An intervention to improve voluntary incident reporting in South Australian public hospitals

Susan Margaret Evans

BN (Deakin), Grad Dip Clinical Epidemiology (Monash)

Volume I

A thesis submitted in 2006 for the degree of Doctorate of Philosophy

Department of Medicine

University of Adelaide

TABLE OF CONTENTS

INDEX TO TABLES

INDEX TO FIGURES

SUMMARY

The majority of care provided to patients in Australian hospitals is excellent; however there is evidence that adverse events do occur, mostly due to vulnerabilities in hospital systems. Incident reporting is a tool which enables healthcare workers to disclose errors, so that underlying contributing factors which may have precipitated the event can be analysed, and corrections made to prevent similar incidents recurring. Unfortunately, incident reporting is not widely used for a number of reasons. The aim of this study was firstly to gather information from (1) consumers on their experiences of adverse events in hospitals and general practice and their attitude towards reporting of errors by healthcare workers; (2) doctors and nurses on current reporting practices and barriers to reporting using focus groups and survey techniques; and use this information to construct a study with the aim of improving reporting rates and changing types of incidents reported. The intervention study was then undertaken and evaluated.

Methods

A random, representative household survey (n=2884) was used to determine consumer-perceived adverse event rates in healthcare settings, and a telephone survey (n=2005) ascertained attitudes towards reporting of error. Focus groups were used to determine current reporting practices and barriers to reporting for doctors and nurses, with each discipline and level of seniority represented individually in a separate focus group. Qualitative analysis was undertaken using Triandis' theory of social behaviour. To further explore themes identified in focus groups and to provide baseline data, a questionnaire was distributed to 263 doctors and 799 nurses in 20 clinical units across 6 hospitals in metropolitan and rural South Australia (response rate 73%).

Focus group and survey data was instrumental in designing an intervention, which was designed as a matched controlled study in 20 units across 4 metropolitan and 2 rural hospitals. The aims were to (1) educate staff about reportable events; (2) ease reporting burden through establishment of a Call Centre, a condensed reporting tool and on-line reporting; (3) provide clinicians with tools to investigate/analyse incident reports; and (4) facilitate feedback of incident data to healthcare workers in clinical areas. Incident reporting rates and types of reports generated were compared for inpatient areas (medical units, surgical units and the Intensive Care Unit (ICU) and the Emergency Department (ED) between; (a) baseline and end-of-intervention and between (b) control and intervention

units. For each intervention unit, there was a control unit matched on specialty type and location of hospital. Success of the intervention in changing attitude towards reporting and addressing barriers identified at baseline was measured by re-surveying 273 doctors and 858 nurses across the intervention and control units, replicating some of the questions asked at baseline and eliciting opinion on reporting processes.

Results

Initial qualitative research

Consumers identified that 7% of hospital admissions were associated with an adverse event; 60% of whom rated the adverse event as serious and 48% stated prolonged hospitalisation was required. Most consumers believed that healthcare workers should report errors, with 68% believing that the reporter should be identified on the report and only 29% favouring anonymous reporting.

Focus groups identified cultural differences between doctors and nurses underpinning attitudes to incident reporting. Common barriers to reporting incidents included time constraints, unsatisfactory processes for reporting, deficiencies in knowledge, cultural norms, inadequate feedback, and a perceived lack of value in the process.

The baseline survey (n=773, response rate =73%) identified that most respondents knew of their hospital's incident reporting system, and that doctors were less likely than nurses to understand reporting processes. Overall, major barriers to reporting incidents were lack of feedback (62%), a belief that there was no point in reporting near misses (49%) and forgetting to make a report when the ward is busy (48%).

Intervention study

Compared with the 40-week baseline period, reporting in inpatient intervention units during the 40-week study period increased significantly, with 60 additional reports per 10,000 occupied bed days (OBD), $p<0.001$) being generated in intervention units compared with control units. In the ED reporting rates increased by an additional 56 reports per 10,000 ED attendances ($p<0.001$). There was significant improvement in reporting within medical and surgical units; however the intervention was not able to significantly improve incident reporting tin ICUs.

The intervention resulted in significantly more doctor-initiated reports in the ED, more nursing reports in inpatient areas and more allied health reports in both inpatient areas and in the ED. Anonymous reporting increased 20-fold in intervention units during the study

period compared to baseline rates. There was a change in incidents reported, with proportionately fewer incidents relating to falls and more documentation, clinical management, patient aggression and environment-related incidents in intervention units compared to control units.

According to analysis of the end of study survey (n=840, response rate 74%), respondents in intervention units at the end of the study were more likely than control units to believe they should report hospital-acquired infections and medication near misses, however they were less likely to believe that they did report certain events. They were less likely to believe that there was no point in reporting near misses (RR 0.63 95% CI: 0.60 to 0.97), that reporting incidents was unlikely to lead to system changes (RR 0.78 95% CI: 0.63 to 0.96) and that if the incident was discussed with the person involved nothing further needs to be done (RR 0.35 95% CI: 0.18 to 0.72).

Conclusions

This intervention incorporating education, simplified methods of reporting, and feedback demonstrated an ability to improve incident reporting and change types of incidents reported in a variety of clinical settings over a sustained period of nine months. Assessment of staff opinion following the intervention in conjunction with evaluation of the heterogeneity in reporting rates between units has been used to develop a blueprint for improving incident reporting.

DECLARATION

I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text. I further consent to the thesis being made available for photocopying and loan if applicable, if accepted for the award of the degree.

Sue Evans

ACKNOWLEDGEMENTS

The work reported in this thesis was made possible by the support of a number of Agencies. In particular, I would like to acknowledge the South Australian Hospitals Safety and Quality Council and Patient Safety International for providing resources to enable this project to be undertaken.

Due to the scope of this project, it would not have been made possible to the extent that it has without support and assistance of the "project team", namely Karen Stead, Pam Selim, Sandy Muecke, Jane O'Shaughnessy, Sue Jones and Rhonda Bills. A special thanks to Jesia Berry for assistance with statistics and for the many evenings spent answering reviewers' comments and writing grant applications. The achievements of this project are testament to their dedication and commitment to improving patient safety.

I thank and acknowledge the support and advice provided by my principal supervisors, Professor Adrian Esterman and Associate Professor Brian Smith, and co-supervisors, Professor Bill Runciman and Professor Guy Maddern. I would like to acknowledge also the assistance of Professor Deborah Turnball for input into the survey design and format.

The medical and nursing Heads of Units, Risk Managers, and Patient Safety Managers have each given their time willingly and on most occasions, enthusiastically. I thank the clinicians at the coalface for supporting the project, particularly those who attended focus groups, completed surveys and submitted reports. I owe a debt of gratitude to Christine Dennis and Christy Pirone in the Clinical Systems Unit, Department of Health for supporting the project from inception to completion.

Finally, my sincere thanks to my husband Colin and four wonderful children Samantha, Ben, Kirsten and Emma for supporting me on this rocky road.

THESIS CONTRIBUTORS

- South Australian Department of Health Clinical Systems Unit (funding and assistance with implementation of centralized incident reporting system-AIMS).
- South Australian Department of Health Centre for Population Studies in Epidemiology (SA Omnibus and Health Monitor).
- Harrison Health Research (conducting Health Monitor and Omnibus survey).
- Patient Safety International (license to use Advanced Incident Monitoring System).
- Royal District Nursing Service (Call Centre).
- Department of Psychology, University of Adelaide (survey design).
- Royal Adelaide Hospital Medical Art Department (one page incident form).
- Flinders Centre for Epidemiology and Biostatistics (statistical support).
- Risk Managers/Quality Improvement Officers at each respective hospital: Tracy Cooke, Trena Mullen, Liz Fitzgerald Megan Adey, Anne Hill, and Dee Whitford.

PREFACE

Part of the work described in this thesis has been published. The publications are listed below.

Refereed journals

1. Evans SM, Berry JG, Smith BJ, Esterman A, Selim P, O'Shaughnessy J, DeWit M. Attitudes and barriers to incident reporting – a collaborative hospital study Qual Safety Health Care (accepted for publication November 2005).
2. Evans SM, Berry JG, Smith BJ, Esterman A. Consumer perceptions of hospitals Biomed Central Journal of Public Health (accepted for publication November 2005).
3. Evans SM, Berry JG, Smith BJ, Esterman A (2004) Anonymity or transparency in reporting of medical error; a community-based survey in South Australia Med J Aus 7 June 2004 180 (11).
4. Kingston M, Evans SM, Smith BJ, Berry JG (2004) Attitudes of doctors and nurses towards incident reporting: a qualitative analysis Med J Aus 5 July 2004.

Oral presentations

1. Smith BJ, Evans SM, Selim P, Runciman W, Esterman A, O'Shaughnessy J, Berry J, Stead K. IRIS intervention impact upon clinician reporting of adverse events and near misses across six city and country South Australian hospitals. Paper presented at the 2nd Australasian Conference of Safety and Quality in Health Care. Adelaide, South Australia, August 2004.
2. Evans SM, Berry JG Esterman A, Smith B. Attitudes and barriers to incident reporting: a collaborative hospital study. Paper presented at the 3rd Asia Pacific Conference on Quality and Safety in Health Care, Auckland, New Zealand, September 2003.
3. Evans, SM, Smith BJ, Berry JG, Esterman A. Reporting of error in the surgical division. Paper presented at the Royal Australasian College of Surgeons Conference- Governing the Ungovernable- the Surgical Perspective. Adelaide, South Australia, October 2003.

4. Evans SM, Berry JG, Smith BJ, Esterman A. Incident reporting to improve systems Proceedings of the 5th Annual Public Health Association of Australia Conference-Mobilising Public Health, Adelaide, South Australia, October 2002.
5. Berry JG, Evans SM, Smith BJ, Esterman AJ. Consumers' perceptions of safety in hospitals and general practice: A South Australian survey. Proceedings of the 8th Annual National Health Outcomes Conference- Health Outcomes 2002 Current Challenges and Future Frontiers, Canberra, ACT, 2002.

Poster presentation

1. Evans SM, Smith BJ, Esterman A, Selim P, Stead K, Muecke S, O'Shaughnessy J, Jones S Views of Doctors and Nurses Following an Intervention to Improve Reporting Practices. Poster presented at the 3rd Australasian Conference on Safety and Quality in Health Care-Evolution or Revolution, Adelaide, South Australia, 11-13 July, 2005.
2. Evans SM, Whitford D, Whitford R., Bills R. Lessons learned in the implementation of a statewide incident reporting system. Poster presented at the 3rd Australasian Conference on Safety and Quality in Health Care- Evolution or Revolution, Adelaide, South Australia, 11-13 July, 2005.
3. Evans SM, Berry JG, Smith BJ, Esterman A. Health Omnibus: Consumer perception of safety in healthcare. Poster presented at the 1st Asia Pacific Conference on Quality and Safety in Health Care, Singapore. September 2002.

Non-refereed journals

1. Evans SM, Smith BJ. IRIS: Culture change. Australian Patient Safety Foundation newsletter: September 2002. Available from http://www.apsf.net.au/dbfiles/Newsletter_2002_09.pdf (accessed 3rd January 2006)

ACRONYMS USED IN THESIS

Abbreviation	Definition
ADE	Adverse drug event
AE	Adverse event
AIMS	Advanced Incident Management System
APSF	Australian Patient Safety Foundation
ED	Emergency Department
EN	Enrolled Nurse
GP	General Practic/titioner(e)
ICU	Intensive Care Unit
IOM	Institute of Medicine
IR	Incident report
IT	Information Technology
JCAHO	Joint Commission on Accreditation of Healthcare Organisations
KPI	Key Performance Indicator
MRR	Medical record review
NASA	National Aeronautics and Space Administration
NHS	National Health Service
NUM	Nurse Unit Manager
OBD	Occupied Bed Day
PSI	Patient Safety International
PSM	Patient Safety Manager
PIT	Principal Incident Type

Abbreviation	Definition
QAHCS	Quality of Australia Health Care Study
RCA	Root Cause Analysis
RCT	Randomised controlled trial
RN	Registered Nurse
SAC	Severity Assessment Code
UK	United Kingdom
US	United States of America
VA	Veterans Affairs

1. INTRODUCTION

1.1. The science of error

> "Ladies and gentlemen, welcome aboard Sterling Airline's Flight Number 743, bound for Edinburgh. This is your captain speaking. Our flight time will be two hours, and I am pleased to report both that you have a 97% chance of reaching your destination without being significantly injured during the flight and that our chances of making a serious error during the flight, whether you are injured or not, is only 6.7%. Please fasten your seatbelts, and enjoy the flight. The weather in Edinburgh is sunny." Would you stay aboard? We doubt it.

This quotation was taken from an article written by Berwick and Leape in 1999[1] and compares adverse event rates experienced in hospitals with that of another high-risk industry, aviation.

Healthcare, exists to alleviate disease and disability, however statistics now demonstrate that a substantial number of patients are harmed by errors that occur while receiving care in hospital.[2]

In the complex and technically sophisticated area of healthcare, it is not surprising that errors occur. In fact, as humans it is not possible to assume that we won't make mistakes. Errors occur when a planned action fails to be completed as intended, or when the wrong plan is used to achieve an aim.[3] Errors occur that are both preventable and unavoidable. Most errors in healthcare delivery do not result in harm. Errors only cause injury in the absence of adequate defences or safeguards. In healthcare, errors that lead to harm are known as adverse events and errors that do not result in harm are referred to as near misses. It has been estimated that near misses occur 3 to 300 times more frequently than adverse events.[4]

Traditionally, the mainstay of dealing with errors has been to focus blame on the person inadvertently making the error; however it is now widely recognised that this attitude rarely makes the healthcare system safer by preventing someone else from committing the same error. A growing body of work around applied cognitive psychology is being used to understand and reduce errors, and improve the fit between people and the technology they use.[5]

As a result of the burgeoning body of work in relation to identifying and reducing error, there has emerged a new field of study with its own definitions and terminology.

1.2. Definitions used in the field of quality and safety

There has been concerted effort over the past few years to standardise definitions with regard to the terms medical error, adverse events, incidents, close calls and near misses. There is a need to ensure consistency of approach, particularly when comparing rates across hospitals and internationally. Table 1-1 defines the terms that have been used in this thesis.

Table 1-1 Definitions of terms used in the thesis

Term	Definition
Adverse event	An incident in which unintended harm resulted to a person receiving health care.[6]
Allied Health professionals	University-trained health professionals (other than medical practitioners or nurses) who are involved in direct patient care and /or services to the community. They include but are not limited to pharmacists, radiologists, physiotherapists, speech therapists, occupational therapists, and dieticians.
Error	Encompasses all occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency.[3] The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning).[7]
Error (active)	An error in which the effects are felt almost immediately.[8]
Error (latent)	An error whose adverse consequences may lie dormant within the system for a long time, only becoming evident when they combine with other factors to breach the system's defences.[8]
Health Care	Services provided to individuals or communities to promote, maintain, monitor, or restore health. Health care is not limited to medical care and includes self care.[6]
Iatrogenic	Arising from or associated with health care rather than an underlying disease or injury. Consequences of omission (failing to do the right thing) as well as commission (doing the wrong thing) are included.[6]
Incident	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage.[6]
Incident reporting	Reporting of adverse events and near misses, traditionally for local management and follow up.[9]
Near Miss	An incident that did not cause harm.[6]

Term	Definition
Patient Safety Manager	Refers to the person responsible in each organisation for the administration of comprehensive safety of care and clinical risk management programs.[10]
Preventive (Preventative)	That which hinders, obstructs or prevents disease. [11]
Preventable	Potentially avoidable in the relevant circumstances. [6]
Root Cause Analysis	A process performed after an adverse event has occurred to identify basic and contributing causal factors, underlying variations in performance associated with near misses, adverse events and sentinel events. Root Cause Analysis seeks to find common causes to improve performance. [12]
Sentinel Events	A type of adverse event, or patient safety incident, that occurs infrequently, but with alarming consequences.[13]

1.3. The patient safety movement

In 1964, Schimmel identified that approximately 20% of patients admitted to hospital suffered one or more "untoward consequences of medical care", with 4.7% of these having serious consequences.[14] In 1974, a study of hospitalised patients in California identified that approximately 1% of patients received negligent care.[15] In 1991, another US study used medical record review to determine that 3.7% of admissions to hospital were associated with an adverse event, of which 27% were deemed negligent and 16% led to permanent disability or death.[2] Other studies in England,[16] New Zealand,[17] Canada,[18] Denmark,[19] and Australia,[20] which were modelled on the audit process used in the US study have demonstrated higher adverse event rates, thought to be due principally to differences in definitions of what constitutes an adverse event.[21-24] Details of each of these medical record review studies are described below in Table 1-2.

Table 1-2 Medical record review studies used to ascertain adverse event (AE) rates, preventability (Prev) and negligence (Neg)

Paper	Study population (year study undertaken)	Inclusion/Exclusion criteria	Outcomes measured	Sample frame	% of pts ≥1 AE	Prev / Neg score
Canadian Adverse Events Study, 2004[18]	3745 medical records from 20 hospitals in Canada. (2000)	**Inclusion**: Patients admitted to acute-care non-specialised hospitals with >1500 admissions/yr and 24 hr Emergency Dept. **Exclusion**: day surgery and psychiatric cases)	**AE rate*** **Prev †:**	1, 2, 3	7.5%	37% (Prev) 64.4% resolved in 6 months 5.2% caused permanent disability 15.9% caused death
British adverse event study, 2001[16]	1.014 medical records from 2 acute hospitals in London (1999)	**Inclusion**: Patients admitted to general medicine, general surgery, orthopaedic surgery and obstetrics units **Exclusion**: all other specialties not included above.	**AE rate*** **Prev †**	1, 2	10.8%	46% (Prev) 66% resolved in 1 month 19% = moderate impairment 6% = permanent disability 8% = death
New Zealand Feasibility Study2001, [17]	1,575 medical records from 3 major public hospitals in Auckland, NZ (1995)	**Inclusion**: Patients admitted to acute-care, non-psychiatric hospital. **Exclusion**: day surgery and psychiatric cases.	**AE rate‡** **Prev†:**	1, 3	10.7%	37% (Prev) 56.3%resolved in 1 month 20.4% resolved b/n 1-12 months 5.6% caused permanent disability 6.3% caused death
Danish adverse event study, 2001[19]	1,097 medical records from 17 acute care hospitals in Denmark (?)	**Inclusion**: Patients admitted to acute-care, hospitals. Representative sample (no over-sampling from high risk areas performed. **Exclusion**: not able to be ascertained.	**AE rate‡** **Prev**	Not ascertained	9%	40.4% (Prev) Most caused minor, transient disabilities 4.6%% caused permanent disability or death caused on average 7 days prolonged hospitalisation

Paper	Study population	Inclusion/Exclusion criteria	Outcomes measured	Sample frame	% of pts ≥1 AE	Prev / Neg score
Utah/Colorado Study, 2000[25]	14,732 medical records from patients separated from 28 hospitals in Utah and Colorado (1992)	**Inclusion**: Patients seen as in-patients and those seen outside hospital (eg. in physician's office, home, day surgery, nursing home)	**AE: rate*** **Neg§**	1, 2	2.9%	29% (Neg) 79% of AE caused minor disability 3.1% caused permanent disability 6.6% caused death
Quality in Australian Health Care Study, 1995[20]	14,179 medical records from patients admitted to 31 hospitals in NSW and SA (1992)	**Inclusion**: Patients admitted to public and private acute-care hospitals with >3000 admissions/yr. **Exclusion**: day surgery and psychiatric cases)	**AE rate*** **Prev: †**	1, 2, 3	16.6%	51.2% (Prev) 77.1% resolved in 1 year 13.6% caused permanent disability 4.9% caused death
Harvard Medical Practice Study, 1991[2]	31,429 medical records from patients separated from 51 hospitals in New York. (1984)	**Inclusion**: Patient admitted to an acute care, non-psychiatric hospital **Exclusion**: psychiatric cases, outpatients	**AE rate*** **Neg§**	1, 2, 3	3.7%	27.6 % (Neg) 70.5% of AE resolved in < 6 months 2.6% caused permanent disability 13.6% caused death
California Medical Insurance Feasibility Study, 1977[15]	Medical records from patients admitted to hospitals in California (1974)	**Inclusion**: Patient admitted to an acute care, non-psychiatric hospital **Exclusion**: psychiatric cases, outpatients	**AE rate****	1, 2	4.6%	1% of patients admitted to hospital suffered harm resulting from negligence

* Adverse event= unintended injury or complication which results in disability, death, prolonged hospitalisation and is caused by health care management rather than patient's disease † Preventability =Error in healthcare management due to failure to follow accepted practice at an individual or system level. ‡Adverse event =unintended injury or complication which results in temporary or permanent disability, including increased length of stay &/or financial loss to patient that was caused by health care management rather than patient's disease. § Negligence = care that fell below the standard expected of physicians in the community. ** Adverse event = injury which was of "potentially compensatable events" Sample frame codes (1) Occurred and discovered during index admission (2) Occurred during index admission, discovered after discharge, (3) Occurred before index admission and discovered during index admission.

In response to growing awareness of the magnitude of the problem, organisations were established within Australia and internationally to develop a comprehensive approach to improving patient safety. In America, a project was initiated in 1998 by the Institute of Medicine (IOM), with the aim of developing a strategy that would result in a threshold improvement in quality over the next ten years.[7] In Australia, the Australian Council for Safety and Quality in Health Care (ACSQHC) was established in 2000 to lead national efforts to improve the safety and quality of healthcare, with a particular focus on minimizing the likelihood and effects of when things go wrong.[26] In the UK, the Expert Group on Learning from Adverse Events was established to advise the Government on steps to ensure that the National Health Service (NHS) learned from its experiences, so that the risk of avoidable harm to patients was minimized.[27]

In Australia, fifty million dollars was allocated by the Government to be distributed over a five year term, with the aim of undertaking activities to reduce the scope of the problem. Funding allocated to enable organisations to undertake interventional projects to improve patient care have often demonstrated promising outcomes.[28]

The scope of interventional studies being undertaken in Australia and internationally is now enormous.[28 29] The level of evidence of their effectiveness in improving patient safety varies significantly. The University of California at San Francisco- Stamford University[29] undertook a study in the US to determine which safety practices were most effective, using an evidence-based medicine (EBM) approach. They found that the majority of practices had not been rigorously evaluated using EBM. Studies shown to have a strong evidence support mostly relate to individual biomedical interventions for drugs, devices and procedures.[30] Few studies assess effectiveness of system-based, error prevention techniques on a large scale with results replicated by others, using blinded randomised controlled trials (considered the gold standard for assessing effectiveness of interventions).

Ioannidis and Lau[31] systematically reviewed randomised controlled trials (RCT) evaluating an intervention against placebo or no intervention and had the specific aim of reducing medical errors as a primary or secondary outcome. They found only thirteen studies among the literature that met these inclusion criteria. Proposed explanations for the paucity of RCT studies, considered the gold standard in evidence based medicine, regarding patient safety activities include:

- Difficulty in determining the effectiveness of system changes at an individual level.[30] For example, RCTs to determine the effectiveness of antibiotic impregnated central

venous catheters in reducing bacteraemia would be easier to perform than RCTs investigating the effectiveness of standardising medication orders to ensure that a leading 0 prefixes all small doses (.1mg vs. 0.1mg).

- The cost associated with undertaking RCTs in patient safety. The cost of implementing a Computerised Physician Ordering Entry (CPOE) system was in excess of $US 1 million.[30] It achieved only moderate evidence of effectiveness because it has only been evaluated in one healthcare setting, largely because of the cost associated with purchasing it.
- The fact that some techniques that have had such overwhelmingly positive results that RCTs were not warranted.[30] It would be difficult to receive ethical approval to undertake an RCT on certain procedures such as initiating sponge/instrument counts following surgery because it makes sense and has been shown to improve patient safety even though no RCT has been performed.
- Applying RCT methodology using a medical model, which provides a narrow biased perspective on assessing the efficacy of an intervention, might not be as relevant as applying models from other industries (such as those used in human factors, engineering, or safety theory).[31]
- Difficulty in blinding study participants to the intervention.[30] Unlike clinical trials where placebo tablets can be given, patient safety activities often involve clinicians and visible changes to clinical practice, making blinding difficult.
- Publication bias, where publication of results is dependent on the magnitude and direction of results.[32 33] More recent studies have questioned whether publication bias exists.[34]

Even in spite of the amount of work being undertaken through Australia and internationally, there remains significant evidence that quality of care in hospitals is variable.[35-40] Investigations undertaken following adverse events have often identified recurring themes (Table 1-3), including the need to develop better systems to identify and manage adverse events (Table 1-4).

Table 1-3 Key findings of investigation into errors in various healthcare settings

	King Edward Inquiry, 2002[35]	Camden and Cambelltown Hospitals Inquiry, 2003[36]	Bristol Inquiry, 2001[39]	Richard Neale investigation, 2004[40]
A culture of blame, unsupportive of open disclosure, errors and adverse events	✔	✔	✔	
Lack of clarification of senior staff responsibilities and accountability	✔			
Non-existent systems to monitor performance and respond to performance issues	✔	✔	✔	✔
Ineffective or non-existent credentialing processes, training, support and performance management to meet the demands and skill requirements of their roles and responsibilities	✔	✔	✔	✔
Failure to meet the emotional needs of patients and families	✔		✔	
Excluding patients and families from decision making and failing to give honest, complete and timely information when errors occurred.	✔		✔	
Failing to address the serious and ongoing management and clinical problems causing serious adverse events and poor outcomes for patients and families	✔		✔	✔
Poor teamwork			✔	
Unacceptable delay in treating patients		✔		
Inadequate resourcing of safety and quality systems and personnel		✔		
Poor documentation in medical records		✔		✔
Lack of feedback from management to staff reporting issues of quality and safety		✔		
No system independent of the hospital to monitor patterns of performance over time			✔	✔
No integration between claims management and quality management with regard to patient complaints				✔
No statutory provision to encourage reporting of adverse events				✔

Table 1-4 Recommendations with regard to improving reporting processes as a result of Inquiries

Inquiry	Recommendation
Cambelltown and Camden Hospital Investigation 2003[36]	There needs to be developed an integrated process for reporting incidents or grievances with regard to individual clinicians and teams.
	There needs to be clear channels that provide practicing clinicians with the ability to raise grievances or concerns of safety.
	The mechanisms and need for all staff to follow the organisation's incident reporting systems needs to be clearly stated and consistently reinforced.
Bristol Royal Infirmary Enquiry, 2001[39]	Incentives for reporting sentinel events should be introduced, whereby healthcare professionals' contracts would provide that they be immune from disciplinary action from their employer or professional body if they were to report a sentinel event within 48 hours.
	Confidential reporting should be provided to staff.
King Edward Hospital Investigation, 2002[35]	An incident reporting process with policies and procedures should be established, that imposes obligation on all clinicians to report incidents.
	A register of incident reports should be developed which is subject to external audit and review.
	The reporting system should require that each incident is reviewed using a systems approach that focuses more on organisational factors and less on individual error.
Richard Neale Enquiry,2004[40]	The National Patient Safety Agency should take a lead in developing adverse event reporting systems.

Incident reporting refers to a process by which information relating to an adverse event or near miss is recorded, usually by those involved in the event.[9] Information gathered from reports can be used to understand why errors occur in hospitals. Endorsement for incident reporting as a means of identifying problems so that improvements can be made to minimize patient harm is widespread. Peak quality and safety bodies from the US[7] and the UK[27] have encouraged the establishment of mandatory and voluntary incident reporting systems. As part of its effort to improve quality and safety in health care, the Australian Council for Safety and Quality in Health Care stated in its Terms of Reference that an agreed national framework for adverse event monitoring, management and prevention, including incident monitoring and complaints needed to be established.[41]

Within pockets of healthcare, information from incident reporting and management systems has been used to improve healthcare delivery. Studies in clinical areas such as the ICU,[42 43] Anaesthesia,[44-47] EDs,[48 49] Medical units,[50 51] Surgical units,[52] Transfusion Medicine,[53] and general practice[54 55] have used incidents reports to identify errors and their contributing factors.

Studies have compared errors reported through incident reports with other techniques such as observational studies,[56] medical record review,[43 51 57] automated data capture systems such as those used for medication administration,[58 59] and patients themselves.[60]

To address the poor reporting rates amongst clinicians, techniques to improve incident reporting have included the introduction of online electronic reporting[54 61 62] and introduction of the option of reporting anonymously.[63 64]

1.4. Outline of the thesis

The thesis comprises five chapters. Chapter 2 provides a detailed critique of the relevant literature. It discusses what is currently known about adverse incidents and what techniques are used to identify adverse events and near misses both within and outside healthcare. Relevant literature has focussed on the identification of barriers to reporting and on the effectiveness of interventions in changing behaviour of healthcare workers. The chapter concludes with a review and outlines aims and hypotheses of the thesis.

Chapter 3 describes the methods used in the study. The chapter is organised around the six components of the thesis: two consumer studies, a baseline staff survey, focus groups for medical and nursing staff, the intervention and an end of study survey. In all sections the study setting and study design are outlined.

Chapter 4 presents the results of the study. This chapter is again divided into six component parts, with summaries of the key findings at the end of each component.

Chapter 5 provides a discussion of the results. In bringing the thesis together, it addresses the five aims of the thesis outlined in the literature review;

1. to understand consumer views on safety in hospitals and general practice, on experience of an adverse event and confidence in healthcare;
2. to understand consumer views on reporting of adverse events by healthcare workers;
3. to identify from doctors and nurses baseline knowledge and use of the reporting system, and to identify barriers to reporting;

4. to determine whether an intervention based on feedback from survey and focus groups can improve reporting rates and change types of incidents reported;
5. to determine whether such an intervention can improve knowledge and self-perceived use of the reporting system and can effectively reduce barriers to reporting.

Reasons for the success of the intervention in some areas and its failure to result in significant improvements in reporting of adverse incidents in other areas are discussed. In concluding, recommendations based on the findings of the literature review and study results are made and suggestions outlined for future research.

Chapter 6, the conclusion provides a personal reflection on what was achieved, including key take home messages. Chapter 7 contains the reference list. The last chapter contains the Appendices and can be found in Volume 2 of the thesis.

1.5. Reporting by allied health professionals

A number of reports were made by allied health professionals during the study period. While baseline reporting rates and study period reporting rates for this group were compared, the intervention did not specifically target this group as it did for doctors and nurses. It was felt that allied health professionals would contaminate control groups because most worked across multiple clinical areas. Although of interest, the change in reporting practices by allied health professionals should not be viewed as being a result of the intervention.

2. LITERATURE REVIEW

2.1. Background to the literature review

This study investigates adverse events and incident reporting from the perspective of consumers and healthcare workers. As such, the literature review critically appraises literature relating to both consumer studies and studies undertaken in healthcare settings.

The first section (section 2.4) focuses on the study of error and what it known about adverse incidents from the literature. It summarises different methods used to identify incidents, including their purpose and application, strengths and limitations.

The second section (section 2.5) focuses on incident reporting as a tool to identify adverse incidents. Because incident reporting has been used successfully in industries outside healthcare, the literature review will discuss attributes of these other reporting systems, so that comparisons can be made with the reporting system established in hospitals. A review of published incident reporting studies and incident reporting systems (mandatory, voluntary, anonymous or confidential) has been outlined in this section.

The third section (section 2.6) outlines the studies in which incident reporting has been compared with other methods of obtaining information about incidents, identified in section 2.4.

The fourth section (section 2.7) provides a literature review of barriers to incident reporting. This has been included to enable comparison of barriers cited in the literature with those identified through focus groups and survey of staff as a component of the study.

The fifth section (section 2.8) discuses what is reported in the literature about advantages and limitations of incident reporting and strategies that have been suggested or implemented to improve incident reporting in hospitals.

Section 2.9 of the literature review reviews ways in which incident reporting can be improved. It discusses change management and organisational development and more specifically identifies interventions that have been undertaken to improve incident reporting.

Finally, Section 2.10 provides a conclusion and justification for the study. It outlines five broad aims and related hypotheses for the study, which were developed to address gaps in current knowledge of incident reporting in the Australian healthcare setting.

2.2. Objectives of the review

The literature review had the following objectives:

1. To understand what is currently known about causes of things that go wrong in health care and what to identify, retrieve and assess all relevant published articles, papers and texts relating to identification of adverse incidents in healthcare.
2. To explore how incident reporting has been used as a tool to identify incidents and their contributing factors, and to explore different attributes of reporting systems within healthcare and in industries outside healthcare.
3. To compare incident reporting as a technique to identify adverse incidents with other methods of detecting error in healthcare.
4. To identify, retrieve and assess relevant articles, papers and texts relating to barriers to reporting of adverse incidents and strategies implemented to address such barriers.
5. To gain a greater understanding of the limitations of incident reporting and its strengths in identifying adverse incidents.
6. To provide an overview of retrieved literature to create an understanding of what is known and not known in relation to the effectiveness of interventions for eliciting change in reporting behaviour by healthcare workers.

2.3. Literature Review Methodology

2.3.1. General search strategy

Reference material used in this thesis was limited to the English language. The following databases were accessed to retrieve information for this thesis:

- Medline- principally sourced for information, accessed through Ovid, using the database Ovid MEDLINE 1966 to present.
- CINAHL database.
- Cochrane Review Library- accessed for reviews relating to audit and feedback
- World Wide Web.
- Textbooks and journals not abstracted by Medline.

A structured literature search was undertaken of the MEDLINE database. The following National Library of Medicine's Medical Subject Headings (MeSH) were used to source

information: ACCIDENTS RISK MANAGEMENT MEDICAL ERROR, SAFETY MANAGEMENT, HOSPITALS, FAMILY PRACTICE, PHYSICIANS, FAMILY, PRIMARY HEALTH CARE, GENERAL PRACTICE, PHYSICIANS, PHYSICIAN-PATIENT RELATIONS, MEDICAL STAFF-HOSPITAL, NURSES, CONSUMER PARTICIPATION, QUALITY OF HEALTH CARE, QUALITY ASSURANCE, HEALTH CARE, EDUCATION, MEDICAL, INTERPERSONAL RELATIONS, SOCIAL BEHAVIOUR. All searches were limited to English and Human studies. Further refinement was obtained using the following keywords: INCIDENT REPORT? CONSUMER, ADVERSE EVENT?, NEAR MISS, STAFF SURVEY, PATIENT SAFETY, FOCUS GROUP, ORGANIZATIONAL INNOVATION, ORGANIZATIONAL CULTURE.

2.4. Error in healthcare

2.4.1. Types of errors

Over the past decade there has been increasing interest in the study of error in health care. The Institute of Medicine report 'To Err is Human"[65] documented the seriousness of the problem, and proposed ways in which errors could be reduced. Reason's text "Human Error[3] has become essential reading for those wishing to understand why errors continue to occur in the health sector. Reason,[3] in adopting principles established by Rasmussen[8] explained three types of errors:

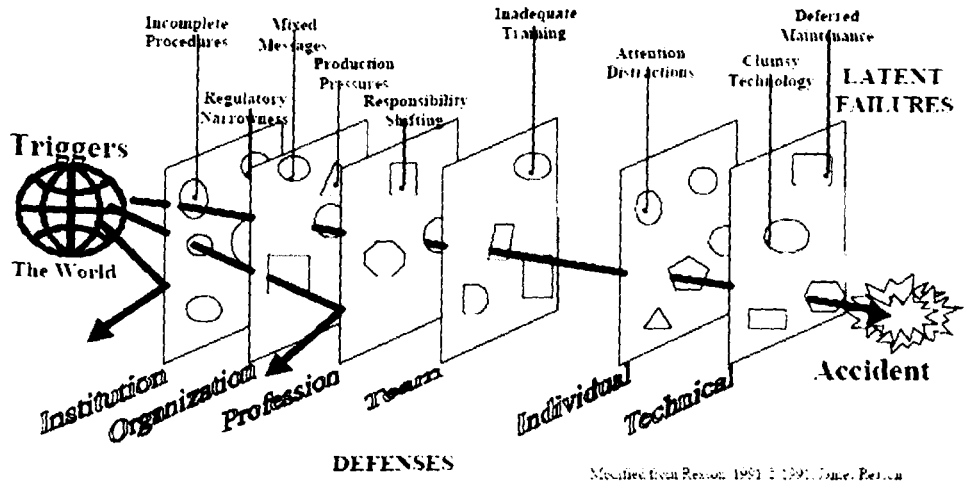
- Skill-based errors (also known as slips and lapses) occur through inattention, usually because of a lack of a timely intentional check, and therefore are monitoring failures.
- Rule-based errors (also known as mistakes) typically result from application of a wrong rule, or because of misapplication of a good rule. Errors occur because of misapplied expertise.
- Knowledge-based errors (also known as mistakes) are more complex and result from situations where the person has no previous exposure to the problem, and therefore no pre-programmed solutions. Errors occur because knowledge relevant to the problem is often incomplete and is sometimes inaccurate. People making these errors may put undue weight on certain aspects of the problem, whilst ignoring other crucial elements. They will likely be able to justify their chosen course of action by erroneously focusing on evidence that favours it and not on evidence against its use. Knowledge-based errors are often caused by biased memory or faulty deliberative processes.

Reason[3] also differentiated between latent errors and active errors. Latent errors are those errors that have delayed effect and constitute vulnerabilities in systems. System deficiencies ("resident pathogens") may lie dormant within the system for a long time, and only cause error when they combine with other factors to breach the system's defence.

Active errors are those errors whose effects are felt almost immediately. Those committing active errors usually bear the brunt of the disciplinary action, as active errors affect those at the "sharp end"; typically doctors or nurses providing clinical care. An example of an active error is when a clinician inadvertently gives 1:1000 adrenaline rather than 1:10,000 in a cardiac arrest situation. Giving the wrong drug constitutes the active error. The latent error constitutes having 1:1,000 adrenaline on the crash cart, stored directly next to the 1:10,000 ampoule, and similarly packaged.

Accidents rarely result from an isolated error, latent or active. Reason explained how latent errors lead to incidents using a Swiss Cheese model, where each hole represents vulnerabilities in system defences. Active errors occur when holes in the Swiss Cheese line up, as represented below (Figure 2-1).

Figure 2-1 Reason's Swiss Cheese Model of dynamics of accident causation



2.4.2. Methods of identifying things that go wrong in healthcare

Introduction

The purpose of identifying adverse events is to determine the extent and the nature of problems in healthcare so that appropriate action can be taken to reduce preventable errors, to monitor the effectiveness of various interventions, and to detect new causes of adverse events as they arise.[60 66]

Adverse events in healthcare can be identified through a variety of mechanisms, including reviewing patient medical records, auditing medical records, charts and legal claims, observing practice, analysing incident reports and through eliciting consumer opinion. Unfortunately, it is usually not possible to compare different approaches to identifying adverse events because of a lack of a universally accepted and used definition of what constitutes an adverse event or an error. Examples of different definitions of adverse event include:

- "When things went wrong."[67]
- "Situations in which an inappropriate decision was made when, at the time, an appropriate alternative could have been chosen."[68]
- "Injury caused by medical management rather than the underlying disease and that prolonged the hospitalisation, produced a disability at the time of discharge, or both."[2 20]
- "An unintended injury or unintended complication (a) resulting in temporary or permanent disability, including increased length of stay and/or financial loss to the patient, (c) that was produced by health care management rather than the underlying disease process."[17]

To narrow the scope of this literature review, this section provides a relatively brief overview of different methods to detect adverse events. In each of the four areas: audit and review, observational studies, consumer input and general practice studies, key articles have been reviewed. Because this project involved two consumer surveys, the literature review focuses only on this aspect of consumer input, and does not review complaints and satisfaction tools.

2.4.2.1. Audit and review

2.4.2.1.1. Purpose and application

Audit refers to a process where formal data is collected, usually specifically for a purpose, and used to change or influence clinical practice.[69] In distinguishing audit from research, research investigates what should be done, while audit investigates whether it is being done. A Cochrane systematic review of articles published up to January 2001 evaluating the effectiveness of audit and feedback in improving professional performance concluded that they have only a small to moderate effect, with greatest benefit recognised when baseline compliance to the procedure is low.[70]

Data may be audited using routinely collected or purposefully collected datasets, to determine whether an adverse event has occurred.

Routinely collected datasets

An example of routinely collected data audited to identify adverse events is the International Classification of Disease (ICD) External cause codes (E codes) used in hospitals both within Australia and internationally.[71-75] Two Australian audits using ICD-9 external cause codes identified that between 4 and 5% of hospital admissions were associated with an adverse event,[71 76] which was half the rate detected through medical record review. The value of using this data is that it is inexpensive to collect, relatively easy to extract and available on all patients admitted to hospital.

Purposefully collected datasets

Information purposefully collected and audited to identify sub-standard care and whether an adverse event has occurred includes the review of entire medical records[2 16 17 20] or components of the medical record such as medication charts,[77 78] and charts used for medical emergencies.[79] Purposefully collected data also includes information obtained from legal claims.

The value of medical record review is that it provides a measure of the relative frequency of some of the major things that have harmed patients and are recorded in the medical record. A summary of large medical record review studies is outlined in Table 1-2. Legal claims can identify factors contributing to adverse events and how hospitals can best manage them.[80 81]

2.4.2.1.2. Limitations of audit and review

Information bias[82] Medical records are often incomplete. Completeness of the record effects whether or not an adverse event is detected.[20]

Audit of legal claims is limited by the fact that claims do not provide representative data of adverse events. The vast majority of adverse events do not translate to legal claims.[83-86]

Lack of consistent definitions: Medical record review to determine adverse event rates has been studied extensively at an international level. However, there have not been homogenous results, with rates as low as 2.9% and as high as 16.6% of all admissions (Table 1-2).

Limitations with coding: Detection of adverse events using ICD codes relies upon the accuracy of the coding. There may be various coding errors,[87] and some adverse events may not have appropriate codes, and are therefore not documented. Coding practices may not be consistent between hospitals, and financial incentives and fear of retribution may also impact on how accurately adverse events are coded. A validity study of Victorian hospital morbidity data using ICD-9 codes identified that errors occurred frequently in the coding fields, with only 27% of the coding fields entered without error. [88]

Hindsight bias: As stated by Henrikson and Kaplan,[89] "We tend to expect that others should know by foresight what we have learned by hindsight". This has been highlighted in a study by Caplan et al[90] in which knowledge of the severity of outcome influenced reviewers' judgment of the appropriateness of care. The lack of contextual information about what was happening in the clinical area at the time of the error may impact on how reviewers assess the quality of care delivered to the patient.

Medical record review has been criticised for over-estimating both morbidity and mortality figures because of a lack of consideration given to the expected risk of death even without a medical error occurring.[91] A study of external adverse event codes for all hospitalised patient deaths in Australia during 1997-98 found that complications which were identified following a procedure and deemed to be caused by the procedure were reported 41 times more often as an additional cause of death than as the underlying cause of death.[88] Making causal assertions from medical record review should be done with considerable caution.[23]

Time consuming and expensive: It relies upon primary and secondary reviewers spending extended periods of time trawling through medical records.

Logistical difficulties in auditing the medical record/claims data: Reviewers are required to review medical records on site. Reviewers may be unable to access records because they are not available in the hospital eg with the coroner. Auditing legal claims is often not possible because much of the information which could lead to system improvement remains in the claims file and is not shared with hospitals.

2.4.2.2. Observational or ethnographic studies

Observational or ethnographic studies are increasingly being used in healthcare to determine adverse event rates and to provide insight into human behaviour to understand why people act in the way they do. Ethnography was originally used in anthropology to describe and analyse routine behaviours in natural settings.[92 93] It involves the prospective technique of observation, and may incorporate formal or informal interviews.

2.4.2.2.1. Purpose and application

Observational studies have been used to assess adverse event rates in ICUs[68 94] and among surgical patients.[52 95] They have been used to detect adverse drug events[96-100] and to monitor error-producing conditions, such as communication issues in an Emergency Department.[101] Through observing patient interactions, one study determined that 46% of patient admissions were associated with adverse events, with 17.7% of those causing serious injury.[68] The difference between the 3.5% adverse event rate in the ICU determined by medical record review[25] and the 46% determined in this study can, in part be explained by differences in definition of what constitutes an adverse event. Observational studies of surgical patients have identified that 28% of patient days were associated with moderate to fatal complications[52] and that 16.9% of admissions in patients admitted for longer than 48 hours resulted in serious adverse events.[95]

Observational studies consistently show that they detect more adverse events than both medical record review and incident reporting.

2.4.2.2.2. Limitations of observational studies

Qualitative in nature: Interpretation of information is largely subjective, and this is further hampered when observers are unable to ask questions or clarify information from staff.[68]

Subjective: An important determinant of the effectiveness of an observational study to explain and give meaning for individuals' actions is the nature of the relationship between the researcher and the person or people being studied.[102]

Hawthorne effect: [103] Another limitation relates to changing behaviour as a result of being watched, causing detection bias, which will likely underestimate the adverse event rate.

Expensive: Ethnography studies are expensive to undertake, because they involve employing a person to monitor and record events over an extended period of time.

2.4.2.3. Consumer input

2.4.2.3.1. Purpose and application

Consumer input into the identification of adverse events has occurred by way of complaints,[104 105] satisfaction tools[106] and surveys. Consumer surveys have been used to gather information about patient safety issues in health care and experiences of medical error in the US[107-112] and in Australia.[67] Table 2-1 details important findings from these studies.

When investigating the proportion of consumers who believe that they have been harmed by medical error, 6% of Americans[108] and 6.5% of Australians[67] stated that they had suffered an injury during the past 12 months. Of those suffering an adverse event in Australia, 45% occurred in doctors' rooms and 32% occurred in hospital.

The adverse event rates experienced in both these studies cannot be directly compared to medical record review studies because the denominator in medical record review studies comprises the number of sampled hospital records of patient admissions within an index period, whereas in the two consumer studies the denominator comprised the total population of adults (>18 years) during the sampling period. Additionally, both consumer studies included experiences of adverse events in settings outside the hospital, such as general practitioner' (GPs) surgeries and specialist rooms. Data from the Kaiser study[108] was not available to determine where adverse events occurred, however Clark[67] found that 45% of errors reported by respondents occurred in the doctor's rooms.

There have been numerous studies investigating adverse events from a consumer perspective, both within Australia and internationally, with consistent findings.

2.4.2.3.2. Limitations of using data from consumer studies

Limited generalisability: Most surveys were undertaken over the telephone. Results can therefore only be generalised to the population they represented,[113] that is consenting adults who are listed in the telephone directory, speak English and were well enough to speak on the telephone. Response rates of less than 50% achieved in these studies makes it difficult to know whether findings are truly representative of the survey population.

With regard to patient complaints, those who complain are not representative of people who suffer adverse events in hospital.[105] For example, the elderly who are most at risk of adverse events[114] are also least likely to complain.[115]

Recall bias: There are inherent risks when using data based on a person's recall, namely limitation of the amount and type of information retained by people over time (recall bias). The time interval since exposure (the adverse event) plays a major factor in recall, as does age, education and socioeconomic status of the person being interviewed.[116]

Not aware of adverse events: Household adverse event rates rely on the person being surveyed being familiar with adverse events which have occurred to themselves and members of their household. It is likely that adverse event rates determined by consumers might be underestimated through them being unfamiliar with household members' medical history or because errors may have been concealed from them.[117 118]

Table 2-1 Summary of studies investigating consumer opinion on healthcare safety and adverse events (AE)

Paper and year of publication	Study population and methodology*	Relevant outcomes measured / questions asked	Key relevant findings
Kaiser Study 2004[109]	Telephone survey of 2014 English-speaking persons aged ≥18 years residing in USA (July-September 2004)	1. Trend in perceived safety in the healthcare environment over the past 5 years **Question**: Compared to 5 years ago, has the quality of health care in this country (a) Gotten worse (b) Stayed about the same (c) Gotten better (d) Don't know	40% believe that quality of health care had deteriorated 17% believed it had improved 38% believed it had not changed.
		2. Experience of an AE in healthcare **Question:** Have you been personally involved in a situation where a preventable medical error was made in your own medical care or that of a family member?	34% had experienced an AE or knew of a family member who had been injured. Of those, 21% resulted in serious health consequences (11%=long term disability and 8% =death), 10% resulted in minor health consequences, 3% believed it had no health consequences
		3. Management of AE by healthcare providers **Question**: (1) Which one of the following comes closer to your views on how medical errors that result in serious injury or harm should be handled: (a) Reporting of serious medical errors should be REQUIRED (b) Reporting of serious medical errors should be VOLUNTARY (2) Assuming that medical errors are reported, should hospital reports of serious medical errors be confidential and only used to learn how to prevent future mistakes or should they also be released to the public?	(1) 92% stated reporting of AE should be required. 6% state that reporting serious errors should be voluntary. (2) 63% stated that hospitals should be required to release details of serious medical errors to the public 31% believe that reports should be kept confidential and only used to learn how to prevent future mistakes. 71% of responders believed that hospitals should be required to report all serious medical errors to a state agency.

Paper and year of publication	Study population and methodology*	Relevant outcomes measured / questions asked	Key relevant findings
Clark, R.B. 2001[67]	Telephone survey of 1501 English-speaking persons aged ≥18 years residing in Australia (November-December 1999). Response rate =43%	1. Annual incidence of self-reported medical AE **Question**: Have you personally, in the last 12 months experienced a situation where your health care has led to harm? (i.e. since November last year (1998), did you suffer any unexpected injury or concern from an adverse event arising from your health care?	6.5% (95%CI: 5.2-7.7%) respondents reported having ≥ one AE which occurred in hospital and non-hospital settings. 45% of AE occurred in Doctors Room/Clinic, 32% occurred in hospital, 14% occurred in home, 3% in ED, 1% in Pharmacy
		2 Perceptions of safety in general practice and in hospital care **Question:** Please tell me on a scale of 1 to 7, how safe you think the following are in Australia Airline travel The workplace Hospital care Food handling Nuclear Power Doctors' surgeries	**General practice (GP):** GPs were perceived as 'moderately to very safe' (rating= 5.5 on a 1–7 scale, where 1 is 'not safe at all' and 7 is 'very safe'). 17.3% of respondents rated them as 'very safe' with 0.8% considering them 'not safe at all'. Respondents felt less safe attending their doctor's surgery if they had experienced an AE in past 12 months. (Point estimate= -0.6 95%CI -0.51to -0.26) **Hospitals:** Hospital care was perceived as 'moderately' safe (rating= 4.9) 9.7% of respondents rated them as 'very safe' with 3.0% considering them 'not safe at all'. Respondents felt less safe going to hospital if they had experienced an AE in past 12 months. (Point estimate =-0.49 95%CI -0.67to -0.07) Education level, household income, whether respondent had been hospitalised in previous 12 months and country of birth was not significant for either doctor's surgery or hospital care
		3. Trends in perceived safety in health care **Question**: Over the past five years, do you think that safety for patients in the Australian health care system has (a) improved (b) stayed the same or (c) become worse?	45% of respondents believed quality of healthcare had become worse, 20% believed it had improved, and 35% thought it unchanged. Respondents aged 45-54 years were more likely than other groups to feel healthcare is getting worse Respondents were more likely to believe healthcare was getting worse if they had experienced an AE in past 12 months. (Point estimate -0.6 95%CI -0.51—0.26)

Paper and year of publication	Study population and methodology*	Relevant outcomes measured / questions asked	Key relevant findings
Kaiser Study 2000[108]	Telephone survey of 1501 English-speaking persons aged ≥18 years residing in USA (July 31-October 9, 2000). Response rate not published	Annual incidence of self-reported AEs **Question:** In the past 12 months, have you personally suffered injury of harm that you feel resulted from a medical error?	6% of respondents reported having ≥ 1 AE during the past 12 months which occurred in hospital and non-hospital settings (e.g. GPs and specialist rooms)
		2 Perceptions of safety in general practice and in hospital care **Question:** Please tell me how concerned, if at all, you are about serious error or mistake leading to injury or harm happening to you or your family in each of the following situations (a) When you fly on US commercial airliners (b) When you eat food purchased at the supermarket (c) When you go to a doctors office for care (d) When you go to a hospital for care (e) When you fill a prescription at a pharmacy	**General practice:** 40% of respondents felt very concerned going to doctor's office for care. 22% felt somewhat concerned, 18% felt not too concerned and 19% felt not concerned at all. Experience of AE in the last year made people feel less safe than those without injury going to their doctor's surgery (14% vs. 5%) **Hospitals:** 47% of respondents felt very concerned going to a hospital for care. 27% felt somewhat concerned, 12% felt not too concerned and 11% felt not concerned at all.
		3. Management of AE by healthcare providers **Question:** Which ONE of these statements comes closer to your views on how medical error that result in serious injury or harm should be handled (a) the government should require health care providers to report all serious errors to make sure this information is publicly available or (b) reporting of serious errors should be done on a VOLUNTARY basis to ensure the personal privacy of the (1) patient and (2) staff involved	73% of responders stated that the government should require health care providers to report all serious medical errors to make sure this information is publicly available (mandatory reporting). 21% of responders believed that reporting of serious medical errors should be voluntary basis

Paper and year of publication	Study population and methodology*	Relevant outcomes measured / questions asked	Key relevant findings
National Patient Safety Foundation Survey (NPSF) 1997[107]	Telephone survey of 1513 adults aged 18 years or older residing in USA July-August 1997	1. Perceived safety in health care **Question:** Please tell me on a scale of 1-7 how safe you feel the following are, with 7 being very safe and 1 being not safe at all (a) Airline travel (b) The workplace (c) Health care (d) Food handling(e) Nuclear power	Healthcare mean score was 4.9 (13% of respondents feeling they were very safe, and 2 % believing them to be very unsafe (scale 1 -7 where 1=safe,. 7=unsafe) Persons who had experienced an AE were significantly less likely to rate healthcare as very safe (9% vs. 16%). Persons on higher income (>US$60,000) were significantly less likely to rate healthcare as very safe compared to those with income <US$15,000) (8% vs. 24%).
		2. Trend in perceived safety in the healthcare environment over the past 5 years **Question:** Over the past 5 years, do you think that patient safety in the health care environment has gotten better, stayed the same or gotten worse?	33% of respondents believed healthcare had improved, 33% believed it had remained unchanged, 31% thought it had deteriorated and 3% did not have an opinion. Persons who had experienced an AE were significantly more likely to believe healthcare had deteriorated over the past 5 years (40% vs. 25%)
		3. Experience of an adverse event in healthcare **Question:** Have you, a close friend or a relative ever been involved in a situation where a medical mistake was made? If yes, Regarding (your/the patients') physical health, emotional health and financial situation, did the mistake have a short-term, long-term or permanent effect, or did it have no effect?	33% had experienced an AE, 48% involved a relative, and 19% involved a close friend. 60% of the AE had occurred in hospital, 22% occurred in a doctor's office. 20% of AEs resulted in no long term physical effects, 22% had no effect on them emotionally, and 50% of adverse events caused no financial effect Of those who experienced permanent effects as a result of the AE, 32% suffered physical effects, 26% suffered emotional effects and 13% experienced permanent financial effects.

* All consumer studies used randomly selected participants, and all provided nationally representative weighted data.

2.4.2.4. General practice studies

General practice as a discipline has become more complex and diffuse.[119] The majority of health care is delivered outside hospitals[120] and in Australia approximately 90% of people see a GP each year.[121] For this reason, there is growing interest in identifying and investigating adverse events in the out-of-hospital setting.

2.4.2.4.1. Purpose and application

It is not currently possible to obtain adverse event rates in general practice because the only studies undertaken have (a) used self-reported incident reports[55 122-125] or legal claims data,[120] which cannot provide reliable epidemiological data; or (b) been limited to the study of medication errors.[126]

Self-reported incident studies[55 122 123 125] by GPs provide the most information about types of adverse events experienced in general practice. The BEACH study was one of the first to document error in general practice and is the only contemporary source of national data about morbidity in general practice.[122] In 1998-99 Britt et al[122] randomly sampled 984 GPs in Australia, and asked them to record details of 100 patient encounters. A total of 865 adverse events were identified; 45% of adverse events related to complications of treatment, and 43% were due to medical agents (mainly side-effects of therapy). Using patient appointments as a denominator, error rates in general practice over a two week period have been estimated to occur at a rate of at 7.7% of patient appointments.[125]

2.4.2.4.2. Limitations of GP studies

Limitations when assessing adverse event rates in general practice include:

Information bias: Self-reporting of incidents from a non-random group of GPs will have questionable generalisability. In spite of the fact that all studies have attempted to minimize this bias by using confidential or anonymous reporting processes, it may be that GPs are less likely to report incidents implicating themselves rather than those attributable to extrinsic factors such as medication side effects.

Recruitment bias: GP studies have been limited to centres where GPs have agreed to participate. Participation rates have been recorded as low as 23% of those invited.[123] This self-selection may mean that only GPs most interested in quality and safety initiatives agreed to participate in the study, and that these differ from those refusing to participate.

2.5. Incident reporting as a tool to identify adverse incidents

Incident reporting refers to the process by which individuals either directly or indirectly involved in adverse events and near misses notify others of the problem. Incident reporting has its foundation in aviation, where it was used as a technique to improve safety and performance.[127] Psychologists gathered information from pilots in World War 2 and pilot candidates who were eliminated from flight training school to determine critical requirements demonstrated to have made the difference between success and failure in combat aviation. This was called the critical incident technique. The critical incident technique involves the identification of preventable incidents by personnel directly involved in the process being investigated at the time the incident occurred.[29] There has been much written about the correlation between aviation and medicine and how lessons from aviation can be transcribed into medicine.[4 117 128-130] It is for this reason that incident reporting in other industries has been included in the literature review.

2.5.1. Incident reporting in industries outside healthcare

In discussing the correlation between pilots and doctors, the differences and similarities between the two are highlighted.[117 130] Similarities include the fact that both are highly skilled, are required to work under intense stress, use high technology equipment, and function in a team environment. Both cultures have an entrenched sense of personal competence and a denial of their own vulnerabilities, particularly to the effects of stress. Differences between aviation and medicine include the more defined nature of aviation events compared to the uncertainty and variability of diseases, and the unpredictability of people as compared to aeroplanes. An obvious but important distinction between the two is that pilots, unlike doctors, are at risk of dying too if errors are not identified and rectified.

In the US, the Federal Aviation Administration (FAA) and the National Aeronautical and Space Administration (NASA) collaborated in establishing a voluntary reporting system for near misses in aviation.[131] Aviation safety experts screen, analyse, respond and provide feedback following voluntarily submitted aviation safety incident reports. Although reporters must initially identify themselves, the system is confidential and all incidents reported are de-identified prior to being entered into the database. The reporting system is protected by federal legislation, so that reports cannot be used in any disciplinary action, except when information concerns criminal offences or accidents.[132] Evaluation of these near misses has led to new safety measures.[133]

In Australia, the Australian Transport Safety Bureau (ATSB) is an independent body which investigates civil aviation, marine road and rail incidents, accidents and safety deficiencies.[33 134] The Aviation Self Reporting Scheme (ASRS) is maintained by ATSB, and enables pilots, licensed aircraft engineers, and air traffic controllers to report contraventions of accepted practice for the sole purpose of preventing the occurrence of future accidents. Reports must be submitted within a timeframe and the reporter must identify themselves, however, as with its US counterpart, only a de-identified summary is entered into the database. The original report and a receipt from the database are returned to the reporter. If the Civil Aviation Safety Authority (CASA), as aviation's policing body identifies the contravention, the reporter can present the receipt and request immunity from further action. During 2003-04, the ATSB received 4,556 notifications of accidents and incidents.[135]

Incident reporting systems have been established in other complex high-risk organisations, such as in nuclear power technology, petrochemical processing, steel production, military operations,[4] diving,[136] and railway networks.[137] In an assessment of twelve non-medical reporting systems, Barach[4] found that seven of them (58%) relied on voluntary contribution but were mandated and implemented by the federal government. Ten of the systems (83%) were confidential, the other two were anonymous. Some offered immunity if reports were submitted in a timely manner.

There is recognition that components of the aviation incident reporting model could be translated into healthcare including providing immunity to reporters, confidential reporting, data de-identification, independent expert analysis of data, rapid feedback, ease of reporting and support of leadership.

2.5.2. Incident reporting in healthcare

Cooper first adapted the critical incident technique used in aviation[127] to anaesthesia and published findings in 1978.[138] In 1988, the Australian Incident Monitoring System (AIMS) was developed for anaesthesia as a self-reporting investigative tool to determine underlying contributing factors which may have precipitated an incident, and to reflect on what factors or actions taken may have minimized or prevented deleterious outcomes.[9] It was later expanded and used in the intensive care setting,[139] and more broadly across all facets of healthcare.[9]

Expert groups established within Australia,[26] the US,[7] and UK[27] to provide direction for patient safety activities, have identified incident reporting as a key component in reducing

preventable patient harm. The Institute of Medicine (IOM) report published in 1999[7] set out a blueprint of strategies that were expected to result in a threshold improvement in quality over a ten year period for American healthcare. In it they highlighted the need to identify and learn from errors through both mandatory and voluntary reporting systems, which would operate separate of each other.

In the United Kingdom, the Expert Group on Learning from adverse events in the National Health Service (NHS) published the report, "An Organisation with a Memory" in 2000.[27] In it they stated that incident reporting systems were poorly developed and systematic reporting of 'near misses' (non-injurious errors) was almost non-existent.[27] One fifth of NHS trusts did not have incident reporting systems that covered the organisation, less than half did not educate staff on reporting, less than a third provided guidance to staff on what to report, and only a third of clinicians were required to report unexpected complications or events. The Expert group advocated the establishment of a mandatory reporting system for specified events and a confidential reporting system. Voluntary reporting systems were seen as vital in providing a core of sound, representative information on which to base analysis and recommendations to improve healthcare delivery.

In Australia, the Australian Council for Safety and Quality in Health Care (the "Council") set out in its publication "Safety in Numbers"[140] a plan to have all health care facilities in Australia using an incident monitoring system which met agreed national specifications and were capable of contributing to a nationally consistent dataset by January 2004. This was reinforced in the Council's National Health Reform Policy.[141] The Council identified incident monitoring as a means of identifying, learning from and preventing error and system failure within healthcare organisations. They advocated a mandatory reporting system for reporting of a key set of incidents, and a voluntary reporting system for other adverse events and near misses.

Table 2-2 outlines some articles where researchers have analysed incident reports. The purpose of each incident reporting article has been to heighten awareness of errors and error-producing conditions. Incidents have been analysed at a hospital-wide level,[142] and within specialty areas, such as intensive care,[143-146] psychiatry,[147 148] emergency medicine, [49] anaesthesia,[149-153] and general practice.[54 55 154 155]

Further to analysing by area, some researchers have chosen to analyse incident reports based on specific factors such as fatigue,[156] nursing staff shortage[157] equipment failure,[158] inexperience, [159] and system-based factors.[160]

Common variables captured in incident reporting studies include

- incident reporting rates[49 143 148 161 162]
- types of incidents reported[43 49 51 54 55 143-145 147 150 152 153 156 157 161]
- severity of incidents[51 55 145 151-153 157 158 163]
- causative factors[43 55 152 153 156 157 163]
- reporter designation[43 49 51 54 143 144]

Occasionally outcomes arising from reports are discussed.[144 151 156 164] Some reporting studies have identified that between 1.1%[145] and 4%[55] of all reports are implicated in the patient's death. As many as 22% of reports in one study were associated with major physiological changes.[157] Recurring contributing factors associated with many studies include haste or inattention,[156 157] and breakdown in communication.[54 165 166] Improvements made as a result of incident reports have been discussed in a number of the studies.[144 146 151 164]

The percentage of reports generated by medical staff is highly dependent on how the study was designed. Most anaesthesia-related studies include only reports submitted by doctors.[149-151 156 158 160 167] Studies in which the medical officer has been actively targeted for participation using facilitation[43 51] or active recruitment[54] have resulted in more medical reports than studies directed more broadly within departments.[49 143 161]

Table 2-2 Summary of studies where incident reports (IR) have been used to identify near misses /adverse events (AEs)

Paper and year of publication	Study population and methodology	Relevant outcomes measured	Key relevant findings
Nakajima et al, 2005[168]	Review of 6041 IR in a Japanese University hospital b/n June 2001 and April 2004	1. AE rate	Approx 18% of discharges resulted in an AE.
		2. Reporter designation	10.2% doctors, 84.7% nurses
		3. Types of IR	47%= medication, 19%= lines and tubes-related, 14%= falls
		4. Contributing factors	53%= clinical process and system, 30%= communication, 15%= supervision
Marang-van de Mheen, 2005[169]	Review of 238 IR reported by surgeons and surgical residents in a surgical unit in 2002	1. AE rate	34.2% of surgical patient admissions resulted in an adverse outcome, however over sampling of high risk patients.
Abeysekera et al, 2005[153]	Review of 896 IR relating to drug error in anaesthesia	1. Types of IR	50% related to syringe or drug preparation error or near miss: 37%=syringe swaps (wrong syringe was injected), 41%=ampoule labelling error. 19% of all equipment errors related to intravenous or central venous catheter, 15.3% due to pump misuse.
		2. Contributing factors	30% =inattention, 21% due to haste, 20% due to drug labelling.
		3. Severity of incidents	73.5% cause no adverse outcome, 0.3% caused death, and 4.7% caused major morbidity.
Osmon, S et al, 2004[143]	Review of 232 incidents in a 19 bed ICU b/n Nov 2002 and May 2003	1. AE rate	31.9% of admissions resulted in an AE. 89.3 AEs per 1000 OBDs.
		2. Reporter designation	59.1% nurses, 27.2% physicians-in-training, 2.6% physicians, 4.7% allied health, 6.5% anonymous.
		3. Types of IR	36.5%=delays or omissions of prescribed nonmedical treatments, diagnostic tests, planned procedures, 20.2%=medication errors.
		4. Severity of incidents	9.9% required additional life-sustaining treatment, 3.0% contributed to death.

Paper and year of publication	Study population and methodology	Relevant outcomes measured	Key relevant findings
Fernald, D et al, 2004[54]	Review of reports from 2 research networks using Web-base, telephone and paper reporting formats in US (33 practices) b/n Oct 2001 and Aug 2003.	1. Reporting process	9% lodged by telephone, 28% by Wold Wide Web, 63% by paper.
		2. Reporter designation	*Overall:* 66% = confidential (n=467) 34%= anonymous (n=241). *Confidential reporting system used by* 55% of clinicians, 84% of nursing staff and 81% of non-clinical staff
		3. Types of IR	*Overall:* 56%= Diagnostic testing errors, 25%= medication errors, 72%= communication errors *Confidential*: 57%= Diagnostic testing errors, 26%= medication, 73%= communication errors. *Anonymous*: 48%= Diagnostic testing errors, 31%= medication errors, 71%= communication errors
		4. Severity of incidents	*Confidential reports*= 10% caused harm, 8% caused increased risk of harm, 68% caused no known harm, and 14% caused unstable/ non-clinical harm. *Anonymous reports:* 10% caused harm, 10% caused increased risk of harm, 64% caused no known harm, and 16% caused unstable / non-clinical harm.
Beckmann et al, 2003[43]		1. Types of IR	26% =problem with patient management environment, 19%=unit management problems, 15%= procedure/catheters/equipment system problems.
		2. Contributing factors	50% due to cognitive-based factors, 50% due to system-based factors.
		3. Reporter designation	49% nurses, 51% doctors.
Hamadeh et al, 2003[148]	Review of 111 IR b/n 1992 and 1999 relating to assaults / injuries incurred by psychiatric staff in a Psychiatric hospital in Bahrain	1. Number of injuries	60.4% of all incidents resulting from assault,† 21.6% resulted while doing home visits, and 18.0% occurred in the hospital.

Paper and year of publication	Study population and methodology	Relevant outcomes measured	Key relevant findings
Thomas et al, 2003[146]	Review of 89 surveys returned from clinical directors of ICUs in the UK (response rate=35%)	1. Number of ICUs with an IR system	61 (69%) had adopted a reporting system, 28 (31%) did not use a reporting system.
		2. Improvements made as a result of IR	(a) Provided evidence for new equipment (b) Improved training, introduction of guidelines/protocols (c) Improve staffing/work arrangements (d) Improve communication b/n departments, including handovers.
Fordyce, et al, 2003[49]	Review of 350 solicited IRs submitted over a 7-day period from an Emergency Dept in US	1. IR rate	36 AE/10,000 ED presentations.
		2. Types of IR	22% = diagnostic related studies, 16%=administrative processes, 16%=pharmacotherapy, 13%=documentation, 12% =communication issues, 11%=environmental maintenance (eg inappropriate stocking, storage, checking of equipment).
		3. Reporter designation	40% = nurses, 18% = medical staff, 19% = Allied health professionals, 19% = clerks.
Kivlahan et al, 2002[61]	Review of 667 paper based and 511 web-based reports each submitted over a 3-month period in US hospital	1. IR rate	*Web-based*= 414 reports/10,000 OBDs. *Paper-based*=315 reports/10,000 OBDs
		2. Types of incidents	*Web-based*= 47% miscellaneous, 26% medication, 11% therapeutic/diagnostic intervention, 9%falls. *Paper-based* =3 9% miscellaneous, 36% medication, 15% fall
		3. Reporter designation	*Web-based*= 63% nurses, 6% doctor, 8% unknown. *Paper-based*= 65% nurses, 2% doctor, 24% unknown.
Amoore, J & Ingram, 2002[164]	Review of IR processes for medical devices in a medical physics department in a major NHS teaching trust	1. Analysis of an IR involving over infusion with a syringe pump	Over infusion due to incorrect recognition by the pump of the 50 ml syringe as a 20 ml syringe. Diligent charting of fluid delivery led to early recognition of the problem.
		2. Improvements made as a result of IR	(a) Anonymous feedback given to staff in the clinical area and throughout the trust, (b) the need to store medical devices safely was highlighted.

Paper and year of publication	Study population and methodology	Relevant outcomes measured	Key relevant findings
Wolff, A et al, 2001[161]	Review of 621 IRs between Oct 1997 and September 1999 in a rural Australian Hospital.	1 IR rate	621 IR containing 66 AEs from hospital staff. 21 IR containing 16 AEs from GPs.
		2. Types of IR	45%= Patient falls, 15%= medication errors.
Weingart, S.N et al 2001[162]	Medical officers working on oncology, cardiology and MICU of a US teaching hospital	1. IR rate	Residents: 88incidents/987 pt admissions=8.9% of pt admissions.
		2. Types of IR	0.5% of admissions= AE. 4.9% of admissions= Potential AEs (near misses), 33% of these due to delayed diagnosis, 21%= delayed treatment. 35% of admissions= other quality problems.
Meurier, CE, 2000[165]	20 Registered Nurses (RNs) each documented a critical incident. 5 were interviewed to gather supplementary information	1. Analysis of the critical incidents using Reason's Organisational Accident Model [3].	One event is described in the article. Latent and active causative factors are discussed.
Kluger, MT et al, 2000[163]	Review of 197 IR in which pre-operative (pre-op) assessment or preparation was inadequate	1. Contributing factors	10% not seen by an anaesthetist pre-op. 23% seen by 1 anaesthetist but administered by another. 29% due to poor airway assessment, 23% due to communication problem, 21% due to inadequate assessment.
		2. Severity of incidents	45%= no adverse outcome, 18%= minor physiological change, 12%= major physiological change, 4%= death.

Paper and year of publication	Study population and methodology	Relevant outcomes measured	Key relevant findings
Morris, M and Morris, 2000[156]	Review of IRs b/n 1987-1997 where fatigue was cited as a contributing factor.	1. Fatigue-related incidents and time of day	Fatigue-positive reports were more common between 1900 and 0300 when compared to other times of day.
		2. Types of IR	More incidents reported for syringe swap or wrong drug incidents (21.7% vs. 5.2% 95%CI: 9.9%-23.1%), overdose (12.5% vs. 6.5% 95%CI: 0.7-11.3%), underdose (9.2% vs. 3.9% 95%CI: 0.7%-9.9%).
		3. Contributing factors	Haste, inattention, failure to check equipment, fault of technique, pressure to proceed, and drug label were more common in fatigue-positive reports.
		4. Factors minimizing incident and corrective strategies	Healthy patient and relief anaesthetist were more likely to be identified as factors minimizing incident in fatigue-positive incidents. Fatigue alleviation routine was cited in 45% of fatigue-positive reports compared to 0.2% of fatigue-negative reports as a corrective strategy.
Flaatten & Hevroy, 1999[145]	Review of 87 IRs in a cardiac/general ICU in Bergen, Norway between Oct 1995 and Nov 1996.	1. Types of IR	60.8% =medication/intravenous fluid errors, 17.2% = technical equipment errors, 21.8% = miscellaneous.
		2. Severity of incidents	63% =no physiological or biochemical consequences, 6.9%= required no intervention, 25% =intervention being required but no damage to the patient, 5.7%=caused temporary damage and 1 incident =lead to patient death.
Wright and Parker, 1998[147]	Review of 98 IRs submitted from 8 psychiatric inpatient services in New South Wales and Brisbane over 3-month period.	1. Types of IR	35% self harm 19% assault on staff member, 12% absent without leave,
		2. Staff factors associated with incidents from 23 factors listed	Inadequate assessment (34), staff inattention (34), staff distracted (33).

Paper and year of publication	Study population and methodology	Relevant outcomes measured	Key relevant findings
Beckmann, U et al, 1998[157]	Review of 3600 voluntary IRs submitted from 24 hospitals relating to nursing staff shortage in the ICU setting	1 Types of IR	89 IR described nursing staff shortages, and in 182 reports it was cited as a contributing factor. 41/89 related to a single patient. IR evenly distributed between day and night shift. Most incidents were related to deficits in planned rostering with as many due to unpredictable increases in unit activity.
		2. Contributing factors	93/182 (51%) = lack of support staff and 93/182 (51%) =distraction/stress.
		3. Severity of incidents	64%=no or minor physiological change, 22%= major physiological change.
Bhasale, A et al, 1998[55]	Review of 805 IRs lodged by 324 general practitioners in Australia between October 1993 and June 1995	1. Types of IR	51%= pharmacological management, 34%= diagnosis, 5%=equipment.
		2. Contributing factors	23%=Poor communication between patient and health professional, 23%= action of others, 22%= error in judgment, 19%= poor communication between health professionals.
		3. Severity of incidents:	*Immediate outcome:* 33% = no harm, 46% = minor harm 17% = major harm and 4% = death. *Predicted long term outcome:* 66% =no long term effect, 22% =minor/moderate sequelae, 4% =major sequelae, 7% =death.
Buckley et al, 1997[144]	Review of 281 voluntary IRs over 36 months relating to critical incidents in an ICU in Hong Kong	1. Types of IR	22% = accidental extubation, 9% = wrong medication management decisions, 7% = inappropriate drug.
		2. Reporter designation	54% reports = medical staff, 43% = nursing staff.
		3. Means of detecting the incident	51% of incidents = direct patient observation, pulse, ventilator alarms and equipment observation each = 9% of incidents.
		4. Improvements made as a result of IR	(a) Replacement of faulty/unsuitable equipment eg laryngoscopes, intra-aortic balloon pump, (b) senior nursing numbers increased + roles redefined with more responsibility for bedside teaching and pt care, (c) protocol for ventilator checks and tracheal tube care, (d) more structured education program for medical and nursing staff, (e) Clinical Nurse Specialist appointed to provide an education program for nurses in the ICU, (f) regular meetings with radiologists and microbiologist introduced.

