

IATROGENIC INJURY IN AUSTRALIA

A report prepared by the Australian Patient Safety Foundation

for the

*National Health Priorities and Quality Branch of the Department of Health
and Aged Care of the Commonwealth Government of Australia*

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Iatrogenic Injury: **Unintended or unnecessary harm or suffering
arising from any aspect of healthcare management**

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Note to readers

- ◆ There has been some repetition of key points in this report. This is because it is anticipated that sections may be read in isolation.
- ◆ This report was originally submitted in August 1999. There have been changes and the release of several key reports in the last 2 years, notably the “Institute of Medicine Report” in December 1999^a and the “NHS Report” in June 2000^b. Brief comments on aspects of these have been included as footnotes.
- ◆ The Australian Council for Safety and Quality did not exist at the time of submission of this report – it came into being some five months later, early in the year 2000^c. It was decided, to avoid confusion, to release this report only after the acceptance by the Australian State and Federal Ministers for Health of the recommendations and reports of this Council in July 2001. Comments on these will be included, where relevant, as footnotes.

^{a,b,c} Additional references on new material in footnotes are denoted by letters of the alphabet and are included in a supplementary bibliography.

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Human Services for its early state-wide adoption of this system.



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A Glossary of terms used in this report

ACHS	Australian Council on Healthcare Standards
ABS	Australian Bureau of Statistics
ACSQHC	Australian Council for Safety and Quality in Health Care
AE	Adverse Event
AIHW	Australian Institute of Health and Welfare
AIMS	Australian Incident Monitoring Study
AMRAS	Australian Medical Record Analysis System
APSF	Australian Patient Safety Foundation
CeDOC	Customised Occurrence Classification
GOC	Generic Occurrence Classification
HMPS	Harvard Medical Practice Study
HSPH	Harvard School of Public Health
ICD	International Classification of Diseases
MBS	Medical Benefits Schedule*
NCCH	National Centre for Classification in Healthcare*
NICS	National Institute for Clinical Studies*
NISU	National Injury Surveillance Unit*
PBS	Pharmaceutical Benefits Schedule*
PIR	Professional Indemnity Review*
QAHCS	Quality in Australian Health Care Study
SAI	Standards Australia International
UTCOS	Utah Colorado Study

* All organisations, schedules and documents are Australian unless otherwise specified.

Executive Summary

“... the value of history lies in the fact that we learn by it from the mistakes of others - learning from our own is a slow process”.

W Stanley Sykes (1894-1961).

It has long been recognised that medical care itself has the potential to cause harm. However, general acknowledgement that much iatrogenic injury may be due to preventable human error or system failure appears to have been slow in coming.

Factors contributing to this late recognition include difficulties in accessing medical records (compounded by the tort system and fear of litigation), difficulties in attributing problems to healthcare management rather than disease processes, and a general reluctance to openly acknowledge and record system failures and human errors when patients have been harmed. Objective information about the relative risks and benefits of diagnostic and therapeutic options is often not available, and, where it is, ways of conveying these to patients, so that they can make properly informed decisions, are not well developed.

Healthcare is a risky business. Simply being a patient in an acute care hospital in Australia carries, on average, a 40-fold greater risk of dying from the care process than from being in traffic, and a 400-fold greater risk than working in the chemical industry.

Iatrogenic injury is costly; at least 10% of admissions to acute-care hospitals in Australia are associated with a potentially preventable adverse event. It has been estimated that the direct medical costs of these events exceeds \$2 billion per year and that the total life-time cost of such preventable injury may be twice that amount; there is also a heavy toll in human costs on both those who are harmed and those who care for them. Furthermore, medical misadventure consumes over half the amount spent on compensation and insurance by State Treasury Departments.

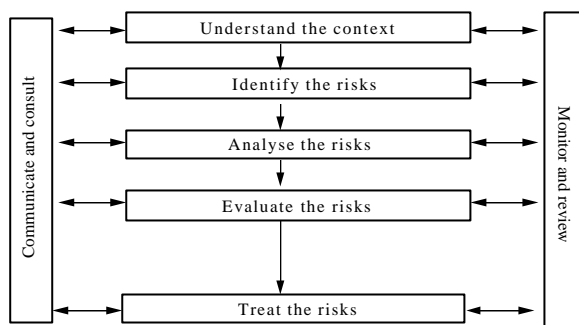
There are ethical, humanitarian and financial imperatives to find out what is going wrong, collate and analyse the information and devise and implement strategies to better detect, manage and prevent these problems. It may be estimated that as much as half of this burden to society may be removed within 5-10 years if the necessary investments are made in a systematic approach to this problem. Failure to do this will result in escalating costs, as the factors contributing to iatrogenic injury will become more prevalent, not less, in the coming years.

It is also necessary to recognise that healthcare is a complex system, and to apply the approaches to system failure and human error which have been proven effective in other complex human endeavours (eg nuclear power stations, off-shore drilling rigs, aviation). We should avail ourselves of the considerable expertise that has been accumulated in these other disciplines, and apply it to the business of health care.

Patient safety is an essential component of risk management, quality improvement and clinical governance. The new Risk Management Standard (AS/NZS4360) provides an explicit framework for addressing iatrogenic injury (see Figure).*

* ACSQHC has agreed to use this standard as a framework for its activities.^d

Figure: A simple representation of the risk management framework in the new Standard AS/NZS4360



First, the context must be understood. This involves an understanding of healthcare as a complex system, of human error and system failure, of issues such as privacy, consent, litigation, risk-benefit ratios and evidence-based medicine, and of the human and economic costs when things go wrong. These issues are addressed in this report.

Second, the risks need to be identified. There are only three ways in which we can find out what happened when things have gone wrong:

- A. those who are involved either in delivering or receiving health care can report details
- B. trained reviewers can extract information from medical and other records, and elicit additional information after the event; and
- C. teams of people can be employed to undertake prospective observations or measurements. This last option is too expensive to be used “across the board”, especially for rare events, and must be reserved for studying specific problems identified by one of the first two more generally applicable methods.

One tried and tested way of finding out what happened when things have gone wrong is incident monitoring. A standardised reporting system has been developed, the Australian Incident Monitoring System (AIMS), which is suitable for use throughout the Australian healthcare system. It is currently in use in all South Australian public hospitals, in four networks in Victoria, and the Northern Territory; plans are underway for its introduction to all of the Australian Capital Territory and Western Australia and to parts of New South Wales, Tasmania and Queensland. It is being used, or has been trialed, by twelve medical specialties.* A new, simpler, more comprehensive version, with the option of reporting electronically via the web, AIMS+, is currently being trialed and introduced.

Another way of finding out what has gone wrong is to extract information from medical and other records. The Australian Institute of Health and Welfare collates information about morbidity and mortality from the various State collections of ICD (International Classification of Disease) codes generated at the time of patient separation, and from the Australian Bureau of Statistics Register of Deaths, and may, in the future, be able to link these with PBS and MBS data. However, the primary emphasis in these collections has been on the underlying disease rather than complications and co-morbidities, and they are currently not reliable or effective for

* It is now being introduced across Western Australia and the ACT and in parts of New Zealand, and the APSF classification system has been chosen for trial as the basis for the newly formed National Patient Safety Agency’s central repository for adverse events and near misses in the United Kingdom.

collecting information about most types of iatrogenic injury. It is proposed to progressively improve the capture of iatrogenic injury information using these established processes.

Standard methods for extracting information specifically about iatrogenic injury using retrospective medical record review were developed in the Californian medical litigation crisis in the early 1970s, were used for the Harvard Medical Practice study in the 1980s and, in the 1990s, for the Quality in Australian Healthcare Study (QAHCS) and the Utah-Colorado Study. By analysing information obtained using these methods it was determined that at least 10% of admissions are associated with a potentially preventable adverse event, and that such adverse events are associated with as many as 50,000 permanent disabilities and 10,000 deaths each year in Australia.

A multi-national collaborative project is being planned to refine the definitions and methodology used and a new streamlined software-based process is being developed - the Australian Medical Record Analysis System (AMRAS). It is proposed that a randomised sample of all hospitals be studied each year and that strata of hospitals in each State be compared between jurisdictions and over time with respect to a “composite indicator”, representing a “basket” of adverse events, analogous to the consumer price index.

Third, the risks need to be collated and analysed. Up until 1995, none of the available systems had the capacity to do this. A Generic Occurrence Classification (GOC) was therefore developed specifically for things that go wrong in healthcare. It comprises a multi-axial framework into which all iatrogenic events may be classified and is designed to elicit their salient features, place them in context and record their contributing factors, be these system- or human-based. The GOC can be used to classify incidents or events identified by incident reporting, medical record review, complaints, morbidity and mortality studies, medico-legal investigations and coronial recommendations. An expanded version of the GOC (GOC+), built from over 50,000 incidents and events from all of these sources, with a new structure designed to facilitate accurate, rapid coding and flexible, comprehensive, cost-efficient reporting and data analysis, is to be trailed and installed at key sites.

The mechanisms exist, therefore, to have a single repository for all things which go wrong in healthcare in Australia. Data from the QAHCS has already shown why a national database is necessary:

- even in large teaching hospitals most types of adverse events occur so infrequently that they cannot be prospectively tracked or sufficiently characterised at a local level to devise remedial strategies
- having data from all available sources in a common repository allows the strengths of each data source to be exploited and for maximum value to be gained from all the available information

AMRAS will provide information about the frequency and, with further work, the costs of adverse events, allowing evidence-based priorities to be set and progress to be tracked. AIMS will provide vital complementary information, as it elicits the underlying human-error and system-based causes of incidents which are not provided in the medical record. These details are essential to obtain the information necessary for devising effective corrective strategies.

AIMS+ is being set up to provide both an easy-to-use tool to manage risk and improve quality and safety at a local level, as well as to capture details about the nature and underlying causes of the majority of events which, individually, occur too infrequently to be characterised at a

local level. AIMS+ also has built-in quality assurance mechanisms to allow comparisons of patterns over time and between health care units and jurisdictions.

Fourth, once problems have been identified and characterised, they must be addressed - this involves coming up with cost- and risk-effective corrective strategies which can be implemented in the context of Australian healthcare. The ways of identifying problems and the types of responses at personal, local, and national levels are summarised in this report. Various existing means for effecting change such as regulatory mechanisms for drugs, devices and procedures, accreditation, recertification, credentialing, informed consent and registration are outlined.

However, as the manner in which these currently operate has been shown to be associated with the current rate of adverse events and rapidly escalating litigation costs (a one thousand-fold increase over 20 years for some specialties), it is clear that a new, integrated, more effective and responsive approach is required for dealing with these problems.

The discipline of anaesthesia has taken such an approach and has demonstrated that, once problems have been properly characterised, system-wide changes can be devised and implemented which can be shown to be effective. AIMS-Anaesthesia was started in 1988, ten national “think-tanks” and consensus conferences have been held, some 50 discussion papers have been produced, and major changes have been instituted and supported by the profession. The mortality attributable to anaesthesia fell five-fold between the mid-1980s, before comprehensive national data were available about what was going wrong, and the mid-1990s, by when a number of corrective strategies had been put into place across both the public and private systems.

The scope and cost of the problem of iatrogenic injury across the whole of the healthcare system was revealed by the QAHCS in 1995. It has taken 4 years to develop and trial the tools for characterising the adverse events making up this problem; this process is now nearly complete.

The “top 250” events have now been identified by combining data from medical record review, incident monitoring and other sources of information. The new integrated approach which is proposed comprises characterising the nature of these problems, estimating their prevalence and cost Australia-wide, identifying and choosing corrective strategies, evaluating them and proving their worth in the Australian context, and, finally, implementing them throughout the system. This will require substantial investment and a concerted, nationally co-ordinated effort.

A start was made with two national meetings addressing issues which have been shown to be important across the whole spectrum of healthcare - nosocomial infection, adverse drug events, thromboembolism, informed consent and falls. National multi-disciplinary working parties were set up to develop proposals for multi-centre studies to be undertaken. It is vital, although the work will have to be carried out at a local level, that there be both State and national co-ordination of research in this area, as, to date, many small, often poorly designed projects have consumed the available resources without producing results which are sufficiently convincing to be applied across the system.*

* The establishment^c of the Australian Council for Safety and Quality in Health Care (ACSQHC) and of the National Institute for Clinical Studies provides the opportunity for these activities to be co-ordinated. Taskforces for addressing medication safety and nosocomial infections have been set up by ACSQHC as templates for others in the future^e and a formal mechanism for co-ordinating efforts^f between ACSQHC and the analogous Councils which had been set up in each State and Territory.

Healthcare is undergoing enormous change and as new systems and procedures evolve, new problems will emerge and will need to be dealt with. Mechanisms must be put into place to rapidly identify and characterise these problems, and processes must be refined for identifying corrective strategies, demonstrating their cost- and risk-effectiveness in the context of Australian healthcare, and then implementing them.**

It is vital that all stakeholders (including government, the professions, healthcare administrators, industry and consumers) be involved at all stages of these processes and that mechanisms for ongoing, effective consultation and communication be provided at local, State and Commonwealth levels.***

Australia is the first country in the world to be able to set evidence-based priorities for addressing the very substantial problem of preventable iatrogenic injury. Appropriate tools, suitable for application at a national level, have been developed and tested. National bodies have been established for co-ordinating the efforts of all with interest and expertise in this area. But a pro-active approach of investing in long term gains, as has been done in areas such as road and industrial safety, must replace the current ineffective local reactions to individual problems.

The challenge now is to apply what we have learnt and developed both to the existing problems that have been identified and to the new ones which are emerging all the time.

Debate can continue indefinitely about the theoretical relative merits and demerits of various approaches. The fact is that the methods that have been used to identify and deal with the problems that cause deaths in road accidents and in anaesthesia are not perfect. However, by applying them, death rates have been dramatically reduced in both of these areas.

The overall impact of iatrogenic injury in human and economic terms is too great to address only selected areas which are amenable to traditional research methods. We must act now, using existing data and methods, whilst striving to develop new scientifically rigorous research methods for addressing low-frequency events. Each step we can take along this path will benefit every stakeholder in the health care system.

** It has been agreed that an Australian Health System Safety Surveillance Unit, analogous to the National Injury Surveillance Unit, be established by the APSF as a Collaborating Unit of the Australian Institute of Health and Welfare, to co-ordinate the ongoing collation and analysis of information at a national level.[§]

*** This is now being co-ordinated by the ACSQHC secretariat.

LIST OF RECOMMENDATIONS

RECOMMENDATION 1

That uniform definitions for events relevant to iatrogenic injury be developed for the National Health Data Dictionary.

RECOMMENDATION 2

That educational packages be produced for health sciences students which provide a background to “health care as a complex system” and a basic understanding of the cognitive psychology of human error.

RECOMMENDATION 3

That easy-to-understand measures of the relative risks and benefits of available diagnostic and therapeutic options be developed, and that means of conveying these to prospective patients in lay terms be made available at the point of care (eg pamphlets, video tapes, web-site addresses, expert systems, references to other material).

RECOMMENDATION 4

That methods be developed for estimating the direct and indirect costs of each component of iatrogenic injury (including tort system costs), and that these costs be published at regular intervals.

RECOMMENDATION 5

That the tort system and methods for compensating those injured by health care management be examined with a view to reform.

RECOMMENDATION 6

That the existing State and Commonwealth legislation for protecting information brought into existence for safety and quality of care be reviewed, and that measures be taken to ensure that comprehensive protection can be provided across the entire spectrum of healthcare in all jurisdictions.

RECOMMENDATION 7

That ongoing commitment to the provision of a stable funding base for generic incident monitoring be sought, so as to allow a uniform, national incident reporting system to be established and maintained across the entire spectrum of health care in all jurisdictions.

RECOMMENDATION 8

That ongoing commitment to the provision of a stable funding base be sought as a matter of urgency so as to allow properly constituted specialty-based incident monitoring to be established and maintained for all health care specialty groups.

LIST OF RECOMMENDATIONS (continued....)

RECOMMENDATION 9

That a systematic process be embarked upon for trialing and progressively refining the Australian Medical Record Analysis System as the basis of a system suitable for national and international use, and for applying it annually to a randomised sample of medical records in each State and Territory.

RECOMMENDATION 10

That existing mechanisms be enhanced for linking morbidity and mortality data and that mechanisms for linking with MPS and PBS data be established, preferably by the introduction of universal unique patient identifiers.

RECOMMENDATION 11

That means be sought to classify the information in all medico-legal files into a national database so that it can be characterised and comparisons with incidents and adverse events from other sources may be made.

RECOMMENDATION 12

That the National Health Complaint Information project be further supported so that complaints data can be coded into a national database so that it can be characterised and comparisons with incidents and adverse events from other sources can be made.

RECOMMENDATION 13

That all “things that go wrong” identified by incident monitoring, medical record review, medico-legal investigations, coronial enquiries, complaints databases, letters to the editor and case reports from selected refereed journals, be classified using the GOC+ and stored in a national database.

RECOMMENDATION 14

That a record be kept in each health facility of all the incidents that have been reported and of the steps taken to deal with them, and that accreditation of each facility is contingent on satisfactory evidence that these have been classified and stored in such a way that they can contribute to a national database.

RECOMMENDATION 15

That the top 1,000 problems that give rise to iatrogenic injury be identified and characterised, and that systematic steps be taken to identify, fund and implement strategies, co-ordinated at a national level, to deal with these problems in a risk- and cost-effective manner.

LIST OF RECOMMENDATIONS (continued....)

RECOMMENDATION 16

That the standard “AS/NZS4360 - Risk Management” be used as the basic framework for addressing the problem of iatrogenic injury and that those in both clinical and corporate government systems be held accountable for ensuring that explicit clinical risk management processes be put in place, in line with this standard.

RECOMMENDATION 17

That the Commonwealth, States and other parties who may benefit from a reduction in iatrogenic injury, fund a feasibility and costing study of a linked facilitated incident monitoring and medical record review system, based on a stratified sample of health care units, to produce information on the incidence, causes and possible preventive strategies for iatrogenic injury.

RECOMMENDATION 18

That the Commonwealth, States and other parties who may benefit from a reduction in iatrogenic injury, fund an Australian Iatrogenic Injury Surveillance Unit as a Collaborating Unit with the Australian Institute of Health and Welfare to develop and co-ordinate the surveillance and monitoring of iatrogenic injury and to contribute to research relevant to iatrogenic injury in Australia.

Part 1 Background

1.1 A Brief History

1.1.1 Overview

It has long been recognised that attempts to ameliorate the effects of injury and disease could themselves lead to harm (see Box below). However, general acknowledgement that iatrogenic injury may be due to preventable human error or system failure appears to have been slow in coming. A review of “Diseases of Medical Progress”, published in 1956, concentrated on adverse drug reactions and “unavoidable” surgical complications; there was no hint that some of these problems may have been avoided by better care.¹

“First, do no harm”. Hippocrates (460-335 BC).²

“All things are poisonous and there is nothing that is harmless; the dose alone decides that something is not poisonous.” Paracelsus (1493-1541).²

“Cure the disease and kill the patient”. Francis Bacon (1561-1626).³

“Cur’d yesterday of my disease,
I died last night of my physician”. Matthew Prior (1664-1721).²

“I do not want two diseases - one nature-made, one doctor-made”. Napoleon Bonaparte (1769-1821).²

“To Nan who pushed me into this labour of Hercules in the first place ... And in memory of my father, who had a cholecystectomy done by a most skilful surgeon, with all the ritual, panoply, safety and security of modern surgery and died thereafter. And in memory of her father, to whom exactly the same tragic thing happened.” W Stanley Sykes (1894-1961).⁴

However, by the early 1970s the problem of iatrogenic injury due to medical negligence had increased to such an extent in California that there was a “litigation crisis”, and a major study into “potentially compensable events” was undertaken in order to examine the feasibility of a “no fault” insurance system. This found that just under 5% of admissions were associated with such an event.⁵ This study was the forerunner of the “Harvard Medical Practice Study” (HMPS)^{6,7}, itself the forerunner of the “Utah-Colorado Study” (UTCOS)⁸ and the “Quality in Australian Health Care Study” (QAHCS)⁹, all of which used the two-stage medical record review methodology developed for the Californian study in the early 1970s (see pages 42-45).

Litigation for iatrogenic injury in other English-speaking countries lagged behind the United States. The medical insurance premium paid each year by the average Australian doctor was less than \$20 in the 1960s, less than \$50 in the 1970s and less than \$200 in the early 1980s.¹⁰ However, premiums rose ten-fold in the 1980s, and for some groups, more than ten-fold in the 1990s.

For example, premiums for specialist obstetricians and gynaecologists rose from \$2,000 per annum in New South Wales in 1988 to nearly \$20,000 by 1993 and to \$40,000 by 1998¹¹; it has

recently been estimated that a premium of over \$90,000 would be needed for this group if there was no cross-subsidy.¹²

The average claim cost in Australia has escalated in the last 5 years from around \$20,000 to over \$100,000, a compounding increase of around 20% per year.¹² Thus, for high risk groups premiums have risen over a thousand-fold over 25 years; those for low-risk “non-procedural” general practitioners have risen thirty-fold to about \$1,500 and those for “procedural” general practitioners have risen a hundred-fold to \$5,000 per annum.

Although medical indemnity had become a matter of considerable concern by the 1990s, the notion that clinicians should take responsibility for systematically reducing the frequency and impact of system failure and medical error had not entered “main-stream” medical thinking. The topic of iatrogenic injury in the most widely-used medical text in the western world, which has been translated into over 10 languages, is dealt with in one quarter of a page out of a total of over 2,500 pages.¹³

The discipline of anaesthesia has been one exception in this respect, with systematic collections and analyses of deaths attributed to anaesthesia dating back as far as the 1930s.¹⁴ An “Anaesthesia Study Commission” reached the conclusion over 50 years ago that over two thirds of anaesthesia-related deaths were preventable.¹⁵ Australia, in 1960, was the first country to institute an ongoing review of all anaesthetic deaths in a jurisdiction with the establishment of the “Special Committee Investigating Deaths Under Anaesthesia in New South Wales”.^{16,18} Neonatal and maternal deaths have also been the subject of systematic appraisal for many years.

In 1988, the Australian Patient Safety Foundation (APSF) was established as a non-profit making organisation with the aim of “promoting, organising, funding, conducting research into, and establishing mechanisms for advancing patient safety”.¹⁹ Although set up to study and improve patient safety across the healthcare spectrum, one of its first projects, the Australian Incident Monitoring Study (AIMS), started as a national voluntary, anonymous reporting system specifically for anaesthesia-related incidents.²⁰ By 1993 over 30 papers had been published on the first 2,000 incidents reported to AIMS, and it was clear that this technique could play an important role in improving the understanding of iatrogenic injury across all of health care.²¹

In 1991 The Commonwealth Government implemented the “Review of Compensation and Professional Indemnity in Health Care” (PIR).²² Some of the concerns that gave rise to its establishment included:

- Very few people who suffer adverse health care outcomes are actually compensated and for these people the common law system is extremely costly and involves unreasonable delays.
- The operation of the current fault-based compensation system sometimes conflicts with broader public health policies.
- The current indemnity, legal and compensation arrangements are ineffective in the prevention of adverse patient outcomes. Three of the five main themes of the PIR’s work were:
 - improving preventive strategies
 - implementing an effective health care partnership
 - establishing effective and accessible complaint and disciplinary processes

In 1992 the APSF and the PIR established that they had some common goals and concerns. In 1993 the PIR funded the APSF to conduct incident monitoring pilot projects as a method of:

- reporting any events which could, or did, give rise to an adverse patient outcome; and
- analysing data to ensure elimination or reduction of the risk.

In the same year the PIR also funded the Quality in Australian Health Care Study (QAHCS), in which the APSF was involved, to identify:

- the underlying causes of adverse patient outcomes and factors contributing to them;
- strategies to reduce the incidence and severity of adverse patient outcomes; and
- mechanisms for routinely collecting data to monitor the incidence and severity of adverse patient outcomes.

Both of these studies were rendered feasible by Quality Assurance (QA) legislation, developed by the PIR, that promoted the wider use of quality assurance measures by providing for the confidentiality of information collected and discussed in QA activities.²³

With respect to the theme “The Health Care Partnership”, the report addressed:

- the lack of available information on risks, benefits and costs of treatment options (including no treatment) for health professionals and consumers
- the lack of available information on the operation of the tort system
- the lack of individual professional and system-wide performance measures and performance standards

This initial funding by the PIR enabled the APSF to conduct pilot projects on incident monitoring in six medical specialties and across six public hospital systems. These pilots confirmed that incident monitoring *can* be applied to the study of “things that go wrong” in a variety of medical specialties as well as across healthcare systems. The findings were summarised in 1994.²⁴ Subsequently the Hospitals Branch of the Department of Human Services provided resources to develop and trial an incident monitoring system suitable for use at a national level.

In November 1998 a meeting was held involving co-ordinators from participating hospitals and specialty-based incident monitoring systems. The findings of this meeting and the progress, status and future potential of incident monitoring are outlined later in this report.

By June, 1995, initial analysis of the results of the QAHCS had been completed. The contract with the University of Newcastle, which was responsible for the administration of the study, made no provision for the results being kept confidential until publication in a peer-reviewed journal. Since they were the property of the Commonwealth of Australia, they were made available, on request, to the Department of Health and Family Services. The then Minister for Health, Dr Carmen Lawrence, released the main findings of the study in Federal Parliament in June, 1995 (Appendix 1). This drew substantial media coverage.

At the time of the release of the findings, the Taskforce on Quality in Australian Healthcare was established (the “Taskforce”) and this met through the rest of 1995 and into 1996. In June 1996 the final report of the Taskforce was submitted to the Australian Ministers for Health,

with its 56 recommendations (Appendix 2).²⁵ Subsequently, a “National Expert Advisory Group on Quality in Australian Healthcare” (the “Expert Group”) was established. It held meetings and took submissions and supplied a final report to the Ministers in July 1999. This report proposed ten national actions and made 4 major recommendations (Appendix 3).²⁶

By mid-1996 questions had been raised with respect to the validity of the findings of the QAHCS, as the rate of adverse events in Australia was apparently five-times that estimated by the Utah-Colorado Study (UTCOS) in the United States of America, a study from the same year, 1992, using similar methodology.⁸⁹ The Minister for Health, Dr Wooldridge, visited the Harvard School of Public Health, which had conducted the original Harvard Medical Practice Study and UTCOS, to discuss the size of the apparent discrepancy. The consensus was that a discrepancy of that size was unlikely to be real, and was likely to be due, at least in part, to methodological differences between the studies, although these appeared ostensibly to be the same.

The Minister for Health, therefore, commissioned a collaborative study to be conducted in two parts. In Part 1 the methods of the two studies (UTCOS and QAHCS) were examined in detail and compared by the Harvard School of Public Health, the APSF and members of the original consortium who had been involved in the conduct of the QAHCS²⁷. In Part 2 a detailed qualitative analysis of the types and severity of the adverse events in the two studies was conducted by the APSF, working in collaboration with the Harvard School of Public Health.²⁸ These studies showed that there were substantial explicit differences in the methodologies used in the two studies, and that these accounted for nearly half the discrepancy. Furthermore, the qualitative study showed that there was a virtually identical “core” of serious adverse events in the two studies. The discrepancy for the remainder was accounted for by the fact that there were far more minor problems in the Australian study and that a wider range of problems were counted as adverse events in the Australian study than the American. In broad summary, it was concluded that:

1. There was no evidence for healthcare in Australia being less safe than in America.
2. At least 10% of acute-care hospital admissions were associated with a potentially preventable adverse event.*

All of this work has led to greater understanding of the issues originally addressed by the PIR and has resulted in the development, by the APSF, of incident monitoring and medical record analysis systems, supported by a classification system, which may be applied at a national level. Several other publications are in preparation.²⁹⁻³²

While this work has been going on, there has been a progressive increase in the understanding and acknowledgement of incidents and accidents in health care. It is now generally recognised that problems arising from the imperfect application of our complex healthcare system are far more pervasive and costly than adverse reactions to appropriately used drugs, or injuries caused by equipment not performing to manufacturers’ specifications, both of which are covered by well established surveillance systems in all developed countries, including Australia. The topic of iatrogenic injury has been addressed at a number of national meetings. It has been recommended by the Australian Medical Association, various specialist Colleges, the Taskforce and the Expert Group, that monitoring of adverse events and the development of strategies to deal with them, should be co-ordinated at a national level.*

* There have now been similar findings in smaller studies in both New Zealand^h and the United Kingdom.ⁱ

* This has now been included in the Terms of Reference of ACSQHC and is to be addressed by one of the five major working parties of ACSQHC which were established in September 2000.^c

It is also apparent that awareness of the problem has been heightened in other countries such as the United States of America and the United Kingdom. In the USA the national Patient Safety Foundation was formed two years ago; a survey by this organisation showed that over 40% of the US population had personally suffered an adverse event or knew of a close friend or relative who had.³⁸ National mechanisms for collecting and studying incidents and accidents in healthcare have been recommended by the Institute of Medicine in the USA^a and by the National Health Service in the United Kingdom^b. There has been considerable interest in these countries in the work being undertaken in Australia as, to date, Australia is the only country which has conducted a nationally representative study of adverse events and developed a system suitable for ongoing incident monitoring and medical record review at a national level.

It is therefore timely to review the background and current status of these issues in Australia, to outline progress to date, and to propose a way forward.

1.1.2 Acceptance of the need for strategies to prevent iatrogenic injury - why only now?

Why has such a large problem not received more attention in the past? There are several complex inter-related reasons why there have been problems obtaining information, openly acknowledging system failures and human errors, addressing issues of risk and benefit and adequately informing patients and society at large. The most striking of these are discussed briefly below.

1.1.2.1 The nature of the doctor-patient relationship

Historically, when someone suffered an injury or became unwell, the doctor would be called, a history would be taken, an examination would take place, and appropriate measures would be prescribed. Later, for serious problems which could not be managed at home, the patient may have been sent to a hospital, where ongoing management would be organised by the doctor. Most of these hospitals originated as "poor houses" and initially only the impecunious or desperately ill would find their way into these institutions. These arrangements meant that there was usually a simple, direct relationship between the doctor and the patient and his or her family.

The need for frankness on the part of the patient in giving a proper history, and the acceptance of the Hippocratic Oath by the medical profession, requiring confidentiality and acting in the best interests of a patient, led to the concept of a special "doctor-patient relationship" (see Appendix 4).

This is held by some to be a "foundation stone" of medical practice, and attempts by governments to regulate, control or intervene in this relationship (including with respect to the matter of fee setting) have generally been strenuously resisted by the medical profession. The confidentiality of medical records, whilst an important part of this relationship, has made the recognition and the study of iatrogenic injury more difficult. In addition, the asymmetrical nature of the relationship, with respect to knowledge and power, has made it difficult for patients to raise issues of error and avoidable undesired effects.

Nevertheless, over the last decade or so various pieces of legislation have been enacted at both Commonwealth and State levels to allow clinical information to be collected either for the publication of aggregated statistical data or in the interests of promoting safety and quality of care, whilst protecting the privacy of both patients and health care professionals (see page 31).

Although the potential for medical care to harm patients has long been recognised, general acceptance of the need for strategies to prevent iatrogenic injury has been slow in coming due to problems with obtaining information, openly acknowledging system failures and human errors, addressing issues of risk and benefit and adequately informing patients and society at large.

1.1.2.2 The tort system

Most doctors believe that they have a direct and personal responsibility for the welfare of the patient, and that they need to take whatever steps are necessary to ensure that they act in their patients' best interests. The tort system has reinforced this concept, as when anything goes seriously wrong, there has been a tendency to examine the standard of practice of the person deemed immediately responsible. This has given credence to the simplistic notion that when something unexpected goes wrong, someone must be to "blame", or at least be held accountable.

Although the reality is that there are many uncertainties in the practice of medicine, and that unexpected outcomes frequently result, the tort system has played a role in constraining full disclosure of all factors relevant to the injury of a patient. It has actively discouraged the recording of any opinions about these factors in the medical record, with the result that retrospective study of medical records yields little about factors contributing to problems, although the problems themselves may be evident in a record.

Patients have had, and still have in the private sector, difficulty in obtaining access to their medical records in the event of a dispute. However, again in the last decade or so, patients have been able to gain access to their medical records in the public sector via "Freedom of Information" legislation.

1.1.2.3 The medical culture

In addition to legitimate concerns about litigation when something goes wrong, there are powerful factors in the "medical culture" which mitigate against errors being brought into the open and freely discussed. These have been eloquently discussed by Leape:³⁴

"... the most important reason physicians and nurses have not developed more effective methods of error prevention is that they have a great deal of difficulty in dealing with human error when it does occur".^{35,36} The reasons are to be found in the culture of medical practice.

Physicians are socialised in medical school and residency to strive for error-free practice. There is a powerful emphasis on perfection, both in diagnosis and treatment. In everyday hospital practice, the message is equally clear: mistakes are unacceptable. Physicians are expected to function without error, an expectation that physicians translate into the need to be infallible. One result is that physicians, not unlike test pilots, come to view an error as a failure of character - you weren't careful enough, you didn't try hard enough. This kind of thinking lies behind a common reaction by physicians: "How can there be an error without negligence?"

Cultivating a norm of high standards is, of course, highly desirable. It is the counterpart of another fundamental goal of medical education: developing the physician's sense of responsibility for the patient.

If you are responsible for everything that happens to the patient, it follows that you are responsible for any errors that occur. While the logic may be sound, the conclusion is absurd,

because physicians do not have the power to control all aspects of patient care³⁷. Nonetheless, the sense of duty to perform faultlessly is strongly internalised.

Role models in medical education reinforce the concept of infallibility. The young physician's teachers are largely specialists, experts in their fields, and authorities. Authorities are not supposed to err. It has been suggested that this need to be infallible creates a strong pressure to intellectual dishonesty, to cover up mistakes rather than to admit them.³⁸

The organisation of medical practice, particularly in the hospital, perpetuates these norms. Errors are rarely admitted or discussed among physicians in private practice. Physicians typically feel, not without reason, that admission of error will lead to censure or increased surveillance or, worse, that their colleagues will regard them as incompetent or careless. Far better to conceal a mistake or, if that is impossible, to try to shift the blame to another, even the patient.

. . . The paradox is that although the standard of medical practice is perfection - error free patient care - all physicians recognise that mistakes are inevitable. Most would like to examine their mistakes and learn from them. From an emotional stand-point, they need the support and understanding of their colleagues and patients when they make mistakes. Yet, they are denied both insight and support by misguided concepts of infallibility and by fear, fear of patient reaction, and fear of litigation. Although the notion of infallibility fails the reality test, the fears are well grounded."

There is a need for health sciences students to gain a basic understanding of system failure and human error; this is addressed later in this report (see pages 12-15).

1.1.2.4 Professional self-regulation

Health professions are largely "self-regulating". They determine their own standards of care and fiercely resist outside influences such as proposals by health service purchasers for managed care. The argument of the professionals and specialities is that only they have the technical knowledge to undertake this task. This has the effect of making the business of quality control, professional standard setting and discipline of those who do not meet standards an internal matter. The orientation is fundamentally good case management and most training and management methods used are individually rather than population oriented.

This approach leads to poor use of population level data and low levels of trust of those who seek an overview of the problem, especially those who are not core members of the profession. There is a strong desire to keep the problem "in-house" and professional indemnity provisions further exacerbate the tendency toward secrecy.

Nevertheless, many health professionals, nearly always on a voluntary basis, have been active and continue to be active in peer review and audit processes, the setting of standards, the creation of clinical pathways and guidelines, counselling "sick doctors", accreditation, recertification and credentialing (see pages 90-92).

1.1.2.5 Policy and management structures

The rapid development of technical medicine and the growth of complex clinical and administrative organisations to provide health care has outstripped the development of management strategies capable of proactively managing emerging issues.

In all developed countries, there has been major concern about the ability to fund health care and strict cost control policies have been put in place. In this climate managers are reluctant to enumerate and describe problems that they see as inevitable and beyond their control. Political

systems, too, are reluctant to receive bad news. The lack of a system for managing and preventing iatrogenic injuries contributes to a reluctance to identify the nature and the scope of the problem, and vice versa.

The rapid development of technical medicine and the growth of complex clinical and administrative organisations to provide health care has outstripped the development of management strategies capable of proactively managing emerging issues. The lack of a system for managing and preventing iatrogenic injuries contributes to a reluctance to identify the nature and the scope of the problem, and vice versa.

1.2 Definitions

Iatrogenic injury means injury originating from or caused by a physician (*iatros*, Greek for “physician”).³⁹ However, the term has come to have a broader meaning and is now generally considered to include **unintended or unnecessary harm or suffering arising from any aspect of health care management**; problems arising from acts of omission as well as from acts of commission are included.

In this emerging field of study many different definitions are used and a common set of terminology has yet to emerge. This makes comparison of different studies and reports problematic. Care must be taken to understand the definitions used before making comparisons across different studies and different countries. To assist the reader, we include definitions of the various terms in common usage. Their meanings, when used in this document, are as set out below. When used here it is implicit that the problems they refer to have been caused by health care management, in its broadest sense, rather than by a disease process.

An incident is any event or circumstance which could have or did harm anyone or result in a complaint, loss or damage. The scope has deliberately been kept very broad and the concept simple to encourage incident reporting.⁴⁰

An adverse event is any event or circumstances leading to unintended harm or suffering which results in admission to hospital, prolonged hospital stay, significant disability at discharge or death (see Appendix 5 for a foreshadowed new definition).⁹

A complaint is considered to have been made when a patient or client of a health care facility, or his or her agent, lodges a complaint about an iatrogenic problem.

A negligent adverse event is an adverse event in which it is considered that there is evidence of significant harm, of causation of that harm by a problem with the health care process, and of a failure of duty of care.

A potentially compensable event is an event that results in disability caused by healthcare management: **disability** is an impairment of physical or mental function (including disfigurement) or economic loss; **causation** is established when the disability is more probably than not attributable to healthcare management, which includes acts of both commission and omission, whether or not such actions or inactions constitute legal fault.⁵



With the trend towards same day surgery, hospital in the home, and more complex investigations and treatments being carried out in an outpatient or day-stay setting, it is clear that the definition of an adverse event and the extent of its impact will have to be altered and more clearly defined for future studies. (This is developed further in Appendix 5.)

RECOMMENDATION 1

That uniform definitions for events relevant to iatrogenic injury be developed for the National Health Data Dictionary.*

1.3 Current knowledge

1.3.1 Health care - A risky business

Comprehending risk is difficult because in estimating risk two elements must be taken into account - the likelihood of the problem occurring and its nature. Some people will make considerable efforts to avoid tiny risks if the manifestation of the risk is particularly abhorrent to them. For example, some will go to considerable lengths to avoid the one-in-ten-million risk of contracting the Human Immunodeficiency Virus after receiving a unit of blood from the Australian Red Cross blood transfusion system, but may think little about the risk of driving to work (also see page 72).

In trying to compare risks from healthcare management with those arising from other spheres of activity, it is useful to choose a single manifestation that is unambiguous and easy to measure. Death is such a manifestation.

Safety, or lack thereof, may be expressed by the Fatal Accident Frequency Rate (FAFR), which has been defined as the number of fatal accidents in a certain place or during a certain activity that occur over 100,000,000 hours of exposure to the place or activity. In the British chemical industry, for example, a FAFR of 4 is considered to be an acceptable rate.⁴

If this is exceeded, steps are taken to try and reduce it. In Table 1 the fatal accident frequency rates for various activities are ranked.

Note that simply being an inpatient in an Australian acute-care hospital is forty times more dangerous than being in traffic, and only ten times safer than leaping out of an aircraft equipped with a parachute. Again, it is clear that the efforts of anaesthetists have paid off, as being anaesthetised in Australia is no more risky than simply being in hospital.

