patients with adverse outcomes was small, so the assessment of between-group differences for failure and patient outcomes was not adjusted for multiple comparisons. The association between intraoperative failures and patient outcomes should be part of future research programmes to validate these findings further.

Collaborators

LEAP Study Collaborators: M. Gohel, P. Hayes (Cambridge University Hospitals NHS Foundation Trust, Cambridge); T. Joseph, A. Sowinski, T. Wilson (North Cumbria University Hospitals NHS Trust, Carlisle); P. Chong, D. Gerrard, A. Croucher (Frimley Health NHS Foundation Trust, Frimley); M. Bown, V. Gokani (National Institute for Health Research (NIHR) Leicester Cardiovascular Biomedical Research Unit and Department of Cardiovascular Sciences, University of Leicester, Leicester); M. McCarthy (University Hospitals of Leicester, Leicester); R. Brightwell, F. Meyer, M. Burrows (Norfolk and Norwich University Hospitals NHS Foundation Trust, Norwich); S. Renton, S. Das, S. Parsapour (North West London Hospitals NHS Trust, London); I. Nordon, S. Baxter, C. Shearman (University Hospital Southampton NHS Foundation Trust, Southampton); M. Jenkins (Imperial College Healthcare NHS Trust, London); B. Modarai, S. Clarke (Academic Department of Vascular Surgery, Cardiovascular Division, King's College London; British Heart Foundation Centre of Research Excellence and NIHR Biomedical Research Centre at King's Health Partners, St Thomas' Hospital, London); A. Thompson, S. Cavanagh, A. Gibson, Z. Coleman (York Teaching Hospital NHS Foundation Trust, York).

Acknowledgements

The authors thank the participants in this study, as well as all attendees at the National Vascular Patient Safety Symposium, and others who helped to shape the outcomes of this report: M. Albayati, L. Allen, P. Avis, L. Bailey, A. Busuttil, B. Byrne, J. Chopade, N. Courtois, A. Davies, L. Desender, A. Forster, M. Hamady, B. Han, T. Hyde, A. James, M. Joseph, R. Kukreja, D. Lewis, M. Li, S. Mason, P. Mayes, M. Metcalfe, M. Mireskandari, A. Morbi, F. Naseem, C. Pettengell, F. Rawf, A. Rolls, N. Rudarakanchana, A. Sharrock, J. Shalhoub, K. Steiner, D. Sykes, C. Thomas, D. Taylor, M. Treherne and I. Yardley. Particular thanks go to N. Sevdalis, D. Wilkins and J. Russell.

This work was supported by the Circulation Foundation (President's Early Career Award to C.D.B.); the NIHR (CDRF-2012-03-040 to R.L.); and the NIHR Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London. The views expressed in this publication are those of the author(s) and not necessarily those of the funders, the National Health Service, the NIHR or the Department of Health.

Disclosure: The authors declare no conflict of interest.

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