

ADVERSE EVENTS
IN NEW ZEALAND
PUBLIC HOSPITALS:
PRINCIPAL FINDINGS
FROM A NATIONAL
SURVEY

Professor Peter Davis
Roy Lay-Yee
Dr Robin Briant
Professor Stephan Schug
Professor Alastair Scott
Sandra Johnson
Wendy Bingley

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ADDRESS FOR CORRESPONDENCE:

Professor Peter Davis
Department of Public Health and General Practice
Christchurch School of Medicine and Health Sciences
University of Otago
PO Box 4345, Christchurch, New Zealand
Phone: +64-3-3640-631
Fax: +64-3-3640-425
Email: Peter.Davis@chmeds.ac.nz



Published by the Ministry of Health, Wellington, New Zealand
PO Box 5013 Wellington
<http://www.moh.govt.nz>
December 2001
ISBN 0-478-26265-5 (Booklet)
ISBN 0-478-26268-X (Internet)

HP 3485

FOREWORD

At a recent Quality Improvement Workshop for District Health Boards, Don Berwick challenged participants to seek out data to help them improve the quality of health care. He emphasised that waiting for data to be good enough is a hallmark of a system using data measurement for judgement, with an inspection orientation, rather than being focused on improvement. In a learning system, people should look forward to what the data could tell us. We encourage readers throughout the New Zealand health sector to approach this study with a learning perspective.

Key results from this study are that 4.5 percent of all admissions in New Zealand public hospitals were associated with highly preventable adverse events; adverse events increase average hospital stays by nine days; 20 percent of the adverse events originated outside the hospital; patient age is a key risk factor; and medication practices invite further review.

The consistency of the findings with those of studies undertaken in Australia and Britain, rather than fostering complacency, should encourage further review of systems and health care at all levels.

Initiatives are being taken throughout the sector to reduce the impact of adverse events. Recently the Ministry of Health issued *Reportable Events Guidelines* that provide guidance on processes and systems for organisational reporting, management and investigation of incidents, accidents and hazards. The Government is introducing changes to improve complaints processes and to ensure health professionals retain their competence as part of a comprehensive bill to address safety and quality in the health sector.

We support the publication of the *Adverse Events in New Zealand Public Hospitals: Principal Findings from a National Survey* study as a valuable contribution to increasing understanding of adverse events, and as a stimulus for further research and efforts to improve the quality of health care.



Robert Logan (Dr)
Chair NHC



Karen O Poutasi (Dr)
Director-General of Health

ADVERSE EVENTS IN NEW ZEALAND PUBLIC HOSPITALS: PRINCIPAL FINDINGS FROM A NATIONAL SURVEY

Peter Davis, Professor, Department of Public Health and General Practice, Christchurch School of Medicine, University of Otago, Christchurch.

Roy Lay-Yee, Analyst, Division of Community Health, Faculty of Medical and Health Sciences, University of Auckland, Auckland.

Robin Briant, Clinical Director, Division of Community Health, Faculty of Medical and Health Sciences, University of Auckland, Auckland.

Stephan Schug, Professor, Department of Anaesthesia, University of Western Australia, Perth.

Alastair Scott, Professor, Department of Statistics, University of Auckland, Auckland.

Sandra Johnson, Manager, Centre for Clinical Research and Effective Practice, South Auckland Health, Auckland.

Wendy Bingley, Data Manager, Division of Community Health, Faculty of Medical and Health Sciences, University of Auckland, Auckland.

NEW ZEALAND QUALITY OF HEALTH CARE STUDY

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Dr Ian Brown

Marion Jones

Dr Anne Kolbe

Dr Andrew Love

Dr Colin McArthur

Arapera Ngaha

Jocelyn Peach

Henri Van Roon

Dr Margaret Wilsher

STUDY TEAM

Professor Peter Davis (Director)

Dr Robin Briant (Principal Investigator)

Professor Stephan Schug (Principal Investigator)

Professor Alastair Scott (Principal Investigator)

Sandra Johnson (Project Manager)

Wendy Bingley (Data Manager)

Roy Lay-Yee (Analyst)

Lisa Fellowes (Support Staff)

ACKNOWLEDGEMENTS

Work on this study was funded by the Health Research Council of New Zealand.

We are very grateful to the 13 New Zealand public hospitals that participated in the study and to Professor David Richmond, Chair, and members of the study's Advisory and Monitoring Committee. We thank our medical review and data processing teams for their meticulous work and hospital records staff for their willing co-operation. Valuable comments were contributed by Dr Gillian Durham, Dr Ashley Bloomfield, Dr Robert Logan, Professor Robert Gibberd, Dr Phil Hider, two anonymous reviewers and the Chief Executive Officer of one of the participating hospitals.

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ABSTRACT

OBJECTIVES: To assess the occurrence, impact and preventability of adverse events recorded in New Zealand public hospitals.

METHODS: A two-stage retrospective review was carried out on 6,579 medical records. These were selected by systematic list sample from admissions for 1998 occurring in 13 public hospitals throughout New Zealand providing acute care and with over 100 beds, excluding specialist institutions. Following initial screening, medical records were subject to structured implicit review (that is, the guided exercise of professional judgement) by a team of trained medical officers using a standardised protocol.

RESULTS: The information available in the sampled medical records was of a quality that permitted the adequate identification and analysis of adverse events. The processes and instruments used in comparator studies internationally were applied in the New Zealand setting with little difficulty. Reliability and validity measures displayed only moderate levels of agreement, however. Analysis of the 850 adverse events identified revealed a distribution, impact, and clinical context comparable with other studies. Adverse events (which may have occurred either within or outside public hospitals) were associated with 12.9 percent of admissions. Approximately 35 percent of adverse events were classified as highly preventable. Although less than 15 percent of adverse events resulted in permanent disability or death, an average of over nine days per event was added to hospital stay. Nearly a fifth of events originated from outside public hospitals, only a quarter of which arose in another institutional context. Patient age was an important risk factor for an adverse event. There were distinct patterns according to clinical and administrative context. Systems errors featured prominently in the analysis of areas for the prevention of recurrence.

CONCLUSIONS: The study provides the base parameters necessary to inform our understanding of patient safety and the quality of care in New Zealand public hospitals. These data have important managerial and clinical implications. Further work could be done on sub-groups of patients and on the clinical detail available in the data. The investigation provides a baseline for more targeted studies and for quality improvement interventions. It also points to the importance of similar research on the sources and characteristics of adverse events outside public hospitals.

1. INTRODUCTION

The subject of patient safety, and the quality of health care, has gained increasing momentum internationally as a major focus of attention in professional and health policy circles. This has been highlighted within the last two years by the report on patient safety from the Institute of Medicine in the United States,¹ the devotion of an entire issue of the *British Medical Journal* to medical error,² and at least two high-profile reports on aspects of patient safety in the National Health Service.^{3,4} Adding to the level of public interest in the United Kingdom have been a number of individual instances, such as the Bristol incident.⁵

Interest in patient safety has also been evident in Australia. Some of the earliest work in this area was published on anaesthesia-related mortality recorded in the late 1960s,⁶ but the first broad-based and representative scientific investigation using internationally standardised and clinically generic procedures of adverse event determination was the Quality in Australian Health Care Study (QAHCS).⁷ In parallel with epidemiological research of this kind, voluntary incident-monitoring studies have continued with implications for clinical risk management.⁸

In New Zealand the question of patient safety has, to date, been the subject of relatively little systematic research. One of the first studies to use a standardised, epidemiological approach was a survey of adverse drug events among over 9,000 admissions to Dunedin hospital in the early 1970s.⁹ The overall frequency of adverse drug reactions resulting in mortality or morbidity was three per 100 patients. While useful research since that time has been carried out on surgical audit¹⁰ and anaesthetic error,¹¹ and while the Ministry of Health has published standardised information across New Zealand hospitals using risk-adjusted mortality and re-admissions indices,¹² no generic, epidemiological

data on adverse events have been published in this country. The absence of such data has been recognised as an obstacle to developing proposals for the regulation of safety in health and disability in New Zealand.¹³ More recently the Ministry has identified credentialling as an important step towards securing patient safety and clinical excellence.¹⁴

A major scientific stimulus to rigorous epidemiological research on patient safety was the development of standardised procedures for the assessment of adverse events using medical records. Important early advances in developing the concept of adverse events were made by Schimmel,¹⁵ and Mills.¹⁶ However, it was not until the Harvard Medical Practice Study (HMPS) that a measurably reliable, valid and generic definition of adverse events was first established across a wide range of clinical settings.¹⁷ This procedure was based on the application of two-stage retrospective review to a sample of medical records. This methodological approach was tested for its applicability in both the British,¹⁸ and Australian⁷ contexts, and has further been tested for its feasibility in New Zealand.^{19,20} This approach provides the basis for the current study.

2. METHODS

This section outlines the principal methodological features of the study. Firstly we outline the overall research design and sample selection strategy. This is followed by an outline of the key data collection and field-work arrangements. Specific empirical issues of data quality and adverse event determination are described in subsequent sections. More detailed treatment of key methodological aspects of the study are provided in Appendices A1–A6. This report aims to be descriptive and no formal statistical testing has been used.

2.1 RESEARCH DESIGN AND SAMPLE SELECTION

Ethics Committee approval was gained on the understanding that the data were anonymised, that it would be impractical to contact patients whose medical records were sampled, and that the overall public benefit of the study outweighed any possible intrusion into patient and practitioner privacy.²¹ Coverage was also obtained for the study under Part VI of the Medical Practitioners' Act 1995, thus bestowing legal protection from disclosure on the data generated by the study. The study was the first application to the Ministry of Health under this provision. All hospitals that were approached agreed to participate in the study.

Medical records were drawn from a nationally representative sample of 13 public hospitals selected from amongst 20 institutions with 100 or more beds (see Appendix A1). The survey population was defined as all patient admissions for calendar year 1998 (excluding day, psychiatric, and rehabilitation-only cases). The New Zealand Health Information Service (NZHIS) selected a random sample of 575 admissions from each of the sampled 13 hospitals for the year 1998. The selected time of admission for sampled cases signalled an index admission (the sampled admission) and provided the point of reference in adverse event (AE) determination.

To be included in the study an AE must:

- (1) have occurred at any time before the index admission and been detected during, or be responsible for, the index admission, *or*
- (2) have occurred during and been detected during the index admission, *or*
- (3) have occurred during the index admission and been detected on a subsequent admission (see Appendix A2).

It should be noted that detection here refers to the original detection of the injury by health care professionals.

An AE could have occurred in the study hospital, another hospital or community settings. The full medical record associated with each index admission was analysed for the occurrence of an AE.

An AE was operationally defined as (1) an unintended injury, (2) resulting in temporary or permanent disability, including increased length of stay and/or financial loss to the patient, and (3) caused by health care management rather than the underlying disease process. Each of these criteria needed to be fulfilled in turn to ascertain whether an AE had occurred.

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; and/or financial loss to the patient.

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.

'System' was defined in two different contexts according to the study protocol. Firstly, an AE could be classified into 'clinical areas' including whether it was a result of 'system error' due to defective equipment/supplies, equipment/supplies not

available, inadequate reporting/communication, inadequate training or supervision of doctors/other personnel, delay in provision/scheduling of services, inadequate staffing, inadequate functioning of hospital services, or no protocol or failure to implement a protocol/plan. Secondly, in relation to areas where effort could be directed to prevent AE recurrence, 'system areas' encompassed policies/protocols, access to/transfer of information, communication, discharge procedures/protocols, organisation management/culture and record-keeping.

In order to assess the representativeness of the sample, the distribution of key patient characteristics were compared with the pattern for all New Zealand public hospital admissions in 1998 (Table 2.1). It should be noted that the data in this study represent an approximately 1 in a 100 sample of all publicly funded hospitalisations. The sample medical records were closely representative of all New Zealand public hospital admissions in a number of key demographic and clinical characteristics, including age, gender, ethnic group, discharge status and mortality. Length of stay in the sample appears to be shorter than the average for all publicly funded hospitalisations in New Zealand for 1998.

Table 2.1 Patient characteristics in public hospitals 1998

Patient characteristics	Sample (screened)	New Zealand*
Number of inpatient admissions [‡]	6,579 [#]	699,095
Mean age (years)	42.6 years	40.3 years
Males (%)	45.1	43.5
Māori (%)	15.4	14.3
Routine discharge (%)	91.6	92.1
Deaths (%)	1.8	1.7
Mean hospital stay (days)	5.1	6.9

* All publicly funded hospitalisations in New Zealand, i.e. may include private hospital admissions (source: New Zealand Health Information Service).

‡ Excludes day and psychiatric patients.

Excludes specialist public hospitals, public hospitals with under 100 beds, and rehabilitation-only patients.