These rough comparisons must be treated with caution, as the extent to which death may be attributed to an accident will vary, with victim- or patient-factors contributing almost nothing

* ACSQHC established a working party in September 2000 to develop definitions for key terms used in the safety and quality literature for the Australian Health Data Dictionary. This is being led by an author of this report (WBR) and has membership from key institutions such as the AIHW, NCCH, NISU and SAI as well as access to members of an international reference group. A web-site has been established to facilitate the exchange of ideas and to facilitate international agreement on key terms.^j

to train or aircraft accidents, possibly up to 50% to traffic accidents (mainly due to being intoxicated) and probably more, on average, for deaths due to iatrogenic injury.^{34,50} Nevertheless, it is evident that healthcare is indeed a risky business. If society at large considers it is worthwhile reducing the preventable risks of driving a car, or working in a factory or on a construction site, it would seem that it may be time for society to consider making an investment in reducing the preventable risks arising from healthcare management.

Table 1: Average Fatal Accident Frequency Rates (deaths per 100 million hours of exposure) for Various Activities (Adapted from Zelders⁴²)

Being pregnant ^a	1
Travelling by train ^b	5
Working at home ^b	8
Working in agriculture ^{10b}	10
Having a unit of donated blood ^c and becoming HIV positive	10
Being in traffic (overall, in any capacity) ^b	50
Working in the construction industry ^b	67
Flying in a commercial aircraft ^b	100
Being a patient in an Australian hospital ^d	2,000
Being anaesthetized ^e	2,000
Parachute jumping ^f	20,000
Having elective abdominal aortic surgery ^g	200,000
Having emergency abdominal aortic surgery ^g	2,000,000

^a Calculated from Dutch health statistics by Zelders.⁴²

^b From references^{43 44 45} which are 20 years old, but give an idea of magnitude (Zelders).⁴²

^c Personal communication,⁴⁶ assuming it takes one hour to transfuse one unit of blood, and one case in 10 million transfused units becomes HIV positive because the donor was in the “window” period. This risk has now been further reduced in Australia with the introduction of nucleic acid testing for HIV.

^d Calculated from the number of deaths associated with preventable adverse events in the QAHCS.⁹

^e Calculated from the number of deaths estimated to be attributable to anaesthesia in Australia (1 per 63,000 hours of exposure to anaesthesia).⁴⁷

^f Calculated from Dutch figures by Zelders.⁴²

^g Calculated assuming a 5% mortality from elective, and a 50% mortality from emergency abdominal aortic aneurysm surgery, with the incremental risk being assumed to arise in the 24 hours during and after the procedure.^{48 49}

There are substantial risks off-setting the great benefits of healthcare. Simply being an inpatient in an Australian acute-care hospital is forty times more dangerous, per hour, than being in traffic, and only ten times safer than leaping out of an aircraft equipped with a parachute.

1.3.2 Contributing processes

1.3.2.1 Changing demography of Australia

The Australian population is ageing rapidly. Aged persons use more health care resources and experience conditions that require more intensive and invasive treatment. The reserves of elderly people are less, so the impact of iatrogenic injury is also greater.

Under this influence, iatrogenic events are more likely to occur and are more likely to have severe consequences. It is essential therefore to develop strategies for managing both their incidence and severity. If management strategies are not put in place, iatrogenic injury will constitute an increasing drain on the resources of the health system.

1.3.2.2 Healthcare - a complex system

The technology of health care is developing rapidly. Treatments are now available for conditions that would only a few years ago have resulted in death or permanent disability. Advances in trauma care and critical care mean that patients with few reserves are often resuscitated and go on to lead productive lives. The margin for error in these situations is very small and it should be expected that the severity of impact of adverse events will continue to increase.

It is essential that iatrogenic injury be considered against the backdrop of health care as a complex socio-technical system. Very often, many factors “upstream” from the incident itself (“resident pathogens”) combine in particular combinations or sequences for a series of what otherwise would be minor misadventures to develop into a medico-legal catastrophe which may lead to the death or permanent harm of a patient.

As Reason has stated⁵⁴

“ . . . these accidents arose from the adverse conjunction of several diverse causal sequences, each necessary but none sufficient to bridge the system’s defences by itself. Moreover, a large number of the root causes were present within the system long before the accident sequence was apparent” and “. . . these problems do not belong exclusively to either the machine or the human domains. They emerge from a complex and as little understood interaction between the technical and social aspects of the system”.

Although Reason was discussing systems such as nuclear power plants, chemical installations, aviation and offshore oil platforms, his statements are just as relevant when things go wrong in health care.⁵²

Very often, many factors “upstream” from the incident itself combine in particular combinations or sequences for a series of what otherwise would be minor misadventures to develop into a medico-legal catastrophe which may lead to the death or permanent harm of a patient.

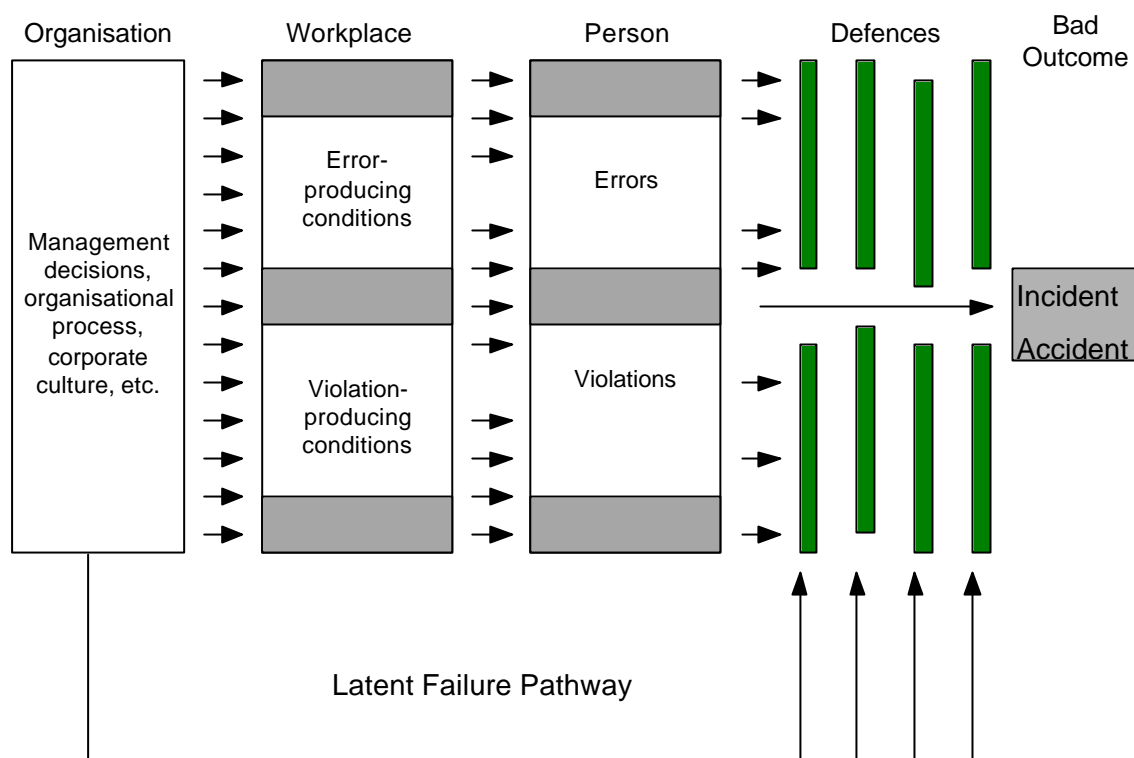
Health care is now delivered in a dynamic environment with complex interactions between patients, their pathophysiological and disease processes, medical and other staff, infrastructure, equipment, policies and procedures.^{53,54} Although human error does play a role in 70-80% of incidents and accidents arising from complex systems, it should be seen against a background of organisational, technical and equipment-interface problems which may not only set the stage for incidents and accidents, but be the prime causes. Equipment or system failure and human error are rarely the sole causes of problems - up to 90% have elements of both.⁵⁵⁻⁵⁷ In other fields, including road and aviation safety, environmental design and system changes have resulted in the greatest reduction in the incidence of injurious events.

A broad typology of contributing processes and type of incident has been developed and is expanded upon below and on pages 62-65.

1.3.2.3 System errors and violations

A diagrammatic representation of the factors involved in the evolution of a typical incident or accident in a complex system is presented in Figure 1, below. Adapted from Reason.⁵²

Figure 1 - Stages in the evolution of an incident or accident.



Management decisions may influence the availability and condition of infrastructure and equipment, and will dictate the number and type of staff employed.

Organisational processes involve the recruitment, training and rostering of staff, the development and use of policies and protocols, the supply and storage of materials, and factors such as the availability of adequate assistance and supervision.

Corporate culture may play a role - in some institutions there may be a "press on regardless" approach, so that, for example, it is unlikely that a poorly prepared pre-operative patient will be able to spend an extra day in hospital in order to be better prepared.

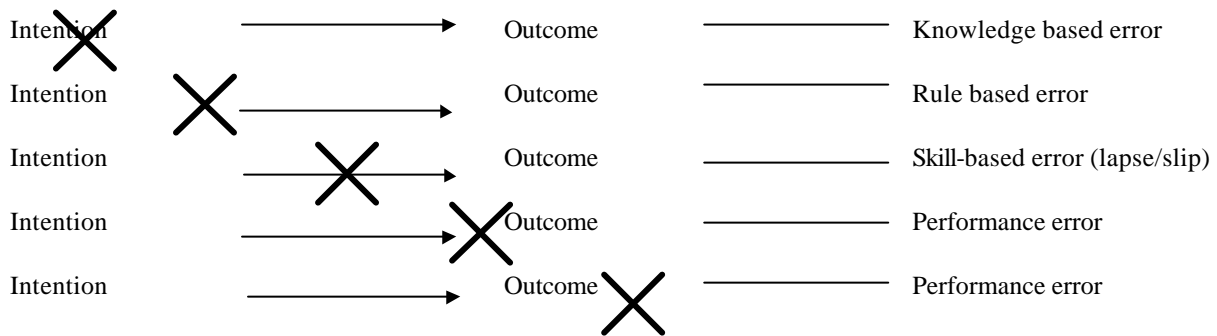
Error producing conditions in the workplace include poor design and maintenance of equipment, poor workplace layout, mismatching staff and tasks, as well as dysfunctional individual and team behaviour.

Violation producing conditions include impractical or poorly designed checklists or protocols, tasks which cannot be performed properly in the time allotted and machines or monitors which produce an excessive number of false alarms. Each of these may induce a health care worker to take a shortcut or respond inappropriately to a potentially hazardous situation.

1.3.2.4 Human errors and violations

It is also important, if insight is to be gained into why things go wrong, to recognise that there is more than one type of human error, and that different strategies will be required to address each type.^{51,52} The types of human error which may occur are outlined in Figure 2.⁵⁸ The stage at which error occurs is indicated by a cross.

Figure 2 - A Classification of Human Error (Adapted from Reason)



Knowledge-based error. This assumes that the error is due to a lack of knowledge in terms of diagnosis, the range of appropriate treatments or the effects of those treatments. There is a perception that most errors in medicine are caused by lack of knowledge, hence the emphasis on continuing education. This perception is not consistent with patterns identified in recent incident monitoring studies.

Rule-based errors. The application of a bad rule or wrong rule leads to many incidents and accidents (eg a routinely inadequate checking process); great attention has been paid to rule-based errors in areas such as aviation, and peer pressure would now prevent most pilots from taking off without having completed a structured "cockpit" checking routine.

Skill-based errors. Absent-minded slips and lapses which occur when skilled people perform many tasks at once are also a rich source of incidents, and are, for example, responsible for the vast majority of "wrong drug errors".⁵⁹ In a series of over 1,000 industrial fatalities, "slips and lapses" were considered to be "prime events" in over one third.⁶⁰

Performance errors. Lack of appropriate technical skills in performing a task or procedure contributes to some incidents. Little is known about the contribution of performance failure to the incidence and severity of events. Mechanisms for teaching and ensuring technical competence are not well developed and most would agree that a more structured approach is desirable. It has been shown, for some common procedures, that a structured teaching process can reduce certain complications up to four-fold.^a

Violations. These are distinguishable from errors, in that there is always a "trade-off" or a motivational component, whereas errors are simply a manifestation of imperfect cognitive function. It is likely that more than 5% of problems are caused by violations⁹.

It is important to distinguish between the various types of error or violation leading to a problem, as the strategies that have to be used to prevent the problem from recurring depend on the type of error or violation which caused it. Although the manifestation of the problem may be the same, (eg exceeding the speed limit whilst driving) it is apparent that the preventative steps that would need to be taken would depend on the underlying cause (eg whether it was due to lack of knowledge about the speed limit, absent-mindedness, a faulty speedometer, or a deliberate "trade-off" against being late for a meeting).

If suitable strategies for the better detection, management, and prevention of problems are to be developed, it will be necessary to elicit and understand the contributing factors.

RECOMMENDATION 2

That educational packages be produced for health sciences students which

provide a background to “health care as a complex system” and a basic understanding of the cognitive psychology of human error.*

1.3.2.5 Risk vs benefit

In all human endeavours, the risk of taking a certain course of action must be considered in relation to the expected benefits. In the practice of medicine, it is perfectly appropriate to embark on a high-risk strategy if it is the only one available, and there is a benefit which may be life-saving. However, an inevitable consequence is that, if there is good access to health care for people of all ages, including those with major pre-existing illnesses and serious diseases, it is to be expected that there will be a substantial number of adverse outcomes arising from health care management, some of which, at least, will be deemed potentially preventable in retrospect.

For many years, patients "put themselves in the hands of their doctor" on the assumption that he or she was both well informed and well motivated and would act in their best interests. It is being increasingly recognised that, although the vast majority of medical practitioners are both well motivated and well informed, decision-making in clinical medicine is complex, and that diagnostic and therapeutic interventions need to be planned in conjunction with each patient.

1.3.2.6 Benefit and evidence-based medicine

It is clear that if a procedure has not been shown to be effective, a properly informed patient may wish to avoid the inevitable concomitant risk by not having the procedure at all. A large number of widely-practiced interventions and procedures have not been shown to be effective and to be associated with certain risks (eg tonsillectomy for tonsillitis, grommets for otitis media with effusion, removal of impacted wisdom teeth, transurethral prostatectomy over less invasive surgical techniques for prostatism and prostatitis, nearly all of the new modalities for treating localised prostate cancer).⁸² If a patient does wish to proceed with a procedure which has not been shown to be effective it is vital that they know this and understand the material risks (also see pages 91 and 92).

A certain number of adverse events arising from the process of health care management is therefore to be expected. However, if a substantial fraction of these risks can be eliminated by improved systems and better practice, then it is clearly appropriate that steps should be taken to achieve this.

1.3.2.7 Risk and informed consent

As the perception of “risk” is a function of both the nature of the hazard and the exposure to it, both need to be considered in each instance.

Some figures about exposure to risk (the frequency of complications) are usually available from the medical literature (eg approximately 1% chance of dying, 1% chance of having a stroke and 1% chance of having a heart attack after a carotid endarterectomy). However, whilst there is usually at least some information about exposure, perceptions of the implications of a particular risk, such as a major stroke, may vary greatly between individuals, who have a right to know about the nature of any “material harm” that may arise. This has been recognised in recent legal decisions such as *Rogers v Whitaker*⁶³ and *Saxon v Tai*⁶⁴, in which it was judged that the medical practitioners involved did not give sufficient detail about the “material harm” that

* A basic text for all health science students “First do no harm” is being prepared by Runciman, Vincent, Barach and Reason which should be published within a year by BMJ Publishers.

could arise from the intended procedures to satisfy the desires of the particular patients involved.

Patients are much less likely to become unhappy and/or angry about an adverse event or outcome if its nature and incidence were clearly outlined before the event, so that the potential risks, as perceived by the patients, could be balanced against the potential benefits of the procedure.

However, properly informing lay-people about details of medical intervention is a difficult and complex issue. One of the proposals arising from this report will be that resources such as video tapes and authenticated sets of information on web-sites, endorsed by the relevant specialist Colleges, be made available to provide the bulk of the information about particular procedures. With time, expert systems could run invisibly behind software-based structured histories and batteries of examinations and tests, adjusting risk:benefit ratios in the context of altered pathophysiology and co-morbidities. These will not replace the need for face-to-face discussions between patient and doctor, but will at least provide a lot of background information, and reduce the considerable burden of properly informing each patient about every risk in face-to-face discussions.

It is vital that both the medical profession and patients understand that risk is an intrinsic part of any intervention, and that health care, as a complex system, is at risk of unexpected and sometimes disastrous failures.

1.3.2.8 Patient factors

Individual patient characteristics have a major impact on the risk of a problem occurring, as well as on the outcome when something does go wrong.

There may be communication difficulties because of problems with language, eye-sight, hearing or intellect, and facts and situations may be interpreted quite differently by people from differing backgrounds and cultures.

Patients may be non-compliant or even hostile and their behaviour may be altered by concerns about their illness and the implications for their family, work prospects and future.

A further dimension is provided by the physical condition of the patient - not only with respect to the immediate problem for which they are being investigated or treated, but also with respect to the patient's age and pre-existing condition. Young, healthy patients may be considered to have an additional layer of endogenous defences inherent in their robust homeostatic mechanisms.

Increased age, the associated severe illnesses and more complex interventions play an important role in both the incidence and impact of problems. In the QAHCS nearly 40% of all adverse outcomes, and over three-quarters of all potentially preventable deaths occurred among patients over 65 years old. The chance of an adverse event resulting in death in this age group was over ten-fold that in the under 45 age group.⁹

The processes that contribute to the current pattern of iatrogenic injury are complex and interact with each other. It is clear that a simple approach to iatrogenic injury that focuses on blaming the proximate individual is unlikely to provide a good basis for management and prevention. It is also clear that responding to the problem on a case by case basis, through clinical review, can only have limited impact.

The remarkable symmetry between adverse event patterns in the United States and Australia indicates that the nature of the problem is a function of the total system and that interventions must take this perspective.^{27,28}

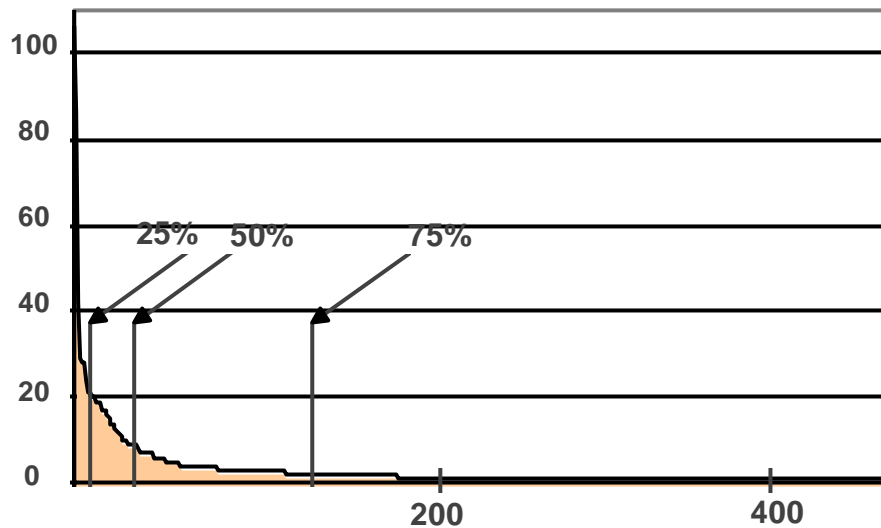
RECOMMENDATION 3

That easy-to-understand measures of the relative risks and benefits of available diagnostic and therapeutic options be developed, and that means of conveying these to prospective patients in lay terms be made available at the point of care (eg pamphlets, video tapes, web-site addresses, expert systems, references to other material).

1.3.3 *Types of iatrogenic events and their distribution*

When the Australian (QAHCS)⁹ and American (UTCOS)⁸ studies were compared, it was found that there were several differences in the methods used, despite previous assumptions to the contrary. Overall, QAHCS used more reviewers and wider inclusion criteria with respect to the likelihood of causation by medical management, the timing of the adverse events in relation to the randomly selected admission, and the type and severity of event.²⁷ When the 2353 QAHCS adverse events were handled in the same way as they would have been had they been analysed in the United States, a set of 1499 remained which could appropriately be directly compared with the 475 UTCOS adverse events. When these datasets were compared, each was found to contain virtually identical numbers of serious adverse events; in each study 0.3% of admissions was associated with an iatrogenic death and 1.7% with major iatrogenic disability. The overall discrepancy was accounted for by a far larger number of minor adverse events in the Australian data set, as Australian reviewers included as adverse events many problems which were not so defined or included by US reviewers.²⁸

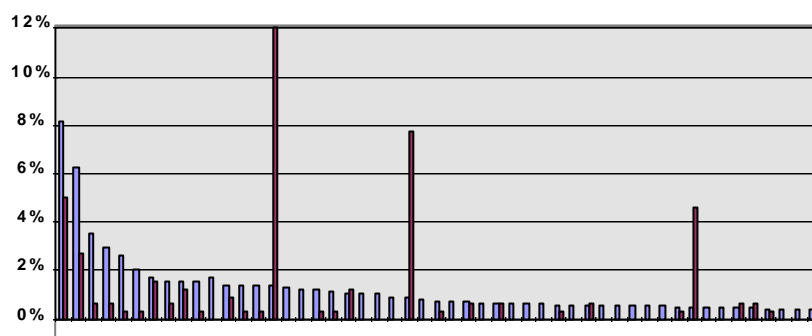
Figure 3 - Distribution of adverse events amongst principal natural categories: the number of adverse events (vertical axis) in each of the 518 principal natural categories identified in the Quality in Australian Healthcare study (horizontal axis).



The distribution of these QAHCS adverse events amongst 518 “principal natural categories” that described the essence or most important feature of each adverse event is shown in *Figure 3*³³² (see Appendix 6 for definitions). The top 10 categories account for 25% of all adverse events, and the top 50 for 50% if all wound infections and adverse drug events are lumped together. It may be seen from *Figure 4* that the pattern of events is quite different for medico-legal claims files, underlining the importance of coding both sets of data.

The number of adverse events represented in *Figure 3* (1,499) is about the number that would be expected each year in a hospital of 250 beds, (assuming 90% occupancy and an average length of stay of 5.5 days). It is evident that only half of the adverse events in such a hospital would be encountered more than 10 times per year, with individual doctors being exposed to a very small number in each category; furthermore a claims file would be opened for only about 2% of these events.⁶⁵ This low individual exposure may go some way to explaining why most clinicians were very surprised at the scope and cost of adverse events when the figures were extrapolated to provide national estimates.

Figure 4 - A comparison of the distribution of adverse events and medico-legal events amongst principal natural categories: percentages (vertical axis) of 1499 adverse events from the year 1992 (lightly shaded bars) and of 334 medico-legal events in claims files opened in a typical tertiary referral hospital in 1998 (dark bars) in each of the top 50 of the 518 principal natural categories (horizontal axis) shown in Figure 3.



One of the most important observations that arises from classifying adverse events into these categories is that only one-quarter of all adverse events occur with sufficient frequency to be amenable to prospective tracking, even in large teaching hospitals. This means that to address the many types of adverse events which occur infrequently, it is necessary to have a national database and to include information from all available sources in order to elicit their salient features and contributing factors.

Although individually rare, these events are collectively important, as many may quite simply be designed out of the system once their true nature has been understood. This may require no work at the individual hospital level, as generic solutions can be applied across the entire health care system for certain problems. For example, getting rid of all Seldinger wires with one sharp end will remove all cardiac tamponade arising from inadvertent insertion of a sharp end. As a further example, all deaths resulting from the inadvertent intravenous administration of concentrated potassium chloride solutions could be eliminated if this preparation was simply removed from the inventories of hospitals, as has been done in the Veterans' Administration hospitals in the United States of America.⁶⁶

About one in ten admissions to acute-care hospitals in Australia is associated with a preventable adverse event - half of these occur before and half during the admission.

Only one-quarter of all events fall into categories which occur sufficiently frequently to be tracked prospectively, even in large hospitals - to gain a proper understanding of the nature of the remainder, a national database is required.

1.3.4 *The costs of iatrogenic injury*

Health economists divide economic costs into direct costs of healthcare (dollars spent on the provision of care), indirect tangible costs (dollars spent on the tort system, for example), and indirect intangible costs, which we have called "human costs" in the discussion below.

1.3.4.1 Human costs

Direct costs are the most common starting point when discussing costs in the health care system. While these are clearly important, this emphasis on direct costs sometimes distracts attention from the important human costs of incidents and errors in health care.

Human costs for the patient include pain and suffering, lost functionality and productivity, sometimes lost independence and the added frustration of trying to get a satisfactory response from a system that for the reasons described earlier in this report may be reluctant to admit liability for a problem that has occurred. Relatives, carers and friends also are deeply affected, not only by the direct consequences of the injury, but by loss of faith in a system of care and the impact of providing for the increased needs of the injured person. Further, employers face production costs as employees take sick leave or are unable to return to work.

The impact on health workers is also considerable. Loss of confidence, stress generated by not being able to openly discuss an incident and to seek the necessary system changes to make another incident less likely, and sometimes feelings of guilt and inadequacy all erode the capacity of the human resources of the health system.*

1.3.4.2 Health system costs

There are six current National Health Priority Areas. These are cardiovascular disease, cancer, mental health, diabetes, injury and asthma. Injury, a subject area that includes medical misadventure as a cause, first became a National Health Priority in 1986. However, iatrogenic injury, the subject of this report, has not so far been included as an area of active attention. This is, at least partly, due to the limitations, in this respect, of classification systems of routinely collected data on deaths and hospitalisations.

The AIHW has produced estimates of health expenditure on various conditions for 1993-94. These are summarised in Table 2.

Failure to creatively and sensitively manage the reality of iatrogenic injury can and does lead to the loss of highly skilled and trained individuals from the health care system.

A further breakdown of injury costs by external cause⁸ shows the five external causes that accounted for the most health expenditure (see Table 3).

* The following is a quotation from the Executive Summary of the IOM Report^a. “*Errors are also costly in terms of loss of trust in the system by patients and diminished satisfaction by both patients and health professionals. Patients who experience a longer hospital stay or disability as a result of errors pay with physical and psychological discomfort. Health care professionals pay with loss of morale and frustration at not being able to provide the best care possible. Employers and society, in general, pay in terms of lost worker productivity, reduced school attendance by children, and lower levels of population health status.*” This issue has also been addressed by Wu.^k

Table 2 Health system costs \$million by health sector (1993-94) and number of deaths (1994) for selected diseases and injury⁶⁷

ICD9 Chapter	Total costs \$m	Hospital (a)	Medical (b)	Pharmaceutical	Allied health	Nursing home	Other (c)	No of deaths
<i>Circulatory</i>	3719	1657	503	715	40	587	218	54888
<i>Digestive (d)</i>	3715	1070	284	275	1849	35	202	3859
<i>Musculo-skeletal</i>	3002	1207	518	276	416	430	154	775
<i>Injury</i>	2601	1663	393	127	160	112	146	7189
<i>Mental</i>	2586	1007	432	198	83	718	147	2985
<i>Respiratory</i>	2521	833	624	784	37	107	135	9958
<i>Nervous system</i>	2334	766	431	248	227	503	159	2944
<i>Cancer</i>	1904	1327	261	53	12	32	219	34206
<i>Other</i>	9015	4532	2194	1366	251	123	552	988
Total	31397	14062	5640	4042	3075	2647	1932	126692

- a) Public and private acute hospitals, repatriation hospitals and psychiatric hospitals including non-inpatient services.
b) Medical services to private patients in hospitals are included under hospitals.
c) Includes breast, cervix, lung and skin cancer public health programs, research and other institutional, non-institutional and administration expenditure. Does not include other public health services, community health services, ambulances or medical aids and appliances.
d) Dental costs are classified as diseases of the digestive system and included under the allied health sector.

Table 3 Health expenditure by type of external cause: 5 leading causes representing 70% of costs.

External cause	Cost \$ million	% of injury costs
<i>Accidental falls</i>	806	31
<i>Adverse effects of medical treatment</i>	401	16
<i>Road traffic accidents</i>	370	14
<i>Homicide and violence</i>	124	5
<i>Suicide and self inflicted injury</i>	72	3

On the basis of these estimates, health system costs attributable to medical misadventure are significant and exceed those of road traffic crashes.* It is well-recognised, however, that these costing methods do not reflect the true costs of iatrogenic injury. These costs are underestimated because only a small proportion of iatrogenic injury is coded to the medical misadventure cause due to limitations of the ICD coding system, because the principal

* The following is a quotation from the Executive Summary of the IOM Report^a. “Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8th leading cause of death. More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).”

diagnoses rather than complications (additional diagnoses) are coded, and because iatrogenic incidents are often not recorded at all in medical records or are recorded in such a way that they are not obvious to coders. Also, there are no systems in place for determining the proportion of bed days that are attributable to the incident rather than the condition, although \$298 million of \$401 million of iatrogenic injury costs were attributed to hospital costs.

A different approach to the estimation of costs was made by the QAHCS. A sample of medical records was extracted and scanned by trained reviewers to identify any adverse event. Medical reviewers then made an estimate of the additional length of stay attributable to the most serious adverse event for each case.⁹

The QAHCS estimated that adverse events associated with hospital admissions alone would account for 3.3 million bed days per year, of which 1.7 million would be from adverse events which were potentially preventable. This amounts to 8% of all hospital bed days in Australia in 1992. Coopers and Lybrand, consultants to the Taskforce on Quality in Australian Health Care, estimated that, based on \$510 per bed day (1992 AUD), the total cost would be \$1683 million and the preventable component (based on the original estimate of 51% preventability) \$867 million per annum.²⁵

Recent studies by the APSF and those by the Harvard group from the United States^{69,70,71} have shown that additional hospital days associated with adverse events cost substantially more than average hospital days. Also, problems dealt with in mental health institutions, nursing homes, day surgeries, domiciliary care and in the consulting rooms of general practitioners and specialists were not included, and nor were those dealt with in emergency departments of hospitals which did not result in admission.

Furthermore, in line with the suggestion of McNeil and Leeder⁷², when all adverse events were re-classified as to whether they fell into one of two categories, “potentially preventable”, or “not preventable with current medical knowledge” rather than using the six-point scale in the QAHCS, it was found that 80% of adverse events fell into potentially preventable categories.²⁹

Initial indications from more detailed studies estimating the number of potentially preventable adverse events that could actually be prevented by the introduction of appropriate measures suggest that, given adequate resources, over half of all events in many categories could realistically be prevented in the next 5-10 years. Making the same assumptions as Coopers and Lybrand, allowing 50% more for the cost per day of an adverse event-related hospital stay, and allowing \$250 million for treating injuries outside acute care hospitals, it may be estimated that the overall direct medical costs of potentially preventable iatrogenic injury could exceed \$2 billion annually.

Finally, direct health care costs form only a small proportion of the total lifetime cost of injuries. Lifetime cost includes the cost of lost earnings, and all other losses and costs associated with the effects of the injury. A recent study on the lifetime cost of injury in Australia estimated the total lifetime cost of non iatrogenic causes of injury is \$13.3 billion per annum.⁷³ This analysis also showed that direct health care costs only represent 37% of lifetime costs. It would seem reasonable to assume that lifetime costs of iatrogenic injury would be at least twice the direct costs.*

* The following is a quotation from the Executive Summary of the NHS Report.^b “... the best research-based estimates we have reveal enough to suggest that in NHS hospitals alone adverse events in which harm is caused to patients:

- ◆ occur in around 10% of admissions – or at a rate in excess of 850,000 a year.
- ◆ cost the service an estimated £2 billion a year in additional hospital stays alone, without taking any account of human or wider economic costs”.

Based on these estimates and assumptions, figures have been drawn together in Table 4 to allow comparison of the range of cost implications. It is clear that this range is large, emphasising the need for further work in this area. However, it is noteworthy that when estimates of Australian, US and UK costs of iatrogenic injury are calculated in Australian dollars, these amount to at least \$100 per person per annum.**

An even greater discrepancy exists in estimates from different sources of the number of deaths attributable to iatrogenic injury. In 1994 there were 53 deaths where medical misadventure and the adverse effects of drugs in therapeutic use were attributed as the principal cause of death by the coronial system.⁷⁴ Australian Bureau of Statistics (ABS) mortality data, although more comprehensive than coronial reports, only record the *underlying* cause of death. Estimates from QAHCS suggested that up to 14,000 deaths were associated with a potentially preventable adverse event in 1992.⁹

Table 4: Comparison of different methods of estimating costs and benefits achievable from prevention of iatrogenic injury.

Source of estimate	Estimated acute care hospital costs \$million pa			Estimated total healthcare costs \$million pa			Estimated total lifetime costs \$million pa		
	Total	Pot. Prev*	Prev within 5-10 years+	Total	Pot. Prev*	Prev within 5-10 years+	Total	Pot. Prev*	Prev within 5-10 years+
AIHW	298	238	119	401	321	160	1203	963	482
QAHCS 1**	1683	1346	678	1933	1546	773	3866	3093	1546
QAHCS 2***	2289	1830	915	2539	2031	1015	5078	4062	2031

Pot. Prev.* Potentially preventable.

QAHCS 1** Original estimates but based now on 80% potential preventability

QAHCS 2*** Revised estimates counting iatrogenic bed days @ 1.5 times normal bed day cost, assuming 80% preventability, and allowing \$250 million per annum for injuries handled on a non-inpatient basis.

+ Assuming adequate resource allocation to identify, trial and implement risk- and cost-effective measures.

The extent to which a problem may be attributed to iatrogenic injury is often debatable. In the case of the 14,000 deaths for example, it is known that the patient died and that there was an iatrogenic event. The extent to which the death was caused by the iatrogenic event compared with the contribution of other causes such as the critical nature of the patient's condition has not been determined, and is the subject of further study.^a The ABS has recently started multiple cause deaths coding. This information, considered in conjunction with the more detailed studies on the attribution of outcomes to adverse events, will allow a more comprehensive picture to emerge.

The following are quotations from the IOM Report.^a “Total national costs (lost income, lost household production, disability and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between \$17 billion and \$29 billion, of which health care costs represent over one-half”. “These figures offer only a very modest estimate of the magnitude of the problem since hospital patients represent only a small proportion of the total population at risk, and direct hospital costs are only a fraction of total costs”.

** Assumptions:

Australia – 18 million people, \$2 billion AUD/year.

USA – 280 million people, assuming \$17 billion USD/year, 56 cents US/AUD

UK – 60 million people, £2 billion/year, 33p/AUD

The potential overall benefit from prevention may exceed \$2 billion within 5 years, with direct savings to the health systems of \$1 billion per annum.

In other areas such as road safety investment in prevention has brought significant rewards. Despite the increase in motor vehicle usage in Australia since the early 1960's, the road toll has been reduced. Male mortality rates fell from 45 per 100,000 in 1968 to 14 in 1997 and female rate from 15 to 6 per 100,000 in 1997.⁷⁴ A similar systematic approach to prevention will need to be taken in the field of iatrogenic injury to achieve the \$2 billion saving outlined above.

It is clear therefore that iatrogenic injury is responsible for a large burden on the health care system and on society at large, and that there is a need for the development of a systematic approach to costing iatrogenic injuries based upon sound economic principles. This will require estimates of the costs of each principal natural category in the context of the Australian healthcare system; the methods for doing this will have to be developed and progressively refined.

RECOMMENDATION 4

That methods be developed for estimating the direct and indirect costs of each component of iatrogenic injury (including tort system costs), and that these costs be published at regular intervals.

1.3.4.3 Tort system costs

1.3.4.3.1 *Tangible costs*

If a patient is inadvertently harmed in the process of health care delivery, he or she may seek compensation by way of the tort system. Although accurate figures are hard to come by - and a lack of willingness by the medical defence organisations to reveal such figures hampered the work of the PIR - it is possible to make some estimates.

In South Australia the cost of claims and premiums on insurance against very large medical misadventure claims was about \$18 million in the year 1997/98.⁷⁵ Extrapolating this figure to the rest of Australia, it may be estimated that "medical misadventure" would cost the public hospital system about \$20 million per annum; a further \$110 million could be added to account for the private hospital system and \$100 million for individual doctors' insurance.⁷⁶

Thus, it is estimated that at least \$400 million or 1% of the total amount spent on health is consumed by legal expenses and compensation arising from medical misadventure.*

It is estimated that the direct medical costs of iatrogenic injury consume over 5% of the \$40 billion spent each year on health care, and that the costs of medico-legal claims filed consume a further 1%.

* The following is a quotation from the Executive Summary of the NHS Report.^b "The NHS pays out around £400 million a year in settlement of medical negligence claims, and has a potential liability of around £2.4 billion for existing and expected claims." When converted to Australian dollars, the estimated annual cost in Australia is very similar per capita to that in the UK.

The Medical Defence Union of Australasia reported that nearly twice as many notifications of potential problems were made in 1997 as in 1990, and that over the five year period from 1992 to 1997 the average cost of settling Australian claims increased nearly two and a half times. There was also an increase in the number and size of large claims.⁷⁷

Although there is ongoing debate as to the extent to which Australia faces a “litigation crisis” similar to the one which led to the original Californian study into “potentially compensable events”⁷⁸; it would seem, even on the limited evidence available, that it would be prudent to invest in reducing the rate of adverse events.

1.3.4.3.2 Human costs

The tort system is associated with massive inequities. At least one in ten admissions is associated with a potentially preventable adverse event. Work done and estimates made by the APSF and the Harvard School of Public Health suggests that between 0.5 and 1% of admissions are associated with adverse events deemed to be caused by negligence.⁷⁹ Direct studies in the USA and estimates from figures provided by the United Medical Protection Society - the largest medical indemnity group in Australia - suggests that only 1 in 25 of those who suffer from a negligent adverse event end up receiving any compensation by the tort system (ie 1 in 250 of those who suffered from a potentially preventable adverse event, or 0.04% of all admissions).

Anyone who has been a plaintiff or defendant in a tort action can confirm that “there are no winners”.⁸⁰ Patients who wish to seek compensation face large, well-funded, sophisticated medical defence organisations, potentially crippling legal fees, and a process that is likely to take years. Defendants, too, face a process that will drag out over many years, may have to tolerate outrageous behaviour on the part of prosecutors in court, and are aware that judgements may be handed down which are quite at odds with expert medical opinion.⁸¹ There is no doubt that outcome bias is a major factor in many cases in both the United States and Australia,¹³⁷ with the tort system apparently sometimes acting as a de facto social security system.

Given the gross inequities with respect to access, the traumatic nature of the process and the high costs (less than half of which end up with a successful plaintiff), it would seem that reform should be placed back on the agenda, a proposal for which there is some support by the Medical Defence Organisations.⁸²

1.3.4.4 Lost opportunities

The cost of providing an insurance system, involving the legal system and treatment for iatrogenic injuries erodes the resource base of health care. Resources are being diverted from health care priority areas to damage control. The costs of iatrogenic injury are not routinely identified in health care budgets because they are hidden as variability in the cost of treating different conditions and of using particular procedures.

When savings are made, they are absorbed within the budgets of health care units. The recent analyses cited above and the additional analyses in this paper indicate the size of these costs.

These represent lost opportunities for health care due to failure to manage the problem, recover the benefits, and redistribute the resources recovered in a systematic and targeted fashion.*

RECOMMENDATION 5

That the tort system and methods for compensating those injured by health care management be examined with a view to reform.

1.4 Context

There have been enormous changes in healthcare in the last decade. It has been realised that with an ageing population and ever expanding possibilities with respect to better but often more expensive diagnostic and treatment options, all that is available will not be affordable.

For most clinicians, the work environment has become progressively more volatile with sometimes competing imperatives impinging on everyday clinical work. Much has been written and said about continuous quality improvement, with demands that more and more measurements be made of adherence to process and of outcomes, while few additional resources have been allocated for these tasks. Some management functions have been devolved to clinicians, but rarely with commensurate devolution of control over how funds may be spent. Chief Executive Officers and Managers have become more accountable and are expected to have in place explicit measures for risk management. There has been much emphasis on doing more with less, and there have been concerns, with the rapidly changing pattern of clinical practice, especially with more being done on an outpatient and day stay basis, that patient safety and welfare may sometimes be compromised.

