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Response to the international comparative survey of medical  
Accident prevention and patient safety policy  
The Australian situation

Respondent: Mary Potter Forbes

A response to the international comparative  
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and  
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**The Australian Situation**

**Respondent: Mary Potter Forbes  
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## Background: The Australian Situation

The Review of Professionals indemnity commissioned the *Quality in Australian Health Care Study* in 1992 in which it was found that an adverse event occurred in 16.6% or over 14 000 admissions to 28 public and private hospitals in New South Wales and South Australia. (An adverse event was defined as an unintended injury which resulted in a disability, including a longer hospital stay or death, which was caused by health care management rather than the patient's underlying disease.) Of these over 50% were regarded as highly preventable and 5% resulted in death.

The Health Ministers commenced a process of planning which culminated in the establishment of the *Australian Council for Safety and Quality in Health Care* in 2000 to lead national efforts to promote systemic improvements in the safety and quality of healthcare in Australia. The mandate of the Council is to develop proactive and innovative responses to the problem through collaborative action with providers and the implementation of tools to lift the 'veil of silence' which inhibits identification and analysis of medical error.

The Council's first report, *Safety first*, was published in the same year in which the approach to safety was outlined and the first national action plan was released in 2001. During the same period the national standards organisation, Standards Australia/New Zealand authored a Risk Management Approach for health care settings which was modelled on the generic Risk Management Standard.<sup>58</sup>

Initiatives have been taken at the local level to collect and analyse data for the implementation of informed and recursive organisational changes – including educational and structural change. An integrated approach which is being replicated elsewhere is the work of the Wimmera Health Care group in Horsham, Victoria which has developed a clinical risk management program, detected adverse events in a variety of ways, analysed both the events and the risks, and taken action to improve care and monitor progress, using a systems approach. The rate of adverse events has been reduced from 1.35% of all patients discharged in the first year of the program to 0.74% in the eighth year. In the emergency department, the rate was reduced from 2.71% of all patients to 0.48%.<sup>59</sup>

Other priorities of the Council during 2001 are:

to address known high-risk areas which contribute significantly to adverse events. These include reducing hospital-acquired infections, promoting safer use of medications and blood products, preventing patient falls and improving patient assessment;

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<sup>58</sup> Standards Australia/New Zealand *HB 228:2001 Guidelines for managing risk in the healthcare sector*

<sup>59</sup> Wolff AA, Bourke IAC & Leembruggen DW (2001) *Detecting and reducing hospital adverse events: outcomes of the Wimmera clinical risk management program* Medical Journal of Australia 174: 621-625

- to develop national standards for credentialling and performance assessment;
- to develop specialist and vocational registers;
- to develop curricula for educational modules in systems safety, human factors and communication;
- to develop standards for national audits and benchmarking, full disclosure of adverse events; to develop standards for organisational certification, accreditation and licensing, addressing such issues as best practice, structured risk management, teamwork and team training, resource use, skill mix and safety standards. <sup>60</sup>

Other activities undertaken by government and research organisations include:

- The development of clinical pathways to address the incidence of 'errors of planning'
- Introduction of adverse event monitoring and reporting of sentinel events
- Workshops on human factors and the development of safety management in the aviation industry
- Reduction of a culture of blame to one of information and learning which included changes to the legal framework through initiatives such as the 'Open Disclosure Project'.

Reducing the incidence of adverse events and improving the communication between providers and consumers has gained further impetus from the collapse of the principal medical defense organisation in Australia in 2002. It has been claimed that United Medical Protection was improperly financially managed with inadequate provisions for claims being made – but its collapse has made it necessary for government to indemnify practitioners operating in the public sector and seen the closure of certain services, such as the *Family Planning Association* medical clinics, which were unable to re-insure.

## **A. Situation on Medical Error**

### ***1. Studies and research activities on medical accidents/errors***

#### ***d. Are there any study on facts and occurrences of medical accidents/errors?***

Since the *Quality in Australian Health Care Study* was funded by the *Tito Review of Professional Indemnity Arrangements for Health Care Professionals* there has been a great deal of research activity on the nature and cost of medical error and the development of methodologies to address the sources of error. In NSW there is currently a NSW Health consultancy to develop a system for error identification, analysis and action in neurosurgery which draws upon the successful earlier work of anaesthesiology in addressing the problem of error in the delivery anaesthesia. A sample of current work is:

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<sup>60</sup> Barraclough B Editorial, *Medical Journal of Australia* 2001; 174: 616-617

