

## Surgical safety can be improved through better understanding of incidents reported to a national database

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## OVERVIEW

The expansion in surgery has been made possible through extraordinary technological advances delivering considerable benefits for patients. However, the increased complexity of procedures and processes has made it more difficult to deliver reliable and safer care.

The number of patients who receive precisely the treatment expected is surprisingly low, whereas the number of patients who experience some consequential error is surprisingly high, with a total rate of fatal adverse events estimated at one per 10,000.

In the UK, the creation of the National Patient Safety Agency (NPSA), and the subsequent development of the Reporting and Learning System (RLS), a database of patient safety incidents (PSIs) is allowing a better understanding of how and why these incidents occur.

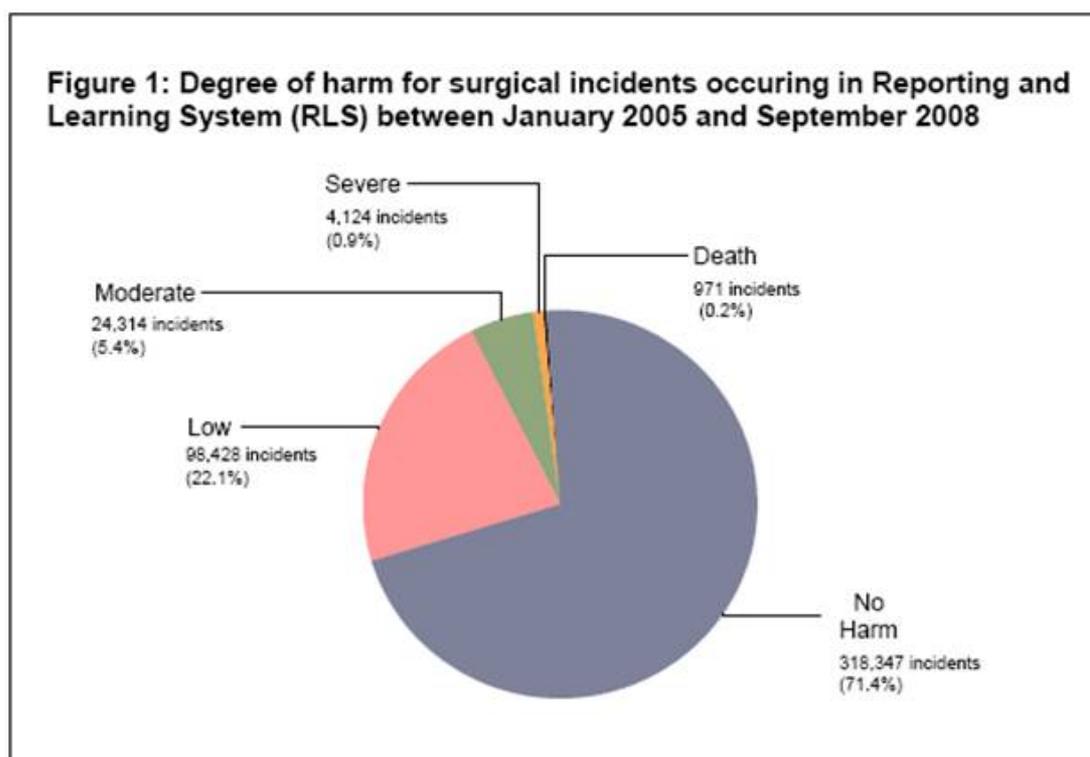
In operation since 2003, the RLS database is now the largest of its kind in the world, already having received over three million reports of episodes of care that could have resulted in or did result in iatrogenic harm.

## Methods

We conducted a review of the RLS database from the initial perspective that human error is systemically predisposed, and that the identification of solutions to surgical safety might be found by examining incident reports. The intention was to identify key performance shaping factors or solutions.

## Results

The analysis of the RLS database for incidents reported between 1 January 2005 and 30 September 2008 gave a useful insight into the epidemiology of PSIs as shown in Figure 1.



The vast majority of incidents related to patient accidents [140,530 (31 per cent)], treatment [58,835 (13 per cent)], infrastructure problems [38,127(9 per cent)], medication [38,093 (9 per cent)] and documentation [35,601(8 per cent)].

Considering the surgical settings where the PSIs occurred, the largest proportion was in trauma and orthopaedics (145,743/ 44,6184; 32.6 per cent) followed by general surgery (132,388/446,184; 29.7 per cent). Urology, ophthalmology, ENT, neurosurgery and cardiac surgery reported 22,649 (5.0 per cent), 15,311 (3.4 per cent), 15,086 (3.3 per cent), 11,119 (2.4 per cent) and 10,264 (2.3 per cent), incidents respectively.

## Discussion

Solutions to safety can be generally of four types:

1. Technological solutions: which allow error to be reduced either by replacing unreliable humans with reliable equipment, or through better human–technology interfaces.
2. Environmental control: either through the reduction in unwanted stimuli (such as distractions) or through the design of workspaces to enhance human ability.
3. Redesign of systems of work: either through simplification, clarification and standardisation of roles and tasks or by providing additional barriers and checks that will capture error.
4. Improved training and selection of humans involved.

Whereas we appreciate that the RLS database has its limitations due to its voluntary self-reporting nature, we believe increased reporting by clinicians will result in useful information that will improve national learning and mitigate against surgical errors. In due course, this database could act as a barometer for surgical safety.

## INTRODUCTION

This review was conducted to examine a range of issues associated with safety in surgery. Its aim was to collate and understand the available evidence on rates, causes, outcomes and solutions to inadvertent harm to patients under surgical care. The review included searching and analysing relevant literature as well as correlating of incident data from the National Patient Safety Agency (NPSA) Reporting and Learning System (RLS) with the published data.

The objective of the review was to take a broad approach to a complex problem, and so it is not intended to be prescriptive. Moreover, it is not based on any particular theoretical perspective aside from the underlying theme that human error is systemically predisposed, and that solutions to surgical safety might be identified by examining incident reports and studies of performance shaping factors and solutions that have either already been mooted or attempted.

Given the breadth of information available (see Appendix), firstly, a representative sample of papers was reviewed to allow more detailed consideration of relevant data. Only methodical studies directly addressing safety in surgery were examined and those on basic behavioural science, hospital management, other industries, methodological critique or 'opinion' papers were not included, except to provide occasional context. In some cases, where more detail was required, related papers were examined and recurring themes, where apparent, were identified. Finally, to ensure relevance to the present healthcare safety climate, the review focused on papers published within the past five years (2003 - 2008). Thus, while this review cannot be considered as truly comprehensive, it does reflect a cross-section of the current level of knowledge regarding safety in surgery.

Secondly, data from the RLS was correlated with those found in the surgical literature. The RLS is currently the largest repository of patient safety incidents (PSIs) in the world. This database, which was established in 2003, now receives more than 900,000 incident reports annually from healthcare staff throughout the National Health Service (NHS) in England and Wales. In addition, more recently, patients and the general public have also started to contribute to this database. Analyses of the 2.7 million reports (up to end of 2008) are being used to help formulate solutions for identified problems and inform important national policy decisions (NPSA 2008).

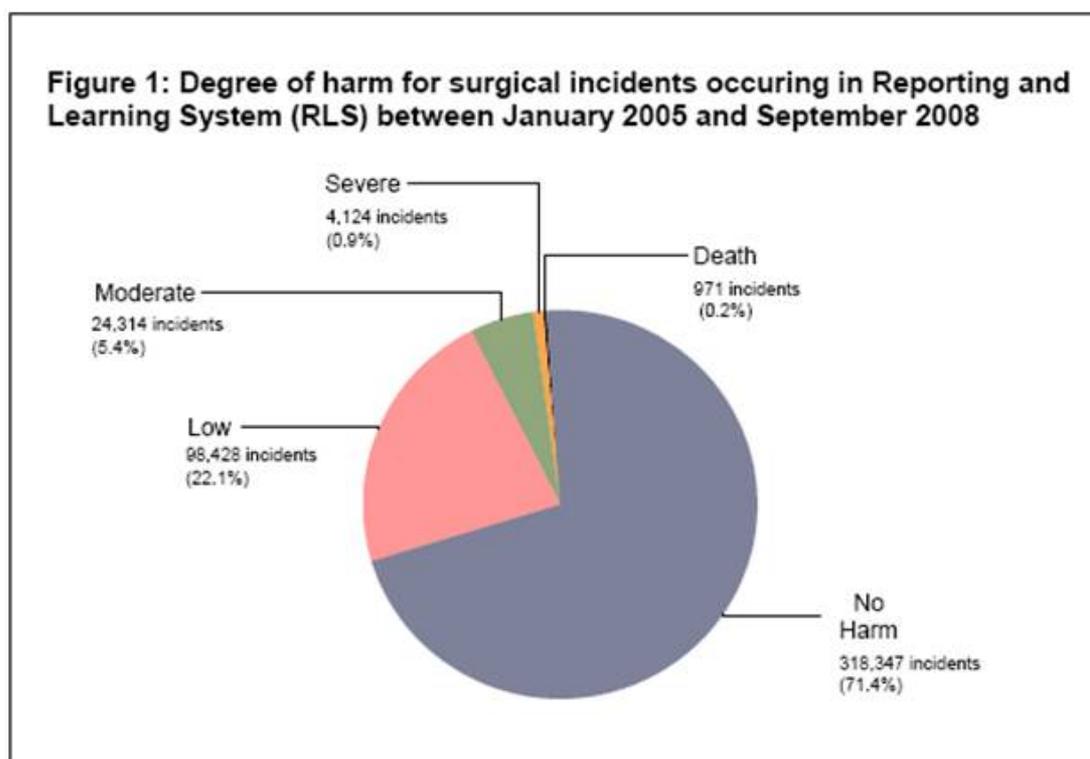
## PATIENT SAFETY INCIDENTS IN SURGERY

To allow meaningful comparison with findings from the RLS, a primary goal of the review was to identify the incidence and types of harm reported in surgical care. A series of retrospective case notes reviews carried out in the USA (Brennan & Leape 1991; Leape et al. 1991), Australia (Wilson et al. 1995), the UK (Vincent, Neale, & Woloshynowych 2001), and Spain (Andrés et al. 2006) provided us a basic understanding of the rates and incidence of harm in patient care. Despite some disparity in absolute rates due to methodological differences (Thomas et al. 2000), these papers suggest an injury rate of between three per cent and 16 per cent per year.

