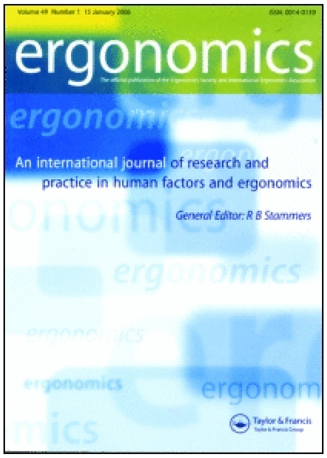

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Identification of systems failures in successful paediatric cardiac surgery

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Patient safety will benefit from an approach to human error that examines systemic causes, rather than blames individuals. This study describes a direct observation methodology, based on a threat and error model, prospectively to identify types and sources of systems failures in paediatric cardiac surgery. Of substantive interest were the range, frequency and types of failures that could be identified and whether minor failures could accumulate to form more serious events, as has been the case in other industries. Check lists, notes and video recordings were employed to observe 24 successful operations. A total of 366 failures were recorded. Coordination and communication problems, equipment problems, a relaxed safety culture, patient-related problems and perfusion-related problems were most frequent, with a smaller number of skill, knowledge and decision-making failures. Longer and more risky operations were likely to generate a greater number of minor failures than shorter and lower risk operations, and in seven higher-risk cases frequently occurring minor failures accumulated to threaten the safety of the patient. Non-technical errors were more prevalent than technical errors and task threats were the most prevalent systemic source of error. Adverse events in surgery are likely to be associated with a number of recurring and prospectively identifiable errors. These may be co-incident and cumulative human errors predisposed by threats embedded in the system, rather than due to individual incompetence or negligence. Prospectively identifying and reducing these recurrent failures would lead to improved surgical standards and enhanced patient safety.

Keywords: Error; Surgery; Observation; Health care; Safety

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1. Introduction

It is estimated that unintended harm in health care costs the UK approximately £2 billion per year in additional hospital stays alone (Department of Health 2000). Retrospective studies suggest that medical error is among the leading causes of death in both the USA and the UK (Kohn *et al.* 2000, Vincent *et al.* 2001). Although some approaches (reported by Shahian *et al.* 2001) have sought to associate, by implication, individuals with medical failures, errors of individual skill or expertise are unlikely to be the only cause of catastrophic events (Cook and Woods 1994, de Leval *et al.* 2000, Way *et al.* 2003, Blackstone 2004). Analysis usually reveals a series of minor failures that were known and tolerated, and created the catastrophe only when combining in close temporal or spatial proximity (e.g. Gaba 1989, Reason 1990, Fennell 1998, Carthey *et al.* 2000, Woolf *et al.* 2004). Human errors, which are unlikely ever to be eliminated, must therefore be seen in the context of inadequate health-care systems (Reason 1990, 2000). The application of this approach to the study of medical error is more likely to be successful in improving safety in medicine (Gaba 2000, Helmreich 2000, Spencer 2000, Carthey *et al.* 2001c, Wieman and Wieman 2004, Willeumier 2004).

Reacting to failures in safety after a poor outcome can help reduce the risk of similar events but is prone to hindsight bias (Fischhoff 1975, Woods and Cook 1999, Berlin 2000), and may not examine the fundamental causes. This can perpetuate the error-inducing system elements embedded in brittle and ineffective safety procedures (Cook and Woods 1994). A systems approach to safety benefits from prospective studies to identify existing process failures and their removal before they can accumulate to affect outcome (Carthey *et al.* 2001a, Vincent 2004). Prospective evaluation of human error in surgery has benefited from direct observation of error (e.g. de Leval *et al.* 2000, Way *et al.* 2003, Bann *et al.* 2004, Weinger *et al.* 2004a,b), but so far has failed to address adequately the systemic causes of failure. A system of surgery requires skilled surgeons, anaesthetists, nursing staff and other specialists, who must work together as a team. An effective process requires a patient who has undergone appropriate diagnostics, a set of well-rehearsed procedures that match the requirements of the patient and a range of equipment, drugs and blood products that must be appropriately organized in a workspace that supports the individuals (Cook and Woods 1996). Furthermore, surgery requires an organization and culture that supports the progress of the patient through their treatment and the activities of the team in the operating theatre (Kirklin *et al.* 1992). The aim of this study was to develop a prospective direct observation methodology for identifying weaknesses in the system of surgery.

Since errors and their causes may not always be directly observed (Lilford *et al.* 2003), there is a need to infer systemic deficiencies from undesirable events. After Reason (1990) and Helmreich (2000), a threat and error model was adapted from similar direct observation studies on the flight deck (Helmreich *et al.* 1999, Klinect *et al.* 1999). In this model, threats are elements of the system that provide the circumstances in which human errors can occur. Failure to compensate for threats leads to an error, and failure to mitigate that error increases the chance of further error. Threats therefore predispose errors, which may then accumulate or cascade to create harm. The surgical system was viewed as being composed of four types of threat: patient threats; task threats; environmental threats (which included equipment and resources); and culture and organizational threats (Vincent *et al.* 1998, 2004). It was important to distinguish between errors of technical skill or expertise (e.g. Way *et al.* 2003, Bann *et al.* 2004, Tang *et al.* 2004), which are formally taught and assessed in health care, and non-technical skills, such as teamwork and general cognitive skills (Helmreich and Schaefer 1994, Helmreich and Musson 2000, Fletcher *et al.* 2003), which are not. By providing a structured approach to the identification of system threats and human error from observations of undesirable events in the operating theatre, the method was developed to measure the incidence of different sources of failure within the system of surgery.

It has been argued previously (Carthey *et al.* 2001b) that cardiac surgery shares many properties with other safety-critical industries. This type of surgery was central to one of the most exhaustively investigated health-care catastrophes of recent years (Kennedy 2001, Keogh *et al.* 2004) and is particularly predisposed to errors because it features multiple specialties, close coupling of concurrent tasks, uncertainty, changing plans and high workload (Xiao *et al.* 1996, Carthey *et al.* 2000), in which paediatric cases are particularly susceptible (Proctor *et al.* 2003). Prospective direct observation analysis in this surgical domain had already offered strong evidence that small errors can influence outcome (de Leval *et al.* 2000). Consequently, paediatric cardiac surgery was again selected as a suitable surgical domain for study. Table 1 illustrates a typical paediatric cardiac procedure.

Table 1. Surgery to correct congenital heart defect. A brief description, in simple terms, of one type of operation to correct a congenital heart defect.