- Williamson JA, Mackay P (1991) *Incident Reporting*. Medical Journal of Australia (155): 340-343.
  - Webb R, Currie M, Morgan CA, et al. (1993) *The Australian incident monitoring study: an analysis of 2000 incident reports*. Anaesth Intensive Care ( 21): 520-528.
  - Commonwealth Department of Human Services & Health (1995) *Review of Professional Indemnity Arrangements for Health Care Professionals* AGPS, Canberra  
A comprehensive review of safety and negligence in the health care sector. The dearth of data upon which policy could be developed lead to the commissioning of a large number of reports – including the *Quality in Australian Health Care Study*
4. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD (1995) “*The Quality in Australian Health Care Study*” Medical Journal of Australia: 163: 458-471  
In this study over 14,000 patient admissions in 28 hospitals in New South Wales and South Australia were reviewed and it was found that 16.6% of *patients* were involved in an ‘adverse event’, of which half were assessed as highly preventable. This study followed the Harvard Medical Practice study and was the first published structured audit of quality of care in Australia.
  5. Bhasale AL, Miller C, Reid SE Britt HC (1998) *Analysing potential harm in Australian general practice; an incident-monitoring study* Medical Journal of Australia (169): 73-76  
Data was collected on incidents of potential or actual harm to general practice patients using a modified critical incidents technique. 324 GPs participated between October 1993 and June 1995. The GPs reported free-text descriptions of incidents and structured responses for preventability, potential for harm, immediate consequences, predicted long-term outcomes, type of incident, contributing factors, mitigating factors, and additional resource use. 805 incidents were reported -- 76% were preventable; 27% had potential for severe harm. No long term harm was predicted for 66% of incidents. Incidents could relate to pharmacological management (51 per 100 incidents), non-pharmacological management (42 per 100 incidents), diagnosis (34 per 100 incidents) or equipment (5 per 100 incidents). The most common contributory factors were poor communication between patients and healthcare professionals and actions of others (23 per 100 incidents each) and errors in judgement (22 per 100 incidents). Human errors and preventable system problems were identified. The incident monitoring technique provided useful data which could be applied to incident prevention strategies.
  6. Roughhead EE, Gilbert AL, Primrose JG et al (1998) *Drug-Related Hospital Admissions: A Review of Australian Studies Published 1996-1998* Medical Journal of Australia 168: 405-408  
Reviewed 14 Australian studies reporting 2.4% to 3.6% of all hospital admissions were drug related and between 32%-69% were preventable.

7. Mathers C & Penm R (1999) *Health System costs of injury, poisoning and musculoskeletal disorders in Australia 1993-1994* AIHW Cat No HWE 12 Australian Institute of Health & Welfare, Canberra  
In a study on the direct health system costs of injury, the adverse effects of medical treatment (misadventure and the adverse effects of drugs in therapeutic use) were estimated at \$401 million, or 15.4% of cost, nationwide.
8. Meredith A B Makeham, Susan M Dovey, Mary County and Michael R Kidd (2000) *An international taxonomy for errors in general practice: a pilot study* Medical Journal of Australia 177 (2): 68-72

An international comparative study, the Primary Care International Study of Medical Errors (PCISME), was undertaken to assist in the development of an international taxonomy describing errors. PCISME was the first international study of medical errors in general practice and involved six countries with similar primary healthcare standards - Australia, Canada, the Netherlands, New Zealand, the United Kingdom and the United States. GP reported errors were electronically transferred to a central database for analysis. The final taxonomy was a five-level system encompassing 171 error types. The first-level classification was "process errors" and "knowledge and skills errors". The proportion of errors in each of these primary groups was similar in Australia (79% process; 21% knowledge and skills) and the other countries (80% process; 20% knowledge and skills). Patient harm was reported in 32% of reports from Australia and 30% from other countries. Participants considered the harm "very serious" in 9% of Australian reports and 3% of other countries' reports.

8. Hargreaves, J (April 2001) Reporting of adverse events in routinely collected data sets in Australia *Australian Institute of Health & Welfare (AIHW) Health Division Working Paper No 3*, Canberra

The paper describes the adverse event reporting in three routinely collected data sets in Australia

- AIHW National Mortality Database
- AIHW National Hospital Morbidity Database
- Bettering the Evaluation and Care of Health (BEACH) continuous survey of general practice activity.

The definition of 'adverse event' depended on the definition used in the data base being used but the classification rubrics that were used "were restricted to the rubrics which were specific for iatrogenesis, indicated causal links between the intervention and the condition, and which may not be regarded as 'expected' consequences of treatment"

9. Australian Council for Safety and Quality in Health Care (July 2001) *Improving Medication*

*Safety: Report of a Medication Safety Workshop*

This workshop was the first initiative of the Medication Safety Taskforce and identified critical factors in system, including the lack of consumer involvement, which lead to error.