2.2 DATA COLLECTION AND FIELD-WORK

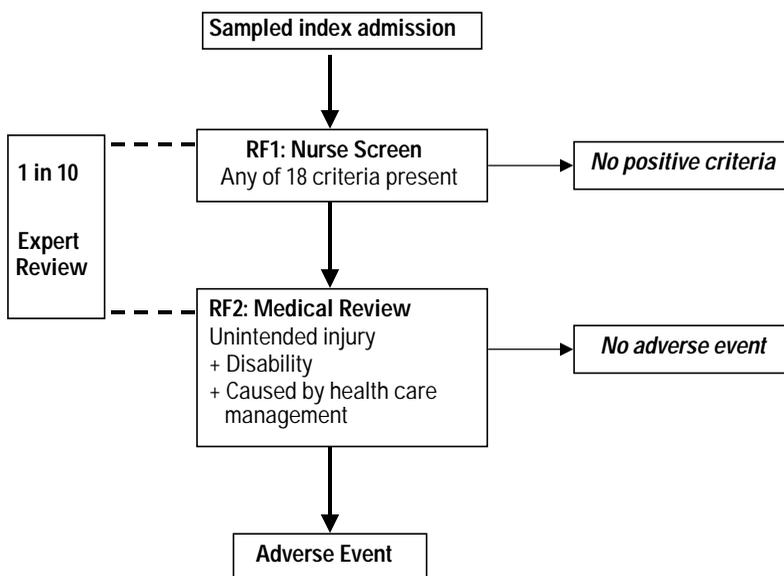
Standard hospital inpatient information for each sampled admission was provided by NZHIS. This included admissions information (dates of admission and discharge, admission type, i.e. planned or acute, and admission source, i.e. routine or transfer from another hospital), socio-demographic data (age, gender, ethnicity, domicile code), and clinical data (diagnostic classification).²² NZDep96* deciles were derived from patient domicile codes as a measure of residential area deprivation.²³

* NZDep96 is an area-based index of socio-economic deprivation, which measures the level of deprivation for each meshblock by combining variables from the 1996 census – income, access to a car, living space, home ownership, employment status, qualifications, support, and access to a telephone.

Principal diagnosis or reason for admission was classified according to 25 Major Diagnostic Categories (MDCs) derived from AN-DRG 3.1.^{#22}

The core data collection procedure of the study was a two-stage retrospective review of a representative sample of medical records from each selected hospital, using the Review Form 1 (RF1) and Review Form 2 (RF2) study instruments. Both of these were closely modelled on the comparable instruments in the American and Australian studies (Figure 2.1).

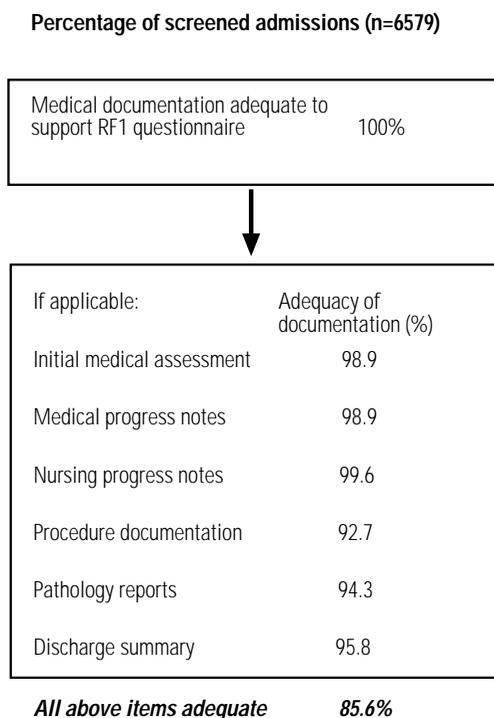
Figure 2.1 Two-stage retrospective review



[#] AN-DRG 3.1 is a system of classifying episodes of inpatient care into clinically meaningful groups with similar resource consumption (Diagnosis-Related Groups or DRGs).

The first stage was the RF1 screen undertaken by the Registered Nurses (RNs). The purpose of this stage was to ascertain if the hospitalisation in question – the index (or sampled) admission – met any of 18 screening criteria selected as potentially indicative of an AE. Figure 2.2 addresses the adequacy of medical records for the screening stage of data collection. For over 85 percent of all sampled records, the available information was sufficient to complete all aspects of the RF1. The remainder, however, were still sufficient to determine criteria presence and thus all records were adequate to support completion of the RF1 questionnaire.

Figure 2.2 Quality of screening data – adequacy of medical records for Registered Nurse screening



Any record showing a positive result on one or more of these criteria was forwarded for full Medical Officer (MO) review. Just over 60 percent of records were forwarded to the second stage (Table 2.2). In over half these cases an ‘unplanned admission (including readmission) as a result of any health care management’ before the index admission was a defining criterion. Virtually all records referred for medical review were coded positive on the first two criteria in the list.

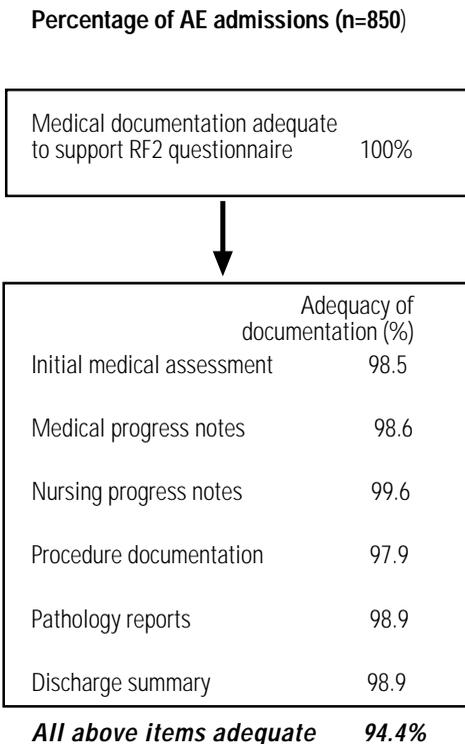
Table 2.2 The 18 criteria used in the RF1 form – the percentage of medical records positive for each criterion (n=6579)

Criteria*	Positive (%)
1. Unplanned admission before index admission	35.0
2. Unplanned readmission after discharge from index admission	23.8
3. Hospital incurred patient injury	5.2
4. Adverse drug reaction	4.2
5. Unplanned transfer from general care to intensive care	4.4
6. Unplanned transfer to another acute care hospital	1.6
7. Unplanned return to the operating theatre	1.5
8. Unplanned removal, injury or repair of organ during surgery	2.6
9. Other patient complications	2.5
10. Development of neurological deficit not present on admission	0.8
11. Unexpected death	1.1
12. Inappropriate discharge to home	2.9
13. Cardiac/respiratory arrest, low Apgar score	1.2
14. Injury related to abortion or delivery	8.6
15. Hospital-acquired infection/sepsis	4.8
16. Dissatisfaction with care documented in medical record	2.5
17. Documentation or correspondence indicating litigation	0.3
18. Any other undesirable outcomes not covered above	18.1
Total screened positive by RNs	62.6

* More than one criterion could be identified by a screener for any given medical record.

The second stage undertaken by trained and experienced MOs used the RF2, an instrument relying on structured implicit review (that is, the guided exercise of professional judgement). The objective of this exercise was to determine whether the index admission was associated with an AE and, if so, to then characterise that AE according to key clinical criteria. Figure 2.3 outlines information on the quality of the review data. For nearly 95 percent of all medical records classed as AEs, the available information was sufficient to complete all aspects of the MO review. For the remainder, all were sufficient to determine whether an AE had occurred.

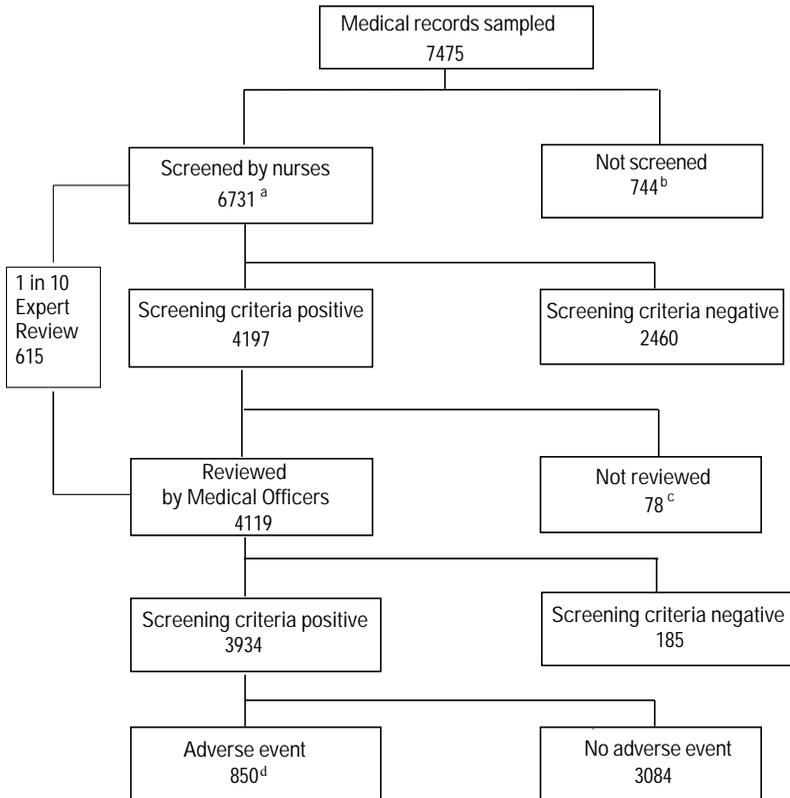
Figure 2.3 Quality of review data – adequacy of medical records for medical officer reviewing



Field-work was conducted over the period from the beginning of July 1999 to the end of May 2000 by a team of four RN screeners and three or four MO reviewers overseen by the Project Manager. An Expert Reviewer arbitrated on discrepant judgements (where a RN and an MO disagreed) and carried out an independent review of a sub-sample of selected medical records. Before the commencement of data collection, field workers undertook an intensive training course. Data collection took place over a period of three weeks at each hospital. Each sampled case was allocated a study identification number so that identifiers allowing linkage to hospital records could be deleted to maintain patient anonymity.

At the heart of this work was the determination of whether or not an AE had occurred. Of the original 7,475 records selected, 744 were not screened for a variety of reasons (including wrongly sampled, record not found, current inpatient). The evaluation of the 6,579 records that comprise the sample is shown in Figure 2.4. An AE was identified in 850 / 6,579 patient records, a rate of 12.9 percent (see Appendix A3).

Figure 2.4 The review process



a Includes 74 linked double admissions.

b Includes:

(i) 613 eligible: 190 missed by nurse, 122 inadequate documentation, 109 current inpatient, 72 record not found, 69 index admission missing, 51 mother/baby record missing;

(ii) 131 ineligible: 81 boarding mother/baby, 37 rehab only, 5 day stay, other 8. Screening success rate = $6731/(7475-131) = 6731/7344$.

c Includes 73 current inpatients, 5 missed by Medical Officers.

d Adverse event rate = $850/(6731-74-78) = 850/6579$.

2.3 DATA MANAGEMENT AND QUALITY CONTROL

Routine quality checks were carried out to improve the quality of information gathered. During both the screening and review stages, forms were checked for completeness and adequacy. During the review stage, RN and MO discrepancies in judgement of criteria presence or AE determination were checked and if necessary forwarded for adjudication to the Expert Reviewer. At the stage of data entry from the completed forms, standard checks for invalid, out-of-range, inconsistent and missing data were used to identify errors. Where medical knowledge was necessary, the Expert Reviewer was consulted.

The inter-rater reliability²⁴ of the judgements on the same cases made by screeners and reviewers was assessed according to the measure of their agreement with each other (see Appendix A4).

The concurrent criterion validity²⁴ of the judgements on the same cases made by screeners and reviewers was assessed according to the measure of their agreement with an Expert Reviewer who carried out blind screening/reviewing of a one in ten randomly selected sub-sample of admissions (see Appendix A4).

2.4 ADVERSE EVENT DETERMINATION

An AE was operationally defined as an unintended injury which resulted in temporary or permanent disability, including increased length of stay and/or financial loss to the patient, and which was caused by health care management rather than the underlying disease process (see Appendix A5).

Examples of common and special occurrences are described in Appendix B.

In order to assist reviewers to judge the degree to which an unintended injury with disability/prolonged stay was caused by health care management, they were guided through a series

of seven evaluation questions. Health care management causation was scored as follows: 1 = virtually no evidence, 2 = slight to modest evidence, 3 = close call (less likely than not), 4 = close call (more likely than not), 5 = moderate or strong evidence, 6 = virtually certain evidence. The full protocol – RF2 – was administered to the 850 cases that were determined to be associated with an AE (AE causation score 2 to 6), and the analysis that follows focuses on these. It is notable that 651 of these showed likely, moderate/strong or virtually certain evidence of management causation (AE causation score 4 to 6); in other words, the majority of AEs considered in this study are ones about which reviewers were highly confident in attributing health care management causation.

3. DISTRIBUTION OF ADVERSE EVENTS

Key findings:

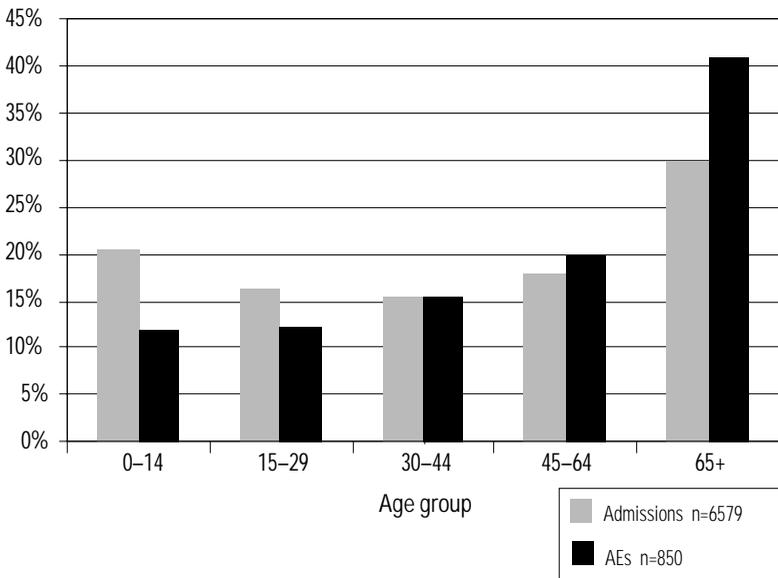
- (1) Adverse events (AEs) were associated with 12.9 percent of admissions.
- (2) AEs were found disproportionately among patients over the age of 65, but were otherwise distributed as expected by deprivation, gender, and ethnic group.
- (3) About half all AEs occurred before the sampled (index) admission and a fifth took place outside a public hospital (mostly in an ambulatory setting).
- (4) Patients experiencing AEs stayed in hospital nearly twice as long as average.

