



THE UNIVERSITY OF  
NEW SOUTH WALES



CENTRE FOR CLINICAL GOVERNANCE RESEARCH

# EVALUATION OF THE SAFETY IMPROVEMENT PROGRAM IN NEW SOUTH WALES: STUDY NO 1



## LITERATURE REVIEW

***The Centre for Clinical Governance Research in Health undertakes strategic research, evaluations and research-based projects of national and international standing with a core interest to investigate health sector issues of policy, culture, systems, governance and leadership.***

First published in 2005 by The Centre for Clinical Governance Research in Health, Faculty of Medicine, University of New South Wales, Sydney, NSW 2052.

Printed and bound by University of New South Wales.

© Peter Nugus, Jo Travaglia, Jeffrey Braithwaite 2005

This report is copyright. Apart from fair dealing for the purpose of private study, research, criticism or review, as permitted under the Copyright Act, 1968, no part of this publication may be reproduced by any process without the written permission of the copyright owners and the publisher.

National Library of Australia

Cataloguing-in-Publication data:

Series Title: Evaluation of the Safety Improvement Program in New South Wales

Report Title: Evaluation of the Safety Improvement Program in New South Wales: Study No. 1 - Literature Review

A report submitted to the Clinical Excellence Commission and the NSW Department of Health evaluating the Safety Improvement Program

Bibliography.

ISBN: 0 7334 2250 0

1. Safety Improvement Program (N.S.W.) - Evaluation.

2. I. Nugus, P. II. Travaglia, J.F. III. Braithwaite, J.

III. Braithwaite, J. IV. University of New South Wales.

Centre for Clinical Governance Research in Health.

## TABLE OF CONTENTS

<b>1 ABBREVIATIONS AND DEFINITIONS</b>	<b>4</b>
1.1 Abbreviations .....	4
1.2 Definitions.....	4
<b>2 EXECUTIVE SUMMARY</b>	<b>5</b>
<b>3 INTRODUCTION</b>	<b>6</b>
3.1 Overview .....	6
3.2 About this report.....	7
<b>4 METHODS</b>	<b>9</b>
<b>5 FINDINGS</b>	<b>10</b>
5.1 Safety Improvement Programs: a structural survey .....	10
5.2 Incident reporting .....	16
5.3 Analysis of adverse events .....	22
5.4 RCA Training .....	26
5.5 Transfer of learning to the workplace .....	27
5.6 Evaluation of training .....	29
<b>6 DISCUSSION</b>	<b>32</b>
<b>7 CONCLUSION</b>	<b>35</b>
<b>8 REFERENCES</b>	<b>36</b>

## 1 ABBREVIATIONS AND DEFINITIONS

### 1.1 Abbreviations

<b>AHS</b>	Area Health Service
<b>CCGR</b>	Centre for Clinical Governance Research at University of NSW
<b>CEC</b>	Clinical Excellence Commission
<b>DOH</b>	NSW Department of Health
<b>IIMS</b>	Incident Information Management System
<b>RCA</b>	Root Cause Analysis
<b>RIB</b>	Reportable Incident Brief
<b>SIP</b>	Safety Improvement Program
<b>SAC</b>	Severity Assessment Code

### 1.2 Definitions

<b>Clinical Practice Improvement</b>	A combination of tools, techniques, skills and attributes designed to enhance care inputs, structures, cultures, processes, outputs or outcomes.
<b>Culture</b>	The configuration of attitudes, values, beliefs, meanings, behaviours and practices which together can be seen to be definitive of 'what people are' or 'where people come from'. Culture can be seen as a 'state' or something people possess, while it appears more fruitful to regard it as performance and also a process.
<b>Ethnography</b>	A research technique used for describing what human beings do in selected settings, usually comprising 'participant observation', field notes, narrative accounts, interviews, and other qualitative research methods.
<b>Evaluation</b>	The systematic examination of a policy, program or project aimed at assessing its merit, value, worth, relevance or contribution.
<b>Formative Evaluation</b>	Evaluation conducted during a course of a policy's, program's or project's life.
<b>Innovation</b>	The rate, propensity, capacity and effectiveness in adopting new ideas, practices or behaviours.
<b>Organisational Culture</b>	The collective set of relationships in organisations that differentiate one group from another in terms of dress, attitudes, values, behaviours, beliefs, language and shared meaning.
<b>Summative Evaluation</b>	Evaluation conducted at the end of a policy's, program's or project's life.
<b>Triangulation</b>	A multi-method research or evaluation design which adduces converging or diverging evidence drawn from pluralist sources to illuminate an object of inquiry.

## 2 EXECUTIVE SUMMARY

This report presents the results of study 1 in the evaluation of the Safety Improvement Program (SIP) in New South Wales. This study provides an analysis of the international literature on safety improvement. The researchers gathered and examined information from international health services and adult education data bases, grey literature on patient safety, and the websites of key patient safety organisations. This resultant review examines, in detail, research into and information on: safety improvement programs; incident reporting systems; analysis of adverse events, including root cause analyses (RCA) processes; and the transfer and evaluation of training.

The literature canvasses many issues about safety improvement. As it currently stands, it is mostly descriptive and little systemic evaluation of safety improvement has been conducted. Thus, although it is valuable, the literature contains limited evidence.

In particular, while there is a large and growing body of literature on adverse events, patient safety, and safety interventions, relatively little is known about the medium or long term effectiveness of safety improvement programs, the use of adverse event analyses tools such as RCAs, or the effectiveness of RCA related training. This review concludes by identifying key learning from the existing literatures, and highlighting areas for future development, particularly in relation to Safety Improvement Program in NSW. We conducted this component of the evaluation in between September and December 2004.

### 3 INTRODUCTION

#### 3.1 Overview

The NSW Department of Health (DOH) and the Clinical Excellence Commission (CEC) have commissioned the Centre for Clinical Governance Research (CCGR) at University of New South Wales to conduct a formal evaluation of the Safety Improvement Program (SIP). This is a program to enhance safety in New South Wales. The DOH has commissioned this evaluation as part of its knowledge management program in safety and quality under CCGR’s contract to Develop and Evaluate a Knowledge Management Program for Quality Branch. The CEC is interested in the extent to which the SIP will make health care in NSW safer and better under CCGR’s contract to conduct a Research and Evaluation Program into Safety and Quality.

*The Evaluation Protocol* for this project noted: “SIP is a comprehensive safety program introduced to the NSW health system in 2002. It aims to improve patient safety by focussing on health care incident management. The objectives of SIP are:

- To make health care safer through constantly correcting system vulnerabilities by understanding why errors occur.
- To develop a culture where health care incidents are identified, reported, investigated, analysed and acted upon in a supported environment.
- To implement an information system that assists health care workers to achieve the first component.”

The overall evaluation of SIP takes the form of 12 inter-related studies (Table 1). This report documents the outcomes of study 1. This review surveys key literature related to the implementation and operation of safety improvement programs in a number of countries around the world. This component of the evaluation was conducted by Mr Peter Nugus, Ms Jo Travaglia and A/Professor Jeffrey Braithwaite.

**TABLE 1: Evaluation Studies**

STUDY	TITLE	COMMENTS, ACTIONS AND TIMEFRAMES	LED BY/TEAM
Study #1	Literature Review	<ul style="list-style-type: none"> <li>• National and international literature on patient safety and RCA processes</li> <li>• Appraisal of the evaluation process through the extant literature</li> </ul>	Peter Nugus, Jo Travaglia, Jeffrey Braithwaite
Study #2	Review of education and training program	<ul style="list-style-type: none"> <li>• 2 a) Triangulated review of educational value of RCA program</li> <li>• 2b) Meta-analysis of SIP training program evaluation forms</li> </ul>	Jo Travaglia, Mary Westbrook, Peter Nugus, Rick Iedema, Debbi Long, Nadine Mallock

<b>Study #3</b>	Achievements of aims and objectives and stakeholder satisfaction	<ul style="list-style-type: none"> <li>• Questionnaire to all course participants</li> <li>• Review of course evaluations</li> </ul>	Mary Westbrook, Nadine Mallock
<b>Study #4</b>	Ongoing applicability of training to participants	<ul style="list-style-type: none"> <li>• Questionnaire to all course participants</li> <li>• Survey of international SIP programs to benchmark the current program in an international context</li> </ul>	Nadine Mallock, Mary Westbrook, Jeffrey Braithwaite
<b>Study #5</b>	Satisfaction of Faculty members	<ul style="list-style-type: none"> <li>• Detailed interviews with faculty staff</li> </ul>	Debbi Long
<b>Study #6</b>	Program outcomes at local, area and state levels	<ul style="list-style-type: none"> <li>• Review of RCA data submitted to the DOH</li> <li>• Questionnaire to all course participants</li> <li>• Interviews with key stakeholders</li> </ul>	Jo Travaglia, Jeffrey Braithwaite, Mary Westbrook, Nadine Mallock, Marjorie Pawsey
<b>Study #7</b>	Lessons learnt	<ul style="list-style-type: none"> <li>• 7 a) In-depth observation and review of RCAs in situ</li> <li>• 7 b) Focus groups</li> </ul>	Rick Iedema, Rowena Forsyth, Christine Jorm, Peter Nugus
<b>Study #8</b>	Return on investment	<ul style="list-style-type: none"> <li>• Questionnaire to all course participants</li> <li>• Interviews with key stakeholders</li> </ul>	Jeffrey Braithwaite, Jo Travaglia, Nadine Mallock, Mary Westbrook,
<b>Study #9</b>	Effectiveness of SIP Committee	<ul style="list-style-type: none"> <li>• Observation of Steering Committee</li> <li>• Review of outcomes</li> </ul>	Nadine Mallock, Jeffrey Braithwaite
<b>Study #10</b>	Management of RIB process	<ul style="list-style-type: none"> <li>• Focus group</li> <li>• DOH data</li> <li>• Interviews with key stakeholders</li> </ul>	Jeffrey Braithwaite, Jo Travaglia, Nadine Mallock, Marjorie Pawsey
<b>Study #11</b>	Reporting processes	<ul style="list-style-type: none"> <li>• Focus group</li> <li>• DOH data</li> <li>• Interviews with key stakeholders</li> </ul>	Jeffrey Braithwaite, Jo Travaglia, Nadine Mallock, Marjorie Pawsey
<b>Study #12</b>	Branch functions and actions	<ul style="list-style-type: none"> <li>• Focus group</li> <li>• DOH data</li> <li>• Interviews with key stakeholders</li> </ul>	Jeffrey Braithwaite, Jo Travaglia, Nadine Mallock, Marjorie Pawsey

### 3.2 About this report

This report presents a review of the key literature related to the implementation and operation of safety improvement programs in a number of countries around the world. The review concentrates on six key areas: international and national safety improvement programs; incident reporting mechanisms; analysis of adverse events; RCA training; transfer of learning; and the evaluation of training programs. These areas were chosen as the most pertinent to the evaluation of the NSW Health Safety Improvement Program, of which this literature review is a component study.

The review begins with an examination and survey of safety improvement programs in English speaking countries. The section on incident reporting discusses the literature pertaining to the main mechanism by which NSW Health seeks to assess, report, investigate, review and respond to undesirable incidents in a coordinated manner (NSW Health Quality and Safety Branch, 2003). The complexity of implementing a SIP in a systemic and coordinated manner is foregrounded by a critical overview of incident reporting systems generally.

The discussion on adverse events analysis considers in detail the particular mechanism, root cause analysis (RCA), used by NSW Health to ascertain the underlying cause of an incident or adverse event as a means of providing system-wide learning to prevent such incidents occurring in the future. Various aspects of the RCA method and implementation include: human factors engineering; selection of incidents on which to conduct RCA; and clinical work culture and practices.

