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A comparison of iatrogenic injury studies in Australia and the USA II: reviewer behaviour and quality of care

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Abstract

Objective. To better understand the remaining three-fold disparity between adverse event (AE) rates in the Quality in Australia Health Care Study (QAHCS) and the Utah-Colorado Study (UTCOS) after methodological differences had been accounted for.

Setting. Iatrogenic injury in hospitalized patients in Australia and America.

Design. Using a previously developed classification, all AEs were assigned to 98 exclusive descriptive categories and the relative rates compared between studies; they were also compared with respect to severity and death.

Main outcome measures. The distribution of AEs amongst the descriptive and outcome categories.

Results. For 38 categories, representing 67% of UTCOS and 28% of QAHCS AEs, there were no statistically significant differences. For 33, representing 31% and 69% respectively, there was seven times more AEs in QAHCS than in UTCOS. Rates for major disability and death were very similar (1.7% and 0.3% of admissions for both studies) but the minor disability rate was six times greater in QAHCS (8.4% versus 1.3%).

Conclusions. A similar 2% core of serious AEs was found in both studies, but for the remaining categories six to seven times more AEs were reported in QAHCS than in UTCOS. We hypothesize that this disparity is due to different thresholds for admission and discharge and to a greater degree of under-reporting of certain types of problems as AEs by UTCOS than QAHCS reviewers. The biases identified were consistent with, and appropriate for, the quite different aims of each study. No definitive difference in quality of care was identified by these analyses or a literature review.

Keywords: adverse events, complications, iatrogenic injury, medical record review, quality of care

Two retrospective reviews of medical records for adverse events (AEs) were reported recently, one in Australia [1] and one in the USA [2]. Both reviews used similar definitions, handbooks and forms {based on the Harvard Medical Practice Study (HMPS) [3]}, and both reviewed approximately 15 000 medical records drawn randomly in 1992 from acute-care hospitals. It was estimated that 16.6% of admissions were associated with an AE in Australia (represented by hospitals in the States of New South Wales and South Australia, QAHCS [1]) whereas an annual incidence of only 2.9% to 3.7% was found in the USA, represented by hospitals in Colorado and Utah (UTCOS [2]) and New York State (HMPS [3]), respectively. This large difference provoked widespread comment and debate [4–6]. To try to gain insight into where the differences might lie, we undertook an analysis of the context, methods, casemix, population, patient and hospital characteristics in QAHCS and UTCOS [7].

We concluded that, had the QAHCS medical records and AEs been analysed in the same way as those in UTCOS, the QAHCS rate would have been estimated at an annual incidence of 10.6%. This reduction, from a greater than five-fold to a three-fold difference, was due primarily to five methodological differences between the studies, details of

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which have been reported elsewhere in this issue [7]. However, a three-fold difference still remained after these factors had been corrected for, and there were no striking differences in case mix, population, patient or hospital characteristics to account for this.

It was therefore decided, in order to gain insight into the basis for the disparity remaining between the two studies after explicit methodological differences had been accounted for, to carry out a qualitative analysis using a specially developed classification for incidents and AEs. It was also decided to examine the distribution of AEs with respect to severity as reflected by estimates by the original reviewers of morbidity, mortality and prolongation of hospital stay.

Methods

Background

The QAHCS was carried out to determine the frequency, nature and cost of AEs in Australia over 1 year. The UTCOS was commissioned to compare the cost of a 'no-fault' insurance system compared with that of the tort system. Both studies used virtually identical methods and training manuals for reviewers, based on those used in the HMPS [3], both studied samples of approximately 15 000 medical records drawn randomly from 1992 acute-care hospital admissions, and both used the same definition of an AE. An AE was defined as an unintended injury or harm to a patient, caused by health care management rather than a disease process, which led to hospitalization, prolongation of hospital stay, morbidity at discharge or death.

The nurse and physician reviewers in both studies underwent formal training by the investigators. Nurse reviewers screened the randomly sampled records for any of 18 criteria previously shown to be associated with AEs (e.g. unplanned admission to an intensive care unit) [2,3]. Records screened 'criterion positive' then went on to review by physicians, who provided a synopsis of any AE detected, together with details about how it occurred, by providing both narrative descriptions and check boxes on a standard review form. Reviewers from both studies recorded a score, on a scale of 1–6, with respect to their degree of confidence that an AE had been caused by medical management. QAHCS reviewers went on to score preventability and UTCOS reviewers went on to score negligence, both using the same 1–6 scale. Both studies had similar reliability for the detection of AEs by physician reviewers ($\kappa = 0.55$ for QAHCS and 0.4 for UTCOS) [1,2].

When it became known that these studies had yielded markedly different results, investigators from both studies collaborated to try to determine the basis for the difference. First, reviewers from each country reviewed and discussed each stage of their counterparts' research process. This led to the identification of the five explicit methodological differences described elsewhere in this issue.