Figure 5 demonstrates that patient safety is an important component of each of the related but sometimes independently administered areas of quality improvement, clinical governance and risk management. These areas, and the manner in which information is handled, constitute the context in which patient safety must be considered.

Figure 5 – The components of patient safety



* The following is a quotation from the Executive Summary of the IOM Report.^a “Errors are also costly in terms of opportunity costs. Dollars spent on having to repeat diagnostic tests or counteract adverse drug events are dollars unavailable for other purposes. Purchasers and patients pay for errors when insurance costs and copayments are inflated by services that would not have been necessary had proper care been provided.”

1.4.1 Risk management

One of the reasons why iatrogenic injury has not received systematic attention is that it has generally not been considered under the overall mantle of “Risk Management”. Some of the reasons for this have already been discussed, such as difficulty in accessing medical records and a reluctance to acknowledge system failure and human error. There is no doubt that a further major contributing factor has been the sequestration of clinical problems from the body of better understood problems to which all complex systems are exposed (eg risk of fire, risk of fraud).

For example, in a recent special report on risk management and governance in the National Health Service of the United Kingdom, the topic “Clinical Risk Management”, although mentioned elsewhere, did not feature as a component of a “Comprehensive Risk Management Model”.^{83*}

Problems readily recognisable as arising from clinical activities have been included in documents expanding and supporting the new Australian/New Zealand standard AS/NZS4360 - Risk Management (see Table 5), confirming that clinical risk management falls firmly into the ambit of overall risk management.^{84**}

Table 5 - Examples of risks that should be addressed from documents supporting the new Australian/New Zealand standard AS/NZS4360 (not listed in the original sequence).

- Risk of injury to staff and clients
- Risk of harm to visitors
- Risk of adverse publicity
- Risk of contracting communicable diseases
- Risk of theft.
- Risk of fraud.
- Risk of storm/water damage

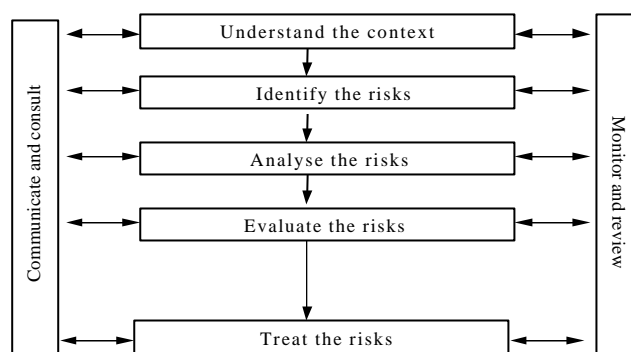
In recent years it has been made quite clear by both Treasury Departments and the relevant Attorneys General that the CEOs of health facilities are responsible for ensuring that appropriate explicit risk management processes are in place.

The diagram in Figure 6 was taken from documentation supporting and expanding “AS/NZS4360 - Risk Management”; the mechanisms proposed in this report on iatrogenic injury are entirely consistent with this model, and indeed, each essential component is systematically dealt with.

* Clinical risk management is now an integral component of overall risk management in the UK. However, this was not the case in the UK or Australia a few years ago.

** This standard has been adopted by the NHS in the UK, by ACSQHC in Australia, as well as by New Zealand, and a set of guidelines have now been developed specifically for managing risk in healthcare.¹

Figure 6 The risk management framework of the new Australia/New Zealand standard AS/NZS4360.



Of the \$33 million outlaid by SAICORP (the captive insurance company of the South Australian State Government) in the 1997/98 year, over half (\$18 million) was paid for claims arising from the South Australian Health Commission and for the medical misadventure component of the premium for very large claims.⁷⁵

Clinical risk management must now be recognised to be the largest component of overall risk management at State government level. It can no longer consist only of ensuring that insurance against litigation for negligent acts is in place and that attempts are made to mediate and conciliate once problems have occurred, but must include active management and prevention.

The concept of risk management in the health sector is developing quickly. However, a systematic commitment to the reduction of risk to those treated by the health care system has yet to emerge. Risk management is still often viewed in terms of control of risk to governments, health care units, and clinicians. This is largely due to the pressing nature of immediate medico-legal issues and to the lack of a coherent overview of the nature and distribution of risk. In this context the focus is on damage control rather than prevention. “Risk managers” in the Australian health-care system are almost solely concerned with “mopping up” after disasters, rather than with ensuring that system-wide measures are put into place for risk reduction, as advocated by the Standard AS/NZS4360.*

Investment in risk reduction through prevention has been the foundation of progress in the road traffic, aviation, manufacturing and construction industries for the last 30 years. In these areas, there has been a marked shift from an individual blame base to a systems view of risk reduction and from incident-by-incident analysis to pooled systematic intelligence. There has been a clear acknowledgement that the system of events is too complex for interventions to be individually identified and implemented in a distributed fashion.

The great need in risk management in Australian healthcare is to overcome the fear of individual blame or responsibility for costs and to move to a proactive approach to risk identification and management.⁶⁶

While there is important work to be done in quality assurance at the health unit and clinical delivery level, failure to provide a coherent support and evidence base at a national level will result in a narrow intervention focus and inefficient identification of both problems and

* This year there have been some major initiatives on the part of risk managers to try to move systems in healthcare towards a pro-active approach, consistent with the Standard AS/NZS4360.

solutions. Experience over the last five years has shown that data from the local level is inadequate to drive a comprehensive risk management approach and that the skills necessary to deal with many of the complex issues are not available and cannot be afforded at the level of individual health units.

The following strategies are required:

- National leadership to develop a proactive and preventive approach to risk management among governments, professions, insurers and consumers.
- Close links between the development of iatrogenic injury surveillance systems and the development of risk management approaches.
- Identification and co-ordination of the many research groups and projects with interest and expertise in this area.

It is extraordinary, for example, that although there is a plethora of health facilities with projects relating to falls and patient injury, there has not been a single prospective study of appropriate design, world-wide, to measure the effects of any intervention in this area.⁸⁵

The Expert Group recommended that a “National Council for Safety and Quality in Health Care” be established. This recommendation was endorsed at the July 1999 meeting of the Australian Ministers for Health, and \$1 million per year was committed for the next 5 years.

A start had already been made by the APSF before ACSQHC had been constituted with the formation of national working parties in areas which had been objectively identified to be important. In March 1998, a national meeting was held on adverse drug events, and a symposium issue of the *Journal of Quality in Clinical Practice* was published with the findings and recommendations of this meeting (see Appendix 7).⁸⁶ In June 1999, a further meeting was held on “Incidents and Accidents in Healthcare”.

This meeting addressed falls, problems arising from thromboembolism and anticoagulants, informed decision making (consent), nosocomial infection, and computerised prescribing, computer-based decision support, unit patient dosing and decision support to enhance the “quality use of medicines” (see Appendix 8).*

1.4.2 Quality assurance

Quality assurance has become a major plank in the strategy to increase and maintain health care standards in Australia. At the most formal level an institution or health care facility may be accredited by the Australian Council of Healthcare Standards (ACHS) using the EQuIP program, by the Australian Quality Council through the Australian Quality Awards or by the international quality assurance standard ISO9000. Accreditation covers a broad range of management and service criteria and aims to provide an incentive for health care units to reach or exceed specific standards.*

The quality assurance movement is broad based, covering a range of disciplines and types of service. It addresses the triad of structure, process and outcome. It aims to optimise functional health status, encourage the application of best clinical practices and progressively improve cost efficiency. However, intrinsic problems are that the importance of these aims differs for

* These areas now form part of the “Action Plan” of ACSQHC, and national “taskforces” are being established to co-ordinate local, state and national initiatives in high-priority areas such as these.^o

* ACSQHC will commission work to set national standards and compliance requirements in this area and has developed an initial scoping paper.^m

different “customers”, such as funders, purchasers, providers and consumers and that some aims are in conflict (eg equity of access and efficiency).

Clinical indicators, such as those developed by the Care Evaluation Programme (CEP) of the ACHS, identify particular measures which may act as flags to identify aspects of clinical care which may require attention. However, most do not inform clinicians about what aspects of process require attention, and hence only constitute the first phase of the quality improvement cycle.

Quality assurance and a focus on patient safety have strong mutual interests. The identification and management of iatrogenic injury is of fundamental relevance to the quality process and the general mechanisms put in place to manage quality provide an important avenue for work on iatrogenic injury. It is not surprising that many of the developments related to iatrogenic injury and processes of incident monitoring and medical record review have been promoted in and by the quality assurance movement.

1.4.3 Clinical governance

There have recently been moves in some jurisdictions to distinguish between corporate and clinical governance, with clinicians having to take responsibility for their collective as well as their individual performance.⁸⁷ However, in making clinicians accountable for clinical practice, the bodies controlling health facilities cannot absolve themselves of the ultimate responsibility of ensuring that the system acts in the best interest of patients, and does not harm them.

The various arms of clinical expertise within the health care setting maintain a degree of independence. Each clinical specialty maintains a program of training and accreditation aimed at maintaining best practice and developing the leading edge of the specialty in an informed and ethical manner. In a health care setting the various clinical specialties reinforce each other and maintain a great deal of interest and control over technical and ethical issues; the current efforts in this area should be reinforced and co-ordinated at a national level. The Committee of Presidents of Medical Colleges provides a mechanism for this and is already active in this area.⁸⁸

Some iatrogenic injury issues are isolated to specific clinical areas, while others span the whole range of clinical endeavour. Management of iatrogenic injury therefore requires close co-operation of all clinical disciplines and the active involvement of leaders in clinical practice.*

1.4.4 Corporate governance

The funding and management of modern health care is a complex task. Given finite resources, questions about the mix of treatments supported, the maintenance of cost effective practice and the co-ordination of an ever-growing range of clinical interests and practices have emerged as important issues. The patterns of functioning and priorities of the whole system including administrative, clinical and other service elements have the potential to increase or decrease the incidence and severity of iatrogenic injury.

Implementing changes to reduce iatrogenic injury will require the issue to be firmly established on the agenda of policy makers and administrators and proper consideration to be given to the need to establish how investment in prevention will provide returns to health care overall.⁸⁹ In addition, in the tight climate for health expenditure, corporate commitment to reinvesting part of the returns in further prevention will be needed. This will require a move to planned

* Regular meetings are now being held of the Chairs of ACSQHC, the newly formed National Institute of Clinical Studies, and the National Health and Medical Research Council and the National Health Priorities Action Council.

management from the reactionary crisis management model used currently to deal with iatrogenic occurrences. Strong leadership and very firm commitment will be needed if this is to be achieved, as annual budget “crises” have become the norm in Australian healthcare facilities.

1.4.5 The appropriate use and protection of information

Australia has a history of particular sensitivity about the collection and processing of identifiable information. The data extracted for identifying iatrogenic injury relates to events that can have high levels of emotional sensitivity for patients, staff and health care units. It is essential therefore that proper protection is put in place to ensure that the processes involved do not compromise the privacy or rights of any party. Even the possibility of negative consequences of providing access to information has the potential to severely undermine the quality and coverage of information and compromise future co-operation by those who report the incidents and who must ultimately implement the corrective strategies. The over-sanitisation of data on the other hand can lead to insufficient information to identify causes and develop interventions. The specific issues encountered in developing iatrogenic injury surveillance systems to data are discussed below.**

1.4.5.1 Privilege

Data received for incident monitoring or extracted from medical records must remain legally privileged. Without this both the quantity and quality of information received would be seriously compromised. Australia has legislation for granting legal privilege at the Commonwealth level,²³ in each State,^{90,94} and in the Australian Capital Territory.⁹⁵ No such legislation exists in the Northern Territory.***

Both AIMS and the QAHCS have been declared under the Commonwealth legislation and administrative processes are in place to ensure that health units are strongly encouraged to apply for cover under the various State Acts.*

It has now been agreed in principle that the APSF is to become a Collaborating Unit of the AIHW, and all projects which have been approved by the AIHW Ethics Committee will have the protection afforded by section 29 of the Australian Institute of Health and Welfare Act 1987. This will allow certain APSF processes to be streamlined and simplified while retaining a high level of protection of sensitive data.**

1.4.5.2 Anonymity

In addition to the protection outlined above for data with identifiers, it is vital that reporters have the option of anonymity.* The importance of robust mechanisms to ensure absolute anonymity was recognised nearly half a century ago by Flanagan, the “father” of incident monitoring.⁹⁶

It is worth quoting Flanagan in full on the subject of anonymity -

“Especially for the collection of information about ineffective behaviour, one of the principal problems is to convince the observer that his report cannot harm the person reported on in any way. Assurances are not nearly so effective in this situation as actual descriptions of techniques to be used in handling the data, which enable the observer to judge for himself how

** This issue was addressed recently in an editorial in the British Medical Journal by one of the authors of this report.ⁿ

*** A document reviewing this issue has been commissioned by ACSQHC and endorsed by Health Ministers.^o

* AIMS has now been “declared” by the Commonwealth Minister for Health for a further 5 years.

** This agreement was formalised in July 2000.^g

well the anonymity of the data will be guarded. Under no circumstances should the confidences of the reporters be violated in any way. The use of sealed envelopes, avoidance of identifying information, the mailing of data immediately to a distant point for analysis, and similar techniques are helpful in establishing the good faith of the interviewer in taking all possible precautions to safeguard the incidents reported."

Although this passage refers to an interview-based system, it is also of fundamental importance when report forms are used. The most important single feature of any incident monitoring study is that the individual reporter has the right to remain completely anonymous. Protection of anonymity has been embedded in AIMS processes. Although individuals may choose to reveal their identities, particularly when no harm has resulted, it is vital that they have an absolute right to complete anonymity. Any identifying information that is inadvertently included on any report form is deleted on receipt of the form, a photocopy is made, and the original form destroyed.

Anonymity provides a basis for increased reporting because it sends the clear signal that the focus of incident monitoring is on aggregated data and systems responses, and not on blame and retribution.

1.4.5.3 Security

The sensitive nature of the data and the fact that its misuse could provide a massive setback for work of this type means that data security is essential. The security system of the APSF is described below as a model that provides the necessary level of protection to ensure that participating organisations and professionals can have full confidence when they provide information on iatrogenic events and injuries.

Security systems are of three types, process, physical and computer-based.

1.4.5.3.1 Process-based security

All the participating hospitals and specialties are encouraged to avail themselves of any State legislation relating to immunity from litigation with respect to information of relevance to quality assurance. Both QAHCS and AIMS have been declared under the relevant Commonwealth Act.²³ Protection is currently being sought for the new Australian Medical Record Analysis System (AMRAS) which is being developed by the APSF. All staff members sign confidentiality agreements and understand that it is a criminal offence to release any information.

All groups reporting have the option to use a process developed by the APSF that involves the Australian Bureau of Statistics (ABS). In this process, the ABS sends an envelope with a number to the reporting group. They put all anonymous forms into this envelope and send them to the ABS. The ABS then allocates a new random number to the batch, places them in a new envelope with this number, and sends them to the APSF. The APSF thus does not know the source of these forms. For feedback, the reverse process is used.*

* With several years' experience, with users having gained confidence in APSF security safeguards, and with the release of the new AIMS+ system, it has been decided that this process involving the ABS will no longer be needed.

When the APSF handles data with identifiers, this is done in batches and each database is discrete, and has its own directory protected by Windows NT security. Security of access to database files is controlled at the file level.**

1.4.5.3.2 Physical security

The APSF premise is located next door to laboratories staffed 24 hours a day. The front door to the APSF has "swipe card" security, ie a computer record is kept of the identity of each person entering the APSF and the time at which he or she entered. The doors to the file server, the QAHCS paper records and to any AIMS forms being processed are locked out-of-hours and are protected by a separate infrared security system, which is set up to alarm in the adjacent laboratories. Once forms have been entered into the database they are returned to the health facility which owns them, or they are shredded.

1.4.5.3.3 Computer-based security

The APSF computer system is protected by the Microsoft Windows NT domain security system. At the end of each day a removable hard drive is stored off the premises, and archives and back-up zip disks of the database are kept on the APSF premises in a fireproof safe.

1.4.5.4 Access and control of data

It is important that advanced security systems do not impede appropriate access to information. Stakeholder organisations that provide data must have access to their own information and appropriate de-identified aggregated information from other sites.

However, safeguards have to be in place to ensure that ethical considerations are satisfied and that representatives of the stakeholder groups have an opportunity to review material which may impact on their group before it is released for publication or dissemination. The adverse event data, which had not been subjected to peer review, were released in Federal Parliament in 1995 as alarming findings, and were widely disseminated without any warning to the medical profession (see Appendix 1). The profession then had to field questions from their patients and the press about these findings without any knowledge of the context, definitions or methodology of the study. As the implications of the findings were that problems leading to patient harm were five times more common in Australia than the United States, this placed many people in a very difficult position.*

At intervals since then there have been further press reports, some accurate and thoughtful, but many sensationalist, inaccurate, misleading and alarming. It is most important that information be disseminated, but it is also important that systematic measures are put into place to try to ensure that those who provide the time, effort and information and who are vital to dealing with the problem of iatrogenic injury are not unnecessarily alienated by the only press coverage being "bad press".

The intention of the safe-guards suggested above is not to censor information in any way, but simply to ensure that it is accurately and appropriately presented, and to allow relevant stakeholders to be forewarned and properly informed if there is the potential for public interest in the information.

** With the new APSF system, the data will be kept in a single database. Data from each source has an identifier, and will be transferred electronically using industry-standard encryption, both for passwords and data.

* This conclusion has been shown to be invalid on re-analysis of the QAHCS and UTCOS data.^{27,28}

RECOMMENDATION 6

That the existing State and Commonwealth legislation for protecting information brought into existence for safety and quality of care be reviewed, and that measures be taken to ensure that comprehensive protection can be provided across the entire spectrum of healthcare in all jurisdictions.**

** A document reviewing this task has been commissioned by ACSQHC and endorsed by Health Ministers.^o

"The aim of science is not to open the door to everlasting wisdom, but to set a limit on everlasting error".

Attributed to Galileo (1564-1642) by Brecht (1898-1956)

2.1 Progress and developments in describing the problem of Iatrogenic Injury in Australia

This section describes the progress made in the development of information sources, and in the classification and analysis of information. Further information can be found in the detailed reports on the AIMS systems.⁹⁸

2.1.1 Incident monitoring and reporting

2.1.1.1 Origins of incident monitoring

Incident monitoring has its origins in the critical incident technique, which was developed during a series of studies by psychologists on the performance of pilots in World War II.⁹⁶ These ranged from an analysis of the reasons for failure in learning to fly for one thousand pilot candidates who were eliminated from flight training schools, to a study of several thousand incidents reported by combat veterans to define the critical requirements of combat leadership. Further studies led to recommendations regarding cockpit and instrument panel design.

The principal objective of these studies was to determine the critical requirements demonstrated to have made the difference between success and failure, from first hand reports or from objective records. The technique was refined and was used to define these requirements for the work of an officer in the United States Air Force, for commercial airline pilots, for research personnel and for air traffic controllers. Later the technique was further developed and was used to determine the critical requirements for people as diverse as assembly line workers, foremen, dentists, book-keepers and life insurance agency managers.

As Flanagan described in his original paper in 1954, it was "essentially a procedure for gathering certain important facts concerning behaviour in defined situations". Requirements of the technique include developing a "classification system for any given type of critical incident" and making "inferences regarding practical procedures for improving performance based on the observed incidents".

The technique was stated to be aimed specifically at defining tasks from the perspective of human behaviour, but it is interesting that the applications listed included not only setting criteria for selection, training, performance and motivation of personnel, but also for improving job design, operating procedures and equipment. The evolution of the technique, as applied to medicine, has remained remarkably consistent with the original description by Flanagan. The main differences have been in the wider recognition of "system based" problems in complex systems, which, although recognised by Flanagan, were not explicitly elicited, and in the use of an approach to system failure and human error which has been developed since Flanagan's original work (see pages 12-15).

Early examples of the use of the critical incident technique in medicine range from studying drug errors by nurses to a study on the effect of doctors' performance on patients.^{99,100} The first

application of the technique to anaesthetic practice was by Cooper et al in 1978;¹⁰⁰ in this study a structured interview technique was used to elicit details about incidents with which anaesthetists had been involved in the past. Two groups in Australia adapted Cooper's methods to study anaesthesia incidents, but sought written, anonymous reports on a structured form as soon after the incident as possible, and one worker independently set out recording details of any significant event which could have adversely affected a patient.¹⁰²⁻¹⁰⁴

2.1.1.2 The origin of AIMS

The leaders of these studies formed the nucleus of a group, co-ordinated by the APSF, which set up the Australian Incident Monitoring Study in July 1988 with the aim of collecting detailed qualitative and anonymous data about any unintended incident, no matter how seemingly trivial or commonplace, which could have or did cause harm.^{19,20} The incident may or may not have been preventable, and may or may not have involved an error on the part of anyone. This was limited, initially, to the study of incidents in anaesthetic practice (AIMS - Anaesthesia)⁰⁵. Similar studies were undertaken in Holland¹⁰⁶ and in Hong Kong.¹⁰⁷, this latter study being based on AIMS methodology. In 1993 a detailed analysis of the first 2000 incidents reported to AIMS was published in 30 papers.² Studies using the same report form, software and classification system, have now been initiated by anaesthetists in about 30 countries.

In April 1991, the Commonwealth Department of Health and Family Services set up the Professional Indemnity Review Committee to look at issues in relation to compensation and professional indemnity in health care.¹¹ The Committee met with the APSF in late 1991 to discuss incident reporting as one means of adopting quality assurance methods to avert the number of compensation claims arising from bad decisions, bad communication, or bad practice.

In February 1992 a discussion paper on "Compensation and Professional Indemnity in Health Care" was published and various groups including the APSF were invited to make submissions to the Review Committee. The APSF submission pointed out that an approach such as AIMS would provide a powerful, effective, politically acceptable and relatively inexpensive method for improving performance in the health care system and have a real impact on reducing harm to patients. The submission suggested that a more effective approach would be to aim for "continuous quality improvement" necessitating:

- Finding out what is going on
- Collating and analysing the data
- Devising preventative strategies
- Implementing the strategies
- Assessing the impact of the implementation

The submission also proposed the introduction of incident monitoring to other medical specialties. As a result, funding was obtained for the APSF to co-ordinate pilot studies of anonymous incident monitoring in six additional medical specialties (Emergency Medicine, Intensive Care, Gastroenterology, General Practice, Obstetrics and Gynaecology, and Psychiatry), as well across six teaching hospital systems.

These studies were reviewed in late November, 1994, at a Conference in Melbourne on "Incident Monitoring and Risk Management in the Health Care Sector", which was sponsored by the Commonwealth Department of Health and Human Services. At this Conference it was demonstrated that incident monitoring could be usefully applied to a diverse range of clinical activities. Taking into account all that had been learnt in the previous studies, it was decided

to develop an integrated incident reporting and monitoring system which could be applied across the entire health care system (system-wide AIMS).

The evolution of the use of the critical incident technique in the discipline of anaesthesia and the development of methodology for its extension across the whole health care system will be outlined using the approach originally proposed by Flanagan in 1954.⁹⁶

2.1.1.3 Aims and definitions

Flanagan indicated that it was necessary to outline an initial general aim, but that, with experience, it would be likely to require revision. He also cautioned that "considerable effort is required to avoid defeating the purpose of the general aim by cluttering up the statement with specific details and qualifying conditions".

In Cooper's (1978) original study⁹⁷, a mishap was labelled a critical incident when it was clearly an occurrence that could have led (if not discovered or corrected in time) or did lead to an undesirable outcome, ranging from increased length of hospital stay to death or permanent disability. In order to be included in this study, each incident was also required to have the following characteristics:

- *To have involved an error by a member of the anaesthesia team or a failure of the anaesthetist's equipment to function properly;*
- *To have occurred at a time when the patient was under the care of an anaesthetist;*
- *To be able to be described in clear detail by a person who either observed or was involved in the incident;*
- *To have been clearly preventable.*

It is clear that this is a somewhat complex definition with a number of qualifiers.

For the AIMS-Anaesthesia study, an incident was defined as:

"any unintended event which reduced or could have reduced the safety margin for the patient".¹⁰⁵

This removed the burden from the reporter of having to decide whether or not there had been an error, and removed any pejorative connotation implied by the use of the term "error".

Incidents deemed unpreventable were also included, both because preventability is context dependent and open to varied interpretation as well as because much useful information can be obtained about how unpreventable incidents present and how they can be managed. This decision has since been vindicated by the observation that although half of all adverse events which led to morbidity at discharge, prolonged hospital stay or death were considered completely or largely unpreventable, many could still have been detected sooner or managed better.¹⁰⁸

For system-wide AIMS, the definition was widened when it was realised that many incidents involved staff and visitors as well as patients, and personal property as well as hospital equipment, and that those affected often suffer just as much from becoming annoyed and frustrated as from a physical injury. It was therefore decided that the definition of an incident

should be "any event which could have, or did harm anyone, or which could result in a complaint".^{40,*}

Potential reporters are told that any incident can be reported, no matter how seemingly trivial, and that it need not have involved error or equipment failure, or be considered preventable. Also, any staff member can report an incident. The aim of AIMS is now evident from this definition of an incident, which is clearly and simply stated, as originally recommended by Flanagan.

2.1.1.4 Plans and specifications

Flanagan indicated that these should "focus attention on those aspects of behaviour which are believed to be crucial in formulating a functional description of the activity"⁹⁶ These are implicit in the data-collection arrangements.

Cooper et al (1978)¹⁰⁰ developed a structured interview technique using a trained interviewer who conducted all interviews. The interviewer was permitted to elicit details that were not volunteered in the interviewee's account of the incident, but was not allowed to suggest any specific type of occurrence. A category called "associated factors" was developed in response to descriptions in interviews, which grew to include forty-four possibly predisposing circumstances associated with incidents (see Table 6 for a summary). These associated factors, with some additions and deletions, became the questions asked in arrays of tick-boxes on report forms developed for subsequent incident monitoring studies.

The form (see Appendix 9) developed for the AIMS-Anaesthesia study included many of these factors in sections listing possible "factors contributing to the incident", "factors minimising the incident", and "suggested corrective strategies", as well as having most of a page available for a "free narrative" description of the incident.

The system-wide AIMS form had a whole page for the section on contributing factors (see Appendix 10), which was laid out in a manner consistent with the schemata outlined in Figures 1 and 2. The form also provided the opportunity for "free narrative" from which other insights and predisposing circumstances could be deduced. Thus, in addition to having focused attention on the "aspects of human behaviour which are believed to be crucial," attention was also focused on the system-based sources of "latent error".^{**}

Table 6 - Summary of associated factors cited by interviewees¹⁰¹

- Inadequate total experience
- Inadequate familiarity with equipment/device
- Poor communication with team, lab etc
- Haste
- Inattention/carelessness
- Fatigue
- Excessive dependency on other personnel
- Failure to perform a normal check
- Distraction
- Poor labelling of controls, drugs etc
- Supervision - other factors
- Situation precluded normal precautions
- Inadequate familiarity with technique
- Teaching activity under way
- Apprehension
- Emergency case

* This has now been widened further, in line with AS6340. An incident is now described as "any event or circumstance which could have or did harm anyone or result in a complaint, loss or damage".^j

** The latest AIMS+ form relies mainly on free narrative descriptions, but has a series of "prompts" which can be tailored to the relevant discipline, site or specialty.^p

- Training or experience – other factors
- Supervisor not present enough
- Environment or colleagues - other factors
- Visual field restricted
- Mental or physical - other factors
- Inadequate familiarity with surgical procedure
- Demanding or difficult case
- Boredom
- Nature of activity - other factors
- Insufficient preparation
- Slow procedure
- Other

2.1.1.5 Collection of the data

Flanagan (1954)⁹⁶ originally stated "the incident may be reported in an interview or written up by the observer himself". In the study by Cooper⁹⁸, incidents were recalled during a structured interview. In most subsequent studies, reporters have been encouraged to fill in a report form as soon as possible after the incident.

The AIMS-Anaesthesia form was composed of four pages and had several sections with lists of tick boxes as well as space for detailed narrative (see Appendix 9).¹⁰⁵ Forms developed for the pilot studies by the additional specialist groups ranged from very simple, consisting almost entirely of space for free narrative, to highly complex. A conscious decision was taken to encourage each group to develop their own form from first principles, so that possibly inappropriate preconceived notions in the minds of those who had been involved with the AIMS-Anaesthesia study would not intrude.²⁴

The most important feedback from all the pilot studies was that a single, simple form was needed. Nearly all hospitals already had incident reporting systems, and some hospitals had several systems in parallel. It was decided that traditional **incident reporting** in which identifying features are included, and **incident monitoring** which is both voluntary and anonymous, each had strengths and would be complementary to each other.

It was therefore decided to include the features of incident reporting and incident monitoring in a single instrument, termed the "generic AIMS form".⁴⁰ In designing these forms, care was taken to eliminate questions that were unnecessary. Experience by now had indicated that the vast majority of the relevant information required is included in the free narrative and it is far better to ask "where did it happen?" and then leave a space for an answer, than to ask the same question and provide an array of 25 tick-boxes including, inevitably, "other".

2.1.1.6 Incident reporting

This involves the reporting of harmful or potentially harmful incidents, traditionally for local management and follow-up, when all those involved are identified. This is usually done when a patient has been harmed, but may also be done when there has been the potential for harm.¹⁰⁹ In some jurisdictions and according to the American Hospitals Association, documentation is required whenever there has been a significant departure from the routine care of a patient.¹¹⁰ In some systems, breaches of safety for staff and visitors are also reportable,¹¹¹ and in others special reporting processes have been developed to address particular problems such as laboratory errors¹¹² and equipment failure.¹¹³

The process is usually orientated specifically towards documenting each particular incident with respect to the identities of those involved (including witnesses), with details of the time, place and outcome, and ensuring that the necessary steps have been taken to look after anyone who has been harmed, sometimes censuring anyone who may have erred, and initiating the process of correcting any local contributing factor (eg a slippery floor in the case of a fall). In some

areas, particularly in the past, reports have been used as a disciplinary instrument in the nursing profession. In the United States of America, such reports are often seen primarily as a means of ensuring accurate documentation of any event which may conceivably give rise to litigation.^{114,115} If a report has been brought into existence purely as documentation for potential litigation, it cannot be accessed by potential litigants in most jurisdictions. However, this generally requires that the document be used only for this purpose, because if used for any other, it may lose its legal immunity.¹¹⁶

Incident reports are usually of undeniable, obvious, witnessed or documented events such as patient injuries and medication errors. For example, in many systems falls make up about 40% of incidents reported in this way.¹¹⁷ However, falls gave rise to only 3% of "adverse events" detected in a retrospective medical record review.⁹ Thus, the vast majority of circumstances which lead to harm are not identified. Although many of these are outside the domain of nursing and would require a broader cross-section of reporters, even those of obvious interest to nurses, such as exposure to body fluids, are grossly under-reported¹¹⁸. In spite of this, hundreds of thousands of such reports are brought into existence each year in Australia and the United Kingdom, and in New York State psychiatric hospitals alone, 100,000 reports are made each year.¹¹⁹ Although some use of these reports has been made in certain institutions for bringing about improvements in areas such as falls^a and medication errors¹²⁰, no health system-wide analyses of this material have been published.

It is obviously desirable for this mass of information to be collated and classified in a standard manner so that patterns can be followed, contributing factors determined, and initiatives undertaken to reduce the frequency and impact of the problems reported. To this end the "generic" AIMS form was developed for system-wide AIMS which could be used both for incident reporting (Part A) and incident monitoring (Part B) (Appendix 10).^{40,*}

2.1.1.6.1 Setting up the system

Once interest in implementing AIMS has been confirmed by the Executive Group of a health unit or specialty, discussions commence with the nominated contact person to ensure that the use of the system has been approved by all relevant committees or groups and that all potential reporters are aware of its pending introduction. Also, a process to identify the proposed number of participating work areas and the recruitment of work area co-ordinators is devised. Once the number of participating work areas in each health unit has been agreed upon, the health unit AIMS co-ordinator notifies the APSF whose staff in turn liaise with the Australian Bureau of Statistics (ABS) for the provision of codes and coded envelopes for handling the anonymous Part B forms. The mechanisms for doing this has been described on page 33*.

2.1.1.6.2 Incident reporting (Part A)

Part A is filled in by one of those involved, or a witness, and handed to the local area manager. It is important that it is handled within the quality system, and not given to a "Risk Manager", as this would compromise the legal privilege. The reverse side of Part A has a section which documents what measures were taken locally in response to the incident (Appendix 10).^{**}

A comprehensive training manual for the utilisation of Part A software was developed and "Train the Trainer" education was conducted by staff of the APSF for the local AIMS co-ordinators. However, many units had difficulty with data entry and coding, mainly due to the

* This is now being replaced by the AIMS+ form, which avoids the repetition inherent in the Part A and Part B system, but retains the option of anonymity.

* Involvement of the ABS is no longer regarded as necessary.

** This is dealt with on page 3 of the AIMS+ form.

allocation of inadequate resources for this, and, increasingly, Part A forms are being sent to the APSF for data entry and coding. In this way a consistent quality of coding can be ensured, and benchmarking can be undertaken between health units.

2.1.1.6.3 *Incident monitoring (Part B)*

This involves the voluntary, anonymous reporting of any event which could have or did harm anyone or could lead to a complaint. The Part B form can be posted in one of the yellow post-boxes supplied by the AIMS system, or sent directly to the APSF. Yellow boxes are placed in each of the work areas.

2.1.1.6.4 *AIMS+*

Up until mid-1999, sensitivities with respect to the APSF handling patient identifiers necessitated the use of this generic instrument with Parts A and B, which proved to be rather cumbersome. However, with the APSF gaining Collaborating Unit status with the AIHW, it was thought that the process could be greatly simplified.

The development of the process was undertaken by a group representing users from several States. The following guiding principles were agreed upon.

- That it be a national system across the entire spectrum of healthcare.
- That the form be suitable for use by staff, patients and relatives, and be sufficiently flexible to cover the requirements of specialty units.
- That reporting be via a web-based system (in parallel with the paper option) that allows secure access from any site. A web-based solution puts the ownership and control of the data in the hands of the users. Coding could be centralised, but accredited coders could be located remotely.
- That there be a single form suitable for local use and for national data collection.
- That instructions for using the form be on the form itself, back-up by a CD-ROM-based interactive teaching module.
- That coding be cost-effective and of high quality, with automated on-line randomised blinded multiple coding of some reports, so that quality of coding can be monitored.
- That reports from the data take four forms:
 - routine (analogous to CeDOC)
 - theme-based (eg falls, problems with warfarin)
 - customised, by agreement with APSF
 - user-generated
- That the next generation of web-based technology will have the ability for users to use a quality query language to run their own reports, customised by the user.
- That the structure of the “national” section of the form facilitates easier and quicker reporting from data.
- That there be space for special questions to be printed which are specific to individual institutions, specialties or disciplines. In this way, the AIMS+ form could also be used as the vehicle for in-house research projects relating, for example, to the establishment of

baseline measurements of a particular phenomenon before an intervention is introduced. The same customised form could then be used later to gauge the effects of the intervention.*

2.1.2 Medical record review

2.1.2.1 The origins of medical record review

The circumstances leading to the development of the medical record review technique used in all the major studies so far are well described in the original report on the Californian litigation crisis in the mid 1970s, “The Medical Insurance Feasibility Study”.⁵

“In the middle of the 1970s California’s professional liability insurance market was in a crisis, affecting both the cost and availability of such insurance. Why this dilemma occurred has been the subject of multiple investigations in and out of government. Attempts at resolutions so far have taken 3 principal paths. The first has involved legislative efforts to modify the frequency and cost (both compensatory and administrative) of claims The second path has involved various attempts by the profession itself to create alternative insurance and co-operative mechanisms, at an initial cost substantially below what is available in the insurance market The third route involves efforts to prevent the types of disabilities which have led patients into the litigation area. Until 1974, however, the data about these disabilities were sparse and uneven. Insurance carriers had not devoted sufficient energy to develop the type of in-depth information necessary to identify patterns of disabilities, their causes and modes of prevention. Outside the insurance industry, only a few observants had personally evaluated enough evidence to appreciate trends and problems. The situation changed in 1974 when Mills ... prepared an analytic design for the identification and classification of such disabilities.”

2.1.2.2 Aims and definitions

2.1.2.2.1 Aims

The “Medical Insurance Feasibility Study” was commissioned by the Californian Medical Association and the Californian Hospital Association in order to accumulate data adequate to determine the cost feasibility of a “non-fault compensation system”, and the methodology developed by Mills was used to determine the type, frequency and severity of patient-disabilities caused by healthcare management in California, without regard to legal fault. The aims of subsequent studies have been similar, but the HMPS and UTCOS made judgements about “medical negligence”, whereas the QAHCS made judgements about preventability rather than negligence.*

2.1.2.2.2 Definitions

The Californian study looked for potentially compensable events (PCEs). The definitions for a potentially compensable event, disability, causation and healthcare management have been given on page 9. All potentially compensable events were divided into six categories. These are similar to those proposed for the new international classification of adverse events, and are discussed in Appendix 5. The subsequent studies (HMPS, QAHCS and UTCOS) all looked for adverse events (AEs) rather than PCEs, a definition for which has also been given on page 9.

* The AIMS+ form has now been introduced at some sites and should be in use at all sites by the end of the year 2001.

* A study by Davis has now been completed in New Zealand^b, a pilot study has been completed in the UK¹, and a study by Schoiler is planned in Denmark – all based on methodology similar to that used for QAHCS, UTCOS and HMPS.

2.1.2.3 Plans and specifications

The plan, therefore, was to determine the type, frequency and severity of PCEs using retrospective medical record review. The method that was developed in the original Californian study involved investigators creating a set of 20 generic (non-disease and non-procedure specific) screening criteria; some modifications were made to these “nurse review” criteria in the subsequent studies (see Appendix 11), but this first stage of medical record review has remained essentially unaltered. The original Californian study showed that the use of these screening criteria eliminated 50% of the sampled medical records whilst missing less than 1% of potentially compensable events. Similar sensitivities and specificities have been shown in the subsequent studies (HMPS,⁶⁷ QAHCS⁹ and UTCOS⁹).

In the Californian studies the remaining records were then reviewed by one or more of the investigators to determine the presence or absence of PCEs. All positive findings were then reviewed in group sessions to confirm the proof required for each PCE and to ensure proper coding.

In the HMPS and QAHCS two independent medical reviewers assessed each medical record screened positive by nurse review, and a further assessor (one of the investigators) adjudicated when there was a discrepancy. In UTCOS only one medical reviewer was used to analyse criterion positive medical records, but all records screened positive were checked by one of the investigators to ensure consistency.

It is unfortunate that slightly different definitions and/or specifications were used in these studies rendering true direct comparisons impossible. As has been described on pages 17 and 18, a specific study was carried out to try to eliminate as many of these differences as possible by treating the datasets from one of the studies (QAHCS) in the same way it would have been treated in another (UTCOS). The broad conclusions from this study have been outlined on page 18.

2.1.2.4 Collection of the data

This is logistically difficult and expensive as the medical records have to remain easily accessible to the medical records departments of the relevant hospitals in case they are needed for patient care. Nurse and medical reviewers have to travel to the hospital selected, and be there daily until the review process has been completed, and the medical review form completed (see Appendix 12). Some medical records randomly selected may be unavailable at the time the investigators are “on site” reviewing records, as they may be required for patient care or for reviewing for workers’ compensation reports, insurance reports and so on. The records have to be drawn and stored in a secure place which may be used by the reviewers. The space occupied by 500 medical records is substantial and the process of physically handling the records requires good organisation, especially if a particular record is needed for patient care and must be found at short notice.

In the Californian study^{5,121} a sample of 20,864 inpatient hospital records with discharge dates in 1974 from 23 representative hospitals was reviewed. The sample so closely matched a sample of over 750,000 patient discharges for the same year, that it was decided that the statistics developed in the study could be generalised to all patients admitted to short-term, acute care general hospitals in California in 1974.

