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General surgical adverse events in a UK district general hospital—lessons to learn☆

S.V. Gurjar [a], S. Roshanzamir [b], Sandeep Patel [c,*], G. Harinath [d,e]

[a] Department of Surgery, Kings College Hospital, Denmark Hill, London SE5 9RS, United Kingdom
[b] The Prince of Wales Hospital, Randwick, Sydney 2031, Australia
[c] Imperial College, London, United Kingdom
[d] Department of Surgery, William Harvey Hospital, Ashford, Kent TN24 0LZ, United Kingdom
[e] Canterbury and Christchurch University, Canterbury, United Kingdom

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ABSTRACT

Background: An adverse event (AE) is defined as an unintended injury or complication caused by healthcare management rather than the disease process that may prolong admission and lead to disability or death. This study retrospectively assessed all reported general surgery-related AEs in a district general hospital in the south-east of England.

Methods: All general surgical AEs arising from adult inpatient admissions between 2002 and 2007, that had been reported to the risk management team, following completion of the standard 'Adverse Incident Report Form', were retrospectively reviewed.

Results: There were 24,185 general surgical admissions over the period of the study; 461 AEs were reported (1.9% mean annual incident rate; 95% CI, 1.3%–2.5%). The majority (85%) were near miss or no injury events (category I and II) while serious/serious near-miss incidents accounted for just 2% of events. Communicative or administrative problems were implicated in 54% of cases while 12% arose from theatre/surgery-related failure. Of 58 medico-legal claims (0.24% of admissions) that were made, 16 (27.5%) progressed to the law courts for formal settlement.

Conclusion: The reported annual AE incident rate of approximately 2% is well below the national average: this may be due to pre-selection of general surgery-related AEs or represent under-reporting of incidents. The vast majority of AEs were related to administrative and communicative error. These areas must be addressed if patient safety and outcome is to be significantly improved.

1. Introduction

It is well recognised that healthcare, although undoubtedly beneficial, can have potentially harmful effects on patients.[1] Surgery is an integral constituent of the healthcare process with an estimated world-wide total of 234 million major procedures performed annually.[2] Recently, there has been a very public, world-wide push for improved patient safety led by the World Health Organisation (WHO),[3] which published guidelines to help improve the safety of surgical patients and led to the adoption of the 'Surgical Safety Checklist'.[4]

Patient safety is a fundamental part of the drive to improve quality in the National Health Service (NHS) in England. An important indicator of patient safety within a hospital is the documented rate of adverse events during the course of inpatient admission. An adverse event (AE) is defined as an unintended injury or complication caused by healthcare management rather than the disease process, leading to prolonged admission, disability at discharge or death.[5,6] All hospital admissions are subject to a degree of risk, which may reflect patient age, reason for admission, type and complexity of procedures undergone during the admission and length of hospital stay. Studies conducted in various developed countries have reported adverse patient events to occur in 3–30% of hospital admissions.[5,7–9] AEs can have medico-legal implications with consequent severe financial penalties – 130 patients with surgical adverse events at a single American hospital resulted in financial liabilities totalling 8.2 million US dollars.[10] It is therefore in the best interests of both patient and the healthcare organisation to minimise AEs and to develop strategies to reduce their prevalence.

In the UK, risk management standards were established in 1995 and most NHS hospitals established reporting systems as part of their risk management program. The National Patient Safety

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* Corresponding author. Tel.: +447817231147.
E-mail addresses: svgurjar@gmail.com (S.V. Gurjar), shahbazroshan@hotmail.com (S. Roshanzamir), Sandeepp99@doctors.net.uk (S. Patel), gharinath@hotmail.com (G. Harinath).

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Agency (NPSA) is an independent body established in 2001 by the Department of Health (DoH) to co-ordinate the reporting of patient safety incidents and to learn from these incidents so that patient safety within the NHS could be improved.[11] One of its core functions is the National Reporting and Learning Service (NRLS), set up to develop a systematic reporting system for patient safety incidents, as well as compiling confidential annual enquiries into patient outcome and death, maternal and child health, and suicide/homicide in the mentally ill population.

Learning from adverse events and near misses is essential for improving patient safety and standards, so that repetition can be avoided. In the UK, AE reporting is currently undertaken in accordance with the local trust policy. As of April 2010, there will be a requirement for the reporting of serious incidents to the NPSA. To date, anecdotal and published evidence confirms that AE reporting still remains patchy.[12,13] There is limited reporting of incidents arising from clinical treatment, with doctors reporting less than 10% of AEs[14] whilst other healthcare staff are responsible for the bulk of reported AEs.

