THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1219 ISSN 1175 8716

Representative case series from public hospital admissions 1998 II: surgical adverse events

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Abstract

Aims. To examine a representative case series of surgical adverse events in New Zealand public hospitals with a view to assessing their occurrence, causation, patient impact and preventability.

Methods. An analysis was carried out on 326 surgical adverse events classified by reviewing physicians. These were identified from among 850 adverse events determined by two-stage retrospective review of a representative sample of 6579 medical records drawn from 13 public hospitals in 1998.

Results. From the four surgical categories—operative, fracture management, therapeutic, and system—there were 326 surgical adverse events, 38.4% of all adverse events identified. Surgical events had the same profile as adverse events overall. Four-fifths of surgical events were directly related to a surgical operation; these affected older patients and were less preventable than adverse events overall. A third of operative events were attributable to technical problems, another third to infections, with the remainder divided between haemorrhagic and cardiovascular complications.

Therapeutic and system events had high preventability, and a significant proportion was related to delay in treatment. Half of events in fracture management were infection-related, patients were younger and, system events apart, had fewer extra bed days than other surgical events or events overall. The major causes of preventable events were avoidable delay in treatment (19.9%) and inadequate monitoring and supervision (13.6%), followed by personnel practising outside their expertise (8.0%) and inappropriate treatment (7.4%).

Conclusions. On average, surgical events are associated with an extra 9.9 days in hospital, but they have a lower level of preventability than adverse events overall. Problems of infection, delay, and other aspects of the quality of care are identified for further consideration.

Adverse events in surgical practice in hospitals are common, are costly, and are a considerable burden. In a review of adverse events occurring in Colorado and Utah hospitals, 60% of such incidents (and more than 12% of hospital deaths) were associated with surgical care.[1]

The impact of these events on patients was high, with nearly one in seven resulting in permanent disability or death. A comparable study of adverse events in hospitals in South Australia and New South Wales had similar findings, with 51% of such incidents associated with surgical care, and one in six resulting in permanent disability or death.[2] Both studies also demonstrated that half or more of adverse events related to surgical care were preventable.

The figures for New Zealand are comparable. The recently completed *New Zealand Quality of Healthcare Study* (NZQHS) examined 6579 medical records using two-stage retrospective review applied to a nationally representative sample of hospital admissions for the calendar year 1998.

Firstly, a random sample of 13 was selected from all 20 public hospitals providing acute care and with over 100 beds (after the exclusion of specialist institutions). Then, secondly, a random sample of admissions (for review) was drawn by systematic list selection from each of the 13 hospitals.

According to the results of that survey, the largest group of adverse events (57.5%) were those related to surgery (including anaesthesiology and obstetrics), with one in eight resulting in permanent disability or death, and nearly a third being highly preventable.[3]

The purpose of this paper is to analyse (in greater depth) that sample of adverse events related to surgery amongst patients admitted to New Zealand public hospitals in 1998. The model to be followed is that of an earlier paper (by the same authors) on drug and related therapeutic adverse events.[4] While (as in the previous paper) the sample is too small for statistical treatment and epidemiological analysis, it is at least representative and provides an opportunity for in-depth clinical insight. Beyond an account of the occurrence of such events, more specific analyses will be provided on the aetiology, impact, and preventability of these events, taking them as being representative of the surgical experience in New Zealand public hospitals.

Methods

The method of data collection used in the NZQHS, as reported elsewhere,[3] was based on that used in the *Harvard Medical Practice Study* (HMPS)[5,6] and the *Quality of Australian Health Care Study*.[7] It involved structured implicit review (that is, the guided exercise of professional judgement) undertaken by specially trained and experienced medical reviewers, of randomly selected hospital records, seeking evidence of potential harm to patients attributable to healthcare management. The study instrument Review Form 2 (RF2) contained evaluative questions that were considered before final determinations were made.[3]

An adverse event (AE) was operationally defined as:

- An unintended injury;
- Resulting in disability; and
- Caused by healthcare management rather than the underlying disease process.