The section on learning reviews current thinking on the transfer of theoretical learning to practical work settings. It then goes on to consider methods for the evaluation of medium and long term, as well as short term, outcomes of training programs.

## 4 METHODS

This literature review specifically targets features of NSW Health's Safety Improvement Program which are analysed in the evaluation. In doing so, the review takes account of, but is not limited to, literature derived from systematic reviews of literature in each of the topic areas in the following databases: CINHALL, EMBASE, ERIC, Emerald, Medline, Medlineplus, PubMed and Web of Science databases were searched from 1990 onwards.

A systematic search was conducted using the terms: safety improvement program and programs, incident reporting, reportable incident briefs, root cause analysis, root cause analyses, human factors, and training evaluation. In total 86 articles were integrated into the review from an initial selection of 448 articles which were derived from targeted term searches. In addition, a series of patient safety organisation websites were reviewed for grey literature in these topics. A total of 103 reports, monographs, policies, guidelines, media statements and studies were found using this method leading to a total of 36 works cited in the review.

These contributions were read by 2 researchers who summarised and categorised them into the themes. The findings which follow group the literature into these themes.

## 5 FINDINGS

### 5.1 Safety Improvement Programs: A structural survey

Safety Improvement Programs (SIPs) currently operate at nation-wide, state, local and organisational levels, across the globe. An examination of SIPs in United States of America (USA), the United Kingdom (UK), Canada, New Zealand and Victoria, Australia provide a system-wide context with which to evaluate the effectiveness of SIP in NSW.

Each of these jurisdictions features SIP models with varying degrees of scale, scope, and underlying research and collaborative input. Characteristics of SIP programs include one or all of the following: incident monitoring and reporting, analysis of adverse events and provision of education both on how to analyse the causes of adverse events, and how to address these causes. Some, but not all, constituencies have legislation which impact on SIPs such as mandatory reporting and protected disclosure.

In general, SIP programs undertaken by private organisations in the USA and publicly by the National Health Service (NHS) in the UK represent the most comprehensive models of safety improvement programming in this survey. The US and the UK provide structural models of system-wide safety programs. The Canadian literature provides insights into the impact of a legislatively based safety improvement program, while the New Zealand section offers a view of the impact of “no fault” systems.

#### **United States of America (USA)**

Although the Australian patient safety movement has been inspired by developments in the USA, the USA is unique in the jurisdictions surveyed because patient safety programs are driven by private rather than government organisations. The USA also has several national organisations that network patient research and initiatives.

Three key agencies were developed in response to the report *To err is human* (Institute of Medicine, 2000) and with the explicit support of President Clinton. These were: the Quality Interagency Council (QulC), Agency for Health Care Research and Quality (AHRQ), and the National Quality Forum. Their charter is to coordinate nation-wide responses in research and clinical practice improvement. The Institute of Medicine (IOM) Report also recommended the establishment of a nationwide, mandatory system for the collection of standardised information on adverse events, by State governments.

Other organisations directly involved in safety improvement in the USA include: the Veteran’s Health Administration (VA) National Centre for Patient Safety (NCPS), the National Patient Safety Foundation (NPSF), state level Quality Improvement Organizations (QIOs), the National Academy for State Health Policy (NAHSP), the USA Patient Safety Institute (PSI), and the American Medical Association (AMA).

In terms of accreditation, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredits more than 15,000 healthcare providers (Joint Commission on Accreditation of Healthcare Organizations, 2005). JCAHO, though private, is the closest equivalent to the Australian Council on Healthcare Standards (ACHS) and the UK's Commission for Health Improvement. Another prominent association involved in patient safety is the Leapfrog Group, which brings together more than 170 public and private organisations that provide health care services. The approximately 32 million health care consumers who are covered by the Leapfrog group use their purchasing power of US\$53 billion to reward institutions that meet specific safety standards (The Leapfrog Group for Patient Safety, 2004).

Private organisations play the most prominent coordinating and standard-setting role in safety improvement in the USA (Gardner, Baker, Norton, *et al.*, 2002). The American Medical Association for example, along with a number of health organisations and professional bodies, has collaborated with national and state organisations in the USA to support a set of "Principles for Patient Safety Reporting Systems", which include: creating an environment for safety; data analysis; confidentiality; information sharing and legal status of reporting system information (American Medical Association, 2000).

The AMA has noted that the absence of federal protection for the information and informants of patient safety systems would discourage the use of such systems. Consequently, in 2004, the USA passed the Patient Safety and Quality Improvement Act (which is still awaiting implementation). The aim of the Act is to develop a culture of safety across USA health care services. Its instigators hope to establish a learning environment which will facilitate and encourage the reporting of errors and continuous improvements in quality. The Act will provide for patient confidentiality; prohibit the disclosure of patient safety work products in civil and administrative legal proceedings; protect individuals who report information to patient safety organisations; and legislate for the establishment of a National Patient Safety Database. It will also authorise grants to healthcare providers for establishing electronic prescription programs and other information technologies aimed at improving quality of care and patient safety. Most of these recommendations stem directly from the IOM report (Institute of Medicine, 2000).

The Veterans Health Administration (VA), which provided the model for the SIP in NSW, defines the goals of its own SIP program as preventing "injuries to patients, visitors, and personnel, and to manage those injuries that do occur to minimise the negative consequences to the injured individuals". The elements of the VA's SIP are very similar to the NSW program, including comprehensive identification and reporting of adverse and sentinel events, as well as close calls; reviewing each of these to identify root causes, dissemination of findings through patient safety alerts and lessons learnt; and prospective analysis of service delivery systems before an adverse event occurs (Department of Veterans Affairs, 2005). The VA's system of Root Cause Analysis (RCA) investigations is widely used in the USA.

Although health care is largely privatised in the USA, the strong influence of the Leapfrog Group, the JCAHO and the VA make them models for SIPs, even in systems with a higher funding and coordinating role from governments, as is the case in the UK, Australia, Canada and New Zealand. This renders the public/ private distinction less relevant in this comparison of patient safety programs.

### **United Kingdom (UK)**

The UK has the strongest direct relationship between the national government and patient safety improvement programs of the jurisdictions surveyed. The NHS has a directive role over its Trusts (regional authorities) through funding and accreditation requirements.

As in Australia, concerns in the UK have been sparked both by research into rates of adverse events (Vincent, Neale and Woloshynowych, 2001) and by the impact of key inquiries into cases of systemic failures to prevent injury to patients (Redfern, Keeling and Powell, 2001). Two key documents drive the UK safety improvement program: *An Organisation with a Memory* and its associated implementation document, *Building a Safer NHS for Patients* (National Health Service, 2000, 2001).

*An Organisation with a Memory* identified pivotal weaknesses in the NHS safety systems. These include the lack of standardised definitions of adverse events, problems with regional variations in reporting, monitoring and response rates, warnings of actual or potential adverse events which were missed by reporting systems, inconsistency in use and types of investigation systems and a failure to learn from past mistakes. The report's major focus lay in this last issue: that is, how to improve the NHS' ability to learn from adverse events. The recommended steps mirror those in both NSW and the VA: understanding of potential for adverse events; adverse events recognised and documented at source; standardised reporting; database maintenance and quality control; analysis of trends and systematic causes; action and feedback, and reduced risk of recurrence. *An Organisation with a Memory* also outlined the proposals for the NHS' mandatory and voluntary reporting systems.

In response, the UK Government issued *Building a safer NHS for Patients*, supported the findings of the previous report, and established the parameters of the National Patient Safety Agency (NPSA). This agency along with the National Institute for Health and Clinical Excellence (NICE) and the NHS Modernisation Agency form the basis of the NHS' organisational responses to patient safety.

The NHS Modernisation Agency spans a range of clinical, educational and organisational features of health services delivery in the UK, constituting a framework rather than an overall program (NHS Modernisation Agency, 2005). The National Institute for Health and Clinical Excellence provides national guidance on public health, health technologies and clinical practice. It has the power to require NHS Trusts and employee to comply with safety initiatives within existing resources<sup>1</sup> (National Institute for Health and Clinical Excellence, 2005).

---

<sup>1</sup> The Report of the Inquiry into recent events at Campbelltown and Macarthur hospitals, delivered by Bret Walker, recommended that the New South Wales Clinical Excellence Commission (formerly Institute for Clinical Excellence) might acquire such a broadly based role for ensuring quality and safety (Walker 2004). If such a recommendation was implemented, the Commission would differ from NICE in having a stronger organisational than clinical role.

Reports and initiatives on patient safety also frequently emanate from the Office of the Chief Medical Officer. This is largely an equivalent role to the Australian Council on Safety and Quality in Health Care.

Yet, the NPSA provides a point of particular distinction from other national systems. Incident reporting in the UK is mandatory and NPSA has a mandate to collect and analyse incident reports. NPSA is required to assimilate other safety-related information from existing reporting systems in the UK and internationally, and to examine and track patterns and trends, which they are then required to feed back to organisations and individuals. Like the USA, considerable amounts of funding are allocated to safety and quality research in the UK although this is funded by the government and tied explicitly to mandatory initiatives, accreditation and incident monitoring. One of the explicit functions of the NPSA is to promote research, to produce solutions to reduce risk and prevent harm to future patients (including establishing national goals and targets) to promote a reporting culture in the NHS and to collaborate with relevant national and international bodies (National Health Service, 2001).

The tight relationship between the NHS and individual health care providers allows the NHS to collaborate extensively and directly in terms of clinical practice improvement and patient safety research. The investigative tools of the NHS differ from those used in Australian states because they also focus on staff. While acknowledging that systems, rather than individual negligence, are usually to blame for medical errors, the NPSA Joint Chief Executive stated that: 'it is essential that staff are suspended when serious concerns are raised and that poor clinical performance is tackled' (National Patient Safety Agency, 2004).

The NPSA developed the Incident Decision Tree (IDT) in 2003 with the intention of encouraging systematic, transparent and fair decisions. This non-mandatory tool has been created to provide a framework for human resource and NHS managers determining the course of action to take with staff who have been involved in a patient safety incident. The objective of the tool is to encourage a consistent and fair approach to staff issues across the NHS. Ultimately, it is intended to allow NHS organisations to avoid unnecessary and costly suspensions and alleviate the anxiety suffered by the staff involved. There are four key areas of questions and options: Deliberate Harm Test, Incapacity Test, Foresight Test, and Substitution Test. The UK's 1998 Public Interest Protection Act provided protection to whistleblowers who may wish to report events, individuals or organisations (NHS Executive Health Service, 1999).

## **Canada**

Safety improvement programs in health care in Canada have developed later than in the UK, the USA or Australia (Bonney and Baker, 2004). Health care in Canada, like the UK, Australia, and New Zealand, is primarily financed through direct and indirect government funding. Canada, like Australia, is a federation, although this appears to have been a stronger impediment to patient safety initiatives than in Australia. The *Canada Health Act 1984* consolidated the public health system, mandating comprehensive, universal, portable, publicly funded and accessible health care.

The Act did not repeal the provisions of the Medicare Act 1966 which made provinces responsible for the delivery of health care (Currie, Lewis, Donaldson, *et al.*, 2001). Although, in theory, this might have resulted in a system of grants tied to quality and safety initiatives, substantial differences in industrial relations as well as devolved responsibilities for health care funding appear thus far to have run counter to the development of large-scale, nation-wide safety programs.

Individual provinces, have, however implemented their own SIPs. Notably, Alberta, Saskatchewan, Manitoba, Nova Scotia and Ontario have institutionalised Patient Safety Programs. The relatively limited number of SIPs in Canada appears to have been influenced by research and approaches from the USA and elsewhere.