Paper and year of publication	Study population and methodology	Relevant outcomes measured	Key relevant findings
Short, TG et al, 1996[151]	Review of 1000 anonymous voluntary IRs over 5 years relating to critical incidents in the Anaesthetic Depts. of 3 large tertiary hospitals in Hong Kong	1. Unsuccessful interventions made in response to clusters of similar incidents	In response to wrong ampoule/wrong syringe incidents, most unsuccessful interventions related to improving awareness of the problem through QA meetings and written reports. In response to equipment malfunctions, unsuccessful interventions included improving preventive maintenance and procedures for withdrawing faulty equipment.
		2. Severity of incidents	Most incidents resulted in no or minor morbidity (average of 88% over 5 years). 5%= prolonged hospitalisation, 3%= major morbidity and 1.6%= death (however death may not have been solely attributable to the incident).
		3. Improvements made as a result of IR	Most success achieved through replacing equipment (laryngoscopes, gas outlet connections, anaesthetic machines), and instigating checking procedures.
O'Neil et al, 1993[51]	Review of 89 facilitated IR in a medical service of an urban university affiliated teaching hospital in US between 13 Nov 1990 and 14 March 1991	1. Types of IR	77% = errors of commission.
		2. Severity of incidents	11%= no impact on length of stay, 85%= increased length of stay, 74%= recovery within 1 month, 2%= permanent disability, 11% = death.
		3. Reporter designation	All reports were medically-initiated.
Runciman, W et al, 1993[160]	Review of 2000 anonymous voluntary IRs relating to system- related incidents	1. System-based IR according to (a) "factors contributing to" (b) "factors minimizing outcomes of" (c) "suggested corrective strategies".	(a) 19% = Monitor/equipment problems, (b) 35% believed monitor detection would have helped, followed by skilled assistance (12%) (c) 7% believed equipment design improvement was the most effective system-based strategy.

Paper and year of publication	Study population and methodology	Relevant outcomes measured	Key relevant findings
Webb et al, 1993[158]	Review of 2000 anonymous voluntary IRs relating to equipment -related incidents	1. Types of IR	177= equipment-failures, 26%=unidirectional valves, 18%= ventilator-related, 6%= blood pressure monitors.
		2. Severity of incident	55% of equipment incidents were potentially life-threatening, and 70% could have been detected using monitors.
Van der Walt et al, 1993[150]	Review of 2000 anonymous voluntary IRs relating to anaesthesia-related recovery room (RR) incidents	1. Types of IR	120= anaesthesia-related, 69%= respiratory system, hypoventilation and laryngospasm of which obstruction accounted for 80% of incidents
		2. Comparison of outcomes between RR and Operating Theatre (OR) incidents	RR incidents were associated with worse outcome than OR incidents (55.9% vs. 23.8% resulting in harm).
Cooper, J.B. et al, 1984[152]	Review of 1089 IR relating to human error or equipment failure in anaesthesia	1. Types of IR	Retrospective reports through interview ** and prospective IR identified 13% due to equipment failure, 68% due to human error, 5% due to disconnection. Most human error incidents related to drug administration (24%) and anaesthesia machine (22%). Frequent critical incidents included breathing circuit disconnection during mechanical ventilation.
		2. Contributing factors	13% of incidents= Failure to check, 12% of incidents= first experience with situation, 11% of incidents- inadequate experience, 10% of incidents= inattention or carelessness.
		3. Severity of incidents	6.4% of all incidents resulted in negative outcomes, 37% of those caused death, and 28% caused cardiac arrest.

* Clinicians = doctors, doctors of osteopathy, physician's assistant, nurse practitioner †Assault= when patients use physical force with their bodies or an object to harm a staff member, ‡=Non patient induced injury = -injury not directly inflicted by patients e.g. falls, needle stick injuries, door closings and road traffic accidents ** interviews conducted with anaesthetists, anaesthetic nurses and Resident Medical Officers

2.5.2.1. Attributes of reporting systems

There are various attributes of incident reporting systems. They may be:

- Voluntary or mandatory
- Confidential or anonymous
- Internal (within hospitals) or external (housed in outside independent organisations).

2.5.2.1.1. Mandatory reporting systems

Mandatory reporting is based on the premise that society has an obligation to protect vulnerable groups. The purported advantages of mandatory reporting include the ability to provide good epidemiological data to identify trends and outliers and to provide accountability to consumers that healthcare facilities are safe.[170]

In Australia, mandatory reporting systems have been legislated for the reporting of child abuse[171] and specific deaths to the Coroner.[172] Failure by doctors or nurses to report suspected child abuse can incur a fine, imprisonment or both. In Western Australia, the reporting of anaesthetic-related deaths has been legislated, while in other Australian states it is mandatory but not legislated.[173] Where legislated, mandatory reporting systems have been introduced with fines for non-compliance. More reports per anaesthetic procedure have been lodged in Western Australia compared to other states or territories.

Sentinel event reporting systems are considered mandatory, but have not been legislated and carry no fines or penalties for non-compliance.[7 174-179] There is widespread acknowledgement that mandatory sentinel event reporting systems grossly underestimate the true numbers of sentinel events that occur in hospitals.[29 180]

2.5.2.1.2. Voluntary reporting systems

In Australia, voluntary reporting is complementary to mandatory reporting and is used to report both adverse events and near misses. Voluntary reporting focuses on gathering information about incidents so that contributing factors can be understood and preventive strategies developed to minimize likelihood of recurrence.[7] Each of the reporting systems outlined in Table 2-2 is voluntary and the work undertaken in this thesis refers to an intervention to improve voluntary reporting in public hospitals in South Australia.

Some reporting systems have statutory immunity, which means that identified information on the report cannot be used in legal proceedings. Protection on identified information, as

with anonymous reporting, has been done to encourage reporting.[9] Australia has legislation for granting legal privilege at State and Commonwealth level. Incident reports submitted as part of the Australian Incident Monitoring System (AIMS) have Commonwealth protection, and most Australian States have also received State legislated protection on incident reporting data. In US healthcare settings where reporting systems offer no protection, hospital leaders were less worried about lawsuits than in settings offering protection.[181]

The Food and Drug Administration (FDA) in the US combine both mandatory and voluntary reporting of adverse events and product problems for all FDA-regulated products by the entire health care community. The mandatory component is completed by manufacturers, distributors and user facilities to comply with regulations. The voluntary component is available for use by health professionals, and has resulted in the detection of many significant adverse events and drug interactions associated with products that were not identified during pre-approval testing.[182]

Advantages of voluntary reporting have been suggested[183] and include the ability to collect more useful information about errors and their contributing factors than mandatory reporting. The rationale is that voluntary reporting is less threatening to frontline practitioners, and encourages reporting of hazardous situations and near misses. This information is not captured in mandatory reporting systems.

Despite acknowledgement by expert bodies that voluntary reporting can improve patient safety, this view was not held by physicians in a survey undertaken by Blendon et al in the US in 2002.[111] The survey of 831 practicing physicians and 1207 consumers revealed that only 21% of physicians believed that encouraging hospitals to voluntarily report serious medical errors to a state agency would be effective in reducing medical errors. Interestingly, more physicians (23%) believed that mandating hospitals to report serious medical errors to a state agency would be a possible solution to the problem of medical error. Consumers were more likely than physicians to see value in the reporting system, with 62% believing that voluntary reporting and 71% believing that mandatory reporting was useful in reducing medical error.[111]

Another survey of clinical staff working in a paediatric hospital[64] found very similar results to that of Blendon,[111] with 21% of staff believing that mandatory reporting would lead to increased reporting of medical error.

The views of hospital Chief Executive Officers (CEOs) and Chief Operating Officers (COOs) with regard to the mandatory reporting of adverse events to a state agency were

similar to those of physicians, with 28% of executives believing that state reporting systems had a positive effect on patient safety and 41% believing it would have no effect.[181] Most hospital leaders believed that mandatory, non-confidential state reporting systems discouraged reporting of medical errors within hospitals and led to more lawsuits, while not demonstrating substantial benefits to patient safety.

2.5.2.1.3. Anonymous reporting systems

It has been espoused that the most important single feature of an incident monitoring system is the reporter's right to remain anonymous[9] and that anonymity is "the quintessential element for any reporting system".[184] Brennan[133] stated that health care should "...recognize, as have safety experts in aviation that anonymity is critical for full reporting". He stated that there were enormous benefits from establishing a database in which anonymously reported errors could be used to undertake epidemiological studies to identify and address system flaws in healthcare. Those supporting anonymity often reflect on the aviation industry's 26 year history of maintaining an anonymous reporting system, and the role that this system has had in improving aviation safety. If anonymity was not maintained, it is believed that there would be an immediate and permanent reduction in the number and seriousness of reports.[184]

Anonymous reporting has been demonstrated to provide an effective, non-punitive, systems-focused approach to identifying errors.[63 147 168 185 186] In Australia it has underpinned AIMS in anaesthesia, which has collected in excess of 10,000 detailed reports from doctors.[46] Anonymous reporting is not meant to replace existing legal and complaints procedures for dealing with adverse incidents. Anonymous reporting has enabled incidents and their underlying contributing factors to be uncovered which would not have occurred had the option to remain anonymous not been available.[63 187]

2.5.2.1.4. Confidential reporting systems

Confidential reporting systems offer the advantage over anonymous reporting systems of enabling follow up of specific events by those with authorised access to the reporting system. A number of studies in health collect information confidentially, and remove identified information after a period of time[62] or when information is sent from individual organisations to a national reporting body.[9] However, clinicians may not trust such a system, fearing that confidential information might be released, leading to punishment, litigation, or loss of face and damage to reputation. The Institute of Medicine report[7] stated of the JCAHO reporting system that "concerns remain regarding the confidentiality of data

reported to JCAHO and the extent to which the information on a sentinel event is no longer protected under peer review if it is shared with JCAHO".

A survey of medical and nursing staff[188] identified that 78% of doctors and 85% of nurses preferred a reporting system which was either strictly confidential (where identifiers were only known to person receiving the report) or had limited confidentiality (reporter's name only disclosed in severe cases). Interestingly, only 18% of doctors and 9% of nurses preferred an anonymous reporting system

There are those within the profession and in the community who see that healthcare workers should be held accountable for their actions, and that a confidential reporting system threatens accountability and transparency within an institution.[80 129 189 190] In a survey of consumers and physicians, 86% of physicians believed that hospital incident reports should be kept confidential and only 14% believed information should be released to the public.[111] This contrasted with the views of consumers, where 34% believed that incident reports should be kept confidential and 62% thought information should be made available to the public ($p<0.001$).[111]

2.5.2.1.5. External/internal reporting systems

External and internal bodies have been used in healthcare to collect and analyse incident reports. External reporting systems have been adopted by military and aviation bodies and have been used with success in health.[191] These systems all contain mechanisms by which reports can be collected in a confidential manner and analysed by peer experts who are external to the organisation from the source file reports.

An example of both an internal and external reporting system is AIMS. It was originally set up independent of regulatory bodies for anaesthetists. When the reporting system diversified to include all clinical areas in hospitals, it fundamentally changed from that of an external, independent reporting system to that of an internal, quality assurance reporting system.

A criticism of external reporting systems is that analysis is too far removed from the clinical setting and that this diminishes the likelihood that changes will be made.[192] There is no evidence to indicate with certainty which approach yields more reports. Anecdotally, it appears that the anonymous AIMS-Anaesthesia reporting system, which collected more than 2000 incident reports from anaesthetists within 2 years of inception without any funding for promotion, has attracted more doctors to report incidents than reporting systems conducted within individual hospitals (with less than 500 doctor-initiated reports in the AIMS national

database being received from individual hospitals since introduced into all clinical areas).[187] Similarly, in the US the National Patient Safety Reporting System, which was established by the Veterans' Affairs (VA) hospitals using an external independent body (NASA) to collect the data, appears to be more effective than the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reporting system in collecting information about adverse incidents. Although an external reporting system, JCAHO as an accrediting body is not independent of hospitals.

2.6. Comparing incident reporting with other methods of detecting adverse events

Incident reporting has historically been perceived as a tool to disclose human error as well as system failures. The type of information on incident reports is often quite different to that found using mechanisms such as medical record audit.

O'Neil et al[51] compared medical record review with physician reporting over a 17 week period. Using medical facilitation, daily reporting prompts to facilitators by the project team, and reminders sent on a weekly basis to all medical staff other than interns, incident reporting was able to detect more preventable incidents (62.5% vs. 32% p=0.003), and more errors due to commission (77% vs. 55% p=0.04) than medical record review.

Beckmann et al[43] compared incident reports lodged by all staff in an ICU with adverse events detected by medical record review. Using facilitation by senior intensive care physicians at the daily ward round they were also able to identify more preventable adverse events using incident reporting than medical record review (84% vs. 20% deemed preventable), however more adverse events were detected using medical record review (1.46 vs. 1.26 incidents per patient admission).

When investigating medication incidents, incident reporting was not able to compare with other methods of adverse event detection, such as using automated detection[58] and nurse or pharmacist chart review.[56, 193] When referring to incident reporting as a tool to identify medication errors, Flynn stated "the very low frequency of errors detected by incident report review limits the value of the results".

Schimidek and Weeks[194] compared adverse events detected through mandatory incident reporting with rates detected through tort claims. They found that only 4% of tort claims were reported in the patient incident reporting system.

Table 2-3 outlines studies where incident reporting has been compared to medical record review and other processes as a means of detecting adverse events. Most have demonstrated that incident reporting does not capture many of the adverse events detected using other methods.

2.6.1.1.1. Limitations of comparing incident reporting with other methods of identifying adverse incidents

Different types of incidents reported using different systems: The fact that incident reporting incorporates both adverse events and near misses, and techniques such as medical record review and audit only detect adverse events, means that there are inherent limitations when undertaking comparisons between the two types of studies.

The type of information uncovered by both is different, as witnessed in studies investigating the overlap between the two methods.[43 51 169 193] Often incident reporting is used to identify process or system issues which are rarely recorded in the medical record. Examples of incidents reported on incident reports but rarely in the medical record include communication breakdown between units/departments leading to delays or inappropriate treatment, equipment faults, mislabelled specimens and incidents relating to poor documentation.

Table 2-3 Summary of studies comparing incident reporting (IR) with other tools to identify adverse events (AE)

Paper	Study population Comparison measures	Outcomes measured	Key relevant findings
Marang van de Mheen, PJ et al, 2005[169]	**Population:** A random sample of 150 surgical patients, with over sampling of re-operation patients, high risk patients and those having complex procedures in Holland in 2002 **Comparison:** (a) Anonymous IR vs. (b) medical record review (MRR)	1. Number of adverse outcomes* for	
		(a) IR	62.5% (238/381)
		(a) MRR	78.2% (298/381)
		2. Seriousness of adverse outcome	
		(a) IR	84.8% (95/112)
		(b) MRR	79.5% (89/112)
Beckmann et al, 2003[43]	**Population:** All patients admitted to a 12-bed, closed ICU in Australia between 15 March 1999 and 15 May 1999 **Comparison:** (a) Anonymous facilitated IR vs. (b) medical record review (MRR) using methodology of the Quality of Australia Health Care Study[18]	1. Number of incidents† and AE ‡per patient admission for:	
		(a) IR	0.57 incidents (100 / 176): AE =17% (30 /176)
		(b) MRR	1.45 incidents (256/176): AE = 43% (76 /176)
		2. Preventability of AE using 6 point scale (cases with score ≥4 = preventable) for:	
		(a) IR	84% preventable (as judged by reporters)
		(b) MRR	20% preventable (as judged by reviewers)
		3. Resource utilization associated with AE case ascertainment for:	
		(a) IR	Little extra time for chart review, 50 hours for data entry, management and coding
		(b) MRR	>310 hours on chart review, 65 hours for data entry, management and coding
		4. Reporter designation	49% nurses, 51% doctors

Paper	Study population Comparison measures	Outcomes measured	Key relevant findings
Flynn, EA et al, 2002[56]	**Population:** Random sample of 36 healthcare facilities with > 25 beds from US, stratified by location and accreditation status **Comparison:** Pharmacist-confirmed ADE compared with (a) IR (b) MRR (c) observation from data collectors following pharmacist confirmation	Number of errors per drug administered identified by:	
		Pharmacist-confirmed	17.9% error rate (457/2556)
		(a) IR	0.04% error rate (1/2556)
		(b) MRR	0.7% error rate (17/2556)
		(c) Observers	11.7% error rate (300/2556)
		2. Cost of errors detected by	
		IR vs. MRR	$0 vs. $0.67 per report
Wolff, AM et al, 2001[161]	**Population:** All patients admitted to or presenting to the Emergency Dept of a rural hospital in Australia **Comparison**: Incidents detected by (a) IR and (2) Targeted MRR	Number of AE‡ detected by:	
		(a) IR	16.3% of all AE detected (66/405). Annual rate=5.17% of all discharges (621/12000)
		(b) MRR	83.7% of all AEs detected. Annual rate=0.74-1.35% of all discharges (49-69 AEs)
Weingart, SN 2000[195]	**Population: All patients admitted to** General Medical service of a US tertiary hospital b/n Aug and Nov 1997. **Comparison**: Incidents detected by (a) interview of doctors at ward rounds and via email (b) IR	Number of AEs§ per patient admission detected by:	
		(a) Doctor interview only	99 incidents detected by doctors, 10 incidents by non-physician
		(b) IR only	57 incidents
		(c) both IR and interview	1 incident

Paper	Study population Comparison measures	Outcomes measured	Key relevant findings
Stanhope, N, et al 1999[57]	**Population:** All 250 consecutive births in 2 London obstetrics units between March and April 1996 (Unit 1) and b/n June and Aug 1996 (Unit 2) **Comparison:** Incidents detected by (a) IR (b) Risk Manager (RM) through document review (c) MRR	Number of AEs‡ detected by:	
		(a) combined (b) IR only (c) MRR only (d) RM only	(a) 39% of all deliveries (196/500), (b) IR= 23% (45/196) (c) MRR=55% (107/196) (d) RM=22% (44/196)
		Seriousness of the AE detected by:	
		(a) IR	48.4% of all serious AEs (15/31), 24.6% of moderate AEs (15/61), 15.2% of all minor AEs (12/79)
		(b) RM only	16.1% of all serious AEs (5/31), 29.5% of all moderate AEs (18/61), 21.5% of all minor AEs (17/79)
Jha, AK et al, 1998[58]	**Population:** All adults admitted to 9 units of a 726 bed tertiary-care teaching hospital in UK over 8 months **Comparison:** Adverse drug events (ADE) detected by (a) IR (b) computer-based physician ordering system (CBPOS) (c) drug record review	1. Number of ADEs per 10000 Occupied Bed Days (OBD) identified by:	
		(a) IR	70 reports
		(b) CBPOS	96 reports
		(c) drug chart review	133 reports
		2. Number of preventable ADEs per 10000 OBD identified by	
		(a) IR	4 reports
		(b) CBPOS	23 reports
		(c) drug chart review	36 reports
Cullen et al 1995[193]	**Population:** All patients admitted to one of 5 units in tertiary US hospital b/n Feb and June 1993. **Comparison:** ADE detected by (a) IR using logs in each medication room (b) Nurse investigator (NI) **	1. Number of ADEs identified by:	
		(a) IR	7.3% (4 /55) of all AE detected
		(b)NI	98% (54/55) of all AE detected
		(c) both methods	3 reports detected by both NI and IR. One incident only detected by IR, 51 reports only detected by NI

Paper	Study population Comparison measures	Outcomes measured	Key relevant findings
Welsh et al, 1996[50]	**Population:** All patients admitted to the internal medical services of a tertiary US hospital b/n May1994 and Jan 1995. **Comparison:** Incident reports lodged following three month cycles of (a) no prompting (b) low level prompting (c)intensive	Number of AEs‡ reported per 100 patient admission by:	
		(a) no prompting	6.8 AE / 100 patient admissions
		(b) low-level prompting	11.4 AE / 100 patient admissions
		(c) intense prompting	19.6 AE / 100 patient admissions
		Number of AEs reported per 1000 OBDs by:	
		(a) no prompting	110 AEs /10000 OBDs
		(b) low-level prompting	157 AEs/10000 OBDs
		(c) intense prompting	297 AEs/ 10000 OBDs
Jayisuriya and Anandaciva, S 1995[45]	**Population:** All anaesthetised patients in a Hong Kong hospital b/n March to May 1994. **Comparison**: AEs detected by (a) IR (b) an intra-operative event form placed in each anaesthetic record	Number of incidents*** reported by:	
		(a) IR	24.8% of all reports (56/226)
		(b) event form	75.2% of all reports (170/226)
Sutton, J et al, 1994[60]	**Population:** Inpatients in 1 of 10 wards in a large acute care hospital in UK on one of the 3 survey days **Comparison:** Incidents detected by (a) IR (b) IR made by patients	1. No. of accidents*** per 10000 OBD for:	
		(a) IR recorded in accident book	83 reports (46 IR/75 patient accidents)
		(b) incidents where no IR was written	44 reports (26 IR/75 patient accidents)

Paper	Study population Comparison measures	Outcomes measured	Key relevant findings
O'Neil et al, 1993[51]	**Population:** All patients admitted to the medical service of an urban university affiliated teaching hospital in US between 13 Nov 1990 and 14 March 1991 **Comparison:** Incidents detected by (a) Facilitated IR by doctors (b) MRR[2]	1. Number of AEs‡ detected by per patient admission detected by:	
		(a) facilitated IR + MRR	1.31% (41 AE / 3128)
		(a) IR only	2.8% (89 AEs / 3128)
		(b) MRR only	2.7% (85 AEs / 3128)
		2. Preventability of AEs using:	
		(a) IR	62.5% preventable
		(b) MRR	32% preventable
		3. Cost associated with AE case ascertainment for:	
		(a) IR	$15,323
		(b) MRR	$54, 462

* adverse outcomes= an unintended and unwanted event or state occurring during or following medical care, that is so harmful to a patient's health that (adjustment of) treatment is required or that permanent damage results. †Incident = any unintended event or outcome which could have or did reduce the safety margin for the patient; it may or may not have been preventable and may or may not have involved an error on the part of the healthcare team. ‡Adverse event= unintended injury or complication that prolonged hospitalisation or led to death or disability at discharge and was caused by healthcare management. § AE=patients injury **Nurse Investigator used drug chart review and by soliciting information from nurses, pharmacists and clerks on a twice daily basis ***no definition provided

2.7. Barriers to incident reporting

Largely as a result of endorsement by experts for incident reporting, there has been a growing body of work investigating why people do and do not report incidents. Most studies have used survey or focus groups, as outlined in Table 2-4. A range of barriers have been highlighted as a result of these studies. Recurring themes include:

- Time constraints on busy clinicians;[196 197 197-200]
- Fear of embarrassment or loss of face, punishment, [137 188 201 202] and litigation;[200 203]
- Inability to report anonymously;[200 201]
- Deficit in knowledge about what to report and by whom an incident should be reported;[64 197 200 201]
- Errors that result in actual harm are more likely to be reported than errors that are caught and corrected before they cause harm;[9 45 64 202 204 205]
- A perception that incident reports do not result in significant changes;[196-199 201]
- The very culture of medicine, which emphases professional collegiality, [162] autonomy and self-regulation;[206]

Incident reports may duplicate data in the medical record[60] and, as such, can easily be seen as redundant in the eyes of the reporters.

Many healthcare workers have difficulty accepting that they make mistakes[117] and most do not discuss errors with their peers, often to their own detriment.[207 208] When errors are made by doctors, reassurance from colleagues is often not forthcoming, and doctors are either passively (through not having a forum to openly discuss errors) or actively (through risk managers and lawyers) discouraged from discussing them with others.[209] The culture of medicine, much like that of aviation, fosters a sense of personal competence and a denial of human weakness, particularly the omnipresent effects of stress.[130] In this culture, it is little wonder that incident reporting has had difficultly getting a foothold.

Many incidents are suppressed by hospitals rather than investigated, which has been shown to result in significant financial costs through claim pay-outs, rises in insurance premiums and unfavourable public relations.[192]

Leape[210] stated that in his experience there were only two reasons why healthcare workers did not report incidents; fear and lack of belief that it results in improvement.

2.7.1.1. Limitations of studies investigating barriers to reporting

The two means by which information on barriers to reporting has been ascertained include focus groups and surveys. Both techniques have inherent limitations.

Information bias: With regard to survey data, closed-question techniques were used, in which barriers were listed and staff were directed to indicate the extent to which they agreed that they impact on their reporting behaviour. This is usually done to reduce survey burden on busy clinicians, and is more effective in increasing response rates.[211] However, in doing so, it may be that the true reasons were not recorded in the survey and so were not measured.

Focus groups analysis is based on interpretation of qualitative data and this can introduce bias.[212] Focus groups are usually undertaken in an artificial environment, which may influence responses (as compared with direct observation of participants in their work environment).[211] They may be biased or directed by a dominant group member as some people may not be as articulate, confident or perceptive as others.[211 213] Some participants may find the group setting to be inhibiting.[212] It is difficult to make generalisations from small, unrepresentative samples and results will probably vary with each focus group run, making results not reliable and reproducible.[214]

Limited generalisability: If the survey response rate is low, it is not considered representative. One survey investigating barriers to reporting had a response rate of only 17%.[197]

Response bias: Regardless of whether or not surveys are anonymous or identified, there may be a bias towards staff responding in a manner which is considered socially acceptable. This is likely to minimize the extent to which barriers prevent clinicians from reporting adverse incidents. Anonymous surveys are less likely to suffer from this bias, nonetheless it must be considered when analysing results. For example, even though an anonymous survey of barriers to reporting was undertaken by Vincent et al[198] it was stated in the article that the authors were well known to staff in the clinical area they were surveying. It must be considered that this familiarity might have impacted on how staff responded to survey questions.

Table 2-4 Summary of barriers to incident reporting

Paper (Year of publication)	Study population and methodology	Response rate (N)	Anonymous (A) Y/N	Relevant outcomes measured	Key barriers to reporting identified
Coyle et al, 2005[196]	**Population:** Residents working in two community-based clinics in the US **Method**: Survey distributed to all participants following a 6-month program to improve reporting	30/30= 100%	Y	Barriers to reporting based on a list of 6 potential barriers (% believing it is a barrier)	**Doctors:** 28%= Lack of time, 13%= too much paperwork, 13%= reporting interrupts work, 15%= career and reputation may be at stake, 6%= wont result in system change, 6%= faculty do not encourage reporting, 2%= timely and high quality feedback not given, 2%= does not assist training.
Taylor, et al, 2004[64]	**Population:** Doctors and nurses working in a paediatric hospital in US **Method**: Survey mailed to randomly selected staff	140/200 = 70%	N	Barriers to reporting based on a list of 9 potential barriers (% believing it is a barrier)	**Overall**: 41%= Unsure of what is considered a medical error, 37%= concern about implicating others, 23%= unsure whose responsibility it is to report, 22%= not important to report error that did not reach patient.
Kingston et al, 2004[200]	**Population:** Doctors and nurses working in 4 metropolitan Australian hospitals **Method**: 5 focus groups * run over 2 hours	n/a		Qualitative data regarding perceptions of barriers to reporting	**Doctors:** do not habitually report incidents, prefer to keep it "in house", insecurity with how the information is used, not enough time, don't know what to report **Nurses:** fear of disciplinary action, insufficient time

Paper (Year of publication)	Study population and methodology	Response rate (N)	Anonymous (A) Y/N	Relevant outcomes measured	Key barriers to reporting identified
Ostergaard, D et al, 2003[188]	**Population:** Doctors and nurses working in units** in University hospitals in Denmark **Method:** Survey distributed by researchers to all staff	2031/4019 =51% (drs=46% nurses=53 %)	Y	Barriers to reporting, based on list of 13 potential barriers provided (% believing it is a barrier)	**Doctors**:39%= No tradition of reporting in my department, 37%= the press might start writing about it, 36%= may appear as a poor doctor, 31%= I might get a reprimand.
Uribe, C et al, 2002[197]	**Population**: Doctors and nurses working in internal medicine and surgical depts. in US hospital. **Method**: Survey distributed to all staff by researchers	122/705= 17.3% (Drs=15% nurses=20 %)	Y	Barriers to reporting, based on list of 17 potential barriers provided ((Mean rating†)	**Doctors**: Not knowing the usefulness of the report (2.76), extra work (2.76) and time consuming (2.76), don't know what to report (2.65), don't know how to report (2.62) **Nurses:** Time consuming (2.48), can't report anonymously (2.45), extra work (2.33), hesitancy regarding telling on somebody (2.12) **Overall:** Time consuming (2.56), extra work (2.52), hesitancy regarding telling on somebody (2.32), not necessary when no negative outcome (2.31), can't report anonymously (2.28)
Ostergaard, D et al, 2003[188]	**Population:** Doctors and nurses working in surgery, anaesthetics and obstetrics units in 3 NHS trusts in UK **Method:** Survey handed to all staff after recruitment by Risk Manager	315/594 =53%	Y	Barriers to reporting others, based on 9 scenarios. Surveys had outcomes ranging from minor to serious (Mean rating‡‡)	**Doctors:** less likely than nurses to report incidents involving others ($p<0.001$) Were more likely to report incidents with serious outcomes **Overall:** All were more likely to report breach of protocol than poor clinical judgment decisions, although doctors unlikely to report this at all (Dr means score= 2.54 for protocol breach vs. 1.90 for poor clinical judgment, nurses 3.68 vs. 2.53, midwives 3.57 vs. 2.46)

Paper (Year of publication)	Study population and methodology	Response rate (N)	Anonymous (A) Y/N	Relevant outcomes measured	Key barriers to reporting identified
Lawton R. Parker D, 2002[215]	**Population**: Doctors and nurses working in specialty units in London and Newcastle, UK and nursing students **Method**: 5 focus groups *** run over 2 hours (except GPs and nursing students which were 1 hr duration)	n/a	n/a	Qualitative data regarding perceptions of barriers to reporting	**Doctors:** (a) Perception that nothing changes, particularly by Consultants (b) Blame culture and lack of anonymous reporting **Overall:** (a) No need to report minor unintentional, one-off errors for which the person is genuinely sorry or has insight. (b) Junior staff do not like reporting to more senior staff. (c) Having to work harmoniously with others for a period of time prevented reporting (d) Workload involved in generating a report (e) Medical culture with lack of unequivocal messages about inappropriate or unacceptable behaviour or practice (f) fear that it will impact on career
Weingart et al 2001[162]	**Population:** cardiac step-down, ICU and oncology unit of tertiary teaching hospital **Method**: Survey emailed to participants	22/31 =71%	N	Barriers to reporting	**Doctors**: 30% residents had difficulty writing reports that might reflect badly on nurse and physician colleagues 2/21 interns had difficulty discussing problems 15/21 interns reported others mistakes but were not aware of any mistakes they had made.
Firth-Cozens et al, 2001[201]	**Population:** cardiac step-down, ICU and oncology unit of tertiary teaching hospital **Method**: Survey emailed to participants	22/31 =71%	N	Barriers to reporting	**Doctors**: 30% residents had difficulty writing reports that might reflect badly on nurse and physician colleagues 2/21 interns had difficulty discussing problems 15/21 interns reported others mistakes but were not aware of any mistakes they had made.

Paper (Year of publication)	Study population and methodology	Response rate (N)	Anonymous (A) Y/N	Relevant outcomes measured	Key barriers to reporting identified
Vincent, C et al, 1999[198]	**Population:** Obstetric and Midwifery staff in 2 Obstetrics Units in the UK **Method**: Survey handed to all staff by researchers	198/209 = 95%	Y	Reasons for not reporting, based on list of 12 potential barriers (Mean rating†)	**Overall:** Reporting is unnecessary (2.8), Increased workload (2.8), Junior staff are often blamed (2.7), When ward is busy, I forget (2.7) **Doctors vs. Nurses:** When ward is busy, I forget (3.19), Don't know whose responsibility it is to report (2.33), Colleagues may be unsupportive (1.74)
Eland, E et al, 1999[199]	**Population:** GPs, surgical specialists (SS) and medical specialists (MS)in the Netherlands **Method**: survey sent to random sample of 10% of medical practitioners	1442/1984= 72.7%	N	Barriers to reporting ADEs based on 16 events.	**Doctors**: Outcomes range from serious to non-serious. (% believing it is a barrier by GP/SS/MS) (a) Drug adverse event too well known to warrant reporting (92% / 91% / 93% agreeing), (b) Too trivial to report (77%/ 81% 69%), (c) Uncertain association between drug and event (77%/ 61% / 66%), (d) Not enough time (42% / 38% / 31%), (e) Too bureaucratic (38% / 40% / 31%)
Wright and Parker, 1998[147]	**Population:** Doctors working in psychiatric units in New South Wales and Brisbane **Method**: Several focus groups	n/a	n/a	Qualitative data regarding perceptions of barriers to reporting	**Doctors:** (a) Insufficient time in a short project (3 months) for staff to get used to the process (b) duplication of IR forms for project with in-house reports (c) form too long and complicated (d) concern with medico-legal aspects (e) no witnesses to provide accurate information about the event (f) uncertainty about what constitutes an incident

Paper (Year of publication)	Study population and methodology	Response rate (N)	Anonymous (A) Y/N	Relevant outcomes measured	Key barriers to reporting identified
Walker, S & Lowe, 1998[202]	**Population:** Nurses working in 6 clinical units in Queensland **Method:** Survey and focus groups with 43 nurses	Not stated n/a	N N	Survey: Barriers to reporting medication incidents Focus groups: Qualitative data	**Survey**: more likely to report a medication incident when patient safety has been compromised, and less likely to report errors in documentation and minor variations from prescription **Focus groups**: a) Fear of reprimand (b) Concern about implicating others with, to a lesser extent, fear of litigation (c) Perception that the event did not warrant an IR eg, a late medication would not be reported unless the patient was harmed (d) Perception that things can be sorted out without resorting to writing a report
Elnitsky et al, 1997[203]	**Population:** Nursing staff who were attending a leadership workshop (74) + contacts § in 15 localities in US (350)	56/132 +350/660 = 51%	Y	Barrier to reporting (% agreeing)	**Nurses:** 36% agree that some incident don't need reporting , 14%agree that incident reports are not valid or reliable, 19% agree that Supervisors used incident reports against employees, 17% agree that Supervisor used incident reports against them in their professional evaluations, 25% agree that reports will give a negative view of the person's skills.

* Five focus groups consisted of one each of (1) consultants (2) registrars (3)resident medical officers/interns (4) senior nurses (5) junior nurses ** Units included internal medicine, anaesthesiology, orthopaedic surgery, general surgery and gynaecology/obstetrics

*** Five focus groups consisted of one each of (1) pre-registration house officers (2) specialist registrars (3) consultants (4) general practitioners (5) 3rd year student nurses

† Rating 1= unlikely to be a barrier. Rating 5= likely to be a barrier

‡Rating 1=very unlikely to report what you have seen to superior. Rating 5= very likely to report what you have seen to superior

§ Contacts= each nurse attending the workshop was asked to distribute a survey to 5 colleagues in the workplace

2.8. Limitations and advantages of incident reporting

2.8.1. Advantages of incident reporting

> "The usefulness of incident reporting lies in the insights that can be gained from careful study of the narratives submitted, in all their contextual richness, not in the quantitative knowledge one can gain from counting adverse events"
>
> Charles Billings, 1999[216]

The advantages of incident reporting are numerous and include:

Ability to gather data soon after an incident occurs: Unlike medical record review and other forms of audit, incident reporting usually identifies adverse events and near misses soon after they occur. The immediacy of the process means that it can be used as an early detection system for potential litigation,[217] and that data is not as affected by faulty recall, medico-legal factors and outcome bias as studies investigating major, serious events.[218]

Inexpensive: Incident reporting is considerably cheaper than both medical record review and ethnography in detecting adverse events.[43 68] Unlike studies which require additional funding (eg ethnography, large scale medical record review), the cost associated with incident reporting is borne by the healthcare institution.[56] Runciman[219] makes the point that analysing incident reporting data yielded identical conclusions to a large randomised clinical trial evaluating the effectiveness of pulse oximeters in reducing anaesthetic deaths. The cost of undertaking an RCT would have been considerably more expensive than reviewing incident report data.

Identifies near misses: Its ability to detect incidents without adverse consequence and near misses, which occur 3-300 times more frequently than adverse events,[4] means that it can play an important role in evoking system change, ideally before someone is harmed.[220] This relies on the fact that systems are in place to monitor and action incident reports, and that hospitals work proactively rather than in a reactionary manner to fix near misses before they become actual adverse events.

Gathers contextual information: While quantitative data is useful for determining counts and rates which can be benchmarked, qualitative data is particularly useful for gathering information on problems that are "complex, contextual and influenced by the interaction of physical, psychological and social factors".[219] This data is information-rich, and is likely to be more useful when determining root causes of problems and contributing factors than counts obtained through quantitative data collection.

Enables anonymous reporting: Reporting in many healthcare settings can be done anonymously,[63 168] thereby providing staff with an opportunity to disclose an incident without fear of personal repercussions. Often incidents reported in this manner would otherwise not see the light of day.

Identifies infrequent events: Rare or infrequent incidents can be identified which might not be detected in the audit process.[9 221] In anaesthesia, analysis of incident reports has resulted in many system-based changes (e.g. mandating pulse oximetry from all anaesthetic procedures in Australia, incorporating innovative technologies such as safety devices, adopting uniform standards and guidelines and simulation training) which have been demonstrated to improve patient safety.[44 83]

Runciman classified adverse events in the Quality of Australia Health Care Study into principal natural categories, whereby each incident was coded according to how it may be prevented.[222] He then used this information to calculate the expected types of incidents in a hospital of 250 beds over a twelve-month period (assuming 90% occupancy and an average length of stay of 5.5 days). He determined that in a hospital of 250 beds only half of the adverse events would be encountered on more than 10 occasions each year. Individual doctors would only be exposed to a miniscule number, and claims files would only identify about 2% of the events.

Can identify more preventable events than medical record review: Facilitated incident reporting has been shown to identify more preventable adverse events compared to casenote audit[43] and at a fraction of the cost.[51]

Involves front-line clinicians: While medical record review and review of legal claims data are often undertaken by people removed from clinical care, incident reporting directly involves front-line clinicians. Having "outsiders" reviewing practice may be threatening to clinicians, particularly if they see themselves as recipients of censure.[223] Self-reporting enables clinician to be active participants in quality activities and may be seen as being less threatening.

2.8.2. Limitations of incident reporting

The subjective nature of reports, the lack of consistency and validation of incident data classification, and under-reporting constrain incident reporting from being used as a reliable epidemiological tool to measure the frequency of events and whether interventions are effective in improving patient safety.[224] Also, the true prevalence of events appropriate for reporting, which is the required denominator for epidemiological studies, is unknown. [225]

In describing the lack of the ability to collect epidemiological data as a limitation of incident reporting, it should be noted that reporting systems were not established with the intention of being able to collect this information.[219]

2.8.2.1. Subjective nature of reports

Incidents often cannot be validated; they are subjective accounts of an event. Two people witnessing an event may well have different accounts of it; particularly when they are from different professional groups. If both individuals report the incident, then this information can be very powerful, however on many occasions only one person reports the event, and this can lead to biased and unrepresentative information. The subjective nature of reporting is also its strength, as in the narrative of an event a large amount of information can be collected about complex factors contributing to human error and system failure.[219]

2.8.2.2. Lack of validated data

Incidents are usually classified into incident types and contributing factors by coders in hospitals. There is little measurement of consistency in coding, which leads to large margins of error when analysing data.[224] Centralised coding of incidents, as in aviation, would assist in ensuring consistent, reliable data; however the cost implication is large.

Work is progressing in Australia and internationally in the development of common terminology and classification schema (taxonomy) for collecting and systematically ordering patient safety data.[123 124 226 227] It is anticipated that this will assist in consistency of classification.

2.8.2.3. Under-reporting

Incident reporting does not provide an accurate account of adverse incidents in hospitals, due to under-reporting by healthcare workers. Under-reporting has been estimated to range from 50% to 90% annually.[129] In one hospital, the reporting system identified only six percent of medication adverse events compared to a computerised system.[193 225] When incident reports were cross tabulated with legal claims data, only 15% of claims had a related report written.[194] When compared to strategies such as medical record review and observational studies, incident reporting has mostly been shown to detect fewer errors. Comparative studies are outlined in Table 2-3.

Under-reporting is largely due to the voluntary nature of the reporting process. As stated by Sullivan[228] in regard to incident reporting as a tool to identify adverse events in family

practices in Canada, "voluntary reporting is only a sign of the conscientiousness of the physician." Barriers to reporting have been discussed in section 2.7

Even though reporting systems underestimate frequency of incidents, there are those who believe that they do not necessarily underestimate the nature of the problems.[47 150] Serious events are more likely to be reported than events without undue consequence,[45] as are those where outcome is immediate.[229] Incidents perceived as dangerous, unusual, or interesting are more likely to be reported than mundane incidents.[45 127]

2.8.2.4. Non- representative

In the AIMS reporting system, the majority of reports are generated by nursing staff. Data from the Australian Patient Safety Foundation[230] indicates that of the 24,770 reports in the AIMS database outside the discipline of anaesthesiology in 2003, 21714 (87.7%) were nurse-initiated, 1402 (5.7%) were allied health worker initiated, 429 (1.7%) were initiated by doctors, 1090 (4.4%) were classified as being reported by "other", 120 (0.5%) were patient-initiated, and 15 (0.1%) were generated by visitors.

A survey of Scottish reports in an ICU revealed similar reporting practices, with 90% of all reports initiated by nurses.[231] The disproportionate number of reports generated by nurses can, in part, be explained by the fact that the reporting system targets the types of incidents to which nurses, more than others, are exposed.[224] Despite a number of incident reporting studies showing high participation rates by doctors,[43 51 139 162] under-reporting by the majority of doctors, especially outside anaesthesiology, remains an ongoing problem.

The issue of under-reporting coupled with habitual reporting of certain incident types means that incident reporting systems often over-estimate certain types of incidents and therefore provide a non-representative view of errors across all spectrums of health care. This is demonstrated when investigating incidents relating to patient falls. While medical record review has identified that less than 2% of injuries in hospitalised patients are as a result of patient falls, these represent nearly 40% of all incidents reported into the AIMS system. [9]

Some studies have attempted to diversify the types of incidents reported by staff to make them more representative of hospital incidents by providing pre-defined lists of potential incidents.[139 147]

2.8.2.5. Not used effectively

There is often no coordinated approach to the tracking and managing of incidents in hospitals.[232] In general, in Australian hospitals there is little, if any aggregation of incidents

within hospitals, or feedback to nursing and medical staff. There is no pattern analysis and often no internal hospital mechanism exists to rectify problems that are identified.[192] A review of Victorian public hospitals revealed that only 58% of hospitals gave regular statistics on clinical risk to their Boards.[233]

2.9. Strategies to improve incident reporting

There is much room for improvement of incident reporting by healthcare workers. Identifying methods to improve incident reporting should largely reflect actions taken as a result of identified barriers to reporting. In looking to other industries, Barach and Small[129] found that a reporting system should:

- Offer immunity as far as practical
- Be confidential or have data de-identified prior to entering it onto a database, so that it is untraceable
- Be collected independent of the reporter's institution
- Have data reviewed and analysed by peer experts
- Provide rapid, meaningful feedback to reporters and interested parties
- Be easy to use
- Be supported by management at a leadership level

In establishing a reporting system for transfusion medicine in the US, experts from aviation safety, nuclear power, cognitive psychology, industrial engineering, artificial intelligence, education and training, and transfusion medicine from the US, England and Australia identified how the ideal system would be designed.[53] Using the characteristics outlined by the expert group, the key requirements for the reporting system were that it should:

- Integrate with Quality Assurance
- Be capable of managing a large volume of reports
- Include a process where reports are sorted to identify new or unique events from routine events
- Be able to classify incidents in a consistent manner by personnel without requiring extensive training.

A survey of 200 staff working in a paediatric hospital in the US,[64] identified that potential changes which would lead clinicians to report medical errors included better education

about what is considered a medical error that should be reported (65% agreed), feedback regarding types and frequencies of reported error on a regular basis (64% agreed), evidence that reporting errors led to system changes (55% agreed), and use of electronic format for reports (45% agreed). Only 9% of respondents believed that providing rewards would make a significant impact on reporting of medical error. There is a belief among anaesthetists that changes need to be made, including simplifying the reporting process and ensuring that information is managed to provide a useful outcome.[234]

Interventions to improve incident reporting have included facilitation, [43 50 51 162] providing financial incentives,[54 123 162 235] using smart information technology, [54 62 236-238] applying academic detailing techniques [143] and providing feedback to clinicians. [168 239]

2.9.1.1. Facilitated reporting

Facilitated or solicited incident reporting has been shown to improve incident reporting.[43 50 51 162] O'Neil et al[51] used daily electronic prompting to facilitate reporting over a four month period and Welsh et al[50] used daily prompting and low level reporting (once or twice weekly) in two three-month bursts. While both studies using prompting showed promising results, reporting rates need to be measured over longer period to determine true usefulness of this approach.

2.9.1.2. Financial incentives

Financial incentives to report incidents have been used with success. In an international study aimed at identifying errors in general practice, Australian GPs who were participating were offered an honorarium if they reported at least ten incident reports.[123] Those reporting ten or more incidents were eligible to claim the equivalent of the general practice fee recommended by the Australian Medical Association for ten standard consultations. They were also eligible for Quality Assurance points through the Royal Australian College of General Practitioners. Reports were lodged over the internet using a personal identification number. The only identifying information on the report form was the country from where the report was generated. The study yielded 134 reports from 23 GPs over a four month period. Even with this financial incentive and ability to report confidentially, the recruitment rate was only 23%.

Offering an incentive of approx AUD$7 per report to doctors improved reporting rates for adverse drug reactions 50-fold when implemented for a six week period, with 90% of reports confirmed as reliable.[235] When the fee was removed rates fell substantially. Another project aimed at improving reporting of adverse incidents offered practices US$50

for each completed report. The payment was reimbursement for time spent answering questions about the report, which took between five and fifteen minutes to complete.[54] The VA hospital have implemented a reward system, where frontline practitioners can get up to US$5,000 for identifying errors and solutions depending on the seriousness of the error and the general applicability of the solution.[240]

A US study[162] paid an honorarium of $100 to each of ten resident medical officers to interview their junior medical staff about barriers to high quality care, injuries or hospitalisations that were extended as a result of care, and medication problems. Interviews took place three times per week on the morning ward round over a three month period and data was entered into an electronic incident reporting system. It is not possible to infer from the study what impact the financial incentive had on motivation to report, as no baseline or comparative results were provided.

There is debate over the ethics of paying people to participate in research studies.[241] Some hold the view that paying clinicians may reinforce the belief that the health system is driven by money and that this will undermine professional altruistic values.[242]

2.9.1.3. Using information technology

The use of technology to improve the collection and dissemination of data is widely recognised. The use of an anaesthesia information management system captured more incidents than through voluntary reporting (adverse event detected in 18.7% of all surgical procedures vs. 5.7%).[236] Automated systems are most often used to identify adverse drug events where they have been found to be more effective than conventional incident reporting.[59] This is not surprising, considering the time it takes to complete a report and the prevalence of adverse drug events. It has been estimated that 30% of hospitalised patients experience an adverse drug event.[243] Other technological advancements, such as the use of handheld computers or personal digital assistants (PDAs) offer opportunities for clinicians to report incidents and monitor performance.[238]

Online incident reporting has been heralded as an effective means of gathering[237] and tracking data[47 61 168 244-246] Web-based systems offer the advantage of being readily accessible to a wide audience, and enabling a large amount of data to be collected centrally, rather than in individual organisations.[247]

A recently designed reporting system in the US provided clinicians with choices of using a web-based form, or reporting by paper or by telephone hotline.[54 62] The reporting system commenced in October 2001 and had enrolled approximately 33 practices (475 clinicians

and staff) after two years, with 14 of those rural or frontier practices (150 clinicians and staff). No details were provided by the authors on clinic attendances. Over a 28 month period, rural practices had contributed 128 reports, to the overall pool of 800 reports. When comparing information from across all the hospitals in the project[54] with those from only the rural or frontier practices,[62] there were differences in reporting practices. As a percentage of all reports generated, rural hospitals were less likely than all hospitals to use paper forms (48% vs. 63%) and the telephone reporting option (2% vs. 9%), and were more likely to use Web reports (50% vs. 28%).

Despite the relatively low rates of telephone reporting in the study by Westfall,[62] other healthcare industries are increasingly using call centres to meet care requirements and to assist service delivery. After hours triage services,[248 249] physician,[250] and pharmacist[251 252] advice services and 'hotline' information lines[253] are just some of the services using call centre technology. The ambulance service has used centralised Call Centres for some time for the purpose of gathering vital emergency information for the efficient dispatch of the ambulance fleet. The US Food and Drug Administration encourage voluntary reporting by health professionals of serious adverse events, product problems or medication errors, and provide a hotline to enable reports to be lodged.[254] More recently in Australia a call centre was established to enable consumers to report medication adverse events.[252]

2.9.1.4. Academic detailing

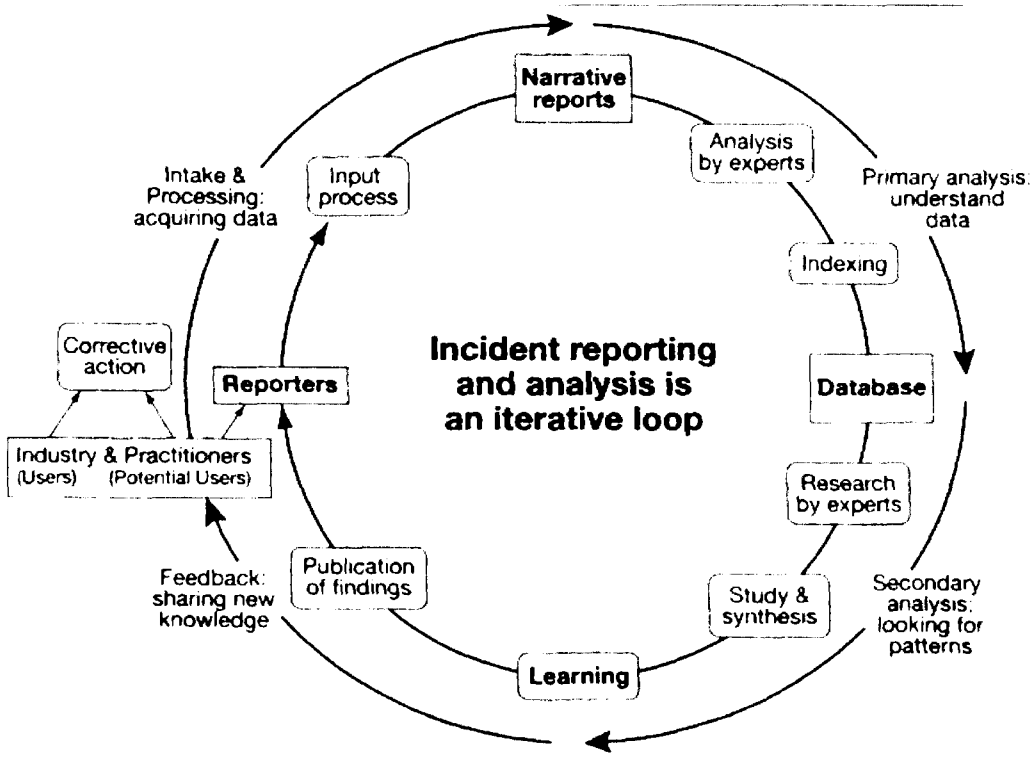
The use of academic detailing has been used extensively to change practices in the pharmaceutical industry and is increasingly being used within hospitals to change physician behaviour. [255] Osmon et al[143] used academic detailing to gain support from clinicians in the establishment of a reporting system. It has been shown that, in combination with distribution of printed material, it was more effective in changing physician practice than distribution of the printed material alone.[256] Facilitated reporting techniques use academic detailing to solicit support and involvement from clinical staff.

2.9.1.5. Feedback

Feedback is principally undertaken to enable clinicians to reflect on their performance and make changes where necessary to improve systems or clinical behaviour.[257] Charles Billings, the founder of the Aviation Safety Reporting System (ASRS) believed that incident reporting should be an iterative process involving data collection, analysis and feedback.[216] In the model developed for aviation (Figure 2-2) a priority was placed on developing a reporting system which enabled dissemination of findings from individual institutions with

others who may experience similar problems, so that patient safety activities can operate from a shared frame of reference.[216]

Figure 2-2 Model of the Aviation Safety Reporting System



The bulk of information directed at improving incident reporting is skewed towards improving the collection of incident data. There is a dearth of information available on how information should be fed back to clinicians and whether current practices are effective.

At a professional level, feedback is usually achieved through publication of aggregate data in peer-reviewed journals and presentation of findings to professional groups at conferences. As outlined in Table 2-2, aggregate findings from incidents have been widely published. In anaesthesia, this has likely been responsible for fostering a belief that it is worthwhile. A survey of 136 New Zealand anaesthetists (response rate 57%) indicated that 97% of respondents believed that incident reporting was of value to anaesthetists and nearly half felt that the AIMS reporting system had changed their practice.[234]

Local organisational[168] and departmental[239] strategies have shown success in disseminating feedback. The use of alerts and newsletters[62] have also been used to disseminate incidents data, although it is difficult to know whether they reach their target audience and were effective drivers of change. Unfortunately, few studies have investigated how best to share lessons to a wide audience, such as at a state, national or international level, principally because most reporting systems established within institutions operate in isolation.[216]

Timely and effective feedback of information which is useful and relevant to staff has been regarded as a crucial element in determining whether organisations willingly adopt incident reporting.[204]

The usefulness of feedback in changing behaviour has been challenged. Findings of a Cochrane systematic review indicate that feedback and audit yields only small to moderate improvement in clinical practice.[70] Additionally, provision of centrally collected feedback data to clinicians has been shown to have little impact on changing physician behaviour.

2.10. Conclusion and justification for this study

People present to hospital with increasingly complex illnesses, receive more procedures by more medical teams, and yet stay in hospital for a shorter period of time than ever before. Adverse events do occur, mostly as a result of latent failures in hospital systems. There are a number of techniques available to identify adverse events and near misses, such as audit and review, observational studies, consumer studies, complaints and incident reporting.

According to observational and audit studies, adverse event rates range from ten to nearly fifty percent of patient admissions. Disparity in findings is largely due to differing definitions of what constitutes an adverse event. To date, there have been no identified studies undertaken from a consumer perspective to determine adverse event rates.

Incident reporting has been identified as an important tool to elicit important information from those working at the coalface about why adverse incidents occur and how they can be prevented. However, in the establishment of an incident reporting system, this literature review has revealed that there remain many issues for which there are no clear-cut answers. Should it be voluntary or mandatory? Should it be anonymous or confidential? Should it report to an outside independent body or to an internal body within institutions? What feedback strategy will be most effective in gaining support from clinicians? Despite the fact that anonymous reporting systems are being advocated, no studies have been identified that determine whether this is in line with or contrary to consumer sentiment.

The literature review identified that endemic under-reporting appears widespread, and that a number of strategies have been used to identify barriers to reporting. Cultural and organisational barriers to reporting have been identified using quantitative and qualitative study techniques. However, to date there is little information on barriers to reporting from an Australian perspective. No published articles were identified in which focus groups or surveys were used to identify barriers to reporting amongst doctors, and among nurses the only Australian study involved a small sample of nurses and related only to reporting of medication incidents.[202] Further to this, there is no evidence in any of the reported studies investigating barriers to reporting, either within Australia or internationally, that the tool used was validated and tested for reliability, to ensure that the results captured accurate and reproducible information.

Strategies to improve incident reporting have been highlighted, and include facilitating the process using clinical champions or academic detailing, providing incentives, providing the option to report anonymously, and employing information technology aids. The use of

various reporting techniques, such as web-based reporting and call centres has only been reported in a rural health setting in the US. Little is known about how feedback of incident data should be presented or disseminated.

A limitation with all studies aimed at improving incident reporting is the lack of rigorously tested interventions to improve incident reporting using a prospective, matched study design. Some studies have used historical data as controls when testing new interventions. Where these studies have shown an intervention to be successful, it is not possible to distinguish whether the outcome was a result of the intervention or whether it reflected the rapidly evolving area of safety and quality.

Many studies have investigated techniques to improve reporting in isolated clinical areas, but no Australian studies have been identified where an intervention was instigated in a number of different types of clinical areas simultaneously.

Strategies aimed at improving reporting have generally been implemented over a short time period. The longest study using facilitated reporting was evaluated over a four-month period.[51] We do not know if these strategies have sustained success, nor do we know how well accepted they were by those expected to contribute to them.

2.10.1. Aims and hypotheses

Following review of the literature to identify gaps in current knowledge of adverse events and near misses in healthcare settings in Australia, the following aims were developed:

AIM 1: To understand consumer views on:

1.1 safety in hospitals and general practice

1.2 the experience of an adverse event in hospital

1.3 confidence in health care.

AIM 2: To understand consumer views on reporting of adverse events by healthcare workers.

AIM 3: To identify from doctors and nurses:

3.1 knowledge of the reporting system

3.2 baseline use of the incident reporting system

3.3 barriers to reporting

3.4 suggestions for improving the reporting system.

AIM 4: To implement an intervention which will result in:

4.1 improved reporting rates

4.2 change in types of incident reported

AIM 5: To identify from doctors and nurses whether the intervention will:

5.1 improve knowledge of the reporting system

5.2 change self-perceived reporting practices

5.3 reduce barriers to reporting

5.4 be well accepted by users

With regard to the above-mentioned aims, the following hypotheses were generated:

- **HYPOTHESIS 1:** The adverse event rates identified by consumers will comparable with that identified through observational studies and higher than that identified through medical record review. The experience of an adverse event in a household member will result in diminished confidence in hospitals and general practice compared to those who did not experience an adverse event.
- **HYPOTHESIS 2:** Consumers will favour an anonymous reporting system if they are informed that anonymous reporting may improve the identification of errors so that system changes can be made to improve care for all.
- **HYPOTHESIS 3:** Barriers to reporting identified through staff survey and focus groups will be congruent and will reflect barriers identified in the literature.
- **HYPOTHESIS 4:** An intervention designed to address current deficits in the current reporting system will result in more incidents reports being submitted and a change in types of incidents reported compared to reporting at baseline.
- **HYPOTHESIS 5:** By utilising information from users and non-users of the current reporting system about current attitudes towards and barriers to reporting in the design of an intervention, this will result in a well-accepted reporting system, increased knowledge of the reporting system, a greater awareness of what should be reported and increased compliance in reporting incidents. This will be assessed by comparing feedback from staff via a staff survey at baseline and at the end of the study.

In establishing a study design it was important to (a) incorporate a number of different clinical areas and have a control and intervention arm to assess what impact the intervention had over and above background work being undertaken in the field of quality and safety in these hospitals; and (b) determine in a scientifically rigorous manner the effectiveness of the intervention in changing attitudes towards incident reporting.

3. METHODS

3.1. Introduction

This thesis comprises an experimental study aimed at improving the reporting of adverse incidents and near misses by medical and nursing staff in clinical units across six hospitals in South Australia. It also comprises two consumer studies. The Methods section has been sub-divided into the following six components of the study:

1. A household-based consumer survey designed to elicit opinion on adverse event rates and perceived safety in hospitals and general practice (Consumer survey 1);
2. A telephone-based consumer survey eliciting opinion of how medical errors should be handled (Consumer survey 2);
3. A staff survey to determine current knowledge and use of the reporting system and barriers to incident reporting (Baseline staff survey);
4. Focus groups for medical and nursing staff derived from a sub-group of intervention arm to gain greater understanding of barriers to incident reporting and methods to improve the current system (Focus groups);
5. The intervention component, which was conceptualised following an extensive literature review and analysis of the baseline staff survey and focus groups. The intervention took place in ten intervention units within six South Australian hospitals, with ten control units matched for type of unit and location of hospital (Intervention);
6. An end of study survey, which was used to evaluate the effectiveness of the intervention in changing attitude towards incidents they believed they did and should report and barriers to reporting. It was also used to gauge satisfaction with components of the intervention (End of study staff survey).

Figure 3-1 outlines the timeline for each component of the study, while Table 3-1 outlines the timeline specifically within each of the ten intervention and ten control units.

Figure 3-1 Timeline for components of the study

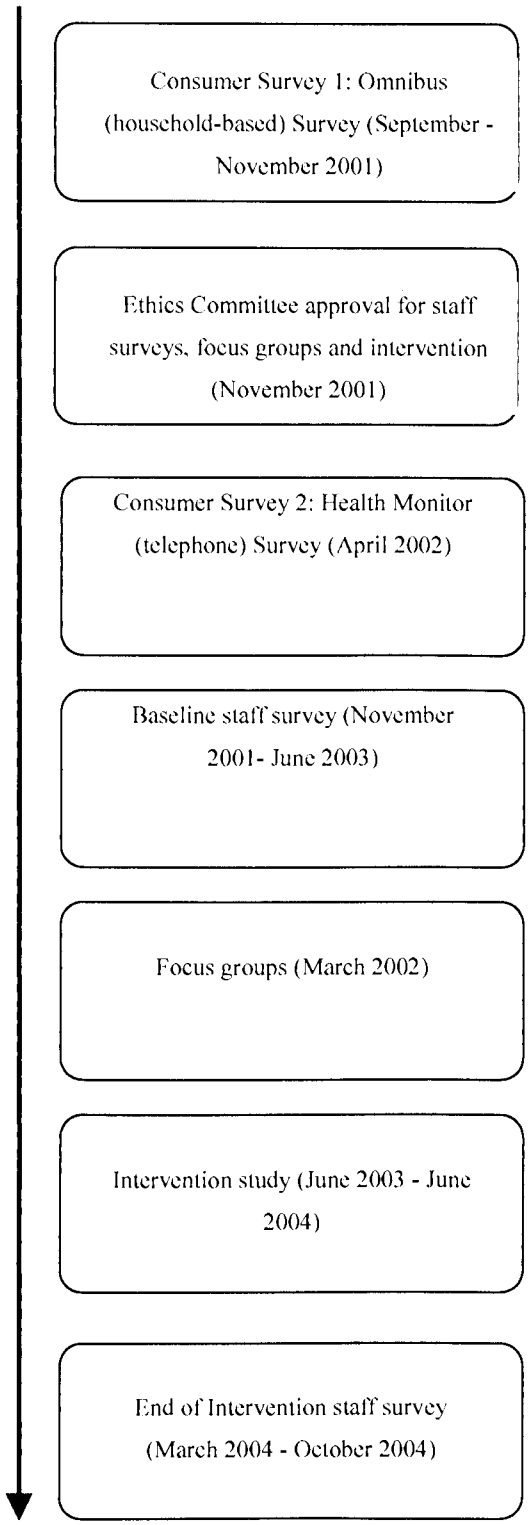


Table 3-1Timeline for the project within individual departments

3.2. Consumer survey 1

3.2.1. Introduction

The first component of the thesis comprised a population survey of people over the age of 15 years residing in South Australia. The study formed part of the Health Omnibus survey[273 274] which is undertaken each year in South Australia. The Omnibus survey is conducted by Harrison Health Research in association with the South Australian Department of Health.

3.2.2. Aims

The aims of this consumer survey, as outlined in aim 1 of section 2.10, were to determine from a community perspective:

- predictors of perceived lack of safety based upon demographic factors as well as experience of adverse events in (i) public hospitals; and (ii) general practice;
- the rate and severity of adverse events experienced in hospitals, using a lay definition congruent with that used by medical record review studies; and
- changes in perceived safety in hospitals between ten years ago and present, based upon demographic factors as well as experience of adverse events.

3.2.3. Survey setting

The data for this study was collected from people aged 15 years or older living in metropolitan Adelaide, South Australia and country centres with a population exceeding 1000 as part of the Health Omnibus Survey 2001, between September and November 2001. The survey consisted of a multistage, systematic, clustered area sample.

3.2.4. Survey design

3.2.4.1. Pilot testing

Survey questions were initially developed and piloted on a sample of ten researchers to test construct validity. The ten researchers were staff in the Clinical Epidemiology Unit, and included four PhD students, two Masters of Public Health students, the Medical Director and three research assistants. The questions were also tested on a lay population of ten, which included family members of the researchers.

Reliability was assessed through test-retest on this sample. There was a seven-day period between initial survey and repeat survey to test reliability of the tool.

Based on feedback, questions were refined and then submitted to the Field Manager for Harrison Health Research for assessment of questions by a quality control committee, which included representatives of users of the survey and was chaired by the Head of the Centre for Population Studies in Epidemiology, Department of Human Services.[275] Following assessment by the panel, questions were piloted on 50 respondents during September 2001 and, where difficulties were apparent, changes were made prior to being used in the actual survey.

3.2.4.2. Interview technique

Household-based interviews were conducted by professional health interviewers at Harrison Health Research. To determine the metropolitan sample, 340 collector districts used by the Australian Bureau for Statistics[276] for the 1996 Census were selected with their probability of selection proportional to their size. Within each collector district, a starting point was randomly selected and interviewers visited every fourth household. Ten dwellings in each collector district were chosen (therefore metropolitan pool equals 340 x 10= 3400).

To determine the country sample, all towns with a population of greater than 10,000 in the 1996 Census were selected automatically. The balance of the country sample was taken from towns with a population of greater than 1000. As with the metropolitan sample, ten dwellings were chosen at each of the 100 starting points (therefore country pool = 100 x 10=1000).

Interviewers selected respondents by asking to interview the household member who had most recently had a birthday. Respondents were provided with prompt cards to assist in categorising their answers.

To validate that the survey had been conducted, 5% of each interviewer's work was selected at random and the respondents re-contacted and asked a number of questions to ensure they had been interviewed appropriately.

3.2.4.3. Sample

The Health Omnibus survey guaranteed a sample pool of 3,000 respondents. A total of 4400 households were selected. The survey was designed to have sufficient numbers to achieve a minimum of ± 1.75% accuracy with 95% confidence for any survey item.

3.2.4.4. Survey question

To determine household sizes, respondents were asked how many people aged 15 or over were living in the household. They were also asked how many children were in the household aged 0-4 years, 5-9 years and 10-14 years. The total pool was a sum total of the children and all those aged over 15 years.

To ascertain public confidence in hospitals and general practice, respondents were asked, 'With regard to mistakes made in medical treatment, how safe would you feel (a) being admitted to a public hospital, and (b) going to your GP?' Responses were rated on a four-point Likert scale of 1) very safe; 2) pretty safe; 3) a little unsafe; and 4) very unsafe.

To determine the rate and severity of adverse events experienced in hospitals, respondents were asked, 'In the last five years, how many times have you and members of your current household been admitted to hospital?' If there had been a hospitalisation they were then asked, 'With regard to those hospitals stays, did anything ever go wrong that you thought might have been due to the way the health care was carried out?' If the respondent answered in the affirmative, they were then directed to rate the severity of the adverse event(s) on a three-point Likert scale of 1) not serious; 2) a little serious; and 3) really serious, and whether or not they thought it required extra time in hospital.

To determine trends in perceived safety in hospitals, respondents were asked, 'Compared to ten years ago, do you think that the chance of mistakes being made in hospitals is less, more or the same?'

Respondent demographic details obtained included age, gender, metropolitan/country residence, annual household income, country of birth and Indigenous status (Aboriginal and/or Torres Strait Islander origin).

3.2.4.5. Statistical analysis

A descriptive analysis was used to determine the adverse event rate and severity of the adverse event, with categorical variables reported as counts. To identify predictors of perceived lack of healthcare safety, univariate analyses were undertaken using a log binomial regression model. The four Likert categories were dichotomised into

- 'feel safe' which incorporated very safe and pretty safe categories; and
- 'feel unsafe', which incorporated a little unsafe and very unsafe categories.

Multivariate analysis was used to determine the best joint predictors of perceptions of lack of safety. The conventional level of $p \leq 0.05$ was taken to represent statistical significance. Trends in hospital safety were analysed using conventional chi-squared tests.

Respondents who did not have a definite answer were excluded from the analyses. For all survey items but one, this represented less than 2.5% of respondents. The exception was the question relating to trends in hospital safety over time, where 8.4% of respondents could not provide an answer. Analyses were weighted by age, sex and geographic region to be representative of the South Australian population. The survey procedures of the Stata statistical software package[277] were used for this analysis.

3.3. Consumer survey 2

3.3.1. Introduction

The second consumer survey was used to ascertain consumers' opinion about incident reporting. A vignette was used to assist consumers in conceptualising an adverse event. Questions posed in this survey were originally intended for use in the Health Omnibus survey (consumer survey 1)[273] but, following pilot of 50 consumers and based on feedback from the quality control committee, were removed because they were considered too complicated for consumers to understand. Following extensive re-evaluation, the questions were inserted into the South Australian Health Monitor consumer survey,[274 278] which is a telephone interview service provided by the Centre for Population Studies in Epidemiology in conjunction with Harrison Health Research.

3.3.2. Aims

As outlined in aim 2 of section 2.10, the aims of this survey were to determine from a community perspective:

- respondents' opinion towards incident reporting by healthcare professionals in hospitals and
- respondents' views on healthcare worker identity disclosure when a medical error occurs.

3.3.3. Survey setting

The data for this study were collected in the 2002 South Australian (SA) Health Monitor Survey.[278] Interviews of people aged 18 years or older living in metropolitan and country areas in South Australia were conducted by telephone, with numbers being randomly selected from respective telephone directories. Interviews were conducted between 4 April 2002 and 14th April 2002.

3.3.4. Survey design

3.3.4.1. Pilot testing

Survey questions were designed in collaboration with researchers from the Clinical Epidemiology and Health Outcomes Unit at the Queen Elizabeth Hospital. The questions were modified from those assessed too complex for inclusion in the Health Omnibus. They were then assessed by a group of ten researchers including four PhD candidates, two

Masters of Public Health students, the Medical Director of the Clinical Epidemiology Unit and three research assistants to assess construct validity.

Following consultation between the group on two occasions and a number of drafts, the questions were piloted on a sample of ten lay people. These people were purposively selected to include a variety of age and ethnic groups from a sample who were attending a cafeteria next to the hospital. Respondents were evaluated by the PhD candidate for response time and their ability to answer each question.

The survey was further modified and then assessed by a qualitative research academic expert (Professor Deborah Turnball, Department of Psychology, University of Adelaide). The survey questions were then forwarded to Harrison Health Research for formal pilot testing on 50 consumers. No difficulties were apparent when tested at this stage.

3.3.4.2. Interview technique

Methods used to collect information for the South Australian Health Omnibus has been previously described.[273] Telephone interviews were conducted by professional health interviewers at Harrison Health Research within a facility where a supervisor was available at all times to manage the survey. Supervisors monitored 10% of each interviewer's work. Telephone calls were made between 10:00am and 9:00pm, seven days a week. Interviewers were directed to attempt up to six call backs at different times of day or evening, and different days of the week. The person in each household whose birthday was nearest to the date of survey was interviewed.

3.3.4.3. Sample

The survey was designed to have sufficient numbers to achieve a minimum of ± 2.0% accuracy with 95% confidence for any survey item.

3.3.4.4. Survey question

To gauge support for incident reporting, respondents were asked to comment on the following vignette, 'A healthcare worker mistakenly gives a hospital patient the wrong medication. No one else has noticed the error. The patient suffers no ill effects other than a minor stomach upset for 24 hours. What do you think the healthcare worker should do?

1. Nothing, we all learn from our mistakes;
2. Fill in a report form giving details of the mistake;
3. Other; or

4. Don't know.'

If respondents replied that a report should be filled out, they were then asked 'If they fill in a report form, should the person:

1. have to write their name on the form, even though they may be reprimanded? The mistake can then be discussed with all staff to prevent it from happening again; or
2. not have to write their name on the form, which might encourage reporting of mistakes? The mistake can then be discussed with all staff to prevent it from happening again.'

Demographic information including age, gender, metropolitan/country residence, annual household income and country of birth were collected.

3.3.4.5. Statistical analysis

Descriptive analysis was used to ascertain the proportion of respondents who wanted incident reporting and healthcare workers identified on incident reports. To identify predictors of those who believed that healthcare workers should write an incident report when an error occurs, poisson regression analysis of demographic factors was used.

To identify predictors of attitudes towards incident reporting and healthcare worker anonymity, univariate analyses of demographic factors were undertaken by generalised linear modelling.

The conventional level of $p \leq 0.05$ was taken to represent statistical significance. Respondents who did not have a definite answer were excluded from analyses (less than 2% of respondents). Analyses were weighted by age, gender and geographic region to be representative of the South Australian population.[279]

3.4. Baseline staff survey

3.4.1. Introduction

A baseline survey of nurses and doctors was undertaken to elicit views on incident reporting.

3.4.2. Aims

The aims of the staff survey, broadly outlined in aim 3 in section 2.10 were to investigate by profession:

1. knowledge and use of the current incident reporting system;
2. staff reporting practices; particularly the types of incidents staff a) were more likely to report, and b) believe should be reported; and
3. barriers to incident reporting.

The objectives of this study were to:

1. ascertain from clinicians working in clinical areas their knowledge of the incident reporting system, and historically their perceived use of the reporting system;
2. identify discrepancies between what medical and nursing staff do report compared with what they felt should be reported;
3. identify the principal barriers to incident reporting so that these can be addressed when designing an intervention aimed at improving reporting rates.