For the HPMS⁶⁷, 30,121 randomly selected records were reviewed from 51 randomly selected acute care, non-psychiatric hospital admissions in New York State from the year 1984. Investigators in that study were also able to develop population estimates of injuries and

compared rates according to the age and sex of the patients as well as the specialties of the physicians.

For the QAHCS⁹, 14,179 admissions to 28 randomly selected hospitals in New South Wales and South Australia in 1992 were reviewed. The demographics of this sample closely matched those of Australian inpatients for that year, and thus extrapolations were also made with respect to adverse event rates for the whole of Australia.

For UTCOS⁸, 13 hospitals in Utah and 15 in Colorado were randomly selected from 71 eligible hospitals in Colorado and 41 in Utah. Fourteen thousand and seven hundred medical records were reviewed from admissions in 1992 and, again, the demographic characteristics of the sample of discharges were shown to be similar to the characteristics of all discharges in each State. This allowed extrapolations to be made for these States as a whole to pave the way for estimates of the cost of no-fault insurance in Colorado and Utah.

Although there are some differences in the definitions used in the studies and in the medical review processes, as well as in the “severity of outcome” criteria, when these were corrected for as far as was feasible, between 1.2 and 2% of the admissions in all studies were associated with an adverse event with serious consequences (temporary disability lasting greater than 6 months, permanent disability or death).^{29*}

2.1.2.5 Setting up the system

Having selected hospitals using an appropriate randomised process, it is necessary to approach the Chief Executive Officer, Chairman of the Staff Society, and if deemed necessary, Union representatives and to provide them with material outlining the reasons for the study and the methods that are proposed to be used. In most hospitals in Australia, a submission has to be made to the relevant Ethics Committee for consent for access to the medical records in order to conduct the study. In the QAHCS an assurance was given, and was required in some cases, that the link between the medical record number and the QAHCS case number would be broken before the QAHCS data were allowed to leave the hospital premises. It is hoped, in the future, when further studies are conducted using AMRAS (see below), that the additional legal protection afforded by the study being under the aegis of the AIHW, with its protective legislation, will allow a copy of a database linking the study numbers and the medical records to be retained at each hospital. In this way, case control studies can be conducted, if deemed necessary in the future, and subsets of information can be sought at a later date for further projects. For example, costing studies and identifying adverse events where there is subsequent litigation would be of interest if a no-fault insurance system was to be considered in Australia.

2.1.2.6 The Australian Medical Record Analysis System (AMRAS)

As there was little value in the information provided by reviewers classifying events into the crude classifications used for HMPS, QAHCS and UTCOS, it was decided to set up a system whereby the nursing and medical reviewers code directly into software on laptop computers using the Australian Medical Record Analysis System (AMRAS). The software for AMRAS is under development and it is hoped that a field trial will be conducted in the year 2000.** With this system, medical reviewers in conjunction with trained nurse coders would provide a brief narrative and then code any adverse events discovered directly into the GOC+ (see page 54).

* After re-analysis by an APSF team, there were strikingly similar results for QAHCS and UTCOS – both of which sampled 15,000 medical records from acute-care hospitals in 1992 (in both studies 1.7% of admissions were associated with major disability and 0.3% with death attributable to iatrogenic injury).

** This is to be addressed by ACSQHC for future work.

This is a vast improvement on the cumbersome, time-consuming, error prone process used by the QAHCS.

2.1.3 Current information sources – incident monitoring and reporting: health care units

2.1.3.1 Description

There are two sources of incident information from health care units. Information that forms part of the routine reporting of incidents within the health care unit is processed and reported on as Part A of the AIMS system. A complementary system of anonymous reporting, that is not necessarily reported to the health care unit's formal process, is processed by APSF and reported on as Part B of the AIMS system. Part A information permits health care units to monitor and follow up their routinely reported incidents while Part B reports, although anonymous, often contain more detail about the causes of the event. The new AIMS+ form, which is under development with extensive input from users, will be a simple single form which will be able to be used in ways analogous to the existing Part A and Part B components of the existing generic form.*

2.1.3.2 Coverage

Incident data is currently received from over 100 health care units. Table 7 shows the distribution of active units by State. Appendix 13 contains a list of participating Units.

Negotiations are underway for AIMS to be introduced into Western Australia, some large hospitals in NSW, and to the Australian Capital Territory.** Approaches have been made to Health Departments in the rest of Australia and to the Executives of the Health Insurance industry about the possibility of introducing the system “across the board” in both the public and private sectors.

Table 7 - Distribution of health care units participating in AIMS in mid 1999^y

State	No. of health units participating
South Australia	65
Victoria	21
Queensland	2
Northern Territory	3

* The new AIMS+ form has now been developed and is progressively being introduced. For health units using AIMS+ forms, all reports are currently coded into CeDOC at unit level, and only selected forms are sent on to the APSF (those from incidents which have a serious outcome, are particularly informative or interesting, and a random sample so that trends over time can be followed).

** It has now been agreed that AIMS will be introduced across these systems. AIMS+ has also been introduced to Waitemata, New Zealand, and negotiations are underway with many other sites in both the public and private sectors in Australia and New Zealand. The latest APSF system for classifying “things that go wrong” in healthcare has been chosen for trial by the National Patient Safety Agency in the UK for its proposed national repository of incidents, adverse events, medico-legal cases, and complaints. The trial phase will last until December 2001, with national “roll out” planned for 2002. The APSF and “Safecode” the system in use in approximately half of the 600 NHS or so Trusts intend to combine the best features of their reporting systems into a new integrated system.

2.1.3.3 Purposes

There are two main purposes of incident monitoring in health care units. The first provides a mechanism at a local level for reporting all the details of an incident, with identifiers, a mechanism for recording what was done about the problem, and what the outcome was. This provides the unit with regular information about patterns of incidents. This can be used to identify individual problems (eg a torn floor covering) as well as clusters of incidents (such as problems with a new piece of equipment) and allows the unit to actively manage risk. The second creates a pool of data across units so that clusters of incidents that are rare in each unit, but generate a considerable burden across the system can be identified and preventive strategies sought at a systemic level.

2.1.3.4 Limitations

Incident monitoring does not provide a true measure of incidence. Different levels of reporting in different settings and across time limit the usefulness of the data for comparing health care units and for identifying trends. The information produced is fundamentally qualitative in nature. Many health care units and administrators want access to stable quantitative incidence measures but have yet to come to terms with the difficulty of achieving this. The measurement of a true incidence of adverse events, in a manner that would satisfy rigorous epidemiological standards, would be a formidable and prohibitively expensive task, and has not been achieved anywhere in the world, except possibly in very circumscribed settings. Combining medical record review with incident monitoring provides a minimum estimate of the frequency of common events, but is too expensive for routine use at a hospital or health unit level.

However, mass data received so far shows remarkable stability in terms of identifying consistent patterns and themes. While true incidence measures cannot be produced, patterns of relative incidence are useful for setting priorities, enhancing interest in the problems reported and providing encouragement to reporters and those who work in the system. Incident monitoring data should be used in this way.* Monitoring of specific types of incidence that are then subjected to intervention will be required to measure the effectiveness of interventions. The new AIMS+ system will have the capacity to handle this function.

2.1.3.5 Barriers to progress

- The lack of financial incentives at a health unit level to reduce iatrogenic injury.
- A lack of long-term commitment to the provision of funds.
- Lack of skills and resources at health unit level to support the effective handling and analysis of available data
- Current coding systems are not easy to manipulate, making transformation of data to useful information more resource intensive than desirable.**
- Inertia, lack of incentives and poorly developed management processes in health units that make the path from information to action difficult.

* Currently the “winner” is regarded as the unit with the largest number of reports (per unit of activity, such as occupied-bed-day or weighted separation) with the smallest number of serious outcomes. It is planned to offer medical record-based audits of problems with serious outcomes to determine the fraction of these that is reported.

** The introduction of the new AIMS system and distance learning courses for coders should improve this situation.

- Rapid staff turnover and poor communication in and between disciplines provide a difficult environment for consistent development. *

2.1.3.6 Necessary conditions

Health care incident reporting and monitoring requires:

- Commitment from senior management as well as professional, clinical and administrative staff.
- Adequate statistical and research skills to interpret and present information correctly and cogently.
- Effective structures to deal with reports and generate risk management and prevention strategies at health unit level.
- Central identification of system factors and patterns of rare incidents, with an “early warning” system.**
- Strong and effective co-ordination of research, intervention and evaluation strategies at health unit, State and national levels.***
- Adequate funds to sustain the process.

2.1.3.7 Current status

Data flow indicates that there is strong commitment by health care providers to report incidents; over 50,000 have been reported to date.**** There is a steep learning curve for those who present the data and those who interpret it and seek to improve risk management. This has resulted in tensions and dissatisfaction with accessibility of data, the nature of reporting and difficulty in turning information into remedial actions.***** Active steps to enhance user involvement in the design and use of these processes had led to substantial improvements in these areas, with plans to facilitate the dissemination and implementation of remedial strategies.

Over 95% of health units have indicated the system is a great improvement over what was in place previously.† Several large hospitals and some small rural hospitals have allocated special resources and staff with sufficient expertise to run the whole system “in-house”, and have managed data entry, coding and reporting without encountering any significant problems.

Staff from these health units have consistently attended “User Group Meetings” and have participated actively and constructively in enhancements to the system.

* A multimedia CD-ROM for nursing staff has the potential to greatly enhance education about incident monitoring, patient safety and quality improvement. Further versions are planned for different environments (eg mental health) and for various medical specialties.

** An e-warning system was under development at the APSF. However, this is to be undertaken by ACSQHC.

*** Close communication between ACSQHC and analogous State Councils will provide a mechanism for this to be done via the ACSQHC-State liaison group (SQOF)^f and via national Taskforces such as those that have been set up for medication safety and for nosocomial infection.

**** There are enormous differences between sites with respect to “uptake” of AIMS and with respect to acting on accumulated data

***** Several sites are now using the AIMS system to good effect and have developed strategies, some of which can be disseminated to other sites, once they have been trialed.

† Assessed by a telephone survey.

Some units have used the option of data entry, coding and report generation being done centrally by the APSF, and have also been satisfied with the process.

However, there have been problems with the system when it has been run by an additional layer of management between the APSF and individual hospitals, and where hospitals have wished to or have been directed to run the system “in-house”, but insufficient resources have been allocated.*

Some early participants got off to a bad start before central coding facilities were offered and attempts were made to use the GOC as the primary coding system, before CeDOC had been developed (see pages 64 and 65). This proved to be far too complex a task to be performed at a local level, and all GOC coding is now done centrally.** The gap between expectations and performance was not well managed for these early participants.

Current work on coding systems will contribute to improvements in this area, but there is also a need for a more strategic approach to training of health care unit staff in the use of incident monitoring data and the development of pathways from information to action.

2.1.3.8 Future directions

Incident monitoring plays an important role in describing patterns of iatrogenic events at health care unit level. Data received to date show the breadth of the problem and indicate that selective event monitoring through incident registers for particular procedures, as suggested by some commentators, while easier to manage, would do little to produce the wider understanding necessary to manage the overall problem of iatrogenic injury.

Future strategies should include:

- Obtaining adequate funds from those who will realise the savings - the funders.
- Ensure that routine reporting is useful to reporters, with better feedback via newsletters and information about successful strategies that have been developed.***
- The provision of access to more complex data in electronic form to aid analysis in health units; this will require resources and the development of skills (eg comparisons via the web).***
- Redevelopment of the coding system to simplify analysis.***
- Clarification with users of realistic expectations regarding quantitative uses of the data.
- Involving users in enhancements to the system and in facilitating the dissemination and implementation of remedial strategies.***

In most health units there appears to have been an unrealistic expectation that collecting, analysing and reporting information about things which go wrong would somehow lead automatically to measures being put into place to prevent them. What has been put into place to date is the necessary first stage for risk management - finding out what is going wrong.**** Attention must now be directed to fixing the problems that have been identified.

* One local AIMS co-ordinator blamed “the AIMS system” when no results were produced; however a site visit by the APSF revealed that no reports had been entered in the 2 years the system had been available.

** However, it is planned to decentralise coding again once the GOC+ coding system and coder training courses have been trialed.

*** The new AIMS system will facilitate this, but additional resources are needed to exploit the information being gathered.

**** This must be done at local, state and national levels.

That ongoing commitment to the provision of a stable funding base for generic incident monitoring be sought, so as to allow a uniform, national incident reporting system to be established and maintained across the entire spectrum of health care in all jurisdictions.*

2.1.4 Current information sources - incident monitoring and reporting: specialities

2.1.4.1 Description

A number of specialties report incidents on an anonymous voluntary basis. Reporting is not only from hospitals in which AIMS has been established for “generic reporting”, and is not always organised on a hospital or unit basis. The systems in place for Obstetrics and Gynaecology and for General Practice are based on individuals reporting directly, not necessarily under the aegis of any particular health unit or practice. Anaesthesia, Emergency Medicine and Rehabilitation Medicine tend to have local co-ordinators based in individual departments or units.** Intensive Care has a well-developed system with local co-ordinators in over 90 units.† Several specialties, including Anaesthesia, General Practice and Obstetrics and Gynaecology allow a reporter to claim “Maintenance of Clinical Standards” points for re-accreditation with their relevant specialist College. The Royal Australasian College of Surgeons has put such a mechanism in place for when their system is reactivated.

2.1.4.2 Coverage

Data are currently or have been received from Anaesthesia, Emergency Medicine, General Practice, Intensive Care, Obstetrics and Gynaecology, Rehabilitation Units, Hyperbaric medicine and Retrieval Services. Over 7,000 reports have been received from each of Anaesthesia and Intensive Care, over 4,000 from each of Emergency Medicine and General Practice and up to 1,000, so far, from Rehabilitation Medicine, Surgery and Obstetrics and Gynaecology.

Reporting has ceased pending further funding, with the exception of Anaesthesia.** Disciplines such as Radiotherapy, Pathology, Radiology and Dentistry have set systems up and have already done considerable ground work, but progress is “on hold” pending the provision of funding.

There has been a widespread misconception that incident monitoring is suitable for “technical” activities such as Anaesthesia and Intensive Care, and that it is unsuitable for areas such as Psychiatry and Internal Medicine. Perusal of the literature and experience from the Australian pilot studies funded by the PIR indicates that this is not the case. For example, adverse drug events consume some \$500 million per annum in Australia²², and are highly relevant in the practice of both physicians and psychiatrists. Work done by the APSF has shown that poor education of patients and inadequate investigations with respect to a wide variety of conditions such as ischaemic heart disease, chronic obstructive airways disease, asthma, anaemia, GI bleeding and psychiatric problems are major causes of adverse events.²⁸ Incident monitoring is a

* This has been agreed on in principle in the UK. ACSQHC has not yet addressed this specifically although identifying the requirements for local and national systems, and for a national repository of data, is on the agenda.

** AIMS-Anaesthesia has been supported by a grant each year from the Australian Society of Anaesthetists.

† The intensive care system has been in abeyance since February 2000 when funding arrangements fell through.

technique that can, and should, be applied across the entire spectrum of healthcare. However, a concerted effort and the provision of adequate funds will be needed to bring more medical practitioners into the process.*

2.1.4.3 Purposes

Data are provided to monitor iatrogenic injury and incidents for certain reporting locations and to identify patterns that are of interest to each specialty as a whole from pooled data.

2.1.4.4 Limitations

Where funds for pilot projects were provided, a lack of timely feedback was a major problem. Contributing factors were a long lead-time in organising the process, small numbers of reports coming into the APSF rendering meaningful interpretation difficult, and a lack of resources on the part of the relevant colleges with respect to collating this information and arranging feedback. APSF too has only had limited resources to work on the task of systematic and informed analysis.

There is a strong perception that system-based problems are the responsibility of “administration”. A major paradigm shift is required for clinicians to accept that they are key players in many of these areas and that they should not only take responsibility for individual patients but should also improve the system as a whole, because system deficiencies at all levels have profound influences on the outcome for their patients.

Further limitations are that the data provided are purely descriptive and generally cannot be used for quantitative analysis. However, opportunities do arise for validation by triangulation.¹⁴⁷

2.1.4.5 Barriers to progress

- The fundamental problem has been a lack of funding, and an unwillingness for funding to be provided by practitioners themselves, who argue that as many of the problems are “system-based”, funds to address them should be provided by “the system” (with the exception of anaesthetists, see footnote on page 49).
- The evolution of a number of models for data collection, co-ordination, data analysis and reporting, some of which are inefficient and expensive.**
- Lack of resources for analysis of existing data.
- Lack of resources to liaise with specialties to develop data collection and analysis systems.
- Lack of resources to analyse and report on data already collected.

2.1.4.6 Necessary conditions

Specialty reporting requires:

- Funding and liaison to analyse existing data, disseminate the results, and devise corrective strategies.

* A “facilitated incident reporting” project was carried out in Intensive Care at the John Hunter Hospital in Newcastle⁹, with medical record review over the same period. Research funds are currently being sought from NH&MRC for a project to objectively evaluate the relative merits of a variety of techniques to promote facilitated incident reporting by hospital doctors as well as other healthcare workers.

** This can now be overcome with the introduction of specialty-based AIMS+ forms and the new classification and data management systems. However, work must be done to customise the system for each specialty.

- Adequate ongoing funding and/or incentives to support ongoing liaison, data collection and analysis.
- Expert input by practising specialists into the design of specialty-specific reporting systems.*
- Timely, systematic and relevant feedback.**
- A guarantee of anonymity and protection of the data from litigation.†
- Effective structures within colleges to oversee data collection and to respond to the results obtained from analysis. This will include responsibility for, and access to, the information by delegated representative/s of the relevant colleges.
- An effective process for managing the media so that reasonable, balanced reporting replaces the current sensational, often inaccurate stories that have been disseminated.

2.1.4.7 Current status

There was unanimous agreement at the AIMS-Speciality Review Meeting of November 1998 that specialty-based incident monitoring systems have great potential value. Limited data collection is continuing for Anaesthesia, Emergency Medicine, Rehabilitation Medicine, Obstetrics and Gynaecology and Hyperbaric Medicine. However, lack of resources to undertake in depth analysis is severely limiting the exploration of what is possible with the existing data and the formation of a basis for negotiating better designed systems; there is an urgent need to analyse and disseminate information which has already been collected.

A firm basis for the proper funding of specialty-based AIMS will have to be established before the end of 1999, or most of these systems will collapse. They would then be very difficult to resuscitate.‡

2.1.4.8 Future directions

Specialty-based incident monitoring systems have great potential value. The specialities have the ability to respond to problems identified and to directly implement preventive and corrective strategies (see pages 68-70); a particular advantage is that those working in both the public and private sectors identify strongly with their specialist colleges, and generally respect and respond to guidelines and strategies which emanate from them. This is particularly important if appropriate steps are to be taken to address new problems in rapidly evolving areas of specialist medicine. Future directions to be taken include:

- Systematic reporting of the recent experiences of practising specialists in their routine regular reviews of clinical practice. It is proposed that this may best be done by “facilitated reporting”. This involves the question “are there any incidents to be reported?” being asked as a standard agenda item at the end of ward rounds and at regular peer review (“audit” or “morbidity and mortality”) meetings. This has been shown to be

* Specialty-based modifications of the AIMS+ form can now easily be achieved using the new software.

** This will be greatly facilitated by the new analysis and reporting systems.

† The AIMS system has been submitted to the Federal Minister for Health for declaration under Section VC of the Health Insurance Act and has been “declared” for a further 5 years. Case law also provides some reassurance in this respect.^o

‡ The attributes of a national incident monitoring system have yet to be finalised by ACSQHC. This will, hopefully, occur in the near future.

effective and to be more useful than the much more expensive routine medical record review.^{123,*}

- Development of multi-skilled partnerships to undertake in-depth analysis of priority areas when resources are available. This will require clinicians to work with data analysts and epidemiologists; it is possible that specialist colleges could encourage senior trainees to take on projects in this area as part of their higher professional training. This will allow AIMS to become a system-wide tool for enhancing the quality, safety and risk management of participant colleges and their members.
- Redevelopment of data collection systems on a more practical and professional basis coincident with the development of the GOC+. A number of models have been used by the various specialities. It is intended to choose the most successful of these and use them as the basis for developing effective, efficient, practical systems for use by all specialties.
- Identification of the volumes of data required to meet the agreed purposes and a focus on increasing data quality. It may be more practical and affordable to work with a representative range of departments, practices and special interest groups rather than try to obtain blanket cover by way of encouraging every specialist to report.

RECOMMENDATION 8

That ongoing commitment to the provision of a stable funding base be sought as a matter of urgency so as to allow properly constituted specialty-based incident monitoring to be established and maintained for all health care speciality groups.

* A comparison is planned between facilitated incident monitoring at discharge, using an “aide memoire” developed by the APSF, and the “limited adverse occurrence screening” system, which has been shown to be effective (see page 54).

2.1.5 Current information sources - medical record review

2.1.5.1 Description

Medical record review provides a basis for systematically identifying iatrogenic injury through the detailed review of randomly sampled medical records; its origins and development have been outlined on pages 42-45.

2.1.5.2 Coverage

The QAHCS has been the only systematic review of adverse events in a representative sample of admissions to acute care hospitals in both the private and public systems of an entire country.*

Limited forms of medical record review are being conducted at a few sites in Australia. A system is in place at the Royal North Shore Hospital, Sydney, in which approximately 10% of medical records are flagged for review; it has been estimated that this picks up about one-quarter of the adverse events which occur in the hospital and are detectable by this method.¹²⁵

A “limited adverse occurrence screening (LAOS)” process is in place in the Wimmera Healthcare Group in Horsham, Victoria.¹²⁶ A recent comparison of the LAOS method with that used by the QAHCS showed that it detects about 5% of all adverse events and about 12% of adverse events with greater than minimal disability.^{127,†} The activities in place at both these healthcare facilities provide a useful focus for quality improvement, but neither method obtains representative samples of medical records; both use modifications of the Harvard Medical Practice Study methodology.

No ongoing review is occurring at a national or state level in Australia. The APSF has an improved, streamlined version of the QAHCS under development (the Australian Medical Record Analysis System, AMRAS), and has proposed that a nationally representative sample of medical records should be reviewed annually. The sample size required needs to be calculated on the level of precision and the number of segments to be compared. Estimates of sample size are provided in Appendix 14.

2.1.5.3 Purposes

The purpose of medical record review is to monitor iatrogenic injury systematically and independently and to produce minimum estimates of the incidence of adverse events. When key information is available about subjects and conditions among cases where no iatrogenic event has occurred, this may be used to provide control subjects for the analysis of incident monitoring data and the determination of odd ratios of risk factors.

2.1.5.4 Limitations

The quality of the medical record is variable, and it has been shown that lower estimates of adverse events are found when medical records are judged to be of poor quality.⁹ As not all adverse events are recorded in the medical record it is certain that medical record review underestimates overall incidence. It is also likely to provide biased estimates of events that are easy to exclude from a formal record. It does, however, provide a stable estimate of the minimum number of adverse events of a type that are undeniable and are therefore likely to be

* Since this report was submitted, a pilot study has been conducted in the UK¹, a study has been completed in New Zealand^h, one is planned in Denmark, and one is planned in Canada.

† The LAOS methodology is now being applied much more widely in the state of Victoria, and the APSF has been approached about classifying the events discovered.

systematically recorded in the medical record (eg a pneumothorax from placement of a central venous catheter which requires an under-water seal drain). At present such reviews are the only objective source of broad-spectrum estimates of incidence.[†]

Important questions have been raised about the inter-rater reliability of reviewers and the effect of vague definitions of the types of adverse events that are to be included.⁸

More work is needed on definitions of events, the development of systematic training of reviewers, and mechanisms for monitoring the performance of reviewers. It is likely that adverse events of various types will be able to be placed into groups or strata based on the kappa scores of reviewers for particular types of events.

Medical record reviews are also costly to conduct. Quality control of the completeness of forms and adherence to definitions in the QAHCS by reviewers was variable; better systems are being developed by AMRAS.

2.1.5.5 Barriers to progress

The major barriers to progress are:

- The provision of adequate resources to develop and maintain the system.
- Concern by epidemiologists about the level of precision achieved.
- Lack of investment in the development of strategies for improving the medical record and event identification.

2.1.5.6 Necessary conditions

Medical record review systems require:

- Clear and unambiguous definitions of categories of event to be included.
- Tight control over the quality of reviewers' work.
- Triangulation with other sources to determine the validity and reliability of incidence estimates.
- Long term investment in the development and validation of methods.

2.1.5.7 Current status

Early proposals have been developed by the APSF to develop and implement an ongoing medical record review system (AMRAS). Recent recommendations by the Expert Group have pointed toward a less comprehensive and more clinically focussed strategy for managing iatrogenic injury. However, the risk is that this will produce "more of the same" and not answer some of the important questions. There is an opportunity to complete the development of a high quality and properly evaluated medical record review system, but funding for a pilot

[†] There has been much "wishful thinking" that routine collection ICD-10 codes at discharge and of coded information from death certificates or coronial data will provide useful information about adverse events. The reality is that only a small biased fraction of adverse events is captured, as the main intention of these collections is to capture information about underlying conditions. Even if all events were captured by these means the classification systems used yield information in a form of no use at all to anyone wishing to devise preventive or corrective strategies[†]. At best, this would allow records with certain codes to be drawn and reviewed individually.

trial and evaluation will be necessary; the necessary infrastructure, software development and coding software can be put in place at short notice.*

2.1.5.8 Future directions

It has been recommended that ACSQHC develop a replicable methodology to provide the basis for national snapshot studies to better identify and analyse adverse events. This methodology may also be used at the local level to measure institutional performance.

Close agreement between America (UTCOS) and Australia (QAHCS) studies with respect to the rate and nature of serious adverse events suggests that, taken as a whole, the techniques used to date are quite robust (see pages 42-44). The large discrepancy overall between the QAHCS and UTCOS was due to a difference in threshold for “calling” adverse events, and also, to some extent, to differences in what was considered an adverse event.^{27,28}

Much has been learnt, from the work to date, about the various types of adverse event, and how they may be defined. It is believed that a robust set of adverse events can be identified which, taken together, can form a “basket” of events which could constitute a reliable composite indicator. The task of moving towards a valid reliable benchmark is not to be underestimated; healthcare is a complex system and it is inevitable that monitoring the problem of iatrogenic injury will not be simple. Nevertheless, on the indicators to date, it seems entirely feasible if a process of progressive refinement of the technique is embarked upon.

It has been suggested that efforts should be concentrated on monitoring sentinel events.¹²⁴ However, this addresses only a tiny fraction of the things that go wrong in health care.

Sentinel event monitoring in the USA detects less than 500 (1%) of the estimated annual 500,000 adverse events (see IOM report, footnote page 5).

To concentrate on a narrow range of indicators and sentinel events, while superficially attractive, will not adequately address the task. Furthermore, a focus on registers and detailed studies of iatrogenic injury related to particular classes of procedure will not provide an adequate basis for determining the incidence and costs of the vast majority of “low frequency” adverse events, or for setting priorities for management and prevention strategies.

Important opportunities for systems-based approaches to prevention will be missed if such an approach is not supported by a wider estimate of the overall incidence and distribution of iatrogenic injury. Case registers and medical record review, used together, will provide an opportunity for cross-validation. Case registers may also be useful for in depth research of a few clear cut problems.

It is possible to develop a system that will provide useful information. There are a number of valid reasons why no attempt should be made to produce healthcare unit level data, but estimates of trends at State level and comparisons of several strata at State vs State, Country vs Metropolitan and perhaps for Public vs Private acute care hospitals should be possible (see Appendix 14). The use of composite indicators of iatrogenic injury (structured indicators analogous in concept to the basket of goods used for the CPI) could be used to provide reliable estimates of comparative incidence even if measures of true incidence of clinically useful sets of events remain too expensive or technically difficult to obtain.

* It has been recommended that ACSQHC develop a replicable methodology to provide the basis for national snapshot studies to better identify and analyse adverse events. This methodology may also be used at the local level to measure institutional performance.

Expertise in stratified sampling techniques and the development of indicators and indices similar to those from fields outside of health will be needed to progress the development of a robust, workable system. With this in mind **future directions are:**

- Further development and evaluation of a medical record review system (AMRAS) to provide a broad description of the scope of iatrogenic injury suitable for use in Australia and other countries.
- Improvement of definitions and methods of case identification including the prospective use of medical record quality control tools and, possibly, systematic sign off of occurrence or non occurrence of major classes of iatrogenic events on discharge.
- Routine reporting at composite indicator level of major trends in the incidence and cost of iatrogenic injury.

RECOMMENDATION 9

That a systematic process be embarked upon for trialing and progressively refining the Australian Medical Record Analysis System as the basis of a system suitable for national and international use, and for applying it annually to a randomised sample of medical records in each State and Territory.*

2.1.6 Current information sources - other sources of information

2.1.6.1 Mortality

The Australian Bureau of Statistics routinely reports on causes of death in Australia.⁷⁴ These data are extracted from coroners' records in the case of external causes and from death certificates processed by the State Registrars of Death for other cases. The external cause data are coded according to the International Classification of Disease (ICD) External Causes classification. Although data reported so far are based on the underlying cause of death, from 1997 coding for multiple causes of death is being developed.

The levels of death by medical misadventure reported are very low, less than 100 cases per year. This is due to the requirement that the cause be the principal cause of death and that the coroner must be certain of the causal link between the medical procedure or agent and the death.*

* Further activity in this area is on the agenda of ACSQHC, but no progress has been made at this stage. The following is a statement from the Executive Summary of a "Technical Options paper for national approach to the use of data for safer health care" which was submitted to and endorsed by the Australian Ministers of Health in July 2001: "Most existing data collections have not been designed to collect data about incidents and adverse events in ways that are useful for improving safety and very few give any information about the factors that contribute to the occurrence of these events. There is no single source of statistics that provides a reliable measure of the frequency or nature of adverse events, nor is there a repository or regular reporting system for these data in Australia or other developed countries."

* An ACSQHC report has stated "The Australian Institute of Health and Welfare (AIHW) has analysed deaths from adverse events for deaths registered in 1998 and 1998 (Hargreaves 2001). The analysis found that, for the two years combined, there were 177 deaths (0.07% of deaths from all causes) where an adverse event was reported as an underlying cause of death, and 5,356 deaths (0.21% of deaths from all causes) where an adverse event was reported as a contributory cause".¹

Over the past three years, coroners across Australia have decided to contribute to a National Coronial Information System. This electronic system will contain much more detail than has been accessible previously and will permit a more detailed understanding of the association between iatrogenic disease and coronially certified cases of death. Unfortunately, there are different requirements in different States regarding the need to report death proximate to medical or surgical treatment.[‡] Nevertheless, comparisons of hospitalisation data with the ABS mortality data, with coronial data from various jurisdictions, and with data from medical record review, will provide much greater insight into this important area. The AIHW holds a “National Death Index”, identifying everyone who has died in Australia over the last 15 years or so, which is linkable, with appropriate ethical approval, to “cause of death” information. This could be used to validate data in comparative studies of data about deaths from the sources listed above.

2.1.6.2 Hospital separations

The Australian Institute of Health and Welfare routinely draws together State collections of data on hospital separations.^{67,68} These data are coded according to the ICD external causes categories for external causes and, to varying extents in different States, for multiple disease and injury conditions. Procedures and Diagnosis Related Groups (DRGs) are also recorded.

The external causes relating to medical misadventure and drugs in therapeutic use have formed the basis of the AIHW estimate of costs of iatrogenic injury. These data are collected within a well-developed infrastructure for classification and collection of the data. However, the coverage of events by the ICD and that by the QAHCS and AIMS systems is quite different. Hospital separations estimates should currently be treated as covering a subset of the problem; also the data do not separately attribute bed days to medical misadventure events, so data on bed days need to be treated as representing the whole range of diagnoses and treatments rather than the marginal impact of the misadventure.*

Nevertheless, as the entire medical record is reviewed for coding, the potential does exist for pursuing use of the existing infrastructure to progressively improve the identification and coding of iatrogenic injuries, at a marginal increase in cost. A “core” set of indicators could be developed for specific problems which are readily identifiable. Also communication between discharging doctors or nurses and coders could further improve the identification and recording of iatrogenic injury in the future. A collaborative study to trial this, involving the AIHW, the APSF and the National Centre for Classification in Health has been proposed.**

[‡] The following is a statement from an ACSQHC report. “Some data of relevance are available from a study conducted by the Victorian Institute of Forensic Medicine. The study looked at 1,053 hospital deaths in 1999 that were reported to the Coroner. Of the reported cases, 338 were further investigated on the basis that there was a high probability that an adverse event had occurred. Of the cases investigated, 96 were considered to have involved system-related adverse events. Extrapolating these data nationally suggests that there may be about 2,000 Coroners’ cases per year worth closer investigation, and that about 700 may identify health care-related factors that may have contributed to the death”.^f

* The following are statements from an ACSQHC report^f. “In 1997-98, there were 264,347 separations where an adverse event was reported, representing 4.75% of separations. Of the separations with an external cause specific to an adverse event, misadventures were reported for 4,877, complications for 190,739 an adverse drug effects for 53,388”. “Hospital separations data in their current form cannot be used to estimate the number of patient days or levels of disability attributable to the injuries, nor the proportion of injuries that may be amenable to preventive measures. Nor can the data at present reliably distinguish those events occurring during the episode of care from those present on admission”.

** The following is a statement from ACSQHC. “Council will commission work to improve the quality of hospital inpatient data as an information source to monitor adverse events, including examining how the codes in the International Classification of Diseases (ICD) might be amended to better distinguish between adverse events and problems arising from the underlying disease or injury.”^f

2.1.6.3 The Australian Drug Reactions Advisory Committee (ADRAC)

ADRAC collects “suspicions of adverse drug reactions (ADRs)” (reactions when drugs are correctly prescribed and administered) and advises the Australian Drug Evaluation Committee on all matters related to ADRs. It was established in 1970, currently holds over 100,000 reports and now receives about 1,000 reports per month. ADRs make up about 5% of medication incident reports. ADRs which have been reported on AIMS forms are forwarded directly to ADRAC, or to those charged with this responsibility.

2.1.6.4 MBS/PBS linkage information

The Commonwealth Government and State Governments are in the process of linking MBS/PBS records with State-level hospital separation data. This linkage will allow the MBS/PBS data to be considered in the context of the ICD and ANDRG coding that accompanies hospital separation data. These data have the potential to provide a comprehensive picture of the overall effect of iatrogenic injury to the patient in terms of additional medications and the number of GP visits post-hospital discharge.

2.1.6.5 Post-discharge telephone interviews

Many large hospitals either use or are assessing the use of computer assisted telephone interview systems. This could be linked to APAC proposals for consumer-based incident reporting (see Appendix) to follow up patients after discharge, for both quality control reasons, and for data collection.

RECOMMENDATION 10

That existing mechanisms be enhanced for linking morbidity and mortality data and that mechanisms for linking with MBS and PBS data be established, preferably by the introduction of universal unique patient identifiers.

2.1.6.6 Medico-legal claims files

At least 300,000 hospital admissions are associated with potentially preventable adverse events each year in Australia.⁹⁰ Medico-legal files for actual or potential claims are opened in about 2% of these cases (ie about 6,000 files per year).⁶⁵ Of these, about one-quarter of such files proceed to some sort of settlement or to litigation. This subset of problems, which has a profile quite different to that of all adverse events, (see page 19) costs the system over \$400,000,000 per year (see page 24). Such information has been used successfully in the USA to improve patient safety.¹²⁸⁻¹³⁸ The APSF has developed the necessary coding systems to accommodate the characteristics of these medico-legal files, and it is proposed that it would be worthwhile to capture this information each year.

Also, work is well advanced on an “aide-memoire”, using a simple 3-level classification, to provide a bridge between clinicians at the time of discharge and researchers and/or coders.

The mechanism proposed is that a trained coder would, under close supervision if necessary, code de-identified information into the GOC on the premises on which the files are normally kept. A copy of what has been coded would then be kept by the organisation which owns the files, so that it can be checked that no unauthorised or sensitive information leaves the premises. This information would be of value to the medical indemnity organisations as well as to consumers and the medical profession.*

RECOMMENDATION 11

That means be sought to classify the information in all medico-legal files into a national database so that it can be characterised and comparison with incidents and adverse events from other sources may be made.

2.1.6.7 Complaints

Many large hospitals have “patient advisers” who handle enquiries and complaints (a complaint in this context constitutes a written complaint which identifies the issues and parties involved). The number of complaints and enquiries at the hospital level usually exceed the number of medico-legal claims files opened by six to eight-fold,⁶⁵ but the number of complaints lodged formally with the various Health Services Commissioners may be estimated at less than 10,000 per annum Australia-wide (by extrapolation from the Victorian experience). It is proposed that it would be valuable for these also to be coded into a national database so that the profile may be compared with that of medico-legal claims files opened, coronial recommendations, and potentially preventable adverse events. In this way, patterns could be identified to assist in developing strategies to deal with common problems about which complaints arise, and to inform the complaints management process. A National Health Complaints Information

* Planning for such a study is well advanced in Australia, and collaborative studies in the USA and the UK are under active consideration.

project has been initiated, and could provide the impetus for this to occur.* Appropriate codes designed to meet the needs of “complaints practitioners” have been included in the GOC+.

RECOMMENDATION 12

That the National Health Complaints Information project be further supported so that complaints data can be coded into a national database so that it can be characterised and comparisons with incidents and adverse events from other sources can be made.

2.1.6.8 Case reports and “letters to the editor”

There is a wealth of information about “things that go wrong” in case reports and “letters to the editor” in refereed medical journals. That they are accepted for publication in this format is a reflection of the fact that it is unlikely that the authors would be able to gain access to more than a few such instances over many years. At the moment, the only way of accessing this wealth of information is via searching for each individual report or letter. It is proposed that information from these sources be systematically coded into a national database, so that this information is available to complement the information available from the other sources of information listed above.

2.1.7 An overview of progress

2.1.7.1 Current status

Australia still has only a tentative understanding of iatrogenic injury. Current information sources are of variable quality and, to date, insufficient resources have been available to extract all meaningful information they contain. Coherent strategic directions have not been settled and sufficient resources have not been earmarked for a co-ordinated approach to this complex area.**

There needs to be commitment to a nationally co-ordinated approach to iatrogenic injury; it is clear that resources are currently being wasted on a myriad of small, often poorly designed projects, most of which are being conducted at health unit level. The potential exists for an organisation such as the APSF to produce guidelines for data collection and to provide support for data analysis. The recently announced Australian Council for Safety and Quality in Health Care will provide the basis for a coalition of interests of various individuals and organisations which have expertise in this area to assist in ensuring a more consistent approach.

None of the existing models of research funding and administration are appropriate in this area, which requires large scale applied research. Work arising from further study of the QAHCS has started to identify high-priority problems⁹⁹ and a start has been made with the formation of national working parties arising from meetings and workshops in these areas (see Appendices 7 and 8). The new Council could consolidate and extend this work, which has been hampered by a lack of resources. The groups have determined that rigorous multi-centre, multi-disciplinary

* Funding for this initiative has not been renewed.

** In July 2000, the Commonwealth and State Ministers for Health in Australia committed \$50 million to patient safety and quality over 5 years. This can be supplemented at State level from the \$100 million per annum earmarked in the various Commonwealth-State Healthcare Agreements over the next 5 years. Recommendations have been made, but resources have not been earmarked.^f

projects are required to systematically address the high priority problems which have been identified. Essential outcomes of these projects must be the development of tools which have been shown to be risk- and cost-effective in the Australian context, and mechanisms must be put into place to ensure their effective implementation (for example, nationally endorsed mechanisms should be required to be in place as a condition for accreditation of health facilities) (see pages 90 and 91).