The QAHCS data were then treated as they would have been had they been processed by UTCOS reviewers. All of the information on the QAHCS review forms (narrative and check box information) was reviewed by an UTCOS investigator and those AEs that would not have met the UTCOS criteria for an AE were eliminated, leaving 1499 QAHCS AEs (from the sample of 14 179 records) to be compared with the 475 UTCOS AEs (from the sample of 14 565 records). There were 5432 surgical procedures in the QAHCS sample of records and 8885 in the UTCOS sample. All of the information available from the physician review forms about each AE from both studies was then coded into basic, principal and dominant natural categories using the generic occurrence classification (GOC).

The classification

Natural categories, arranged in a hierachial classification, comprise the GOC [8]. Natural categories are descriptors of incidents or AEs which are recognizable by and potentially useful to clinicians so that clinical problems, together with their causes, potential preventability and outcomes can be characterized, priorities can be set, comparisons can be made, and the stage set for trends to be tracked over time. They are designed to capture the salient features of AEs, place them in context together with their associated conditions, and elicit any system- or human-error based contributing factors. The development and structure of the GOC has been described in detail elsewhere [8].

Each AE may be coded into as many basic natural categories (BNCs), from about 12 500 in the GOC, as are necessary to characterize it. BNCs capture such attributes of an event as which medical speciality was responsible, where the event took place, what pre-existing conditions the patient had, and what the outcome was in pathophysiological terms. Principal natural categories (PNCs) allow each AE to be coded into a single category according to how it may be prevented. Dominant natural categories (DNCs) comprise one or more PNC and were devised so that sufficient AEs could be aggregated into like-categories to allow comparison between QAHCS and UTCOS. To illustrate the relationship between BNCs, PNCs and DNCs, an example of the make-up of the DNC complication–intubation (from Set 1, Table 1) is given below:

The relationship between dominant, principal and basic natural categories.

The DNC complication–intubation is presented as an example to demonstrate the relationship between BNCs, PNCs and DNCs. The AEs in this DNC fall into six PNCs. There are three QAHCS AEs and two UTCOS AEs in one PNC – damage to teeth/dental work during intubation, and one QAHCS AE in each of the following: premature extubation requiring re-intubation; dysphonia resulting from laryngeal damage; acute laryngeal spasm complicating a difficult intubation; traumatic haematoma to the soft palate following difficult intubation; and tracheal stenosis following prolonged intubation. It is evident that the events in each of these PNCs would require a different

Table 1 Dominant natural categories with no statistical differences between the Australian and the US study (Group 1)

Dominant natural categories	No. in QAHCS	No. in UTCOS	Odds ratio QAHCS/ UTCOS	95% CI
Set 1 – with six or more AEs in either group				
Haemorrhage	48	43	1.15	0.76–1.73
Medication–side effect or toxic effect	34	26	1.34	0.81–2.24
Infection–abscess/other	31	23	1.38	0.81–2.38
Damage to internal organs and major blood vessels	27	33	0.84	0.51–1.40
Circulatory and organ failure/SIRS/sepsis/death	25	21	1.22	0.68–2.19
Infection–drain/catheter/implanted device/IVC	24	16	1.54	0.82–2.90
Deep vein thrombosis	19	9	2.17	0.98–4.79
Pulmonary embolus	19	9	2.17	0.98–4.79
Medication–allergy/idiosyncratic effect	17	17	1.03	0.52–2.01
Cerebrovascular accident	15	10	1.54	0.69–3.43
Fall–hospital	14	8	1.80	0.75–4.29
Post-operative pneumonia	14	7	2.05	0.83–5.09
Pneumothorax	11	11	1.03	0.45–2.37
Nerve damage	10	11	0.93	0.40–2.20
Fistula	9	3	3.08	0.83–11.4
Infection–bacteraemia/septicaemia/endocarditis	9	3	3.08	0.83–11.4
Orthopaedic problem	9	5	1.85	0.62–5.52
Complication–intubation	8	2	4.11	0.87–19.4
Foetal–major problem	8	4	2.05	0.62–6.82
Treatment–delay/failure to order/wrong choice	8	6	1.37	0.48–3.95
Hypertension/hypotension	7	5	1.44	0.46–4.53
Apnoea/respiratory arrest/hypoventilation	6	2	3.08	0.62–15.3
Myocardial infarction	6	9	0.68	0.24–1.92
Procedure–delay/wrong choice	6	7	0.88	0.30–2.62
Peripheral circulatory	2	6	0.34	0.07–1.70
Total – Set 1	386	296	1.34	1.15–1.56
Set 2 – with five or fewer AEs in both groups				
Anaemia	5	1	5.14	0.60–44.0
Fit/seizure	5	4	1.28	0.34–4.78
Vaginal tear	5	3	1.71	0.41–7.17
Aspiration pneumonia/pneumonitis	3	2	1.54	0.26–9.22
Hemiplegia/paraplegia/quadriplegia	3	1	3.08	0.32–29.7
Injuries–other	3	4	0.77	0.17–3.44
Angina	2	1	2.05	0.19–22.7
Foreign body	2	1	2.05	0.19–22.7
Peritonitis	2	1	2.05	0.19–22.7
Atelectasis	1	1	1.03	0.06–16.4
Gangrene/necrosis	1	1	1.03	0.06–16.4
Meningitis	1	1	1.03	0.06–16.4
Rash	1	1	1.03	0.06–16.4
Total – Set 2	34	22	1.59	0.93–2.72
Group 1 total (% of grand total)	420 (28%)	318 (67%)		

CI, Confidence interval.

set of preventive or corrective strategies, which is why each was allocated a separate PNC.