Patient impact was measured by disability defined either as temporary (if it lasted up to a year) or permanent (more than 1 year) impairment of function, or death. Attributable (or added) bed days refer to those extra days associated with an AE that were spent in the study hospital during one or more admissions.

Preventability was assessed as an error in healthcare management due to failure to follow accepted practice at an individual or system level.

Judgements on the degree to which an individual bad outcome was caused by healthcare management, or an individual AE was preventable, were also made. The medical reviewer scored causation and preventability on a scale of 1 to 6, where 1 represents no evidence of causation or preventability, 6 represents virtually certain evidence, and 3 and 4 are on either side of a 50:50 likelihood.[3]

AEs were classified by study reviewers into broad specialties and a number of clinical areas, including ‘operative’, ‘system’, ‘drug’, ‘therapy’, ‘diagnosis’, ‘procedure’, and ‘other’. AEs attributed to surgical activities (except those associated with anaesthesia, obstetrics and neonatal care) are further analysed here, using the data provided by the medical reviewer applying the study instrument RF2. Each AE was identified from patient records and then detailed in the clinical summary portion of the RF2.

Figure 1. Examples of surgical adverse events (AEs)

Technical/haemorrhage:
A patient with myelofibrosis and a huge spleen underwent splenectomy. She was hypotensive in the first few hours after surgery and was returned to operating theatre where a tear in the liver was found and repaired. Subsequently there was acute renal failure, adult respiratory distress syndrome and sepsis requiring prolonged ICU stay and 24 extra hospital days.
Sequence of adverse outcomes beginning with technical problem.
Preventability: moderate.

Postoperative infection:
A 10 year-old presented with 1 day of abdominal pain without fever or leucocytosis. He underwent laparascopic appendicectomy, a normal retro-caecal appendix was removed. Three days later he had severe abdominal pain and laparoscopy revealed peritonitis which was treated with antibiotic. Further abdominal pain and sub-acute bowel obstruction occurred at 6 months and laparoscopy showed multiple adhesions.
Wrong diagnosis of appendicitis led to laparoscopy-induced peritonitis and adhesions.
Preventability: moderate-high.

Inadequate preoperative preparation/system failure:
An elderly patient who had suffered at least 4 serious episodes of acute coronary syndromes requiring hospital admission over the preceding 11 years, was considered to be "stable" before he underwent laparoscopic cholecystectomy. His cardiac medications were continued through surgery. Immediately after the operation he developed atrial fibrillation and was found to have had another myocardial infarction. He recovered after a stay in ICU and an extra 7 hospital days. It was found that he had had a Stress Test in preparation for the operation, it was strongly positive, but the result was not in the notes and had not been sought by the admitting doctor.
Patient unsuitable for surgery, relevant information not filed and not utilised in decision making.
Preventability: high.

Delay:
A young adult, with a past history of quinsy requiring drainage was on the waiting list for tonsillectomy. The index admission was acute severe tonsillitis that needed IV antibiotic and fluids and several days in hospital to settle. In all there were 7 hospital admissions with tonsillitis before tonsillectomy was done.
Long delay for elective surgery.
Preventability: high.

Fracture management:
A 13-year-old girl sustained a distal fracture of radius and ulna in a fall from her horse. This was manipulated under anaesthetic to a satisfactory position, but at check 1 week later the bone ends had slipped and she proceeded to open reduction and internal fixation of the fracture.
Appropriate initial attempt at closed reduction of fracture.
Non-preventable.

The majority of the surgical AEs were 'operative' (that is, events directly related to an operation or occurring in the 30-day postoperative period). These events largely fell into four broad groups: technical problems, infections, bleeding, and cardiovascular complications. Three other areas of clinical application were fracture management, therapeutic (correct diagnosis but inappropriate or delayed treatment), and system-related (equipment or supplies, reporting or communication, training or supervision of personnel, delay, staffing, service functioning, protocol, or other). Clinical examples are shown in Figure 1.