The specific training programs and operationalisation of safety improvement schemes in Canada have targeted medication error (Health Canada, 2002). While efforts are being made, these do not seem to have been cross-fertilised across provinces. Programs are increasingly being coordinated from the Institute (Canadian Patient Safety Institute, 2001), although some provinces have been reluctant to participate (Bonney and Baker, 2004). A high profile voluntary reporting scheme is the Canadian Medication Incident Reporting and Prevention System (CMIRPS) although this does not have the breadth and scope of the Australian Incident Monitoring Scheme (Health Canada, 2004). Root cause analyses are being conducted by Canadian health care providers, particularly in Saskatchewan (Tilley, 2004). Yet, overall, Canada's approach to patient safety programs thus far has been fragmented like the USA's. Canada has not to this point followed the UK and harnessed the potential of the public system.

### **New Zealand**

The structure of health care in New Zealand is most like that of the UK with a central unitary system of government and corresponding unitary health care sector. This, in theory, might have meant that New Zealand had a tighter regulatory association between the central government and health care providers. Unlike the UK, New Zealand's incident reporting programs are not as yet mandated, although this has been recommended by the Cull report into adverse medical errors (Cull, 2001).

Cull found that New Zealand has some fourteen organisations that could potentially undertake investigations into the same adverse event, including the Accident Compensation Commission, the Health and Disability Commissioner, the Medical Misadventures Unit, the Medical Council of New Zealand and the Medical Practitioners Disciplinary Tribunal (Cull, 2001). The report recommended that there be mandatory reporting of practitioners whose practice is below acceptable standards, and that the New Zealand Medical Council be given the power to suspend practitioners if the public is at risk, even before charges are laid at the Disciplinary Tribunal.

This is particularly interesting in light of New Zealand's unique position in having a 'no fault' compensation system. This means that patients who have suffered an adverse event can take action against the institution but not against the clinician. It has been suggested that, because this does not include punitive and exemplary damages, complaints have actually increased. As a result some Australian states are considering reforms to tort law and insurance guidelines, rather than the introduction of a no fault system (Medical Defence Association of Western Australia, 2002).

New Zealand has directed patient safety efforts to the institution of databases. It has, registered all patients and their episodes, as well as all clinicians, in the centralised National Health Index database (New Zealand Health Information Service, 2005).

The attention to medication error is also a strong focus of the New Zealand Ministry of Health. This is evident in the establishment of *Medsafe*, the *New Zealand Medicines and Medical Devices Safety Authority* (New Zealand Medicines and Medical Devices Safety Authority, 2005).

### **Victoria, Australia**

The State of Victoria, like NSW, has undertaken a range of safety improvement initiatives as part of the institution of an overall SIP. Victoria has a sentinel event program which utilises root cause analyses (State Government of Victoria, 2005). The Sentinel event program Annual Report 2003-2004 strongly recommended that all staff at all clinical and executive levels be encouraged to undertake root cause analysis training (Metropolitan Health and Aged Care Services Department, 2004).

Like NSW, reporting of adverse events is currently voluntary, although hospitals are required to report on the implementation of their Clinical Risk Management Plan and Annual Quality of Care Report and for smaller rural hospitals their quarterly Limited Adverse Occurrence Screening (LAOS). The Victorian Quality Council (VCC) has launched its Healthcare Quality and Safety Data Directory (Victorian Quality Council, 2004). This Directory is a repository and evaluation of information on clinical best practice and quality and safety initiatives. The Council has also sponsored an Infection Control Working Group to promote, educate and voluntarily evaluate protocols and procedures (Victorian Quality Council, 2003a). Research projects of the Council have included a report on Falls Analysis (Victorian Quality Council, n.d.) and State-wide Pressure Ulcer Point Prevalence Survey (Victorian Quality Council, 2005). Education has included the Acute Pain Management Workshop (Victorian Quality Council, 2003b) and publications on adverse events including *Riskwatch* (Victorian Government Health Information, 2004)

Table 2 provides a summary of some of the key characteristics of international and national SIPs we have discovered. It shows how the responses to safety improvement programs have varied across jurisdictions. The limits to the scope of responses to date indicate health systems which are have only begun to address longer term issues of industry collaboration and safety research, choosing to focus, much like NSW, on the core actions of incident reporting and analysis as the first steps to implementation of SIPs.

**TABLE 2: Characteristics of international and national SIPs**

	Mandatory Incident Reporting	Voluntary Incident Reporting	Causal Analysis	Safety Research	Industry Collaboration	Evaluation of SIPs
JCAHO/ VA	N	Y	Y	Y	Y	Y
NHS	Y	Y	Y	Y	Y	Y
Canada	N	Y	Y	L	L	N
NZ	N	Y	Y	L	L	N
Victoria	N	Y	Y	L	L	N

N = No, Y = Yes, L = Limited in scope

## 5.2 Incident reporting

Incident reporting is at the core of many safety improvement programs (Vincent, 2004). The Institute of Medicine report *To Err is Human* (2000) claims that health services have much to learn from the analysis of medical errors. The authors argue strongly that all adverse events resulting in death or serious injury should be evaluated. The aim of such evaluations is to assess whether improvements to the health care system can reduce the likelihood re-occurrence of similar events. Adverse events that do not result in harm (“near misses”) represent an important opportunity prospectively to identify system improvements.

Both the NPSA in the UK (National Patient Safety Agency, 2005b) and the USA’s Agency for Healthcare Research and Quality (AHRQ) (Agency for Healthcare Research and Quality, 2003) are placing significant organisational and financial resources into reporting processes. In NSW, the Reportable Incident Brief (RIB) is ‘the method for reporting defined health care incidents to the NSW Department of Health’ (NSW Health Quality and Safety Branch, 2003) but a variety of incident reporting systems and methods currently operate in Australia, and internationally. As in New Zealand (Cull, 2001) any number of organisational, professional, health service and legal bodies may be jointly or independently able to request or mandate for the reporting of adverse events.

Differences in reporting reflect differences in the severity or type of adverse event, in the person (staff member, patient, other stakeholder) reporting, or in the length of time since the incident. They also reflect differences in reporting requirements between, and within, countries, states and regions (National Health Service, 2000). Incident reports can be made at any or all of unit, department, facility, organisational, regional, state or national levels. Types of reporting processes currently utilised include mortality and morbidity reviews, peer reviews, case recognition (Weingart, Wilson, Gibberd, *et al.*, 2000), case audits, record reviews (Wilson, Harrison, Gibberd, *et al.*, 1999) direct observation (Andrews, Stocking, Krizek, *et al.*, 1997), record review (Brennan, Leape, Laird, *et al.*, 1991) as well as systemic reporting systems, both mandatory and voluntary (Institute of Medicine, 2000). Coroner’s reports and major inquiries are also utilised to inform patient safety improvement programs (Cull, 2001).

## Severity Assessment

Most incident reporting systems require some form of assessment as to whether an event merits entry into an incident reporting system, that is, whether it is “reportable” under the particular set of parameters established by the reporting agency. NSW, like the NHS in the UK, utilises the Severity Assessment Code (SAC) developed by the VHA as a way of determining both the impact of the adverse event, and consequently the need to report it. The NSW SAC, like that of the VA, is allocated on the actual or potential severity of an incident and the likelihood of the event occurring again. The matrix identifies specific actions to be undertaken for given scores (NSW Health Quality and Safety Branch, 2003).

NSW Health’s instructions on the RIB process are that reportable incident processes require managers to report incidents with a SAC rating of 1 to the Department within 24 hours, and also ‘incident(s) ... rated at 2, 3 or 4 ... (if it) is likely to attract external attention ...’. All SAC ratings of 1 or 2 are required to be reported to the AHS CEO or their delegate. A SAC rating of 1 is allocated if the event has serious consequences – that is, it results in the death of a patient, visitor or staff member, and the probability of its reoccurrence is rated as frequent, likely, possible or even unlikely, to occur again. SAC 1 ratings are also allocated to major event which do not result in death, but where there is a major permanent loss of function, and where the possibility of reoccurrence is either frequent or likely. Furthermore, ‘... the RIB should contain facts, initial analysis and future actions. Opinion and subjective comment are to be avoided’ (NSW Health Quality and Safety Branch, 2003).

A central message from the literature is that SAC score allocation methodology needs to be open to constant revision as the nature of adverse events, near misses, human factor engineering and clinical work culture come to be better understood. Radtke provided advice on the complex task of defining and categorising adverse events and near misses. She recommended that managers base their decision to review a serious adverse event on the outcome of the case and not on any assumed causes. The example she provides is of a patient who dies (in NSW Health, a SAC 1) but who at the time of admission was considered highly likely not to survive. In this case, the incident would not be deemed a sentinel event, all other cases however, would be, and would require root cause analyses (Radtke, 2004).

Critiques of SAC methods focus on the potential inconsistency in the reasoning about potential or actual adverse events (Kaplan and Fastman, 2003). As a response, Kaplan and Fastman recommended broadening issues for RCA investigation to make use of a ‘risk matrix’ and to include, for example, financial loss. They also recommended a category of ‘events without harm’, or simply ‘events’ (with the potential for harm).

## Reporting systems

A UK study found that prior to the implementation of *An Organisation with a Memory* one fifth of NHS Trusts had no organisation-wide reporting systems. Less than half of the same Trusts provided specific training in risk management or incident reporting and fewer than one third provided guidance to staff on what to report and only a similar number required clinicians to report unexpected operational complications or events (Dineen and Walsh, 1999).

A study conducted by the National Academy for State Health Policy (NASHP) in the USA identified a number of barriers to the introduction to state reporting systems. These included: financial barriers (including the costs of designing, operating and maintaining systems, as well as the implications of implementing incident reporting programs without the allocation of resources to ensure the effective collection of data); political barriers (including resistance from healthcare services who fear disclosure of information, unwillingness to antagonise service providers, and possible clashes with federal systems); legal barriers (issues of confidentiality, disclosure and limited liability); and lack of evidence that the reporting systems and collection of data actually reduce errors (Rosenthal, Booth and Barry, 2001).

A number of researchers and patient safety organisations have attempted to identify the key features of a successful incident reporting system. Table 3 provides a summary of these features.

**TABLE 3: Factors affecting incident reporting systems**

DESIGN AND USE FACTORS	
<ul style="list-style-type: none"> <li>▪ Design</li> </ul>	<ul style="list-style-type: none"> <li>▪ Integration with existing reporting mechanisms</li> <li>▪ Ability to accept mandatory, voluntary and anonymous reports</li> <li>▪ Ability to continuously accept reports</li> <li>▪ Ability to deal with high volumes of reports</li> <li>▪ Standardized and simple classifications</li> <li>▪ Ability to compute root cause</li> <li>▪ On-line confidential reporting systems</li> </ul>
<ul style="list-style-type: none"> <li>▪ Reporting systems</li> </ul>	<ul style="list-style-type: none"> <li>▪ Ability to investigate all reports</li> <li>▪ Ability of system to sort reports as routine, new or unique incidents</li> <li>▪ Accuracy of reporting</li> <li>▪ Ability to analyse common factors and causes</li> <li>▪ Ongoing and timely analysis of all reports</li> <li>▪ Ability to identify corrective action at a local level</li> <li>▪ Ability to obtain and evaluate preventive plans to eliminate reoccurrence</li> </ul>
<ul style="list-style-type: none"> <li>▪ Protections</li> </ul>	<ul style="list-style-type: none"> <li>▪ Immunity which does not affect ability to prosecute for malpractice</li> <li>▪ Confidentiality</li> <li>▪ Stronger sanctions for trying to block investigations</li> </ul>

**DESIGN AND USE FACTORS**

- Staffing/resources
  - Increased involvement of professional licensing agencies
  - Independently employed risk managers
  - Training on reporting
  - Education
  - Restructuring peer review and credentialing processes to assure fairness and objectivity
- External factors
  - Media awareness of true nature of adverse outcomes and errors
  - Reducing malpractice litigation
- Follow up
  - Corrective action plans that are non-punitive
  - Timely investigations with sound plans of correction
  - On-site follow up
  - Rapid and meaningful feedback to general staff and reporting individuals
  - Comparative data on trends, common problems and effective solutions collected and distributed from a central service
  - Encouragement of continued reporting through feedback
- Evaluation
  - Evaluation at local level of both system and corrective actions
  - Ability to demonstrate improved outcomes

Sources: Barach and Small, 2000; Battles, Kaplan, van der Schaaf, *et al.*, 1998; National Health Service, 2000; Rosenthal, Booth and Barry, 2001.