Systematically working through high priority problems is in accordance with the Berwick aphorism “take one hill at a time”.⁸⁹ To “take a hill” it is necessary to invest the necessary resources to take it efficiently and comprehensively, and then to ensure that it remains secure. Some of these projects will require many hundreds of thousands of dollars. However, rough calculations reveal that in this area adequate investments are likely to produce far greater yields than areas in which investments are currently well accepted (eg road safety, air safety, occupational health).

2.1.7.2 Important barriers

- Lack of access to sufficient specifically earmarked resources.
- Inadequate resources, to date, for the co-ordination and development of appropriately skilled teams to develop the necessary remedial strategies.
- Inadequate resources, to date, for co-ordinating and trialing remedial strategies in areas of high priority and for determining their risk- and cost-effectiveness.
- Inadequate resources, to date, for managing the implementation of interventions at a systemic level.

2.1.7.3 Possibilities for future development

Possibilities for the future are discussed in more detail below and in Part Three. Here, it is important to note the importance of having adequate data to drive the processes of prevention and intervention. Development of appropriate data and management systems will require considerable investment and should try to involve and inform all those with an interest and expertise in this area.*

2.1.8 Classifying and analysing information

A number of classification systems have been used to describe some aspects of some of the “things that go wrong” in healthcare. However, this was not the primary intention of the classification systems in existence until 1995; although specific codes have been developed to describe aspects of iatrogenic injury, the structures of the classification systems were not primarily to accommodate these codes. Hence they are cumbersome to use with respect to iatrogenic injury. For this reason, it was decided to develop a classification specifically for things which go wrong in healthcare. Some of the pre-existing systems are described below, and then the recently developed systems.

2.1.8.1 International classification of diseases

The International Classification of Disease (ICD) classifies information relevant to iatrogenic injury in two ways.

* A start has been made by ACSQHC with the formation of national taskforces for medication safety and nosocomial infection.^c

The first is a classification of an external cause. The level of detail varies from ICD-9, which was used for coding medical records up until June 1997 in some States of Australia, and up to June 1998 in others, and ICD-10, which is now used throughout Australia.¹⁴¹ Three types of codes, medical misadventure, complications and problems arising from drugs and drug administration form the framework for identifying iatrogenic events. These provide somewhat narrow definitions of the problem. From the year 2000, the “place of occurrence” data has included “health service area” as a specific category. Also, in the future, the “activity while injured” data may be improved to include a specific category such as “receiving healthcare”.

The second is a clinical coding chapter that codes the physical effects of injuries. Thus, by providing more detail in some categories and by combining the two classifications it is possible to get a rudimentary view of iatrogenic injury.

However, the ICD coding and classification systems provide neither adequate coverage of events nor adequate descriptions of the events that are coded.* Moreover, coders are trained to adhere to a standard which specifies that only information which is explicitly described can be coded. Most adverse events are not explicitly described as such, and therefore cannot be coded even if there is an appropriate code. Coders are therefore constrained by what is written in the medical record, and how events are described. Thus data coded using ICD provide at present only a crude estimate of incidence of only some classes of iatrogenic injury. For example, direct validation of adverse drug events by medical record review, when compared with codes previously assigned by the usual coders, show that only 11-31% of these events were coded using the appropriate adverse event codes.¹⁴²

2.1.8.2 Other widely used classification systems

A number of other coding systems provide useful classifications of indirectly relevant information. The International Classification of Procedures, which has been superseded in Australia by MBS-E (Medical Benefits Schedule - Extended), a multi-axial coding system, provides a systematic way of recording types of procedure^b and is a part of ICD-AM (ICD-Australian Modification). The Diagnosis Related Group (DRG) classification provides cost-weighting for aggregations of types of diagnosis (some sub-classified by age, presence or an absence of complications and/or co-morbidities and/or types of procedures) and may be used for calculating incidence adjusted exposure for iatrogenic injury.

Other classifications such as SNOMED¹⁴³, used by pathologists, and Read codes¹⁴⁴, both multi-axial classification systems, also offer possibilities for structured coding of relevant information. The principal use of these systems in the context of iatrogenic injury is for aggregating data and presenting exposure-adjusted incidence measures.*

2.1.8.3 Keywords and free text searches

Many studies (included AIMS) originally assigned key words to incidents and entered these into a database for subsequent retrieval. Also once “free narrative” has been entered into a database

* The following are statements in an ACSQHC report^f. “In 1997-98, there were 264,347 separations where an adverse event was reported, representing 4.75% of separations. Of the separations with an external cause specific to an adverse event, misadventures were reported for 4,877, complications for 190,739 an adverse drug effects for 53,388”. “Hospital separations data in their current form cannot be used to estimate the number of patient days or levels of disability attributable to the injuries, nor the proportion of injuries that may be amenable to preventive measures. Nor can the data at present reliably distinguish those events occurring during the episode of care from those present on admission”.

* SNOMED has absorbed Read codes and will be adopted by the UK in 2003. Discussions are to be held in October 2001 about liaison between SNOMED and the APSF about the possible role of GOC codes in SNOMED.

various proprietary software packages, such as NUDIST¹⁴⁵, allow content analysis to be used. However, these methods are somewhat complex and are very time consuming to use.

2.1.8.4 Australian developed coding systems

2.1.8.4.1 The Generic Occurrence Classification (GOC)

The GOC is a classification developed by the APSF specifically for “things that go wrong” in health care based, essentially, on keywords (natural categories) arranged in a hierarchical structure according to “natural mapping” principles.¹⁴⁶

It comprises a framework into which any relevant event or occurrence may be classified, and is designed to elicit the salient features of an event, place the event in context and record the important contributing factors, be they system or human-based. It may be used in any environment (eg manufacturing, running a taxi company, aviation) but is used here, in the context of the health care system, to provide a structured record of any event which could have or did harm anyone or which could or did result in a complaint, loss or damage.

The GOC is an infinitely expandable structured classification, restricted only by practical processing limits. It is essentially “data-driven” or empirically based, ie. events which occur commonly appear at the most superficial levels of the structure. However, the sets of choices relating to a particular topic, although empirically driven, also have a reasonably intuitively obvious structure. For example, choices relating to operator error, equipment failure, or outcome are grouped together.

The GOC can be used to classify adverse events identified by incident reporting, medical record review, complaints, morbidity and mortality studies, coronial enquiries and both current and “closed” medico-legal files. Information from any source can be classified and tracked using a relational database design. For example, although all incidents reported to system-wide AIMS are classified using the GOC, those from each specialty or interest group can be separately analysed and controlled. Care has been taken to ensure that the classification for any specialty or from any source is consistent with the rest of the GOC so that if a problem, for example, with an infusion device is identified by one specialty, the whole database can be searched for similar problems.

The GOC is based on the concept of classifying each incident into one or more natural categories, with each incident being linked to its contributing factors, demographics, preventative factors and factors minimising outcome.* The current version of the GOC, which was released in July 1997, was built by iteratively coding 800 adverse events from the QAHCS and 2,000 incidents from Australian hospitals and is comprised of some 12,500 natural categories.

An expanded version of the GOC (GOC+) is to be trialed in 2001; this will have been built from over 50,000 incidents, adverse events, medico-legal files, complaints and coronial recommendations and from information from over 40 specialty and sub-specialty groups.

The primary purpose of the original GOC was to provide a basis for qualitative analysis. It has now become evident that many users need to be able to produce a quantitative understanding of their data. GOC+, therefore, has a completely different structure. It contains additional descriptors to meet the extended needs identified following the coding of many thousands of incidents from a wide range of settings. In addition a different format is being introduced to increase the ability to systematically code complex cases without making the size of the coding

* The “reference model” for the new APSF system may be inspected.^j

system unwieldy. Attention is being paid to building in the ability to report quantitatively without resorting to complex query structures.

The original GOC and its development is described in a manuscript which has been published in the *Journal of Quality in Clinical Practice*.¹⁴⁶ It is intended to improve linkages between GOC+, systems such as SNOMED/Read (SNOMED and Read codes are merging), and the US National Library of Medicine's Unified Medical Language System (UMLS).

2.1.8.4.2 *The Customised Occurrence Classification (CeDOC)*

CeDOC was developed because the GOC proved to be too complex to use at health unit level. Also, because the GOC is so detailed, each classification "cell" contained too few events or features of events to allow meaningful trends or comparisons to be displayed with small datasets. The CeDOC coding system is simple, and focuses on arranging reported data into straightforward aggregated classes (eg medication error, documentation problem, outcome). It is based on 262 tick-boxes arranged in 12 sets, chosen because they were shown to describe the most common adverse events. When an event falls into the "other" category a brief "free text" description may be given. CeDOC produces reports which provide both useful trends of common events and descriptions of those which do not fit into the 262 categories. It does not have the potential of the GOC to systematically identify causal patterns. Its use therefore is primarily for routine reporting of events at the health care unit or department level.

The CeDOC provides standard reporting mechanisms that allow health care units to compare themselves with like institutions, and to compare their profile of incidents with that of the health care system as a whole.**

Standardised reports based on CeDOC may be customised for different types of health care units (eg acute care hospital, domiciliary care, and mental health). Reports are currently adjusted for exposure by using rates per 1000 bed days. Most importantly, feedback is provided on a regular basis in a comprehensible form to those who do the reporting. The CeDOC categories and standard reporting formats were evolved after extensive consultation between the relevant stakeholders and the APSF.†

2.1.8.5 **Qualitative analysis**

Initially a qualitative approach to analysis of data was followed, relying on detailed descriptions and the coexistence of patterns of factors with types of iatrogenic events, to isolate causal factors and facilitate the identification of possible interventions. When opportunities for triangulation with the results of large prospective studies arose a remarkable concordance between quantitative and qualitative findings could be shown.¹⁴⁷

Qualitative methods have also proven useful in related areas such as occupational health and safety and transport safety research. However, this type of analysis does not fall within the traditional training and focus of many health researchers and is viewed with considerable suspicion by those who have only had quantitative, empirical training. The GOC was designed to facilitate qualitative analysis, but in its early form has proven to be resource hungry when used for quantitative analysis. Current re-development of the GOC is designed to solve this problem and permit the extraction of related case sets, factors and agents in a way that will be more useful in formal case study and content analyses.

** CeDOC is being superseded by "Basic Hospital Incident Categories" which will have these attributes, but will also accommodate contextual information, contributing factors and outcomes.

† CeDOC reports may now be downloaded from the GOC+, as, potentially, can reports from any other system, such as "Safecode" in the UK. This is seen as an interim arrangement to provide a "bridge" between trend reports from legacy systems and the more detailed reports possible from the new APSF system.

2.1.8.6 Quantitative analysis

Quantitative analysis is the core paradigm of health research. The desire to move to quantitative approaches to iatrogenic injury is therefore very strong. It is difficult to gain credibility and resource priority in an era of evidence based medicine if sound empirical analyses are not available. The push by health authorities for benchmarking processes has been particularly strong. It is clear that the technical difficulties in obtaining reliable incidence measures and time stable rate data using appropriate denominators are considerable. The expectations of decision makers are often out of line with what is possible and the limitations of the methods used attract unfair criticism due to a lack of understanding of the state of both the data collection and statistical arts available. A few key issues need to be individually discussed.

2.1.8.6.1 Measuring incidence

Incidence measures are difficult because of the nature of the problem. The following factors make incidence measurement difficult.

- Lack of agreement about what constitutes an adverse event and how agreed classes of events should be defined.
- Incidents and adverse events can often not be independently observed or detected, as the majority of types of incidents occur only rarely.
- Information in medical records does not always provide all of the necessary information to determine whether an event is iatrogenic or part of the natural history of patients' pre-existing or current conditions.
- A "blame" culture provides an incentive to hide the occurrence and nature of some events, and provides a bias toward undercounting.
- What is reported in voluntary systems is influenced strongly by the culture of the discipline, profession and workplace.

Evidence from other areas underlines the problems of trying to estimate incidence by relying on those who work in the healthcare system to report or record the relevant occurrences. For example, as few as 10% of all cases of certain communicable diseases are reported, even when reporting is required by law and their occurrence is no-one's "fault".¹⁴⁸ Moreover, comparing data from QAHCS and AIMS suggests that even in-hospital falls resulting in fractures are only formally registered on an incident form in less than 1 in 4 cases. This tendency to keep adverse events away from official scrutiny calls into question the reliability of relying on healthcare workers reporting all iatrogenic events for entry into registers.

Nevertheless, not having any idea of the incidence of such important and costly problems, at least on a relative basis, is unacceptable. At the very minimum estimates of the incidence of patient injury should be provided at an aggregated level, using a basket of events which are clearly defined and which have a high likelihood of being recorded in the medical record. By triangulating estimates based on different methods and approaches, it will be possible to provide much more precise estimates of incidence than are currently available.

2.1.9 An integrated approach - exploiting strengths of both qualitative and quantitative approaches

The problem of iatrogenic injury is too large and costly to fail to address because of concerns with respect to the problem of ensuring that the demands of a doctrinaire quantitative approach

are met in a domain characterised by large numbers of uncontrolled difficult-to-define variables. A wealth of useful information about what is going wrong and what factors are important in the genesis of these problems may be obtained by collating information from all available sources. Data from medical record review and from incident monitoring may be used in a complementary way - each approach has weaknesses but each also has strengths which may be exploited. Likewise quantitative and qualitative approaches may be used in a complementary manner.

2.1.9.1 Exposure adjusted measurement and benchmarking

Administrators in particular want exposure-adjusted measures of incidents. The most commonly used adjustment is the calculation of rates per 1,000 occupied bed days, although rates per “weighted separation” is an alternative. This is often done to allow comparison of one health unit with another. While this method is broadly accepted, it is fraught with difficulties. There has been a rapid trend towards investigations and processes being done on an outpatient basis, weakening the association between occupied bed bodies and activity. The distribution of pre-morbid condition, of age and the type of procedures used in health care units all need to be taken into account before comparisons are made. At present many of these denominator measures are not available. The desire to benchmark hospitals therefore, while laudable, does not take into account the reality of the unavailability of time-stable incidence data, properly constituted denominator data and standardisation techniques.

It may well be that the importance of making comparisons has been over-estimated. The stability of the overall patterns of iatrogenic injury seen in incident monitoring data and the QAHCS and UTCOS strongly suggests the problems are fundamentally system based rather than institution based. System wide solutions are therefore likely to be the basis of the most important changes in incidence and severity rather than the separate improvement of strategies in each health care setting. The desire to compare individual units comes from an accounting mentality which may well not be very relevant for this issue. An analogy would be to concentrate on comparing traffic accidents in different Council areas rather than on identifying problems and introducing systemic remedial strategies such as wearing seat belts, random breath testing and laser “speed guns”.

RECOMMENDATION 13

That all “things that go wrong” identified by incident monitoring, medical record review, medico-legal investigations, coronial enquiries, complaints databases, letters to the editor and case reports from selected refereed journals, be classified using the GOC+ and stored in a national database.

2.2 Identifying and responding to problems

It has been a longstanding practice for healthcare professionals to observe and document things which go wrong in the delivery of healthcare. However, the vast majority of problems have been identified and considered on a case-by-case basis and have been dealt with informally or at a local audit, peer review or management meeting. From time-to-time this has resulted in a change in practice at a departmental or hospital level, but, with a few exceptions, there has been no systemic attempts to collect information on a large scale or to respond to problems at a State or national level. Adverse drug reactions and equipment failure have been exceptions where there have been longstanding mechanisms for collecting information at a national level,

and for taking the necessary steps when these are required.^{149,150} However, it is now evident that adverse drug reactions (problems arising when drugs are used correctly) comprise less than 5% of adverse drug events¹⁵¹ and that equipment failures make up only less than 10% of problems arising from the use of equipment,⁵⁶ with the vast bulk of things that go wrong being made up of system or human failure in the *use* of drugs and equipment. It is only recently that attempts have been made to collect information at a national level, identify and prioritise problems, and try to come up with co-ordinated responses to these problems. Some of the reasons for the late emergence of these systematic efforts will be discussed below, before outlining progress that has been made in identifying and responding to problems.

2.2.1 Background to incident monitoring in Australia

Although the origins and status of incident monitoring have been reviewed on pages 34-42, further background information is required to provide insight as to why incident monitoring has, to date, been more successful in some areas than in others.

Incident monitoring at a national level started in Australia with AIMS-Anaesthesia in 1988 (see pages 36-42). Within 5 years of its inception some 40 manuscripts had resulted, there had been major changes in anaesthetic practice throughout Australia and within neighbouring countries, and International Standards for Anaesthesia Patient Safety had been profoundly influenced by the AIMS results.¹⁵²⁻¹⁵⁶ These standards were endorsed by the World Federation of Societies of Anaesthesiologists at their quadrennial World Congress in 1992, and disseminated to the relevant authorities and organisations in some one hundred member countries; the President of the APSF (WBR) was the Chairman of the Safety and Quality of Practice Committee of this World Federation (1992-2000).

The fact that anaesthetists had taken the necessary steps to establish an ongoing mechanism for critically examining their practice, and that this had contributed to major changes in the practice and safety of anaesthesia, was apparent to many outside the discipline. When the QAHCS results were released by the then Minister for Health, Carmen Lawrence, anaesthesia was the only discipline to receive favourable commentary.¹⁵⁷ Although half of all the QAHCS adverse events were associated with surgery, anaesthesia-related events made up only 2% of all the events, and these anaesthesia-related events were associated with less harm and fewer extra days in hospital.¹⁵⁸

This led to widespread expectations that the introduction of incident monitoring to other disciplines would lead to substantial changes in practice within a similar timeframe.

However, it is now 5 years since incident monitoring studies in six other specialities and 6 teaching hospitals were funded by the PIR and 5 years since the release of the QAHCS findings and, so far, this has not come to pass. Although there was unanimous agreement about the applicability and potential of incident monitoring in other disciplines and across healthcare at the AIMS review meeting at the end of 1998, AIMS has not yet had the same impact in these areas as it had in anaesthesia.

With the wisdom of hindsight, it seems that the rapid transformation of AIMS data to useful information, and of this information to the implementation of changes in anaesthetic practice, was due to the pre-existence of national and international networks and “effector pathways” in the discipline of anaesthesia, the analogues of which do not exist in as developed a form as other disciplines. The reasons for the existence of these in anaesthesia will be reviewed briefly before a general consideration of progress and developments in identifying and responding to problems. Some of the lessons learnt in anaesthesia are applicable in the short term to other disciplines and to healthcare in general, but, to effect pervasive, lasting change many of these

problems will require a co-ordinated systematic approach and substantial investment over a considerable period of time.

Many other disciplines have, of course, made important contributions to patient safety and have developed their own techniques and pathways. However, as our practical experience in effecting change has largely been in the field of anaesthesia, most of the examples in this report will be from this discipline.

As indicated in the background to this report, anaesthetists have recognised for over 50 years that the majority of anaesthesia-related deaths are preventable.^{14,15} Moreover, for many years there has been a strong tendency for anaesthetists to be "blamed" when an anaesthesia-related death occurs. Contributing factors to this tendency are the facts that cause and effect are usually "tightly-coupled" in anaesthetic disasters¹⁵⁹, that there are several immediate witnesses and that anaesthesia *per se* does not have any intrinsic therapeutic benefit and hence is expected, unreasonably, to be risk-free. This has resulted in anaesthetists having a long history of being concerned about reducing the risks of anaesthesia, which led to the development of extensive mechanisms for safe-guarding and enhancing patient safety.¹⁷

At the time that AIMS was producing its first results the Australian and New Zealand College of Anaesthetists (ANZCA) had already promulgated 28 documents providing guidelines with respect to minimum requirements for the safety and quality of anaesthetic practice (see Appendix 16). Likewise, the Association of Anaesthetists of Great Britain and Ireland had issued 11 documents, and bodies representing anaesthetists in many countries had put similar mechanisms in place.

Hence, when the APSF published important findings from AIMS, ANZCA was quick to respond by putting into place mechanisms for addressing the issues raised.

It did this by producing new guidelines for patient monitoring, by updating several other quality and safety documents, and by ensuring, during inspection of departments for accreditation for training trainee specialties, that these measures were in place. The Australian Society of Anaesthetists (ASA) also greatly aided dissemination of this information by having articles in its regular quarterly newsletters devoted to issues raised by AIMS and the APSF (see Appendix 17). "Ownership" of many of these issues by practising anaesthetists was promoted by sessions devoted to these topics at the Annual National Scientific Meetings of ANZCA and the ASA, and by the APSF holding 2-day national workshops in association with each National Scientific Meeting of the ASA (see Appendix 18). The opportunity for every practitioner to have access to the national AIMS database and to be able to contribute to the analysis and findings of the data and to the development of interventions, is a vital component of the overall strategy for gaining acceptance of change, and has resulted in several publications (Appendix 19).^{160,161}

The process of discussing AIMS and QAHCS data at Annual Scientific Meetings has now started for the disciplines of Intensive Care, Emergency Medicine, Rehabilitation Medicine and Pathology.^{162,165} Overall, however, the available resources for disciplines other than anaesthesia have been consumed dealing with the processes of obtaining participation, negotiating the structure of reporting forms, arranging reporting processes and producing preliminary reports. The issues arising from generic incident monitoring, in particular, are complex and multi-disciplinary and are generally more difficult to deal with than those involving a single speciality group.

It will take considerable time to establish machinery in all disciplines similar to that in anaesthesia, and a number of different approaches will be required to accommodate the needs of different specialties and craft groups. Also, now that the QAHCS data are available, it is

also more appropriate that information from *all* sources be used in identifying and responding to problems.*

2.2.2 Background to medical record analysis in Australia

Although the origins and status of medical record review have been reviewed on pages 42-45, a brief discussion is required of why so little action has been taken to date as a result of publications arising from the use of this technique, except in the area of adverse drug events which have consistently accounted for 10-20% of problems.^{70,71,166}

When the results of the QAHCS were first published in 1995, it was apparent that, although a problem of alarming proportion had been identified, the descriptions of the nature of the problem were too primitive to provide any useful information about what steps could be taken.

The APSF first gained access to the QAHCS data in early 1997 and was able to use it to provide the necessary case-detail to construct the GOC. The first version of the GOC was available for use in July 1997, allowing problems to be identified at a sufficiently detailed level to allow the development of remedial strategies.

Australia is the only country in which evidence-based priorities can now be set with respect to the things that go wrong in healthcare. The APSF has now identified the top 250 adverse events and started the process of organising national working parties and conferences to address the issues raised in 1998.**

2.2.3 Identifying Problems

There are a number of mechanisms by which problems may be identified and a number of reasons why there may be some urgency in addressing certain problems. These are discussed below.

1. **Because a problem is shown to be relatively common.** Paradoxically, people and systems become desensitised to common problems and may tolerate them for years even though the outcomes can sometimes be serious. The best example from the public health area is that of smoking. Although smoking is arguably the greatest public health problem in Australia and is responsible for ten times more deaths than traffic accidents (20,000 versus 2,000 each year), society is still remarkably tolerant of a small group of people profiting from a business which produces no discernible benefit but causes massive suffering and economic loss. Incident monitoring and medical record analysis have provided evidence that certain iatrogenic problems are common and should therefore be dealt with.

An example from anaesthetic practice is the problem of disconnection of a paralysed patient's breathing circuit from a ventilator. Literally thousands of patients have suffered brain damage and death from this problem, world-wide, from the time of the introduction of muscle relaxants in the late 1940s.¹⁵⁶ Although, in engineering terms, there are simple solutions to this problem, it was not until the late 1980s that "disconnect alarms" were commonly used. Accidental breathing circuit disconnection remains the commonest anaesthesia-related incident reported to AIMS, but since recommendations by ANZCA and

* Analysing the mass of information in the incident reports collected so far will require additional resources; ACSQHC has made two encouraging recommendations.^f ACSHC will: (1) "work with States and Territories and other key stakeholders to ensure that incident data can be appropriately aggregated in a form suitable for analysis and action at the national level"; (2) "commission work to make best use of national incident data to analyse and report trends and to develop improvement strategies to prevent problems in the future."

** This work is now to be co-ordinated nationally by ACSQHC; the first taskforces, those for medications and nosocomial infection, have now been formed.^g

the APSF with respect to the use of "disconnect alarms", patient harm resulting from this problem is now very rare and only occurs when the recommended procedures are not followed.

2. **Because a problem can have dangerous manifestations, and may be prevented by a readily identified mechanism.** A problem may be worth addressing, even if it is rare, if it has a significant predilection for causing serious morbidity or death and may readily be prevented. One example already given is the use of a Seldinger wire with one sharp end; another is the inadvertent intravenous injection of a concentrated potassium chloride solution. The former may be prevented by purchasing only Seldinger wires with two "floppy" ends and the latter by only purchasing dilute electrolyte solutions. It is worth noting that although these problems may be prevented by readily identified mechanisms, it is not necessarily easy to introduce them, due to the relatively primitive state of mechanisms for introducing even simple changes across the whole healthcare system.
3. **Because a problem has a high abhorrence factor.** A recent example is the public interest generated by the tragic case of a young person becoming HIV positive after receiving a unit of blood which had been tested after donation in the "window period" (ie after infection of the donor, but before antibody development). Although there are many problems which cause many times more disability and death than those arising from blood transfusions, \$14 million per year have been allocated to reducing the "window" for HIV and hepatitis C from 12 to 6 weeks.⁶ Although spending disproportionately large sums of money on preventing such problems is irrational, as the money will then be unavailable for saving far more lives on more cost-effective measures for other problems, society, at the moment, seems to demand this. To what extent such demands genuinely reflect the desires of society as a whole, and to what extent they are created by irresponsible behaviour on the part of the mass media is open to debate. There is certainly an argument for the public being educated about cost- and risk-benefit in decisions in healthcare, and about the notion that the finite sum available for health care should be spent so as to yield maximum value.
4. **Because an issue is topical.** An example in the anaesthesia area was the widespread publicity given to a case of "awareness" under anaesthesia, due to a vaporiser problem, in a patient undergoing a hip replacement. The issue was aired on national radio and television. As a result of this the APSF extracted the data on vaporiser problems from its database and wrote a discussion paper.¹⁶⁷ ANZCA, shortly thereafter, issued a guideline requiring every patient undergoing general anaesthesia to have an in-line volatile agent monitor by 1 January 1998. It is important to note that the solutions proposed initially both by the professional bodies representing anaesthetists and by the organisations representing the manufacturers and distributors of the equipment proved to be entirely inappropriate once the evidence had been obtained from the AIMS data base. Again, AIMS data confirmed that actual vaporiser failure is rare, in the sense of a vaporiser not meeting its manufacturer's specifications, but that problems arising at the vaporiser-user interface are both common and potentially lethal. Further points to note are that there was almost no useful information in the conventional body of literature and that, at the time of this problem, the APSF had received twenty times more reports on vaporiser problems than the Therapeutic Goods Branch of the Department of Health.
5. **Because more needs to be found out about how a rare condition presents and evolves, so that better guidelines can be developed for its diagnosis and management.** Many textbook descriptions of rare problems contain information which is unreferenced and appears to be there as a result of "ritual inclusion". This appears sometimes to have been based on the experience of a now deceased author, at some distant time in the past, of only a handful of such events. One example from the AIMS study is

that life-threatening anaphylactic reactions present as frequently with bradycardia as with tachycardia, although the traditional "teaching" is that the hypotension of anaphylaxis is associated with a reflex tachycardia. Many AIMS reports by anaesthetists confronted with a patient with anaphylaxis described delayed diagnosis and treatment of the problem because of what appeared to be an atypical presentation. It is obviously very useful to know that anaphylaxis presents as frequently with bradycardia as with tachycardia.

6. **In order to determine the applications and limitations of biomedical devices in actual use under "field conditions"**. The performance of biomedical devices under conditions of actual use can be determined by incident monitoring. Profiles of the applications and limitations of the pulse oximeter, the capnograph, the electrocardiograph, blood pressure monitors, the oxygen analyser, unidirectional circle-circuit valves, infusion systems and blood warmers are examples that have been studied in anaesthesia.¹⁶⁸⁻¹⁷⁴ In all cases additional new information was obtained from AIMS about both the useful applications and the limitations and modes of failure of these monitors. Practising clinicians, thus forewarned, are fore-armed.
7. **In order to determine the frequency and pattern with which certain signs and symptoms are the manifestations of particular problems**. Clinicians may be faced with constellations of signs and symptoms which indicate that a major problem is occurring, but which are not specific to any particular problem. For example, arterial desaturation may be the first manifestation of over 20 life-threatening conditions during anaesthesia, many of which require specific diagnostic and therapeutic measures.¹⁷⁶ As there may be only a few minutes in which a correct remedial action must be taken, it is important to immediately take an appropriate, well-validated series of steps. A "core" crisis management algorithm with 26 sub-routines has been developed by the APSF which has been designed to cover any problem which develops unexpectedly under anaesthesia.¹⁷⁵ The first 4,000 incidents reported to AIMS were used to check and validate these algorithms.¹⁷⁶⁻¹⁹⁶ It is anticipated that an incident databases, similar to that for AIMS-Anaesthesia, but developed from incidents from other disciplines, would be equally useful in developing algorithms for these disciplines which could then be checked against events which have occurred in the real world. Examples of events for which this has been done include life-threatening anaphylactic reactions, pneumothorax, gas embolism and water intoxication during transurethral prostatectomy.

2.2.4 Responding to problems

Once a problem has been identified, it is desirable to come up a remedial strategy and to put this into place. Solutions may range from the very simple, for which it is obvious that there is benefit and very little cost, to highly complex strategies which themselves carry some risk and may be expensive. It is, therefore, highly desirable to demonstrate that strategies are both risk and cost-effective, and a culture needs to be established in which this is done whenever possible. However, this is frequently not practical in the current healthcare "system", not least because it has not been traditional to allocate sufficient resources to allow the proper design and rigorous conduct of such studies. As a result many responses to problems are local, piecemeal, and of unproven efficacy and unknown cost- and risk-effectiveness. One of the problems has been that it is often difficult to attribute a change or desirable outcome to a particular intervention, as many forces come to bear on an issue in the complex, changing environment of healthcare. It is therefore appropriate to examine this issue briefly before giving examples of progress that has been made in responding to problems that have been identified.

2.2.5 Attribution of change to an intervention

There are examples where a single intervention, arising from information in an incident report, leads to an identifiable change which would not otherwise have occurred at that time. For example, an incident report of hypoxic gas mixtures being produced by a faulty rotameter in a brand new anaesthetic machine because of an "O ring" problem led to a change in the quality control processes on the manufacturer's assembly line. This change was made by the manufacturer on the day the manufacturer was made aware of the problem, and the reporter from the APSF was invited to visit to confirm that the change had been made.

However, a system change is often the result of a number of forces and agents acting in concert, and it is not possible to gauge the relative importance of each. For example, it had been apparent for a long time at the Royal Adelaide Hospital that drugs being "jumbled up" in the drawers of a variety of different drug trolleys in a range of operating theatres made stock control, checking and drug selection difficult, time consuming and accident prone. However, it was only when several dangerous incidents were documented and collated (see box for examples) that the hospital administration agreed to rank a longstanding request for new, standardised custom-built trolleys sufficiently highly on an equipment-purchasing list to ensure they would be purchased.

In this case, the procurement authority had down-graded the ranking of the 30 drug trolleys requested (\$45,000 @ \$1,500 each) in favour of automated blood pressure monitors, devices which were ranked much lower by the requesting anaesthetists.

Representations were made to the CEO by the anaesthetists, citing the various problems reported on individual monitoring forms, and the very considerable work that had gone into the design and testing of a prototype trolley, and the decision was reversed. Although the reports had raised the collective awareness of everyone of the problem, had led to the idea of standardised trolleys, and had played a role in reversing the decision of the CEO, it was nevertheless not possible to attribute the arrival of the standardised drug storage trolleys entirely to the incident monitoring process.

Examples

- 1: On several occasions it had not been detected that adrenaline was missing at the start of the day, because the drugs were not stored in an organised manner. The fact that the drug was missing was only discovered when it was needed in an emergency.
- 2: As it was not possible to be sure when a heat-labile drug, such as suxamethonium, had originally been placed in the drawer, there was a widespread practice of a double dose being used in emergency situations as it was recognised that the potency of the drug in the drawer was unknown and questionable. This led to severe bradycardia on a number of occasions.
- 3: Adrenaline was given instead of neostigmine as a "like-looking" small brown adrenaline ampoule had been placed, after being removed from its "blister pack", in a container labelled "neostigmine".

Furthermore, although it would have been desirable to demonstrate that the outlay on trolleys had produced tangible results, it was not practical to prospectively measure the influence this change may have had on the rate of missing urgently needed drugs or on the rate of unintended drugs being drawn up from like-looking ampoules, because the manifestation of these "resident

pathogens" is rare. Nevertheless, prosecution of the exercise to its conclusion was thought intuitively to be worthwhile, as manslaughter charges have been laid when look-alike drugs have been inadvertently administered during emergencies, and patient harm has resulted when urgently needed drugs are missing.

Continuous improvement initiatives such as these are often not amenable to evaluation with respect to outcome. As funding for new initiatives is very hard to obtain in the current climate, strategies which require even modest amounts are hard to implement. Incident monitoring and medical record review at least have the potential to detect changes in the pattern of events and, with time, may provide evidence of success which may slowly change the attitude of administrators towards funding such initiatives.

2.2.6 *Types of responses*

Teacher and Student

... And not only are the reactions themselves variable, but we, the doctors, are so fallible, ever beset with the common and fatal facility of reaching conclusions from superficial observations, and constantly misled by the ease with which our minds fall into the ruts of one or two experiences. ...

William Osler (1849-1919)

It is important, before responding to a problem that has been identified, to review all the information available about the nature of the problem, how it presents, and how it evolves. It is common for people to have preconceived notions which subsequently prove to have been based on one or two experiences which were not representative of the problem in general.

The vaporiser problem described on page 72 is an example of such a situation. Experienced users, manufacturers and suppliers of vaporisers were all shown to have a very poor understanding of the nature of the problems which were occurring during the actual use of vaporisers. Examination of the incident monitoring data provided the real profile of the problems that were occurring in clinical practice, and allowed an appropriate solution to be identified and introduced.

The type of response is obviously constrained by the nature of the problem and by what is achievable in the context in which the problem occurs. Many of the responses given below would be greatly improved if unique patient identification, electronic medical records and the facilities for computerised support and expert systems were available. For example, adverse drug events were reduced by 50% when computerised prescribing with decision support was introduced to a large hospital in the USA.¹⁶⁶ It is now recognised that it will still be some years before these comprehensive information-technology based systems are in place in Australia. In the interim, local systems can be developed and applied at a local level. A number of types of responses, with examples, are given below in descending order of desirability.

1. **To redesign the system so that the problem cannot recur.** This approach is the most robust and therefore most desirable if a problem is amenable to it.¹⁹⁷ To use the Seldinger wire example again (see page 72), to avoid cardiac tamponade and perforation of the right atrium or ventricle after the inadvertent insertion of the sharp end of the Seldinger wire, the solution is simply to ensure that only wires with two "floppy" ends are manufactured. This may be impractical, so the next best option is to ensure that only approved wires are available in Australian hospitals. To actually do even this may in fact be more difficult than first imagined, as there are several overseas suppliers and hospital purchasers can change from one product to another without consulting clinicians, and without realising the implications.

Another example from the discipline of anaesthesia is that several reports were received that the distal end of the tube connecting the breathing bag on a circle system was being forced onto the scavenging outlet of the ventilator, leading to dangerously high-pressures being applied to a patient's airway and lungs - a potentially fatal situation. In this instance the international standard was changed, on the advice of a representative of the APSF, in such a way that this could not recur (see page 89). The modification is inexpensive, and, once in place, will prevent such a situation from arising again. Many solutions such as these can be embedded into the system without the operators even realising they have been put into place. As a further example, there was a spate of reports soon after the introduction of menu-driven microprocessor-controlled multi-parameter physiological monitors into anaesthesia, that operators could adjust the software so that dangerous alarm conditions could result (eg a delay for a ventilator disconnection of 30 minutes rather than 30 seconds). The next operator would be unaware of this, and a death could ensue. All manufacturers contacted agreed to modify the software so that all monitors defaulted to standard alarm parameters on being turned on. Some manufacturers responded immediately by installing software upgrades on all existing machines as well as introducing the changes on new monitors. However, others, whose systems are set up in such a way that compliance is difficult, have yet to introduce the changes.

In all of these instances the "affordances" of objects have been altered in such a fashion that they could no longer be configured into the dangerous mode that had been identified.

However, eternal vigilance is required as determined people can circumvent most safety features. It has been said that "it is impossible to make anything foolproof, because fools are so ingenious". A manslaughter charge was laid recently because a piece of equipment, deliberately designed so that it could only be used in a safe configuration, had been modified in a hospital workshop by an unqualified technician so that it could be used in a dangerous configuration. When the device was used in such a dangerous configuration during an emergency resuscitation, it caused complete obstruction of the patient's breathing circuit, and it was suggested that this had contributed to the patient's death. This case involved a soda-lime canister in an anaesthetic circuit, designed so that it could only be inserted in the "normal" way, which had been modified so it could be inserted in such a way that it caused complete obstruction of the breathing circuit. It had been installed in a machine used to resuscitate a patient who had suffered an anaphylactic reaction on induction of anaesthesia, and the anaesthetist had been unable to ventilate the patient with the machine. However, the patient was suffering from severe bronchospasm as part of the anaphylactic reaction and the manslaughter charge was dropped because there was evidence that the patient had also been almost impossible to ventilate using an alternative device.

- 2. To provide standard protocols and ensure that they are followed.** Well thought out standardised protocols eliminate the need for clinicians to work from first principles, and reduce the possibility of error. These protocols are currently usually available in a printed form. For example, instructions as to how to make up an infusion or formulate the dose of a drug can be incorporated into a printed order for the use of the drug in which it is necessary only to choose the dose or rate from a range of recommended options (see Appendices 20 and 21). This avoids mistakes in calculating doses and concentrations and avoids the problems that arise from difficult-to-read or illegible handwriting. Such protocols can also contain instructions as to what to do when there may be some undesirable consequences as a result of using the drug ordered. For example, a standard order for anti-emetics can be an integral part of a protocol for prescribing opioids, with instructions as to when these should be given.

3. **To develop clinical pathways with checklists.** Standardised approaches to common clinical conditions and situations may be developed, with checklists to ensure that certain diagnostic and therapeutic measures are carried out in an appropriate sequence and at appropriate times.¹⁹⁸⁻²⁰⁰ Such systems can greatly enhance patient safety because it becomes obvious if, for example, thromboembolism prophylaxis is not being carried out when an independent check is carried out each day and that portion of the form cannot be “ticked”. An example from the discipline of anaesthesia flows from an analysis of incident monitoring data which revealed that patient mortality, when inadequate pre-operative assessment had been carried out, was increased six-fold. A major project is underway in which it is intended to produce a standard software-based pre-operative assessment tool in which much of the routine work can be carried out by trained nurses, freeing the anaesthetist to concentrate on more complex problems and on ensuring that the patient understands what is going to happen. This tool will have a structured section for history and examination, supported by expert systems for producing protocols for which pre-operative tests should be done, for peri-operative thromboembolism prophylaxis, for peri-operative antibiotic use, for peri-operative anti-emetic use, and for peri-operative pain management. This will address four of the problems in the “top twenty” (see page 18).
4. **To replace a disorganised system with the one that is well organised.** The example given on pages 74-75 describes the replacement of a disorganised drug trolley system with one that is much more organised and less likely to contribute to problems. Another example from anaesthesia is the use of a standardised well-validated checklist for checking anaesthetic equipment and monitors before use.²⁰¹ This allows a standardised check to be used by technical personnel before the start of a working day, and for the various steps of the validated process to be “ticked off” on an approved form which can be signed, dated and attached to all machines that have been checked.
5. **To replace a complex process with a simple one which provides fewer opportunities for error.**¹⁹⁷ Analysis of information on adverse drug events from the generic hospital-wide AIMS system revealed that problems with the anticoagulant heparin were common. Analysis of the contributing factors showed that inexperienced staff and staff who had not been appropriately orientated were major contributing factors. In essence, the message was that with the current high staff turnovers, the management of heparin infusions, which involves making up the desired concentration of heparin and then adjusting an infusion pump rate according to the results of anticoagulant activity tests on repeated blood samples, was too complex a process to be reliably performed in the average ward. This complex process can be replaced in most clinical situations by the simple one of using a new low molecular weight heparin formulation which can be injected subcutaneously twice a day, which has been shown to be equally efficacious, and which does not require dosage adjustment or frequent blood tests. Although the actual cost of the drug is higher, the overall cost to the system is much lower and patient safety is enhanced.