Table 1. Characteristics of adverse events (AEs): patient age, added bed days, level of causation and preventability, and patient impact

Variable	Surgical AEs					All AEs
	Operative	Fracture management	Therapeutic	System	All Surgical AEs*	
Number	258	35	17	16	326	850
Mean age of patient (years)	55.1	42.7	42.9	52.5	53	51.5
Mean added bed days	10.7	3.9	14.5	3.6	9.9	9.3
% High causation†	91.5	88.6	94.1	75.0	90.5	89.2
% High preventability†	15.9	42.9	88.2	62.5	24.9	37.1
Patient impact (%)						
Disability < 1 month	58.5	45.7	58.8	75.0	58.0	61.6
Disability 1–12 months	24.0	25.7	29.4	18.8	24.2	19.1
Permanent disability	11.6	17.2	5.9	0	11.4	10.1
Death	4.3	0	5.9	6.2	4.0	4.5
Unable to determine from medical record	1.6	11.4	0	0	2.4	4.7
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

*Surgical AEs group include operative, fracture management, therapeutic and system AEs. Surgical AEs are a sub-group of all AEs. †Likelihood greater than 50:50; i.e. "more often than not".

Results

Basic information on surgical AEs is presented in Table 1. Of the total 850 events identified in the study, 326 (38.4%) were classified as surgical, 80% of these being operative. Surgical events (as a category) differed little from AEs as a whole when judged on patient age, mean added bed days, patient impact, causation score, or preventability—although fewer were judged to be highly preventable. However, there were variations between clinical areas.

Thus, fracture management and therapeutic categories affected younger patients, fracture management and system added fewer days in hospital (and correspondingly had less impact on patients), and therapeutic and system were more (and operative much less) highly preventable. However, the numbers of cases in these three categories were small and estimates may not have been as reliable as for operative events, which—preventability apart—followed the pattern of events overall more closely.

Operative AEs were divided among four categories—technical problems, infections, bleeding, and cardiovascular complications. These are outlined in Table 2. Technical issues were the highest area of concern, accounting for more than a third of operative AEs (96, 37.5%).

The commonest technical problems were persistence of the initial problem (21, 8.2%); persistent or recurrent bowel dysfunction and abdominal pain (17, 6.6%); damage to organs (10, 3.9%); or persistent anastomotic leaks (9, 3.5%). Infections were the second highest, accounting for slightly more than a third of operative events (88, 34.4%).

Of these, 47 (18.2%) were surgical site infections, of which 34 occurred in clean wounds. There were 16 postoperative chest infections. The 25 other infections were made up of 8 infections in prostheses (4 in hip prostheses, 2 in ventriculo-peritoneal shunts, and 2 other); 6 vaginal and urinary tract infections after gynaecological surgery; 2 cases of *Clostridium difficile* diarrhoea; and 9 individual infective complications.

Significant bleeding was a complication in 34 cases (13.3%), of which 7 were serious (2 related to laparoscopic cholecystectomy, 2 related to joint replacement, and 3 others). Twelve of the bleeds were from ENT surgery—10 tonsillectomies and 2 nose procedures. There were 15 haemorrhages from a range of other operations.

Cardiovascular complications were a particular feature of operations and were noted in 38 instances. Of these, 13 patients suffered perioperative myocardial infarction, of whom 3 died. The average age of these 13 patients was 73.9 years, and they had a mean of 9 added days in hospital. The myocardial infarctions occurred in 8 elective operations; of the acute operations, 2 were fracture fixations.

Nine patients developed heart failure postoperatively, again mostly after elective surgery. Poor fluid management was the feature of this group. There were 6 cerebrovascular events, 2 related to carotid surgery, and 1 to CABG. There were 10 instances of deep venous thrombosis or pulmonary embolism (1 a septic embolus from an infected venous line), 5 related to hip and knee replacement, and 3 to abdominal and pelvic surgery.