While designing an approach to identify the causes of and to reduce injury to patients, there are two important considerations to bear in mind (Runciman et al. 2000): first that the range of causes can be enormous, and so the study of adverse events should be conducted with large data sets; and second, that it is important to focus on minor problems as well as the more serious ones. Runciman et al. (2000) found that delays in the treatment of ischemic heart disease are serious both from mortality and morbidity points of view, whereas pain and restricted movement following back surgery result in the next highest level of disability (even though this is not a mortality problem). Indeed, delay in treatment is a frequent feature in many reports, suggesting that there may be a common mechanism for many different aspects of patient harm. The Spanish study (Andrés et al. 2006) found that a quarter of the eight to ten per cent of patients experiencing an adverse event did so because of technical problems in a procedure. As with many similar studies, approximately 15 per cent of the incidents led to serious injury, and another 40 per cent to moderate harm.

### Incidence and types of harm reported in surgical care

In a six-month period in one US surgical centre, the **death rate due to error** was one in 270 (0.4 per cent), of which 65 per cent (12.6 per cent of all deaths) were deemed preventable (Calland et al. 2002). However, the authors did not consider causality in detail. Similar results emerged from the RLS database for all PSIs related to the field of surgery. Between 1 January 2005 and 30 September 2008, 446,184 incidents with varying degrees of harm were reported (Figure 1).

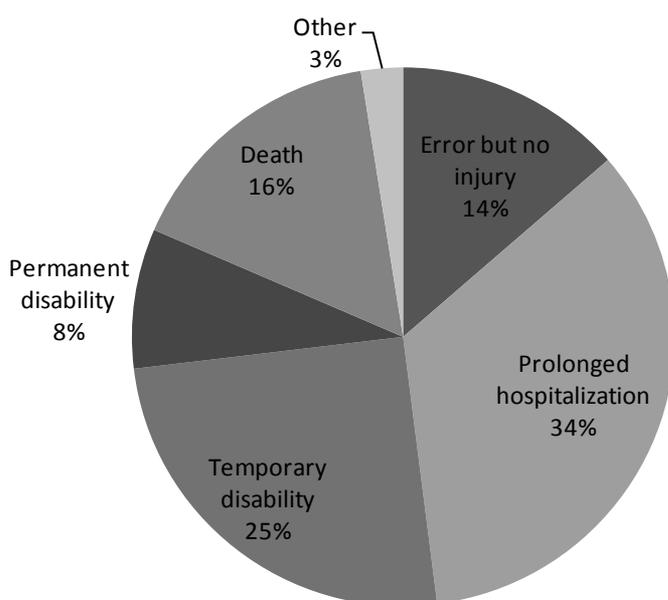


These results must be interpreted with caution as the absolute value in the categories 'severe' and 'death' were 5,095 incidents.

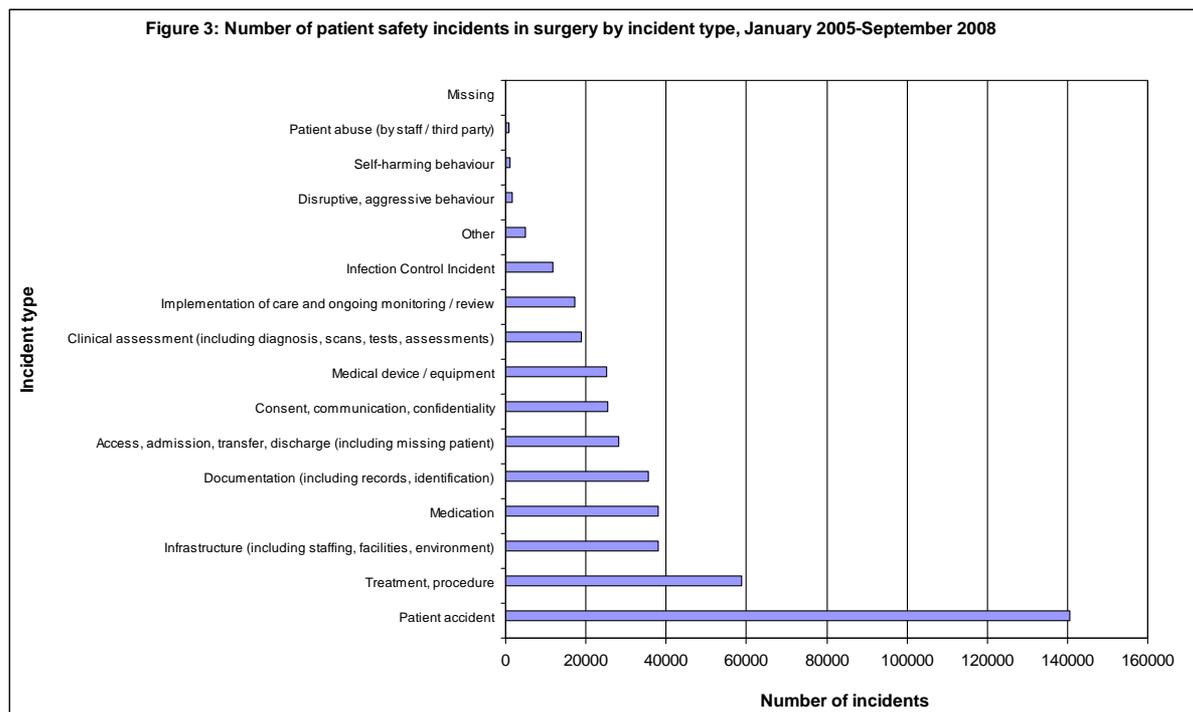
Chappy (2006) found that the three **most common types of reported incidents** were incorrect counts, equipment malfunction and medication errors. There were considerable differences between providers with regard to the types of incident reported. Choy (2006) found that incident reports relating to cardiac arrests in the operating theatre were more frequent among patients already suffering from cardiovascular problems, and presenting for emergency operations. Although this suggests that events are more likely (at least to be reported) in complex, emergency surgery in already ill patients, it may be due in part to the phenomenon that reporting of incidents is more likely in such situations. On assessing incidents discussed in mortality and morbidity meetings, El Dawlatly et al. (2004) also found that most of these were reported in patients in a poor condition undergoing emergency surgery. Approximately a third of incidents were related to circulatory events and another third were related to respiratory events. Technical problems were responsible in one-fifth of cases, and 62 per cent were attributed to human error or poor communication. These factors were also found to have a major role in incidents reported from a Saudi hospital system (Qadir et al. 1998), although only 13 per cent led to a negative outcome. However, Qadir et al state that there are could be some role of blame attribution as they found that 'irresponsible behaviour' was among the most frequently reported human error. The limitations of such a perspective become more apparent on examining more evidence, which revealed the complexity of behaviour in surgery.

In a more recent study, Fabri & Zayas-Castro (2008) investigated the link between **complications and error** in 9,830 surgical procedures. Major complications occurred in 3.4 per cent of patients; errors occurred in four in five cases with complications and had the major part to play in three-quarters of the complications. In other words, of 322 complications, about 60 per cent were predominantly due to human errors. This supports the view that, if such errors can be addressed, about half of surgical complications could be avoided (Leape et al. 1991; Vincent, Neale, & Woloshynowych 2001). The errors were related to surgical technique (63.5 per cent), judgement (29.6 per cent), inattention to detail (29.3 per cent) and incomplete understanding (22.7 per cent). In contrast to other studies, system errors (2 per cent) and communication errors (2 per cent) were infrequently identified. The distribution of the types of injury in this study is shown in Figure 2.

**Figure 2: Distribution of injury (Fabri & Zayas-Castro 2008)**



We then compared the topography of PSIs in the RLS database to that found in the surgical literature. The vast majority of PSIs related to patient accidents [140,530 (31 per cent)], treatment [58,835 (13 per cent)], infrastructure [38,127(9 per cent)], medication [38,093 (9 per cent)] and documentation [35,601(8 per cent)], as shown in Figure 3. A breakdown of these categories is given in the *high-level surgical overview* (Figure 3).



### PSIs in different surgical settings

In a review of 310 clinical risk incidents reports made by staff on a **labour ward** of a district general hospital in the period between 1996 and 2000, Lakasing and Spencer (2002) found care management problems occurred in one in every 111 deliveries. The main human issues related to interpretation of fetal monitoring, poor operative technique and non-standard practice/poor clinical judgement. The attributed system-based problems included insufficient staff numbers, ineffective teamwork and problems with equipment maintenance.

In Thailand, Charuluxananan et al. (2008) found that the surgical specialties with a high risk of incidents were **neurosurgery**, **otorhino-laryngology**, **urology**, and **cardiac surgery**, presumably in part because some of these specialties undertake the most complex and high-risk operations. However, in this study, the cause and effect of the errors was somewhat mixed, with clinical presentations (arrhythmia, desaturation and death within 24 hours) accounting for nearly two-thirds of the incidents, and process problems (difficult intubation, equipment and drug error) account for another 15 per cent. The factors considered as the causes of the errors were inexperience, lack of vigilance, inadequate pre-anaesthetic evaluation, inappropriate decisions, emergency condition, haste, inadequate supervision, and ineffective communication.