Research is underway in the discipline of anaesthesia in which the multi-stage process of identifying an ampoule, drawing the contents up into a syringe, and labelling the syringe manually can be replaced with anaesthetists being supplied with syringes which have been filled with the appropriate drugs by the manufacturer. These are in sealed colour coded bags which are large enough for very clear labelling. The syringes themselves also have labels on them, placed by the manufacturer, which are also easy-to-read and colour coded. In this way a number of steps, which have been shown by incident monitoring to be prone to be incorrectly performed, will have been eliminated.

6. **If a problem cannot be eliminated to ensure that it is reliably detected in time to prevent harm from resulting.** The example of accidental breathing circuit disconnection

given on page 71 may again be used here. Although it is possible to design circuits with connections which will not come apart, the problem is that if these are "snagged" by another piece of equipment in the operating theatre, or by an inadvertent movement on the part of an operator, this would result in the endotracheal tube being dislodged from the patient's airway (an "accidental extubation"). As some patients are in the prone position this would create a dangerous situation from which it would be difficult to recover. Hence it is best if circuits are so constructed that they can "fall apart" if sufficient force is applied to them. Having accepted this, it becomes necessary to ensure that any disconnection is immediately and reliably detected and that this is brought to the attention of the anaesthetist.^{202 203} This requires the availability and consistent use of "disconnect alarms" which cannot be cancelled or set in dangerous modes. Their universal availability is now required wherever anaesthesia is conducted in Australia.

7. **If a problem is detected, to ensure that a response ensues which will reliably prevent harm to the patient.** In the discipline of anaesthesia, a major project has been undertaken over the last 10 years to come up with robust algorithms which provide defined responses to certain types of problems. This has been a major task, but has been an important one as there is simply insufficient time for certain rare problems to be identified from first principles in rapidly evolving crises to guarantee patient safety.¹⁷⁶⁻¹⁹⁶ Such crisis management algorithms, and training in their use, are desirable in other areas in which there may be sudden failure of complex human-machine systems. For example, it has been shown that certain failures of cardiothoracic bypass systems cannot be reversed even by experienced personnel unless they have been specifically trained to do this and the necessary back-up equipment is available in an organised form.³ Such algorithms and the accompanying training are well established in areas such as aviation and it is important that they become equally well established in clinical medicine. An important start has been made with the availability of sophisticated simulators, analogous to those in aviation, in New South Wales, Victoria and Western Australia.⁴

2.2.7 Levels at which responses to problems may occur

Responses to problems may be at a number of levels (personal, department or practice, systemic) and instituted "from the bottom up" or may be suggested or implemented "from the top down". The former are more effective at the personal or local level. The latter are best implemented at a systemic level, but can also be effective at local and personal levels.

2.2.8 At a personal level

2.2.8.1 "Top down" changes

Personal behaviour and performance can be improved by "top down" initiatives. These include providing time and funding for education and training activities and by introducing various measures for some degree of surveillance of individual performance. These can range from annual performance reviews to random checking of record keeping and adherence to protocols and pathways. Formal checks of responses to crises in simulators are becoming a reality for some clinicians, and may become a requirement at some stage in the future.²⁰⁴

Recognition of good performance both in the workplace and by the community is also likely to reinforce high quality practice.

Although there is increased pressure to measure outcomes resulting from the work of individual clinicians, there is recognition that it will be important to establish that such measurements are valid, reliable and fair. At the moment the means for correcting for casemix and co-morbidity

are too poorly developed to allow comparisons between individuals for most procedures or clinical conditions. However, it is relatively easy to check that certain procedures are being adhered to; random checks of anaesthetic records, for example, can provide a powerful mechanism for encouraging adherence to departmental protocols, and for recognising those who consistently do so.

2.2.8.2 “Bottom up” changes

An awareness of the scope and consequences of iatrogenic injury and of the role of system failure and the various types of human error (and violations) can alter the behaviour of clinicians in the workplace and can encourage them to be pro-active in not only safeguarding the welfare of the patients they are directly responsible for, but for the larger constituency of patients collectively.

Health care workers frequently encounter problems or are involved in "near misses" which were quite obviously "accidents waiting to happen". They often feel helpless and angry when they have to work under conditions in which they know they are exposing themselves and their patients to potentially avoidable adverse events, but are not in a position to address the root causes. When the last event in a chain of misadventures was an error on their part - sometimes a minor slip or lapse whilst having to perform several tasks at once - they feel aggrieved because they have been put into that position by the system and because of the realisation that failure to perform perfectly in an imperfect system is inevitable from time to time, with the consequent exposure of themselves and their patients to risk and anxiety, at best, or, at worst, physical harm or death.

Health care is unique in that clinical health care workers at all levels are exposed at times to situations they would rather not be in, over which they have little control at the time, and which they would like to avoid in the future.

Incident reporting provides a mechanism whereby the circumstances and consequences of things which have actually gone wrong can be described by those who were involved, with suggestions as to what the contributing factors were and how such problems could be avoided in the future. It may have been quite obvious, for example, that an incident occurred because the staff allocated to a task were unfamiliar with the equipment to be used; incident reporting provides a legitimate mechanism whereby a junior staff member can ensure that attention is drawn to the problem. It provides a mechanism whereby their report can be seen to be valued and empowers them to precipitate a change and influence management processes in a way and at a level which may not be possible in the normal course of events. People who have reported incidents gain satisfaction from seeing changes implemented at a local level as a result of their reports. They have an opportunity within the report to outline the contributing factors even though the precipitating factor may have been an error on their part. However, there are limitations as to what is likely to be reported when all those involved can be identified, particularly in hierarchical organisations which may have people with vengeful personalities in positions of power.*

In this situation anonymous incident monitoring provides a mechanism whereby a completely frank report can be made. As indicated above, it is not reasonable to expect a junior staff member to insist on a form with identifiers being completed when it is quite clear that a senior staff member may have played a major role, wittingly or unwittingly, in an incident or adverse event. Anonymous reporting also provides a mechanism for reporting when no harm has occurred, but the reporter did something silly or made a bad decision, and does not necessarily wish to expose himself or herself to scrutiny or censure.* Finally, when harm has occurred,

* This was addressed in a recent editorial by one of the authors.ⁿ

reporters can satisfy "a desire to confess" which allows them to work through a problem and resolve some inner tensions when it may not be appropriate to reveal the full circumstances of the problem to others in the workplace.

Regardless of the circumstances or outcome of a particular event, an opportunity is afforded to make sure that the information is logged, so that it may contribute to the design of strategies to reduce the chance of a similar problem happening again.

2.2.9 At a local, departmental or practice level

2.2.9.1 "Top down" changes

The Director or Head of Department (or a designated person for a private hospital or private practice group) has the responsibility for ensuring that all guidelines promulgated by the relevant specialist Colleges are being adhered to. In some cities in Australia there is a liaison officer representing the Australian Society of Anaesthetists for each private hospital. As this can be a very substantial task, one approach is for this person to ask each full time clinician to take on a small number of safety and/or quality portfolios and to encourage them to form small teams with trainees and other relevant people to discharge their duties with respect to each portfolio.²⁶⁵ For example, if the portfolio is to ensure that the ANZCA patient monitoring guidelines are being adhered to, the clinician may form a team with a trainee anaesthetist, an anaesthetic nurse and a biomedical engineer. They can allocate tasks amongst themselves to ensure that the appropriate number of devices have been purchased, that they are distributed in the correct places, that they are being properly maintained and looked after, that they are checked before use, that "back up" units are readily available and that the appropriate crisis management algorithms are in place. A long-term aim of the APSF is to develop software packages which can provide structured algorithms for conducting such activities and for documenting that each component has been carried out. An example of where this has happened is for acute pain services; this will be considered below.

Another mechanism is to keep an up-to-date department "operations manual" which contains all administrative and clinical policies, protocols and guidelines. This manual should, ideally, be available at all points of care and in each clinician's office. However, paper manuals of this nature are very hard to keep up-to-date and "version control" is a major challenge. A great advance in this respect has been the increasing availability of personal computers in the offices of clinicians and at "points of care" in the workplace. Examples of electronic versions of such manuals, one for departments of anaesthesia, and one for intensive care units, have been included in Appendix 21. Again, a long-term aim is to gain national acceptance of the modules contained in such manuals so that standardised national protocols can be used for common problems. It is intended to start with relatively mundane topics such as gaining acceptance of a standard protocol for making up and giving an adrenaline infusion or of a standard guideline or clinical pathway for managing and investigating a patient in intensive care who has taken a drug overdose.

Regular audits or peer review sessions should also be held.²⁶⁵ In most departments these are held weekly or monthly and all issues which have come up in the time since the previous meeting should be placed on the agenda and discussed. It is important that minutes be kept and that the problems discussed have solutions proposed and that these solutions be followed through.

Some departments of anaesthesia use incident monitoring as the main means of supplying information for discussion at these meetings, whereas other departments have less formal audits and separate meetings to discuss incidents. Using incident reports provides a mechanism for

exploiting a “bottom up” approach to provide information for the generation of “top down” solutions.

2.2.9.2 “Bottom up” changes

Individuals may anonymously draw the attention of the local AIMS co-ordinator to a particular problem or set of problems via a simple report, or a local AIMS co-ordinator may identify issues or patterns of events which require attention from a number of similar reports. These may range from quite trivial problems which can be easily fixed through to major problems with processes, infrastructure or equipment. Anonymous incident reporting has frequently been used to formally draw attention to systematic problems which the Head of Department or Practice Manager may not wish to acknowledge or address. In this way the topic is forced out into the open where it can be discussed by all department or practice members.

In the past, problems could seldom be properly addressed if they involved a component of human error, as drawing attention to the problem inevitably involved the potential exposure of an individual, if not to censure or medico-legal risk, at least to some embarrassment. Although a climate of “blame” in the workplace is undesirable, it is still common, and anonymous incident reporting provides a mechanism for placing problems on record and encouraging debate and suggestions about how they might be addressed without exposing those involved to censure.²⁰⁶

Thousands of changes have been introduced in departments and practices as a result of these activities. In some institutions a formal record is kept of a summary of the incidents discussed and the steps taken, whereas in others no record is kept, but the changes are made. The latter arrangement is often in place because some reporters have a possibly legitimate concern that records of meetings may allow a problem to be traced back to them, with possible medico-legal consequences.

An example of synopses of anaesthesia-related incidents with some interpretations and suggestions from a publication in the late 1980s is given in Table 8.

Note that three of the seven events involved breathing circuit disconnections, that “disconnect alarms” were not in use and that alternative means for ventilating patients’ lungs were not universally available. Both of these are now required. Local reporting thus led to systemic change.

It has been pointed out that certain “human factor” problems such as failure to check equipment tend to persist despite repeated attempts to draw people’s attention to the problem, whereas getting rid of latent errors in the system have high rates of success.¹⁰⁷ This has been confirmed in a number of contexts. A report on an incident reporting system based on AIMS which was set up in Hong Kong stated “strengths of incident reporting included the continuous nature of the audit in the open format which allowed diverse problems to be reported through a common channel of communication. The programme was effective in its ability to detect latent errors in the anaesthesia system.

When a response was made to these latent errors they did not recur, providing evidence for the effectiveness of this approach in the anaesthetic setting. The extent of the well-known problem of human error in anaesthesia was also revealed. However, although critical incident reporting undoubtedly increased awareness of this problem, we found no evidence that increased awareness, was, per se, effective in reducing its frequency”.¹⁰⁷

Table 8: Example of a feedback report from the late 1980s.^b Each report consisted of between 20 and 30 such events and every case was identifiable to the respondent by its unique number

appearing on the blank form.

Event No.	Comment
H17	Disconnection of fresh gas flow between rotameters and vaporisers not immediately detected. Patient ventilated with expired air until Ambu bag available. Low pressure alarm not available which may have detected leak earlier if set correctly.
W58	Pumping up operating table broke off fresh gas flow entry into circle. No Ambu bag available immediately and edges of broken connection held together until another anaesthetic machine available.
W11	Thiopentone inadvertently injected into arterial line injection port proximal to flushing device. Mistake realised only after lack of effect. Arterial and venous lines were crossing each other and presumably unlabelled. Should be “fault of technique” as well as accident. Please re-read guidelines and samples.
W15	Break in fresh gas flow entry to circle during transfer of patient to theatre table (see W58). This time Ambu bag available until another machine found. Second case of breakage here.
W75	Patient fasted 10 hours for “D&C”. Only after patient asleep on table was it revealed that procedure intended was colpocentesis for ?ruptured ectopic pregnancy. Patient vomited under anaesthesia resulting in hypoxia and hypotension. No report of aspiration. Inadequate communication between anaesthetic and surgical staff.
W47	Tracheostomy under local anaesthetic and sedation for partial airway obstruction. Sedation contributed to worse obstruction before rapid completion of procedure - hypertension and ventilator ectopic beats.

Examples of changes which have been recently made at the local level in two intensive care units and an emergency department are given in Appendix 22.

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That a record be kept in each health facility of all the incidents that have been reported and of the steps taken to deal with them, and that accreditation of each facility is contingent on satisfactory evidence that these have been classified and stored in such a way that they can contribute to a national database.

There are a number of models for collating information and translating this into changes at a local, departmental or practice level. Although activity at this level will always be required, it is most important that the data also be collated in a central repository, and that clusters of events are analysed so that systemic solutions may be sought and implemented at a national or international level. In this way progress may be tracked by the pattern or profile of incidents changing over time as the systemic measures take effect. The systemic changes suggested as a result of analysing the first 2,000 incidents reported to AIMS-Anaesthesia and the levels or mechanisms by which these changes were effected are listed in Appendix 23.

2.2.10 At a systemic level

2.2.10.1 Existing mechanisms for effecting change

The mechanisms by which changes may be effected in the discipline of anaesthesia have been outlined on pages 68-70, and largely involve pathways which have evolved specifically for this specialty. Although such pathways already exist in some specialties and may be strengthened in others, existing mechanisms must be better exploited and new means must be developed for effecting change across the entire spectrum of healthcare. Some existing mechanisms for regulating and influencing aspects of healthcare will be outlined briefly, before going on to describe an integrated multi-disciplinary approach for problems which affect healthcare in the broader context.

Via professional organisations. A case history about how widespread changes in monitoring standards were achieved is presented in the box below.

2.2.10.2 Case report - monitoring standards in anaesthesia

When AIMS was started, in the late 1980s, many anaesthetics were being administered with no monitors at all other than a stethoscope and a sphygmomanometer. Anaesthetists had traditionally made very few demands on hospital budgets with respect to equipment and the role of monitors had not been established. Indeed, although there had been some dramatic improvements in technology, there was a school of thought which proposed that the increased complexity that monitors brought to the practise of anaesthesia may more than offset their advantages.²⁰⁷ However, AIMS established beyond doubt that the advantages of monitors vastly outweighed their disadvantages.¹⁶⁸

In the analysis of the first 2,000 anaesthesia-related incidents reported to AIMS, it was shown that in over a half of the relevant incidents a monitor detected the incident first (ie before the anaesthetist).¹⁶⁸ Oximetry and capnography first detected over half of the monitor-detected incidents. It was also shown that a pulse oximeter, used on its own, would theoretically have detected 82% of applicable incidents (nearly 60% before any potential for organ damage) and that capnography would have detected 55% (43% before any potential for organ damage). If oximetry and capnography were combined nearly 90% of applicable incidents would have been detected, with no potential for organ damage in 65% of cases. These data lent strong support to the introduction of "Monitoring Guidelines of the Australian and New Zealand College of Anaesthetists" (1990) and also profoundly influenced the recommendations made in the "International Standard for the Safe Practise of Anaesthesia".¹⁵²⁻¹⁵⁶

The Australian and New Zealand College of Anaesthetists established a requirement that a pulse oximeter "must be exclusively available for every anaesthetised patient from January 1, 1989" and that "a carbon dioxide monitor must be exclusively available for every intubated and ventilated patient" from January 1, 1992. Most importantly, information from AIMS led to recommendations that oximetry and capnography be purchased in developing countries before compressed gas anaesthesia machines.¹⁵³ Up until the time of the publication of the AIMS data on monitors, many anaesthetists placed a lot of faith in a continuous recording of the electrocardiograph, and the sequence of monitor acquisition in nearly all developing countries was following the sequence of monitor acquisition in the developed countries. Historically, the first monitor to be purchased after a stethoscope and sphygmomanometer was usually an electrocardiograph. This was because this was the only widely available continuous electronic monitor of a physiological parameter in the 1960s, and continued to be the only one widely used right up to the end of the 1980s. In 1988, for example, there were teaching hospitals in Australia performing 20,000 anaesthetics per annum, with over 20 anaesthetics being

administered simultaneously on a busy working day, which possessed only 3 capnographs and 3 oximeters. The AIMS study showed conclusively that the electrocardiograph can remain absolutely normal with respect to rate, rhythm and configuration under general anaesthesia whilst potentially fatal perturbations to oxygen delivery, carbon dioxide elimination and hydrogen ion status are occurring.¹⁷ Many tragedies have occurred over the years because it was believed that the electrocardiograph would warn the anaesthetist that some disaster was developing.

As indicated above, AIMS data provided the evidence to allow firm recommendations to be made in International Patient Safety standards with respect to the sequence of monitor acquisition. These recommendations were endorsed by the World Federation of Societies of Anaesthesiologists (WFSA) and disseminated to its 98 member countries. There has been much feedback to the Society that these recommendations and standards have had a major impact on the relevant authorities in the various countries both with respect to obtaining funds for purchasing monitors and equipment, and with respect to buying the right equipment.

It has been gratifying for APSF and WFSA representatives, when travelling to remote areas, to find that a pulse oximeter is being used in preference to an electrocardiograph in most places, and that these have been marked improvements in patient safety. The major change in anaesthesia between the 1980s and the 1990s was the universal availability by 1992, of heartbeat-by-heartbeat readings of the oxygen saturation of patients' blood and breath-by-breath evidence of effective ventilation. Mortality directly attributable to anaesthesia fell from 1 in 20,000 to 1 in 150,000 anaesthetics over this period.⁴⁷

2.2.10.3 The jig-saw puzzle approach

An approach which can be used in any health care facility is to develop one of the quality and safety portfolios in such a way that the resulting new system is suitable for use in other health care facilities. An analogy is that whilst implementation of the grand vision may have to wait until developments such as a new universal information technology system is in place, pieces of the jig-saw puzzle can be developed now, ready to be fitted into the overall picture at a later date. This is, in essence, the approach being used by the Outcomes Branch of the Department of Health and Aged Services in funding demonstration hospital projects and in providing seeding funding for the development of tools such as incident monitoring and adverse event analysis systems. A case history of such a project, the development of an acute pain service, which was funded as a demonstration project by the Commonwealth Government in 1989, is presented in the box below.

2.2.10.3.1 Case report - an acute pain service

Only ten years ago, the management of acute pain in large teaching hospitals in Australia was abysmal. It seemed strange that a woman could get good pain management in an obstetric hospital during labour, but would have to suffer severe post-operative pain after a cholecystectomy in a general hospital. There were specialists running intensive care units and high-dependency units who were repositories of a full suite of misconceptions including:

- that morphine 10mg or pethidine 100mg should be prescribed 4-6 hourly for the management of pain - as suggested in the standard out-dated textbooks;
- that patients were at risk of opioid addiction as a result of opioid treatment for acute pain in hospital;

- that increasing the dose of opioids was likely to produce serious cardio-respiratory depression without improving the pain;
- that patients who got into trouble as a result of being unable to cough or move because of severe pain did so because they were "wimps" or of an ethnic background which predisposed them to complain.

These widely held misconceptions were prevalent at a time when it had been shown, quite convincingly, that severe acute pain could be virtually eliminated with the appropriate use of standard drugs such a morphine.^{208,209}

In 1988, it was decided that there was a need, at one such large teaching hospital, to do something about the problem of acute pain. All anaesthetists were exhorted to make sure that pain orders were written up at the end of each surgical procedure, and to encourage the resident staff to make sure the nursing staff communicated closely with patients and took the trouble to give more of the ordered drug when necessary.

Thus, an attempt was made by reinforcing good intentions and increasing the amount of effort to produce a change in the effectiveness of pain management. However, as attitudes were entrenched and the system virtually immutable, the result was that nothing changed. Morphine was still prescribed "10mg six hourly prn", nursing staff frequently did not ask patients whether they had pain, and even if patients complained, opioids were usually only given once per shift to fit in with other nursing duties because of the inconvenience of having to access drugs in the locked "drugs of dependence" cupboard.

All of this took place against a background of a typical large teaching hospital - 20,000 procedures per year, many surgical specialties, patients with significant co-morbidities, ever-changing nursing resident and registrar staff, and ritualistic post-operative management passed on generation-to-generation by the mentor system.

Was there really a problem? Studies showed that up to 75% of post-operative patients suffered moderate to severe pain which could impede movement and breathing.²⁰⁹ It had also been shown that inadequate pain relief may be associated with a number of adverse physical and psychological effects if severe and undertreated, and, once established, could lengthen hospital stay and carry significant morbidity and mortality.²¹⁰ Furthermore, patients with significant chest injuries, particularly if they were smokers, frequently ended up in the intensive care unit, sometimes requiring artificial ventilation for up to a month. The extent of the problem was confirmed when it was shown that inadequate pain relief was one of the "top 10" categories of adverse events in Australian hospitals in 1992 (see page 18).

What were the requirements for a new system? To get acceptance of the facts:^{210,212}

- that acute pain could be reduced to low levels with a low incidence of serious side-effects in the vast majority of patients;
- that this could be done with conventional, inexpensive drugs such as morphine;
- that the dose of morphine is better predicted by patient age rather than weight and that the dose required varied over an 8-10-fold range between individual patients in the post-operative period;
- that the dose response-curve in an individual patient was steep;

- that the previous two facts necessitated titrating the dose of opioid against the amount of pain whilst monitoring both effectiveness and side-effects.

As there were sound financial as well as humanitarian imperatives to address the problem of acute pain, it was decided that a totally new system had to be put into place which bypassed each of the bottlenecks or rate limiting steps in the previous system. It was decided that the following requirements had to be met.

- The new system had to be embedded into normal medical and nursing practices and become an integral part of the usual medical care. This required a six month lead-up phase for the development of standardised charts and scoring systems for pain, respiratory depression (assessed using a sedation score), for orders for drugs providing pain relief and for recognition and treatment of side effects.
- All nursing staff would have to attend a course providing the rationale for such a system and to teach them the essential elements of operating such a system, ie scoring pain and sedation, setting up the equipment, identifying problems, treating them and knowing when to call for help.
- All medical staff would have to agree that the acute pain service could be contacted directly if any patient was thought to have inadequate pain relief.
- Baseline measurements were to be made of the attitudes of patients, nursing and medical staff to the provision of opioid analgesia for acute pain, and patient scoring and psychometric testing was undertaken in a group of patients. All of this was to be repeated at intervals after the introduction of the acute pain service.²¹³
- Funding had to be obtained for a sufficient number of patient controlled analgesia systems and for the necessary medical and nursing staff to set up and provide the education and accreditation system, and to do daily rounds on all patients who were to be managed by the acute pain service. A minimum dataset was to be collected every day, and a database set up to keep records and important features of every patient.
- The system had to be set up so that patients could obtain pain relief on demand. Even standard orders could be adjusted over a four-fold range with nursing staff flexibility as to the size of the bolus dose as well as patient flexibility with respect to how frequently they receive the bolus doses.

After a year's preparation the Acute Pain Service was started in 1989. Experiences from the first 1,000 patients managed were outlined in a publication in the Medical Journal of Australia.²¹⁴ Over 20,000 patients have now been treated. Incident monitoring forms the core of the Acute Pain Service quality improvement process, and weekly meetings are held to discuss the incidents reported in the previous week.

A large number of changes in clinical practice have been instituted as a result of incidents being reported. Also, all complications can be extracted from an electronic database which contains a minimum dataset with information about all patients managed by the Acute Pain Service.²¹⁵

A standard text book on how to set up and run an acute pain service "Improve Traditional Methods of Pain Relief Throughout a Hospital" is now about to enter its second edition²¹, and the acute pain protocols, forms, syllabus and course have been disseminated to over 100 hospitals throughout Australia and overseas.

The story of setting up an acute pain service provides a good example of how “more of the same” is doomed to failure within the traditional healthcare system. The whole process had to be re-engineered and a system instituted which was responsive to patient needs and to feedback about things which go wrong. In this way the service was progressively improved until a generic well-validated process had been developed which could be disseminated throughout the healthcare system. The challenge is now to do exactly this and to move inadequate pain relief from one of the “top 10” problems nationally to a much lower ranking in the league of adverse events; an incentive could be provided by requiring adequate acute pain management processes to be in place as a requirement for hospital accreditation.

The “package” developed for an acute service constitutes a jig-saw puzzle piece for the bigger picture of a consumer orientated, improved health care system.

2.2.10.4 Regulatory mechanisms for drugs, devices and procedures

Healthcare in Australia currently suffers from being subject to controls which range from stringent to non-existent. The controls with respect to allowing a drug into Australia at all and then with respect to how and by whom it may be prescribed, are amongst the most stringent in the world; there is also a highly regarded national mechanism for reporting and responding to adverse drug reactions.^{149,150} However, those for registering medical devices and equipment for sale and use in Australia may best be described as rudimentary (except for 12 special categories), and those for how devices may be used and what procedures may be undertaken by medical practitioners are, for practical purposes, non-existent. There is vast scope for improvement.

The good news is that some important changes are imminent with respect to medical devices; a process of “global homogenisation” with respect to standards for drugs and devices is well underway, and Australia is an active participant in the international global homogenisation taskforce.

Prior to 1984 there was piecemeal regulation of biomedical devices in Australia, with a patchwork of ineffective, uncoordinated State and Federal regulations. In that year it was realised that a batch of artificial heart valves (“Bjork-Shiley” valves) had been “dumped” on the Australian market, even though it was known in the United States of America that these valves were subject to sudden catastrophic mechanical failure causing the immediate death of the recipients. To compound the problem, there was no tracking system for who had received these valves and it was considered in any event that it was more risky to replace them than to live with the possibility of sudden failure. This led to the commencement of direct government involvement in the regulation of medical devices (Stage 1).

Stage 2 started with the Therapeutic Goods Act in 1989, which in 1991 introduced a system of regulation for both medical devices and medicines, with the Australian register of therapeutic goods as the central point of control for the legal supply of devices in Australia. Although the Australian Therapeutic Goods Administration has an excellent international reputation, requirements for the registration of devices, other than those listed in the twelve categories in Appendix 24 remain quite rudimentary and superficial.

Stage 3 began in 1998, with an in-principle agreement by the Federal Government to participate in an international process of homogenisation of the regulation of medical devices in line with international best practice. A new system for classifying devices with respect to risk, and for demanding minimum safety and performance requirements is expected to be put into place during the year 2000. A background paper from the Therapeutic Goods Administration web page on these proposed new regulatory requirements for medical devices is included as Appendix 25.

It is anticipated that the new Therapeutic Goods Act will provide a very substantial impetus for manufacturers to meet international standards with respect to the design, manufacture and distribution of medical devices. This is because, for many devices, conformance with the safety and performance requirements of the new Act will, at least in part, be satisfied by meeting such standards.

2.2.10.5 Standards Australia International

“Standards Australia” already has a set of standards for medical devices and is actively involved in the International Standards movement. As indicated on page 76, the best solution to a problem is to “design it out”.

Most manufacturers are prepared to accept suggestions with respect to design change if these are evidence-based, and information from incident monitoring has already been shown to be sufficiently convincing to produce changes in some international standards. (for example, AS/NZS2496:1995 - Breathing attachments for anaesthesia purposes for human use).

Standards Australia provides a mechanism whereby standards can be set by general agreement of committees of voluntary experts. Over 10,000 committee members, supported by over 300 staff, have now promulgated over 6,000 standards. Of these, over 300 are of direct relevance to medical practice and patient safety; these are contained in a booklet entitled SLO1-Healthcare - “Standards Australia”. They range from standards for toothbrushes and single-use syringes to standards for surgical implants and the obstacle-climbing ability of electric wheelchairs.

There are currently no regulatory requirements for health facilities to use only equipment and devices which meet Australian and/or International Standards.

However, because of the safety and performance requirements of the new legislation, it is likely that in the future most devices will have to meet these standards in order to be registered for sale in Australia.

There is no regulatory control over how devices should be used or what procedures may be performed. There is a generally accepted convention that invasive procedures should be performed by registered medical practitioners, but there is no requirement that this should be so. Needles are inserted by non-medical practitioners as an integral component of acupuncture and in tattoo parlours. There are also lay people who specialise in piercing body parts to accommodate rings and other jewellery. In the medical profession, there are no limits as to what procedures a general practitioner may undertake, except by convention. In remote areas and in the not too distant past, general practitioners could and would (appropriately) turn their hands to almost anything.

However even in “mainstream” medicine, a number of procedures were come across in the QAHCS which could be described as unnecessarily invasive or unconventional. It would seem desirable to try to work towards a more structured approach to the introduction of new devices and procedures. For example, laparoscopic cholecystectomy is widely practised and generally accepted as a reasonable proposition, but evidence from Western Australia indicates that laparoscopic surgery has been associated with a doubling in the rate of bile duct injury - a most undesirable complication.²⁷ This issue is under active review by the specialist colleges, and

steps have been taken at many institutions to allow only appropriately credentialed people to carry out some of these procedures (see below).*

2.2.10.6 Accreditation

There are a number of mechanisms whereby a healthcare facility may be accredited (see page 30). In order to be accredited certain standards have to be met with respect to structure, process and outcome. Some of these, particularly with respect to structure, are generic standards (eg building codes, fire safety requirements) which are clearly specified. Others, however, are specific to the health industry and may be less clearly defined.

Nevertheless, the accreditation process can require systems to be improved to meet standards in line with currently acceptable practice, and the organisations responsible for accreditation have been shown to be both willing and able to respond to evidence-based suggestions for such standards. There is a large time-lag in the process of promulgating and disseminating formal International and Australian Standards and Codes, and in rapidly evolving areas of medical practice this time-lag may be unacceptable. If the medical profession is able to reach consensus and propose that certain standards be met (for example, as occurred with respect to minimum monitoring requirements in anaesthesia), then the accreditation process provides a powerful and flexible mechanism to ensure that these *de facto* standards are implemented in a reasonable time-frame. A mechanism, therefore, exists via the accreditation process to effect change in the area of quality and safety in healthcare, and may be further exploited as cost- and risk-effective strategies for improving the quality and safety of healthcare are identified and agreed upon.*

2.2.10.7 Recertification

All the Specialist Colleges now have mechanisms in place whereby specialists recognised by the relevant college can participate in a scheme which documents their “maintenance of practice standards” activities. Some form of recertification has been foreshadowed as a requirement for the ongoing recognition of all specialists, although in most Colleges these schemes are currently voluntary. They are compulsory in the specialties of obstetrics and gynaecology, and for general practice. This is another means whereby mechanisms could be put in place to ensure that practitioners are familiar with or at least have access to up-to-date guidelines. It is expected that conformance with guidelines, clinical pathways and protocols will be greatly facilitated by the spread of information technology, whereby practitioners will be able to access these tools on computers at the point of care.

2.2.10.8 Credentialing

Healthcare facilities have the power to decide who may practice in each facility by requiring prospective practitioners to be “credentialed”, and may specify what areas those who have been credentialed may practice in. Although there are currently no generic mechanisms for controlling what procedures are done by whom, to what standards, or for what indications, credentialing does provide a facility-specific mechanism whereby a local Medical Advisory Board can ensure that certain standards are met and can limit the activities of a medical practitioner who is perceived to have inadequate qualifications or to be practising in a manner deemed unacceptable.

Although formal credentialing of individuals to do certain procedures within particular organisations is common in areas of the United States, this level of specificity with respect to

* A proposal is being developed by ACSQHC and a draft document was presented at the July 2001 meeting of the Australian Ministers for Health.⁵

* ACSQHC plans to set standards for these processes.¹

credentialing is usually not explicit in Australian institutions. However, there is much informal credentialing. For example, in a large teaching hospital only certain anaesthetists at any time would be practising cardiothoracic anaesthesia, or would work in the chronic pain area. No-one in such a department would expect or accept a person practising in these areas unless they had undergone a period of training and acclimatisation and had been informally credentialed.

Medico-legal protection for those credentialing their peers is available under section VC of the Commonwealth Quality Assurance legislation,²³ but has not, to date, been sought. Credentialing is another area, therefore, which does provide a means whereby more control could be exerted over the clinical practice of individuals in the interests of quality and safety, and a mechanism does exist for protecting those credentialing their peers.*

2.2.10.9 Consent

There has been concern that patients may not always be fully informed of the potential risks of procedures they are about to undergo.

A first stage in the process of being able to inform patients about the risks and benefits of a procedure is to have objective evidence as to the status of that procedure with respect to alternative forms of treatment, including no treatment.

A mechanism has now been put into place whereby the safety and efficacy of new procedures can be objectively evaluated in the Australian context. The Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S), under the auspices of the Royal Australasian College of Surgeons, is producing documentation about such new procedures. This organisation classifies procedures into three grades (see Table 9). Note that a grade 3 classification indicates that the safety and efficacy of a procedure has been shown to be unsatisfactory, and that it should not be used.

Table 9: The ASERNIP-S procedure classifications

-
1. Safety and efficacy is established. Procedure is equal to, or better than the nominated gold standard. Procedure may be introduced into practice.

 2. The safety and efficacy of the procedure can not be determined due to an incomplete and/or poor quality evidence-base. One of the following recommendations is made:
 - 2.1 an audit is required
 - 2.2 a controlled clinical trial, preferably prospective with concurrent controls is required
 - 2.3 a randomised controlled clinical trial is required

 3. Safety and efficacy of procedure is shown to be unsatisfactory. Procedure should not be used.
-

It would seem reasonable that moves should be made to research the evidence-base and classify all diagnostic and interventional procedures according to this classification, and that it be a basic requirement that patients be informed as to the classification of the intervention they are about to undergo (see page 16). If indemnity by the Medical Defence Organisations was

* A proposal is being developed by ACSQHC and a draft document was presented at the July 2001 meeting of the Australian Ministers for Health.⁵

contingent on such a consent procedure, a powerful mechanism would be provided to ensure the patients are not unwittingly undergoing procedures which have not been properly assessed and deemed acceptable with respect to safety and efficacy.

This is a contentious area and there is much work to be done. Indeed, for many common well-accepted procedures, the evidence-base may be adequate only for a grade 2 classification, and there are difficult ethical questions about randomisation and patient selection in designing studies of the necessary scientific rigor. This is an area which requires attention, as there are possible alternative qualitative research methods for adding to the evidence-base with respect to forming judgements about the safety and efficacy of existing as well as new procedures.

2.2.10.10 Registration

Mechanisms are in place whereby the practice of medicine by a qualified medical practitioner may be curtailed by a State Medical Registration Board. Recommendations may range from periods of surveillance and/or retraining through to complete suspension of registration. However, it is necessary for a complaint to be made and for this to be sustained. Although this is a mechanism for dealing with serious breaches of practice and conduct, it is not a practical mechanism for enhancing the overall safety and quality of patient care. As has been pointed out by Berwick, if the distribution of quality and/or safety is represented by a bell-shaped curve, then the outcomes from “bad eggs” are represented by the small area under the trailing edge of the curve and those from outstanding practitioners by the area under the leading edge of the curve. Elimination of these bad eggs is both time consuming, difficult and medico-legally risky. It is far better to shift the entire curve to the right by a small amount, as this will achieve a far greater increase in safety and quality overall. The mechanisms for improving the outcomes of *all* practitioners have to be systemic and, as indicated above, are best achieved by redesigning equipment and devices and re-engineering processes so that common problems are simply “designed-out” of the system.*

2.2.10.11 New Mechanisms - adopting an integrated approach

Although some of the mechanisms outlined above have been in place for many years, the evidence is that over 10% of admissions to acute care hospitals in Australia are nevertheless associated with a potentially preventable adverse event (see page 18). It is clear that additional mechanisms are required which are more responsive to problems which have been identified recently and which are effective across all disciplines and the entire spectrum of health care.

The APSF has identified the top 430 principal natural categories of adverse events from the QAHCS and is in the process of identifying the top 1,000 events by combining data from adverse event and incident monitoring studies as well as from other sources of information.**

Many of the problems identified span a range of disciplines and a range of situations in which healthcare is delivered. For example, the anticoagulant warfarin may be prescribed by cardiothoracic surgeons after heart valve surgery, by general and other surgeons after a variety of major procedures, by physicians for patients with recurrent thromboembolic problems and by general practitioners for patients with atrial fibrillation. A variety of loading dose regimens are used, and a variety of protocols used for adjusting ongoing dosage. Therapy may be initiated by a specialist team in an acute-care hospital but ongoing surveillance may be expected to be carried out by a general practitioner. Warfarin is notoriously liable to variations in bio-

* ACSQHC commissioned work on a model for national medical registration which was endorsed, in principle, by the Australian Minister for Health.^u

** A systematic approach is required for making the best use of information already in existence. This is on the agenda of ACSQHC, but no specific steps have yet been taken.

availability and effect as a result of interference by a number of common extrinsic factors (eg concurrent illness, interactions with other drugs). If the effect is inadequate, a patient may suffer an embolic stroke. If the effect is excessive a patient may suffer a haemorrhagic stroke or a bleed elsewhere in the body (eg the gut, the urogenital tract, the retroperitoneal region).

It has been estimated by the APSF that warfarin problems may cost as much as \$100,000,000 each a year in direct medical costs alone.³²

It is clear that the system needs to be re-engineered with respect to warfarin. The role of care pathways for doctors, of patient education, of specially trained nursing or paramedical staff controlling a cohort of patients on warfarin, of anticoagulant clinics, and of practice- or home-based devices for measuring patients' coagulation status, all need to be examined and their relative feasibility and risk- and cost-effectiveness determined in the Australian setting.

This will require multidisciplinary co-ordination at a national level and appropriate funding. There is no question that the current rate of warfarin-related adverse events could be halved by the systematic adoption of better methods for managing this drug. A 10% reduction in this problem alone would pay for a comprehensive Australia-wide incident monitoring and medical record review system.*

Many other problems have been identified from incident monitoring reports and from the QAHCS which will be just as difficult, but also just as rewarding, to deal with in the complex milieu of the health system. The time has come for comprehensive decision support to be introduced for such complex problems. Interventions using computerised decision support that are targeted to specific problems have been shown to be effective in reducing error and cost in health care.^{218 219} The opportunity to use a national database to reduce error holds vast opportunity. The consistency of preventable problems across the health sector, as shown by the QAHCS and AIMS data, is evidence that successful decision support systems would have wide applicability and therefore good cost-benefit.

The recommendations of the Taskforce and Expert Group have been valuable with respect to identifying general areas which require improvement (see Appendices 2 and 3) but we must now begin to address the specific problems that have been identified. Each will need to be thoroughly characterised and solutions found and shown to be cost- and risk-effective in the Australian context. In the words of Berwick, we must "take one hill at a time".⁸⁹

A generic approach to deal with these problems is proposed below.