10. Runciman WB & Moller J (August 2001) Iatrogenic Injury in Australia: A Report Prepared by the Australian Patient Safety Foundation

A comprehensive review of the status of the identification, monitoring, analysis and risk management of iatrogenic illness in Australia. The report was first submitted in 1999 but has been revised to accommodate the work of the U.S. Institute of Medicine's 1995 Report, 'To Err is Human'; U.K. 'NHS Report'; and the establishment of the *Australian Council for Safety and Quality in Healthcare*. It reviews the issue within the context of the changing doctor-patient relationship, the cost of iatrogenic events & the strained tortious compensation system, and the efficacy of professional self-regulation.

Recommendations are made in regard to: risk management, quality assurance, clinical governance, and incident monitoring and reporting systems as well as the use of administrative data bases as information sources.

11. Wolff AM, Bourke J, Campbell I, Leembruggen D (2001) *A clinical risk management program: detecting and reducing hospital adverse events. Medical Journal of Australia* (174): 621-625.

An integrated clinical risk management program was developed by the Wimmera Health Care group in Horsham, Victoria, to detect adverse events in a variety of ways, analyze both the events and the risks, and then take action to improve care and monitor progress. Through this systemic approach, the rate of adverse events was reduced from 1.35% of all patients to 0.74% eight years later. In the emergency department, the rate was reduced from 2.71% of all patients attending to 0.48%.

12. Kable AK, Gibberd RW & Spigelman AD (2002) "Adverse events in surgical patients in Australia" International Journal for Quality in Health Care 14:4 pp269-276

Researchers in the *Health Services Research Group and Faculty of Health at the University of Newcastle* estimated the incidence of adverse events for surgical patients in Australia in 1992 as 21.9% with 13% resulting in permanent disability and 4% in death – 2.8% of all resulting in permanent disability and less than 1% in death. The risk factors for an adverse event were identified as age and procedure and it was concluded that prophylactic interventions for infection and deep vein thrombosis could reduce the occurrence of adverse events in hospitals.

13. Potter-Forbes M & Aisbett C (*NSW Injury Risk Management Research Centre*) – work in progress  
The project involves an estimation of the *whole-of-life* cost of injury in NSW in 1998-1999 from the *NSW Inpatient Statistical Collection*. It includes an analysis of the incidence and cost of adverse events until recovery or death where cost is defined as 'the person-based economic cost of



medical and other care directly attributable to the incident as well as the economic and personal losses associated with the resultant disability and death.' The methodology utilized, firstly Diagnostic Related Group (DRG) categorisation, and published data on other direct costs, and secondly, allocated a cost to indirect and intangible losses by applying a monetarised value of a year of healthy living to the estimated number of *Disability Adjusted Life Years* lost to injury in that year.

The cases for which an adverse event, defined as *complications of care* (ICD-10AM Chapter XX categories Y40-Y84), was recorded represented 28% of all hospitalisations in 1998-1999 and without adjustment for co-morbidities, represented approximately 40% of hospital costs – over 90% of the cost being for 'complications not mentioned at the time of the event' (Y83-Y84). Further work needs to be undertaken to refine this estimate and statistical analysis is being undertaken in conjunction with one of the developers of the DRG grouper used by NSW Health, Chris Aisbett.

Although cases categorised as 'complications of care' are identified in the study in the comparative analysis, it was decided to fully cost only those events that were attributable to an *accidental injury* which were presumed to be those due to actual *medical and surgical misadventures* (ICD10AM codes Y60-Y69) – events such as leaving an item in a surgical wound as opposed to an event such as deep vein thrombosis. The hospitalisation cost for this category was \$9.7 million and \$13.6 million in direct costs overall. Total lifetime costs were \$15.9 million in NSW in 1998-1999 – indirect costs and intangible losses contributed little to the cost because of the few deaths and the very low incidence of long term disability associated with the injuries.

Furthermore, although the admission rate for 'complications of care' in the study year of 1998-99 was 1,082.7 cases per 100,000, 38% of the cases had no negative outcome recorded – no 'n-code' despite the e-coding. If these cases are excluded from the count then the rate drops to 646.6. If only those cases coded to 'medical and surgical misadventure' are counted then the rate falls to a mere 26.4 cases per 100,000 – but at the highest average *direct* cost per case of \$9,430 or average lifetime cost of \$11,074.

