Health Care

The Quality in Australian Health Care Study

Ross McL Wilson, William B Runciman, Robert W Gibberd, Bernadette T Harrison, Liza Newby and John D Hamilton

A review of the medical records of over 14 000 admissions to 28 hospitals in New South Wales and South Australia revealed that 16.6% of these admissions were associated with an "adverse event", which resulted in disability or a longer hospital stay for the patient and was caused by health care management; 51% of the adverse events were considered preventable. In 77.1% the disability had resolved within 12 months, but in 13.7% the disability was permanent and in 4.9% the patient died. ***(Med J Aust 1995; 163: 458-471)***

Iatrogenic injuries or adverse patient events (AEs) in hospitalised patients have been recognised for a long time, but their epidemiology has not been well documented. Over 30 years ago, Shimmel reported that 20% of patients admitted to a university hospital suffered iatrogenic injury, and that 20% of the injuries were serious or fatal.[1]

In United States hospitals, AEs have been studied in the context of malpractice litigation and negligence. The Medical Insurance Feasibility Study of the California Medical Association reported a 4.6% incidence for all measured classes of "potentially compensable events" occurring in 1974,[2] and the 1984 Harvard Medical Practice Study (HMPS), reported by Brennan and colleagues, showed that adverse events occurred in 3.7% of hospitalisations, with 27.6% of these being caused by medical negligence and 69% by human error.[3-5] An AE rate of 11% in the medical service of an urban US teaching hospital was reported earlier this year: 42.5% of the AEs were judged to be preventable, and 80% caused disability lasting at least one month, a minimum of four added hospital days, or death.[6]

Leape,[7] in reviewing these studies, wondered why this issue has not received more attention and suggested that the magnitude of the problem has not been appreciated because hospital-acquired injuries are usually not reported systematically (in comparison with car or aircraft accidents). The medical culture of striving for "error-free practice", the fear of litigation, and the lack of definitions of the scope and nature of the problem, inhibited routine reporting of AEs. Until these issues are addressed preventive measures cannot be undertaken.[7]

A feasibility study by the Australian Institute of Health and Welfare in three hospitals in 1992[8] concluded that, with some modifications, the methods used by the HMPS could be successfully applied to a review of the medical records of admissions to Australian hospitals. The major value of such a study would be quality improvement, and hence a measure of preventability should replace determination of negligence. This would enable the study to be conducted in a positive and constructive environment, rather than in a negative or potentially antagonistic one. The 1994 Quality in Australian Health Care Study (QAHCS) was commissioned by the Commonwealth Department of Human Services and Health to determine the proportion of admissions associated with an AE in Australian hospitals.

We report on the adequacy of the methods used, the characteristics of patients with AEs, the major diagnostic categories and specific specialties associated with AEs, and measures of disability and preventability. Human and system-based factors identified as contributing to AEs are discussed, focusing on possible areas for prevention in the future.

For editorial comment, see page 453.
See also commentaries on pages 472 and 475.

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Abstract

Objective

To estimate patient injury (and its direct consequences) caused by health care in Australian hospitals.

Methods

14 179 admissions to 28 hospitals in two States (New South Wales and South Australia) in 1992 were reviewed in two stages.

- The medical records for these admissions were screened by registered nurses (RNs) for one or more of 18 explicit criteria indicating the possibility of an injury caused by health care.
- Those records screening positive were subject to further detailed independent review and documentation by two or, when there was disagreement, three medical officers (MOs) to decide whether an adverse event had occurred.

An adverse event (AE) was defined as an unintended injury or complication which results in disability, death or prolonged hospital stay and is caused by health care management.

Main outcome measures

- Adequacy of the medical record and reliability of the method of medical record review;
- Proportion of admissions associated with AEs;
- Clinical categories of AEs;
- Characteristics of patients with AEs;
- Extra bed-days attributable to AEs;
- Disability attributable to AEs; and
- Preventability of AEs.

Results

Screening by RNs:

6200 of the 14 179 medical records (43.7%) were positive for one or more of the 18 explicit criteria, of which 13 were statistically significant predictor variables for AEs ($P < 0.01$). The proportion of admissions associated with AEs was highest in those with complete medical records. The sensitivity and specificity of the RN screening process were 97.6% and 67.3%, respectively. Agreement between duplicate screening by RNs was 84% (κ, 0.67).

Review by MOs:

In 2353 of the 6200 medical records an AE was confirmed. Overall, 73% of the medical records were judged to be of sufficient quality to complete all aspects of the MO review, and the remainder were adequate to determine whether an AE had occurred. There was 80% agreement on the presence of an AE (κ, 0.55); 58% agreement for preventability of an AE (κ, 0.33); and 87% agreement for disability or prolonged hospital stay resulting from an AE (κ, 0.49).

Main findings:

- 16.6% (95% confidence interval [CI], 15.2%–17.9%) of admissions were associated with an AE, and for 8.3% of admissions the AEs were judged to have high preventability.
- 49% of the AEs occurred before, and were responsible for all or part of, the sampled admission (the index admission); 51% of AEs occurred during the index admission, but 12% were not detected until after the index admission.
- 46.6% of AEs caused minimal disability; in 77.1% of AEs (95% CI, 75.2%–79.0%) the disability had resolved within 12 months.
- 13.7% of AEs (95% CI, 12.2%–15.2%) resulted in permanent disability (excluding death); and
- 4.9% of AEs (95% CI, 3.8%–6.0%) resulted in death.
- The proportion of admissions associated with permanent disability or death due to AEs increased with age; however, temporary disability and preventability were not associated with age or other patient variables.
- A significantly lower proportion of the AEs were reported for obstetrics (7.2%) and ear, nose and throat surgery (7.9%) than for other specialties, while a higher proportion were associated with digestive (23.2%), musculoskeletal (21.9%) and circulatory (20.2%) disorders.
- AEs accounted for an average of 7.1 additional days in hospital.
- 51% of AEs were judged to have high preventability.
- Disability and preventability varied between specialties, between diagnostic categories and according to the location in which the AE occurred.
- AEs resulting from problems with "decision-making" were generally associated with increased preventability, permanent disability and death.
- Errors of omission (52% of AEs) were almost twice as common as errors of commission (27% of AEs).

Conclusions

A retrospective review of hospital medical records was a reliable method of estimating patient injury caused by health care. Extrapolating the data on the proportion of admissions and the additional bed-days associated with AEs to all hospitals in Australia in 1992 indicated that about 470 000 admissions (95% CI, 430 000–510 000) and 3.3 million bed-days (95% CI, 3.0 million – 3.6 million) were attributable to AEs. These national estimates provide empirical data for further studies on quality of care in Australian hospitals. The implications of our study in terms of preventable adverse outcomes for patients and the use of health resources are substantial.

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Methods

Sample selection

The target population, estimated to be 2.82 million, was all patients admitted to public and private acute-care hospitals in Australia in 1992 (excluding day-only admissions and admissions to designated psychiatric wards).[9] (Estimates for private hospitals were obtained from the Australian Institute of Health and Welfare, Canberra.)

The sample size was calculated on the assumption that the proportion of all admissions associated with an AE would be 3.5%, and that for individual hospitals the proportions would range from 2.8% to 4.2%.[3] A stratified, two-stage cluster sample of 30 hospitals, with 500 medical records from each, would provide an estimate of this proportion with a standard error of 0.17%.

The hospitals sampled were, for logistical reasons, in two States: New South Wales (NSW; population, 5 958 716) and South Australia (SA; population, 1 456 424), together constituting nearly half the population of Australia. We selected 31 hospitals from six hospital strata (listed below) using computer-generated random numbers. The number of hospitals sampled within each stratum were proportional to the total number of eligible admissions within that stratum. Hospitals with less than 3000 eligible admissions per annum were not included in the study population.