In another surgical setting [US **clinics** ('in-office' surgery)] over half the deaths and complications were associated with cosmetic procedures in otherwise healthy patients (Coldiron et al. 2005; Coldiron, Healy, & Bene 2008). Although a range of other organisational and professional factors were also involved, this analysis implied that the use of general anaesthesia was to blame, and local anaesthesia (where there were no deaths) was recommended. This raised the issue that, although anaesthetic adverse events are often considered independently from those associated with surgical care, there is clearly a substantial cross-over, both in terms of outcome and the root cause. Indeed,

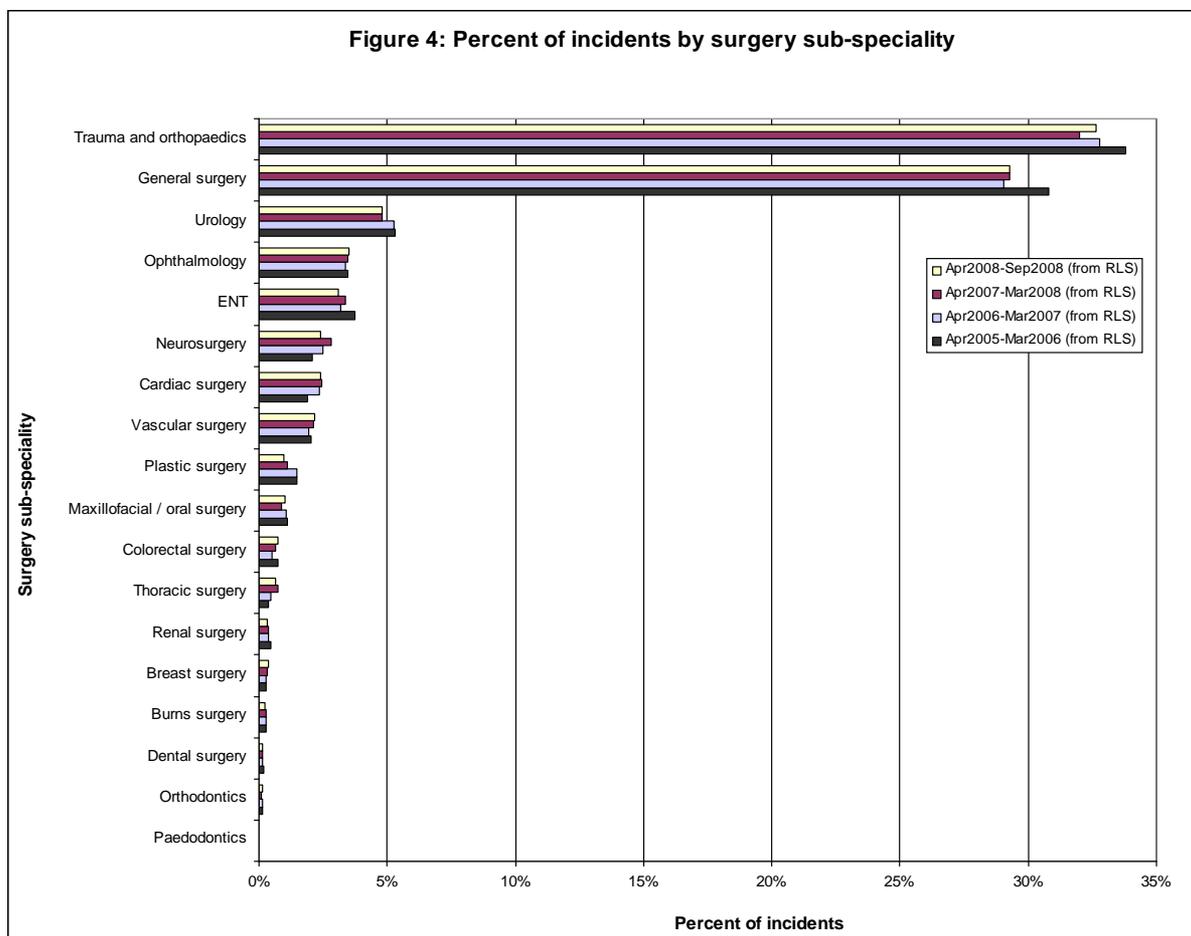
the understanding of error and the reporting culture (particularly in Australia) in anaesthesia is more advanced than in most surgical disciplines. Consequently, for this review, we examined a number of articles specifically associated with anaesthesia in surgery.

### Role of anaesthesia in PSIs in surgery

Grant et al. (2008) used an automatic system based on physiological measures for detecting potential adverse events in **anaesthesia** and found an overall adverse event incidence of 3.3 per cent; the levels of harm were not given.

In an older study (Short et al. 1993), human error was a factor in 80 per cent of incidents, with problems often being associated with inadequate checking of equipment such as airways, breathing systems, and drug administration. Half of the incidents were recognised by the anaesthetists themselves, and only a third by technological means. This poses a problem: on the one hand, although improvement in vigilance may be important, a system that relies on fallible human abilities for safety will remain vulnerable; on the other hand, technology too may not provide a sufficient safety mechanism.

Analysis of reports from the RLS database (1 January 2005 to 30 September 2008) revealed that the largest proportion of PSIs occurred in trauma and orthopaedics (145,743/446,184; 32.6 per cent), followed by general surgery (132,388/446,184; 29.7 per cent). Urology, ophthalmology, ENT, neurosurgery and cardiac surgery reported 22,649 (5.0 per cent), 15,311 (3.4 per cent), 15, 086 (3.3 per cent), 11,119 (2.4 per cent) and 10, 264 (2.3 per cent) incidents, respectively (Figure 4).



A series of papers on the first 2,000 incidents reported to the Australian Anaesthetic Incident Reporting System (AIMS) examined a number of specific complications. **Pre-operative incidents** (Ludbrook et al. 1993), which were found in 35 reports (1.75 per cent of all incidents), led to significant delays in operating lists, and cancellation of surgery in one-third of those. The causes cited were inadequate coordination between surgical and anaesthetic staff in patient preparation, problems with pre-medication drugs, and incorrect patient identification.

There were 19 cases (0.95 per cent of incidents) of **air embolisms** (Williamson et al. 1993), which were mostly caused by air entering via the surgical field. There was a suggestion of influence of the type of operation, as 47 per cent of the cases occurred during head and neck surgery. A range of monitoring equipment was examined, and capnography, invasive blood pressure monitoring and pulse oximetry were found to be important in identification and rectification of errors.

**Ventilation problems** were found in 317 (15.8 per cent) of the 2,000 incidents (Russell et al. 1993), with complete failure to ventilate in 143 incidents. The most frequent immediate cause was disconnection (47 per cent), which, in one-third of the cases, was associated with interference from a third party, and also was frequently associated with surgery on the head and neck. Alarms failed to warn about the disconnection in 12 incidents. Leaks affecting ventilation were reported in 129 incidents and misconnections occurred in 36 incidents. The authors recommended having protocols for checking and monitoring for failure of ventilation, and, interestingly, for examining the safety of **induction room use** – anaesthetic machine checks failed more frequently when carried out in an induction room than when a patient was anaesthetised on the table. There are some similarities between the analysis of ventilation problems and a later consideration of **accidental bronchial intubation** (McCoy, Russell, & Webb 1997), which accounted for 154 (3.7 per cent) of 3,947 AIMS reports. One-third of cases were associated with head or neck surgery, and a third party was implicated in 36 (23.4 per cent) cases. Virtually all were considered preventable. Major morbidity occurred in three cases and unplanned intensive care admission was required in another five cases.

These above studies together presented the most consistent use of incident reports for understanding surgical safety and seem an excellent example of how data of this type can be used to enhance professional practice. However, several caveats must be placed on the findings. For example, the finding that embolism, ventilation and intubation incidents occurred more frequently in head and neck surgery may be because there are predisposing factors in this specialty or simply because the propensity to report these errors in head and neck surgery is higher. Moreover, these studies only evaluated errors related to anaesthesia, and were carried out over 15 years ago. In a more recent study (Raksakietisak et al. 2002), **desaturation** (where oxygen saturation was below 90 per cent for more than three minutes) was found in about 270 patients, although in this study the error was more frequent among elective patients (1 in 243) than among emergency patients (1 in 714 patients). The causes were airway obstruction, hypoventilation, endotracheal tube problems, aspiration, atelectasis and pulmonary oedema.

The management of **perfusion** in procedures requiring cardio-pulmonary bypass (CPB) is a particularly interesting area. It is a safety-critical process conducted in high-risk operations with very sick patients, and requires close coupling of technology with the healthcare team and the procedure for success. Several studies have examined incident reports related to the process of perfusion. In France (Charriere et al. 2007) a questionnaire study that included 57 centres found one incident report for every 198 CPB runs with one permanent injury or death for every 3,220 procedures. The three most frequent perfusion incidents were adverse reaction to protamine (1 in 1,702 patients), dissection at the arterial cannulation site (1 in 1,792 patients) and coagulation of the circuit (1 in 4,864 patients). An earlier study (Stammers & Mejak 2001) of over 1,000 centres in the USA used similar techniques and drew similar conclusions, with arterial dissection and coagulation errors resulting in the highest mortality. However, these data seem to show some improvement compared with those of

Jenkins, Morris, & Simpson (1997), who found an overall rate of serious injury or death of one in 1,300 cases, despite relatively reliable use of safety monitoring equipment.

Sai et al. (2008) highlighted the technical complexity and risky nature of CPB in their report of a case in which the tubing in the pump ruptured during an operation. The surgical team managed to rescue the situation by quickly replacing the tubing in the time the patient had a cardiac arrest. Although the cause of rupture was not clear, several factors were implicated, including a manufacturing flaw, inappropriate use of equipment and deviation from protocol. These authors also emphasised the importance of vigilance. Recent analyses in this area suggest a major role for teamwork in safety during CPB (*'a shared responsibility between the perfusion technician... the surgeon... and the anaesthetist'*, Kennedy (2001, p. 629)). Even in those hospitals where adherence to communication protocols is high, there are likely to be considerable hierarchy issues in a multidisciplinary team that comprises a mix of grades and specialties, which predisposes to problems. Thus, specific attention to perfusion problems in cardiac surgery might provide substantial and measureable improvements to patient safety in this area.

