Surgical errors

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A protocol for the reduction of surgical errors

S Bann, A Darzi

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The importance of reporting errors in ''real time''

Medical errors make headline news. The headlines will always emphasise the human suffering associated with medical error, but the prevention of such errors comes as the result of detailed analysis of their circumstances. One area of particular concern to surgeons is wrong site/wrong side surgery. Although its occurrence is rare, it is potentially avoidable. A notable recent case in the UK was that of a patient who died from renal failure after the removal of his healthy kidney and not his diseased one. Worldwide systems should be in place to prevent this occurring, but the data revealing the extent of the problem have not been readily available.

In the past there has been little opportunity to understand the cause of errors as such events—although rare—were often not reported and not collated with other similar events, preventing their repeated recurrence. Not surprisingly, doctors were often reluctant to disclose such errors or ''near misses''. But attitudes and practices are changing. In the USA the Joint Commission on Accreditation of Healthcare Organizations (JCAHO; www.jcaho.org; see box 1) has shown that, by the voluntary reporting of serious errors to a central body, these events can be analysed. This has revealed not only the relative rarity of wrong site/wrong side surgery, but has also allowed the pooling of data and their analysis, permitting guidelines to be drawn up to prevent their potential recurrence.

When retrospective studies are undertaken, these suggest that at least 5–10% of hospital admissions will suffer an adverse event.[1–5] By inference and extrapolation, this would imply that 1.3 million people in the USA are harmed annually and in the UK the figure would be over 400 000.[1] Within these figures, surgery is rated the highest risk factor for all adverse events.[6] Root cause analysis of medical errors leading to adverse events reveals them to be multifactorial.[7] In the case of wrong site surgery, this will involve a breakdown in communication between members of the surgical team and the patient and his/her family. Contributory factors will include problems with the routine process of ''site marking'' (that is, marking the site of the operation with indelible ink before anaesthesia), failure in the verification of a preoperative checklist, incomplete patient assessment, missing patient notes, distraction, and various other organisational issues. However, a major problem with these retrospective studies is that it is difficult to obtain ''real time'' information regarding the circumstances.

In the USA the JCAHO has been supporting a voluntary reporting system since 1996 that potentially allows clinicians to report errors as they occur; it also examines other sources such as the media. This information is collated and examined and reported as a periodic newsletter called *Sentinel Event Alerts* which describes common causes and suggests steps for elimination and prevention of their recurrence. This includes not just wrong site surgery but also other areas such as medication errors, blood transfusions, and postoperative complications.

For wrong site/wrong side surgery the JCAHO has so far reported 150 cases, with root cause analysis available for 126: 75% were on the wrong body part or site, 13% were for wrong patient surgery, and 11% for the wrong surgical procedure. Over 80% of these incidents were self-reported, with the remainder arising mainly from patient complaints. In New York State, where a mandatory system for reporting is in place, there were 46 cases in 2 years,[8] which suggests that these voluntary figures could be a vast underestimate. A recent survey of hand surgeons in the USA found that at least 20% of them had undertaken wrong site surgery at least once in their career, and a further 16% had only avoided this at the time of incision.[9] This reinforces the necessity for prospective reporting.

From their analysis of prospective reporting of wrong site surgery, the JCAHO has issued the ''Universal protocol for preventing wrong site, wrong procedure, wrong person surgery'' which has been endorsed by the major American medical associations. These recommendations stress the importance of risk reduction strategies including checking and rechecking. The marking of the surgical site should involve the patient; the use of verification checklists and the availability of the appropriate documents such as notes and *x* rays; verification by the patient of the site in the operating theatre complex; and the monitoring of these processes; a final time out is suggested before starting the procedure with active communication involving the whole operative team. An important concept promoted by the protocol is the active involvement of the patient in the process. This requires the clinical team to involve patients in decisions about their care.

In the UK this could be extended to include a second patient signature on the consent form to confirm, where appropriate, that the site or area marked is correct to the best of the patient's knowledge. At present in the UK there are no nationally applied guidelines or protocols regarding site marking; local practice often requires that the nursing staff merely document that the site or side is marked, but the operating surgeon ultimately takes responsibility and this potentially provides a source of individual error.