***b. Is the number of medical accidents increasing?***

This is uncertain but the information could be extracted from such databases as the *Inpatient Statistical Collection* of NSW Health. There is some uncertainty, however, as to the reliability of the classification system and of coding practice, as well as little work conducted on the contribution of co-morbidities to the severity of adverse event outcomes. Intra-institution reporting systems are varied in NSW and it has been reported anecdotally that some hospital pharmacists record out-of-date drugs held at ward level as constituting an adverse event – in many circumstances such poor housekeeping may not even constitute a 'near miss' – whilst others do not. Standardisation of definition and classification is a priority.

*c. How much is budgeted for those studies and research activities?*

Under the auspices of the *National Council on Safety and Quality in Healthcare*, the State Ministers of Health have agreed in principle to an allocation of \$50 million over 5 years for the development of national programs on patient safety.

At the state level, the Victorian Department of Human Services has allocated \$4.8 million to establish clinical risk management programs based on the Wimmera model in every Victorian public hospital in 2001–2002. I am unsure of the situation in the other states.

*d. Is the status of medical errors understood well in your country?*

There has been great deal of work done on developing an understanding of the nature and cause of errors and the development of a conception of system errors rather than individual fault, which has drawn on the decades of work done in other industries - such as aviation, mining and road safety – as well as from human-factors engineers and cognitive psychologists, about how to shift to a system that, although inevitably high risk, has high reliability. The most fundamental shift has been a recognition that a no-blame data collection system needs to be introduced and that the information generated is fed back into the system for change and action.<sup>61</sup>

The general nature of the problem includes:

- Communication problems, from language through to a failure to inform,
- procedural problems, such as a failure to check medical records;
- clinical problems where inappropriate or wrong treatment was given', and
- external problems – equipment faults, unpredictable drug effects, patient non-compliance.

According to the APSE, a multinational collaborative project is being planned to refine the definitions and methodology for data collection and a software program is being developed – the Australian Medical Records Analysis System (AMRAS). After the establishment of the Safety & Quality council, a multi-axial *Generic Occurrence Classification (GOC)* in which all adverse events could be classified was developed.<sup>62</sup>

In the interim, the 'top 250' iatrogenic events have been identified by combining medical record review, incident monitoring and other sources of information and related national meetings on nosocomial infection, adverse drug events, thromboembolism, informed consent and falls have taken place<sup>63</sup>.

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<sup>61</sup> Runciman WB & Moller J (2001) *Iatrogenic Injury in Australia: A Report prepared for the Australian Patient Safety Foundation*

<sup>62</sup> Runciman WB & Moller J (2001) op cit 4

<sup>63</sup> Runciman WB & Moller J (2001) op cit 4

In the recent work undertaken by the Wimmera Health Group, actions taken to reduce the frequency of adverse events included: changes to local protocols, audits, worksheets and supervision practices, as well as the incorporation of feedback, discussion, checklists and assessment tools.

## *2. Public concern for medical accidents/errors*

### *c. To what extent are medical accidents/errors getting public concern in your country?*

The 1995 *Quality in Healthcare Study* generated a great deal of media interest but lately the concern has been associated with the collapse of the principal medical indemnifier, United Medical Protection, which has necessitated a government indemnification for all medical practitioners treating public patients. There is a view that the court awards compensating for severe and life long injury associated with conditions that would previously have resulted in death – obstetric adverse events for instance - are excessive.

There have been not been any high profile adverse events associated with gross negligence – such as incorrect surgery or incorrect patient - publicised by the media in recent years, that I can recall.

### *d. Is the number of lawsuit against medical accident increasing?*

There is a perception, at least amongst medical practitioners, that there is a litigation crises. This cannot be substantiated given the absence of easily accessible data collection systems and all evidence is anecdotal – but there has been an increase in defensive medicine (e.g. over-ordering of tests thereby increasing costs).

In the 1995 Review of Professional Indemnity Arrangements for Health Care Professionals it was argued that the crises mentality was fostered by some medical defence organisations to deflect attention away from their own “irresponsible financial management”. Although an increase in incident reporting was noted, this was not reflected in any increase in claims filed<sup>64</sup>. There could have been out-of-court settlements, however, with confidentiality clauses attached. Nevertheless, the Review found that few people who made initial complaints of injury were compensated, and that of the claims actually pursued, approximately 60% failed.<sup>65</sup> There is a public perception that the number of suits, and the size of the awards, are rising, which is fueled by a few recent high profile cases of multi-million compensatory figures for birth injuries resulting in permanent and total disability.

