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SURGEONS' PERCEPTIONS OF THE CAUSES OF PREVENTABLE HARM IN ARTERIAL SURGERY: A MIXED METHODS STUDY

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Short title: Causes of preventable harm in arterial surgery

Manuscript category: original article

Word Count: 3513

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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. What this study adds is 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.

ABSTRACT

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 fifteen AEs. The causes of AEs were multi-factorial (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 as compared to

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.

Key words: 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 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, multi-centre 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 in order 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 in terms of level of training and geographical work location was obtained.

Materials and methods

A validated framework of factors known to contribute to adverse events in healthcare 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 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 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. However, 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 due to 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 analysis¹³ to ensure a systematic approach (box 1). The researcher (RL), who had received formal training in the framework method through an 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, which was comprised of 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.

Box 1: Steps in qualitative data management using the Framework approach¹³

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.

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%). 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 are 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 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 2.

- Tables 1 & 2 –

Overview of contributory factors

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). 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% (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 was 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 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, $p = 0.017$).

- Table 3 -

Most frequently reported themes arising from survey responses and thematic analysis of interview transcripts 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.

- Table 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 demonstrate 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.)

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% 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.

Lack of supervision/training

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).

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 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 5 -

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.

We adopted a mixed-methods approach for this study. We report surgeons' survey responses using an existing framework, but we also searched for additional themes in interview transcripts, and we provide direct quotations from interviews with surgeons in this report. Although this 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 topic¹⁴. 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 triangulation¹⁵. Indeed, in the present study, the independent responses of survey respondents and interviewees both 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 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, particular 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 to 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 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 utilise 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 procedures²³. 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, multi-centre study of intraoperative failures in aortic procedures in the UK, in which procedure type independently predicted intraoperative failure rate - with endovascular procedures associated with significantly higher rates of intraoperative equipment-related and communication failures⁹. 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, we need 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 Surgery²⁶, clearly play an important role in reducing the number of preventable adverse events in vascular patients.

Investigating the causes of adverse events in healthcare is challenging due to the broad range of potentially relevant contributing factors. There are a number of approaches that can be taken to address the problem and we have used a mixed-methods approach 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, we found no significant differences in the profile of contributory factors between elective and emergency procedures. However, our dataset was incomplete and a larger sample size may yield different results. Finally, recommendations to improve safety were based on interviews with ten 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.

Ethical approval: The study obtained ethics approval from the North West London REC (12/LO/0710)

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.

Competing interests: None

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Table 1: Procedures 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 | - |

Table 2: Details of three adverse events reported by interviewees (for illustrative purposes)

| Details of adverse event | Contributory factors as perceived by the interviewee |
|--|--|
| <p>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.</p> | <ul style="list-style-type: none"> • 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 |
| <p>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.</p> | <ul style="list-style-type: none"> • 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 |
| <p>Large man with ruptured AAA transferred from the emergency department to the interventional radiology department without proper anaesthetic support or emergency equipment. Patient died.</p> | <ul style="list-style-type: none"> • Ruptured aneurysm/emergency case • Heavy workload - lots of emergencies happening at the same time • Skeleton staff at night time - noone 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 |

Table 3: Profile of factors contributing to 77 adverse events reported by survey respondents

| 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: | | | 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 | 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 |

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 & responsibilities | 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 | | |
| 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 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) |

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 quote (participant ID number, level of training) |
|--|------------------------|--|
| Team training | 5 | <i>"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."</i> (interviewee 6, registrar) |
| Further protocols or checklists to standardise & facilitate key processes | 4 | <i>"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"</i> (interviewee 3, consultant) |
| Better escalation procedures to ensure experienced staff available when required | 3 | <i>"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"</i> (interviewee 2, consultant) |