

Reporting of adverse events in routinely collected data sets in Australia

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Foreword

For several years, adverse events have been a subject of interest in Australia, not least because of uncertainty about how often they occur, and their impact.

The recently established Australian Council for Safety and Quality in Health Care has a charter to lead national efforts to promote systematic improvements in the safety and quality of health care in Australia. In its action plan for 2001, the Council identified four priority areas, one of which is better use of data and information throughout the system to support safer patient care. Its Data and Information Working Group has in turn been charged with, among other things, improving the capacity of existing data collections to provide information on the occurrence of adverse events.

This working paper describes adverse events reported in three routinely collected data sets in Australia, and offers suggestions for further assessment and improvement of the data collections to allow the occurrence of these conditions to be gauged more accurately.

It should prove a useful contribution to deliberations on improving health information systems to measure adverse events and monitor the efforts to reduce them.

Richard Madden
Director
April 2001

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Summary

Objective: To describe the nature and frequency of adverse events reported in routinely compiled national mortality and hospital morbidity data collections, and to gauge the usefulness of these data collections (using ICD to classify injury and poisoning, and external causes) as sources of data on adverse events in Australia. Adverse events reported in a national survey of general practitioner activity will also be described.

Design: Retrospective analysis of data in the AIHW National Mortality Database, the AIHW National Hospital Morbidity Database and the BEACH survey of general practitioner activity.

Subjects: Deaths registered in Australia in 1997 and 1998, admitted patient episodes (separations) in almost all Australian hospitals in 1997–98, and 201,757 weighted patient encounters with randomly selected general practitioners in 1998–99 and 1999–00.

Main outcome measures: Numbers and proportions of deaths registered with an adverse event as a cause of death, numbers and proportions of separations from hospital with an adverse event reported as a diagnosis or as an external cause of injury or poisoning, and proportions of general practitioner–patient encounters with an adverse event reported as a problem managed.

Results: A total of 2,594 deaths registered in 1997 (2.0% of all deaths) and 2,939 registered in 1998 (2.3%) had an adverse event reported as a cause of death, an average of 14.9 deaths per 100,000 population per year. The adverse event was reported as the underlying cause of death for 177 of these deaths in the two-year period. Complications of surgical and medical care were the reported adverse events for 73.3% of the 5,533 deaths, adverse drug effects for 26.6%, iatrogenic diseases for 62.4% and misadventures to patients for 1.3%.

An adverse event was reported as a diagnosis or an external cause of an injury or poisoning for 264,347 separations from Australian hospitals in 1997–98 (4.75% of all separations). Complications of surgical or medical care were reported for 72.2% of these, drug adverse effects for 20.2%, iatrogenic diseases for 75.8% and misadventures to patients for 1.8%.

An adverse event was a reported problem for about 0.9% (95% CI 0.8%–1.0%) of general practice encounters in both 1998–99 and 1999–00. The problems were mainly adverse effects of medical agents and complications of treatment.

Conclusions: The mortality and hospital morbidity databases have the advantages of being routinely collected, fully covering deaths and hospital separations in Australia, and being supported by substantial national data collection infrastructures. They appear to usefully record a range of adverse events. However, some features of the ICD-9(-CM) (and ICD-10(-AM)) classifications and of the source material (death certificates and hospital medical records), and uncertain data quality mean that their use in routine monitoring of the occurrence of adverse events may not be possible without further assessment. For hospital data, in particular, it could be important to undertake studies of the validity of the coded data against medical records (for example, to assess the capacity of hospital morbidity data to record various types of adverse events) and enhancements to the ICD-10-AM classification and other changes to data collection practices that would improve the sensitivity of analyses of the data for adverse events.

1 Introduction

Adverse events are an important cause of morbidity and mortality. Retrospective studies of medical records in the United States have found that about 3% of admissions to hospital are associated with adverse events, and that a proportion of these are fatal (Brennan et al. 1991, Thomas et al. 2000a). In Australia, the Quality in Australian Health Care Study found that 16.6% of admissions in 1992 were associated with an adverse event (Wilson et al. 1995), although recent reanalysis of the data suggests that a smaller proportion (2%) are serious adverse events and occur at similar rates to that of the serious adverse events in the American studies (Thomas et al. 2000b).

Representative retrospective medical record studies are very resource-intensive. They are not undertaken routinely and it is unlikely that they will play a major role in assessing levels of adverse events nor in monitoring the changes that may occur as a result of efforts to reduce them by, for example, the recently formed Australian Council for Safety and Quality in Health Care (ACSQHC).

In that context, and as recommended by the ACSQHC (ACSQHC 2000), other methods to routinely monitor iatrogenic harm should be assessed as alternatives to retrospective medical record review as a method of monitoring iatrogenic harm. The ICD-coded mortality data and the hospital morbidity data that are routinely compiled for all hospitalised patients in Australia and elsewhere are two data sources that could be assessed, particularly because these data collections have the advantages of being routinely collected, essentially fully covering deaths and hospital separations in Australia, and being supported by substantial national data collection infrastructures.

Overview analysis of 1995–96 data in the Australian Institute of Health and Welfare (AIHW) National Hospital Morbidity Database showed that about 4% of separations (admissions) included an external cause code for an adverse event (Hargreaves & Madden 1997) and suggested that, despite problems with the data, the database had potential for use in monitoring iatrogenic harm.

This report presents a preliminary update of the 1995–96 National Hospital Morbidity Database analysis with 1997–98 data and presents similar data from the AIHW National Mortality Database and an Australian survey of general practice activity. Some aspects of the ICD-9(-CM) classification and the nature of the data collections are discussed in the context of the sensitivity of analyses of these data collections for adverse events. This discussion could be used to inform development of ICD-10(-AM) and the mortality and hospital morbidity data recording systems for improved adverse event monitoring using routinely collected data.

A more comprehensive analysis of these data will be presented elsewhere.

2 Methods

Data on adverse events were retrospectively analysed from three routinely compiled data collections, the AIHW National Mortality Database, the AIHW National Hospital Morbidity Database and a continuous survey of general practice activity referred to as BEACH (Bettering the Evaluation and Care of Health).

Definition of adverse events

The definition of adverse events for this study was guided by the definitions used:

- by Brennan et al. (1991): ‘an injury caused by medical management rather than by the underlying disease or condition of the patient’; and
- in the United States Institute of Medicine’s recent report *To err is human* (Kohn et al. 2000): ‘an injury resulting from a medical intervention’.

It has also been guided by the definition proposed by the Australian Patient Safety Foundation (Runciman et al. 1999):

- ‘unintended or unnecessary harm or suffering arising from any aspect of health care management’.

The term is synonymous with the term ‘iatrogenic harm’, with ‘iatrogenic’ meaning arising from health care, rather than from the patient’s underlying disease or injury.

These definitions encompass adverse events that could be regarded as preventable and harm that would not be regarded as currently preventable. They do not include incidents or ‘near misses’ that do not result in harm to the patient.

In addition, by the use of the words ‘unintended or unnecessary’, the Australian Patient Safety Foundation’s definition includes only harm or suffering that is not unavoidable. This concept was also incorporated into the definition of adverse events used in the Quality in Australian Health Care Study (‘an unintended injury or complication which results in disability, death or prolonged hospital stay and is caused by health care management’) (Wilson et al. 1995). Thus, conditions considered to be normal or expected consequences of treatment are not included. Such conditions were excluded from the definition of an adverse patient occurrence (‘an untoward event which under optimal conditions is not a natural consequence of the patient’s disease or treatment’) in an adverse occurrence screening program in Victoria (Wolff 1995).