It is clearly important that, if errors occur, lessons should be learnt to prevent their recurrence. The JCAHO approach has shown that, with voluntary collection, it is possible to capture details of errors in ''real time'', although this may not reflect the true incidence of errors. Analysis of the information provided by the clinicians reporting the errors can aid the development of guidelines aimed at preventing their recurrence. In the UK the National Patient Safety Agency (www.npsa. nhs.uk) is developing a national reporting system for patient safety incidents which is being implemented in England and Wales—the National Reporting and Learning System (NRLS). This has been trialled by 39 health service organisations and is in the process of being rolled out nationally. The aim is to identify recurrent patterns of behaviour and practice associated with errors and to feed this back to ensure safer care. It is envisaged that, by encouraging the reporting of errors, their number will decline, paralleling the airline industry. However, it should be recognised that, despite increasing technical reliability, human error can never be totally removed.[10]

The reporting of medical errors in ''real time'' will reveal a truer picture of their frequency. This offers the potential of providing solutions that will reduce the risk or even prevent their occurrence

Box 1 JCAHO

The JCAHO, founded over 50 years ago, has a declared mission to improve continuously the safety and quality of care provided to the public. A major role is to identify the cause of harmful errors and facilitate their reduction through analysis, reporting, implementation, and monitoring of any applied policies. An effective reporting system is an essential prerequisite for serious event analysis and needs to be within a framework that allows the information to be legally protected from disclosure so that data can be seen as *Sentinel Event Alerts*. Data from the analysis of reported serious events are used as the foundation for the formulation and implementation of safety and quality guidelines.

likelihood of the junior surgeons and staff challenging their senior colleagues is much less likely.[11] Indeed, in the case of the patient whose wrong kidney was removed, it is reported that a medical student present in the operating theatre did suggest wrong side surgery. Any guidelines issued must therefore provide backing for issues that may arise from this challenge.

The JCAHO has shown the way with the reporting and analysis of these incidents. We must ask whether there is any reason why the UK should not adopt the protocol that has emerged from their experience.

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in identical circumstances. Patient involvement seems simple but is, in fact, a major shift in emphasis. Despite evidence from the airline industry where safety is also paramount, the junior staff have clear instructions to challenge their seniors in situations of potential error whereas in surgery the

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"No blame" culture
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Creating a "no blame" culture: have we got the balance right?

M Walton

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There is a need to clarify where and how professional responsibility fits into the "no blame" culture

How the media reports patient harm associated with adverse events continues to cause public concern and disturb health professionals. The need for health professionals to communicate more effectively with the public about medical errors has been identified,[1][2] but to date there is little evidence of this happening. Tensions surrounding professional responsibility and accountability (as opposed to institutional accountability) and the quality and safety "no blame" approach within the health system prevent health professionals communicating clearly with the public. How can we give a clear message to the public

when we do not have a clear understanding of these issues ourselves?

The current focus on improving care by redesigning systems, tasks and workforce[3] necessarily emphasises the multiple factors underpinning errors, relies on reporting systems for capturing errors, and advocates a "blame free" environment so that staff will report their mistakes or near misses. This approach examines system factors as causes of errors rather than individuals. Evidence from other industries and disciplines supports this approach.

The safety agenda requires us to switch from an individual focus to a system focus but, in making this switch,

professional accountability has been cast as the "black sheep" of safety improvement. Undeveloped systems of professional accountability, inadequate support from professional bodies for professional regulation, inadequate understanding of public interest, and inadequate rules for reporting serious misconduct have let this happen. This is no criticism of safety advocates whose job is to reduce patient injury: too many messages can be detrimental to success. But have we got the balance right? System theorists and industries upon which health relies for systems redesign and remedies pay a lot of attention to the role violations play in the system. Reason[4] argues that, in addition to a systems approach to error management, we need effective regulators with the appropriate legislation, resources and tools. Regulators, being separate from organisations, are best placed to identify unsatisfactory work practices or conditions that workers tolerate or work around.

The perceived contest between whether individuals or bad systems cause patient injuries has confused many health professionals and managers. It is not a case of accepting one over the other. The focus on the system as the problem does not mean that

m as the problem does not mean that individuals do not have to maintain competence and practice ethically or be called to account when they act unprofessionally. Accentuating the system and downplaying professional responsibility may be politically expedient to some groups, particularly those professional groups opposed to external scrutiny. But sacrificing professional accountability increases the risks to patients. The failure to urge professional responsibility concurrently with calls for a ''blame free'' approach to error reporting sends the public the message that the health system favours one above the other.