Key phases of surgery in the arterial switch operation

The arterial switch operation corrects an otherwise fatal congenital heart abnormality known as transposition of the great arteries, where the child is born with aortic and pulmonary arteries connected to the heart in the opposite way to a normal heart. In the operation, which takes between 5 and 7 h and is performed within the first 2 weeks of life, the two arteries are swapped to provide the anatomical correction.

1. The patient is anaesthetized in the anaesthetic room, which adjoins the operating theatre.
2. The patient is transferred to operating table in the operating theatre.
3. Once the patient is ready, the first incision is made.
4. The sternum is split and the ribs are spread.
5. Heparin is given to the patient. This increases the clotting time of the blood to allow cardio-pulmonary bypass.
6. Cannulae are inserted into the ascending aorta and the atrial appendage and attached to the bypass machine.
7. Cardio-pulmonary bypass is initiated and ventilation is switched off.
8. Patient is cooled to between 18°C and 28°C to protect against neurological damage.
9. Cross-clamp is applied to the aorta and cardioplegia (a potassium-based solution) is infused into the coronary arteries to prevent the contraction of the heart muscle during the operation. This is re-applied approximately every 20 min for the duration of the treatment.
10. The aorta and pulmonary artery are transected, the coronary arteries are mobilized from the aorta.
11. The aorta is stitched back to the great vessel arising from the left ventricle.
12. The coronary arteries are connected back to the new aorta.
13. The great artery arising from the right ventricle is reconstructed and stitched to the pulmonary artery.
14. If present, the ventricular septal defect is closed.
15. The cross-clamp is removed.
16. The patient is slowly warmed and the heart is observed to beat normally.
17. The patient is weaned from bypass.
18. Electrocardiography is used to assess the stability of the patient. An echocardiogram may be conducted to examine the success of the repair.
19. Protamine is introduced to the patient to reverse the effects of the heparin, and bleeding is controlled. Various drugs, drains and cardiac pacing may also be utilized to aid the recovery.
20. The chest is closed and the patient is transferred to the intensive care unit.

Following previous attempts to identify the system components of patient safety, most notably of Kaplan *et al.* (1998), Vincent *et al.* (1998) and Helmreich (2000), the aim was to develop a method to evaluate aspects system failure and to arrive at a mature understanding of surgical error. Of substantive interest were the range, frequency and types of failures that could be identified and whether there was evidence that minor failures could accumulate to form more serious events. Since errors are more likely when systemic demands are already high (Woods and Patterson 2004), it was hypothesized that high-risk cases would have more minor and major failures. A similar effect was expected in longer operations, since operative duration is closely related to operative risk and intra-operative complications (e.g. Mrowczynski *et al.* 2002, Nateghian *et al.* 2004, O'Brien *et al.* 2004). Ultimately, the plan was to apply the methodology to identify systems solutions for improvements in patient safety in paediatric cardiac surgery.

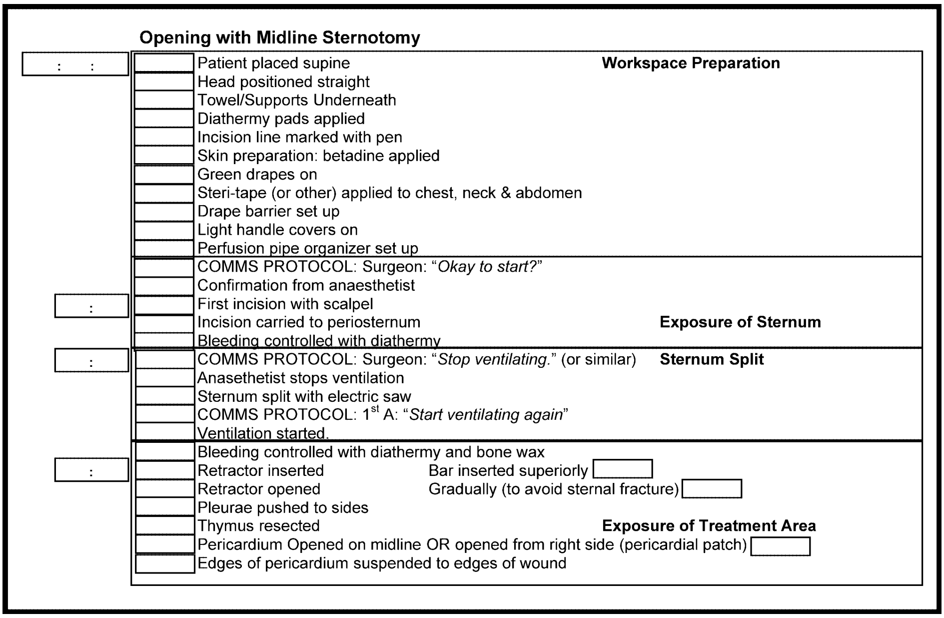
2. Method

An opportunity sample of 24 paediatric cardiac cases was studied between October 2003 and July 2004. All cases utilized midline sternotomy and cardio-pulmonary bypass (CPB), although there was considerable variation in the complexity and duration of the operations. A single observer was present during each case and utilized both implicit and explicit data collection techniques (Lilford *et al.* 2003). Observations were classified into major and minor failure categories, and minor failures were then classified according to one of 29 types. These minor failure types were systematically associated with threats and errors through a weighting technique described as the failure source model. This provided the method by which the systemic contribution to intra-operative failures and human errors could be measured. In all cases a video recording was made of the surgical field, the operating theatre team from two views and the video output from the anaesthetic workstation. Risk scores, explicitly based upon the procedure performed, were assigned to each case utilizing the RACHS-1 method (Jenkins *et al.* 2002). Operative duration (first incision to final closing suture) was also recorded in order to calculate threat and error rates, as well as offering a surrogate measure of intra-operative performance. CPB and deep hypothermic circulatory arrest times were also collected, but were not used since there were systematic problems with these measurements. Patient weight and the composition of the surgical team were used to provide qualitative detail to the case mix. Ethical approval was obtained from the local research ethics committee, and consent for participation was granted from the parents of the patients and all staff involved in the studies.

The observer was a human factors practitioner, experienced in observational methods, human performance measurement and in the evaluation of non-technical skills (Catchpole *et al.* 1999, 2001, 2004, Emery *et al.* 2001, Zon *et al.* 2004). This expertise was central to the assessment of the system, since it did not bias observation toward the technical skills of any individual specialist. Technical knowledge was obtained by studying text-book descriptions of the procedures and observing 38 similar operations prior to data collection. Technical observations were informally assessed by three surgeons and were frequently checked with other surgical, anaesthetic, perfusion and nursing experts. A second observer, who had prior experience of working in operating theatres, did not develop sufficient understanding of both surgery and human factors to make suitable observations (see also de Leval *et al.* 2000, Carthey, 2003).

