



THE UNIVERSITY OF  
NEW SOUTH WALES



CENTRE FOR CLINICAL GOVERNANCE RESEARCH

# EVALUATION OF THE INCIDENT INFORMATION MANAGEMENT SYSTEM 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***

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## 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>CGU</b>	Clinical Governance Unit
<b>IIMS</b>	Incident Information Management System
<b>NSW Health</b>	NSW Department of Health
<b>PSCQP</b>	Patient Safety and Clinical Quality Program
<b>PHO</b>	Public Health Organisation
<b>PSI</b>	Patient Safety International
<b>QSB</b>	Quality and Safety Branch, NSW Health
<b>RCA</b>	Root Cause Analysis
<b>RIB</b>	Reportable Incident Brief
<b>ROI</b>	Return on Investment
<b>SAC</b>	Severity Assessment Code
<b>SIP</b>	Safety Improvement Program
<b>SIM</b>	Strategic Information Management Branch, NSW Health

### 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>Leximancer</b>	A software package which identifies the key ideas, concepts and themes in text-based documents, allowing researchers to examine the concepts, and the relationships between them, in detail.
<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 outlines the results of study 1 in the evaluation of the NSW Health Incident Information Management System (IIMS). This study analyses international literature on incident reporting processes and mechanisms. The literature was drawn from key databases and grey literature, including reports from national health services and international patient safety organisations. The initial component of the evaluation was conducted between December 2005 and January 2006. Literature was continuously updated until May 2006.

We report on the origin of IIMS, which is based on the Advanced Incident Monitoring System (AIMS) designed by Patient Safety International (PSI). The literature review is grounded in a Leximancer analysis of the key concepts in the literature, and deals with the basic requirements of incident reporting, including the need for better information, timely and accurate responses to reporting and positive feedback mechanisms with non-punitive and improvement-oriented approaches. We note how incident reporting is an international issue, and that key considerations are severity assessment and the monitoring, reporting and feedback of data about incidents.

There are various barriers to introducing reporting systems that include financial, political and legal hurdles and a lack of evidence that reporting and reporting systems reduce errors. We categorise the features of successful incident reporting systems such as good design, well organised systems, establishing various protections, and ensuring adequate trained staff and resources are available.

We look at barriers and incentives to reporting that include legal, cultural, regulatory and financial barriers and incentives. We also consider failure factors in incident reporting systems such as the difficulty of reporting, lack of feedback to notifiers of incident reports, and other factors such as fear of blame and operational costs of systems.

### 3 INTRODUCTION

#### 3.1 Overview

The NSW Department of Health (NSW Health) commissioned the Centre for Clinical Governance Research (CCGR) at University of New South Wales to conduct a formal evaluation of its Incident Information Management System (IIMS) as part of a contract to identify and evaluate a Knowledge Management program for Quality and Safety Branch. NSW Health requested the evaluation to assess the success of the implementation and effects of the project against the project objectives and key expected benefits.

The objective of IIMS at the time the evaluation was commissioned was to provide an electronic system that:

- Recorded all healthcare incidents
- Assisted managers through a workflow module to manage the incidents that occurred in their area
- Recorded the results of reviews or investigations of incidents
- Provided reports on all incidents that had been recorded in the system.

The evaluation aims to utilise the multi-method, triangulated approach employed in the *Evaluation of the Safety Improvement Program*, conducted by CCGR for the Clinical Excellence Commission (CEC) and NSW Health in 2004-2005. The IIMS evaluation was agreed to be a synthesis of 10 inter-related studies (Table 1). This evaluation was conducted by A/Professor Jeffrey Braithwaite, Ms Jo Travaglia, Conjoint A/Professor Mary T. Westbrook, Dr Christine Jorm, Dr Cynthia Hunter, Ms Katherine Carroll, A/Professor Rick Iedema and Ms Mahalakshmi Ekambareshwar.