With regard to the aims, the following hypotheses were generated:

Primary hypothesis 1

Medical staff will have less knowledge of the reporting system and will have used it on fewer occasions than nursing staff.

Primary hypothesis2

Medical and nursing staff will differ in their perceptions of which incidents should be reported. There will be differences for certain incident types in what is currently being reported when compared to what staff feel should be reported.

Primary hypothesis 3

There will be differences in barriers to incident reporting between professional groups, and in relation to medical and nursing seniority.

3.4.3. Survey setting

Hospitals sampled included three principal referral metropolitan public hospitals (each with >300 acute inpatient beds), one major referral metropolitan public hospital (<200 acute inpatient beds) and two major rural base public hospitals (each with <120 acute inpatient beds) in South Australia. Public hospitals in South Australia are funded jointly by the Commonwealth and State Governments. Eligible persons can receive care in a public hospital free of charge.[258]

The four metropolitan hospitals are located within a 40km radius of the Central Business District of Adelaide, which is the capital city of the state of South Australia. Adelaide has a population of approximately 1,527,000 people according to the 2003 Census.[259] The two rural hospitals in Whyalla and Mt Gambier service a population of approximately 23,000 and 22,000 people (Table 3-2). The location of the rural hospitals is shown in Figure 3-2.

The two rural hospitals were selected by the funding body without input from the project team. A condition of the funding agreement was that the study also included two rural hospitals.

Figure 3-2 Map of Australia and South Australia

Rural hospitals

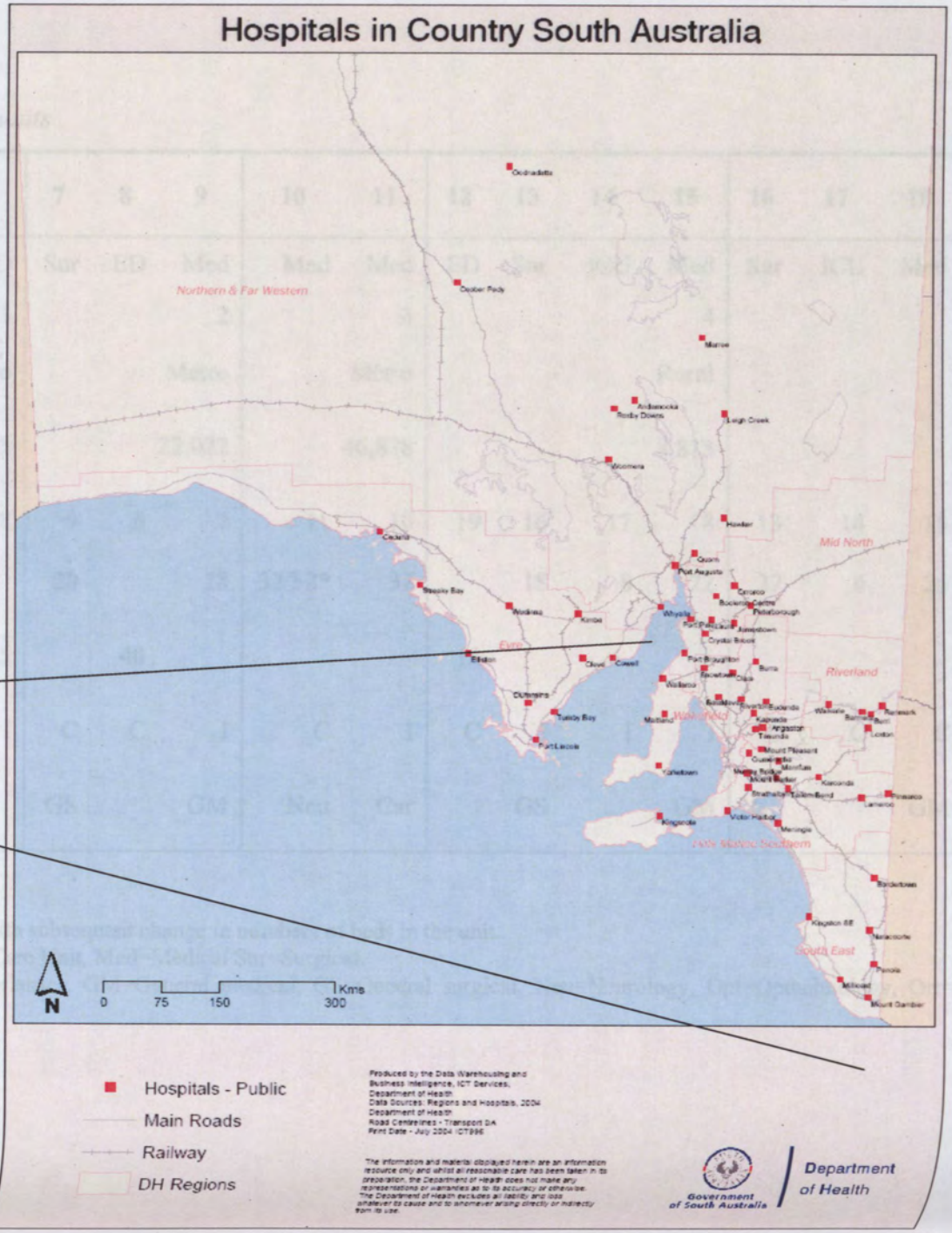


Table 3-2 Details of participating hospitals and units

Department number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Type of Dept	ICU	Med	Sur	Med	Sur	ED	Sur	ED	Med	Med	Med	ED	Sur	ICU	Med	Sur	ICU	Med	ED	ICU
Hospital number						1			2		3				4				5	6
Metropolitan/ Rural hospital						Metro			Metro		Metro				Rural				Rural	Metro
Number of patient admissions/year						45,075			22,022		46,878				8,813				5,195	64,262
Matched Dept number	20	11	5	10	3	8	9	6	7	11	10	19	16	17	18	13	14	15	12	1
Beds in Unit	15	32/38 *	36	32	36		20		28	32/52*	32		18	8	22	27	6	25		34
ED attendances per year (10,000s)						35		40				12							15	
Control/ Intervention	C	C	C	I	I	I	C	C	I	C	I	C	I	I	I	C	C	C	I	I
Specialties in Dept	Level 4	Car	UGI CR Opt	Neu Ger	Ort Pla		GS		GM	Neu	Car		GS		GM	GS		GM		Level 4

Key: *= Wards relocated during the study period with subsequent change in numbers of beds in the unit.
Type of Dept: ED=Emergency Department, ICU=Intensive Care Unit, Med=Medical Sur=Surgical.
Specialties in Dept: Car=Cardiothoracic, CR=Colorectal, Ger=Geriatrics, GM=General medical, GS=General surgical, Neu=Neurology, Opt=Opthalmology, Ort=Orthopaedic, Pla=Plastics, UGI=UpperGI,

3.4.4. Study design

The sampling frame for the survey consisted of doctors and nurses working in twenty clinical areas in four metropolitan and two rural hospitals. The staff survey formed the basis of the larger project, in which half the units would become intervention and the other half would become control units. For this reason, it was important that comparable units were chosen at this stage of the project design.

Rural hospitals

Within each of the two rural hospitals, the medical, surgical, ED and ICU were sampled. In both the rural hospitals, there was only one of each type of unit.

Metropolitan hospitals

Within the metropolitan hospitals, clinical areas were purposively selected so that for each intervention unit there was a matching control unit based on type of clinical area (ED, ICU, medical and surgical units), size of the unit (numbers of discharges, ED attendances), and specialty service available (neurology, cardiology, general medicine, general surgery, level 4 ICU). These are outlined in Table 3-2.

One of each type of unit was selected in hospital 1, because this was where the project team was based, and so from a human resources perspective, it would be easiest to administer the project at this site. The medical and surgical intervention units in hospital 1 were purposively sampled to minimize the likelihood that the two supervisors of the project based at the hospital (Professor Brian Smith and Professor Guy Maddern) would have any contact with staff in them. Each medical and surgical intervention unit was matched with a medical and surgical unit in hospital 1. Although there was a greater likelihood that the two supervisors would have contact with staff in these control units, this would only lead to a diminished effect of the intervention. Professor Maddern operated on patients in the control surgical unit, and Professor Smith occasionally assisted in the management of cardiac patients admitted with respiratory co morbidities in the cardiology unit.

Medical units matched by specialty were selected from hospital 3. The neurology medical ward chosen as the intervention unit in hospital 1 was matched with a neurology unit in hospital 3. Similarly, the cardiology medical unit chosen as the control unit in hospital 1 was matched with the cardiology medical unit in hospital 3. Surgical units were not invited to participate in the study in hospital 3 because of limited resources available to the study.

Initially the ICU at hospital 3 was approached to be the intervention ICU, with its matched control unit based at hospital 1. Unfortunately, the Clinical Director declined the invitation to participate in the study. For this reason, the ICU in hospital 4 was approached to participate in the study because it was the only other ICU in metropolitan Adelaide of similar size and able to treat patients of similar acuity to those in hospital 1. Agreement was obtained and the ICU in hospital 4 was allocated as an intervention unit. Even though one supervisor (Professor Bill Runciman) had a clinical load for one week in seven in the ICU in hospital 4, an undertaking was made that he would have no input into promoting the project in this unit.

The ED in hospital 1 was matched to an ED in hospital 2. The Clinical Director of the ED in hospital 2 agreed to have the ED participate as a control unit, but refused to participate as an intervention unit because of commitments to a number of other studies. For this reason, the ED in hospital 1 was selected as the intervention unit.

The medical and surgical Heads of Unit in hospital 2 were approached to participate in the study, one as an intervention unit and the other as its control. Upon agreement, it was decided that units would be randomised into control and intervention units following the survey component of the project.

Inclusion criteria

The sample pool consisted of all medical and nursing staff rostered to work in the twenty clinical areas during the survey period. Also surveyed were Agency nursing staff working in the area when surveys were distributed. Agency nurses were nurses employed on a casual basis by an independent employment agency, and who were contracted to work in hospitals on a shift-by-shift basis.

Exclusion criteria

The following exclusion criteria were determined for both the baseline and end of intervention surveys:

- Nurses working for the hospital pool. These were nurses employed to work in the hospital, but not on the roster in any one clinical area. They were allocated to wards on a shift-by-shift basis, depending on where shortfalls in nurse-patient ratios occurred. It was felt that if these staff were included they would contaminate results in the end-of-intervention survey as they worked in both intervention and control units.

- Visiting medical staff specialists attending rural hospital 5. The six specialists attending this rural hospital visited from hospital 1, and four of them worked in the intervention units. The units they would be sampled from in the rural hospital were all control units.
- Medical and nursing staff on the roster but on leave during the period that surveys were distributed.
- Staff other than nurses and doctors. Other staff such as ward clerks and allied health professionals were considered but, because they usually worked across multiple units, it was felt that they would introduce contamination if included.

3.4.5. Survey design

To develop the question format, a literature search was undertaken to identify existing surveys in this field which were both valid and reliable. No surveys relating to this topic reported validity or reliability data.

A decision was made to modify and extend a survey reported by Vincent et al[198] and perform appropriate testing of the tool to assess validity and reliability. Vincent's survey was implemented on medical and nursing staff in a British Obstetrics and Gynaecology Unit and questions relating to the types of incidents they believed they did and should report were very specific to this population. We modified the types of incidents to make them more relevant to a wider population.

We included barriers to reporting used by Vincent et al, because we felt it would be useful to compare whether doctors in nurses working in a different clinical area in another country would identify similar barriers to reporting. Permission was obtained from Vincent prior to modifying their survey. Set out in section 3.4.5.1 and 3.4.5.2 below are the processes undertaken to assess the validity and reliability of the survey tool. Throughout the different stages of the survey design, Project Officers and the Principal Supervisor met to discuss, refine and adjust survey items.

3.4.5.1. Validity

The validity of a survey relates to the ability of the item in a survey to measure the phenomenon it purports to measure.[260] Content validity refers to the "degree to which a measure covers the range of meanings included within the concept".[260] To assess content validity, the survey was assessed by a panel of people comprising a (a) qualitative research

expert; (b) Respiratory physician and Director, Clinical Epidemiology Unit; (c) medical student; (d) Clinical Nurse Consultant (CNC) in the ED; and (e) CNC, Neurology Unit.

Construct validity was determined by Q-sort. Q sort is a technique used to investigate self-concept, or how items are perceived by individuals.[261] The Q sort technique asks respondents to classify themes among data. Participants are asked to do this without consulting others. Categories for the Q sort were developed in collaboration with the qualitative research expert (Professor D Turnbull, Dept of Psychology, Lecturer: Qualitative Research Methods, University of Adelaide).

Reporting practices

Participants were asked to classify each of the eleven adverse events listed on the survey into one of following four themes the following themes:

- Hospital acquired infection/injury
- Act of commission (incorrect treatment or management)
- Act of omission (failure to diagnose or treat)
- Near miss (an event or situation that could have resulted in harm to a patient, but didn't, either because of good luck or timely intervention)

Barriers to reporting

Participants were asked to classify each of the nineteen barriers listed on the survey into one of following four themes:

- Disciplinary/legal/privacy barriers
- Practical barriers
- Peer-related barriers
- Unnecessary /ineffective/ communication barriers.

A convenience sample of five doctors (two interns and three consultants) and five nurses (three Registered Nurses and two Enrolled Nurses) were drawn from a variety of clinical areas in two public hospitals to participate in the Q sort. Recruiting staff for the Q sort used purposive sampling, a technique previously described.[214]

The PhD candidate elicited support from three consultants who were affiliated with the project as members of the project team. The two interns and all nurses were selected from the four types of units in hospital 1 to ensure that they represented a range of clinical areas

and ages. The PhD candidate approached nursing staff and interns and asked them to identify a time when they might spare ten minutes to assist with research. They were shown the Ethics Committee approval. By negotiating a time that best suited each person, all staff approached to participate in the Q sort were able to participate.

3.4.5.2. Reliability

Survey reliability refers to the ability of questions within a survey to provide accurate, consistent and trustworthy results, despite background fluctuations.[262] To be reliable a survey result should be reproducible and self-consistent.[263]

Test-retest reliability was undertaken on a convenience sample of fourteen medical (five Interns, one resident medical officer, six registrars, and two consultants) and ten nursing staff (four NUMs, four registered clinical nurses and two enrolled nurses). Participants were purposively selected by Project Officers to ensure that a range of seniority, clinical areas and ages was represented. At least one doctor and one nurse was chosen from each hospital.

Surveys were repeated seven to eight days after the initial survey was completed. Test-retest reliability was determined using a kappa statistic, and only questions for which there was at least moderate reproducibility (kappa ≥ 0.4) were included in the final survey tool.

Internal consistency, or the ability for related items within the survey to correlate with each other,[260] was measured for reporting barriers. Three questions measuring the same concept were inserted to gauge whether respondents reliably answered the questions.

I am worried about disciplinary action	=	I don't want to get into trouble
I don't feel confident that the form is kept anonymous	=	Even if I don't give my details, I'm sure that they'll track me down
The incident form takes too long to complete and I just don't have the time	=	The AIMS form is too complicated and requires too much detail

3.4.5.3. Pilot testing

The anonymous survey was piloted on a convenience sample of ten doctors (eight Consultants and two final year medical students) and ten nurses (three NUMs, six RNs and one EN). As with the Q sort mentioned in section 3.4.5.1, purposive sampling ensured that there was a range of clinical areas and ages represented in the pilot test.

At the completion of the pilot, staff were asked if there were any questions they had difficulty understanding or answering. Respondents were evaluated by the PhD candidate

for response time and their ability to answer each question. Following the pilot, a few minor changes were made in regard to the survey layout and this was subsequently reviewed by those participating in the pilot and found to be satisfactory.

3.4.6. Survey questions

In considering the survey content, and in view of the sensitive nature of the topic, a decision was made to make the survey self-administered to facilitate frank comment without fear of disclosure. Being self-administered, there was a need to keep the survey relatively short, as many clinicians had little time available to complete surveys. The survey contained only closed questions; however there was room at the end of the survey for respondents to document further comments in regard to reporting barriers. Closed-ended questions were chosen because they provided greater uniformity of responses thus making data processing and analysis relatively easy. A copy of the survey can be seen in Appendix 1.

Question 1 asked staff, "Does this hospital have an incident reporting system?" Those answering in the affirmative were asked, "Have you ever filled in an incident form?" Respondents were then asked, "Do you know how to locate or access the incident form?" Following this, they were asked, "Do you know what to do with the completed incident form?" In order to ascertain whether they knew which form to use, Question 5 asked respondents, "For each incident that you report, do you (1) use only the hospitals incident form; (2) use only the AIMS+ form; (3) use both the hospital incident form and the AIMS+ form; (4) use one or other, whichever I feel is more appropriate; (5) Never know which form to use. Most hospitals did not have a universal incident report form, but had a multitude of report forms for specific events. One metropolitan hospital had seven different report forms; one each for needle stick injuries, adverse drug events, Occupational Health and Safety injuries, buildings and maintenance faults, medical equipment and device incidents, and infection control incidents.

In Question 6, staff were asked, "Have you ever posted an anonymous AIMS+ form directly to the Australian Patient Safety Foundation (APSF)?" The role of the APSF in anonymous incident reporting is outlined in section 3.6.5.

Question 7 measured reporting practice. Staff were provided with eleven patient incidents representing a diverse range of common iatrogenic injuries.[20] Respondents were asked to comment on how often they did and how often they thought they should report each of these twelve incident types, using a four-point Likert scale (never, <50% of occasions, 50% or more of occasions, always).

To determine barriers to reporting, Question 8 provided respondents with nineteen barriers to reporting. Staff were asked to comment on the degree to which they regarded them as barriers, using the following Likert scale: 1 = strongly agree, 2 = agree, 3=neither agree nor disagree, 4 = disagree, 5= strongly disagree. If there were any barriers they felt were important but not captured, they were asked to include them in Question 9.

Questions 10 to 13 asked respondents to provide the following demographic details: gender, age, profession, and years post entry-level qualification spent in the acute health sector.

As discussed by Jackson and Furnham,[214] the layout of the survey was such that it started with straightforward questions, with sensitive questions in the middle and ended with easy questions The survey was designed to fit on an A3 sheet of paper, photocopied each side. Different coloured paper was used, dependent on the type of unit being surveyed. Surveys sent to staff on medical wards were coloured blue, surveys sent to surgical wards were coloured green, EDs were yellow and ICU surveys were white in colour. This served two purposes:

- It was easily identifiable. When contacting staff to improve response rates, researchers referred to the colour of the survey.
- It provided researchers with identification of the type of unit from which surveys came, thus assisting in targeting non-responders, and providing additional demographic data.

No more than one question was placed on each line of the survey, to minimize risk that questions would be skipped. Questions were short and succinct to make them easy to read and to give as much "white space" on the form as possible. Questionnaires that are cluttered with more than one question per line increase likelihood of achieving a poor response rate.[260]

3.4.7. Survey distribution

A consistent approach was used in the distribution of staff surveys across control and intervention units. A standard PowerPoint presentation was developed which outlined the reason for the study, the anonymous nature of the survey and its purpose in defining current reporting practice and barriers to reporting. Attached to each survey was an information sheet explaining the reason for the survey, names of contact persons and confirmation of the fact that the project had been reviewed by each hospital's Ethics of Human Research Committee (Appendix 2).

Nursing staff

The Director of Nursing (DON) and Nurse Unit Manager (NUM) of each department was contacted by the PhD candidate. Following a meeting to outline the components of the project and to ensure ongoing support, Project Officers allocated to areas commenced distribution of surveys. Each NUM was asked to provide Project Officers with a list of nursing staff so that they could tick off staff as they handed them a survey. Project Officers attended handover sessions in afternoons and overnight to give the presentation and distribute surveys. A box with narrow openings (to prevent staff from retrieving surveys out of the boxes) was left in each tearoom with a pile of blank surveys.

Medical staff

The Medical Head of each department selected for participation in the project was initially contacted by a Principal Investigator and the PhD candidate to explain the study and obtain support. Where possible, surveys were distributed at departmental meetings following the PowerPoint presentation. Where there was no departmental meeting, such as in one rural hospital and one metropolitan unit, doctors were contacted by telephone prior to posting surveys or delivering them in person. As has been shown to improve survey response rate,[264] each survey posted to doctors was accompanied by a personalised letter and a stamped return envelope.

Returned surveys were entered into a Microsoft Access database, allowing for Project Officers to tabulate response rates by type of unit (medical, surgical, ICU and ED) and by level of seniority within professions. Following distribution of surveys and allowing two weeks for responses to the posted in to the Clinical Epidemiology Unit, where response rate (for each level of seniority) was below 80%, the Head of Unit for that area was contacted and asked to remind staff to complete the survey. If after a subsequent two-week period the response rate remained below 80%, each doctor in that particular clinical area was contacted by a Project Officer and offered the opportunity to receive another survey if they had not returned the initial one. Non responders were those who could not be contacted by telephone after six to eight attempts were made, following confirmation that they were still employed in the relevant area.

3.4.8. Statistical analysis

Comparisons were made for doctors and nurses by profession, level of qualification, years post entry-level qualification spent in the acute health sector and rural/metropolitan location. For knowledge and use of reporting systems, log binomial generalised linear models adjusting for clustering by hospital were used. Likert scales were dichotomised into <50% of occasions or 50% or more of occasions for reporting practice, and into agree or not agree for reporting barriers. Analyses of reporting practices and barriers were undertaken using Fisher's exact tests. The conventional level of $p \leq 0.05$ was taken to represent statistical significance. Concordance between views on current reporting behaviour and necessity of reporting was determined using an intraclass correlation coefficient (ICC).

3.5. Focus groups

3.5.1. Introduction

Qualitative research using focus groups was undertaken to balance the quantitative data collected in the staff survey. Focus groups are considered by some to be the most suitable means of exploring the complexities of cultures which exist in health organisations.[265 266] They were used as a means of collecting data on incident reporting because (a) they provided an opportunity for doctors and nurses to discuss sensitive issues they may not have been addressed through the reasoned responses to direct questions in the survey;[211 213] (b) information could be collected more economically and quicker than using individual interviews;[212] and (c) it was thought that through interacting as a group they could provide historically important information about reporting and cultural issues relating to it.[211 212]

3.5.2. Aims

The aims of the focus groups relate to aim 3 of section 2.10. The focus groups aimed to:

1. use the structured format of Triandis' Behavioural Modelling Theory to examine attitudes of medical and nursing staff towards reporting incidents (adverse events and near misses); and
2. identify strategies to improve incident reporting.

With regard to each aims, the following hypotheses were generated.

Primary hypothesis 1

There will be differences in attitude towards incident reporting based on profession and level of experience within each profession.

Primary hypothesis 2

By asking users and non-users of the incident reporting system what works and what doesn't work, suggestions can be identified which can then be incorporated into the study design.

3.5.3. Focus group setting

Focus groups were conducted over a two hour period in the conference room of a health research organisation. This venue was chosen because it had built-in audio-visual equipment and a separate room with one way mirrors which enabled researchers to view the group and communicate with each other without intimidating or disrupting group

discussion. It was also chosen because it was independent of the hospitals from which respondents were chosen. If interviews were held at one hospital it could introduce bias into the study, as these people may feel more or less comfortable when compared to people from other hospitals.

The focus groups were conducted by an independent experienced health moderator for a number of reasons. Firstly, it was probable that a group might more readily disclose information to a person not associated with their hospital, particularly for a sensitive topic such as reporting of adverse events. Secondly, the PhD candidate had limited experience in conducting focus groups and it is recognised that moderators with little or no experience have been shown to inhibit conversation by adhering more strictly to guides, creating a more formal atmosphere and therefore stifling spontaneous conversation.[267] Thirdly, it was thought that the independent moderator would be less likely to introduce bias into the discussion, and would be able to provide another opinion in the analysis of the transcripts.

Three meetings were held with the moderator prior to the focus groups to provide verbal and written information about the subject area.

3.5.4. Focus group design

3.5.4.1. Sample

Recruitment for the focus groups was through purposive sampling from five units across three tertiary metropolitan public hospitals in Adelaide, South Australia (hospitals 1, 2 and 6). Each of the participating hospitals used the AIMS incident report form. Details of hospital demographics are provided in Table 3-2.

Only five of the ten intervention units were represented in the survey because, at the time that focus groups were being arranged, only three hospitals were included in the study (hospital 1, 2 and 5). Funding by the Department of Health enabled the project to be conducted in rural hospitals and in another metropolitan hospital, but this occurred after focus groups were arranged.

Non-random (purposive) selection of staff to attend focus groups occurred for two reasons;

- Focus groups were part of an intervention targeting selected clinical areas, and so it seemed appropriate to have staff of different seniority from those areas participate

- It was important to have a combination of people who used the reporting system and people who did not use it, to provide a balanced perspective. With only eight participants in each group it was likely that this would not occur without purposively sampling the population.

Medical and Nursing Heads of each five intervention units (two medical wards, one surgical ward, one ICU and an ED) were approached six weeks prior to the scheduled focus group dates and asked to suggest staff who might be advocates for, and opponents of incident reporting. A total of five focus groups for medical and nursing staff were pre-determined; one each for Consultants, Registrars, Residents and Interns, Senior nursing staff and Junior nurses and Enrolled nurses. The intention was to have six to eight participants in each focus group.

Separate focus groups according to seniority were specifically designed to;

- enable participants to voice opinion without fear of repercussion from more senior colleagues;
- provide a homogenous group dynamic to encourage individual opinion without fear of embarrassment, and minimize the likelihood of the group norm;
- assess the validity of the research through triangulation, a technique using different methods of data sources to compare findings.[268]

Focus groups were held over a two day period in March 2002. Participation was voluntary, and to encourage attendance transport costs were met, lunch or supper was provided and a modest honorarium provided (A$20). Heads of Units and Business Managers were advised that backfill for staff attending the focus groups would be provided from project funds. Reminders were sent to the Heads of Units a month before the scheduled dates for the focus groups, and thereafter on a weekly basis. Once participants were identified by the Medical and Nursing Heads they were individually contacted by the PhD candidate or a member of the project team to thank them for their participation and to explain the process. Times for the focus groups were arranged to maximise convenience for staff and are set out below in Table 3.3.

Table 3-3 Focus group timetable

Staff member designation	Focus Group timetable
Junior nursing staff	Tuesday 1430hrs – 1630hrs.
Interns and Resident Medical Officers	Tuesday 1630hrs – 1830hrs.

Staff member designation	Focus Group timetable
Consultants	Tuesday 1900hrs – 2100hrs.
Senior nurses	Wednesday 1430hrs – 1630hrs
Registrars	Wednesday 1630hrs – 1830hrs

3.5.4.2. Focus group guide

To assist in achieving objectives, a guide was constructed to be used by the moderator in extracting appropriate information from participants (Table 3-4). Although it was considered not necessary to strictly follow the order of the guide, it was important that members of each group covered the points in the guide.

Table 3-4 Topic guide for the focus groups

Question	Relevant aim
What comes to mind when you hear the word incident reporting?	1
What is the current reporting process in your organisation	1
Can you think of any positive things that have occurred as a result of completing an incident report? Can you think of any negative things?	2
How would you rate the current reporting system?	2
If you were in charge of the incident reporting system, what changes, if any, would you make?	3
How many times a year, on average, do people in your position fill out incident reports?	1, 2
Why do people decide to complete an incident report?	2, 3
How do you think people feel when they complete an incident report?	2
Based on your experience, how many times a year should people in your position fill out an incident report?	2
What makes a person decide not to complete a report?	2, 3
Does the seriousness of the situation have any bearing on whether an incident report is made, or not?	2
On the sheet, I have listed some o the obstacles to reporting. Do you have any comments? Which of these do you regard as the really big issues? Are there any other obstacles?	2
Would having a form with the option of not identifying the reporter make a difference?	3
Is there anything else we should have discussed that we haven't touched on yet?	

3.5.4.3. Ethics approval

Approval was obtained from each of the Research and Ethics Committees involved in the focus groups: the North West Adelaide Health Service (The Queen Elizabeth Hospital and Lyell McEwin Health Service) and Royal Adelaide Hospital (Appendix 2).

3.5.5. Statistical analysis

Transcripts of the focus groups were entered into NU*DIST software[269] for semi-quantitative analysis, utilising categories of behaviour prediction (habit, intention, motivation, perceived consequences, social and emotional factors and facilitating conditions) comprising Triandis' Model of Social Behaviour (Figure 3-3). While there are many models used to assess reasons for behaviour, Triandis' Model was chosen because it was seen to have much greater relevance for health education when compared to other more popular models, such as the Health Belief Model and the Theory of Reasoned Action Model.[270] Due to the exploratory nature of the research, the equation was used for thematic categorisation rather than prediction of behaviour.

Figure 3-3 Triandis' Equation

Probability of an act = (Habit + Intention*) x (Motivation x Facilitating Conditions)

*** Intention = Social factors (subjective culture) + Affect + Value of perceived consequences (positive and negative)**

Transcripts were initially reviewed independently by the PhD candidate and a Project Officer (Marilyn Kingston, RN RM BAPsych [Hons]). Using Triandis' Model, comments were categorized according to which of the six components of the equation were best suited.

Definitions in Table 3-5 were used to clarify comments. Comments were classified into the appropriate category by the PhD Candidate and a Project Officer (Marilyn Kingston, RN, RM, BAPsych (Hons)) independent of each other. Following this, they met to discuss the branches of the tree into which comments had been classified. On the rare occasion that there was not agreement on where comments should be categorised, a third person (another Project Officer) adjudicated. An independent report was written by the moderator following the focus groups to further assess reliability of the findings.

Table 3-5 Definition of terms in Triandis' Equation

Term	Definition
Habit	Situation-behaviour sequences that are or have become automatic, so that they occur without self-instruction. The individual is not usually "conscious" of these sequences.[271] With the exception of new situations (which require deliberate and controlled effort) habits are the most important predictor of behaviour.
Intention	Self-instruction to perform an act. It comprises social factors, affect and perceived consequences.
Social factors	"Comprise the individual's internalisation of the reference group's subjective culture, and specific interpersonal agreements that the individual has made with others, in specific social situations, constitute social factors that determine behavioural intentions".[271] Beliefs, attitudes, ideals, roles, norms and values of peers that impact on a person's decision to perform an act.
Affect	Refers to the emotions a person feels at the thought of the behaviour and includes such emotions as joy, disgust, depression, displeasure, intimidation, and embarrassment.
Perceived consequences	Each act is perceived as having some consequence. Perceived consequences may be positive or negative, and are often dependent on previous experiences.[272]
Motivation	The ability to stimulate the interest of a person in an activity, and is closely linked to perceptions of positive consequences.
Facilitating conditions	Objective environmental factors that several observers can agree make an act easy to do.[271]

3.6. Intervention

3.6.1. Introduction

The intervention was implemented in ten units across six hospitals in South Australia, and comprised a number of different strategies aimed at improving reporting rates by medical and nursing staff. These were developed after analysis of focus group transcripts and the staff survey (see section 4.4.6 for summary of staff survey results and section 4.5.3 for summary of results of focus groups).

Initially, an outline will be provided of:

- The aims, study design and setting for the project
- A description of the current reporting processes in place for staff in each of the participating hospitals at baseline
- A description of the pre-existing AIMS+ reporting system and the Advanced AIMS database used in intervention units during the study period.

Following this, the intervention will be discussed according to the four components targeted in the design of the study, following analysis of the focus group and staff survey results:

- a need to make the reporting system easier to use.
- a need to make the processes for managing incidents less threatening and more effective in ensuring that appropriate people responded to incidents.
- a need to provide education to doctors and nurses about protection afforded to the system and incidents that should be reported.
- a need to provide feedback about outcomes arising from incident reports.

Finally, the implementation aspects of the project will be discussed, including the roles of the project team.

3.6.2. Aims

The aims of the intervention were broadly outlined in aim 4 of section 2.10. The intervention was designed to elicit from staff whether strategies developed following analysis of the staff survey and focus groups would result in:

- Improved reporting rates by medical and nursing staff compared to baseline;

- A change in types of incident reported by medical and nursing staff compared to baseline.

With regard to each aims the following hypotheses were generated:

Primary hypothesis 1

The implementation of an intervention that addresses barriers to reporting will result in an increase in reporting rates from baseline and an increase in satisfaction with, and understanding of the incident reporting system by nursing and medical staff.

Primary hypothesis 2

Through education and discussion with medical and nursing staff, and by addressing issues identified through incident reporting, there will be a change in the pattern of incidents (types of incidents and incident severity) reported over the study period.

3.6.3. Study setting

The study population was identical to the population surveyed in section 3.4.3 of the staff survey.

3.6.4. Study design

This study was designed as a matched controlled study to compare incident reporting rates and types of reports generated between (a) control and intervention units and between (b) baseline and the study period.

The sample, including inclusion and exclusion criteria were identical to that in the staff survey, as set out in section 3.4.4 of the staff survey.

3.6.4.1. Control and intervention units

Rural hospitals

In rural hospitals departments were allocated into intervention and control units. The rural ED in hospital 5 and the inpatient areas in hospital 4 were allocated as intervention units. Control units were areas in the corresponding rural hospital. This was done because the rural ED in hospital 5 was staffed by its own doctors, whereas the ED in hospital 4 was staff by GPs who also managed patients in inpatient areas. Because the intervention could be relatively contained in the ED, it would reduce contamination of inpatient areas.

The study design was such that the rural control ED was staffed by GPs who were also working in intervention inpatient areas. This meant that if GPs reporting practices improved

as a result of the intervention, it might also lead to improved reporting in the control ED, thus diminishing the effect of the intervention.

Metropolitan hospitals

Each metropolitan hospital had one or more control unit. Medical intervention units in hospital 1 and 3 were matched with other medical units in the same hospital as well as with specialty medical units in the other hospital (see section 3.4.4). Figure 3-2 shows the location of the rural hospitals and Table 3-2 outlines the type of unit, the matched units, bed numbers in Department or, in regard to EDs, the number of ED attendances per year.

In most metropolitan hospitals departments were allocated into intervention or control units. The exception was the medical and surgical departments in hospital 2 which were randomised into control and intervention units after the survey component of the project was completed.

3.6.4.2. Baseline and study periods

Incident reports lodged during the 40-week intervention period were compared with incident reports generated for the same period of time in the preceding year. This was designed to take into account seasonal factors which might affect incident reporting. Seasonal factors include (a) recruitment of new staff, which often occurs at the start of the year for junior doctors and nurses (b) cyclic trends in reporting (historical data showed that most reports were generated in the months April to July and fewer reports generated between November and February).

The project timeline is outlined in Table 3-1. For each unit there was a window period of two months between baseline and intervention periods when staff education commenced. As seen in Table 3-1, staff surveys were distributed in both the control and intervention units in the few months prior to the baseline reporting period. Additionally, a sub-group of staff from five intervention units attended focus groups prior to the baseline period.

3.6.5. Background- the existing reporting system

3.6.5.1. Reporting processes

As discussed in section 2.5.2 of the literature review, the AIMS reporting system was established in 1988 in Australia with the aim of collecting detailed qualitative and anonymous data about any unintended incident.[9] Initially it was used for anaesthetic-related incidents, but in 1992 it was introduced into other clinical areas. There were various

iterations of the report form, but for at least five years hospitals involved in the project had been using the AIMS+ incident report form (Appendix 3).

Data from AIMS+ forms were entered into an AIMS+ database, which was configured as a stand-alone application on personal computers. Prior to the intervention, incident reports in each of the participating hospitals were managed in a similar way, as set out below.

Nursing staff

Nurse-generated reports were completed and left for a doctor to complete their section of the report. In most instances the reports were validated and commented on by doctors. Once completed, the incident report form was forwarded to the NUM either by having forms left on notice-boards, placed in a tray in the ward clerks area, placed on the NUM's desk, under the door to the NUM's office or left on the desk in the nurses' station. The role of the NUM as set out by the Nurses (ANF - South Australian Private Sector) Award 2003[273] was to provide leadership at a departmental level.

Once received by the NUM, nurse-initiated reports were followed up and results of evaluation following investigation were recorded in the management report, which was on the back page of the incident form. The NUM was responsible for giving each incident an outcome measure of between 1 and 8 (see Appendix 4 for description of categories).

The report would then be sent to respective third parties for comment if the NUM thought this appropriate. If the report was sent to a third party, it was often photocopied, faxed or sent in the internal mail service. Examples of reports sent to third parties for comment include:

- Equipment faults sent to biomedical engineering
- Medication incidents sent to a pharmacist
- Incidents implicating staff in other areas (eg staff in the ED or Operating Room) sent to respective Managers
- Staff accident reports sent to Occupational Health and Safety representative
- Incidents regarded as having a high risk of leading to legal action by the patient were forwarded to the Risk Manager
- Incidents implicating medical staff or relating to medical management sent to Medical Head of Unit/Director of Medical Services.

Following investigation and comment by the third party, the incident report would be returned to the NUM of the initiating department or forwarded directly to the NUM's line manager for comment. In metropolitan hospitals, it was the Divisional Nursing Head and in rural hospitals reports it was the Director of Nursing. From there, reports would be sent in batches to the clinical coder in each metropolitan hospital and to a central coder in rural hospitals, where details from the report were entered into the AIMS+ database. It was not uncommon for there to be a four to six month interval between generation of the report and entry of report details onto the database.

Medical staff

Doctor-initiated reports were initially sent to the NUM. The NUM would investigate where necessary and complete a senior staff member's comment in the management section of the report and also the incident outcome code, before forwarding a copy of the report to the Medical Head of Unit for their information and for them to action where necessary. Where relevant, the Medical Head of Unit would place a comment in the management report to "sign off" that the appropriate steps were taken. The Medical Head of Unit would normally be responsible for discussing outcomes of the report with the reporter; however it was generally the NUM who would forward reports to relevant third parties for comment and action, and send the report to the coder to be entered into the AIMS database.

Anonymous reports

There was provision in the reporting system for staff to report anonymously through their hospital's reporting channel or by sending their report directly to the APSF.

If staff reported anonymously within their own hospital, reports were lodged through their line manager in the same way as for identified reports. Staff in focus groups (see section 4.5) voiced concern that their line manager could identify their handwriting, and that they were required to sign the report which made it very difficult to remain anonymous. Many doctors and nurses in the focus group were unfamiliar with the fact that they had an option to report anonymously. Despite the fact that the AIMS incident report form used in each of the hospitals stated that staff were not required to identify themselves, this was difficult to see on a very busy form. The AIMS form is attached as Appendix 3.

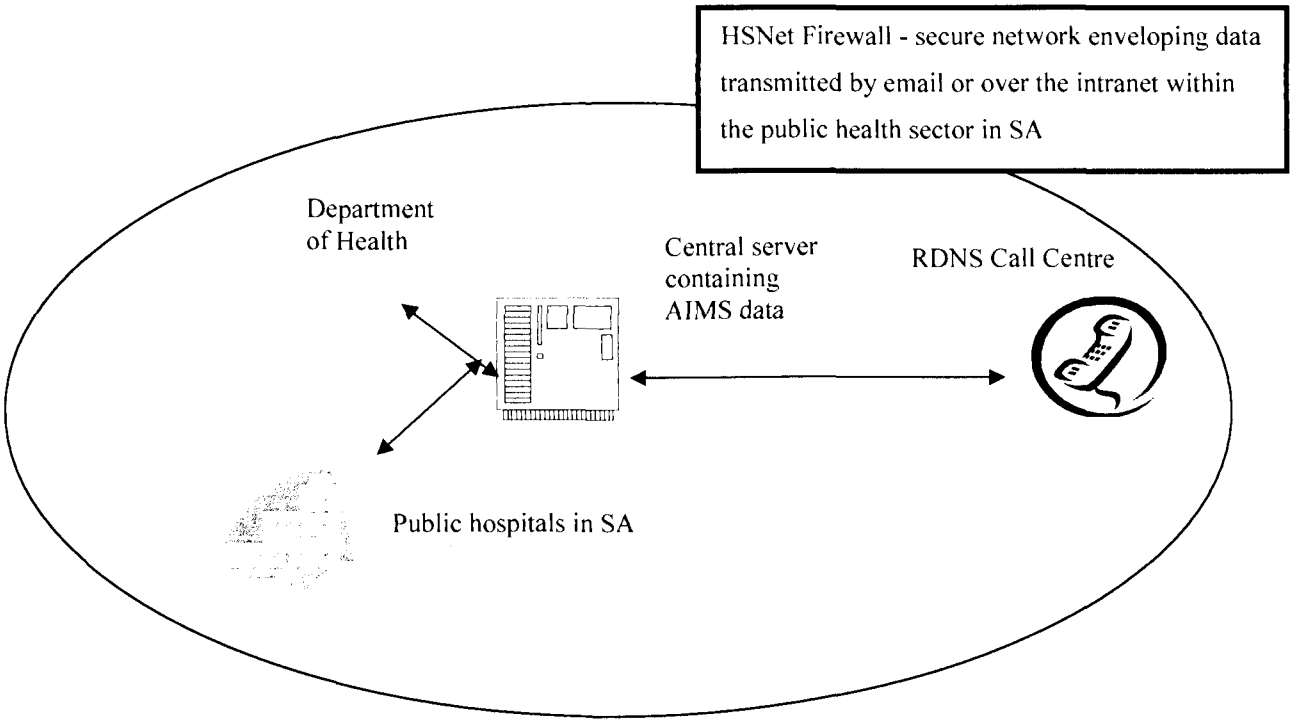
If doctors and nurses sent their incident report directly to the APSF, all identifiable data was removed prior to being entered into the national database. Obviously, for these incidents it was not possible for report details to be sent back to the hospital from where it had been generated so that local action could be taken.

3.6.6. The Advanced AIMS reporting system

In early 2003, the Department of Human Services purchased from Patient Safety International (the for-profit arm of the APSF) an upgraded version of AIMS (Advanced AIMS) which was designed to be used as a centralised application. Both the AIMS+ and the Advanced AIMS reporting systems were protected as quality assurance exercises under the Health Insurance Act, 1973 (Appendix 5).

The centralised 'Statewide' incident reporting system was developed at the same time as this project, with the first institutions to pilot the use of the Advanced AIMS database being the intervention units in this project. Figure 3-4 shows that the centralised application was configured to enable information to be transmitted via a secure network (HSNet).[274]

Figure 3-4 Network environment established for AIMS



Important differences between the AIMS+ database and the Advanced AIM database were associated with the classification of incident types and the severity scales. These will now be discussed.

3.6.6.1. Incident types

Incidents entered into both the AIMS+ and the Advanced AIMS databases were classified with a Principal Incident Type (PIT). The PIT refers to the incident type that resulted in the worst outcome or potentially the worst outcome in the case of a near miss. The Advanced AIMS system included more PITs than the earlier AIMS+ system (Appendix 6). Examples

of each of the fifteen PITs in the Advanced AIMS reporting system are outlined in Table 3.6.

Table 3-6 Examples of incidents in each of the Principal Incident Type (PIT) categories in the Advanced AIMS reporting system

Field name Advanced AIMS	Examples of incidents
Fall	Walking, running, standing, sitting, attempting to sit or stand, getting in or out of bed, climbing over or around bedrails, bending, leaning or reaching over, transferring, other
Medication or IVs	Prescribing, dispensing, labelling, delivery, supply or ordering problem, omission, suspected omission, underdose, overdose, suspected wrong dose, wrong medication or IV fluid, medication or IV fluid administered when not prescribed, wrong route, patient, timing, frequency or rate, formulation, presentation or device for administration, allergic reaction, other
Documentation	Content not entered, incorrect, difficult to read, ambiguous or difficult to understand, transcription error, incorrect document, document not available or absent, wrong patient's document used, document damaged, design problem, filing or storage problem, other.
Behaviour/ human performance	Communication problem, inconsiderate behaviour, inappropriate behaviour, did not follow requests, instructions or advice, non-compliance or obstructive behaviour, discrimination, prejudice or harassment, intended self-harm, suicidal or attempted harm, attempting to abscond or absconded, self-discharge, medication misbehaviour problem, illegal substance problem, other
Aggression	Discrimination, prejudice or harassment, verbal aggression, bullying or intimidation, aggression towards an inanimate object, throwing of an object, physical assault, death threat, sexual assault, other
Accident/OH&S	Needle stick injury, exposure to a hazardous substance, a patient sustains an injury of unknown origin, a staff member sustains a burn after spilling a hot drink over their arm, a wet or slippery floor surface.
Pressure ulcer	New pressure ulcer, worsening of existing pressure ulcer
Medical device, equipment, property	Not used, incorrect or inadequate use, difficult to use, damaged, malfunction, wrong equipment used, inappropriate for task, poorly designed, dislodgment or disconnection, unintentional removal, not removed when ordered or indicated, service or maintenance problem, not checked or calibrated, unclean or unsterilised, not safe to use, availability problem, software problem, other
Buildings, fittings, fixtures, surrounds	Damaged, faulty or worn, inadequate design, inadequate function, contamination or environmental hazard, pest infestation, exposed wiring, other

Field name Advanced AIMS	Examples of incidents
Blood or blood products	Prescribing or ordering problem, dispensing problem, delivery problem, omission, wrong blood or blood product, wrong timing frequency or rate, wrong dose or volume, administered with contraindicated substance, administration technique error, poor blood quality, reaction, storage or waste problem, group, cross match or save not performed, patient refused, other
Oxygen/ gases	Omission, not prescribed, wrong gas, rate, frequency, time, route, concentration, gas given when not prescribed, cylinder labelling/identification problem, storage problem, contamination, other
Security	Presence of an unauthorised person, person behaving suspiciously, keys or access device problem, criminal concerns, security of information or breach of confidentiality, area not secured, security alarms not set, no one allocated to perform task, no regular schedule, detection or surveillance not performed or inadequately performed, other
Clinical management	Not done, delayed, incorrect or inadequate, wrong body part or site, unnecessary assessment, test or procedure, patient preparation and education, maintenance of care, difficult to insert, removed when not indicated, not removed or ceased when indicated, inadequate universal precautions, non-adherence to rules, policy, procedure, protocol, post-procedural disorder, other
Hospital-acquired infection	Infected IV site, bacteraemia
Organisational management	Delayed, inappropriate, inadequate, not available, non-existent,

3.6.6.1.1. Classification of incident types

In the baseline period, most incidents were entered into the AIMS+ database by the hospital or regional clinical coder. The exceptions were all incidents in hospital 2, and for a four-month period in hospital 5, where no data entry had occurred. Clinical coders for each organisation were RNs who had undergone a training course in data entry techniques and classification of incidents.

Each incident recorded into the Advanced AIMS database during the study period in the intervention unit was classified into one of fifteen PITs by either the reporter (on-line reporting), the Call Centre registered nurse (telephone reporting), the Patient Safety Manager (anonymous paper-based reports), the line manager (one page reports) or Project Officers (one page reports).

It was often difficult to classify the PIT. For example, a fall resulting from postural hypotension caused by an overdose of antihypertensive medication may have had either fall or medication as its PIT. To assess the consistency of the incident type classification in the Advanced AIMS system, fifteen incident reports from most of the Advanced AIMS PITs were selected, all identifying information and the PIT category was removed and they were independently reclassified by an Advanced AIMS clinical coder in the Department of Health.

3.6.6.2. Incident severity

In addition to documenting the incident type, each incident was assessed for its severity and given an outcome measure. Baseline data in the AIMS+ database was classified according to levels set out in Appendix 4, while intervention units classified incidents according to the Risk Matrix outlined in Appendix 7. Due to differences in the severity scoring system between the two databases, it was not possible to accurately compare the data in the baseline and intervention periods. For this reason, severity analysis was not undertaken as a component of this study.

3.6.7. Making the reporting process easier

Three strategies were developed as part of the intervention to make the reporting process less cumbersome for staff. The AIMS+ form was simplified and reduced to a single page. A Call Centre was introduced to enable doctors and nurses to lodge reports at any hour of the day or night over the telephone. Electronic reporting was introduced to enable reporters to lodge a report directly into the database. Each of these three strategies will now be discussed.

3.6.7.1. Single page incident report form

Form design

Based on feedback from the focus groups, in which staff stated that a simpler form would provide greater incentive to reporting, the form was condensed to a single page. To reduce burden the form was collected only a minimum dataset. The form was purposely designed using similar colours to the AIMS form, to make it recognisable to staff who were familiar with the AIMS form. Once the fields for inclusion into the form and colours were determined, a graphic designer assisted in producing the finished product.

The form incorporated a Risk Matrix developed by the Department of Veterans Affairs National Center for Patient Safety as a means of categorising incidents in hospitals.[275 276]

The risk matrix is attached as Appendix 7. Four months after the project commenced, the form was modified from the 4x4 table to a 5x5 matrix, which was adopted from the Australian Standard 1999: 4360 Risk Management[277] (Appendix 7). The reason for changing to the 5X5 matrix was to be consistent with the matrix adopted by the Clinical Systems Unit, Department of Health, Government of South Australia for use in the Statewide AIMS database. Appendix 8 shows the amended incident form, known as the IRIS (Incident Reporting to Improve Systems) form. Reporters were asked to rate the actual severity of the incident as it was at the time of the report, and the likelihood that the event would recur.

In contrast to the AIMS report form used in the baseline period, the single page form was developed without a management component, for the following reasons:

- It was important that NUMs and Heads of Units became familiar with and use the AIMS database. A forcing function for having them use the database was removing the possibility that they could use the form.
- The form needed to look simple, so that staff would not perceive it as being too onerous to complete the form. By removing the management component, all details could be condensed to a single page.
- It may have been perceived by reporters that they were required to hand the form to their supervisors for comment if the management component remained on the form Some junior staff had stated reluctance to do this in focus group discussions. By removing this section there could be no confusion over where the form was to be sent.

Pilot testing

The single-page form was initially assessed by members of the IRIS Committee, which was established prior to the intervention commencing as a means of seeking input from and sharing information with staff from each of the hospitals involved in the project. The Terms of Reference, including Committee membership are attached as Appendix 9.

Nurses

Following feedback from the Committee and subsequent modification, meetings with senior nursing staff (six NUMS) and junior nursing staff (three RNs and two ENs) were held to gather feedback on the form design and other components of the intervention, prior to its implementation. Teleconferencing was made available to enable one senior nurse and one

junior nurse from an intervention unit at each of the rural hospitals to participate. The meeting was informal and was facilitated by the PhD candidate.

Doctors

The Medical Head of each respective unit participating as an intervention unit in the study was contacted and given a copy of the form for comment. Medical Heads were provided with the existing AIMS form and the proposed form for comparison. In addition to having the form assessed by the Medical Head of Unit, six randomly selected doctors working in three of the metropolitan intervention units in one hospital were asked to comment on the form layout, readability and functionality.

All proposed revisions to the form were discussed by members of the project team prior to being implemented.

3.6.7.2. Call Centre

In response to feedback from the staff survey in which a large percentage of medical staff reported that they did not know how to locate a form or know what to do with a completed form, and as a means of facilitating reporting, a Call Centre was introduced in the intervention units as one means by which doctors and nurses could report incidents.

Call Centre design

Essential criteria in developing a Call Centre was that

- it be accessible 24 hours a day, 7 days a week because adverse incidents are not confined to office hours
- it involve contact with a person rather than an automated service. It was felt that staff would prefer to speak to a person rather than a machine and the complexity of incidents would require reporters to answer a number of different questions which would be difficult to achieve using an answering machine. Using touch tone telephone prompting was an option, but researchers considered that added inconvenience would deter rather than encourage reporting. Additionally, it was anticipated that staff might report using mobile phones in the car, and touch tone prompting would not be advisable in this setting. If incidents were recorded onto an answering machine, they would still need to be transcribed into a database, making direct entry reporting into a database by a person a more timely mechanism
- calls be answered by an RN. It was felt that (a) an RN would be familiar with hospital activity and would likely have greater rapport with reporters when

compared to people without this knowledge; (b) familiarity with medical terminology was important; and (c) accuracy of the report was critical, particularly when staff made anonymous reports where there was no capacity to clarify or seek further information.

Legal considerations

In developing a Call Centre to facilitate incident reporting, legal implications needed to be considered. It was imperative that the introduction of a third party (Call Centre RNs) to whom reports were to be made would not hinder the legal protection afforded to the process. Following advise from legal counsel (Solicitor from the Crown Solicitor's Office), strategies were introduced to enable the process to maintain its legal protection (Table 3-7).

Table 3-7 Issues raised by legal counsel regarding Call Centre development, and strategies implemented to address them

Issue raised	Strategy/ies implemented to address issues
Authorisation must be given by each hospital's Chief Executive Officer and Board to release information to the Call Centre for the purpose of obtaining confidential information about adverse incidents within their institution.	Consent was provided from each hospital's CEO and Board
Contract should have a Confidentiality clause stating that information must be kept confidential and a fine imposed for non-compliance	Confidentiality clause inserted. The Call Centre provider was also required to show that they had appropriate Indemnity Insurance.
Reporters should be informed of the legal protection afforded to the reporting process and the need to report separately to the Risk Manager if there was any likelihood that the incident might result in a claim being lodged by patient/ family member.	Disclaimer inserted stating that "Information given cannot be used in legal proceedings, so it is important that you let your Risk Manager know if you think there is any chance of litigation. Make sure that you keep medical records up-to-date".
To minimize any risk of disclosure, the Call Centre provider should not hold any incident details on site.	Incident information recorded directly into a centralised database. Notes were to be shredded and disposed of in a confidential waste receptacle by a registered waste management company. If the AIMS system could not be accessed, reports were to be faxed to the Clinical Epidemiology Unit and the original shredded. The fax number was to be programmed into the machine. Both machines were to be housed in a secure lockable room where there was no thoroughfare.

Telephone number

It was important that the telephone number for staff to contact the Call Centre be easy to remember by doctors and nurses. A freecall number was considered preferable so that people could feel free to ring from mobile phones without incurring the cost. Freecall numbers generally begin with 1800 preceding 6 digits. Project Officers were asked to nominate some 6 letter words for consideration. The two most popular words were 'report' and 'notify'. Notify was felt to have a less punitive connotation. The telephone number 1800 NOTIFY (1800 668 439) was secured six months prior to intervention commencing, allowing time for promotional material to be produced.

Reporting process

The Call Centre operated twenty four hours a day, seven days a week. Reports were entered by Call Centre personnel directly into the AIMS database. If the central database was not able to be accessed because of technical difficulties, Call Centre nurses were directed to fax the incident report directly to the Clinical Epidemiology Unit, where it would be sent on accordingly.

Pilot testing

The Call Centre was piloted over a one month period. Mock reports were lodged by four researchers from within the Clinical Epidemiology Unit and two medical officers who were not working in the intervention units at the time of the study. Evaluation was based on the Call Centre RN's ability to (a) remain objective; (b) take a thorough and factual account of the event; and (c) accurately document details into the database in a timely manner. A total of twenty reports were lodged over the pilot period. Feedback from reporters was recorded on a form, and the researchers met with Call Centre educators to discuss results and modifications to the reporting process weekly for one month. Modifications included shortening the disclaimer as much as was possible whilst ensuring that it still contained key messages and changing some mechanisms for collecting data.

Key performance indicators (KPIs)

As part of the Contract, a number of KPIs were established which were based on widely accepted industry performance indicators[278] and were chosen to assess the following:

1. Whether the Royal District Nursing Service was adequately staff to accept calls in a timely manner (indicator 1, 2, 3);
2. Proficiency of the call centre operators to collect and record information (Indicators 4 5 and 6);

3. Professionalism of the approach of call centre operators (Indicator 7).

The expected level of achievement in Call Centres reflects the type of information they are collecting. For example, a KPI for the Emergency Services Call Centre (telephone number 000) is that 85% of emergency calls using the emergency service number 000 or 112 are answered within 5 seconds, and that 95% are answered within 10 seconds.[279] The KPIs set for this project were considered very hard to achieve by most commercial industries[280] and are listed in Table 3-8.

Table 3-8 Key performance indicators used to evaluate the Call Centre

Indicator	Key performance measure
The percentage of calls answered within a timeframe	Greater than 90 % of calls will be answered within 20 seconds. The remaining 10% will be answered within 1 minute
The percentage of calls that leave the Call Centre without being answered	Less than 2% of calls will leave the Call Centre unanswered (Incomplete Calls).
The percentage of calls which are placed 'on-hold' whilst a report is being taken	Less than 10% of calls will be placed on hold and that this will not be for longer than 30 seconds.
The percentage of calls which are completed within a given timeframe	90% of calls will be completed within 10 minutes. The remaining 10% will be completed within 20 minutes.
The percentage of incidents which are entered into the AIMS database in a timely manner	90% of incidents will be forwarded within 30 minutes of a completed call, with remaining 10% forwarded within 1 hour of the report being generated, unless this is not possible due to IT problems in which case, the reports will be forwarded within 1 hour of the system being operational.
The percentage of incident reports which are completed in an accurate manner	Less than 10% of reports will contain errors, as audited by IRIS Project Officers
The number of complaints received by the Client.	Less than 5% of callers will complain about the service, where a complaint is defined as 'any expression of dissatisfaction with the provision of a telephone service'. This will be assessed through audit, which will occur on an on-going basis

3.6.7.3. On-line reporting

On-line or electronic incident reporting enabled medical and nursing staff in one intervention unit to lodge a report directly into the AIMS database. Security settings ensured that staff accessing the AIMS database to lodge a report were only given access to

details of their own reports, including all comments inserted by senior staff members and third parties. Staff were not given permission to lodge a report from any area other than the ICU. Following scheduled education in-service sessions for day and night staff, staff were invited to nominate a username and password confidentially if they thought that they would use the on-line reporting option. An information card explaining how to access AIMS database and the sorts of incidents staff should report was placed above each computer on a notice board. To attract attention to the information card, it was fluorescent yellow in colour.

The metropolitan hospital ICU was chosen as the most appropriate site to introduce on-line reporting. Only one intervention unit was chosen for the following reasons:

- Rural hospitals were only permitted to have AIMS accessible on eight computers, because there was limited bandwidth available in rural hospitals to transmit information to the centralised server.
- The establishment of on-line reporting required considerable infrastructure and resources to establish, particularly in regard to Information Technology support.
- On-line reporting required that staff logged in to the database using their own user name and password. Providing staff members with access permissions was time-consuming and difficult to administer, so it was considered most appropriate to trial it in a smaller area, acknowledging that results could only be generalisable to similar clinical settings.
- It was surmised that staff in ICU would be more likely to adopt on-line reporting than other clinical areas because there was a computer stationed next to each bed in single rooms, and staff in ICUs were required to have knowledge of the computer as it was used to record and retrieve patient information.

Two suggestions made in focus groups to make the reporting process easier were not implemented because they were not seen as being sustainable after the project finished. The first involved having a Project Officer attend daily ward rounds and complete incident reports when adverse events were identified. A study by Leape,[281] in which pharmacist participation on Physician's rounds in an ICU resulted in an increase in detection of adverse drug effects, however this was not sustainable due to increased costs. The on-going funding for a Project Officer to attend ward rounds was unlikely. A compromise was to have the medical staff and nursing staff educated about incident reporting and simplifying the process. The second suggestion not implemented involved paying incentives for incident

reporting. Although there is evidence that financial incentives are effective in improving incident reporting (see Section 2.9.1.2), this was not implemented because it excluded people who reported anonymously and was also not considered sustainable after conclusion of the project.

3.6.8. Improving reporting processes

Focus group participants, particularly junior nursing staff and medical staff voiced concern over the perceived dominance of the reporting system by nurses. Junior nurses were concerned about disciplinary action arising form reports. The reporting process was changed in the intervention units, as outlined below.

Single page report form

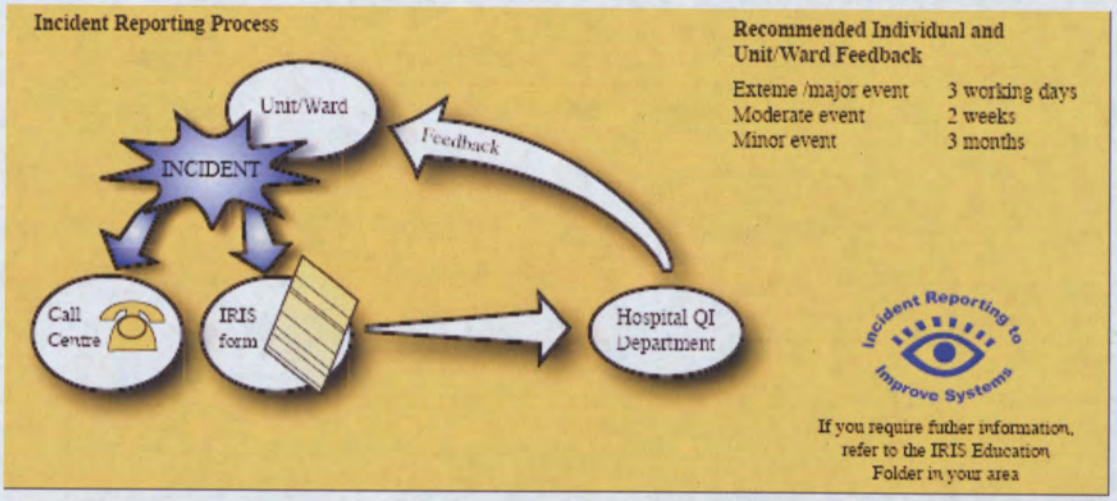
All paper report forms were initially sent to a designated person within the Quality Improvement Department in each hospital, as outlined in Table 3-9.

Table 3-9 Position title and department where incident reports were sent in the intervention units

Hospital	Position title	Department
1	Patient Safety Manager	c/- IRIS Project Officer, Clinical Epidemiology and Health Outcome Unit
2	Patient Safety Manager	c/- Quality Improvement Office
3	Patient Safety Manager	c/- Clinical Practice Unit
4	Patient Safety Manager	c/- IRIS Project Officer
5	Quality Improvement and Customer Liaison Officer / Patient Safety Manager	c/- IRIS Project Officer
6	Patient Safety Coordinator	Clinical Practice Unit

In this way, reports initially bypassed the NUM (see Figure 3-5). Attached to each incident report was a freepost pre-addressed envelope which enabled staff to send incident reports using the internal mail service in each hospital or from outside the hospital via conventional mail service.

Figure 3-5 The reporting process documented on the back of each on-page incident report form



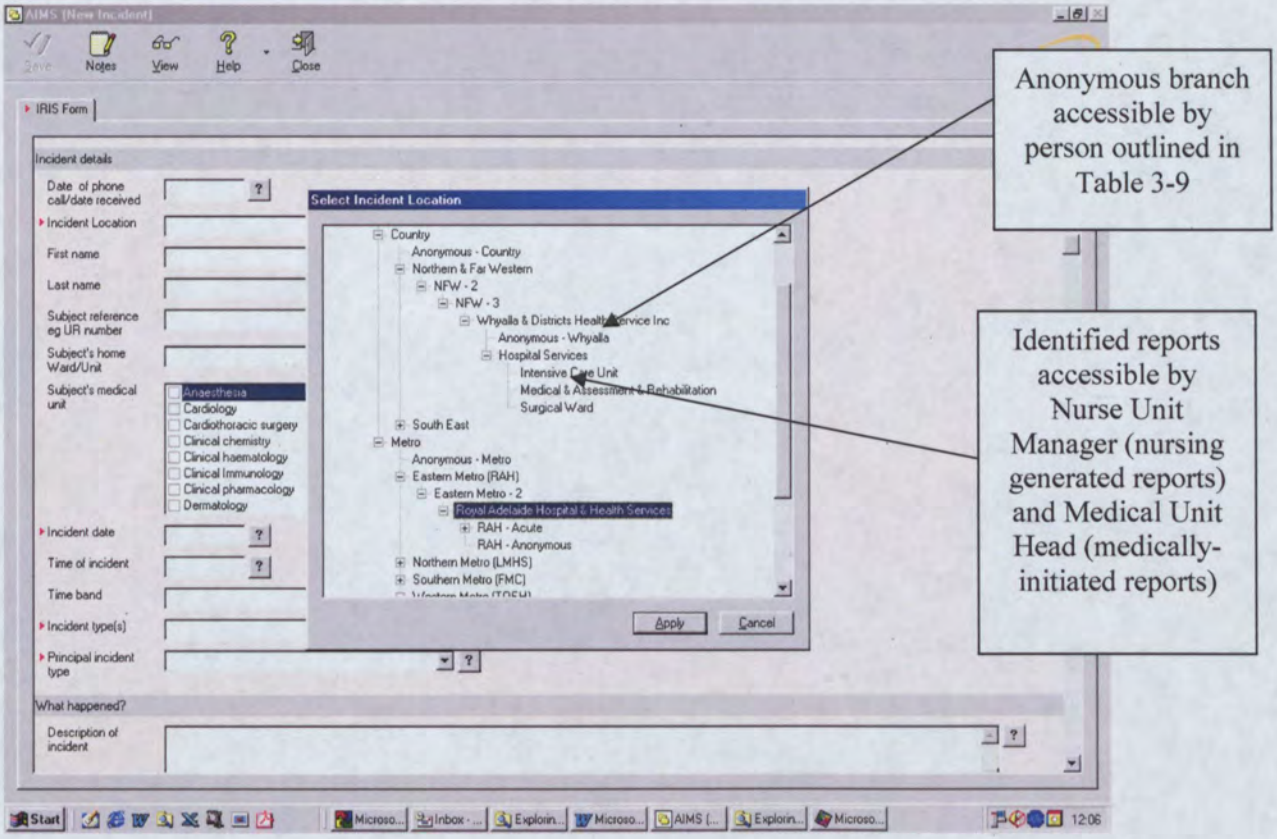
Within the department receiving the incident reports, the Patient Safety Manager or Project Officer reviewed the form to ensure that (1) incidents with the worst outcome were processed first; and (2) reporters had correctly categorised the incident by its outcome. The report was then entered into the AIMS database. A report was said to be 'anonymous' if it:

1. Provided the reporter's name but not the location of the incident
2. Provided the location of the incident, but not the reporter's name
3. Provided neither the location of the incident nor the reporter's name.

Call Centre reports

Call Centre personnel asked reporters if they would like to report anonymously. If they made an anonymous report, these were entered into the respective branch in the organisational tree, such that only the Patient Safety Manager would have access to the report (Figure 3-6). If staff were happy to be identified, incident reports were forwarded to their NUM (nurse-initiated reports) or to the Medical Head of Unit (doctor-initiated reports). This was explained to reporters at the time of the phone call.

Figure 3-6 Branches of the AIMS tree



On-line reporting

There was no provision for staff to lodge a report on-line anonymously, because by logging into the database they were required to use a personal identification number that made them identifiable for the purpose of auditing data entry. Staff in the ICU were provided with education detailing the lack of anonymity if they used this approach.

3.6.8.1. Managing incident reports

With regard to education about investigating incidents, all NUMs, Medical Heads of Units and Patient Safety Manager were invited to attend one of three Root Cause Analysis workshops held over two days during the study period, which was coordinated and run by the Department of Health, South Australia. Root Cause Analysis is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with an adverse event or near miss.[275] The purpose of the RCA workshop was to provide participants with an understanding of human factors and cognitive engineering concepts as they applied to health care delivery, and thus provide an introduction into a systems approach to investigating errors.

A barrier to reporting highlighted by focus group participants was that incident reports were often left in inappropriate places and were viewed by people who had no right or need to see

them. Examples were cited of reports being left on noticeboards and left in medical records. In designing the process to minimize threat to staff, the system was established so that only authorised staff could have access to the reporting system.

Once reports were entered into the AIMS database either by the clinical coder, call centre nurse or the reporter themselves, incidents were managed according to whether the reporter reported anonymously or provided details of their profession and location of the incidents. Figures 3-7, 3-8 and 3-9 provide flow diagrams for anonymous reports, nursing and medical reports respectively and how they were managed according to severity. The SAC score (or Severity Assessment Score) mentioned in the diagram refers to the score given to each incidents when completing the Risk Matrix, as outlined in Appendix 7.

Figure 3-7 Management of anonymous incident reports according to the Severity Assessment Score

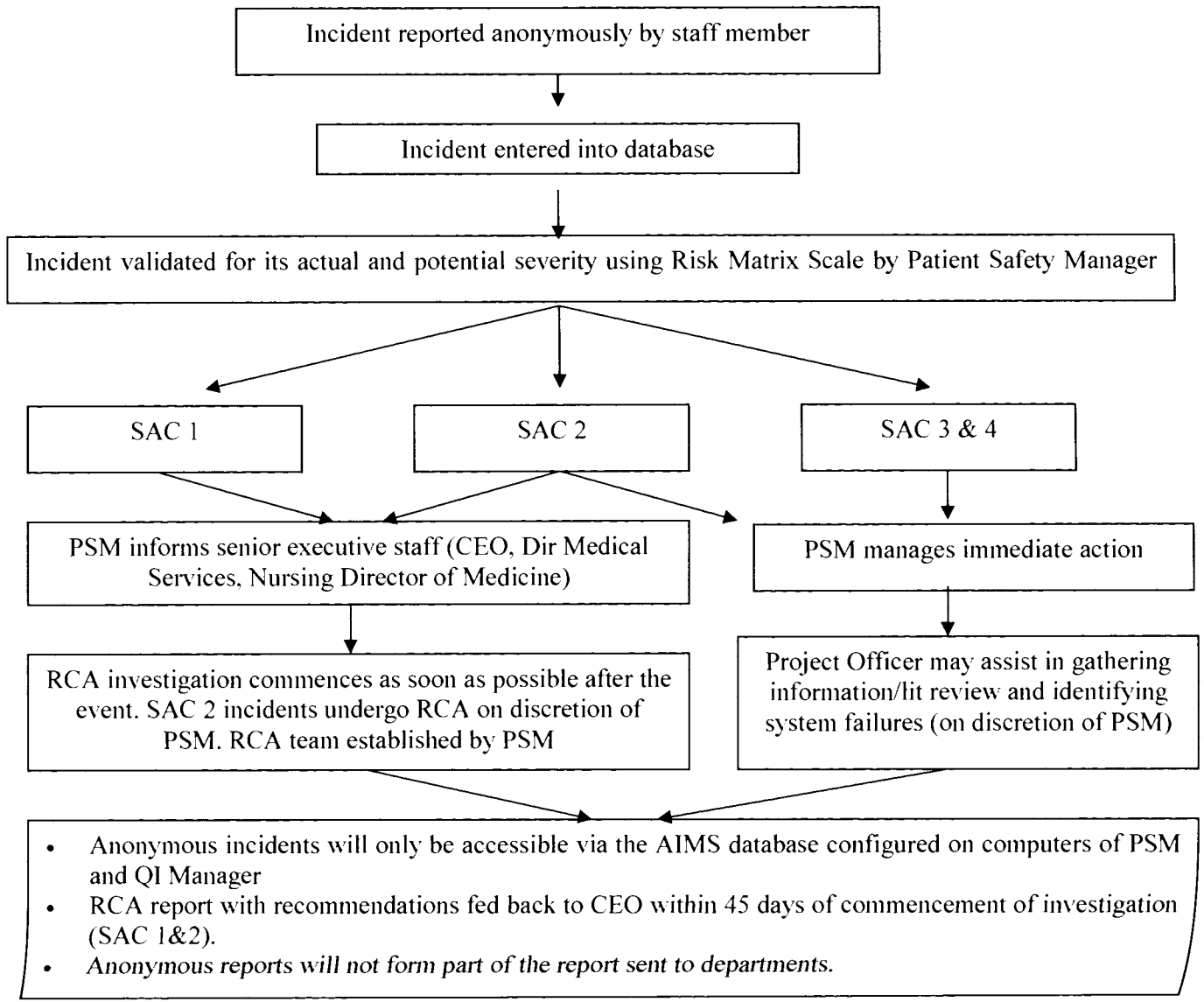


Figure 3-8 Management of nurse-initiated incident reports according to the Severity Assessment Score

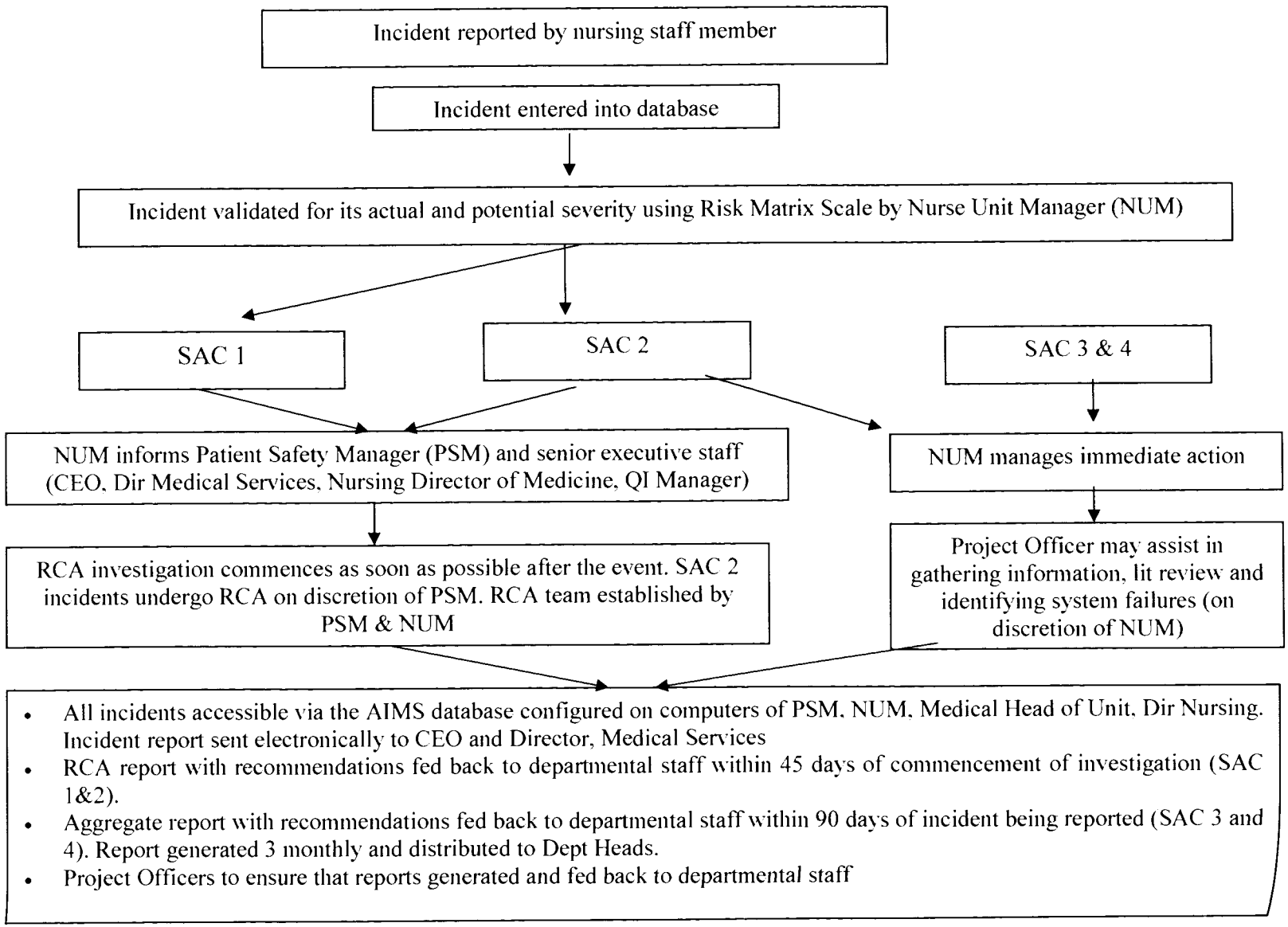
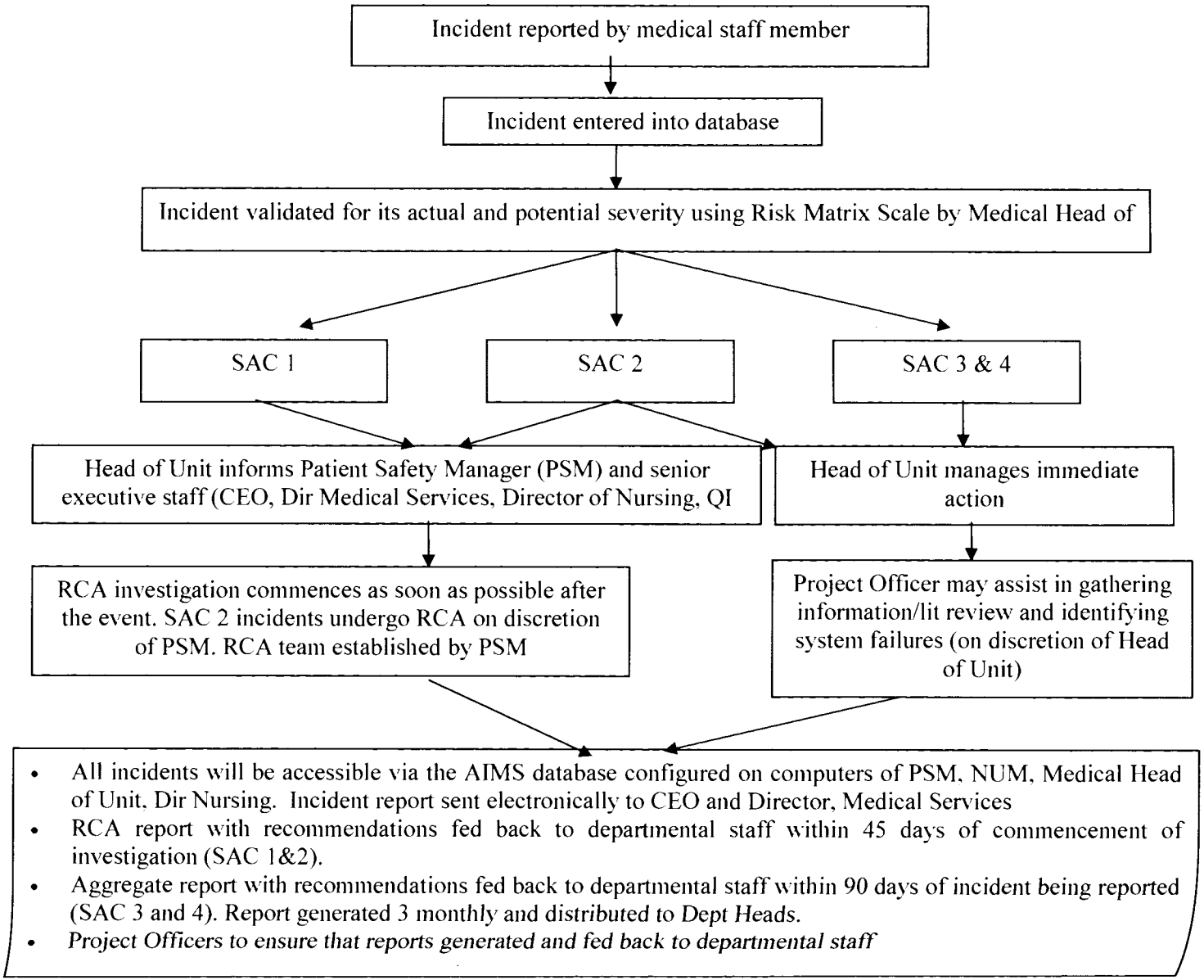


Figure 3-9 Management of medically-initiated incident reports according to the Severity Assessment Score



The Advanced AIMS database could be configured to enable notification of incidents and copies of incident reports to be directed to designated people who had security access to see the AIMS database. As in the baseline period mentioned in section 3.6.5.1, certain types of reports may need to be seen by designated people within the institution. Using the Advanced AIMS system, automatic notification of an event could occur via electronic mail to people who were required to action the report. For example, all incidents relating to medical devices could trigger a notification to the Biomedical Engineer, who would then access the database to see only those types of reports. Further examples are given in Appendix 10.