From the preliminary work a task analysis and an explicit procedural-based error-capture checklist were produced. This checklist allowed structured error-capture observations using surgical task descriptions coupled with specific local practices and protocols and more general elements of safety, culture and teamwork. The checklist was modular, consisting of general and treatment-specific procedural sequences, but allowed for adaptations by the surgical team. For example, procedures for midline sternotomy, cannulation for CPB, initiation of CPB, wean from CPB and chest closure were similar across all operations, but some modules required procedure, patient or surgeon specific variations. As far as possible these alternatives were included in the modules. Other modules were specific to the planned surgical procedures. The checklist for midline sternotomy is shown in figure 1. From pilot studies it was apparent that this explicit error-capture technique would not be sufficient, so it was also necessary to make detailed notes of activities and communications. This produced descriptions of events in theatre and the time at which those events occurred. The subsequent analyses relied heavily on these implicit observations as they provided the richest source of observational data. Each video recording was watched by the observer in order to confirm, and provide further detail of, the in-theatre observations, but ethics constraints limited access to the video recording to the single observer.

Two levels of observation were used. Major failures were described as events that came close to an incident or accident (Klinect *et al.* 1999). Minor failures were identified where observed events were judged to have had small negative effects on the duration or difficulty of the operation, the risk to the patient or the demand for resources. Examples of minor failures can be found in table 2. Where major failures or unusual or complex



Opening with Midline Sternotomy

: :

☐ Patient placed supine **Workspace Preparation**
☐ Head positioned straight
☐ Towel/Supports Underneath
☐ Diathermy pads applied
☐ Incision line marked with pen
☐ Skin preparation: betadine applied
☐ Green drapes on
☐ Steri-tape (or other) applied to chest, neck & abdomen
☐ Drape barrier set up
☐ Light handle covers on
☐ Perfusion pipe organizer set up

☐ COMMS PROTOCOL: Surgeon: "*Okay to start?*"
☐ Confirmation from anaesthetist
: ☐ First incision with scalpel
☐ Incision carried to periosternum **Exposure of Sternum**
☐ Bleeding controlled with diathermy

: ☐ COMMS PROTOCOL: Surgeon: "*Stop ventilating.*" (or similar) **Sternum Split**
☐ Anasethetist stops ventilation
☐ Sternum split with electric saw
☐ COMMS PROTOCOL: 1st A: "*Start ventilating again*"
☐ Ventilation started.

☐ Bleeding controlled with diathermy and bone wax
: ☐ Retractor inserted Bar inserted superiorly ☐
☐ Retractor opened Gradually (to avoid sternal fracture) ☐
☐ Pleurae pushed to sides
☐ Thymus resected **Exposure of Treatment Area**
☐ Pericardium Opened on midline OR opened from right side (pericardial patch) ☐
☐ Edges of pericardium suspended to edges of wound

Figure 1. Error capture checklist module for midline sternotomy. This is an example of the most frequently used module from the explicit error capture checklist. The checklist for an arterial switch operation was composed of this and nine other similar modules.

Table 2. Descriptions and examples of minor failure types.

Failure	Description and example
Absence	Lack of personnel when required. Example: runner is absent when scrub nurse needs more suture material.
Cannulation difficulties	Problems encountered during arterial or venous cannulation. Example: arterial cannula is not cleanly inserted first time, and some blood loss results.
Coordination/ communication failure	Failures in task coordination and communication between individuals. Example: ventilation is not switched off before sternum is split with saw.
Decision-related surgical error	Surgeon fails to make the appropriate decision. Example: surgeon asks not to give the heparin when heparin is required immediately.
Distraction	Disturbance from external sources not related to current case during a critical period. Examples: (i) mobile phone rings in theatre; (ii) Another consultant enters theatre and distracts the surgeon.
Equipment/workspace management failure	Failures in the organization of workspace and equipment. Examples: (i) the defibrillator is unplugged when attempting to use it; (ii) infusion lines become caught on clothing.
Equipment configuration failure	Failure to set-up or operate equipment appropriately. Example: transducer is not zeroed correctly, leading to false readings.
Equipment failure	Interoperative equipment failure. Examples: (i) malfunctioning pacing lead; (ii) faulty transducer.
Expertise/skill failure	Failures associated with lack of expertise or skill, usually in trainees. Example: consultant surgeon captures error made by trainee surgeon.
External pressures	Requirements of the external organization that impact upon the operation. Example: team rushing to complete current case in order to start the next case.
External resource failure	Failures in elements of the external organization to provide equipment or human resources. Examples: (i) lack of blood products; (ii) cardiologist not available to conduct a post-cardio-pulmonary bypass (CPB) echo.
Fatigue	Clear indication that individuals in theatre are suffering from lack of sleep. Example: anaesthetist falling asleep during CPB.
Fault resolution failure	Failure to identify sources of problems. Example: anaesthetist and perfusionist unsure why pressure is low and have only minimal discussions.
Patient-sourced procedural difficulties	Features of the patient that make the planned procedure more challenging to carry out than would be expected from the pre-operative diagnosis. Example: LeCompte manoeuvre impossible in arterial switch operation due to anatomical restrictions.
Known problem	Failure to address known risk to operative success. Example: operating team know of serious limitation in current provision of resources but do not consider means of reducing occurrence or potential effects.
Perfusion difficulties: non-technical	Problems with management of CPB or cardioplegia, not sufficiently addressed. Example: the perfusionist cannot keep the surgical field clear of blood due to anaesthetic induced vasodilatation.