Table 2. Distribution of operative adverse events among main categories

Categories	N		%
Technical issues			
Persistence of original problem	21		8.2
Postoperative bowel obstruction, ileus, abdominal pain	17		6.6
Damage to organs	10		3.9
Persistent anastomotic leak	9		3.5
Wound breakdown/hernia	7		2.7
THJR recurrent dislocation	6		2.3
Damage to limb	5		2.0
Bladder obstruction/clots	5		2.0
Miscellaneous	16		6.3
Sub-total	**96**		**37.5**
Infections			
Surgical site infection:	47		18.3
- Clean surgery		34	
- Contaminated surgery		6	
- Uncertain		7	
Pneumonia/chest infection	16		6.2
Other non-wound infection	25		9.8
Sub-total	**88**		**34.4**
Haemorrhage			
Serious bleed:	7		2.7
- Laparoscopic cholecystectomy		2	
- Joint replacement		2	
- Various		3	
ENT operation:	12		4.7
- Tonsils		10	
- Nose		2	
Other bleeds	15		5.8
Sub-total	**34**		**13.3**
Cardiovascular complications			
Myocardial infarction	13		5.0
Pulmonary embolism/DVT	10		3.9
Heart failure	9		3.5
CVA	6		2.3
Subtotal	**38**		**14.8**
Total	**256***		**100**

*2 cases had missing data; CVA=cerebrovascular accident; DVT=deep vein thrombosis; ENT=ear-nose-throat; THJR= total hip joint replacement.

It was not always clear from the clinical summary if thromboprophylaxis was given appropriately, but low preventability scores for this subgroup (mean 2.0) suggests that few management deficiencies were identified.

The surgical therapeutic and system AEs were largely made up of administrative delays in the provision of surgery in both elective and acute situations, rather than delays caused by late diagnosis (Table 3). In 27 cases, there were delays on the waiting list for elective procedures that led to recurrence of the patient's problem and readmission. Nine patients awaiting cholecystectomy had recurrent biliary colic requiring readmission, and 5 patients awaiting vascular surgery (4 CABG and 1 AAA) had further vascular events while on the waiting list. The other 9 patients had a

variety of problems that flared and required readmission, including two patients with incarcerated hernias and 2 with severe recurrent tonsillitis.

Table 3. Two areas of focus: therapeutic and system adverse events (AEs) associated with delays in surgery; fracture management AEs

Therapeutic and system AEs—delays in surgery			
Type of surgery	**N**		**%**
Elective surgery delay			
Recurrence of patient problem and readmission:	27		87.1
- Biliary colic		9	
- Vascular		5	
- Hernia		2	
- Tonsillitis		2	
- Other		9	
Acute surgery delay			
Prolonged hospital stay and disability:	4		12.9
- Spinal compression		1	
- Other		3	
Total	**31**		**100%**
Fracture management AEs			
Type	**N**		**%**
Loss of position, requiring further attention	14		41.2
Non-union	4		11.8
Perioperative infections:	8		23.5
-Bone or wires		3	
-Pneumonia		2	
-Pressure sores		2	
-Skin		1	
Other	8		
Total	**34**		**100%**

There were 5 patients admitted for elective procedures, but who were discharged without operation when operating time ran out and were later readmitted for surgery. There were 4 patients whose acute surgery was delayed, prolonging their hospital stay. One of them, a patient with spinal compression had a 12-hour delay for surgery, which may have contributed to permanent disability.

Fracture management AEs are presented in the lower panel of Table 3. Of these 34 cases, 14 involved problems with maintaining the position of reduced fractures, and required re-manipulation or internal fixation; most of them (10) involving the upper limb.

There were 4 instances of non-union, 8 instances of perioperative infections (3 infections of bone or wires, 2 pneumonia, 2 pressure sores, and 1 skin). The remainder were problems with metalware, delayed service, or ‘sundry other’. This group of patients was younger (42.7 years) than the overall AE group, and had a shorter stay in hospital (3.9 additional days). They had the highest rate of permanent disability of any group (17.1%), however, although it was difficult to separate the disability caused by the initial fracture from that caused by the AE.

Where preventability of any degree was identified, the reviewer was required to indicate what steps might have been taken to secure prevention of an event (see Table

4). In 176 surgical AEs (60%), the reasons for failure to prevent were: avoidable delay in treatment (35, 19.9%); inadequate monitoring or supervision (24, 13.6%); doctor or other health professional practising outside his/her expertise (14, 8%); inappropriate treatment (13, 7.4%); and failure to take precautions to prevent an accidental injury (10, 5.7%).

