

IATROGENIC INJURY IN AUSTRALIA

A report prepared by the Australian Patient Safety Foundation

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

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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.

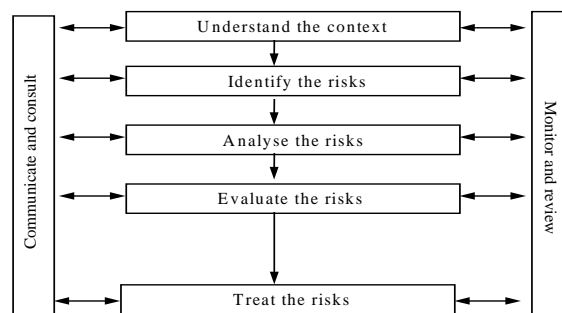
Iatrogenic injury is costly; at least 10% of admissions to acute-care hospitals in Australia are associated with a potentially preventable adverse event. It has been estimated that the direct medical costs of these events exceeds \$2 billion per year and that the total life-time cost of such preventable 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).*

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,

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

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 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,

* 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.

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.*

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.

* 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.

** 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.^g

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