(*continued*)

Table 2. (*Continued*)

Failure	Description and example
Perfusion difficulties: technical	Difficulties with perfusion sufficiently discussed. Example: cause of low pressure identified as being due to aortic cannula obstruction.
Planning failure	Failure to anticipate or discuss future task requirements. Example: haematocrit target is agreed after modified ultrafiltration has started.
Pre-operative diagnosis failure	Failure to provide accurate diagnosis prior to operation. Example: undiagnosed intramural coronary arteries found upon anatomical inspection.
Procedure-related error	Procedural errors by surgeon, assistant surgeon, anaesthetist, perfusionist, scrub nurse or runner. Examples: (i) ventilation switched off before full-flow CPB has been achieved; (ii) scrub nurse is slow to give surgeon retractor; (iii) filtration finishes before haematocrit is checked.
Psychomotor error (general)	Handling errors. Example: retractor is dropped.
Psychomotor-related perfusion error	Technical manipulation errors by perfusionist. Example: cardioplegia pump is run too fast.
Psychomotor-related surgical error	Technical manipulation errors by surgeon. Examples: (i) incorrectly placed sutures are removed and suturing starts again; (ii) incision is not wide enough.
Resource management	Failures in the organization of available people or things in the operating theatre. Example: consultant leaves theatre to find cardiologist, unnecessarily removing senior member of the team.
Safety consciousness	Failures to observe basic elements of patient safety. Examples: (i) mask violations; (ii) chewing gum in theatre.
Team conflict	Team members have differing opinions or give conflicting commands, which are not resolved. Example: anaesthetist and surgeon give perfusionist conflicting commands.
Temperature control difficulties	Problems with management of patient temperature. Examples: (i) patient temperature overshoots to 37°; (ii) patient temperature falls unnoticed.
Unintended effects on patient	Problems arising with the patient, as a result of the treatment, which are unplanned. Example: considerable post-CPB bleeding requiring extra sutures.
Vigilance/awareness failure	Failures to notice immediately important aspects of the task or the patient. Example: (i) surgeon fails to spot bleeding sites; (ii) perfusionist unaware that surgeon has asked to begin rewarming.

minor failures occurred, brief reviews were conducted with the individuals involved within 24 h of the operation to ensure that the appropriate specialist information had been recorded. Following the completion of all 24 operations, the detailed event descriptions were used to group the minor failures into 29 different types that provided equivalence across all the studied procedures. Careful definitions for each of the minor failure types (table 2), and re-analysis following changes to the classification system, ensured consistency. Each of the major failures was also deconstructed into the minor failures from which it was formed. This allowed the description of events in terms of the number and types of failures that could be observed, allowed the identification of major failure sequences that were present and provided a consistent way in which to observe error-related behaviours.

Minor failures formed a level of quantifiable undesirable event observed in the operation that sometimes reflected individual errors, sometimes failures in group processes, sometimes threats outside theatre that affected events in theatre and sometimes combinations of all three. As most failures arose from an interaction between several threats and errors, a single classification for each observable failure was insufficient. Furthermore, sometimes these threats or errors were not directly observable. For example, a difficult cannulation arises because of the interaction between the task requirements for cannula sizing and insertion, the anatomy of the patient and the technical ability of the surgeon to compensate for the limitations of both. Following detailed considerations and further discussions with a range of medical and safety-related practitioners, each of the 29 minor failure types was associated with one or more threats and errors, according to a failure source model. After Reason (1990), Vincent *et al.* (1998, 2004) and Helmreich and Musson (2000), table 3 provides full definitions of the threat and error types and their association with different types of minor failure, which formed the failure source model. Patient threats and cultural/organizational threats were both associated with seven different minor failure types, task threats were associated with 16 different minor failure types and environmental threats were associated with four different minor failure types. Technical errors were associated with 11 different minor failure types, and non-technical errors were associated with 14 different types of minor failure. As it was not always possible to observe the specific source of the failure in every case, the model assumed that all potential sources had contributed in equal proportions. Applying this failure source model allowed the generation of a threat and error profile for each operation (Vincent *et al.* 2004), which was used in the final systems analyses.

3. Results

3.1. *Case mix*

The intra-operative reports, videos and subsequent failure, threat and error analyses provided a rich source of data. None of the operations studied was considered to be outside normal system function, in terms of the individuals who were involved in the operations, the procedures that were planned or the condition of the patient. Composition of the surgical teams varied considerably and although the same members were frequently involved, all members and roles were not identical. One operation was level 1 risk, thirteen were at level 2 risk, three were at level 3 risk, four were at level 4 risk and three were at level 6 risk. Operative duration was not normally distributed, with a median of 231 min, 5th percentile of 121 min, and 95th percentile of 366 min and interquartile range of 145 min. The age of the patients ranged from 2 d to 9 years and weights ranged from 2.5 kg to 19.3 kg. No patient died within 28 d of the operation and no failure was deemed worthy of further investigation, either by the individuals involved or by the hospital.

Table 3. Sources of failure. This defines the threat and error types, and shows how they were associated with minor failures in the failure source model.

Failure source	Component	Definition	Associated failure types
	Cultural and organizational threats	Threats that arise in theatre due to aspects of the organization or culture.	Absence; Distraction; External pressures; External resource failure; Fatigue; Known problem; Safety consciousness
Threats	Patient threats	Threats relating to patient anatomy and physiology beyond those specified pre-operatively.	Cannulation difficulties; Patient-sourced procedural difficulties; Perfusion difficulties: non-technical; Perfusion difficulties: technical; Pre-operative diagnosis failure; Temperature control difficulties; Unintended effects on patient
	Tasks threats	Threats arising from the processes, protocols or techniques employed to complete the operation, beyond those specified pre-operatively. They reflect unusually difficult process requirements.	Cannulation difficulties; Equipment/workspace management failure; Fault resolution failure; Patient-sourced procedural difficulties; Perfusion difficulties: non-technical; Perfusion difficulties: technical; Planning failure; Procedure-related error; Psychomotor-related perfusion error; Psychomotor-related surgical error; Pre-operative diagnosis failure; Temperature control difficulties; Unintended effects on patient
	Environmental threats	Threats that arise from deficiencies in equipment, workspace and resources (human and material).	Equipment/workspace management failure; Equipment configuration failure; Equipment failure; External resource failure
Errors	Technical errors	Human errors associated with knowledge, technical skill or expertise.	Cannulation difficulties; Decision-related surgical error; Equipment configuration failure; Fault resolution; Perfusion difficulties: non-technical; Perfusion difficulties: technical; Psychomotor error (general); Psychomotor-related perfusion error; Psychomotor-related surgical error; Temperature control difficulties; Expertise/skill failures
	Non-technical errors	Human errors associated with team working and general cognitive skills.	Coordination/communication failure; Decision-related surgical error; Equipment/workspace management failure; Fault resolution failure; Perfusion difficulties: non-technical; Planning failure; Procedure-related error; Resource management failure; Team conflict; Temperature control difficulties; Vigilance/awareness failure

3.2. *Minor and major failures*

In the 24 operations studied, a total of 366 minor failures were identified. Figure 2 shows the distribution of minor failures in the study, which varied between two and 34 in each operation, with a mean of 15.3 (SD 7.3). A two-tailed Spearman's rho correlation showed a moderate relationship between operative duration and the number of minor failures in an operation (rho = 0.647, n = 24, $p < 0.001$). Seven operations contained major failures that came close to an incident or accident. These can also been seen in figure 2 and are described in table 4. The operations where major failures occurred generally had more minor failures than those operations that did not feature any major failure. A Mann-Whitney U test between these two groups showed a significant difference between them (u = 14.0, n = 24, $p < 0.005$), although this difference disappeared when those minor failures were removed that were directly associated with the major failure. In terms of operative risk, the proportion of operations experiencing major failures increased in the higher risk operations. Grouping the minor failures into low risk (levels 1 and 2) and high risk (levels 3, 4 and 6) categories (Jenkins *et al.* 2002), a Mann-Whitney U test (u = 29.5, n = 24, $p < 0.05$) showed a significant difference between the numbers of minor failures found in each group. Thus, the number of minor failures and major failures encountered in each operation related both to risk and operative duration.