**Table 1: Evaluation Studies**

STUDY	TITLE	COMMENTS, ACTIONS AND TIMEFRAMES	LED BY/TEAM
<b>Study #1</b>	Literature review	<ul style="list-style-type: none"> <li>▪ National and international peer reviewed and professional journals</li> <li>▪ Databases</li> <li>▪ Websites</li> <li>▪ Relevant industry and research bodies</li> </ul>	Christine Jorm, Jeffrey Braithwaite, Jo Travaglia
<b>Study #2</b>	Review of the education and training program	<ul style="list-style-type: none"> <li>▪ Prospective analysis of IIMS' face to face and online training</li> <li>▪ Retrospective analysis of IIMS' pilot training program evaluation forms</li> </ul>	Mahalakshmi Ekambareshwar, Jo Travaglia, Jeffrey Braithwaite, Mary Westbrook
<b>Study #3</b>	Review of the project implementation process for IIMS	<ul style="list-style-type: none"> <li>▪ Interviews with key stakeholders</li> <li>▪ Review of project implementation plan</li> <li>▪ Questionnaire</li> </ul>	Jeffrey Braithwaite, Mary Westbrook, Jo Travaglia

<b>Study #4</b>	Analysis of the success of the “reach” of IIMS within the health system	<ul style="list-style-type: none"> <li>▪ Questionnaire</li> <li>▪ Interviews</li> <li>▪ Focus groups</li> <li>▪ Walk around surveys</li> </ul>	Jo Travaglia, Cynthia Hunter, Katherine Carroll, Jeffrey Braithwaite
<b>Study #5</b>	Assessment of the satisfaction of IIMS users with the system	<ul style="list-style-type: none"> <li>▪ Questionnaire</li> <li>▪ Comparison with international and industry programs</li> </ul>	Mary Westbrook, Jo Travaglia, Jeffrey Braithwaite
<b>Study #6</b>	Map of the facility processes involved in implementing IIMS and handling incidents	<ul style="list-style-type: none"> <li>▪ Interviews with key stakeholders</li> <li>▪ Focus group of key stakeholders</li> </ul>	Jo Travaglia, Jeffrey Braithwaite, Mary Westbrook
<b>Study #7</b>	Examination of incident reports and management responses	<ul style="list-style-type: none"> <li>▪ Comparison of IIMS with other reporting mechanisms pre- and post- IIMS</li> <li>▪ Comparison with international approaches</li> </ul>	Jo Travaglia, Jeffrey Braithwaite, Mary Westbrook
<b>Study #8</b>	Review of the dissemination of lessons learned	<ul style="list-style-type: none"> <li>▪ Questionnaire</li> <li>▪ Interviews with key stakeholders</li> </ul>	Jo Travaglia, Jeffrey Braithwaite, Mary Westbrook
<b>Study #9</b>	Assessment of the value and use of IIMS to the CEC	<ul style="list-style-type: none"> <li>▪ Interviews with CEC staff</li> </ul>	Jeffrey Braithwaite, Jo Travaglia
<b>Study #10</b>	Examination of the reporting processes, including change in management of RIBS post IIMS	<ul style="list-style-type: none"> <li>▪ NSW Health data</li> <li>▪ Interviews with Quality and Safety Branch staff</li> </ul>	Jo Travaglia, Jeffrey Braithwaite

This report documents the outcomes of study 1. It reviewed the international literature on incident reporting and monitoring. This component of the evaluation was conducted by Dr Christine Jorm, A/Professor Jeffrey Braithwaite and Ms Jo Travaglia.

### 3.2 About this report

The next section, section 4, *Methods*, documents the search process utilised by the researchers. Section 5 presents the findings of this process, while section 6 discusses the findings in relation to the key research questions. The conclusion, section 7, briefly outlines the implications of this literature review for the evaluation of IIMS as a whole.

## **4 METHODS**

### **4.1 Overview**

This report presents an analysis of the international literature on incident reporting processes and mechanisms. The report reviews key aspects of incident reporting and monitoring including: the development and role of incident monitoring and reporting in quality and safety strategies; the basic requirements for incident reporting systems; issues with incident monitoring and reporting; and learning from incident monitoring and reporting systems. These aspects were chosen because they were the most relevant to the evaluation of IIMS, of which this literature review is the first study.