At the core of this study is the assessment of AEs. In this section the distribution of AEs is considered, first by socio-demographic attributes of patients and secondly by the clinical and administrative characteristics of events.

3.1 SOCIO-DEMOGRAPHIC FACTORS

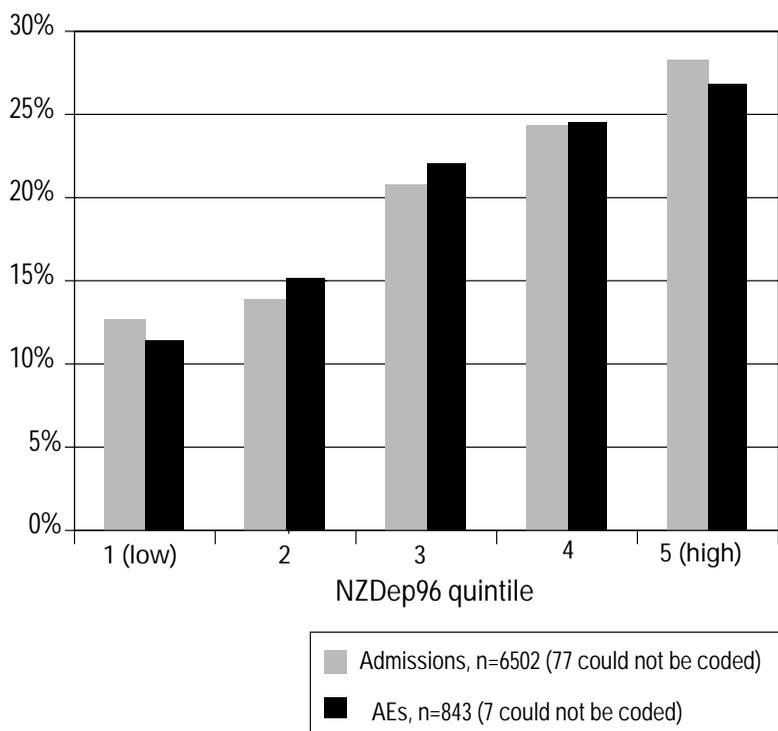
In this section the distribution of AEs is considered against the socio-demographic pattern of the full sample of admissions. AEs were found disproportionately among patients over the age of 65; thus, while a third of admissions were in this category, this was true of about 40 percent of AEs (Figure 3.1). The reverse pattern was evident for patients under the age of 30; that is, proportionately more admissions and correspondingly fewer AEs.

Figure 3.1 Distribution of admissions and adverse events, by age group



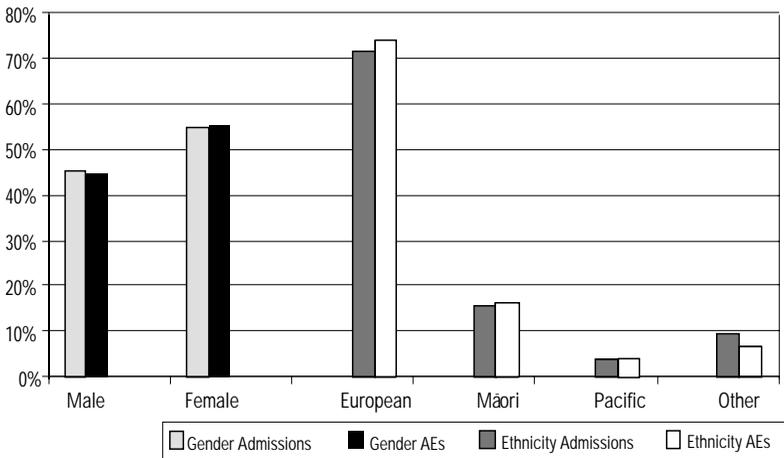
A different picture emerges in the analysis by the deprivation characteristics of the patient's area of residence (Figure 3.2). Although patients from deprived areas were strikingly over-represented – approximately 25 percent in the sample distribution as against the expected 20 percent – there is little evidence of any discrepancy between the distributions of AEs and admissions.

Figure 3.2 Distribution of admissions and adverse events, by area deprivation score



In the analysis of gender and ethnic group there is similarly little evidence of any marked discrepancy between the distributions of admissions and AEs (Figure 3.3). The ethnic distribution of both admissions and AEs closely mirrored that of the population – over 70 percent European, 15 percent Māori, and smaller proportions for Pacific and Other.

Figure 3.3 Distribution of admissions (n=6579) and adverse events (n=850), by gender and ethnic group



3.2 EVENT CHARACTERISTICS

Information on the timing and location of AEs is presented in Table 3.1. About a half of all AEs occurred before the sampled (index) admission, and a fifth took place outside a public hospital, mostly in ambulatory settings. A substantial proportion, nearly two-fifths, of AEs occurring before the index admission took place outside a public hospital (generally ambulatory).

Table 3.1 Distribution of adverse events, by location and timing of occurrence

Location	Before index admission (n=437)	During index admission (n=413)	All AEs (n=850)
Inside Public Hospital	61.8%	100%	80.4%
Outside Public Hospital	38.2%	0	19.6%*
	100%	100%	
All AEs	51.4%	48.6%	100%

* Doctor's office 6.4%, ambulatory care unit 1.3%, home 5.3%, rest home 3.8%, private hospital 2.0%, other 0.9%.

In Table 3.2 admissions and AEs are presented by major diagnostic category (MDC), ordered according to percentage of admissions. AEs seemed to be over-represented in injury-related and in musculoskeletal MDCs, but seemed less common in birth-related admissions. Otherwise the distributions of AEs and admissions closely mirrored each other.

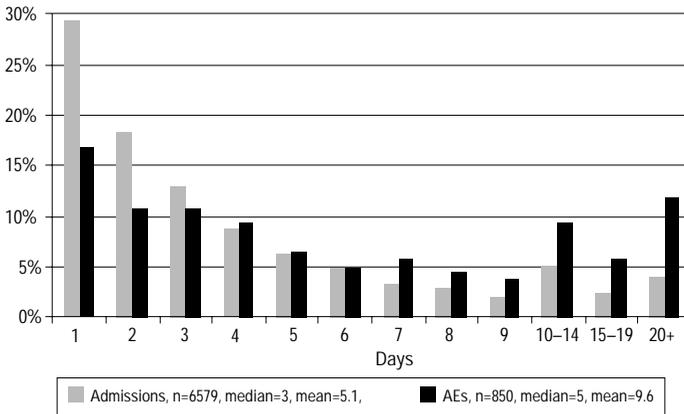
Table 3.2 Distribution of admissions and adverse events, by major diagnostic category (MDC)

MDC*	Admissions (%)	AEs (%)
Circulatory system	13.4	13.5
Musculoskeletal system	11.3	17.7
Pregnancy, childbirth	11.2	6.6
Digestive system	10.1	11.7
Respiratory system	8.6	6.0
Newborns/neonates	7.4	4.0
Nervous system	6.5	4.9
Skin, tissue & breast	3.9	3.9
Kidney and urinary tract	3.7	4.9
Injuries, poisonings & drugs	3.3	6.5
Other (remaining 15 MDCs)	20.7	20.4
Total	100% (n=6579)	100% (n=850)

* Ordered according to percentage of admissions.

The effect of AEs on hospital workload is considered in Figure 3.4, which shows the distribution of bed days (length of stay) related to the index admission for all admissions compared with those admissions associated with an AE. Patients experiencing AEs tended to stay longer in hospital – approximately twice as long – with median and mean stays of 5 and 9.6 respectively, compared with the overall sample figures of 3 and 5.1. While nearly a third of admissions lasted only a day, this was true for little over half that proportion of AEs; conversely, less than 5 percent of admissions lasted 20 days or longer, against over a tenth of AEs.

Figure 3.4 Distribution of admissions and adverse events, by length of stay for index admission



4. IMPACT OF ADVERSE EVENTS

Key findings:

- (1) For nearly half of all affected patients the hospital stay in its entirety was due to the AE.
- (2) Most patients suffered an impairment judged to be minimal, but on average an extra nine days were spent in hospital due to the AE.
- (3) AEs seemed to have greater impact among older patients and for some clinical categories (for example, respiratory and nervous system disorders).
- (4) AEs occurring outside public hospitals had greater than average impact.

The crucial feature of AEs – and what makes them of clinical and managerial significance – is their impact on patients and on the workload of the health care system. This section outlines, first, the basic dimensions of AE impact and secondly its distribution by socio-demographic and event characteristics.

4.1 DISABILITY STATUS AND HOSPITAL STAY

In considering the impact of AEs on the patient, three dimensions of AEs are assessed – the proportion of hospital stay affected, the impact on patient health status, and attributable bed days (i.e. the number of total bed days in the study hospital, spent over one or more admissions, associated with an AE) (Table 4.1). For nearly half of all patients affected, hospital stay was attributable in its entirety to the AE; for just over 15 percent there was no apparent effect. Although most patients – about 60 percent – suffered an impairment that was judged to be minimal (lasting less than a month), over nine extra days on average were spent in hospital due to an AE. The extent of impairment that patients suffered was also related to the characteristics of hospital stay.

Thus, patients assessed as suffering a greater impairment were reported as having on average more bed days attributable to the AE, and as also being more likely to experience a hospital stay due in its entirety to the AE.

Table 4.1 Impact of adverse events – disability status by hospital stay

Disability	AEs (%)	Entire hospital stay due to AE* (%)	Attributable bed days per AE# mean (median)
Minimal <1 month*	61.6	45.8	4.7 (3)
Moderate 1–12 months	19.0	45.7	13.8 (8)
Permanent ≤50%	7.9	67.2	23.8 (13)
Permanent >50%	2.3	57.9	38.7 (35)
Death	4.5	31.6	11.5 (4)
Unable to determine from medical record	4.7	47.5	11.6 (7)
All AEs (n=850)	100	47.2	9.3 (4)

* Hospital stay related to the Index Admission; for 15.4% of AEs none of hospital stay was due to the AE; for 37.4% of AEs a portion of hospital stay was due to the AE.

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

* Period of disability.

4.2 SOCIO-DEMOGRAPHIC FACTORS AND EVENT CHARACTERISTICS

The analysis of the distribution of AEs has already demonstrated that among certain groups (such as patients over the age of 65) AEs are more common. Table 4.2 displays attributable bed days (ABDs) and levels of permanent disability (including death) by age group, gender, ethnic group, and area of deprivation. The most consistent pattern evident in the table is that for age group; AEs associated with permanent disability or death are more prevalent among older patients. There was an indication of a similar trend by deprivation. ABDs also seemed to be patterned by age group.

Table 4.2 Impact of adverse events, by age group, gender, ethnic group and area deprivation score

	Permanent disability and death (%)	Mean attributable bed days per AE*
Age group		
0–14	6.9	11.0
15–29	1.9	3.6
30–44	10.9	6.7
45–64	21.3	10.6
65+	18.8	10.9
Gender		
Male	16.3	10.5
Female	13.2	8.4
Ethnic group		
European	16.0	9.6
Māori	10.4	9.2
Pacific	9.4	6.2
Other	12.3	8.6
Area deprivation score (quintile)		
1	8.3	8.8
2	14.1	8.1
3	16.2	10.0
4	15.0	9.7
5	16.3	9.4
All AEs (n=850)	14.5	9.3

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

Table 4.3 outlines the distribution of two impact criteria by MDC. Using the criterion of permanent disability and death, respiratory and nervous systems showed markedly higher impact. Digestive system and kidney and urinary tract were also above average. Some, but not all, of these categories also showed higher than average ABDs.

Table 4.3 Impact of adverse events, by major diagnostic category (MDC)

MDC*	Permanent disability and death (%)	Mean attributable bed days per AE [#]
Nervous system	28.6	8.7
Respiratory system	23.5	8.9
Digestive system	19.2	14.6
Kidney and urinary tract	19.1	11.5
Circulatory system	17.4	9.0
Musculoskeletal system	16.7	11.2
Skin, tissue and breast	6.1	6.8
Pregnancy, childbirth	3.6	2.5
Injuries, poisonings and drugs	3.6	7.9
Newborns/neonates	2.9	3.5
Other (remaining 15 MDCs)	12.1	9.0
All MDCs (n=850)	14.5	9.3

* Ordered according to % permanent disability and death.

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

Finally, the assessment of AE impact by location of occurrence is shown in Table 4.4. In general, AEs occurring outside a public hospital were associated with a hospital stay that was slightly lengthier, more likely to be due to the AE in its entirety, and slightly more likely to produce a greater impairment.

Table 4.4 Impact of adverse events, by location of occurrence

	Inside public hospital	Outside public hospital*
Mean attributable bed days [#]	9.1 days	10.1 days
% Entire hospital stay due to AE	39.1%	80.2%
% Minimal disability (less than 1 month)	63.0%	56.3%
% Moderate disability (1–12 months)	19.0%	19.2%
% Permanent disability and death	13.9%	17.4%
% Remainder [†]	4.1%	7.1%
	100%	100%

* Mostly in ambulatory settings.