In Australia, the Australian Incident Monitoring System (AIMS) was introduced in 1996, as a result of the Quality in Australian Health Care Study (Wilson, Runciman, Gibberd, *et al.*, 1995). It provides a mechanism for the reporting of any adverse event via a standard form. Incidents are categorised using a classification system developed by the Australian Patient Safety Foundation. The system is based on one developed for anaesthesia errors in the late 1980s. It is currently being instituted in NSW.

**Barriers to reporting**

At an individual level, empirical studies suggest that many adverse incidents are not reported, even though they are designated as reportable and reporting systems exist. Findings vary from one third (Jayasuriya and Anandaciva, 1995) to less than a quarter (Vincent, Stanhope and Crowley-Murphy, 1999) of reportable incidents are reported.

A survey of reportable incidents in anaesthesia revealed that reporting was higher for more serious incidents and those in which the patient recovered, and poorer for relatively common incidents (Jayasuriya and Anandaciva, 1995). Recommendations are made for simplifying and streamlining incident reporting systems (Stanhope, Crowley-Murphy, Vincent, *et al.*, 1999; Vincent, Stanhope and Crowley-Murphy, 1999) which are among the stated aims of the numerical SAC allocation (NSW Health, 2005).

Research into the resistance to reporting of adverse drug reactions in the UK has exposed a range of reasons for resistance to reporting, including: dislike of reporting confidential information, uncertainty as to how to report an adverse drug event, concerns at appearing foolish, fear of exposure to legal liability and reluctance to admit that harm has been caused to a patient (Bateman, Sanders and Rawlins, 1992; Belton, Lewis, Payne, *et al.*, 1995). A study of why ICU staff across Europe and the USA were reluctant to report identified issues of reputation, threat of malpractice, job insecurity, disciplinary actions by licensing boards and the expectations of other team members and patients' family and society (Sexton, Thomas and Helmreich, 2000). Conversely, a study of ICU staff in Australia indicated that high rates of reporting compliance could be achieved with continual reinforcement of staff, particularly during periods of staff rotation or holiday breaks (Beckmann, West, Groombridge, *et al.*, 1996).

Empirical support exists for the primacy of workplace culture as a source of failure to report, despite the designation of reportability for particular incidents. Among the findings of a study of reportable incidents in two obstetrics units are that junior staff are more likely than senior staff to report incidents, and that junior staff are less likely to feel supported by colleagues than senior staff (Stanhope, Crowley-Murphy *et al.*, 1999). Further, the main reasons for failing to report such incidents were fear by junior doctors that they would be blamed for the incident, the belief that the incident was not worthy of reporting, even though it was formally designated as reportable, and high workload (Stanhope, Crowley-Murphy *et al.*, 1999).

Barach and Small (2000) identified a number of barriers and incentives to incident reporting at individual, organisational and society levels. These are shown in summary in Table 4.

**TABLE 4: Barriers and incentives to incident reporting**

	INDIVIDUAL	ORGANISATIONAL	SOCIETY
<b>Legal</b>			
Barrier	Fear of reprisals, lack of trust	Fear of litigation, sanctions undermine trust, bad publicity	Legal impediments to peer review, confidentiality, and multi-institutional databases
Incentive	Provide confidentiality and immunity	Provide confidentiality and immunity	Ensure accountability, enforce reporting statutes

<b>Cultural (values, attitudes, beliefs)</b>			
Barrier	Dependent on profession, code of silence, fear of colleagues in trouble, skepticism, extra work	Dependent on organisation, pathological, bureaucratic, generative cultures, don't want to know	Wide public trend towards disclosure, lack of trust owing to highly publicized medical errors, concerns that professions are too privileged, lack of education about systems effects
Incentive	Professional values, philanthropic, integrity, educational, cathartic	Become a leader in safety and quality, good for business	Enhanced community relations, build trust, improve health care, transparency
<b>Regulatory</b>			
Barrier	Exposure to malpractice, premiums will go up, investigation and potential censure, license suspension and subsequent loss of income	It doesn't apply to us, we do our own internal analysis process, they can't understand our problems anyway	Need more effective regulations, resource intensive
Incentive	Prophylactic, follow the rules	Fear of censure	Enhances regulatory trust, more public accountability
<b>Financial</b>			
Barrier	Loss of regulation, loss of job, extra work	Wasted resources, potential loss of revenue, patient care contracts, not cost effective	Cost more tax dollars to enforce, more bureaucracy
Incentive	Safety saves money	Publicity relations, improve reputation of quality and safety	Improves confidence in healthcare system
Source: Barach and Small (2000: 761)			

Evidence exists for the benefits of collecting and monitoring of adverse incident data, even across a diverse population such as general practitioners (Britt, Miller, Steven, *et al.*, 1997) although such data can become unwieldy in applying the findings to system-wide practical improvement (Tsatsoulis and Amthauer, 2003). In the wake of events at Campbelltown and Camden hospitals, the Walker Inquiry recommended that models, performance indicators and corrective action systems be devised and implemented in response to the analyses of RIBs (Walker, 2004).

### 5.3 Analysis of adverse events

This section of the literature review covers four key inter-dependent areas: Root Cause Analysis (RCA); Human Factors Engineering (HFE); categorising adverse events for the purpose of conducting RCAs; and work practices and cultures.

#### Root Cause Analysis

Root Cause Analysis (RCA) is a retrospective, qualitative approach to error analysis. Its own roots are in human factors engineering and industrial psychology. It has been used widely in a number of industries such as nuclear power, aviation, and chemical plants (Carroll, Rudolph and Hatekanaka, 2002) as a way of investigating accidents and incidents (Reason, 1990).

RCAs have been used sporadically in health services for some years. In 1997 JCAHO mandated the use of RCAs within the organisations it accredited (Wald and Shojania, 2001). By 2000, RCAs were being utilised by the National Centre for Patient Safety (NCPS) of the Department of Veterans Health Affairs (VHA) in the USA (Bagian, 2001; Bagian, Gosbee, Lee, *et al.*, 2002).

RCAs are based on the premise that errors occur in health care systems and that they follow a pattern that can and should be uncovered (Boggett, 2004; Donchin, Gopher, Olin, *et al.*, 1995). Reason identified two major categories of errors: active errors which occur when humans interact with complex systems and latent errors which occur as a result of failures in the design of systems (Reason, 1997; Reason, 2000). By examining the latent errors, more attention can be paid to the context in which an incident occurs – the ‘error producing conditions’ (including the management, regulatory and legislative factors) that facilitate occurrence of the adverse event, rather than blaming the individuals involved (Leape, 1994).

RCA investigations focus on the identification of latent errors which underpin adverse events, while at the same time identifying and acknowledging active errors. The recommendations which emerge from RCAs are intended to prevent mistakes from re-occurring by helping organisations to learn the outcomes of the RCAs (Boyer, 2001; Rex, Turnbull, Allen, *et al.*, 2000; Shinn, 2000). In brief, the RCA method involves the investigation of adverse events, near misses and/or close calls. RCAs are generally conducted by members of a multidisciplinary team. Members are those who understand the context and issues involved, but have not been directly involved in the incident being investigated. It is generally advised that team members be trained in how to conduct RCAs.

The need for an RCA arises once an adverse event or near miss is identified. Once this has occurred the incident is usually given a severity rating (Gosbee and Anderson, 2002) based on a schema such as the SAC used in NSW and by the VHA. RCAs involve a staged process guided by key questions: what happened; why did it happen; and how can it be prevented to happening in the future? (Bagian, Gosbee *et al.*, 2002, quoted in (Gosbee and Anderson, 2003).

Data are collected through interviews with relevant individuals, document reviews and at times field observation. These data are used to establish a timeline of the incidents, and associated events. Once the event is sequenced, it is analysed in order to identify the causal factors which resulted in the adverse event. In the NSW process, as with VHA, a list of possible contributing factors is provided in the form a checklist.

Common types of contributing factors include institutional, regulatory, organisational, management, physical environment, team, staff or task factors, communication, and patient characteristics. A causal tree is then developed. The final step in the RCA is to identify which of these factors are generalizable and/or reproducible, and what policies, procedures, actions etc could prevent them from re-occurring (Bagian, Gosbee, Lee, *et al.*, 2002; Bagian, Lee, Gosbee, *et al.*, 2001; Bancroft, 2002; Bancroft K., 2002; Boyer, 2001; Braithwaite and Westbrook, 2005; Burroughs, Cira, Chartock, *et al.*, 2000; Connor, Ponte and Conway, 2002; Hirsch and Wallace, 2000; Kaplan and Fastman, 2003; Latino, 2000; Williams, 2001).

The use of RCAs in both health services and other industries is not, however, without concerns or criticism. One of the key concerns is that there is no real assurance that the findings of the RCA process are in fact the cause of the adverse event, (Runciman, Sellen, Webb, *et al.*, 1993) or indeed that there is a single cause for any incident (Vincent, 2000, 2003). Discrepancies may occur for many reasons, including the depth of the analysis (Reason, 1990), the “political” context of the day and the organisation (Rasmussen, 1990) and/or team member’s hindsight bias (Caplan, Posner and Cheney, 1991; Rex, Turnbull, Allen, *et al.*, 2000), amongst others. Furthermore there have been very few studies on the use of RCAs in health care which demonstrate its success or failure, as there is a number of possible confounding factors (e.g. the impact of the media, concurrent organisational changes including the implementation of SIPs) even when reduction in adverse events is attributed to RCAs (Rex, Turnbull, Allen, *et al.*, 2000). One of the strongest criticisms has been that RCAs are by definition retrospective rather than prospective analyses. Some writers believe that prospective tools, such as failure mode and effects analyses (FMEA) will eventually take over from retrospective tools, and contribute to making health care safer (De Rosier, 2002; DeRosier, Stalhandske, Bagian, *et al.*, 2002; Vincent, 2004).

### **Human Factors Engineering**

In their proposed patient safety framework, Affonso and Doran (2002) include four key areas. These are: firstly, the development of tools and technology to deal with drugs and devices in a safer manner; secondly, the application of human factors design to create safer work environments; thirdly, the reformation of organizational cultures in order to create the appropriate environment for critical thinking, ethical practice and to build learning organisations; and finally, the creation of processes to provide optimal safe care (Affonso and Doran, 2002).

Human factors analysis, design and engineering are all used in patient safety programs as methods of analysing, and potentially reducing the negative impact of, humans in adverse events. One of the most common ways of examining the role of people in medical errors is through human factors analysis, which at its simplest can be defined as the study of people at work. In practice this can include everything from identification of error types through to the development of safety cultures.

Human Factors Engineering (HFE), a more specific subset of human factors analysis, is defined as the study of the interaction between humans and complex systems and machinery. HFE can be seen as a framework for efficient and constructive thinking that includes methods and tools that can help RCA perform patient safety analyses.

It is concerned with the design of "... tools, machines, and systems that take into account human capabilities, limitations and characteristics. The goals are to design for safe, comfortable and effective human use." (Bagian, Gosbee, Lee, *et al.*, 2002) and to develop devices that "... users accept willingly and operate safely in realistic conditions." (US Food and Drug Administration, 2003).