Figure 3 shows the mean number of observations per operation of each type of minor failure. The minor failure type of highest observed frequency – coordination (1.95 per operation) – related to problems either in the distribution of important information within the surgical team or to the timely execution of procedural sequences requiring interaction between individuals. Although process-related, and therefore not always of direct threat to the patient, this type of failure might have serious consequences at certain

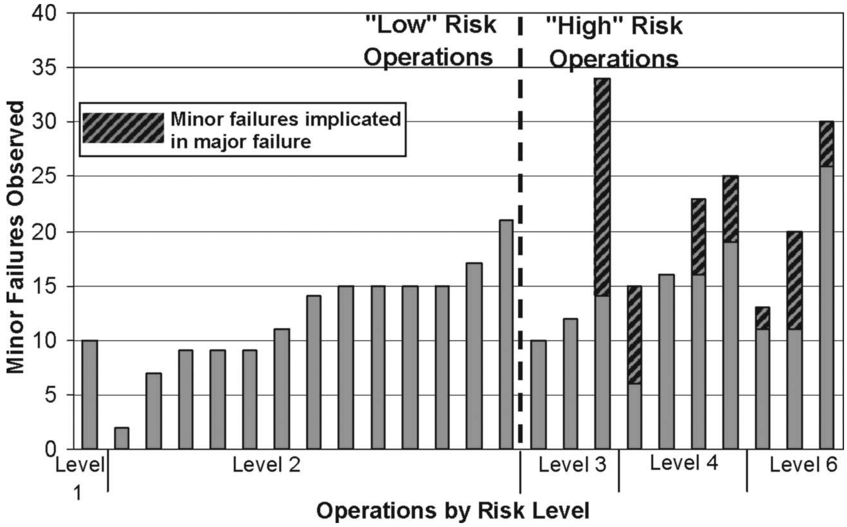


Figure 2. Minor failures by operation and risk level. Operations are organized on the y-axis by risk level (Jenkins *et al.* 2002), and then by increasing numbers of minor failures. Shaded areas indicate those minor failures sequences that were implicated in major failures. The 'low' and 'high' risk categories that were used in the analysis are also indicated here.

Table 4. Major failures and associated minor failures.*

Major failure	Associated minor failures
1. Mastoid strip causes compression of right coronary artery	Absence Equipment/workspace management × 2 Trainee expertise/skill failure Unplanned procedural affects on patient Vigilance/awareness failure
2. Ex-sanguination during post-bypass haemofiltering	Coordination/communication failure × 2 Planning failure Team conflict
3. Omission of key surgical step	Absence Coordination/communication failure × 2 Distraction Procedure-related surgical error Sub-optimal diagnosis Temperature control difficulties
4. Breakdown in teamwork	Coordination/communication failure × 2 External resource failure Procedure-related surgical error Procedure-related perfusion error Team conflict × 2 Temperature control difficulties Vigilance/awareness failure
5. Aortic homograft ruptured during redo midline sternotomy	Absence Cannulation difficulties Coordination/communication failure Decision-related surgical error Equipment failure × 2 Equipment configuration failure Equipment/workspace management failure × 2 External resource failure Patient-sourced procedural difficulties Planning failure Psychomotor-related surgical error × 2 Resource management failure Team conflicts × 2 Unplanned procedural affects on patient × 2
6. Incorrectly labelled homograft	External resource failure Known problem
7. Difficult management of activated clotting time	Absence × 2 Coordination/communication failure Equipment failure Patient-sourced procedural difficulties × 3 Unplanned procedural affects on patient Vigilance/awareness failure

*Associated minor failures have been organized alphabetically rather than chronologically.

points in the operation and was a feature of all but two major failures. Absences that had some form of negative effect on the procedure were also frequent (1.67 per operation), as were equipment problems, either in terms of a direct failure (such as non-serviceable instruments or malfunctioning equipment; 1.21 per operation) or in terms of difficulties in

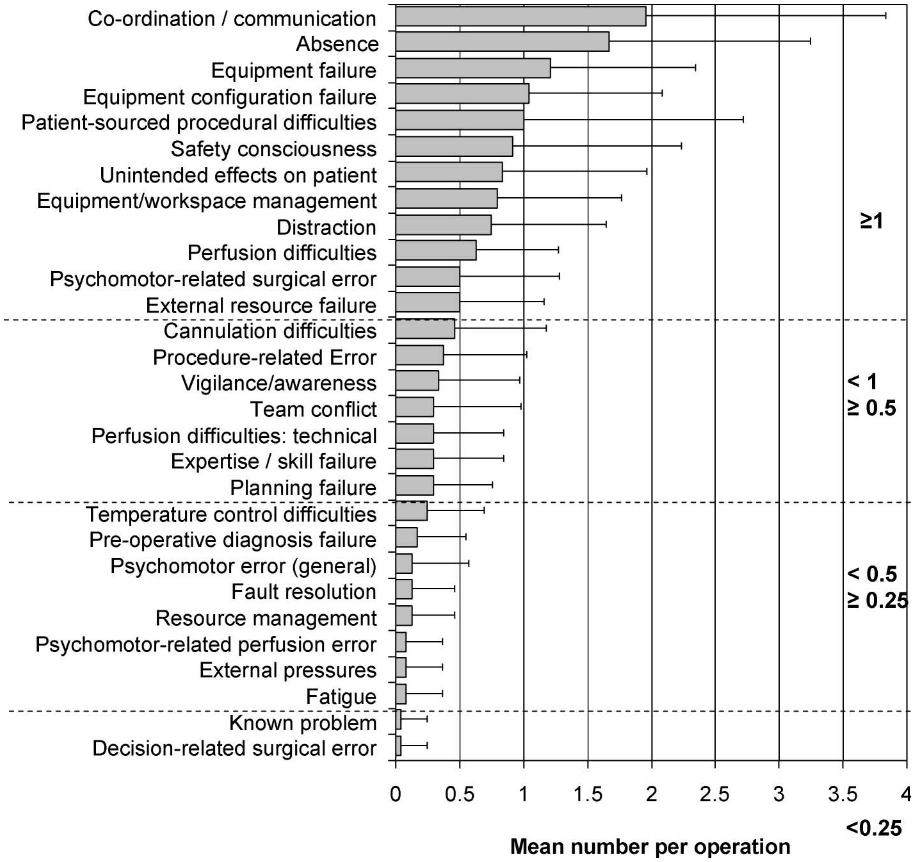


Figure 3. Mean rate per operation of minor failure types. Minor failure types are organized with the most frequent at the top, and least frequent at the bottom. Error bars show mean plus 1 SD.