Each of the AEs in both QAHCS and UTCOS was allotted approximately 10 BNCs. For example, premature extubation requiring re-intubation had the following eight BNCs: inadequate dose of medication–drug involved–morphine; inadequate dose of medication–drug involved–midazolam; location–intensive care unit; staff problem–inappropriate staff; staff problem–inexperienced staff; staff problem–unfamiliar with protocol; outcome–airway obstruction; and outcome–desaturation.

Creating DNCs led to the existence of categories of disparate types, the essence of some of which is a deficiency in process, whilst the essence of others is the pathophysiological outcome. For example, the category management/planning/education problem (from Set 2, Table 2) comprises AEs for which the bad outcome was essentially a prolongation of the pre-existing suffering or disease, and an AE was 'called' because this state of affairs had been allowed to continue without proper investigation or management. The AE was categorized primarily by the deficient process, not by the somewhat non-specific outcome. For example, the 27 events which made up one of the 51 PNCs in this DNC were cases of no investigation, a delay in investigation, or inadequate investigation of ischaemic heart disease.

On the other hand, the category cerebrovascular accident (CVA), for example, comprises AEs with a particular type of poor outcome, when the actual details of precisely how this came about were either not known or not recorded. This DNC is made up of six PNCs of which five were common to QAHCS and UTCOS, two which occurred only in QAHCS and one which occurred only in UTCOS. These were: CVA secondary to atrial fibrillation – warfarin not started or stopped (four AEs in QAHCS, two in UTCOS); CVA-neurosurgery (three in each study); perioperative CVA–cardiopulmonary bypass (three in each study); CVA–perioperative but not after cardiopulmonary bypass, neurosurgery or carotid endarterectomy (two in QAHCS, one in UTCOS); CVA–post-carotid endarterectomy (two in QAHCS); CVA secondary to chemotherapy (one in QAHCS) and CVA secondary to thrombolytic therapy (one in UTCOS). The essence of these AEs for the DNC is captured by the outcome rather than the processes, which are captured, however, by the PNC, allowing potential corrective strategies to be considered.

Most DNCs, like the examples given above, comprise several PNCs. However, some comprise only one (e.g. gastrointestinal bleed induced by non-steroidal anti-inflammatory drugs (NSAIDs) and post-procedure ileus/pseudo-obstruction). It is important to note that many mundane events, such as ileus and post-operative pain, technically meet the definition of an AE if they prolong stay or cause morbidity at discharge, and therefore qualify as AEs.

It is also important to emphasize that coding incidents, AEs or medico-legal files into BNCs simply provides a compendium of descriptors, arranged so that they can be located easily by coders, which exist by virtue of the fact that they were deemed relevant by physician reviewers in the case of AEs, by reporters in the case of incidents, or by risk managers in the case of medico-legal files. The GOC can be expanded whenever a relevant feature cannot be coded into the existing set of descriptors. The manner in which these basic descriptors are coalesced depends on the purpose of the exercise. In the case of PNCs the purpose was to rank clusters of events according to how they may be prevented so that priorities could be set for addressing the clinical problems they represent. In the case of DNCs, the aim was to be able to gain insight into the basis for the disparate AE rates in QAHCS and UTCOS. Other categories can be constructed, using BNCs as descriptive building blocks, with other aims in mind. For example, events could be clustered on the basis of the triad structure, process, outcome; this might be desirable with respect to providing a profile for a regulator inspecting a health care facility. Finally, wherever possible, the GOC has been arranged so that its categories can be cross-mapped to other classifications, such as the International Classification of Diseases – Version 10 or the Occupational Health and Safety classification used by Federal Agency for Occupational Health and Safety in Australia.

The process

All of the information from the 1499 AEs from the QAHCS was entered into a computer database and software was written so that investigators could call up and read all the narrative and check box information from windows on a single computer screen for each AE. In this way interpretation and assimilation was possible of the originally hand-written information from two or three 16-page physician review forms representing each AE. Once an investigator had assimilated information about an AE, it was coded into BNCs in Version 1 of the GOC, which comprised some 12 500 BNCs [8]. All of the information from the UTCOS AEs was assimilated by reading print-outs of the check box information and typed synopses of the events provided by UTCOS investigators, and then coded into Version 1 of the GOC.

Coding the 1499 Australian AEs yielded 15 641 BNCs and coding the 475 US events yielded 5316 BNCs; because many AEs were similar, all AEs in both studies were represented by only 2511 BNCs.