A comprehensive review of literature was conducted on this topic via the CINAHL and Medline databases searched from 1966 onwards. A variety of search terms, outlined in Table 2, was used. In addition, grey literature, including organisational reports and policies and studies conducted for specific health services, was reviewed. Key websites were examined in detail, with two providing on-line bibliographies. The literature was read by the first author, who analysed, summarised, and categorised into themes. The literature was then reviewed for validity and updated and synthesised by the second and third authors.

### **4.2 Review questions**

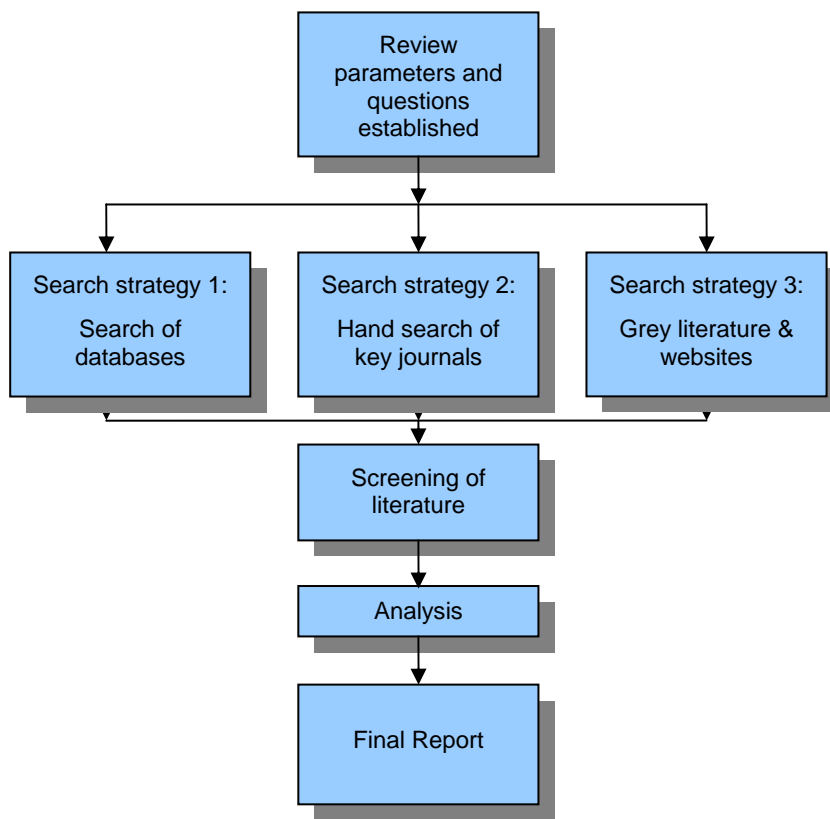
The review questions were formulated by the evaluators based on the brief provided by NSW Health. The questions directed the search and analysis process. The broad questions were:

- What are the features of incident reporting systems?
- How do incident reporting systems operate?
- How are critical incidents monitored and reported in health services?
- What is the appropriate coupling between reporting and action?
- What are the known barriers to effective use of such a system?
- How useful are such systems? What is their place in patient safety?

### **4.3 The review process**

Figure 1 provides a schematic diagram of the review process. It shows how three distinct search strategies and three methods were used to conduct the analysis of the literature.

**Figure 1: Schematic diagram of the research process**



#### 4.4 Search strategies

##### 4.4.1 Search strategy 1: search of databases

Databases were systematically scrutinised to find all relevant published literature. The databases searched included CINAHL (nursing and allied health literature, searched from 1982) and Medline (medical literature, searched from 1966). The searches were conducted in December 2005, and the databases were reviewed regularly for updates until Week 3, May 2006. References with abstracts were downloaded to Endnote version 9.0, a software package, for further processing and analysis.

With the systematic reviews, two authors independently reviewed the relevance of references, identified key articles, and qualitatively analysed them. The search terms were as follows (Table 2). “\$” is used for truncation in the databases searched.