Table 4. Distribution of preventable surgical adverse events (AEs) by reason for failure to prevent

Reasons for failure to prevent surgical AEs (where preventability is present)	N	%
Avoidable delay in treatment	35	19.9
Inadequate monitoring/supervision	24	13.6
Doctor/other practising outside expertise	14	8.0
Inappropriate treatment	13	7.4
Failure to prevent accidental injury	10	5.7
Patient inadequately prepared	8	4.5
Failure to take adequate history/do examination	7	4.0
Failure to act on result of tests	7	4.0
Other	58	32.9
Total	**176**	**100**

There were 11 deaths in the surgical group, 7 related to operation; they will be reported in another paper.

Discussion

Key findings—Over half of all adverse events identified in a representative survey of admissions to New Zealand public hospitals were associated with surgery. This proportion is very similar to that recorded in comparable US and Australian studies.[1,2] For our analysis, we excluded the anaesthetic, obstetric, and neonatal clinical areas, thereby reducing this proportion to 38%, with four-fifths of these being operative.

The case profile of operative events was very similar to that of AEs taken as a whole, except that average age was higher (55.1 vs 51.5 years) and the proportion of highly preventable events was much lower (15.9% vs 37.1%) (Table 1). Nearly 90% of surgical therapeutic adverse events were highly preventable, as were nearly two-thirds of system incidents, in large part reflecting the influence of delays and other organisational issues.

Patients suffering fracture management AEs were (on average) the youngest among all the groups, and this led to the lower average age for the surgical group compared to the operative alone group. The average age is higher than the 38.9 years in the Colorado and Utah study,[1] but this could be explained by their inclusion of obstetrics within the surgery-related AEs.

The Australian study showed an increase in AE rates with age, and older people had a higher degree of disability or death, and more added bed days.[2] Also, bed days that were attributable to AEs were higher among surgical AEs than all AEs, and there were 7.1 added bed days compared with our study's 9.9 days; this also could be explained by their inclusion of the obstetric group.

Within the operative clinical area, about a third of AEs were due to technical issues, another third were infections, and 28% were made up of haemorrhagic or cardiovascular complications (Table 2), a distribution similar to that recorded in the Colorado/Utah and Australian studies.[1,2]

Technical problems are a diverse group and it is not possible from this study to comment upon technical skill. However, surgical competence comprises more than technical competence: it entails a combination of sound decision-making before, during and after operation; high performance of all the team members; plus the technical skill of the surgeon. Whilst there were isolated examples of what appears to be incompetent operative practice, the areas of decision-making and care seem to provide the best prospects for improvement.

An 'appropriate' operation has been defined as one that can be expected to provide a benefit (e.g. increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) that exceeds the expected negative consequences (e.g. mortality, morbidity, anxiety, or pain related to the procedure; time lost from work).

Unless the benefits of a procedure can reasonably be expected to outweigh the adverse effects by a suitable margin, then the procedure is not indicated.[8–10] The 21 patients where the original problem persisted after surgery may represent inappropriate choice of surgery in the first instance.

There were 13 instances where the reviewer judged the surgical treatment to be inappropriate,[11] and another 14 where a health professional was working outside their area of competence. In surgical practice, the consequence of working outside one's expertise may be more obvious than for a non-procedural specialist. The 14 cases noted here may reflect junior staff assuming (or being given) difficult tasks, being unsupervised, and being in out-of-hours situations.[12]

Some problems may have been related to low case-loads in smaller centres. A considerable number of the problems were anastomotic leaks and other complications after colon surgery. Evidence shows that better outcomes and lower complication rates occur where a surgeon or procedurist handles large numbers of cases.[13,14] The attempt to reach this state of affairs is an important reason behind the closure of small units, concentrating expertise in a few locations.