The set of BNC codes for each AE were then reviewed again, and the AEs were clustered into some 250 exclusive categories which captured the essence of each AE. The AEs in these categories were then reviewed yet again and some were coalesced further so as to make up 98 DNCs. PNCs were then derived as subsets of the DNCs by placing them in clusters according to how they could be prevented. For example, the DNC infection–wound was broken up into 15 PNCs for QAHCS (nine of which were represented in UTCOS). This was done because different antibiotic regimes and strategies would be used to prevent the different types of infection (e.g. there were 31 wound infections following abdominal or pelvic procedures in QAHCS and six in UTCOS, and six following head and neck procedures in QAHCS and one in UTCOS).

Table 2 Dominant natural categories with statistical differences between the Australian and the USA Study (Group 2)[1]

Dominant natural categories	No. in QAHCS	No. in UTCOS	Odds ratio QAHCS/ UTCOS	95% CI
Set 1 – minor/transient signs and symptoms				
Pain	36	3	12.3	3.80–40.0
Haematoma	33	9	3.77	1.80–7.87
Urinary retention/incontinence	26	5	5.34	2.05–13.9
Post-operative nausea and vomiting	18	3	6.16	1.82–20.9
Haematuria/clots/bladder spasm	15	1	15.4	2.04–117
Headache	15	2	7.70	1.76–33.7
Fever*	10	2	5.14	1.13–23.5
Arrhythmia	9	0		
Effusion	7	0		
Foetal–minor problem*	6	0		
Total – Set 1	175	25	7.19	4.73–10.9
Set 2 – AEs involving reviewer judgement				
Management/planning/education problem	144	12	12.3	6.84–22.2
Diagnosis–delay/no or wrong	88	25	3.62	2.32–5.64
Unsatisfactory functional/cosmetic result	42	8	5.39	2.53–11.5
Unnecessary operation	25	3	8.56	2.58–28.4
Premature discharge	22	1	22.6	3.05–168
Delay in admission	9	0		
Total – Set 2	330	49	6.92	5.12–9.35
Set 3 – other AEs				
Infection–wound	112	25	4.60	2.98–7.10
Breakdown/failure of repair/rejection	53	11	4.95	2.58–9.48
Pressure injury/skin tear/abrasion	41	1	42.1	5.79–306
Urinary tract infection	41	1	42.1	5.79–306
Medication–overdose	35	12	3.00	1.55–5.77
Wound breakdown/dehiscence	28	1	28.8	3.91–211
Scar formation or late tissue response	26	3	8.90	2.69–29.4
Technical or mechanical failure	25	2	12.8	3.04–54.2
Hernia–recurrent/incisional	24	1	24.7	3.33–182
NSAID–gastrointestinal bleed	24	1	24.7	3.33–182
Inadequate manipulation/reduction of fracture	21	0		
Fall–outside hospital	20	2	10.3	2.40–44.0
Sequelae of radiation/chemotherapy	20	0		
Ante/postpartum haemorrhage/retained products	17	3	5.82	1.71–19.9
Implanted prosthetic device–problem with*	16	6	2.74	1.07–7.00
Complication–percutaneous needle/catheter/tube*	11	3	3.77	1.05–13.5
Inadequate excision of a lesion	11	2	5.65	1.25–25.5
Total – Set 3	525	74	7.29	5.71–9.31
Group 2 total (% of grand total)	1030 (69%)	148 (31%)		

[1] All statistically different at the $P < 0.01$ level, except those marked * which are different at the $P < 0.05$ level. There were more than six times as many minor (see Table 4) AEs in QAHCS than in UTCOS.

The 1499 QAHCS AEs fell into 518 PNCs and 91 DNCs and the 475 UTCOS AEs fell into 262 PNCs and 78 DNCs. Because many AEs were similar, all of the AEs in both studies were represented by 654 PNCs and 98 DNCs. A detailed description of the distribution of AEs amongst PNCs is to be published elsewhere [WB Runciman *et al.*, manuscript submitted for publication].

For this study, the difference in proportion of each DNC between QAHCS and UTCOS was calculated and the statistical significance of the differences determined using

Table 3 Dominant natural categories with five or fewer AEs reported in only one study (Group 3)

Dominant natural categories		
Set 1 – represented only in the Australian study		
Complication–eye surgery	5	
Maternal injury or problem–other	5	
Abnormal fluid and electrolytes–other	4	
Ileus	4	
Removal of metal	4	
Hyperglycaemia/hypoglycaemia	4	
Administrative	3	
Eye damage	3	
Reflex sympathetic dystrophy	3	
Colloid or blood product problem	2	
Glaucoma after cataract procedure	2	
Swelling/oedema	2	
Aneurysm after vascular catheter	1	
Complication–endoscope	1	
Consent–problem with	1	
Cerebrospinal fluid leak	1	
Hypernatraemia/hyponatraemia	1	
Incontinence–faecal	1	
Jaundice	1	
Post-operative peptic ulcer	1	
Total – Set 1 (% of grand total)	49	(3%)
Set 2 – represented only in the USA study		
Asthma due to medication	2	
Hyperkalemia	2	
Chest pain and tachycardia	1	
Complication–circumcision	1	
Peritoneal fluid collection	1	
Subcutaneous emphysema	1	
Syncope	1	
Total – Set 2 (% of grand total)	9	(2%)
Group 3 total	58	

Epi-info6 [9]; relative risks were also performed on QAHCS and UTCOS frequencies of AEs by DNC.