**Table 2: Search terms**

1. Safety
2. Risk management
3. Medical error\$
4. Adverse event\$
5. Medication error\$
6. Disclosure

7. Reporting
8. Management information system\$
9. Information system\$
10. Database
11. Incident report\$
12. Error report\$
13. Adverse event report\$
14. Voluntary report\$
15. Mandatory report\$
16. Incident monitor\$
17. Critical incident review
18. Error analysis

#### 4.4.2 Search strategy 2: hand search of journals

Hand searches were conducted of key journals using the search terms in Table 2. The journals were selected mainly because of the frequency with which they deal with incident monitoring and reporting topics. A second factor was the availability of the journals to the researchers. These following journals were hand searched for the period 2004-2006:

- International Journal for Quality in Health Care
- International Journal of Medical Informatics
- Journal of Biomedical Informatics
- Journal of the American Medical Informatics Association
- Quality and Safety in Health Care.

#### 4.4.3 Search strategy 3: grey literature and websites

Grey literature includes materials such as unpublished reports, policy documents and frameworks relating to incident monitoring and reporting. Search terms used in Table 2 formed the basis of the search.

Key organisational documents from health services in Australia, the United Kingdom, the United States of America, Canada and New Zealand were searched, largely via relevant websites. The websites of patient safety research centres, institutes and organisations were targeted in particular. Selection of material was limited to English speaking documents.

Key websites searched included:

- Agency for Healthcare Research and Quality Patient Safety Network, United States
- Australian Commission on Safety and Quality in Health Care
- Australian Department of Health and Ageing
- Australian Health Information Council

- Australian Institute of Health and Welfare
- Canadian Patient Safety Institute
- Departments of Health in all States and Territories across Australia
- Department of Health, United Kingdom
- Health Canada
- Institute for Healthcare Improvement
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Joint Commission International Centre for Patient Safety
- National Health Service, United Kingdom
- National Institute of Clinical Studies
- National Institute for Health and Clinical Excellence (UK)
- National Patient Safety Agency (UK)
- National Patient Safety Foundation (US)
- Patient Safety International
- Veterans' Affairs National Centre for Patient Safety
- World Health Organization, World Alliance for Patient Safety.

Two additional sources of information were the National Patient Safety Foundation's on-line bibliography for patient safety and the Agency for Healthcare Research and Quality (US) Patient Safety Network's on-line resource collection. Both of these websites provided additional links to both published and unpublished articles and reports.

## **4.5 Analysis of searches**

### **4.5.1 Database search**

A large body of literature on incident reporting was identified through the three databases selected. This literature covers incident monitoring and reporting processes and mechanisms, as well as the use of this approach in patient safety and quality improvement. Table 3 presents the results of this search. Where "\$" is used for truncation in the databases searched, "exp" refers to a MESH term which has been "exploded" for the widest possible capture of the term.

**Table 3: Search results**

SEARCH TERM	DATABASE RESULTS: NUMBERS OF ARTICLES	
	CINAHL	MEDLINE
1. Safety exp	30456	28631
2. Risk management exp	4427	84238
3. Medical error\$ exp	0	50176
4. Adverse event\$	3973	25430
5. Medication error\$ exp	3546	5798
6. 1 or 2 or 3 or 4 or 5	36015	175780
7. Disclosure exp	0	16894
8. Reporting	8575	43554
9. Management information system\$ exp	1006	24742
10. Information system\$ exp	24299	85054
11. Database	8629	49558
12. 7 or 8 or 9 or 10 or 11	36318	174811
13. 6 and 12	2368	11799
14. Incident report\$	1122	573
15. Error report\$	162	189
16. Adverse event report\$	257	402
17. Voluntary report\$	634	169
18. Mandatory report\$	1565	1256
19. Incident monitor\$	18	92
20. Critical incident review	13	3
21. Error analysis	392	490
22. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21	3697	3039
23. 13 or 22	5098	13935
24. limit 23 to English	5060	13349

A total of 18,409 articles was identified. Because of the size of the data file, and given the scope of the report, we refined this to the most recent, the seminal papers (ie those that were referenced repeatedly) and those that were most relevant to incident management, reporting and systems. This created a sample of approximately 10% of the most relevant literature, or 1,840 references. The abstracts of all these references were read and sorted into the categories. The authors used a grounded method<sup>1 2</sup> of analysis which included reviewing the literature to secure a clear categorisation of it.