Because this study used retrospective analysis of existent data, the actual definitions used differed from these definitions. For each of the data sources, the definition used for adverse events (detailed below) depended on the definitions used for the data collections, and on the nature of the classifications used for information on causes of death, diagnoses and problems, respectively.

ICD-9(-CM) external cause and disease/diagnosis codes for adverse events

For 1997 and 1998, Australian mortality data were multiply coded. Therefore, injury and poisoning deaths were assigned both ICD-9 external cause codes and disease codes.

Similarly, injury and poisoning diagnoses recorded as ICD-9-CM (or ICD-10-AM) codes in Australian hospital morbidity data systems are usually (but not always) accompanied by codes for the external cause of the injury or poisoning. Hence, analysis of the mortality or morbidity data for adverse events can be undertaken using both adverse event disease/diagnosis codes and adverse event external cause codes.

External cause codes

In terms of ICD external cause codes, the definitional material above was interpreted as the ICD-9(-CM) external cause codes that are specific for adverse events, that is, these three rubrics (World Health Organization 1974; NCC 1996):

- E870–E876 Misadventures to patients during surgical and medical care (abbreviated as ‘Misadventures’ for this analysis);
- E878–E879 Surgical and medical procedures as the cause of abnormal reaction of patient or later complication, without mention of misadventure at the time of procedure (abbreviated as ‘Complications’); and
- E930–E949 Drugs, medicaments and biological substances causing adverse effects in therapeutic use (abbreviated as ‘Drug adverse effects’).

The latter category includes correct drug properly administered in a therapeutic or prophylactic dosage as the cause of any adverse effect. Accidental overdoses of drugs, wrong drugs given or taken in error, drugs taken inadvertently and accidents in the use of drugs and biologicals in medical and surgical procedures are classified as Accidental poisoning by drugs, medicaments and biologicals (E850–E858). This category would be used for deaths/separations from some external causes that would meet the definition of adverse event; however, it would also be used for deaths/separations resulting from poisoning that would not be regarded as an adverse event, for example in the event of a drug being inadvertently taken by a child, or for the overdose of a heroin user.

Other external cause groups, such as Accidental falls (E880–E888), would similarly be used for both adverse event deaths/separations and non-adverse event deaths/separations.

All these categories which could be used for both adverse event deaths/separations and non-adverse event deaths/separations were not used in this analysis, as they were not specific for adverse events. This means, however, that the number of deaths/separations identified as having an external cause because of an adverse event is likely to have been underestimated.

Disease/diagnosis codes

In terms of ICD disease codes, the definitional material above was interpreted as the ICD-9(-CM) disease codes that are apparently specific for adverse events (Table 1).

The ICD-9(-CM) disease classification (which includes injury and poisoning) contains one main section which is specific for adverse events:

- 996–999 Complications of surgical and medical care, not elsewhere classified.

As the title implies, other parts of the disease classification are also used to classify iatrogenic harm; this rubric specifically excludes adverse effects of medicinal agents; burns from local applications and irradiation; complications of surgical procedures during abortion, labour and delivery; poisoning and toxic effects of drugs and chemicals; and other specified complications classified elsewhere in the disease classification.

A large number of other rubrics within ICD-9(-CM) could also be used for deaths or separations resulting from adverse events. However, most of them are not specific for adverse events as they could be used also for non-iatrogenic harm. Therefore, none of them were used to identify adverse events in the analysis. These rubrics included those as diverse as Viral hepatitis (code 070), Hypertensive heart and renal disease (code 404), Pneumonia (codes 480–486) and Poisoning by medicaments and biological substances (codes 960–979), which includes overdoses and wrong substances given or taken in error. Coding conventions would mean that external cause codes accompanying these disease codes (in multi-cause coding), if present, could sometimes be used to distinguish between adverse event deaths/separations and non-adverse event deaths/separations.

Also excluded, because of non-specificity, were codes for conditions which would usually be considered largely preventable (for example, Fourth degree perineal laceration during delivery (code 664.3) and Haemolytic disease due to Rh isoimmunisation (code 773.0)). Codes such as these could be indicative of an adverse event having occurred, but would be more appropriately used as less specific screens for adverse events (Agency for Healthcare Policy and Research 1999) than to specifically identify adverse events.

Table 1: ICD-9(-CM) disease rubrics apparently specific for adverse events

Code	Description	Comments
244.3	Other iatrogenic hypothyroidism	
245.4	Iatrogenic thyroiditis	
253.7	Iatrogenic pituitary disorders	
349.0	Reaction to spinal or lumbar puncture	
349.1	Nervous system complications from surgically implanted device	
380.52	Acquired stenosis of external ear canal secondary to surgery	ICD-9-CM (hospital data) only
415.11	Iatrogenic pulmonary embolism and infarction	ICD-9-CM (hospital data) only
458.2	Iatrogenic hypotension	
512.1	Iatrogenic pneumothorax	
519.0	Tracheostomy complication	
569.6	Colostomy or enterostomy malfunction	
668	Complications of the administration of anaesthetic or other sedation in labour and delivery	
669.4	Other complications of obstetrical surgery and procedures in labour and delivery	
760.6	Fetus or newborn affected by surgical operation on mother	
763.2	Fetus or newborn affected by forceps delivery	
763.3	Fetus or newborn affected by delivery by vacuum extractor	
763.4	Fetus or newborn affected by Caesarian delivery	
763.5	Fetus or newborn affected by maternal anaesthesia and analgesia	
909.3	Late effects of complications of surgical and medical care	
909.5	Late effects of adverse effect of drug, medicinal or biological substance	Excludes late effects of poisoning by these substances
995.2	Unspecified adverse effect of drug, medicament and biological	Correct medicinal substance properly administered
995.4	Shock due to anaesthesia	Correct substance properly administered
996–999	Complications of surgical and medical care NEC	

Other rubrics had titles which were more specific for an iatrogenic origin, but were not included in the analysis because the terms used in the title did not strongly indicate a causal link between a medical intervention and the condition. Several of these used terms such as 'following' or 'post-surgical' and thus indicated a temporal link but not necessarily any other link, so were not included in the analysis to identify adverse events. These included Encephalitis following immunisation procedure (code 323.5), Post-ablative ovarian failure (code 256.2), States associated with artificial menopause (code 627.4), and Post-laminectomy syndrome (code 722.8). Some of these conditions were also excluded because they may be considered to be normal or expected consequences of treatment and therefore not regarded as an adverse event, for example using the Australian Patient Safety Foundation definition above. These included States associated with artificial menopause (code 627.4) and Post-ablative ovarian failure (code 256.2).

In summary, in order to ensure high specificity, the disease rubrics used to identify adverse event separations and deaths in this analysis (abbreviated as 'Iatrogenic diseases') were restricted to the rubrics which were specific for iatrogenesis, indicated causal links between the intervention and the condition, and which may not be regarded as 'expected' consequences of treatment. This high specificity (and low sensitivity) would mean that the number of deaths and separations identified as having an iatrogenic disease is likely to have been underestimated.

This working paper presents summary data based mainly on the external cause codes. More comprehensive analysis incorporating information on the diagnosis/disease codes will be presented elsewhere.

Mortality data

The AIHW National Mortality Database includes cause of death information for 1997 and 1998 coded by the Australian Bureau of Statistics (ABS) using an automated ICD-9 coding system developed in the United States (ABS 1999). This system codes the underlying cause of death and also any other cause of death recorded on the death certificate. In the case of injury and poisoning deaths, both the external cause and the nature of the injury and poisoning are recorded.