The manager of the biomedical engineering department, pharmacy, security department, occupational health and safety unit, and the infection control practitioner were each provided with education about how to use the system and how to provided feedback to the person reporting the incident. The Occupational Health and Safety officer was not able to provide feedback because they were only provided with access to de-identified information because of the statutory immunity afforded to the reporting system. Managers were directed to ask the Project Officers for assistance if they needed to generate a report. Table 3-10 outlines the potential advantages and disadvantages associated with the changes incorporated into managing incidents in the intervention units.

Table 3-10 Summary of potential advantages and disadvantages of changes proposed in the intervention units.

Standard Practice	Anticipated change	Potential advantages of the change	Potential disadvantages of the change
Reports processed through NUM to Director of Nursing	Reports sent directly to a coder where they were entered into a database	• Problems detected in a timely manner thereby reducing negative repercussions from adverse events, including complaints and litigation • Real-time reports can be generated, making them more relevant • Reduced likelihood that reports could be lost, or inadvertently stored in an inappropriate place • Increased security of data and therefore increased probability that incident reports maintain the privilege afforded to them.	• Delay in recognition of problems if incidents are not entered into the database in a timely manner. This has potential to increase risk of complaint and litigation, particularly if those who should know of an incident are not informed by any means other than the incident report. • The NUM has reduced dominance over the reports, therefore reports without foundation or punitive in nature would be entered onto the database.
No ability for reporters to report anonymously within the hospital, except through their NUM	Provision for reports to be generated anonymously and managed by a person who is not the line manager eg Patient Safety Manager instead of the NUM	• People will report incidents they would not have reported to line manager because of fear of punitive consequences.	• If Patient Safety Manager acts in a punitive way, this will undermine the purpose of bypassing line managers. • It is difficult to action anonymous reports without hospital-wide risk analysis e.g. if an anonymous report identifies a security breach, without knowing the area in which the report was generated, security throughout the organisation will need to be investigated. • It is difficult for Patient Safety Manager to maintain confidentiality, particularly if reporter becomes known during investigation.

Standard Practice	Anticipated change	Potential advantages of the change	Potential disadvantages of the change
Incidents are entered in a hospital-based reporting database	Incident information is entered into a centralised database for South Australia	• Aggregate reports from within the state can be analysed for trends, and to detect infrequent incident occurrences	Perceived threat by clinicians that incident data will be viewed by health administrators in the Department of Health and used for purpose contrary to its intended use.
Reports are generated on a 4 page incident report form	Reports generated using 1-page form, Call Centre or on-line. Reports viewed from a database instead of from a paper form	• Different reporting options and introduction of a shorter report form might improve reporting and assist in changing types of reports submitted. • Reports can be electronically forwarded to relevant people as an alert as soon as a report is entered into a database. • With on-line and Call Centre reporting, it is possible to introduce a paperless reporting system, thereby reducing data entry time by coders.	• Even though forms are shorter, more reports might result in delay entering reports into database. • more variety might cause confusion and thereby diminish reporting rates. • relies on staff having access to, and knowledge of the database and accessing their email on a regular basis, which might not occur in all areas • (d) on-line reporting shifts the data entry from the coder to the staff reporting the incident. Unless it is as easy to complete as a paper report, it might be an inefficient use of their time.

3.6.9. Education

As highlighted in baseline staff survey results (section 4.4), there was a need to provide education as a core component of the intervention.

3.6.9.1. Educational tools

An 'aide memoir' listing adverse events identified by medical reviewers through an audit of 14,000 casenotes undertaken in 1995 in New South Wales and South Australia[20] was used as an education tool to doctors and nurses in the intervention units. The aide memoir was developed by Professor Runciman, and permission was obtained prior to using it in the study. It was circulated to NUMs and Medical Heads of Units in the intervention units for comment prior to being distributed to a wider audience. Based on feedback from this group, examples of an adverse event from each of the fourteen major categories of adverse events were included in the aide memoir. The aide memoir formed part of the education manual, which outlined the reporting process and all aspects of the study (Appendix 11).

The education manual was delivered by hand to each o NUM and Medical Head of Unit in the intervention units. Where possible, a copy of the education manual was personally delivered by the rural project officers to each GP involved in the study. On four occasions where this was not possible, one was posted to them.

3.6.9.2. Educational sessions

At the commencement of the project, the PhD candidate and on most occasions the Principal Supervisor presented an overview of the project to medical staff in their departmental meeting. This presentation also included a mock call to the call centre to lodge a report. Examples of adverse incidents were given to explain what constituted an adverse incident. Some of these examples were drawn from those mentioned in the education manual.

It was anticipated that staff would gain a greater understanding of what constituted an incidents when feedback was provided to them in their departmental meeting on scheduled occasions throughout the study period. Even though it was possible that contamination may have been introduced, the PhD candidate also presented examples of adverse incidents and an outline of the reporting process for intervention units at the Grand Round on two occasions in one hospital (Hospital 1).

3.6.10. Feedback

Individual feedback

Lack of feedback was considered in the staff survey to be the most commonly cited barrier to reporting. As such, providing feedback was seen as crucial to the project's success. As a means of balancing the need to provide feedback with ensuring sustainability after completion of the project, the following criteria were introduced in regard to method and timeliness of feedback, and are based on the reporter's perception of the risk:

- Anonymous reports by their very nature meant that individual feedback could not be given.
- SAC 1 incidents (as illustrated in the Risk Matrix-Appendix 7) were perceived by the reporter to be serious, resulting in permanent disability or death. A response time of three days was set for feedback, to enable reports being sent via the external mail service to reach the Quality Unit.
- SAC 2 incidents as rated by the reporter using the Risk Matrix were given a response time of two weeks. For identified reports, the NUM/Head of Unit would principally be responsible for providing this feedback.
- SAC 3 or SAC 4 were minor events. Feedback was to be given via aggregate reports presented at departmental meetings and in the newsletter. Managers were not required to give individual feedback.

Departmental feedback

Medical and Nursing Heads of Units were approached at commencement of the project to determine whether their clinical unit had regular scheduled meetings in which feedback of aggregate data, case studies and incident outcomes could be given. Each Medical Head in metropolitan hospitals agreed to have this feedback scheduled every three months. In the rural hospital, there was recognition that GPs meeting were scheduled through the Royal Australian College of General Practitioners, and that the Medical Head had no ability to provide authorisation.

While it has been recommended that departmental meetings be held on a monthly basis to discuss adverse incidents[239] and there is strong evidence to suggest that increased frequency of meetings will improve dissemination of knowledge and change in practice, it was also necessary to be pragmatic and recognise that this was not always possible in every unit for a

number of reasons. Some strategies employed as part of the project to increase participation in the three-monthly meetings included:

- Surgical meetings attracted Continuing Professional Development (CPD) points through the Royal Australian College of Surgeons (RACS).[282] The purpose of the CPD programme is to advance the individual surgeon's surgical knowledge and skills for the benefit of patients; and provide tangible evidence that individual surgeons are participating in activities that maintain and enhance knowledge and skills.
- Medical meetings attracted Maintenance of Professional Standards points.[283] As with CME points for surgeons, MOPS points are designed to validate that physicians are actively participating in quality improvement programs that are endorsed by the College.
- Meetings with GPs provided participants with Maintenance of Professional Standards (MOPS) points through the Royal Australian College of General Practitioners.[284]
- The Medical Defence Association of South Australia (MDASA) provided points to doctors participating in the meetings, such that this would reduce medical indemnity insurance premiums.

Newsletters

Feedback on reported incidents was provided through newsletters, which were distributed to staff bi-monthly. A total of five newsletters were developed. Each newsletter was printed on both sides of an A4 sheet of paper with attention paid to graphic layout. Newsletters were drafted following discussion with Epidemiology Unit staff. The design for the newsletter was modelled on the Australian Therapeutic Device Bulletin,[285] a newsletter published by the Therapeutics Goods Administration in association with the Commonwealth Department of Health and Aged Care, because it gave succinct examples of problems and recommendations, was well known to doctors throughout South Australia and was well designed.

Newsletters were sent via the internal mail service or distributed at departmental meetings to each doctor working in metropolitan intervention units. Newsletters were sent through the conventional mail service to each GP working in rural hospital intervention units.

The first three newsletters were distributed to nursing staff via the most effective mechanism suggested by the NUM. This included having approximately ten copies of the newsletters placed in the communication book, in the handover room, or on notice boards in tearooms. In each intervention unit, newsletters were placed in the tearoom. Newsletters were not distributed to each nurse in the intervention unit, as they were to each doctor because it was not considered sustainable to do this after completion of the project. However, because we were uncertain as to what extent, if any, nursing staff were actually receiving the newsletter, the last two newsletters were individually posted to each nurse on the request of the Principal Supervisor.

3.6.11. Project implementation

The Chief Executive Officer (CEO) of each hospital was initially contacted and an appointment made to explain the project. Following this meeting, they were asked to sign a statement clarifying their support of the project. This was attached to the Ethics Committee application in each hospital. They were also required to sign authorisation to enable Call Centre personnel to take incident reports from employees in each of their respective hospitals.

Following the letter of support from the CEO, an appointment was scheduled with each of the Directors of Nursing and Medical Services, Patient Safety Managers, and Medical and Nursing Heads of Units involved in the project, so that the project could be explained to them. The AIMS database had been loaded onto a laptop computer so they could view the database, and be shown how its use would be envisaged to impact on them. Reinforced throughout the meetings with senior administrators was the fact that this was an experiment and that it was for a finite period of time, after which the impact it has had on them and on the reporting rates would be assessed. As Berwick[286] explained in an article exploring why change is adopted in some organisations but not in others, the knowledge that an innovation is being tested on a small scale without be implementing everywhere increases likelihood that change will be accepted.

The Manager, Information Technology of each hospital was contacted to authorise access to the centralised database and commit staff to assist in its implementation. Training in use of the database commenced immediately after the programme was installed in each hospital.

3.6.11.1. Project team

There were five Project Officers working on the project; two rural and three based in metropolitan Adelaide, in addition to the PhD candidate. The two rural Project Officers

were based in each respective rural hospital. All Project Officers were RNs with more than five years experience in the public sector acute nursing. On a day-to-day basis, rural Project Officers worked in collaboration with both the Patient Safety Manager and the PhD candidate, Clinical Epidemiology Unit, Queen Elizabeth Hospital. Metropolitan Project Officers liaised directly with the PhD candidate.

Department allocation of Project Officers and respective full time equivalent (FTE) load in areas were set out as follows:

- Project Officer A: supported Departments 4 and 11 (Metro) 0.4 FTE
- Project Officer B supported Departments 5 and 9 (Metro) 0.4 FTE
- Project Officer C supported Departments 6 and 20 (Metro) 0.4 FTE
- Project Officer D supported Departments 13, 14 and 15 (Rural) 0.8 FTE
- Project Officer E supported Department 19 (Rural) 0.2 FTE

Support that Project Officers provided to Departments included providing education to nurses about the project, training staff in use of the AIMS database, modifying education manuals as the project evolved, distributing surveys, developing content for newsletters, facilitating or contributing in RCAs, and in the initial stages assisting managers with follow up of incidents.

The database used to store staff survey data was designed by one of the Project Officers. Project Officers, with the support of the PhD candidate, wrote the applications to relevant Colleges to obtain quality assurance points for medical staff attending the departmental meetings. Project Officers were trained in the use of the AIMS database and attended a Root Cause Analysis (RCA) workshop to gain greater understanding of how to investigate adverse events in a non-punitive system-based approach. One project and the PhD candidate were trained in academic detailing techniques.

Project Officers provided ongoing assistance in the follow up of incidents in the first four months and then progressively assisted less and less to enable NUMs, Medical Heads of Units and PSMs to take more of a leading role. While assisting in the conduct of RCAs and ad hoc investigations, their principal role after the initial four months was to support the line managers, by assisting in the generating of reports, and provision of feedback to staff by way of education sessions and through the newsletters. At conclusion of the intervention, Project Officers distributed repeat surveys to staff in their allocated departments.

The PhD candidate was responsible for overall project management; including writing Ethics and grant applications, seeking legal privilege for bi-monthly IRIS Committees, establishing contracts with the call centre, educating Call Centre RNs, doing site visits to provide education and support to Project Officers, providing statistics as required to the IRIS Committee, providing feedback of outcomes to medical staff in all units, facilitating Root Cause Analyses from incidents reported during the intervention in one hospital, interacting with Unit Heads on an ongoing basis on issues arising from the intervention, coordinating input into the newsletter, designing, testing, distributing and analysing staff surveys.

The Principal supervisor provided advice and input in all aspects of the study. The PhD candidate reported progress to the Principal Supervisor and to the IRIS Committee, which met on a bi-monthly basis to evaluate progress and to discuss issues arising throughout the intervention. The Terms of Reference for the IRIS Committee are set out in Appendix 9. Formal weekly to fortnightly meetings during the intervention period were held with the Principal Supervisor and Project Officers to discuss ongoing implementation issues and to develop strategies to address weak response areas. The Principal Supervisor and PhD candidate did various site visits to encourage uptake and later to encourage survey return.

3.6.12. Statistical analysis

The study was assessed on its ability to improve incident reporting in intervention units above its own baseline reporting rates, and above any increase in reporting detected in control units between the baseline and study period. To compare overall reporting rates between the intervention unit and their matched control units at baseline and for the study period, comparison of two rates using Fishers exact tests were undertaken.

To assess whether there were differences in each of the matched control and intervention units, negative binomial regression analysis was used for most comparisons, however poisson regression analysis using robust variance with clustering by hospital was used for comparison of ICU data as this was the best fit for the data, and where convergence could not be achieved using generalised linear modelling. Denominators of both occupied bed days (OBD) and patient discharges were used for the analysis, with reports presented as incidents per 10,000 OBD or per 100 patient discharges. For anonymous reports, the denominator used was reports per 10,000 OBD and 10,000 ED attendances combined because, by their very nature it was not possible to determine whether the report was made in an inpatient are or in the ED.

Goodness of fit was tested for each exposure using Poisson regression, Negative binomial regression, Zero inflated Poisson and Zero inflated negative binomial regression. The test with the most negative Bayesian Information Criterion was considered the best fit for the data.

Subgroup analysis using the following variables was performed:

- **Reporter designation**: Reporting rates by medical staff, nursing staff, allied health professionals and anonymous reports were compared against its own baseline period using Fishers exact test. Reports were classified as being anonymous in both the baseline and study period if they did not identify the reporter or the location of the incident. To assess whether there were differences in each of the matched control and intervention units according to professional designation of reporter poisson regression analysis was used for comparisons adjusting for clustering by hospital.
- **Mechanism for reporting incidents** in the intervention units: Comparison of call centre, single page report form and online reporting mechanisms was undertaken using Fishers Exact test.
- **Types of incidents**. Principal incident types in the control and intervention unit were compared using Chi squared ($\chi 2$) tests. Inter-rater reliability of the PITs was initially assessed between coders, with kappa statistic reported for each incident type.

Sample size calculation

The baseline incident reporting rate in control and intervention units was determined to be approximately 4% of patient discharges. The intervention aimed to increase incident reporting to 10% of patient discharges. With required power of 80% and using a significance level of 0.05 two sided, it was estimated that there would need to be approximately 435 patient discharges in each of the two groups. Because it was anticipated that clustering by hospitals would occur and that sub group analysis would be undertaken on the four types of units, we increased by four the sample size required. As such, a sample size of 1740 patient discharges in each of the control and intervention units was required.

Software

All analyses were undertaken using Stata Statistical package version 8.2.[287]

3.6.13. Ethics and confidentiality

Ethics approval was obtained from the each of the following bodies responsible for approving research activities:

- North Western Adelaide Health Service Ethics of Human Research Committee (for both the Queen Elizabeth Hospital and Lyell McEwin Health Service)
- Royal Adelaide Hospital Human Ethics Committee
- Flinders Medical Centre Ethics of Human Research Committee (which incorporated Mt Gambier Hospital and Health Service)
- Whyalla Hospital and Health Service Board of Management Committee

The IRIS Committee (originally titled the North Western Adelaide Health Service/ Royal Adelaide Hospital Incident Monitoring Committee) was established for the purpose of evaluating and reporting progress of the project. At the time of its conception, it was envisaged that sensitive confidential information may be discussed at this meeting, including on occasion individually-identifying information from incident reports. Because of the sensitive nature of the reports, approval was sought to have the committee authorised under Section 64D of the South Australian Health Commission Act 1976. The relevant section of the Act and authorisation is attached and marked as Appendix 12.

Confidential information enclosed in incident reports is protected under Commonwealth legislation (see Appendix 5). Release of individually identifying information from the AIMS database is considered an offence of the Act, and could result in fine or imprisonment.

3.7. End of study staff survey

3.7.1. Introduction

The end of study survey was distributed to medical and nursing staff working in the ten control units and ten intervention units, and constituted one means by which the effectiveness of the intervention could be measured.

Actual reporting practices in the intervention and control units were measured as part of the intervention component of the study and are reported in section 4.6.7. Analysis of incident data from the AIMS database showed that reporting increased in both intervention and control units between the baseline and study period. Adjusting for differences at baseline between the control and intervention arm, the increase was significantly higher in all intervention units except in ICUs at the end of the study period. Reports submitted by doctors, nurses and anonymously increased in the intervention units significantly more than the control units. Reporting by doctors in the control unit did not change, in contrast to the sixteen-fold increase in reporting by doctors in the intervention unit. Reporting by nurses increased one and a half fold in the intervention units compared to the control arm after adjusting for differences at baseline.

While the information on reporting rates mentioned above was derived from actual incident reports in the AIMS database, the end of study survey provided self-reported information on awareness and use of the incident reporting system and barriers to reporting. Information contained in this survey supplemented objective data gathered during the preceding nine month intervention period. Comparison of attitude between baseline and the end of study was made in both arms of the study to understand more about reporting culture in the units. It should be noted that this is a cross sectional study and not a cohort study, as those answering the survey at the end of the study period were not necessarily those completing the survey at baseline. These aims, along with others are set out below.

3.7.2. Aims

The aims of the end of study staff survey, broadly outlined in aim 5, section 2.10, were to investigate by profession:

1. knowledge and use of the reporting system, comparing control and intervention arms at baseline and at the end of study period

2. the types of incidents staff (a) were more likely to report; and (b) believe should be reported comparing control and intervention arms at baseline and at the end of study period
3. barriers to reporting in control and intervention arms at baseline and at the end of study period
4. elicit from staff working in intervention units their opinion on components of the intervention, including how reports were handled, mechanisms for reporting and feedback of outcomes arising from reports
5. Determine from staff working in the control units their opinion on the impact various components of the intervention would have on their reporting practices.

In relation to each of the above aims we proposed the following hypotheses:

Primary hypothesis 1: There are differences in knowledge and use of the incident reporting system between control and intervention arms and in relation to profession, based upon comparison of data in the baseline survey with that obtained at the end of study period. Staff in intervention units at the end of the study will be more knowledgeable about the existence of a reporting system and the relevant reporting process when compared against baseline knowledge in the intervention units and with improvement in the control arm over time.

Primary hypothesis 2: There are differences in types of incidents staff believed they did and should report between control and intervention arms and in relation to profession, based upon comparison of data in the baseline survey with that obtained at the end of study period. Staff in intervention units at the end of the study will be more likely than staff in control units to (a) state that they report all types of incidents; and (b) believe they should report more types of incident.

Primary hypothesis 3: There are differences in barriers to reporting between control and intervention arms and in relation to profession, based upon comparison of data in the baseline survey with that obtained at the end of study period. The implementation of an intervention which addresses barriers to reporting will result in fewer barriers compared to the control arm.

Primary hypothesis 4: There are differences in attitude towards components of the intervention based on (a) professional designation of reporter and (b) the type of unit in which the respondent was working (c) whether respondents worked in rural or metropolitan hospitals.

Primary hypothesis 5: There are differences in relation to attitude towards what motivates staff to report incidents between professional groups.

3.7.3. Survey setting

The survey setting was identical to the baseline staff survey as discussed in section 3.4.3.

3.7.4. Survey design

The design for the survey was similar to the baseline survey. Most of the questions asked at baseline were repeated verbatim in the end of study survey. The following questions differed between the baseline and end of study survey:

- Question 5: For each incident that you report, do you use only a hospital incident form, use only an AIMS+ form, use both, use whichever is more appropriate, never know which form to use. This question was excluded because, although it was useful to get a baseline understanding of reporting systems people believed were available in their hospital for reporting, the addition of the Call Centre, one page form and on-line reporting meant that the question would have been very long.
- Question 7: Have you ever posted an anonymous AIMS+ form to the Australian Patient Safety Foundation.? This was excluded because there did not appear to be any benefit in asking it again.
- Question 3: Do you know how to locate or access a report? In the intervention arm, this question was changed to ask, "Do you know how to make a report?" Because there were different methods to report during the intervention it was felt more appropriate to encompass all of these in the question, rather than restricting it to the paper-based form.
- Question 4: Have you ever filled in an incident form was changed to Have you filled out an incident report in the last nine months (constituting the study period).

In order to add questions relating to aspects of the intervention and keep the survey relatively uncluttered on an A3 sheet of paper, only questions yielding the most important information were included.

3.7.4.1. Validity

The validity of most of the questions had been assessed in the baseline survey, and so was not repeated for the end of study survey. Validity testing occurred for aspects of the survey not included at baseline. Content validity was assessed by the same panel that assessed it

for the baseline survey (see section 3.4.5). Construct validity was assessed used the following techniques:

- Where respondents indicated that they used more than one method to report an incident, eg Call Centre and one page form, then sections that relate to both Call Centre and one page form were assessed to ensure that they had both been completed.
- For questions relating to overall impression of the reporting process in the intervention unit, staff were asked if they were aware that they would get feedback after making a report. They were also asked if they understood timeline for getting feedback on the incident they reported. Whilst these questions answer two slightly different issues, for the purpose of this survey, it was assumed that if respondents did not know whether or not they would get feedback, they would not know when the feedback would be given to them.

3.7.4.2. Reliability

Survey reliability was tested using test-retest on a sample of ten staff members (four medical staff, three RNs, one NUM and two ENs). Questions were administered initially and then repeated seven to eight days later.

3.7.4.3. Pilot testing

A sample of four doctors (one Registrar, one Intern and two Consultants) and four nurses (one Enrolled Nurse, three Registered Nurses) was used as pre-test subjects to ensure that each questionnaire item was clear and unambiguous. Respondents were evaluated by the PhD candidate for response time and their ability to answer each question. Following the pilot, a few minor changes were made in regard to the survey layout and this was subsequently reviewed by those participating in the pilot and found to be satisfactory.

3.7.4.4. Sample

The survey population and sampling frame for the end of study survey was identical to that used in the baseline survey (see section 3.4.3).

Inclusion and exclusion criteria

Inclusion and exclusion criteria were identical to those implemented in the baseline survey and outlined in section 3.4.4. Despite the fact that there may have been staff working in the control units who had spent time in the intervention units during the study period, they were not excluded from the survey. To determine the degree of contamination, a question was

asked to all nursing staff in control units at the beginning of the survey to elicit if they had spent any time working in the intervention unit/s in their respective hospitals during the intervention period.

3.7.4.5. Survey distribution

Surveys were distributed to doctors and nurses over a four-week period. Attached to each survey was a chocolate frog, a return-paid addressed envelope and an information sheet outlining the project. Survey distribution to nursing staff was principally in handover sessions in the morning, afternoon and overnight.

Medical staff surveys were distributed in departmental meetings in which feedback was not provided. The exception was in one metropolitan control unit where the project was promoted at the same time as surveys were distributed. In this meeting, only two surveys were returned. Surveys were distributed through postal survey to those not attending the meeting and GPs in both rural hospitals.

Returned surveys were entered into an Access database to enable Project Officers to tabulate response rates by level of seniority within professions for each of the clinical areas. Three weeks after surveys were distributed telephone calls were made to all doctors working in units where response rate for each level of seniority was below 80%. This was undertaken over a three-week period. In one control unit, recruitment was extended to six weeks because of poor response rates. A telephone call or personal contact was made by the Principal Supervisor to the Medical Head of Units with a response rate of below 30% following telephone calls to doctors, to solicit their support in prompting staff to complete the survey.

3.7.5. Survey questions

As with the baseline staff survey, the end of study survey did not ask respondents to personally identify themselves. It asked for the following demographic details: age, gender, profession, and years post entry-level qualification spent in the acute health sector were collected on all respondents. Surveys were colour-coded in the same way as was done at baseline. A copy of the survey distributed to intervention and control units is attached as Appendix 13 and 14 respectively

With regard to knowledge and use of the reporting system (aim 1), all staff were asked if they knew whether their hospital had an incident reporting system and whether they knew what to do with a completed incident form. Staff in control units were asked if they knew

how to access or locate the form and what to do with a completed form while intervention unit staff were asked only if they knew how to make a report.

To measure reporting practice (aim 2), staff were asked to estimate how often they (a) reported and (b) felt they should report, the same eleven patient incidents identified in the baseline survey.

To determine barriers to reporting (aim 3), staff were provided with a list of the same potential reasons for not reporting as the baseline survey.

To elicit information from staff in the intervention arm about components of the intervention (aim 4), they were first asked whether they had made a report in the last nine months (constituting the intervention period). Those answering in the affirmative were then asked eight questions about their impression of how the incident was managed, the feedback they received, and whether they thought it was a worthwhile exercise. They were then asked more specific questions about the reporting process they used to report. Further to commenting on their reporting experience, intervention unit staff were asked about their exposure to the project using a four-point scale (too much, about right, not enough, none) and on feedback they may or may not have received through departmental meetings and newsletters.

To determine from control arm staff their opinion on the impact that various components of the intervention would have on their reporting practice (aim 5), staff were asked to comment on the extent to which six aspects incorporated in to the intervention units would entice them to report incidents, using a four-point scale (a lot, a moderate amount, a little bit, not at all).

3.7.6. Statistical analysis

To compare knowledge and use of the reporting system, reporting practices, and barriers to reporting at baseline with end of study in intervention and control arms, log binomial generalized linear models were used, adjusting for clustering by hospitals. Where convergence could not be achieved Poisson regression analysis was used, adjusting for clustering by hospitals, and allowing for robust estimates of standard errors. End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalised linear models.

To determine views of doctors and nurses in the intervention arm on perceptions of the intervention, the five categories on the Likert scale (strongly disagree, disagree, neither

agree nor disagree, agree and strongly agree) were dichotomised into (a) strongly agree and agree and (b) neither agree not disagree, disagree and strongly disagree. Percentages were then compared using Fishers exact test. To determine views within the four types of units involved in the study, dichotomised data were analysed using log binomial generalized linear models, adjusting for clustering by hospitals.

With regard to questions regarding facets of the intervention including overall, Call Centre, one-page form and on-line reporting, results were dichotomised into agree or not agree. The 'not agree' category comprised answering where respondents stated they 'neither agree not disagree', 'disagree' or 'strongly disagree'. Analyses were undertaken using Fishers exact test.

To analyse perceived exposure to outcomes arising from reports in the intervention arm, percentages were compared using $\chi 2$ tests.

To determine control arm staff views of proposed changes to the reporting process to improve reporting, percentages were compared using log binomial generalized linear modelling adjusting for clustering amongst hospitals. When comparing doctors and nurses, data using four categories on the Likert scale (a lot, a moderate amount, a little bit and not at all) were dichotomised into (a) a lot and a moderate amount and (b) a little bit and not at all. Comparisons between the two groups were undertaken using Fishers Exact test.

The conventional level of $p \leq 0.05$ was taken to represent statistical significance. Comparisons were made for doctors and nurses by profession, level of qualification, years post entry-level qualification spent in the acute health sector, type of unit and rural/metropolitan location.

4. RESULTS

4.1. Introduction

Chapter 4 has been divided into the six components of the project in the same way as was done for the Methods chapter; the two consumer surveys, the focus groups, the intervention and the end of study survey. To enable ease of reading, each of the aims set out under the six components of the study in the Methods chapter are reported under headings in the Results chapter.

With regard to the intervention component in the Results chapter, prior to addressing the aims of the intervention, an explanation is provided as to how the study was established to address the four key issues arising from focus groups and the staff survey; the need to make the reporting system easier to use; the need to improve reporting processes to make it less threatening for staff to report and more effective in facilitating improvements in patient care; the need to provide education to staff and the need to provide effective feedback to staff.

4.2. Consumer survey 1

4.2.1. Response rate

From the initial 4,247 households selected randomly, 552 households were not contactable, 590 refused to be surveyed, 158 were either not available/too sick and 63 spoke no English. A total of 2,884 interviews were conducted, a response rate of 78.1%.

4.2.2. Demographic details

Table 4-1 outlines the demographic profile of the respondent sample (n = 2884), which was weighted by age, sex and geographical region to be comparable with the total population of South Australia in 2000 (n = 1 497 600).[288] There were marginally more female respondents compared with males (51% female vs. 49% males). The age bracket 18-39 years contains the most respondents, with 42% of males and 40% of females falling into this category. The majority of respondents lived in the metropolitan area (70% vs. 30%).

Respondents were asked how many children resided in the house and how many people aged over 15 years (including themselves) lived in the house. The household population consisted of: 501 children aged between 0-4 years, 550 children aged between 5-9 years and 510 children aged between 10-14 years. There were 6507 people in the household aged over 15 years including the respondent. The total household population was 8,068 persons.

Table 4-1 Demographic profile of the respondent sample (weighted n = 2884), which was weighted by age, sex and geographical region to be comparable with the total population of South Australia in 2000 (n = 1,497,600). *[288]

Variable	N	Men % (95%CI)	N	Women% (95%CI)	N	Total % (95%CI)	SA Census 2001**[288]	
Age (yrs)		n = 1,402		n = 1,482		n = 2,884		
18-39	585	41.8% (38.7%-44.9%)	586	39.6% (36.9%-42.2%)	1,171	40.6% (38.6%-42.7%)		
40-59	499	35.6% (32.7%-38.6%)	505	34.1% (31.5%-36.7%)	1,004	34.8% (32.9%-36.8%)		
60+	318	22.7% (20.4%-25.1%)	391	26.4% (24.3%-28.6%)	709	24.6% (23.0%-26.2%)		
Residence		n = 1,402		n = 1,482		n = 2,884		
Country	428	30.5% (27.5%-33.7%)	433	29.2% (26.7%-31.9%)	861	29.9% (27.9%-31.9%)		
Metropolitan	974	69.5% (66.3%-72.5%)	1,049	70.8% (68.1%-73.3%)	2,023	70.1% (68.1%-72.1%)		
Annual Household Income (AUD)		n = 1,274		n = 1,288		n = 2,562	n = 514,598†	
≤20,000	288	22.6% (20.2-25.2%)	393	30.5% (28.2%-33.0%)	681	26.6% (24.9%-28.4%)	84,306	16.4%
20,001-80,000	738	57.9% (54.7-61.0%)	727	56.5% (53.7%-59.2%)	1,465	57.2% (55.1%-59.3%)	354,933	69.0%
80,001+	248	19.5% (16.9%-22.3%)	168	13.0% (11.1%-15.3%)	416	16.2% (14.6%-18.0%)	75,359	14.6%
Country of birth		n = 1,401		n = 1,482		n = 2,883	n = 1,458,912	
Australia								
Non-Indigenous	1,011	72.2% (69.3%-74.8%)	1,091	73.6% (71.3%-75.9%)	2,102	72.9% (71.1%-74.7%)	1,076,166	73.8%
Indigenous	20	1.4% (0.8%-2.5%)	20	1.3% (0.8%-2.1%)	40	1.4% (1.0%-2.0%)	23,425	1.6%
Europe								
UK/Ireland	171	12.2% (10.4%-14.3%)	183	12.4% (10.8%-14.1%)	354	12.3% (11.1%-13.6%)	127,274	8.7%
Other	97	6.9% (5.6%-8.5%)	92	6.2% (5.0%-7.6%)	189	6.5% (5.6%-7.6%)	75,723	5.2%
Asia	30	2.1% (1.3%-3.5%)	28	1.9% (1.3%-2.8%)	58	2.0% (1.5%-2.8%)	34,948	2.4%
Other	72	5.1% (4.0%-6.7%)	68	4.6% (3.6%-5.8%)	140	4.9% (4.1%-5.8%)	121,376	8.3%

* 2001 Census data for annual household income and country of birth are provided for comparison. These data were not available for weighting the respondent sample when the survey was conducted in 2001. † Census data missing for 52,476 households.

For each question asked in the survey, the question was tested for association with the following variables:

- Age- 3 categories 18-39 years, 40-59 years and age 60 years or over (60+)
- Gender
- Residence: whether respondents lived in rural or metropolitan South Australia.
- Annual household income: categories collapsed into less than AU$20,000, between AU$20,001-$80,000 and more than AU$80,000 per year
- Country of birth: categories collapsed into Australian (subgroup indigenous and non-indigenous), Europe (UK/Ireland and other), Asia and Other (see categories in Appendix 15).

4.2.3. To understand consumer views on (a) safety in public hospitals and general practice (aim 1.1)

4.2.3.1. Safety in public hospitals

Of the 2,884 adults interviewed, 5.2% indicated that they would feel very unsafe admitted to hospital, 19.8% would feel a little unsafe, 51.6% would feel pretty safe and 23.3% would feel very safe.

Univariate analysis

People aged between 40 to 59 years were most likely to feel unsafe when compared to younger people aged between 18 to 39 years (Table 4-2). Compared to males, females were more likely to feel unsafe (27% vs. 23% felt unsafe p=0.013). People living in metropolitan areas were more likely to feel unsafe compared to their rural counterparts (28% vs. 18% felt unsafe p<0.001). Those people on an annual income of greater than $80,000 were significantly more likely than those earning less than $20,00 to feel unsafe going to hospital (31% vs. 24% felt unsafe p=0.019).

The country of birth of respondents did not affect whether they felt unsafe attending hospitals. Based on the assumption that people born in Australia, UK and Ireland all have English as their first language, when this group were compared with those born in Europe, Asia and the other category, there was no significant difference in whether they felt unsafe going to hospital (Relative Risk=1.14 95% CI: 0.9, 1.4).

Table 4-2 Public perceptions of lack of safety in public hospitals -univariate analysis

Variable	Feel unsafe		Feel safe		RR	95% CI	P-value*
	N	%	N	%			
Age (yr)							
18-39	262	22.6%	895	77.4%	1.0		
40-59	288	29.2%	700	70.8%	1.3	1.1 - 1.5	0.002
60+	156	23.2%	518	76.8%	1.0	0.8 - 1.2	0.797
Gender							
Male	314	22.7%	1067	77.3%	1.0		
Female	392	27.3%	1046	72.7%	1.2	1.0 - 1.4	0.013
Residence							
Country	154	18.2%	690	81.8%	1.0		
Metropolitan	552	28.0%	1423	72.0%	1.5	1.2 - 1.9	<0.001
Annual household income							
<$20,00	154	23.6%	498	76.4%	1.0		
$20,001-$80,000	355	24.5%	1,093	75.5%	1.0	0.9 - 1.2	0.665
>$80,0001	126	30.8%	283	69.2%	1.3	1.0 - 1.6	0.019
Country of birth							
Australia: Non-Indigenous	509	24.6%	1557	75.4%	1.0		
Australia: Indigenous	10	25.6%	29	74.4%	1.0	0.5 - 1.9	0.991
Europe: UK/Ireland	84	24.5%	259	75.5%	1.2	0.9 - 1.5	0.954
Europe: Other	51	28.5%	128	71.5%	1.1	0.9 - 1.5	0.294
Asia	14	24.6%	43	75.4%	1.1	0.5 - 2.0	0.935

* Weighted log binomial generalized linear model

Multivariate analysis

The best joint predictors for perceptions of lack of safety in public hospitals were age (those aged between 40 years and 59 years felt the least safe), residence (people residing in metropolitan areas felt the least safe) and gender (females felt the least safe) (Table 4-3). Whereas annual income was a predictor of feeling unsafe using univariate analysis, this did not come out as a significant predictor when multivariate analysis was undertaken.

Table 4-3 Public perceptions of lack of safety in public hospitals -multivariate analysis

Variable	Feel unsafe		Feel safe		RR	95%CI	P-value*
	N	%	N	%			
Age (yr)							
18-39	262	22.6%	895	77.4%	1.0		
40-59	288	29.2%	700	70.8%	1.3	1.1 - 1.5	0.004
60+	156	23.2%	518	76.8%	1.0	0.8 - 1.2	0.843
Gender							
Male	314	22.7%	1067	77.3%	1.0		
Female	392	27.3%	1046	72.7%	1.2	1.0 - 1.4	0.021
Residence							
Country	154	18.2%	690	81.8%	1.0		
Metropolitan	552	28.0%	1423	72.0%	1.5	1.2 - 1.9	<0.001
Annual household income							
<$20,00	154	23.6%	498	76.4%	1.0		
$20,001-$80,000	355	24.5%	1,093	75.5%	1.0	0.8 - 1.2	0.912
>$80,0001	126	30.8%	283	69.2%	1.2	0.8 - 1.5	0.234

*Weighted log binomial generalized linear model with all significant univariate variables included

4.2.3.2. Safety in General Practice

The majority of adults felt safe visiting their GP, with 0.6% stating that they would feel very unsafe, 5.7% would feel a little unsafe, 39.7% would feel pretty safe and 54.1% would feel very safe.

Univariate analysis

When analysing predictors of feeling unsafe attending a general practitioner, people aged less than 60 years were more likely to feel unsafe when compared to older people aged over 60 years (Table 4-4). Indigenous Australians and those of Asian origin were more likely to feel unsafe visiting their general practitioner compared with non-indigenous Australians. People born in Europe, but not in the United Kingdom or Ireland, were also less likely to feel safe visiting their general practitioner, compared with non-indigenous Australians. People on a higher annual income were less likely to feel safe compared with those people earning less than $20,000 per year. There was no significant difference in perceptions of lack of safety in general practice by gender or metropolitan/country residence.

Table 4-4 Public perceptions of lack of safety in general practice -univariate analysis

Variable	Feel unsafe n = 706		Feel safe n = 2113		RR	95% CI	P-value*
	N	%	N	%			
Age (yr)							
18-39	82	7.1%	1068	92.9%	1.0		
40-59	71	7.2%	915	92.8%	1.0	0.7 - 1.4	0.925
60+	26	3.7%	675	96.3%	0.5	0.3 - 0.8	0.004
Gender							
Male	86	6.3%	1286	93.7%	1.0		
Female	92	6.3%	1371	93.7%	1.0	0.9 - 1.1	0.992
Residence							
Country	55	6.5%	795	93.5%	1.0		
Metropolitan	123	6.2%	1863	93.8%	1.0	0.9 - 1.0	0.840
Annual household income							
<$20,00	32	4.8%	636	95.2%	1.0		
$20,001-$80,000	94	6.5%	1357	93.5%	1.3	0.9 - 2.0	0.133
>$80,0001	39	9.7%	368	90.3%	2.0	1.3 - 3.2	0.004
Country of birth							
Australia: Non-Indigenous	107	5.2%	1963	94.8%	1.0		
Australia: Indigenous	10	27%	28	73%	5.2	2.6 - 10.4	<0.001
Europe: UK/Ireland	24	7.1%	323	92.9%	1.4	0.8 - 2.1	0.200
Europe: Other	18	9.5%	168	90.5%	1.8	1.1 - 3.1	0.030
Asia	12	21.7%	45	78.3%	4.2	1.9 - 9.2	<0.001

* Weighted log binomial generalized linear model

Multivariate analysis

Multivariate analysis is summarised in Table 4-5. The best joint predictors for perceptions of lack of safety in general practice were age (those aged 59 years and under felt the least safe), and country of birth (those born in Asia, those from countries in Europe other than the United Kingdom and Ireland, and those of Indigenous origin felt least safe). Compared to non-Indigenous Australians, those of Indigenous background were more than five times more likely to feel unsafe when attending their GP.

Table 4-5 Public perceptions of lack of safety in general practice - multivariate analysis

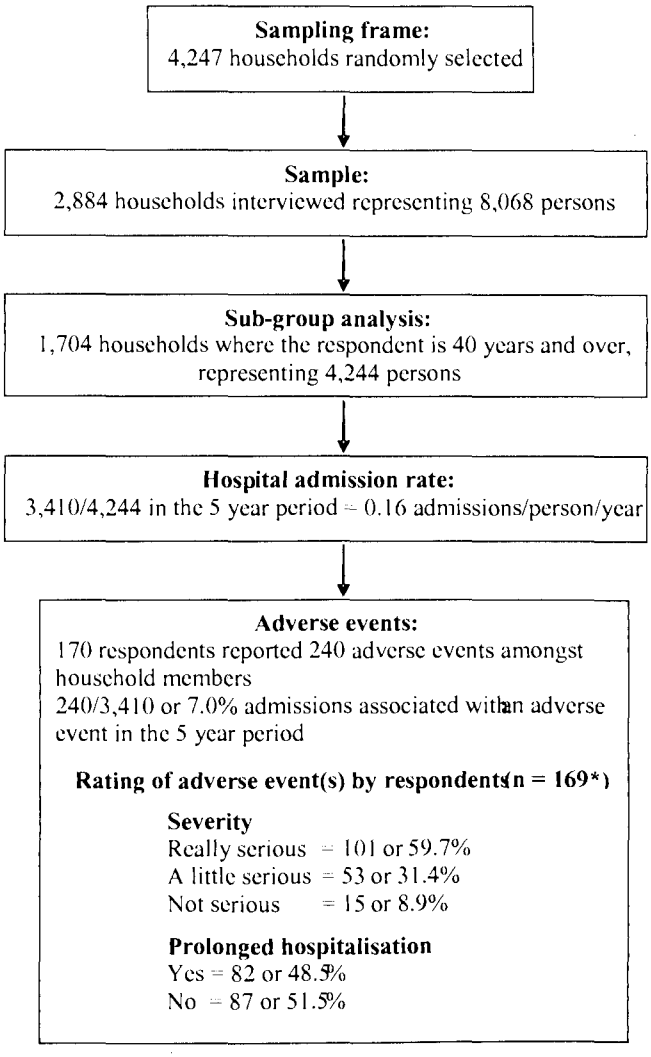
Variable	Feel unsafe		Feel safe		RR	95%CI	p-value*
	N	%	N	%			
Age (yr)							
18-39	82	7.1%	1068	92.9%	1.0		
40-59	71	7.2%	915	92.8%	1.0	0.7 - 1.4	0.805
60+	26	3.7%	675	96.3%	0.6	0.4 - 0.9	0.026
Total	179		2658				
Country of birth							
Australia: Non-Indigenous	107	5.2%	1963	94.8%	1.0		
Australia: Indigenous	10	27.0%	28	73.0%	5.3	2.6 - 11.1	<0.001
Europe: UK/Ireland	24	7.1%	323	93.0%	1.4	0.8 - 2.3	0.212
Europe: Other	18	9.5%	167	90.5%	2.0	1.1 - 3.6	0.023
Asia	12	21.7%	45	78.3%	3.5	1.5 - 8.6	0.005
Other	7	4.8%	131	95.2%	0.9	0.4 - 2.1	0.832
Total	178		2657				
Annual household income							
<$20,00	32	4.8%	636	95.2%	1.0		
$20,001-$80,000	94	6.5%	1357	93.5%	1.3	0.8 - 1.9	0.258
>$80,0001	39	9.7%	368	90.3%	1.9	1.1 - 3.2	0.013
Total	165		2361				

* Weighted log binomial generalized linear model with all significant univariate variables included

4.2.4. To understand consumer views on the experience of an adverse event (aim 1.2)

In this section, a decision was made only to include the findings for households in which the individual surveyed was 40 years or more. This sub-group analysis was undertaken because the time frame involved for the questions relating to adverse events and trends in healthcare safety was five and ten years prior to the survey date. It was considered likely that answers would be more reliable for older respondents, and therefore those aged 18-39 years were excluded from these analyses. As questions asked were in relation to the entire household, the sample pool consisted of 4,244 people (Figure 4-1).

Figure 4-1 Sampling frame



* One respondent did not indicate the severity of the adverse event or the impact that it had on length of stay

Of the 170 respondents who reported an adverse event amongst household members, 129 respondents indicated that one mistake had occurred, 27 respondents reported two mistakes, eight respondents reported three mistakes, five respondents reported between four to six mistakes, and one respondent reported that mistakes had occurred seven to eight times over the past five years.

When asked to rate the seriousness of the adverse event, 101 respondents (59.7%) rated the adverse event as serious, and 82 (48.5%) indicated that extra time in hospital was required.

Table 4-6 indicates that more Indigenous Australians reported that adverse events had occurred in their household compared to non-Indigenous Australians (37% vs. 14%; p = 0.019) but numbers were small (6 vs 107). Those born in countries where English is not the first language (Europe and Asia) were no more likely to report that an adverse event had occurred compared to non-Indigenous Australians.

Table 4-6 Demographic profile of respondents over 40 years who perceived that an adverse event had occurred to themselves or a household member - univariate analysis

Variable	Adverse event		No adverse event		RR	95% CI	P-value*
	N	%	N	%			
Age (yr)							
40-59	112	17.3%	536	82.7%	1.0		
60+	58	12.2%	419	87.4%	0.7	0.5 - 1.0	0.025
Gender							
Male	74	13.7%	468	86.3%	1.0		
Female	96	16.4	488	83.6%	1.2	0.8 - 1.6	0.244
Residence							
Rural	48	13.5	307	86.5%	1.0		
Metropolitan	122	15.8	648	84.2	1.2	0.8 - 1.7	0.417
Country of birth							
Australian: Non-Indigenous	107	14.0%	656	86.0%	1.0		
Australian: Indigenous	6	37.1%	10	63.0%	2.6	1.2 - 5.9	0.019
Europe: UK/Ireland	31	18.2%	141	81.8%	1.3	0.9 - 1.9	0.183
Europe: Other	18	15.8%	95	84.2%	1.1	0.7 - 1.9	0.654
Asia	1	8.4%	14	91.6%	0.6	0.1 - 3.9	0.595
Other		15.2%	40	84.8%	1.1	0.5 - 2.2	0.822
Annual household income ($AUD)							
<$20,00	59	15.6%	323	84.4%	1.0		
$20,001-$80,000	77	15.8%	412	84.2%	1.0	0.7 - 1.4	0.928
>$80,0001	23	15.6%	124	84.4%	1.0	0.6 - 1.7	0.996

* Weighted log binomial generalized linear model

There was no significant difference in the respondent's perceptions of feeling unsafe in public hospitals or in general practice according to whether or not any member of their household had been admitted to hospital in the last five years or whether the person was born in a country where English is not the first language (Europe and Asia). However, if respondents reported that an adverse event had occurred for any household admission, they felt significantly more unsafe attending both hospital and their GP (Table 4-7). The degree to which a person felt unsafe correlated with the perceived seriousness of the adverse event.

Table 4-7 Perceptions of feeling unsafe in public hospitals and general practice in those aged 40+ years.

Variable	Feel unsafe		Feel safe		RR	95%CI)	P-value*
	N	%	N	%			
Public hospitals							
Previous hospital-acquired adverse event							
No	199	21.6%	724	78.4%	1.0		
Yes	79	46.9%	89	53.1%	2.2	1.7 - 2.7	<0.001
Total	278		813				
Severity of that hospital-acquired adverse event†							
No adverse event	199	21.6%	723	78.4%	1.0		
Not serious	4	29.2%	11	70.8%	1.4	0.6 - 3.0	0.453
A little serious	19	36.6%	33	63.4%	1.7	.1.1 - 2.6	0.012
Really serious	55	54.6%	46	45.4%	2.5	2.0 - 3.2	<0.001
Total	277		813				
General Practice							
Previous hospital-acquired adverse event							
No	47	5.0%	892	95.0%	1.0		
Yes	17	9.7%	154	90.3%	1.9	1.1 - 3.5	0.031
Total	64		1046				
Severity of that hospital-acquired adverse event‡							
No adverse event	47	5.0%	892	95.0%	1.0		
Not serious	1	3.2%	15	96.8%	0.6	0.1 - 4.6	0.646
A little serious	7	13.9%	46	86.1%	2.8	1.2 - 6.3	0.016
Really serious	9	8.6%	92	91.4%	1.7	0.8 - 3.6	0.164
Total	64		1045				

Weighted log binomial generalized linear model. Data missing † feels unsafe n=277 ‡ feels safe n=1045

4.2.5. To understand consumer views on confidence in healthcare (aim 1.3)

As with section 4.2.4, analysis on changes in consumer confidence in healthcare was only performed on those adults aged over 40 years. Almost half of respondents aged 40 years or more (47%, 95% CI: 45% to 50%) reported that the chances of an error occurring in hospitals today was greater than ten years ago, compared to 18% (95% CI: 16% to 20%) believing it to be less and 35% (95% CI: 32% to 37%) believing it had remained constant. Females were more likely than males to believe that more errors were occurring today compared to ten years ago (Table 4-8). Those who reported a prior adverse event in their household were more likely than those who did not, to believe that the chance of errors occurring today was greater than ten years ago (Table 4-8). The degree to which this occurred correlated with the perceived seriousness of the reported adverse event.

There were no significant differences in public opinion regarding trends in hospital safety over time by age, annual household income, country of birth, Indigenous status, metropolitan/country residence, or prior admission to hospital.

Table 4-8 Perception of trends in hospital safety over time in those aged 40+ years

Variable	More	Less	Same	N	P-value*
Age (yr)				***N=1545***	
40-59	49.6%	17.8%	32.7%	940	
60+	43.8%	18.5%	37.5%	605	0.088
Gender				***N = 1546***	
Male	44.7%	21.9%	33.3%	738	0.020
Female	49.7%	14.5%	35.8%	808	
Residence				***N=1546***	
Country	42.1%	20.6%	37.4%	475	
Metropolitan	49.7%	16.9%	33.4%	1071	0.059
Country of birth				***N=1544***	
Australia: Non-Indigenous	46.5%	19.1%	34.5%	1060	
Australia: Indigenous	31.6%	23.2%	45.2%	18	
Europe: UK/Ireland	54.3%	12.3%	33.4%	254	
Europe: Other	44.0%	19.6%	36.4	144	
Asia	30.2%	37.3%	32.6%	12	
Other	47.5%	15.6%	37.0%	56	0.208
Annual household income				***N= 1385***	
<$20,00	44.3%	17.7%	37.9%	469	
$20,001-$80,000	47.1%	19.4%	33.5%	717	
>$80,0001	55.2%	15.6%	29.2%	198	0.136
Previous hospitalisation				***N= 1538***	
No	49.7%	15.5%	34.8%	514	
Yes	46.4%	19.1%	34.5%	1024	0.224
Previous hospital-acquired adverse event				***N = 1014***	
No	43.2%	20.7%	36.2%	856	<0.001
Yes	63.2%	10.7%	26.2%	158	
Severity of that hospital-acquired adverse event				***N = 1013***	
No adverse event	43.2%	20.7%	36.2%	856	<0.001
Not serious	42.3%	5.2%	52.5%	15	
A little serious	66.6%	8.5%	25.0%	49	
Really serious	64.6%	12.7%	22.6%	93	

* Chi-squared tests.

4.2.6. Summary of Results for Consumer survey 1

A South Australian consumer survey (n=2884, response rate=78.1%) to identify hospital adverse event rates and perceptions of safety in hospital and general practice revealed that the majority of people felt safe going into hospital and attending their GP (75% and 94% felt very safe or pretty safe respectively). Those people most likely to feel unsafe going to hospital were; females, aged between 40-59 years, and resided in metropolitan Adelaide. Those who felt most unsafe going to their GP were; aged over 60 years, receiving an income in excess of $80,000 per annum, and from Aboriginal or Torres Strait Islander background.

Sub group analysis of people over the age of 40 years (n=1704), revealed that 67% had reported at least one hospital admission over the past five years (3410 hospital admissions in total), of which 7% (170 subjects) reported that something went wrong that they thought might have been due to the way the health care was carried out. The majority of these events were considered serious (60%) and nearly half of them (48%) resulted in extended hospitalisation. Almost half of the respondents (47%) believed that more errors were occurring today compared with 10 years ago, with 18% believing less mistakes occurred today and 35% believing it had remained constant.

Respondents aged 40 years or over who had knowledge of a household member who had experienced an adverse event in hospital were more likely than those who had not experienced one, to feel unsafe being admitted to hospital (47% vs. 22% $p<0.001$), to feel unsafe visiting their GP (10% vs. 5% $p=0.031$), and to believe that more errors were happening today compared to 10 years ago (63% vs. 43% $p<0.001$).

4.3. Consumer survey 2

4.3.1. Response rate

From the initial 3,400 households selected randomly, 711 households were not able to be contacted (370 were disconnected or a fax/modem, 274 no contact was made despite six call backs, 67 were non-residential numbers), 420 refused to be surveyed, 181 were either away for the duration of the survey or too sick/hearing impaired and 83 spoke no English. This left a total of 2,005 interviews conducted, giving a response rate of 74.6%.

4.3.2. Demographic details

Table 4-9 outlines the demographic profile of the respondent sample (n = 2005), which was weighted by age, sex and geographical region to be comparable with the total population of South Australia in 2000 (n = 1 497 600).[288] There were marginally more female respondents compared with males (51% female vs. 49% males). The age bracket 18-39 years contains the most respondents (40.6%). Compared to rural dwellers, the majority of respondents were from the metropolitan area (74% vs. 26%).

Table 4-9 Demographic profile of the respondent sample, weighted by age, sex and geographical region to be comparable with SA population Australia

Variable	Male			Female			Total			SA Census 2001[288]	
	N	%	95%CI	N	%	95%CI	N	%	95%CI	N	%
Age (yrs)*			n = 980			n = 1,020			n = 2,000		
18-39	406	41.4	37.6 - 45.3	407	39.9	36.5 - 43.3	813	40.6	38.1 - 43.2	438,681	39.5
40-59	349	35.6	32.3 - 39.1	346	33.9	31.0 - 37.0	695	34.8	32.5 - 37.1	396,630	35.7
60+	225	23.0	20.4 - 25.8	267	26.2	23.6 - 28.9	492	24.6	22.8 - 26.5	274,956	24.8
Residence											
Country	263	26.8	23.6 - 30.2	258	25.2	22.6 - 28.0	521	26.0	23.9 - 28.2	392,809	26.9
Metropolitan	718	73.2	69.8 - 76.4	766	74.8	72.0 - 77.4	1484	74.0	71.9 - 76.1	1,066,103	73.1
Annual Household Income (AUD) †			n = 913			n = 889			n = 1,803		
≤20 000	173	18.9	16.5 - 21.7	245	27.5	24.8 - 30.4	418	23.2	21.3 - 25.2	84,306	16.4
20 001-80 000	522	57.2	53.4 - 60.9	509	57.3	53.8 - 60.6	1031	57.2	54.7 - 59.8	354,933	69.0
80 001+	218	23.9	20.4 - 27.7	135	15.2	12.6 - 18.2	353	19.6	17.4 - 22.0	75,359	14.6
Country of birth			n = 981			n = 1024			n = 2005		
Australia	763	77.8	74.8 - 80.6	814	79.5	76.8 - 82.0	1577	78.7	76.7 - 80.6	1,099.591	75.4
Europe: UK/Ireland	106	10.8	8.8 - 13.1	118	11.5	9.7 - 13.6	224	11.2	9.8 - 12.7	127,274	8.7
Europe: Other	57	5.8	4.4 - 7.6	36	3.5	2.5 - 4.9	93	4.6	3.8 - 5.7	75.723	5.2
Asia	10	1.0	0.4 - 2.1	12	1.2	0.6 - 2.5	22	1.1	0.6 - 1.9	34,948	2.4
Other	45	4.6	3.4 - 6.3	44	4.3	3.0 - 6.0	89	4.4	3.5 - 5.6	121,376	8.3

Data missing * (male n=980, female n=1020, total n=2000) and for SA Census 2001 (0-18yrs n=348,645, total n=1,458,912) † (male n=913, female n=889, total n=1802) and for SA Census 2001 (n households =514,598, total households n=567,074)

For each question asked in the survey, the question was tested for association with the following variables

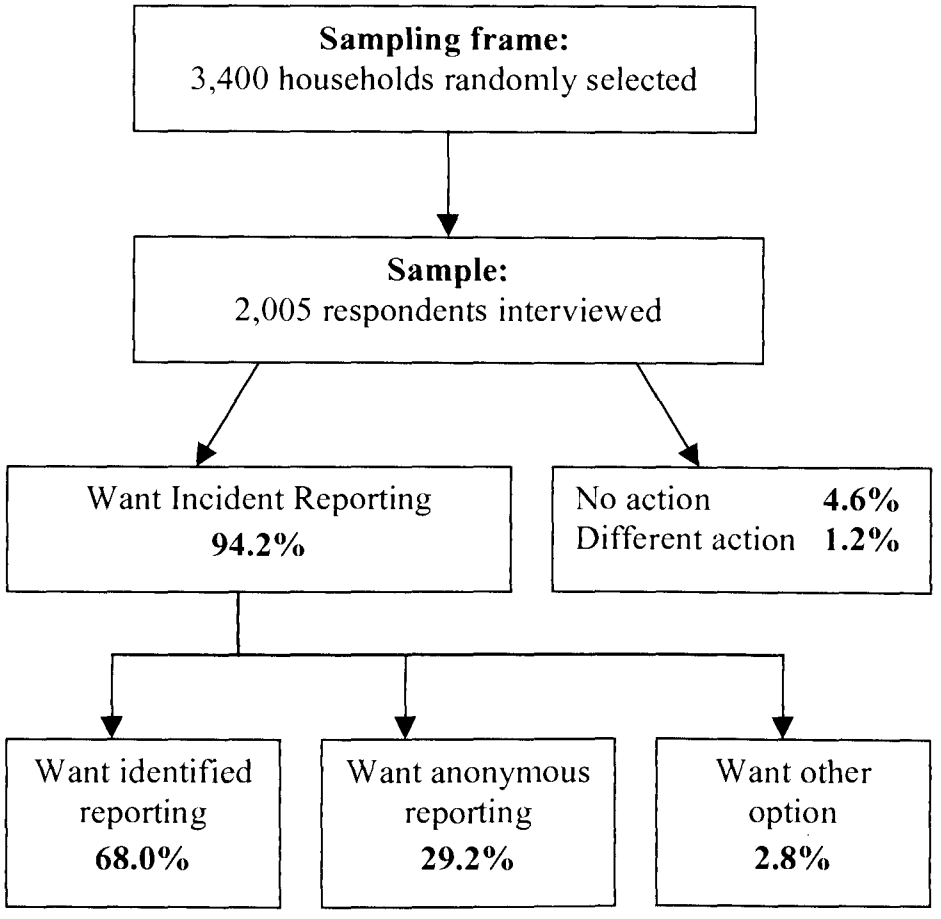
- Age- 3 categories 18-39 years, 40-59 years and age 60 years or over (60+)
- Gender
- Residence: whether respondents lived in rural or metropolitan South Australia.
- Annual household income: categories collapsed into less than AU$20,000, between AU$20,001-$80,000 and more than AU$80,000 per year
- Country of birth: categories were collapsed into Australian (subgroup indigenous and non-indigenous), Europe- UK/Ireland and other, Asia and Other (see categories in Appendix 16).

4.3.3. To understand consumer views on reporting of adverse events by health care workers (aim 2)

To gauge support for incident reporting, respondents were asked to comment on whether or not a healthcare worker should fill out a form, do nothing or take some other action when a medication error occurs which causes minor side-effects for the patient.

When asked to comment on what action, if any, should be taken in the vignette, 1,856 respondents or 94.2% (95% CI: 93.0% to 95.2%) of those with an opinion (n=1970), believed that a report should be written giving details of the mistake. Only 90 respondents or 4.6% (95% CI: 3.7% to 5.7%) thought reporting of the incident described was unnecessary and 24 respondents or 1.2% (95% CI: 0.8% to 1.9%) thought a different and unspecified action should be taken (Figure 4-2).

Figure 4-2 Flow diagram of respondent's opinions on incident reporting



Numbers were small in the category of respondents who did not believe that a report should be written, either (a) because it was unnecessary (n=92) or (b) because another action should be taken (n=24). For this reason, the two groups were collapsed into one for analysis. Univariate analysis showed that older people (aged over 60 years) were less likely than younger people (those aged between 18-39 years) to believe that an incident report should be written (Table 4-10). Respondents from households with an annual income of over $20,000 were more likely to believe that an incident report should be written when an error occurs (95.7% vs. 90.2% $p<0.001$).

Table 4-10 Consumer perceptions of whether healthcare workers should report when an error occurs –univariate analysis

	Want incident reporting		Do not want incident reporting		RR	95%CI	P value*
	N	%	N	%			
Age							
18-39 years	777	95.9%	33	4.1%	1.0		
40-59 years	652	95.2%	33	4.8%	1.0	0.97 - 1.02	0.555
60+ years	422	89.9%	10	10.2%	0.94	0.91 - 0.97	<0.001
Gender							
Male	893	93.3%	64	6.7%	1.0		
Female	964	95.1%	50	4.9%	1.02	0.99 - 1.04	0.117
Residence							
Country	474	93.7%	32	6.3%	1.0		
Metropolitan	1383	94.4%	83	5.6%	1.0	0.97 - 1.02	0.603
Annual household income							
≤$AU20,000	366	90.2%	40	9.8%	1.0		
$AU20 001-80 000	969	95.3%	48	4.7%	1.06	1.03 - 1.10	0.001
$AU80 000+	341	96.9%	11	3.1%	1.07	1.04 - 1.12	<0.001
Country of birth							
Australia	1469	94.5%	85	5.5%	1.0		
Europe - UK/Ireland	207	95.0%	11	5.0%	1.0 9	0.97 - 1.04	0.772
Europe – Other	78	87.4%	11	12.6%	0.92	0.85 - 1.0	0.050
Asia	22	100%	07	0%	1.06	1.04 - 1.07	<0.001
Other	79	92.3%		7.7%	0.98	0.92 - 1.04	0.457

*generalised linear modelling using a log binomial regression model

4.3.3.1. Consumer views on healthcare worker identity disclosure following an error

Of those in favour of incident reporting and who had an opinion regarding anonymous or identified reporting (n= 1,825), 1,237 consumers or 68.0% (95% CI: 65.5% to 70.5%) thought that the healthcare worker should identify themselves on the incident report form, even though this may lead to disciplinary action. Only 532 consumers or 29.2% (95% CI: 26.7% to 31.7%) thought that the report should be anonymous in order to encourage reporting and 51 consumers or 2.8% (95% CI: 2.1% to 3.7%) thought other unspecified options should be taken (Figure 4-2).

Univariate analysis

Table 4-11 outlines the characteristics of respondents who believed that healthcare workers should be required to identify themselves when completing an incident report. Univariate analysis showed that as respondents aged, they were more likely to favour a system where healthcare workers were required to identify themselves on a report form, however in real terms, there was only a ten percent increase between those aged less than 39 years and those aged more than 60 years.

Table 4-11 Relationship between consumer characteristics and preferences for incident reporting by healthcare workers – univariate analysis

	Healthcare worker should be identified on report		**Healthcare worker can remain anonymous**		**RR**	**95%CI**	**P value***
	N	**%**	**N**	**%**			
	1237	68.0%	532	29.2%			
Age							
18-39 years	489	65.0%	263	35.0%	1.0		
40-59 years	448	72.6%	170	27.4%	1.1	1.0 - 1.2	0.014
60+ years	300	75.1%	99	24.9%	1.1	1.09 - 1.3	0.001
Gender							
Male	605	70.4%	254	29.6%	1.0		
Female	637	69.6%	278	30.4%	0.99	092 -.06	0.735
Residence							
Country	333	74.5%	114	25.5%	1.0		
Metropolitan	908	68.5%	418	31.5%	1.1	10 -12	0.034
Annual household income							
<=$AU20,000	255	72.5%	97	27.5%	1.0		
$AU20 001-80 000	646	69.9%	278	30.1%	0.96	0.90 - 1.04	0.344
$AU80 000+	225	67.8%	107	30.0%	0.93	0.80 - 1.05	0.268
Country of birth							
Australia	979	69.6%	428	30.4%	1.0		
Europe – UK/Ireland	149	75.3%	49	24.7%	1.08	0.99 - 1.19	0.097
Europe - Other	55	76.4%	17	23.6%	1.1	0.95 - 1.27	0.209
Asia	13	60.2%	9	39.8%	0.87	0.54 - 1.38	0.548
Other	45	60.7%	29	39.3%	0.87	0.70 - 1.08	0.214

*generalised linear modelling using a log binomial regression model

Multivariate analysis

Significant variables in the univariate analysis were included in the multivariate model. Using multivariate analysis, people most in favour of identification of a healthcare worker who makes a mistake were those aged over 60 years and residing in rural South Australia (Table 4-12). There was no significant difference in attitudes towards identification of healthcare workers who make a mistake by gender or annual household income.

Table 4-12 Relationship between consumer characteristics and preferences for incident reporting by healthcare workers – multivariate analysis

	Healthcare worker should be identified on report		Healthcare worker can remain anonymous		RR	95%CI	P value
	N	%	N	%			
	1237	68.0%	532	29.2%			
Age							
18-39 years	489	65.0%	263	35.0%	1.00		
40-59 years	448	72.6%	170	27.4%	1.12	1.02 - 1.22	0.013
60+ years	300	75.1%	99	24.9%	1.15	1.05 - 1.25	0.002
Residence							
Country	333	74.5%	114	25.5%	1.00		
Metropolitan	908	68.5%	418	31.5%	1.09	1.01 - 1.17	0.028

4.3.4. Summary of Results of Consumer Survey 2

A South Australian consumer survey of whether or not healthcare workers who err should complete an incident report and have to identify themselves (n=2005) revealed that the majority of people (94.2%) believed that when a healthcare worker erred they should be required to complete a report form giving details of the mistake. Even though they were informed that anonymous reporting might encourage reporting of mistakes, most respondents did not favour anonymous reporting, with the majority believing that the reporter should have to identify themselves even if this led to a reprimand.

4.4. Baseline Staff Survey

4.4.1. Survey tool

4.4.1.1. Validity

External validity was assessed using Q sort methodology (described in section 3.4.5.1).

Reporting practices

Appendix 17 show the groups into which the barriers were allocated. In analysing the level of agreement between doctors and nurses, a decision was made to combine the peer-related answers with disciplinary/legal/privacy. There was good agreement for categorising questions relating to reporting barriers tested for content validity (kappa 0.9 for doctors and 0.7 for nurses).

Barriers to reporting

Appendix 18 shows that there was excellent agreement for categorising questions relating to types of incidents for doctors (kappa 0.9) and moderate agreement for nurses (kappa 0.6).

4.4.1.2. Reliability

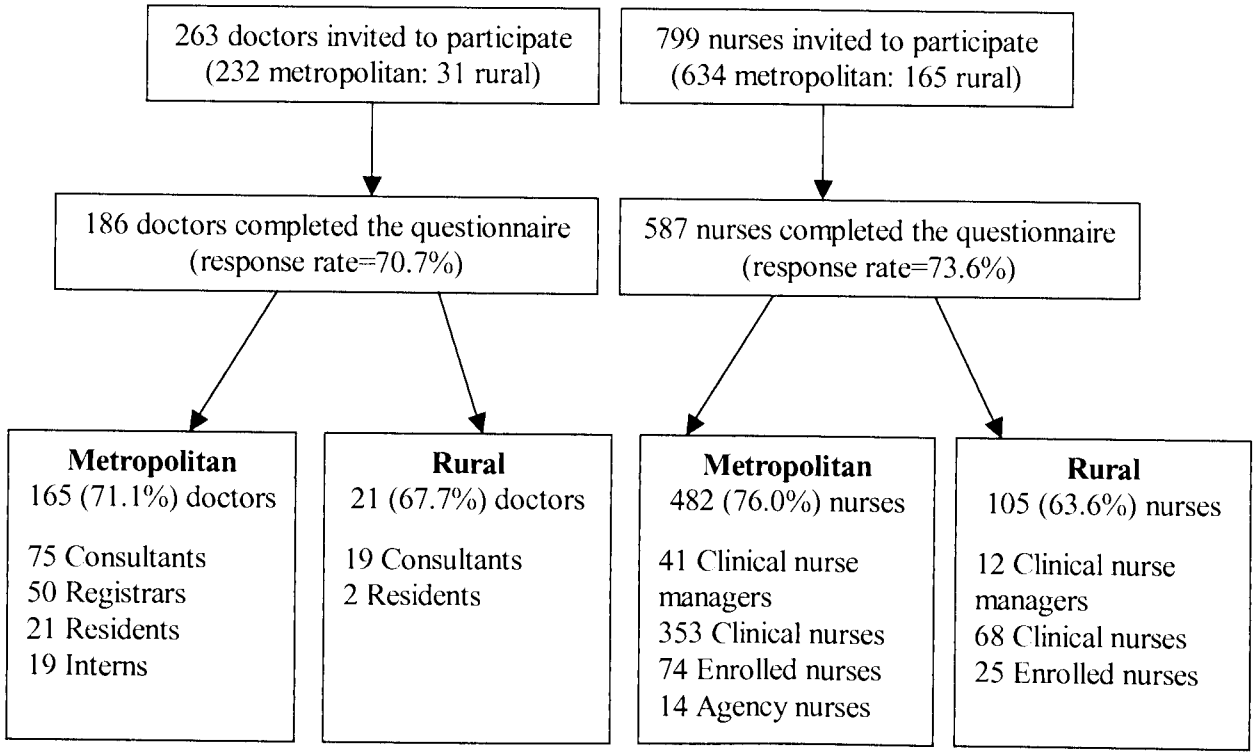
Test-retest reliability demonstrated that there was one type of incident and two barriers to reporting which showed poor reproducibility (kappa= less than 0.5) and so were removed from the survey (Appendix 18). The survey had good internal consistency with Cronbach's alpha ranged from 0.7 to 0.9 for the three similarly worded questions relating to reporting barriers.