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

† Reviewers unable to determine level of disability from medical record.

5. PREVENTABILITY OF ADVERSE EVENTS

Key findings:

- (1) In a third of cases reviewers judged there to be virtually no evidence of preventability.
- (2) There were few clear patterns in the distribution of preventable AEs. However, there seemed to be a higher proportion among older patients, in some clinical categories, and among AEs occurring outside public hospitals.
- (3) In identifying 'areas of effort' to prevent recurrence, system factors, consultation and education together accounted for nearly three-quarters of AE mentions assessed by study reviewers.

A key consideration with AEs is the extent of their preventability. This section canvasses various dimensions of this issue ranging from the assessment of preventability, through the distribution of preventable AEs, to the potential for corrective action.

5.1 THE ASSESSMENT OF PREVENTABILITY

AEs were assessed by the MO reviewers for the extent of preventability (Table 5.1). As in the case of AE determination, so in attributing preventability reviewers were required to work through a series of preparatory questions and then to estimate the extent to which they believed a given AE could have been prevented (see Appendix A6). In a third of cases the reviewers judged there to be virtually no evidence of preventability. For another two-fifths of cases the evidence was weak to equivocal, while for the remainder the judgement of preventability was much more firm.

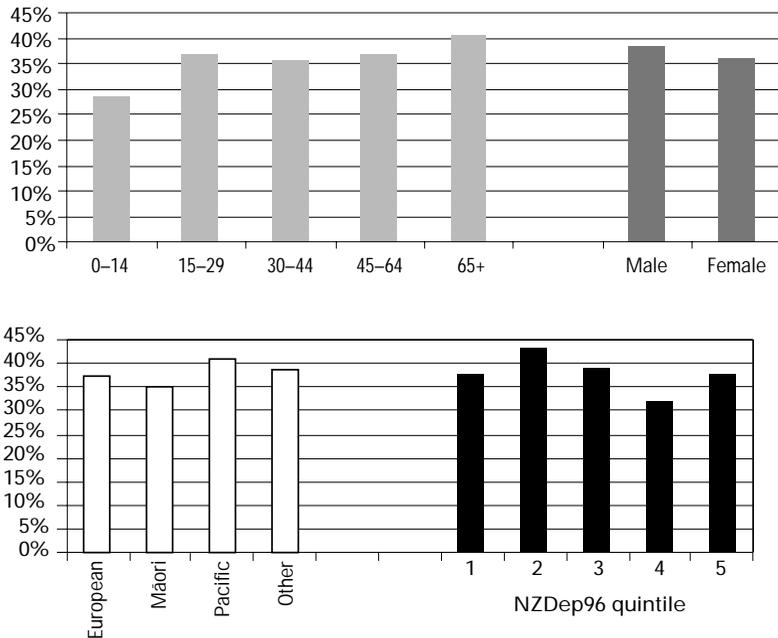
Table 5.1 Adverse events – attribution of preventability

Preventability score	Frequency	Percentage
1. Virtually no evidence	319	37.5
2. Slight to modest evidence	143	16.8
3. Close call, <50:50	73	8.6
4. Close call, >50:50	135	15.9
5. Moderate/strong evidence	132	15.5
6. Virtually certain evidence	48	5.6
Total adverse events	850	100

5.2 THE DISTRIBUTION OF PREVENTABILITY

In this section the preventability of AEs is considered according to socio-demographic factors and key event characteristics. In Figure 5.1 the relationship between patient characteristics and preventability is assessed. Few clear patterns emerged here. While there appeared to be a slight tendency for the proportion of highly preventable AEs to increase with age, few other trends were evident in the data.

Figure 5.1 High preventability (score 4–6), by age group, gender, ethnic group and area deprivation score



When considered by major diagnostic category there were some indications that preventability varied according to clinical circumstances (Table 5.2). Thus, digestive, respiratory, skin, tissue and breast MDCs appeared to have higher than average levels of preventable AEs, while birth-related categories had lower than average levels.

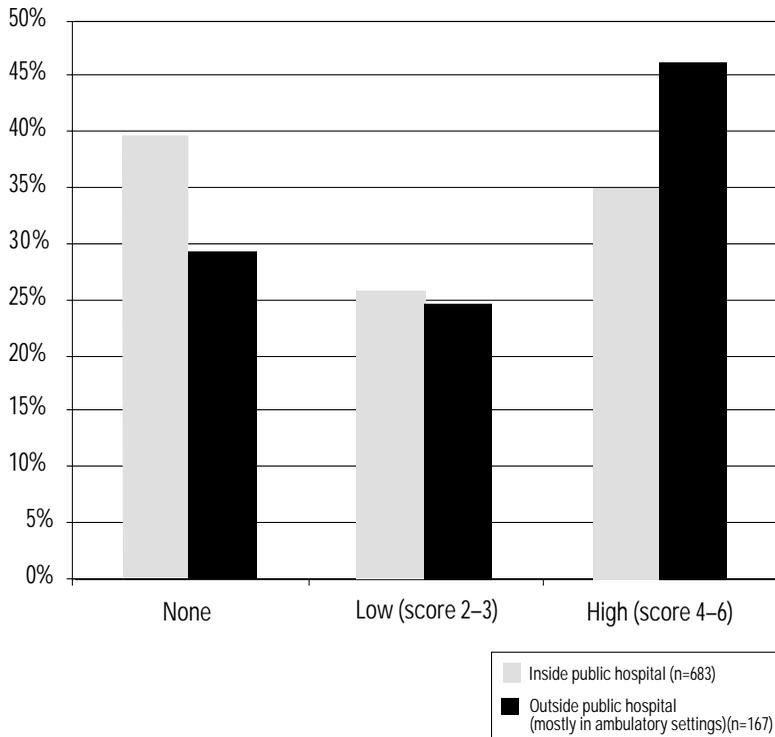
Table 5.2 High preventability (score 4–6), by major diagnostic category (MDC)

MDC*	High preventability (%)
Digestive system	49.5
Skin, tissue and breast	48.5
Respiratory system	47.1
Circulatory system	41.7
Nervous system	35.7
Kidney and urinary tract	35.7
Musculoskeletal system	32.0
Injuries, poisonings and drugs	29.1
Pregnancy, childbirth	19.6
Newborns/neonates	11.8
Other (remaining 15 MDCs)	39.9
All MDCs (n=850)	37.1

* Ordered according to % high preventability.

Finally in assessing AE characteristics it appears that incidents occurring outside public hospitals had a greater chance of being classified as highly preventable – nearly half – while 40 percent of incidents inside hospital were classified as not preventable (Figure 5.2).

Figure 5.2 Adverse events – preventability by location of occurrence



5.3 THE POTENTIAL FOR PREVENTION

An essential aspect of the assessment of the preventability of AEs was the potential for preventing the recurrence of such incidents. In Table 5.3 'area of effort' is considered alongside impact and preventability. The largest category identified by reviewers was system, followed by consultation and education. These three categories accounted for nearly three-quarters of all AE mentions. There were no strong patterns evident on impact and preventability. The categories of consultation, resources, system and 'other' showed higher than average proportions of AEs resulting in permanent disability or death. In this grouping there was also evidence of longer hospital stay. For preventability quality assurance also featured.

Table 5.3 Prevention of adverse event recurrence – areas of effort by impact and preventability

Area for attention*	All AEs (n=850) (%)	Permanent disability and death (%)	Mean attributable bed days [†]	High preventability (score 4–6) (%)
System [#]	30.8	15.7	10.9	63.0
Consultation [†]	21.4	20.3	11.1	69.2
Education	18.0	13.1	8.8	75.8
Resources [‡]	9.9	15.5	16.6	53.6
Quality assurance	6.9	11.9	6.7	67.8
Other	12.8	15.6	9.7	48.6
Total		14.5	9.3	37.1

* The percentage for each area is the percentage of all 850 AEs; more than one area could be identified so the percentages do not add to 100%.

[†] Bed days in the study hospital, spent over one or more admissions, associated with an AE.

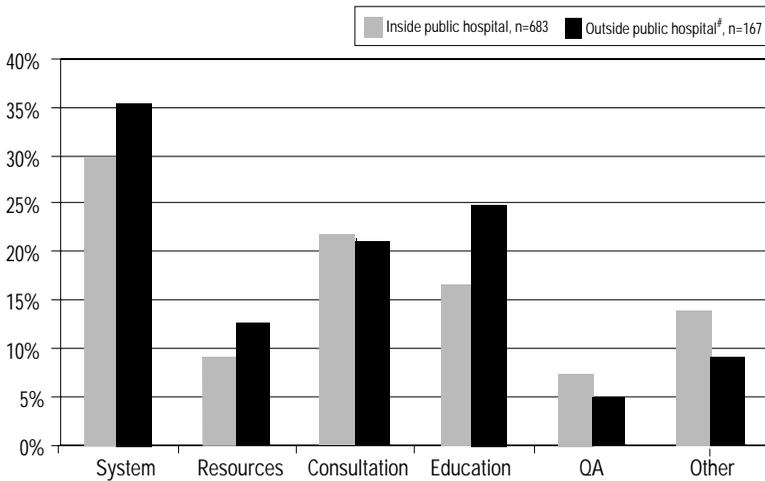
[#] Policies/protocols, access to or transfer of information, communication, discharge procedures/protocols, organisation management/culture, record-keeping, other.

[†] Consultation with specialists or peers.

[‡] Personnel, equipment/other physical resources, other.

Considering 'area of effort' and location (Figure 5.3), there seemed to be no apparent pattern, although system and education issues were slightly more prominent for AEs occurring outside a public hospital.

Figure 5.3 Prevention of recurrence – areas of effort* by location



* Percentage of all AEs, more than one area could be identified.

Mostly in ambulatory settings.

6. CLINICAL AND ADMINISTRATIVE CONTEXT OF ADVERSE EVENTS

Key findings:

- (1) Over half of the AEs were associated with surgery, most of them predictably operative incidents. A third of the remainder were recorded in medicine, with drug events being characteristic.
- (2) AEs classified in medicine were nearly twice as likely than average to occur outside a public hospital, more likely to be associated with an acute admission, to have greater impact on patients, and to be more preventable.
- (3) Among screening criteria, unplanned admission and readmission accounted for most cases and were also reasonably predictive of an AE. Age and certain diagnostic criteria were also predictive. Of the three administrative variables considered, none had any useful predictive power in identifying AEs.

This section considers the clinical and administrative context in which AEs occurred. Firstly, in the course of the assessment of AEs medical reviewers identified clinical features of these incidents. Secondly, an important objective of the study was to determine the extent to which information available either from routinely collected hospital data or from the review form could assist in the understanding of AEs.

6.1 CLINICAL CONTEXT – SPECIALTY AND CLINICAL AREA

Reviewers classified AEs according to specialty and area of clinical application (Table 6.1). Over half of AEs were associated with surgery. Operative and system-related incidents were the commonest clinical areas involved, with the former being naturally characteristic of surgery and the latter – together with drug events – being commoner in medicine.

Table 6.1 Specialty and clinical area

Clinical Area*	Specialty			All AE mentions (%)
	Surgery [#] (%)	Medicine ² (%)	Other ^{**} (%)	
Operative	42.4	0.8	4.9	24.3
System [†]	20.6	26.1	38.3	24.0
Drug	2.4	30.0	0	12.3
Therapy [‡]	6.6	11.9	4.9	8.4
Diagnosis	6.1	12.1	2.5	8.0
Procedure	4.6	13.7	2.5	7.7
Other [§]	17.4	5.4	46.9	15.3
Total mentions	100	100	100	100 (n=1060)
All AEs	57.5	35.7	6.8	100 (n=850)

* % of mentions. A 'mention' refers to an instance where a reviewer identified a particular clinical area. Clinical areas are mutually exclusive except that 'system' may be identified alone or additional to another clinical area, e.g. an AE could be classified as both 'operative' and 'system' thus contributing two mentions. Note that the total number of mentions is greater than the total number of AEs.

[†] Defective equipment or supplies; equipment or supplies not available; inadequate reporting or communication; inadequate training or supervision of doctors/other personnel; delay in provision or scheduling of services; inadequate staffing; inadequate functioning of hospital services; no protocol / failure to implement protocol or plan; other.

[‡] Correct diagnosis but inappropriate or delayed treatment.

[§] Falls, fractures, obstetrics, neonatal, or anaesthesia.

[#] Includes all surgical specialties plus anaesthesiology and obstetrics.

² 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.

Features associated with AEs are presented by specialty in Table 6.2. AEs classified in medicine were nearly twice as likely than average to occur outside a public hospital, and more likely to be associated with an acute admission.