- The World Health Organization definition of the *underlying cause of death* is used: the disease or injury which initiated the train of morbid events leading directly to death.
- *Multiple causes of death* are defined as all morbid conditions, diseases and injuries entered on the death certificate. These include those involved in the morbid train of events leading to the death that were classified as the underlying cause, the immediate cause or any intervening causes, and those conditions which contributed to death but were not related to the disease or condition causing death. For deaths where the underlying cause was identified as an external cause (injury or poisoning), multiple causes include circumstances of the injury and the nature of the injury, as well as any other conditions reported on the death certificate (ABS 1999).

Definition of adverse events

- Adverse events for the mortality data were defined as the underlying or other cause of death recorded with an ICD-9 external cause code and/or disease code specific for an

adverse event. A death with an adverse event was defined as a death for which one or more adverse event disease or external cause codes was recorded.

Hospital morbidity data

The AIHW National Hospital Morbidity Database is a compilation of electronic summary records collected in admitted patient morbidity data collection systems in Australian hospitals since July 1993. Data relating to almost all hospitals are included; exceptions within the public sector are very limited and those within the private sector account for about 5% of all private hospital separations each year (AIHW 2000a).

Each record is for a hospital separation, that is, for an episode of admitted patient care that ended with a discharge, transfer, death or change in care type. Each year's data are for the year's separations, thus the 1997–98 data relate to hospital separations in the period 1 July 1997 to 30 June 1998. A record is included for each separation (including same-day separations), not for each patient, so patients who are hospitalised more than once will have more than one record in the database.

Hospital morbidity records include multiple diagnosis data and can include multiple external cause data. For 1997–98, this information was classified and coded according to the second edition of the Australian ICD-9-CM (NCC 1996). Essentially all hospital morbidity records have a principal diagnosis reported, and most also have one or more additional diagnoses (AIHW 2000a). External causes should be reported for all diagnoses in the injury and poisoning chapter of ICD-9-CM (NCC 1996) and may be reported with diagnosis codes from elsewhere in the classification, as appropriate. The *National Health Data Dictionary* (AIHW 2000b) definitions are used:

- The *principal diagnosis* is defined as 'the diagnosis established, after study, to be chiefly responsible for occasioning the admitted patient's episode of care in hospital'.
- *Additional diagnoses* are defined as 'a condition or complaint either coexisting with the principal diagnosis or arising during the episode of care. Additional diagnoses are conditions that affect patient management in terms of requiring therapeutic treatment, diagnostic procedures and/or increased nursing care and/or monitoring, and will generally result in an extended length of hospital stay'.
- *External causes* are defined as 'the environmental events, circumstances and conditions as the cause of injury, poisoning and other adverse effects'.

The number of external causes reported in the National Hospital Morbidity Database may be restricted by hospital recording systems and software. However, at least one external cause can be reported by each jurisdiction. This usually relates to the principal diagnosis but sometimes relates to an additional diagnosis if no external cause relates to the principal diagnosis.

This reporting limitation is likely to have affected the reports of adverse events included the database; for example, if only one external cause could be reported, if a patient were hospitalised for an injury or poisoning (such as a car accident) and then suffered an adverse event, the car accident would be likely to be reported as the external cause, and the adverse event would only be identifiable in the data if an adverse event-specific diagnosis was applicable.

Definition of adverse events

- Adverse events for the hospital morbidity data were defined as the principal diagnosis or an additional diagnosis recorded with an ICD-9-CM diagnosis code specific for an adverse event, or an external cause of injury or poisoning recorded with an ICD-9-CM external cause code specific for an adverse event. A separation with an adverse event was defined as a separation for which one or more adverse event diagnoses or external cause codes was recorded.

The BEACH survey of general practice activity

Bettering the Evaluation and Care of Health (BEACH) is a continuous survey of general practice activity, undertaken by the General Practice Statistics and Classification Unit (GPSCU) of the University of Sydney, a collaborating unit of the AIHW. It is maintained as a SAS data set at the GPSCU and at the AIHW.

In the first data collection year (April 1998 to March 1999), a random sample of 984 general practitioners (38.4% of those with whom contact was established) took part, each recording details of 100 consecutive patient encounters (Britt et al. 1999). Data collected for each encounter included the age and sex of the patient and up to four diagnoses/problems managed at the encounter. The GPSCU weighted the encounter data to adjust for the slight under-representation of younger general practitioners and for the activity level of the sampled general practitioners. The weighted data comprised 96,901 encounters. In the second data collection year (April 1999 to March 2000), 1,047 general practitioners (39.1% of those contacted) participated, and the final data (weighted as for the first year) comprised 104,856 encounters (Britt et al. 2000).

The general practitioners reported the diagnoses/problems as free text, and this was classified and coded at the GPSCU using the ICPC-2-PLUS, an extended vocabulary of terms classified according to the International Classification of Primary Care, version 2 (Classification Committee of the World Health Organization of Family Doctors 1997). A *diagnosis/problem* was defined as:

- a statement of the provider's understanding of a health problem presented by a patient, family or community.

GPs were instructed to record at the most specific level possible from the information available at the time, which may have been limited to the level of symptoms.

Definition of adverse events

Adverse events were defined as diagnoses/problems recorded using one of the three ICPC-2 rubrics specific for adverse events:

- A85 Adverse effect medical agent—symptoms and complaints attributed to the proper use of medication, rather than due to disease or injury;
- A87 Complication of treatment—an unexpected disorder resulting from surgical, medical or X-ray treatment, or any other medical management; and
- A89 Effects prosthetic device.

An encounter with an adverse event was defined as an encounter at which one or more adverse event diagnoses/problems were managed.

3 Results

Mortality data

An overview of data on deaths reported with an adverse event cause is presented in Tables 2 and 3. In 1997 and 1998 combined, adverse events were reported as the underlying cause of death for 177 deaths, and as any cause of death (underlying cause or other cause) for 5,533 deaths (2.2% of the total). These deaths comprised 3,425 with both an adverse event disease code and an adverse event external cause code, 25 with an adverse event disease code only and 2,083 with an adverse event external cause code only (Table 2).

Table 2: Deaths registered in Australia, by type of adverse event cause of death, 1997 and 1998 combined

	Deaths with an external cause code specific for adverse events	Deaths without an external cause code specific for adverse events	Total
Deaths with a disease code specific for adverse events	3,425	25	3,450
Deaths without a disease code specific for adverse events	2,083	251,019	253,102
Total	5,508	251,044	256,552

Table 3: Deaths registered in Australia with an adverse event as underlying cause or any cause, by adverse event group and year, 1997 and 1998

	1997			1998			1997 and 1998 combined		
	Underlying cause deaths	All cause deaths	All cause: underlying cause ratio	Underlying cause deaths	All cause deaths	All cause: underlying cause ratio	Underlying cause deaths	All cause deaths	All cause: underlying cause ratio
Misadventures	28	44	1.6	20	28	1.4	48	72	1.5
Complications	33	1,884	57.1	65	2,171	33.4	98	4,055	41.4
Drug adverse effects	8	712		16	761	47.6	24	1,473	61.4
<i>Total external cause deaths</i>	<i>69</i>	<i>2,581</i>	<i>37.4</i>	<i>101</i>	<i>2,927</i>	<i>29.0</i>	<i>170</i>	<i>5,508</i>	<i>32.4</i>
Iatrogenic disease	2	1,486		5	1,964		7	3,450	
Total^(a)	71	2,594	36.5	106	2,939	27.7	177	5,533	31.3
Total per 1,000 total deaths	0.55	20.1		0.83	23.1		0.69	21.6	
Total deaths per 100,000 population^(b)	0.35	12.81		0.52	14.21				

(a) Categories do not necessarily sum to the totals, as shown, because multiple causes can be registered for each death.

