Adverse Events Regional Feasibility Study: indicative findings

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Abstract

Aims. To identify substantive findings of potential clinical and managerial significance from a regional feasibility study of adverse events (AEs).

Methods. A standardised protocol using structured implicit review was applied to 142 AEs generated in an audit study of three public hospitals in the Auckland region for admissions in 1995. Areas of potential significance addressed were: timing, location and impact of AEs; preventability; and clinical context and predictability.

Results. 142 cases were identified as AEs (10.7% of 1326 screened records). In 102 cases, 7.7% of all screened records, it was considered to be more likely than not that health care management contributed to the AE. About half the reported AEs occurred before the index admission, the majority outside hospital. Over half of all events resulted in disability that was resolved within a month. An average 6.7 extra days stay in hospital were attributable to AEs. For 60% of AEs the evidence for preventability was either low or non-existent. Areas of potential prevention were predominantly educational. Over half of all AEs occurred in a surgical context. Medical AEs were more likely to have occurred outside hospital, to be drug-related, to be associated with an acute admission, to be classified as highly preventable, and to have a greater impact on hospital stay.

Conclusions. Although the data generated by a feasibility study must be treated with caution, the pattern of results is consistent with comparable Australian findings and is of potential clinical and managerial significance.

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The subject of patient safety, and the quality of health care, has gained increasing momentum. Although it has been over a decade since the publication of the first authoritative estimates of adverse events (AEs) in the Harvard Medical Practice Study (HMPS),[1] within the last eighteen months there has been a report on patient safety from the Institute of Medicine[2] and an issue of the British Medical Journal devoted to medical error.[3] Other journals have also canvassed the question[4-6] and studies on AEs and medical error have been published in other developed countries.[7,8] The matter has also gained attention in the United Kingdom because of highly-publicised incidents, such as the Bristol affair.[9]

Interest in patient safety has also been evident in Australia, with some of the earliest work published on anaesthesia-related mortality.[10] The first broad-based and representative investigation using internationally standardised and clinically generic procedures of AE determination was the Quality in Australian Health Care Study (QAHCS).[11]

In New Zealand the question of patient safety has, to date, been little researched. The methodological results from a feasibility study designed to test the application of such standardised epidemiological techniques in the New Zealand setting is reported in the preceding article.[12] This article presents some key substantive findings from the feasibility study that may be of clinical and managerial significance. These relate to the timing, location and impact of AEs, their preventability, and their clinical context and predictability.

Methods

Sampling and data collection. Three major public hospitals were selected for study in the Auckland region. The survey population was defined as all patient admissions to these hospitals for calendar year 1995 (excluding day and psychiatric cases). Fuller details on sampling are provided in the preceding paper.[12]

Standard hospital inpatient information for each sampled admission was provided by NZHIS. This included admissions information (dates of admission and discharge, admission type and source), socio-demographic data (age, gender, ethnicity, domicile code), and clinical data (ICD9 and AN-DRG3.1 diagnostic classifications).

The core data collection procedure of the study was a two-stage retrospective review of medical records for selected cases using the Review Form 1 (RF1) and Review Form 2 (RF2), both closely modelled on the comparable instruments in the American and Australian studies. In two of the three hospitals an Expert Reviewer (ER) administered "blind" the full cycle of data collection on a one-in-ten sub-sample. Fuller details on data collection are provided in the preceding paper.[12]

Definitions.[11] An AE was defined as (a) an unintended injury or unintended complication, (b) resulting in temporary or permanent disability, including increased length of stay and/or financial loss to the patient, (c) that was caused by health care management rather than the underlying disease process.

Disability was defined as: temporary, lasting up to a year, or permanent impairment of function; death; or prolonged hospital stay even in the absence of impairment.

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

Potential for prevention of recurrence of particular AEs was assessed by MO reviewers identifying broad 'areas of effort'.

Because of the small size of the sample – 142 AEs – no formal statistical analysis is used in this paper. Any evaluative judgements applied to patterns in the data, therefore, while they may be suggestive of clinical or managerial relevance, do not imply statistical significance.

Results

Frequency. Of 1575 medical records sampled, and allowing for missing and excluded data, 515 were screened criteria positive and went on to medical review.[12] Of these, 142 cases were identified as AEs (10.7% of all screened records). In 102 cases, 7.7% of all screened records, it was considered to be more likely than not that health care management contributed to the AE.