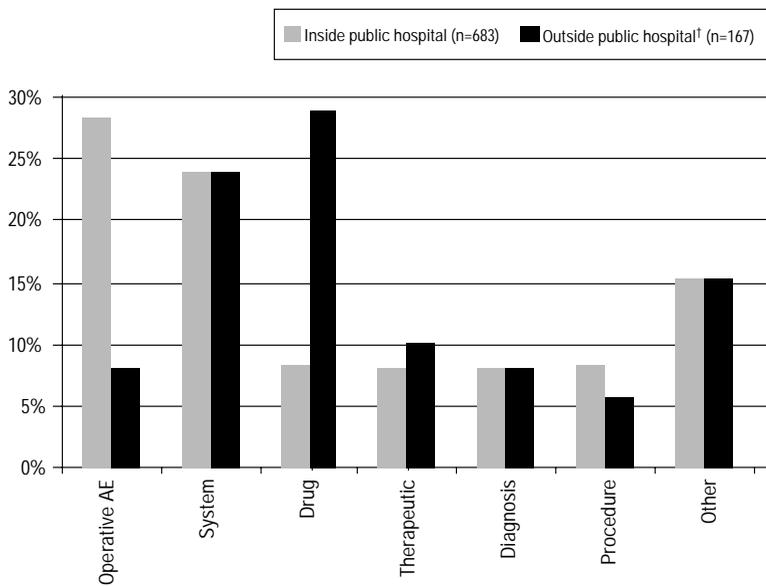
Table 6.2 Specialty, by location of occurrence, admission source and admission type (n=850)

	Outside public hospital* (% of AEs)	Transfer admission (% of AEs)	Acute admission (% of AEs)
Total	19.6	5.7	66.1
Specialty			
Surgery (n=489)	6.3	4.7	55.0
Medicine (n=303)	34.3	6.9	82.8
Other (n=58)	55.2	6.9	72.4

* Mostly in ambulatory settings.

The distribution of AEs across clinical areas varied considerably by location (Figure 6.1). Operative incidents were more characteristic of AEs occurring within hospital, while drug-related events were features of cases outside public hospital (principally ambulatory and community-based).

Figure 6.1 Distribution of adverse events, by clinical area*



* % of all mentions; system may be identified alone or additional to another clinical area.

† Mostly in ambulatory settings.

The impact and preventability of AEs by specialty and clinical area are assessed in Table 6.3. Incidents classified in medicine (and 'other') tended to have a greater adverse impact on patients, to require a longer stay in hospital, and to be more highly preventable. Systems errors tended also to follow this pattern. Operative incidents were much less likely to be judged highly preventable, whereas system errors were more likely to be judged highly preventable.

Table 6.3 Impact and preventability, by specialty and clinical area

	Permanent disability and death (%)	Mean attributable bed days per AE*	High preventability (score 4–6) (%)
Total (n=850)	14.5	9.3	37.1
Specialty			
Surgery (n=489)	12.1	8.8	30.1
Medicine (n=303)	18.5	9.9	46.2
Other (n=58)	15.5	10.3	48.3
Clinical area[#]			
Operative (n=258)	15.9	10.7	15.9
Drug-Related (n=130)	12.3	7.8	43.9
System (n=254)	16.1	9.7	70.5
Other (n=418)	14.8	9.3	46.2

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

[#] System may be identified alone or additional to another clinical area.

6.2 CLINICAL CONTEXT – SCREENING CRITERIA

In the course of initial data collection screeners assessed medical records for key signs potentially predictive of an AE. These screening criteria referred to significant clinical aspects of the case. As such they may provide insights into the prediction of AEs. This possibility is considered in Table 6.4 where univariate odds ratios for the predictive power of screening criteria are outlined. These values were estimated by logistic regression and represent the relative likelihood that an AE has occurred, without controlling for any other variables in the data set.

Table 6.4 Clinical indicators – univariate odds ratios for association with an adverse event

18 Screening criteria (reference=no criterion present)	AEs positive (%) (n=850)	Odds ratio (AEs vs 5729 non-AEs)		
		All AEs (n=850)	In hospital* AEs (n=683)	Preventable, [#] in-hospital AEs (n=413)
1. Unplanned admission before index admission	54.7	2.56	2.27	2.56
2. Unplanned readmission after discharge from index admission	41.6	2.67	2.98	3.18
3. Hospital incurred patient injury	16.6	5.44	5.71	6.99
4. Adverse drug reaction	13.3	5.27	4.56	4.41
5. Unplanned transfer from general care to intensive care	10.6	3.27	3.44	3.30
6. Unplanned transfer to another acute care hospital	2.8	1.98	2.16	2.39
7. Unplanned return to the operating theatre	6.9	10.10	12.33	11.37
8. Unplanned removal, injury or repair of organ during surgery	7.1	3.84	4.52	2.85
9. Other patient complications	9.8	7.36	8.52	7.70
10. Development of neurological deficit not present on admission	2.7	4.95	5.65	3.97
11. Unexpected death	2.2	2.50	2.62	3.27
12. Inappropriate discharge to home	7.5	3.59	3.94	4.21
13. Cardiac/respiratory arrest, low Apgar score	3.2	3.58	3.98	3.55
14. Injury related to abortion or delivery	8.0	0.91	1.09	0.54
15. Hospital-acquired infection/sepsis	18.5	7.89	9.38	8.62
16. Dissatisfaction with care documented in medical record	6.1	3.27	3.54	3.51
17. Documentation or correspondence indicating litigation	1.2	6.81	5.92	4.19
18. Any other undesirable outcomes not covered above	40.8	4.01	4.01	4.27

* AE occurred inside public hospital, healthcare management score 2–6.

Preventability score 2–6.

The strongest odds ratios in the table are those associated with screening criteria that describe events closely linked with adverse clinical circumstances – hence, unplanned return to the operating theatre, patient complication, hospital-acquired infection, and evidence of litigation. However, these refer to a tiny proportion of cases and many occur after the fact of adverse clinical outcomes. Hospital-incurred patient injury and adverse drug reaction were other strong predictors that are close to clinically adverse outcomes. Unplanned admission and readmission accounted for most cases referred for medical review in the study, and were predictive of AEs. It is also notable that there was little variation in the value of odds ratios across the three columns; in other words, regardless of whether we consider all AEs, those occurring within hospital, or preventable AEs within hospital, the predictive power of screening criteria remained the same.

6.3 ADMINISTRATIVE CONTEXT – PREDICTIVE VALUE OF NZHIS DATA

A similar approach is adopted with the data available in the patient record from the NZHIS. Again, a logistic regression analysis was run to estimate univariate odds ratios (Table 6.5). Variables from the NZHIS data set (a subset of the National Minimum Data Set) were grouped into three: socio-demographic (age, gender, ethnicity, area deprivation), admission (type and source), and diagnosis.

Table 6.5 Hospital inpatient variables – univariate odds ratios for association with an adverse event

Hospital inpatient variables	Odds ratio (AEs vs 5729 non-AEs)		
	All AEs (n=850)	In-hospital* AEs (n=683)	Preventable,# in-hospital AEs (n=413)
Age			
Reference is 0–24 years	1.00	1.00	1.00
30–64 years	1.70	1.60	1.91
65+ years	2.30	1.89	2.25
Gender			
Reference is Female	1.00	1.00	1.00
Male	0.98	0.96	0.93
Ethnicity			
Reference is European and Others	1.00	1.00	1.00
Māori	1.05	1.20	1.13
Pacific	1.05	1.13	1.38
Area deprivation score⁺			
Reference is 1–5	1.00	1.00	1.00
High 6–10	1.02	1.09	1.03
Admission type			
Reference is Planned	1.00	1.00	1.00
Acute	1.03	0.84	1.09
Admission source			
Reference is Routine	1.00	1.00	1.00
Transfer	1.91	2.20	2.06
Principal diagnosis (categories >5% of sample):			
Reference is Other 18 MDCs	1.00	1.00	1.00
Circulatory	0.88	0.89	0.81
Musculoskeletal	1.48	1.43	1.44
Pregnancy, childbirth	0.48	0.59	0.37
Digestive	1.02	1.16	1.26
Respiratory	0.58	0.62	0.73
Newborns/neonates	0.44	0.55	0.32
Nervous system	0.63	0.62	0.56

* AE occurred inside public hospital, health care management score 2–6.

Preventability score 2–6.

+ NZDep96 decile derived from patient domicile code.

^B Major Diagnostic Category 3.1 (derived from AN-DRG 3.1).

It is clear from this analysis that some variables have no predictive power, with odds ratios close to one. Thus, gender, ethnicity, area deprivation, and admission type, were not predictive of the likelihood of an AE (at least when considered at the univariate level). Older patients were twice as likely to suffer an AE, as were those on transfer (rather than routinely admitted). Certain diagnostic categories were also predictive of an AE; musculoskeletal and digestive were associated with an AE, whilst women in childbirth had less than average chance of suffering an AE.

6.4 ADMINISTRATIVE CONTEXT – ‘CONFIRMATORY’ VALUE OF NZHIS DATA

One further application of routinely-collected hospital information was in assessing the extent to which such data might assist in the prediction of AEs (as a confirmatory exercise). Three potential confirmatory variables selected were discharge mode (the event end type code), ICD9 external cause code (E-codes 870–879, 930–949), and length of stay for the index admission (Table 6.6).²²

Table 6.6 Adverse event status by discharge mode, E-code and length of stay for index admission

		Adverse event			
Discharge mode*		AE-Present	AE-Absent		
Non-routine (n=551)		24.0%	76.0%		100%
Routine (n=6028)		11.9%	88.1%		100%
Positive predictive value [#] =24.0%					
Negative predictive value ⁺ =88.1%					
E-code:^β		AE-Inside	AE-Outside	Non-	
Accident in hospital		hospital	hospital	AE	
Positive (n=468)		38.9%	11.1%	50.0%	100%
Negative (n=6111)		8.2%	1.9%	89.9%	100%
Positive predictive value=38.9%					
Negative predictive value=91.8%					
Length of stay		AE-Present	AE-Absent		
> Mean (n=1614)		24.2%	75.8%		100%
<=Mean (n=4965)		9.3%	90.7%		100%
Mean=5.1 days					
Positive predictive value=24.2%					
Negative predictive value=90.7%					

* Event end type code identifies how a health care event ended; 'non-routine' was defined as other codes than 'DR' (ended routinely).²²

[#] Percentage of those cases positive on the item that was also judged AE present.

⁺ Percentage of those cases negative on the item that was also judged AE absent.

^β ICD9 external cause of injury code.²²

The occurrence of an AE is assessed against the mode of discharge. Very little discrimination is evident; discharge mode seemed to make little difference to the judgement of the presence or otherwise of an AE. While nearly 90 percent of cases in which discharge was routine were judged not to be associated with an AE (high negative predictive value), only 24 percent of non-routine discharges were associated with an AE; in other words, discharge mode had very low positive predictive value in finding AEs.

A similar picture emerged in the analysis of the diagnostic code assigned for accidents in hospital. While an AE was absent for over 90 percent of cases without a hospital accident code, less than 40 percent of these diagnostic codes were associated with an AE; again, the administrative code had very low positive predictive value in identifying AEs.

Length of stay information was not much more successful in confirming the presence of an AE. While for over 90 percent of cases in which hospital stay was lower than average no AE was present, under a quarter of cases with a longer than average hospital stay were associated with an AE.

7. PREVENTABLE IN-HOSPITAL ADVERSE EVENTS

Key findings:

- (1) Concentrating on preventable, in-hospital AEs reduced the overall rate of inpatient AEs by a half, and eliminating AEs occurring before the index (sampled) admission reduced the rate by a half again.
- (2) Preventable in-hospital AEs were associated with age – a higher rate among older patients – and with particular clinical conditions (e.g. injury, poisonings and drugs).
- (3) Nearly three-quarters of preventable in-hospital AEs were judged to have 'minimal' or 'moderate' impact, but older patients and certain clinical categories (such as nervous and digestive system disorders) experienced greater than average impact.
- (4) A half of all preventable in-hospital AEs had a component of system failure in their causation as identified by study reviewers. However, routinely collected administrative data were of little assistance in predicting AE occurrence.

The sections so far in this analysis have provided important contextual information to the understanding of patient safety in New Zealand public hospitals. It is important at this stage, and before concluding, to focus on those dimensions of patient safety that are both preventable and specific to hospital practice. Therefore, in this final section analysis is performed on preventable, in-hospital AEs; that is preventable AEs that occurred inside public hospitals (Table 7.1). These represent about half of all AEs recorded in the study. It should be noted that eliminating AEs occurring before the index (sampled) admission reduced the rate by a half again.

Table 7.1 Rates for different subsets of adverse events

	No. of AEs	AE rate (n=6579)* (%)
All AEs	850	12.9
AEs that occurred inside public hospital	683	10.4
AEs that occurred inside public hospitals, and were preventable (score 2–6)	413	6.3
AEs that occurred inside public hospitals, and were preventable, and occurred during index admission	248	3.8

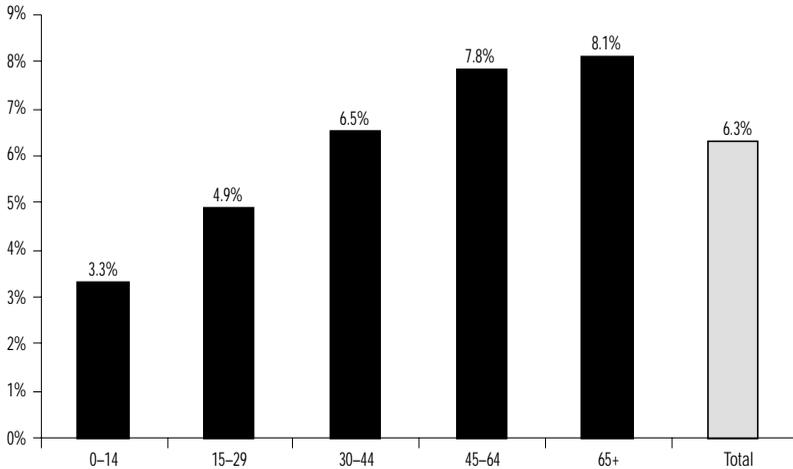
* Rates are expressed as percentages of all 6579 sampled admissions.