The number of hospitals sampled by strata were:

Teaching or principal referral hospitals ($n = 10$);
Major referral hospitals ($n = 4$);
Major rural base hospitals ($n = 2$);
District high activity level hospitals ($n = 3$);
District medium activity level hospitals ($n = 6$); and
Private hospitals ($n = 6$).

This resulted in the selection of eight hospitals from SA and 23 from NSW. One SA teaching hospital declined to participate and two hospitals were omitted because their medical records were on microfiche, making them unsuitable for review. Thus, a total of 28 hospitals were sampled.

The sampled admission was called the index admission. A minimum of 520 eligible admissions from each hospital were randomly selected by computer from inpatient databases. Database files provided information on day of admission, medical record number, and age and sex, allowing medical records staff to retrieve the medical records. Estimates of the proportion of admissions associated with AEs for specific categories of patients or admissions were determined by age, sex, insurance status and Australian national diagnosis-related groups (AN-DRG)[10] categories, all of which were obtained from the inpatient database files.

Ethics committee approval and consent to conduct the study were obtained from the relevant bodies (including each State's health department).

Table 1: The 18 criteria used in the RF1 form,* the percentage of medical records positive for each criterion and its odds ratio for association with an adverse event

Criteria	Positive	Odds ratio (95% CI)
1. Unplanned admission before index admission	23.5%	7.2 (6.5–7.9)
2. Unplanned readmission after discharge from index admission	14.1%	4.8 (4.3–5.4)
3. Hospital-incurred patient injury	3.0%	5.1 (4.1–6.4)
4. Adverse drug reaction	2.8%	4.7 (3.9–5.6)
5. Unplanned transfer from general care to intensive care	3.1%	2.4 (1.9–3.0)
6. Unplanned transfer to another acute care hospital	0.5%	6.3 (4.0–9.9)
7. Unplanned return to the operating theatre	1.3%	14.5 (10.6–19.8)
8. Unplanned removal, injury or repair of organ during surgery	1.3%	7.8 (5.7–10.7)
9. Other patient complications (AMI, CVA, PE, etc.)	6.4%	5.8 (5.0–6.6)
10. Development of neurological deficit not present on admission	1.2%	5.1 (3.6–7.1)
11. Unexpected death	1.0%	5.3 (3.7–7.5)
12. Inappropriate discharge to home	0.9%	5.1 (3.5–7.5)
13. Cardiac/respiratory arrest, low Apgar score	0.7%	2.8 (1.8–4.4)
14. Injury related to abortion or delivery	3.9%	1.3 (1.0–1.6)
15. Hospital-acquired infection/sepsis	5.5%	7.6 (6.5–8.9)
16. Dissatisfaction with care documented in the medical record	1.0%	2.0 (1.3–3.0)
17. Documentation or correspondence indicating litigation	0.1%	3.9 (1.5–10.2)
18. Any other undesirable outcomes not covered above	6.5%	3.8 (3.2–4.6)

* Complete definitions for each criterion can be obtained from the authors. AMI = acute myocardial infarct. CVA = cerebrovascular accident. PE = pulmonary embolus.

Medical record review

Review personnel

Review teams of registered nurses (RNs) and medical officers (MOs) spent 2–4 weeks at each hospital with a team leader (RN) who managed the review process.

The nine RNs each had at least five years' clinical nursing experience; all underwent an intensive two-week training course in the study protocols and were provided with a review manual. Each RN reviewed from 636 to 2683 records.

The 21 MOs were all specialists with at least 10 years' experience, and most were senior specialists in hospitals. They included nine physicians, five anaesthetists, four obstetricians, two surgeons and one paediatrician. All underwent a two-day training course and were provided with a review manual. Five MOs reviewed 62% of records, with the remaining MOs reviewing from 100 to 750 records each. An additional panel of 22 MOs was available to provide specialist advice to the reviewing MOs as required.

At each hospital a two-stage review of the index admission was carried out:

Review by registered nurses (RF1)

The first stage involved screening by an RN of each medical record, looking for at least one of 18 explicit criteria that indicated that an AE might have occurred (Table 1). Any medical record with one or more of these criteria was forwarded for medical review, together with the first review form (RF1) listing the criteria, a summary of the salient features of the admission, and information on the quality of the medical record.

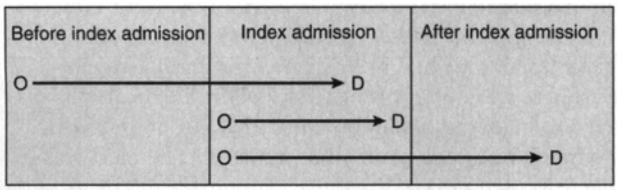
Review by medical officers (RF2)

The second stage required detailed independent analyses by two MOs of the medical record and the RF1 forwarded by the RN to determine whether an AE

1: Definitions and causation and preventability scales

An **adverse event** (AE) was defined as
(1) an unintended injury or complication which
(2) results in disability, death or prolongation of hospital stay, and is
(3) caused by health care management rather than the patient's disease.

The **index admission** was the admission sampled. AEs were recorded if they occurred before or during the index admission, or were discovered during or after the index admission. AEs occurring before the index admission were included only if they were responsible for all or part of the index admission. A diagram showing the occurrence and detection of AEs in relationship to the index admission is shown below.



O = Adverse event occurred; D = Adverse event detected.

Disability was temporary or permanent impairment of physical function (including disfigurement) or mental function or prolonged hospital stay (even in the absence of such impairment). **Temporary disability** included AEs from which complete recovery occurred within 12 months; and **permanent disability** included AEs which caused permanent impairment or which resulted in permanent institutional or nursing care or death.

Causation was present if the AE was caused by health care management rather than the disease process. It included acts of omission (failure to diagnose or treat) and acts of commission (incorrect treatment or management). A scale from 1–6 was used to determine whether an AE was caused by health care management or the disease process.

1= Virtually no evidence for management causation;
2= Slight-to-modest evidence for management causation;
3= Management causation not likely, less than 50–50 but close call;
4= Management causation more likely than not, more than 50–50 but close call;
5= Moderate/strong evidence for management causation; and
6= Virtually certain evidence for management causation.

Preventability of an AE was assessed as "an error in management due to failure to follow accepted practice at an individual or system level"; accepted practice was taken to be "the current level of expected performance for the average practitioner or system that manages the condition in question".[6]

The degree of preventability was scored on a 1–6 scale, grouped into three categories.

No preventability
1= Virtually no evidence for preventability.
Low preventability
2= Slight-to-modest evidence for preventability;
3= Preventability not likely, less than 50–50 but close call.
High preventability
4= Preventability more likely than not, more than 50–50 but close call;
5= Strong evidence for preventability; and
6= Virtually certain evidence for preventability.

The preventability scale was applied uniformly to all hospitals regardless of size or available resources.

had occurred. For each medical record, each MO examined the RF1 form and then undertook his or her own detailed analysis of the medical record, reviewing the entire index admission and any other relevant admissions and completing a second review form (RF2). A brief clinical summary and a validation of the RF1 findings were given, as well as an assessment of the adequacy of the medical record.

Steps in determining an adverse event

Definitions of adverse event (AE), index admission, disability, causation and preventability are given in Box 1, together with scales for determining disability and preventability. Box 2 (page 462) contains illustrative case summaries with and without adverse events and preventability.

- *For the index admission to be associated with an AE, the AE had to occur during the index admission or be an ongoing reason for the index admission.* This required examining admissions before and after the index admission.
- *If the first two elements of the adverse event definition were satisfied* (Box 1), the MOs considered the extent to which health care management rather than the disease process was responsible for the AE. The MOs gave a confidence score for causation using the scale given in Box 1.
- *If either of the first two elements of the adverse event definition was not satisfied* (Box 1), or there was no causation (causation score 1), the review ceased ("no AE").
- *If the first two elements were present and the causation score was 2–6*, the review continued with a series of questions about the nature of the AE: where it occurred; the specialty involved; extra bed-days attributable to the AE; the extent of the disability arising from the AE; and when the AE occurred with respect to the index admission.
- *The degree of preventability was then scored on a 1–6 scale*, similar to that used for the causation scale (Box 1). These scores were grouped into three categories:

No preventability (score = 1);
Low preventability (score = 2, 3) and
High preventability (score = 4, 5 and 6).