Timing, location and impact. Information on the timing, location and impact of adverse events is presented in Table 1. Looking at all AEs, about a half occurred before the sampled (index) admission and an extra 6.7 days was added to hospital stay. A third of all AEs took place outside a public hospital (mostly in ambulatory settings) and had a greater than average effect in lengthening hospital stay. Over half of all events occurring before the index admission took place outside a public hospital. AEs occurring inside hospital and

during the index admission had least impact on length of hospital stay.

Table 1. Distribution of AEs – by location and timing of occurrence.

Location	Before index admission		During index admission		All AEs	
	Percent	Mean ABD*	percent	Mean ABD	Percent	Mean ABD
Inside Hospital	42.3%	8.9	100%	4.5	68.3% (n=97)	6.1
Outside Hospital	57.7%	8.0	-	-	31.7% (n=45)	8.0
	100%		**100%**			
All AEs	54.9% (n=78)	8.4	45.1% (n=64)	4.5	**100% (n=142)**	6.7

*Attributable bed days in the study hospital, spent over one or more admissions associated with an AE.

The effect of AEs on the health status of patients is assessed in Table 2. For most patients - more than half - any disability suffered as a result of an AE resolved within a month. The impact on hospital workload - as measured by attributable bed days (ABD) - increased noticeably for more severe and more long-term disability.

Table 2. Impact of AEs – disability status by hospital stay.

Disability	Percent (n=142)	Mean ABD*
Minimal < 1 month†	56.3%	4.1
Moderate 1-12 months	20.4%	11.0
Permanent ≤50%	3.5%	23.4
Permanent >50%	2.1%	27.5
Death	6.3%	3.9
Unable to tell	11.3%	4.3
All AEs	100%	6.7

*Attributable bed days in the study hospital, spent over one or more admissions associated with an AE. †Period of disability.

Preventability. Information on reviewer assessments of the preventability of AEs is presented in Table 3. In a third of cases the reviewers judged there to be virtually no evidence of preventability. For another third of cases the evidence was weak to equivocal, while for the remainder the judgement of preventability was much more definitive.

Table 3. AEs – Attribution of preventability.

Preventability*	Frequency	Percent
1. Virtually no evidence	45	31.7%
2. Slight to modest evidence	27	19.0%
3. Close call, <50:50	14	9.9%
4. Close call, >50:50	25	17.6%
5. Moderate/strong evidence	22	15.5%
6. Virtually certain evidence	8	5.6%
Missing	1	0.7%
All AEs	**142**	**100%**

*Categories 4, 5 and 6 are classified as 'high' preventability.

In Table 4, 'areas of effort' - that is, the potential for the prevention of recurrence - are considered alongside impact and preventability. The largest category identified by reviewers was improved education, followed by improved resources, quality assurance, communication, and systems reorganisation. The area with the greatest adverse impact was poor quality assurance, while the area with the highest level of preventability was systems error. Improved education was the largest category for prevention, but its profile was an average one for both impact and preventability.

Table 4. Prevention of recurrence – areas of effort by impact and preventability.

Area for Attention*	% All AEs	%Perm. disability /death	Mean ABD†	% High preventability
Education	41.6% (59)	13.6%	6.9	61.0%
Resources	10.6% (15)	13.3%	6.7	66.7%
Quality assurance	9.2% (13)	30.8%	10.2	61.5%
Communication	9.2% (13)	23.1%	7.5	61.5%
System	6.3% (9)	11.1%	6.5	88.9%
Other	14.8% (21)	4.8%	9.9	66.7%
All AEs	100% (n=142)	12.0% (n=17)	6.7	38.7% (n=55)

*More than one area could be chosen. †Attributable bed days in the study hospital, spent over one or more admissions associated with an AE.

Clinical context and predictability. Reviewers classified AEs according to specialty and area of clinical application. This information, together with other features of clinical context, is presented in Table 5. Overall, AEs were reasonably evenly distributed across medicine and surgery. Operative and drug-related incidents were the commonest clinical areas involved. The former were more characteristic of surgery and of AEs internal to hospital, the latter of medicine and of AEs external to hospital. Events classified in medicine were also more likely – when compared (conservatively) to AEs overall - to occur outside hospital, to be associated with an acute admission, and to have co-morbidity present.