The analysis will follow the pattern of earlier sections, but will be abbreviated, including only a selection of results most pertinent to an understanding of the data.

7.1 PREVENTABLE IN-HOSPITAL ADVERSE EVENT OCCURRENCE RATES

In Figure 7.1 the rates of occurrence of preventable, in-hospital AEs are considered against patient age group. There is clear evidence of an age-related trend, with higher than average rates among patients over the age of 45, and lower than average rates among patients below the age of 30.

Figure 7.1 Preventable in-hospital* adverse event rates, by age group (n=413)



* AEs that occurred inside public hospital, health care management score 2-6, preventability score 2-6.

Table 7.2 considers the occurrence of preventable, in-hospital AEs by diagnosis. The level of occurrence is twice as high than average for ‘injuries, poisonings and drugs’, and half the overall rate for childbirth-related categories.

Table 7.2 Preventable in-hospital* adverse event rates, by major diagnostic category (MDC)(n=413)

MDC#	AE rate (%)
Injuries, poisonings and drugs	13.1
Musculoskeletal system	9.6
Digestive system	9.0
Kidney and urinary tract	7.8
Circulatory system	5.9
Skin, tissue and breast	5.9
Respiratory system	5.5
Nervous system	4.2
Pregnancy, childbirth	2.9
Newborns/neonates	2.5
Other (remaining 15 MDCs)	6.3
All MDCs (n=413)	6.3

* AEs that occurred inside public hospital, health care management score 2–6, preventability score 2–6.

Ordered according to percentage of AEs.

7.2 IMPACT OF PREVENTABLE IN-HOSPITAL ADVERSE EVENTS

The impact of preventable, in-hospital AEs is considered in Table 7.3. Sixty percent of such cases resulted in temporary patient disability of less than a month. Permanent disability and death accounted for 7 percent of cases. Considering the impact on hospital stay, in 40 percent of instances AEs were associated with the entire hospital stay. As expected, there was an association between disability and impact. Thus, patients permanently disabled were much more likely to suffer an AE that accounted for their entire hospital stay. Similarly, the number of extra days in hospital for these patients were very much higher than for the sub-sample as a whole, being on average greater than a month.

Table 7.3 Impact of preventable in-hospital* adverse events – disability status by hospital stay (n=413)

Disability	AEs (%)	Entire hospital stay due to AE# (%)	Mean attributable bed days per AE +
Minimal <1 month*	59.3	40.4	5.0
Moderate 1-12 months	20.8	39.5	15.2
Permanent <=50%	6.5	63.0	33.0
Permanent >50%	1.5	50.0	48.5
Death	5.8	20.8	11.6
Unable to determine from medical record	6.1	28.0	12.2
All AEs (n=413)	100	40.0	10.3

* AEs that occurred inside public hospital, health care management score 2–6, preventability score 2–6.

Hospital stay related to the Index Admission; for 15.5% of AEs none of hospital stay was due to the AE; for 44.6% of AEs a portion of hospital stay was due to the AE.

+ Bed days in the study hospital, spent over one or more admissions, associated with an AE.

* Period of disability.

As indicated in Figure 7.1, there was a discernible relationship between age group and the likelihood of occurrence of a preventable in-hospital AE. In Table 7.4 the impact of AEs by age group is considered. According to these data, not only did older age groups suffer more AEs of this kind; they were also more likely to experience death or permanent disability in consequence. The same assessment of impact is made in relation to principal diagnosis. Using the criterion of permanent disability and death, cases of digestive, respiratory, and nervous systems and kidney and urinary tract appeared to experience AEs with higher than average patient impact. These conditions, except respiratory, were also those that displayed longer stay in hospital.

Table 7.4 Impact of preventable in-hospital* adverse events, by age group and major diagnostic category (MDC) (n=413)

	Permanent disability and death (%)	Mean attributable bed days per AE⁺
Age Group		
0–14	9.1	16.2
15–29	0	4.4
30–44	9.2	6.2
45–64	18.5	10.7
65+	18.9	12.1
MDC[#]		
Nervous system	27.8	11.9
Digestive system	23.3	18.6
Respiratory system	22.6	7.3
Kidney and urinary tract	21.1	13.5
Circulatory system	15.4	9.8
Musculoskeletal system	14.1	10.4
Injuries, poisonings and drugs	3.6	9.6
Pregnancy, childbirth	0	2.8
Newborns/neonates	0	6.0
Skin, tissue and breast	0	8.7
Other (remaining 15 MDCs)	9.3	7.8
All AEs (n=413)	13.8	10.3

* AEs that occurred inside public hospital, health care management score 2–6, preventability score 2–6.

⁺ Bed days in the study hospital, spent over one or more admissions, associated with an AE.

[#] Ordered according to % permanent disability and death.

Finally, impact is considered against areas of effort to prevent AE recurrence in Table 7.5. Half of all preventable, in-hospital AEs were associated with systems issues, followed by consultation and education (with approximately a third each). Consultation and, to a lesser extent, resources, were the only areas of attention with apparently greater than average impact (using the two criteria).

Table 7.5 Preventable in-hospital* adverse events – prevention of recurrence – areas of effort by impact (n=413)

Area for attention[#]	All AEs (n=413) (%)	Permanent disability and death (%)	Mean attributable bed days⁺
System	49.2	13.8	10.2
Consultation	35.6	21.8	12.2
Education	27.1	13.4	9.4
Resources	15.3	15.9	16.6
Quality assurance	12.4	13.7	6.5
Other	21.8	14.4	9.5
Total		13.8	10.3

* AEs that occurred inside public hospital, health care management score 2–6, preventability score 2–6.

[#] More than one area could be identified.

⁺ Bed days in the study hospital, spent over one or more admissions, associated with an AE.

7.3 CLINICAL CONTEXT

In Table 7.6 preventable, in-hospital AEs are considered in a clinical context. Just over 60 percent of such events occurred in surgery. Operative and system errors were the most frequent events, accounting for half of all AEs. Aside from system errors, operative events were naturally more characteristic of surgery, and drug, therapy and diagnosis more characteristic of medicine.

Table 7.6 Preventable in-hospital* adverse events – specialty and clinical area (n=413)

Clinical area [#]	Specialty			All AE mentions (%)
	Surgery (%)	Medicine (%)	Other (%)	
Operative	31.7	1.0	9.7	20.3
System	31.2	35.2	51.6	33.6
Drug	2.0	18.7	0	7.5
Therapy	10.2	13.0	3.2	10.7
Diagnosis	8.5	18.1	3.2	11.4
Procedure	4.8	10.4	3.2	6.6
Other	11.6	3.6	29.0	9.9
Total Mentions	100	100	100	100 (n=577)
All AEs	62.5	32.9	4.6	100 (n=413)

* AEs that occurred inside public hospital, health care management score 2–6, preventability score 2–6.

% of mentions; clinical areas are mutually exclusive except that ‘system’ may be identified alone or additional to another clinical area, e.g. an AE could be classified as both ‘operative’ and ‘system’ thus contributing two mentions. Note that the total number of mentions is greater than the total number of AEs.

The impact of AEs is considered in a clinical context in Table 7.7. Levels of permanent disability and death appeared to be higher than average for AEs occurring both in medicine and in operative errors. There was little variation in extra days in hospital, however.

Table 7.7 Preventable in-hospital* adverse events – impact, by specialty and clinical area (n=413)

	Permanent disability and death (%)	Mean attributable bed days per AE [#]
Total (n=413)	13.8	10.3
Specialty		
Surgery (n=258)	12.8	10.0
Medicine (n=136)	17.7	11.2
Other (n=19)	0	9.2
Clinical Area⁺		
Operative (n=117)	18.0	11.9
Drug-Related (n=43)	9.3	7.3
System (n=194)	13.9	8.9
Other (n=223)	13.5	10.8

* AEs that occurred inside public hospital, health care management score 2–6, preventability score 2–6.

[#] Bed days in the study hospital, spent over one or more admissions, associated with an AE.

⁺ System may be identified alone or additional to another clinical area.

7.4 ADMINISTRATIVE CONTEXT

In this section the predictive power of administratively-collected data is considered. In Table 7.8 preventable, in-hospital AEs are displayed by discharge status. The discriminatory power of this variable was limited. Fewer than an eighth of non-routine discharges were associated with a preventable, in-hospital AE. A similar exercise is mounted for the ICD external cause codes relating to 'accident in hospital'. Less than a quarter of these codes were associated with a preventable, in-hospital AE. Finally, AEs are considered against length of stay for index admission. In admissions associated with a longer than average hospital stay, AEs were more frequent, but not markedly so; about an eighth of admissions of greater than mean length were associated with a preventable, in-hospital AE.

Table 7.8 Preventable in-hospital* adverse events, by discharge mode, E-code and length of stay for index admission

Adverse event			
Discharge mode	AE-Present	AE-Absent	
Non-routine (n=551)	13.1%	86.9%	100%
Routine (n=6028)	5.7%	94.3%	100%
<i>Positive predictive value=13.1%</i>			
<i>Negative predictive value=94.3%</i>			
E-code:	AE-Present	AE-Absent	
Accident in hospital			
Positive (n=468)	20.5%	79.5%	100%
Negative (n=6111)	5.2%	94.8%	100%
<i>Positive predictive value=20.5%</i>			
<i>Negative predictive value=94.8%</i>			
Length of stay	AE-Present	AE-Absent	
> Mean (n=1614)	12.8%	87.2%	100%
<=Mean (n=4965)	4.2%	95.8%	100%
<i>Mean=5.1 days</i>			
<i>Positive predictive value=12.8%</i>			
<i>Negative predictive value=95.8%</i>			

* AEs that occurred inside public hospital, health care management score 2–6, preventability score 2–6.

8. DISCUSSION AND CONCLUSION

In this report we have published results of the first nationally representative study of the quality and safety of care provided in New Zealand public hospitals. In this, the final section of our report we wish, first, to summarise the principal findings from our work, secondly, to consider some of the possible methodological and other shortcomings to the investigation, and, finally, to outline some of the implications of this research.

8.1 PRINCIPAL FINDINGS

The starting point – and fundamental result – for this investigation has been the estimation of the rate of AEs associated with admissions to New Zealand public hospitals. The overall rate is calculated to be 12.9 percent, representing the proportion of hospital admissions associated with an AE (Figure 2.4). This rate stands almost midway between the levels of AEs recorded in two countries with shared medical traditions in training and practice, Australia and the United Kingdom – with reported rates, respectively, of 16.6 percent⁷ and 10.8 percent.¹⁸ All these rates cluster at a level about two to three times higher than that reported for the United States.²⁵ This apparent anomaly is discussed further in the methodological section below.

A second important finding – and one that is consistent with the international evidence^{7,18,26} – is that much of this burden of AEs is not preventable, at least when considered against the backdrop of current medical knowledge and available technology. In the case of nearly 40 percent of AEs medical reviewers could detect – ‘virtually no evidence’ of preventability (Table 5.1). Excluding these cases from the calculation of the rate of AEs would reduce it to 8.1 percent; in other words, this represents the proportion of hospital admissions associated with an AE of any degree of

preventability. Analyses in this report on preventability have been conducted largely on the approximately 35 percent of AEs classified as highly preventable, although all preventable incidents were included in the analysis of in-hospital events. It should be noted, however, that reviewers were able to identify possible areas for the prevention of recurrence in the case of all AEs, not just those classified as preventable (Table 5.3).

A third notable result from this study is the quite mixed signals emanating from the information on the impact of AEs (Table 4.1). Considering patient impact, an important conclusion – consistent with international findings^{7,18,27} – is that only a small proportion of AEs result in permanent disability or death; overall, less than 15 percent of AEs were associated with permanent disability or death. Yet, from the point of view of impact on hospital workload, nearly half of all AEs were associated with practically the entire hospital stay, while AEs added an average of over nine days to the expected hospital stay; the Australian study also found a similar proportion with an average of just over seven days.⁷

A fourth area of interest to emerge from this investigation is that a significant proportion of AEs associated with hospital treatment originated outside a public hospital, in most instances arising from care in an ambulatory or community setting. Nearly a fifth of AEs originated in this manner, only a quarter of which arose in another institutional context (either rest home or private hospital). This result has not been previously reported in the international literature and points to the potential importance of quality and safety issues outside public hospitals. Nevertheless, from the perspective of hospital care and safety, if we take this result together with the data on preventability, then the rate of preventable, in-hospital AEs is 6.3 percent (Table 7.1 and Figure 7.1), approximately half the overall rate reported above.

A final point of discussion concerns the extent to which the study was able to reveal any patterning of AEs, either by patient attributes or by clinical and administrative characteristics. In considering the socio-demographic attributes of patients, the only factor to emerge relatively consistently was that of age. Older patients were more likely to suffer AEs – taken either overall (Figure 3.1), or as preventable, in-hospital incidents (Figure 7.1) – and these AEs seemed to have a greater adverse impact (as judged by permanent disability and death) (Table 4.2 and Table 7.4). Clinically, while more AEs occurred in surgery – especially operative (Table 6.1) - they were generally less preventable and their impact was less severe (Table 6.3). The opposite pattern applied to medicine. Specific diagnostic categories were also predictive – childbirth was markedly safer, injuries, poisonings and drugs markedly less so (Table 3.2) – and a history of recent hospital treatment was also a potential alarm signal (Table 6.4). Administratively available information largely reinforced this picture – that is, older patients, specific diagnoses (Table 6.5) – but otherwise provided few other useful pointers.