#### 4.5.2 Hand search of journals

Many articles identified through the hand search were already available through the database search. A number of additional articles on computerised prescribing systems and various others of relevance to this literature review were identified through this method.

#### 4.5.3 Grey literature and websites

The grey literature contributed a number of useful references, particularly a study<sup>3</sup> and literature review<sup>4</sup> conducted in preparation for the new NHS (UK) national reporting system. Use of grey literature is important. While it is not usually peer-reviewed, it shows current thinking and is a component in what has been called 'realist review',<sup>5</sup> which centres on explicating the inner workings of interventions.

Two American websites were particularly useful. These websites were originally searched in

January 2006, but were monitored for updates until the completion of this report. These were the National Patient Safety Foundation (NPSF) and the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Network.

The online bibliographies of both of these websites were searched. The NPSF produced an additional 206 references, while the AHRQ provided 580 references. In both cases, the majority of the articles listed replicated material that had already been identified through the database analyses. The bibliographies proved useful for identifying information from organisational websites and media reports.

#### **4.5.4 Content analysis**

We assessed 1,840 articles, papers and reports using Leximancer, a content analysis tool. Leximancer facilitates the creation of a map of the core concepts embedded in the literature. Its function is explained in greater detail in the next section.

## 5 FINDINGS<sup>1</sup>

The findings from our literature review are summarised under nine headings. Firstly, we cover three headings: origins of IIMS; review of AIMS; and overview of the main concepts in the literature. We then move to deal with six key issues, one per heading: the fundamental requirements of a computerised incident reporting system; incident reporting; severity assessment; barriers to introducing reporting systems; barriers to and incentives for reporting; and failure of incident reporting systems.

### 5.1 Origins of IIMS

IIMS is NSW Health's name for the Advanced Incident Monitoring System (AIMS). AIMS was developed by Professor Bill Runciman of the University of Adelaide, a world expert in patient safety. The system was originally developed and marketed by the Australian Patient Safety Foundation (APSF) (<http://www.apsf.net.au>). The APSF's commercial partner, Patient Safety International (PSI) (<http://www.patientsafetyint.com>), now has responsibility for these functions. A brief history of AIMS in Australia is as follows:<sup>6</sup>

- 1987 - national voluntary anonymous reporting system in anaesthesia established
- 1993 - funding to extend this system into other specialties, pilot studies were performed, and disciplines were encouraged to develop their own forms and reporting systems. This was felt to be successful, especially in Intensive Care Units (ICU) but most were abandoned through lack of funding. As part of the analysis of pilots in 1994: "It was concluded that the right to anonymity was important, that much value lay in having simple forms with plenty of space for free narrative"<sup>6</sup>
- 1993 - funding obtained to trial generic AIMS
- 1994 - development of Generic Occurrence Classification (GOC) – 'natural categories' to replace use of keywords and text analysis. The GOC is described as a multi-axial classification system for things that go wrong in healthcare – including contributing factors, salient features and outcomes.
- 2000 - AIMS-2 software package released, with a conceptual framework based on Reason's work,<sup>7-9</sup> with standardized definitions and terminology and a coding classification process where questions are specific to incident types.

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<sup>1</sup> As well as the literature analysis specifically performed for this study, we also draw on a literature review we conducted during our evaluation of the safety improvement program in NSW: see Braithwaite J, Travaglia J, Mallock N, Iedema R, Westbrook MT, Long D, Nugus P, Forsyth R, Jorm C, Pawsey M. *Evaluation of the patient safety program in New South Wales: Overview of studies*. Sydney: Centre for Clinical Governance Research Monograph, University of New South Wales, 2005.