Table 5. Specialty and clinical area.

	AEs Occurred		All AEs	Specialty		
	Inside hospital	Outside hospital		Surgery*	Medicine†	Other‡
	68.3% (n=97)	31.7% (n=45)	100% (n=142)	51.4% (n=73)	44.4% (n=63)	4.2% (n=6)
Clinical Area§						
Operative	33.3%	9.6%	25.5% (40)	47.0%	1.4%	
Drug	12.4%	36.5%	20.4% (32)	7.2%	37.7%	
System	16.2%	17.3%	16.5% (26)	15.7%	17.4%	
Other¦¦	38.1%	36.5%	37.6% (59)	30.1%	43.5%	
Total mentions	100%	100%	100% (157)	100%	100%	
% of AEs: Outside Hospital			31.7%	12.3%	50.8%	
% of AEs: Transfer admission			7.0%	8.2%	4.8%	
% of AEs: Acute admission			68.3%	48.0%	92.1%	
% of AEs: Co-morbidity present			47.2%	39.7%	55.6%	

*Includes all surgical specialties plus anaesthesiology and obstetrics. †Includes all medical specialties plus psychiatry and paediatrics. ‡Includes dentistry/oral surgery, dietary, hospital physical plant, midwifery, nursing, pharmacy, occupational therapy, physiotherapy, podiatry, transportation support services, speech/language therapy. §An AE in a particular clinical area could be additionally classified as 'system'. ¦¦Therapy, procedures, diagnosis, falls, fractures, obstetrics, neonatal, or anaesthesia; each area contained <10% of mentions.

The impact and preventability of AEs by specialty and clinical area are shown in Table 6. Incidents classified in medicine tended to have a greater effect on hospital stay and were seen as more highly preventable than surgical AEs. Drug-related events had a greater impact on bed days, and systems errors were seen to be more preventable.

Table 6. Impact and preventability - by specialty and clinical area.

		% permanent disability/death	Mean ABD*	% High Preventability
All AEs	**(n=142)**	12.0% (n=17)	6.7	38.7% (n=55)
Specialty				
Surgery	(n=73)	8.2%	6.0	24.7%
Medicine	(n=63)	14.3%	7.7	56.5%
Other	(n=6)	33.3%	5.6	33.3%
Clinical Area†				
Operative	(n=40)	7.5%	5.7	20.0%
Drug-Related	(n=32)	15.6%	8.4	43.8%
System	(n=26)	19.2%	7.0	76.0%
Other	(n=59)	10.2%	6.4	42.2%

*Attributable bed days in the study hospital, spent over one or more admissions associated with an AE. †An AE in a particular clinical area could be additionally classified as 'system'.

Discussion

Many of the key substantive findings outlined in this paper are not only of potential clinical and managerial significance; they also add to confidence in the overall study because of their consistency with the comparable Australian results. For example, about half of AEs occurred before admission, a high proportion of events were regarded as not preventable, the great majority of events resulted in disability that was temporary, but resulted in an average of just under seven extra days hospital stay. These are all findings of intrinsic clinical and policy interest, but they are also of an order of magnitude comparable with results generated in QAHCS.[11]

There are other findings reported here that were relatively unanticipated and that invite further attention. For example, a third of all AEs occurred outside the hospital setting. Similarly, and related to this, there appeared to be a pattern of drug-related events, many of which occurred outside hospital. Furthermore, routinely-collected hospital data showed some predictive power, with over 90% of medical AEs and about half of surgical AEs associated with an acute admission.

These two findings - the importance of adverse drug events (ADEs) and the possibilities of administrative data - provide examples, respectively, of potential clinical and managerial significance. They have been reported elsewhere in the literature and underline the potential for further development in these areas. Thus, Bates et al evaluated fifteen screening criteria for their sensitivity and specificity in predicting AEs, preventable AEs, and serious AEs.[13] Although no set of administrative data was particularly sensitive - that is, able to predict a high percentage of AEs - using such data was much less costly than other methods of detection. Similarly with ADEs; a high proportion are preventable.[14] Data of this kind in turn can lead to a search for causes.[15]

In conclusion, this feasibility study has generated substantive results that not only engender confidence in the methodology - being generally consistent with findings reported from other studies - but are also of potential clinical and managerial application.

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