MOs were asked to record whether there were underlying human errors or violations. A separate question was asked about whether the AE was caused by a system error and, if so, what type of error. Questions were then completed

2: Examples of adverse event classification

Complication, no causation (no adverse event)
An elderly man was admitted to hospital after a fall leading to a fractured neck of femur, which was managed with early fixation, without complication. Three days later the patient had a major upper gastrointestinal bleed and died of the consequences of hypotension and anaemia. There was no history of gastrointestinal bleeding or its investigation, nor any reason for having a high index of suspicion. The situation appeared to have been promptly recognised and assessed.
The patient had a complication causing death but this was judged not to be caused by health care management.

Injury, no disability (no adverse event)
A patient with profound central nervous system impairment was hospitalised for assessment and rehabilitation, and suffered recurrent urinary tract infection in conjunction with the use of an indwelling urethral catheter. Although this required specific therapy on more than one occasion, it did not prolong hospitalisation beyond what was required for the patient's underlying condition.
The patient had a complication caused by health care management but had no resulting disability.

Adverse event, no preventability
A 50-year-old woman underwent coronary angiography for unstable angina. During the angiogram she sustained an anaphylactic reaction to the contrast, with cardiac arrest. She was able to be resuscitated promptly, without permanent sequelae, and hospitalisation was prolonged by 10 days. Evidence for prior contrast reactions was sought and not found.
The patient had a complication, disability and causation and hence had an adverse event. It was judged not to be preventable.

Adverse event, high preventability (Surgery)
A 67-year-old woman underwent a laparoscopic cholecystectomy, which proceeded to an open operation. Endoscopic retrograde cholangiopancreatography was undertaken eight days after the operation to remove a gallstone in the common bile duct; cannulation was not possible and the procedure was aborted. Ten days after the operation the patient collapsed and died suddenly. Autopsy findings showed extensive deep venous thrombosis and saddle pulmonary embolus. There was no documented evidence of thromboembolic prophylaxis in the medical record.
The patient had an adverse event resulting in death, with high preventability.

Adverse event, high preventability (Internal medicine)
A 55-year-old man with a history of multiple admissions for anxiety and palpitations was admitted in 1992 (index admission) with pleuritic chest pain and a provisional diagnosis of pneumonia. Chest x-ray examination revealed a 6 cm mass lesion in the basal segment of the right upper lobe. Review of the medical record showed that a lesion in the right upper lobe had been found on a chest x-ray in 1989. There was no report of the lesion in the record; it was referred to in an outpatient note in 1989, but no follow-up or treatment had been planned or initiated. The mass was a large cell carcinoma of the lung, with mediastinal and cerebral metastases. The patient underwent a course of chemotherapy and radiotherapy but died eight months later.
The patient had an adverse event resulting in death, with high preventability.

Adverse event, high preventability (Nursing)
An 87-year-old woman with osteoporosis underwent open reduction and internal fixation with an Austin–Moore prosthesis and received antibiotic therapy for a urinary tract infection. Five days after the operation it was noted that the patient had developed bilateral decubitus ulcers on her heels. No pressure-area care had been documented. The ulcers required daily dressings in hospital, and dressings by a community nurse were still required at discharge. The patient's hospital stay was extended to 39 days.
The patient had an adverse event resulting in disability and prolonged hospital stay, with high preventability.

about: complexity; urgency and expected benefit; how the AE may have been prevented; the reasons for failure to prevent the AE; whether it was an error of omission or commission; data on follow-up; and areas to which attention should be directed to prevent AEs.

On completion, the RF2s were collated by the team leader.

Disagreement between MOs

If the two reviewers disagreed about the presence of an AE, the type of AE or the causation or preventability score, the medical record was reviewed again jointly by the two MOs, who presented their RF2s to a third MO and a consensus was obtained. A third RF2 was then completed for the questions dealing with presence of an AE and preventability. For these cases, the remaining information was obtained from the RF2 form that agreed with the third RF2.

On 51 occasions, usually in complex cases, the consensus was that neither of the primary reviewers had chosen the AE that caused the most disability (when more than one AE was evident). The causation and preventability scores were entered into the third RF2, but the information required for the other data items was not completed. Hence, the denominator is 2302 rather than 2353 for these data items.

Statistical methods

The QAHCS used a stratified two-stage cluster sample to choose eligible admissions for review, and the estimators and their standard errors (SEs) should reflect both the stratification and the clustering employed in the design. SUDAAN[11] software was used to obtain estimates of proportions and their SEs and to perform the logistic regression analyses, as it adjusts for the sampling design. It was found that the crude proportions were similar to the estimates from SUDAAN, but that the unadjusted SEs were usually half the value of the adjusted SEs. The differences in the esti-

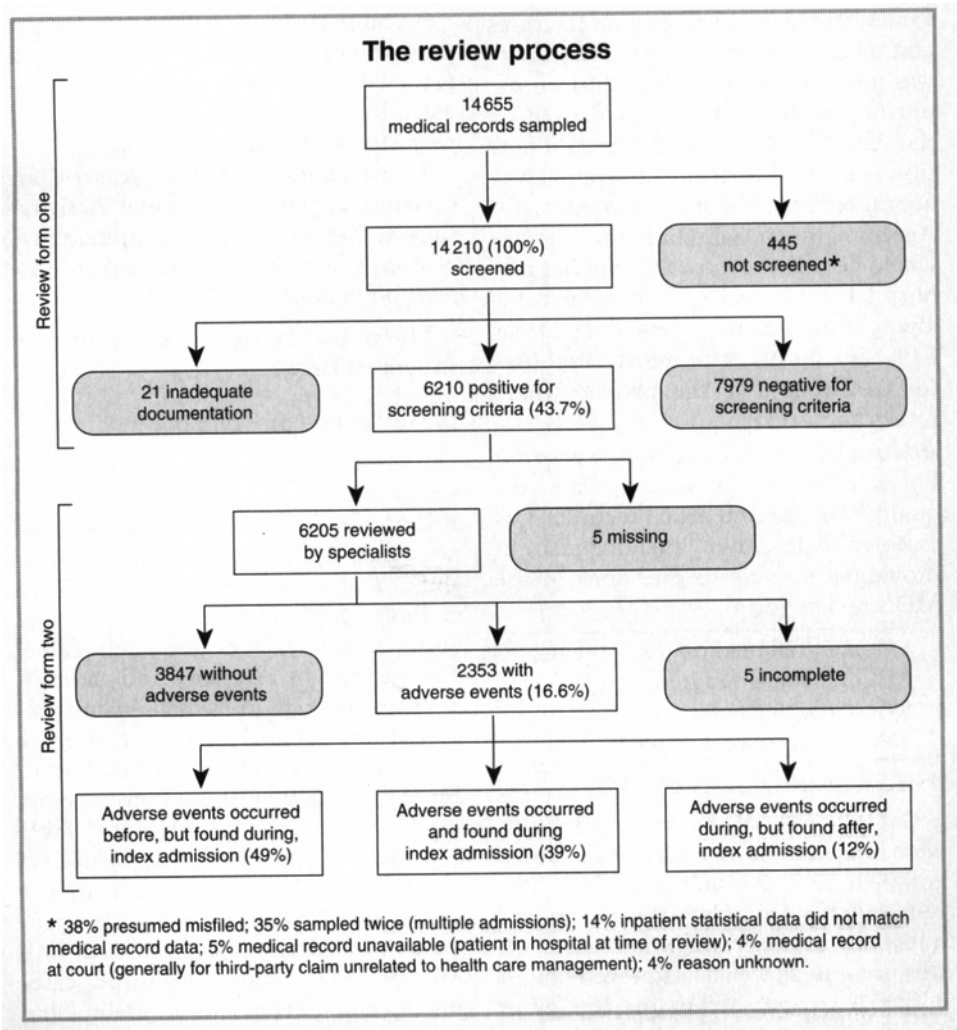
mates of the SEs are due to interhospital variation in the proportions, which are not accounted for in the usual binomial expression for SEs. Hence, for simplicity we report the unadjusted proportions, but for accuracy report the 95% confidence intervals (CIs) using the SEs that were obtained from SUDAAN.