To examine the distribution of AEs with respect to severity, as attributed by the respective reviewers from the original studies, odds ratios were calculated, considering the Australian health care system as the exposure, with 95% confidence intervals. Estimates based on a compound severity indicator, incorporating both disability scores and attributed bed days, were also compared (see Table 4 for definitions). These estimates were based on scores by the original reviewers. These original UTCOS scores differ from those reported in the UTCOS publication, because the latter were adjusted before publication by medico-legal malpractice claims adjustors to provide a valid basis for costing. Also, investigators re-allocated QAHCS 18 deaths from QAHCS category 8 (see Table 4) to one of QAHCS categories 4–7, so as to align QAHCS category 8 with category 8 (death) in UTCOS, as death could not be attributed to the AE in these 18 QAHCS cases. All deaths could be attributed to be the AE in the cases allocated to category 8 by the original UTCOS reviewers.

Results

All of the AEs in both studies were accommodated by 98 DNCs, of which 27 represented events in only one study; reliability of coding has been reported previously [8]. The remaining 71 DNCs accounted for 1916 (97%) of all the AEs (see Figure 1 and Tables 1, 2 and 3).

Of these, there was a core of AEs of similar frequencies in both studies (Group 1, Figure 1 and Table 1), represented by 25 DNCs for which there were no statistical differences between the studies (Set 1, Table 1) and 13 with too few events to show a difference (Set 2, Table 1). This accounts for 67% of the USA and 28% of the Australian AEs.

There were also 33 DNCs with statistically significant differences between QAHCS and UTCOS (Group 2, Figure 1 and Table 2). There were, on average, just under sevenfold more AEs in QAHCS than UTCOS in this group, which accounts for a further 1030 (69%) of the Australian AEs and 148 (31%) of the USA AEs.

Only 6–7% of all events in both studies were in categories with insufficient numbers to demonstrate significant differences (Set 2, Table 1 and Table 3). There was no DNC with a statistically greater proportion of AEs in the USA than the Australian study.

The comparisons of the QAHCS and UTCOS studies with respect to indicators of severity, as assessed by the original reviewers, are presented in Table 4. There was a very similar core of serious AEs comprising 2% of admissions in both studies (major morbidity 1.7% and death 0.3% in both studies).

Discussion

It is apparent that there are some striking similarities, but also some major qualitative differences between the AEs in QAHCS and UTCOS, both with respect to the severity profile and to the distribution of AEs in DNCs.

Analysis of the DNCs shows that there is a core of AEs, representing over two-thirds of the USA and almost one-third of the Australian AEs, which is made up of categories for which there are no statistical differences between QAHCS and UTCOS. This is made up mainly of serious events which, in most cases, would readily be considered iatrogenic. Both studies also had a core of serious AEs, as assessed by the original reviewers, which was associated with 2% of admissions.

However, there were six times more minor AEs in QAHCS than UTCOS (Table 4) and 33 categories with, collectively, seven times more AEs in QAHCS than UTCOS.

Thus, despite the similar core of serious events, there were over three times more AEs in the Australian than the USA study. The most obvious reason for this is that this is a real

Table 4 Comparison of Australian and USA data by outcomes

	Source		Odds ratio	
	Australia	USA	Australia/ USA	95% CI
All cases reported	1499[1]	475	3.2	2.92–3.60
Disability				
Minor disability	1121[2]	189[3]	6.1	5.21–7.12
Major disability	249[2]	248[3]	1.0	0.82–1.13
Compound severity indicator[4]				
Minor: < 1 bed-day or minor disability	1140	204	5.7	4.94–6.68
Major: at least 1 bed-day and major disability	212	204	1.1	0.88–1.30
Death	44	38	1.0	0.83–1.13

[1] Disability score for 35 Australian events not originally recorded and 50 scored in category 9.
[2] Australian disability scores: Minor = 1 (minimal impairment and/or recovery in 1 month), or 2 (moderate impairment, recovery in 1–6 months); Major = 3 (moderate impairment, recovery in 6 months–1 year), 4 (permanent impairment, disability 1–50%), 5 (permanent impairment, disability > 50%), 6 (permanent nursing), or 7 (institutional care); 8 = death; 9 = cannot tell from the medical record (from Medical Record Review Manual for Australian Hospital Care Study).
[3] USA disability scores: Minor = 1 (emotional disability only), 2 (insignificant injury), or 3 (minor temporary); Major = 4 (major temporary), 5 (minor permanent), 6 (significant permanent), or 7 (major permanent); 8 = death.
[4] Not all events are within these categories.