the operation of equipment (1.04 per operation). Although this was non-critical equipment, the failure of which could usually be compensated for, it was often the same pieces of equipment that created repeated problems in different operations. As might be expected with this type of surgery, patient-related difficulties, usually anatomical in nature, appeared on average once per operation, requiring a more complicated surgical strategy and greater surgical skill.

Minor failures that appeared on average in a quarter of operations or more, but less than once per operation, were a mix of procedural, perfusion, skill, teamwork and cultural difficulties. On average, in most operations, failures were observed that suggested reduced safety consciousness (0.92 per operation), usually relating to mask discipline in theatre. The failure to control distractions was similarly related to culture (0.75 per operation). The patient reacted to the treatment in a way that complicated the procedure and created a greater challenge for the team on average every 0.83 operations. Perfusion management problems (0.29 per operation) arose through the tolerance of the patient to CPB, the CPB requirements for a given procedure or task and technical errors in the management or configuration of the cannulae, which were often difficult to insert

(0.46 per operation). Perfusion problems were more often than not compounded by problems in coordination between surgeon, anaesthetist, and perfusionist (0.625 per operation), which sometimes made it difficult to ascertain the precise nature of the problem. Control of patient temperature is a similarly shared task, but failures were considerably less frequent (0.25 per operation). Conflicts either in task or understanding occurred in nearly one-third of cases (0.29 per operation). Problems with the management of equipment and workspace – ensuring everything was in the right place when needed – were among the more frequent failures (0.79 per operation), as was the provision of equipment, supplies and personnel external to theatre (0.5 per operation) whilst the direct impact of planning failures was less apparent (0.29 per operation). Given the length and technical demands of the operation, surgical errors (0.5 per operation), procedural errors (0.37 per operation), vigilance and awareness (0.33 per operation) and other expertise or skill failures (0.29 per operation) were relatively infrequent, although they were also difficult to observe.

The minor failures, which appeared on average in less than one-quarter of cases, were also mixed, with failures to address a known problem and in decision making (both 0.04 per operation, one each observed) the least frequent, while evidence of fatigue, external pressures and perfusion control failures were only slightly more common (all 0.08 per operation, two each observed). Three observations each were noted for general psychomotor errors, fault resolution failures and resource management failures (0.125 per operation). Finally, four pre-operative diagnosis failures were observed (0.166 per operation), one of which was a particularly difficult undiagnosed intramural coronary artery pattern.

3.4. *Failure source model*

From the failure source model it was possible to examine the systemic sources of threat and error for the 366 minor failures. Cultural and organizational threats were the most frequently encountered single type of threat (associated with 85 minor failures or 23% of the total number of minor failures). Task threats were the most common, although not appearing as frequently on their own (33 minor failures or 9% of the total), they often appeared in combination with patient (87 minor failures or 24%) and environmental (19 minor failures or 5%) threats. Patient threats always appeared in conjunction with task threats. Environmental threats alone accounted for 54 minor failures (15%) and a further 12 minor failures (3%) were a combination of environmental and cultural/organizational threats. Finally, 76 minor failures (21%) suggested errors that had no clear threat associated with them.

The most numerous error was non-technical (100 minor failures or 27% of the total), but nearly half the failures did not feature any observable error by the team (174 minor failures or 48%). Technical error accounted for 67 minor failures (18%) and only a small proportion showed evidence of both technical and non-technical error (25 minor failures or 7%).

Using this information, the final analysis examined the individual instances of threats and errors associated with the minor failures. From the 366 minor failures, a total of 406 threat instances were identified, with a mean of 16.9 (SD 8.2) per operation. A total of 218 errors were identified, with a mean of 9.1 (SD 5.2) per operation. Operative duration correlated moderately well with the number of intra-operative threats (rho = 0.616, $p < 0.005$) and weakly with the number of intra-operative errors (rho = 0.410, $p < 0.05$). Task-related threats were judged to be the most numerous, with a total of 139 instances.

Cultural and organizational threats accounted for just under one-quarter of the total number of threats with 97 instances, with patient- and environment-related threats reflecting similar numbers of instances (87 and 85 respectively), each accounting for just over one-fifth of the total number of threats. In both high- and low-risk groups, task threats occurred at a higher rate than other types of threats, as can be seen in figure 4. There was little difference between the rate of threat occurrence in high- and low-risk operations. Of the errors observed in this study, 125 were non-technical and 92 were technical. Non-technical errors occurred at a slightly higher rate than technical errors (figure 5), although there was little difference between high- and low-risk operations.

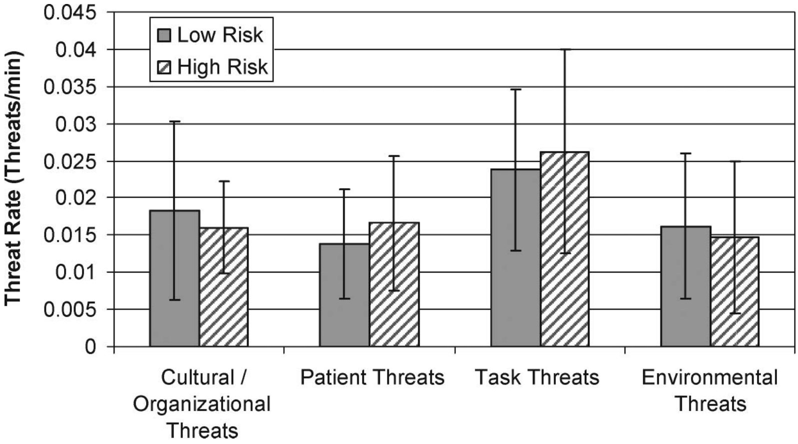


Figure 4. Threat rate, threat type and operative risk. The mean rate of each threat type over the 24 operations, grouped into high- and low-risk categories, is displayed. The vertical bars indicate the mean ± 1 SD.