Medical defense unions provide services to member’s which may include legal costs for civil liability and disciplinary proceedings, advice on medico-legal matters, and assistance with hospital and employment disputes. There *have not been* requirements for such organisations to adopt the accounting, prudential and reporting requirements to which insurance companies have been subject – although the recent collapse of general insurer HIH indicates the possibility of genuine insurers under-reserving given the current regulatory regime. All medical defense organisations retain an exclusive discretion as to whether they will indemnify the negligent acts of a member and, if so, for how much.<sup>66</sup>

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<sup>64</sup> Blomberg C (1996) *The Professional Indemnity Review: what did it accomplish?* Medical Journal of Australia (164): 502

<sup>65</sup> O’Donnell C (1999) 1 op cit p 55

<sup>66</sup> O’Donnell C (1999) *Unintended outcomes of health care delivery and the need for a national risk*

### *c. Is the industry interested in patient safety?*

There is a great deal of activity in the area and major initiatives driven by the Federal Government to improve quality and safety in health care. For example:

1. Alexander Henderson & Associates, 2002, *Lessons for Health Care: Applied Human Factors Research: prepared for the Australian Council for Safety & Quality in Health Care & NSW Ministerial Council for Quality in Health Care: November 2000*
2. Standards Australia/New Zealand HB 228:2001 *Guidelines for managing risk in the healthcare sector*
3. Australian Council for Safety and Quality in Health Care, July 2000, *Safety First: Report to the Health Minister's Conference 27 July 2000*, AGPS Canberra
4. Wilson R, Harrison B, Gibberd R & Hamilton (1999) *An Analysis of the Causes of Adverse Events from the Quality in Australian Health Care Study* Medical Journal of Australia 170: 411-415
5. Law Reform Committee, Parliament of Victoria 1997, *Legal Liability of Health Service Providers: Final Report* Government Printer, Melbourne, p.41
6. National Expert Advisory Group on Safety and Quality in Australian Health Care, 1999, *Implementing Safety & Quality Enhancement in Health Care: National Actions to support Quality and Safety Improvement in Australian Health Care*, AGPS, Canberra
7. National Expert Advisory Group on Safety and Quality in Australian Health Care, 1998, *Commitment to Quality Enhancement; Interim Report*, AGPS, Canberra,
8. Australian Health Ministers Advisory Council 1996, *The Final Report of the Taskforce on Quality in Australian Health Care*, Commonwealth Department of Health and Family Services, AGPS, Canberra
9. Australian Patient Safety Foundation Inc. (APSF) 1997, *Australian Incident Monitoring System (AIMS)*, Royal Adelaide Hospital, Adelaide.
10. Australian Council on Healthcare Standards (ACHS) 1997, *Promoting Quality Health Care: ACHS Care Evaluation Program*, Fitzroy, Victoria.
11. Review of Professional Indemnity Arrangements for Health Care Professionals 1995, *Compensation and Professional Indemnity in Health Care (Tito Report)* Commonwealth Department of Human Services and Health, Canberra
12. Wilson R, McL, Runciman WB, Gibberd RW et al (1995) *The Quality in Australian Health Care Study* Medical Journal of Australia 163: 458-471
13. Standards Australia/Standards New Zealand 1994, *Risk Management*, AS/NZ 3460
14. McDonald JS & Peterson S (1985) *Lethal Errors in Anaesthesiology*, Anaesthesiology 52

### *3. Impact of IOM report*

Is a report from the Institute of Medicine in the U.S., "To Err is Human", published in November 2000 known in your country? And if so, did it have influence?

Australia has been moving in tandem with the United States since 1992 and is developing an equally sophisticated analytical framework. There tends to be, however, a concentration on the identification and implementation of Cochrane 'best practice' medical intervention without a coherent approach to patient safety generally. There is a need to ensure that 'Safety First' is a reality.

There are nevertheless many fundamental similarities in approach, including the emphasis on the development of an organisational culture that encourages recognition and learning from errors with an emphasis on governance by professional ethics, norms and expectations.<sup>67</sup>

## **B. Action by Stakeholders**

### ***1. Government action toward medical accidents/errors and patient safety***

***Is there a governmental policy especially for medical accidents?***

If there is, please describe the policy including the historical development of the policy.

The *Review of Professional Indemnity Arrangements for Health Care Professionals (1995)* found a wide range of problems in the current approach to managing risks to patients and dealing with the effects of unintended consequences of health care provision, including an inadequate focus and evidentiary basis for many health care treatments. There was found to be little data driven quality directed activity and a lack of meaningful information upon which health care consumers could evaluate prospective providers.<sup>68</sup> The Review looked at the incidence and nature of health care injuries, compensation and structured settlements for personal injuries, facilities for the disabled, professional indemnity arrangements, “defensive’ medicine and informed consent, birthing issues and information guidelines for patients and providers. Given the absence of data, the Review commissioned the *Quality in Australian Health Care Study*.<sup>69</sup>

The advisory committee convened by the Health Ministers, *National Expert Advisory Group on Safety and Quality in Australian Health Care (1998)*, supported the development of national health standards and supporting risk management structures through recommending that government health care agreements and related contracts require health care organisations to ‘develop, maintain and review readily accessible consumer information’.