## 5.2 Reviews of AIMS

Only two reviews of the parent AIMS software are available. Neither provides a great deal of detail. The Clinical Governance Unit of the Hunter Area Health Service distributed a 12 point questionnaire to 12 current users of AIMS in 2002.<sup>10</sup> Subjects were able to find some improvements or measurable outcomes which they attributed to the AIMS system and for this small sample overall benefit ratings were high. Three major benefits were:

- Developing an awareness of error and safety culture with less emphasis on a 'blame' approach
- The ability to monitor, trend and review incident data including investigations and incidents
- Increased consistency and identification of incident reporting and investigation including prioritization and prevention of adverse events and near misses.

Secondly, AIMS methodology was classed by the recent Health Technology Assessment Report on critical incident investigations as having moderate theoretical validity, as studies using the system usually describe what happened or how it happened but not why.<sup>11 p59</sup>

## 5.3 Overview of the main concepts in the literature

Leximancer is a software program which automatically emulates the techniques used in a concept analysis, by tagging, mapping and mining conceptual information from text-based documents. It enables researchers to explore the key ideas, concepts and themes in any written or spoken materials. The concepts can either be identified automatically by the program and or "seeded" (that, is included) by the researcher. The program examines a text and, using Bayesian theory to conduct predictive modelling, is able to create a taxonomy of key concepts which it presents as a ranked list of concepts (as in table 4), and a cluster map (as in figure 2). The list provides insights into the strength of relationships between concepts (the top concept being the one to which the largest number of other concepts have a relationship), while the map provides a visual representation of the networks and patterns of these relationships.<sup>12</sup> The concepts can then be analysed thematically (conceptually) and relationally (semantically).<sup>13</sup>

The Leximancer analysis conducted on the incident reporting literature revealed a complex picture in the incident information management literature. The map (figure 2) shows that the literature is centrally and semantically concerned with a few core concepts, and is largely focused on reporting of incidents about patients, particularly on computerised and systematic forms, and longitudinally. The literature is preoccupied not only with adverse events and patient safety but also with specific topics such as comparative safety performance, medication errors, clinical management, sexual cases and abuse.



health	1096	34.6%
cases	1057	33.3%
medical	1037	32.7%
risk	1032	32.5%
report	984	31%
system	982	31%
significant	948	29.9%
incident	931	29.3%
drug	874	27.5%
years	858	27%
event	856	27%
errors	853	26.9%
significantly	748	23.6%
analysis	744	23.4%
incidents	737	23.2%
efficacy	720	22.7%
studies	713	22.5%
hospital	711	22.4%
placebo	707	22.3%
groups	700	22.1%
children	692	21.8%
total	673	21.2%
compared	668	21%
information	667	21%

#### 5.4 Fundamental requirements of a computerised incident reporting system

What are the fundamental requirements of incident reporting systems? Three experts have looked at these (Table 5).

**Table 5: Requirements for incident reporting systems**

	BILLINGS <sup>14</sup>	LEAPE <sup>15</sup>	NYSSSEN <sup>16</sup>
<b>Initially</b>	“The first and most critical requirement ... is a demonstrated, tangible, widely agreed upon need for more and better information.” <small>17 p52</small>		
<b>Management</b>	Independent analytic body. <sup>17</sup> <small>p52</small> Analysis of computerised incident reports must be objective and disinterested, and performed by analytic experts rather than clerks.	Independent – independent of any authority with power to punish the reporter or the organisation  Expert analysis – by those who understand the clinical circumstances and are trained to recognise underlying system causes	Medical – involvement of domain experts in collection and analysis of data  Technical – methods of collection and analysis must be appropriate for the goals

<b>Chief characteristics</b>	<p>Stakeholders need to use the new knowledge to “spur new analysis, new research, to guide regulation, to inform management decision making, to change performance” <sup>17 p56-57</sup></p> <p>Adequate time for establishment and to “sell the system” to the recipients of its products <sup>17 p52</sup></p>	<p>Timely – reports analysed promptly and recommendations rapidly disseminated to those that need to know</p> <p>Systems Oriented</p> <p>Responsive – the agency that receives reports is capable of disseminating recommendations, and participating organizations agree to implement recommendations when possible</p> <p>Non-punitive – there will be no retaliation or punishment from others as a result of reporting</p> <p>Confidential – identities of the patient, reporter and institution are never revealed to a third party</p>	<p>Feedback and dissemination of information</p> <p>Need long term assessment of the tool – its effects on work situations, scope of reporting, classification and analysis schemes and the success of remedial and preventative actions</p> <p>Organisational – positioning the system in a culture of quality and patient safety improvement rather than a blame culture</p> <p>Legal – protection of data, along with reporters and managers of systems</p>
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The requirements in the table above represent an overview of some of the major issues in information management systems. This leads to incident reporting itself.