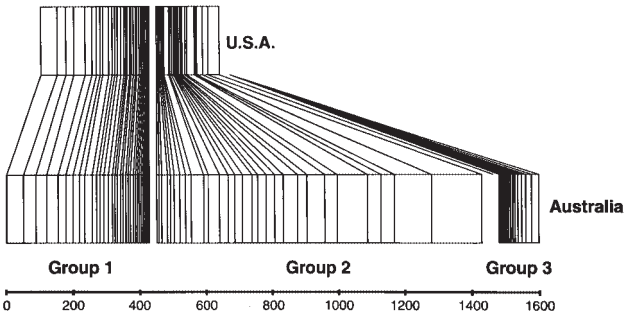

Figure 1 A comparison of sizes of dominant natural categories of AEs in Australian and USA studies. Group 1 represents those categories of AEs for which there were no significant differences between Australia and the USA ($P < 0.05$). Group 2 shows AE categories where a statistical difference was shown between studies (see Table 2). Group 3 shows categories where there was a zero count in one of the studies.

difference and reflects worse care in Australia. However, if this was the sole reason, one would expect an across the board difference, rather than the essentially bi-modal distribution evident in Figure 1 and Tables 1–4.

Instead, differences in reviewer behaviour or perception as to what constitutes an AE may underlie this pattern. Both studies used the same definition for an AE. However, Australian reviewers were then asked to score preventability on a 1–6 scale, whereas USA reviewers were asked to score negligence on the same scale. Also, Australian reviewers knew that the study was intended to identify the frequency and nature of all AEs, in order to estimate the burden they placed on the system, whereas USA reviewers knew that exposure to litigation and claims for compensation were being assessed. This may have led to different perceptions as to what was considered to be an AE in the two studies, and the evolution of different operational definitions by the two sets of reviewers. Possible manifestations of such differences are discussed below.

The events in Group 2, of which there were seven-fold more in QAHCS than UTCOS, were divided into three sets in an attempt to facilitate discussion (see Table 2). Of the 200 events in Set 1 of Table 2, 181 (91%) were post-procedural; virtually all were unremarkable phenomena commonly encountered clinically. It would seem that some of these AEs were either not recorded in the USA or were not perceived to be serious enough to constitute AEs.

In 1992 there was more pressure to discharge, or not to admit, patients in the USA than in Australia, potentially excluding some USA incidents from qualifying as AEs (average length of stay 5 versus 7 days [1,2]). Also, there is no doubt that many patients in both countries would have been discharged postoperatively with some nausea, some pain, some haematuria, a headache, a mild fever and so on. Technically, any disability at discharge would constitute an AE; in reality some arbitrary threshold had to be chosen. It seems reasonable to conclude that the differences in Set 1, Table 2 may be attributed largely to differences in threshold for admission or discharge, or for recording or perceiving an AE.

The next group of significantly different categories (Set 2, Table 2), comprising 330 Australian and 49 USA events, was characterized by the fact that reviewers made a judgement about quality of care in 'calling' an AE. AEs in this category seem to have been perceived because the care was considered 'not to be good enough' in the context of the overall health

care system. Events were generally placed in this group, with the exception of unnecessary operations, because the patients suffered prolongation of their problems but no other specific adverse outcomes.

A large category in the Australian database was the management/education/planning group. Included in this category in the Australian study were 40 events related to management of cardiovascular problems (e.g. a patient with angina whose angiogram was cancelled three times), 24 concerning respiratory problems, 14 involving delay and inappropriate treatment of fractures (e.g. a fractured forearm scheduled for reduction 3 days later), and 12 other cancelled, delayed, or abandoned operations. USA investigators acknowledge that most of these would not have been regarded as AEs in UTCOS, but were given the benefit of the doubt in this analysis because some morbidity was involved and the investigators did not have access to the original medical records for this re-analysis.

Set 3 of Table 2 represents 525 events in QAHCS and 74 in UTCOS; 355 (two-thirds) and 56 (three-quarters) respectively, represent post-operative problems at the procedural site. However, where independent data are available, these do not point to any major systematic geographic variations. For example, 192 wound infections, amongst 5432 surgical procedures, were coded into the GOC amongst the 2353 AEs listed in the original QAHCS study [1]. This rate of 3.5% is similar to the estimated 1992 USA-wide rate of 4% [10]. The apparent Australian rate, if only the 1499 QAHCS events comparable with the USA events are considered, including 28 cases from the wound breakdown category, may be calculated at 2% (120/5432), and the comparable apparent USA rate (26/8885) at less than 0.3%. Clearly, some wound infections in QAHCS and many in UTCOS were not regarded as AEs [11], possibly because less serious cases were not recorded, were overshadowed by more serious problems, were considered not to prolong stay or not to constitute morbidity at discharge, or because they only manifested after discharge. A three- to four-fold under-reporting of wound infections using retrospective medical record review has been noted previously in the USA [6].