UNDERSTANDING VIOLATIONS

Patients making complaints about their health care are entitled to have their individual care examined to see if there has been a departure from the required standard. System issues may be the main cause. But health providers may also have cut corners and broken rules. Medical standards may have been breached and substandard care provided. Rules are broken so often in hospitals—for example, non-compliance with a protocol such as failure to wash hands—that we have become immune to them. It is easier to blame such violations solely on the system than to require individuals to meet their professional responsibilities. Reason defines a violation as a deviation from safe operating procedures, standards, or rules.[4] He categories violations as routine, optimising, and necessary. The first two relate to personal characteristics while necessary violations are linked to organisational failures. Cutting corners are routine violations that thrive in work environments that rarely sanction violations or reward compliance[4]—for example, not following protocols, inadequate handovers, inadequate infection control, and not attending on-call requests. Optimising violations involve individuals motivated by personal goals such as greed or thrills from risk taking—for example, letting inexperienced junior staff operate without supervision when a consultant is busy with private patients, experimenting with unproven procedures, and doing inappropriate procedures. Necessary violations comprise work environments and circumstances which force workers to break rules to get the job done. Deliberate violations—those where there is an intention to act as distinct from a violation caused through ignorance—are recognised and managed. Intentional violations do not necessarily intend a bad outcome.[4] Poor understanding of professional obligations and a weak infrastructure for managing unprofessional behaviour in hospitals provide fertile ground for aberrant behaviour to flourish.

LEARNING FROM THE PAST

The main avenue of redress for patients suffering adverse events during the 1980s and 1990s was to make a complaint. Health professions and organisations were deaf to stories of inadequate or substandard treatments and focused on the messengers (regulatory authorities, consumer groups, complaint agencies, or lawyers) as the problem. Professional accountability was the focus of these investigations, with no attention to the role played by the system. We should learn from that experience. Just as it was wrong in the past to focus only on individuals, it is equally wrong today to think that all adverse outcomes are caused by systems problems with no attention to professional duties and responsibilities.

A WAY FORWARD

In my experience as both a regulator and safety exponent,* systems issues usually accompany breaches of professional responsibility (weak regulations, reporting requirements, or inadequate training). It depends how you look and where. A root cause analysis[5] would nearly always identify systems problems and rarely individuals. Systems failures may also mitigate the level of responsibility for the individuals. Where and how professional responsibility fits into the ''no blame'' culture is unclear. How can we make it clearer?

Public trust requires both a redesigned health system delivering safe

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and quality health care and a strong professional ethic and accompanying accountability system. As a first step, three things should happen:

- professionalism in the workplace needs to become part of the safety agenda;
- methods for managing and responding to intentional violations by individuals in the workplace need to be debated and designed: building in sanctions for routine violations and rewards for workplace compliance is a first step;
- teaching clinicians about the inevitability of mistakes is already happening but we also need to teach them how to respond to mistakes.

Disciplinary outcomes for doctors are largely determined by peer review and focus on the actions taken after the mistake rather than the mistake itself.[6] Demystifying accountability mechanisms and educating professionals about their ethical obligations will help them identity systems problems and the appropriate remedies and professional issues and their appropriate response.

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Doctors' hours of work

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What matters more in patient care? Giving doctors shorter hours of work or a good night's sleep?

J Firth-Cozens, H Cording

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Focusing only on reducing hours of work may not have the desired effect of reducing symptom levels

The long hours that doctors work, and the length and quality of their sleep, have long been viewed as influencing their health and the safety of care they give.[1] In 2000 it was agreed by the European Parliament that the Work-time Directive, which had limited working hours in general, should also apply to doctors in training. This will mean no more than 58 hours per week by August 2004 and eventually a maximum of 48. In Europe this has more to do with the risks towards the doctor while in the US efforts to reduce long hours have come more from their threat to patient safety. But is this focus on hours the right one?