The sensitivity of the initial screening by RNs (RF1) was estimated by having an MO complete an RF2 on 413 medical records assessed by RNs as negative for the 18 criteria for a possible AE in the first two hospitals sampled. Throughout the study, the RN team leader undertook a second review of 50 randomly chosen records at each hospital to assess the reliability of the RF1 review process. When records were reviewed twice, the kappa (κ) statistic was used to report agreement,[12] and the SE was calculated under the null hypothesis of $\kappa = 0$. The percentage of records for which there was agreement is also given.

To obtain population estimates for the number of admissions associated with AEs, the sample proportions were applied to the target population of 2.82 million hospital admissions. To estimate the number of AEs, or deaths from AEs, it was necessary to correct for the fact that an AE may be related to several admissions. This was done by assuming that the ratio of AEs per admission is 80% of the proportion of admissions with AEs.

Results

The number of medical records screened and reviewed is shown in the flow diagram of the review process (Figure). In 4035 cases the patient had sustained an injury, and in 3471 cases this had resulted in a disability or prolonged hospital stay. After determining causation, 2353 cases satisfied these three elements and were classified as having an AE.



Evaluation of the review process — review form 1

Reliability of screening criteria: Table 1 (page 460) lists the 18 criteria used in the RF1 form. The percentage of admissions with one, two, three and four or more positive criteria was 23%, 13%, 5% and 2%, respectively. At least one criterion was positive for 43.7% of all admissions. All criteria had a positive association with AEs, with unplanned return to the operating theatre having the highest odds ratio of 14.5. A logistic regression model with AE as outcome and all 18 criteria as predictor variables found that five criteria (5, 10, 13, 16 and 17) were not statistically significant at the 0.01 level.

Agreement between RNs: For 2574 admissions two RF1 forms were independently coded by RNs as part of the quality control: the agreement for the presence of positive criteria was 84% (κ, 0.67; SE, 0.02). These duplicate reviews also assessed the agreement for individual criteria. Criteria that performed less well were: 8, 9, 10, 12, 13, 16 and 18 (κ, 0.16–0.45); criteria with κ values over 0.60 were: 1, 2, 7 and 14 (Table 1).

Agreement between RNs and MOs: For the 6200 positive RF1 admissions, the MOs recorded whether they were in agreement with the RN's positive criteria. For 6125 (98.7%) admissions, there was complete agreement. In nine (0.1%) cases, both MOs disagreed with the RN's positive criteria, and for 66 (1.1%) of the cases one MO agreed and the other disagreed. For the 413 criteria-negative records which were given RF2 reviews, there was a 98.1% agreement between the RN and the MO.

Sensitivity of RF1 screening: Three AEs were found in the 413 criteria-negative RF1 admissions and we estimate that the number of admissions with AEs missed as a result of the RF1 screening was 58 (7979 x 3/413). The sensitivity of the RF1 screen is therefore 97.6% (2353/2411; 95% CI, 94.4%–99.1%) and the specificity is 67.3%.

Completeness of the medical records: The completeness of the medical records for the purposes of the screening process was assessed.

77% had an initial medical assessment;
74% had medical progress notes;
99% had nursing progress notes; and
72% a discharge summary.
If applicable:
91% had procedure documentation; and
81% had reports of diagnostic investigations.

53% of records were missing one or more of these elements.

The proportion of admissions associated with AEs was highest in those with records with no components missing (18.4%), and declined to 16.8%, 14.4%, 13.0% and 11.5%, respectively, for those with one, two, three and four medical record components missing. This result was not due to confounding with hospital strata, and suggests that, when documentation is missing, AEs are less likely to be detected.

Evaluation of the review process — review form 2

Number of reviews: More than 14 000 MO reviews were completed for 6200 medical records, of which 1993 were third MO reviews. The presence or absence of an AE was ascertained by two reviews for 4207 records; AEs were found in 20% of these. Of the 1993 discrepant cases requiring a third review, there was disagreement about the presence of an AE in 1375 cases, while in the remaining 618 cases the two reviewers agreed an AE was present but disagreed on causation and preventability scores. Of the 1375 medical records needing a third review to ascertain final AE status, 906 (66%) were found to have AEs and 469 did not have AEs. "Rule-based" errors — when an MO missed some documentation in the record, or was concerned with a different injury, or incorrectly applied a study protocol — accounted for 195 of the discrepant cases.

Agreement between MOs: In the RF2, agreement between MO reviewers on the presence of an AE was 80% (κ, 0.55). There was a 74% agreement on the existence of an injury or complication (κ, 0.43), and an 87% agreement on having a disability or prolonged hospital stay (κ, 0.49). The causation score was aggregated to three categories (1, 2–3 and 4–6) and the agreement between MOs was 71% (κ, 0.42).

Table 2: Comparison of study patients and patients admitted to New South Wales public and private hospitals

Patient data	Sample	NSW hospitals
Mean age (years)	43.8	44.8
Males (%)	42.8%	43.6%
Private hospital admission (six hospitals) (%)	21.5%	22.1%
Medical insurance (%)	37.8%	46.5%
Aboriginal (%)	1.2%	1.7%
Discharged (%)		
To home	90.7%	91.8%
To another hospital	4.3%	4.1%
Deaths (%)	1.9%	1.9%
Mean (SD) hospital stay (days)	6.2 (9.1)	7.1 (25.1)

With the same categories for the preventability score, agreement was 58% (κ, 0.33), and κ values for the remaining questions ranged from 0.30 to 0.77, indicating the difficulty in making identical clinical judgements. Questions on system error, therapeutic error and to a lesser extent medical error gave low κ values. Agreement was best on fractures and injuries related to obstetrics. There was a 62% agreement (κ, 0.39) on the portion of the hospital stay caused by the AE. Whether the AE caused a portion of or the entire hospital stay accounted for 56% of the disagreement. Agreement on whether the patient would be able to return to his or her prehospital state (over and above any disability from the underlying disease) was 81% (κ, 0.40), with most responses (80%) being that the patient would return to normal.

Adequacy of the medical records: For admissions classified as AEs, the quality of the medical records was assessed to determine their adequacy in providing answers to questions in the MO's review form.

85% of initial medical assessments,
87% of medical progress notes,
99% of nursing notes, and
96% of procedure documentation,

were adequate for completion of the RF2.

Overall, 73% of the medical records were judged to be of sufficient quality to complete all data required for RF2. The remainder were adequate to answer questions to ascertain whether an AE was present, as well as its preventability and associated disability. In 24 cases an AE was strongly suspected, but there was insufficient evidence or documentation in the medical record to confirm this suspicion.

Sample characteristics

The casemix of the sample was compared with that of Australian public hospitals,[9] using AN-DRG 1.[10] For 87 AN-DRGs which were not represented in the sample, fewer than three admissions were expected. More than 400 AN-DRGs were present in the sample, with frequencies that were within three standard deviations of the expected number: the AN-DRGs which were over-represented were more likely to be in a surgical category, obstetrics or cardiology. AN-DRGs with large differences were those for psychiatric disorders. These AN-DRGs were under-represented because patients in designated psychiatric wards were excluded from the study owing to anticipated difficulties in reviewing these cases.