(b) Directly age-standardised using 5-year age groups and the 30 June 1991 Australian population as the standard.

Compared with deaths with adverse events as an underlying cause, there were 31.3 times as many deaths reported with an adverse event as any cause (Table 3) in 1997 and 1998 combined, particularly for complications (a ratio of 41.4 between underlying cause deaths and any cause deaths), drug adverse effects (a ratio of 61.4) and iatrogenic disease. There was an average of 14.9 deaths with an adverse event as any cause per 100,000 population each year (unadjusted). Some deaths had more than one adverse event reported and, as the data have been presented as counts of deaths rather than counts of causes, counts of deaths presented here do not always add to the totals.

External causes reported

As indicated in Table 2, adverse event deaths were reported with an external cause code, an iatrogenic disease code, or both. However, external causes were reported for 99.5% of the adverse event deaths (Table 4).

The misadventure categories are defined to be used when a misadventure is noticed at the time of the procedure, and would have been used to accompany a disease code that would have described the condition that resulted from the misadventure. Complication categories are defined to be used when a misadventure was not noticed at the time of a procedure but an abnormal reaction or complication has nevertheless been described as having been caused by the procedure (and coded using a disease code). Reflecting that difference between the two groups, the misadventure categories are mostly quite detailed (for example, E870.4 Accidental cut, puncture, perforation or haemorrhage during endoscopic examination, and E876.3 Endotracheal tube wrongly placed during anaesthetic procedure), whereas the complication categories describe procedures more generally (for example, E878.0 Surgical operation with transplant of whole organ).

Misadventures

Misadventures were reported as the underlying cause for 48 deaths, and were reported elsewhere on the death certificate for an additional 24 deaths. Thus most of the misadventure deaths were reported as the underlying cause, indicating that the misadventure (such as an accidental cut) was considered to have led, ultimately, to the death. Multiple-cause misadventure deaths constituted a markedly smaller proportion of multiple-cause adverse event deaths (1.3%) compared with underlying cause deaths (27.1%). This may indicate that incidents noticed at the time of procedures are more likely to be recorded as underlying causes of death than if they are not noticed at the time, and recorded as complications.

Within this group, the three-digit group with the most deaths was Accidental cut, puncture, perforation or haemorrhage during medical care (E870), with 37 deaths having this as the underlying cause and an additional 7 having it as an additional cause.

Complications

Complications were reported 41 times more often as an additional cause of death than as the underlying cause of death. This indicates that complications were not usually considered to have led eventually to the death, but were considered to have contributed to the death in some way. Overall, there were 98 deaths with a complication as the underlying cause and a total of 4,055 deaths with a complication as an additional cause.

At the four-digit level of the classification, the most commonly reported underlying cause of death in this group was an unspecified surgical and medical procedure (E878.9) (26 deaths)

and Surgical operation with implant of artificial internal device (E878.1) (25 deaths). The most commonly reported causes (underlying or other) were Removal of other organ (E878.6) (639 deaths) and Surgical operation with implant of artificial internal device (625 deaths).

Table 4: Deaths registered in Australia, with an adverse event as underlying cause or any cause, by external cause^(a), 1997 and 1998 combined

External cause		Underlying cause deaths	All cause deaths	All cause: underlying cause ^(b) ratio
E870–E876	Misadventures	48	72	1.5
E870	Accidental cut, puncture, perforation or haemorrhage during medical care	37	44	
E871	Foreign object left in body during procedure	0	1	
E872	Failure of sterile precautions during procedure	0	1	
E873	Failure in dosage	0	6	
E874	Mechanical failure of instrument or apparatus during procedure	0	2	
E875	Contaminated or infected blood, other fluid, drug or biological substance	4	9	
E876	Other and unspecified misadventures during medical care	7	9	
E878–E879	Complications	98	4,055	41.4
E878	Surgical operation and other surgical procedures	78	3,397	43.6
E878.0	Surgical operation with transplant of whole organ	1	155	
E878.1	Surgical operation with implant of artificial internal device	25	625	25.0
E878.2	Surgical operation with anastomosis, bypass or graft, with natural or artificial tissues used as implant	4	503	
E878.3	Surgical operation with formation of external stoma	2	114	
E878.4	Other restorative surgery	1	415	
E878.5	Amputation of limb(s)	2	197	
E878.6	Removal of other organ (partial) (total)	6	639	
E878.8	Other	11	354	32.2
E878.9	Unspecified	26	469	18.0
E879	Other procedures	20	685	34.3
E879.0	Cardiac catheterisation	0	9	
E879.1	Kidney dialysis	0	76	
E879.2	Radiological procedure and radiotherapy	0	234	
E879.3	Shock therapy	0	1	
E879.4	Aspiration of fluid	0	10	
E879.6	Urinary catheterisation	6	71	
E879.8	Other	14	286	20.4
E879.9	Unspecified procedure	0	2	

(continued)

Table 4 (continued): Deaths registered in Australia, with an adverse event as underlying cause or any cause, by external cause^(a), 1997 and 1998 combined

External cause		Underlying cause deaths	All cause deaths	All cause: underlying cause ^(b) ratio
E930–E949	Drug adverse effects	24	1,473	61.4
E930	Antibiotics	3	56	
E931	Other anti-infectives	0	6	
E932	Hormones and synthetic substitutes	3	162	
E933	Primarily systemic agents	2	409	
E933.1	Antineoplastic and immunosuppressive drugs	2	400	
E934	Agents primarily affecting blood constituents	5	486	
E934.2	Anticoagulants	4	451	
E935	Analgesics, antipyretics and antirheumatics	3	60	
E936	Anticonvulsants and anti-Parkinsonism drugs	0	12	
E937	Sedatives and hypnotics	0	5	
E938	Other central nervous system depressants	1	21	
E939	Psychotropic agents	3	46	
E940	Central nervous system stimulants	0	3	
E941	Drugs primarily affecting the autonomic nervous system	0	1	
E942	Agents primarily affecting the cardiovascular system	0	55	
E943	Agents primarily affecting the gastrointestinal system	0	2	
E944	Water, mineral and uric acid metabolism drugs	0	16	
E945	Agents primarily acting on the smooth and skeletal muscles and respiratory system	0	1	
E946	Agents primarily affecting skin and mucous membrane, ophthalmological, otorhinolaryngological and dental drugs	1	31	
E947	Other and unspecified drugs and medicaments	3	126	
E948	Bacterial vaccines	0	1	
E949	Other vaccines and biological substances	0	4	
<i>Total external cause deaths</i>		<i>170</i>	<i>5,508</i>	<i>32.4</i>
<i>Iatrogenic disease only</i>		<i>7</i>	<i>25</i>	
Total adverse event deaths		177	5,533	31.3

(a) External causes are presented in groupings of adverse event type, as ICD-9 three-digit categories and selected four-digit categories. Fourth digit categories for which no deaths or small numbers of deaths were recorded are not shown. Categories do not necessarily sum to the totals, as shown, because multiple causes can be registered for each death.

(b) For categories for which there were 10 or more deaths with an adverse event as the underlying cause.

Drug adverse effects

Twenty-four deaths were reported, in 1997 and 1998 combined, with an adverse drug effect as the underlying cause of death. As for complications, adverse drug effects were more commonly reported as additional causes of death rather than the underlying cause of death. Overall, there were 1,473 deaths with an adverse drug effect included on the death certificate, 61 times as many as had an adverse drug effect as the underlying cause of death. This indicates that, for most of these deaths, the adverse drug effect was not considered to be the underlying cause of death, but was another condition directly leading to death, or another antecedent cause, or another significant condition contributing to the death.