8.2 METHODOLOGICAL ISSUES

The current investigation displays both strong and weak points. It appears to be largely representative, the medical records were adequate to the task, and there was a degree of internal consistency on key variables. On the debit side, however, there are questions about the reliability and validity of the key outcome.

The sample was selected in a multi-stage fashion – hospitals first, then records – but overall, assessed in simple numerical terms, represented an approximately one in a 100 selection from all publicly funded hospitalisations in 1998 (Table 2.1). Assessed according to patient and administrative characteristics, the sample was closely representative in most respects. The only noticeable difference was in length of stay (5.1 in the sample, 6.9 for all publicly funded hospitalisations).

Another strength to the study is the apparent adequacy of medical record documentation for key research outcomes. Although nearly 10 percent of records could not be located (Figure 2.4), those that were screened (Figure 2.2) and reviewed (Figure 2.3) provided sufficient information for study purposes.

Finally, it should be noted that there are a number of areas where study findings showed internal consistency and face validity. In the case of AE determination, the pattern of judgements made by reviewers was strongly consistent and plausible. Thus, reviewers were highly confident in attributing AE status where they could find few alternative explanations for the incident, a note in the medical record alluding to the role of management in the outcome, the timing of the event was suggestive, the event responded to new management, and the condition was seen to be widely recognised as problematic (Table A10).

A similar pattern was evident in ascertaining preventability. Reviewers attributed high preventability where there was a perception of relative professional consensus, inappropriate management, substantial deviation from accepted management, and lack of acceptability of treatment (Table A12). The judgement of patient impact also showed a pattern of consistency and plausibility. The more severe patient disability was judged to be, the greater the number of days spent in hospital due to the AE (Table 4.1).

Yet there are clear weaknesses in the methodology. As discussed above, while the overall AE rate compares closely with results from Australia and England, this cluster of rates differs significantly from those reported for the United States. The Australian and American results have been compared and assessed in a recent investigation. While some of the discrepancy in results can be attributed to identifiable but slight differences in methodology,²⁸ the authors conclude that the principal factor

in explaining the discrepancy lay in contrasting study purposes – medico-legal in one case (the United States), quality in the other. A closer analysis of the results showed that the two sets of studies were quite comparable in the case of more serious events, but that the Australian investigation had a much longer ‘tail’ of less serious events, albeit incidents of potential significance to quality improvement.²⁹

While there may be some reassurance at the level of research design in reconciling apparently discrepant research results, there still remains the issue of the adequacy of screener and reviewer judgements about clinical outcomes. The degree of physician agreement in this kind of study has been found to be low,³⁰ a result not out of keeping with the general conclusion that the level of physician agreement on the quality of care is often only slightly better than chance.³¹ Concretely, kappa scores for agreement between reviewers in recently published studies of this type have varied between 0.4²⁵ and 0.55⁷.

In the present investigation measures of agreement were derived in two ways: reliability, between screeners and reviewers (Table A7); concurrent criterion validity, between an external criterion (the study Expert Reviewer) and study personnel (Table A8). Levels of agreement on screening – both reliability and concurrent criterion validity – appear to be relatively high. Reviewers rejected only a minority of screeners’ referrals, and the agreement between screeners and the study Expert Reviewer was just acceptable (kappa of 0.42), with nearly two-thirds of Expert Reviewer–judged outcomes being ‘correctly’ called by screeners. Levels of agreement for AE presence and determination were lower. For reliability, although a screener/reviewer kappa of 0.47 was derived, in the presence of an AE the probability of calling it correctly was only just over 50 percent. A similar level of agreement was derived between reviewers and the study Expert Reviewer.

Overall, the levels of reliability and concurrent criterion validity derived in this study are moderate to weak. Without invalidating the research, such an outcome adds to the uncertainty surrounding any conclusions that might be drawn from the study. It should be noted, however, that lower kappa levels may be more acceptable in circumstances where the objective is to predict outcomes not for individuals but for groups of subjects.³²

8.3 IMPLICATIONS AND CONSEQUENCES

This study provides broad parameters to our understanding of patient safety and the quality of care in New Zealand public hospitals. In essence, about one in eight admissions to a hospital are associated with AEs (which may have occurred within or outside public hospitals); half of these are both preventable and hospital incurred. The majority of such incidents have relatively minor impact on patients (though there is a significant proportion who suffer permanent disability or death), but their effects on hospital workload and thus costs to the health system are substantial.

One area in which more could be done with the data is in identifying sub-groups of patients for which safety issues are a matter of interest. Such analyses have been carried out on drug events,³³ surgical interventions,³⁴ the elderly,³⁵ and other vulnerable populations, such as the poor and ethnic minorities.³⁶

Aside from identifying special sub-groups of patients, are there any further initiatives that could be taken with data that might have reasonably concrete implications for hospital care? Study reviewers were required to identify potential areas for improvement for each AE. In a third of cases 'system' factors were seen by reviewers to be involved, followed by the need for consultation with colleagues – a further fifth – and also for education – another fifth (Table 5.3). Once the sample was reduced

to preventable, in-hospital AEs, the proportion of cases linked to – ‘system’ factors increased to about a half. A further third required consultation, and another quarter was judged to need education (Table 7.5).

This broad-brush report does not provide detailed signposts for the way ahead, though closer analysis of case material from the study would be useful in gaining insights into areas of intervention.³⁷ The study provides a baseline and addresses only one dimension of the potential for quality improvement, albeit one that has been used to good effect in the Australian context.^{38,39} More targeted studies are required (possibly with case-control methodology)⁴⁰ as are investigations into potential interventions for reducing preventable, in-hospital AEs.⁴¹ Further work is also required to help identify the possible levels and sources of non-hospital AEs.

Further more detailed analysis of the study results and the AEs will be performed. This should give more insight into the patterns of AEs and their preventability than has been possible in the summarising analysis presented here, and thereby lead to suggestions for improvement of system factors and education and for further studies.

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APPENDIX A: METHODOLOGICAL ASPECTS

A1 SAMPLING AND WEIGHTING

A1.1 Sampling

A stratified two-stage cluster sample design was used, firstly selecting a representative sample of 13 from 20 public hospitals with more than 100 beds, and secondly drawing a random sample of admissions within each hospital. Sampling of hospitals followed stratification by hospital type and geographical area across New Zealand. The three strata were: (1) six large tertiary service facilities; (2) seven secondary service facilities with more than 300 beds; (3) seven secondary service facilities with less than 300 beds. The national sample comprised all six hospitals from the first stratum, a probability proportional to size (PPS) sample of four hospitals from the second stratum, and a PPS sample of three hospitals from the third stratum (Table A1).

Table A1 Sampling scheme for New Zealand public hospitals

Stratification of public hospitals (non-specialist, >100 beds)	Number of beds in stratum	Number of hospitals in stratum	Number of hospitals sampled	Number of admissions sampled/ screened
1. Tertiary service facilities	3863	6	6	2994
2. Secondary service facilities with >300 beds	2791	7	4*	2070
3. Secondary service facilities with 100-300 beds	1416	7	3*	1515
Total	8070	20	13	6579

* Probability proportional to size sample.

The survey population was defined as all patient admissions for calendar year 1998 (excluding day, psychiatric, and rehabilitation-only cases). The sampling frame for each hospital was the list of all eligible admissions in that hospital. The New Zealand Health Information Service (NZHIS) selected a systematic list sample of 575 admissions from each of these hospitals for the year 1998, with cases ordered by admission date. The number of records was divided by 575 to give a sampling interval, and then a random starting point between 1 and 100 was used to determine the first record sampled. This generated a sample of the requisite size according to standard and accepted principles of sampling of this kind.

A1.2 Weighting

The cases needed to be weighted to account for unequal selection probabilities in the sample design. Each hospital was given a weight inversely proportional to its selection probability when calculating estimates of rates, proportions and means. In actuality, weighting the cases gave similar results, so for simplicity the crude estimates are reported, aside from the overall AE prevalence and incidence rates (see below Tables A4 and A5).

Standard errors also need to be adjusted for the stratified two-stage cluster design. The effect of the design can be measured by the design effect which is the square of the ratio of the actual standard error of an estimate to the standard error that would be obtained for a simple random sample of the same size (here $n=6579$). Design effects have been calculated for the overall AE prevalence and incidence rates respectively in order to provide adjusted confidence limits (see below Tables A4 and A5).

A2 TIMING OF ADVERSE EVENT OCCURRENCE AND DETECTION

According to study protocols, to qualify as an AE an incident had to have taken place and/or been detected during the index admission. Table A2 describes the distribution of AEs according to the timing of their occurrence and detection. A half of all AEs occurred prior to the index admission and were detected in the course of the index admission. A third both occurred and were detected in the index admission.

Table A2 **Distribution of adverse events, by timing (occurrence and detection)**

Before index admission	Index admission	After index admission	No of AEs	% of AEs
O	—————▶D		437	51.4%
	O	▶D	298	35.1%
	O	—————▶D	115	13.5%
Total			850	100%

O = Occurrence of AE.

D = Original detection of AE by a health care professional.

A3 CALCULATING ADVERSE EVENT RATES

A3.1 Prevalence and Incidence Rates

The initial New Zealand figure of 12.9 percent represents an estimate of the prevalence of adverse events occurring over the period of study – that is, incidents detected both during admission to hospital in 1998 and up to the year of data collection (1999–2000). Many of these incidents occurred before 1998. Table A3 presents the distribution of all incidents according to date of occurrence. Therefore, the *occurrence* of adverse events may have taken place over a reasonable time. The rate being estimated here is that of all incidents *detected* by a health care professional over

the period 1998–2000 in a population of hospital patents admitted in 1998. This is a period prevalence rate. However, an adjustment needs to be made for the sample design.

Table A3 Distribution of adverse events, by year of occurrence

	Year of AE occurrence		
	Before 1998	1998	Total
Number of AEs	170	680	850
(%)	(20.0%)	(80.0%)	(100%)

The prevalence rate counts all the adverse events found by the review process, following the Australian convention. The crude adverse event rate for the total sample of 6,579 admissions in all the hospitals combined ($850/6,579 = 12.92\%$) needs to be adjusted for the different numbers of beds represented by each of the three strata. The weight for each stratum will be its proportion of the total number of beds.

Therefore:

$$r = (r_1w_1 + r_2w_2 + r_3w_3) / (w_1 + w_2 + w_3)$$

or

$$r = \sum r_i w_i / \sum w_i$$

where:

r is the adjusted rate

r_i is the estimated rate for the i th stratum ($i=1$ to 3)

w_i is the weight for the i th stratum ($i=1$ to 3)

$$w_i = p_i / \sum p_i$$

p_i is the number of beds for the i th stratum

$\sum p_i$ is the total number of beds

$\sum w_i = 1$ (the sum of the weights)

After adjusting for the sample design, the estimated prevalence rate becomes 13.14 percent (Table A4). For this prevalence rate, the estimated design effect is 1.35. This means that the standard error and confidence limits need to be increased by about 16 percent ($\sqrt{1.35}=1.16$) over their simple random sampling equivalents.

Table A4 Adverse event prevalence rate for admissions

	Prevalence rate (admissions)
Crude rate (all adverse events)	850/6,579 = 12.92%
Adjusted for sample design	13.14% (95% CI: 12.19 - 14.09)

In calculating the incidence rate of adverse events – that is, the number of new cases – we include only those incidents detected during the index admission, following the rule used by the American studies. This removes 115 adverse events (those detected after the index admission) from the numerator of the rate. Adjusting for this produces an overall incidence rate of 11.17 percent. As in the case of the prevalence rate, an adjustment needs to be made for the sample design which results in an estimated rate of 11.33 percent and a design effect of 1.23 (Table A5).

Table A5 Adverse event incidence rate for admissions

	Incidence rate 1998 (admissions)
Crude rate (adverse events detected during index admission)	735/6,579 = 11.17%
Adjusted for sample design	11.33% (95% CI: 10.48 - 12.18)

A3.2 International Comparison of Adverse Event Rates

The comparator studies in Australia and the United States differed both in the cut-off for management causation and in the inclusion criterion for the timing of the discovery of adverse events. Comparisons are made in Table A6. Thus, when the full range of management causation and all AEs were included regardless of when they were detected – the Australian study protocol – the New Zealand rate came in at a lower level than the Australian one. On the other hand, when the AEs under consideration were restricted to those with more certain management causation scores and those detected in the course of the index admission, the rate was over double that recorded in the American studies.

Table A6 Adverse event rates – international comparison of five studies

Study details	AE health care management causation score >=2		AE health care management causation score >=4			
	NZ (NZQHS)*	Australia (QAHCS)#	NZ (NZQHS)	USA (HMPS)+	USA (UTCOS)§	UK*
Year of index admissions	1998	1992		1984	1992	1998
Place	New Zealand	New Sth Wales, Sth Australia		New York state	Utah, Colorado	London
No. of hospitals	13	28		51	28	2
No. of records reviewed	6,579	14,179		30,195	14,700	1,014
No. of medical reviewers	1	2		2	1	1
AE rates						
All AEs	12.9%	16.6%	11.5%			
AEs detected during Index Admission only			10.0%	3.7%	2.9%	10.8%**

* New Zealand Quality of Healthcare Study.

Quality in Australian Health Care Study.⁷

+ Harvard Medical Practice Study.^{26,27}

§ Utah and Colorado Study.²⁵

* Feasibility study.¹⁸

** AEs that occurred during the index admission.

A4 RELIABILITY AND VALIDITY OF TWO-STAGE RETROSPECTIVE REVIEW

A4.1 Reliability

The inter-rater reliability of judgements on the same cases made by screeners and reviewers was assessed according to their agreement with each other. Reliability measures are outlined for the extent of agreement between screeners and reviewers in judging criteria and AE presence (Table A7). It should be noted that, although screeners and reviewers only agreed about 50 percent of the time on the presence of an AE, their overall level of agreement was over 80 percent.