A comparison of patient data for the sample with data for NSW public and private hospital admissions (data provided by NSW Health) for the financial year 1991–92 is given in Table 2.

These data and the Australian Casemix Report on Hospital Activity[9] suggest that our sample is representative of both the NSW and Australian hospital populations.

The main findings of the study are shown in Box 3.

Disability and preventability

For 51 of the 2353 AEs, details on disability were not obtained; hence disability results are reported for the remaining 2302 AEs. The data for disability and preventability are presented in Tables 3–13, and the main results are outlined below or beside each Table. The degrees of disability and the proportion with high preventability are presented in Table 3, and the average number of bed-days attributable to AEs by age, disability and preventability are shown in Table 4 (page 466). Table 5 (page 466) gives the proportion of adverse events by age, sex and insurance status, and Table 6 (page 467) the proportion of admissions associated with AEs for the major diagnostic categories, and permanent disability and

3: Summary of main findings of QAHCS

Adverse events

The proportion of admissions associated with an adverse event (AE) was 16.6% (95% CI, 15.2%–17.9%).

The timing of the AE with respect to the index admission was: 83% of AEs occurred in 1992, 8% in 1991 and the remainder before 1991.

For 39% of AEs, the AE occurred and was detected during the index admission, and 12% occurred during the index admission but were detected during a subsequent admission to the same hospital. The remaining 49% occurred before the index admission, with the index admission being a consequence of the AE. For 10% of admissions, the AE occurred more than 12 months before the index admission.

Disability

The proportions of admissions with each measure of disability were:

Death	0.79% (95% CI, 0.59%–0.99%)
Permanent disability	
Greater than 50%	0.77% (95% CI, 0.59%–0.95%)
Less than 50%	1.45% (95% CI, 1.23%–1.67%)
Temporary disability	
1–12 months	4.95% (95% CI, 4.48%–5.42%)
Less than 1 month	7.57% (95% CI, 6.83%–8.31%)

Disability was unable to be reasonably judged for 100 AEs (that is, 0.71% [95% CI, 0.49%–0.92%] of all admissions).

The total prevalence of the first three disability categories given above (death and greater than and less than 50% permanent disability) was 3.01% (95% CI, 2.60%–3.42%). The two temporary disability categories were responsible for a large proportion of extra bed-days in hospitals (1775 cases [12.5% of admissions]).

Preventability

The proportion of AEs with high preventability was 51.2% (95% CI, 47.9%–54.5%) for all AEs, but for the two disability categories of death and greater than 50% permanent disability the high preventability proportions were 69.9% (95% CI, 61.3%–78.0%) and 57.8% (95% CI, 48.1%–67.5%), respectively. There was a statistically significant relationship between disability and preventability, with high preventability being associated with greater disability ($P < 0.0001$).

Hospital stay

The AE was responsible for the whole duration of the index admission in 43.2% of cases (95% CI, 40.5%–46.0%) and for a portion of the index admission in 37.1% (95% CI, 33.9%–40.3%). The mean number of bed-days attributable to the AE (for all cases with AEs) was 7.1 bed-days; 18% spent more than 10 extra days in hospital (range, 0–120 days). Sixty-four per cent of bed-days attributable to AEs involved AEs causing temporary disability.

Australia-wide estimates

Extrapolating the estimated proportion of admissions associated with an AE (16.6%) to all Australian hospitals implies that about 470 000 (95% CI, 430 000–510 000) admissions are associated with AEs annually in Australian hospitals. These would account for 3.3 million bed-days per year, of which 1.7 million (8% of all hospital bed-days in Australia) are for AEs which have high preventability. The number of patients dying or incurring permanent disability each year in Australian hospitals as a result of AEs is estimated to be: 18 000 deaths (95% CI, 12 000–23 000); 17 000 (95% CI, 12 000–22 000) cases with permanent disability (> 50%); and 33 000 (95% CI, 27 000–37 000) cases with permanent disability (< 50%). There are estimated to be 280 000 (95% CI, 260 000–310 000) AEs resulting in temporary disability.

high preventability proportions for each category.

Tables 7–13 show the proportions of AEs judged to have high preventability, and the proportions associated with permanent disability or death, divided into: specialty involved; category of AE; and location of AE (page 468); areas for attention to prevent recurrence; category of system errors; factors relating to urgency, complexity and expected benefit; and classes of drugs related to AEs (page 469).

For each of the clinical categories of AE shown in Table 8, additional specific questions were asked about the nature of the problem. Frequent use of "other" demonstrated difficulty in obtaining well defined categories that are exhaustive and exclusive. Detailed analyses of all categories will be presented in future publications, but the findings with respect to the use of drugs presented in Table 13 (page 469) provide an illustration. There were 233 (10% of all cases) responses to the category "drug responsible for the AE". Of these, the most frequent error category was "other" (drug category not provided). In 19% the reviewer would not have prescribed the drug used in the context of the AE.

Discussion

This study reports a major retrospective clinical review of 14 179 admissions to a representative sample of Australian hospitals in 1992; 16.6% (2353) were associated with an AE, of which 51% had high preventability.

The sample was representative of the target population in terms of age, sex and casemix. The sensitivity of the screening process was high (97.6%) and the specificity lower (67.3%). There was good agreement between RNs and between RNs and MOs in the screening of records for detailed review, and between MOs on the presence of AEs in

Disability and preventability

Table 3: Percentage of adverse events rated no preventability, low preventability and high preventability for each level of disability, and total adverse events by disability

Disability	Preventability			Total adverse events (%)
	No	Low	High	
Less than 1 month	23.3%	29.7%	47.0%	1073 (46.6%)
1–12 months	16.0%	30.1%	54.0%	702 (30.5%)
Permanent < 50%*	20.9%	32.5%	46.6%	206 (8.9%)
Permanent > 50%*	16.5%	25.7%	57.8%	109 (4.7%)
Death	4.5%	25.9%	69.6%	112 (4.9%)
Unable to determine/unknown†	10.0%	31.0%	59.0%	100 (4.3%)
Total	**19.0%**	**29.8%**	**51.2%**	**2302 (100%)**

* Assessed qualitatively from the medical records by the reviewing medical officers.
† Excluding the 51 cases with no responses to these questions.

- 46.6% of adverse events (AEs) caused minimal disability;
- 77.1% (95% CI, 75.2%–79.0%) caused disability that was resolved within one year; and
- 18.5% (95% CI, 16.8%–20.3%) caused varying levels of permanent disability, including death (4.9% CI, 3.8%–6.0%).
- There was a statistically significant relationship between disability and preventability, with high preventability being associated with greater disability ($P < 0.0001$).
- High preventability was found in:
  - 51.2% (95% CI, 47.9%–54.5%) of all AEs;
  - 57.8% (95% CI, 48.1%–67.5%) of AEs resulting in >50% permanent disability; and
  - 69.6% (95% CI, 61.3%–78.0%) of AEs resulting in death.

Hospital stay

Table 4: Bed-days attributable to adverse events on index admission, by age, disability and preventability

	Average number of attributable bed-days per AE
Age	
0–14	4.1
15–29	5.2
30–44	6.1
45–64	6.9
65+	8.8
Total	**7.1**
Disability	
Minimal < 1 month	3.3
Moderate 1–12 months	8.9
Permanent < 50%	11.7
Permanent > 50%	23.1
Death	8.2
Preventability	
No preventability	5.9*
Low preventability	6.5
High preventability	7.8*

* $P = 0.003$ for no versus high preventability.

There was an *increase* in the average number of bed-days attributable to an adverse event (AE):
- with age;
- with severity of disability; and
- with preventability (to a lesser extent).