This study, like that in the US,[1] shows infection to be a very important cause of operative complications; one concerning figure is the number of surgical site infections in apparently clean surgical fields (34 of 47 surgical site infections). There is much still to be learnt about optimal decontamination of surgical fields[15] and optimal use of prophylactic antibiotics. [16] But there is plenty of opportunity for the implementation of infection control procedures already known to be effective.[17,18]

Inadequate assessment before and inadequate monitoring/supervision after surgery were noted as the basis of 24 AEs. Eight patients were inadequately prepared for surgery, resulting in myocardial infarction or heart failure in the perioperative period.

Much is now understood about the hazards of general anaesthesia and surgery for high-risk patients, and the benefit-risk ratio must be carefully considered.[19] Furthermore, pharmacologic prophylaxis may be needed when major non-cardiac surgery is undertaken,[20–22] and, in the symptomatic patient, CABG or coronary angioplasty may need to be performed first.

In perioperative situations, careful nursing observations and early intervention in fluid balance, drug administration, and pain control are vital to the outcome, especially in frail patients and those in high-risk categories. Indeed, inadequate response to deterioration in vital signs was evident in a number of the postoperative AEs.

The biggest group of fracture management problems occurred where the first attempt at fracture reduction produced an unstable result, and then internal fixation often became necessary. In many instances, the initial attempt at reduction was well justified, and only in hindsight was shown to be unsatisfactory. There were some infections in this group, but only three involved bone and metalware, and most were relatively minor.

Delays in the provision of surgery, particularly delays for elective operations, were associated with surgical therapeutic and system AEs. Recurrence of patient problems and readmission were mainly due to delays in the waiting list for elective surgery. Several patients were ready (starved and pre-medicated) for operation when they were discharged from hospital because the operating time had run out. In this study, there were relatively few acute patients whose surgery was significantly delayed, and few where diagnostic delay caused an adverse outcome.

Strengths and limitations—The strength of this study is its nationally representative sample of New Zealand hospitalised patients and its internationally-based methodology. The consistency of certain findings with those of the Australian and American studies also add to its strength.

The documentation in sampled medical records was sufficiently detailed and comprehensive to permit full completion of the study instrument.[3]

The moderate reliability of judgment between reviewers is one of the important concerns about the method of retrospective record review for identifying AEs; this is discussed in an earlier publication.[4]

Also, with the increase of ambulatory surgery, a group of surgical AEs might have been missed—or patients might have received care at a sampled hospital but then been admitted to a non-sampled hospital when a complication occurred.[1]

The small sample of surgical AEs described in this paper is insufficient for statistical analysis; therefore, further research with increased numbers is required.

Interpretation and implications—The study shows that age might be a risk factor for surgical AEs, and that surgical AEs (compared with AEs overall) were slightly more likely to be associated with permanent disability and with more added bed days. Infection, haemorrhage, and cardiovascular events were prominent among the serious outcomes.

The most common failure of prevention was an avoidable delay in treatment, with illness recurring during a lengthy period on a waiting list. Inappropriate surgical management was noted in several cases. Solutions to funding concerns include a proper level of fund allocation, careful use of resource, and avoidance of waste in inappropriate high-cost interventions.

Although more than half of AEs related to surgery were preventable, generally low preventability scores suggest that we have much to learn in the prevention of infectious, haemorrhagic, and cardiovascular complications of surgery. However,

some problems arose where strategies known to be beneficial were not implemented. In the management of complicated postoperative situations, the problem was often an inadequate response to deterioration in vital signs; these are areas where efforts for improvement could certainly be made.

Conclusion

AEs related to surgery are quite frequent and some are preventable; better understanding of the nature of these events and implementing of known prevention strategies may reduce the occurrence of these events and so reduce the impact on patients and the health system.

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Acknowledgements: This study was funded by the Health Research Council of New Zealand. We are very grateful to the 13 New Zealand hospitals that participated in the study as well as Dr David Richmond (Chair) and members of the study's Advisory and Monitoring Committee. We also thank Professor Stephan Schug, Professor Alastair Scott, Sandra Johnson, and Wendy Bingley; our medical review and data processing teams; and hospital records staff.

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