Table A7 Agreement between screener and reviewer judgements

	Percent agreement*	Kappa†			
Inter-rater reliability#					
RN [§] /MO [†] : criteria presence** (n= 4,119)	95.5%	–			
RN/MO: AE presence (n=4,116)	81.6%	0.47			
				MO – Yes	– No
			RN – Yes	3934	185
			– No	–	–
			RN – Yes	535	444
			– No	313	2824

* Percentage of all cases that was judged similarly by both RN screener and MO reviewer.

† Kappa is a measure of strength of agreement; 0 = expected by chance agreement, and 1 = perfect agreement.

Reproducibility of information obtained on the same cases by RN screener and MO reviewer.

§ Registered Nurse.

† Medical Officer.

** Only cases screened positive by RNs were further reviewed by MOs; thus kappa is not applicable.

A4.2 Validity

The concurrent criterion validity of the judgements on the same cases made by screeners and reviewers was assessed according to their agreement with an external criterion; in this case, Expert Reviewer screening/reviewing of a one in ten sub-sample of admissions carried out 'blind'. The Expert Reviewer ratings were treated as the 'true value' or 'gold standard' against which the RN screeners and MO reviewers were judged (Table A8). In the case of screeners, there was a greater degree of agreement on criteria than on AE presence. For AE determination, there was a reasonable degree of agreement – as judged by the kappa statistic – between the Expert Reviewer and reviewers. Kappa is a measure of the strength of agreement, with a score of zero indicating agreement expected by chance and a score of one indicating perfect agreement. It should be noted that, although there was only 50 percent agreement on the presence of an AE, the overall level of agreement was nearly 90 percent. The value of kappa is low but typical of this kind of study; in particular it is comparable to values obtained by the Australian and American studies. Note that there is balanced disagreement on AE determination between the Expert Reviewer and the MO Reviewer with similar numbers of cases in the two off-diagonal cells. This means that there will be little bias in the overall prevalence estimates.

Table A8 Concurrent criterion validity of screener and reviewer judgements

		Percent agreement*	Kappa†		
Concurrent criterion validity[‡]					
RN [§] /ER [#] : criteria presence (n=614)		70.7%	0.42	ER – Yes	– No
	RN – Yes			257	148
	RN – No	32	177		
RN/ER: AE presence (n=613)		83.7%	0.35	ER – Yes	– No
	RN – Yes			39	66
	RN – No	34	474		
MO [*] /ER: AE determination (n=615)		87.5%	0.47	ER – Yes	– No
	MO – Yes			45	38
	MO – No	39	493		

* Percentage of all cases that was judged similarly by both RN (or MO) and Expert Reviewers.

† Kappa is a measure of strength of agreement; 0 = expected by chance agreement, and 1 = perfect agreement.

‡ The validity of the judgements on the same cases made by RN screeners and MO reviewers was assessed according to the measure of their agreement with an external criterion, i.e. the judgements of the Expert Reviewer (ER).

§ Registered Nurse.

Expert Reviewer.

* Medical Officer.

Another possible source of bias affecting estimation of the AE rate could be that events were missed by the screening process. The Australian study¹ reviewed a sub-sample of 413 criteria-negative records in their first two hospitals and found only three AEs missed by the RF1 screen; extrapolating to their whole sample, their corrected estimate of AE rate was 17.0 percent compared with the crude rate of 16.6 percent.

¹ Quality in Australian Health Care Study : Part 1, Final Report to the Commonwealth Department of Human Services and Health - Hamilton J, Wilson R, Harrison B, et al. Health Services Research Group, University of Newcastle, 1996, pp 37–38.

A5 ADVERSE EVENT DETERMINATION

Of the nearly 4,000 records correctly forwarded by the screeners for medical review, nearly three-quarters were judged to show no evidence of patient injury. About a further 250 records were either not reviewed or were assessed to be incorrectly referred (that is, false positives). Of just over 1,000 records showing evidence of patient injury, fewer than a fifth were determined to have experienced neither disability nor prolonged hospital stay or outpatient visits (Table A9).

Table A9 Unintended patient injury, and disability / prolonged length of stay

	Frequency	Percent
Total screened positive	4197	-
Screened positive, not reviewed	-78	-
Screened positive, reviewed negative	-185	-
Total assessed for injury	3934	100
No unintended patient injury	2862	72.8
Unintended patient injury	1072	27.2
Total assessed for disability	1072	100
Disability/death	115	10.7
Prolonged stay/outpatient visits	533	49.7
Disability/death & prolonged stay/outpatients visits	244	22.8
Neither	180	18.8

The nearly 900 cases of injury associated with disability and/or prolonged hospital stay were assessed for the extent to which the outcome was caused by health care management rather than by the underlying disease process. In order to assist reviewers to make this judgement they were guided through a series of seven evaluation questions (Table A10). Reviewers were much more likely to be certain about attributing an AE where there were few other explanations for the outcome and where there was a note in the medical record suggesting that health care management had played a role in the incident. A note in the record predicting injury from disease (rather than management) was not as discriminatory. Where the reviewer assessed that the timing of the incident was suggestive of an AE, they were much more likely to be certain about attributing that status. Perceived opportunity for prevention was not a discriminating feature. Where the reviewer judged the case to have convincingly responded to new management and where the intervention in question was recognised to cause this kind of injury, the certainty of AE attribution was high.

Table A10 AE attribution ('virtually certain evidence') by evaluation category – percent agreement and predictive value

Evaluation category (POSITIVE / negative)	AE status, n=892 (PRESENT, n=433 / absent)		
	Percent agreement*	Positive predictive value#	Negative predictive value*
Q. Is there a note in the medical record which indicates or suggests that health care management caused the injury? YES / no	64.9%	58.4%	92.8%
Q. Is there a note in the medical record which predicts the possibility of an injury from the patient's disease? NO / yes	44.3%	31.4%	47.1%
Q. Does the timing of events suggest that the injury was related to the treatment ? LIKELY / possible, unlikely	61.2%	55.8%	93.6%
Q. Are there other reasonable explanations for the cause of the injury? NONE, FEW / some, many	73.8%	67.4%	85.6%
Q. Was there an opportunity prior to the occurrence of the injury for intervention which might have prevented it? YES / possibly, no	55.8%	58.3%	54.9%
Q. Is there recognition that the intervention in question causes this kind of injury ? WIDELY / recognised by other specialists, no	58.6%	56.4%	66.1%
Q. Did the adverse event respond to new management to neutralise or modify the effects of former management? CONVINCING/suggestive, no	60.3%	59.7%	61.7%

* Percentage of all cases that was judged similarly on both evaluation category and AE status.

Percentage of those cases judged positive on evaluation category that was also judged AE present.

+ Percentage of those cases judged negative on evaluation category that was also judged AE absent.

Following these seven evaluation questions reviewers were then required to make an assessment of the degree to which the outcome was ‘caused’ by health care management. The results of this exercise are outlined in Table A11. For nearly half of all cases with both injury and disability or longer hospital stay there was, in the opinion of the reviewer, virtually certain evidence of management causation. For fewer than 5 percent there was little evidence of causation.

Table A11 Health care management causation

Causation score	Frequency	Percent
1. Virtually no evidence	42	4.7
2. Slight to modest evidence	59	6.6
3. Close call, less than 50:50	33	3.7
4. Close call more than 50:50	107	12.0
5. Moderate/strong evidence	218	24.4
6. Virtually certain evidence	433	48.5
Sub-total: adverse events	850	95.3
Total assessed for causation	892	100
Screened positive, not reviewed	78	
Screened positive, reviewed negative	185	
No injury, no disability	3042	
Total screened positive	4197	

A6 ASSESSMENT OF ADVERSE EVENT PREVENTABILITY

In order to assist reviewers in making a judgement about the preventability of AEs they were required to work through ten preparatory questions (Table A12). Where the reviewer felt that the case was very complex, or where they saw it as one about which there was very little consensus on treatment, they were much less likely to judge the AE as highly preventable. Where patients were judged to be inappropriately treated, reviewers were much more likely to see the AE as highly preventable. The extent of patient co-morbidity did not seem to affect the judgement of preventability. Where a case was judged to be of critical urgency and where it represented little deviation from normal management, the reviewer was much less likely to assess the AE as being highly preventable. A lower rating of the possible benefits of treatment and high assessed risk of an AE were associated with a greater likelihood of perceived preventability. Lack of acceptability of the treatment, was associated with a high level of perceived preventability.

Table A12 High preventability (score 4–6) by evaluation category – percent agreement and predictive value

Evaluation category (POSITIVE / negative)	High Preventability of AEs, n=850 (PRESENT, n=315 / absent)		
	Percent agreement*	Positive predictive value#	Negative predictive value†
Q. Is there consensus about diagnosis and therapy regarding this case? GREAT DEAL / some, very little	50.6%	36.6%	62.7%
Q. How complex was the case? UNCOMPLICATED / moderate, very	53.2%	38.0%	63.6%
Q. Was the management in question appropriate ? NOT, POSSIBLY /probably, definitely	84.5%	80.8%	86.4%
Q. What was the co-morbidity of the case in which the AE occurred? NONE / moderate, very ill	52.4%	36.9%	62.8%
Q. What was the degree of deviation of management from the accepted norm? SEVERE, MODERATE / little	86.4%	83.7%	87.8%
Q. What was the degree of emergency in management of the case prior to the occurrence of the adverse event? NONE / moderate, critical	53.9%	37.7%	63.4%
Q. What potential benefit was associated with the management? MINOR / major, life-saving	68.7%	34.0%	75.9%
Q. What was the chance of benefit associated with the management? HIGH / moderate, low	34.9%	21.6%	64.8%

Evaluation category (POSITIVE / negative)	High Preventability of AEs, n=850 (PRESENT, n=315 / absent)		
	Percent agreement*	Positive predictive value#	Negative predictive value*
Q. What was the risk of an adverse event related to the management? HIGH, MODERATE / low	55.3%	30.2%	78.5%
Q. On reflection, would a reasonable doctor or health professional do this again? NO, PROBABLY NOT / probably, definitely	85.3%	81.5%	87.5%

* Percentage of all AEs that was judged similarly on both evaluation category and high preventability.

Percentage of those AEs judged positive on evaluation category that was also judged highly preventable.

* Percentage of those AEs judged negative on evaluation category that was also judged not highly preventable.

APPENDIX B: EXAMPLES OF COMMON AND SPECIAL OCCURRENCES

B1 EXAMPLES OF COMMON OCCURRENCES

Post-operative:

- Wound infection and breakdown
- Post operative pneumonia
- Infection in prosthetic joints
- Infection in intra-venous cannulae
- Bleeding following surgery

Drug Related:

- Gastrointestinal bleed from non-steroidal anti-inflammatory drugs
- Low blood pressure and collapse from high blood pressure drugs
- Antibiotic-induced diarrhoea

System Related:

- Falls in care causing fractures
- Recurrence of gall bladder inflammation and pain while on waiting list for gall bladder surgery

Procedure Related:

- Post lumbar puncture headache
- Bleeding following childbirth
- Lung congestion from intra-venous fluid overload
- Fractures not uniting, or losing position before union

B2 EXAMPLES OF SPECIAL OCCURRENCES SYNTHESISED FROM REAL CASES

Medication Error – Prior to Hospitalisation:

A fit elderly man presented with blood in his urine. For 3 years had been on warfarin anticoagulant for his heart condition and his blood tests to monitor the dose had been stable. The admission test showed marked loss of clotting ability, INR* over 20. It was found that he had been prescribed his usual dose of warfarin 4x1 mg tablets daily, but dispensed as 4x5 mg tablets daily. Problem settled with temporary withdrawal of warfarin, there were no longer term consequences.

Adverse event = medication dispensing error

Preventability = high

Disability = low, 3 days in hospital.

Operative / Fracture Management:

Young right handed man sustained a fracture of the radius within the wrist joint. It required operative reduction, K-wire fixation and bone grafting. At the 10-day check the position had shifted and re-operation was required. The end result was very good.

Adverse event = operative

Preventability = low – very difficult reduction that was done well but still failed

Disability = moderate – six days extra in hospital, an additional operation.

* INR = International Normalised Ratio. This is a test for fine-tuning the warfarin dose.

No Adverse Event / Outcome Of Disease:

An 80-year-old man presented with a myocardial infarction, with three hours of chest pain. He was treated promptly with streptokinase, heparin and aspirin. On day 3 he had further chest pain, with new ECG changes, and he died 12 hours later of cardiogenic shock.

No adverse event = no medical causation - outcome of disease.

Systems Problem:

A known substance abuser with recent history of self-harm was admitted to hospital with pneumonia. A 24-hour watch was ordered but not supplied. On day 2 the patient walked out of hospital and attempted suicide. He was returned to hospital and transferred to psychiatry when pneumonia settled.

Adverse event = system failure

Preventability = high

Disability = low.

Infective Complication / Gynaecology:

A 40-year-old woman with heavy vaginal bleeding, not responding to medication, had an elective vaginal hysterectomy with appropriate antibiotic cover. At 10 days post-operation she developed pelvic pain and fever, ultrasound showed a collection; assumed to be abscess, treated with intravenous antibiotic.

Adverse event = complication of medicated operation

Preventability = low, no additional preventative strategy identified

Disability = moderate.