At the three-digit level of the ICD-9 classification, Agents affecting blood constituents (E934) (486 deaths) and Primarily systemic agents (E933) (409 deaths) were the most commonly reported causes of death. At the four-digit level of the classification, Antineoplastic and immunosuppressive drugs (E933.1) (400 deaths) and Anticoagulants (E934.2) (451 deaths) were the most commonly reported.

Hospital morbidity data

In 1997–98, adverse events were reported in the National Hospital Morbidity Database for 264,347 separations. These separations comprised 181,446 (68.6%) with both an adverse event disease code and an adverse event external cause code, 18,818 (7.1%) with an adverse event disease code only and 64,083 (24.2%) with an adverse event external cause only (Table 5).

There was a total of 14.2 separations with an adverse event per 100,000 population (unadjusted), and 4.75% of separations included an adverse event code. Adverse event external cause codes were reported for 4.4% of separations.

It should be noted that the counts in Table 5 are of separations, not of adverse events or adverse event codes. For some separations, more than one adverse event code was reported. In some cases, there would be an iatrogenic disease code and an external cause code that related to the same adverse event; the group of 181,446 separations in Table 5 is likely to include adverse events reported in this way. In other cases, there could be more than one adverse events, reported using more than one iatrogenic disease code and/or more than one adverse event external cause code. Thus, for example, there were 245,529 separations with adverse event external cause codes, but there was a total of 275,947 adverse event external cause codes reported.

Table 5: Separations by type of adverse event code, Australia, 1997–98

	Separations with an external cause code specific for adverse events	Separations without an external cause code specific for adverse events	Total
Separations with a diagnosis code specific for adverse events	181,446	18,818	200,264
Separations without a diagnosis code specific for adverse events	64,083	5,298,727	5,362,810
Total	245,529	5,317,545	5,563,074

Only five jurisdictions were able to report more than one external cause code in their hospital morbidity records in 1997–98. For these jurisdictions, there were 7,619 separations reported to the National Hospital Morbidity Database that had an external cause reported other than for an adverse event, followed by an external cause for an adverse event. These separations comprised 4.3% of the adverse event separations in those jurisdictions.

These data indicate the importance of having a capacity to record more than one external cause. Although a specific adverse event disease code could sometimes be reported instead of an external cause code when reporting of external cause codes is restricted, it is nevertheless likely that this means that the separations with adverse events are likely to have been slightly underestimated for the jurisdictions which could only report one external cause code, and for Australia overall.

External causes reported

Adverse events were identified with an adverse event external cause code for 245,529 separations in 1997–98, 92.9% of the total separations with adverse events. Misadventures were reported for 2.0% of the separations with adverse event external causes, complications for 77.7% and adverse drug effects for 21.7% (Table 6).

As in ICD-9 for the mortality data, the misadventure categories are defined to be used when a misadventure is noticed at the time of the procedure, and would have been used to accompany a diagnosis code that would have described the condition that resulted from the misadventure. Complication categories are used when a misadventure was not noticed at the time of a procedure but an abnormal reaction or complication has nevertheless been described as having been caused by the procedure (and coded using a diagnosis code).

As there were many more complications reported than misadventures, this indicates that most of the procedure-related adverse events reported in 1997–98 did not result from misadventures noticed at the time of the procedure. However, this could also indicate that the detailed information required to use the misadventure categories was not available, so complication codes were used instead.

Misadventures

Misadventures were reported for 4,877 separations. Within this group, the three-digit group with the most separations was Accidental cut, puncture, perforation or haemorrhage during medical care (E870), with 3,760 separations, 2,580 of which were for the four-digit category relating to surgical operations.

Complications

A total of 190,739 separations was reported with an external cause code for a complication. Surgical operations and other surgical procedures (E878) was a reported cause for 81.0% of these, and other procedures (E879) for 20.3%. Within the E878 and E879 groups, the proportions of separations reported using the 'Unspecified' category (E878.9, E879.9) were quite small (0.7% and 2.2%, respectively), indicating that information on the nature of the procedure was usually available to the coders. However, the proportions of separations reported using the 'Other' categories was relatively large (31.1% for E878.8 and 47.1% for E879.8), indicating that the categories available in the classification were not well suited to the range of procedures to be coded.

At the four-digit level of the classification, disregarding the 'Other' categories, the most commonly reported external cause in the complications group were Surgical operation with implant of artificial internal device (E878.1, 38,263 separations) and Surgical operation with anastomosis, bypass or graft, with natural or artificial tissues used as implant (E878.2, 26,267 separations).

Adverse drug effects

At the three-digit level of the ICD-9 classification, Primarily systemic agents (E933, 7,924 separations) and Analgesics, antipyretics and antirheumatics (E935, 7,352 separations) were the most commonly reported adverse drug effects. At the four-digit level of the classification, Antineoplastic and immunosuppressive drugs (E933.1, 7,508 separations) and Anticoagulants (E934.2, 3,714 separations) were the most commonly reported.

Table 6: Separations^(a) in Australia, with an adverse event, by adverse event external cause, 1997–98

External cause		Separations
E870–E876	Misadventures	4,877
E870	Accidental cut, puncture, perforation or haemorrhage during medical care	3,760
E870.0	Surgical operation	2,580
E871	Foreign object left in body during procedure	232
E872	Failure of sterile precautions during procedure	38
E873	Failure in dosage	104
E874	Mechanical failure of instrument or apparatus during procedure	156
E875	Contaminated or infected blood, other fluid, drug or biological substance	12
E876	Other and unspecified misadventures during medical care	601
E878–E879	Complications	190,739
E878	Surgical operation and other surgical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of operation	154,421
E878.0	Surgical operation with transplant of whole organ	4,186
E878.1	Surgical operation with implant of artificial internal device	38,263
E878.2	Surgical operation with anastomosis, bypass or graft, with natural or artificial tissues used as implant	26,267
E878.3	Surgical operation with formation of external stoma	4,009
E878.4	Other restorative surgery	7,845
E878.5	Amputation of limb(s)	2,382
E878.6	Removal of other organ (partial) (total)	23,810
E878.8	Other	47,953
E878.9	Unspecified	1,043
E879	Other procedures, without mention of misadventure at the time of procedure, as the cause of abnormal reaction of patient, or of later complication	38,741
E879.0	Cardiac catheterisation	3,682
E879.1	Kidney dialysis	2,660
E879.2	Radiological procedure and radiotherapy	7,262
E879.4	Aspiration of fluid	898
E879.6	Urinary catheterisation	5,064
E879.8	Other	18,249
E879.9	Unspecified	855
E930–E949	Drug adverse effects	53,388
E930	Antibiotics	6,040
E930.0	Penicillins	1,899
E930.5	Cephalosporin group	1,074
E931	Other anti-infectives	974
E932	Hormones and synthetic substitutes	5,157
E932.2	Ovarian hormones and synthetic substitutes	592

(continued)

Table 6 (continued): Separations^(a) in Australia, with an adverse event, by adverse event external cause, 1997–98