During the period 1 January 2005 to 30 September 2008 38 PSIs potentially attributable to the area of perfusion were reported to the RLS; however, on analysis, 24/38 (63.2 per cent) errors were not related to perfusion. Of the 14 PSIs that were related to perfusion, eight (57.1 per cent) were related to failure of the perfusion equipment. The remaining six (42.9 per cent) were due to lack of clinical expertise.

*'During a cardiac surgery operation, the Perfusion equipment malfunctioned which led to the patient being off bypass for 7–8 minutes while the fault was corrected...'* (failure of the perfusion equipment)

*'Patients coronary artery bypass graft surgery had to be cancelled due to lack of staff in cardiac recovery...'* (lack of clinical expertise)

[Extracts from RLS incident reports]

### Other peri-operative causes of PSIs in surgery

Risk factors for the **retention of foreign bodies** have also been evaluated in several studies that examined incident reports and legal claims. Gawande et al. (2003) found that two-thirds of the items retained were sponges and one-third were instruments. They also found that emergency surgery, a change in surgical procedure, and a higher body–mass index were all factors that were likely to increase the chance of retention. Kiernan et al. (2008) emphasised the importance of adhering to swab counts and avoiding changes in staff during the procedure. They speculated that an increase in laparoscopic procedures could result in lower sponge retention. Lincourt et al. (2007) found that the likelihood of retention of sponges was only slightly greater than retention of instruments. However, the overall likelihood was increased by having multiple teams carrying out multiple procedures at the same time, as well as an incorrect count. A recent survey of all PSIs reported to the RLS (1 April 2007 and 31 March 2008) revealed 496 incidents of retained or missing swabs, needles or instruments. Most of these did not result in any harm (464/496, 94 per cent; Table 1). However, the *potential* for harm remains great.

**Table 1: Patient safety incidents reported to the RLS and pertaining to retained or missing swabs, needles or instruments**

Degree of harm	Frequency	Per cent
No harm	386	78
Low harm	78	16
Moderate harm	21	4
Severe harm	11	2
Death	0	0
<b>Total</b>	<b>496</b>	<b>100</b>

The percentages have been rounded to the nearest whole number.

*'On the last swab count one set of 10 x 10 ( 5 ) swabs was missing. Operating theatre searched including garbage bags but none was found. Anaesthetic bin had been emptied and disposed of in the general waste. Xray was carried out on the table. No swabs found in the chest as verified by surgeon. Documentation done in the patient notes...'*

*'Needles found to be missing during needle count after operation. X-ray taken - no needles found in pt...'*

[Extracts from RLS incident reports]

Finally, another PSI that has received substantial interest is **wrong site surgery**. It is often catastrophic for the patient (though perhaps less frequently fatal) and is a popular (and clearly delineated) error topic for reporting by mainstream media. The cause appears to be systemic predisposition. Of particular interest of late have been the areas of spinal and neurosurgery, where wrong site surgery occurs in between one in 4,550 and one in 780 cases, depending on the procedure and other factors such as fatigue, time pressure, changes to the operation, unusual patient anatomy and radiographic problems, which have all been identified as common risk factors (Ammerman & Ammerman 2008; Jhawar, Mitsis, & Duggal 2007).

Elghrably & Fraser (2008) found 44 left/right transposition errors in 32 sets of notes for ophthalmic surgery, with most of the errors occurring in outpatient notes. Even though 60 per cent of the errors had later been corrected, three consent forms had the incorrect eye denoted and one patient was listed for surgery on the wrong side. Similarly, Giles et al. (2006), through 38 interviews, found that most surgeons had experience of wrong site surgery. Marking practices varied, and a lack of formal policies were noted, with some surgeons believing that site marking could increase the risk of wrong site surgery. Some surgeons are also of the view that marking can contaminate the surgical site, although this has not been borne out in at least two studies (Cronen et al. 2005; Rooney et al. 2008). More worryingly, Kwaan et al. (2006) report that in an analysis of 25 wrong site surgery operations, current protocols could not have prevented one-third of the incidents. A more detailed study of 427 wrong site surgery near-misses or interventions found that patient positioning, anaesthesia before a time-out, verification of consent or site marking, and a proper time-out process are all frequently not done (Clarke, Johnston, & Finley 2007). Even following the appropriate process was unsuccessful in preventing 31 cases of wrong site surgery, suggesting that this approach can fail to capture a subset of such incidents.

Between 1 September 2007 and 31 August 2008, 728 cases of wrong site PSIs were reported to the RLS. Of these, 26 (3.57 per cent) cases involved the wrong patient, 62 (8.52 per cent) involved wrong side block, 150 (20.6 per cent) involved wrong side marked on consent form, 78 (10.71 per cent) involved wrong side marked on patient, 353 (48.49 per cent) involved wrong side marked on theatre list and 59 (8.10 per cent) involved wrong side surgery (Table 2).

**Table 2: PSIs pertaining to wrong site surgery**

Degree of harm	Frequency	Per cent
No harm	628	86
Low harm	57	8
Moderate harm	32	4
Severe harm	11	2
<b>Total</b>	<b>728</b>	<b>100</b>

The percentages have been rounded to the nearest whole number.

*'The theatre porter was directed to hand in a theatre slip. The theatre slip was left on the nursing desk with the porter stating that patient was to walk down. Staff member did not read or confirm the name on the theatre slip as there was only one patient on the bay, staff was preparing to go to theatre. Staff member retrieved patient's notes and check details and pre-op checklist. When staff arrived with patient to the anaesthetic room one, it was found out that the patient was not the patient theatre had sent for. As a result the right patient operation was delayed by half an hour...'* (wrong patient)

*'Femoral nerve block inserted in the wrong leg. Patient having a Left total knee replacement. Protocols followed and documented for 'correct site surgery'. Femoral nerve block inserted into Right leg. Femoral nerve block then inserted into Left leg.'* (wrong side block)

*'Operative list and consent for left total knee replacement. Patient stated in anaesthetic room for right knee replacement. Right knee marked. Doctor [Staff name] informed and consent form changed. Scrub staff informed...'* (wrong side marked on consent form)

*'The above pt was incorrectly marked for surgery in theatre 7. Reported to Surgeon who confirmed it was a mistake and that it was pts left knee not the right...'* (wrong side marked on patient)

*'The operating list stated that a Left total knee replacement was to be carried out. However the pt was consented for the Right and the Right side was indeed the side intended to be operated on...'* (wrong side marked on theatre list)

*'2 simultaneous emergency admissions to ITU. Patient one had to be taken to scan immediately and on return to SITU. 2nd patient rushed to theatre. consent form number 4 with patient stating left mini-craniotomy for ICH. Patient taken to theatre and stabilised for surgery. after 1 hour of surgery, surgeon stated he had opened the wrong side of the head. Operation site closed and other side of head opened. On call consultant informed. Contributing factors included the arrival of 2 simultaneous emergencies and need to expedite treatment in both cases...'* (wrong side surgery)

[Extracts from RLS incident reports]

## Summary

In the literature pertaining to PSI there are considerable variations in data collection methods and consequently some differences in findings. Many studies have found that human error and communication issues make a significant contribution to PSIs, although some of the suggested solutions, such as improved vigilance, belie the complexity of these causes and suggest an over-reliance on humans not to make errors. Equipment problems are also frequently cited, but there are differences among the findings from studies on elective and emergency surgery, although which is more incident-prone seems to depend upon the type of incident, surgery or the setting.

Extensive and high-quality analyses of data relating to anaesthetic incidents also shows a relation with the surgical procedure being performed. Although caution is necessary while interpreting data on

frequency or relative incidence, there is a growing body of knowledge in this area with regard to both analytical techniques and substantive conclusions.

In the next section, rather than evaluating incidents per se, we examine the performance shaping factors that provide the conditions in which incidents occur or are avoided.

## PERFORMANCE SHAPING FACTORS

According to the systems model of organisational accidents, deficient components of a healthcare system predisposes to human errors; and it is when humans fail to recognise or mitigate a particular threat to safety that harm occurs. Importantly, this systemic predisposition to error – albeit infrequently – can lead to actual harm. For this reason, we conducted a review of the performance shaping factors that enhance or reduce the opportunity for error before harm occurs. The aim was to understand, without hindsight bias, what can be done to enhance a given healthcare system either by improving the recognition and response to emerging incidents, or designing out the predisposing systemic threats.

### Culture and organisational issues

Safety requires a trade-off with systems performance: for example, patients undergoing surgery for improvements in the long term will be exposed to risks in the short term. Humans in particular, in any given task can trade speed for accuracy or vice versa. In a high-risk organisation, these trade-off decisions happen all the time, and the term 'safety culture' has been used to explain the cultural acceptable trade-offs within such organisations. It is no surprise then, that safety culture is a complex issue that is usually deeply embedded in most organisations.

Several tools have been developed or are in development, the most familiar being the Manchester Patient Safety Framework (MaPSaF; Ashcroft et al. 2005), to help understand where an organisation sits on a safety culture continuum. The one limitation in this area of research is that although tools can identify cultural deficiencies, they do not necessarily offer solutions. However, use of the tools can provide a focus for organisational leadership and the impetus for improvement.

Many cultural assessments address hospitals as a whole, rather than surgical departments separately. Even so, in one of the most interesting series of studies in safety culture in surgery, conducted using ethnographic methods, the researchers found that staff often focus on working quickly as opposed to working safely (Waring, McDonald, & Harrison 2006)

The most widely used culture and teamwork assessment tool is the Safety Attitudes Questionnaire (SAQ), which was developed from the Flight Management Attitudes Questionnaire (FMAQ) used in aviation. When comparing attitudes to safety of operating theatre and intensive care unit staff with those of airline crew, Sexton, Thomas, & Helmreich (2000) found that 70 per cent of surgeons and half the anaesthetists denied the effects of fatigue on performance, compared with 26 per cent of pilots. Both the pilots and the intensive care staff almost universally felt that steep hierarchies were detrimental to safety, but only about half of consultant surgeons concurred with this. Consultant surgeons perceived teamwork to be doing much better than did trainees or nurses, illustrating the difficulties faced by most leaders in recognising problems in their own teams. Two-thirds of staff did not think that that errors were handled appropriately at their hospital, and half found it difficult to discuss mistakes, whereas one-third did not acknowledge that they made errors.