The aim of this study was to identify all reported general surgery-related AEs that occurred in a typical District General Hospital in south-east England, to determine their characteristics, causality and what steps might be taken to minimise their repetition.

2. Methods

This study retrospectively assessed all reported AEs relating to acute and elective inpatient general surgical admissions in a typical district general hospital in the south-east of England over a five-year period. This hospital dealt with almost 5000 acute and elective general surgical admissions annually, with seven full-time consultant surgeons who offered general surgical care. The hospital had in place an active policy of adverse event reporting, as part of its overall strategy of risk management.

Over a five-year period from April 2002 to March 2007, all general surgical AEs that occurred in a clinical environment and had been formally documented by use of the hospital's 'Adverse Incident Report Form', were retrospectively reviewed. The study included all adult emergency and elective admissions with a documented minimum inpatient hospital stay of 24 h. Paediatric AE's were excluded due to small numbers.

Clinical incident forms contained mandatory data fields, with space for free text, to allow for a fuller explanation of the nature of the adverse incident. Once an adverse incident form was completed and signed by a line manager, it was passed on to the Risk Management team for data entry and analysis. A trained member of the risk management team reviewed the reported AE and graded it for severity using the Datix® Common Classification System (CCS) for incidents in healthcare.

The categorisation of incident severity is summarised in Table 1. A clinical incident is defined as "any event that has given or may give rise to actual or possible personal injury, patient dissatisfaction, or to property loss or damage" (NHS Risk Management Standard, Oct 2001). Near misses are defined as "an occurrence which but for luck or skilful management, would in all probability have become an incident". They are AEs that could have led to harm but did not. Serious such events are termed 'serious near misses' and incidents that might have been category 4 incidents. No injury defined as clinical incidents, which delayed patient discharge, but no actual harm occurred.

The Medical Director was informed of all serious incidents (Category 3a, 4, and 4b incidents). He would determine the level of investigation to be undertaken, and whether the AE warranted the involvement of the Chief Executive or relevant Clinical Director. In exceptionally serious or high impact incidents, the Chief Executive would involve the Trust Chairman or Trust Board.

All AE data supplied by the Risk Management Team was entered onto an Excel® spreadsheet and analysed without adjustment for age, sex or prevailing co-morbidity. Total general surgical admissions occurring each fiscal year over the five-year period was also determined for the purposes of analysis. All AEs were individually classified by discussion between the lead authors into five main root causes: surgery/theatre-related, medical (including medication problems & non-surgery related medical mishaps), nursing & allied healthcare related errors, communication and administrative error (the latter category included delays and bed shortages).

3. Results

A total of 24,185 general surgical admissions took place during which 461 reported AEs [1.9% mean rate; 95% CI, 1.3%–2.5%]. Table 2 reveals the annual rates over the five-year period of the study.

AE categorisation by incident severity is shown in Table 3. Of the 461 incidents, the vast majority (84.8%) were 'no injury' or 'near miss' events. 10% of incidents resulted in non-significant injury. Reported events included care management failures such as failure to monitor a patient appropriately, incorrect risk assessment, faulty management, failure to seek help and administering of the wrong treatment. Ten events were category 4 or 4b events (2.2% of all events). These included patients being mistakenly booked in for removal of the incorrect limb or breast, delay in senior staff attending to deteriorating patients, and inadequate early management of a deteriorating patient despite early warning signs.

Examination of all AEs revealed their breakdown by root cause analysis, as shown in Fig. 1.

- Communicative or administrative error - a failure in appropriate communication or efficient and accurate administration resulting in an adverse event. Eg. A patient being missed on the ward round - 239 AEs (52%)
- Nursing-related issues - a failure to maintain appropriate nursing standards resulting in an adverse event. Eg. An incorrect blood product being given to a patient by nursing staff on the ward - 102 AEs (22%)
- Surgery/theatre-related failures - An adverse event occurring within or due to the theatre environment but not being due to an administrative or communicatve failure. Eg. Unforseen complications during an operation or procedure - 52 AEs (11%)

Table 1
Categories of incident severity.

Category	Severity
0	Ungraded/awaiting grading
1	Near miss
2	No injury
3a	Significant injury
3b	Non-significant injury
4	Death or very serious incident
4b	Serious near miss

Table 2
Surgical admissions, adverse events & AE rate.

Year	Total admissions	No of AE's	AE Rate %
2002/3	5493	103	1.9
2003/4	4497	51	1.2
2004/5	3938	108	2.7
2005/6	5045	126	2.5
2006/7	5212	73	1.4
Total:	24185	461	Mean AE rate: 1.9%