## 5.5 Incident reporting

Incident reporting is at the core of many safety improvement programs.<sup>18</sup> The Institute of Medicine report *To Err is Human*<sup>19</sup> 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<sup>20</sup> and the Agency for Healthcare Research and Quality (AHRQ)<sup>21</sup> in the USA allocate significant organisational and financial resources to reporting processes. In NSW, the Reportable Incident Brief (RIB) is the method for reporting defined health care incidents to NSW Health<sup>22</sup> but a variety of incident reporting systems and methods currently operate in Australia, and internationally.

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.<sup>23</sup> 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,<sup>24</sup> case audits, record reviews,<sup>25</sup> direct observation,<sup>26</sup> record review<sup>27</sup> as well as systemic reporting systems, both mandatory and voluntary.<sup>28</sup> Coroner’s reports and major

inquiries are also utilised to inform patient safety improvement programs.<sup>29</sup>

## 5.6 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 Veterans Administration (VA) in the USA 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.<sup>22</sup>

## 5.7 Barriers to introducing reporting systems

Incident reporting and severity assessment, then, are important. What about barriers in establishing incident reporting systems? A UK study found that prior to publishing *An Organisation with a Memory*<sup>23</sup> one fifth of NHS Trusts had no organisation-wide reporting systems. Less than half of the sampled Trusts provided specific training in risk management or incident reporting and fewer than one third provided guidance to staff on what to report and a similar number required clinicians to report unexpected operational complications or events.<sup>30</sup>

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.<sup>31</sup>

Researchers and patient safety organisations have attempted to identify the key features of a successful incident reporting system. Table 6 provides a summary of these features.

**Table 6: Features of successful 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>

DESIGN AND USE FACTORS	
▪ Reporting systems	<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>
▪ Protections	<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>
▪ Staffing/resources	<ul style="list-style-type: none"> <li>▪ Increased involvement of professional licensing agencies</li> <li>▪ Independently employed risk managers</li> <li>▪ Training on reporting</li> <li>▪ Education</li> <li>▪ Restructuring peer review and credentialing processes to assure fairness and objectivity</li> </ul>
▪ External factors	<ul style="list-style-type: none"> <li>▪ Media awareness of true nature of adverse outcomes and errors</li> <li>▪ Reducing malpractice litigation</li> </ul>
▪ Follow up	<ul style="list-style-type: none"> <li>▪ Corrective action plans that are non-punitive</li> <li>▪ Timely investigations with sound plans of correction</li> <li>▪ On-site follow up</li> <li>▪ Rapid and meaningful feedback to general staff and reporting individuals</li> <li>▪ Comparative data on trends, common problems and effective solutions collected and distributed from a central service</li> <li>▪ Encouragement of continued reporting through feedback</li> </ul>
▪ Evaluation	<ul style="list-style-type: none"> <li>▪ Evaluation at local level of both system and corrective actions</li> <li>▪ Ability to demonstrate improved outcomes</li> </ul>
Sources: NHS 2000; Rosenthal et al 2001; Barach 2000; Battles et al 1998 <sup>23 31-33</sup>	

## 5.8 Barriers to and incentives for reporting

Empirical studies across jurisdictions suggest that many adverse incidents are not reported, even though they are designated as reportable, and reporting systems exist. Although findings vary, from one third<sup>34</sup> to less than a quarter<sup>35</sup> of reportable incidents are reported. Figures from the CEC for the last six months of 2005 indicate that across NSW on average 5,500 incidents per 100,000 separations (not including Ambulance or Justice Health) were 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.<sup>36</sup> Recommendations are made for simplifying and streamlining incident reporting systems<sup>35 37</sup> which are among the stated aims of the numerical SAC allocation.<sup>38</sup>

Research into the resistance to reporting of adverse drug reactions in the UK has exposed a range of reasons for resistance, 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.<sup>39 40</sup> 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.<sup>41</sup> 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.<sup>42</sup>

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.<sup>37</sup> 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.<sup>37</sup>

Barach and Small<sup>32</sup> identified a number of barriers and incentives to incident reporting at individual, organisational and society levels. These are shown in summary in Table 7.