### ***2. Action by other stakeholders***

***Is there a policy by provider association, medical doctor, nurse, or hospital?***

Yes. The Chair of the NSW Ministerial Advisory Committee on Quality in Health Care, Dr Ross Wilson, is Senior Specialist in intensive care and the Director of Quality Assurance at the Royal North Shore Hospital in Sydney. Such a role exists in almost all hospitals.

Notably, over the last eight years, the Wimmera Health Care Group has developed an integrated risk management approach which systematically identified sources of error and adapted the system to reduce the incidence of error – 1.35% of all discharges to 0.74%.

The self governing professional bodies have their innovations but given their role in the licensing of *individuals* they must retain a focus on individual competence and accountability – although peer judgement does tend to reward ethical disclosure and penalise avoidance of responsibility and the

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<sup>67</sup> McNeill PM & Walton M (2002) *Medical Harm and the consequences of error for doctors* MJA 176: 222-225

<sup>68</sup> O’Donnell (1999) *ibid* 1 p46-48

<sup>69</sup> Blomberg (1996) *The Professional Indemnity Review: what did it accomplish?* Medical Journal of Australia (164):502

'cover-up'.

### **3. Action by patients, patient groups or representatives**

***Do patients, patient groups or representatives have a strong influence on governmental or health care professionals' activities for medical error prevention?***

Since the legal case of *Rogers v Whitaker* where a duty to warn patients of material risks to them individually – a subjective objective test of responsibility – the patient's point of view has become increasingly important. Prior to that time, however, consumer activism in all sectors since the 1960's had been voiced through various non-specific forum. The establishment of the Health Care Complaints Commissions in each state reflects the demand for an avenue for complaints *separate* from that of the professional bodies – a vehicle to represent the consumer in negotiations; the Commission lays legal complaints on its own behalf.

The Australian Patient Safety Foundation Inc. (APSF) is a non-profit independent organisation dedicated to the advancement of patient safety ([www.apsf.net.au](http://www.apsf.net.au))

### **4. Third Party Accreditation**

**With regard to quality, third party organization accredits and evaluates hospital performance in many countries. And in some cases, the organization rates/ benchmarks hospitals or health care institutions. Is there any such an organization in your country?**

The *Australian Council on Healthcare Standards (ACHS)* performs this role in Australia and takes an integrated management approach in its Evaluation and Quality Improvement Program, which provides a range of outcome and process related standards to assist audit in the health industry.

## **C. Information System**

### **1. Reporting system/ information system**

**Is there any nation wide reporting system for medical accidents, e.g. a reporting system in aviation industry or adverse event reporting system in Australia?**

*If there is,*

***a. Is it obligatory or voluntary?***

***b. Who collect data?***

***e. Who analyze the data?***

Currently data collection and analysis is ad hoc at the hospital level, dependent upon the drive of the local staff, and where there are existing administrative data collection systems in place, such as the *NSW Inpatient Statistical Collection*, usefulness is limited by definitional and classification issues. A standardised reporting system, *Australian Incident Monitoring System*, has been developed by the Australian Patient Safety Foundation and it is in use in all South Australian public hospitals, in four networks in Victoria and in the northern Territory, and it has been introduced across Western Australia and in parts of New Zealand. The Foundation's SYSTEM classification system has been chosen for trial in the UK at the National Patient Safety Agency's central repository for adverse events and near misses.

***d. Is there any legal protection for reported cases against lawsuit?***

The 'Open Disclosure Project' in NSW is an attempt to address this problem. The objective of the

recent 'open disclosure' project was to protect health care providers from the legal presumption of admission of liability by actions taken to report, analyse and alleviate harm. Indeed, research has suggested that some medical litigation is generated by the anger of poorly treated victims of adverse events when the provider goes into legal defensive mode rather than being conciliatory and communicative.<sup>70</sup>

## *2. Complains from patients or their family*

### *Is complain data collected and analyzed? If so, how?*

This has not traditionally been done but some analysis is conducted by the the *Health Care Complaints Commission*. The aims of the Commission include facilitating the maintenance of standards of health services, promoting the rights of clients by providing mechanisms for resolution of complaints, and providing an independent mechanism for assessing whether disciplinary action should be taken against health practitioners who are registered under health health registration acts - whether the complaints are referred to a disciplinary body, NSW Medical Board or Nurse's Registration Board, for instance. The commission is complainant in all disciplinary inquiries which are heard by a professional registration board, professional standards committee or a tribunal.<sup>71</sup>

(The legal framework of health law in Australia has traditionally been founded on three branches of law: the civil compensatory or tort system; the administrative apparatus of the disciplinary and regulatory function of registered self-governing professional bodies; and the criminal law for breaches punishable by the generic criminal code e.g. sexual assault. In 1993 the administrative arm was strengthened by the introduction of the *Health Care Complaints Commission* which is the major avenue for complaints resolution.)