A possible reason for the low rates in UTCOS for late complications such as wound breakdown, scar formation, technical failure, hernia or inadequate manipulation of a fracture is that these constitute well-recognized, common sequelae of procedures – although it may be argued that they all technically meet the criteria for an AE. There is a similar pattern for other AEs.

The QAHCS AE rate for pressure injury and urinary tract infections was 0.29% and the UTCOS rate was 0.007%, 40-fold lower. Large reviews reporting studies from several countries report prevalence rates for pressure injuries of 3–14% [12–16], including a rate of 9.2% across 148 acute-care facilities in the USA [17]. It is clear that many of these common, but frequently fairly minor disabilities were not regarded as AEs in both studies.

Similarly, many medication overdoses were not considered to have satisfied the criteria for an AE, as only 0.25% of QAHCS and 0.08% of UTCOS admissions were reported to have been associated with them; the rate for medication overdoses has been reported at 0.7% of admissions in Australia [18]. The drugs most commonly involved were similar in both studies (anticoagulants, opioids, anticonvulsants, cardiovascular agents). This problem has been shown previously to be threshold sensitive with respect to whether or not events are regarded as AEs, as rates differing by greater than an order of magnitude have been obtained in the same institution by using different techniques [6]. In the USA, less than 10% of adverse drug events have been found to satisfy the definition used in UTCOS for an AE [19].

Admissions for gastrointestinal bleeds associated with NSAID use may be calculated at 0.15% (or 1.5/1000 admissions) from the QAHCS study, a figure consistent with the lower end of independent calculations for Australia [20, 21]. Although we do not know the rate of NSAID use in the USA, odds ratios of 2–3 for NSAID-induced gastrointestinal bleeds have been calculated by meta-analysis; geographical locations or nationality were not identified as sources of heterogeneity, although studies from Australia, Canada the UK and the USA were included [22,23].

In summary, the AE rates for some of the problems reported in the USA study were much lower than the frequency with which these problems have been found in studies of different design. Many would not have met the criteria for an AE; the nature of the events which were reported seemed, on review, to be reasonable in the context of a study set up to estimate the exposure of institutions to litigation or claims for compensation. In this context relatively common, minor, well understood problems are of little relevance.

In QAHCS, there was a very similar core of major events to that in UTCOS, but, in addition, there were six to seven times more minor events. Although some problems were also frequently not regarded as AEs in this study, the nature of the events which were reported seemed, on review, to be reasonable in the context of a study set up to estimate the frequency, nature and total annual hospital costs attributable to AEs, whenever or wherever they had occurred in the Australian health care system. Such an approach is appropriate if the overall impact of AEs on a universal health care system is to be estimated.

Thus, on balance, different thresholds for admission, discharge, or morbidity, with certain categories of events being regarded as AEs less frequently in UTCOS than QAHCS, seem likely to be the major factors in the three-fold rate difference between the USA and Australian studies. USA reviewers have, in the past, judged care appropriate more often than their UK counterparts for identical clinical problems [24]; such a difference may have contributed to the disparity.

There are many features of these two studies, such as their common methodological heritage, similar sample size and timing, which invited comparison. However, through analyses using natural categories of AEs and of indicators of severity, it has been possible to detect specific biases consistent with the disparate underlying objectives of the two studies. No definitive difference in the quality of care between Australia

and the USA could be identified by these analyses or review of the literature.

Ideally, in order to truly compare the rates of AEs in Australia and the USA, it would be necessary to perform a specific study which incorporated this intention within its aim and which controlled for confounding factors within its methodological design. Alternatively, and more realistically, the adoption of an improved reference, or gold standard, methodology for AE studies applicable in different health care settings would facilitate more direct comparisons. This analysis has provided much greater insight into how an AE might be defined; this new information is being used to design a better record analysis system for future studies.

Regardless of any speculation about relative or absolute rates, and the fact that retrospective medical record analysis provides only a minimum rate, these studies show that potentially preventable AEs are occurring in both Australia and the USA at rates which are a cause for concern.

Any groups of AEs which are potentially preventable should be addressed with respect to identifying cost- and risk-effective measures for their better detection, prevention and management. The classifications used in publications so far [1–3] have been too crude to be useful for identifying clinical problems with sufficient specificity to be of any use in devising such measures, except in general areas such as medication [6,19]. Indeed, most of the dominant categories used in this analysis are too general to be used for devising practical preventive strategies [8]. For this reason, the AEs in each DNC have been clustered into PNCs according to how they may be prevented. This will allow the nature of clusters of clinical problems to be identified in sufficient detail to set priorities and devise preventive strategies [25]. The GOC can codify virtually all relevant information about 'things which go wrong' in health care, not only from retrospective medical record reviews, but from incident reports, coroners' recommendations, mortality and morbidity studies, complaints and medico-legal closed claims.