4.4.2. Response rate

The response rate was 72.8%; with 773 of the 1062 staff approached taking part. The response rate was 70.7% for doctors (186 out of 263 doctors returned the survey) and 73.6% for nurses (587 out of 798 nurses returned the survey) (Figure 4-3)

The response rate for metropolitan hospitals was 74.7%, with 71.1% of doctors (165 out of 232 doctors) and 76.0% of nurses (482 out of 634 nurses) returning the survey. In the rural hospitals, the response rate was 64.3%, with 67.8% of doctors (21 out of 31 doctors) and 63.6% of nurses (105 out of 165) returning the survey. As the questionnaire was anonymous, we were unable to ascertain the demographic features of non-respondents.

Figure 4-3 Sampling frame for baseline staff survey



For each question on the staff survey, the following associations were considered:

- Profession (doctor or nurse)
- Seniority within profession (Consultant, Registrar, Resident, Intern, NUM, RN, EN)
- Location of hospital (Rural or metropolitan)

Even though age, gender and years post qualification experience in the public health sector were collected, analysis showed that results for females mirrored those for nurses, and age and years post qualification experience correlated strongly with seniority within professional groups. The purpose of the survey was to understand deficit in knowledge of the reporting system and barriers to reporting. Strategies to address these issues can be targeted based on profession, level of seniority and location of the hospital; however it would not be possible to target strategies based on age, gender or years post qualification in the acute health sector. In retrospect, it served little purpose to collect these demographic details. For this reason, age, gender and years post entry-level qualification results have not been reported in the analysis.

4.4.3. To identify knowledge of the incident reporting system (aim 3.1)

Nurses had a greater awareness of, and used the incident reporting system more than doctors (Table 4-13). Although almost all doctors and nurses knew that the system existed (98%), only 78% knew how to locate or access the form and 74% knew what to do with the form once completed. Approximately half of all respondents (52%) always used the AIMS+ form to make a report, with 17% of respondents having never lodged a report. Only a small percentage (5%) had sent an anonymous report directly to the APSF, and there was no significant difference between the number of doctors and nurses who have reported anonymously directly to the APSF (3.9% vs. 6.5%; p=0.275).

Table 4-13 Awareness and use of the incident reporting system

	Doctors (%)		Nurses (%)		p value*
	Yes	N	Yes	N	(doctors vs. nurses)
Awareness of hospital incident reporting system	93.6	174	99.8	586	0.053
Ever completed an incident report	64.6	115	89.2	520	<0.001
Know how to locate/access an incident form	43.0	77	88.3	515	<0.001
Know what to do with a completed incident form	49.7	89	81.9	476	<0.001

* Fishers exact test

Senior doctors (registrars and consultants) were significantly less likely than junior doctors (interns and residents) to have ever completed an incident form (58% vs. 85%; p=0.001). However, there was no significant difference by level of qualification in awareness of the hospital incident reporting system, knowing which form to use, how to locate or access the form and what to do with the form once completed. Neither was there any significant difference by seniority in use of the AIMS+ form or anonymous reporting directly to the APSF.

Senior nurses (NUMs) were significantly more likely than all other nursing staff to know which incident report form to use (100% vs. 91%; p=0.004), know how to locate it (100% vs. 87%; p=0.001), know what to do with it once completed (100% vs. 80%; p<0.001), have ever filled it out (100% vs. 88%; p=0.004), and to have ever reported anonymously directly to the APSF (17% vs. 5%; p=0.005). Enrolled and registered nurses were similar in their reporting behaviour. Agency nurses were significantly less likely than all other nurses to know how to locate or access an incident form (57% vs. 89%; p=0.003), to know what to do with the incident form once completed (50% vs. 83%; p=0.006), and to have ever filled out

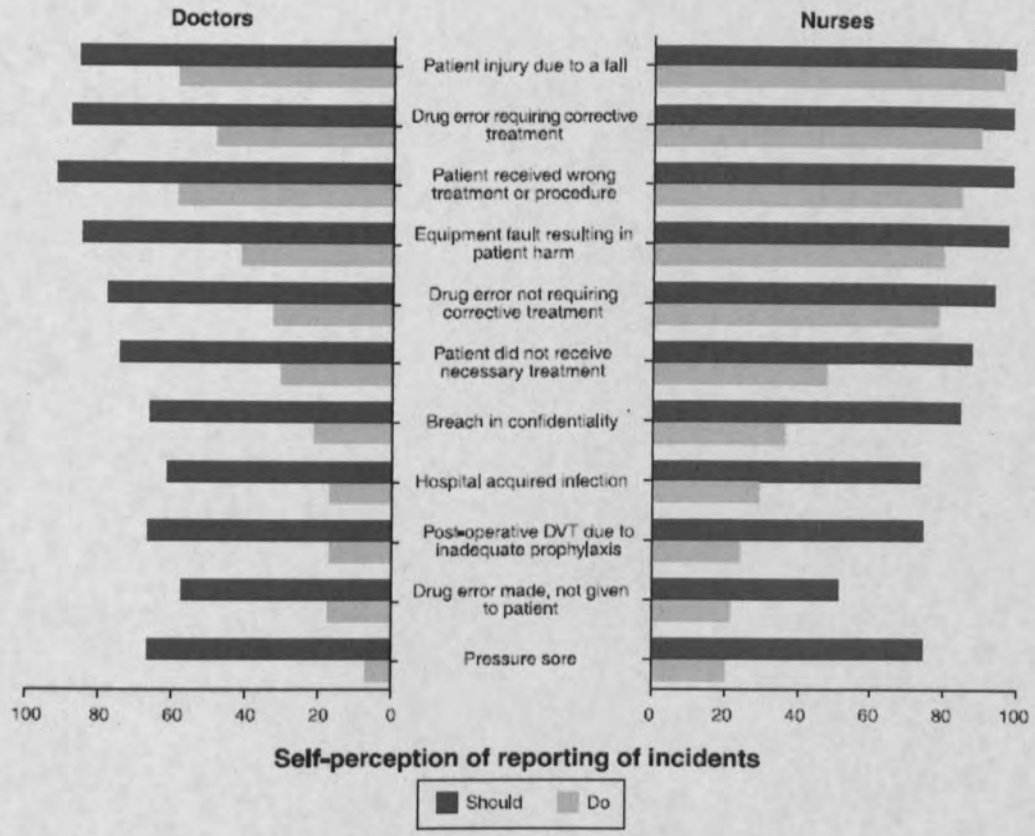
an incident form (57% vs. 90%; p=0.002). There was no significant difference according to level of qualification in awareness of the hospital incident reporting system, and always using the AIMS+ form to make an incident report.

There was no significant difference between metropolitan and rural staff in awareness that an incident reporting system existed (98% vs. 98%; p=0.362), or knowing which form to use (87% vs. 89%; p=0.552) or what to do with the form once completed (73% vs. 81%; p=0.056). However, metropolitan staff were less likely to know how to locate or access the form (76% vs. 86%; p=0.013) or to have ever filled in an incident form during their career (82% vs. 89%; p=0.048). There was however, no significant difference between the proportion of metropolitan and rural staff who reported anonymously directly to the APSF (6% vs. 3%; p=0.212).

4.4.4. To identify baseline use of the reporting system (aim 3.2)

Figure 4-4 shows the percentages of doctors and nurses who perceived that they reported incidents on 50% or more of occasions, and outlines their views on the necessity of reporting incidents.

Figure 4-4 Staff perception of incident reporting on 50% or more of occasions



Doctors were less likely than nurses to believe it necessary to report any incident on 50% or more of occasions, with the exception of post-operative deep vein thromboses (DVTs) due to inadequate prophylaxis, medication near misses and pressure sores, for which there were no significant differences according to profession (Table 4-14). Near misses were viewed as the lowest priority to report for both doctors and nurses.

Table 4-14 Staff self-perception of incident reporting practices

INCIDENT	**Doctors (%) who report incident ≥ 50% of occasions (N)**	**Nurses (%) who report incident ≥ 50% of occasions (N)**	**p value***
Patient injury due to a fall	58.6 (157)	95.5 (555)	<0.001
Drug error given, corrective treatment needed	48.0 (154)	89.1 (521)	<0.001
Patient received wrong treatment or procedure	58.3 (156)	83.9 (520)	<0.001
Equipment fault resulting in patient harm	41.2 (153)	79.0 (533)	<0.001
Drug error given, no corrective treatment needed	32.3 (158)	78.0 (518)	<0.001
Patient did not receive necessary treatment	30.1 (153)	47.4 (496)	<0.001
Breach in confidentiality	21.0 (143)	36.0 (468)	0.001
Hospital acquired infection	16.6 (157)	29.0 (524)	0.003
Post-operative DVT due to inadequate prophylaxis	16.4 (146)	23.9 (474)	0.065
Drug error made, not given to patient	17.2 (157)	21.2 (523)	0.279
Pressure sore	6.3 (142)	20.2 (510)	<0.001

*Log binomial generalized linear model

Doctors reported that they completed incident reports most often for patient falls, and least often for pressure sores. When asked to comment on what incidents should be reported, most doctors believed that incidents where the patient received the wrong treatment should be reported (92% agreeing); however only 57% thought they should report a drug error near miss (Table 4-15).

Table 4-15 Staff views on the necessity of reporting incidents

INCIDENT	**Doctors (%) who should report incident ≥ 50% of occasions (N)**	**Nurses (%) who should report incident ≥ 50% of occasions (N)**	**p value***
Patient injury due to a fall	85.6 (153)	98.7 (538)	<0.001
Patient received wrong treatment or procedure	91.4 (162)	98.1 (522)	<0.001
Drug error given, corrective treatment needed	87.3 (158)	98.1 (530)	<0.001
Equipment fault resulting in patient harm	84.7 (157)	96.7 (541)	<0.001
Drug error given, no corrective treatment needed	76.5 (162)	93.0 (525)	<0.001
Patient did not receive necessary treatment	74.0 (150)	87.0 (493)	<0.001
Breach in confidentiality	66.2 (151)	83.9 (491)	<0.001
Post-operative DVT due to inadequate prophylaxis	66.7 (150)	74.2 (462)	0.075
Hospital acquired infection	61.0 (154)	73.1 (509)	0.005
Pressure sore	53.6 (140)	69.0 (480)	0.075
Drug error made, not given to patient	57.2 (159)	50.9 (496)	0.172

*Log binomial generalized linear model

Agreement between what doctors did compared with what they thought they should report was low, ranging from an ICC of 0.50 for medication incidents where corrective treatment was required to an ICC of 0.10 for pressure sores (Appendix 19). Senior doctors were less likely than junior doctors to report patient falls (50% vs. 85%; p<0.001). There were no significant differences in reporting practices among doctors according to rural/metropolitan location.

With regard to current reporting practices, nurses perceived that they reported most incidents more often than doctors (Figure 4-4), with exceptions being for post-operative DVT due to inadequate prophylaxis and medication near misses, for which there were no significant differences in reporting practices by profession. Nurses reported that they completed incident reports most often for patient falls and least often for pressure sores (95.5% and 20.2%, respectively) (Table 4-14). Nurses regarded falls as the most important incidents to report and drug error 'near misses' as the least important (98.7% and 50.8%,

respectively) (Table 4-15). The correlation between what nurses did compared with what they thought they should report ranged from an ICC of 0.85 for medication incidents where corrective treatment was required, to an ICC of 0.24 for pressure sores and DVTs through inadequate prophylaxis (Appendix 19). For the majority of incidents, there were no differences according to seniority with regard to self-perception of actual reporting practices and opinion as to how often these incidents should be reported. Rural nurses were more likely than their metropolitan counterparts to report patient falls (100.0% vs. 94.6%; p=0.013), but not other incidents.

4.4.5. To identify barriers to reporting (aim 3.3)

Table 4-16 shows that the major barriers to reporting incident were lack of feedback, a belief that there was no point in reporting near misses, and forgetting to make a report when the ward is busy. Fear of litigation was of concern for only a fifth of all respondents with percentages almost identical in both nursing and medical arms. Disciplinary action was a reason for not reporting incidents for fewer doctors than nurses (Table 4-16).

Significant barriers to reporting incidents for doctors were; lack of feedback, an opinion that the incident form takes too long to fill out, a belief that the incident was too trivial and a belief AIMS+ form is too complicated and requires too much detail (Table 4-16). There were no significant differences between doctors with regard to reporting barriers according to level of qualification or whether doctors worked in rural or metropolitan hospitals.

For nurses, significant barriers to reporting incident were; lack of feedback, a belief that there was no point in reporting a near miss, and an opinion that the incident was too trivial (Table 4-16). Senior nursing staff were less likely than junior nursing staff to agree that the following were barriers (a) worried about disciplinary action (4% vs 19% agree; p=0.004), (b) worried about litigation (8% vs 22% agree; p=0.018), (c) my co-workers may be unsupportive (8% vs 22%; p=0.012), (d) the form is not kept anonymous (15% vs 31% agree; p=0.017) and (e) junior staff are often blamed unfairly for adverse incidents (6% vs 28% agree; p<0.001). Agreement between metropolitan and rural nurses for these barriers was similar.

Table 4-16 Self-perceived barriers to reporting- percent who agree with the statement

Incident	Overall % (N)	Doctors % (N)	Nurses % (N)	P*
I never get any feedback on action taken	60.9% (740)	57.7% (170)	61.8% (570)	0.371
When the ward is busy I forget to report	47.7% (741)	47.3% (167)	48.1% (574)	0.930
The incident form takes too long to fill out and I just don't have the time	46.6% (739)	54.2% (168)	44.1% (571)	0.022
When it is a near miss, I don't see any point	46.0% (741)	36.0% (172)	49.0% (569)	0.003
The incident was too trivial	43.6% (735)	51.2% (170)	41.2% (565)	0.027
The AIMS+ form is too complicated and requires too much detail	34.5% (728)	31.9% (163)	35.0% (565)	0.512
I wonder about who else is privy to the information that I disclose	32.3% (738)	27.1% (170)	33.8% (568)	0.112
Adverse incident reporting is unlikely to lead to system changes	29.8% (739)	28.6% (171)	29.9% (568)	0.775
I don't feel confident the form is kept anonymous	28.4% (742)	22.6% (168)	30.0% (574)	0.065
Junior staff are often blamed	26.8% (742)	31.0% (171)	25.6% (571)	0.169
I am worried about litigation	20.6% (743)	20.7% (169)	20.6% (574)	1.000
My co-workers may be unsupportive	19.3% (740)	13.8% (167)	20.8% (573)	0.045
I don't know whose responsibility it is to make a report	17.1% (742)	37.9% (169)	10.8% (573)	<0.001
I don't want to get into trouble	16.9% (739)	10.6% (169)	18.6% (570)	0.014
It's not my responsibility to report somebody else's mistakes	16.6% (736)	17.2% (169)	16.4% (567)	0.814
I am worried about disciplinary action	16.0% (738)	8.3% (168)	18.1% (570)	0.002
Even if I don't give my details, I'm sure that they'll track me down	15.4% (731)	8.4% (167)	17.0% (564)	0.006
If I discuss the case with the person involved nothing else needs to be done	14.6% (735)	24.9% (169)	11.5% (566)	<0.001
I don't want the case discussed in meetings	13.8% (741)	7.2% (167)	15.5% (574)	0.005

* Fishers exact test

4.4.6. Summary of Results from Staff Survey

A total of 773 medical and nursing staff, or 72.8% of all staff surveyed, responded to the survey.

There were a number of key findings from this survey which we believed needed to be incorporated into the intervention for it to effectively change reporting behaviour.

Firstly, there was a need to provide education about the reporting system to doctors. Most nurses and doctors knew that their hospital had an incident reporting system (99.8% and 93.6% respectively); however less than half of the doctors knew how to access a report (43.0%) or what to do with it once completed (49.7%). Doctors, more than nurses cited lack of knowledge about who should report as a barrier (37.9% of doctors agreeing vs. 10.8% of nurses agreeing $p<0.001$). Doctors were also more likely than nurses to believe that there is no need to report an incident if the issues were discussed with the person involved (24.9% vs. 11.5% $p<0.001$).

Secondly, there was a need to provide education about types of incidents staff should report. For each incident type, both doctors and nurses believed that they should report the incident more often than they did report it. This was most pronounced for reporting of pressure ulcers, (65.5% believed they should, 17.2% believed they did report it on 50% or more of occasions) and deep vein thromboses (72.5% believed they should, 22.35% believing they did report on 50% or more of occasions). Only 50% of nurses and 57% of doctors believed that they should report medication near misses.

Thirdly, there needed to be feedback of outcomes arising from reports, as this was the most significant barrier to reporting for both doctors and nurses (58% and 62% agreeing respectively).

4.5. Focus groups

4.5.1. Sample

Table 4-17 describes the demographic profile of focus group participants. Group size ranged from four in the Consultant group to eleven in the senior nurse group.

Table 4-17 Demographic profile of focus group participants

Profession	Position	Females	Male	Age Range
Nurses	Senior nurses*	6	5	24 – 47
	Junior nurses†	7	1	22 – 46
Doctors	Consultants	0	4	41 – 63
	Registrars	1	3	29 – 37
	Resident Medical Officer	4	2	24 – 33

*Senior nurse: nurse undertaking advanced clinical practice in senior management position within the ward/unit.

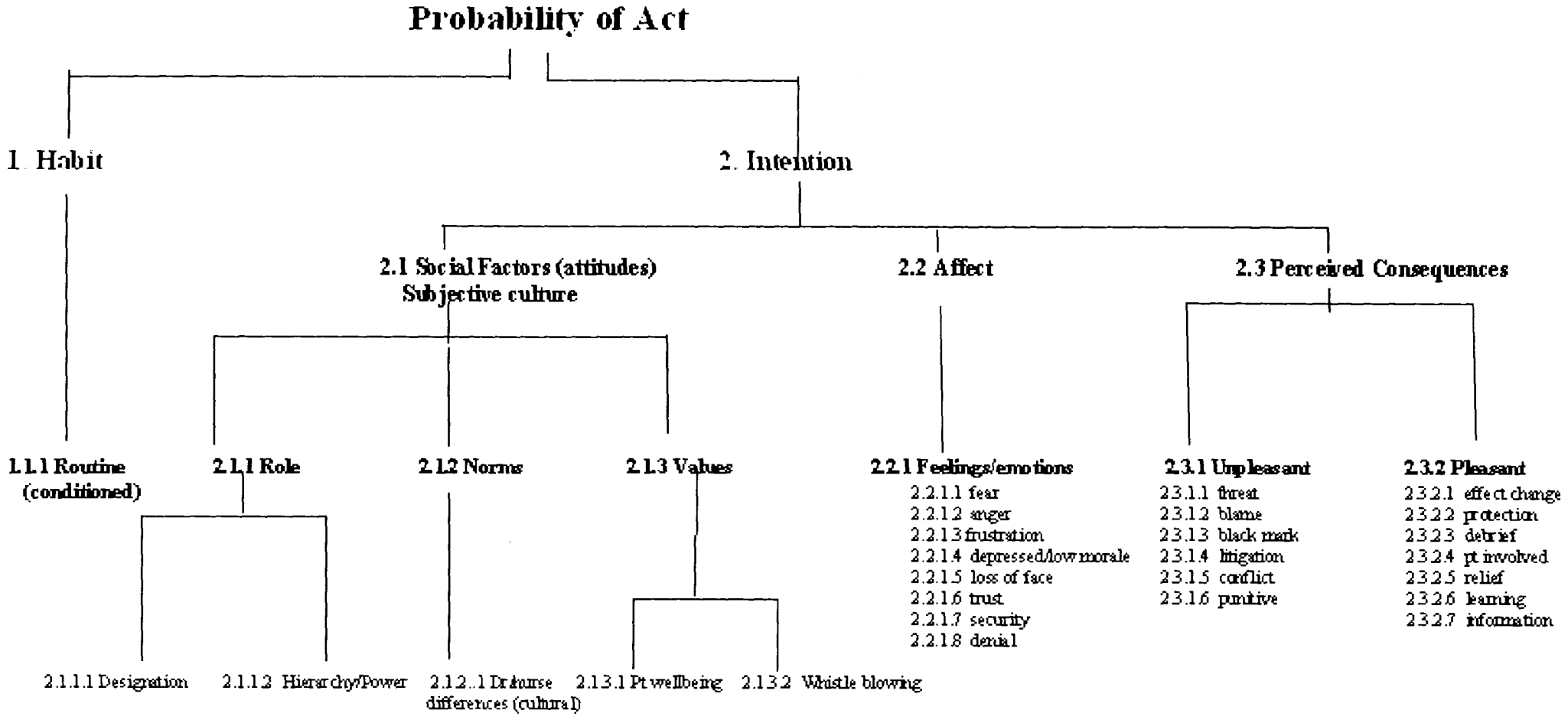
† Junior nurse: registered nurse or enrolled nurse undertaking clinical practice under the supervision of a senior nurse.

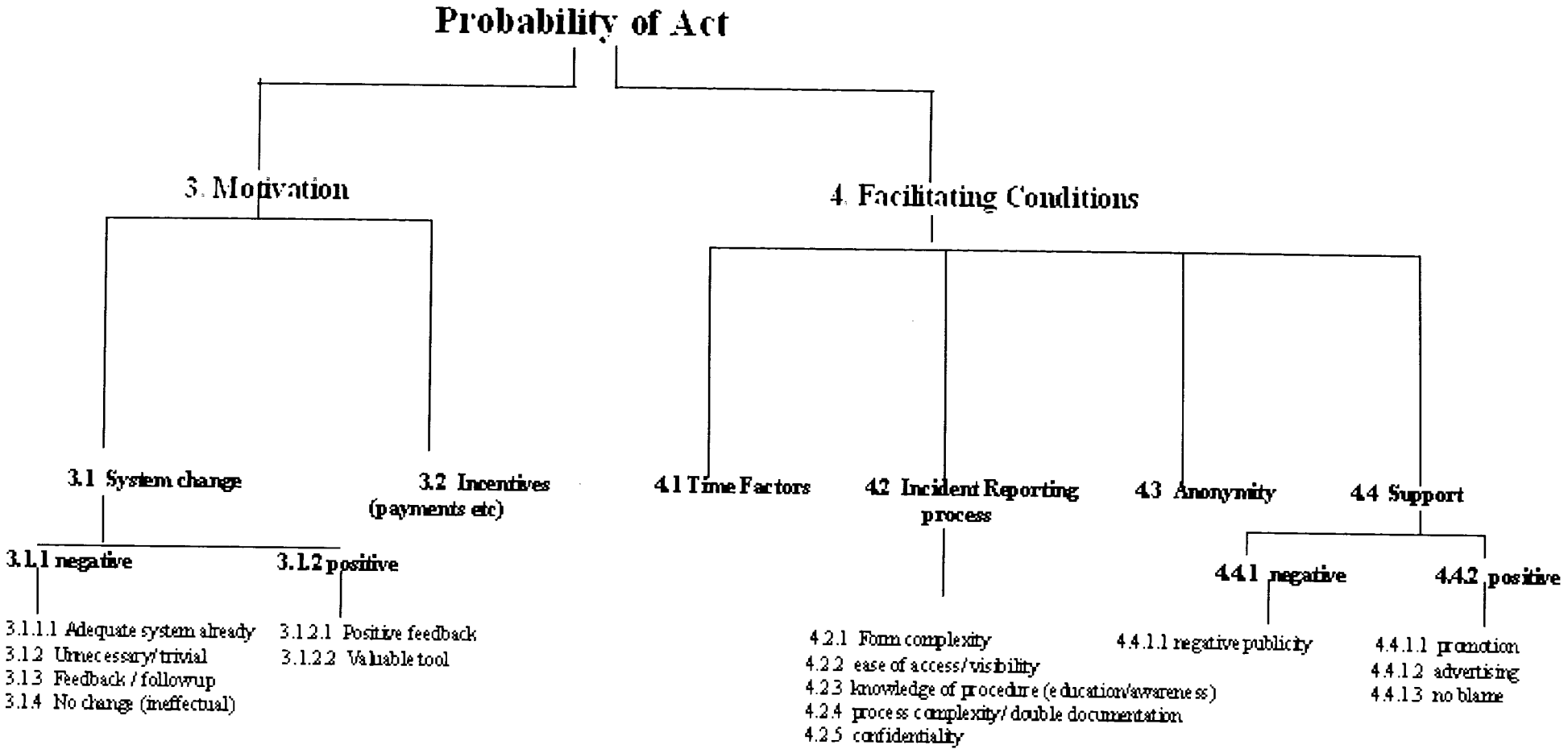
4.5.2. To identify knowledge of the reporting system (aim 3.1), baseline use of the reporting system (aim 3.2) and barriers to reporting (aim 3.3)

As discussed in the Methods section, Triandis' Model of Social Behaviour was chosen to provide a framework to help explain reasons for health-related behaviour in regard to incident reporting. The formula was used simply as a means by which to organise a lot of information so that precise theoretical statements could be formulated.[289]

Figure 4-5 outlines the "branches" of the tree which were developed during analysis of the focus group transcripts.

Figure 4-5 Barriers to incident reporting using Triandis' Equation




Probability of Act
3. Motivation
4. Facilitating Conditions
3.1 System change
3.2 Incentives (payments etc)
4.1 Time Factors
4.2 Incident Reporting process
4.3 Anonymity
4.4 Support
3.1.1 negative
3.1.2 positive
4.4.1 negative
4.4.2 positive
3.1.1.1 Adequate system already
3.1.2 Unnecessary/trivial
3.1.3 Feedback / followup
3.1.4 No change (ineffectual)
3.1.2.1 Positive feedback
3.1.2.2 Valuable tool
4.2.1 Form complexity
4.2.2 ease of access/visibility
4.2.3 knowledge of procedure (education/awareness)
4.2.4 process complexity/ double documentation
4.2.5 confidentiality
4.4.1.1 negative publicity
4.4.1.1 promotion
4.4.1.2 advertising
4.4.1.3 no blame

Uppermost branches (Habit, Intention- Social factors, Affect, Perceived Consequences, Motivation and Facilitating Conditions) were taken directly from Triandis' Model and used in the first instance by the two reviewers to broadly classify comments. The tree grew more branches as the themes emerged during analysis of the transcripts. The tree displayed in Figure 4-5 was used in conjunction with the transcripts when classifying incidents. It was possible to put one comment in multiple categories. The following example is used as an example of the coding process.

"The first time I had to fill one of these out was when the nurse was telling me 'You have to fill out an incident form'. It scared me because I didn't know what that meant. Oh my goodness, what was this for? What did I have to do? And it's so long. And I asked 'what's this for?' and like she said' Oh, it's just something that has to be done...it's nothing'' OK, I said, so do I still have to fill this in?" [Registrar]

Using the tree outlined in Figure 4-3, comments were classified as shown:

"The first time I had to fill one of these out was when the nurse was telling me 'You have to fill out an incident form'. It scared me (Branch 2.2.1) *because I didn't know what that meant. Oh my goodness, what was this for?* (Branch 4.2.3) *What did I have to do? And it's so long.* (Branch 4.2.1*) And I asked 'what's this for?' and like she said' Oh, it's just something that has to be done...it's nothing'* (Branch 1.1.1) *OK, I said, so do I still have to fill this in?* (Branch 2.1.2)" [Registrar]

As discussed in section 3.5.5, a report was submitted by the facilitator following the focus groups by the independent moderator, and is attached as Appendix 20. As mentioned in the Methods section, the Project Officer, Marilyn Kingston and Ph D candidate independently classified all comments from focus groups discussions and together designed the tree from which these comments have been taken.

Comments from focus group transcripts were classified into themes by both the PhD candidate and a Project Officer, who is first author on the published manuscript[200] However, the interpretation of comments for the purpose of this section are those of the PhD candidate.

4.5.2.1. Habit

Habits develop where certain behaviour becomes automatic. Other than in new situations, when an act requires deliberate and controlled effort, habit is the most important predictor of behaviour.[271]

There were marked differences found between doctor and nurse attitudes towards reporting and habitual behaviours (see Comments relating to Habit below). Doctors did not report through habit, as they did not see reporting as being part of their role. On the rare occasion when an incident was reported by medical staff, it was completed by junior doctors after being initiated by nurses. Doctors thought of incidents as being for minor events and therefore fell into the nursing domain of responsibility.

In contrast, nurses identified incident reporting as being part of their role, citing directives and protocols that instructed them to fill out reports. Nurses reported certain types of incidents habitually, such as patient falls and medication errors. Incident reporting was often dependent on where the incident occurred. For example, a skin tear occurring on a ward was more likely to be reported than if it occurred in the operating theatre.

Comments relating to Habit

*"I think they're (*nurses*) better trained in the process than we are..."* [Consultant]

"There was what I consider a serious incident during the procedure...I think it would fill the criteria of an incident and it would be appropriate for an incident form... the nursing staff initiated the form but the doctors should have done it themselves ...that might have been because of a cultural thing with incident forms, because we're not filling them out as often..." [Registrar]

"It just doesn't occur to me that an incident report should be made" [Registrar]

*"We do (*complete incident reports*) but the nurses are the ones who initiate it. It's not the doctors who make that decision."* [RMO]

"Our organisation tells us that we need to fill out these forms, therefore we do. We have directives, whether we do them well or not that's another question" [Senior Nurse]

"I know a lot of people who don't fill it out, if they haven't hurt themselves, but you're supposed to record those..." [Junior Nurse]

Intention, being a self instruction to perform an act,[271] comprises social factors, affect and perceived consequences.

4.5.2.2. Intention - Social Factors

Social factors represent how a person perceives their environment through beliefs, attitudes, ideals, roles, norms, and values.[271]

Both doctors and nurses saw little value in the existing incident reporting system. Comments raised during general discussion in each focus group of doctors revealed a preference to keep adverse events 'in-house'. They believed loyalty to colleagues was important, and that incident reporting constituted whistle blowing, which was unethical and unsupportive. Because doctors believed that most incidents reported by nursing staff were trivial, reporting was thought of as a menial task and was usually delegated to junior doctors. More serious events were not regarded as something that they would report using an incident report. Many incidents were not regarded so much as incidents as known complications. One consultant stated that nurses were better at reporting incidents because of their relative powerlessness, and it was their only recourse to improving a situation.

Nurses felt frustrated and resentful by what they perceived as doctors' lack of accountability. Most incidents reported by junior nurses were done so after instruction from senior staff. Whereas doctors were most concerned about issues of maintaining loyalty, nurses appeared to be more concerned about protecting themselves. Nurses said that they commonly reported incidents to cover their actions. They felt that by reporting they had protected themselves from punitive or what they perceived of as legal repercussions. Although there was mention of the importance of reporting to improve patient care, this was not reflected as strongly as the desire to protect themselves.

Comments relating to Intention (Social Factors)

"Nurses are the main movers in incident reporting and generally call on the doctor to include an opinion or a comment on the form" [Consultant]

This (incident reporting) *fits the nursing mould of thinking which is very rigid and you know black and white...I see a problem; I can deal with this by communicating with the people concerned without going to paperwork. Nurses don't think like that. Nurses think this must be reported, put on paper and some action must occur that's official."* [Consultant]

"(Doctors) *are not very good at dealing with adverse events, mechanical, psychological and other impediments"*

[Consultant]

"Nurses by and large claim that they are not in power, that they don't have the power to change things and the doctors are the ones with the power and that's probably shifting a bit, but it may well be that the nurses only course to improve the situation is to go through the formal process, whereas the doctors may feel that these things happen...you carry on, you pick yourself up and you try to do better next time. You don't go through the formal process of analysing it. I think that's probably how doctors mostly behave." [Consultant]

"We deal with bigger issues" [Registrar]

"If they are forms for anyone, as doctors we often think why do we need to fill this in? Can't somebody else do it?" [RMO]

"I've never heard a doctor say we have to fill one (incident report) in" [RMO]

"Patient didn't die, what's the problem?" (comment on doctors' attitudes towards reporting) *[Senior Nurse]*

"a very strong, almost a network, covering each others' back most of the time" (in reference to the medical culture) [Senior Nurse]

"*I would have trouble selling this* (incident reporting) *to the consultants... 'yeah' they'll say, 'Yeah, it's a good idea and all'* (group laughs) *but that's exactly what it is."* [Senior Nurse]

"*I don't see why we have to chase them* (doctors) *up, they're a separate entity, they're lacking with discipline, and they're lazy... Generally it's the medical officers that let the side down"* [Junior Nurse]

"...you do (complete an incident report) *to cover yourself"* [Junior Nurse]

4.5.2.3. Intention - Affect

Affect or emotions result from previous experiences with the same behaviour.[271] There were many emotions expressed in relation to errors and incident reporting (see Comments below).

Doctors were concerned about how information was to be used after it had been reported. There was distrust that the hospital would use it solely for the purpose of quality assurance. They felt frustration towards the present system, which they regarded as a waste of time and

provided little value. There was ambiguity amongst the consultants about whether they would support a system where errors were disclosed. Consultants, more than other groups of doctors, were worried about medico-legal implications of submitting a report. One Consultant believed that a major barrier to a more open and transparent reporting system was denial by doctors that mistakes were made. There was a feeling by senior doctors that reporting took a great deal of courage, because they were admitting their own fallibility.

Nurses also felt anxious about having to face punitive repercussions from senior personnel. Like doctors, they too felt frustration that the current system was not providing them with feedback or any real incentive to report. Nurses often personalised mistakes, regarding them as a sign of incompetence or lack of aptitude. They felt a profound sense of embarrassment at having made a mistake, but accepted the need for a reporting system, and some nurses reported feeling relieved at having dealt with an incident. Some senior nurses believed the organisation tried to cover up incidents to protect themselves against litigation.

Comments relating to intention (Affect)

"I think there are other aspects, perhaps slightly more dangerous aspects which might be doctors potential to deny adverse events, which psychologically is more important if you're totally responsible for the adverse event..." [Consultant]

"So it's not protected information by any means. Unless you have protected, confidential information, you don't get the facts." [Consultant]

"For example, there was an incident where a medical registrar couldn't attend a code black and the nurse went ballistic and filled out the incident form as a way of emphasising how irritated she was, and I thought that was a very inappropriate use of incident form filling" [Registrar]

"The loss of face amongst peers and yeah sometimes embarrassment" [RMO]

"I find it a little intimidating. It's very scary if something happens. I don't feel happy because I have to fill a form out and I think I feel a little frightened that I'd get blamed for it." [Senior Nurse]

"And they're put up all over the place for people to just look through...if you have a box to put them into that'll be great because people wouldn't mind filling it in. You sign it and people look at you and think, 'What's she got against me?' [Junior Nurse]

4.5.2.4. Intention - Perceived Consequences

Triandis' theory describes a cognitive schema where predicted consequences occur through previous exposure to objective outcomes of an event. These impact on belief systems and serve to reinforce associated behaviours.[271]

Negative consequences

Doctors described instances where the reporting system was misused as a tool to inform against them, often providing no right of rebuttal. There was consensus in the belief that the report often served no purpose when it was actioned by the NUM, who was seen as the wrong person for the task.

Nurses were worried about being blamed if they wrote a report and there were many junior nurses who felt particularly vulnerable to being bullied by more senior staff. A number of junior nurses believed that incident reports were kept in personnel files and were used against them, particularly if they were seeking employment elsewhere. Job insecurity and threats to future employment as a result of writing an incident report were repeatedly expressed by both senior and junior nurses; however this was more evident in junior staff. Senior staff who received the statistics from aggregated reports stated that they were meaningless to them, and did not tell them what they needed to know. Reporting rates and types of reports were felt to not help them address problems that needed to be solved.

Positive Consequences

Doctors of all seniorities could see benefit in a reporting system which provided prompt feedback. A comment was made by a Consultant that incident reporting ought to work in conjunction with evidence-based medicine to effect change and create a safer working environment. There was a belief among senior doctors that, while in its current environment there was no evidence of incident reporting being used in a constructive way, it could become more accepted as people were beginning to talk more about errors in different forums. Similar to nurses, they believed that it could be an effective tool to make governing bodies aware of problems in the health system.

Nurses saw that it could, and sometimes did provide information, increase awareness and effect positive change. They cited examples where it had made an impact, such as improved work conditions in the ED, the presence of a security guard after hours in the ED, purchase of new equipment, as well as the psychological benefit it provided in enabling debriefing of

an event through writing the report. They spoke about where it could potentially evoke change in providing additional staffing and workplace support. By documenting justification for procedures such as restraining aggressive patients, junior nurses believed reporting also provided defence against patient complaints and litigation.

Comments relating to Intention (Perceived Consequences)

"It would be nice to know that the treatments that we offer actually do anything at all." [Consultant]

"Filling a form seems to not, a couple of things actually, not immediate enough or not addressing the right person, and also um, when things are written, you always worry about I suppose the legal implications..." [RMO]

"People don't know it's a recurrent problem, they think it's a one off, but then if all the AIMS (incident form) *are filled out, and it's a recurrent problem, then hopefully practices will be changed..."* [Senior Nurse]

"They [nurse colleagues] were too scared to do this [fill in a report] because they thought this was a personal threat because they were told that this stays in your file, and this can be used against you further on" [Junior nurse]

"On page two, there's a place for a signature and we have been told that regardless it had to be signed, and if it's signed, it's not anonymous" [Junior nurse]

"*Why would you want to sign one of these forms if you get caught or something, I wouldn't want to do it."* [Junior Nurse]

"*Makes you feel better when you can be talked through an incident to (sic) senior staff"* [Junior Nurse]

4.5.2.5. Motivation

Triandis described motivation in terms of physiological arousal with the individual being in a high needs state, or in a situation that is relevant to his or her values.[271]

Despite the perceived inadequacies of the present system, both doctors and nurses believed that a reporting system which was (a) quick and simple to use; (b) effective in bringing about change; (c) ensured that reports were handled without threat or blame attached; and (d) able to provide prompt relevant feedback with which to support improvements in health

administration would entice them to report. There was acknowledgment that they would "give it a go".

A number of doctors referred to the fact that they would be motivated to support an intervention which was supported by evidence based principals. They were less inclined to report simply for the sake of reporting.

Comments relating to motivation

"Well, I mean I think immediately of a case when I had a migraine patient with two prolonged convulsive seizures that was never reported to me or anyone else and not even written into the case notes. I guess we could have filled out one of these forms then, instead of complaining about it maybe we could have got better co-operation if we'd filled out one of these forms." [Consultant]

".. what sort of incidents are really worth reporting? What's the evidence that certain incidents are worth reporting, and is there evidence that certain incidents are not worth reporting? Because if you report every damn incident you finish up with a huge amount of information and you've got several people employed to analyse that information.....I'm professionally a sceptic and by inclination and so when I'm asked to contribute to something I want to know why, why are we contributing to this? [Consultant]

"If we don't report it, document it and practice it, it won't change, or we won't be aware of problems, particularly recurrent problems." [Senior Nurse]

4.5.2.6. Facilitating Conditions

These were defined by Triandis as objective environmental factors "that several observers can agree make an act easy to do."[271]

Each focus group expressed strongly that time constraints were important barriers to reporting. Most thought that the form in its current format was unsatisfactory because of its length. Suggestions included shortening the form to just one page and making it more accessible. It was suggested by a Consultant that computers be utilised or a Project Officer with a health background be employed to identify incidents and report them. Both doctors and nurses felt there was a need for a clearer definition of adverse event.

Senior doctors believed that the reporting process should be more relevant to doctors and suggested decreasing threat by renaming the form, increasing awareness and knowledge of

the process, and providing guaranteed protection of the person and information from liability. The feasibility of an anonymous option was questioned by both doctors and nurses. Anonymous reporting was not always felt to be possible or desirable by some doctors, who preferred having the information confidential and legally protected. There were a few senior doctors who were loath to trust in a confidential system. They questioned the degree of protection from litigation it would provide, and wanted guaranteed protection of the person. Many felt that anonymity would prevent discussion of issues. A suggestion was made by a Consultant that people be given financial incentives for reporting incidents.

Nurses wanted a system which did not rely on input from doctors. They spoke about the inconvenience and time wasted through having to 'chase up' doctors for their input. They advocated education at orientation for both nurses and doctors. While most nurses supported an anonymous reporting system as a positive means of addressing the issues and not the person, senior nurses voiced concern that they would not be able to adequately follow up an incident if the reporter was not known. There was scepticism by senior and junior nurses over whether it was possible for a person not to be identified, although overall, they did support an anonymous option. They saw it as a positive means of increasing reporting and felt that people would focus more on the event than looking to blame the person they saw as being responsible.

Comments relating to facilitating conditions

"There's no incentive either to really fill it in. I mean, if you paid someone five bucks a form, it would be interesting to know..." [Consultant]

"Yet another form" [RMO]

"Frustration through lack of feedback" [Senior Nurse]

"And get some sort of definition and some guidelines" [Senior Nurse]

"We had so much that happens in our area, that we would spend all day, eight hours of the day filling these in, on every single patient that comes through the door, so I think I can, well I see that they're useful, they're also very time consuming" [Junior nurse]

"Only a resource tool and therefore shouldn't require names on them" [Junior Nurse]

"Time is a big factor" [Junior Nurse]

4.5.3. Summary of Results of Focus Groups

There is a huge cultural divide between doctors and nurses in regard to incident reporting. Doctors do not report habitually, with many seeing it as a form of whistle blowing or a sign of disloyalty to colleagues. Doctors were worried about internal and external factors such as litigation and what happened to the information within the hospital. In its current format, doctors were reluctant to support the reporting system they see as being nurse-orientated, time consuming, and providing little value.

Nurses report habitually, even though they are often concerned about disciplinary action arising from reports. This disciplinary action was felt to predominantly come from within the clinical area, and there was fear that reporting would reflect badly on their personnel record. As with doctors, nurses believed the current reporting system was time-consuming and offered little value. They were frustrated at having to ask for medical input, and at the lack of privacy afforded to the reporting process. Senior staff felt that reports generated from the current reporting system were not helpful in directing organisational change.

Following analysis of the focus group transcripts, suggested strategies to identified barriers were listed as pre-requisites in the development of an effective reporting system, and are attached as Appendix 21.

4.6. Intervention

4.6.1. Introduction

As discussed in the Methods section 3.6.1, the intervention was developed following analysis of focus group transcripts and staff survey findings. There were four key areas that were targeted;

1. the need to make the reporting system easier to use;
2. the need to improve reporting processes to make it less threatening for staff to report and more effective in facilitating improvements in patient care;
3. the need to provide education to staff and;
4. the need to provide effective feedback to staff and demonstrate changes/outcomes to sustain interest.

The Results section will first provide a broad overview of strategies to address each of these four key areas listed above. It will then provide results on the effectiveness of the intervention in:

- improving incident rates, by departments, types of unit (medical, surgical, ICU, ED), location of hospital (rural and metropolitan) and professional groups (doctors, nurses, allied health, anonymous, and other)
- changing the types of incidents reported, by units and professional groups.
- changing self-reported reporting practices, by comparing follow up survey with baseline.

The rationale for undertaking analysis based on units was that people contemplating introducing a reporting system such as this, would be most interesting in understanding how it was accepted in their type of clinical area.

4.6.2. Making the reporting process easier

4.6.2.1. Single-page incident form

A single page incident form was developed to capture a minimum dataset of information. The single-page form developed for use in the intervention units was initially known as an Event Notification Form and later became known as the IRIS Form.

Some information contained in the four-page existing AIMS form was not collected in the IRIS form (Appendix 22). At the outset, there was concern raised by NUMs about the brevity of the form, and whether enough information could be recorded on the form to enable them to manage the incident effectively. Another concern raised was that there would be potentially less information available to coders to enable accurate and meaningful classification.

At a meeting with the NUMs (see section 3.6.7.1) there was agreement that the form could be trialled and modified if necessary after a three-month period. Re-iterated to the group on a number of occasions was the fact that this was an experiment, and that concerns they raised would be answered through the intervention.

The removal of the section where medical staff were directed to report on each incident reported was welcomed, as was the change in reporting process (described in section 3.6.8.1).

With regard to the positioning of incident forms in intervention units; where possible, incident reports were placed in Perspex holders and attached to the walls in most of the intervention units. In the event that there was no space or permission was refused to put the boxes on the walls, incident reports were placed in places where they would get maximum exposure. Appendix 23 outlines where incident reports were placed in each of the intervention units.

4.6.2.2. Call Centre

Based on the essential criteria listed in section 3.6.7.2 that the Call Centre operate 24 hours a day and be staffed by Registered Nurses, there were only two Call Centres eligible for inclusion. Both provided extensive training for the RNs however one was located in Adelaide while the other was based in Western Australia. A decision to use the local Adelaide Call Centre operated by the Royal District Nursing Service (RDNS) was based on the following rationale:

- The Adelaide Call Centre was already part of HSNet (outlined in section 3.6.6 and shown pictorially in figure 3-4). This meant that data could be transmitted into the centralised database within a secure firewall without any additional expense.

- Call costs to a local (12 cents per minute) or regional (15 cents per minute) telephone using the freecall service were considerable cheaper than long distance calls (27 cents per minute).
- Being close to both the software provider's office and the project team, meant that training and information technology support were readily accessible.

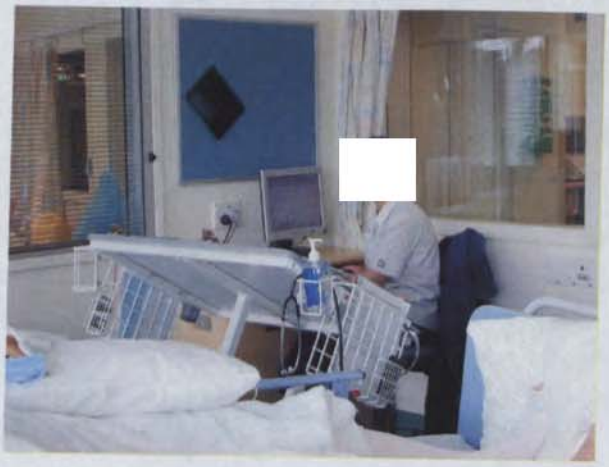
The procurement process, including Contract negotiations took approximately six months. The Strategic Procurement Office, Department of Health worked with the PhD candidate in the establishment of the Contract.

4.6.2.2.1. Key performance indicators

With regard to the key performance indicators established as part of the Contract with the RDNS, Appendix 24 describes how the Call Centre performed in relation to each of them.

4.6.2.3. On-line reporting

On-line reporting refers to the process by which clinicians directly log into the AIMS database to write a report. On-line reporting was only established in Department 20 as part of the intervention. Department 20 was an ICU, which had a computer beside each bed. The ICU had 217 nursing staff members on the roster. To introduce on-line reporting education sessions were held for nursing and medical staff during handover, in the evenings and overnight. A total 113 staff members requested to have access to the AIMS database. Each staff member was asked to provide a username and password to the Project Officer at the conclusion of the education session. They were able to access the system within 24 hours of attending the education session. An A5 laminating form was placed in each patient bay as a prompt to encourage reporting in ICU.



4.6.2.4. The Advanced AIMS database

Training sessions for the AIMS database were available to senior administrators, Call Centre personnel, educators and NUMS and Heads of Medical Units either on an individual basis or as a group activity. An education folder was developed for Call Centre personnel to assist them in completing database fields accurately (Appendix 25).

In rural hospitals, initial training sessions were coordinated by the Project Officer and conducted by the PhD candidate. However, ongoing sessions were conducted only by the Project Officer. All NUMs participated in training sessions and received ongoing support from Project Officers with regard managing incidents throughout the intervention.

Each Medical Head of Unit was shown the AIMS database by a Project Officer and was given authorisation to access it via a personal identification number. Only one Medical Head of Unit (ED in metropolitan hospital-Department 6) entered their comments directly into the AIMS database. All other Medical Heads asked that the incident reports be exported and sent via electronic mail to them as an attachment. They would then send their response to the incident via an email to the Project Officer who would enter it into the database.

At the commencement of the study PSMs agreed that reports from the control units were to be entered into the pre-existing AIMS+ database for the project duration, however after six months (from January 1 2004) most hospitals chose to have their clinical coders enter all AIMS reports from their hospital into the Advanced AIMS database in preference to the AIMS+ database. Even though reports were entered only after they had been actioned by the NUM (section 3.6.5.1) and the NUMs and Medical Heads of Units of control units were not given access to the database until after the project concluded, in hospital 3 control units were provided comparative reports detailing their department's performance in relation to other departments in their hospital. This meant that they were able to compare their performance against the cardiology intervention unit.

4.6.3. Provide a non-punitive reporting system

4.6.3.1. Anonymous reports

As part of the study design to make the reporting system less threatening, provision was made for staff to report anonymously. These reports were actioned by the PSM instead of the NUM. Reports were deemed anonymous if the reporter (a) did not write their name or location of the incident; or (b) wrote the location of the incident but not their name; or (c) wrote their name but no location. The number of anonymous reports submitted is outlined in section 4.6.7.5.4. The management of anonymous reports was difficult for a number of reasons:

- The PSM was required to address incidents so that the reporter could not be identified. In most cases, anonymous reports were not particularly sensitive and, this was not an issue. However, one report in which the reporter discussed performance management issues could not be actioned without identification of the source so that issues could be clarified.
- The PSM was required to address incidents so that the line manager was not implicated. This meant more work than was often required, in order to address issues which were isolated to only one area.

The PSM was unable to action many minor anonymous incidents (SAC 3 and 4 incidents). They were not included in aggregate reports to individual units but were reported to the Safety and Quality Committee (or equivalent) within each hospital.

Despite providing education about the reporting process for anonymous reports, in one rural hospital, the Project Officer determined that some staff were not writing their names because they thought that the NUM would be able to recognize their writing and so saw no need. They did not realize that, by not writing their name, the report would not be seen by their NUM.

4.6.3.2. Identified reports

Because paper forms were sent to the Quality Unit in each hospital, reports were initially screened by the PSM prior to being entered onto the database. Serious events (SAC 1 or 2 events as classified by the reporter) were reviewed by the PSM and the SAC score was validated. Validated SAC 1 events generated an automatic email alert which was sent to

those given authorisation (usually the Director of Medical Services and Director of Nursing, NUM and Medical Head of the Unit), and usually resulted in a Root Cause Analysis (RCA) investigation being commenced. Less serious events were entered into the database within 48 hours of being receipted in the Quality Unit.

Despite efforts to encourage Medical heads of Units to use the database, with the exception of one clinical area, they preferred to have a copy of the incident report emailed to them as an attachment, thus negating the need for them to access the database. Where there was a need for Medical Heads to investigate incidents, they would do so and email actions implemented to the NUM or Project Officer. These actions would be added into the management section of the database.

As part of the study design, PSMs, Medical Heads of Units and NUMs were invited to attend a Root Cause Analysis (RCA) workshop to assist them in adopting a systems approach to investigating errors. All PSMs and NUMs of each of the intervention units attended the workshop at the commencement of the project.

Three GPs in Hospital 4 were invited to attend, and an offer was made to pay for airfares, accommodation and wages lost in attending the workshop. This was particularly important for GPs who would otherwise have been without income for the day. Despite providing two months notice and distributing reminders to medical staff, support for attending RCA workshop was variable. In the rural hospitals, the Medical Director of hospital 4 attended, but no GPs attended from hospital 4 and no medical staff attended from hospital 5. In metropolitan hospitals, three out of the six Medical Heads of Unit attended the workshop; those declining were from a surgical unit, ICU and medical unit.

Identified incidents not warranting an RCA investigation were managed at a local level according to the following factors:

- **The potential risk associated with the event.** The same risk matrix used for the actual events was used to determine the potential SAC score. A sum of the actual and potential SAC provides a priority scale for incidents eg actual SAC score of three, but potential SAC of one = aggregate SAC score of four. For example, a patient on the neurology ward fell out of a very unsteady commode. Because he was fastened into the chair, it fell on top of him. He sustained a laceration to the head, but there was likelihood that his injuries may have been more severe. Because

patients suffering hemiplegia in the neurology ward often required assistance using a commode, fixing the problem was given high priority.

- **Work currently being undertaken to address the problem.** Some incidents were being addressed as part of the hospital quality improvement program. For example, falls working groups were trialling non-slip mats around bed areas, falls risk assessment tools, and were renovating bathrooms to avoid water pooling in dangerous areas.
- **How easily the problem could be rectified.** Some incidents could easily be actioned to minimize likelihood of recurrence. For example, an incident report was generated when cross-transmission of head lice occurred between three patients in the same bay. Nurses had identified the lice, but were awaiting orders to be written by a doctor, so that they could begin treatment of the infected patient. Following consultation with pharmacy and medical staff, procedure was changed to enable nurses to order the lice treatment without requiring medical authorisation.
- **The cost associated with minimizing risk of an incident recurring.** Costs requiring small outlay of money were easier to fix that those requiring large outlay (>$AU10000 in most instances) because they were processed differently though hospital administration.

4.6.4. Provide education to doctors and nurses

Initially, all medical staff in the metropolitan hospitals were provided with education about the project in their departmental meetings. In hospital 4, a rural hospital with three intervention units, there was no departmental meeting or forum where all GPs met. To introduce the project, a letter outlining the hospital's involvement in the project was signed by the hospital's Chief Executive Office and Director of Medical Services and another letter explaining the role of the Project Officer was signed by the Principal Supervisor, PhD candidate and Project Officer. Each GP was also provided with an education folder and aide memoir (attached as Appendix 11) outlining events that should be reported.

4.6.4.1. Promotional material

In providing information about the Call Centre and types of incident to be reported, a number of promotional strategies were used (Appendix 26):

- Pens, on which the telephone number for the Call Centre and the name of the project was printed;
- Stickers, containing the project logo and the telephone number of the call centre was placed on the handsets of telephones;
- Four posters, developed by Project Officers, were placed in strategic places such as in the Resident's Lounge, clinical education/tutorial rooms, on the doors of rooms where departmental meetings were held and in Staff Rooms. They were not put in predominantly patient access areas;
- Screen savers, placed on computers in workstations, with the telephone number of the Call Centre and the project name; and
- "Cheat sheets," available for staff in the ED and ICUs which contained lists of biochemistry and pathology normal ranges and a list of incident types that staff should report.

4.6.5. Provide feedback to doctors and nurses

Feedback occurred at both individual and departmental level.

4.6.5.1. Individual feedback

The feedback given to reporters was dependent on the severity of the incident. Incidents given a SAC 1 status by the reporter required that feedback be provided by the PSM within three days of the report being generated. This timeline was achieved on all occasions. On a number of occasions reporters misclassified the incident. They were contacted by the Project Officer or PSM within the 48 hours so that the Risk Matrix could be explained to them.

Incidents given a SAC 2 rating by the reporter required that feedback be given within two weeks of the report being generated by the line manager, or by the Project Officer in the initial two month establishment period. Liaison between the Project Officers and the NUMs occurred on a weekly to two-weekly basis to ensure that targets were being met and to provide assistance where required.

4.6.5.2. Departmental meetings

It was anticipated that meetings be held on the three monthly basis to provide feedback to clinicians about outcomes arising from incidents. In some units, a request was made to have meetings more frequently and, in other units, despite providing assurances that time would be allocated to provide feedback, this did not occur. Feedback to nurses occurred on a regular basis (monthly in most departments). Table 4-18 outlines how many departmental meetings were held for clinicians in intervention units during the study period. For medical staff, the frequency of the meetings appeared to impact on reporting rates, where those units participating in more meetings were also those with more doctor-initiated incidents.

In each hospital, a person was nominated to be the contact person for report generation, and it was generally this person who ran the reports. Reports could be generated on any fields in the database. The most common reports were summary reports of individual de-identified incidents that were used to discuss incidents at departmental meetings, and aggregate reports based on incident types.

Table 4-18 Frequency of departmental meetings for medical and nursing staff

Department (Dept) number	**4**	**5**	**6**	**9**	**11**	**13**	**14**	**15**	**19**	**20**
Type of Unit	Med	Surg	ED	Med	Med	Surg	ICU	Med	Ed	ICU
Hospital number	1	1	1	2	3	4	4	4	5	6
Location of hospital	Metro	Metro	Metro	Metro	Metro	Rural	Rural	Rural	Rural	Metro
Details of outcomes provided	Y	Y	Y	Y*	N	Y	Y	Y	Y	Y
Medical meetings										
Number of medical dept. meetings	4	3	6	5	2	1	1	1	1	3
Time allocation at meetings (minutes)	20	10	30	15	10	60	60	60	60	30
Attendance rate % (N)	80% (10)	59% (27)	33% (27)	70% (23)	58% (21)	41% (22)	41% (22)	41% 22)	66% (6)	37% (27)
Nursing meetings										
Number of nursing dept. meetings	13	13	13	13*	13	13	7	13	13	16
Time allocation at meetings (minutes)	10	10	30	10	10	10	10	10	10	10
Reports generated during study period										
Medical reports†	7/108	5/81	23/80	4/153	3/102	0/84	0/37	2/249	3/101	2/116
Number of doctors submitting reports	4	4	8	3	1			1	3	2
Nursing reports	99/108	72/81	56/80	135/153	93/102	70/84	29/37	210/249	34/101	107/116

*outcomes only provided for months 1-2, and 7-9

† a total of 57 reports were submitted by doctors during the study period however for 8 reports the ward was not identified

Feedback to nurses and doctors in rural and metropolitan hospitals differed, and will be discussed separately.

Metropolitan medical meetings

Departmental meetings in metropolitan hospitals ranged from two monthly meetings with thirty minute time allocation to discuss reports generated (Department 6) to six monthly meetings with ten minutes allocated for discussion of incidents (Department 11). A similar format was used for each meeting. At the initial meeting the Principal Supervisor and PhD candidate introduced themselves and provided a synopsis of the project. At subsequent meetings incidents reported since the last meeting were discussed. Where no reports had been made by doctors, other de-identified incidents, including findings from Root Cause Analysis investigations, which were seen as relevant and interesting were discussed. These usually incorporated events made by doctors in other intervention units. The purpose of this feedback was to highlight the non-punitive system-based approach to management of incidents. Listed below are details of how each metropolitan departmental meeting functioned.

Department 4 held their departmental meetings in the afternoon, once a week. The sessions were informal and well attended by doctors and the NUM. Being a small unit with only 10 doctors assisted in making the meetings informal with time allocated to discuss incidents in detail. The PhD candidate presented at each of these four meeting throughout the study period.

The metropolitan surgical intervention unit Department 5 held their departmental meeting once a week in the morning, prior to surgery commencing. The tight scheduling meant that only ten minutes was allocated for the Project Officer to speak. These meeting were well attended by medical officers and medical students, and were also attended by the NUM, clinical pharmacist and other allied health professionals. There was little opportunity to discuss incidents and interact with doctors in discussion of incidents.

Department 6 held weekly meetings and a journal club. It was at the journal club that the PhD candidate or a Project Officer was given opportunity to update medical officers about the intervention. During the 30 minutes allocated, the Medical Head of Unit assisted in presenting outcomes. The meetings were scheduled during overlap of staff in the afternoon to maximize attendance, however being a busy ED, on average only 30% of all medical staff on the roster attended these sessions. On two occasions, the clinical pharmacist and the radiographer attended the meeting. To compensate for the lower attendance rates, Project

Officers and the Medical Head presented incidents over a 30-minute period every two months.

Department 9 held meetings weekly in the morning. An initial meeting with medical officers introduced the project and reporting processes. For subsequent two meetings, the PhD candidate and the Project Officer were prohibited from providing feedback on individual incidents to doctors. However, at the last two meetings the Risk Manager, PhD candidate and the Project Officer discussed individual incidents and outcomes resulting from investigation with doctors, the NUM, medical students and allied health personnel. Difficulty in participating in this departmental meeting was largely due to the fact that the PhD candidate and the Project Officer were employed by another hospital, and therefore had little input into investigation following generation of incident reports.

Department 11 faced same limitations as Department 9 in having no Project Officers employed in the hospital. Weekly meetings were held at 0800 in the morning prior to commencing rounds. The PhD candidate presented an overview of the project at the commencement of the study, but was only given one other opportunity to speak at the departmental meeting, and this occurred six months into the project for 10 minutes. In attendance at this meeting were doctors and medical students.

Department 20 held journal clubs weekly in the afternoon, and it was in this forum that feedback was provided on a three monthly basis. Doctors, medical students and the pharmacist attended the journal club. An overview of the project was provided at baseline by a Supervisor and the PhD candidate. Feedback at the second meeting was given by the PhD candidate and nurse educator in the department. The third meeting was conducted by the Project Officer and the PhD candidate, and the last meeting was conducted by the Principal Supervisor, Project Officer and PhD candidate. As with Department 6, due to the number of doctors employed to work in the unit, only a third attended journal club on any given day.

Rural medical meetings

Department 12-14 were intervention units in a rural hospital (hospital 4) where all doctors were GPs. The GPs in these departments voluntarily participated in medical education sessions, which were held monthly in the evenings and were coordinated by the Royal Australian College of General Practitioners. There was opportunity to use this forum only once during the study period to discuss the project and incident management.

Because of the limited exposure gained through only participating in one education session with GPs, a number of other techniques were used to increase awareness of the project in the rural hospital:

- An education session was scheduled for all GPs in the hospital conference room in the first month of the intervention. The session was to be given by the Principal Supervisor, PhD candidate and Project Officer. The session was booked from 5:30pm to 6:30pm on a weeknight and it was fully catered for through project funds. On following up the invitation (which was sent five weeks in advance) with a telephone call to each GP the week prior to the scheduled event, the Project Officer was forced to cancel the meeting due to lack of attendance.
- Visits were made to a number of GPs on a three monthly basis. On the advice of the Director of Medical Services, three GPs who had demonstrated an interest in quality improvements exercises in the hospital were contacted and asked to support the project (one surgeon, and two GPs affiliated with the University of Adelaide). Two of these were visited again after three months where issues relating to poor reporting rates were discussed. A further three GPs were contacted at three months and the project was explained to them by the Principal Supervisor, PhD candidate and Project Officer

With regard to the evening education session, a number of strategies were employed to increase participation.

- The evening was coordinated by the Project Officer based in the rural hospital, who was known to most of the doctors.
- Invitations were issued to the session two months in advance. Follow up telephone calls were made to all GPs to encourage participation.
- A three course dinner with beverages was fully catered for by project funds. The venue was the most popular one used for the education sessions.
- The program consisted of (a) an overview of the South Australian Safety and Quality framework which was presented by the Executive Director, Clinical Systems, South Australian Department of Health; and (b) discussion of incident reporting and outcomes arising from reports in participating hospitals, which was provided by the Project Officer and the PhD candidate.

- The meeting was accredited with the Royal Australian College of General Practitioner as a quality assurance activity. This enabled all attending GPs to collect Maintenance of Professional Standards (MOPS) points as discussed in section 3.6.10.
- The Medical Defence Association of South Australia supported the session by allocating reduced fee for medical indemnity insurance.

A total of eleven GPs attended the session which constituted 46% of all GPs invited to attend.

Department 19 was an ED in a rural hospital (hospital 5). Following an initial meeting with the Director of Medical Services and Head of ED education sessions were scheduled on a three-monthly basis with ED medical officers. However, soon after the project commenced the hospital underwent considerable redesign. The GPs and medical specialists from the local community who were providing clinical care to in-patients were no longer doing so, and visiting specialists were contracted to provide this service. Doctors who were initially employed to work solely in the ED were required to also work in other departments. As a result of this redesign, the Director of Medical Services informed the Project Officer that the scheduled medical departmental meetings to provide feedback on incident reports were to be temporarily deferred. Only one medical departmental meeting was held six months after commencement of the study. The meeting was conducted in the morning for one hour by the Principal Supervisor, PhD candidate and Project Officer. Four out of the six medical officers employed in the ED attended the session.

Metropolitan nursing meetings

Nursing departmental meetings were generally held in the conference room or handover room in each of the clinical areas. Unlike medical departmental meetings, Project Officers had little difficulty scheduling times to discuss incidents with staff. In each of the intervention units, meetings were held on a monthly basis, however in the initial month each department was visited on a weekly basis so that staff could become familiar with the Project Officers and ask questions about the reporting process.

The same format used in medical departmental meeting was employed for nursing meetings (see metropolitan medical meetings). De-identified incidents from their clinical area and also other incidents which were relevant and interesting were discussed. Where possible, the Project Officer allocated to the Unit and the NUM presented feedback to the staff. In the metropolitan ICU, a total of 16 meetings were held during the study period. More

sessions were held in this department because there were in excess of 200 nursing staff on the roster, and it was necessary to meet with as many as possible.

Rural nursing meetings

As with metropolitan hospitals, Project Officers in rural hospitals initially visited the intervention units on a weekly basis for the first month of the project so that nursing staff could ask questions and become familiar with the Project Officers. Following the first month, in hospital 4 informal meetings were held with nursing staff on the medical and surgical units on a monthly basis, however the Project Officer was only able to provide feedback to staff in Department 14 on a three monthly basis. In hospital 5, the Project Officer provided feedback to ED staff on a monthly basis.

A combined three monthly meeting in both rural hospitals was held for all nursing staff, where the PhD candidate and Project Officer discussed outcomes across the intervention units. In hospital 4, these meetings were attended by the clinical pharmacist.

4.6.5.3. Newsletters

In addition to providing feedback via departmental meetings, feedback was also provided in newsletters which were distributed to clinical areas and medical staff on a two-monthly basis, as outlined in section 3.6.10. Each of the five newsletters is attached as Appendix 27. The format of the newsletter was consistent throughout the intervention. The front page of the newsletter informed staff about facets of the project and the back was dedicated to explaining outcomes arising from reports across the hospitals. Each incident report summary provided a background, discussed factors that contributed to the event and outcomes arising from the report. The newsletter was predominantly used to demonstrate that action occurs as a result of incident reports, and that outcomes were being achieved or at least attempted.

Content for the newsletter was sourced by Project Officers and the PhD candidate from all departments involved as intervention units in the study. Project Officers approached the NUM and, where medical reports had been initiated, the Medical Head of Unit was asked to provide details of outcomes arising from reports. In many instances, where the PhD candidate and Project Officers contributed to the investigation, the report was written by them, and assessed by the appropriate Head of Unit prior to printing and distribution. A variety of incident types were discussed in the newsletters as a means of diversifying clinicians' perception of what constituted an incident.

4.6.6. Project implementation

A total of ten intervention units participated in the study. Initially the project was due to commence in March 2004 and run for a twelve month period, however delay in having the software completed meant that it was set back until June. For this reason, the project was shortened to 40 weeks, instead of the originally intended 52 weeks. The project was progressively rolled out to intervention units, for the following reasons:

- **Information technology (IT) issues**: Configuring the connection on each computer in the intervention units and Call Centre to provide a link with the main central terminal server so that staff could access the AIMS database, required IT support from within the hospital/RDNS and from EDS, the company responsible for managing the database in the Department of Health. In some instances, computers needed to be upgraded to run the program. There were limitations on the number of computers given access to the AIMS centralised database in rural hospitals because of bandwidth restrictions on transmission of data. In hospital 3, rollout was delayed for an extended period because the person allocated to set up connections became ill, and the IT Department could not spare resources to have it installed by another IT Support Officer.
- **Demand on the Call Centre** was unknown, so staggering the rollout enabled researchers to analyse its use and ensure that the Call Centre was appropriately staffed so that it met its key performance indicators (outlined in Table 3-8).
- **Limitations on Project Officers**, who were themselves learning to use the system and at the same time teaching others. There were many demands on Project Officers in the early stages of the project. Staggering the rollout helped them to become proficient in using the AIMS database, setting people up and educating them about using the system.
- **External delays.** At the time rollout of the project was scheduled, it was anticipated that staff in the metropolitan ICU would have moved into a new ICU complex. However, building delays meant that at the time they were meant to commence they were still in their old premises, and organising the move. To alleviate stress on all staff, implementation was postponed for two months, to enable them to settle into their new unit.

On a bi-monthly basis, representatives from all hospitals participating in the study communicated with each other via the IRIS Committee (Terms of Reference attached as

Appendix 9). Where possible, these meetings were scheduled to enable rural Project Officers to attend. These forums provided a valuable opportunity for staff to share strategies and discuss problems, for the software company to meet directly with the users to get feedback on how it could be improved or modified, and for the PSMs to be aware of issues facing the project team, such as problems with information technology or classification of incidents.

4.6.7. To improve reporting rates (aim 4.1)

4.6.7.1. Denominators used for reporting rates

In deciding which denominator to use for analyses, consideration was given to the diverse types of units involved in the study. Studies investigating changes in reporting rates in the ED were most accurately reported over a denominator of ED attendances. Studies investigating adverse event rates using medical record review[2 20] and incident reporting[43] predominantly reported findings over a denominator of either patient discharges or admissions. Discharge and admission data over time is almost identical. Variation exists where there is time fluctuation of available beds. For example, over Christmas when beds are closed there will be more discharges than admissions, however in January when beds re-open there will be more admissions than discharges. When combining December and January data and comparing admissions with discharges the margin of error is expected to be ± 5%.

Some studies have reported findings using Occupied Bed Days (OBDs)[60 143] which provide the most accurate data, particularly in clinical areas where patients have extended length of stay, such as ICUs.

Aggregate reporting rates have been based on whether the reports were made on inpatients (therefore those made in the ICU, surgical and medical units) or on patients in the ED. Inpatient rates have been reported using both incident reports per 10,000 OBD and also as incident reports per 100 patient discharges. ED statistics have been reported as incident reports per 10,000 ED attendances. Definitions of each denominator are listed into Table 4-19.

Table 4-19 Definitions of denominators

Term	Definition
Emergency attendance	A person who has registered to be seen in the ED by a medical officer
OBD	The total number of beds occupied at the census taking hour for a specified period. In most hospitals the patient count occurred at 12 midnight, however in hospital 3, bed census occurred at 0600 hours each day.
Patient discharges	A discharge from or death within the specified department. Separation data were collected in preference to admission data because this was considered to be more accurately collected than admission data in one particular rural hospital.

In-patient reporting rates

Overall incident rates in the intervention units increased from 83 reports per 10,000 OBDs (398/48073) or 5.3 reports per 100 patient discharges (398/7444) at baseline to 190 reports per 10,000 OBD (930/49061) or 12.2 reports per 100 patient discharges (930/7599) in the study period. There were 854 more incident reports lodged in the study period compared with the baseline period. Incident rates in the control unit increased from 54 reports per 10,000 OBDs (242/44380) or 3.3 reports per 100 patient discharges (242/7357) at baseline to 101 reports per 10,000 OBD (462/45762) or 5.4 reports per 100 patient discharges (462/8559) in the study period. There were 220 more incident reports lodged in the study period compared to the baseline period.

Adjusting for reporting practices at baseline, there was a significant increase in reporting in the intervention units when compared to control units ($p<0.001$). There was an absolute increase in reporting in intervention units compared to control units of 60 reports per 10,000 OBD or 5 reports per 100 patient discharges (Table 4-20 and Table 4-21 respectively).

ED reporting rates

Incident reporting rates in ED intervention units increased from 6.3 reports (24/37781) to 46.5 reports per 10,000 ED attendances (181/28888) in the study period. Reporting rates increased in the control units from 21.5 reports (85/39504) to 22.2 reports per 10,000 ED attendances (86/38760) during the study period.

Adjusting for reporting practices at baseline, there was a significant increase in reporting in intervention EDs when compared to control EDs ($p<0.001$). There was an absolute increase in reporting in intervention EDs compared to control EDs of 56 reports per 10,000 ED attendances (Table 4-20).