A number of benefits have been claimed for taking a Human Factors Engineering approach. The USA Food and Drug Administration (FDA) states that, in medical applications, HFE helps improve human performance and reduce the risks associated with use error. Vicente argues that a focus on HFE implies a radical behavioural shift away from "blame and shame" emphasising further training, systems thinking, and improved system design (Vicente, 2003).

HFE is used in RCA to move the analysis away from more 'obvious' causes such as training, to design issues and informal norms in the work culture. Vincent *et al.* (1998) argue that it is imperative for RCA teams to consider aspects such as heavy staff workloads, stressful environments, rapid organisational change, incompatible organisational goals, lack of resources and maintenance of work environment and equipment. Other factors include inadequate knowledge or experience of staff, inadequate supervision, incompatible goals between management and staff and inadequate systems of communication (Vincent, Taylor-Adams, Chapman, *et al.*, 2000).

Studies have been conducted into HFE in health settings. Weinger and Slagle describe a study of human factors in anaesthesia patient safety. The aim of the research was to identify the factors that affected the job performance of anaesthesiologists and which could therefore place patients at risk of errors. Their case study involved task analysis and workload assessment during actual patient care, and the use of cognitive task analysis to study clinical decision making (Weinger and Slagle, 2001).

Gosbee and Anderson (2003) re-traced the case of a sponge that was left in a patient following cardiac surgery. The study followed the shift in attitudes of the team conducting the RCA as they were trained in HFE. It was difficult to identify the root causes that resulted from the investigation without some knowledge of HFE. Gosbee and Anderson (2003) concluded that simply adopting a 'no blame' policy but excluding HFE can lead to paralysis in which problems are accepted because they are 'human nature'. HFE supports the need for health care work and RCA investigations to be viewed as emergent social practices. It is insufficient for RCA teams merely to know that their brief is to target system vulnerabilities rather than to blame individuals.

In their study of the application of RCA in a chemical plant, Carroll *et al.* (2002) argued that the practice of RCA itself directs an organisation towards more trust and openness. They drew on HFE to link RCA indissolubly with culture and organisational learning and pointed out that having worked through the RCA process with support, staff were better able to examine how human factors such as assumptions and "mental modes" have a direct impact on behaviour and workplace performance (Carroll, Rudolph and Hatakanaka, 2002).

Short term safety training courses run the risk of missing context (Croskerry, 2003; Woodward, 2004) and presenting aspects of human-machine interface merely as 'light relief' between lessons on the practical implementation of RCA. Skills in integrating HFE into RCAs need to be developed in an efficient, practical and effective manner. HFE ought to provide the opportunity to take aspects of work culture into account as potential root causes. Integrating RCA with Performance Management might enhance systemic responses to adverse events.

### **Narrative and experience as windows onto clinical culture and work practices**

A broader issue is the need to value the experience of patients and staff members involved in potential or actual adverse events. While HFE targets the interaction of humans with their work environment, RCAs cannot mechanise the opportunity to respond to staff and patients for whom the health care system functions.

A clear example of devaluing the reported experience of staff members using their own words is provided by Kaplan and Fastman (2003). While they acknowledge that free text provides 'context and nuance' they recommend 'the expansion of coding schemes...to capture nuance and context'. Research indicates that clinicians also use language to make patterns and (re)construct the experiences which are evoked through the RCA process itself (Iedema, Braithwaite, Forsyth, *et al.*, 2004).

A commitment to process and language can yield systematic root causes. For instance, Batty *et al.* traced an RCA investigation of a needle stick and an eye splash injury which two doctors suffered whilst removing a chest drain from an HIV-positive patient in a busy intensive care unit. The investigation team initially assumed that cultural issues relating to role-modelling and peer pressures were responsible. In depth interviews were conducted with those involved in the event (Batty, Holland-Elliott and Rosenfeld, 2003).

The investigation found that, despite visible policies, the 'guided tour' and briefing received by doctors was less formal, documented and systematic than that received by nurses, and that their line of command regarding safety issues was less clear than nurses. The more senior doctors training more junior doctors did not wear eye protection, for example. Appraisals of doctors were carried out by the consultant but focused on academic assessment. Little was written down. Sharing incidents was not encouraged and the doctors reported that they would be stigmatised if they did (Batty, Holland-Elliott and Rosenfeld, 2003).

RCA aims to target system-wide problems. Marck conducted in-depth interviews and observed the work of registered nurses in hospitals in Alberta, Canada, arguing that RCAs have the potential to unearth widespread deterioration of work cultures and ethics. Paralleling nurses' work with the threats posed by technology to ecological restoration efforts, he argued that monitoring patients, making decisions and other forms of communication and coordination were neglected so that other tasks, less important and less productive but more immediate tasks, were the focus of attention (Marck, 2000).

## 5.4 RCA Training

A variety of courses and programs can be included under the term “safety improvement training”. At its widest safety improvement can encompass all training from occupational health and safety, small team or unit training to improve practice or intervention skills or knowledge, through to patient safety management systems training. A plethora of public and private training providers can be accessed. For the purposes of this review however, we will consider only the longest standing providers of RCA training (as delineated by the terms of this study), those of the NPSA in the UK and VHA in the USA.

### UK

SIPs initiated by the National Health Service (NHS) of the UK are worthy of review for three reasons. First, the NHS has tied compliance with SIPs to funding and accreditation. Second, the RCA program delivered by the NHS is staggered over a longer period and among smaller, more localised, groups of participants than the NSW Health system’s current RCA training program.

Participants are thus able to share and learn from experiences of practical implementation of RCAs and build learning relationships in localised networks. Third, training in RCA also involves the Incident Decision Tree (IDT) which might be a useful organisational learning tool for health care providers in NSW.

The NSW health system also utilises RCAs, although RCA training in the NHS differs from the NSW Health program in a number of ways. Variations of RCA training programs delivered by the NHS are: a One Day RCA Foundation Training Events (principles and techniques); Two Day RCA Foundation Training Events (more in-depth and practice implementing) which also covers the IDT communication with patients and their families; and, a Three Day RCA Networked Training Events Program which involves three free one-day training events (one per month for three months) which allows six or seven geographically close organisations to network, discuss and re-train in RCA implementation. The NPSA also provides an on-line RCA toolkit which allows individuals to undertake the basics of RCA training at a convenient time (National Patient Safety Agency, 2005a).

### USA

The NCPS regularly offers RCA training across the USA. Their Root Cause Analysis/Patient Safety Improvement Training course is designed for VA health care employees, but they also run courses for staff from other health care organisations and allocate places to the general public on a space available basis. They note that there is a short waiting list for the course. The NCPS training is a 3-day workshop, conducted by NCPS staff. Its stated aim is “... to support improved clinical practice and help participants perform systematic root cause analysis (RCA) to find the real fixable root causes of problems”.

The program includes practical applications of concepts through exercises and demonstrations, as does the NSW SIP program. The program covers how to: use the general guidelines for RCAs in the VHA National Patient Safety Improvement Handbook; identify critical steps in conducting an RCA; utilise tools to identify and analyse factors that contribute to a given adverse or sentinel event; and develop an action plan for a given adverse or sentinel event.

The NCPS also uses the training program to introduce participants to reference materials for RCA team members. These include human factors-oriented tool kits that promote patient safety while enhancing the user's awareness of the importance of developing a culture of safety, as well as cognitive aids to further reduce the risk of causing inadvertent harm to patients. These "flip books" include "NCPS Triage Cards for Root Cause Analysis" and "Root Cause Analysis Tools." There is a tuition fee for the three day course.

The NCPS also provides a range of other forms of training and curriculum development. Personnel conduct just in time training for RCA team members, and provide tailored root cause analysis (RCA) feedback for facilities and networks. RCAs submitted to them by RCA teams are reviewed and evaluations are sent back to them to optimise the learning process.

In the medium and longer term, the NCPS is working with several USA facilities on a three-month-long pilot program to evaluate the effectiveness of team training in high risk environments in the VA healthcare system. The NCPS is also working with healthcare professionals from VA medical centres and associated universities who have volunteered to assist with the development and pilot testing of a patient safety curriculum. The pilot is for residents, medical students, nurses, pharmacists, and other allied healthcare workers. The NCPS has been also been designated by the Department of Health and Human Services' Agency for Healthcare Research and Quality to formulate, manage and implement a multifaceted training program for state health officials and their selected hospital partners. It is expected to improve patient safety nationwide (VA National Centre for Patient Safety, n.d.).

## **5.5 Transfer of learning to the workplace**

One of the most difficult issues in the field of adult education is the post training problem: how to facilitate and measure the transfer of learning to the workplace (Kirkpatrick, 1998). While numbers vary, some researchers indicate that approximately only 20% of training investment actually results in transfer to the job (Goldman and Schmalz, 2005).

There is very little literature on the evaluation of RCA training programs or the post training problem. This section, therefore, concentrates on the broader context of research into learning transfer from a theoretical to a practical site. This literature takes into account the knowledge and skills levels, and political and organisational culture, of learning transfer, all of which affects participants who have undertaken RCA training. The literature surveyed supports the need to take some account of the organisational environment beyond the skills and knowledge needed merely to undertake an RCA itself. Both descriptive and prescriptive articles were included (Sun, 2003) in this survey.

Among the articles that targeted the immediate impact of training programs Burrow and Berardinelli conducted an in-depth case study of a global manufacturing training department, advocating a tight link between training to productivity and performance measures (Burrow and Berardinelli, 2003), given, for instance, that managers expect tangible learning outcomes (Longenecker, 2004). Campbell showed that various job performance aids, such as instructional booklets, were essential to retaining complex skill levels for practical application (Campbell, 1999). Nevertheless, the scope for evaluating the effectiveness of RCA training is more immediate, focused and manageable than for general programs because it targets a specific process that will, in any case, be implemented.

A longitudinal survey conducted by Belling et al. revealed that 'program learning design' needed to be taken into account in a training program because of the role of two key features in learning transfer: mentoring, and personal values of the participant (Belling, James and Ladkin, 2004). Significantly, Codling drew on two in depth case studies in the transportation field to argue that the socio-cultural environment was crucial to the successful practical transfer of theoretical learning (Codling, 1998). Table 5 identifies a range of factors which have been identified as affecting, creating barriers to, or facilitating workplace learning.

**TABLE 5: Factors affecting transfer of learning**

FACTORS	
Factors affecting workplace learning	<ul style="list-style-type: none"> <li>▪ Characteristics of individual learner (including psychological presence, scripts and schemas, personal capacity for transfer, openness to change)</li> <li>▪ Training program undertaken</li> <li>▪ Transfer design of training program</li> <li>▪ Workplace environment (including the routinization of work, roles, role conflict and institutional structures)</li> <li>▪ Immediate manager/supervisor</li> </ul>
Barriers to workplace transfer	<ul style="list-style-type: none"> <li>▪ Unclear aims, objectives and/or competencies</li> <li>▪ Workplace environment</li> <li>▪ Workplace pressures and demands, schedules, stress levels</li> <li>▪ Group resistance to training</li> <li>▪ Lack of empowerment to work with new ideas or competencies</li> <li>▪ Non-supportive organisational/management/peer culture</li> <li>▪ Perceived content validity</li> <li>▪ Low motivation to use knowledge and expertise</li> <li>▪ Organisational politics and hidden agendas</li> <li>▪ Low motivation to transfer learning</li> <li>▪ Transfer effort to implement learning</li> <li>▪ Performance expectations</li> <li>▪ Participants' negative perception of quality of training content and processes</li> </ul>

FACTORS	
Barriers to workplace transfer (continued)	<ul style="list-style-type: none"> <li>▪ Pressure from peers to resist training and/or changes from training</li> <li>▪ Negative personal/professional outcomes</li> <li>▪ Supervisor/manager sanctions</li> </ul>
Factors facilitating transfer of learning	<ul style="list-style-type: none"> <li>▪ Support of supervisors prior, during and after training</li> <li>▪ Pre-course needs assessments</li> <li>▪ Clear communication of aims, objectives, outcomes and content of course</li> <li>▪ Appropriate instructional design and methods</li> <li>▪ Work related examples and exercises</li> <li>▪ Aids to make the job easier</li> <li>▪ Trainers use a variety of techniques and methods to suit a range of learning styles</li> <li>▪ Feedback/performance coaching</li> <li>▪ Opportunity to apply learning as soon as possible</li> <li>▪ Post training coaching, mentoring and role-modelling</li> <li>▪ Support from peers and managers</li> <li>▪ Networking with other learners and trainers for support</li> </ul>
Sources: Currie, Lewis, Donaldson, <i>et al.</i> , 2001; Donovan, Hannigan and Crowe, 2001; Goldman and Schmalz, 2005; Karakowsky and McBey, 1999; Kirkpatrick, 1998; Newstrom, 1986; Tannenbaum and Yukl, 1992.	

