WHILE YOU WERE SLEEPING

Making surgery safer

Surgery has seen rapid improvements in recent years; however, errors do still occur. Further improvements will need a more detailed understanding of the prevalence of harm, a change in culture and the use of innovative new tools, such as surgical checklists.

KEY POINTS

- Around 7.9 million surgical procedures are carried out in England each year, 10 times the number of births.
- Having an operation is usually a safe experience for the patient, but things can and sometimes do go wrong.
- In 2001, 20,130 people died within 30 days of surgery. It is not known how many of these deaths were preventable. Whilst 30-day mortality is regarded as a good indicator of the quality of surgical care, it is no longer systematically analysed in the NHS.
- In 2007, more than 129,416 errors involving surgical patients were reported to the National Patient Safety Agency; these errors included wrong site operations, incorrect patient details and mistaken surgery.
- Specific examples of surgical adverse events reported to the National Patient Safety Agency included 14 cases of operations on the wrong side of the skull and 14 deaths following the use of cement in hip replacements.
- More attention needs to be given to reducing error in surgery, including the routine use of checklists and risk scores (an opportunity is provided by the World Health Organization's Global Patient Safety Challenge on safe surgery).

In the years before the NHS existed, a medical committee wrote to the Minister of Health to express concerns based on its experience of complaints and litigation against doctors.

One of the examples raised was the ambiguity surrounding the accountability of surgeons, anaesthetists and nurses when patients were undergoing operations. In the first full year of the NHS, 1949, an incident occurred where a swab was left in the abdomen of a child undergoing emergency surgery. Leaving a swab or surgical instrument in a patient's body is a recognised, though uncommon, error. It can have serious repercussions for the patient and almost always requires a second operation to remove the foreign body. Sixty years later it may seem surprising that similar incidents are still happening, and that issues concerning clinical accountability are still being debated (see Box 1).

Over decades, many aspects of surgery worldwide have become safer. Yet many errors still recur. Although this seems an unacceptable situation, the ways to comprehensively eliminate or reduce risk have not been found.

Surgical harm and error

Around 7.9 million surgical procedures are carried out in England each year. This is more than 10 times the number of births, arguably an area where there is much more public concern about, and scrutiny of, the risks.

In 2001, 20,130 people died within 30 days of having an operation. The measure of 30-day surgical mortality is regarded as an important marker of the quality of surgical care. However, it is no longer routinely analysed across the NHS. So, it is not easy to determine whether the position has improved or worsened over the last six years. Nor is it really possible to assess the proportion of the 20,000 or so deaths that could be prevented each year.

Some data on the risks of surgery are available from the National Patient Safety Agency. It receives adverse event reports from across the NHS and was established following the publication of my report, *An Organisation With A Memory*, in 2000. This patient safety database is now the largest in the world with over 2 million case reports. Steps are being taken to refine its methodology and deal with the issue of under-reporting.

Box 1: Accountability is still hotly debated

Errors in operating lists

The National Patient Safety Agency received 129,416 reports of potential errors involving surgical procedures during 2007. Amongst these incident reports, 1,136 errors involved operating lists (the process by which hospital staff draw up lists for surgery).

Errors in this category included:
- wrong site operations
- incorrect patient details
- mistaken surgery.

Approximately three patients per day sustain an error related to the operating list. One patient per day is listed for the wrong operation. In most cases, the error will have been detected before the surgery is carried out, though it is likely that the number of errors involving operating lists are under-reported.

The process of creating operating lists is complex, requiring an understanding of the patient in question, their diagnosis and suitability for the proposed procedure, logistical issues related to timing and the experience of surgeons required to operate. Junior medical staff, who are responsible for compiling the operating list, often lack understanding of the potential for error at each stage of the process.

The creation of operating lists is not standardised across the NHS. Procedures vary from computerised systems relying on data entry clerks, to junior doctors manually entering patient details. Sophisticated independent checking mechanisms applied in other high-risk industries are rarely applied. This has led to errors such as patients receiving the wrong strength lens for eye surgery because the lists were changed at the last minute and the surgeons assumed they were operating on a different person.

Wrong site surgery

Errors involving operations on the wrong side or part of the body are particularly worrying for the public, especially when they seem to be repeated. Operating on the wrong site has devastating consequences for patients. The events leading to wrong site surgery involve multiple factors ranging from incorrect identification of patients, to inappropriate or absent markings of patients before the operation starts.

An example of this type of error is found in brain surgery. Patients suffering serious head trauma may require an operation to release blood that is pressing on the brain. The procedure, known as a burr hole, is performed by neurosurgeons and involves drilling a hole in the skull bone. Blood typically collects on one side beneath the skull above the tight covering which lines the brain. In the past three years, 14 cases were reported to the National Patient Safety Agency of burr holes drilled on the wrong side of the skull. A second set of holes then had to be drilled on the correct side. Although the number of these errors is relatively small, many people would be incredulous that it could happen at all, let alone be repeated.