External cause		Separations
E930–E949	Drug adverse effects (continued)	
E933	Primarily systemic agents	7,924
E933.1	Antineoplastic and immunosuppressive drugs	7,508
E934	Agents primarily affecting blood constituents	5,388
E934.2	Anticoagulants	3,714
E934.7	Natural blood and blood products	1,153
E935	Analgesics, antipyretics and antirheumatics	7,352
E935.2	Other opiates and related narcotics	2,726
E935.3	Salicylates	799
E935.6	Antirheumatics	1,363
E936	Anticonvulsants and anti-Parkinsonism drugs	1,866
E936.1	Hydantoin derivatives	724
E936.3	Other and unspecified anticonvulsants	840
E937	Sedatives and hypnotics	453
E938	Other central nervous system depressants and anaesthetics	1,103
E939	Psychotropic agents	4,494
E939.0	Antidepressants	964
E939.1	Phenothiazine-based tranquilisers	820
E939.3	Other anti-psychotics, neuroleptics, and major tranquilisers	819
E940	Central nervous system stimulants	50
E941	Drugs primarily affecting the autonomic nervous system	826
E942	Agents primarily affecting the cardiovascular system	6,188
E942.0	Cardiac rhythm regulators	924
E942.1	Cardiotonic glycosides and drugs of similar action	1,909
E942.4	Coronary vasodilators	911
E942.6	Other antihypertensive agents	2,119
E943	Agents primarily affecting the gastrointestinal system	481
E944	Water, mineral and uric acid metabolism drugs	2,047
E944.4	Other diuretics	1,399
E945	Agents primarily acting on the smooth and skeletal muscles and respiratory system	453
E946	Agents primarily affecting skin and mucous membrane, ophthalmological, otorhinolaryngological and dental drugs	706
E947	Other and unspecified drugs and medicaments	2,516
E948	Bacterial vaccines	269
E949	Other vaccines and biological substances	262
<i>Total separations with external causes</i>		<i>245,529</i>
<i>Separations with no external cause</i>		<i>18,818</i>
Total adverse event separations		264,347

(a) External causes are presented in groupings of adverse event type, as ICD-9-CM three-digit categories and selected four-digit categories. Fourth digit categories for which no separations or small numbers of separations were recorded are not shown. Categories do not necessarily sum to the totals, as shown, because multiple external causes can be recorded for each separation.

Place of occurrence

ICD-9-CM includes a classification for the place of occurrence of external causes. This information is reported to the National Hospital Morbidity Database by each jurisdiction for the first-reported external cause and, by some, for subsequently reported external causes. As a place of occurrence can be reported for each external cause reported, rather than for each separation, the place of occurrence data reported for adverse event external causes is presented in Table 7 as counts for external causes, not separations.

In 1997–98, there was no information on the place of occurrence for 64.1% of adverse event external causes, and 60.3% of those that were first-reported external causes. This compares with 38.2% of all other first-reported external causes having no data on place of occurrence.

It is likely that the place of occurrence would not always be documented and coded and, for external causes that are not the first-reported, there can be restrictions on the reporting of associated place of occurrence information in some hospitals. However, the large proportion of external causes for which there was no place of occurrence information would also reflect the Australian Coding Standard that was part of the ICD-9-CM classification (NCC 1996). The standard specified that, for surgical complications and adverse effects of drugs, the category 'residential institution' (which includes hospitals) should only be assigned when the postoperative complication occurred during the episode of care during which the surgery was performed, or when the drug was prescribed in hospital and the patient was treated for the adverse effect during the same episode of care. The standard specified that the category 'unspecified place' should be used if the postoperative complication occurred after the patient was discharged from hospital following the surgery, or if the drug adverse effect occurred post-discharge, or if it related to a drug prescribed by a general practitioner. These instructions seem to have been inappropriate, as they refer to the place of manifestation of the condition that was the result of the external cause, rather than to the place of occurrence of the cause (the operation, or the administration of the drug). In addition, instead of allowing the 'place of manifestation' to be reported appropriately (for example, as 'home'), the standard has required use of the 'unspecified place' category. Last, the effect of the standard would have been that only 'residential institution' and 'unspecified place' would have been reported if it had been uniformly applied, but other categories were used, so it appears that it was not applied on all occasions.

The standard means that these data are difficult to interpret accurately. However, they provide some information that is useful in describing adverse events reported to the National Hospital Morbidity Database. Disregarding the 'unspecified place/not reported' category, 92.1% of adverse event external causes were reported with 'residential institution' as the place of occurrence, and 5.4% with 'home'. A greater proportion of misadventures was reported as occurring in a residential institution than complications or drug adverse effects, reflecting the fact that misadventures are noticed at the time of the procedure. The adverse effects of drugs were reported to have occurred at home more frequently than misadventures or complications (18.3%, 1.2% and 3.1%, respectively, disregarding those for which no information was available).

Table 7: Reported place of occurrence for each adverse event external cause, Australia, 1997–98

	Misadventures		Complications		Drug adverse effects				Total
	Separations	% of total	Separations	% of total	Separations	% of total	Separations	% of total	% of known
Home	38	0.8	2,459	1.1	2,904	5.2	5,401	2.0	5.4
Farm	9	0.2	287	0.1	67	0.1	363	0.1	0.4
Mine and quarry	5	0.1	86	0	21	0	112	0	0.1
Industrial place and premises	5	0.1	89	0	87	0.2	181	0.1	0.2
Place for recreation and sport	3	0.1	59	0	32	0.1	94	0	0.1
Street and highway	3	0.1	41	0	21	0	65	0	0.1
Public building	11	0.2	323	0.2	102	0.2	436	0.2	0.4
Residential institution	2,977	59.3	75,828	35.3	12,510	22.4	91,315	33.1	92.1
First reported external cause	2,242	67.6	56,492	38.5	8844	24.3	67,578	36.3	
Other specified place	13	0.3	1,070	0.5	148	0.3	1,231	0.5	1.3
Unspecified place/not reported	1,959	39.0	134,841	62.7	39,949	71.5	176,749	64.1	
First reported external cause	1,002	30.2	86,400	60.0	27,645	67.6	112,227	60.3	
Total	5,023	100.0	215,083	100.0	55,841	100.0	275,947	100.0	100.0

General practice activity data

A total of 865 adverse event problems (weighted as described on page 7) was reported in the 1998–99 BEACH data collection year and 958 in 1999–2000 (Table 8). Complications of treatment (ICPC–2 rubric A87) were reported most frequently (44.8% of the total), with post-operative pain and infections common among them. Adverse effects of medical agents comprised 43.3% and were mainly described as side effects (ICPC–2–PLUS term A85008) and adverse effects (A85006). Complications of treatment and Adverse effect medical agent were also the ICPC–2 categories with the most weighted encounters per 100 total encounters in each of the reporting years. All the ICPC–2–PLUS categories had low reporting rates, with 95% confidence intervals including zero.

Overall, an adverse event problem was managed at 0.89% (95% CI 0.8% to 1.0%) of all encounters in 1998–99 and at 0.91% (95% CI 0.8% to 1.0%) of encounters in 1999–00.

A simple extrapolation of the data presented here to the approximately 103 million general practice Medicare item numbers claimed suggests that, each year, there are about 927,000 general practitioner–patient encounters at which adverse events are managed.

Table 8: Adverse event problems reported in the BEACH survey of general practice activity, 1998–99 and 1999–00^(a)

ICPC–2 problem category or ICPC–2–PLUS term	Reports of adverse event problems managed (weighted)		Encounters with adverse event problems per 100 total encounters (weighted)			
	1998–99	1999–00	1998–99		1999–00	
			Rate	95% CI	Rate	95% CI
A85 Adverse effect medical agent	355	435	0.37	0.2–0.5	0.41	0.3–0.6
A85003 Drug reaction	51	51	0.05	0–0.4	0.05	0–0.4
A85004 Allergic reaction; drug(s)	36	48	0.04	0–0.4	0.05	0–0.4
A85006 Adverse effect, medication	83	62	0.09	0–0.4	0.06	0–0.4
A85008 Side-effect; medication	151	204	0.16	0–0.4	0.19	0–0.4
A87 Complications of treatment	406	411	0.42	0.3–0.6	0.39	0.3–0.5
A87003 Infection, wound, post-op	63	77	0.07	0–0.4	0.07	0–0.4
A87004 Pain, post-op	123	97	0.13	0–0.4	0.09	0–0.4
A87009 Complication, post-op	53	61	0.05	0–0.4	0.06	0–0.4
A87039 Infection	65	64	0.07	0–0.4	0.06	0–0.4
A89 Effects of prosthetic device	107	115	0.11	0–0.4	0.11	0–0.4
Total	865	958	0.89	0.8–1.0	0.91	0.8–1.0

(a) Totals may not represent the sum of their components, as presented, because not all ICPC–2–PLUS categories are shown and more than one problem could be reported for each encounter.