## 5.6 Evaluation of training

This evaluation of the RCA training program draws on Kirkpatrick's four-part model comprising the evaluation of reaction, learning, behaviour and results (Kirkpatrick, 1998). This model is structured and provides various options in terms for the depth and level of evaluation which suit evaluation of training programs in specialised environments. Evaluating any program is complex and challenging because the goals of evaluation involve multiple purposes at different levels (Eseryel, 2002) and vary among stakeholders (Hum and Simpson, 2002). Bober identified seven factors which influence the implementation of the outcomes of a training program evaluation: communication quality; timeliness; commitment to and/or receptiveness to evaluation; evaluation quality; relevance; credibility; trustworthiness of findings (Bober, 2001).

Brinkerhoff and Dressler argued that training programs ought to be assessed through focussing on a small number of trainees. Nevertheless, the overarching approach of this evaluation is to apply mixed methods to optimise the depth and range of views available (Brinkerhoff and Dressler, 2002).

Michalski and Cousins (2001) noted that stakeholder evaluation was common in general program evaluation but very rare in training evaluation practice. In analysing the perspectives of stakeholders in the RCA training program, this evaluation draws on Michalski and Cousin's useful distinction between three key stakeholder groups: sponsors (NSW Health), presenters (expert quality and clinical staff from NSW Health), and participants (clinical and quality staff of particular health care providers) (Michalski and Cousins, 2001). An earlier study by Michalski and Cousins (2000) applied techniques of 'concept mapping' and 'pattern matching' to the qualitative data of these three stakeholder groups and found, significantly, that expectations and perceptions of a training program were consistent with others from the same stakeholder group and collectively different from other stakeholder groups (Michalski and Cousins, 2000).

The literature search identified three types of training evaluation programs, fitting into a typology implied by Eseryel (2002). The first is 'surface level evaluation' (Brown, Li, Sargent, *et al.*, 2003) with, for example, formative evaluations that were not explicit and summative evaluations which were incomplete (Eseryel, 2002). There is strong evidence that training evaluation programs in different international settings have been simplified and superficial, for example restricting their analysis to reaction type (Al-Athari and Zairi, 2002; Blanchard, Thacker and Way, 2000) not to mention empirically weak (Kruijver, Kerkstra, Francke, *et al.*, 2000). Nevertheless, the framework of the aforementioned studies was on skill development, albeit in the longer term, rather than a structured program of skill development. Such evaluation programs are operational rather than strategic and take little account of context (Eseryel, 2002).

The second type of training evaluation is a 'systems' approach in which the context of the training program takes centre stage. Such an approach has been criticised for being difficult to structure and less amenable to a detailed, granular account of a training program (Eseryel, 2002). Other studies claimed to extend their methodologies beyond the development of immediate skills in their training programs, for example, to analyse 'value added training' rather than mere 'return on investment' (Kearns, 2003). A clear example of this is an argument by Moy and McDonald that the broader notion of return on training investment (ROTI) ought to replace the notion of mere return on investment (ROI) because it is broader in scope (Moy and McDonald, 2000). Some studies (Twitchell, Holton and Trott, 2000) which considered external factors were somewhat staged in their approach and did not account for the influence on the broader work context.

A third approach, that of a structured and contextualised evaluation, follows Kirkpatrick's four stage model (Kirkpatrick, 1998) applied in this evaluation. This multi-level evaluation is not without criticism, largely because its supposed assumption that each level (reaction, learning, behaviour, results) is necessarily associated with the previous and next levels. Yet, this appears to be an unfounded criticism of Kirkpatrick's approach. Kirkpatrick's model has displayed its flexibility in other training program evaluations which have also accounted for needs analysis and broader societal impacts of training (Tamkin, Yarnall and Kerrin, 2002).

Further, no evidence was found in the literature which suggested that Kirkpatrick's model must be applied in a staged manner, that it cannot represent various types of level of evaluation, nor that it cannot be verifiable, contextualised, collaborative, strategic (as well as operational), and incorporate a variety of stakeholder perspectives. Arguments in favour of Kirkpatrick's model, in preference to the systems approach, include that its structure provides for detailed, 'granular' analysis of a training program (Eseryel, 2002). Thus the approach that has informed this evaluation is that weaknesses in training evaluation methodology are not caused by following Kirkpatrick's model, but are caused by an inadequate application of Kirkpatrick's model.

## 6 DISCUSSION

This literature review highlights a range of themes. Firstly, as shown in Table 6, there are many good ideas on which to draw about SIPs elsewhere.

**TABLE 6: Summary of Information about Safety Improvement Programs**

SAFETY IMPROVEMENT PROGRAMS
<ul style="list-style-type: none"> <li>▪ Canada, New Zealand and the State of Victoria, provide an array of safety initiatives on which NSW Health can draw. In addition, private organisations in the USA (such as JCAHO, Veterans' Affairs and Leapfrog) and the NHS represent strong models of coordinated safety improvement programming at a structural level.</li> <li>▪ The NHS organises smaller, localised and regular follow-up groups of RCA participants which have the potential to build learning relationships and enhance the quality of RCAs amongst individual health care providers.</li> <li>▪ The National Institute of Clinical Excellence (NICE) in the NHS has a directly controlling role, coordinating clinical practice improvement programs in return for accreditation and funding. The emerging role of the Clinical Excellence Commission, in the wake of the Walker Inquiry, is to be less prosecutory (a role delegated to the Health Care Complaints Commission) and more strongly focussed on organisational development.</li> </ul>

Turning to the issue of incident reporting, it is clear that every health system is striving to improve reporting rates and the quality of data produced. Table 7 summarises our analysis of reporting of incidents.

**TABLE 7: Two main points about reporting incidents**

REPORTABLE INCIDENT BRIEFS
<ul style="list-style-type: none"> <li>▪ There is evidence for the educational and systemic value of collecting and centrally monitoring adverse incidents.</li> <li>▪ Nevertheless, clinical work cultures can subvert the imperative to report incidents. For example, reporting of adverse incidents is higher for serious incidents and those in which the patient recovers than for relatively common incidents. Junior staff are more likely than senior doctors to report incidents, and less likely to feel supported by colleagues, and more likely to feel blamed for adverse incidents.</li> </ul>

Once information is reported, it is necessary to do something about it. This requires a thorough analysis of adverse events. Table 8 summarises our findings.

**TABLE 8: Summary of information about the analysis of adverse events**

ANALYSIS OF ADVERSE EVENTS
<ul style="list-style-type: none"> <li>▪ An understanding of the human-machine interface (Human Factors Engineering) directs RCA team members away from pleas for more staff, resources, training and policies. A mere 'no blame' policy in the absence of HFE results can paralyse an organisation through perceptions of the inevitability of human error.</li>   <li>▪ A culture of low expectations rewards users of unnecessarily complex equipment. Training is a proposed corrective action masquerading as a root cause, while the root cause itself might actually be the mental model held by users regarding the way in which the equipment operates.</li>   <li>▪ The allocation of Severity Assessment Codes (SACs) must reflect the fact that the outcome is unanticipated and not a natural course of the illness or the result of an underlying condition that existed at the time of admission. For instance, death ought not automatically qualify for a SAC rating of 1. If, at the time of admission, the patient's condition indicates that he or she has a high likelihood of not surviving the episode of care, then that patient's death ought not be considered an adverse incident.</li>   <li>▪ The narrativised experiences of patients and clinicians provide learning opportunities for the organisation which numerical coding cannot. The construction of experiences evoked by the RCA process itself can reveal, for instance, deterioration of work cultures and ethics, such as the emphasis on ensuring that less important but more demonstrably productive tasks were focused on, while patient care and communication were neglected. A commitment to language and process enables the RCA team to identify issues such as role modelling, hierarchy, education and training.</li>   <li>▪ Several articles provide advice and a broad range of techniques for conducting RCAs.</li> </ul>

There are many training programs on which to draw about running SIPS or conducting RCAs. Two key points about learning transfer are made in Table 9.

**TABLE 9: Two main points about transfer of learning**

TRANSFER OF LEARNING
<ul style="list-style-type: none"> <li>▪ A practical approach to transfer of RCA learning must go beyond the skills for conducting an RCA, but develop in the participant the capacity to recognise political and organisational culture (which impact, for instance, on decisions about which events or near misses to subject to RCA), the dynamics of the RCA team, and the organisational response to investigations.</li>   <li>▪ The effectiveness of training programs is less a feature of the size and structure of the organisation, but a function of the reputation and position of the individuals seeking to implement the change.</li> </ul>

Finally, this literature review's purpose is to inform a large scale evaluation of SIP in NSW. Some key lessons learnt about program evaluation are summarised in Table 10.

**TABLE 10: Three main points about program evaluation**

PROGRAM EVALUATION
<ul style="list-style-type: none"><li>▪ Seven factors which influence the outcomes of a training program evaluation are: communication quality; timeliness; commitment to and/ or receptiveness to evaluation; evaluation quality; relevance; credibility; and trustworthiness of findings.</li><li>▪ Stakeholder evaluation is common in general program evaluation but very rare in training evaluation. The current evaluation is unique in drawing on the views of three key stakeholder groups: sponsors (NSW Health), presenters (expert quality, clinical and training staff from NSW Health), and participants (clinical and quality staff of individual health care providers as potential RCA team members).</li><li>▪ Kirkpatrick's multi-layered, structured and contextualised model provides an appropriate conceptual framework for a multi-method evaluation, reaching beyond 'surface level evaluation' and 'systems' evaluation.</li></ul>

## 7 CONCLUSION

This literature review documented the expanding scope and scale of SIPs, and their context and tools of analysis and implementation as part of a broad program to make health care safer and providers more accountable for the provision of safe and high quality clinical care. The literature delivers warnings that SIPs and their evaluations run the risk of being valueless if they are too mechanistic, narrowly focused, irregular, fragmented, punitive or generalised. The influence of private organisations in the USA shows that the administrator of a SIP must have the capability of influencing the clinical culture in which the program is intended to be implemented. RCA programs in the UK are conducted more locally, in smaller groups, with regular follow up and the opportunity to build networks and learning communities. This also complements best practice in adult education as shown in the literature.

RCA team members must be *skilled* in interviewing and deriving qualitative data, rather than merely *knowledgeable* in the mechanics of the three phases of the investigation process, to be able to influence the social and educational environments which impede safe clinical practice and incident monitoring. The literature argues that specific aspects of this environment include its hierarchical nature and how professional role modelling is poor. Such depth in investigation will help target a culture of low expectations to find systemic root causes beyond unhelpful calls for more training, more staff and more resources.