Age, sex and insurance status

Table 5: Number of admissions and proportion associated with adverse events and categories of disability, and proportion of adverse events with high preventability, by age, sex and insurance status*

	Number of admissions	Adverse events	Disability				High preventability
			<1 month	<12 months	Permanent	Death	
Age							
0–14	2020	10.8%	7.1%	1.9%	0.9%	0	48%
15–29	2818	10.3%	6.1%	2.4%	1.2%	0.1%	45%
30–44	2505	14.6%	7.7%	4.4%	1.6%	0.1%	46%
45–64	2891	19.3%	7.7%	7.0%	2.5%	0.6%	50%
65+	3945	23.3%	8.7%	7.2%	3.8%	2.3%	56%
Total	**14179**	**16.6%**	**7.6%**	**5.0%**	**2.2%**	**0.8%**	**51%**
Sex							
Male	6066	17.3%	7.5%	5.2%	2.5%	1.1%	53%
Female	8113	16.0%	7.6%	4.8%	2.0%	0.6%	50%
Insured (missing 1563)†							
Yes	4771	15.5%	7.4%	5.1%	1.5%	0.5%	42%
No	7845	17.1%	7.8%	4.8%	2.5%	0.9%	55%

* Percentages in disability columns are based on 2302 adverse events, of which 100 cases with disability could not be determined, and 51 missing values are not reported.
† Information about insurance not in medical record.

The proportion of:
- admissions associated with adverse events (AEs) increased with age over 30.
- admissions resulting in minimal disability (< 1 month) were not strongly related to age.
- admissions resulting in more serious disability (> 1 month or permanent disability) or death increased markedly with age.

The proportion of:
- AEs with high preventability were not strongly associated with age.
- AEs, categories of disability and high preventability showed no major differences between the sexes.
- AEs for uninsured and insured patients were similar, with a slightly higher rate for uninsured patients. (This may be due to age or casemix differences; when a logistic regression model was used to correct for age differences, no difference remained between patients with and without insurance.)

Major diagnostic categories

Table 6: Number of admissions by major diagnostic category (MDC), proportion of admissions associated with adverse events, percentage with permanent disability (including death) and percentage with high preventability

Major diagnostic category	Number of cases	Adverse event proportion	Permanent disability	High preventability
0 Pre MDC*	32	46.9%	66.7%	40%
1 Nervous system	717	14.8%	37.1%	55%
2 Eye	280	11.8%	3.2%	36%
3 Ear, nose and throat	949	7.9%	9.6%	27%
4 Respiratory system	1086	12.9%	17.8%	58%
5 Circulatory system	1697	20.2%	25.8%	56%
6 Digestive system	1463	23.2%	16.1%	51%
7 Hepatobiliary system and pancreas	360	16.1%	21.4%	59%
8 Musculoskeletal system and connective tissue	1721	21.9%	21.7%	52%
9 Skin, subcutaneous tissue and breast	596	18.5%	15.0%	43%
10 Endocrine, nutrition and metabolic disease	183	18.0%	25.0%	55%
11 Kidney and urinary tract	426	19.7%	13.3%	52%
12 Male reproductive system	263	14.4%	13.2%	58%
13 Female reproductive system	589	19.7%	3.5%	51%
14 Pregnancy, childbirth and puerperium	2090	7.2%	2.0%	51%
15 Newborns and other neonates with condition originating in perinatal period	408	10.3%	5.4%	50%
16 Blood and blood-forming organs	108	23.1%	28.0%	36%
17 Myeloproliferative disorders	227	14.1%	32.3%	44%
18 Infectious and parasitic diseases	165	30.3%	18.0%	60%
19 Mental diseases and disorders	80	15.0%	33.3%	75%
20 Substance use and substance induced organic mental disorder	56	7.1%	0	75%
21 Injuries, poisonings and toxic effects of drugs	262	30.9%	13.8%	46%
22 Burns	13	7.7%	0	100%
23 Factors influencing health status and other contacts with health service	212	11.8%	24.0%	52%
24 Unrelated	196	31.6%	28.3%	35%

* Consists of patients having tracheostomy, bone marrow or liver transplantation.

- The adverse event (AE) proportion was significantly *lower* for admissions for:
  - Ear, nose and throat
  - Pregnancy, childbirth and puerperium.
- The AE proportion was significantly *higher* for admissions for:
  - Infectious and parasitic diseases
  - Injuries, poisonings and toxic effects of drugs
  - Digestive system
  - Circulatory system
  - Musculoskeletal system.

  (In these categories, the proportion of AEs was much higher for surgical admissions.)
- There were *fewer* AEs resulting in permanent disability for:
  - Pregnancy, childbirth and puerperium
  - Female reproductive system.
- There were *more* AEs resulting in permanent disability for:
  - Circulatory system
  - Nervous system.

the screened records. The medical records were adequate for estimating AEs and their consequences.

Factors that may have contributed to the proportion of admissions associated with AEs being underestimated (by at least 2.2%) include:

- Medical records with missing components;
- Missing AEs (those detected outside the hospital in which the index admission occurred or after the completion of data collection in 1994); and
- The sensitivity of the screening process (RF1).

Factors that suggest the proportion of admissions associated with AEs was overestimated include:

- The lower estimate from SUDAAN (see ***Statistical methods*** section) (16.3%);
- Correcting for the casemix differences between the sample and Australian public hospitals gave a rate of 15.8%; and
- The sampling error resulted in a confidence interval of 15.2% to 17.9%.

Our estimate of 16.6% of hospital admissions associated with AEs translates into an estimate of about 13% for the AE ratio (defined as the number of AEs occurring per 100 admissions) used in the Harvard Medical Practice Study (HMPS). This is still considerably higher than the 3.7% recorded in the HMPS. The reasons for the differences between the two studies are discussed in Box 4 (page 470).

Of AEs, 18.5% resulted in permanent disability or death and, overall, AEs accounted for 7.1 additional bed-days on average. Extrapolation to all acute hospitals within Australia in 1992 indicates that 50 000 patients would have suffered permanent disability and 18 000 would have died as a result of their health care, and that the 470 000 admissions associated with AEs would have required 3.3 million bed-days.

The AEs in this study have a wide range of resulting disabilities which represent a balance between the injury or complication suffered by the patient and the ability of that patient to withstand such an injury. Clearly, there are many factors that alter this balance, but our results show that increasing patient age is a strong predictor of more serious disabilities resulting from AEs. The increase in preventable AEs causing death for patients over 65 years may well represent the complex balance of risk and benefit, or it could indicate that clinical assessment is more difficult in the elderly, and more susceptible to

Specialty

Table 7: Adverse events by specialty of attribution, proportions with permanent disability (including death), deaths and high preventability

Specialty	Adverse events	Permanent disability	Deaths*	High preventability
General surgery	317 (13.8%)	15%	3%	53%
Orthopaedic surgery	285 (12.4%)	19%	1%	48%
Internal medicine	150 (6.5%)	41%	20%	73%
Family practice	147 (6.4%)	16%	5%	69%
Obstetrics	140 (6.1%)	6%	0	54%
Gynaecology	134 (5.8%)	6%	0	53%
Cardiology	118 (5.1%)	25%	8%	58%
Urology	86 (3.7%)	12%	1%	37%
Nursing	85 (3.7%)	26%	8%	68%
Cardiac surgery	77 (3.3%)	14%	6%	40%
Vascular surgery	71 (3.1%)	32%	8%	49%
Otorhinolaryngology	59 (2.6%)	12%	0	19%
Neurosurgery	57 (2.5%)	33%	2%	42%
Colon/rectal surgery	53 (2.3%)	25%	4%	43%
Plastic surgery	49 (2.1%)	14%	0	41%
Paediatrics	49 (2.1%)	8%	0	53%
Anaesthesiology	47 (2.0%)	4%	2%	38%
Gastroenterology	43 (1.9%)	16%	7%	63%
Emergency	34 (1.5%)	9%	6%	82%
Ophthalmology	28 (1.2%)	11%	0	32%
Medical oncology	25 (1.1%)	20%	12%	24%
Other	248 (10.8%)	24%	7%	40%
Total	**2302 (100%)**	**19%**	**5%**	**51%**

* Based on small numbers. All percentages have number of AEs (column 1) as the denominator.