Subsequent studies in the USA (Fleming et al. 2006) and Scotland (Flin et al. 2006) also confirmed inherent group differences in the perceptions of safety, based on seniority and profession; the failure to acknowledge individual vulnerability to error, even though respondents seem to recognise the ubiquity of error; the difficulties of discussing safety issues; reluctance of senior theatre staff to accept input from junior members; and poor support from management. Another study (Makary et al. 2006), found large variations between hospitals, but not by surgical specialty. All the above studies, which used the same or very similar data collection techniques, have thus demonstrated that culture can vary with professional status and seniority, from hospital to hospital, and even within locations in one hospital.

Clearly there are marked differences in performance between organisations, which can have subtle but considerable technical effects. For example, CPB is nearly three times safer in US institutions that perform both adult and paediatric surgery (Stammers & Mejak 2001). This may be simply an issue of surgical volume, but one might also speculate that differences in the approach to adult and paediatric cardiac surgery also have an impact – adult surgery is comparatively invariant and process-oriented (and thus reliable), and paediatric surgery is often highly case-specific (and thus requiring the responsive skills that provide resilience when problems arise). This perspective is supported by the interesting findings of Silber et al. (1992) that while the rate of occurrence of adverse events is associated primarily with the patient, the failure to rescue a harmful situation is associated more with the hospital. Thus, teams that have to regularly respond to patient-related difficulties (as occur in paediatrics) will be more practised in the skills required for recovery.

**Fatigue** is amongst the most well-recognised contributors to the potential for error (even given the level of denial reported by Sexton et al. 2000). When examining the effects of time of day on adverse events, Wright et al. (2006) found that an adverse event was four times more likely in an operation started at 4pm than at 9am. However, the authors admit this may be due to patient-related factors (and may also be related to time pressure on operating lists, discussed in detail later). A web survey of 2,737 US resident doctors (Barger et al. 2006) also found that long work shifts were associated with an increased risk of significant medical errors, adverse events and attention failures in trainees. Most recently, a large retrospective analysis (Morrison, Wyatt, & Carrick 2008) found decreased mortality and morbidity in trauma patients when doctors were limited to an 80-hour working week. In an older study (Rocke et al. 1992), anaesthetists admitted to fatigue in three per cent of procedures, and in 11 per cent of cases the **patient was left by the anaesthetist**. In seven per cent of cases no record was made of the anaesthetic or of the parameters monitored, with one in 18 cases associated with a critical incident.

Although practice may have changed since the publication of Rocke and colleagues' now dated report, problems with fatigue and absences from theatre have also been observed more recently (Catchpole et al. 2006). Finally, although often mooted as a major threat, **staff changes at a specific time of year** has not been found to be associated with an increased number of errors or adverse outcomes (Borenstein et al. 2004); however, in this study the reliability of the data from incident reports is questionable.

Between 1 January 2005 and 30 September 2008, the RLS database received 593/2,572 reports of incidents related to overwork and stress. The frequency with which different groups of healthcare workers cite fatigue as the cause of PSIs is as follows: nurses (525/593; 89 per cent), junior doctors (25/593; four per cent), consultant surgeons (31/593; five per cent) and consultant anaesthetists (12/593; two per cent). These figures indicate the paucity of available data in this rather nebulous area.

*'Staff nurse cancelled early shift which couldn't be filled. One staff nurse who was working in the pelvic unit had to do the work of two staff nurses. There was increased workload for the remaining staff on the ward with fewer breaks and higher levels of stress...' (nurse)*

*'Nurse spoke to on call SHO to advised him that a patient had arrived on the ward and had not been through Pre-Admission Clinic and that this patient needs to be seen as he was cancelled before at an earlier date. SHO stated that she would come soon but also became very rude towards this nurse who told Senior Nurse what had happened. A few hours later SHO bleeped again to let her know that the patient was waiting to see her and also patients needed their Warfarin to be prescribed so staff can administer them. SHO stated to a nurse that the staff would have to come to her. The Senior Nurse took various drug charts to be prescribed to her and also to let her know that it has now been 3 hrs and still the patient hasn't been seen. She stated saying to the Senior Nurse don't stress her out.'* (junior doctor)

*'The Senior Nurse told her that he wasn't happy with her attitude towards his colleagues and her behaviour was unacceptable. He also added that if this continued he would speak to her Consultant. She bluntly stated to go ahead and do it. 101 on call has been notified and aware of the situation...'* (nurse)

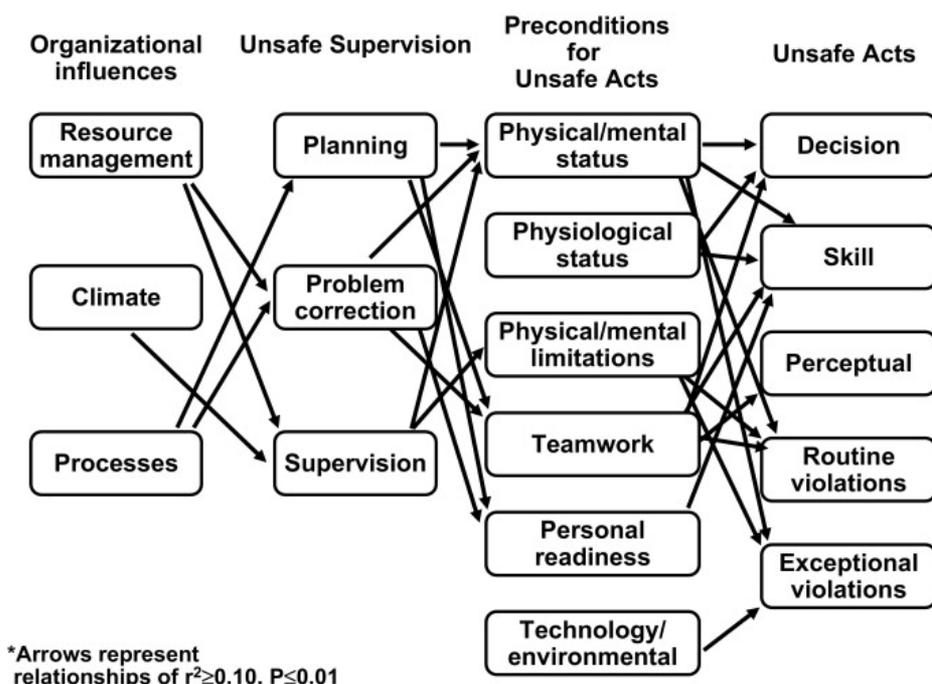
*'No juniors for my clinic – 18 new and 26 follow up patients - too stressful to sort problem out – General Manager informed 09.05, 09.20 and 09.40 – Nothing done no juniors at 10.40 – discussed with Dr [Staff Name].'* (consultant surgeon)

*'Regarding theatre C – anaesthetic room. Monitor – ECG, BP is not working – old monitor. Probably needs upgrading for cardiac and high risk patients this monitor is not very good. Putting anaesthetist under stress !!.'* (consultant anaesthetist)

[Extracts from RLS incident reports]

Overall, while there are considerable local, professional, seniority and other personal variations, the review indicates that by and large healthcare does not have a strong culture of safety, specifically in the understanding of stress, fatigue, error management strategies and management engagement. Through interviews with cardiac surgery staff, Elbardissi et al. (2008) attempted to map the complex relationship between organisational and behavioural components of safety (Figure 5). Although this is an excellent attempt to describe how culture can affect behaviour over time, this model does not account for the moment-to-moment changes in human performance than can also be brought about by the situations in which healthcare practitioners find themselves. In the next section, therefore, we discuss the studies that have examined the relation between individual performance, process reliability and outcome.

**Figure 5: A model of cultural influence on behaviour (reproduced from Elbardissi et al. 2007)**



## Studies in the process of surgery

A number of studies have sought to examine the relationship between the process of a surgical operation and the outcome; why some situations lead to incidents and others do not; which processes are unreliable; and how they can be improved. Such evaluations have the potential benefit not only of enhancing safety through more predictable and better managed processes, but also to reduce waste, and improve working conditions for staff. These studies generally look for disruptions in surgical 'flow', glitches or issues that might signal the likelihood for error, and usually involve direct observation of a number of operations where problems are documented and analysed. These studies have been conducted in a range of operations, and, much like in incident reporting, the absolute frequency of problems varies with the operation and the method of evaluation used. Although the large number of terms and assessment methods that can be used to describe the events observed make comparison difficult, the overall message is similar – that the small things matter, and can give a window on what is wrong with the system.

In a review of studies of the peri-operative process, Wong et al. (2006) found 1,627 problems in 464 procedures, with a mean of 3.5 and maximum of 26 per procedure. One-third of the problems were considered major and included surgical problems, pump failure, and drug errors. Although most problems were perceived as having been resolved, one-third were never discussed with the team, so little would have been learned about their cause or correction for future operations, resulting in their reoccurrence. Christian et al. (2006) examined ten general surgery operations by recording observations in the field that were later coded and analysed. Problems in communication, information flow, workload and competing tasks were found to have a negative impact on performance and safety in every case. The authors suggested that the **counting protocol** was a barrier to progressing through the operation and thus compromised rather than enhanced safety.

In a series of similar studies (Catchpole et al. 2005; 2006; 2007) observations were made during paediatric cardiac and orthopaedic operations. Co-ordination and communication problems, equipment problems, a relaxed safety culture, patient-related problems and perfusion-related problems were the most frequently occurring problems, along 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. In eight cases, frequently occurring minor failures threatened the safety of the patient. These results showed a strong association between risk, performance, teamwork, and the number of minor problems. The authors reported that about ten minor problems could be expected per operation without an increase in time required, but above that each problem adds about three minutes to the operating time. With up to 40 problems in an operation, this can lead to a substantially longer procedure. Catchpole et al. also found that effective teams have fewer minor problems per operation and consequently higher performance and shorter operating times – a finding supported by Healey et al. (Healey, Undre, & Vincent 2006; Undre et al. 2006a; 2007), who reported that a large number of **distractions** in the operating theatre can have an impact on team performance and potentially on outcome.