Table 4-20 Comparison of reporting rates (incident reports per 10,000 occupied bed days OR 10,000 Emergency Department attendances) by departments

Type of Unit	Rural (R) Metro(M)	Control		Inter-vention		Baseline				End				Significance of the interaction term†	Absolute difference in change b/n intervention and control units ± 95% CI
		Dept no.	Hospital no	Dept no.	Hospital no.	Control (n/ OBD)	Intervention (n/ OBD)	Rate ratio *	95%CI	Control	Intervention	Rate ratio *	95%CI		
ICU	M	1	1	20	5	3.3 (1/3045)	70.4 (75/10659)	0.05	0.01-0.2	3.1 (1/3227)	99.5 (116/11663)	0.03	0.01-0.2	0.063	29.3 ± 25.6
Med	M	2‡	1	4§	1	70.4 (55/7811)	16.4 (10/6108)	4.30	2.2-8.3	188.7 (167/8850)	193.4 (108/5583)	1.0	0.8-1.2	<0.001	58.8 ± 50.9
Surg	M	3	1	5	1	22.2 (24/10795)	15.0 (11/7322)	1.48	0.7-3.0	39.6 (32/8076)	112.8 (81/7181)	0.3	0.2-0.5	<0.001	80.4 ± 30.8
Med Surg	M	7	2	9	2	47.3 (29/6129)	162.3 (114/7025)	0.29	0.2-0.4	103.1 (69/6693)	229.6 (153/6663)	0.4	0.3-0.6	0.013	11.5 ± 56
Med	M	10§	3	11‡	3	65.0 (34/5230)	50.8 (35/6892)	1.28	0.8-2.0	107.7 (92/8543)	142.6 (102/7155)	0.7	0.6-1.0	<0.001	49.1 ± 44.9
Med	M	2‡	1	11‡	3	70.4 (55/7811)	50.8 (35/6892)	1.37	0.9-2.1	188.7 (167/8850)	142.6 (102/7155)	1.3	1.0-1.7	<0.001	-26.5 ± 47
Med	M	10§	3	4§	1	65.0 (34/5230)	16.4 (10/6108)	3.97	2.0 - 7.9	107.7 (92/8543)	193.4 (108/5583)	0.6	0.4-0.7	<0.001	134.0 ± 49
ED	M	8	2	6	1	23.5 72/30591	7.9 (21/26621)	0.30	0.2-0.5	24.7 (75/30358)	29.5 (80/27436)	0.84	0.6-1.1	<0.001	20.4 ± 10.6
Surg	R	16	5	13	4	68.4 (34/4967)	101.2 (36/3558)	0.67	0.4-1.1	83.2 (39/4689)	218.1 (84/3759)	0.4	0.3-0.5	0.001	102.1 ± 67

Type of Unit	Rural (R) Metro(M)	Control		Inter-vention		Baseline				End				Significance of the interaction term†	Absolute difference in change b/n intervention and control units ± 95% CI
		Dept no.	Hospital no	Dept no.	Hospital no.	Control (n/ OBD)	Intervention (n/ OBD)	Rate ratio	95%CI	Control	Intervention	Rate ratio	95%CI		
ICU	R	17	5	14	4	80.2 (8/998)	234.2 (33/1409)	0.34	0.2-0.7	68.2 (6/880)	289.1 (37/1280)	0.2	0.1-0.5	0.318	66.9 ± 145
Med	R	18	5	15	4	105.5 (57/5405)	164.7 (84/5100)	0.64	0.5-0.9	116.6 (56/4804)	431.0 (249/5777)	0.3	0.2-0.36	<0..001	255.2 ± 76
ED	R	12	4	19	5	14.6 (13/8913)	2.7 (3/11160)	5.46	1.7-23.8	13.1 (11/8402)	88.2 (101/11452)	0.15	0.08-0.3	<0.001	87.0 ± 20.7
Total Inpatients						**54.5 (242/44380)**	**82.8 (398/48073)**	**0.66**	**0.6 - 0.8**	**101 (462/45762)**	**189.6 (930/49061)**	**0.5**	**0.5- 0.6**	**<0.001**	**60.3 ± 18.6**
Total ED attendances						**21.5 (85/39504)**	**6.3 (24/37781)**	**3.39**	**2.2 - 5.4**	**22.2 (86/38760)**	**46.5 (181/28888)**	**0.35**	**0.3- 0.5**	**<0.001**	**39.5 ± 11.5**

* Fishers Exact Test (mid-P) †All analyses performed using negative binomial regression except for the Intensive Care Units, where Poisson regression analysis was used, adjusting for clustering by hospitals, and allowing for robust estimates of standard errors. In order to test for the significance of the intervention effect, the statistical significance of the interaction term was assessed. ‡Cardiology Unit §Neurology Unit

Table 4-21 Comparison of reporting rates (incident reports per 100 hospital discharges) by Departments

Type of Unit	Rural/Metro	Control		Inter-vention		Baseline				End				Significance of the interaction term†	Absolute difference in change b/n intervention and control units ± 95% CI
		Dept no.	Hospital no	Dept no.	Hospital no.	Control (n/ OBD)	Intervention (n/ OBD)	Rate ratio	95%CI	Control (n/ OBD)	Intervention (n/ OBD)	Rate ratio	95%CI		
ICU	M	1	1	20	5	0.9 (1/114)	32.7 (75/229)	0.03	0.01-0.1	0.9 (1/106)	38.4 (116/302)	0.02	0.01-0.1	0.393	5.7 ± 10.5
Med	M	2‡	1	4§	1	5.3 (55/1045)	1.5 (10/687)	3.62	1.9-7.5	12.6 (167/1321)	17.0 (108/635)	0.74	0.6-0.9	<0.001	8.2 ± 4.1
Surg	M	3	1	5	1	2.7 (24/881)	1.0 (11/1095)	2.71	1.3-5.7	2.8 (32/1143)	5.5 (81/1479)	0.51	0.3-0.8	<0.001	4.4 ± 2.0
Surg/ Med	M	7	2	9	2	1.9 (29/1497)	8.8 (114/1297)	0.22	0.1-0.3	3.1 (69/2210)	10.7 (153/1423)	0.29	0.2-0.4	0.147	0.8 ± 2.2
Med	M	10§	3	11 ‡	3	2.9 (34/873)	2.1 (35/1679)	1.86	1.2-3.0	7.4 (92/1244)	6.4 (102/1593)	1.15	0.9-1.5	<0.001	-0.2 ± 2.4
Med	M	2‡	1	11 ‡	3	5.3 (55/1045)	2.1 (35/1679)	2.52	1.7-3.9	12.6 (167/1321)	6.4 (102/1593)	1.97	1.5-2.5	<0.001	-6.2 ± 2.8
Med	M	10§	3	4§	1	3.9 (34/873)	1.5 (10/687)	2.85	1.3-5.7	7.4 (92/1244)	17.0 (108/635)	0.43	0.3-0.6	<0.001	12.0 ± 3.9
Surg	R	16	5	13	4	2.3 (34/1492)	3.5 (36/1028)	2.28	0.4-1.0	2.9 (39/1333)	7.9 (84/1040)	0.37	0.2-0.5	0.001	3.8 ± 2.4
ICU	R	17	5	14	4	2.9 (8/273)	10.1 (33/327)	0.29	0.1-0.6	2.4 (6/245)	10.9 (37/340)	0.22	0.09-0.5	0.660	1.3 ± 5.7
Med	R	18	5	15	4	4.8 (57/1182)	7.6 (84/1102)	0.63	0.4-0.9	5.8 (56/957)	31.6 (249/787)	0.18	0.1-0.2	<0.001	23.0 ± 4.7
Total inpatients						**3.3 242/7357**	**5.3 (398/7444)**	**0.61**	**0.52-0.72**	**5.4 (462/8559)**	**12.2 (930/7599)**	**0.44**	**0.4 - 0.5**	**<0.001**	**4.8 ± 1.1**

* Fishers Exact Test (mid-P) †All analyses performed using negative binomial regression except for the Intensive Care Units, where Poisson regression analysis was used, adjusting for clustering by hospitals, and allowing for robust estimates of standard errors. In order to test for the significance of the intervention effect, the statistical significance of the interaction term was assessed. ‡ Cardiology Units §Neurology Units

4.6.7.2. Reporting rates - Departments

Appendix 28 provides a timeline of incident reports generated in each control and intervention units in the baseline and intervention period over denominators of (1) patient discharges in inpatient areas; and (2) ED attendances. The timeline included the 40 week pre-intervention period for all departments other than the surgical unit (Department 13) in rural hospital 4, which only had a 38-week intervention period. The reason for the shorter intervention period (and hence shorter baseline period) in this department was because it closed for a three-week period over Christmas 2003, and it was not possible to extend the intervention period for longer.

Table 4-20 and 4-21 provides comparison between control and intervention units at baseline and during the study period using a denominator of OBDs and patient discharges respectively. At baseline, there was a significant difference in reporting between the two metropolitan ICUs, with more reports being generated in the intervention unit (70.4 vs. 3.3 reports per occupied bed day or 32.7 vs. 0.9 reports per patient discharge).

There was an increase in reporting in most intervention units after adjusting for differences at baseline (Table 4-20). There was no significant improvement in reporting in either the metropolitan or rural ICU, not was there improved reporting when one cardiology unit was compared with another cardiology unit in another hospital.

4.6.7.3. Reporting rates - type of unit

There was an increase over and above baseline differences in the ED, Surgical and Medical Units intervention units involved in the project (Table 4-22). There was no significant improvement in reporting in ICUs during the study period when analysing data using either occupied bed days or separations. The ED intervention units had an absolute increase of 39 reports per 10,000 ED attendances compared to control units. The surgical and medical units had an absolute increase of 3.6 and 4.5 reports per 100 hospitals discharges respectively (75 and 84 reports per 10,000 OBD respectively).

Table 4-22 Comparison of reporting rates (incident reports per 100 hospital discharge, 10,000 OBDs/ED attendances) by type of unit

Type of Unit	Baseline				End				Significance of the interaction term ‡	Absolute difference in change b/n intervention and control units ± 95% CIs
	Control Reports *	Intervention Reports*	Rate ratio†	95% CI	Control Reports*	Intervention Reports*	Rate ratio †	95% CI		
Reporting rates per 10,000 occupied bed days										
ICU	22 (9/4043)	89(108/12068)	0.25	0.1 - 0.5	17 (7/4107)	118 (153/12943)	0.1	0 -0.3	0.094	34 ± 31.7
Surg	39 (87/21891)	43 (47/10880)	0.9	0.6 - 1.3	72 (140/19458)	151 (165/10940)	0.5	0.4 -0.6	<0.001	75 ± 29.7
Med	79 (146/18446)	97 (243/25125)	0.8	0.7 - 1.0	141 (313/22197)	243(612/25178)	0.6	0.5 -0.7	<0.001	84 ± 30.4
Reporting rates per 100 patient discharges										
ICU	2.3 (9/387)	19.4 (108/556)	0.12	0.1 - 0.2	2.0 (7/351)	23.8 (153/642)	0.08	0 - 0.1	0.294	4.1 ± 5.7
Surg	2.2 (87/873870)	2.2 (47/2123)	1.0	0.7 - 1.5	3.0 (140/4686)	6.6 (166/2519)	0.46	0.4 - 0.6	<0.001	3.6 ± 1.4
Med	4.7 (146/3100)	5.1 (243/4765)	0.9	0.7 - 1.1	8.9 (313/3522)	13.8 (612/4438)	0.65	0.6 - 0.7	<0.001	4.5 ± 1.8
Reporting rates per 10,000 ED attendances										
ED	21.5 (85/39504)	6.3 (24/37781)	3.4	2.2 - 5.4	22.2(86/38760)	46.5 (181/28888)	0.35	0.3 - 0.5	<0.001	39 ± 11.5

* All rates per 10,000 occupied bed days except for ED attendances where rate uses 10,000 ED attendances. †Comparison made using Fishers exact test. ‡ Comparison between baseline and end of intervention made using negative binomial regression analysis adjusting for clustering by hospitals. In order to test for the significance of the intervention effect, the statistical significance of the interaction term was assessed with interaction term and exposure of patient discharges with exception of ICU where poisson regression analysis using robust variance

4.6.7.4. Reporting rates –Location of hospital

Table 4-23 provides an overall comparison of report rates submitted in rural and metropolitan hospitals. In both the rural and metropolitan hospital there was a significant improvement in reporting in intervention units with absolute increases of 130 and 23 reports per 10,000 OBD and ED attendances respectively ($p<0.001$).

4.6.7.5. Reporting rates - professional designation of reporter

Figures 4-6 and 4-7 provide an overall breakdown of incident reports generated by nurses, doctors and allied health professionals in the baseline and study period in the control units and intervention units respectively. Table 4-24 provides comparison of reporting rates of doctors, nurses, allied health professional and anonymous reports in the baseline and study period in the control and intervention units using denominator data of OBDs, patient discharges and ED attendances. Table 4-25 provides a comparison of the proportion of incident reports submitted by professional groups according to which type of unit they were working in and the location of the hospital. In some cases the actual numbers of reports in Table 4-24 and Table 4-25 are not the same. This is because if a person identified their profession when submitting an anonymous report, this was reported in Table 4-25 under their professional group. Because it was not known whether they were working in an inpatient area or the ED, this data could not be included in Table 4-24.

Table 4-23 Comparison of reporting rates (incident reports per 10,000 OBDs/ED attendances) by location of hospital

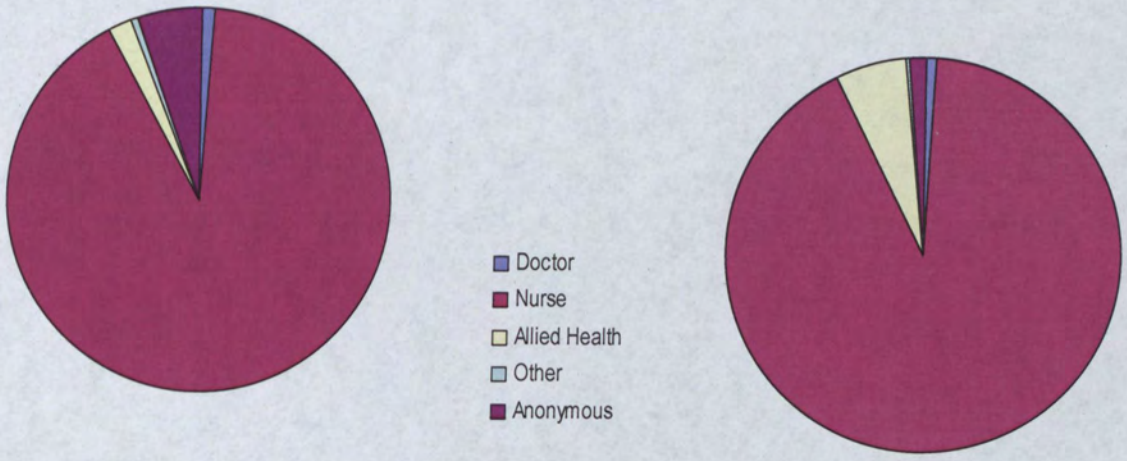
Location of hospital	Baseline				End				Significance of the interaction term‡	Absolute difference in change between intervention and control units ± 95% CIs
	Control Reports *	Intervention Reports*	RR †	(95 % CI)	Control Reports*	Intervention Reports*	RR †	95%CI		
Rural	55.2 (112/20283)	73.5 (156/21227)	0.75	0.6 – 1.0	59.7 (112/18775)	208.1 (471/22628)	0.29	0.2-0.3	<0.001	130.1 ± 26.6
Metropolitan	33.8 (215/63601)	41.2(266/64627)	0.82	0.7 – 1.0	66.3 (436/65747)	97.4 (640/65681)	0.68	0.6-0.8	<0.001	23.7 ±11.8

*All rates calculated using sum of occupied bed days and ED attendances x 10,000

† Comparison made using Fishers exact test

‡ Negative binomial regression used, adjusting for clustering by hospitals. In order to test for the significance of the intervention effect, the statistical significance of the interaction term was assessed.

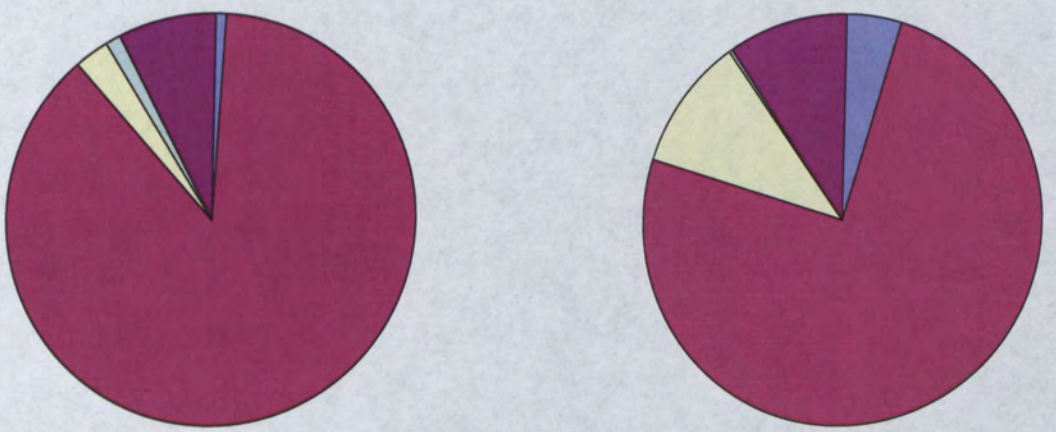
Figure 4-1 Incident reporting by profession in CONTROL units- Pie chart



Baseline: Control Units

Study period: Control Units

Figure -4-2 Incident reporting by profession in INTERVENTION units- Pie chart



Baseline: Intervention Units

Study period: Intervention Units

Table 4-24 Comparison of reporting rates (incident reports per 100 patient discharges, 10,000 OBDs/ED attendances) by profession

Professional designation	Baseline				End				Significance of the interaction term †	Absolute difference in change b/n intervention and control units ± 95% confidence intervals
	Control Reports	Intervention Reports	Risk ratio *	95% CI	Control Reports*	Intervention Reports*	RR	95% CI		
Reporting rates per 10,000 occupied bed days										
Doctors	0.2 (1/44380)	0.6 (3/48073)	0.4	0 - 3.4	0.6 (3/45762)	6 (31/49061)	0.1	0 - 0.3	0.213	5 ± 3.8
Nurses	50 (224/44380)	80 (386/48073)	0.6	0.5 - 0.7	88 (405/45762)	177 (870/49061)	0.5	0.4 - 0.6	<0.001	64 ± 17.9
Allied Health	1 (5/44380)	5 (25/48073)	0.2	0 - 0.5	3 (15/45762)	15 (71/49061)	0.3	0.1 - 0.4	<0.001	8 ± 4.4
Reporting rates per 100 patient discharges										
Doctors	0.05 (4/7357)	0.04 (3/7444)	1.3	0.3 - 7.2	0.03 (3/8559)	0.41 (31/7599)	0.08	0 - 0.3	0.153	0.4 ± 1.6
Nurses	3.0 (224/7357)	5.2 (386/7444)	0.6	0.5 - 0.7	4.7 (405/8559)	11.4 (870/7599)	0.4	0.4 - 0.5	<0.001	4.5 ± 1.1
Allied Health	0.07 (5/7357)	0.33 (25/7444)	0.2	0 - 0.5	0.17 (15/8559)	0.93(71/7599)	0.2	0.1 - 0.3	<0.001	0.5 ± 2.8
Reporting rates per 10000 ED attendances										
Doctors	0.8 (3/39504)	0 (0/37781)	n/a		0.3 (1/38760)	9 (26/28888)	0.03	0 - 0.2	0.001	9 ± 3.7
Nurses	19 (74/39504)	6 (22/37781)	3.2	2.0 - 5.3	19 (75/38760)	31 (90/28888)	0.6	0.5 - 0.8	0.302	25 ± 9.2
Allied Health	0.3 (1/39504)	0 (0/37781)	n/a		0.3 (1/38760)	21 (61/28888)	0.1	0 - 0.06	0.001	21 ± 5.3
Reporting rates per 10000 ED attendances+ 10,000 OBDs (combined)										
Anonymous‡	4.1 (18/43884)	0.7 (6/85854)	5.9	2.4-13.5	9.4 (43/84552)	15.8 (123/77949)	0.3	0.2-0.5	<0.001	9.8± 3.1

*Comparison made using Fishers exact test † Comparison between baseline and end of intervention made using Poisson regression analysis, adjusting for clustering by hospitals, and allowing for robust estimates of standard errors. In order to test for the significance of the intervention effect, the statistical significance of the interaction term was assessed.
‡Anonymous reports = where either the reporters name/designation or the location of the incident was not recorded.

Table 4-25 Comparison of reporting rates (incident reports as a proportion of reports generated) by profession

Professional designation	Control % reports (N)	Baseline Intervention % reports (N)	Risk ratio *	95%CI	Control % reports (N)	End Intervention % reports (N)	Risk ratio*	95%CI	Comparison at end adjusted for baseline†
Doctor	**1.2% (4/328)**	**0.7% (3/421)**	**1.71**	**0.43-6.83**	**0.7% (4/548)**	**4.4% (57/1275)**	**0.16**	**0.06 -0.43**	**0.003**
Type of Unit									
Intensive Care Unit	0 (9)	0 (108)	*n/a*		0 (7)	1.3% (153)	*n/a*		
Emergency Dept.	3.5% (86)	0 (24)	*n/a*		1.2% (86)	14.4% (181)	0.1	0-0.4	
Surgical Units	1.1% (87)	0 (46)	*n/a*		0.7% (140)	3.0% (165)	0.2	0-1.7	
Medical Units	0 (146)	1.2% (243)	*n/a*		0.6% (315)	2.6% (612)	0.2	0-0.9	
Anonymous	0 (0)	0 (0)	*n/a*		-	4.9% (164)			
Hospital location									
Rural	0.9% (112)	1.3% (155)	0.7	0.0-9.1	0 (113)	1.0% (518)	*n/a*		
Metropolitan	1.4% (216)	0.4% (266)	3.7	0.4-97.3	0.9% (435)	6.9% (757)	0.1	0-0.3	
Nurse	**90.9% (298/328)**	**91.7% (386/421)**	**0.99**	**0.9-1.2**	**87.6% (480/548)**	**75.3% (960/1275)**	**1.16**	**1.04-1.30**	**<0.001**
Type of Unit									
Intensive Care Unit	100% (9)	98.2% (108)	1.0	0.5-1.9	85.7% (7)	88.9% (153)	0.96	0.4-2.0	
Emergency Dept.	86.1% (86)	92.0 % (24)	0.9	0.6-1.6	87.2% (86)	49.7% (181)	1.74	1.3-2.4	
Surgical Units	93.1% (87)	82.6% (46)	1.3	0.8-1.7	92.9% (140)	86.1% (165)	1.08	0.8-1.4	
Medical Units	91.8% (146)	90.6% (243)	1.0	0.8-11.3	85.4% (315)	87.7% (612)	0.97	0.8-1.1	
Anonymous	(0/0)	(0/0)			-	33.5% (164)			
Hospital location									
Rural	91.1% (112)	85.8% (155)	1.06	0.8-1.4	94.7% (113)	67.37% (518)	1.40	1.1-1.7	
Metropolitan	90.7% (216)	95.1% (266)	0.94	0.8-1.1	85.7% (435)	80.7% (757)	1.06	0.9 - 1.3	

Professional designation	Baseline				End				Comparison at end adjusted for baseline†
	Control % reports (N)	Intervention % reports (N)	Risk ratio *	95%CI	Control % reports (N)	Intervention % reports (N)	Risk ratio*	95%CI	
Allied Health	**1.8% (6/328)**	**5.9% (25/421)**	**0.3**	**0.1-0.7**	**2.9% (16/548)**	**10.4% (132/1275)**	**0.3**	**0.2-0.5**	**0.141**
Type of Unit									
Intensive Care Unit	0 (9)	1.85% (108)	n/a		14.3% (7)	5.2% (153)	2.7	0.1-17.1	
Emergency Dept.	1.2% (86)	0 (24)	n/a		1.2% (86)	33.7% (181)	0.1	0-0.2	
Surgical Units	0 (87)	17.4% (46)	n/a		2.1% (140)	9.7% (165)	0.2	0.1-0.7	
Medical Units	3.4% (146)	6.2% (243)	0.55	0.2-1.5	3.5% (315)	7.7% (612)	0.5	0.2-0.9	
Hospital location									
Rural	1.8% (112)	12.9% (155)	0.14	0-0.5	2.7% (113)	22.0% (518)	0.1	0.03-0.3	
Metropolitan	1.8% (216)	1.9% (266)	0.98	0.2-3.9	3.0% (435)	2.2% (/757)	1.3	0.6-2.8	
Other	**0.6% (2/328)**	**0.2% (1/421)**	**2.6**	**0.2-75.7**	**0.9% (5/548)**	**2.6% (3/1275)**	**0.4**	**0.1-0.9**	**0.602**
Type of Unit									
Intensive Care Unit	0 (9)	0 (108)	n/a		0 (7)	1.3% (153)	n/a		
Emergency Dept.	1.1% (86)	4.2% (24)	0.28	0-10.9	0 (86)	0.6% (181)	n/a		
Surgical	1.1% (87)	0 (46)	n/a		0.7% (140)	0 (165)	n/a		
Medical	0 (146)	0 (243)	n/a		1.3% (315)	0 (612)	n/a		
Anonymous	**5.5% (18/328)**	**1.4% (6/421)**	**3.8**	**1.6-10.6**	**7.8% (43/548)**	**9.6% (123/1275)**	**0.81**	**0.6-1.1**	**0.012**
Type of Unit									
Intensive Care Unit	(0/9)	(0/108)	n/a		(0/7)	3.3% (5/153)	n/a		
Emergency Dept.	8.1% (7/86)	4.2% (1/24)	2.0	0.3-44.4	10.5%(9/86)	1.7% (3/181)	6.3	1.8-28.9	
Surgical Units	4.6% (4/87)	(0/46)	n/a		3.6% (5/140)	1.2% (2/165)	2.9	0.5-22.0	
Medical Units	4.8% (146)	2.1% (243)	2.3	0.7-8.0	9.2% (315)	2.0% (612)	4.7	2.4-9.5	
Anonymous	0	0	n/a		-	61.6% (164)	n/a		
Total	**100 (328)**	**100% (421)**			**100 (548)**	**100 (1,275)**			**<0.001**

*Fishers exact test † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalized linear models.

4.6.7.5.1. Medical reports

Baseline

Table 4-25 shows that there were no significant differences at baseline between intervention and control groups with respect to doctor-initiated reports (intervention: 1.2% vs. control: 0.7%). In both the intervention and control units combined, only 7 reports were lodged by medical staff in the baseline period.

Study period

Inpatient reporting rates: In inpatient units (ICUs, medical and surgical units), the intervention did not result in significant improvement in incident reporting by doctors. Doctor-initiated incident reports increased in absolute terms by 5 reports per 10,000 OBDs or 0.4 reports per 100 patient discharges (Table 4-24).

ED reporting rates: In the ED, the percentage of all reports submitted by doctors increased in intervention units from 0 to 14%, while it declined in control units from 3.5% to 1.2% (Table 4.25). In intervention units, reports submitted by doctors increased in absolute terms by 9 reports per 10,000 ED attendances (Table 4-24).

All incidents: Table 4-25 demonstrates that having adjusted for differences in reporting at baseline, the study resulted in proportionately more incidents being reported by doctors in the intervention unit compared to the control unit (0.7% to 4.4% of all reports in intervention units vs. 1.2% to 0.7% of all reports in control units). The majority of all reports lodged by medical staff in the intervention unit during the study period came from the ED, accounting for 53% of all medically-initiated reports where the reporter was not anonymous. Ninety one percent of all medically-initiated reports during the study period in the intervention unit came from metropolitan hospitals, with only five reports being submitted by doctors in rural hospitals.

4.6.7.5.2. Nursing reports

Baseline

Table 4-25 demonstrates that there were no significant differences at baseline between the percentage of nurse-initiated reports in the control units and in intervention units (90.9% vs. 91.7% p=0.99).

Study Period

Inpatient reporting rates: In inpatient units, the intervention resulted in significantly more incidents being reported by nurses (386 in baseline period and 960 in study period). However, as a percentage of all reports generated the rate fell from 91.7% to 75.3%, as a result of improved reporting by other professional groups (Table 4-25). Nurse-initiated incident reports increased in absolute terms by 64 reports per 10,000 OBDs or 4.5 reports per 100 patient discharges (Table 4-24).

ED reporting rates: In the ED, the intervention did not result in significant improvement in incident reporting by nurses despite there being 68 more reports generated in the study period compared to the baseline period (Table 4-25). Reporting in the control unit remained largely unaltered between the baseline and study period. Nurse-initiated incident reports increased in absolute terms by 25 reports per 10,000 ED attendances (Table 4-24).

All incidents: Table 4-25 demonstrates that, having adjusted for differences in reporting at baseline, the study resulted in more incidents being reported by nurses in the intervention unit compared to the control unit ($p<0.001$). Nurse-initiated incident reports increased in absolute terms by 25 reports per 10,000 ED attendances (Table 4-24)

4.6.7.5.3. Allied Health reports

Baseline

Table 4-25 demonstrates that at baseline there were more allied health initiated reports in the intervention unit when compared to the control unit (5.9% vs. 1.8%), with the majority of reports generated in medical units (15 reports) and in rural hospitals. As with doctors, reporting rates in this population were very low at baseline

Study period

Inpatient reporting rates: In inpatient units, the intervention resulted in significant improvement in incident reporting by allied health professionals (Table 4-25). Allied Health-initiated incident reports increased in absolute terms by 8 reports per 10,000 OBDs or 0.5 reports per 100 patient discharges (Table 4-24).

ED reporting rates: In the ED, the intervention resulted in significant improvement in incident reporting by allied health professionals. Allied health-initiated incident reports increased in absolute terms by 21 reports per 10,000 ED attendances (Table 4-24).

All incidents: Adjusting for differences in reporting at baseline, the study did not result in more incidents being reported by Allied health professionals in the intervention unit

compared to the control unit (1.8% to 2.9% of all reports in control unit vs. 5.9% to 10.4% of all reports in intervention units [p=0.141]). The vast majority of all allied health reports submitted during the study period in intervention units were generated in the ED where rates increased from 0 at baseline to 33.7% of all reports during the study period (Table 4-25).

4.6.7.5.4. Anonymous reports

Anonymous reporting enabled reporters to notify people in the Quality Unit (or equivalent) of each hospital that a problem existed without having to go through their line manager. In education sessions, staff were informed of this reporting option and were also informed that by its very nature, if a person reported anonymously no feedback as to what action was taken as a result of the anonymous report being made could be provided.

Anonymous reports in the baseline reporting period and in the control unit during the study period could be submitted to the NUM or posted directly to the APSF. Anonymous reports sent to the APSF contained no identifying information, making it impossible to track their source. For this reason we cannot include reports submitted in this way in the baseline period. In the baseline staff survey it was determined that 5% of staff had *ever* reported an incident directly to the APSF. Our findings for anonymous reports are based on the assumption that the same number of staff in both the control and intervention units would have posted a report anonymously to the APSF during the baseline and study period.

Baseline

In the baseline reporting period, anonymous reports consisted of those reports where the reporter did not identify themselves on the report form, yet submitted the report through the hospital reporting system. Table 4-25 demonstrates that at baseline there were more anonymous reports in control units compared to the intervention units (5.5% vs. 1.4% of all reports).

Study period

Combined inpatient and ED reporting rates: Because reports were de-identified, it was not possible to determine whether they were lodged from an inpatient area or the ED in hospitals with more than one intervention unit. Assuming that the number of reports submitted anonymously to the APSF was the same in both intervention and control units during the study period, the intervention resulted in significant improvement in anonymous incident reporting (4.1 to 9.4 reports/combined OBD and ED attendances in control unit vs. 0.7 to 15.8 reports/combined OBD and ED attendances in intervention unit, $p<0.001$) (Table

4-24). In absolute terms, the intervention resulted in 10 more reports being lodged anonymously per 10,000 OBDs/ED attendances.

All incidents: Table 4-25 demonstrates that having adjusted for differences in reporting at baseline, the study resulted in proportionately more incidents being reported anonymously in the intervention unit compared to the control unit (5.5% to 7.8% of all reports in control unit vs. 1.4% to 9.6% of all reports in intervention units [p=0.0.12]) In some of these reports, the reporter identified only their profession (38.4% of all reports, n=63), however for the majority of anonymous reports, neither the location nor the designation of reporter were disclosed (61.6% of all reports, n=101).

Appendix 29 shows that when comparing incident reports lodged by doctors and nurses during the study period (n=1017), significantly more anonymous reports were generated by doctors when compared to nurses (8/57=14.0% vs. 55/960=5.8%, p=0.011).

In order to assess whether the types of incidents submitted anonymously were different to identified reports, incident types were categorised into two groups:

- Group 1: incident types which often contained system failures involving the line manager (clinical management, organisational management and behaviour/human performance incidents) and
- Group 2: incident types less likely to involve the line manager (all other categories including falls, medication, aggression, accidents, security, building, fittings, blood, and documentation incidents).

Of the 164 anonymous reports lodged during the study period, there were proportionately more reports generated anonymously in the Group 1(n=121) compared with Group 2 (n=43), however this did not achieve statistical significance (p=0.009) (Appendix 29).

4.6.7.6. Reporting rates – process used to lodge a report

There were two mechanisms by which reporters from all intervention units could lodge a report, using a one page report form or through the Call Centre. Additionally, electronic (on-line) reporting was offered in one clinical unit during the study period. Table 4-26 demonstrates that the 78% of all reports were lodged using the one-page incident report form, 21% used the Call Centre and 0.5% of all reports were lodged electronically.

With regard to the reporting tool used to lodge a report, there was heterogeneity amongst departments. Metropolitan hospitals used the Call Centre more than their rural counterparts. There was no significant difference between doctors and nurses in which tool they used to

report. Senior doctors (Registrars, Consultants and GPs) used the form on 79% of occasions compared with junior doctors who used it on 91% of occasions (30/38 vs. 20/22 p=0.231). Senior and junior nurses both preferred to use the one-page form compared to the Call Centre (30/36 vs. 1037/1261 p=0.865).

Table 4-26 Demographic profile of reports submitted by reporting mode

	Reports generated using one-page form	Reports generated using call centre	Reports generated online	P value*
Type of Unit				**<0.001**
Medical	70.3%	29.7%	*n/a*	
Surgical	78.2%	21.8%	*n/a*	
Intensive Care Unit	86.9%	9.1%	3.9%	
ED	97.2%	2.8%	*n/a*	
Anonymous	83.5%	16.5%	*n/a*	
Rural/metro location				**<0.001**
Rural	95.9%	4.1%		
Metropolitan	67.1%	32.1%	0.8%	
Profession†				**0.933**
Doctor	82.5%	17.5%		
Nurse	74.8%	24.6%		
Total	**78.8% (n=1005)**	**20.7% (n=264)**	**0.5% (n=6)**	

* Fisher's Exact test † Allied Health and Other category reports not included in analysis

With regard to the types of incidents reported using the different reporting option, Table 4-27 demonstrates that significantly more reports relating to documentation were reported using the one page form while more incidents relating to behaviour and human performance issues were reported using the Call Centre.

Table 4-27 Comparison of reporting rates (Principal Incident Types) by reporting mode

Incident type	One page report % reports (N)	Call Centre % reports (N)	Rate ratio*	95% CI
Falls	22.4% (225)	29.5% (78)	0.76	0.6-1.0
Medication	28.7% (288)	25.0% (66)	1.15	0.9-1.5
Documentation	13.1% (132)	4.9% (13)	2.67	1.6-4.9
Clinical Management	12.1% (122)	9.1% (24)	1.33	0.9-2.1

Incident type	One page report % reports (N)	Call Centre % reports (N)	Rate ratio*	95% CI
Medical device	4.5% (45)	5.3% (14)	0.84	0.5-1.6
Aggression	4.3% (43)	4.9% (13)	0.89	0.5-1.5
Accident/OH&S†	4.3% (43)	6.8% (18)	0.63	0.4-1.1
Organisational Management	4.2% (42)	3.8% (10)	1.10	0.6-2.3
Behaviour/Human Performance	2.3% (23)	7.2% (19)	0.32	0.2-0.6
Security	1.4% (14)	0.4% (1)	3.68	0.6-78.5
Buildings	1.3% (13)	0.8% (2)	1.71	0.4-11.2
Blood/ blood products	0.6% (6)	0.8% (2)	0.79	0.2-5.7
Other: Oxygen, nutrition, infection, pressure ulcer	0.9% (9)	1.5% (4)	0.59	0.2-2.2
Total	**100% (1005)**	**100% (264)**	**<0.001**	

* Fishers exact test †Occupation Health and Safety

Call Centre reports

A total of 264 calls were logged through the Call Centre during the study period. Appendix 30 details Call Centre reports made by the time of the day that reports were logged, day of the week that calls were made to the Call Centre and the length of time it took to lodge a report. Fifty seven percent of all reports were logged out of office hours. Most of the reports made to the Call Centre were logged on a Wednesday (18%), with least reports logged on Saturdays (10%).

The average time it took to lodge a Call Centre report increased from 7 minutes 50 seconds in the first month to 11 minutes 50 seconds at the end of the study (Appendix 30). In September 2003 the initial database established for the project was merged with the statewide database, which had just been established. Whereas in the intervention study an attempt was made to minimise the amount of information obtained on the form and through the Call Centre, on merging with the statewide database, many of the questions not asked during the first three months were asked by Call Centre personnel. This had the effect of increasing the time it took to take a report. Additionally, there were four reports which took in excess of twenty minutes to complete due to reporter demand, which had the effect of increasing the mean time taken in months March, April and May 2004. If these outliers were removed, the time taken to make a report average 9 minutes 20 seconds.

On-line reporting

A total of six incidents were logged using on-line reporting, constituting 5% of all reports generated in Department 20. One reporter used on-line reporting on four occasions, and another two people accounted for the remaining two incidents. All on-line reporters were Registered Nurses. Two reports logged on-line were related to medical devices, two related to medication incidents, one related to a fall and one to a documentation issue.

4.6.8. To change types of incidents reported (aim 4.2)

4.6.8.1. Reliability of the classification of Principal Incident types (PITs).

As discussed in section 3.6.6.1 each incident was given an incident type. Because incidents had been classified by many different people in the intervention unit during the study period and because the PIT category into which they were place was often difficult to determine, internal reliability of the tool was assessed on a subset of incidents. Where possible, 15 incidents from each PIT which were entered into the Advanced AIMS database during the intervention period were independently recoded by a clinical coder in the Department of Health who was not involved in the project. All identifying information and the PIT assigned to the report was removed form the report.

Results

For incident types where there were only a few incidents logged, it was not possible to assess interrater reliability. For example, there were only two incidents with a PIT of pressure ulcer in the Advanced AIMS database and so reliability could not accurately be reported. For this reason, only incident types with more than ten incidents were selected for independent assessment.

For the eleven PITs able to be assessed, the overall weighted kappa statistic for agreement between the PIT recorded in the database and the independent coder was moderate (kappa=0.62), with agreement on 66.2% of occasions. There was heterogeneity in findings, as seen in Appendix 31, with agreement between coder and staff as little as 47% for clinical management incidents, and as high as 100% for falls.

4.6.8.2. Coding PITS

Based on the poor level of agreement between the coder and staff for some incidents, and the fact that PITs had changed between baseline and the study period because of the two types of databases used (AIMS+ and Advanced AIMS), a decision was made to have coders reclassify incidents in both the baseline and study period for the intervention and control

units. Incidents allocated as having a PIT category of Fall in either the baseline or study period were not reclassified because of excellent inter-rater reliability for this category when formally tested (kappa=1.0). Each coder chosen to independently classify the incidents was not connected in any way with the study, and had been trained in classification of incidents using the AIMS database. Financial re-imbursement for time spent classifying incidents was offered to each institution.

For baseline AIMS+ data, coders were asked to reclassify each incident (other than falls) into its respective PIT in the Advanced AIMS database. In some hospitals, where the narrative had been entered into the AIMS+ database, this was simply a matter of printing out specific narrative fields (What happened? Why did this incident happen? How could the incident have been prevented?) and having the clinical coder mark on the printout to which PIT the incidents belonged. For hospitals where the narrative was not entered into the AIMS+ database, each paper incident report form was retrieved and coders were asked to record the Advanced AIMS PIT on the actual report form. On these incident forms the reporter's name and department were recorded, making it impossible to blind coders. To minimise the impact of not being able to blind coders, they were not informed what departments were control and intervention units.

Four coders classified the incidents. Coder A was employed by Hospital 1 as the AIMS clinical coder for five years. Coder B was employed by the Department of Health as a clinical coder and was responsible for classifying all AIMS reports incidents in regional South Australia. Coder C was employed by Hospital 3 as the AIMS clinical coder, and had been in the role for five years. Coder D was the AIMS clinical coder for hospital 6, and had been in the role for six years.

Hospital 1 baseline and intervention data were categorised by Coder A (n=449).

Hospital 2 baseline and intervention data were categorised by Coder B. All data was blinded (n=307)

Hospital 3 baseline and intervention data were classified by Coder C (n=138).

Hospital 4 baseline and intervention data were classified by Coder B (n=444).

Hospital 6 baseline and intervention incidents were classified by coder D (n=202).

Hospital 5 began entering all incident data into the Advanced AIMS database from week 29 in the intervention period, which meant that for all incidents submitted in the control units after this date, independent blinded categorisation of PITs was performed by coder B (n=33

incidents). All AIMS+ data in hospital 5 prior to week 29 was unable to be independently classified, because incident reports were not permitted to leave the hospital premises and there was no coder on site. Most incidents entered into AIMS+ related to patient falls (107/170= 61%) and did not require independent categorisation (Appendix 32). All incidents given a PIT of medication in AIMS+ (38/170=22%) were also categorised as medication incidents when allocating a PIT for the final analysis. The other 30 incidents (17% of all AIMS+ incidents) were classified by the PhD candidate using telephone consultation with coder B. Set out below is the breakdown of data housed on the two databases and associated incident categories.

4.6.8.3. Reporting rates – PITSs

Table 4-28 compares the types of incidents reported in intervention and control units in the baseline period and study period. At baseline there were more medical device and equipment incidents reported in the intervention units compared with the control units (6.9% vs. 2.7% of all reports; p=0.40, 95% CI: 0.18 to 0.82).

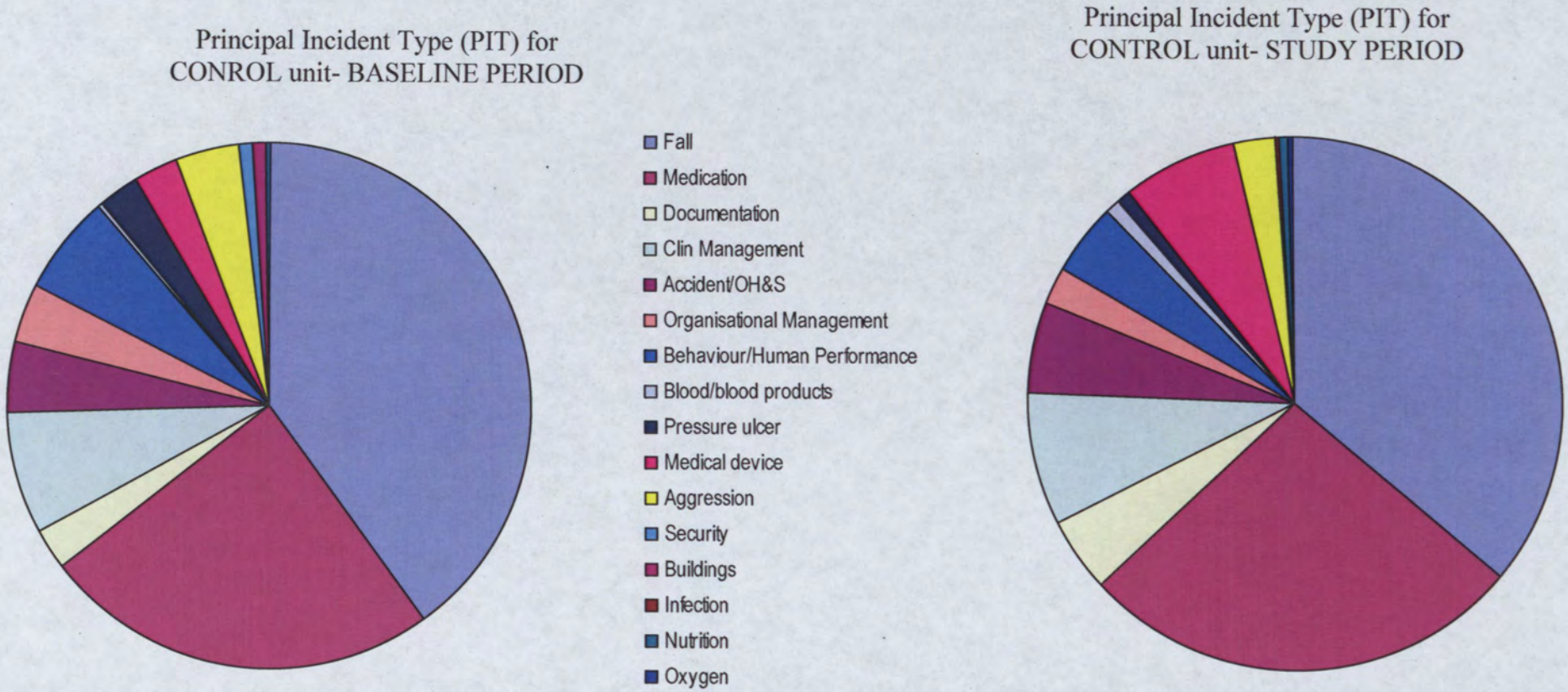
Table 4-28 Comparison of reporting rates by Principal Incident Type

Principal Incident Type	Baseline				End				Comparison at end adjusted for baseline P value†
	Control % of reports (n)	Intervention % of reports (n)	Rate ratio*	95%CI	Control % of reports (n)	Intervention % of reports (n)	Rate ratio*	95% CI	
Fall	39.9% (131)	36.1% (152)	1.1	0.9-1.4	48.0% (263)	23.8% (304)	2.01	1.7-2.3	<0.001
Medication	24.4% (80)	26.8% (113)	0.91	0.7-1.2	25.2% (138)	27.9%(356)	0.90	0.7-1.1	0.942
Documentation	2.7% (9)	4.5% (19)	0.61	0.3-1.3	3.0% (16)	11.4% (146)	0.25	0.1-0.4	0.004
Clinical Management	7.3% (24)	8.1% (34)	0.91	0.5-1.5	5.3% (29)	11.4% (146)	0.46	0.3-0.7	0.035
Accident/OH&S	4.6% (15)	5.5% (23)	0.84	0.4-1.6	4.0% (22)	4.8% (61)	0.84	0.5-1.3	0.949
Organisational Management	3.7% (12)	2.4% (10)	1.54	0.7-3.7	5.7% (31)	4.1% (53)	1.36	0.9-2.0	0.868
Behaviour/human performance	6.1% (20)	4.3% (18)	1.43	0.7-2.7	3.5% (19)	3.3% (42)	1.05	0.6-1.8	0.339
Blood/blood products	0.3% (1)	0.9% (4)	0.32	0-2.6	1.1% (6)	0.7% (8)	1.74	0.6-5.1	0.147
Pressure ulcer	2.4% (8)	0.9% (4)	2.56	0.8-9.8	0	0.3% (4)			0.010
Medical device/equipment	2.7% (9)	6.9% (29)	0.40	0.2-0.8	1.3% (7)	4.8% (61)	0.27	0.1-0.6	0.720
Aggression	4.0% (13)	2.4% (10)	1.67	0.7-3.9	1.8% (10)	4.4% (56)	0.41	0.2-0.8	0.011
Security	0.6% (2)	0	-		0.9% (5)	1.2% (15)	0.78	0.2-2.1	0.290
Buildings/fittings / surrounds	0.9% (3)	0	-		0	1.2%(15)			0.005
Infection	0	0.2% (1)	-		0.2% (1)	0.3% (4)	0.58	0-4.6	0.806
Nutrition	0.3% (1)	0.7% (3)	0.43	0-8.0	0.2% (1)	0.4% (5)	0.46	0-3.4	0.723
Total	**100% (328)**	**100% (421)**	**0.045**		**100% (548)**	**100% (1275)**	**<0.001**		**<0.001**

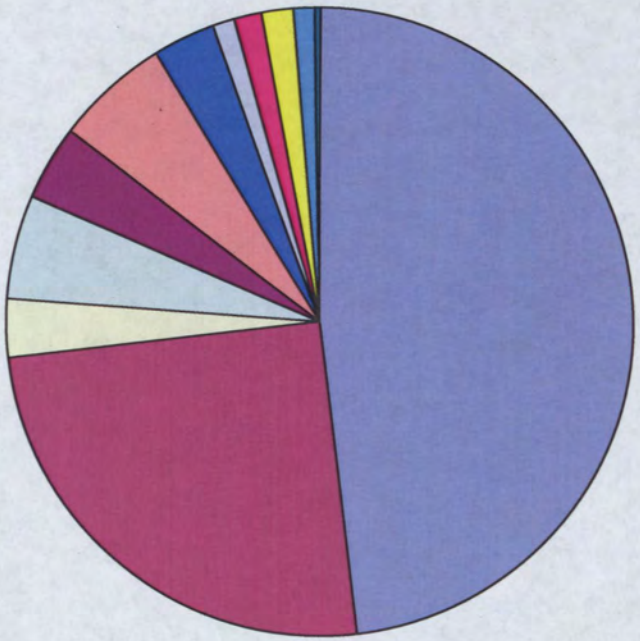
* Fishers Exact test † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalised linear models

Comparison of intervention and control unit data at the end of the study adjusted for baseline showed that intervention unit reports during the study period were more likely to contain documentation, clinical management, and aggression as the PIT than in the control units. In the intervention units, even though the medical device incident reporting rate doubled (29 vs. 61 incidents), as a percentage of all reports this type of incident declined during the study period (6.9% to 4.8% of all reports). Adjusting for differences at baseline, the intervention unit reports during the study period were statistically more likely to be related to documentation ($p=0.004$), clinical management ($p=0.035$) and buildings, fittings and surrounds ($p=0.005$). Figure 4-8 provides pie chart diagrams of PITs reported during the baseline and study period in both intervention and control units.

Figure 4-8 Comparison of Principal Incident Types at baseline compared with end of study in Control and Intervention Units



Principal Incident Type (PIT) for
INTERVENTION unit- BASELINE PERIOD



Unit

- Fall
- Medication
- Documentation
- Clin Management
- Accident/OH&S
- Organisational Management
- Behaviour/Human Performance
- Blood/blood products
- Pressure ulcer
- Medical device
- Aggression
- Security
- Buildings
- Infection
- Nutrition

Principal Incident Type (PIT) for
INTERVENTION unit- STUDY PERIOD

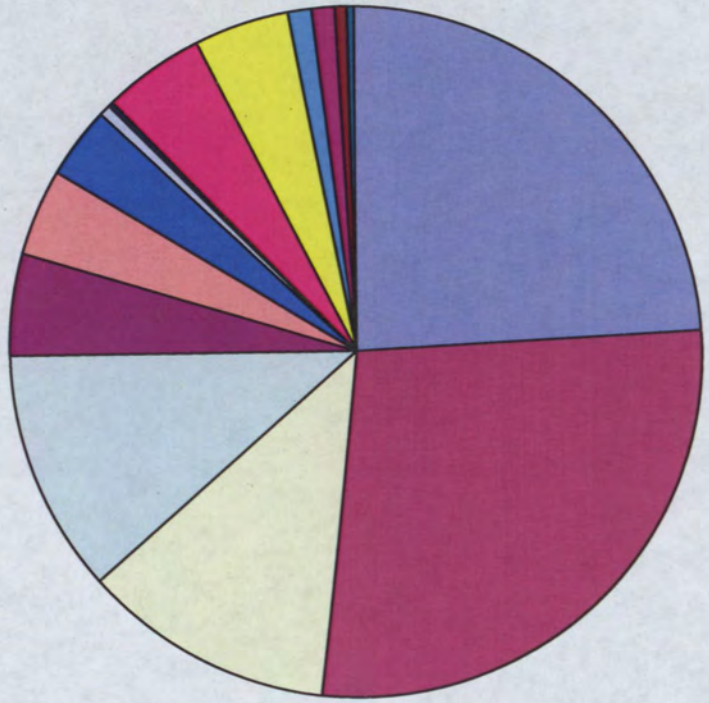


Table 4-29 provides a comparison of the types of incidents reported in each type of unit at baseline and during the study period. It was not possible to formally test changes in some PITs by types of units, because there were no incidents reported at baseline.

During the study period there were significantly fewer falls-related incidents in ICUs (12.9% to 4.6% RR 2.6) and medical units (47.7% to 33.8% RR=1.4). Additionally, there were fewer organisational management incidents (29.2% to 6.6% RR=4.4) and behaviour and human performance incidents (16.7% to 1.7% RR=10.1) in the ED during the study period in intervention units (29.2% to 6.6%).

During the study period there were significantly more clinical management incidents in the ICU (12.0% to 28.1% RR=0.4). In the medical units, there were more organisational management incidents (0.4% to 2.6% RR=0.2) and medical devices related incidents (0.4% to 2.6% RR=0.2). Although unable to be formally tested because there were no incidents at baseline, there was an increase in the reporting in EDs of documentation-related incidents (0 to 38.2%) and clinical management incidents (0 to 13.3%).

Table 4-29 Comparison of reporting rates (Principal Incident Types) by type of units in the intervention units during the study period

Principal Incident Type	ICU				ED				Surgical units				Medical units			
	Base-line % N=108	End % N=153	Rate ratio *	95% CI	Base-line % N=24	End % N=181	Rate ratio *	95% CI	Base-line % N=46	End% N=165	Rate ratio *	95% CI	Base-line % N=243	End % N=612	Rate ratio *	95% CI
Fall	12.0	4.6	2.6	1.2-5.9	20.8	9.4	2.2	0.7-5.7	39.1	21.8	1.8	1.0-3.1	47.7	33.8	1.4	1.1-1.8
Medication	29.6	30.7	0.9	0.6-1.5	12.5	10.5	1.2	0.2-3.6	30.4	34.5	0.9	0-1.5	26.3	29.1	0.9	0.7-1.2
Documentation	3.7	3.9	0.9	0.2-3.5	-	38.2	-	-	2.2	9.1	0.2	0.2-2.1	4.9	7.8	0.6	0.3-1.2
Clinical management	12.0	28.1	0.4	0.2-0.8	-	13.3	-	0-4.4	8.7	11.5	0.8	0.4-7.2	7.0	5.9	1.2	06-2.1
Accident/OH&S	8.3	4.6	1.8	0.7-5.2	4.2	5.5	0.7	*0.0-4.5*	6.5	3.6	1.8	0-5.2	4.1	5.2	0.8	0.4-1.6
Organisational Management	0.9	3.9	0.2	0.0-1.6	29.2	6.6	*4.4*	*1.6-11.2*	2.2	3.0	0.7	0-4.0	0.4	2.6	0.2	0-0.8
Behaviour/ performance	4.6	1.3	3.5	0.7-26.4	16.7	1.7	10.1	2.1-53.9	2.2	3.6	0.6	0.0-4.0	1.2	4.1	0.8	0.3-1.7
Medical device /equipment	22.2	11.8	1.9	1.0-3.5	4.2	7.2	0.6	0-3.3	6.5	6.1	-	0.2-3.7	0.4	2.4	0.2	0.0-0.9
Aggression	0.9	4.6	0.2	0-1.3	-	3.3	-	-	2.2	1.8	1.0	0-11.2	3.3	5.1	0.6	0.3-1.4
Buildings, fittings, surrounds	-	3.9	-	-	-	-	-	-	-	1.2	-	-	-	1.0	-	-
Other	-	3	-	-	-	-	-	-	2.2	2.4	-	-	2.5	-	-	
Total (%)	**100%**	**100**			**100**	**100**			**100**	**100**			***100***	***100***		

* Fishers Exact test

Table 4-30 and 4-31 provide a breakdown of the types of incidents reported in the baseline and study periods by doctors and nurses respectively. Because the numbers of reports generated by medical staff was small, no statistical analysis was undertaken. However, it can be seen that the intervention had most success in increasing reports relating to documentation, clinical management and medications. There were significant differences in nurse reporting practices as a result of the intervention. Compared to baseline, at the end of the study period, there was a decline in the percentage of reports relating to falls and an increase in the number of reports relating to clinical management, aggression and buildings/fittings/surrounds.

Table 4-30 Comparison of Principal Incident Types at baseline and end of study- Doctors

Principal incident type	**Baseline**		**End**	
	Control	**Intervention**	**Control**	**Intervention**
	N	**N**	**N**	**N**
Fall	0	0	0	5
Medication	2	3	2	13
Documentation	1	0	1	6
Clinical Management	0	0	0	18
Accident/OH&S	0	0	0	2
Organisational Management	0	0	0	4
Behaviour/human performance	0	0	0	1
Blood/blood products	0	0	0	0
Pressure ulcer	0	0	0	0
Medical device/equipment	0	0	1	6
Aggression	1	0	0	0
Security	0	0	0	0
Buildings/fittings/ surrounds	0	0	0	0
Infection	0	0	0	0
Nutrition	0	0	0	0
Total	**4**	**3**	**4**	**57**

Table 4-31 Comparison of Principal Incident Types at baseline and during the study period - Nurses

	Baseline				End				Comparison at end adjusted for baseline† P value
	Control % of reports (N)	Intervention % of reports (N)	P-value *	95% CI	Control % of reports (N)	Intervention % of reports (N)	P value*	95% CI	
Fall	41.6 (124)	38.3 (148)	1.08	0.8-1.4	48.7 (234)	27.6 (265)	1.77	1.5-2.1	<0.001
Medication	22.8 (68)	24.6 (95)	0.93	0.7-1.3	25.2 (121)	25.7 (247)	0.98	0.8-1.2	0.758
Documentation	2.7 (8)	3.9 (15)	0.69	0.3-1.6	1.9 (9)	6.5 (62)	0.29	0.1-0.5	0.083
Clinical Management	7.7 (23)	7.5 (29)	1.03	0.6-1.8	5.6 (27)	11.6 (111)	0.49	0.3-0.7	0.023
Accident/OH&S	4.7 (14)	5.7 (22)	0.82	0.4-1.6	4.4 (21)	5.2 (50)	0.84	0.5-1.4	0.936
Organisational Management	4.0 (12)	2.6 (10)	1.55	0.6-3.7	5.6 (27)	4.2 (40)	1.35	0.8-2.2	0.991
Behaviour/human performance	6.0 (18)	4.4 (17)	1.37	0.7-2.7	3.7 (18)	3.8 (37)	0.97	0.5-1.7	0.364
Blood/blood products	0.3 (1)	1.0 (4)	0.32	0.1-2.6	0.6 (3)	0.6 (6)	1.0	0.2-4.0	0.364
Pressure ulcer	2.3 (7)	1.0 (4)	2.27	0.7-8.8	0	0.4 (4)	-	-	0.030
Medical device/equipment	2.7 (8)	7.5(29)	0.36	0.2-0.8	1.2 (6)	5.4 (52)	0.23	0.1-0.5	0.736
Aggression	3.4 (10)	2.3 (9)	1.44	0.6-3.7	1.9 (9)	5.2 (50)	0.36	0.2-0.7	0.015
Security	0.3 (1)	0	-		0.6 (3)	1.3 (13)	0.46	0.1-1.5	0.209
Buildings/fittings/surround	1.0 (3)	0	-		0	1.5 (14)	-		0.004
Infection	0	0.3 (1)	-		0.2 (1)	0.4 (4)	0.5	0.0-4.0	0.920
Nutrition	0.3 (1)	0.5 (2)	0.65	0.0-8.5	0.2 (1)	0.5 (5)	0.4	0.0-2.9	0.834
Oxygen	0	0.3 (1)	-		0	0		-	
Total	**100 (298)**	**100 (386)**			**100 (480)**	**100 (960)**			

* Fishers Exact test † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalised linear models

4.6.9. Summary of Results of the Intervention with respect to number and types of reports

The intervention component of this study was conducted in ten intervention units across six hospitals in South Australia. There were ten control units, matched for location (rural and metropolitan), hospital, type of Unit (ICU, ED, medical, and surgical) and specialty (Neurology and Cardiology). The intervention consisted of an education campaign at commencement of the project, simplifying the reporting process (one page report form, Call Centre and on-line reporting in one clinical area), changing the method in which reports were processed, and provision of feedback (individual feedback for serious events, aggregate feedback at departmental meetings, and newsletters distributed two monthly).

With the exception of ICUs in both metropolitan and rural South Australia, incident reporting increased all intervention units during the study period after adjusting for differences at baseline. Overall numbers of reports increased three-fold from 421 reports at baseline to 1275 reports in the study period. In some departments, reporting increased more than 30-fold (ED in rural South Australia). Comparison of intervention and control units with adjustment for differences at baseline demonstrated that in medical, surgical and EDs the study resulted in significant reporting improvement; however it had little effect in the ICU.

In the intervention unit, medically-initiated reports increased from a low baseline rate of 1.2% (n=3) to 4.4% (n=57) of all reports during the study period. In control units, reporting by medical staff declined slightly from a baseline rate of 1.2% (n=4) to 0.7% (n=4) of all reports during study period. As a percentage of all reports generated, reporting by nurses decreased in the intervention units from 91.7% (n=386) of all reports in the baseline period to 75.3% (n=960) during the study period. Rural hospitals increased overall reporting rates in intervention units during the study period, however despite attempts to encourage reporting; only three reports were lodged by GPs. A total of 9.6% of all reports generated in the study period were reported anonymously. The option to report anonymously within the hospital (where location of incidents was not documented) was not available to nurses or doctors in the baseline period.

After adjusting for differences between the control and intervention units at baseline, there were significant differences in types of incidents reported during the study period when compared to baseline. As a percentage of all reports generated, there were fewer reports relating to falls during the study period compared with baseline in the intervention unit

(36.10% vs. 23.84%), while reporting of falls increased in the control unit (39.94% vs. 47.99%). Intervention unit staff reported significantly more incidents relating to documentation (4.5% of all reports at baseline compared to 11.4% during study period p=0.004), and clinical management (8.1% of all reports at baseline compared to 11.4% during study period p=0.035).

The majority of staff used the one page form to report incidents (78.8% of all reports generated), with Call Centre reports accounting for 20.7% of all reports and only 0.5% of reports being submitted electronically. It should be noted that electronic reporting was only available in one clinical area because of the infrastructure required to have it established. Call Centre reporting was mostly used in the medical units (20% of all reports) and was rarely used in the ED (2% of all reports).

Even though it was anticipated that feedback could be given on a regular basis in all units, this did not occur for a number of reasons. There was a correlation between the numbers of departmental meetings provided to medical staff and reporting practices by doctors, with more medically-initiated reports being submitted in units where feedback could be provided at least three monthly. The exception was in the ICU of a metropolitan hospital where feedback did not improve reporting practices by doctors.

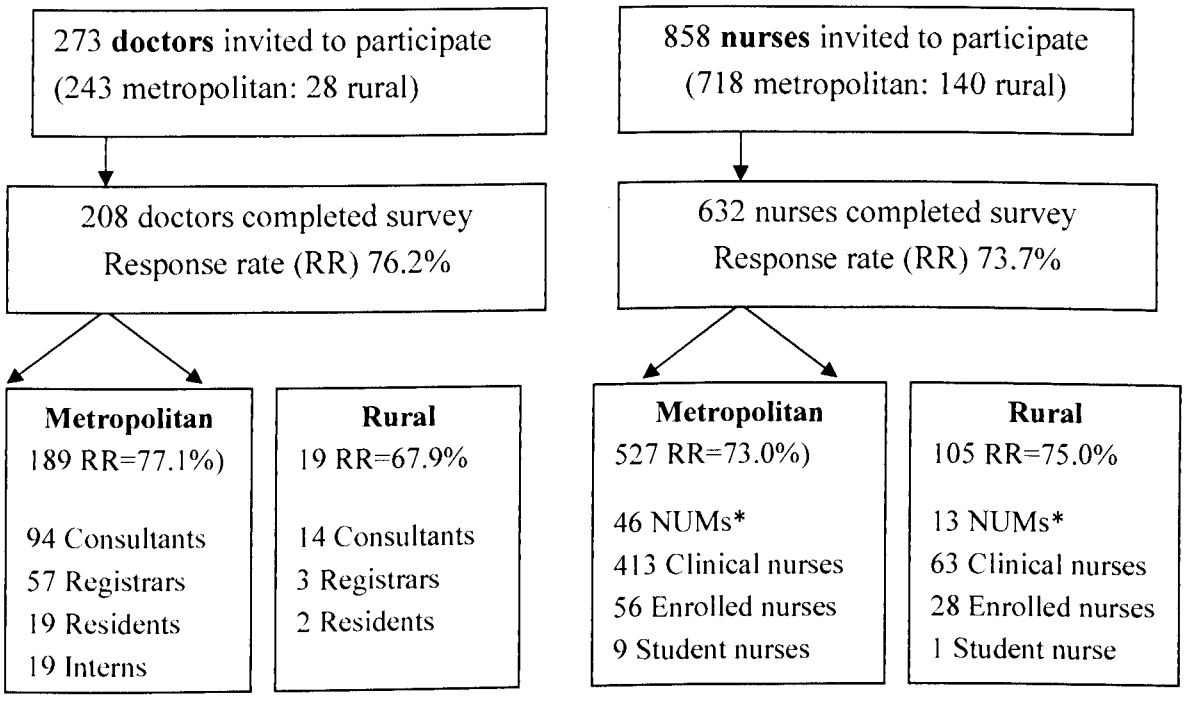
4.7. End of study survey

4.7.1. Reponses rate

The sampling frame for the end of study survey is shown in Figure 4-9. The overall response rate to the end of study survey of medical and nursing staff was 74.3%; with 840 of the 1131 staff approached taking part The response rate was 76.2% for doctors (208 out of 273 doctors returned the survey) and 73.7% for nurses (632 out of 858 nurses returned the survey).

The response rate was slightly higher in metropolitan hospitals compared with rural hospitals (74.3% vs. 73.8%). In metropolitan hospitals, 77.1% of doctors (189 out of 245 doctors) and 73.3% of nurses (527 out of 718 nurses) returning the survey. In the rural hospitals, 67.9% of doctors (19 out of 28 doctors) and 75.0% of nurses (105 out of 140) returning the survey. As the survey was anonymous, we were unable to ascertain the demographic features of non-respondents.

Figure 4-9 Sampling frame for end of study staff survey



For each question on the staff survey, the following variables were tested:

- Profession (doctor or nurse)
- Seniority within profession (Consultant, Registrar, Resident, Intern, NUM, RN, EN)
- Location of hospital (Rural or metropolitan)

4.7.2. Survey tool

4.7.2.1. Reliability

Test-retest reliability on a sample of ten demonstrated that for most questions there was good reproducibility. Questions with a kappa of less than 0.5 and therefore demonstrating poor reproducibility were removed (Appendix 33).

4.7.3. To improve knowledge of the reporting system (aim 5.1)

Q1: Does this hospital have an incident reporting system? Table 4-32 shows that, when comparing baseline with end of study data, there was no significant relative change in respondents' knowledge of the incident reporting system in intervention units compared to control units. In both the control and intervention units, baseline knowledge of the existence of a reporting system was very good.

Q2: Do you know how to locate/access/make a report? When assessing baseline understanding of the reporting process, respondents were asked whether they knew how to locate or access a report. In the intervention units, this question was modified at the end of the study to ask respondents if they knew how to make a report because there were a variety of different methods to report an incident in the study period aside from the paper form. There was no overall improvement in understanding of the reporting process between baseline and the end of the study in the control and intervention units. However sub-group analysis by type of unit showed that understanding improved significantly in Surgical Units (Table 4-33).

There was significant improvement in knowledge of how to make a report in rural intervention units during the study period when compared to baseline. At baseline 54% (7/13) of general practitioners did not know how to make a report compared to the end of study where all GPs stated that they knew how to make a report (15/15).

Table 4-32 Comparison of knowledge and use of the reporting system between baseline and end of study by profession

	Baseline				End				Comparison at End adjusted for Baseline†	
	Control % (N)	Intervention % (N)	RR *	95% CI	Control % (N)	Intervention % (N)	RR *	95% CI	RR	95% CI
Overall										
Awareness of reporting system	99.4% (314)	97.8% (457)	1.0	0.9-1.2	99.2 (385)	99.2% (474)	1.0	0.9- 1.1	1.02‡	1.01-1.04
Know how to make a report §	77.8% (312)	77.6% (450)	1.0	0.8-1.2	84.3% (382)	89.6 (473)	0.9	0.8-1.1	1.07	0.98-1.17
Doctors										
Awareness of reporting system	97.0% (65/67)	91.9% (111)	1.1	0.8-1.4	96.7% (92)	99.1% (113)	1.0	0.8-1.3	0.99	0.98-1.06
Know how to make a report	42.4% (66)	42.1% (107)	1.0	0.6-1.6	59.3% (91)	81.4% (113)	0.7	0.5-1.0	1.38	0.92-2.08
Nurses										
Awareness of reporting system	100% (244)	99.7% (342)	1.0	0.8-1.2	96.7% (92)	99.1% (113)	1.0	0.7-1.3	0.99	0.98-1.01
Know how to make a report	88.1% (243)	88.5% (339)	1.0	0.8-1.2	91.8% (281)	92.1% (343)	1.0	0.8-1.2	1.00	0.92-1.08

* Fishers exact test. † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalised linear models ‡poisson regression used adjusting for clustering by hospitals, and allowing for robust estimates of standard errors § In the control unit staff were asked if they knew how to locate or access a report form, in the intervention unit staff were asked if they knew how to make a report

Table 4-33 Comparison of knowledge of how to make a report (intervention unit) and locate a form (control units) by location of hospital and type of unit

	Baseline				End				Comparison at End adjusted for Baseline†	
	Control % (N)	Intervention % (N)	RR *	95% CI	Control % (N)	Intervention % (N)	RR *	95% CI	RR	95% CI
Location of hospital										
Rural	93.7% (48)	82.9% (70)	1.1	0.8-1.7	93.7% (64)	100.0% (61)	0.9	0.7-1.3	1.21	1.01-1.46
Metropolitan	75.0% (264)	76.6% (380)	1.0	0.8-1.2	82.4% (318)	88.1% (412)	0.9	0.8-1.1	1.05	0.94-1.17
Type of Unit										
ICU	75.7% (70)	80.5% (159)	1.1	0.8-1.5	89.0% (73)	87.9% (173)	1.0	0.7-1.3	0.93	0.88-0.98
Emergency Dept.	75.9% (54)	87.5% (56)	1.1	0.8-1.8	80.0% (75)	89.7% (78)	1.2	0.8-1.6	0.97	0.85-1.12
Surgical	81.2% (96)	75.0% (76)	0.9	0.6-1.3	83.6% (117)	92.4% (53)	1.1	0.8-1.5	1.20	1.07-1.33
Medical	77.2% (92)	74.7% (146)	1.0	0.7-1.3	84.6% (117)	89.3% (149)	1.0	0.8-1.4	1.09	0.83-1.44

* Fishers exact test † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalised linear models

4.7.4. To change self-perceived reporting practices (aim 5.2)

4.7.4.1. Staff reporting practices

Q10: Please comment on how often you report the following incidents, and then record how often you think you should report the events. Figures 4-10 and 4-11 outline perceptions of how often staff believe they do and should report various types of adverse events in the intervention and control units at baseline and at the end of study period. Table 4-34 and 4-35 compares baseline and study period perception of how often staff believe they do and should report certain types of incidents in both the control and intervention units.

Compared to the controls, intervention staff at the end of the study were *more* likely to:

- believe they should report hospital-acquired infections (RR 1.06 95% CI: 1.02 to 1.10)
- believe they should report when staff made a medication error but it was not given to the patient (near miss) (RR 1.23 95% CI: 1.12 to 1.37).

and were *less* likely to:

- believe that they did report when staff made a drug error requiring corrective treatment (RR 0.88 95% CI: 0.8 to 0.98)
- believe they did report problems with machinery or equipment which resulted in patient harm (RR 0.91 95% CI: 0.87 to 0.94)

Appendix 34 provides a summary of significant findings when reporting practices were analysed according to the professional designation of the respondent.

Compared to the controls, doctors in intervention units at the end of the study were *less* likely to:

- believe they did report hospital-acquired infections (RR 0.48 95% CI: 0.34 to 0.67)
- believe they did report medication near misses (RR 0.38 95% CI: 0.21 to 0.67)
- believe they did report medication errors not requiring corrective treatment (RR 0.65 95% CI: 0.51 to 0.85)
- believe they did reported problems with machinery or equipment which resulted in patient harm (RR 0.55 95% CI: 0.41 to 0.73)

Compared to the controls, nurses in intervention units at the end of the study were *more* likely to:

- believe they did report medication near misses (RR 1.47 95% CI: 1.23 to 1.74)

Figure 4-10 Percentage of times that staff believed they reported specified adverse incidents- Intervention units

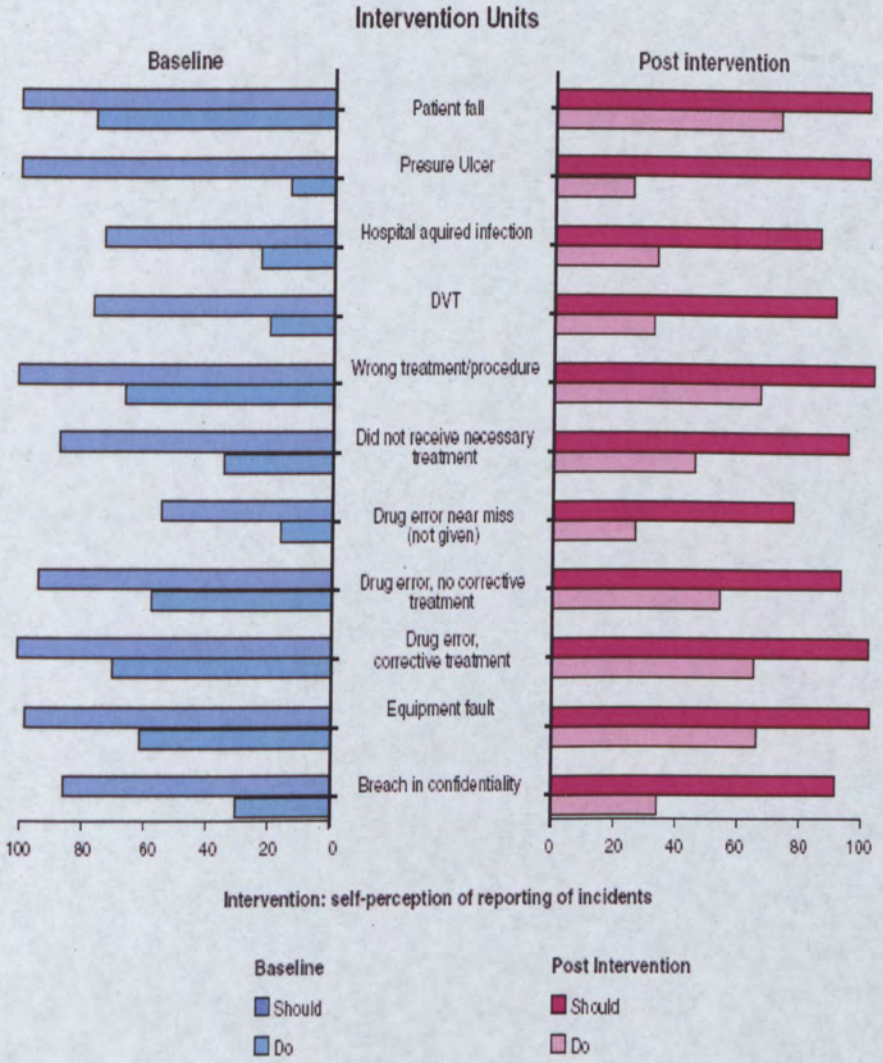


Figure 4-11 Percentage of times that staff believed they reported specified adverse incidents-Control Units

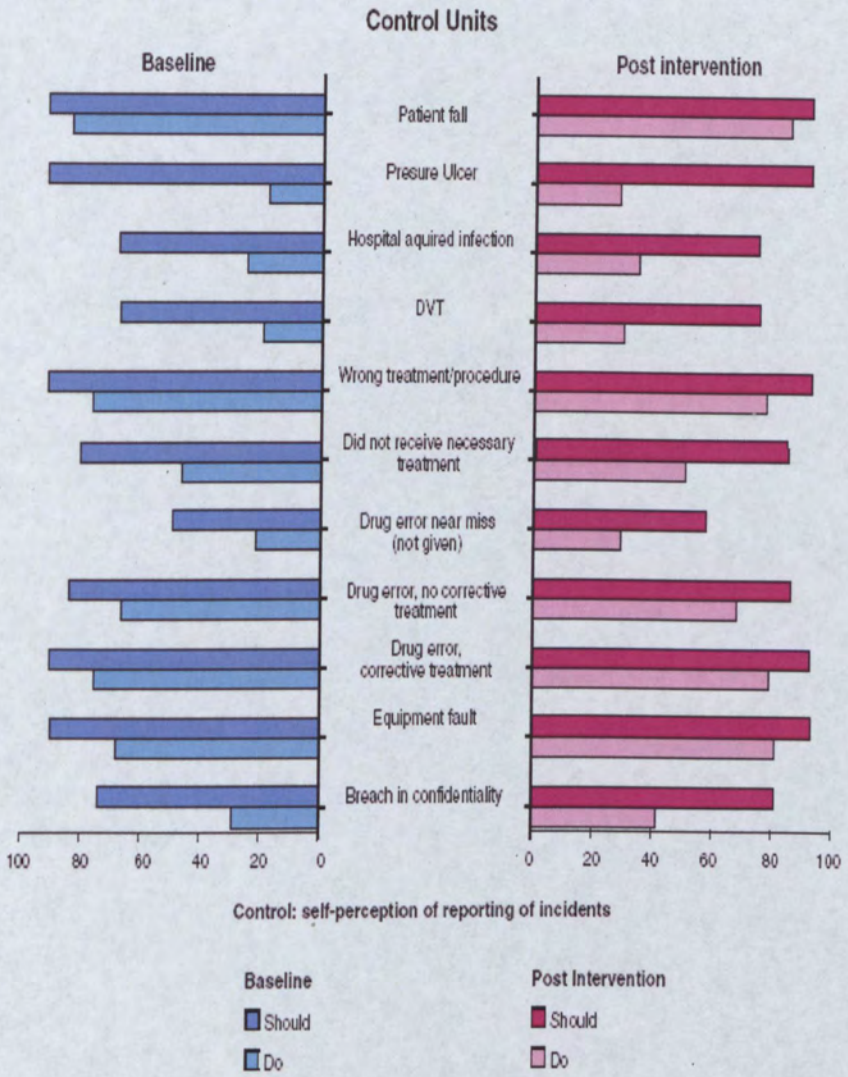


Table 4-34 Comparison of staff who believe they DO report incident types more than 50% of the time at baseline and end of study.