Attention can now be directed to evidence-based priorities and progress can be monitored system-wide using a composite indicator comprising the 71 DNCs common to both studies [8,25]. The fractions of each potentially preventable category which are realistically preventable by applying published best practice, and the resultant potential savings, are currently being identified [25]. The challenge will be to use these and other available data to address each problem systematically and rigorously. Strategies shown to be cost and risk-effective will need to be introduced at a national, or, ideally, international level [26] to reduce the current unacceptably high rate of iatrogenic injury.

References

1. Wilson RMcL, Runciman WB, Gibberd RW *et al.* The Quality in Australian Health Care Study. *Med J Aust* 1995; **163:** 458–471.

2. Thomas EJ, Studdert DM, Burstin HR *et al.* Incidence and types of adverse events and negligent care in Utah and Colorado in 1992. *Med Care,* 2000; **38:** 261–271.

3. Brennan TA, Leape LL, Laird NM *et al.* Incidence of adverse events and negligence in hospitalized patients. *N Engl J Med* 1991; **324:** 370–376.

4. Van Der Weyden, MB. Politics and publishing: the quality in Australian health care study [editorial]. *Med J Aust* 1993; **163:** 453–454.

5. McNeil JJ, Leeder SR. How safe are Australian hospitals? *Med J Aust* 1993; **163:** 472–475.

6. James BC. Every defect a treasure: learning from adverse events in hospitals. *Med J Aust* 1997; **166:** 484–487.

7. Thomas EJ, Studdert DM, Runciman WB *et al.* A comparison of iatrogenic injury studies in Australia and the United States I: Context, methods, casemix, population, patient and hospital characteristics. *Int J Qual Health Care,* 2000; **12:** 371–378.

8. Runciman WB, Helps SC, Sexton EJ, Malpass A. A classification for incidents and accidents in the health care system. *J Qual Clin Practice* 1998; **18:** 199–211.

9. Epi-info6, Centre for Disease Control, Atlanta, 1997.

10. Wenzel RP. Preoperative antibiotic prophylaxis. *N Engl J Med* 1992; **326:** 337–339.

11. Leaper DJ. Prophylactic and therapeutic role of antibiotics in wound care. *Am J Surg* 1994; **1671A** (suppl)**:** S15–S21.

12. Wright R, Tiziani A. Pressure Ulcer Point Prevalence Study. *Primary Intention* 1996; **4:** 18–23.

13. McGowan S, Hensley L, Maddocks J. Monitoring the occurrence of pressure ulcers in a teaching hospital: a quality improvement project. *Primary Intention* 1996; **4:** 9–17.

14. Girvan J, Griffiths JA. Toward prevention. *Nursing Times* 1989; **85:** 64–66.

15. Barbenel JC, Jordan MM, Nicol SM, Clark MO. Incidence of pressure sores in the Greater Glasgow Health Board area. *Lancet* 1977; **2:** 548–550.

16. Leigh IH, Bennett G. Pressure ulcers: prevalence, etiology and treatment modalities. *Am J Surg* 1994; **1671A** (suppl)**:** S25–S30.

17. Meehan M. Multisite pressure sore ulcer prevalence survey. *Decubitis* 1990; **3:** 14–17.

18. Larmour I, Dolphin RG, Baxter H *et al.* A prospective study of hospital admissions due to drug reactions. *Austral J Hosp Pharm* 1991; **21:** 90–95.

19. Bates DW, Cullen DJ, Laird N *et al.* Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Study Group. *J Am Med Assoc* 1995; **274:** 29–34.

20. Henry D, Dobson A, Turner C. Variability in the risk of major gastrointestinal complications for non-aspirin non-steroidal anti-inflammatory drugs. *Gastroenterology* 1993; **104:** 1078–1088.

21. Roughead L, Moller J. Pattern of non-steroidal anti-inflammatory drug use in Australia. *Med J Austral* 1996; **165:** 530–531.

22. Gabriel SE, Jaakkimainen L, Bombardier C. Risk for serious gastrointestinal complications related to use of nonsteroidal anti-inflammatory drugs; A meta-analysis. *Ann Intern Med* 1991; **115:** 787–796.

23. Bollini P, Garcia-Rodriguez LA, Perez-Gutthann S, Walker AM. The impact of research quality and study design on epidemiologic estimates of the effect of nonsteroidal anti-inflammatory drugs on upper gastrointestinal tract disease. *Arch Intern Med* 1992; **152:** 1289–1295.

24. Brook RH, Kosecoff JB, Park RE *et al.* Diagnosis and treatment of coronary disease: comparison of doctors' attitudes in the USA and UK. *Lancet* 1988; **1:** 425–445.

25. Rigby K, Clark RB, Runciman WB. Adverse events in health care: setting priorities based on economic evaluation. *J Qual Clin Pract* 1999; **19:** 7–12.

26. Runciman WB. Editorial: Incidents and accidents in health care: it's time! *J Qual Clin Pract* 1999; **19:** 1–2.

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