At the institutional level, there have been positions created in recent years for "patient representatives" and other liaison roles - usually undertaken by those with qualifications in public relations and marketing, so the system learning of the role is questionable if the incumbent is unable to develop effective feedback mechanisms.

## D. Legislation

a. With regard to a legal system, if someone reports a case and the error is not caused by her/his negligence or system error, we heard that there is indemnification system in some countries. Do you have the same system in your country as well?

In an attempt to encourage the communication about adverse events so that organisational learning and change can come about, and so that victims can be acknowledged and responded to compassionately at the time of the incident, an 'Open Disclosure Project' was recently undertaken to prevent the discovery and use of institutional and professional responses to the adverse event in any latter civil proceedings. It has been recognised that failure to adequately communicate with the victims of an adverse event is significantly correlated with litigation.<sup>72</sup> So the Open Disclosure Project effectively targets both organisational learning and a reduction in the aggregate compensatory cost of adverse events.

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<sup>70</sup> Suzie Linden (2001), health lawyer, Phillips Fox, Melbourne – presentation on Risk Management

<sup>71</sup> O'Donnell (1999) *ibid* 1 p54

<sup>72</sup> Suxie Linden (2001) *ibid* 12

b. Is there any no fault compensation scheme for medical errors similar to a no fault compensation scheme for side effects of drug?

The system in Australia remains an adversarial and fault based one such that there are negative effects on rehabilitation and difficulties in obtaining relying incidence and severity data.<sup>73</sup>

The 1995 *Professional Indemnity Review*, recommended *against* a 'no-fault' scheme of compensation. It was considered inequitable as the full burden of the cost of all injuries would fall on the community – and not just those due to actual negligence – through increased taxes. There was concern that as entry into the scheme would be determined purely on the basis of one's injury status, the quantum allocated for care would have to be limited to meet the many more claims that would be eligible than under the current fault based system – with the result that insufficient resources would be available for the long term care of those severely and avoidably injured. This is the trade-off in these schemes.<sup>74</sup>

Alternative methods of compensation were looked at but lump sum awards are minimally adequate to provide for the care of a severely disabled person over a lifetime. Structured or serial payments in the place of lump-sum awards were offered as a solution to avoid the premature dissipation of court awards, leaving the injured party relying on the public health and welfare system.<sup>75</sup>

## E. Concept of Quality and Safety

### *1. Health care quality and medical error/accident*

In the IOM report, "To Err is Human", there is a discussion that we have to take a measure against both health care quality and medical errors because they have the same root cause. Is this concept prevailing in your country?

The relationship between error and quality is well understood – the tendency to focus first on 'quality' issues does mean that safety is conceptually viewed as one of the dimensions of quality - so the overall safety of the patient care system does not necessarily lead research into error but is integral to quality of medical care approaches.

### *2. Concept of patient safety*

In the same report from IOM, the importance of a concept of patient safety is proposed against risk management to hospitals for litigation. Does a concept of patient safety prevail in your country?

There has never really been a focus on *risk management* in the past given the predominately publicly funded nature of the system. According to O'Donnell (1999), increased interest about patient safety followed the *Hilmer Report (Independent Committee of Inquiry 1993)* in which it was recommended that market focuses should apply to all market participants regardless of ownership status – legislation is being progressively introduced to bind the behaviour of government organisations.<sup>76</sup>

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<sup>73</sup> O'Donnell (1999) op cit 1. P55

<sup>74</sup> Personal communication Philip Bates, Barrister-at-Law, Sir Owen Dixon Chambers, Sydney

<sup>75</sup> Blomberg C (1996) *ibid*

<sup>76</sup> O'Donnell (1999) op cit 1 p 46



Wilson (2001) also suggests that hospital management has traditionally not had the cost of litigation taken out of their budgets so there has been little incentive to adopt a coherent risk management approach.<sup>77</sup>

## **F. Risk Management at Hospital or Clinic level**

### ***1. Risk Manager***

#### **a. Is there an organization to train a risk manager in your country?**

Formal risk management qualifications can be obtained from the School of Safety Science at UNSW.