	Baseline				End				Comparison at End adjusted for Baseline†	
	Control % do report >50% of the time (N)	**Intervention** % do report >50% of the time (N)	**RR ***	**95% CI**	**Control** % do report >50% of the time (N)	**Intervention** % do report >50% of the time (N)	**RR ***	**95% CI**	**RR**	**95% CI**
Patient sustained a pressure ulcer	19.4% (263)	15.8% (387)	0.81	0.57-1.16	29.6% (314)	27.8% (395)	0.94	0.67\-1.32	1.16	0.78-1.71
Patient injury due to a fall in hospital	89.5% (295)	86.5 (416)	0.97	0.90-1.04	90.3 (361)	81.6 (414)	0.90	0.86-0.95	0.93	0.85-1.02
Hospital-acquired infection	26.6% (278)	26.2% (401)	0.98	0.64-1.50	36.7% (330)	37.1% (402)	1.01	0.58-1.75	1.03	0.84-11.26
Patient sustained a DVT due to inadequate prophylaxis	21.2% (255)	22.9% (362)	1.08	0.82-1.43	31.4 (299)	36.2 (378)	1.15	0.87-1.53	1.06	0.87-1.29
Patient received wrong treatment or procedure	81.1% (281)	75.6% (394)	0.93	0.83-1.05	82.2% (343)	74.9% (394)	0.91	0.86-0.97	0.98	0.85-1.13
Patient did not receive necessary treatment/procedure	49.3% (270)	39.3% (377)	0.80	0.68-0.94	53.2% (327)	51.2% (387)	0.96	0.77-1.19	1.21	1.04-1.40
Staff made a medication error but it was not given (near miss)	22.7% (282)	18.6% (397)	0.82	0.59-1.15	30.5% (347)	29.7% (407)	0.97	0.69-1.37	1.18	0.93-1.51
Staff made a drug error which did not require corrective treatment	70.9% (278)	65.4% (396)	0.92	0.79-1.07	71.9% (352)	60.8% (388)	0.85	0.77-0.93	0.92	0.79-1.06
Staff made a medication error requiring corrective treatment	80.4% (276)	79.7% (399)	0.99	0.87-1.12	83.7% (344)	73.4% (383)	0.88	0.83-0.93	0.88	0.80-0.98
Problem with equipment/machinery resulting in patient harm	72.4% (283)	69.4% (402)	0.96	0.89-1.03	85.8% (337)	74.5% (385)	0.87	0.82-0.92	0.91	0.87-0.94
Breach in confidentiality	30.6% (258)	34.2% (357)	1.11	0.88-1.41	43.9% (310)	38.1% (368)	0.87	0.54-1.40	0.78	0.44-1.37

* log binomial generalized linear models adjusting for clustering by hospitals † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalised linear models

Table 4-35 Comparison of staff who believe they SHOULD report incident types more than 50% of the time at baseline and end of study

	Baseline				End				Comparison at End adjusted for Baseline†	
	Control	Intervention			Control	Intervention				
	Should report >50% of the time (N)	Should report >50% of the time (N)	RR *	95% CI	Should report >50% of the time (N)	Should report >50% of the time (N)	RR *	95% CI	RR	95% CI
Patient sustained a pressure ulcer	65.0% (260)	66.3% (356)	0.81	0.57-1.16	77.8 (320)	81.0% (401)	0.94	0.67-1.31	1.02	0.96-1.09
Patient injury due to a fall in hospital	96.9% (292)	95.7% (397)	0.99	0.96-1.02	97.0% (368)	96.2% (418)	0.99	0.97-1.02	1.00	0.92-1.10
Hospital-acquired infection	71.7% (198)	70.0% (384)	0.98	0.83-1.15	78.7% (334)	81.4% (409)	1.03	0.89-1.20	1.06	1.02-1.10
Patient sustained a DVT due to inadequate prophylaxis	71.1% (253)	73.6% (356)	1.03	0.96-1.11	78.8% (312)	85.9% (396)	1.09	1.0-1.19	1.05	0.97-1.14
Patient received wrong treatment or procedure	96.6% (291)	96.2% (400)	1.00	0.95-1.04	97.5% (367)	97.9% (420)	1.00	0.98-1.02	1.00	0.96-1.06
Patient did not receive necessary treatment/procedure	85.2% (231)	83.5% (369)	0.98	0.89-1.07	89.3% (336)	90.1% (403)	1.00	0.95-1.07	1.03	0.96-1.10
Staff made a medication error but it was not given to the patient (near miss)	52.6% (272)	52.0% (379)	0.99	0.80-1.22	60.3% (348)	73.6% (417)	1.22	1.05-1.42	1.23	1.12-1.37
Staff made a drug error which did not require corrective treatment	88.9% (289)	89.6% (395)	1.01	0.95-1.07	90.9% (363)	88.2% (417)	0.97	0.94-1.01	0.96	0.90-1.04
Staff made a medication error requiring corrective treatment	95.8% (286)	95.7% (400)	1.0	0.98-1.02	97.5% (364)	96.7% (422)	0.99	0.96-1.02	0.99	0.97-1.02
Problem with equipment/machinery resulting in patient harm	95.2% (292)	93.6% (404)	0.99	0.95, 1.02	98.1% (363)	97.2% (423)	0.99	0.97-1.01	1.01	0.96-1.05
Breach in confidentiality	78.1% (274)	81.4% (366)	1.04	0.98, 1.10	85.2% (332)	87.0% (407)	1.02	0.93-1.12	0.98	0.89-0.08

* log binomial generalized linear models adjusting for clustering by hospitals † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalised linear models

4.7.5. To reduce barriers to reporting (aim 5.3)

Q11: I don't report incidents because... Questions relating to reporting barriers were compared between baseline and the study period to ascertain whether the intervention had made any impact in changing perceptions of why staff do not report incidents. All barriers included at baseline were repeated, however with regard to the statement, "The AIMS form is too complicated and requires too much detail", this was not analysed because it was confusing for staff in intervention units who had not been exposed to the AIMS form during the study period. Table 4-36 outlines the overall results on the comparison between baseline and the study period in the intervention and control units. There were no significant differences between the control and intervention units at baseline.

Comparison of barriers at baseline and at the end of the study period shows that intervention unit staff were *more* likely than control unit staff to:

- believe that when the ward was busy they forgot to report incidents (RR=1.28 95% CI: 1.19 to 1.39)

and were less likely to:

- believe that there was no point in reporting near misses (RR=0.76 95% CI: 0.60 to 0.97);
- believe that reporting incidents was unlikely to lead to system changes (RR=0.78 95% CI: 0.63 to 0.96);
- believe that if the incident was discussed with the person involved nothing further needs to be done (RR=0.71 95% CI: 0.54 to 0.94).

Table 4-36 Comparison of barriers to reporting at baseline and end of study

	Baseline				End				Comparison at End adjusted for Baseline†	
	Control	Intervention			Control	Intervention				
	%agree (N)	% agree (N)	RR *	95% CI	% agree (N)	% agree (N)	RR *	95% CI	RR	95% CI
I never get any feedback on what action is taken	59.8(303)	61.4 (437)	1.03	0.89-1.18	59.9 (374)	38.4 (445)	0.64	0.39-1.06	0.63	0.34-1.02
When it is a near miss, I don't see any point in reporting it	48.0 (302)	44.4 (439)	0.92	0.75-1.14	37.6 (372)	26.5 (446)	0.70	0.54-0.92	0.76	0.60-0.97
When the ward is busy I forget to make a report	47.8 (301)	48.1 (439)	1.00	0.90-1.12	45.5 (371)	58.8 (449)	1.29	1.10-1.51	1.28	1.19-1.39
The form takes too long to fill out /I don't have the time	46.7 (302)	46.2 (437)	0.99	0.78-1.25	34.4 (372)	36.8 (445)	1.07	0.87-1.32	1.08	0.88-1.33
The incident was too trivial	43.1 (299)	43.7(436)	1.01	0.83-1.24	38.6 (370)	35.1(155)	0.91	0.72-1.14	0.90	0.72-1.11
I worry about who is privy to information that I disclose	32.7 (302)	31.8 (436)	0.97	0.72-1.31	29.1 (375)	28.3 (445)	0.97	0.71-1.34	1.00	0.66-1.53
I don't feel confident the form is kept anonymous	28.3 (302)	28.0 (440)	0.99	0.73-1.33	27.5 (375)	22.8 (443)	0.83	0.51-1.35	0.84	0.60-1.17
Incident reporting is unlikely to lead to system changes	28.2 (299)	30.5 (440)	1.07	0.87-1.31	21.8 (376)	18.2 (446)	0.83	0.64-1.09	0.78	0.63-0.96
Junior staff are blamed unfairly for adverse incidents	26.6 (302)	26.7 (440)	1.00	0.74-1.36	25.1 (375)	24.6 (448)	0.98	0.68-1.41	0.97	0.61-1.57

	Baseline				End				Comparison at End adjusted for Baseline†	
	Control	Intervention			Control	Intervention				
	%agree (N)	% agree (N)	RR *	95% CI	% agree (N)	% agree (N)	RR *	95% CI	RR	95% CI
I am worried about litigation	20.9 (304)	20.2 (439)	0.97	0.79-1.19	16.7 (371)	20.0 (444)	1.20	0.92-1.57	1.24	0.87-1.77
I don't want to get into trouble	18.3 (303)	16.3 (436)	0.89	0.63-1.27	16.6 (378)	13.8 (441)	0.83	0.64-1.09	0.93	0.64-1.36
My co-workers may be unsupportive	17.6 (301)	20.6 (439)	1.17	0.70-1.93	15.9 (372)	21.6 (449)	1.36	0.87-2.14	1.17	0.83-1.64
Even if I don't give details, I'm sure they'll track me down	17.4 (300)	14.2 (431)	0.82	0.56-1.18	12.6 (374)	12.7 (447)	1.01	0.75-1.38	1.24	0.76-2.02
I am worried about disciplinary action	17.0 (300)	15.1 (436)	0.89	0.55-1.43	12.3 (375)	11.7 (445)	0.95	0.71-1.27	1.07	0.59-1.95
It's not my responsibility to report somebody else's mistakes	15.7 (302)	17.1 (434)	1.09	0.72-1.66	14.2 (374)	13.7(444)	0.97	0.66-1.43	0.89	0.49-1.60
I don't know whose responsibility it is to make a report	15.6 (303)	18.0 (439)	1.16	1.00-1.32	12.3 (375)	14.2 (445)	1.15	0.76-1.75	1.00	0.64-1.56
I don't want the case discussed in meetings	14.7 (301)	13.2 (440)	0.90	0.65-1.23	12.6 (372)	10.6 (444)	0.84	0.57-1.24	0.93	0.66-1.32
If I discuss the case with the person nothing needs to be done	12.4 (301)	15.3 (434)	1.23	0.97-1.57	13.9 (375)	12.2 (444)	0.88	0.63-1.22	0.71	0.54-0.94

* log binomial generalized linear models adjusting for clustering by hospitals. † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalised linear model

4.7.5.1. Barriers to reporting- type of unit

Subgroup analysis was undertaken on the top ten barriers to reporting, to identify whether the area in which staff worked impacted on barriers to reporting. Control unit data showed little change form baseline to end of study (Table 4-37). At the end of the study, significantly fewer staff in the ED thought that the form took too long and they didn't have time to complete it.

Table 4-38 showed that at the end of the study intervention staff (a) in ICUs were less likely to believe that when it is a near miss, there is no point in reporting it; (b) in EDs and surgical units were less likely to believe they never get any feedback on what action is taken; and (c) in medical units were less likely to believe that when it is a near miss, there is no point in reporting it, that they never get any feedback on what action is taken, that incidents are unlikely to lead to system changes and that the incident was too trivial to report.

Table 4-37 Comparison of top ten barriers to reporting at baseline and end of study by type of units (control units)

Barrier	ICU				ED				Surgical units				Medical units			
	Baseline % agree (N)	End % agree (N)	Rate ratio*	95% CI	Baseline % agree (N)	End % agree (N)	Rate ratio*	95% CI	Baseline % agree (N)	End %) agree (N)	Rate ratio*	95% CI	Baseline % agree (N)	End %) agree (N)	Rate ratio*	95% CI
I never get any feedback on what action is taken	65 (69)	69 (72)	0.9	0.6-1.4	66 (53)	57 (74)	1.2	0.8-1.8	55 (92)	62 (113)	0.9	0.6-1.2	56 (87)	54 (115)	1.0	0.7-1.5
When it's a near miss, I don't see any point reporting it	57 (69)	49 (72)	1.1	0.7-1.8	40 (53)	33 (73)	1.2	0.7-2.2	52 (92)	38 (112)	1.4	0.9-2.1	42 (86)	33 (115)	1.3	0.8-2.0
When the ward is busy I forget to make a report	48 (69)	48 (73)	1.0	0.6-1.6	70 (53)	62 (74)	1.1	0.7-1.7	42 (92)	43 (109)	1.0	0.6-1.5	40 (87)	36 (115)	1.1	0.7-1.8
The form takes too long to fill out /I don't have the time	44 (69)	29 (72)	1.5	0.9-2.6	75 (53)	40 (72)	***1.9***	***1.2-3.0***	46 (92)	41 (113)	1.1	0.7-1.7	33 (88)	28 (115)	1.2	0.7-2.0
The incident was too trivial	57 (69)	45 (73)	1.2	0.8-2.0	43 (53)	36 (73)	1.2	0.7-2.1	42 (90)	37 (112)	1.1	0.7-1.8	33 (85)	38 (112)	0.9	0.6-1.4
I worry about who is privy to information I disclose	33 (69)	36 (73)	0.9	0.5-1.6	42 (53)	26 (74)	1.6	0.9-3.0	32 (91)	21 (114)	1.5	0.9-2.6	28 (87)	35 (114)	0.8	0.5-1.3
I don't feel confident the form is kept anonymous	31 (68)	29 (73)	1.1	0.6-2.0	36 (53)	26 (73)	1.4	0.7-2.6	23 (92)	25 (114)	0.9	0.5-1.6	28 (87)	30 (115)	0.9	0.5-1.5
Incident reporting is unlikely to lead to system changes	32 (69)	18 (73)	1.8	0.9-3.7	35 (51)	27 (74)	1.3	0.7-2.5	30 (92)	20 (115)	1.5	0.9-2.7	18 (86)	23 (114)	0.8	0.4-1.5
Junior staff are blamed unfairly for adverse incidents	26 (69)	28 (72)	0.9	0.5-1.8	27 (53)	23 (74)	1.1	0.6-2.3	24 (92)	22 (114)	1.1	0.7-1.8	30 (87)	28 (115)	1.1	0.6-1.8
I am worried about litigation	17 (69)	18 (73)	1.0	0.4-2.1	26 (53)	14 (71)	1.9	0.8-4.4	18 (92)	20 (112)	0.9	0.5-1.8	23 (87)	15 (115)	1.6	0.8-3.0

* Fishers Exact test

Table 4-38 Comparison of top ten barriers to reporting at baseline and end of study by type of units (intervention units)

Barrier	ICU				ED				Surgical units				Medical units			
	Baseline % agree (N)	End % agree (N)	Rate ratio*	95% CI	Baseline % agree (N)	End % agree (N)	Rate ratio*	95% CI	Baseline % agree (N)	End %) agree (N)	Rate ratio*	95% CI	Baseline % agree (N)	End %) agree (N)	Rate ratio*	95% CI
I never get any feedback on what action is taken	67 (156)	55 (170)	1.2	0.9-1.6	61 (54)	34 (73)	**1.8**	**1.1-3.0**	65 (74)	25 (48)	**2.6**	**1.4-5.0**	54 (140)	27 (137)	**2.0**	**1.4-3.0**
When it's a near miss, I don't see any point in reporting it	54 (157)	30 (169)	**1.8**	**1.3-2.6**	32 (56)	24 (74)	1.3	0.7-2.6	41 (74)	30 (49)	1.3	0.7-2.5	42 (139)	20 (137)	**2.0**	**1.3-3.3**
When the ward is busy I forget to make a report	51 (156)	63 (170)	0.8	0.6-1.1	46 (56)	70 (74)	0.7	0.4-1.1	45 (74)	44 (50)	1.0	0.6-1.8	49 (142)	57 (139)	0.9	0.6-1.2
The form takes too long to fill out /I don't have the time	50 (155)	37 (168)	1.4	1.0-1.9	48 (56)	26 (72)	1.8	1.0-3.3	33 (73)	30 (50)	1.1	0.6-2.1	49 (140)	44 (139)	1.1	0.8-1.6
The incident was too trivial	47 (156)	41 (168)	1.1	0.8-1.5	34 (56)	38 (71)	0.9	0.5-1.6	33 (72)	33 (49)	1.0	0.5-2.0	49 (140)	27 (137)	**1.8**	**1.2-2.7**
I worry about who is privy to information that I disclose	40 (156)	34 (169)	1.2	0.8-1.7	34 (56)	26 (73)	1.3	0.7-2.5	28 (71)	27 (49)	1.0	0.5-2.2	22 (140)	20 (137)	1.1	0.6-1.8
I don't feel confident the form is kept anonymous	39 (157)	32 (168)	1.2	0.8-1.7	25 (56)	14 (72)	1.8	0.8-4.2	22 (74)	22 (50)	1.1	0.5-2.5	19 (141)	17 (137)	1.1	0.7-2.1
Incident reporting is unlikely to lead to system changes	31 (158)	19 (170)	1.6	1.0-2.5	34 (56)	19 (73)	1.8	0.9-3.6	33 (73)	22 (49)	1.5	0.7-3.1	28 (140)	14 (137)	**2.1**	**1.2-3.5**
Junior staff are blamed unfairly for adverse incidents	34 (157)	25 (170)	1.3	0.9-2.0	29 (56)	18 (73)	1.6	0.8-3.4	29 (73)	20 (49)	1.4	0.7-3.1	17 (141)	29 (138)	0.6	0.3-1.0
I am worried about litigation	24 (156)	21 (165)	1.2	0.7-1.8	18 (56)	21 (73)	1.6	0.8-3.4	19 (74)	27 (49)	0.7	0.3-1.5	16 (142)	14 (139)	1.1	0.6-2.1

* Fishers Exact test

4.7.5.2. Barriers to reporting- professional designation of reporter

Subgroup analysis of doctors revealed that those working in the intervention unit at the end of the study were less likely than doctors working in the control units to believe that (a) the incident was too trivial to report (RR=0.58 95% CI: 0.50 to 0.68) and that (b) if the case was discussed with the person involved nothing else needed to be done about it (RR=0.35 95% CI: 0.18 to 0.72) (Appendix 35). Nurses in the intervention units were more likely that their control unit counterparts to believe that when the ward was busy they forgot to report incidents (RR=1.37 95% CI: 1.20 to 1.57) and that the incident forms takes too long and they just don't have the time (RR=1.25 95% CI: 1.06 to 1.48) (Appendix 35).

4.7.5.3. Staff who had lodged a report during the study period

All staff were required to identify barriers to reporting, whether or not they had lodged a report during the study period. Subgroup analysis was performed on all staff in the intervention units during the study period to determine whether barriers were the same regardless of whether they had submitted a report. Table 4-39 indicates that those who submitted a report during the study period in the intervention unit were less concerned than those who did not report about litigation (16.5% vs. 25.7%) and were less likely not to know (or more likely to know) whose responsibility it was to report (9% vs. 22%).

Table 4-39 Comparison of barriers to reporting for those who did and did not submit a report in intervention units during the study period

	Did make a report % agree (N)	**Did not make a report % agree (N)**	**Rate ratio**	**95% CI***
I never get any feedback on what action is taken	35.7 (272)	42.6 (169)	0.840	0.6-1.1
When it is a near miss, I don't see any point in reporting it	23.4 (274)	32.1 (168)	0.727	0.5-1.1
When the ward is busy I forget to make a report	61.4 (275)	54.4 (169)	1.129	0.9-1.4
The form takes too long to fill out /I don't have the time04	36.3 (273)	38.3 (167)	0.946	0.7-1.3
The incident was too trivial	35.8 (274)	33.5 (164)	1.066	0.8-1.5
I worry about who is privy to information that I disclose	26.8 (272)	29.0 (169)	0.926	0.6-1.3
I don't feel confident the form is kept	20.7 (271)	25.7 (167)	0.800	0.5-1.2

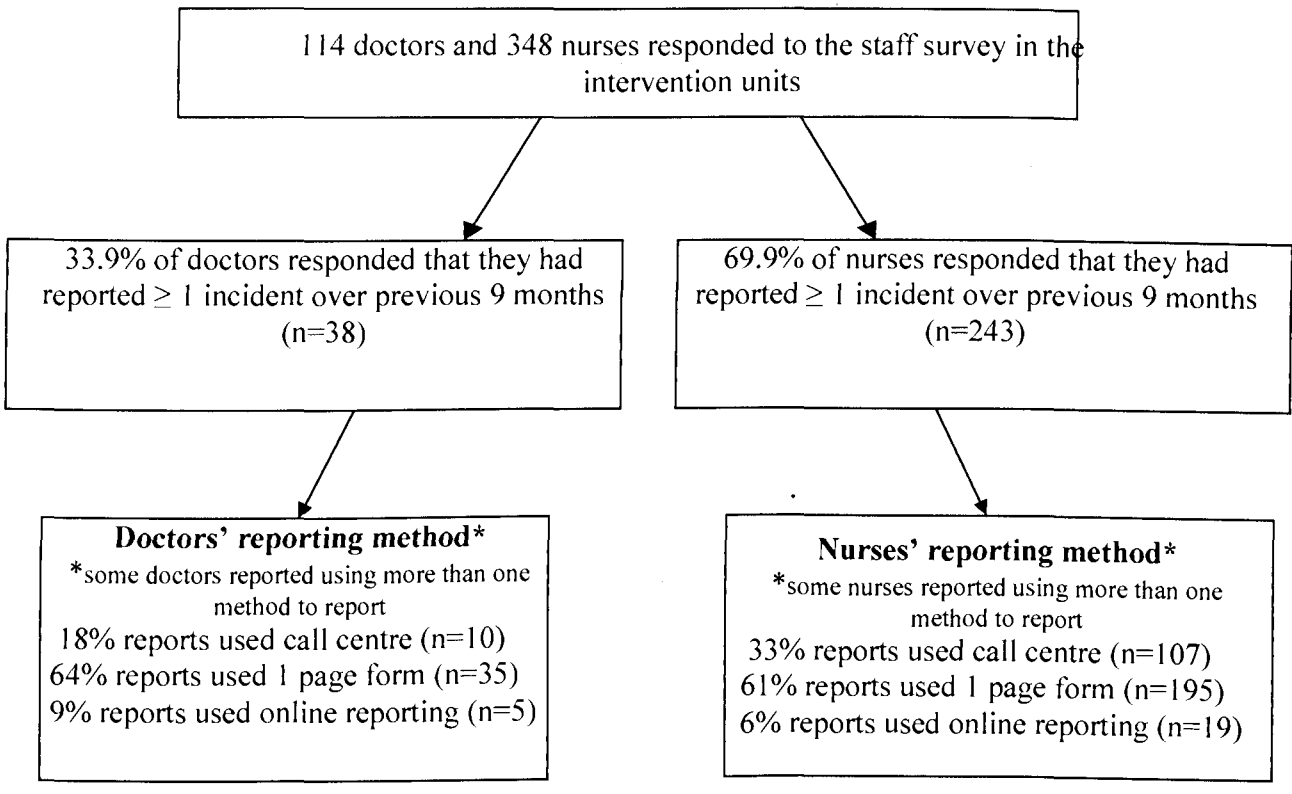
	Did make a report % agree (N)	Did not make a report % agree (N)	Rate ratio	95% CI*
anonymous				
Incident reporting is unlikely to lead to system changes	16.9 (272)	20 (170)	0.846	0.5-1.3
Junior staff are blamed unfairly for adverse incidents	24.7 (275)	24.8 (169)	0.995	0.7-1.5
I am worried about litigation	16.5 (272)	25.7 (167)	0.643	0.4-0.9
I don't want to get into trouble	14.1 (269)	13.7 (168)	1.032	0.6-1.7
My co-workers may be unsupportive	22.6 (274)	20 (170)	1.131	0.7-1.7
Even if I don't give details, I'm sure they'll track me down	13.5 (274)	10.6 (169)	1.268	0.7-2.3
I am worried about disciplinary action	10.6 (273)	12.6% (167)	0.845	0.5-1.5
It's not my responsibility to report somebody else's mistakes	13.1 (274)	15.1 (166)	0.872	0.5-1.5
I don't know whose responsibility it is to make a report	9 (272)	22 (168)	0.417	0.2-0.7
I don't want the case discussed in meetings	9.2 (271)	12.4 (169)	0.742	0.4-1.3
If I discuss the case with the person nothing needs to be done	9.9 (272)	16.1 (168)	0.618	0.4-1.1

*Fishers exact test

In addressing barriers to reporting it was important to gather feedback from those using the reporting system to assess its effectiveness in meeting the needs of reporters. This section focuses on opinion of staff working in the intervention unit during the study period. It has been designed to elicit information from those who made a report about the reporting process. All staff in intervention units were asked to comment on the exposure they had received to the project.

Q5: Have you reported an incident in the last nine months? Of those who stated that they had completed an incident report in the intervention unit during the study period, 86.5% of respondents were nurses (n=243) and 13.7% were doctors (n=38) (Figure 4-12).

Figure 4-12 Reporting methods used by staff in intervention units



Q6: Which method did you use to make a report? When asked to comment on which method staff used to report incidents, the majority stated that they used a paper-based incident report form (62% n=230), with 31% of staff using the Call Centre (n=117) and 7% of staff stating that they had attempted to use online reporting (n=24). A total of 23% of staff stated that they used more than one method to report.

Doctors used the paper-based form on 70% of occasions (n=35), the Call Centre on 20% of occasions (n=10) and online reporting 10% of the time (n=5). Nurses used the paper-based form 61% of the time (n=195), the Call Centre 33% of the time (n=107) and online reporting 6% of the time (n=19). Twelve staff using the Call Centre and five using the form did not state their profession.

4.7.6. To introduce a reporting system which is well accepted (aim 5.4)

Q7: If you have made a report in the last 9 months, please comment of the following statements:

- *I felt it was worth my while making a report:*
- *I understood I would get feedback after making a report*
- *I was unaware of the timeframe for getting feedback on the incident I reported*
- *I understood how the incident was followed up*
- *I felt apprehensive about the person investigating the incident*
- *I felt the incident was managed in a blame-free way*
- *I felt uncomfortable having adverse events discussed with others eg in meetings, tutorials or handover sessions*
- *I never got feedback*

When asked to comment on overall impressions of the incident reporting system in the intervention units, most staff felt that it was worthwhile making a report (83% agree), that they did not feel apprehensive having the incident investigated (89% agree) and were comfortable having the event discussed with others (84% agree). However, 40% of reporters did not understand that they would receive feedback, either individually for serious events or as an aggregate report on a 3-monthly basis and 40% were unaware of the timeframe for receiving feedback. Doctors felt significantly more apprehensive about the person investigating the incident when compared to nurses (20.5% vs. 9.6% p=0.04) (Table 4-40).

Table 4-40 Perceptions of the intervention by doctors and nurses

	Doctors	Nurses	
	% agree (N)	% agree (N)	P value*
Worthwhile making a report	75.0 (40)	83.9 (242)	0.166
Understood that feedback would be given	52.6 (38)	59.5 (242)	0.412
Aware of the timeframe for feedback	37.5 (40)	40.2 (243)	0.750
Understood how the incident was followed up	51.3 (39)	43.8 (241)	0.383
Not apprehensive about the person investigating the incident	79.5 (39)	90.4 (239)	0.044
Incident was managed in a blame-free way	68.4 (38)	67.4 (238)	0.897
Felt comfortable having incidents discussed with others	81.6 (38)	83.3 (238)	0.797
Received feedback after making a report	47.2 (36)	55.8 (239)	0.333

* Fishers exact test

With regard to perceptions of the reporting system, there was considerable heterogeneity among responses based on types of units (Table 4-41). Compared to staff in all other units, staff in ICU were less likely to feel that reporting was worthwhile (71% vs. 89%, $p<0.001$), that they would get feedback (39% vs. 70%, $p<0.001$), that they understood how the incident was investigated (28% vs. 54% $p<0.001$), and that the incident was followed up in a blame free manner (50% vs. 77%, $p<0.001$).

When examining perception of the reporting system by hospital, it can be seen that there were differences between hospitals with regard to whether or not staff felt reporting was worthwhile, whether they knew that they would get feedback and the timeframe for feedback, whether they felt the incident was managed in a blame-free manner and whether they actually got feedback (Table 4-41).

Table 4-41 Percentage of staff who agree with the statements relating the components of the intervention by type of unit

	ICU % agree (N)	ED % agree (N)	Surgical % agree (N)	Medical % agree (N)	P value*
Worthwhile making a report	71.1 (90)	88.5 (52)	87.12(39)	89.6 (106)	0.003
Understood that feedback would be given	39.3 (89)	67.3 (52)	79.5 (39)	70.0 (104)	<0.001
Aware of the timeframe for feedback	31.5 (89)	40.4 (52)	38.5 (39)	47.7 (107)	0.147
Understood how the incident was followed up	27.6 (87)	57.7 (52)	47.4 (38)	54.2 (107)	0.001
Not apprehensive about the person investigating the incident	89.5 (86)	90.2 (51)	97.4 (39)	87.7 (106)	0.385
Incident was managed in a blame-free way	50.0 (86)	66.7 (51)	71.8 (39)	83.8 (105)	<0.001
Felt comfortable having incidents discussed with others	84.9 (86)	90.2 (51)	89.5 (38)	78.3 (106)	0.178
Received feedback after making a report	41.6 (89)	61.2 (49)	72.2 (36)	62.3 (106)	0.004

* log binomial generalized linear models adjusting for clustering by hospitals.

Call Centre

Q 7: If you used the Call Centre:

- *I was happy with the length of time it took to make a report*
- *I was worried that the report wouldn't accurately reflect what I was trying to say*
- *The call Centre nurse remained objective when taking the report*
- *I prefer to use the Call Centre to the IRIS form*

Of those who used the Call Centre, 39% of staff were unhappy with the time it took to lodge a report (20% of doctors and 39% of nurses, p=0.242). Most doctors and nurses believed that the Call Centre nurse would accurately reflect what they were trying to say (80% and 79% agreeing respectively). Despite the fact that 78% of reporters using the Call Centre believed the nurse remained objective when taking the report, doctors were more likely than nurses to feel that the Call Centre nurse was not being objective (55% vs. 20%, p=0.016).

There were no significant differences within types of units, or rural/metropolitan hospital of the reporter with regard to time taken to lodge a report, perceived accuracy of the report or objective manner of the nurse. For staff who used both the Call Centre and the paper-based form (n=62), 58% of doctors would prefer the Call Centre compared to 33% of nurses.

Staff in intervention units were asked whether there was an appropriate place in their workplace to phone through a report to the call centre. A total of 69% of staff believed there was such a place (69.6% of nurses vs. 65.5% of doctors p=0.413). There was no significance difference in responses based on whether staff worked in rural or metropolitan hospitals (74% vs. 68%, p=0.396) however staff working in the ICU were less likely than other types of units to believe that there was an appropriate place to lodge a report to the call centre (61% in ICU, 71% in ED, 76% in surgical and 74% in medical units).

Paper form

Q7: If you used the IRIS one page form

- *There was insufficient room to write all I wanted*
- *I had difficulty locating the form*
- *I prefer the one page IRIS form to the 4 page AIMS form*

Most staff stated that there was sufficient room on the single page report form to document the incident (75% of doctors and 73% of nurses agreeing) and that they had no difficulty locating the form (79% of doctors and 88% of nurses agreeing). There were no significant differences within types of units, or rural/metropolitan hospital with regard to perceived length of the form or ability to locate it in the ward/unit. When asked to compare the one page form with the traditional four page form, 81% of staff preferred the shorter form, however doctors were significantly less likely to prefer the shorter form when compared to nurses (60% vs. 85% agreeing respectively, p=0.001). Staff working in the ICU were less likely than those working in the ED, surgical units or medical units to prefer the single-page form (74% vs. 92%, 81% and 86% respectively, p=0.004).

Online reporting

Q7: If you attempted to report on-line

- *I had difficulty remembering my password*
- *The on-line form looked easy to complete*

- *I felt that I could not remain anonymous*

Twenty four staff who had made an attempt to report on-line were asked to answer questions about ease of reporting and perceived ability to report anonymously (5 doctors and 19 nurses). Most had difficulty remembering their password to log in to the reporting system (80% of doctors and 74% of nurses), and only 42% of staff felt that the online form looked easy to complete. When asked whether staff reporting online felt that they could remain anonymous, all doctors and two-thirds of nurses believed they could maintain anonymity when reporting.

Q 8: There has been an incident reporting project in this unit/ward for the last nine months called the IRIS project.

Q8.1: How much information have you seen or heard about IRIS?

Table 4-42 details how much information staff believed they had received either through distributed paper documentation, or through attending sessions held throughout the intervention period. Five percent of staff felt they had received too much information about the project, 70% believed it was about right, 20% believed not enough and 5% stated they had received no information about the project. Staff working in rural hospitals were more likely than staff in metropolitan hospitals to feel that they had received too much information.

Table 4-42 Exposure to the reporting project by profession, type of unit and location of hospital

	N	Too much % agree (N)	About right % agree (N)	Not enough % agree (N)	None % agree (N)	P value*
Profession						***0.786***
Doctor	112	6.25 (7)	66.96 (75)	22.32 (25)	4.46 (5)	
Nurse	340	4.72 (16)	71.09(241)	19.17 (66)	5.01 (17)	
Type of Unit						***0.231***
ICU	171	3.51	64.22	26.32	5.85	
ED	78	5.13	71.79	21.79	1.28	
Surgical	54	3.7	79.63	11.11	5.56	
Medical	146	3.42	74.66	15.75	6.16	
Location of Hospital						***0.003***
Rural	61	11.48	78.69	9.84	0	
Metropolitan	407	3.93	69.29	21.13	5.65	

* Fishers exact test

Q8.2: How much have you been informed about outcomes resulting from IRIS reports?

Most staff felt that they had received about the right amount of information about outcomes, however 26% said they had received not enough and 19% said that they had received no outcomes. There were no significant differences with regard to profession. Staff in rural hospitals more likely than their metropolitan counterparts to state that they received the right amount of information about outcomes and less likely to believe they received no feedback regarding outcomes (Table 4-43).

Table 4-43 Exposure to outcomes arising from reports by profession, type of unit location of hospital and overall

	N	Too much %	About right %	Not enough %	None %	P value *
Profession						
Doctor	108	0.93	49.07	23.15	26.85	
Nurse	339	0.59	47.04	33.73	18.64	0.132
Type of Unit						
ICU	170	0	30	42.35	27.65	
ED	77	2.6	49.35	28.57	19.48	
Surgical	53	0	71.70	15.09	13.21	
Medical	145	0	59.31	24.14	16.55	<0.001
Location of Hospital						
Rural hospital	60	1.67	70	21.67	6.67	
Metropolitan hospital	403	0.5	45.41	31.51	22.58	<0.001
Overall	**447**	**3.13%**	**52.13%**	**25.73%**	**19.02%**	

* Chi squared test

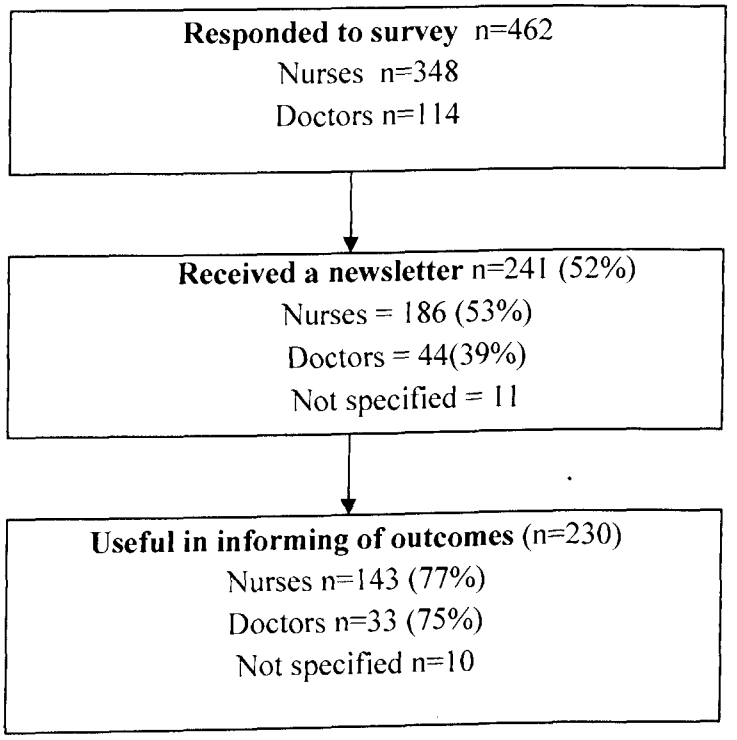
Q 8.4: Recently you were sent an IRIS newsletter. Did you receive it? Was it useful in informing you of outcomes following reports?

Of the 462 surveys returned from staff working in the intervention units during the study period, only 52% (n=241) recalled reading or sighting a newsletter from the project team in which outcomes arising from reports were documented. Nurses were significantly more likely than doctors to state having received a newsletter (Figure 4-13).

Despite the fact that newsletters were individually posted to all doctors on a bi-monthly basis (a total of five newsletter distributed during the study period), 61% of doctors did not recall having received it. Of those doctors who recalled receiving a newsletter (44/114), 75% believed it was useful in informing them of outcomes arising from reports. A total of 54% of those who had seen the most recent newsletter had also seen previous ones.

With regard to the 186/348 nurses who recalled seeing a newsletter, 79% found it informative. As with doctors, most nurses (81%) who had seen the most recent newsletter had also seen previous ones. Newsletters were left in tearooms and in communication books for nursing staff to read, and on one occasion were individually posted to all nurses working in the intervention unit. Whether staff worked in a rural or metropolitan hospital and the type of unit they worked in made no significant difference to whether or not they received a newsletter or how useful they perceived it was in informing them of outcomes.

Figure 4-13 Flow chart of those who received a newsletter and its perceived usefulness



Where did you see the newsletter?

As expected, of those doctors who responded that they had received a newsletter, all said that it was posted to them. Of the 153 nurses who reported having seen a newsletter, 43 or 28% had seen the newsletter in more than one location.

In addition to asking questions about current reporting practices and barriers to reporting, staff in the control units were asked to comment on whether processes available in the

intervention units during the study period would motivate them to report adverse incidents. Results are outlined in Table 4-44. Whereas shortening the AIMS form to one page would motivate 79.9% of staff either a moderate amount or a lot, introducing a Call Centre would motivate only 51.9% of staff to report. There were no significant differences between doctors and nurses with regard to the impact that all techniques would have on improving incident reporting (Appendix 36)

Table 4-44 Control unit views on changes to the reporting process

Reporting process	N	A lot % agree	Moderate amount % agree	Little bit % agree	Not at all % agree
A one page form instead of the 4 page AIMS form	373	49.1%	30.8%	11.8%	8.3%
A process existed where de-identified reports could be discussed amongst peer.	367	36.8%	32.4%	20.4%	10.3%
Feedback was given via departmental meetings/handovers	359	29.2%	34.8%	19.5%	16.4%
Feedback was given via newsletters	347	29.1%	34.3%	15.6%	21.0%
Ability to report on-line	371	24.8%	28.4%	20.2%	31.5%
Reports bypassed the line manager in the first instance, going directly to the PSM*	371	21.3%	31.0%	19.4%	28.3%
The form did not require medical officers to countersign	353	25.0%	26.9%	14.5%	33.7%
A confidential Call Centre operated by Registered Nurses was available	372	20.2%	22.0%	19.3%	38.4%

4.7.7. Summary of Results of the Final Staff Survey

Knowledge and use of the reporting system

A total of 840 medical and nursing staff responded to the survey (response rate=74.3%). Nearly all staff knew of the existence of a reporting system in their hospital. Compared to control units, more staff in the intervention units at the end of the study knew how to make a report, with greatest improvement evident in surgical units (RR=1.20, 95% CI=1.07 to 1.33). However, knowledge of how to make a report also increased in control units compared to baseline, particularly in the ICUs.

Reporting practices

Adjusting for differences between the control and intervention groups at baseline, staff in the intervention units were more likely at the end of the study to recognize that they do not currently report certain incidents, including when a medication error is made requiring

corrective treatment (RR=0.88, 95% CI=0.80 to 0.98) and problems with equipment or machinery (RR=0.91, 95% CI=0.87 to 0.94). Compared to control units, more staff in intervention units at the end of the study believed that they did report when patients did not receiving a necessary treatment or procedure (RR 1.21, 95% CI=1.04 to 1.40).

Fewer doctors in intervention units at the end of the study believed they reported hospital acquired infections (RR=0.48, 95% CI=0.34 to 0.67), problems with machinery or equipment (RR=0.55, 95% CI=0.41 to 0.73), medication near misses (RR=0.38, 95% CI=0.21 to 0.67), medication errors requiring corrective treatment (RR=0.56, 95% CI=0.45 to 0.70) and medication errors not requiring corrective treatment (RR=0.65, 95% CI=0.51 to 0.85) at the end of the study period, compared to doctors in the control units. More nurses in the intervention unit at the end of the study believed they reported near misses than control unit nurses (RR=1.47, 95% CI=1.23 to 1.74).

Barriers to reporting

Staff in intervention units were significantly less likely at the end of the study when compared to baseline to believe that (a) there was no point in reporting near misses (RR=0.76, 95% CI=0.60 to 0.97); (b) incident reporting is unlikely to lead to system changes (RR=0.78, 95% CI=0.63 to 0.96); and (c) if the incident is discussed with the person involved nothing else needed to be done (RR=0.71, 95% CI=0.54 to-0.94). Staff in intervention units were more likely to believe that when the ward was busy they forgot to report at the end of the study when compared to baseline and to changes in the control units (RR=1.28, 95% CI=1.19 to 1.39).

Aspects of the intervention

The majority of staff working in the intervention units during the study felt that it had been worth their while making a report (75% of doctors and 84% of nurses), however despite ongoing education sessions only half of those surveyed understood how the incidents was followed up and believed that they received feedback, and even fewer were aware of when they would receive feedback. Of concern was the fact that 30% of staff did not feel that their report was followed up in a blame-free way. Staff working in the ICUs were least aware of reporting process during the intervention, and were more likely than other units to feel that their incident was not handled in a blame-free manner. They were also least likely to believe that the reporting process was worthwhile. Despite posting five newsletters to doctors during the study period, two thirds did not recall receiving one. Just over half of the

nurses surveyed recalled sighting a newsletter, which were initially placed in strategically located places in the intervention units, and later also posted individually to each nurse.

Staff in control units were most likely to believe that shortening the form would improve their reporting practices, with half of all respondents believing that it would motivate them a lot. The call centre was least likely to motivate them to make a report.

4.8. Overlap of results between different components of the study

Many parts of the Results section overlap. Whereas the Consumer surveys are distinct entities, the focus groups, two staff surveys and the intervention all have intermingling components. It is not possible to directly compare perceived baseline reporting practices in the staff survey with the actual reporting practices as outlined in the baseline intervention AIMS data, because time series do not correlate. The baseline data collection period consisted of nine months, while in the staff survey question at baseline staff were asked if they had ever reported incidents. However, the end of study staff survey can be compared with AIMS data because the survey asked respondents to comment on their reporting practices over the study period.

Qualitative analysis of the barriers to reporting as discussed in the focus groups can be compared with quantitative data on barriers to reporting as identified in the staff surveys.

This section will provide some results from amalgamated surveys, focus group and intervention components.

4.8.1. Staff reporting practices

Table 4-45 details some types of incidents that staff believed they did report in the staff survey, and the actual numbers of incident reports lodged during the study period in the intervention unit and control units by doctors and nurses. There were four questions asked regarding incidents in the staff survey that can be directly related to an AIMS principal incident type. More doctors at the end of the study in the control units believed they reported faulty medical devices and equipment compared to intervention unit doctors (71% vs 49% respectively). Despite this difference, more doctors in the intervention unit during the study period had reported faulty medical devices compared with control unit reports (6 vs 1). Even though it is of interest to note the differences in actual reporting rates and perception of how often incidents are reported, it is not possible to deduce any findings without understanding the true incidence of these four incidents during the study period.

Table 4-45 Comparison of staff survey findings and AIMS report data for the study period in intervention and control units

Staff survey question (Principal Incident type in AIMS database)	End of study staff survey		AIMS data	
	Control* % (n)	Intervention * % (n)	Control n	144
Doctors				
Pt sustained injury due to fall (Fall)	66.7 (78)	45.4 (97)	0	5
Patient sustained a pressure sore whilst in hospital (Pressure ulcer)	21.9 (64)	12.8 (94)	0	0
Patient sustained a hospital-acquired infection (Infection)	32.0 (75)	18.7 (96)	0	0
Problem with equipment/machinery resulting in patient harm (Medical device/equipment)	70.8 (72)	48.9 (94)	1	6
Nurses				
Pt sustained injury due to fall (Fall)	97.1 (273)	92.6 (313)	234	265
Patient sustained a pressure sore whilst in hospital (Pressure ulcer)	31.1 (241)	32.0 (297)	0	4
Patient sustained a hospital-acquired infection (Infection)	37.5 (245)	42.6 (303)	1	4
Problem with equipment/machinery resulting in patient harm (Medical device/equipment	89.4 (256)	82.6 (287)	6	52

* % of doctors reporting they do report >50% of the time (n)

4.8.2. Barriers to reporting

The staff survey at baseline was used in conjunction with focus group findings to assist in the development of an intervention to improve incident reporting. Even though it is not possible to quantify qualitative data, focus groups provided a different qualitative perspective and gave additional emphasis to fear of blame, loss of face and litigation.

With regard to barriers to reporting identified by doctors, a number of focus group participants from all levels held the view that incident reports were best handled "in house". The staff survey also supported this view, where a quarter of all respondents believed that if the case was discussed with the person involved, nothing else needed to be done about it. This contrasted views of nurses who were more likely to disagree with this statement. (25% vs. 11% $p<0.001$). The staff survey supported focus group findings that many doctors were of the opinion that many incidents were too trivial to warrant a report form. Also supporting

focus group findings was the fact that in the survey many doctors stated that they did not know how to access a report, who should report incidents and what the reporting process involved. While fear of litigation was more strongly voiced by doctors in focus groups, the staff survey demonstrated that this was also a concern for nurses (21% vs. 21% agreeing p=1.0).

Nurses more than doctors in the focus groups cited fear of disciplinary action as a major barrier to reporting. In the staff survey, nurses were more likely to believe this is a barrier compared with doctors (19% vs. 11% p=0.002) however less than twenty percent thought that it was a barrier to reporting. The staff survey supported the finding of the focus groups that nurses were more fearful of punitive action from within their organisation when compared with views of doctors.

5. DISCUSSION

5.1. Introduction

Whereas previous chapters have been divided into six distinct categories incorporating the two consumer surveys, the focus groups, baseline and end of study staff surveys and the intervention, this chapter will look across the studies and address the aims and hypotheses generated and outlined in section 2.10 of the thesis.

5.1.1. To understand consumer views on (a) safety in public hospitals and general practice (aim 1.1)

The consumer survey demonstrated that, although the majority of respondents felt safe attending both their GP and a public hospital, there was a fourfold increase in feeling unsafe going to a public hospital when compared to general practice ($p<0.001$). Those people most likely to feel unsafe going to hospitals were women, and those aged between 40 and 59 years and those on a high annual income. Those who felt unsafe going to their GP were most likely to be elderly and on a high annual income. Although numbers were small, Indigenous people or those from a country where English is not the first language spoken were nearly three times less likely to feel safe going to their GP compared to non-Indigenous Australians and those born in a country where English is the first language spoken.

The finding that people felt safer visiting their GP than attending hospitals makes intuitive sense given that visits to GPs are generally for minor, self-limiting illnesses[290] and that people usually present to hospitals in the acute stage of their illness, are usually unfamiliar with the surroundings and personnel in this setting, and often receive complex, numerous procedures in a short period of time. It is also supported by other consumer studies undertaken in Australia[67] and the US.[107 108] The National Patient Safety Foundation showed that more people believe that they would be more likely to encounter a mistake in hospital (14% felt it very likely) than at the doctor's office (6% felt it very likely).[107]

The finding that Indigenous Australians and those from countries where English was not the first language spoken were less likely to feel safe going to see their GP supports the findings of a US consumer survey[108] which identified that racial and ethnic minorities (Afro-Americans and Hispanics) were more likely than Anglo-Saxons to say that they were concerned about mistakes happening in hospital (62% and 69% agreeing vs. 44% agreeing).

Clark's Australian survey[67] did not identify country of birth or household income as having any bearing on how safe people felt attending their GP or going to hospital, however as with our study, he identified that people in the middle-age bracket were most likely to feel unsafe going to hospital. In another consumer study in the US,[107] people on higher incomes (>US$60,000) were significantly less likely to rate healthcare as very safe compared with those with an income below US$15,000. It may be that people on higher incomes (who often had higher educational status) were more aware of the risks associated with procedures undertaken in hospital and in general practice.

5.1.2. To understand consumer views on the experience of an adverse event (aim 1.2)

Consumers aged over forty years were asked to comment on whether they or any household members had been hospitalised in the last five years, and if any of those hospital encounters were associated with an adverse event. An adverse event was defined as a situation where something went wrong that they believed may have been due to the way the healthcare was carried out. A total of 66.7% of those surveyed in this age group (n=1704) had experience of a hospitalisation in the previous five years, and 7.0% of those hospital admissions were associated with one or more adverse event. Over half of consumers who reported an adverse event in members of their household, regarded the consequence to be really serious.

The experience of an adverse event in hospital had a deleterious impact on consumer confidence in both their GP and in public hospitals. The severity of the adverse event was the key factor in determining the extent to which consumers felt unsafe, with serious adverse events leading to a doubling in the likelihood that a person would feel unsafe in both general practice and in public hospitals.

Even though we chose to use lay terminology to describe an adverse event, the 7% adverse event rate identified in this consumer study is within the adverse event range identified by medical record review, which has estimated that between 2.9%[25] and 16.6%[20] of hospital admissions were associated with adverse events. Even the higher rate identified by Wilson et al[20] likely underestimates the true incidence, given that many adverse events are not recorded in medical records, [51] and prospective studies[52 68 95] and incident report studies[143] in high risk areas have identified higher rates.

Although our survey was applied specifically to hospital-acquired adverse events, other consumer studies have found the medical error rate in any health care setting identified by consumers as also being within the boundaries of the medical record review studies. Clark's

study[67] identified that 6.5% of those surveyed had experienced an unexpected injury or concern from an adverse event arising from their health care (including problems in hospitals and in the community) in the previous twelve months. Clark's study built on work undertaken in the US by the Kaiser Family Foundation in association with the Agency for Health Care Research and Quality.[108] The Kaiser study, which was comparable with the Australian study by Clark (although the question was worded slightly differently) identified that 6% of those surveyed had personal experience of an adverse event in some health care setting in the past 12 months. Our findings validate those found by other consumer surveys, in which the experience of an adverse event was associated with decreased confidence in healthcare in general.[67 107 108]

5.1.3. To understand consumer views on confidence in healthcare (aim 1.3)

We found that half of all consumers surveyed felt that healthcare was less safe today compared with ten years ago. Other studies have evaluated differences in perceived safety in hospitals over a five year time period. Even though we asked people to compare with ten years ago and not five, our findings were similar to those undertaken in Australia[67] and the US,[109]which asked for changes in perceived safety over the past five years. These studies showed that 40%[67] and 45%[109] of consumers respectively felt healthcare safety was declining.

5.1.3.1. Limitations in addressing aim 1 (to understand from a consumer perspective views on perceived safety, the experience of an adverse event and confidence in healthcare)

Limitations when interpreting consumer studies have been discussed in section 2.4.2.3 of the literature review and include limited generalisability, recall bias and information bias. More specific to this particular study, there were a number of limitations.

Not representative of the population of South Australia: Even though the use of a household-based survey is largely representative, it does not represent those who do not live in their own dwelling. Additionally, surveyors were only able to interview those who were well enough to answer the door, were agreeable to respond to questions, and who spoke English, and so results can only be generalised to this population.

Definition of an adverse event is subjective and not validated: The survey represents self-reported experiences by the public, using lay judgement of what constitutes an adverse event, based on their interpretation of the definition provided. There is no national or

international consensus on a consumer definition of an adverse event. Various studies have used different lay descriptions to determine adverse event rates amongst consumers. We chose to use the phrase "when things went wrong' to define an adverse event. Another study used the word "medical mistakes"[107] while another, which believed the word mistake carried pejorative connotations, used the phrase "where your healthcare has led to harm"[67] to define an adverse event. These semantics may influence how people interpret the question. Additionally, as there have been no studies validating consumer reported adverse events with medical record review, it is difficult to know whether there is any correlation between the two techniques.

Recall bias: There are inherent problems when asking respondents to recall adverse events which may have occurred five years prior to the survey being conducted. While respondents might have experienced more than one adverse event for the household, they were only asked to rate one of them. It may be the case that, for those who reported multiple adverse events, only the most severe adverse event was cited, resulting in an overestimate of severity and an underestimate of the adverse event rate.

5.1.3.2. Significance of the findings with regard to aim 1 (to understand from a consumer perspective views on perceived safety, the experience of an adverse event and confidence in healthcare)

This study has built on work undertaken by others to elicit consumer opinion on healthcare and the impact that adverse events have on confidence in many facets of healthcare delivery. It has added a new dimension by enabling the adverse event rate as identified by consumers to be compared with that identified through medical record review.

5.1.3.3. Future research

There needs to be further research to understand why people of Indigenous status feel unsafe attending their GP. Indigenous Australians are in worse health than all Indigenous populations of comparable developed countries, have a life expectancy of approximately 20 years less and a mortality rate approximately three times higher than non-Indigenous Australians.[291] They are also three times less likely to visit their GP compared to the general Australian population.[292] Identifying and addressing reasons for feeling unsafe may assist in improving their health.

Research should be undertaken to investigate more thoroughly what types of adverse event consumers recall and whether these can be validated in the medical record. This is not to say that if they are not recorded in the medical record they are not adverse events. Such a

study will likely lead to better understanding by health care workers of the impact that different adverse events have on consumers. It will provide greater understanding of how healthcare providers can best support consumers.

5.1.4. To understand consumer views on reporting of adverse events by health care workers (aim 2)

This survey identified that nearly all consumers believed healthcare workers should report errors, even when the outcome was only transient and had no long term health effects for the patient. Two-thirds of consumers in favour of incident reporting believed that healthcare workers should have to identify themselves, despite the suggestion in the vignette that this might discourage people from openly disclosing mistakes. Even highlighting the advantages of an anonymous reporting system did not convince the majority of consumers that this is an acceptable trade-off.

Even though this study highlighted only a minor medical error, our finding was consistent with a US survey, which found that 94% of consumers believed that medical errors resulting in serious injury or harm should be reported, either on a voluntary or mandatory basis.[108] The Kaiser study did not elicit to whom the incidents should be reported, but the emphasis of the survey was on ensuring public accountability.

Eliciting consumer opinion on healthcare is progressively being seen as an important tool in improving clinical care.[293] Our findings suggest that the majority of consumers favour a system where transparency is assured through the identification of the person making a report. Reasons for this are likely to be complex. Reluctance by consumers to accept anonymity may reflect scepticism that information will be effectively managed by healthcare institutions if people are not identified, and that the interests of the healthcare worker and/or hospital could be placed above those of the consumer.[294] By withholding the reporter's details, consumers might assume that the patient details are also withheld and that the incident might not be fully investigated.

Requiring identified reporting may also indicate that consumers still regard errors to be the result of a particular person not performing to standard. It is likely that consumers are influenced by media coverage of adverse events, which often focus attention on individual negligent clinicians. A recent English study of healthcare practice indicated that media scrutiny is greater than ever before.[295] High profile cases such as those of Betsy Lehman who died following an overdose of chemotherapy medication in the US,[296] Wayne Jowett who died following inadvertent administration of vincristine intrathecally in the UK[297] and

Calandre Simpson who recently received a record compensation payout for damages she received at birth in Australia,[298] highlight the role the media has taken in making consumers aware of the mistakes of individual clinicians and the risks associated with delivery of health care.

The "individualising" of errors is contrary to current quality improvement philosophy, which promotes a system-based approach to the handling of errors, having recognised that serious errors are usually linked to the failure of multiple systems and the involvement of many individuals.[183] A considerable body of work is being undertaken in Australia to encourage cultural change in healthcare, by focussing on improving systems rather than fostering the traditional approach of shaming and blaming individuals who err.[299] Unfortunately, individuals such as Dr Harold Shipman, a UK GP who was convicted for murdering 15 of his patients and was implicated in the death of between 215 and 260 patients,[300] and more recently in Australia Dr Jayant Patel, a general surgeon who has been implicated in 87 patient deaths,[301] highlight the need by consumers to be vigilant when seeking medical attention. Although details of Dr Patel's practices were not identified until after this survey was conducted, at the time of the survey there was intense media scrutiny on the medical indemnity crisis, largely seen to have been caused by high compensation payouts to victims of individual healthcare worker negligence.[302] Ascribing adverse events to individuals can only serve to further diminish public confidence in healthcare safety and lead to a call for greater transparency within organisations.

This survey identified that the majority of consumers do not want anonymous reporting, which is at odds with the way incident reporting systems have been established in Australia. Incident reporting in Australia was founded as an anonymous reporting tool for anaesthetists and was based on the premise that system flaws and not poor performance by individuals underpin most preventable adverse events, and that anonymity afforded to reporters enables a 'rich mass of human factors information that would not otherwise be reported to be reported.'[221] As discussed in Section 2.5.2.1.3, the establishment of an anonymous reporting system has been successful in identifying problems in hospitals,[63 147 186] and has resulted in many system-based improvements in delivery of health care.[44]

The fact that consumers want healthcare workers who err identified provides a challenge for quality improvement programs to meet the needs of both consumers and healthcare workers. It is likely that consumers need to be educated, as healthcare workers are being educated, about the complexities of errors in hospitals, and the vulnerability of healthcare workers to mistakes. It is also the responsibility of hospital administrators and clinicians to ensure that

an open and transparent system of disclosing errors to consumers is fostered and that, where appropriate, the focus be placed primarily on system failures rather than individuals who make mistakes. Fostering open disclosure will be a challenge if recent findings in the United States[111] reflect sentiment in Australia. These indicated that 62% of consumers and only 14% of physicians believed that hospital reports of serious medical error should be released to the public.

5.1.4.1. Limitations in addressing aim 2 (to understand consumer views on reporting of adverse events by health care workers)

In addition to the limitations of consumer studies discussed in section 2.4.2.3 of the literature review (limited generalisability, recall bias and information bias), more specific to this particular study, the following limitations applied:

Limited generalisability: To decrease the burden on consumers we used a single vignette relating to a minor error, so the outcome has limited generalisability. Our rationale for choosing a minor error was that if consumers were in favour of incident reporting for minor errors, then it would be unlikely they would oppose incident reporting for more serious errors. A recent survey supports this argument- that more serious outcomes for patients result in consumers demanding greater accountability.[111] When consumers were provided with a single vignette involving a medical error and given two different patient outcomes, one resulting in death and the other in complete recovery, consumers were more likely to support imposing fines, suspending healthcare workers from duty, and initiating malpractice lawsuits, if the medical error lead to the patient's death.

Survey question was biased: We believe that the way in which the vignette was constructed may have biased consumers to answer in support of anonymous reporting. We specifically identified that incident reporting may lead to a reprimand and that anonymous reporting might encourage reporting of mistakes. This makes the finding that the majority of consumers did not favour anonymity even more significant.

Survey provides only a snapshot in time which might change: As outlined in the literature review, the more recent exposure that adverse events have had in the media may influence how consumers respond to the questions. In Australia, there has been considerable attention focussing on clinical errors and purported 'cover ups' by the medical profession, which might explain the call for accountability.[35]

5.1.4.2. Significance of the findings with regard to aim 2 (to understand consumer views on reporting of adverse events by health care workers)

A review of the literature has revealed no other studies in Australia where consumers have been asked their opinion on whether incident reporting should occur. We could identify no studies that have asked consumers whether they would be willing to allow staff to report anonymously if it meant that, in doing so, incidents might be reported which might otherwise not be identified.

5.1.4.3. Future research

There needs to be greater understanding as to why consumers require healthcare worker identification when errors occur.

5.1.5. To identify knowledge of the reporting system by hospital staff (aim 3.1)

In this section, findings from the baseline staff survey will be discussed.

The baseline staff survey demonstrated that despite most staff knowing that an incident reporting system existed, almost a quarter of all staff did not know how to access the report or what to do with it once completed and over forty percent of consultants and registrars had never completed a report.

The finding that there is disparity between knowing that a reporting system existed and knowing how to make a report is a problem common across healthcare systems internationally. Vincent et al's study of doctors and midwives in a UK Obstetrics and Gynaecology Unit[198] identified that seven percent of staff did not know of the existence of a reporting system, one third of physicians did not know how to find the list of reportable incidents and fifteen percent did not know how to make a report. In a study investigating knowledge and use of an adverse drug reporting system in the Netherlands,[199] most doctors knew of the existence of a reporting system (93% of GPs and medical specialists, 85% of surgical specialists), however between 20% and 36% of doctors did not know how to report an incident.

If lack of knowledge of how to make a report impairs incident reporting, then efforts to improve knowledge of how to make a report needs to be considered a priority when designing an intervention to improve reporting rates.

5.1.6. To identify baseline use of the reporting system (aim 3.2)

In this section, findings from the baseline staff survey and the baseline AIMS data will be discussed.

With regard to self-reported incident reporting practices, doctors and nurses believed that they report incidents less often than they should. There was very poor correlation between actual reporting practices and what people thought they should report for reporting of incidents where patients sustained deep vein thromboses due to inadequate prophylaxis (ICC=0.24), pressure sores (ICC=0.23) and hospital-acquired infections (ICC=0.29). Only half of the staff surveyed believed medication near misses should be reported, indicating that recent literature emphasising the importance of reporting near misses[4 129] is not translating to change in attitude or clinical behaviour.

In the baseline period, the most common events that staff believed they did report were patient falls, when a patient received the wrong treatment and a medication error requiring corrective treatment. Falls and medication errors were the most commonly reported incidents using the AIMS system in the 40 week baseline period, constituting two thirds of all incidents reported. This suggests that staff perception of how they rank the frequency with which they report incidents is probably pretty accurate even if the actual rate with which they report is perhaps not so accurate.

To explain this further, we need to look to studies which have reported frequency of adverse events in hospitalised patients. At baseline, a quarter of all staff believed that they reported hospital-acquired infections on 50% or more of occasions. Actual AIMS incident reporting data on hospital-acquired infection during the baseline period indicated that the reporting rate equated to one infection per 14, 801 patient discharges (or 0.007 incident reports per 100 patient discharges). With conservative estimates that approximately five nosocomial infections will occur per 100 patient discharges,[303] it appears that there is more than a 700-fold difference between actual and expected reporting rates.

Similarly, when investigating medication errors there appears to be under-reporting. At baseline, 80% of all staff stated that they reported when a drug error occurred where corrective treatment was needed. There were 193 drug errors reported in AIMS during the 40-week baseline period. This equated to a drug error reporting rate of 1.3 reports per 100 patient discharges. Estimates have indicated that 30% of hospitalised patients experience an adverse drug event during their hospital stay.[243 304 305] Given that information collected in

incident reports relate to both actual adverse drug events and near misses either most are not reported or the estimate is wrong.

Staff perception of how often they reported patient falls at baseline is likely to be more accurate; however the fact that reporting of falls nearly doubled during the study period compared to baseline indicates that under-reporting still probably occurred at baseline. Eighty three percent of staff believed that they reported patient falls on 50% or more of occasions at baseline. Falls were reported at a rate of 1.9 reports per 100 patient discharges at baseline and 3.5 reports per 100 patient discharges at the end of the study. Retrospective medical record review identified that patient falls occurred in 0.5% of patient admissions.[20]

The finding that 91% of medical staff thought they should report when a patient gets the wrong treatment, and yet only 74% believed they should report when a patient does not receive necessary treatment is important, given that acts of omission have been implicated in resulting in twice as many adverse events as acts of commission.[20]

Quantitative analysis of survey data and AIMS data showing that incident reporting under-estimates adverse event rates has been discussed in section 2.8.2 of the Literature Review. However, even given the fact that it was not established with the intention of identifying all errors, considerable work needs to be done to make it more representative of the range of errors and near misses that occur in hospitals throughout South Australia.

5.1.7. To identify barriers to reporting at baseline (aim 3.3)

In this section, findings from the baseline staff survey and focus groups will be discussed.

Barriers to reporting were detected using mixed methods of quantitative and qualitative research collected sequentially. Quantitative analysis has been used to identify barriers to incident reporting in a number of studies in the US,[64 197 203] Denmark,[188] Netherlands,[199] and the UK.[198 215] Focus group studies to identify barriers to reporting have been undertaken both in Australia[147 202] and in the United Kingdom.[201]

The staff survey asked respondent to comment on the extent to which they believed nineteen pre-defined barriers inhibited their reporting practices. Only nineteen barriers were chosen because of the burden imposed on staff in completing the survey. The qualitative focus groups allowed participants to explore barriers without any restrictions. In this way, it was expected that potentially more barriers would be identified using focus group methodology.

There were a number of key findings when analysing transcripts of focus group participants. Although participants supported the drive to improve patient safety by adopting non-

punitive attitudes, there was a chasm between what the reporting system currently delivers and what it could deliver.

Based on findings from both the staff survey and focus groups, there appear to be two major themes arising in regard to barriers to reporting; organisational and cultural barriers. Organisational barriers relate to structures and processes that inhibit reporting[197] such as inadequate feedback, long forms, privilege afforded to the reporting system and insufficient time to report. Cultural barriers relate to social attitudes of doctors and nurses towards each other and within their own profession.

5.1.7.1. Organisational barriers

Lack of feedback: The most common barrier to reporting cited by staff survey respondents was lack of feedback. Nearly two thirds of respondents believed that it was a barrier to reporting. Focus groups conducted with nurses identified that many were frustrated at the lack of any further action being taken.

A literature review identified only one study where lack of feedback was included in pre-defined lists of barriers to reporting for staff surveys[169 196] and in only two where it had been identified in focus groups as being a deterrent to reporting[169 205 306] (one of which was the focus group undertaken as part of this study). The survey of medical residents conducted by Jeffe et al[205] identified that only one resident doctor out of the twenty two regarded lack of timely feedback as a deterrent to reporting. It may be that lack of feedback is unique to the Australian health sector or that other studies have confined investigation to cultural issues.

Lack of knowledge about who should report: There was uncertainty about who should complete the report. Compared with nurses, doctors were significantly less likely to know whose responsibility it was to make a report (40% vs. 11%, $p<0.001$). Focus group discussion identified that doctors generally regarded incident reporting as the nurses' responsibility (see section 4.5.2.1). There were a number of Consultants in the focus groups who, even though they were aware of there being an incident reporting system in their hospitals, had never seen an incident report form.

Many of our results support those obtained internationally, including the finding that only a small percent of medical staff formally report incidents,[197 215] and unfamiliarity with the reporting process results in a poorer reporting culture.[199] Our finding that 17% of staff overall did not know who should report incidents was similar to that of Uribe et al[197] (23%), in a study population which was evenly mixed between doctors and nurses. That study did not provide further sub-analysis by profession.

The lack of clarity by medical staff regarding who should report likely results from a lack of appropriate education provided by medical schools, a lack of direction provided by those distributing the system into clinical areas and a lack of guidance by hospital personnel. There has traditionally been very little, if any, education provided to doctors in medical school about disclosing and discussing error.[307] In one article[308] the comment was made that if there was an epidemic that resulted in 44,000–98,000 deaths annually in the US alone, it would quickly become part of the formal medical curriculum. However, patient safety is uncharted territory and threatening to some. This is slowly changing, with greater emphasis now being placed on the nature of human vulnerabilities in medicine. Instances like that described by Branch et al[309] where medical students were asked to write critical incident reports at the beginning, middle and end of third year, may serve to educate them about whose responsibility it is to report and what should be reported.

The lack of knowledge about who should report incidents may also be due to confusion about whose role it is to complete the form.[117 147 201] In attempting to answer the question about who should report, this depends largely upon what is being reported. It is likely that nurses have more contact with individual patients in the ward setting and might therefore be more likely to witness a fall or act of aggression, or be aware of medication errors when they are principally responsible for administering them. These should obviously be reported by nurses. However, there are also incidents which may only be known to doctors. For example, delays in treatment, tests and procedures that are not ordered, not carried out or not followed up, adverse reactions, referrals to services or professionals which were not provided, equipment malfunctions, surgical misadventures, errors of omission such as prophylaxis and treatment medications, and patients given the wrong treatment are examples of just a few. For these incidents, it should be the doctor's responsibility to report and this should be reinforced by the organisation.

Lack of knowledge about what should be reported: The finding that staff reported 80% of adverse events listed in the survey on less than 50% of occasions may indicate a lack of knowledge about what should be reported. Both doctors and nurses commented in focus groups that there was a need for clearer guidelines about what should be reported.

The finding that staff, and particularly doctors, often did not know what to report has been identified in a number of studies as a barrier to reporting.[60 64 147 197] As with lack of knowledge about who should report, it reflects a lack of education and a lack of clear guidelines provided to doctors and nurses.

Lack of time: Half of all doctors responding to the baseline survey stated that the form was too long and that time constraints prevented reporting. This has also been well recognised in the literature, where it is the most commonly cited barrier to reporting.[147 147 169 196-199 201] Nurses also reported lack of time and being too busy as important barriers to reporting.

There are many competing demands on healthcare workers' time. Within the Australian health care system there has been a progressive reduction in average length of stay and this has been accompanied by increased throughput. The national average length of stay in public hospitals has fallen from greater than seven days in 1992, to 4.1 days in 1999 to 3.9 days in 2004.[310] This is almost entirely due to the trend towards more same-day treatment rather than overnight stays. In 2003-04, 48% of all patients were admitted and discharged on the same day, compared with around 43% of patients in 1998-99. Even though the number of nursing and medical staff working in Australian hospitals has increased to meet this demand,[311 312] focus group discussions revealed that incident reporting was not a priority in their work schedule.

It is likely that when doctors and nurses have stated that they do not have time to report incidents it is in the context that the effort required to complete an incident report is not equivalent to the return they get. Perhaps they would not have stated that they didn't have enough time to report if they had received feedback or felt that the report was used constructively to improve patient care. Our finding that 30% of staff believed adverse event reporting is unlikely to lead to system changes, contrasts with the views of 136 anaesthetists of whom nearly all believed incident reporting was of value and nearly half reporting that AIMS had changed their practice.[234]

5.1.7.2. Cultural barriers

It is clear from analysing focus group transcripts and staff survey results that both nursing and medical cultures remain steeped in tradition.