There is certainly some evidence that a long working week will affect your health: a meta-analytical review of workers in general found small but significant positive correlations between overall health symptoms, physiological and psychological health symptoms, and hours of work.[2] In Japan, where working hours are particularly long, this has been implicated in cardiovascular disorders and diabetes mellitus.[3] Nevertheless, most studies show surprisingly little evidence for the relationship between hours of work and psychological well being: even when hours are long, they have little or no correlation with levels of stress or depression.[4][5] On the other hand, a combination of the intensity of demands (rather than long hours per se) combined with low discretion over how one's work is done continues to be an influential model of the causes of job related stress.[6] Doctors have consistently shown unusually high levels of stress symptoms and consider overwork to be involved in this.[1] What is likely, however, is that the tiredness caused by long hours makes any potential job related stressors— such as lack of support, dealing with patient deaths, or the high cost of error in medicine—much more difficult to cope with and, in this way, stress symptoms may be a mediator between hours worked and psychological disorders such as depression or anxiety.[7] Focusing only on reducing hours of work may not have the desired effect of reducing these symptom levels.

> "... it may be better to aim for ensuring good support, leadership, and teamwork ..."

Nevertheless, doctors certainly see overwork—both long hours and a lack of support—as contributing to incidents of poor care,[8] and evidence from a military study suggests that individual errors increase with fatigue.[9] However, the same study found that, over time, the team can compensate for these errors, and so those who worked together over a longer period had higher individual error scores but lower team error scores than those working together only briefly. It seems that the relationship of hours to error is complex,[7] mediated by such factors as the support of colleagues, including leaders, as well as the levels of control one has over one's job.[6] Certainly for younger doctors, long hours of work, well managed,[10][11] may be a relatively insignificant factor compared with the positive effects of being part of a team and the enjoyment of practising medicine. Rather than continuing the pursuit of a shorter working week, it may be better to aim for ensuring good support, leadership, and teamwork since good teams have healthier staff and better outcomes.[12][13]

Although there is inevitably a relationship between hours of work and hours of sleep, the negative effects of sleep loss on both mood and performance have been found much more consistently than those of long hours. Sleep deprivation necessarily varies in real life studies, but most definitions involve fewer than 4 hours sleep in 24, or frequently interrupted sleep. Most studies show that mood is lowered after a long on-call shift and young doctors report feeling more confused and less confident.[14]

These psychological effects are mirrored where the quality of care is considered. Errors increase with sleep loss, and data on shift work show a rise in industrial injuries on the night shift.[15] In medicine, such data are rarely collected and instead a variety of cognitive tests are used as proxy measures of performance—assessing memory, concentration, alertness, and attention to detail after nights on call. Review studies[16] and meta-analyses[17] agree that sleep deprived people perform significantly less well than controls, particularly in terms of mood and cognitive tasks, whether proxy assessments or simulations are used. For example, surgical house officers following a weekend on call showed significant impairments in concentration and speed.[14] Performance in general was highly related (0.5–0.6) to the number of hours of sleep: an impairment to vigilance estimated to be close to that caused by 0.7 g/kg alcohol which, as they point out, is near the legal UK limit. Simulations of laparoscopic surgery show that more errors occur with increasing sleep loss[18] and after a night on call.[19] Moreover, there is some evidence to suggest that there are deleterious effects even 2 days later.[20]

In the short term, an educational approach to the dangers of sleep loss and ways to improve sleep quality may be useful, alongside encouraging leaders to ensure that those deprived of sleep are not put in potentially dangerous

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Key messages

- There is only a small complex relationship between hours of work and performance or mood.
- Other factors such as team relationships, leadership, and job design may matter more.
- Lack of sleep or disturbed sleep, in particular, leads to substantial decrements in performance.
- Remedying the raft of factors is likely to improve both working lives and patient safety more than focusing simply on a shorter working week.

situations.[10] The benefits of napping[21] or rest periods[22] in terms of subsequent performance have been reported and could be built into the working day officially rather than surreptitiously by individuals. However, it seems important that we integrate our approaches to improving working lives and patient care,[1] and resist focusing only on hours or any single factor. What is needed is a systems approach towards a cultural change that uses an evidence base to address the complex factors that contribute to staff working below par, and that treats healthy alert staff as a key element of patient safety.

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Stroke

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Knowledge and action in stroke—are either good enough?

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It is important that education on stroke is provided in ways that people can really understand

Getting people to hospital quickly for specialist care after a stroke saves lives and reduces disability.[1] However, for many people, the most appropriate care is delayed and, in some cases, may not happen at all. Other than the ongoing lack of specialist stroke services, what is it that impedes access to best services for patients who have a stroke?