4 Discussion

This overview of adverse events reported in routinely collected national data collections in Australia shows that the data sets appear to usefully record a range of adverse events but, in their present form, their sensitivity for iatrogenic conditions is limited, and data validity is uncertain. However, the well-established national infrastructures that underpin the national mortality and hospital morbidity data collections mean that these sources of data on adverse events could be further assessed and improved.

Only some of the external cause and disease rubrics available in ICD-9(-CM) (and in ICD-10(-AM)) and ICPC-2 for coding adverse events are specific for it. The analysis in this working paper was restricted to the use of these iatrogenic-specific rubrics (which indicated causal links between an intervention and a condition), to provide information on adverse events recorded in these data collections that was not overestimated. Hence, this working paper is likely to have underestimated the occurrence of adverse event reports in the data collections.

Iatrogenic accidental poisonings and falls are important types of adverse event that cannot be identified in ICD- and ICPC-2-coded data because of the non-specific nature of the rubrics. Future editions of ICD-10(-AM) and ICPC would be better for recording iatrogenic harm if there were categories created for adverse events of this nature, or if changed data collection arrangements allowed a distinction to be drawn between adverse events and other falls and accidental poisonings.

Improved coding of 'activity while injured' information in ICD-10(-AM) could be a relatively straightforward change in data collection arrangements that would enable a distinction to be made in the data between iatrogenic and non-iatrogenic falls, accidental poisonings and other conditions. A category such as 'receiving health care services' would need to be introduced, and could become an effective flag for adverse events within these data collections. It may also be useful to have some sub-categories, for example 'as an admitted patient in a hospital' and 'as a non-admitted patient in a hospital'.

The introduction of appropriate 'activity while injured' categories in ICD-10-AM could be achieved relatively quickly, as this Australian adaptation of ICD-10 is updated every two years. For mortality coding, a change to ICD-10 would need to be agreed internationally. However, in advance of international changes, mortality coding by the Australian Bureau of Statistics could incorporate a 'flag', to be used in conjunction with the ICD-10 codes, to indicate that a cause of death was an adverse event. Prior to the introduction of ICD-10, Australian mortality data coding similarly allowed for flags for conditions such as AIDS, which were not represented in ICD-9.

The 'place of occurrence' reporting in the hospital morbidity data is poor and better reporting could assist in characterising, and perhaps identifying, iatrogenic falls and other conditions. The codes available in ICD-9(-CM) were also not useful in characterising or distinguishing adverse events, as the categories were very broad; the code used for hospital also included other residential institutions such as gaols. This situation is set to improve, however, because in Australia's second edition of ICD-10-AM (National Centre for Classification in Health 2000), there is now a code for 'Health service area' (Y92.22), which encompasses hospitals and non-hospital health care settings. If the Australian hospital morbidity data are to be used to monitor iatrogenic harm, it may, however, be useful to have a finer categorisation for this place of occurrence, to separate hospitals and other types of health care establishments. In addition, as described above, the ICD-9-CM Australian

Coding Standard provided apparently inappropriate guidance for place of occurrence coding for adverse events in hospital morbidity data. This has apparently led to continuing uncertainty about this coding in ICD-10-AM which the National Centre for Classification in Health is currently addressing (National Centre for Classification in Health 2001).

Within the complications group of external causes, the 'other' categories were reported commonly, in particular the categories for 'other' surgical operations and 'other' (non-surgical) procedures in the hospital morbidity data, and the latter category in the mortality data. The equivalent categories in ICD-10-AM (Y83.8 Other surgical procedures, and Y84.8 Other medical procedures) were similarly reported commonly in ICD-10-AM-coded data provided by four jurisdictions for the National Hospital Morbidity Database for 1998–99 (data not shown). These categories are designed to be used when there is information available on the nature of the surgical operation or procedure, but it is not classifiable to the other categories. This therefore indicates that it would be useful to create some more-detailed categories describing surgical operations and other procedures in ICD-10-AM for recording these external causes with more detail.

The misadventure codes contain more detail on the nature of surgical operations and other procedures but can only be used, as described above, when the misadventure is noticed at the time of the procedure. The usefulness of this distinction between misadventures and complications in the ICD could be reviewed; it may be that the detail in the misadventure codes could be useful for any adverse event that can be attributed to a specific incident, whether noticed at the time or determined afterwards. That is, it may be sufficient to have a range of more and less detailed categories (equivalent to the misadventures and complications groups combined), which can be used, as appropriate, depending on the information available on the circumstances of the adverse event rather than on whether the misadventure was noticed at the time of the procedure.

Australian mortality data have only been multiply coded since 1997, so the data presented here are for the first years of coding causes of death in this system. The number of deaths with an adverse event external cause recorded as the underlying cause of death for each of these years is not dissimilar to those recorded since the introduction of ICD-9 in Australia in 1979 (data not shown). The numbers of deaths with any adverse event external cause reported was not dissimilar between 1997 and 1998, with complications comprising the majority group in each year (as they do in the hospital morbidity data).

Information recorded on Australian death certificates about causes of death is not always accurate (for example, Boyle & Dobson 1995). Some of these adverse event deaths will have been certified by a coroner, and it could be expected that the information about these deaths could be more accurate than the information about some other deaths. Additional analysis of the mortality data to determine the proportion of them certified by a coroner is being undertaken and will be reported elsewhere. This, and comparison in the future with data in the National Coroners' Information System (MUNCCI 2001) may provide some information on the validity of these data. An assessment of the extent to which adverse events are recorded on death certificates could also be valuable in determining the sensitivity of this death certificate-derived information, and therefore the appropriateness of using mortality data to monitor adverse events that are a cause of death.

The hospital morbidity data indicate that about 4.75% of Australian hospital separations had an adverse event external cause recorded. This is less than the 5% of separations with adverse event external cause codes reported for Victorian hospitals by O'Hara and Carson (1997), possibly attributable to the fact that Victorian hospitals are able to report more than one external cause code, unlike some hospitals in other States and Territories. The 4.4% of separations with adverse event external cause codes is somewhat more than the 4.0%

reported for the National Hospital Morbidity Database for 1995-96 (Hargreaves & Madden 1997), probably attributable to an increasing proportion of hospitals being able to report more than one external cause, and improvements in data quality stemming from coder education activities associated with the introduction of the Australian editions of ICD-9-CM, and with increasing casemix funding of hospitals since 1995.

Assessment of the validity of the morbidity data would also be important in determining how they could be used to monitor iatrogenic harm. Little is known about the validity of Australian hospital morbidity data. However, a validity study conducted on 1994-95 Victorian data concluded that the use of external cause codes for injury surveillance is feasible and reliable, and data on complications of medical and surgical care are a valuable data source for the study of adverse hospital events (MacIntyre et al. 1997). It may be useful to undertake a similar assessment of the validity of more recent data, coded in ICD-10-AM, against medical record information, possibly in association with the coding audits that are regularly undertaken in several jurisdictions in Australia.