1. Choose a problem that has been identified.
2. Form a national working party with representatives from key groups, each of whom must be active and have an interest in the relevant area.
3. Characterise the nature of the problem by analysing data from AIMS, QAHCS and the literature.
4. Estimate its prevalence Australia-wide by extrapolation from the QAHCS and by analysis of any other available data.
5. Conduct a literature search using the Cochrane Collaboration Database and other databases to:

* Anticoagulants are to be addressed by the Medications Safety Taskforce which has recently been formed by ACSQHC.⁹

- compare the Australian frequency with the frequency elsewhere
 - identify a range of preventive strategies, and
 - identify a new prevalence if “best practice” was applied
6. Choose strategies thought practical in the Australian context and plan their implementation.
 7. Develop an instrument for measuring the frequency of the relevant problem prospectively.
 8. Organise a national meeting which attracts workers in Australia with an interest or expertise in the area, to prepare and review this information and refine the proposed strategies and measuring tools.
 9. Develop multi-disciplinary, multi-centre research proposals.
 10. Obtain the necessary funds for the proper prosecution of the proposed project/s.
 11. Identify volunteer test sites and gather baseline measurements.
 12. Implement the remedial strategies at the test sites.
 13. Re-measure after a suitable time.
 14. Conduct a follow-up national meeting which would include:
 - cost-benefit calculations of the broader implementation of the preventive strategies
 - planning of methods to implement the strategies across the healthcare system, and
 - identification of indicators or surrogate outcome markers that could be easily monitored to assess the impact of the implementation
 15. Implement the strategies across the health care system.
 16. Ongoing surveillance of the frequency and nature of the problem and repeat the cycle, as necessary. To do this, ongoing information from both AIMS and AMRAS would be necessary.*

* This approach has been suggested for the new taskforces set up by ACSQHC.

Figure 7 - A conceptual framework for safety and quality management in healthcare

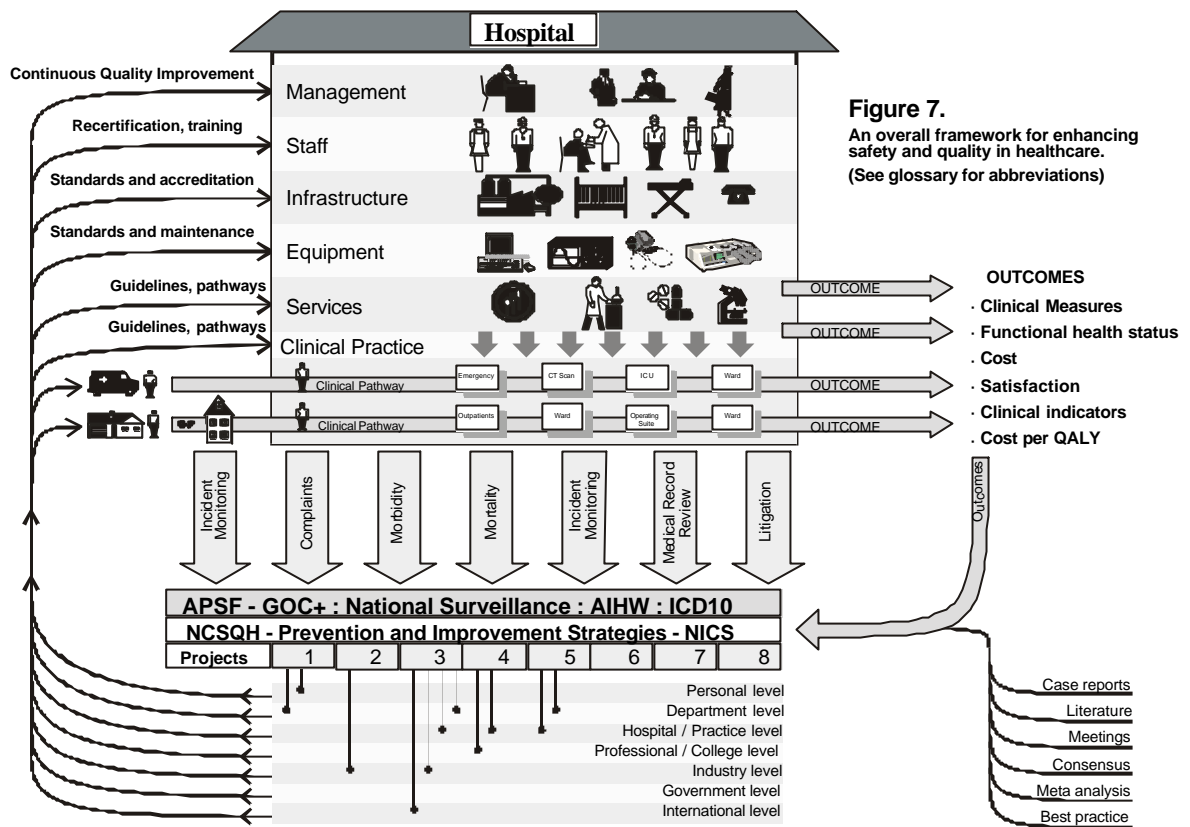


Figure 7. An overall framework for enhancing safety and quality in healthcare. (See glossary for abbreviations)

This is clearly an ambitious and comprehensive approach but components have already been successfully carried out for a number of problems. The basis for this plan was proposed and accepted at a national meeting on Adverse Drug Events which was held in Adelaide in March 1998. Some 13 papers and three editorials were published in the Journal Quality in Clinical Practice as a result of this meeting.^{6b} A limited number of copies of this journal are available on application for those who are active in the area of iatrogenic injury. The Australian Medications Safety Working Group, which was formed to deal with this problem of adverse drug events, is now waiting developments at the national level before progressing to the next stage.*

A further national meeting, on “Incidents and Accidents in Australian Healthcare”, was held in June 1999. Five important areas, identified from the priority list developed from analysis of the QAHCS adverse events, made up the themes for this meeting (see Appendix 8). The model developed at the previous meeting was followed and national working parties were established in each of the key areas.

A table of the top 250 problems that may give rise to iatrogenic injury, in order of frequency of occurrence, has been constructed from the QAHCS and AIMS databases. An extensive phase of data analysis is now required to characterise these problems, and to seek any further information about them that may be available by searching the literature and seeking expert opinions. Much information of direct relevance to these problems in the context of the

* An ACSQHC Medication Safety Taskforce has recently been established.^c

Australian healthcare system can be obtained by exploiting the strengths of the data available from both AIMS and QAHCS and of both qualitative and quantitative approaches.

The big challenge is to respond to these problems appropriately. As indicated elsewhere in this report, this will require substantial investment. With the establishment of the Australian Council for Safety and Quality in Healthcare, an appropriate co-ordinating mechanism has been put into place. One of its first jobs will be to find the necessary funds to begin this task.* It is most important that problems be prioritised on the basis of objective information and each problem be dealt with comprehensively by a single well co-ordinated, scientifically rigorous project. For substantial funds to go towards priority-driven research that contributes directly to population health and evidence-based healthcare is entirely consistent with Chapter 3 of the “Strategic Review of Health and Medical Research” recently published by the Commonwealth of Australia.²²⁰

RECOMMENDATION 15

That the top 250 problems that give rise to iatrogenic injury be characterised, and that systematic steps be taken to identify, fund and implement strategies, co-ordinated at a national level, to deal with these problems in a risk- and cost-effective manner.

* Funding of £1 million pa for the council and of £10 million pa for commissioned work was confirmed at the meeting of Australian Health Ministers in July 2001.

3.1 Overall vision

Iatrogenic injury must be considered in the complex milieu of rapidly advancing technology, increasing complexity, an ageing population, expanding possibilities, greater accountability and increased expectations. All governments are concerned that healthcare costs, if allowed to increase at the rate predicted by current extrapolations, would place an unacceptable burden on society. Most of the factors contributing to iatrogenic injury will become more prevalent, not less, in coming years.

With iatrogenic injury already consuming as much as 2 billion dollars each year in direct medical costs (5% of the total amount spent on health) the time has come for a systematic nationally co-ordinated approach to this problem. The new Australian Risk Management Standard (AS/NZS4360) provides the framework for a structured approach; it has already been used as the basis for a proposal for integrated risk management within the health industry in Western Australia (see Appendix 26).*

3.1.1 Risk management as a basis for operation

Although the concept of risk management is developing in the health sector, a systematic commitment to the reduction of risk to those treated by the health care system has yet to emerge.^{25,26,87,89} The focus is still on damage control, rather than prevention, and is still often viewed in terms of control of risk to governments, health care units and clinicians rather than patients. This is largely due to the pressing nature of immediate medico-legal issues and to the lack of a coherent overview of the nature and distribution of risk to patients.**

The great need in risk management in Australia is to overcome the individual fear of blame or responsibility for costs and to move to a proactive approach to risk identification and management.^{34,58,66}

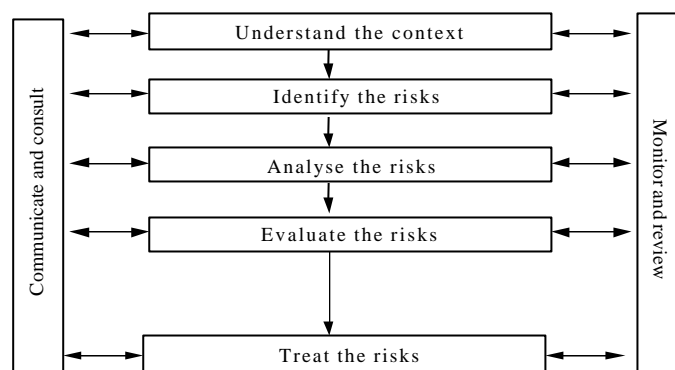
Investment in risk reduction through prevention has been the foundation of progress in the road traffic and aircraft industries for the last 30 years. In these areas, there has been a marked shift from an individual blame base to a systems view of risk reduction and from incident by incident analysis to pooled systematic intelligence. There has been a clear acknowledgement that the system of events is too complex for interventions to be individually identified and implemented in a distributed fashion.

The discussion below will be based on the framework which is used in the new standard AS/NZS4360 - Risk Management.⁸⁴

* It has now been adopted as a framework for ACSQHC and the NHS in the UK.^{d1}

** This has recently been emphasised in a comprehensive text on risk management.^v

Figure 8 - A simple representation of the risk management framework



An approach based on risk management has a number of advantages. First, as it has been successfully applied outside healthcare, it provides a bridge between clinicians and those from other domains who have expertise and experience in risk management that should be applied to healthcare. Second, administrators understand that they are responsible for ensuring that explicit risk management processes are to be in place, and that they are accountable for funds wasted by inadequate risk management (for example, see Appendix 26). By contrast, accountability for poor quality or inept clinical governance is harder to ensure, and performance in these areas, or a lack thereof, is not usually expressed in dollar terms. Third, by bringing clinical risk management under the mantle of overall risk management, and expressing the losses in dollar terms, the amounts that can be saved become tangible to funders and purchasers. This is necessary for arguments to be successful for the large investments necessary for the system changes that will be required if we are to move away from the current ineffective short-term reactive responses to individual iatrogenic injuries, and towards the application across healthcare of remedial measures which have been shown to be effective. In addition, the human cost of iatrogenic injury, both on patients and providers must be kept in mind.

It is clear that three levels of activity are needed. **At the first level**, healthcare units need to develop processes to manage their own risk locally. This would involve, ideally, a combination of incident monitoring and limited clinical and medical record review, appropriate follow-up and implementation of remedial strategies, and ongoing surveillance of problems identified. A good example of such a model in Australia is that in use by the Wimmera Healthcare Group (see Appendix 27).^{*} All research must ultimately be conducted at a local level and the right mix of local ownership of projects and appropriate national co-ordination will be important.

The second level represents co-ordination at a State level of all the local healthcare projects and collation of relevant State-wide data, to ensure that all projects and activities contribute to and are consistent with the strategies developed at the third or national level, and that they are registered at the national level. Ownership at State level of components of the nationally co-ordinated research effort will be important as some of the funds will have to come from the State Departments of Health.^{*}

^{*} Some elements of this have been introduced in Victoria, but incident monitoring is ad hoc and piecemeal and there is no central repository for collecting the less frequent events which make up the bulk of this problem.

^{*} Formal mechanisms for managing this have been developed by ACSQHC.^{f,w}

Activities at **the third level** will require the development of systems to manage risk at a national level. This will require a national iatrogenic injury surveillance strategy that pools information from a number of sources and then identifies, trials and implements appropriate interventions on a system-wide basis. This will require careful analysis of mass data and the implementation of specific studies including the maintenance of incidence registers, case control studies and evaluation of the cost- and risk-effectiveness of promising interventions.

Research should be co-ordinated nationally so that available resources are directed towards properly designed multi-centre, multi-disciplinary projects, rather than the current situation in which they are consumed by small projects, some poorly designed, which are being conducted in isolation in multiple centres by multiple disciplines.

There is unequivocal evidence of the need for a national system to ensure adequate coverage of the problems which arise from the range of processes, techniques and settings in a rapidly evolving healthcare system,^{29,32} and to promote an understanding of the issues among clinicians, administrators, policy makers, researchers and consumers.³⁷ The system must be able to:

- Understand and manage the context, identify and involve the stakeholders, including consumers, and maintain an up-to-date national register of research activities.
- Identify the risks; adequately describe the patterns and costs of iatrogenic injury at health unit level, clinical specialty level and across the health system.
- Evaluate the risks; provide sufficient information at the national level to permit priority setting and the development of intervention techniques.
- Treat the risks; co-ordinate multi-disciplinary, multi-centre studies of the risk-and cost-effectiveness of these intervention techniques.
- Communicate and consult with stakeholders, including consumers, at each level.
- Monitor and review; measure progress in countering iatrogenic injury problems on an ongoing basis once these interventions are in place.

RECOMMENDATION 16

That the standard “AS/NZS4360 - Risk Management” be used as the basic framework for addressing the problem of iatrogenic injury and that those in both clinical and corporate government systems be held accountable for ensuring that explicit clinical risk management processes be put in place, in line with this standard.

3.1.2 Understanding and managing the context

The factors contributing to iatrogenic injury and some important contextual influences have been outlined on pages 12-16. Further work on defining these and determining their relative importance with respect to iatrogenic injury is important, as reform in these areas will have a great impact on the frequency, pattern, impact and cost of iatrogenic injury. Examples of areas which need urgent attention are:

- informing healthcare professionals and consumers about risks in relation to expected benefits and developing mechanisms for doing this, such as producing informative video

tapes and web-based information for each diagnostic or therapeutic intervention (see pages 16, 91 and 92)

- ensuring legal privilege, and, where necessary, anonymity for risk management and quality improvement activities for those at the “coal-face” (see pages 32-33)
- moving towards greater accountability at the system level for iatrogenic injury and its consequences
- reform of the expensive, inefficient and inequitable tort system (see pages 24 and 25)

This will require substantial political will, as there are powerful vested interests that would seek to perpetuate the longstanding complacency in these areas.

The major stakeholders with respect to iatrogenic injury are:

- Governments - State and Federal
- Professions - medical, nursing and paramedical
- Insurers - both health industry and professional indemnity insurers
- Industry - both pharmaceutical and medical device manufacturers
- Health care facilities and their administrators
- Consumers - patients and their relatives

It is important that a balanced mix of representation of the stakeholders be involved in all key aspects and at all levels of the process.

While there is important work to be done in quality assurance at the health unit and clinical delivery level, failure to provide a coherent support and evidence base at a national level is likely to result in a narrow intervention focus and inefficient identification of both problems and solutions. Experience over the last five years has shown that data from the local level is inadequate to drive a comprehensive risk management approach and that the skills necessary to deal with many of the complex issues are not available and cannot be afforded in each health unit.

National leadership, co-ordinating the efforts of all the stakeholders at local, State and national levels is required to develop a proactive and preventive approach to risk management. A necessary first step will be to establish and maintain a register of all relevant research activities and of researchers with interest and expertise in the relevant areas.*

* ACSQHC has commissioned some work to “map” various agencies and projects with an interest in the safety and quality in healthcare.[†]

3.1.3 *Identifying the risks: the essential elements of an iatrogenic injury surveillance system*

3.1.3.1 *Estimation of incidence: medical record review (AMRAS) and ICD-10 coding*

Routine monitoring of adverse events from a representative sample of all Australian hospitals on an ongoing basis is needed to estimate the incidence and distribution of iatrogenic injury. AMRAS is being progressively refined to provide definitions of the various categories of iatrogenic injury which will allow them to be monitored consistently on a population basis, providing time trend and comparative information. At a composite indicator level (broad classes of iatrogenic injury) regional comparisons will be possible. It is estimated that medical record review of approximately 16,000 cases per annum would provide adequate coverage and precision at an acceptable cost (see Appendix 15).

It is important that experience from case note review for the detection of adverse events be used to progressively refine the routine collection of hospital morbidity data and ABS mortality data (see pages 54-59). The GOC has been set up so that cross-mapping may be undertaken between the GOC, used by AMRAS, and ICD-10, used for routine collection of morbidity and mortality data. In this way the strengths of both systems may be exploited.

3.1.3.2 *Detailed description of frequent events: health system-wide incident monitoring (generic AIMS)*

Medical record review does not provide sufficient detail of the events leading to iatrogenic injury to drive intervention development. Generic incident monitoring that reports at the health unit level, but which is also pooled centrally, has the capability of filling this gap and of providing constant feedback to health units. The last five years has shown that anonymously reported incident monitoring provides a rich description of the iatrogenic injury events that occur every day. While health units are most interested in local trends to guide their quality assurance processes, the pooling of data permits sufficient numbers of cases to be collected to identify the common causal patterns. The expertise to undertake this sort of analysis is not available at health unit level and indeed, even if it were available, each health unit would not have sufficient cases of a type to be able to undertake meaningful analysis.

Health units already have shown a desire for monitoring their own iatrogenic injury patterns, but do not want to be burdened with the more detailed coding of information needed for national trends or in-depth analysis. Generic incident monitoring should therefore be based on provision of a service to health units to assist in the collection and processing of their own data. The data systems already in use by the APSF undertake this role and in addition receive the extra text based information required for pooled analysis. Improvements planned for coding systems and streamlining of processes should improve the accessibility and usefulness of data to health units and assist with pooled data analysis. In addition, facilitated incident monitoring based on a selected sample of health care units is required to ensure that the level of detail required to drive prevention is obtained. The units undertaking this level of reporting would need to be externally funded and it would be beneficial if the medical record review system was based on the same sample.

3.1.3.3 Detailed description of high risk settings and procedures: specialty-based AIMS

Specialty-based incident monitoring provides direct access to information about iatrogenic injury patterns associated with the leading technical edge of health care. While the volumes of data processed are much lower than for generic incident monitoring, events are reported with the eye for detail of a specialist in the area. It is clear however that best use of these data can only be made if there is a workable partnership between clinicians, researchers and data managers. None of these groups, in isolation, has the requisite range of skills to make best use of the data by themselves. Where the teamwork has been developed in anaesthesia, a great deal of useful research has resulted in real reductions to iatrogenic injury. Several speciality groups have made a commitment to the process, but operations have been based on short-term pilot project budgets with no known future. Whilst funding the pilot projects has been most valuable, the current funding hiatus has limited progress. If provided with adequate resources on a long term basis speciality incident monitoring provides great promise for early identification of interventions and consequent reductions in iatrogenic injury, particularly in rapidly evolving high-risk areas of practice.*

3.1.3.4 Consumer perceptions of quality of care: complaints and medico-legal incident monitoring

Consumers of health care have a different perspective of iatrogenic injury to those who work within the health care system. It is important to monitor the incidents where the matter is viewed as being so unsatisfactory that a complaint is made or legal action is contemplated. It is also important to ensure that the events that staff are willing to report in generic or speciality based incident monitoring are complemented with events described by patients. Data are already collected on these issues in many hospitals, but these systems focus mainly on administrative matters such as complaints management.¹³⁹ There are also systems in place in each State for handling and collecting complaints. Upgrading of these systems to be more consistent and to report detailed information on complaints and the circumstances surrounding them would add substantially to the coverage of relevant cases in an integrated iatrogenic injury monitoring system, and would inform processes for preventing some of these problems. The National Complaints Information Project is well-placed to co-ordinate this.¹⁴⁰

3.1.3.5 Sentinel event surveillance

It has been proposed that sentinel events, as defined and developed by the Joint Commission in the United States (JAHCo), be used as the main method for surveillance of iatrogenic injury in Australia (See Appendix 27). However, the same problems exist with respect to definitions and reliability of reporting as with incident monitoring. The APSF has evidence that even serious iatrogenic injuries, such as sustaining a fractured neck of femur whilst in hospital, are grossly under-reported. There is little reason to expect that sentinel surveillance would outperform generic incident monitoring in developing an understanding of iatrogenic injury. Also, as sentinel events are exceedingly rare, attention would be paid to only a minuscule fraction of what is going wrong in healthcare. Sentinel events are simply a subset of incidents

* Activity in this most important area has “stalled”, as there has been no funding and no attention given to it, as yet, by ACSQHC.

* This, too, has “stalled” as the project was not funded.

with particularly bad outcomes, and whilst they should be monitored, such monitoring would not constitute an adequate approach to the overall surveillance of iatrogenic injury.**

3.1.3.6 Short term projects

Short term projects of particular procedures or events may supplement routine surveillance, especially where particular details need to be reported. They will be useful for a more in-depth consideration of narrowly defined issues and may be used to provide a profile of the frequency and pattern of a particular event before and after an intervention. AIMS+ is being developed so as to facilitate such projects. However, these methods are not capable of driving the broad priority setting tasks that are required and are likely to be most efficiently used based on the knowledge gained from the broader monitoring activities outlined above.

3.1.3.7 Existing mechanisms

Clinical indicator monitoring. Clinical monitoring and review is most useful at the health care unit level. It assists health care staff to become familiar with basic concepts of risk management and clinical audit and can sometimes lead to important intervention strategies being developed. Further work is needed to improve the reliability and validity of indicator collection if it is to be used in the wider system.

Morbidity and mortality data. These datasets have been described in pages 57-59; it is important that this information be collected and used as a complementary component of the overall process of a comprehensive iatrogenic injury surveillance system.

3.1.4 Evaluating the risks

The software infrastructure for a national data repository will exist by the end of the year 2001 in Australia for information from any source about things that go wrong in healthcare, all of which can be classified using a single comprehensive system (the GOC+, see page 64). GOC+ has been developed from over 50,000 incidents, both generic and specialty-based, all the adverse events in the QAHCS and UTCOS, and collections of reports from medico-legal files, complaints data-bases and coroners' recommendations.

The information from different sources can be coded into this system in a compatible manner so that it can be pooled and analysis of causal patterns and trends undertaken. Current trends towards fragmented decisions on data content and definition in different health units and specialities must be discouraged as this will severely limit the capability of the data to identify and drive preventive activity. Modern data systems are capable of supporting a common core set of information while supporting the short term and special needs of health units, specialities and other users and decision-makers. AIMS+ is being developed so as to serve both local and national needs. Adopting a common set of definitions and typology of adverse events and detailed coding of at least a significant sub-sample of all data collected is vital to the development of information systems capable of meeting the challenge of reducing iatrogenic injury.*

** Attention is now being paid to "sentinel events" in many institutions. There are valid socio-political reasons for this – it is important that activity be seen when something terrible has happened – but this in no way defines or characterises the vast bulk of the things that go wrong in healthcare.

* The process of gaining agreement on a standard "reference model" and definitions of key terms for the safety and quality literature is well underway.¹

Urgent attention needs to be paid to making best use of the data that are already available from all sources including the GOC, the current literature, expert opinion and developments in other jurisdictions (eg the National Patient Safety Foundation in the USA and the National Health Service in the UK). It is clear that the mere existence of data does not result in its effective use. Analytical techniques need to be advanced and resources provided for partnerships between clinicians and researchers aimed at moving forward towards prevention.

To meet these needs a three pronged strategy is required.

- I. Examination of the current data to provide the necessary information for intervention trials in a number of demonstration areas.
- II. Development of an overview of the needs of major users of the data and in response to this a coherent set of detailed data definitions and reporting standards relating to iatrogenic injury.
- III. Training of those with an interest in iatrogenic injury in the proper use of data for assessing risk, identifying causes and developing and testing interventions.

3.1.5 *Treating the risks: the essential elements of an iatrogenic injury management system*

Ways of identifying problems have been outlined on pages 68-73. In some cases no further evaluation may be necessary, as it may be quite obvious what the problem is and what should be done about it. If this is clearly cost- and risk-effective then elaborate studies are not necessary. More often, however, a detailed evaluation from relevant available sources of information will need to be undertaken, the status of the problem established both internationally and in Australia, and information from all sources exploited in order to come up with preventive strategies (see pages 75-83).

3.1.5.1 Determining causes

The causes of iatrogenic injury appear to be systemic. The remarkable constancy of pattern across the Australian and US healthcare systems for serious injuries bears witness to the fact that despite all of the differences in structure, training and practice, similar patterns of iatrogenic injury are observed.²⁸ It is likely therefore that the determination of causes will not be able to be based on measurement of single causal factors but must involve analytical techniques that are capable of dealing with a complex system of events. Traditional medical research and the clinical paradigm will only be able to deal with a small proportion of the causal relationships. Collaboration with safety engineers, cognitive psychologists and professional agents for change will be needed. Some important contacts have already been made in these areas and it will be necessary to continue and broaden collaboration with experts outside the healthcare domain.

Progress indicators will include:

- Rapid identification of straightforward causal links by direct observation.
- Utilisation of traditional research techniques to identify common but more complex causes.
- Development of new research models that are capable of handling rare problems and complex system interactions.

3.1.5.2 Setting priorities

In such a complex area priority setting is vital. The problem is so large and diverse that it will be easy to continue to approach the quest for solutions in an inefficient manner. Many of the recommendations made by the Taskforce and the Expert Group are general in nature, and do not assist health practitioners or researchers in deciding where to start or what to do.

Traditionally, priorities have been set on mortality and severe injury rates. A broader approach is required here because much of the cost of iatrogenic injury is created by high frequency, relatively low severity events. National priorities need to be identified on the basis of frequency, severity and amenability to risk reduction. Australia is the only country that has access to information from a national study of adverse events, and evidence-based priorities can be set. Some areas for attention have already been identified,^{29,30} but more detailed costing is needed. It is intended to identify the “top 1000” things that go wrong and suggest how they should be addressed. There is an urgent need for a national register of researchers and research projects in this area, and for funds to be earmarked for those who participate in strategically directed research.

3.1.5.3 Developing interventions

The work with anaesthesia has demonstrated that systematic monitoring, in depth analysis and co-operation within a professional group can lead to the identification and implementation of appropriate interventions (see pages 82-88). Replicating this approach across the complex web of services and techniques is not a simple matter. Systematic investment is needed to develop applied research teams to undertake the development, testing and implementation of interventions. Progress indicators will include

- The availability of resources to effectively utilise those data that are currently available to identify possible interventions.
- Commitment to the development and testing of possible interventions across a broad range of services and settings.
- Documentation of new interventions, evidence for their effectiveness and plans for implementing them system wide.

3.1.5.4 The need for national strategies

Those providing health care services are currently bearing much of the burden of researching iatrogenic injury, but are usually developing solutions for local use only.

While the development of interventions at health unit and specialty level is laudable, such fragmented approaches are likely to be cost inefficient due to duplication of effort. A program aimed at identifying and developing national risk management and prevention strategies is needed to cost effectively deal with iatrogenic events and injuries. Both priority setting and strategy development require a high quality surveillance system to operate on a continuing basis. Research at a local level should always be regarded as being directed towards producing one piece of a “jigsaw puzzle” for the national picture (see page 85). The focus should always be on producing practical tools that can be implemented across the entire healthcare system. Nevertheless, care must be taken to ensure that there is local ownership and recognition for researchers at health care unit level, as, ultimately, this is where the research must be undertaken and where the implementation of strategies will take place.

3.1.5.5 Investment oriented philosophy

There is a need to move toward an investment oriented philosophy. Road safety has for years taken this approach. By investing in prevention, it has made significant savings and been able to fund research into better prevention.

This philosophy has not been prominent in the health sector. However, it is clear that prevention is not a luxury that should only be afforded when possible at some indefinite time in the future, but should be an integral part of the current strategy to increase the efficiency of the health system.

The move to an investment based philosophy will require much better costings to be undertaken, the estimation of benefit/cost ratios and a commitment to actively manage the savings made through prevention. Savings must be identified and returns on investment used to fund further preventive measures.

3.1.6 Communication and consultation

3.1.6.1 Stakeholder involvement

Implementation of effective solutions can only be done with the participation and co-operation of the full range of stakeholders, including clinicians, administrators, policy makers and consumers. The involvement of opinion leaders at all levels has been a major focus of AIMS development. This needs to be expanded in order to facilitate progress in the most difficult phase - that of change and the implementation of interventions.*

3.1.6.2 Multidisciplinary co-operation

The breadth of issues to be dealt with will require wide multi-disciplinary co-operation. The solutions to some clinical issues will not be clinical solutions and the research models required will not be health research models. It is essential therefore to cultivate the involvement of all necessary disciplines and to involve each discipline in the area where it has most expertise, in partnership with all other relevant disciplines.

3.1.6.3 Quality processes

Using existing processes and networks which have been developed for quality improvement in health units and local monitoring of iatrogenic injury are core components if interventions are to be implemented efficiently and effectively. Specialty involvement is also vital to ensure development of risk control measures with respect to rapidly evolving diagnostic and treatment techniques. The decisions to be made in these areas, however, need to be linked firmly to an overall picture of the problem. The nature and distribution of the iatrogenic injury problem means that it cannot be properly identified and responded to without a consistent multidisciplinary overview across the health system. Some of the most damaging and expensive problems identified to date have “orphan” status in that they do not fall firmly under the purview of any particular group (eg thromboembolism and management of anticoagulants, the early diagnosis of cancer, the co-ordinated care of ischaemic heart disease and respiratory problems).

* ACSQHC has developed a consumer focus and one of its five standing working parties is to ensure consumer involvement.[†]

3.1.7 *Monitoring and reviewing: measuring future progress*

Despite its size and cost, there is still a very limited understanding, even internationally, of the scope and nature of preventable iatrogenic injury. Lack of clear definitions and a typology of iatrogenic injury mean that it is hard to make comparisons of patterns in Australia or internationally.

The recent work done by the APSF and the Harvard School of Public Health on the QAHCS and UTCOS has shown that what appeared to be significant differences in the frequency of iatrogenic injury between Australia and the US were due to artefacts of measurement, definitions and documentation systems.^{27,28} Active collaboration is continuing between the APSF and key researchers in other areas to work towards terminologies and systems that can be applied both nationally and internationally.

Progress indicators will include:

- Development of a nationally and internationally accepted typology for iatrogenic injury and agreed means of undertaking quantitative measurement of key composite indicators.*
- Development of a systematic epidemiology of iatrogenic injury.
- National and international strategies for measuring and exchanging information about iatrogenic injury.**

3.1.7.1 *Measuring outcomes*

The health industry has developed a sharp focus on measuring outcomes. Unfortunately this is more rigorously applied to emerging areas of interest than those that have existed for some time. As an emerging area of study, iatrogenic injury experiences greater demands for evidence of effectiveness than is commensurate with the resources provided to generate the evidence and the techniques available to create the evidence base required. Outcomes need to be measured at two levels. Firstly, measurement of the effect size of a proposed intervention. Secondly, measurement of the impact of system wide implementation of multiple interventions. The first is straightforward where the intervention is applied as a single intervention at the patient level. The gold standard here is the Randomised Controlled Trial (RCT). However as soon as the intervention becomes multi-modal or the point of intervention moves to a system or process, the capacity of traditional models to evaluate the effect is limited. System wide assessment of impact of a program of interventions is a more complex issue. New evaluation techniques are needed before systematic measurement of outcomes is feasible.

Progress indicators will include:

- Development of a research infrastructure to build the evidence base for iatrogenic injury prevention.
- Development of improved methods of measuring effectiveness and effect size of systems-based interventions.
- An emerging evidence base for iatrogenic injury prevention.

* This project has started.^j

** The journal Quality in Healthcare is to be renamed Quality and Safety in Healthcare by BMJ, and published and launched in March 2002 with a new editorial board.^w

- Measurement of system wide reduction in iatrogenic injury.

It is premature to assess outcomes in terms of changes in rates and patterns of iatrogenic injury. The lead-time to these changes is probably three to five years with the greatest benefits being seen in about ten years. It takes this long to identify interventions, test them, negotiate implementation and measure results. For example, evidence of a substantial reduction in deaths attributable to anaesthesia since the introduction of the new monitoring guidelines in the early 1990s was published only recently.⁴⁷

3.1.8 Benefits to key stakeholders

The following summarises the kinds of benefits that can accrue as a result of operating injury surveillance and patient safety systems more broadly in the Australian health care system. These include:

To the tax-payer

- improved output from the public health sector, with no additional taxation impost
- reassurance that the money allocated is not being wasted

To the patient

- increased safety while under the care of health service providers
- minimised risk of avoidable long term disability or death
- improvement in likelihood of better health outcomes
- improvement in confidence and satisfaction with the health-care system

To practitioners/staff

- improvement in conditions through the identification and revision of issues shown to be contributory to adverse events
- increased locus of control through participation in incident monitoring in a culture of continuous improvement
- decreased stress through a decrease in the number of adverse incidents
- protection under quality assurance legislation
- a smaller chance of being sued

To ward/divisional management

- feedback on the frequency and type of local incidents
- monitoring of local preventive interventions, protocols and procedures
- comparison with organisational benchmarks
- meaningful involvement in a broad patient safety movement.

To the health care unit or supervening corporation

- investigation, analysis and review of incidents which occur within the organisation, in both aggregated form, and broken down by location, division etc.
- improved systems and integration between systems and divisions through continuous improvement

- reduced costs associated with increased or unplanned procedures or treatment and/or readmission
- reduced costs through lower insurance premiums, and the avoidance of potential litigation with its associated, legal defence and court costs
- facilitated targeting of interventions to problem areas
- information input into quality assurance processes
- monitoring organisational performance compared to benchmarks

To State and Territory Governments

- reduced costs for compensation
- reduced re-insurance costs
- reduced number of iatrogenic cases treated (avoidance of "iatrogenic cascade")
- reduced waiting lists
- reduced unplanned re-admissions
- higher rate of individual patients treated
- reduced opportunity cost
- increased efficiency

To the Commonwealth Government

- increased efficiencies under the Australian Health Care Agreements
- decreased costs for the Medical Benefits Schedule system
- decreased costs for the Pharmaceutical Benefits Schedule system
- increased quality of the national health care system
- improved population health outcomes

To the professional bodies/medical colleges/training institutions

- being pro-active in addressing the dictum "*primum non nocere*"
- satisfying professional pride
- quality improvement
- assistance with the development of useful clinical indicators and guidelines

3.2 Structures required

3.2.1 National and state iatrogenic injury prevention co-ordination groups

The July 1999 meeting of the Australian Ministers for Health endorsed the prime recommendation of the Expert Group, that an Australian Council for Safety and Quality in Health be established, and pledged \$1 million per year for 5 years. It has also been decided to establish a National Institute for Clinical Studies under the auspices of the NH&MRC, with some cross-membership with the Australian Council. This will provide an opportunity for clinical risk management to be co-ordinated at a national level. There is a need for similar bodies at State level to help co-ordinate these activities. Suitable bodies already exist in some

States, but will need to be set up in others. These bodies could then identify and support working groups.*

Given the systemic nature of the problem, it would be unwise to set up working groups that are focussed on a single profession or discipline. Specific issue multi-disciplinary national working groups that exist only until an issue is dealt with seem the best option. This is being used successfully by the APSF in anaesthesia, for adverse drug events and for a number of other areas. There is a need to identify priority issues at a national level and co-ordinate activities at national, State and local levels. The national co-ordinating group should minimise duplication by States by ensuring information is interchanged and by assisting with negotiating different complementary emphases by State working groups covering similar areas.* The challenge will be to harness the considerable energy, enthusiasm and expertise which is currently being dissipated on many small projects, so that it can be directed efficiently into national initiatives.

In June 1999 a Conference on “Incidents and Accidents in Australian Healthcare” attracted a great deal of interest. One of the most striking findings to emerge from the discussions was the huge number of small pieces of research and attempts at intervention that were being undertaken within the limitations of health care unit budgets. Few of these interventions or the research relating to them were being conducted in a systematic fashion that could result in the creation of a sound evidence base. In addition, there was massive duplication of effort. There is an urgent need to co-ordinate these efforts; a government-led mechanism to do this is now in place.

3.2.2 An Australian Health System Safety Surveillance Unit

Surveillance data collected by even large health care units does not provide a sufficient base for dealing with 75% of iatrogenic injury issues (see pages 18 and 19). It will therefore be necessary to pool data from many sites to permit enough cases to be generated to study the less frequent types of iatrogenic injury.

Each health unit wishes to collect information about iatrogenic injury to manage its own affairs. Given the number of cases reported and the resources available, health units have opted to collect and process only relatively simple data. This type of data is not particularly useful in assessing causal factors or for developing preventive strategies.* In order to gain the more detailed data needed, text data from reporting systems must be used with extensive coding, particularly of relevant contextual and contributing factors. To date this has been on an “as available” basis. A more structured approach is needed.

An Australian Health System Safety Surveillance Unit (AHSSSU) would co-ordinate the systematic collection of detailed incident data from a sample of health care units and specialities. The health units would be chosen to cover the full range of services provided and facilitated reporting systems in these units would optimise both the level and quality of reporting. In addition, the AHSSSU would oversee and process information from a national medical record review system. The information from this system would provide the AHSSSU

* These bodies have been established, with mechanisms for co-ordination between them.^f It was confirmed at the July 2001 meeting of the Australian Ministers for Health that \$10 million pa would be made available for the work of ACSQHC, and arrangements have been agreed upon for how contributions from the states may be met, in part, “in kind”.^w

* Detailed information may be obtained by applying “root cause analysis” to individual cases. However, the particular circumstances may not occur again in that institution and there is currently no mechanism for this information to be added to a national pool of such information.

with additional case data and with control data for use with incident monitoring data. The base of these systems would be a rolling stratified sample of health care units constructed to permit the estimation of national trends in compound indicators of key types of iatrogenic events. AIMS and AMRAS have been developed to undertake these tasks. The use of a common sampling base enables comparison of data using different methods and a better estimation of the overall error of measurement through direct comparison of case identification at unit record level.

This would mean that health care units that wished to participate would be involved with the collection of simple data for their own purposes that would be shared with the AHSSSU in order to make sure that no important issues were being overlooked by the sample-based, more detailed system. The national sample of health care units, stratified to cover all major health care unit types, could then be supported to undertake detailed facilitated incident reporting. One fifth of the sample would be rolled over each year to increase the total number of health care units covered in a ten-year period. (This sampling method has been used in the UK, Holland and the USA for injury surveillance systems.) The pooled data would then be used to undertake detailed studies of patterns of iatrogenic injury and routinely report on priority issues.*

In addition, in collaboration with, and under the auspices of, the AIHW, AHSSSU would monitor hospital separations data, ABS deaths data and MBS and PBS data of relevance to iatrogenic injury, and seek to develop formal links with the new National Coronial Information System⁴⁰ as well as with State and local complaints and medico-legal databases.

It is important that such a system be set up properly and a feasibility and design study is required to develop the sampling design and provide estimates of running costs.

RECOMMENDATION 17

That the Commonwealth, States and other parties who may benefit from a reduction in iatrogenic injury, fund a feasibility and costing study of a linked facilitated incident monitoring and medical record review system, based on a stratified sample of health care units, to produce information on the incidence, causes and possible preventive strategies for iatrogenic injury.

3.2.3 Cost sharing

The study of iatrogenic injury is important, but it will require funding. It is recommended that the costs of such a system be based on a beneficiary pays basis. The major beneficiaries will be those who fund health care in Australia, the Commonwealth and State governments and the health insurers. Table 10 provides a broad map of funding sources for the recommended activities.

* An alternative, currently proposed, is that details of all problems with serious outcomes, those which are informative or interesting, and a random sample (to allow trends to be followed) be sent forward from each collection for coding and inclusion in a national database.