**Table 7: Barriers to and incentives for 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<sup>43</sup> although such data can become unwieldy in applying the findings to system-wide practical improvement.<sup>44</sup> 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.<sup>45</sup> This was in part the stimulus for NSW Health to acquire IIMS.

## 5.9 Failure of incident reporting systems

About 40% of information technology developments in healthcare are either abandoned or fail and less than 40% of large systems purchased from vendors meet their goals.<sup>46</sup> Attempts to introduce computerised medical records or computerised prescribing systems are subjects of substantial recent literature. These computerised systems will inherently be more difficult to implement than a computerised incident reporting system, however powerful resistance of users has surprised those in charge of implementation.<sup>47</sup> Reasons for failure of computerised incident reporting systems provide potentially strong evidence to support success hypotheses.

User dissatisfaction with introduction of a computerised incident reporting system forms a case study in a 2005 health informatics textbook.<sup>48</sup> The reason for failure of computerised incident reporting systems is user dissatisfaction; commonly cited causes of this are:

1. Time consuming reporting and/or reporting is not easy.<sup>16 48 49</sup>

One group with a successful computerised incident reporting system had aimed to have 3min entry time, but in practice it required greater than 7 minutes, despite only 3 screens to be navigated.<sup>50</sup> While time consumed by reporting is sometimes reduced to a number: eg the average time reported for ICU-SRS completion is 12.45min (SD 8.41),<sup>51</sup> of greater importance is how the staff perceive this length of time. In this ICU study only 20% found this too time consuming. The extent of requested reporting also determines its time consuming nature. UK authors suggest "A balance needs to be struck between trying to encourage staff to report as

many critical incidents as possible while at the same time not risking 'reporting fatigue' whereby, over time, even serious incidents no longer get reported".<sup>52</sup>

2. Lack of feedback to originators of incident reports.<sup>16 48</sup>

This has been described as one of the "basic difficulties with IT in general".<sup>48</sup> Feedback also includes improvement: "timely feedback and local usefulness of reporting systems determine user adoption or mere compliance"<sup>49</sup>

3. Other: fear of blame and running costs.<sup>16</sup>

These points about blaming and costs appear in the table of requirements for successful computerised reporting systems. Therefore it behoves us in the evaluation of the IIMS system to pay special attention to these issues, which have been observed multiple times.

## 6 DISCUSSION

Most commentators recognise the potential of incident reporting to provide effective, usable data and improved manageability of adverse events and near misses. IIMS has been designed to facilitate reporting in a systematic way, and to aggregate reported data into functional formats.

Incident information monitoring, management and reporting holds promise in terms of tackling adverse events and near misses, but to date the literature suggests this promise is as yet unrealised in the science of demonstrably improving health systems safety. In short, evidence thus far assembled is not convincing that incident reporting systems have yet had the desired effect in improving patient safety. Nevertheless, there are concerted international efforts across developed health systems to improve incident monitoring and error reporting.

There are recognised barriers both to the introduction of incident reporting systems and to their operation. Incentives to reporting can be built into health systems: legal, cultural regulatory and financial incentives are typically discussed in the literature. Warnings about failures of information technology implementations generally, and computerised incident reporting systems more specifically, have been discussed.

External evaluations of specific incident management systems have not been effectively realised to date. The task in the ensuing sections of this evaluation is to document our studies of the implementation of IIMS in the NSW health system.

## 7 CONCLUSION

The literature review presented here sets the scene and provides the context for the evaluation studies which follow. We turn to these, explicating in turn each study summarised in Table 1.

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