- The number of adverse events (AEs) attributed to each specialty reflects both the caseload as well as the AE rate.
- For most specialties, close to 50% of AEs had high preventability — family practice, internal medicine and emergency medicine had the highest proportion of AEs with high preventability.
- Internal medicine had the highest proportion of AEs with permanent disability and death.

Clinical category

Table 8: Adverse events by clinical category, proportions with permanent disability (including death), deaths and high preventability

Category*	Adverse events	Permanent disability	Deaths	High preventability
Operative†	1159 (50.3%)	17%	3%	44%
Diagnosis‡	314 (13.6%)	32%	13%	81%
Therapy§	276 (12.0%)	29%	12%	72%
Drug	249 (10.8%)	17%	8%	43%
Medical¶	197 (8.6%)	16%	3%	40%
Fracture	126 (5.5%)	16%	2%	59%
Obstetric	126 (5.5%)	4%	0	51%
Fall	66 (2.9%)	21%	5%	62%
Anaesthesia	51 (2.2%)	8%	6%	41%
Neonatal	30 (1.3%)	20%	3%	60%
System	358 (15.6%)	25%	11%	78%
Total	**2952**	**20%**	**6%**	**56%**

* These categories are not mutually exclusive and hence the total is more than 2302.

† An adverse event occurring in relation to operation or within 30 days of operation.
‡ An adverse event arising from a delayed or wrong diagnosis.
§ An adverse event arising when a correct diagnosis was made but there was incorrect therapy or a delay in treatment.
¶ An adverse event resulting from a medical procedure such as coronary angiography or endoscopy.

- Half the adverse events (AEs) were associated with an operation (50.4%).
- Diagnostic, system or therapeutic errors gave higher proportions of AEs with permanent disability and high preventability.
- Diagnostic, system or therapeutic errors accounted for 64% of deaths.
- For all clinical categories combined, the reason for the performance error was provided in only 26% of AEs:
  - 27% were rule-based errors (such as failure to check or follow protocol);
  - 26% were skill-based errors (slips, lapses);
  - 25% were technical errors (procedure was correct and indicated);
  - 16% were knowledge-based errors; and
  - 7% were violations (deliberate disregard of rule or protocol).

Location

Table 9: Location in which the adverse event occurred, proportions with permanent disability (including death), deaths and high preventability

Location	Adverse events	Permanent disability	Deaths	High preventability
Operating room	1077 (46.8%)	16%	2%	43%
Patient's room	577 (25.1%)	24%	10%	63%
Doctor's office	200 (8.7%)	24%	6%	65%
Labour and delivery	87 (3.8%)	6%	1%	45%
Patient's home	56 (2.4%)	14%	5%	46%
Nursing home	41 (1.8%)	29%	7%	68%
Other	264 (11.5%)	14%	6%	49%
Total	**2302 (100%)**	**19%**	**5%**	**51%**

- Just under a half of all adverse events (AEs) occurred in the operating room.
- A quarter of AEs occurred in the patient's room.

Prevention of recurrence

Table 10: Areas for efforts to prevent recurrence, proportions with permanent disability (including death), deaths and high preventability*

Area for attention	Adverse events	Permanent disability	Deaths	High preventability
Quality assurance	1296 (56.3%)	19%	6%	63%
Education	724 (31.5%)	20%	8%	74%
System	343 (14.9%)	23%	9%	77%
Communication	255 (11.1%)	28%	9%	81%
Credentialling	126 (5.5%)	37%	10%	80%
Resources	90 (3.9%)	37%	11%	74%
Retraining	86 (3.7%)	33%	13%	83%
Record keeping	35 (1.5%)	26%	11%	69%

* Reviewers were allowed to choose more than one area for each adverse event; hence there are 2955 in the adverse event population, 2093 in the high preventability group, and 653 in the permanent disability group.

Areas to which efforts should be directed to prevent recurrence of adverse events (AEs) were:

- quality assurance/peer review (56.3% of AEs);
- education (31.5% of AEs);
- system change (14.9%); and
- improvement in communication (11.1%).

Complexity, urgency and expected benefit

Table 12: Number of adverse events by case complexity, urgency, and potential benefit of management, proportions with permanent disability (including death), deaths and high preventability

Nature of case	Adverse events	Permanent disability	Deaths	High preventability
Complexity				
Very complex	184 (8.0%)	47%	18%	40%
Moderately complex	1125 (48.9%)	23%	6%	50%
Uncomplicated	976 (42.4%)	8%	1%	56%
Urgency				
Very urgent	265 (11.5%)	31%	11%	50%
Urgent	1117 (48.5%)	20%	6%	51%
Not urgent	887 (38.5%)	13%	2%	52%
Expected benefit				
Life saving	563 (24.5%)	26%	9%	46%
Major quality of life	1081 (47.0%)	17%	2%	50%
Minor quality of life	369 (16.0%)	7%	1%	53%
Not applicable	267 (11.6%)	27%	12%	66%

Percentages in column 2 are of total number of adverse events (2302). The individual categories do not sum to 100% because this information could not be determined for all cases. Percentages in columns 3 and 4 are of column 1 totals.

- A higher proportion of adverse events (AEs) resulting in permanent disability and death occurred among:
  - complex cases compared with uncomplicated cases;
  - very urgent cases compared with cases which were not urgent;
  - cases in which management was considered life-saving; and
  - cases in which management was expected to provide a major improvement in quality of life.
- Nearly half of all the deaths reported occurred in association with life-saving interventions; and
- A further 26% of deaths occurred in association with interventions for which a major improvement in quality of life was expected.

System errors

Table 11: Number of adverse events involving system errors, proportions with permanent disability (including death) and high preventability

System error	Adverse events	Permanent disability	High preventability
Absence of or failure to use policy, protocol or plan	188 (53%)	24%	80%
Inadequate reporting	62 (17%)	29%	84%
Inadequate training or supervision of staff	44 (12%)	32%	73%
Delay in providing service	26 (7%)	27%	81%
Inadequate function of services	16 (5%)	19%	69%
Defective equipment	5 (1%)	0	40%
Inadequate staffing	5 (1%)	20%	80%
Equipment not available	3 (1%)	0	67%
No response	9 (3%)	22%	44%
Total	358 (100%)	25%	78%

- System errors accounted for 16% of all adverse events (AEs).
- Errors of omission were judged to have occurred in 52% of AEs and errors of commission in 27%; the type of error could not be determined in 21%.

Reasons for failure to prevent the AE were reported in 1743 cases (76% of AEs). Of these:

- 25% involved failure to take precautions to prevent accidental injury;
- 10% involved failure to employ indicated tests;
- 9% involved avoidable delay in treatment;
- 6% involved failure to act upon the results of findings or tests;
- 6% involved failure to take an adequate history or physical examination; and
- 4% involved the doctor or other health professional practising outside his or her area of expertise.

The category "other prevention error" was the most common response (39%).

Drugs

Table 13: Drug-related adverse event (by drug type), by permanent disability (including death) and high preventability

Drug type	Adverse events	Permanent disability	High preventability
Other*	74 (31.8%)	17%	47%
Antibiotic	30 (12.9%)	13%	30%
Cardiovascular†	27 (11.6%)	11%	74%
Anticoagulant	25 (10.7%)	32%	40%
Antineoplastic	22 (9.4%)	14%	9%
Antihypertensive	19 (8.2%)	16%	16%
Other drug categories	36 (15.4%)	16%	16%
Total	233 (100%)		

* Drug category not provided. † Excluding antihypertensive agents.

- The drug category was not provided for 31.8% of adverse events (AEs) related to drugs.
- The most common reasons for drug-related injury were:
  - error in the method of use or dose, 18%;
  - drug used inappropriately, 14%; and
  - inadequate monitoring of drug levels or other follow-up, 12%.