Table 10 - Structure and funding of iatrogenic injury surveillance and research

Function	Method	Source of funding
<i>Health care unit level monitoring of iatrogenic injury</i>	<ul style="list-style-type: none"> Health unit based incident monitoring (generic-AIMS) 	<ul style="list-style-type: none"> State Health departments for the public sector Health insurers for the private sector
<i>National monitoring of iatrogenic injury</i>	<ul style="list-style-type: none"> Australian Medical Record Review System (AMRAS) Specialty-based facilitated incident monitoring (specialty-AIMS) National repository for: <ul style="list-style-type: none"> Sentinel events Incidents with bad outcomes Interesting/informative incidents Random sample of incidents Complaints Medico-legal claims Coroners' recommendations Case reports Letters to the Editor Morbidity and mortality data 	<ul style="list-style-type: none"> Commonwealth Department of Health and Aged Care (AMRAS) Medical Defence Organisations, professional bodies, and "user-pays" (specialty-AIMS)
<i>Identification and evaluation of prevention strategies</i>	<ul style="list-style-type: none"> Analysis of mass data Register of relevant research projects and organisations Funding national working parties and taskforces Studies of cost- and risk-effectiveness of interventions Randomised controlled trials and other evaluation studies Ongoing post-intervention surveillance 	<ul style="list-style-type: none"> Commonwealth Department of Health and Aged Care Australian Council for Safety and Quality in Health State Health departments using Medicare Agreement funds for safety and quality NH&MRC Health insurers Producers and distributors of medications and devices used in health care Philanthropic and other research funding organisations

That the Commonwealth, States and other parties who may benefit from a reduction in iatrogenic injury, fund an Australian Health System Safety Surveillance Unit as a Collaborating Unit with the Australian Institute of Health and Welfare to develop and co-ordinate the surveillance and monitoring of iatrogenic injury and to contribute to research relevant to iatrogenic injury in Australia.*

* As indicated in the “Note to Readers” on page I, release of this document was delayed until some substantive reports and recommendations by ACSQHC had been “signed off” by the Australian Ministers for Health at their July 2001 meeting. A surprisingly high proportion of its contents remain directly relevant in spite of frenetic activity both nationally and internationally since its original submission in August 1999.

An author of this report (WBR) is President of the APSF and is also a member of ACSQHC, a situation which involves a potential conflict of interest. Such conflicts also exist for other members of ACSQHC and quite explicit and comprehensive procedures have been established and endorsed by Ministers to deal with this situation.^x WBR has already indicated to Council that he has a potential conflict of interests in many of the Council’s areas of activity and will be guided by Council as to which processes he should not participate in.

Had ACSQHC not come into being, the APSF would have continued to try to act as a national broker and co-ordinator for information and activities of relevance to patient safety. With the formation of ACSQHC, however, the APSF gave a commitment to Bruce Barraclough, Chair of ACSQHC, that it would co-operative and collaborate with ACSQHC in such a way that ACSQHC would clearly be seen to be the lead body for patient safety in Australia, with carriage of responsibility for informing and involving the many stakeholders and constituencies with an interest in patient safety, including the media. It is clear that it is entirely appropriate and desirable for ACSQHC to be leading reform with respect to setting national policy and standards for safety and quality in healthcare via action in areas such as registration, accreditation and credentialing, and to be acting as the hub and co-ordinator of collaborative activities with purchasers, suppliers, providers and consumers of healthcare.

This raises the question of the future role of the APSF. Most of the original aims of the APSF, set out in 1988,¹⁹ are still relevant and appropriate. In a preamble to setting out the aims of APSF, it was stated “it is not the intention of the APSF to compete with or duplicate the functions of any existing organisation, nor to act in any way as a regulatory body, but rather to promote, co-ordinate and complement activities relating to patient safety, to provide a forum for the free interchange of ideas, and to act as a clearing house for information”. The APSF remains committed to these principles.

The specific aims of the APSF outlined in 1988 were:¹⁹

1. to conduct equipment evaluation studies
2. to organise and conduct “workshops” and “think-tanks”
3. to organise and conduct educational activities and courses
4. to prove handbooks and manuals for procedures and equipment
5. to promote, organise and co-ordinate incident reporting and critical incident reporting studies
6. to promote, conduct workshops in, and carry out medical decision-making analyses
7. to promote, advise on and co-ordinate the setting up of computer-orientated anaesthetic records and records of procedures
8. to offer services relating to patient safety
9. to act as a clearing house for information
10. to be self-funded

Aims 2, 5, 8, 9 and 10 now constitute the main areas in which the APSF is active. Involvement in some major initiatives in patient safety in the USA and UK have provided an international focus, as has, for example, APSF personnel being involved in the project being conducted under the auspices of ACSQHC to standardise the definitions of key terms in the safety and quality literature.^j

ACSQHC is setting standards for basic requirements in the safety and quality area, all entirely consistent with the recommendations in this report, and will be commissioning or letting tenders for work in some of these areas. It is the intention of the APSF to remain in the vanguard of the patient safety movement by continually advancing concepts in this area, facilitating discussion and debate, and developing and continually improving working tools for applying strategies identified for the progressive improvement of patient safety. APSF will continue to support the pre-eminent role of ACSQHC in promoting safety and quality in healthcare in Australia and will remain active in its areas of interest by competing on the open market, in collaboration, where necessary, with others, for a role in those aspects of patient safety in which it believes it is able to provide the best systems and most useful contributions.

References

1. Moser RH. Diseases of Medical Progress, *New England Journal of Medicine*, 255 (13), 1956; 255(13): 606-614.
2. Cited in "Clinical Pharmacology", cover page, Eds, Laurence DR and Bennett PN, Churchill Livingstone, London, 1995.
3. Cited in "The Concise Oxford Dictionary of Quotations", Oxford University Press, London, 1964, pp. 14.
4. Dedication to "Essays on the First Hundred Years of Anaesthesia", Sykes WS, Volume 1, pp.1, Churchill Livingstone, London, 1960, pp.1.
5. Mills DH. Report on the Medical Insurance Feasibility Study, Sutter Publications, San Francisco, 1977.
6. Brennan TA, Leape LL, Laird N, et al. Incidents of adverse events and negligence in hospitalised patients: results of the Harvard Medical Practice Study I. *New England Journal of Medicine*, 1991; 324: 370-376.
7. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalised patients: results of the Harvard Medical Practice Study II. *New England Journal of Medicine*, 1991; 324: 377-384.
8. Thomas MJ, Studdert DM, Newhouse JP. Costs of Medical Injuries in Utah and Colorado. *Inquiry*, 1999, 36:255-264.
9. Wilson RMcL, Runciman WB, Gibberd RW, et al. The Quality in Australian Healthcare Study, *The Medical Journal of Australia*, 1995, 163 (9): 458-471.
10. Medical Defence Union, London.
11. Tito F. Compensation and Professional Indemnity in Healthcare, Final Report, Australian Government Publishing Service, Canberra, November 1995, p. 206.
12. Tjong R. Chairman's Report, *United Medical Protection Journal*, 1999, 3: 3-5.
13. Harrison's Principles of Internal Medicine, 13th edition, Eds Isselbacher KJ, Braunweld E, Wilson JD, et al, McGraw-Hill, New York 1994.
14. Trent JC, Gaster E. Anesthetic deaths in 54,128 consecutive cases. *Annals of Surgery*, 1944; 119: 954-8.
15. Ruth HS. Anesthesia Study Commissions, *Journal of American Medical Association*, 1945, 127: 514-17.
16. Holland R. Special Committee Investigating Deaths Under Anaesthesia: report on 745 classified cases, 1960-68. *The Medical Journal of Australia*, 1970, 12: 573-94.

17. Holland R. Anaesthesia-related mortality in Australia. In *Analysis of Anaesthetic Mishaps* (eds Pearce EC and Cooper JB), Little, Brown and Company, Boston. *International Anesthesiology Clinics*, 1984, 22: 61-71.
18. Holland R. Anaesthetic mortality in New South Wales. *British Journal of Anaesthesia*, 1987, 59: 834-41.
19. Runciman WB. The Australian Patient Safety Foundation, *Anaesthesia and Intensive Care*, 1988, 18 (1): 114-116.
20. Runciman WB. Report from the Australian Patient Safety Foundation: Australasia Incident Monitoring Study. *Anaesthesia and Intensive Care*, 1989, 17:107-108.
21. Runciman WB, Holland RB. Symposium - The Australian Incident Monitoring Study. *Anaesthesia and Intensive Care* 21, 1993,(5): 502-694.
22. Tito F. *Compensation and Professional Indemnity in Healthcare, Final Report*, Australian Government Publishing Service, Canberra, November 1995, pp. 6.
23. Health Services, *Quality Improvement Act 1994; Health Insurance Act (Part VC)* (Commonwealth).
24. Report on "Incident Monitoring and Risk Management in Health Care", Commonwealth Department of Health and Family Services, November, 1994.
25. *The Final Report of the Taskforce on Quality in Australian Healthcare, The Taskforce on Quality in Australian Healthcare*. Australian Government Printing Service, Canberra, 1996.
26. *Implementing safety and quality enhancement in healthcare. Final report to Health Ministers from the National Expert Advisory Group on Safety and Quality in Australian Healthcare*, July 1999. Commonwealth Department of Health and Aged Care web-site at: <http://www.health.gov.au/hsdd/nhpq/pubs.htm>.
27. Thomas EJ, Studdert DM, Runciman WB, et al. A comparison of iatrogenic injury studies in Australia and America 1: context, methods, casemix, population, patient and hospital characteristics. *Quality in Healthcare*, 1999, 12(5):371-378.
28. Runciman WB, Webb RK, Helps SC, et al. A comparison of iatrogenic injury studies in Australia and America 2: a review of behaviour and quality of care. *The International Journal for Quality in Healthcare*, 1999, 12(5):379-388.
29. Runciman WB, Edmonds M, Sexton EJ, et al. Setting priorities for patient safety in Australia. For submission to the *Medical Journal of Australia*.
30. Runciman WB, Edmonds M, Douglas T, et al. A tool for facilitated incident monitoring. For submission to the *Journal of Quality in Clinical Practice*.
31. Runciman WB, Edmonds M, Pradhan M, et al. On the attribution of outcomes to adverse events in healthcare. For submission to the *British Medical Journal*.
32. Rigby K, Moller J, Runciman WB, et al. On costing of adverse events in healthcare. For submission to the *Journal of Quality in Clinical Practice*.

33. Public opinion of patient safety issues: research findings. National Patient Safety Foundation at the AMA, 1997, Chicago.
34. Leape LL. Error in medicine. *Journal of American Medical Association*, 1994, 272: 1851-1857.
35. Hilfiker D. Facing our mistakes. *New England Journal of Medicine*, 1984, 310: 118-122.
36. Christensen JF, Levinson W, Dunn PM. The heart of darkness: the impact of perceived mistakes on physicians. *Journal of General Internal Medicine*, 1992, 7: 424-431.
37. Berwick DM. E.A. Cogman and the rhetoric of battle: a commentary. *Milbank Q*, 1989, 67: 262-267.
38. McIntyre N, Popper KG. The critical attitude in medicine: the need for a new ethics. *British Medical Journal*, 1989, 287: 1919-1923.
39. The Macquarie Dictionary, 1981, Macquarie Library Pty Ltd, Sydney.
40. Runciman WB. Incident monitoring, *Clinical Anaesthesiology. Quality Assurance and Risk Management in Anaesthesia*, 1996, 10(2): 333-356.
41. Kasperson RE. Acceptability of human risk. *Environmental Health Perspectives*, 1983, 52: 15-20.
42. Zelders T. Patient risks: an underdeveloped area. *Journal of Clinical Monitoring*, 1996, 12: 237-241.
43. Kietz TA. The risk equations. *New Scientist*, May 12 1977: 320-322.
44. Dinman BD. The reality and acceptance of risks. *Journal of the American Medical Association*, 1980: 244: 1226-1228.
45. Pochin EE. The acceptance of risks. *British Medical Bulletin* 1975; 31: 184-190.
46. Davis K, Personal communication, Transfusion Medicine Department, Institute of Medical and Veterinary Science, Adelaide.
47. Davis NJ. Anaesthesia related mortality in Australia 1994-1996. Report of the Committee convened under the auspices of the Australian and New Zealand College of Anaesthetists, 1999.
48. Semmens JB, Lawrence-Brown M, Fletcher DR, et al. The quality of surgical care project: a model to evaluate surgical outcomes in Western Australia using population-based record linkage. *Australia and New Zealand Journal of Surgery*, 1998, 68: 397-403.
49. Semmens JB, Lawrence-Brown M, Norman PE, et al. The quality of surgical care project: benchmark standards of open resection for abdominal aortic aneurysms in Western Australia. *Australia and New Zealand Journal of Surgery*, 1998, 68: 404-410.
50. Garcia-Martin M, Lardelli-Claret P, Bueno-Kavanillas A, et al. Proportion of hospital deaths associated with adverse events. *Journal Clinical Epidemiology*, 1997, 15(12): 1319-1326.

51. Reason J. The contribution of latent human failures to the breakdown of complex systems. *Philosophical Transactions of the Royal Society, London*, 1990, 327: 473-484.
52. Reason J. Safety in the operating theatre - Part 2: Human error and organisational failure. *Current Anaesthesia and Critical Care*, 1995, 6: 121-126.
53. Gaba DM, Maxwell M, DeAnda A. Anaesthetic mishaps: breaking the chain of accident evolution. *Anesthesiology*, 1987, 66: 670-676.
54. Gaba DM, Fish KJ, Howard SK. *Crisis management in anesthesiology*, 1994, Churchill Livingstone, New York.
55. Williamson JA, Webb RK, Sellen A, et al. Human failure: An analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21 (5): 678-683.
56. Webb RK, Russell WJ, Klepper ID, et al. Equipment failure: An analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21 (5): 673-677.
57. Runciman WB, Webb RK, Lee R, et al. System failure: An analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21 (5): 684-695.
58. Runciman WB, Sellen A, Webb RK, et al. Errors, incidents and accidents in anaesthetic practice. *Anaesthesia and Intensive Care*, 1993, 21 (5): 506-519.
59. Currie M, Mackay P, Morgan C, et al. The "wrong drug" problem in anaesthesia: An analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21:596-601.
60. Feyer AM, Williamson AM. A classification system for causes of occupational accidents for use in preventive strategies. *Scandinavian Journal of Work Environment and Health*, 1991, 17: 302-311.
61. Reynolds F. Dural puncture: avoid the first but treat the second. *British Medical Journal*, 1993, 206: 874-875.
62. *Clinical evidence - a compendium of the best available evidence for effective health care.* British Medical Journal Publishing Group, 1999, 1: 1-598.
63. *Rogers v Whitaker*, 175 Commonwealth Law Review, 1992, 479.
64. *Tai v Saxon*, Supreme Court of Western Australia (unreported), 8 February 1996.
65. Hooper J, Risk Manager, Royal Adelaide Hospital, personal communication, 1999.
66. Leape LL, Woods DD, Hatlie MJ, et al. Promoting patient safety by preventing medical error. *Journal of the American Medical Association*, 1996, 280(16): 1444-1447.
67. Mathers C, Penn R. Health system costs of injury, poisoning and musculo-skeletal disorders in Australia 1993-1994, AIHW Health and Welfare Expenditure Series, Canberra, 1999, p. 2.
68. Mathers C, Penn R. Health system costs of injury, poisoning and musculo-skeletal disorders in Australia 1993-1994, AIHW Health and Welfare Expenditure Series, Canberra, 1999, page xiii.

69. Rigby K, Clark RB, Runciman WB. Adverse events in health care: setting priorities based on economic evaluation. *Journal of Quality in Clinical Practice*, 1999, 19(1): 7-12.
70. Bates DW, Cullen D, Laird N, et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. *Journal of the American Medical Association*, 1995, 274: 29-34.
71. Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalised patients. *Journal of the American Medical Association*, 1997, 227: 307-311.
72. McNeil JJ, Leeder SR. How safe are Australian hospitals? *Medical Journal of Australia*, 1995, 163(9); 172-174.
73. Moller J. Estimated lifetime cost of injury in Australia 1995-97. National Injury Surveillance Unit, 1998.
74. National Injury Surveillance Unit Routine Injury Data Mortality Tables, unpublished data, 1999.
75. Markic J. South Australian Health Commission, personal communication, 1999.
76. Calculated from membership numbers and premiums, *United Medical Protection Journal*, 1999, vol. 2: pp. 3-4.
77. Tomkins C. *The Journal of the Medical Defence Union*, July 1998: 2-4.
78. Lilienthal C. Is there a medical malpractice crisis? *The Journal of the Medical Defence Union*, July 1988: 1.
79. Studdert DM, Burstin HR, Zhar BIW, et al. Suing for medical malpractice in Utah and Colorado in 1992. Submitted to *Medical Care*, 1999.
80. Jones I. The emotional stress of litigation. *The Journal of the Medical Defence Union*, July 1997: 4-6.
81. Gerber P. *Lipovac v Black: was Dr Black negligent? Yet another aberration of the legal system?* *Medical Journal of Australia*, 170: 550-552.
82. Hunter A. Tort law reform, *United Medical Protection Journal*, 1999, 2: 23-24.
83. Leatherman S, Sutherland K. Evolving quality in the new NHS: policy, process, and pragmatic considerations. *Quality in Health Care* 1998, 7(suppl): S54-S61.
84. The Australian Standard AS/NZS4360 - Risk Management. Web-site: <http://www.standards.com.a>
85. Evans D. Falls research in acute and residential care, for submission to the *Journal of Quality in Clinical Practice*, 1999.
86. Towards the safer use of drugs and blood products in Australia. *Journal of Quality and Clinical Practice* 1999, 19(1): pp. 1-72.

87. Buchan H. Different countries, different cultures: convergent or divergent evolution for healthcare quality? *Quality in Healthcare* 1998 (suppl): S67-S67.
88. The Committee of Presidents of Medical Colleges. Secretariat, c/o the Australian and New Zealand College of Anaesthetists, 630 St Kilda Road, Melbourne.
89. Berwick DM. A primer on leading the improvement of systems. *British Medical Journal*, 1997, 312: 619-622.
90. Health Administration Act 1982 (NSW).
91. Health Services Act 1986 (Vic).
92. Health Services Act 1991 (Qld).
93. Health Commission Act 1976 (SA).
94. Health (Regional Boards) Act 1991 (Tas).
95. Health Services Act 1990 (ACT).
96. Flanagan JC. The critical incident technique. *Psychological Bulletin*, 1954, 51: 327-358.
97. Windows NT Security, Microsoft Corporation, Redmont, Los Angeles.
98. The Final Report on the Australian Incident Monitoring Study to the Outcomes Branch of the Department of Health and Aged Services of the Commonwealth Government of Australia, 1998.
99. Safren MA, Chapanis A. A critical incident study of hospital medication errors. *Hospitals*, 1960, 34: 32-66.
100. Sanazaro PJ, Williamson JW. Physician performance and its effect on patients: a classification based on reports by internists, surgeons, paediatricians and obstetricians. *Medical Care*, 1970, 8: 299-308.
101. Cooper JB, Newbower RS, Long CD, et al. Preventable anaesthesia mishaps: a study of human factors. *Anaesthesiology*, 1978, 49: 399-406.
102. Morgan C. Incident reporting in anaesthesia. *Anaesthesia and Intensive Care*, 1988, 16(1): 98-100.
103. Williamson JA, Webb RK, Pryor GL. Anaesthesia safety and the "critical incident" technique. *Australian Clinical Review*, 1985, 5: 57-61.
104. Currie M, Pybus DA, Torda TA. A prospective survey of anaesthetic critical events: a report on a pilot study of 88 cases. *Anaesthesia and Intensive Care*, 1989, 16:103-107.
105. Webb RK, Currie M, Morgan CA, et al. The Australian Incident Monitoring Study: An analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21 (5): 520-528.

106. Chopra V, Bovill JG, Spierdijk, et al. Reported significant observations during anaesthesia: a prospective analysis over an 18 month period. *British Journal of Anaesthesia*, 1992, 68: 13-17.
107. Short TG, O'Regan, A, Lew J, et al. Critical incident reporting in an anaesthetic department quality assurance programme. *Anaesthesia*, 1992, 47: 3-7.
108. Runciman WB, Webb RK, Klepper ID, et al. Crisis management: validation of an algorithm by analysis of 2000 incident reports, *Anaesthesia and Intensive Care*, 1993, 21(5): 579-592.
109. Capstick B. Incident reporting and claims analysis. *Clinical Risk*, 1995, 1: 165-167.
110. Robbins D. Incident report analysis. The experience of one large labour and delivery unit. *Journal of Perinatal and Neonatal Nursing*, 1987, 1 (2): 9-18.
111. Roberts G. Untoward incident reporting: quality improvement and control. *Clinical Risk*, 1995, 1: 168-170.
112. Lapworth R, Teal TK. Laboratory blunders revisited. *Annals of Clinical Biochemistry*, 1994, 31: 78-84.
113. Holland RB. The therapeutic device evaluation committee. *Anaesthesia and Intensive Care*, 1988, 16 (1): 14-15.
114. Bednar B, Duke MC. Realising maximum benefits from incident reporting. *Nephrology News and Issues*, August 20, 1990: 22-28.
115. Joseph VD, Jones SK. Incident reporting: the cornerstone of risk management. *Nursing Management*, 1984, 15 (12): 22-23.
116. Williams CW. Guide to hospital incident reports. *Health Care Management Review*, 1985, 10: 19-25.
117. Goodwin MB, Westbrook JJ. An analysis of patient accidents in hospital. *Australian Clinical Review*, 1993, 13: 141-149.
118. Lynch P, White MC. Perioperative blood contact and exposures: a comparison of incident reports and focused studies. *American Journal of Infection Control*, 1993, 21 (6): 257-363.
119. Cohen L, Guin P. Implementation of a patient fall prevention program. *Journal of Neuroscience Nursing*, 1991, 23 (5): 315-319.
120. Hartwig SC, Denger SD, Schneider PJ. Severity-indexed, incident report-based medication error-reporting program. *American Journal of Hospital Pharmacy*, 1991, 48: 2611-2616.
121. Mills DH. Medical Insurance Feasibility Study - a technical summary. *Western Journal Medical*, 1978, 128: 360-365.
122. Thornton PD, Simon S, Mathew TH. Towards safer drug prescribing, dispensing and administration in hospitals, *Journal of Quality and Clinical Practice* 1999, 19(1): 41-46.

123. O'Neil AC, Petersen LA, Cook F, et al. Physician reporting compared to medical-record review to identify adverse medical events. *Annals of Internal Medicine*, 1993, 119: 370-376.
124. McNeill JJ. Report on Patient Safety Monitoring Systems, Monash University, Melbourne.
125. Wolff A. Limited adverse occurrence screening: a medical quality control system for medium sized hospitals. *Medical Journal of Australia*, 1992, 156: 449-452.
126. Wolff A. Limited adverse occurrence screening: an effective and efficient method of medical quality control. *Journal of Quality in Clinical Practice*, 1995, 15: 221-233.
127. Wolff A. Using medical record review to find adverse patient events, a report for the Department of Health and Aged Services. Wimmera Health Care Group, Horsham, Victoria.
128. Kroll DA, Caplan RA, Posner, K, et al. Nerve injury associated with anesthesia. *Anesthesiology*, 1990, 73: 202-7.
129. Caplan RA, Ward RJ, Posner, K, et al. Unexpected cardiac arrest during spinal anesthesia: a closed claims analysis of predisposing factors. *Anesthesiology*, 1988, 68: 5-11.
130. Caplan RA, Posner K, Ward K, et al. Peer reviewer agreement for major anesthetic mishaps. *Quality Review Bulletin*, 1988, 14: 363-368.
131. Cheney FW, Posner K, Caplan RA, et al. Standard of care and anesthesia liability. *Journal of the American Medical Association*, 1989, 261: 1599-1603.
132. Tinker JH, Dull DL, Caplan RA, et al. Role of monitoring devices in prevention of anesthetic mishaps: a closed claims analysis. *Anesthesiology*, 1989, 71: 541-546.
133. Caplan RA, Posner KL, Ward RJ, et al. Adverse respiratory events in anesthesia: a closed claims analysis. *Anesthesiology*, 1990, 72: 828-833.
134. Kroll DA, Caplan RA, Posner K, et al. Nerve injury associated with anesthesia. *Anesthesiology*, 1990, 73: 202-207.
135. Posner KL, Sampson PD, Caplan RA, et al. Measuring interrater reliability among multiple raters: an example of methods for nominal data. *Statistics in Medicine*, 1990, 9: 1103-1115.
136. Chadwick HS, Posner K, Caplan RA, et al. A comparison of obstetric and nonobstetric anesthesia malpractice claims. *Anesthesiology*, 1991, 74: 242-249.
137. Caplan RA, Posner K, Cheney FW. Effect of outcome on physician judgments of appropriateness of care. *Journal of the American Medical Association*, 1991, 265: 1957-1960.
138. Cheney FW, Posner KL, Caplan RA. Adverse respiratory events infrequently leading to malpractice suits. *Anesthesiology*, 1991, 75: 932-939.
139. Health Services Commissioner, Annual Report, 1997-1998, Melbourne.

140. Pilcher F, Project Manager, National Health Complaints Information Project, ACT Complaints Commission, Canberra.
141. The International Statistical Classification of Diseases and Related Health Problems, 10th revision, Australian Modification. National Centre for Classification in Health, Sydney, July 1998.
142. Roughead EE. The nature and extent of drug-related hospitalisations in Australia, *Journal of Quality in Clinical Practice*, March 1999, vol. 19, issue 1, pp. 19-22.
143. SNOMED International, College of American Pathologists, 1992.
144. Read Codes, Clinical Terms Version 3, 1988. NHS Centre for Coding and Classification, Woodgate, Loughborough, Leicestershire, UK.
145. NUDIST - web-site <http://www.qsr.com.au/software/n4/n4.htm>.
146. Runciman WB, Helps SC, Sexton EJ, et al. A classification for incidents and accidents in the health-care system. *Journal of Quality in Clinical Practice*, 1998, 18, 199-211.
147. Runciman WB. Qualitative versus quantitative research - balancing cost, yield and feasibility, Editorial, *Anaesthesia and Intensive Care*, 1993, 21(5): 502-505.
148. Kirke K, Executive Director, Anti Cancer Foundation, personal communication, 1999.
149. Adverse Drug Reaction Advisory Committee, Commonwealth Department of Health and Aged Care, GPO Box 100, Woden ACT 2606.
150. Therapeutic Goods Administration - <http://www.health.gov.au/tga>
151. Malpass A, Helps SC, Runciman WB. An analysis of Australian adverse drug events. *Journal of Quality in Clinical Practice*, 1999, 19(1): 27-30.
152. International Task Force on Anaesthesia Safety (Australia, Runciman; Canada, Duncan; Finland, Tammisto; France, Desmonts; Germany, Stoeckel; Japan, Ikeda; Netherlands, Booij; UK, Hanning; USA, Eichhorn & Gravenstein). National standards documents, 1993, *European Journal of Anaesthesia*: 2.
153. International Task Force on Anaesthesia Safety (Australia, Runciman; Canada, Duncan; Finland, Tammisto; France, Desmonts; Germany, Stoeckel; Japan, Ikeda; Netherlands, Booij; UK, Hanning; USA, Eichhorn & Gravenstein). International standards for a safe practice of anaesthesia. *European Journal Anaesthesia*, 1993, 10(7): 12-15.
154. International Task Force on Anaesthesia Safety (Australia, Runciman; Canada, Duncan; Finland, Tammisto; France, Desmonts; Germany, Stoeckel; Japan, Ikeda; Netherlands, Booij; UK, Hanning; USA, Eichhorn & Gravenstein). Commentary on Equipment Recommendations. *European Journal Anaesthesia*, 1993, 10(7): 16-18.
155. Runciman WB. International Task Force on Anaesthesia Safety. Discussion on the International Standards. *European Journal Anaesthesia*, 1993, 10(7): 19-23.
156. Runciman WB. Risk assessment in the formulation of anaesthesia safety standards. *European Journal Anaesthesia*, 1993, 26-32.

157. Richardson G. Hospitals: God help us. *The Bulletin*, June 13, 1995: 96.
158. Runciman WB, Bowie A, Levings B. Anaesthesia-related incidents and adverse events. For submission to the *Journal of Anaesthesia and Intensive Care*, 1999.
159. Gaba DM, Maxwell M, DeAnda A. Anesthetic mishaps: breaking the chain of accident evolution. *Anesthesiology*, 1987, 66: 670-676.
160. Kluger MT, Bukofzer M, Bullock M. Anaesthetic assistants: their role in the development and resolution of anaesthetic incidents. *Anaesthesia and Intensive Care*, 1999, 27(3): 269-274.
161. Sinclair M, Simmons S, Cyna A. Incidents in obstetric anaesthesia and analgesia: an analysis of 5000 AIMS reports. *Anaesthesia and Intensive Care*, 1999, 27(3): 275-281.
162. Beckmann U, Runciman WB. The role of incident reporting on continuous quality improvement in the intensive care setting. *Anaesthesia and Intensive Care*, 1996, 24: 311-313.
163. Beckmann U, West LF, Groombridge GJ, et al. The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. The development and evaluation of an incident reporting system in Intensive Care. *Anaesthesia and Intensive Care*, 1996, 24: 314-319.
164. Beckmann U, Baldwin I, Hart GK, et al. The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. An analysis of the first year of reporting. *Anaesthesia and Intensive Care*, 1996, 24: 320-329.
165. Wright N, Parker G. Incident monitoring in Psychiatry. *Journal of Quality in Clinical Practice*, 1998, 18: 249-261.
166. Bates DW. The impact of computerised physician order entry on medication errors: results of two studies. Annenberg Centre for Health Sciences at Eisenhower, Rancho Mirage, California, 1998, pp. 122-125.
167. Runciman WB, Webb RK. A report from the Australian Incident Monitoring Study: problems with vaporizers. *Australian Society of Anaesthetists Newsletter*, July 1994; pp. 16-19.
168. Webb RK, Van Der Walt JH, Runciman WB, et al. Which monitor? An analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21(5): 529-542.
169. Runciman WB, Webb RK, Barker L, et al. The pulse oximeter: applications and limitations - an analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21(5): 543-550.
170. Williamson JA, Webb RK, Cockings J, et al. The capnograph: applications and limitations - an analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21(5): 551-557.
171. Ludbrook GL, Russell WJ, Webb RK, et al. The electrocardiograph: applications and limitations - an analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21(5): 558-564.

172. Cockings J, Webb RK, Klepper ID, et al. Blood pressure monitoring: applications and limitations - an analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21(5): 565-569.
173. Barker L, Webb RK, Runciman WB, et al. The oxygen analyser: applications and limitations - an analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21(5): 570-574.
174. Klepper ID, Webb RK, Van Der Walt JH, et al. The stethoscope: applications and limitations - an analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21(5): 575-578.
175. Runciman WB, Webb RK, Klepper ID, et al. Crisis management - validation of an algorithm by analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21(5): 579-592.
176. Runciman WB, Morris RW, Paix AD, et al. Crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
177. Visvanathan T, Kluger MT, Webb RK, et al. Obstruction of the natural airway: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
178. Visvanathan T, Kluger MT, Webb RK, et al. Laryngospasm: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
179. Kluger MT, Visvanathan T, Myburgh JA, et al. Regurgitation, vomiting and aspiration: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
180. Paix AD, Williamson JA, Runciman WB. Difficult intubation: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
181. Szekely SM, Runciman WB, Webb RK, et al. Desaturation: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
182. Westhorpe RN, Davies JM, Ludbrook GL, et al. Bronchospasm: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
183. Chapman MJ, Myburgh JA, Kluger MT, et al. Pulmonary oedema: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
184. Watterson LM, Morris RW, Westhorpe RN, et al. Bradycardia: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
185. Watterson LM, Morris RW, Morgan CA, et al. Tachycardia: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
186. Morris RW, Watterson LM, Westhorpe RN, et al. Hypotension: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
187. Paix AD, Runciman WB, Horan BF, et al. Hypertension: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.

188. Ludbrook GL, Webb RK, Currie M, et al. Myocardial ischaemia and infarction: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
189. Morgan CA, Morris RW, Watterson LM, et al. Cardiac arrest: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
190. Currie M, Kerridge R, Bacon AK, et al. Anaphylaxis and allergy: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
191. Williamson JA, Helps SC, Westhorpe RN, et al. Embolism: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
192. Bacon AK, Paix AD, Williamson JA, et al. Pneumothorax: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
193. Osborne GA, Bacon AK, Morgan CA, et al. Awareness: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
194. Singleton RJ, Kinnear S, Currie M, et al. Vascular access problems: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
195. Griggs WM, Morris RW, Runciman WB, et al. Trauma: an analysis of 4000 reports - development of a sub-algorithm. *Anaesthesia and Intensive Care*, for submission in 1999.
196. Myburgh JA, Chapman MJ, Szekely SM, et al. Sepsis: crisis management during anaesthesia. *Anaesthesia and Intensive Care*, for submission in 1999.
197. Plsek PE. Systematic design of healthcare processes. *Quality in Healthcare*, 1997, (6): 40-48.
198. Grimshaw J, Fremantle N, Wallace S, et al. Developing and implementing clinical practice guidelines. *Quality in Healthcare*, 1995, 4: 55-65.
199. Rice MS. Clinical practice guidelines. *The Medical Journal of Australia*, 1995, 163: 144-145.
200. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of the rigorous evaluations. *The Lancet*, 1993, 342: 1317-1322.
201. Runciman W. The Preoperative Check - A report from the APSF. *Australian Society of Anaesthetists Newsletter*, pp. 22-26.
202. Russell WJ, Webb RK, Van Der Walt JH, et al. Problems with ventilation: an analysis of 2000 incident reports. *Anaesthesia and Intensive Care*, 1993, 21(5): 617-620.
203. Runciman WB, Ludbrook GL, Paix AD. APSF: On the airway, breathing and filters. *Australian Society of Anaesthetists Newsletter*, April 1998; pp. 19-20.
204. Gaba DM. Improving anesthesiologists performance by simulating reality. *Anesthesiology*, 1992, 76(4): 491-494.
205. Runciman WB. Quality assurance. *Clinical Anaesthesia* (eds Jones and Aitkenhead), Churchill Livingstone, London, 1993.

206. Vincent CA. Research into medical accidents: a case of negligence? *British Medical Journal*, 1999, 2: 1150-1153.
207. Runciman WB. Monitoring and patient safety: an overview. *Anaesthesia and Intensive Care*, 1988, 16(1): 11-13.
208. Austin KL, Stapleton JV, Mather LE. Relationship between blood meperidine concentration and analgesic response: a preliminary report. *Anesthesiology*, 1980, 53(6): 460-66.
209. Cousins MJ, Phillips GD. Acute pain management. *Clinics in Critical Care Medicine*, Cousins MJ and Phillips GD (eds), Churchill Livingstone, New York, 1986.
210. NHMRC Acute Pain Management: scientific evidence 1998, Canberra. www.health.gov.au/nhmrc/publicat/pdf/cp57pdf
211. Macintyre PE, Ready LB. Acute Pain management: a practical guide. WB Saunders Company Ltd, London, 1996.
212. Macintyre PE, Jarvis DA. Age is the best predictor of postoperative morphine requirements. *Pain*, 1995, 64: 357-364.
213. Hart L, Macintyre PE, Winefield H, et al. Re-evaluation of patient, medical and nursing staff attitudes to post-operative analgesia after establishment of an Acute Pain Service. 7th World Conference on Pain, Paris, August 1993, Congress Abstracts, IASP Publications, p. 397.
214. Macintyre PE, Runciman WB, Webb RK. An acute pain service in an Australian teaching hospital: the first year. *Medical Journal of Australia*, 1990, 153(7): 417-421.
215. Macintyre P. Nine year's experience in an acute pain service. *Australasian Anaesthesia. Australia and New Zealand College of Anaesthetists*, Melbourne, 1998, pp. 79-90.
216. Therapeutic Goods Administration - <http://www.health.gov.au/tga>
217. Valinsky LJ, Hockey RL, Hobbs MST, et al. Finding bile duct injuries using record linkage: a validated study of complications following cholecystectomy. *Journal of Clinical Epidemiology*, 52(9): 893-901, 1999.
218. Overhage JM, Tierney WM, Zhou XH, et al. A randomized trial of "corollary orders" to prevent errors of omission. *Journal of the American Informatics Association*, 1997, 4(5): 264-75.
219. Shea S, DuMouchel W, Bahamonde L. A meta-analysis of 16 randomized controlled trials to evaluate computer-based clinical reminder systems for preventive care in the ambulatory setting. *Journal of the American Informatics Association*, 1996, 3(6): 399-409.
220. The virtuous cycle - working together for health and medical research. Health and Medical Research Strategic Review Summary, December 1998. Commonwealth of Australia.

Supplementary references to footnotes

- a. To Err is Human: building a safer health system. Kohn LT, Corrigan JM and Donaldson MS, Eds. Institute of Medicine, National Academy Press, Washington DC, 1999. The full text is available at: www.nap.edu (The IOM report).
- b. An organisation with a memory. Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer. The Stationery Office, London, 2000 (the NHS Report).
- c. Safety First: report to the Australian Health Ministers' Conference 27 July 2000, Canberra: Australian Council for Safety and Quality in Health Care 2000.
- d. Data and information working group of the Australian Council for Safety and Quality in Health Care meeting, 7 November 2000.
- e. Australian Council for Safety and Quality in Healthcare meeting, 16 August 2001.
- f. State Quality Officials Forum (SQOF) established by the Australian Council for Safety and Quality in Healthcare in June 2000.
- g. Agreement between the Australian Patient Safety Foundation Inc and the Australian Institute of Health and Welfare concerning co-operation in collection and publication of data on patient safety, adverse events and related matters for the period 1 July 2000 to 30 June 2005. Australian Patient Safety Foundation, Adelaide and Australian Institute of Health and Welfare, Canberra.
- h. Davis P, Lay-Yee R, Schug S, et al. Adverse Events Regional Feasibility Study: methodological results. *New Zealand Medical Journal*, 2001, 114:200-205.
- i. Vincent CA, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001; 322:517-519.
- j. Shared meanings: www.safetyandquality.org
- k. Wu AW. Medical Error: the second victim. *British Medical Journal*, 2000, 320:726-727.
- l. Guidelines for Managing Risk in Healthcare: HB228:2001. Australia/New Zealand Handbook, Standards Australia, Sydney.
- m. Core Standards for Healthcare Safety. Consultation paper, August 2001, Australian Council for Safety and Quality in Healthcare.
- n. Runciman WB, Merry A, McCall Smith A. Improving patients' safety by gathering information: anonymous reporting has an important role. *BMJ* 2001, 323:298.
- o. Public interest in healthcare qualified privilege. Issues paper, August 2001, Australian Council for Safety and Quality in Healthcare.
- p. Australian Patient Safety Foundation, Adelaide.

- q. Beckmann U, Bohringer C, Carless R, Gillies D, Runciman WB. Quality Improvement in Intensive Care. A combined approach to two methods. In preparation, Australian Patient Safety Foundation, 2001.
 - r. Safety in Numbers: a technical options paper for a national approach to the use of data for safer health care, Australian Council for Safety and Quality in Health Care, August 2001.
 - s. Credentials and Clinical Privileges Guidelines (working draft for consultation). Australian Council for Safety and Quality in Healthcare, August 2001.
 - t. Safety in Practice: making healthcare safer. Australian Council for Safety and Quality in Healthcare, August 2001.
 - u. A Model for Medical Registration Incorporating: vocational registration, revalidation, national portability. Prepared by the New South Wales Medical Board for the Australian Council for Safety and Quality in Healthcare, August 2001.
 - v. Clinical Risk Management: enhancing patient safety, 2nd ed. Charles Vincent, BMJ Books 2001, London.
 - w. Process for recognising “in kind” contributions from jurisdictions. Australian Council for Safety and Quality in Healthcare, August 2001.
 - x. Financial principles, processes and protocols. Australian Council for Safety and Quality in Healthcare, June 2001.
-