According to Wiegmann et al. (2007), operative errors during cardiac surgery are associated with disruption of the surgical flow. Generally, these disruptions consisted of a variety of systemic factors, which included teamwork problems, equipment factors, extraneous distractions, training-related issues, and resource accessibility. These authors also found that intra-operative teamwork issues are associated strongly with surgical error. In their seminal work, De Leval et al. (2000) demonstrated a statistical link between small process problems and surgical outcome; but they did not examine how or why these small problems had occurred. They were subsequently able to infer, however, that the behaviour of the surgeons may have had an influence (Carthey et al. 2003).

Thus, even though the relationship between process and outcome is non-linear, most studies have found that even small events in the operating theatre can have a significant impact on safety. In

cardiac surgery at least, there is strong evidence that large numbers of small problems can impact on patient outcome, and that teamwork has some influence on how many of such problems occur. The most obvious result of small process problems is the increase in operation time, which is specifically related to outcome in some operations (such as cardiac surgery, where bypass time can be critical). There is considerable variation in the type and severity of process problems, which in turn may be related to observed variability in surgical outcomes. Although such research is labour intensive and biased by what can be observed, the data do suggest that reducing the chances of reoccurrence of failures would lead to improved surgical standards and enhanced patient safety. (Wiegmann et al. 2007)

In the next section we examine the impact of teamwork and communication in relation to surgical error.

## Teamwork and communication

On reviewing the surgical literature, the theme of teamwork and communication occurs frequently in studies of surgical performance and patient safety; this is in part because most surgical care is delivered by multi-professional teams, and because teamwork can arbitrate the relationship between system threats and human errors. In principle, good teamwork results in better avoidance of error-inducing situations (through anticipation and workload management), an improved ability to detect mistakes (through mutual monitoring and support), and better response in a crisis.

Catchpole et al. (2008) examined teamwork skills in to the context of process problems. They found that in some operations, the operating time increased significantly with better anaesthetic leadership but decreased with better surgical leadership. There are two explanations for this: either that longer and more difficult operations required better leadership from the anaesthetist, or that stronger leadership from an anaesthetist might help surgeons (who often pride themselves on how quickly they can perform an operation) to consider safety over speed. Errors in surgical technique had a strong association with surgical **situation awareness**, while most other process problems were related to the leadership and management skills of the nurses. Elbardissi et al. (2008) also found a strong correlation between technical error and teamwork failure, and suggested familiarity is important; another series of studies (Healey, Undre, & Vincent 2006; Undre et al. 2006b; Healey, Catchpole, & Yule 2008) sought to define from first principles the teamwork skills required for surgery, and confirmed the existence of the relationship between teamwork and process in a range of operations.

Lingard and colleagues conducted an excellent series of studies that looked specifically at **communication** in operating teams. In the first study (Lingard et al. 2002), the researchers noted that the dominant themes of communication were time, safety and sterility, resources, roles and situation. At least one instance of tension from these communications occurred in every one of the 35 procedures observed, which had a negative impact on teamwork and other aspects of performance. Surgical trainees' propensity to either not communicate or simply mimic the senior surgeon appeared to make these conflicts worse. In a later study (Lingard et al. 2004), communication failures were found in 30 per cent of team exchanges, with a third of these leading to process problems, increased cognitive load, interruptions, or increased tension, thus jeopardising patient safety. Poor timing, missing information, unclear purpose, and wrong audience were cited as the sources of the communication failures.

All of the above studies and other researchers investigating teamwork seem to confirm that communication is a vital component of safety in healthcare. Better teams operate more quickly with less process problems, although roles, professional status and external factors can force team members into conflicts that split the team, and can have knock-on effects, especially on junior members of staff. What is measured as 'teamwork' varies considerably between studies and commentators, and there is considerable zeal among those seeking to learn from other industries,

that is, the purported success of teamwork training in aviation is applicable in healthcare (Kao & Thomas 2008; Wilson et al. 2005) even though the evidence of success in aviation is limited (Salas et al. 2001).

A significant proportion of PSIs in surgery in the RLS database relate to communication issues [25,458/446,184 (5.7 per cent); RLS search date 1 January 2005 – 30 September 2008] and resulted in varying degrees of harm. Of 16,216 incidents that occurred as a result of communication failure, in most the communication failure occurred outside the immediate team (6949/16126; 43.1 per cent), followed by communication failure within the team (5410/16126; 33.5 per cent).

*'List communication very poor between theatre staff and dr. 1st pt nursing skill not available therefore cancelled, 2nd pt, equipment not available used by other surgeon, pt anaesthetised but not have surgery. 3rd pt, Botox injection drugs not advised by surgeon, caused delay. 4th pt came late when arrived therefore cancelled...' (communication failure within the team)*

[Extracts from RLS incident reports]

## Technical errors

Perhaps the most difficult errors to prevent are surgical technical errors, since there are few systemic defence mechanisms that can prevent such mistakes. They are also amongst the most potentially potent, with clear implications for the success of the surgery. Most obviously, higher performance can be achieved through better training, and the use of simulation (which warrants a separate review, so has not been covered here) may help surgical trainees to reach the appropriate level of technical competency without having to practise on real patients. However, the performance shaping factors that can modify the chance for error are often ignored by the surgical community. Several studies have investigated the components of technical error, predominantly in laparoscopy, since the abstraction of the surgeon from the surgical field has clear technical implications. Cholecystectomy in particular has received much attention. This is because it is conducted frequently with little variation in the tasks that need to be accurately completed. However, the small number of potential complications can have particularly serious consequences.

Tang et al. (2004) evaluated laparoscopic cholecystectomy and found 2,242 errors in 38,062 surgical steps in 200 operations. This equated to a probability of error of five per cent per surgical step, and a mean of 11 technical errors per operation, of which approximately four per operation were considered consequential in the study. The most serious consequences were encountered during dissection with the electro-surgical hook knife. Similar studies in anaesthesia (Montague, Lee, & Hussain 2004) found 87 errors in 55 procedures, with only seven per cent of procedures being error free, and 53 per cent of procedures having multiple errors. In a follow-up study, videotapes of simulated laparoscopic cholecystectomies performed by 60 trainees were used for the analysis (Tang, Hanna, & Cuschieri 2005). A total of 331 consequential and 736 inconsequential errors were identified, giving a total error rate of 18 per procedure. This study also found a wide variation in the number of errors between the surgeons. Omission of important steps, execution of the steps in the wrong sequence, and the use of excessive force accounted for 92 per cent of consequential errors.

More recently, Parker, Johns, & Hellige (2007) reviewed videotaped procedures in which malpractice had been alleged. These authors found evidence that situation awareness and principles derived from aviation crew resource management may be adapted to help avoid systems error, as Mishra et al. (2008) have subsequently demonstrated. Previously, Way et al. (2003) analysed 252 laparoscopic bile duct injuries, and suggest that the primary cause of error in 97 per cent of cases was a visual perceptual illusion, that faults in technical skill were present in only three per cent of cases of harm, and that knowledge and judgement errors may have played a part, but were not the primary cause. One-quarter of the harms were identified during the operation itself, but only six per cent were identified soon enough to limit the injury. The lack of monocular depth cues that could create visual

misperception have been recognised for some time (Cuschieri 1995), and might be improved through a variety of technological developments. In later publications, Cuschieri (2003; 2006) has advocated a battery of techniques for safety improvement including psychology, human factors, human reliability assessment techniques, teamwork, governance and incident analysis. Clearly, addressing surgical technical errors properly will require a collection of approaches.

## Equipment problems, delays, cancellations and time pressure

Equipment problems have been cited in both incident reports and studies of observations of the surgical process. **Dropping instruments and implants** in theatre is common, and leads to increased operating time and extra resources, puts additional strain on the operating team, and can thus have safety implications. In a recent study, the observer found that instruments or implants were dropped in 32.5 per cent of all cases, and that two-thirds of these were in emergency, rather than elective, surgery. Two-thirds of the time the operating surgeon was responsible for the error, with the nurse responsible less than 10 per cent of the time. An average delay of 7.6 minutes was noted after the fall of the instrument or implant (Khan et al. 2008). In another study (Courdier et al. 2008) that looked at equipment failure in gynaecologic **endoscopy**, at least one equipment failure occurred in 38.8 per cent of procedures, with a mean delay of 5.6 minutes per failure. One in five of the failures could have led to serious complications, but none were noted in the study. If even relatively simple equipment is frequently failing and threatening safety through poor design, maintenance or training, as has also been reported by many others (De Leval et al. 2000; Wong et al. 2006; Catchpole et al. 2007; Wiegmann et al. 2007), the implications for the case for more complex surgical technology (Borden, Jr. et al. 2007) are not encouraging.

To study the effects of **delays** in the surgical process in more detail, Saha et al. (2008) measured a range of time points during the patient journey through the operating theatre. In 55 operations that were divided into over 22 lists, the longest period was identified as the time taken to transfer a patient from the ward into the anaesthetic room, leaving the rest of the team waiting for an average of 22 minutes between operations. Overall this led to a loss of between one and four hours for an operating list. The authors suggested that having two anaesthetists would allow monitoring recovery of one patient during the induction of the next, thus reducing the delay. However, this would have additional cost and other implications for the rest of the patient pathway.

Concomitant analysis of the RLS database (1 January 2005 – 30 September 2008) revealed 24,171 PSIs to do with a delay/failure in the treatment/procedure. There were 275 incidents of patients receiving the inappropriate treatment/procedure, and 8,762 incidents of patients receiving the wrong treatment/procedure.