  In 49% the reviewer indicated that none of the listed categories applied.

4: Comparison of the Quality in Australian Health Care Study and the Harvard Medical Practice Study

The Quality in Australian Health Care Study (QAHCS) was modelled on the Harvard Medical Practice Study (HMPS) and, with some modifications, the same methods were used. A major difference was that a measure of preventability was used in place of determination of negligence.

The HMPS estimated a rate or, strictly, a ratio, defined as the number of adverse events (AEs) occurring per 100 admissions.[3] The QAHCS, however, estimated the proportion of admissions associated with an AE, as this more closely reflects the impact of AEs on hospitals. The HMPS rate or ratio only counted an admission in the numerator if the AE was first detected during the index admission, whether it occurred during or before the index admission. The QAHCS proportion includes the index admission in the numerator if the AE was detected before the index admission but was still responsible for the index admission. Hence, the numerator is higher in the QAHCS proportion than in the HMPS ratio (estimated as 20%–25% higher) as some AEs result in multiple admissions.

Our estimate of 16.6% of hospital admissions with AEs translates into an estimate of about 13% for the AE ratio, and is considerably higher than the 3.7% recorded in the HMPS. There are two possible reasons for this:

- The HMPS was concerned with medical negligence and malpractice; the QAHCS focused on prevention, which may produce different incentives for the reporting of AEs.
- Both studies surveyed medical records, the HMPS in 1984 and the QAHCS in 1992; the quality of the medical record (which our study has shown influences the detection rate) may have improved in the intervening years.

These factors suggest that the HMPS could have underestimated the AE rate.

The nearly fourfold difference in the AE ratio between the two studies stems from two sources. The first screen, RF1, while similar in the two studies, produced 26% of records screening positive in HMPS, but 44% in the QAHCS. Of those screening positive, the medical review, RF2, in the HMPS classified 17% as AEs, while our study found 40%. Thus, both the first stage screening and the second stage medical review processes contributed equally to the differences between the two studies.

Despite these major differences, there were similarities. After adjusting the QAHCS to estimate the ratio of AEs per admission, the timing of the AEs was similar in both studies: about 50% of AEs occurred and were detected during the index admission and nearly 40% occurred before but were detected during the index admission. Also, both studies reported that most AEs resulted in temporary disability (73% and 77%), with 0.5% of the patients in the HMPS dying as a result of their adverse event, compared with 0.79% in the QAHCS.

error. Qualitative methods and a more detailed review of the clinical situations are needed to clarify this issue.

These data are supported by the good agreement between the reviewers about whether the medical record contained the necessary information, and by the small proportion of AEs (10%) in which disability was not clearly reported in the record.

The conclusion that an AE caused death requires a note of caution. Many of these patients were elderly (80% older than 65 years), and had a serious underlying disease which severely shortened their life expectancy independent of any AE. Also, some may have requested and received limited care, despite the absence of such documentation in the medical record. This information was sought at medical review and found only once. A more helpful way of quantifying AEs resulting in death would be to measure the person-years of life lost, but this has not been attempted. The following comment reported in the HMPS also applies here: "none of this is to say that deaths of sick, elderly patients due to adverse events is excusable, only that the number of deaths we report here is not directly comparable in economic terms to the number of deaths from automobile accidents, for example, in which the victims are usually younger and healthier."[3]

The large number of AEs with minimal disability have an appreciable impact on the health system, given the prolonged hospital stay, the increase in number of tests, treatments and consultations, and hospital readmissions. The impact in personal, social and productivity terms for the patient has not been measured in our study, but must be substantial. Hence, the consequences of all the disability from adverse events are important.

Preventability was not strongly associated with age, sex or insurance status, nor was it associated with the level of disability, except for death (in which 70% of AEs showed high preventability). Only 1.2% of AEs in the "no preventability" category resulted in death, compared with 4.1% in the "low preventability" category and 6.5% in the "high preventability" category. Some of this association between preventability and death could be ascribed to outcome bias.[13]

Preventability was higher than average for family practice, internal medicine and emergency medicine, for AEs associated with diagnostic and therapeutic errors, and for AEs originating in a hospital ward or a doctor's office. Preventability was somewhat lower than average for AEs arising from medical procedures, anaesthesia, some surgical disciplines and for AEs originating in the operating theatre. Thus, AEs associated with high preventability tended to be associated with decision-making rather than procedures.

In considering the contributing factors to AEs, it is necessary to recognise that health care represents a "complex system".[14] As in other complex systems, such as aviation, AEs in health care seldom arise from a single human error or the failure of one item of equipment, but are usually associated with complex interactions between management, organisational, technical and equipment problems, which not only set the stage for the AE but may be the prime cause.[15,16] Thus, although human error plays a role in 70%–80% of problems in

complex systems, including those in health care, it is often only one link in a chain of interacting problems.[14,17,18]

Factors relating to the severity of the patient's illness and the risks of management to be undertaken will both contribute to the severity of the outcome of an AE. Our study demonstrates that the disabilities of AEs are more severe in complex cases, cases requiring urgent treatment or those with expectations of life-saving benefit. These are the circumstances of high risk medicine. Nevertheless, 40%–50% of these AEs are still deemed to have high preventability and this demands that any contributing factors be identified to better devise preventive measures.

The reviewers were asked to record, if possible, the type of human error that may have contributed to each AE, using a classification which has been applied to studies of complex systems.[16,18] In 74% of cases, however, the reviewers did not record any opinion as to what type of human error, if any, may have been involved. Their reluctance to do so may be understandable, as there are clear limitations as to the extent to which inferences may be drawn about factors contributing to an AE from a medical record. However, each type of error was represented, and there were associations between certain types of AE and certain types of error. This underlines the importance of conducting error analysis for each category of AE, as preventive strategies will depend on the type of error. For example, the solution to problems arising from rule-based errors may lie in the implementation of checklists and crisis management protocols, whereas that for skill-based errors has to lie in redesigning the working environment or equipment so that these random human failures can not be committed or are detected early.

Conclusions about the contribution of system errors in our study must be very tentative and may be underestimated. The general question on system error was only answered positively for 16% of AEs. In most studies of complex systems, some form of system problem is usually judged to be a contributing factor in up to 90% of cases.[14,17] The low proportion in this study may reflect difficulties eliciting such data either from the medical record, or from sections of the RF2, or the reticence of the MOs to invoke these factors. Further analysis of these data may assist in an understanding of the system contribution to AEs. When this question was answered, absence of or failure to use a policy, protocol or plan was recorded in over half the cases. Inadequate reporting was the next most common cause.

Broad categories of AEs serve only to highlight areas that require attention, with the wide range of different patterns emphasising the complex nature of the problem. They are not particularly useful for the development of preventive strategies,[19-21] as the same manifestation of many medical problems may have different underlying causes. Thus, for example, death from a pulmonary embolus may occur because:

- A particular institution has a ("bad") routine of not using any prophylactic measures for thromboembolism;
- An intern intended to but forgot to order prophylactic measures; or
- Prophylactic measures were ordered but the order was misfiled.

Different solutions are required for each of these causes. Qualitative analysis is required both of the study's categories and "clinical situations" or "natural categories",[20,21] supplemented by information from literature searches and from other areas, such as incident monitoring.

The data presented here confirm that a wide range of human and system-based failures contribute to AEs, and also suggest that in up to half of them practical strategies may be available to prevent them. Non-preventable AEs also merit further study, as means can be found to detect them early and lessen their impact. The fact that half of all AEs are deemed to have low or no preventability is an important point to be grasped by prospective patients and the legal system in order to avoid an inappropriate presumption of culpability when things go wrong.[16]

Our results can be used in the policy debates on patient education, litigation in health care, medical quality of care and quality improvement, including the development of safer protocols or practices. The implications in terms of preventable adverse outcomes for patients and use of health care resources are substantial.

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