As the mortality data rely on information on death certificates, the hospital morbidity data rely on information in hospital medical records, and usually only that explicitly recorded by clinicians. Thus, it may also be useful to make an assessment of the extent to which adverse events are explicitly recorded in hospital medical records in codable form. A recent reanalysis of the data from the Quality in Australian Health Care Study categorised 22% of the adverse events as having been detected on the basis of reviewer judgment of the quality of care, rather than on the basis of an adverse outcome (Runciman et al. 2000). Because these types of adverse events did not lead to adverse outcomes that were explicitly recorded in the medical record (and therefore codable as additional diagnoses), it is likely that they would not be recorded in hospital morbidity data systems. Comparisons between adverse events reported in the Quality in Australian Health Care Study (and its reanalysis) and in the National Hospital Morbidity Database are currently being undertaken to describe these apparent differences in more detail, and will be reported elsewhere.

Analysis of adverse events reported in the National Hospital Morbidity Database is also hampered by lack of information on the timing of adverse events in relation to the separation in which they are reported, and on the links between diagnoses, procedures and external causes. Additions to the National Minimum Data Set for Admitted Patient Care (that is the basis of this collection), which would flag whether the adverse event occurred during the separation, would be a valuable addition. Victoria's system of the use of prefixes to distinguish complications from comorbidities (Victorian Department of Human Services 2000) could in this way be a useful enhancement for national hospital morbidity data. This, with improved 'place of occurrence' and 'activity while injured' recording, would yield information as to whether an adverse event occurred during the current admission, during a previous admission or at a community health centre or at home, for example. Linkage of hospitalisation records for individuals would achieve similar results, but only in relation to iatrogenic harm occurring during hospitalisation. Similarly, analysis of adverse events reported in Australian mortality data would be facilitated if the information on the duration of the condition that is reported on death certificates were to be included in the AIHW National Mortality Database.

Queensland has attempted to introduce linked recording of diagnosis and external cause information in its hospital morbidity data recording systems but has not yet achieved reliable linkage. Linkage of information in electronic hospital morbidity data, as under consideration in Norway (Steinum 1999), could preserve relationships between external causes, complications, diagnoses and procedures, enabling a structured view of the occurrence of adverse events. Recording of the date of surgery could also enhance the

usefulness of the data. This information is included in some systems in the United States and enables the data to be screened for adverse events with more accuracy, because assumptions can be made about the likelihood that surgery would have been undertaken when a patient was suffering from a complication/comorbidity such as pneumonia (Agency for Healthcare Policy and Research 1999).

Recent proposals for changes to ICD-10-AM for recording of adverse events in hospital morbidity data have included the greater use of 'normal' diagnosis codes, rather than diagnosis codes for 'complications of care' to describe the nature of adverse events, and discontinuation of the use of external cause codes, and diagnosis-external cause code pairs in some instances. It was proposed that codes would instead be assigned simply in an order reflecting when events 'occurred' (for example, a diagnosis code following a procedure code), a process which would limit the need for coders to make judgments about causation (Roberts et al. 2000).

The use of the 'normal' diagnosis codes would also be an improvement in many cases as currently used 'complication' diagnosis codes (which are quite general) could be replaced with codes providing more detail about the condition. For example, the code used for postoperative infections (998.5 in ICD-9-CM, T81.4 in ICD-10-AM) could be replaced with codes detailing the aetiology and manifestation of the infection, and allow wound and other infections to be identified accurately in the data.

However, the limited use of external cause codes could present difficulties with future analyses of adverse event reported in hospital morbidity data. First, iatrogenic harm acquired in previous admissions or in non-hospital settings would be more difficult to identify; in the Quality in Australian Health Care Study, 56% of adverse events occurred before the index admissions (Wilson et al. 1995). Second, although the external cause codes may not have been assigned appropriately on all occasions, the data presented here indicate that codable information on the circumstances of adverse events has been available in hospital medical records. This information would have ongoing uses in describing adverse events and should not be discarded without careful consideration. The type of information and advice available to coders on the assignment of external cause codes may, however, need to be improved, to limit the need for coders to make judgments about causation, and to ensure validity of the codes. Clinicians will ideally have a role to play in providing such information and advice in the future.

In addition, as mentioned above, there may be a need to revise the misadventure and complications external cause codes, to make available a range of categories of varying specificity, designed to suit varying types of information on attribution. In parallel with ACSQHC directions, the category descriptors would ideally also be revised, to remove words that signify error or blame. This would enable the external cause information that is documented to be reflected in the coded data, and therefore retained for use in appropriate analyses of patterns of adverse events.

The hospital morbidity data do not include any measure of severity of the adverse events that they record. It is therefore difficult to gauge their exact impact except when the adverse event is reported as the principal diagnosis (to be reported elsewhere). Similarly, the data do not include any measure of the preventability of the adverse events. Without such information, the data cannot be used to estimate the number of patient days of hospitalisation or levels of temporary or permanent disability attributable to the injuries, nor the proportion of harm that may be amenable to preventative measures. This type of information is, however, more likely to be collected and useful within more detailed but smaller scale studies of adverse events.

Also more amenable to study on a smaller scale would be adverse events for which attribution is not readily documented on a patient by patient basis in medical records, and instead requires the use of epidemiological methods to assess risks of various exposures in the occurrence of adverse event outcomes in groups of patients.

Last, it should be noted that the hospital morbidity data cannot readily be used to estimate the incidence of adverse events, because the data systems are designed to measure morbidity as treated in hospital, not incidence of conditions. Exceptions (using appropriate analyses, or with future identification of readmissions, for example) are conditions such as some types of community-acquired non-iatrogenic injury that are severe enough to always require hospitalisation, if they are not fatal.

The systems are designed to measure morbidity treated in hospital, because diagnoses and external causes are recorded if the conditions meet the Australian definition of a principal or additional diagnosis (AIHW 2000b), which essentially means that they are the 'cause' of the hospitalisation, or affect the hospitalisation in some way. If they do not affect the hospitalisation, they will not be recorded. However, if they affect more than one hospitalisation (because a patient is readmitted because of an adverse event that had been identified and recorded in a previous admission), then the adverse event will be counted twice.

This issue affects retrospective medical record review in a similar way, in that, generally, conditions and events recorded in the hospital medical record are those which are pertinent to the hospitalisation; wound infections that manifest after discharge are relatively common (Mitchell et al. 1999), for example, and would not usually be recorded in the hospital medical record unless resulting in readmission. Indeed, the Quality in Australian Health Care Study's retrospective medical record review measured 'admissions associated with adverse events' (Wilson et al. 1995) and, although also providing an estimate of incidence (Wilson et al. 1996), included adverse events which occurred in the community (which would not be included if the incidence of in-hospital adverse events was the subject of study) and was not able to include adverse events that manifested after discharge and did not result in readmission to the hospital at which the adverse event occurred.

This general issue of what is to be measured for adverse event monitoring using hospital medical record-based information could be usefully further debated. For good incidence or incidence rate information, the populations at risk would need to be defined (for example, hospitalised patients, hospital episodes, or hospital and community-based health care service events), and methods would need to be devised to follow up adverse events manifesting only after discharge and to identify multiple admissions (to any hospital) 'caused' by an adverse event. The last of these may be accommodated if unique patient identifiers are introduced nationally, but this is not likely to occur in the near future, and follow up of patients post-discharge may also need to await the introduction of a universal system of comprehensive electronic health records.

The use of hospital morbidity data to monitor adverse events is therefore more likely, in the shorter term, to be more important in recording hospital-treated morbidity due to adverse events, rather than the incidence of these conditions.

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