*'Patient waited more than 48 hours for surgery 5 days wait # Proximal humerus.'* (delay/failure in the treatment/procedure)

[Extracts from RLS incident reports]

About one in seven operations in a recent study of 13,000 operations were **cancelled** (Sanjay et al. 2007); half were cancelled within 24 hours of surgery. Patient-related reasons were most common, suggesting that better pre-operative preparation – mental as well as physical – might help reduce these problems. Furthermore, since list **overruns** accounted for 16 per cent of the cancellations, there may also be implications for intra- and inter-operative delays. In a study specifically examining maxillo-facial surgery, broadly similar results were found (Sundaram et al. 2007), and an older, US-based study also suggests a link between cancellation and hospital bed occupancy (Robb et al. 2004).

Similarly, forward planning can go a long way in reducing economic healthcare costs and potential PSIs attributable to a lack of the same. Analysis of the RLS database (1 January 2005 – 30 September 2008) identified 4,792 cases where there was a lack of or delayed availability of general surgery beds. In 956 incidents a lack or delayed availability of high dependency or intensive care beds caused concern. It is of concern that 5,994 incidents were related to a lack of/delayed availability of the operating theatre.

*'Patient waited in Recovery for over 11 hours. Waiting over 1 hour for HDU to take patient, HDU called at 10:30 patient not transferred until 00:15..' (lack or delayed availability of high dependency or intensive care beds)*

[Extracts from RLS incident reports]

McDonald and colleagues' (2005) ethnographic research provides a revealing picture of how **time pressures** impact on safety, efficiency and performance, and why they appear to be amongst the most persistent and frustrating aspects of operating theatre work. Pressure from waiting lists to utilise operating theatres to their full extent, along with the mistaken assumption that all the components of surgical care function and integrate as they should, leads to demanding and tightly coupled working schedules. This means that when a patient's arrival in theatre is delayed or the surgery takes longer than planned – both of which are inevitable and frequent – it is difficult to get back on schedule. A team that is running behind then feels it is their duty to speed up, trading accuracy and safety for speed. This unfortunately encourages cutting corners along with discouraging the team members from conducting equipment checks, communicating fully, or pausing to discuss important decisions. All these, or the lack of, actions increase the chances of error and process problems, which almost certainly lead to further delays even if nothing more serious occurs.

Similar ethnographic work by Catchpole et al. (2005) showed that surgeons frequently start the operation before the rest of the team are ready, leading to a chain of events resulting in a 'near-miss' that the team members may then be reluctant to report because they feel responsible.

McDonald et al. (2005) also described how failure to start lists on time, for example, because of poor communication between theatres and the ward, meant that operating theatre staff habitually arrived late, which resulted in further delays. They also noted how most solutions focused on management audits of late starts and delays, 'blaming' offenders into working faster, thus exacerbating and perpetuating the problem, rather than developing a lasting solution at a systemic level.

## Summary

The above review leaves no doubt that the issue of patient safety in surgery is a highly complex. In fact some commentators have concluded that because of this complexity, the systems approach is unsuitable for healthcare (*'There is no point in saying that systems approaches will prevent problems because we don't have a system..'* (Tracy, Jr. et al. 2003). However, it is also clearly apparent from the review how interconnected many of the performance shaping components are to each other, and to critical incidents themselves.

It is inevitable that an operating team will be highly predisposed to causing iatrogenic injury if:

- it works in a culture that encourages throughput over safety;
- is under pressure to finish a list and avoid cancellations;
- experiences regular delays in transfer of patient from the ward;
- its members co-ordinate poorly as they hurry to start the procedure;
- is under further time pressure and is error-prone because of a sequence of recurrent equipment and process problems and unexpected patient difficulties during the operation; and
- its junior members do not speak up (either because they are concerned about their professional status, or simply because they are also keen to finish the list).

Such a team's members will be reluctant to report, discuss or learn from events afterwards because they may feel personally responsible or disempowered and 'set up to fail' by the management. This

happens when management does recognise some of the problems, but rather than addressing the complex source(s) of the problems, it seeks solutions that simply place emphasis on the need to work harder (the implication being that it is deficient, lazy or irresponsible individuals who cause the problems). With this in mind, the next section addresses the need for specific, empowering solutions to surgical safety.

## IMPROVING SAFETY IN SURGERY

Solutions to safety can be broadly divided into four categories:

1. Technological solutions: these enable error to be designed out either by replacing the 'unreliable' human factor with the more reliable technological controls, or through improvements in the human–technology interface.
2. Environmental solutions: examples include designing of workspaces to enhance human ability and reduction of external distractions during performance of a role.
3. Redesign of systems of work: examples include simplification, clarification and standardisation of roles and tasks, or provision of additional barriers and checks that will capture error.
4. Improved selection and training of human resources.

The fourth category perhaps offers the most immediate solution, but it is also probably the least effective, since basic human abilities are difficult to change quickly. New technology (category 1 above) often promises far more than is eventually delivered. Rather than reducing the chance for human error, it often creates a new set of potential errors. Indeed, solutions that stress on 'trying harder' or on more training are not likely to be effective as they do not address the complex interactions between people, processes, technology and the environment, and are often a thinly veiled attribution of blame. Thus, it is one thing to identify sources of error and injury, but it is another to develop effective solutions. In this section a number of improvement interventions and their effects are examined, but first, it is worth collating the recommendations made in the articles reviewed so far.

Virtually every commentator or research paper that was reviewed had multiple suggestions for improving patient safety, including:

- enhancing safety through better incident reporting, which in turn would be enhanced by standardising the language of the reports as well as the reporting mechanisms (Chappy 2006);
- avoiding equipment failures by use of checklists that ensure the correct configuration of equipment before the operation (Courdier et al. 2008);
- providing better training, better communication, use of checklists, better supervision, improved equipment and improved drug storage (El Dawlatly et al. 2004);
- providing better quality control, more guidelines for clinical practice, better training and communication, more supervision, and more personnel (Charuluxananan et al. 2008); and
- effective teamwork training, and intra-operative briefings and workload management to reduce technical errors (Mishra et al. 2008).

Elbardissi et al. (2008) suggested that cardiac surgery would also benefit from improved teamwork and communication via pre-operative briefings, standardised communication practices, and post-operative debriefings (reiterated by Catchpole et al. 2006), and also recommended that operating teams should be organised to ensure that members stay together, or at least are familiar with the surgeon. Plasters, Seagull, & Xiao (2003) noted that correct information tools are important to support co-ordination between distributed teams.

The causes of PSIs cited most frequently are human error, poor teamwork, and lack of appropriate communication. However, it is important to recognise that this is because healthcare relies on people

not to fail, to work in multi-disciplinary teams whose members do not train together, and to communicate between departments, professions, and grades without providing the time, facilities, methods, or encouragement to do so. McDonald et al.'s study discussed above elegantly illustrates how an inappropriate solution can lead to more, rather than less error.

**Patient involvement** is seen to be critical in efforts to reduce harm, and in particular to minimise wrong site surgery. Indeed, Clarke et al. (2008) have pointed out that verification with the patient is the most effective of the three steps of the Universal Protocol and also the value of encouraging junior members to speak up. However, DiGiovanni, Kang, & Manuel (2003) found that 41 of 100 patients had not helped to prevent wrong site surgery even when asked to do so; they suggest that many patients expect the system to work without their involvement.

**Pre-operative briefings** significantly reduce the perceived risk for wrong site surgery and improve perceived collaboration among operating theatre personnel (Makary et al. 2007). Page (2006) stated that briefings can improve operating team behaviour, and particularly the accuracy of perceptions of own behaviour, increasing efficiency and quality and reducing cost. Wears (2005) had already postulated that these observations were too broad, non-specific, and somewhat optimistic. One study that evaluated the use of briefings found a 30 per cent reduction in delays, in part because the briefing reduced the communication breakdowns that led to delays (Nundy et al. 2008). Another study found that briefings more than halved the number of communication failures during an operation (Lingard et al. 2008).

There is a similar note of optimism among advocates of **team** or **'human factors' training programmes**, with many articles enthusing about their benefits (Leonard, Graham, & Bonacum 2004). However, among the studies examining positive attitudes among staff to such programmes (Awad et al. 2005), only one demonstrated a positive clinical benefit (Morey et al. 2002). Such programmes, which appear to be derived largely from aviation, and where objective proof of operational benefits has not been definitively demonstrated (Salas et al. 2001), are in their infancy, and may not always have a strong foundation in science and may not have been effectively translated from aviation to healthcare (MacDonald et al. 2005). It is worth noting that the introduction of such programmes in aviation was inevitable once reliability had been achieved as far as possible through technology and process redesign. Since healthcare has not yet reached this stage, interventions involving training programmes currently in place may be attempting to build a reasonable edifice on less than ideal foundations.

More generally, solutions targeted at humans only (such as training or awareness raising) may demonstrate beneficial effects in the short term (Stevenson et al. 2007; Zohar et al. 2007) but could fail under pressure from other aspects of healthcare delivery or without continual reinforcement. They also do not address the complexity of systemic predisposition to error, in part emphasising a reliance on humans to 'save the day' (and by implication blaming them when things still go wrong). Benefiting from such programmes is not entirely impossible; but the most effective solutions require much deeper, multi-component approaches over longer periods of time. Perhaps the most important benefit of the human factors approach is that, rather than setting out skills to improve teamwork and communication, it provides a set of principles that help practitioners to understand the effect of complex and interacting system components on humans, thus laying down the foundations for the future understanding of safety and a culture that moves away from blame.

An interesting **systemic redesign** study in surgery was conducted in Taiwan and focused on avoiding common bile duct injury in laparoscopic cholecystectomy (Lien et al. 2007). The history and causes of this complication in one hospital were analysed over a period of 14 years with respect to the patient, the environment, the procedure, and the operating surgeon. Based on the analyses, strategies were developed to prevent injury, such as a more refined patient selection programme, controlling the surgical environment and introduction of error-proof procedures, as well as designing safety

programmes. There was a marked reduction in the likelihood of common bile duct injury from one in 370 before the changes, to zero (in 2,967 cases) afterwards. Clearly, the authors were able to overcome the substantial difficulties of implementing such a programme, and it would be interesting to see whether such a programme can be delivered in Western surgical culture. Practices such as **Lean Thinking**, for which there is little objective evidence but much enthusiasm (Young & McClean 2008), may help to make incremental systemic changes which improve safety over time, rather than making many major changes in a short space of time.