The extent of wrong site operations spans multiple surgical specialties – for example, operations removing bone from the wrong foot, knee replacements on healthy knees, wrong incisions for access to abdominal organs and implantable hearing aids for the wrong ear.

Uncertainty about policy on risk

Analysis of other surgical errors reveals inconsistency in clinical policy, possibly allowing risks to prevail which could be reduced or eliminated. For example, in this country 50% of total hip replacements are performed using special cement to hold the whole prosthesis (artificial metal joint) in place.

Bone cement implantation syndrome (BCIS) is a complication of surgery which takes place immediately following the use of cement in joint replacement operations. This has severe effects on the normal functioning of the heart and lungs and can cause death in severe cases. It is thought to be due to globules of fat being pushed from the hollowed-out inside of the bone through to the blood when the cement and artificial joint are placed by the surgeon. The metal joint and cement are held under pressure within the bone while the cement undergoes a chemical reaction, which causes it to become very hot and solidify, enabling fixation of the artificial joint. Other causes of this syndrome have been postulated to be the temperature change of the cement within the bone; air, gas or debris from the bone passing into the blood; an allergic reaction; or a severe drop in blood pressure caused by the cement.

Several techniques to reduce occurrence have been suggested. These include thoroughly assessing high-risk patients and selecting the joint technique best for them, controlling pressure in the bone during the placement of cement, using advanced cementing techniques or opting for not using cement at all.

Bone cement implantation syndrome only occurs when cement is used for hip replacements. In contrast with the 50% of cases fully using cement in the United Kingdom, in Canada only 3% of operations are completed using cement for the whole joint. The National Patient Safety Agency National Reporting and Learning System recorded 14 deaths and 9 serious reactions related to the use of cement in hip replacements in 2007. Guidance about the risk of cement has been conveyed to surgeons in this country, but change in practice has not occurred at the same rate as that in North America.

Surgical audits

The professional bodies representing surgeons and anaesthetists have undertaken much good work over the years to study the risks of surgery and ways to reduce them. An early example was undertaken by the Association of Surgeons and Anaesthetists. This work was subsequently taken over by the National Confidential Enquiry into Perioperative Deaths (subsequently renamed the National Confidential Enquiry into Patient Outcome and Death – NCEPOD). The audit data revealed some valuable information.

Early studies showed that patient outcomes for those who were operated on outside of normal hours were significantly worse than for those operated on during the day. This led to changes in clinical policy. Routine surveillance data on surgical outcomes have not been collected for the last six years. Instead, the work of NCEPOD has focused on topic-based studies.

The Royal College of Surgeons of England

The Royal College of Surgeons of England currently offers a course to address patient safety issues. This involves surgeons and representatives from other high-risk industries. It targets issues of leadership, effective teamworking and risk reduction to improve patient safety.

A recent NCEPOD study, looking specifically at deaths following first-time coronary artery bypass grafts, found that where death occurred, the patient received care that was considered by other heart surgeons to have been good practice only 38% of the time. The study found that 16% of patients who died had received an inappropriate operation. The study also identified 95 patients where it was felt that inadequate management of complications may have led to the death of the patient.

The Scottish Audit of Surgical Mortality reviews all deaths in hospital of patients who are cared for by a consultant surgeon. This is regardless of whether they have had an operation or not. Surgeons and anaesthetists complete detailed forms which are scrutinised by their colleagues. Over 1,000 clinicians participate and approximately 4,500 deaths are analysed every year. Commitment to such rigorous practice has resulted in the opportunity for identifying high-risk situations and subsequent learning. No such national system exists in England.

World Health Organization

As with many other complex areas of healthcare, in patient safety many of the problems we see in our country also occur worldwide.

In 2008, the World Health Organization launched its campaign, 'Safe Surgery Saves Lives', to reduce the number of errors occurring in surgery. The focus of the campaign is the Surgical Safety Checklist. The checklist identifies three phases of an operation, each corresponding to a specific period in the normal flow of work – before the induction of anaesthesia ('sign in'), before the incision of the skin ('time out'), and before the patient leaves the operating room ('sign out'). In each phase, a checklist coordinator must confirm that the surgery team has completed the listed tasks before it proceeds with the operation.

Checklists are routinely used in other high-risk industries. There is no such thing as an error-free situation. Risk is recognised and systems, such as checklists, are implemented to prevent adverse events, even if they are very unlikely. This is common practice in high-risk areas as diverse as aviation, nuclear power and Formula 1 racing.