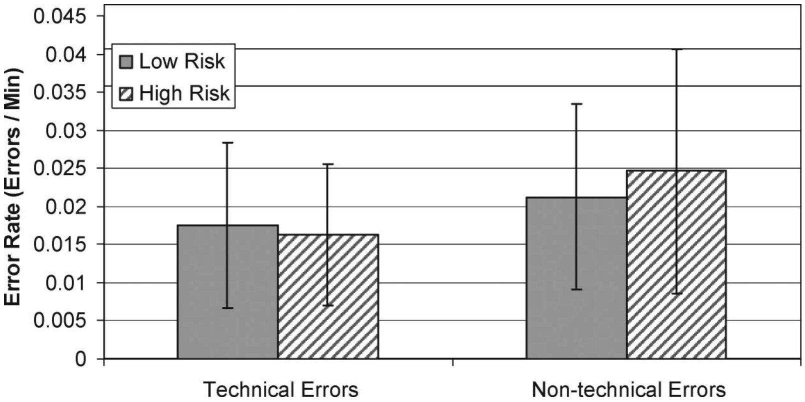


Figure 5. Error rate, error type, and operative risk. The mean rate of each error type over the 24 operations, grouped into high- and low-risk categories, is displayed. The vertical bars indicate the mean ± 1 SD.

4. Discussion

In this study, all the operations had a successful outcome, but minor failures that resulted in small increases to the duration or difficulty of the operation, risks to the patient or demands for resources were frequent and showed considerable variability in type and number between operations. Coordination and communication problems, equipment problems, elements of safety culture, patient-related problems and perfusion-related problems were most frequent, with a smaller number of skill, knowledge and decision-making failures. They derived from many different sources and were not considered to be important enough to warrant recording in any incident reporting or post-operative review mechanism. All the health-care professionals studied were highly skilled and suitable for the roles they filled. Since there was considerable variation in the composition of the surgical teams across the 24 operations, these failures largely reflect elements of the system, rather than the unique failings of individuals. By examining these events in more detail than has been attempted before, it is possible to suggest ways in which threats predispose human errors and how these can cascade to form more serious events.

Longer and more risky operations were likely to experience a greater number of minor failures than shorter and lower risk operations. Increasing demands on the team increase the chance for human error (e.g. Cook and Woods 1994), although since longer operations are usually higher risk, they may feature more failures simply because there is more time and opportunity. Operations where a high number of minor failures were observed also tended to contain a major failure. While it is possible that this arises because the observer was more likely to note minor failures in those operations containing major failures, it is the composition of the major failures that is most important. One major failure (table 4, item 6) occurred as a result of an unusual error outside theatre, but the remaining six major failures contained commonly occurring minor failures. The most serious major failure (table 4, item 5), a potentially catastrophic bleed, was triggered by a single event that is an acknowledged risk of that procedure (Follis *et al.* 1999) but was then compounded by a sequence of common minor failures occurring under considerable time pressure. This included the only observed decision-making error in the study, absences, team conflicts and equipment problems. The major failure that otherwise had the most impact on the patient interoperatively (table 4, item 1) arose through a window of opportunity 2 h before the sequence of events themselves. The patient's anatomy, which required an unusual surgical approach, resulted in more bleeding than normal in the post-bypass period. A failure in the management of the bleeding, which featured absence, vigilance and expertise failures, allowed an overlooked swab to prevent blood flow to the heart and led to an increasingly unstable patient. Despite excellent coordination, the team found it difficult to identify what was happening because the situation was unusual.

In all cases the team mitigated the effects of the failures and prevented adverse patient outcomes, but during the analysis of these data it became apparent that a similar patient not involved in this study had experienced a serious event in theatre that had adversely affected outcome. Discussions with the surgeon revealed that three of the five failures observed most frequently in these studies (equipment configuration, equipment failure and coordination and communication) directly contributed to this event. Although the resultant complication was specific to that particular type of operation, the causative errors were far from unique to the case, to the particular type of operation or to the group of individuals involved on that day. It was the accumulation of errors predisposed by properties of the system, rather than the isolated failings of individuals, that had led to an undesirable outcome.

Frequently occurring and apparently innocuous failures can accumulate in specific circumstances to bring about an event with adverse impact. Either a sequence of small failures can build to create something more dangerous, or a single, more serious mistake is exacerbated by a sequence of smaller failures. Since both can work together, the propagation of error from minor isolated failures to major failure sequences is a combination of cumulative effect and critical coincidences. Presumably, these common failures were allowed to recur because they are considered, in isolation, to be innocuous. However, the evidence presented here suggests that when co-incident with other types of failure, especially in higher-risk operations, they can be highly potent. This also demonstrates the misleading effect that can be created by weighting failure types for severity. A failure that is innocuous in one situation can be critical in another. This may explain why the causes of failures resulting in mortality can remain undetected during a large number of seemingly isolated events (Kennedy 2001) and large numbers of cases (Vincent *et al.* 2001). If the instances or accumulation of frequently occurring failures could be avoided, more successful outcomes would be achieved.

Through the deconstruction of observations of failures into threats and errors, previous attempts (Kaplan *et al.* 1998, Vincent *et al.* 1998, Helmreich 2000, Helmreich and Musson 2000) have been followed to study systemic threats to patient safety. Nearly half the observed failures did not relate to an error in the operating theatre. This suggests that there was a high prevalence of threats in the system prior to the operation, for which the operating team successfully compensated during the operation. The view that operating theatre teams should be 'able to cope with anything' (Carthey *et al.* 2000) and the tendency instead to develop practical solutions rather than report failures (Tucker *et al.* 2002, Tucker 2004) results in their perpetuation. There are three approaches to the reduction of adverse outcomes in surgery: ideally, the avoidance of failure by the resolution of systemic properties that predispose human error (e.g. Dekker 2002); the early capture of errors before they can accumulate to generate a more dangerous situation (e.g. Gaba 1989, Helmreich 2000); and the early mitigation or compensation for major failures before they can impact on patient mortality and morbidity (e.g. de Leval *et al.* 2000). On an industry-wide scale, this study provides data that can be used to inform and validate predictive human reliability models (e.g. Joice *et al.* 1998, Yu *et al.* 1999, Cuschieri 2000, Inoue and Koizumi 2004, Tang *et al.* 2004), in order to understand how different elements of the system can contribute to interoperative risk, and thus to mortality and morbidity, across the health-care system. Since the present study suggests that a detailed analysis of the task, upon which many of these methods are based, may not suit the assessment of errors in surgery, a different approach can now be offered. Formal validation of the current threat, error and failure model would allow the weighing of these elements in relation to a range of outcome measures and thus provide a predictive means to assess the impact of particular solutions on patient safety and surgical quality.