Huge efforts have been made to highlight the seriousness of stroke and the importance of getting swift medical attention. However, the long lasting effects of education and screening campaigns are debatable,[2–4] providing a reminder (if one were needed) of the complexity of health promotion for behaviour change. Key questions to face are whether the level of knowledge about stroke is good enough, and whether that knowledge leads to appropriate action when people experience a stroke.

A number of recent studies have explored the quality of the public's knowledge about stroke and many make depressing reading.[2 3] The recent study by Carroll et al[5] (summarised in the ''Echo'' which appears on page 168 of this issue of QSHC) presents contrasting findings about the level of knowledge, and prompts some interesting questions about what we do in relation to that knowledge that is important for practitioners, researchers, and policy makers alike. On the positive side, Carroll et al[5] found a ''good'' level of knowledge among four groups of people (comprising patients in hospital after a stroke, those at risk of stroke from specialist clinics, members of the public who were visitors to other wards of the hospital, and nurses on general medical wards) in comparison with other studies. The majority knew at least one symptom of stroke and considered the event a medical emergency. Interestingly, hospital nurses were the only group who did not consider it to be an emergency, although this may result from their frame of reference (an acute medical ward) leading to a tighter definition of medical emergency such as cardiac/respiratory arrest. It would be interesting to know how primary care health professionals in the area—including district nurses, health visitors and general practitioners—would answer the same questions, given their role in the community to advise people who are at risk of or experience a stroke. Certainly, a recent study of general practitioners found that the majority considered stroke an emergency and would call an ambulance.[6] Most participants in the study by Carroll et al stated that they too would call an ambulance for assistance. However, the reality of what actually happened was different, with those in the stroke group calling their general practitioner or seeking help from a family member to do so.

The apparent conflict between what people say they would do and what they actually do is intriguing. On the one hand, it is not unusual for people—including probably most of us—to make plans for actions that are then not carried out, particularly in new and stressful circumstances. Along with this general caveat, it may also be that factors such as severity and type of stroke are important mediators of action taken. One could imagine that severe signs of stroke such as unconsciousness, hemiparesis, or aphasia might be more likely to prompt a call for an emergency ambulance than less obvious or transient symptoms including visual disturbance, weakness in a limb, or slurring of speech. Certainly, people who have had a stroke have reported not recognising the symptoms they experience because they were so different from those they had read about.[7] Furthermore, if a diagnosis of stroke is not always straightforward for qualified medical practitioners,[8] it is perhaps not surprising that patients themselves have difficulty in self-diagnosis or are reluctant to call out emergency services. It would seem that, in order to design and target education more effectively, further exploration concerning the messages people actually hear about stroke from the information given is needed.

The title of Carroll et al's paper states that "knowledge was good but action was poor", yet the figures for recognition of risk factors, particularly among the health professional group, seem low (median of 2 for nurses compared with a median of 1 for the other groups). This level of knowledge is surely not good enough, given that these were staff in medical wards (albeit not specialist neurology wards) and that a number of important and modifiable risk factors such as atrial fibrillation were rarely mentioned. As for the people who actually had risk factors, only one third could recall having been advised of that risk. Interestingly, the investigation by Sug Yoon et al[7] found that those who recalled being advised about their risk of having a stroke were actually no better at recognising their own symptoms.

So where does this leave us when thinking about and targeting education on risk factors and their relation to stroke? Given that stroke remains a common and poorly understood condition,[9 10] education for the general population and health professionals, as well as those with risk factors, is vital. There is no doubt that advances have been made in understanding the importance of the content, context and timing of "information giving" to enhance knowledge. However, while knowledge is power in some domains of life, catalysts to action are clearly less well understood in the case of stroke. It is important that we provide education—whether for at risk groups or the general population—in ways that people can really understand and, indeed, act upon the knowledge gained. Simply providing "more" education is not an adequate response.

With the continued efforts of organisations such as the Stroke Association and others, increased prioritisation of research into stroke appears to be happening, at least in the UK. Along with other research priorities, how people make potentially life and death decisions when they have a stroke is clearly worth more detailed investigation if we are to provide timely appropriate services and improve our record in stroke care.

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