Although the literature supports monitoring adverse events, empirical studies point to the over-arching strength of professional hierarchies which can impede progress in improving rates of incident reporting. This places empirical social research into clinical cultures at a premium. This also places the success and failure of RCA at the mercy of broader political, educational and economic forces, the challenge of which is to build a culture of safety.

## 8 REFERENCES

- Affonso, D.D. and Doran, D. (2002). Cultivating discoveries in patient safety research: a framework. *International Nursing Perspectives*, 2(1), 33-47.
- Agency for Healthcare Research and Quality (2003). *AHRQ's Patient Safety Initiative: building foundations, reducing risk. Interim report to the Senate Committee on Appropriations*. Rockville, MD: Agency for Healthcare Research and Quality.
- Al-Athari, A. and Zairi, M. (2002). Training evaluation: an empirical study in Kuwait. *Journal of European Industrial Training*, 26, 169-176.
- American Medical Association (2000). *General principles for patient safety reporting system*. Available at: [www.ama-assn.org/ama/pub/articler/4119-4314.html](http://www.ama-assn.org/ama/pub/articler/4119-4314.html) accessed on: 15 January 2005.
- Andrews, L.B., Stocking, C., Krizek, T., et al. (1997). An alternative strategy for studying adverse events in medical care. *Lancet*, 349, 309-313.
- Bagian, J.P. (2001). Patient safety-the VA's experience. *Michigan Health & Hospitals*, 37(4), 62-63.
- Bagian, J.P., Lee, C., Gosbee, J., et al. (2001). Developing and deploying a patient safety program in a large health care delivery system: you can't fix what you don't know about. *Joint Commission Journal on Quality Improvement*, 27(10), 522-532.
- Bagian, J.P., Gosbee, J., Lee, C.Z., et al. (2002). The Veterans Affairs root cause analysis in action. *Joint Commission Journal on Quality Improvement*, 28(10), 531-545.
- Bancroft, K. (2002). Job hazard analysis for unsafe acts. *Occupational Health and Safety*, 71(9), 206, 208-215.
- Barach, P. and Small, S.D. (2000). Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *British Medical Journal*, 320, 753-763.
- Bateman, D.N., Sanders, G.L.S. and Rawlins, M.D. (1992). Attitudes to adverse drug reaction reporting in the Northern Region. *British Journal of Clinical Pharmacology*, 34, 421-426.
- Battles, J.B., Kaplan, H.S., van der Schaaf, T.W., et al. (1998). The attributes of medical event reporting systems: experience with a prototype medical event reporting system for transfusion medicine. *Archives of Pathology Laboratory Medicine*, 122, 231-238.
- Batty, L., Holland-Elliott, K. and Rosenfeld, D. (2003). Investigation of eyesplash and needlestick incidents from an HIV positive donor in an intensive care unit using root cause analysis. *Occupational Medicine*, 53(2), 147-150.
- Beckmann, U., West, L.F., Groombridge, G.J., et al. (1996). The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. The development and evaluation of an incident reporting system in intensive care. *Anaesthesia & Intensive Care*, 24(3), 311 - 313.

- Belling, R., James, K. and Ladkin, D. (2004). Back to the workplace: how organisations can improve their support for management learning and development. *The Journal of Management Development*, 23(3), 234-255.
- Belton, K.J., Lewis, S.C., Payne, S., *et al.* (1995). Attitudinal survey of adverse drug reaction re-reporting by medical practitioners in the United Kingdom. *British Journal of Clinical Pharmacology*, 39, 223-226.
- Blanchard, P.N., Thacker, J.W. and Way, S.A. (2000). Training evaluation: perspectives and evidence from Canada. *International Journal of Training and Development*, 4(4), 295-304.
- Bober, C.F. (2001). Utilization of corporate university training program evaluation. In Aliaga, O. A. (Ed.), *2001 Conference proceedings: Academy of Human Resource Development*. Tulsa, Oklahoma: Academy of Human Resource Development.
- Boggett, A.M. (2004). A statistical comparison of three root cause analysis tools. *Journal of Industrial Technology*, 20(2), 1-15.
- Bonney, E. and Baker, G. (2004). Current strategies to improve patient safety in Canada: an overview of federal and provincial initiatives. *Healthcare Quarterly*, 7(2), 36-41.
- Boyer, M.M. (2001). Root cause analysis in perinatal care: health care professionals creating safer health care systems. *Journal of Perinatal and Neonatal Nursing*, 15(1), 24-25.
- Braithwaite, J. and Westbrook, M.T. (2005). Rethinking clinical organizational structures: an attitude survey of doctors, nurses and allied health staff in clinical directorates. *Journal of Health Services Research and Policy*, 10, 10 - 17.
- Brennan, T.A., Leape, L.L., Laird, N.M., *et al.* (1991). Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *New England Journal of Medicine*, 324(6), 370-376.
- Brinkerhoff, R.O. and Dressler, D. (2002). Using evaluation to build organizational performance and learning capability: a strategy and a method. *Performance Improvement*, 41(6), 14-21.
- Britt, H., Miller, G.C., Steven, I.D., *et al.* (1997). Collecting data on potentially harmful events: a method for monitoring incidents in general practice. *Family Practice*, 14(2), 101-106.
- Brown, T.C., Li, S.X., Sargent, L.D., *et al.* (2003). What went wrong at university hospital? An exercise in assessing training effectiveness. *Journal of Management Education*, 27(4), 485-496.
- Burroughs, T.E., Cira, J.C., Chartock, P., *et al.* (2000). Using root cause analysis to address patient satisfaction and other important opportunities. *Joint Commission Journal on Quality Improvement*, 26(8), 439-449.
- Burrow, J. and Berardinelli, P. (2003). Systematic performance improvement. *The Journal of Workplace Learning*, 15(1), 6-13.
- Campbell, C.P. (1999). Instructional materials: their preparation and evaluation. *Journal of European Industrial Training*, 23(2), 57-107.

Canadian Patient Safety Institute (2001). *Introduction*. Available at: <http://www.hc-sc.gc.ca/english/care/cpsi.html> accessed on: 21 January 2005.

Caplan, R.A., Posner, K.L. and Cheney, F.W. (1991). Effect of outcome on physician judgments of appropriateness of care. *Journal of the American Medical Association*, 265, 1957-1960.

Carroll, J.S., Rudolph, J.W. and Hatekanaka, S. (2002). Lessons learned from non-medical industries: root cause analysis as a cultural change at a chemical plant. *Quality and Safety in Health Care*, 11(3), 266-269.

Codling, B.S. (1998). Benchgrafting: A model for successful implementation of the conclusions of benchmarking studies. *Benchmarking: An International Journal*, 5(3), 158-164.

Connor, M., Ponte, P.R. and Conway, J. (2002). Multidisciplinary approaches to reducing error and risk in a patient care setting. *Critical Care Nursing Clinics of North America*, 14(4), 359-367.

Croskerry, P. (2003). Cognitive forcing strategies in clinical decision-making. *Annals of Emergency Medicine*, 41(1), 121-122.

Cull, H. (2001). *Review of processes concerning adverse medical events*. Wellington: Ministry of Health.

Currie, G., Lewis, S., Donaldson, C., et al. (2001). The future of health care in Canada. *British Medical Journal*, 323, 926-929.

Department of Veterans Affairs (2005). *National Centre for Patient Safety*. Available at: <http://www.va.gov/ncps/index.html> accessed on: 17 February 2005.

DeRosier, J., Stalhandske, E., Bagian, J.P., et al. (2002). Using health care failure mode and effect analysis: the prospective risk analysis system. *Joint Commission Journal on Quality Improvement*(28), 248-267.

Dineen, M. and Walsh, K. (1999). Incident reporting in the NHS. *Health Care Risk Report*, March, Special edition.

Donchin, Y., Gopher, D., Olin, M., et al. (1995). A look into the nature and causes of human errors in the intensive care unit. *Critical Care Medicine*, 23(2), 294 - 300.

Donovan, P., Hannigan, K. and Crowe, D. (2001). The learning transfer system approach to estimating the benefits of training: empirical evidence. *Journal of European Industrial Training*, 25(2/3/4).

Eseryel, W.P. (2002). Approaches to evaluation of training: theory and practice. *Educational Technology and Society*, 5(2), 93-98.

Gardner, J.P., Baker, G.R., Norton, P., et al. (2002). *Governments and patient safety in Australia, the United Kingdom and the United States: A review of policies, institutional and funding arrangements and current initiatives*. Ottawa: Advisory Committee on Health Services Working Group on Quality of Health Care Services.

- Goldman, D.D. and Schmalz, K.J. (2005). Yes, you can take it with you! Transfer of learning: from workshop to workplace. *Health Promotion Practice*, 6(1).
- Gosbee, J. and Anderson, T. (2002). Human factors engineering and patient safety. *Quality and Safety in Health Care*, 11(4), 352-354.
- Gosbee, J. and Anderson, T. (2003). Human factors engineering design demonstrations can enlighten your RCA team. *Quality and Safety in Health Care*, 12, 119-121.
- Health Canada (2002). *A medication incident reporting and prevention system for Canada*. Therapeutic Products Directorate. Available at: [http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/cmirps\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/cmirps_e.html) accessed on: 2 June 2005.
- Health Canada (2004). *Canadian medication incident reporting and prevention system*. Available at: [http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/fact\\_cmirps\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/fact_cmirps_e.html) accessed on: 15 January 2005.
- Hirsch, K.A. and Wallace, D.T. (2000). One hospital's view of software facilitation of root cause analysis in error reduction. In Spath, P. L. (Ed.), *Health Care: a systems approach to improving patients*. San Francisco: Jossey-Bass Publishers.
- Hum, D. and Simpson, W. (2002). Public training programs in Canada: a meta-evaluation. *Canadian Journal of Program Evaluation*, 17(1), 119-138.
- Iedema, R., Braithwaite, J., Forsyth, R., *et al.* (2004). The intensification of communication in modern health care: where narrative meets accountability, *British Medical Association*. London.
- Institute of Medicine (2000). *To err is human: building a safer health system*. Washington: National Academy Press.
- Jayasuriya, J.P. and Anandaciva, S. (1995). Compliance with an incident report scheme in anaesthesia. *Anaesthesia*, 50(10), 846-849.
- Joint Commission on Accreditation of Healthcare Organizations (2005). *What is the Joint Commission on Accreditation of Healthcare Organizations?* Available at: <http://www.jcaho.org/general+public/who+jc/index.htm> accessed on: 17 February 2005.
- Kaplan, H.S. and Fastman, B.R. (2003). Organization of event reporting data for sensemaking and system improvement. *Quality and Safety in Health Care*, 12, 1168.
- Karakowsky, L. and McBey, K. (1999). The lessons of work: toward and understanding of the implications of the workplace for adult learning and development. *Journal of Workplace Learning: Employee Counselling Today*, 11(6), 192 - 201.
- Kearns, P. (2003). Prioritizing training to maximize results: the 3 box system. *Educational Technology*, 43(1), 45-49.
- Kirkpatrick, D.L. (1998). *Evaluating training programs*. San Francisco: Berrett-Koehler.