#### **b. Is there any post taking charge of medical error prevention such as risk manager in a hospital?**

It is locally structured although the integrated approach of the Wimmera study has been adopted by other institutions; and health care providers are seeking experienced practitioners for their health care organisation. It has been argued that hospital managers lack incentives for risk management as the cost of litigation does not come out of their budget.<sup>78</sup> There is a great deal of literature which explores the cultural problems of health care organisations which precludes the intrusion of non-practitioners into clinical areas. Research into clinical pathways and corporate governance are an attempt to restructure relationships so that there is responsiveness at the clinical level.<sup>79, 80</sup>

### **2. CQI (Continuous Quality Improvement) / Patient Safety**

#### ***Do you have integrated managing unit in hospital for quality and error?***

Quality programs have been of interest for more than a decade. There are wide ranging strategies from clinical peer review, external accreditation, implementation of clinical pathways, research into clinical governance, and the development of computerised longitudinal patient records.

### **3. Fail Safe and Fail Fault System**

Extensive analysis has previously been undertaken in anaesthesia and in NSW there is a human factors and risk management initiative in the area of neurosurgery. There may well be other initiatives in other states.

### **4. Specific Measure for High Frequency Risk Procedure**

This would be done after environmentally specific analysis – and again the Wimmera project provides a model for the development of an integrated risk management strategy, incorporating human factors analysis, in health care facilities.

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<sup>77</sup> Wilson LL & Fulton M (2000) *Risk Management: how doctors, hospitals and MDOs can limit the costs of malpractice litigation* Medical Journal of Australia 172: 77-80

<sup>78</sup> Wilson LL & Fulton M (2000) *Risk Management: how doctors, hospitals and MDOs can limit cost of malpractice litigation* Medical Journal of Australia 172:77-80

<sup>79</sup> Degeling P, Kennedy J, Hill M, Carnegie M & Holt J (1998) *Professional Sub-Cultures and Hospital Reform* Centre for Hospital Management and Information Systems Research, University of New South Wales and The Department of Social Policy, University of Newcastle upon Tyne, UNSW, Sydney

<sup>80</sup> Degeling P, Sorensen R, Maxwell S, Aisbett C, Zhang K & Coyle (2000) *The Organisation of Hospital Care and its Effects* Centre for Clinical Governance Research, UNSW, Sydney

## 5. Risk Analysis Method

*What methods are generally employed to analyze risks associated with medical errors at health care institutions?*

There has been the production of a Risk Management Standard by Standards Australia – *HB 228:2001 Guidelines for managing risk in the healthcare sector* – which is founded on the Standards Australia/Standards New Zealand 1994, generic standard, *Risk Management, AS/NZ 4360*. The standard requires the identification of the strategic, organisational and risk management context before carrying out a process of identifying and analysing the risks for action, followed by monitoring and review of the process to provide a new baseline for future action.

Current methodologies for the identification of risk have included retrospective record audit, prospective incident monitoring, the development of a classificatory index of types of error and the conduct of human factors research in health care.

A recent significant initiative was the development of an integrated risk management approach in Wilceena which has since been adopted in other Victorian jurisdictions.

## 6. Education and Training for Employee

*c. Is there any training course for employees in a hospital?*

A Safety & Quality Council recommendation which follows the exhaustive recommendations of the Professional Indemnity Review.

*d. Is there any hospital or clinic which develops educational tools and/or training materials designed to alter behaviors to prevent errors and increase safety?*

There is currently work in this area. NSW Health has just contracted with human factors researchers and educators to work with neurosurgeons in the development of a system for analysis and action. At a more general level, the *Australian Council for Safety & Quality in Health Care & NSW Ministerial Council for Quality in Health Care* sponsored a workshop on applied human factors research in 2002.<sup>81</sup>:

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<sup>81</sup> Alexander Henderson & Associates, 2002, *Lessons for Health Care: Applied Human Factors Research: prepared for the Australian Council for Safety & Quality in Health Care & NSW Ministerial Council for Quality in Health Care*

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<sup>i</sup> The fiscal year in Japan starts on April 1 and ends on March 31, so FY 1998 began in April of that year, shortly after the Yokohama accident. Research funding can be divided into two categories, special and general. Special funding is usually a one-year contract targeted at special emergency issues, while general funding is a competitive grant representing long-term funding for one to three years.

<sup>ii</sup> Ministry of Health, Labour, and Welfare. *Iryou anzen suishin sougou taisaku: Iryou jiko o mizen ni boushi suru tame ni* [Preventing medical accidents: General measures to promote medical safety], 2002.