The WHO initiative is being piloted at eight sites internationally including St Mary's Hospital, London. Twelve of the United Kingdom's professional organisations in surgery, nursing and anaesthesia have endorsed the checklist and more plan to follow.

World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

☐ **PATIENT HAS CONFIRMED**
- IDENTITY
- SITE
- PROCEDURE
- CONSENT

☐ **SITE MARKED/NOT APPLICABLE**

☐ **ANAESTHESIA SAFETY CHECK COMPLETED**

☐ **PULSE OXIMETER ON PATIENT AND FUNCTIONING**

DOES PATIENT HAVE A:

KNOWN ALLERGY?
☐ NO
☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
☐ NO
☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
☐ NO
☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

☐ **CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE**

☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM**
- PATIENT
- SITE
- PROCEDURE

ANTICIPATED CRITICAL EVENTS

☐ **SURGEON REVIEWS:** WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?

☐ **ANAESTHESIA TEAM REVIEWS**: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?

☐ **NURSING TEAM REVIEWS:** HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
☐ YES
☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
☐ YES
☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

☐ **THE NAME OF THE PROCEDURE RECORDED**

☐ **THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT** (OR NOT APPLICABLE)

☐ **HOW THE SPECIMEN IS LABELLED** (INCLUDING PATIENT NAME)

☐ **WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED**

☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT**

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

Surgical scoring systems

Scoring systems for assessing individual patient risk are another useful tool to reduce errors in surgery and increase the resilience of the safety system to withstand mistakes. Scoring systems are well established in some areas of medicine. The Glasgow Coma Scale and the Apgar score are examples of two universally used scales. The Glasgow Coma Scale facilitates communication by way of a simple score, which accurately reflects a patient's consciousness level. It is used routinely in almost every hospital in the world for making decisions about the initial management of patients with an acute head injury or coma, and for careful monitoring of neurological status.
The Apgar score is a 10-point score for newborn babies. A low score equates with a difficult delivery and a higher chance of the baby dying within one month of birth. This revolutionised post-delivery care, allowing doctors and nurses to understand the risk to the newborn baby and communicate it to others in a concise way. Not only did it achieve safer care, but it also paved the way for developing improved management for sick babies and a research framework for testing new treatments. There is no doctor involved in child delivery who would not consider using it.

Dr Atul Gawande, the leader of the World Health Organization's 'Safe Surgery Saves Lives' programme, has pioneered a simple surgical risk score comparable to the Apgar baby score. Dr Gawande's score assesses blood loss, blood pressure and heart rate during the operation. These measures are used to create a score which gives an accurate picture of the risk of death from an operation if measured immediately afterwards. The lower the surgical score post-operatively, the higher the chance of death or a major complication at 30 days after the operation.

This enables patients to be classed as high, medium or low risk after an operation and is a useful tool for all members of the healthcare team to communicate and make decisions about appropriate patient care.

A study of 4,119 patients revealed that the Gawande score gives an indication of how well the operation has gone and conveys useful predictions of the patient's post-operative course, when used in isolation or in combination with scores of pre-operative risk.

Conclusion

Surgical care provides life-saving interventions and life-transforming treatments. It is provided in complex healthcare settings with non-standardised systems supporting its delivery. NHS staff have reported substantial numbers of errors occurring in these systems. Most result in no harm because they are recognised and corrective action taken. However, not all errors are detected in time and harm does occur to patients. Much of this harm is avoidable.

In some areas of surgery, the adoption of safer techniques has not kept pace with similar healthcare environments in other countries. It is essential that risks in surgery are analysed and clear decisions and plans made to ensure that surgical care is safer. Medicine has a well-developed paradigm in some care settings for the use of checklists, together with scorecards and scales, as reliable methods of assessing a patient's condition. The use of a standardised checklist in operating theatres and a surgical scale, analogous to the Apgar score, could improve the safety of patient care in surgery.

"Over decades many aspects of surgery worldwide have become safer. Yet many errors still recur. Although this seems an unacceptable situation, the ways to comprehensively eliminate or reduce risk have not been found."

RECOMMENDATIONS

- The National Patient Safety Agency should establish a clinical board for surgical safety which should include the Royal College of Surgeons, the Royal College of Anaesthetists, the National Confidential Enquiry into Patient Outcome and Death, nursing bodies, and other relevant professional organisations.
- Immediate attention should be given by this board to the two areas of surgical risk identified in this report (wrong site neurosurgery and cemented hip replacements).
- The World Health Organization checklist and the Gawande score should be piloted by clinical teams as measures to improve the safety of surgical care.
- Regular collection and analysis of 30-day surgical mortality and morbidity should be introduced nationally and be part of public reporting of surgical outcome.