Task threats were the most salient source of failure in spite of the fact that only one of the most frequently occurring major failure types was associated with task threats. This illustrates the importance of adopting a threat and error analysis methodology, which assesses the sources of intra-operative failure, rather than just the failures. Task threats underlie many different types of minor failure and were often co-incident with patient threats. Patient threats never occurred without a corresponding task threat because unexpectedly difficult or unusual patients require the completion of extra tasks, which introduce their own additional risks. Surgical teams must frequently trade transient increases in risk for benefits in the longer term. Task threats reflect this option to increase risk and the observed failures are where the team had not directly compensated for the corresponding increase in difficulty. Cannula selection is an excellent example of this, where a wider aortic cannula bore will result in better perfusion during CPB, but will increase the difficulty of inserting the cannula into the aorta, providing a task threat during cannulation. Greater understanding of failures in risk/benefit trade-offs will help to enhance the certainty of these decisions and offer ongoing improvements to medical practice beyond the traditional specialist technical developments (e.g. Reitz 2004). In contrast to task and patient threats, environmental threats relate only to a small number of frequently recurring failures. Addressing these failures through improvements in design and maintenance of equipment may therefore be especially worthwhile (Cooper *et al.* 1978, Dain 2002, Ward and Clarkson 2004), even before the development of technologies that support the surgical process (Morgan *et al.* 2004, Suematsu and del Nido 2004).

Organizational and cultural threats were generally independent, being unrelated to, but at least as frequent as, other threat types. These threats, which were generally related to discipline or nosocomial infection risks, could be addressed through improved management practices, for example, by ensuring that masks are worn at all times in the operating theatre, and that team members have no reason to be absent from theatre during an operation (see Kennedy 2001).

Given that the individuals studied were generally extremely experienced and competent, the technical errors observed here are not expected to be the result of technical deficiencies in any specialty. Certainly, the management of trainees in the operating theatre might warrant further consideration, but there is also an argument for partial cross-training of specialist skills in the operating theatre (Frommater *et al.* 1995, Null and Bonser 1997, Cannon-Bowers *et al.* 1998, Eaves and Flagg 2001), particularly for improved management of perfusion. Perfusion can be seen as the sole responsibility of the perfusionist, but since it affects, and is dependent upon, the actions of the surgeon and the anaesthetist (Carthey *et al.* 2000), it needs to be considered across specialties (Kennedy 2001). Improving understanding between specialties could reduce the perfusion-related failures and may also reduce blame and improve responses when things go wrong (Veith 1998). A breakdown in this relationship was directly responsible for two major failures (table 4, items 2 and 4). Clearly, shared tasks are also dependent upon non-technical skills, which accounted for the majority of the human errors observed here. These skills are neither formally taught, nor included in competence assessments. Training would be beneficial in improving the knowledge and coordination of effort among surgeons, anaesthetists, perfusionists and nursing staff (de Leval *et al.* 2000, Helmreich 2000, Fletcher *et al.* 2002, Carthey *et al.* 2003, Healey *et al.* 2004). A consequence of this training would be to provide surgical teams with an enhanced ability to identify sources of recurrent failure and develop strategies for their management and future reduction through pre-operative briefings and post-operative debriefings. Since these types of preparation and review activities are extremely rare in surgery, it would almost certainly help to eliminate many recurrent minor failures (Hofer and Hayward 2002). This study provides a framework for such an endeavour, and a checklist based on the failures identified here could aid theatre teams in anticipation, assessment and reduction of failures.

This study demonstrates the potential benefit of comprehensive data on intra-operative failures. It is, however, subject to fundamental difficulties with the measurement and classification of errors obtained from observations of events (Battles and Lilford 2003, Lilford *et al.* 2003). The quantification of failures may always be imprecise, given that certain failures (such as pre-operative diagnostic failures) can have longer lasting effects than other, more transient failures (such as a dropped scalpel), while weighting for severity, as has already been argued, can also be misleading. While some technical errors will not have been captured by the expert observer, this method enabled the identification of failures that would have otherwise been accepted as normal by medically trained participants (Carthey 2003). Bias away from individual technical skills was appropriate for a study that sought to avoid blame and examine systemic properties, and in the measurement of problems between specialties this approach is preferable to observations biased toward any single specialty. This supports the view that observation by non-medically trained observers is not only valid, but is indeed a vital component of the understanding and reduction of medical errors.

The difficulty with obtaining intra-observer assessments has been a limitation of previous work in this type of surgery (de Leval *et al.* 2000, Carthey 2003) and, as a result, judging the reliability of the methodology is difficult. Operating teams are often reliant upon implicit procedures or concepts of good practice, which change from team to team and are consequently highly variable. The largely unfruitful attempts to define processes and error through task analysis reflect this and suggests that observation methods used in health care cannot be directly transferred from aviation or other highly procedural industries. The definition of minor failures allowed flexibility in the observation of undesirable events, but required informed judgement by the observer, which means reliability might be difficult to achieve without reducing validity. More recent work utilizing the present method with dual observers in orthopaedic surgery (Catchpole *et al.* 2005) suggests that the present definition of minor failures allows the reliable determination of more or less failure-prone operations. Future work will develop the minor failure definitions into an explicit checklist and will examine the reliability of minor failure classification to improve the value of this tool. With an improved approach it would be expected that the most frequently observed failures would still be frequent and, given the large number of failures studied, any considerable change in the results of the threat and error analysis would not be anticipated. The purpose of providing transparency, both in the definitions used and the failure source model adopted for the second stage of assessment, is to allow scrutiny of this method and re-assessment of the data where other models may be considered more appropriate in the future. This approach therefore complements the continuing development of methodologies for the direct observation of human error in medicine (Xiao *et al.* 1996, de Leval *et al.* 2000, Mackenzie and Xiao 2003, Mackenzie *et al.* 2003, Weinger *et al.* 2003, 2004a,b, Healey *et al.* 2004).

The evidence offered by this study supports the application of a threat and error assessment approach to the prospective identification of threats to patient safety in surgery. Adverse events in surgery are likely to be associated with a number of recurring and prospectively identifiable co-incident and cumulative human errors. These are predisposed by threats residing in the system, rather than individual incompetence or negligence. Reducing these recurrent failures would lead to increases in patient safety, and a range of strategies have been suggested. It is reasonable to think that the generic findings of this study are applicable to other surgical centres and the further development and deployment of this approach to improve surgical standards and enhance patient safety is recommended.

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