In terms of incremental change, the most successful approach to date appears to be the **care bundle** approach (Pronovost et al. 2006). This approach addresses specific complications only, but does so through simplification and standardisation of procedures – which is a more effective approach than training or raising awareness, and a more immediate solution than a technological one – and is now being extended to a range of care settings. Clearly, many potential safety solutions might already have been identified; an equally important issue now is how to best to implement such solutions in a way that is justifiable and sustainable.

### **Ten essential objectives for safe surgery (from the WHO Safe Surgery Saves Lives programme)**

- **Objective 1.** The team will operate on the correct patient at the correct site.
- **Objective 2.** The team will use methods known to prevent harm from anaesthetic administration, while protecting the patient from pain.
- **Objective 3.** The team will recognize and effectively prepare for life-threatening loss of airway or respiratory function.
- **Objective 4.** The team will recognize and effectively prepare for risk of high blood loss.
- **Objective 5.** The team will avoid inducing an allergic or adverse drug reaction known to be a significant risk to the patient.
- **Objective 6.** The team will consistently use methods known to minimize risk of surgical site infection.
- **Objective 7.** The team will prevent inadvertent retention of sponges or instruments in surgical wounds.
- **Objective 8.** The team will secure and accurately identify all surgical specimens.
- **Objective 9.** The team will effectively communicate and exchange critical patient information for the safe conduct of the operation.
- **Objective 10.** Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results.

A growing number of organisations are attempting to improve safety by working with healthcare providers on these new ways of thinking – systems redesign, human factors, checklists – and delivering markedly improved care. The work of the Institute for Healthcare Improvement and the Health Foundation has generated a great deal of interest in the UK, although there is little scientific or otherwise objective information about their success. There is also surprisingly little information about the work that has been done as part of these initiatives.

The **WHO (World Health Organization) Safe Surgery Saves Lives Programme** is transparent and easily accessible. The four goals of this programme are to prevent surgical site infection, improve safety in anaesthesia and more generally among surgical teams, and to improve the measurement of surgical services. The first product of this substantial effort is a well-publicised surgical safety checklist. Currently under evaluation, the checklist will not address all of the safety issues in surgery, but it is clearly incremental progress in the right direction, with claims of an increase from 50 per cent

to 80 per cent in appropriate surgical care delivery. There are concerns that unless it is mandated, it may not be followed by teams under time pressure, and that even if it is mandated it will not be conducted in the spirit in which it is intended. However, as the beginning of a worldwide effort for safer surgery, it is an excellent first solution. The more pressing concern is that, of the ten objectives only one emphasises hospital or health system responsibility. Meeting these objectives will require much more than a 'blame and train' approach, and the work will need to continue and take into consideration the systems of work that underlie risk and injury.

In the UK, the checklist has been adapted by the NPSA in collaboration with a multi-professional expert reference group, for use in England and Wales. The checklist outlines essential standards of surgical care and is designed to be a simple and widely applicable tool to improve surgical safety. The key messages of the Safer Surgery Alert developed by the NPSA, launched on 15 January 2009 ([www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/](http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/)), are, to:

- ensure an executive and a clinical lead are identified to implement the surgical safety checklist within the organisation;
- ensure the checklist is completed for every patient undergoing a surgical procedure (including local anaesthesia);
- ensure that the use of the checklist is entered in the clinical notes or electronic record by a registered member of the team, for example, surgeon, anaesthetist, nurse or ODP.

The NPSA is working in partnership with the Patient Safety First Campaign, 1000 Lives Campaign and The Productive Operating Theatre Project to ensure an integrated approach to the implementation of the checklist.

The Welsh 1000 Lives Campaign is another substantial and ambitious initiative that is targeting a wider range of safety issues, and aiming for: improved leadership for quality; reduced healthcare associated infections; improved critical care; improved medicines management; a reduction in surgical complications; and improved general medical and surgical care. This is far less prescriptive than the WHO approach, and has a major 'hearts and minds' component, emphasising involvement and the sharing of good practice. A considerable range of documentation is available to aid the participating hospitals in understanding as well as addressing problems. The result is a set of products that are more comprehensive and ambitious in their application than the WHO surgical checklist, based on existing evidence of good practice, and providing a greater depth of solutions along the care pathway, but in a form that is considerably more weighty ('Reducing Surgical Complications' is 53 pages long, and is one of seven that encompass the whole initiative). Thus, the content is less directly usable by clinicians, and may be more difficult to evaluate. The success of both the WHO and Welsh programmes will be followed with great interest.

There is still a long way to go in understanding not only *what* should be done to reduce injury, but *how* those solutions should be implemented. There are practical issues to consider – solutions have to be developed with local practices and limitations in mind, and without compromising other aspects of safety or performance. Then there are the issues of measurement and evidence – clinical benefits are extremely difficult to measure, and so the measurement of aspects of process as a surrogate for outcome becomes valuable; but measurement is vital since change may be negative as well as positive. Finally, reliance only on human-based solutions such as checklists, protocols and procedures is to be avoided, since too many of these create rigid, brittle and inflexible organisations, as well as adding to the workload of professionals who may be under considerable strain already.

Scientific evidence is highly valued in medicine, but those implementing interventions are often not academic scientists, so perhaps demand less stringent measures. Academic scrutiny reserved for interventions and outcomes makes it easier for researchers to fund and publish methodology, opinion, or problem-finding papers, but these often do little to advance our understanding of how progress in safety can be made. Consequently, there are many more articles recommending or evangelising

about solutions to safety than studies that have genuinely implemented solutions and measured their effects. Those that have often find the solutions are often less beneficial than the naturally optimistic advocates suggest. In essence, solutions to patient safety are certainly possible and demonstrable, but are likely to arise from a range of incremental changes in practice over many years rather than as a huge benefit from a single intervention. The advantage is that, given the levels of harm, and the ubiquity of the problems, even relatively simple improvements may have a large number of quality, safety and efficiency benefits. In this regard, Pronovost's 'bundles' work has led the way, and may herald the future of quality improvement science in healthcare.

## SUMMARY

Safety studies generally look at either incidents of harm or processes problems, with only a few papers making the link between the two. Although caution is required when looking at the results of both types of study, the former is useful for understanding incidence and severity and the latter for understanding causation and systemic predisposition to injury. The majority of work has focused on cardiac surgery (as it is high risk), laparoscopic cholecystectomy (as it is relatively invariant, but with serious potential complications), and anaesthesia (which has a longer history of this type of research, and a more homogeneous set of tasks).

Estimates suggest about 1:270 deaths are associated with errors in surgical care, although this will vary considerably with procedure (in particular elective versus emergency surgery), patient condition and the care centre involved. Around 80 per cent of surgical complications may also be due to error; and sometimes these are considered independently of safety.

There is also a growing interest in the factors that shape surgical performance. Cultural surveys reveal a range of misconceptions about safety and teamwork, and models have begun to be proposed that can link organisational factors with individual performance. Process problems are frequent and usually undocumented, but provide the context in which harm happens. Many studies have qualitatively examined cascades of errors that arise through these process issues to harm patients, although quantitative links between process and outcome are more difficult to make.

The evidence regarding effective solutions is growing, and the most successful solutions are not those that have addressed deep systemic issues, but those that have tackled specific complications. Such approaches are likely to be beneficial, provided they do not all rely on human behavioural change. Correctly designed checklists, protocols and procedures can be extremely effective, but if poorly designed, at worst will not be used, and may also contribute to additional errors.

## APPENDIX: SEARCHES CONDUCTED

Surgery + Injury = 27,6613

Surgery + Error = 9064

Surgery + Human Error = 100\*

Surgery + Incident = 2100

Surgery + Critical incident = 52\*

Surgery + Critical incidents = 59\*

Surgery + Adverse Event = 1069

Surgery + Adverse events = 6225

Surgery + Adverse events + Error = 72\*

Surgery + Medical Error = 70\*

Surgery + Delay + Safety = 347\*

Perfusion + incident = 88\*

Surgery + Teamwork: 401\*

### Numbers of articles considered, by topic and data type (NB: not all were eventually reviewed)

Topic	Case Report	Incident Reports	Legal	Notes Review	Outcome Data	Prospective/Process	Questions/Interview	Review	TOTAL
Awareness	1	0	0	0	0	0	0	0	1
Dental	0	1	0	0	0	0	0	0	1
Fire	1	0	0	0	0	0	0	0	1
Major incident	0	0	0	0	0	0	0	1	1
Pre-op	0	0	0	0	0	0	0	1	1
Communication	0	0	1	0	0	0	0	1	2
Equipment	0	1	0	0	0	1	0	0	2
Morbidity and mortality	0	0	0	0	0	1	0	1	2
Rescue	0	0	0	0	2	0	0	0	2
Bloods	1	0	0	0	0	0	0	2	3
Perfusion	2	0	0	0	0	0	0	1	3
Drug errors	3	0	0	1	0	0	0	0	4
Opinion	0	0	0	0	0	0	0	5	5
Patient	1	0	1	0	0	0	2	1	5
Complication	3	0	0	1	0	1	0	1	6
Healthcare-associated infections	1	0	0	0	0	2	0	3	6
Retention	2	1	0	1	0	0	0	2	6
Theory	0	0	0	0	0	0	0	6	6
Solution	0	2	0	0	0	3	1	8	14
Methods	3	5	1	1	0	4	1	7	22
Performance shaping factors	1	0	1	0	0	22	6	6	36
Rate/cause	0	19	2	2	5	9	6	1	44
<b>TOTAL</b>	<b>19</b>	<b>29</b>	<b>6</b>	<b>6</b>	<b>7</b>	<b>43</b>	<b>16</b>	<b>47</b>	<b>173</b>

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