- Kruijver, I.P.M., Kerkstra, A., Francke, A.L., *et al.* (2000). Evaluation of nursing training programs in nursing care: a review of the literature. *Patient Education and Counseling*, 39(1), 129-145.
- Latino, R.J. (2000). Automating root cause analysis. In Spath, P. L. (Ed.), *Health Care: a systems approach to improving patients*. San Francisco: Jossey-Bass Publishers.
- Leape, L.L. (1994). Error in medicine. *British Medical Journal*, 272, 1851 -1857.
- Longenecker, C.O. (2004). Maximizing transfer of learning from management education programs. *Development and Learning in Organizations: An International Journal*, 18(4), 4-6.
- Marck, P.B. (2000). *Technology and registered nurses' work in acute care: a healing enquiry*. Canada: University of Alberta.
- Medical Defence Association of Western Australia (2002). *No faulty or faulty towers?* Perth: Available at: [http://www.mdanational.com.au/news/newstemplate\\_2002\\_7\\_26\\_1.asp](http://www.mdanational.com.au/news/newstemplate_2002_7_26_1.asp) accessed on: 20 February 2005.
- Metropolitan Health and Aged Care Services Department (2004). *Sentinel Event Program: Annual Report 2003 - 2004*. Melbourne: State Government Victoria. Available at: <http://www.health.vic.gov.au/clinrisk/annrep0304.pdf> accessed on: 10 March 2005.
- Michalski, G.V. and Cousins, J.B. (2000). Differences in stakeholder perceptions about training evaluation: a concept mapping/pattern matching investigation. *Evaluation and Program Planning*, 23(2), 211-230.
- Michalski, G.V. and Cousins, J.B. (2001). Multiple perspectives on training evaluation: probing stakeholder perceptions in a global network development firm. *American Journal of Evaluation*, 22(1), 35-53.
- Moy, J. and McDonald, R. (2000). *Analysing enterprise returns on training*. Adelaide, South Australia: National Centre for Vocational Education Research.
- National Health Service (2000). *An organisation with a memory: a report of an expert group on learning from adverse events in the NHS*. London: Department of Health.
- National Health Service (2001). *Building a safer NHS for patients - implementing an organisation with a memory*. London: Department of Health.
- National Institute for Health and Clinical Excellence (2005). *About NICE*. Available at: <http://www.nice.org.uk/page.aspx?o=aboutnice> accessed on: 12 April 2005.
- National Patient Safety Agency (2004). *NPSA launches decision making tool to reduce unnecessary suspensions and support a safety culture*. Available at: <http://www.npsa.nhs.uk/web/display?contentId=3036> accessed on: 17 February 2005.
- National Patient Safety Agency (2005a). *RCA Training and RCA toolkit*. Available at: <http://www.npsa.nhs.uk/web/display?contentId=2665> accessed on: 21 April 2005.
- National Patient Safety Agency (2005b). *Reporting incidents*. National Health Service. Available at: <http://www.npsa.nhs.uk/health/reporting> accessed on: 3 April 2005.

- New Zealand Health Information Service (2005). *National Health Index*. Available at: <http://www.nzhis.govt.nz/nhi/index.html> accessed on: 1 March 2005.
- New Zealand Medicines and Medical Devices Safety Authority (2005). *Regulatory Information*. Wellington: Available at: <http://www.medsafe.govt.nz/reg.htm> accessed on: 1 March 2005.
- Newstrom, J.W. (1986). Leveraging management development through the management of transfer. *Academy of Management Review*, 55, 33 - 45.
- NHS Executive Health Service (1999). *HSC 1999/198: the Public Disclosure Act 1998 whistleblowing in the NHS*. Available at: <http://www.dh.gov.uk/assetRoot/04/01/21/38/04012138.pdf> accessed on: 10 March 2005.
- NHS Modernisation Agency (2005). *About the NHS Modernisation Agency*. London: Available at: <http://www.content.modern.nhs.uk/cmsWISE/aboutUs/AboutMA.htm> accessed on: 15 March 2005.
- NSW Health (2005). *Patient Safety and Clinical Quality Program. First report on incident management in the NSW public health system 2003-2004*. North Sydney: NSW Department of Health.
- NSW Health Quality and Safety Branch (2003). *Reportable Incident Briefs to the NSW Department of Health*. Sydney: Circular No. 2003/ 88 (File No. 03/ 11299).
- Radtke, K. (2004). JCAHO solutions: get to the root of sentinel events involving infection control. *Nursing Management*, 35(6), 18, 22.
- Rasmussen, J. (1990). Human error and the problem of causality in analysis of accidents. *Philosophical Transactions of the Royal Society B: Biological Science*, 327, 449 - 460.
- Reason, J.T. (1990). *Human error*. Cambridge: Cambridge University Press.
- Reason, J.T. (1997). *Managing the risks of organizational accidents*. Hampshire, England: Ashgate Publishing Co.
- Reason, J.T. (2000). Human error: models and management. *British Medical Journal*, 320, 768-770.
- Redfern, M., Keeling, J. and Powell, E. (2001). *The Royal Liverpool Children's Inquiry*. London: The House of Commons.
- Rex, J.H., Turnbull, J.E., Allen, S.J., *et al.* (2000). Systematic root cause analysis of adverse drug events in a tertiary referral hospital. *Joint Commission Journal on Quality Improvement*, 26(10), 563-575.
- Rosenthal, J., Booth, M. and Barry, A. (2001). *Cost Implications of State Medical Error Reporting Programs: A Briefing Paper*. Rockville, MD.: Agency for Healthcare Research and Quality.

- Runciman, W.B., Sellen, A., Webb, R.K., *et al.* (1993). The Australian Incident Monitoring Study. Errors, incidents and accidents in anaesthetic practice. *Anaesthesia & Intensive Care*, 21(5), 506-519.
- Sexton, J.B., Thomas, E.J. and Helmreich, R.L. (2000). Error, stress, and teamwork in medicine and aviation: Cross sectional surveys. *British Medical Journal*, 320, 745 - 749.
- Shinn, J.A. (2000). Keeping pace: root cause analysis: a method of addressing errors in patient risk. *Progress in Cardiovascular Nursing*, 15(1), 24-25.
- Stanhope, N., Crowley-Murphy, M., Vincent, C., *et al.* (1999). An evaluation of adverse incident reporting. *Journal of Evaluation in Clinical Practice*, 5(1), 5-12.
- State Government of Victoria (2005). *Clinical risk management*. Available at: <http://www.health.vic.gov.au/clinrisk/> accessed on: 18 April 2005.
- Sun, P.Y.T. (2003). Exploring the divide: organisational learning and the learning organisation. *The Learning Organisation: An International Journal*, 10(4), 202-215.
- Tamkin, P., Yarnall, J. and Kerrin, M. (2002). *Kirkpatrick and beyond: a review of models of training evaluation: IES Report No. IESR392*. United Kingdom: Grantham Book Services.
- Tannenbaum, S. and Yukl, G. (1992). Training and development in work organisations. *Annual Review of Psychology*, 43(399 - 441).
- The Leapfrog Group for Patient Safety (2004). *The Leapfrog group fact sheet*. Available at: [http://www.leapfroggroup.org/about\\_us/leapfrog-factsheet](http://www.leapfroggroup.org/about_us/leapfrog-factsheet) accessed on: 17 February 2005.
- Tilley, G. (2004). *Patient safety: the value of a national approach*. Ottawa: Canadian Patient Safety Institute.
- Tsatsoulis, C. and Amthauer, H.A. (2003). Finding clusters of similar events within critical incident reports: a novel methodology combining case study reasoning and information retrieval. *Quality and Safety in Health Care*, 12(Supplement 2), 1124-1132.
- Twitchell, S., Holton, E.F. and Trott, J.W. (2000). Technical training evaluation practices in the United States. *Performance Improvement Quarterly*, 13(3), 84-109.
- US Food and Drug Administration (2003). *What is Human Factors?* Available at: <http://www.fda.gov/cdrh/humanfactors/whatis.html> accessed on: February 10 2005.
- VA National Centre for Patient Safety (n.d.). *VA NCPS program and initiative highlights*. Available at: [http://www.va.gov/ncps/NEWS/NCPSBg/bg\\_NCPSProgramInitiative\\_040904.doc](http://www.va.gov/ncps/NEWS/NCPSBg/bg_NCPSProgramInitiative_040904.doc) accessed on: February 10 2005.
- Vicente, K.J. (2003). What does it take? A case study of radical change toward patient safety. *Joint Commission Journal on Quality & Safety*, 29(11), 598-609.
- Victorian Government Health Information (2004). *Risk Watch newsletters*. Melbourne: Available at: <http://www.health.vic.gov.au/clinrisk/riskwatch.htm> accessed on: 20 March 2005.

- Victorian Quality Council (2003a). *Victorian Quality Control: Infection Control Working Group action plan summary 2003/2004*. Victorian Quality Council. Available at: <http://www.health.vic.gov.au/qualitycouncil/infcontrolactplan.pdf> accessed on: 10 May 2005.
- Victorian Quality Council (2003b). *Acute pain management workshop*. Melbourne: Victorian Quality Council. Available at: <http://www.health.vic.gov.au/qualitycouncil/plans/acute.htm> accessed on: 10 May 2005.
- Victorian Quality Council (2004). *Healthcare quality and safety data directory: a guide of data collections to support health service quality and safety improvement*. Melbourne: Metropolitan Health and Aged Care Services Division, Victorian Government Department of Human Services. Available at: <http://www.health.vic.gov.au/qualitycouncil/plans/documents/datadictionary.pdf> accessed on: 17 February 2005.
- Victorian Quality Council (2005). *Statewide Pressure Ulcer Point Prevalence Survey (PUPPS 2)*. Melbourne: Victorian Quality Council. Available at: <http://www.health.vic.gov.au/qualitycouncil/plans/pupps.htm> accessed on: 10 January 2005.
- Victorian Quality Council (n.d.). *Minimising the risk of falls and falls injuries: guidelines for acute, sub-acute and residential care settings*. Melbourne: Available at: <http://www.health.vic.gov.au/qualitycouncil/plans/documents/fallschart1.xls> accessed on: 10 January 2005.
- Vincent, C., Stanhope, N. and Crowley-Murphy, M. (1999). Reasons for not reporting adverse incidents: an empirical study. *Journal of Evaluation in Clinical Practice*, 5(1), 13-21.
- Vincent, C., Taylor-Adams, S., Chapman, E.J., *et al.* (2000). How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol. *British Medical Journal*, 320, 777 - 781.
- Vincent, C., Neale, G. and Woloshynowych, M. (2001). Adverse events in British hospitals: preliminary retrospective record review. *British Medical Journal*, 322(7285), 517 - 519.
- Vincent, C. (2003). Understanding and responding to adverse events. *New England Journal of Medicine*, 348, 1051 - 1056.
- Vincent, C.A. (2004). Analysis of clinical incidents: a window on the system not a search for root causes. *Quality and Safety in Health Care*, 13, 242 - 243.
- Wald, H. and Shojania, K.G. (2001). Chapter 5. Root cause analysis. In Shojania, K. G., Duncan, B. W., McDonald, K. M., Wachter, R. W., and Markowitz, A. J. (Eds.), *Making health care safer: a critical analysis of patient safety practices*. Rockville, MD.: Agency for Healthcare Research and Quality.
- Walker, B. (2004). *Final report of the Special Commission of Inquiry into Campbelltown and Camden hospitals*. Sydney: New South Wales Attorney General's Department.
- Weingart, S.N., Wilson, R.M., Gibberd, R.W., *et al.* (2000). Epidemiology of medical error. *British Medical Journal*, 320(7237), 774-777.

Weinger, M. and Slagle, J. (2001). Human factors research in anaesthesia patient safety, *Proceedings/American Medical Informatics Association Symposium* pp. 756-760).

Williams, P.M. (2001). Techniques for root cause analysis. *Baylor University Medical Centre Proceedings*, 14(2), 154-157.

Wilson, R.M., Runciman, W.B., Gibberd, R.W., *et al.* (1995). The Quality in Australian Health Care study. *Medical Journal of Australia*, 163(9), 458-471.

Wilson, R.M., Harrison, B.T., Gibberd, R.W., *et al.* (1999). An analysis of the causes of adverse events from the Quality in Australian Health Care Study. *Medical Journal of Australia*, 170(9), 411-415.

Woodward, S. (2004). Achieving a safer health system: Part 3: investigating root causes and formulating solutions. *Professional Nurse*, 19(7), 390-394.