If the issue is discussed with the person involved nothing else needs to be done: A dominant view held by many of the doctors across seniorities in focus groups was that if the incident was discussed with the person involved it was not necessary to formally report it, and that whistle blowing was unethical and unsupportive. There was a preference to manage incidents "in house" without resorting to paperwork. Although discussed by a few nurses, this attitude was more prevalent among medical staff, as highlighted in staff survey

findings. A quarter of all doctors agreed with the statement "If I discuss the case with the person involved nothing else needs to be done" compared to only 11% of nurses ($p<0.001$).

Firth-Cozens[201] identified that doctors and nurses did not feel the need to write a report for minor or unintentional mistakes errors, one-off errors or ones for which the person involved is obviously sorry or has insight. Others have also identified that doctors are reluctant to openly discuss incidents with others.[209] In Leape's paper, "Error in Medicine"[117] he discussed why doctors were reluctant to disclose errors; that the medical culture perpetuates an environment where errors are rarely admitted or discussed by reinforcing the concept that only bad doctors make mistakes. It is likely that to prevent public humiliation doctors chose to discuss adverse events only with the person involved in the error. Whether as a result of ignorance or malevolence, the pervading culture of secrecy means that errors continue to recur because the underlying causes are rarely explored.

The incident was too trivial: Doctors were more likely than nurses to believe that they did not report trivial incidents (51% vs. 41% $p=0.027$), however they were less likely than nurses to agree with the statement, "When it's a near miss, I don't see any point" (36% vs. 49% $p=0.003$). Nurses appeared to be more comfortable reporting minor events. In focus groups they referred to protocols which needed to be followed with regard to incident reporting, whereas doctors were less inclined to feel they needed, or had, protocols to follow.

Cultural division exists between doctors and nurses.[232] Doctors prefer to support professional autonomy, collegiality, and self-regulation and personalised organisationally opaque systems of accountability. A survey by Degeling et al[313] using a randomly selected stratified sample of nurses, doctors and allied health professionals in Australia demonstrated the polarity in views by doctors and nurses with regard to how they work. Doctors' responses displayed individualistic preference towards clinical work while nurses supported an institutional collective orientation. These findings reinforce those in our study.

Fear of litigation and disciplinary action: Doctors in focus groups mentioned concern over litigation and a need for the reporting system to be legally protected. However, in the staff survey only 21% of doctors and nurses agreed that they were worried about litigation.

The pervading fear by nurses of getting into trouble was a recurring theme in focus groups and was also reflected in the staff survey. Nurses operated more defensively within their culture and were principally concerned with being disciplined for making an error from

within their organisation. Results of the staff survey showed that significantly more nurses than doctors responded that they were worried about disciplinary action (18.1% vs. 8.3% p=0.002) or getting into trouble (18.6% vs. 10.6% p=0.014), and that co-workers might be unsupportive (20.8% vs. 13.8% p=0.045)

The lower than expected percentage of staff fearing litigation was also reported by Uribe et al[197] but was in contrast to findings in other studies. [203 314] A number of studies have investigated why nurses are more concerned with disciplinary action from within their profession,[203 315] with views ranging from nursing being an oppressed profession to disenfranchising work practices. A survey of 424 nurses in the UK[203] identified that nearly 20% of nurses believed that their supervisors used incidents reports against employees and 17% stated that their supervisors used incidents reports against them in evaluating their performance. A quarter of all nurse respondents believed that incident reports gave their supervisor a negative view of their skills.

Based on analysis of staff survey and focus groups, it is clear that cultural and organisational barriers were often strongly intertwined. This is demonstrated when discussing the lack of knowledge about who should report. Reasons for lack of knowledge stem from organisational factors such as a lack of support and education, but also from deeply seated cultural barriers perpetuating the norm that incident reporting is a nursing tool.

For a strategy to improve incident reporting the focus groups and surveys have demonstrated that there is a need to more accurately define (1) what it is that people should report; and (2) whose responsibility it is to report. Education campaigns to improve reporting must target the different priorities of doctors and nurses to increase the probability that it will be effective in changing practice. It must be considered by staff to be a worthwhile use of their time. Feedback to staff is vital. To overcome cultural barriers staff should have the ability to report anonymously, and, concurrently, there should be an education campaign to assist managers to manage reports in a just manner.

5.1.7.3. Limitations in addressing aim 3(to identify knowledge, use and barriers to use of the reporting system)

There are a number of limitations to focus groups and staff surveys which must be considered when interpreting the findings. Generic limitations to focus group and survey studies have been outlined in section 2.7.1.1 of the Literature review. Limitations specific

to this study and ways in which the study was designed to address these limitations are discussed in this section.

With regard to focus groups:

1. **Analysis was based on interpretation of the data.** This can introduce bias into the findings.[212] To reduce likelihood of bias, tapes were transcribed by an independent person. Two researchers independently coded comments and where consensus could not be reached, a third independent adjudicator was used. This occurred on only two occasions.

2. **Participation bias:** Focus groups may be biased or directed by a dominant group member as not all people are equally articulate, confident or perceptive.[211 316] Participants might know each other and have an existing social hierarchy which might impact on their participation in open discussion. Additionally, some participants may find the group setting to be inhibiting.[212] Because the moderator is outnumbered, there is the potential to lose control over the line of questioning.[211]

   Strategies introduced to provide a non-threatening environment included (a) using an experienced moderator to ensure representative participation; (b) ensuring that participants were all of the same seniority in each focus group; (c) providing food and beverages; and (d) outlining the following "rules of participation" at the start of each meeting- all input is important and valued, each person would get a say and no person should interrupt when another was talking.

3. **It is difficult to make generalisations from small, unrepresentative samples.** In designing the focus groups we purposively sampled to include both users and non-users of the reporting system and sought people from a variety of age groups. However we were unable to recruit any female medical Consultants to attend the focus group session.

   Because results will vary with each focus group, it is difficult to validate results.[214] For this reason, focus groups were used in conjunction with staff survey findings in the development of the intervention. Also, having five focus groups enabled common themes to emerge. Although our findings were consistent across the three hospitals represented in the study, results of this study may not be generalizable to other healthcare settings.

With regard to the survey:

1. **Response bias:** Despite a 73% response rate, those who participated may be in some way different from those who did not respond. Because the survey was anonymous, we could not get demographic data from non-responders.
2. **Not generalisable to areas not studied:** Although we surveyed many clinical areas including medical and surgical units, ICUs and EDs in rural and metropolitan hospitals, caution should be exercised when interpreting data in areas such as general practice and psychiatry. However, barriers to reporting identified in our study had many similarities to those identified in the UK,[198 201] Denmark[188] and the US[64] incorporating specialties such as obstetrics, paediatric medicine, anaesthesiology, surgery and internal medicine.
3. **May not have identified all relevant barriers:** There may be potentially important variables and barriers not included in the questionnaire because of the need to limit questionnaire burden.
4. **Socially acceptable response bias:** Despite being anonymous, respondents may have provided more socially acceptable responses for fear of identification, which might explain why cultural barriers identified in focus groups were not reported as significant deterrents to reporting in the survey.
5. **Incident data captured elsewhere:** We did not investigate why staff reported certain incidents more frequently than others. Perhaps staff did not define the less frequently reported incidents as incidents, or believed tools exist to detect/monitor them or that, in the case of senior medical staff, they implicitly delegated reporting to junior staff.

5.1.7.4. Significance of the findings with regard to aim 3 (to identify knowledge, use and barriers to use of the reporting system)

The findings that one quarter of all staff did not know how to access or locate an incident form, that a third of all doctors had never made a report and that just over half of all doctors did not know what to do with a completed form is important when developing strategies to improve incident reporting.

The finding that less than three quarters of all staff believe they should report DVTs due to inadequate prophylaxis, hospital-acquired infections, injuries, and medication near misses indicates that staff do not regard these in the same way as events such as patient falls, adverse medication events, and equipment faults. Education targeting these types of incidents might improve perception of how often they should be reported.

Barriers to reporting adverse incidents have been explored using both focus groups and staff surveys. However no studies could be found that used both methods in the same study population. The mixed methods used in this study provided validation of some findings and ability to explore issues using both mediums.

While there have been many studies identifying barriers to reporting, only one other study was identified[61] where a cultural assessment of the study population was undertaken prior to implementation of a project. In this study, the cultural assessment was not repeated after the intervention was introduced, so it is not possible to know whether attitudes and barriers were altered as a result of the project.

The scope of this survey is larger than others published in the literature. Other studies have investigated barriers within departments or divisions. However, this cross sectional study in a number of hospitals enabled issues in rural hospitals to be compared with those in metropolitan hospitals and across a range of specialities.

The qualitative study design of focus groups allowed for candid contributions by participants through the use of single specialty groups. A literature search revealed no previous reports of similar qualitative studies differentiated by profession and seniority in Australia.

5.1.8. To improve reporting rates (aim 4.1)

Incident reporting during the study period increased in inpatient areas from 83 to 190 reports per 10,000 OBD in intervention units, and from 54 to 101 reports per 10,000 OBD in control units. Reporting in the ED stayed constant in the control units but increased from a low baseline of 6 to 46 reports per 10,000 ED attendances. Compared to control units, the intervention resulted in 60 more reports per 10,000 OBDs ($p<0.001$) or five reports per 100 patient discharges in inpatient areas ($p<0.001$) and 39 more reports per 10,000 ED attendances ($p<0.001$).

Because it is not possible to find other studies evaluating reporting in identical study populations, when comparing results of this study with others, it was necessary to divide the discussion of reporting rates into four sections:.

Section 1: Reporting in inpatient areas (Medical, Surgical and ICUs);

Section 2: Reporting by professional designation of reporter;

Section 3: Reporting in different types of units;

Section 4: Reporting by the method used to make the report.

5.1.8.1. Section 1: Reporting rates in inpatient areas

5.1.8.1.1. Inpatient areas- reporting rate changes- by 10,000 OBDs

Crude comparisons of our results with those identified in the literature identified that our reporting rate of 190 reports per 10,000 OBD was higher than that recorded by Sutton et al[60] (83 reports per 10,000 OBD) and Jha et al[58] (7 reports per 10,000 OBDs) but lower than that reported by Kivlahan et al[61] (415 reports per 10,000 OBDs).

The study by Sutton et al[60] focussed on accidents rather than incidents. While Sutton did not define an accident, it likely included all patient injuries and medication errors. There are some obvious differences when comparing these results with ours, namely;

- Sutton et al's study was conducted over three days in one hospital, while ours was conducted over nine months in six hospitals. It is not possible to know whether reporting practices in the three days are representative of longer-term reporting practices.
- Sutton et al's study was conducted in ten ward locations, including surgical and medical units. We do not know whether the two studies had comparable 'at risk' populations. Unlike our study, Sutton et al's included a psychogeriatric unit, where more falls may have occurred. There is evidence that falls are more common in the elderly and in areas where patients are taking antipsychotic medication.[317]
- Definitions between the two studies are not comparable. Whereas staff in our study were encouraged to report adverse events and near misses (including such events as poor documentation, communication issues, malfunctioning equipment, security breaches), Sutton et al's study was confined to accidents.

The study by Jha et al[58] compared voluntary reporting of adverse drug events with those identified by chart review and a computer detection strategy. If our study compared only medication incidents with the results obtained by Jha et al rates would have been very similar (7.3 vs 7 medication-related reports per 10,000 OBD). However, when the study by Jha et al compared the voluntary reporting rate with the rate detected by a computer detection system and with that obtained by medical record review, a much higher event detection rate was obtained in the latter two groups (96 and 133 adverse drug events per 10,000 OBDs respectively).

Kivlahan et al[61] provides results from a hospital-wide incident reporting system in the US before and following introduction of a web-based reporting system. The traditional paper-

based reporting system identified a reporting rate of 316 reports per 10,000 OBDs, while the web-based system identified 415 reports per 10,000 OBDs. The US reporting system differed from ours in that it was used by staff, physicians, patients, visitors and families and it purposely did not define an adverse event so as to not limit what could be reported. If only reports generated by doctors and nurses were included, the traditional paper-based reporting system would have identified a reporting rate of 211 reports per 10,000 OBDs, while the web-based system identified 242 reports per 10,000 OBDs. This rate more closely resembles the rate of 190 reports per 10,000 OBD achieved in our study.

5.1.8.1.2. Reporting rate changes- by 100 patient discharges

We were unable to compare the studies by Sutton, [60] Jha[58] and Kivlahan[61] with ours using patient discharges as a denominator because this was not reported in their studies. Our reporting rate of 12.2 reports per 100 patient discharges across all inpatient areas was higher than that reported by Wolff et al (5.2 reports per 100 patient discharges),[161] O'Neil (2.8 reports per 100 patient admissions)[51] and Weingart (8.9 reports per 100 patient admissions)[162] yet was significantly lower than those reported by Welsh (19.6 reports per 100 admissions)[50] and Marang-van de Mheen (34.2 reports per 100 admissions).[169] It was almost identical to the reporting rate achieved by Nakajima et al[168] in a Japanese University hospital (12.8 reports per 100 patient discharges). These will now be discussed further.

Wolff et al[161] described reporting practices in an Australian rural hospital over a 23-month period. The rural hospital contained an ED, a residential care facility, medical ward, surgical ward operating theatre and midwifery unit. Incident reports in the ED were not included because the number of ED attendances was not provided in Wolff et al's article, making a comparison not possible. The reporting rate identified by Wolff is similar to the baseline rate of 6.2 reports per 100 patient discharges obtained when using only rural inpatient data, but significantly lower than the rate of 16.6 reports per 100 patient discharges obtained during the study period in rural intervention inpatient wards. Because the study by Wolff et al used the AIMS reporting system, the definition of an incident is directly comparable, however as with studies by Sutton et al[60] and Jha et al,[58] it is not possible to know whether demographics of the patient population are comparable.

The study undertaken by O'Neil et al[51] involved facilitated reporting, where doctors were reminded to report on a daily basis via electronic mail, and weekly at scheduled departmental meetings. Unlike our study, O'Neil et al's study was conducted over a shorter time period (four months) and only involved medical staff and *potential* incidents in which they themselves were involved (self reporting). If we were to compare only medical reports

in inpatient areas, our study would have identified significantly fewer reports than O'Neil et al (0.41 vs 2.8 reports per 100 patient discharges).

As with the study by O'Neil et al, the study by Weingart et al[162] targeted doctors, but included in the results were reports from nurses, doctors and allied health workers. Ninety percent of all reports were submitted by doctors. Weingart et al's study was performed in a cardiac unit, oncology unit and medical ICU in the US over a shorter time period (three weeks for residents and four weeks for interns), and was facilitated through interviews which were conducted three times a week. An honorarium of US$100 (AU$130) paid to all participating doctors. This may have contributed to the stronger reporting rate identified by Weingart et al.[162]

The study by Welsh et al[50] which used daily prompting six days per week resulted in a higher reporting rate (19.6 reports per 100 patient admissions) than that reported in our study. However, when prompting occurred only once or twice a week or not at all, rates were higher in our study (11.4 and 6.6 vs. 12.2 reports per 100 patient admissions respectively). Unlike our study, this population was restricted to medical staff working only in an internal medicine service, and each phase of the study took place over a two-month period. Additionally, doctors were asked only to report "an injury that was a consequence of care provided in the hospital (medical management) rather than the patient's disease process." Near misses were not included in the study.

The study by Marang-van de Mheen et al[169] was conducted only among surgeons and surgical residents in a surgical division in a Dutch hospital. The study identified an adverse outcome rate of 34% of admissions, much higher than the rate identified in surgical patients in this study. Results of this study will be compared with ours in the section related to surgical unit reporting (section 5.1.8.3.3).

The study by Nakajima et al[168] involved the introduction of an anonymous web-based reporting system. Results are provided for a 45-month period. However, only one annual discharge rate has been provided. Extrapolating rates from one year to the three year project, a rate of 12.8 reports per patient discharge was calculated. However, this rate will be inflated because it includes outpatients and ED reports in the numerator, whereas the denominator included only patient discharges. If our study included ED reports in the numerator but used only patient discharges as a denominator, we would have achieved an apparent rate of fifteen reports per 100 patient discharges (1111/7599). Even though the reporting system was anonymous, the professional designation of the reporter was collected and reported in Nakajima's findings.

Crude comparisons can be made by comparing rates between studies, however there are inherent problems which make comparisons of incident reporting projects fraught with difficulty:

- The lack of a consistent outcome being measured (adverse events, accidents)
- The lack of standard definitions even when the same outcome is being measured.
- The different patient populations being studied.
- The different target group being studied
- The different time periods over which the study was conducted.

5.1.8.1.3. Reporting rate changes- control units

Even though reporting in intervention units was significantly higher than control units when evaluating both inpatient and ED data, the increased reporting in inpatient areas by control units during the study period is notable. Incident reporting increased from 54 to 101 reports per 10,000 OBDs and from 3.3 to 5.4 reports per 100 patient discharges.

There are a number of possible reasons for the increased reporting rates in inpatient areas by control unit staff:

1. **Contamination:** The way in which hospitals are structured means that staff assigned to the intervention unit may also have worked in the control unit at some time during the study period. Staff rotate through various units as part of normal hospital activity. Because patients are not always admitted to their 'home ward', medical staff are often required to manage patients across multiple wards. Junior nursing staff are required to rotate through a number of different types of units as part of their training program.

   There were fifteen incident reports lodged using the call centre during the study period which were submitted from staff in control units. When this occurred, a paper report form was written and it was directed back to the NUM to be managed in the normal manner. Additionally, there were five reports lodged using the single page form which had also come from control units. We determined that staff who had worked in intervention units during the study period had returned to intervention units to source a report form.

2. **Other quality activities in the hospital at the time of the intervention:** There were a number of quality improvement activities being undertaken in hospitals throughout South Australia at the time of the project. Most notable of those were the following two statewide projects:

- A statewide education campaign to introduce Root Cause Analysis into hospital risk management programs had commenced. The scale of this quality improvement exercise was unprecedented. During the study period there were three Root Cause Analysis workshops, each run over a course of three days. Each of these workshops catered for 100 people. Approximately ten people from each hospital in our study attended each workshop in addition to the Medical Heads of Units and NUMs from intervention units. As the aim of the workshop was to foster reporting it is probable that this impacted on reporting rates in control units.

- A statewide incident reporting project was being introduced at the time of the project. Although control unit staff did not have access to the database at the time of the study, they did receive reports detailing their unit performance compared to the performance of intervention units in their hospital in the last few months of the project (see section 4.6.2.4). This may have encouraged control unit staff to improve reporting, however timelines in Appendix 28 do not indicate an acute increase in reporting in control units in the final stages of the intervention.

5.1.8.2. Section 2: Reporting rates by reporter designation

5.1.8.2.1. Doctors

The intervention did not demonstrate significant improvement in reporting by doctors in inpatient areas (Table 4-24). Incident reporting increased in intervention units from 0.6 to 6 reports per 10,000 OBDs, and in control units from 0.2 to 0.6 reports per 10,000 OBDs. Doctor-initiated reports constituted less than five percent of all reports generated in intervention units during the study period, compared with less than one percent of all reports at baseline.

In contrast to reporting by doctors in inpatient areas, there were significantly more reports generated by doctors in ED intervention units compared with control units. Incident reporting increased in intervention units from 0 to 9 reports per 10,000 ED attendances, and decreased by in control units from 0.8 to 0.3 reports per 10,000 ED attendances. Reasons for these differences will be discussed in section 5.1.8.3.4.

The marginal increase in reporting by doctors across all areas other than the ED was disappointing. Other studies have also had difficulty encouraging doctors to report. A study in Japan[168] indicated that doctors contributed at a rate of less than one report per 100 patient discharges. Strategies to improve reporting through making the reporting system

easy to use and providing education sessions and feedback had no significant overall impact.

To understand why the reporting system did not gain widespread support, it is important to understand broadly what influences the rate and spread of change and its perceived acceptability.

According to Berwick[286] effective change management, is dependent upon:

- Firstly, how the innovation is perceived by people expected to use it. This is dependent on (1) the perceived benefit that the change offers; (2) whether the change is compatible with the values, beliefs, past history and current needs of the individual; (3) the complexity of the innovation; (4) whether they have been provided with an opportunity to trial it without being forced to adopt it; and (5) whether they have witnessed the tool and viewed the ease with which it can be used.
- Secondly, the characteristics of the people who are expected to adopt the innovation. Early adopters and the early majority constitute approximately 47% of those involved in adopting change. These are followed by the late majority (34%) and the laggards (16%).
- Thirdly, the characteristics of the organisation or social system in which the change is being introduced. Organisations that provide a nurturing workplace by encouraging innovation and providing a forum to disseminate new ideas may see faster dissemination of change when compared to organisations which stifle new ideas.

Based on Berwick's recommendations, strategies such as (1) ensuring that doctors were informed that the study was developed following feedback from them; (2) highlighting the simple nature of the report form and telephone reporting service; (3) providing demonstrations of the call centre reporting service at departmental meetings; (4) explaining to staff the methodology of the study design and timeline for the intervention; (5) educating leaders; and (6) attempting to harness clinical champions, were employed to maximize potential of the intervention to change doctors' practices.

There are a number of proposed reasons for the lack of uptake of incident reporting by doctors in inpatient intervention units:

1. **Entrenched culture that does not support change:** An intervention to improve incident reporting requires people within organisations to change current practice. It is

widely recognised that changing behaviour can be difficult, particularly in professional organisations, where work is complex and is required to be carried out by trained specialists who often work relatively independently of their colleagues.[318] People habitually work certain ways, fear the unknown, and often selectively process information to ignore information that challenges the world they have created.[319]

There has been increased focus on encouraging multidisciplinary collaboration between healthcare providers,[320] as there appears to be an association between poor communication among professional groups and poor patient outcome. For this reason, incidents were discussed in departmental meetings where other professional groups were in attendance. The end of study survey indicated that most doctors were not averse to having incidents discussed in meetings; however we did not stipulate who would attend these meetings. Perhaps, had the intervention not fostered a multi-disciplinary approach, we may have had more support by doctors.

2. **Lack of prompting:** Other studies have demonstrated that medical staff will report better when they are prompted on a regular basis.[50 51] While other studies have used daily email prompting, in the Australian context this would have little value, because most junior medical staff did not have access to the hospital email service at the time of the study. The sustainability of email prompting in improving reporting has not been established.

3. **Lack of effective clinical champions:** In most departments we did not have strong advocates for the reporting system. To avoid contamination, Professor Runciman and Professor Maddern (both supervisors) did not play an active role in encouraging incident reporting. This may have been perceived as indifference by doctors in these areas.

   While Heads of Units agreed in principal to support the project and encourage reporting, in many places this did not translate into practice. This will be discussed in greater depth when discussing incident reporting within units in section 5.1.8.3.

   The effect of local medical opinion leaders in changing behaviour[321] and adopting new technologies[321 322]is well recognised. Studies that have effectively improved reporting rates have usually had the presence within the clinical area of medical facilitators to encourage incident reporting.[43 51 245] It is recognised that greater exposure translates to greater uptake of interventions.[323]

   In Beckmann et al's study[43] which took place over a two month period in an ICU, 51% of all reports were generated by doctors (n=51). Facilitation involved a senior intensive

care physician 'encouraging' staff to report incidents on ward rounds and at clinical sessions. In the study by Fordyce et al[49] 17% of all reports or 61 reports over a seven day period were generated by doctors. As with Beckmann's study, Fordyce facilitated reporting by prompting staff to report during the shift.

4. **Lack of effective feedback:** We attempted to facilitate incident reporting through departmental meetings, however these were not frequent enough to maintain support by doctors (Table 4-18). Lack of feedback was the most commonly cited barrier to reporting at baseline, yet despite attempts using newsletters and departmental meeting, half of all doctors responding to the end of study staff survey indicated that they had received not enough or no feedback arising from reports. Forty percent of doctors at the end of the study still felt they never got feedback (down from 52% at baseline).

   Each of the five newsletters distributed throughout the study were placed in doctors' pigeonholes in clinical units by Project Officers. However, only thirty percent of doctors recalled receiving them. Consultants who worked on intervention units throughout the study period would have had five sent to them. Junior doctors (residents and interns) would have only seen one or two newsletters, as they rotated through medical units each six to eight weeks. Registrars should have received at least two newsletters. It is probably the case that doctors either chose not to read them or did not associate them with the study in which they were participating.

   There is little doubt that doctors face "information overload", with the typical doctor having less than one hour per week to read literature.[324] It is perhaps not surprising (however disappointing) that many do not recall receiving a newsletter.

5. **Lack of trust:** The end of study staff survey finding that doctors were twice as likely as nurses to feel apprehensive about how the incident was investigated (20% vs 10%- Table 4-40) indicates that this may have influenced reporting behaviour.

6. **Barriers to reporting identified at baseline not adequately addressed by the intervention:** While the intervention was designed to address barriers to reporting identified at baseline, the subsequent survey of doctors identified that it did not have a significant impact with regard to many key areas (Appendix 36). Thirty five percent of doctors still didn't know whose responsibility it was to make a report (down from 39% at baseline). The intervention appeared to impact on only two barriers; (1) Doctors were less likely to state that incidents were too trivial to report and (2) were less likely to state that if they discussed the incident with the person involved nothing else needed to be

done. These issues will be discussed further in section 5.1.12 when addressing aim 5.3 (to reduce barriers to reporting).

GPs

Most GPs working in the rural hospital showed little interest in using the reporting system. Numerous attempts were made by members of the project team and strategies developed to encourage reporting. However, in total, only five reports came from doctors in rural intervention units over the forty week intervention period.

Other Australian studies have had more success in obtaining incident reports from GPs than us.[55 325] These studies have shown that incident reporting can be successfully applied in general practice and information from reports can be used to identify common factors contributing to adverse events so that preventive interventions can be developed.[122 154 155 326-329]

Reasons why other studies have succeeded in improving incident reporting by GPs, where we could not, might include the following:

1. **Reporting to an external body:** In studies by Bhasale[55] and Britt,[325] GPs reported incidents to their professional College, while in the study by Rubin et al[125] GPs reported to a university. In our study, GPs were required to report incidents to the hospital. It may be that GPs perceived that hospitals were going to use incident reporting data for a purpose it was not intended, a view shared by others.[330] Interview of doctors in the United Kingdom revealed that they did not trust activities of non-medical groups, which is how they perceived hospital quality departments.[331] Doctors were more likely to regard incident reporting systems as worthwhile if it was managed from within their own discipline. This was because they felt data would be more appropriately and constructively applied to improving clinical care.
2. **Apprehension about purpose of reporting:** GPs might fear disciplinary action, or even removal of privileges to practice in the hospital if they reported incidents which may have been perceived as being caused by poor individual performance rather than system issues.
3. **Inability to guarantee anonymity:** With regard to anonymous reporting, other studies have been developed to ensure that reports go to an external third party,[55 122 124 125] while in our study they were sent to their local hospital to be managed by the Patient Safety Manager. GPs may have been more worried that their anonymity could not be maintained when reports were collected within their hospital.

4. **Intent to treat vs. self-selected group**: In all other studies, GPs were invited to participate and could opt out if they chose.[55 122 124 125] It is likely that those who agreed to participate in the study were more motivated than those who declined. Unlike those studies, GPs were not self-selected in our study.

5. **Not consulted when formulating study design:** GPs were not involved in the conceptualisation of the project or its implementation. Even though we surveyed GPs, they were not involved in focus groups, did not have a representative attending the RCA workshop, and did not have a representative championing the project. Other successful studies had GPs themselves leading the project.[122 124 125]

5.1.8.2.2. Nurses

Table 4-24 demonstrates that the intervention was able to significantly improve reporting by nurses in intervention inpatient areas. Incident reporting increased from 80 to 177 reports per 10,000 OBD in intervention units and from 50 to 88 reports per 10,000 OBD in control units. In inpatient intervention units the study resulted in approximately 59 more nurse-generated reports written per 10,000 OBDs.

The intervention was not able to demonstrate improved reporting by nurses in the ED. Incident reporting increased in intervention units from a low baseline of 6 to 31 reports per 10,000 ED attendances and remained constant at 19 reports per 10,000 ED attendances in control units.

Identified nursing reports constituted 73% of all reports generated in intervention units during the study period as compared to 92% at baseline. The incident reporting system was used more than twice as frequently by nurses in intervention units during the study period compared to baseline. However, nursing staff in control units also used the traditional reporting system more during the study period. Reasons for increased reporting by control unit staff have been discussed in section 5.1.8.1.3.

Of interest was the finding that, despite the significant improvement in reporting by nurses, the end of study staff survey indicated that only 40% of nurses were aware of the timeframe for feedback and only marginally more (44%) understood how the incident was followed up (Table 4-40). In the ICUs, where baseline reporting was high but where the study made no significant impact in improving reporting rates, nurses were less likely than other units to feel that they got feedback yet were more likely to see a point in reporting near misses. Nurses were significantly less apprehensive about how the incident was followed up compared with doctors, with less than ten percent feeling apprehensive (Table 4-40). This

is in spite of the finding that thirty percent of nurses felt the incident was managed in a punitive manner.

These findings suggest that many nurses report in spite of having little understanding of the reporting process or need for feedback, and many face punitive consequences. With the staff survey showing that 90% of nurses did not feel apprehensive about the person investigating the incident, yet 32% felt the report was managed in a blameworthy manner, it would be interesting to determine what motivated nurses to report. Unfortunately, our survey was limited to identifying why staff do not report. Possible reasons for improved reporting by nurses include:

1. **Driven by protocol:** Nurses, more than doctors, work collectively and are more driven by protocols;[232]
2. **Altruism:** A transcending desire to have problems bought to the attention of those in a position to fix it, even if it holds no personal gain.
3. **Reporting options:** The new process for reporting using the shorter form or call centre may have motivated nurses to report.
4. **Education campaign:** The education campaign likely heightened awareness of incident reporting.
5. **Increased exposure:** Promotional material such as posters on walls, stickers on telephones and pens distributed during handovers likely increased exposure to incident reporting. Incident report forms were placed in a more prominent position on intervention wards during the study period (see Appendix 23).

The significance of the additional reports made by nurses lies not only in the number of reports made, but also in the types of reports generated. This will be discussed in section 5.1.9.

While web-based reporting systems[332] and strategies such as intense bursts of reporting[60] have been used to facilitate reporting by nurses, there have been few studies where nurses have been specifically targeted in the same way as has occurred for doctors.[50 50 51 238]

The reporting rate generated by nurses in our study was lower than that identified by Sutton et al[60] in a study conducted over three days in ten wards (177 vs. 242 reports per 10,000 OBD). Details of this study are outlined in section 5.1.8.1.1.

The finding that three quarters of all reports were made by nurses is consistent with the literature. Kivlahan et al[61] identified that 65% of all paper-based incident reports were

initiated by nurses. This reduced to 63% after a web-based reporting system was introduced which encouraged anonymous reporting and targeted doctors. Nakajima et al[168] reported that 85% of all incident reports were initiated by nurses.

5.1.8.2.3. Allied Health

The intervention significantly improved reporting by allied health professionals in intervention inpatient areas. Incident reporting increased in the intervention units from 5 to 15 reports per 10,000 OBDs) and in control units from 1 to 3 reports per 10,000 OBDs. There were approximately seven more allied health-generated reports written per 10,000 OBDs in intervention units during the study period compared with baseline and changes in control unit reporting practices.

Reporting by allied health workers also increased significantly in the ED from 0 to 21 reports per 10,000 ED attendances, and remained constant in control units. Reasons for these differences in the ED will be discussed in the next section.

The increased reporting by allied health professionals in both inpatient and ED intervention settings during the study period occurred despite not having targeted education and feedback sessions. There were marginally more incident reports made in control units over the study period, mostly as a result of reporting by pharmacists (see section 5.1.8.1.3).

The increased reporting rate in the allied health professional group during the study period was likely due to a number of strategies:

- **Education campaign:** While not specifically targeted to allied health professional, it is likely that they received education through the same method used to educate doctors in metropolitan hospitals because they were present at departmental meetings where feedback was provided to doctors. Some allied health professionals also attended nursing handover sessions and Grand Rounds, where the project was discussed. Information was not collected on which allied health groups were represented at departmental meetings. Although not formal education sessions, it is likely that allied health professionals, such as ward attendants and security staff (particularly in the ED) may well have learned about the project through contact with the nursing team.
- **Increased exposure:** As mentioned for nurses, allied health professionals were exposed to promotional material.

- **Reporting options:** providing different reporting processes may have eased the reporting burden on allied health professionals. It is likely that the barriers identified by doctors and nurses also reflected those experienced by allied health professionals.
- **Changed reporting process**: all medication incidents were reviewed by pharmacists in Hospital 1, 2 and 4 (see Appendix 10). These three hospitals captured seven of the ten intervention units. In these three hospitals, a pharmacist representative was provided with access to the AIMS database and was asked to enter details into the management section if required. Feedback was provided to the reporter by the pharmacist. It was likely that pharmacists reporting on intervention units received more feedback as a result of changes to the way in which reports were processed during the study period, and that this motivated them to report.

Incident reporting studies predominantly involve doctors and nurses, however pharmacists[244 333 334] and physiotherapists[335] have used incident reporting data to improve detection of medication-related incidents and develop strategies to prevent falls in the elderly. A literature review revealed no incident reporting studies in the disciplines of dietetics, occupational therapy and speech therapy. However, in many Australian hospitals these professional groups use the AIMS reporting system.

The rate of reporting by allied health professionals likely grossly underestimated the true rate of adverse events and near misses in this group. No published studies were identified which examined incident reporting by allied health professionals using denominator data, so it is not possible to provide comparative analysis of reporting rates. The lack of evidence to show that any substantial body of work has been done to improve reporting by allied health professionals indicates that this is an area requiring further investigation. It is likely that the rate identified in this study can be increased further by providing allied health professional with more intense education and feedback which is tailored to their needs.

5.1.8.2.4. Anonymous

Anonymous reporting increased from 0.7 to 14 reports per 10,000 OBD and ED attendances. As a percentage of all reports submitted, anonymous reports increased in intervention units from less than two percent at baseline to nearly ten percent during the study period.

We found that there was heterogeneity among hospitals with regard to the numbers of incident submitted anonymously. In two of the three hospitals in which there was only one intervention unit there were no anonymous reports, whereas in a hospital with three

intervention units, anonymous reports accounted for 23% of all reports (Appendix 29). It may have been that staff in hospitals with only one intervention unit were not confident that their report would be kept anonymous when their department could be easily identified.

Reasons postulated for the overall increase in anonymous reports in intervention units during the study period include:

1. **Changed reporting process:** A change to the way in which reports were processed provided staff with greater confidence to report an incident they might otherwise not have reported. The increase in anonymous reports relating to clinical management, organisational management and behaviour and human performance issues compared to identified reports suggests that this might be the case (see Appendix 29).
2. **Greater awareness:** Awareness of the ability to report anonymously was provided through (a) education campaigns to staff in intervention units (b) changing the incident form design so that it was prominently recorded at the top of the form and not at the bottom of the back page; and (c) having call centre nurses specifically ask reporters if they wanted to identify themselves or remain anonymous.

When comparing the rate of anonymous reports obtained in our study with others, it is important to distinguish between them. Some incident reporting systems were entirely anonymous,[63 168] others reported to outside organisations (university, patient safety organisation),[55 139 147] others offered the option to report anonymously or confidentially within their institution.[186 336]

Kivlahan et al's study[336] in a US metropolitan hospital introduced the ability for staff to report anonymously. To make it possible to compare our findings with those obtained by Kivlahan, we compared reporting rates only with those metropolitan hospitals with more than one intervention unit. The rate of seventeen percent identified by Kivlahan et al was marginally lower than the rate of 23% identified in our study.

An anonymous reporting system established in an ED[63] identified that 43 reports were written per 10,000 ED attendances. It is not possible to directly compare these studies with results obtained in our study because we were unable to separate inpatient and ED reports. Also, the reporting system reported in this study was entirely for anonymous reports whereas the majority of reports submitted in our study were not anonymous. It is not possible to know how many reporters in their study would have identified themselves had they been given the opportunity.

Nakajimi et al's[168] entirely anonymous reporting system achieved a reporting rate almost identical to that reported in our study. In describing why an entirely anonymous reporting system was established in Japan, the authors wrote; "In view of findings in the literature that physicians preferred email reporting under non-punitive, confidential and voluntary conditions, we decided to develop an anonymous and blame-free web-based incident reporting system."

Anonymity has been advocated by leaders in patient safety as being the most effective method of collecting incident reporting data.[133 221] For a system to be successful in encouraging reporting there needs to be an assurance that incidents will be managed in a blame-free manner. This is difficult to guarantee when individual managers are responsible for investigating incidents. It takes only one bad experience for incident reporting to be abandoned.

5.1.8.3. Section 3: Reporting rates by type of unit

In this section, different types of units will be compared in an effort to explain the heterogeneity in uptake of the reporting system.

5.1.8.3.1. Intensive Care Units

The finding that we were unable to significantly improve incident reporting in either the rural or metropolitan ICUs was disappointing, particularly when there is evidence that more than thirty percent of patient admissions to ICU result in adverse events[143] and that half are due to system-based factors which are often amenable to preventive strategies.[43]

The rate of 23.8 reports per 100 patient discharges in ICU achieved in our study was less than half that obtained by Beckmann et al[43] but three times more than that obtained by Buckley et al in a Hong Kong ICU. [144] In the study by Beckmann et al[43] nearly half of all incidents reported in the ICU were initiated by nursing staff. The study by Buckley et al[144] focused on the reporting of critical incidents, which were defined as any incident which affected or could have affected the safety of the patient while under ICU management. This definition is comparable with that used in our study which also focused on both adverse events and near misses. Although the reporting rate was lower than ours, more than half of all incidents were reported by medical staff. This contrasts with our study where only two reports or 1.3% of all reports generated in ICU were initiated by doctors (Table 4-25).

There are several possible reasons why reporting in ICU did not improve significantly as a result of the intervention.

1. **Lack of feedback:** It was difficult to disseminate outcomes and education to staff in the metropolitan ICU because of the size of the unit. There were over 200 nurses and 40 medical staff working in the ICU. This was the largest intervention unit. Nursing staff were provided with 16 education and feedback sessions during the 40 week intervention period which was higher than other units, because there were so many staff (Table 4-18). Medical staff were provided with only three education sessions because there was much demand on time allotments in the departmental meeting and this was all that could be fitted in.

   Results of the end of study survey indicated that this was not sufficient to properly educate staff in ICUs. Staff in the intervention ICUs were significantly less likely than staff in other types of units to understand how incidents were followed up, what the timeline was for feedback and that they would even get feedback. It may also be the case that staff in ICU were more likely to report anonymously, for which no feedback could be given to individuals.

   The Project Officer in the rural hospitals was not able to provide feedback to staff in the ICU to the same extent as in other intervention units in the hospital. Despite being given two weeks notice, staff from the ICU were not present when the PhD candidate provided three monthly feedback to staff. Although staffing levels can restrict staff attending education sessions, it is unlikely that this can account for the ongoing problems identified by the Project Officer.

2. **Higher baseline reporting rate:** Incident reporting in the metropolitan ICU was higher than in other areas at baseline, making it potentially more difficult to achieve improvement. The best predictor of the size of improvement is the extent to which the group deviated from best practice at baseline. Those with good reporting practice are not as likely as those with poor reporting culture to see improvement.[70] At baseline, 33% of patient discharges were associated with an incident report (Table 4-21), which although likely under-estimating the true incidence, was higher than that achieved by most other units during the study period. A study of errors in a hospital in Bahrain[94] identified that 554 human errors were reported during a four month period by the medical staff. There was an average of 178 activities per patient per day and an estimated number of 1.7 errors per patient per day. A severe or potentially detrimental error occurred approximately twice a day, with doctors and nurses both contributing equally to the number of errors, despite the fact that nurses performed many more activities per day.

3. **No Project Officers based in the ICU**: Project Officers were not able to provide a constant presence in the ICU to encourage reporting. In the metropolitan ICU their role was restricted to that of educating staff, assisting in the generation of reports and providing feedback based on action taken by staff in the ICU. Unlike other studies which have been successful in improving reporting in ICUs,[43 144] in this study there were no Project Officers employed to work specifically in the metropolitan ICU, or even the hospital. Lessons learned from the aviation industry have shown that organisational culture is a powerful disincentive to reporting. [129] Despite having experience and qualification in ICU nursing, Project Officers were unable to make inroads in this area. Future efforts to improve incident reporting in ICUs should be conducted or facilitated by staff within the clinical area

4. **Too many options:** It may be that staff in the metropolitan ICU were confused by the numbers of different mechanisms by which they could report. Unlike other areas which had a choice of two options, ICU staff had a choice of three reporting options; call centre, paper form and online reporting. However, this seems unlikely given the fact that there were only six on-line reports generated during the study period.

5. **Lack of support:** Even though support for the project was given by the Medical Head of Unit, this did not translate into facilitating reporting amongst medical staff in the ICU. Despite being given incentives, no medical representative attended the Root Cause Analysis workshop. Even though one of the supervisors (Professor Runciman) worked in the unit one week in every seven, to avoid contaminating the findings of the study, he did not encourage reporting, nor did he report incidents during the study period. This may have been mistaken for lack of interest or support for the project. The importance of a clinical champion and effective leadership in fostering a culture of safety is highlighted in an article by Sleigh et al[337] and reflected on by Larson et al.[338] Sleigh contrasted two different management styles and reflected on the difference that a supportive team atmosphere which fostered consultation and learning had on preventing error. Larson demonstrated how the leaders within a hospital encouraged incident reporting.

6. **Used other processes:** It may have been that medical staff in ICU used a different process to identify errors and that this was not immediately obvious to the researchers. However, there was no morbidity and mortality meeting in the Unit.

7. **Relocation of unit:** The metropolitan ICU had recently relocated. In the initial stages it may not have been seen as a priority, but reporting trends indicated that reporting did

not improve over time. There is evidence that relocation of an ICU can lead to greater mortality[339] which might reasonably be expected to lead to more incidents reports. However, this was not our experience.

8. **Did not like single-page report form:** The end of study staff survey indicated that shortening the form was well accepted by most staff, however only 74% of staff working in ICU preferred the shorter form compared with 92% in the ED, 81% in medical units and 86% in surgical units. It may be that this deterred some of them from reporting.

9. **Punitive management of reports:** It was surprising that reporting rates were as high as they were in the ICU given that the survey indicated that only 50% of ICU staff who had made a report during the study period felt that it was handled in a blame-free manner. This will be discussed further in section 5.1.12. Because of the size of the metropolitan ICU, follow up of nursing-initiated incidents was undertaken by one of the three clinical nurse specialists, whose role was to support and educate nurses working in the ICU. Although the NUM had attended the Root Cause Analysis workshop, none of the three nurses responsible for undertaking investigation of incidents attended.

   There is considerable evidence that this punitive culture is counter productive in fostering a culture of safety and incident reporting.[117] While survey and focus group discussions by others and by us have identified this as a barrier to reporting, this study has demonstrated that reporting rates, while not improving, did not decline even when a large proportion of those who were reporting felt it was not well managed.

10. **Not seen as relevant:** Even though provision was made to give feedback to medical staff on a three monthly basis, this had limited success because the lack of doctor-initiated reports generated by ICU staff meant that reports may not have been regarded as relevant to them.

5.1.8.3.2. Medical Units

Each metropolitan medical unit was matched broadly with another medical unit in the same hospital and was also matched more specifically to a similar type of medical unit in another hospital. For example, within one hospital, a neurology medical unit was compared with a cardiology medical unit in the same hospital, and with a neurology unit in another hospital. In one metropolitan hospital, the fact that there was only one medical unit meant that it had to be compared with a surgical unit. A rural medical unit was compared with a medical unit in another rural hospital

At baseline, reporting rates in intervention medical units ranged from 16 to 164 reports per 10,000 OBD (Table 4-20) or from 1.5 to 8.8reports per 100 patient discharges. Rates during the study period ranged from 142 to 431 reports per 10,000 OBD (Table 4-20) or from 6.4 to 31.6 reports per 100 patient discharges (Table 4-21). The unit with the highest reporting rate during the study period was the rural medical unit. This unit was of similar size to other units, but the number of reports lodged during the study period in this unit amounted to 70% of all of the incidents reported in the three metropolitan medical intervention units (249 reports vs 363 reports).

Reasons for heterogeneity in reporting across medical units likely reflects:

1. **Variable exposure to the project:** The metropolitan medical unit which showed the least improvement (Department 11) was situated in a hospital with only one intervention unit. There were only three medical reports from this department and the PhD candidate was only able to provide feedback to medical staff on two occasions throughout the study period (Table 4-18). The lack of intervention units, coupled with the fact that they were situated in hospitals where Project Officers worked less than one day per week, meant that Project Officers were not well known to staff. Both the rural and metropolitan medical units with the highest reporting rates (Departments 15 and 4 respectively) had Project Officers based in the hospital who worked four days per week.

   The rural Project Officer had an office directly outside the medical unit. This may well have contributed to the strong reporting culture. The finding that rural medical units reported so much better than their metropolitan counterparts may be explained in part by the findings of the end of study staff survey. Rural intervention units were more likely than their metropolitan intervention units to believe they had received too much or about the right amount of information about the project (90.2% vs. 73.3%)

2. **Reporting by a few dedicated staff:** Even though reports were generated by many nurses, there were three nurses in the rural medical unit who were particularly strong reporters. They not only reported themselves, but encouraged others to do so.

Improvement in medical units over the study period was not dependent on baseline reporting rates. The medical units with the highest reporting rates based on OBD data during the study period (Department 9 and Department 15) also had high baseline reporting rates. However, another medical unit with only a marginally lower reporting rate than Department 15 had the lowest baseline reporting rate of all the medical units at baseline. The three medical units each had different Project Officers working with staff in them, the

NUMS had different management styles, and in one medical unit we were not permitted to play any role in investigation or feedback of outcomes.

Comparison between metropolitan medical and surgical units in the same hospital (Departments 9 and 10): When the medical metropolitan intervention unit (Department 9) was compared with the surgical metropolitan control unit (Department 7) in the same hospital, the increase in reporting seen in the intervention unit was not significant when observed over a denominator of patient discharge data, but was significant when observed over a denominator of OBD. This can be explained by the fact that OBD rates will be more sensitive to detecting small changes compared to the more crude measurement of patient discharges. Of particular note in this hospital was the fact that there was only one intervention unit and that reporting in the control unit more than doubled during the study period. In addition to the issues addressed in section 5.1.8.1.3, the small size of the metropolitan hospital increased likelihood of contamination (Table 3-2).

Comparison between metropolitan specialty medicals units from different hospitals: In regard to reporting in specialty medical units, this study demonstrated that the cardiology control unit increased reporting rates significantly more in the study period than the intervention cardiology unit. By having an intervention and control unit matched by specialty we were able to demonstrate that factors other than the intervention impact on reporting rates. It also highlights the diversity in reporting cultures between units.

Some possible reasons for the increased reporting in the control cardiology unit compared with the intervention cardiology unit are:

1. **Other quality activities impacted on reporting rates:** The control cardiology unit introduced individual patient supply for inpatient medication during the study period as part of a pilot study. This accounted for six of the ten additional reports made by allied health professional in control units during the study period. Medication incidents in this cardiology control unit increased from 15 medication incidents at baseline to 52 reports during the study period.
2. **Contamination:** It may be that there was greater contamination in the control cardiology unit which was situated in a hospital with three intervention units, whereas the intervention cardiology unit was the only intervention unit in that hospital.
3. **Higher baseline reporting rate**: The control cardiology unit had a better reporting culture at baseline compared with the intervention unit.

With regard to the Neurology Unit, reporting improved significantly in the intervention unit compared to the control unit. There was likely less contamination of the control unit because there was only one intervention unit in the hospital.

Other studies conducted in medical units include that by O'Neil,[51] which has been discussed in section 5.1.8.1.2 and that by Witham et al. [340] Both studies were restricted to reports by medical officers. In the study by Witham et al[340] on a medical unit in Australia, a total of 168 reports were generated over a six-month period. This study was limited by the fact that 85% were made by members of the medical team under the direction of the first author (76% were generated by the first author himself).

5.1.8.3.3. Surgical units

Reporting in surgical units increased by a factor of three in intervention units, while reporting in control units remained largely unaltered. Even though this increase is encouraging, reporting in surgical units remained lower than in all other areas. With a rate at the end of the study of less than seven reports per 100 patient discharges, this was only marginally higher than reporting at baseline in the medical units.

There were only five reports from four doctors in the two surgical intervention units over the forty-week study period, and these were all generated in the metropolitan hospital. When surgeons were interviewed to determine their opinion of the reporting system in the UK, there was widespread apathy towards reporting.[331] The results of this study revealed that, aside from GPs, this group were the most reluctant reporters.

With regard to rural surgical units; there were only two surgeons regularly attending patients in the hospital. Visiting surgeons attending the hospital were not included in the intervention because there were many of them, they only stayed for a short period of time and handed information over to either the local surgeons or GP, and many were working in control units in the metropolitan hospitals. It was felt that, if local GPs and surgeons were educated, they could report incidents on the surgical intervention unit. Reasons for lack of uptake by GPs have been discussed.

A number of studies have been conducted to identify adverse event rates and reporting rates in the surgical patient population, with most focussing on only serious surgical adverse events.[95 169 341] In our study there were seven reports per 100 patient discharges. This is considerably lower than the adverse event rate detected by other studies in surgical patient populations.

A major tertiary hospital in Australia[95] detected that nearly 17% of patients undergoing surgery and staying for longer than 48 hours in hospital suffered a serious adverse event; defined as an acute myocardial infarction, pulmonary embolus, pulmonary oedema, unscheduled tracheostomy, respiratory failure, cardiac arrest, cerebrovascular accident, severe sepsis, acute renal failure, emergency admission to an ICU or death. Another study identified that 14% of patients undergoing lower extremity bypass grafting and 19% of patients undergoing abdominal aneurysm repair suffered serious adverse events.[341] Medical record review undertaken for the Quality in Australia Health Care Study (QAHCS).[20] identified that 14% of patients admitted under general surgical units suffered an adverse event.

A reporting rate of 32 reports per 100 patient discharges was achieved by surgeons and surgical residents in a US study by Marang-van de Mheen et al.[169] The high reporting rate may have been due to the over-representation of high risk patients in the study population, the fact that data were collected and managed by the doctors, or the fact that there was a long-standing history of having weekly audits undertaken to assess whether incident reports had been completed. There are many aspects to Marang-van de Mheen's[169] study which we attempted to incorporate into this study. However there were crucial elements missing in our study; it was not owned by the surgeons, meetings were held three monthly not fortnightly and there was no reporting culture prior to commencement of the study

While reporting rates trebled in intervention units during the study period, it is evident from examining the literature that our study did not capture many adverse events occurring in surgical patients.

5.1.8.3.4. Emergency Departments

Incident reporting in the Emergency Departments increased significantly in the intervention units compared to control units. An additional 39 reports were generated per 10,000 ED attendances in intervention units over the study period compared to control units. Reporting increased more than seven-fold in intervention units, to a rate of 46 reports per 10,000 ED attendances. The reporting rate in control units remained constant at 22 reports per 10,000 ED attendances during both the baseline and the study period.

More reports were generated in the ED by doctors than in any of the other intervention units. Approximately forty percent of doctor-initiated reports were generated by doctors working in a metropolitan ED intervention unit. In this ED, 29% of all reports were generated by doctors.

There were several possible reasons for this:

1. **A greater presence by the project team in the hospital/department:** The ED was situated in the hospital where the metropolitan study Project Officers were employed and where the Principal Supervisor and PhD candidate were based.

2. **Reporting by a few dedicated staff:** There were a few enthusiastic reporters in the ED. The twenty three reports by medical staff during the study period were by only eight enthusiastic doctors (Table 4-18).

3. **Effective feedback:** There were more meetings for doctors and meetings were of longer duration in the metropolitan ED than other areas. A total of six meetings were held for medical staff during the study period, each lasting approximately 30 minutes. This equated to a meeting every six weeks.

   Meetings were held in the afternoon and were informal in nature. The PhD candidate and Head of Unit discussed incidents with staff in an atmosphere which encouraged participation. This was not the case in other intervention units.

   Feedback to medical staff in the ED was more relevant to doctors in this area, because it related to incidents identified and reported by them. In other areas where medical reports were scarce, the PhD candidate outlined outcomes arising from reports in other areas (usually the ED) during the study period. Even though it is likely that most of the types of errors reported in the ED could also potentially occur in the inpatient setting, it may be that they were not seen as relevant to doctors in these areas

4. **Support by senior staff:** The Medical Head of the ED was a clinical champion. He attended the two day Root Cause Analysis workshop (see section 3.6.8.1), regularly accessed the database to generate reports which he presented at departmental meetings, and actively encouraged staff to report incidents. This was in contrast to other intervention units. Only three out of the six Medical heads in metropolitan hospitals attended the Root Cause Analysis, and no GPs attended. No other Medical Head directly accessed the AIMS database to enter comments or generate reports. While these two activities are unlikely to directly result in more incidents being generated, it does suggest a level of commitment and enthusiasm not seen in other areas. A UK study identified that leaders who use the reporting system in clinical areas were more likely than those not using it to believe it is worthwhile and a valuable part of improving patient care.[146]

Despite improved reporting in EDs by doctors during the study period (Table 4-24), reporting did not improve significantly for nurses. The overall reporting rate was significantly lower than that achieved by Fordyce et al in the US,[49] where a rate of 1808 reports per 10,000 ED attendances was achieved. Reasons for the 39 times greater reporting rate obtained by Fordyce et al, include the fact that intense solicitation of reporting was undertaken by researchers. Staff were observed throughout a one-week period by researchers. The staff were interviewed every three to four hours to obtain information about errors in patient care. In addition to this, researchers were available to assist and educate staff about errors 24 hours a day for the period of the study. The study by Fordyce would be very difficult to sustain because of the cost involved in having a researcher in the department at all times.

A study by Sucov et al[63] in a US trauma ED investigated whether a voluntary, anonymous reporting system was more effective than their hospital's traditional reporting system in identifying adverse incidents by doctors and nurses. They identified a rate of 43 reports per 10,000 ED attendances when anonymous reporting was introduced, a rate equivalent to that achieved in this study. However, whereas this study was conducted over a nine-month period, Sucov et al reported results over a three-month period.

Results from the ED intervention units demonstrated that it is possible to make a considerable contribution to improving incident reporting by doctors. It provided the most encouraging results amongst doctors seen in this study.

5.1.8.4. Section 4: Reporting rates by process used to lodge a report

5.1.8.4.1. Call Centre reports

With regard to the different methods for reporting incidents, we found that the call centre was used to report 21% of all reports, and that it was as popular among doctors as nurses. The call centre was not used extensively in rural hospitals compared to metropolitan hospitals (5% vs. 32% of all reports). This was in spite of the finding in the end of study staff survey which showed that there were equal numbers of staff in both hospitals who felt that there was an appropriate place in their workplace to phone through a report. The call centre was used in the ED on less than 3% of occasions.

Of interest was the finding that more than 20% of all calls lodged via the call centre were reported anonymously. Staff were three times more likely to use the call centre to report behaviour or human performance- related incidents compared with a written report form, but were half as likely to use it to report documentation-related incidents (Appendix 29).

The completeness of the data collected using the call centre was much higher than that collected using the single page report form, largely because call centre nurses prompted reporters to answer all questions and consider factors which may have contributed to the event. This was of particular relevance for anonymous reports, for which there was no ability to collect additional information later.

The length of time required to lodge a report through the call centre increased over the study period from under eight minutes to nearly 12 minutes, largely as a result of changes to the configuration of the database. This occurred when it became necessary to merge the database developed specifically for the project for its minimalist approach to collecting data to a Statewide database which contained more fields (Appendix 22). We found only one other study in which the time taken to lodge a report was documented. In the study of a US web-based reporting process, the average time to complete a report was nine minutes, which the authors felt was a short amount of time.[168]

In attempting to understand why rural hospitals rarely used the call centre a number of reasons are suggested:

1. **Directed not to use call centre:** In discussion with staff in the rural ED, the Project Officer determined that nursing staff had been given a directive from a senior staff member in the ED not to use the telephone to report. It was felt that, to the patients and their relatives in cubicles within sight of the telephone, nurses were not busy when they were talking on the telephone. In contrast, filling out forms gave the impression that they were busy. Had there been a telephone in the ED which was not visible to patients and relatives in cubicles, this may have made it more acceptable. However, moving out of the view of patients could be potentially dangerous, particularly in rural EDs where there are only a few staff on duty at any one time.
2. **Poor service:** In discussion with staff in the rural medical intervention unit, the Project Officer identified that a few staff members had been required to "hold" on the phone for a protracted period of time during the initial few weeks of the project when the call centre had just begun taking calls. Despite repeated requests by the Project Officer for staff in rural hospital to use the call centre following further training of call centre operators, the bad experience at the start appeared to stifle any further attempts to motivate reporting.

We decided to use call centre nurses because it was thought to address many of the barriers identified in the staff survey; notably the lack of time, the lack of knowledge regarding the

paper-based process, the immediacy of the process, and its accessibility for busy doctors. When it was developed it was anticipated that it would be attractive to doctors who used mobile phones extensively, particularly while travelling in the car.

The time it took to lodge a report was of concern to the project team, and this was reflected when ascertaining the views of users of the system. When asked in the end of study survey about the time it took to lodge a report, 39% of staff who used the call centre felt that it took too long. Discussion with call centre registered nurses determined that on many occasions, despite attempting to shorten the call, it was the caller who wanted to take a long time to report the incident. Many call centre nurses felt that reporters used the call centre to debrief following an incident.

Education of call centre nurses focused on the importance of remaining impartial when taking a report, and not being judgmental. When surveyed at the completion of the study 78% of reporters felt the call centre nurse remained objective, however subgroup analysis by profession identified that only 55% of doctors felt the nurse remained objective. Reasons for the difference in how the call centre nurse was perceived by doctors and nurses were not addressed in the staff survey. It may be that the call centre nurses treated doctors differently, or that doctors were more sensitive than nurses to being asked questions about the event. It might also reflect the gender of the reporter, but because this information was not captured, this can only be postulated.

The use of call centres for reporting incidents from hospitalised patients is a new domain. While there has been an example of call centre technology used in the primary care setting in the US, no other studies could be found where it had been used for routine reporting of adverse incidents in hospitalised patients. Section 2.9.1.3 identifies areas in the wider healthcare setting where call centre technology has been used to enhance patient safety.

In a US study aimed at improving incident reporting in primary practice,[54] only nine percent of reports were lodged through a call centre. The majority of reports were made using paper-based reports. As with our telephone reporting system, the US study used a toll-free telephone hotline, however it was not possible to ascertain whether the call was taken by a registered nurse, clerical staff or by a computer assisted telephone interviewing (CATI) service and whether the service operated 24 hours a day, seven days a week.

It is not possible to explain why our telephone service received more reports than the one established in primary practice in the US. We chose not to use CATI because previous

statistics from the call centre and from other services (Life Line and Youth Crisis Line) had revealed a high drop-out rate when the call was not answered by a person.[280]

5.1.8.4.2. Paper report forms

The vast majority of reports were submitted on paper forms. Unlike traditional report forms, we developed a single page form to reduce the burden on reporters. The single page form was used almost exclusively in the ED and in rural hospitals, accounting for 97% and 95% of all reports submitted. Other than the form being shorter, the major difference between the traditional AIMS form and this report form was the removal of the area for doctors to write a comment on the report. This meant that nurses and other staff could report incidents relating to patients without knowledge of the report being written by the doctor treating the patient.

A concern when the shorter form was introduced was that it would not provide enough information to enable meaningful follow-up of the event, and that there would be insufficient information collected to enable classification of events. The finding that over the study period the NUMs became increasingly supportive of the shorter forms and found that enough information was available in most instances to enable investigation of the event provides reassurance that shorter forms are a viable alternative to the longer ones traditionally used.

The majority of staff using the shorter forms also preferred them to traditional forms, with 60% of doctors and 85% of nurses agreeing with the statement "I prefer the one-page IRIS form to the 4 page AIMS form". Only 25% of staff felt that there was insufficient room to write all they wanted to report. As mentioned in section 5.1.8.3.1, despite widespread acceptance of the shorter form, ICU staff were less supportive of the shorter form compared with other units.

Variation in the reporting process used by intervention units, such that paper-based forms were sent to the Quality Department in the hospitals prior to being seen by the NUM, appeared to work well. The NUMs were informed through other channels of communication such as at handover rounds. The Patient Safety Managers found this system much better in informing them of events that had occurred in the hospital. Whereas in the past, some events would be identified by the Patient Safety Manager up to six months after the event, with this system they usually found out about them within 48 hours. The increase in anonymous reports in conjunction with increased timely awareness of events provides

real incentives to altering the reporting process currently in place in hospitals using the AIMS reporting system.

There does not seem to be legitimate reason for not having reports sent directly to the Quality Department for entry into the database. The only consideration needs to be to ensure that reports are entered into the database in a timely manner. This requires provision of adequate human resources.

The methods used by hospitals to process incident reports vary. Some have reports sent to the line manager in the first instance,[332] others have centralised collection, entry and management of incidents within hospital or healthcare organisations[48 53 54 143 168 342] and yet others are managed outside their organisation by members of a professional body[43 55 147 343] or by an independent entity.[47 185] Many reporting systems described in the literature are established and managed within individual departments, usually by medical staff.[49 151 169] Khare[344] described a reporting system which was strictly maintained within an individual department by an authorised, dedicated team. All identifying information was removed from the database and feedback was provided to the reporter only by a member of this team.

5.1.8.4.3. Online reporting

Online reporting was implemented in only one clinical area, because of the infrastructure required to set it up. Despite having computers available at each bedside it was poorly used in this area. Potential reasons why online reporting was not well accepted by staff are:

1. **It required staff to use a customised login name and password**: The use of passwords to access a multitude of systems (eg e-mail systems, voice mail systems, networks, corporate and human resources systems, academic journal Web sites) is well recognised as a source of frustration to many people.[345] When investigating methods used to make a report in the end of study staff survey, three quarters of staff who attempted to use online reporting could not easily remember their personal identification number. If generic access were provided, it may have been better accepted.
2. **Interface design**: The way in which the database was designed might have deterred staff from using the online system. Only 42% of staff felt that the online form looked easy to complete. The online form was presented on a grey background with many drop-down boxes. There were two sides to the screen; the left side enabled a narrative to be written, while the right side asked a multitude of questions related to the specific types of incidents reported. Others have commented that on-line reporting processes are off-putting to staff, because they can be difficult to navigate and enter information.[43 224]

The use of pull down menus can be time consuming and, unlike paper forms, if mistakes are made on web-based forms they are often difficult to rectify.

3. **Staff tried to access the wrong database:** The configuration of the database may have confused staff. There were two forms in the AIMS database; one used for this intervention and another form which was being developed for another project. Staff may have inadvertently tried to access the other database and been prohibited. On a few occasions when Project Officers tested the database on terminals within the ICU, the database had been defaulted to the other database.

4. **Slow dissemination of new technology:** Staff were familiar with the paper-based reporting system. They may have felt less threatened using the system they knew, rather than a new and unfamiliar system which required some effort to access. Healthcare is often slow to achieve uptake and acceptance of new technologies and treatments.[209 286]

5. **Time consuming:** Online reporting offered no incentives to staff and likely took considerably longer than a single page form. While it meant that information from a form did not need to be transcribed by a coder and that reports could be accessed quicker by their line manager, which theoretically could have led to quicker action and reduced turn-around time for feedback, these advantages were not immediately obvious to the reporter.

An advantage of on-line reporting is that it reaches the line managers and/or PSM quicker than a paper-based system. It also removes the need for clerical entry of paper-based reports and increases overall security and integrity of data. Where on-line reporting has been adopted successfully it is generally in an environment where staff did not have diversity of reporting options.[61 168 344] When staff were given the option of reporting on-line, by paper or by telephone in a US study,[54] they, like us, found paper reporting to be the most popular method.

In reviewing the methods by which reporters lodge reports, it is clear that it is preferable to provide staff with choices. The call centre offers the ability to collect a more complete dataset; however, its poor uptake in rural areas and EDs is a reason why it should not be implemented exclusively. The single page report form was generally well accepted as was the change to the way in which reports were processed as part of this intervention. These are important findings which will assist in determining future reporting structures and processes for incident reporting in South Australia.

5.1.9. To change types of incidents reported (aim 4.2)

We set out to diversify the types of incidents reported. To determine changes in types of incidents reported, AIMS data from the baseline period was compared with AIMS data collected during the study period. To understand why changes occurred, the data will be discussed in conjunction with the end of study staff survey results, in which questions were asked about various components of the intervention. The fact that there were fifteen incident types meant that the sample size was too small to monitor changes in each incident type at departmental level.

This study employed strategies such as educating staff, promoting anonymous reporting, making available an aide memoire, developing promotional posters outlining incident types and providing feedback to staff to diversify reports submitted by doctors and nurses (see sections 3.6.9 and 3.6.10). One of the most significant outcomes of the study was the change in reporting of some incident types during the study period (see pie chart- Figure 4-8). However, while it was successful in changing some types of incidents reported, it had little impact on others. It is not possible to determine with certainty which strategies used to encourage reporting were most successful. However, responses to the staff survey provide some clues.

The newsletter, which was intended to provide examples of types of incidents to be reported, especially for those unable to attend handovers and departmental meetings, was not recalled to have been seen by almost half of the nurses and two thirds of all doctors, obviously impacting on its influence in changing reporting practices.

In the intervention ICUs, seventy percent of staff stated that they had received not enough or no outcomes arising from reports. Yet, in this area, the intervention saw clinical management incidents increase by a factor of three, and falls decease by half over the study period compared to baseline.

The following reasons are put forward to explain why reports changed in an environment where many staff had little exposure to the intervention:

1. **Reporting by a few dedicated staff:** It may be that those who were exposed to the project were responsible for generating the majority of the reports.
2. **Other strategies employed:** It may be that staff were educated about types of incidents to be reported in ways other than by feedback and the newsletters. For example, in the ICU staff were provided with "cheat sheets" which they attached to the back of their ID

labels (Appendix 26). We did not ask staff at the end of the study period how helpful these were in changing types of incidents reported. Staff may also have been educated by peers, rather than Project Officers.

3. **Other quality activities impacted on reporting rate:** It may be that activities other than those in our project were responsible for changing types of incidents reported in ICU.

The new and varied types of incidents reported resulted in some very meaningful changes to hospital processes and environment. A few of the changes are outlined in the newsletters attached as Appendix 27. Different types of incidents will be discussed below.

5.1.9.1.1. Falls

Overall, the percentage of all incidents reported that were related to falls decreased from 36 to 24% of all reports in the intervention units during the study period, whereas reports increased from 40 to 48% of all reports in control units (Table 4-28). In both the control and intervention units, the number of fall-related reports doubled during the study period. Most fall-related incidents were reported in the medical units and few falls were reported in the ICU.

The rise in falls-related incident reports during the study period was not anticipated, as it was generally felt that this was already well reported at baseline. At baseline, the staff survey indicated that 96% of nurses and 59% of doctors felt that they reported patient falls on 50% or more of occasions. These results suggested a strong reporting culture. Runciman[9] highlighted this when comparing falls identified in incident reports compared to those identified in medical record review. Medical record review identified that less than 2% of injuries in hospitalised patients were as a result of patient falls; however, these represented nearly 40% of all incidents reported into the AIMS system. The increase in falls-related reports is likely to be as a result of increased recognition and reporting, and not the fact that more falls were occurring during this 40 week study period.

With regard to our finding that there were more falls-related incidents in medical wards, other studies have demonstrated that incidents reported often reflect the environment in which they are being implemented. For example, reports generated in mental health units predominantly reflect aggression-related incidents[148] and in general practice reports often reflect complications of treatment,[122] medication errors,[55 124] and communication issues.[54 125] Anaesthetic and intensive care reporting systems focus largely on equipment,[144 146]

medication errors[143-145 151 153] and delays or omission of treatment.[43 143] Reports generated from EDs often reflect communication issues and administrative procedures.[49]

The doubling of falls-related incidents in the control units is difficult to explain, as there did not appear to be any targeted hospital-wide strategies for falls reporting during the study period in the control unit. In addition to the likelihood of contamination, it may have been due to the fact that a number of wards were relocated during the intervention period. Three control units and two intervention units relocated. A change in physical environment such as change in floor surface, lighting or drainage in bathrooms may have resulted in more falls compared to baseline. Staff may have been more likely to critique a new environment and report issues.

The proportion of all reports related to falls that we identified at baseline (38% of all reports) was similar to that of Wolff,[161] who determined that 45% of all clinical incidents in his hospital reporting system were related to falls.

The increase in reporting of falls-related incidents raises questions about the usefulness of acquiring this information. If falls reporting data was considered a valid and reliable epidemiological tool capable of monitoring trends in types of incidents, then improved capture of these events is helpful when assessing the effectiveness of preventive strategies. On the other hand, given that it is not a good tool for reasons outlined in section 2.8.2, there may be little point in collecting more data on causation and prevention when there is already a large body of work in this area.[346-348] A more efficient and effective use of time for staff may be to report incidents for which little is known about causation and prevention.

In our study, falls data were used both to provide evidence in support of the introduction of preventive strategies and in assessing the impact of strategies introduced. In this way it was used as an epidemiological tool.

Increased reporting of falls in intervention units may have resulted from:

1. **Increased recognition of the consequences of falls:** Among the 304 falls reported in intervention units were two patients who sustained a fractured neck of femur directly resulting from a fall in hospital, and one subdural haematoma which resulted in patient death. When this data were presented to staff in departmental meetings and handover sessions, staff stated on many occasions that they were surprised at both the frequency and severity of many of the falls reported.
2. **Recognition of the need to assess strategies being introduced to reduce falls:** Staff were informed of the need to understand whether strategies were increasing or

decreasing risk of falls. Because no routinely collected data were available to assess this, staff were asked to be vigilant in their reporting of falls.

5.1.9.1.2. Medication

The actual number of incident reports related to medication errors increased in intervention units from 113 to 356 and in control units from 80 to 138 reports (Table 4-28). However, proportionate to all reports submitted, medication reports in both intervention and control units increased by only one percent at the conclusion of the study.

The types of incidents reported at baseline in our study were similar to those published in the literature. The percentage of reports relating to medication was higher at baseline in our study than that in Wolff's (26% vs. 15%) but comparable with the range of 20% to 26% identified in an ICU study[143] and a study in general practice.[54] Incident reporting will not capture the majority of medication errors. This has been discussed in section 5.1.6.

While it is important to recognise the shortfalls of incident reporting in being a data collection tool for medication errors, it should also be noted that in our study it did detect some important issues which led to change in practice. By involving the pharmacist in assessing and determining action following medication reports, some of the changes made included the stocking of recombinant tissue plasminogen activator (rtPA) in the ED for use on patients who had suffered a stroke, the introduction of individual patient supply across a hospital, the removal of certain medications from ward imprest stores, redesign of the intravenous medication chart, and improving standard orders for patients in rural hospitals undergoing bowel preparation prior to endoscopy. Many of the incidents identified in this study relating to medication errors had not previously been bought to the attention of the pharmacist and these problems were not subsequently reported during the study period following action being taken.

In intervention units, the study improved reporting of medication errors, even though staff felt they reported less compared with baseline. Strategies such as involving the clinical pharmacist in reviewing all medication errors should be introduced as standard practice as this resulted in many changes at departmental level in intervention units.

5.1.9.1.3. Documentation

The number of reports principally related to documentation issues increased in the intervention units from 19 to 146 reports while in control units it increased from 9 to 16 reports. Nearly half of all documentation incidents during the study period in intervention units related to incorrect labelling of pathology results in an ED, with other incidents

relating to illegible handwriting, absence of necessary documents, transcription errors, and documents being unavailable.

In the staff survey, because we only looked at patient injuries we did not ascertain from staff how often they reported documentation incidents and how often they thought they ought to be reported as we did for medication errors and patient falls. Therefore, we cannot assess attitude change over time.

Documentation incidents occur frequently in healthcare and are responsible for many errors. The impact of documentation errors on patient outcomes is however, largely unknown.[349] Incident reporting provides valuable information about contributing factors related to documentation errors because this information is rarely captured elsewhere. A study by Fordyce et al[49] in the ED determined that poor documentation contributed to 13% of errors; a rate similar to the 11% identified in this study.

The impact of having more documentation-related events was that a number of changes were made. The number of reports relating to poor labelling of blood specimens resulted in improved access to patient identification labels in the ED and standardised practices being introduced to ensure that the risk of blood being sent off with no or inadequate labelling was reduced. Ongoing audit will assess the impact of these changes. Documentation errors relating to intravenous medications resulted in a new IV medication chart being developed which included clear directions for two signatures next to each order.

5.1.9.1.4. Clinical management

Clinical management refers to the way in which clinical work is coordinated and carried out in hospitals. Incidents relating to clinical management may involve (a) aspects of care not done, delayed, incorrect or inadequate; (b) procedure or operation on a wrong body part or site, (c) unnecessary assessment, test or procedure; or (d) non-adherence to rules, policy, or procedure. The number of reports classified as having a principal incident type of clinical management increased in intervention units from 34 to 146 reports while in the control units it increased from 24 to 29 reports.

Clinical management incidents were reported more than any other incident types by doctors during the study period. Most clinical management incidents related to poor communication between staff members. Incidents relating to clinical management involved such events as poor scheduling of operating time relating to the management of an MRSA colonised patient, the lack of coordination when transferring a patient, inadequate information prior to

a procedure, and inadequate infection control precautions in a surgical unit. Most clinical management incidents in intervention units were reported in the metropolitan ICU.

As with documentation incidents, clinical management incidents cannot be routinely collected from another source. They are often complex in nature and as the examples above indicate, they often involve implicating individuals although systems problems may be the real cause. The sample size was not big enough to determine whether clinical management incidents were more likely to be reported anonymously. To provide more power to the analysis, we sub-divided the PITs into two groups:

- Group 1 contained PITs which were more likely to reflect subjective inter-personal issues- clinical management, organisational management and behaviour/human performance incident types.
- Group 2 contained PITs which were more likely to reflect objective outcomes- falls, medication incidents, documentation, accidents, medical device and equipment.

Appendix 29 shows that there was a tendency for staff to use anonymous reporting option more for group1 incidents than group 2 incidents, however this did not reach statistical significance.

Unlike our findings, a study comparing anonymous and confidential reports submitted to an outside third party identified that no particular types of events were reported more or less frequently by anonymous reports.[54] This suggests that staff in our study chose to report anonymously because they did not want it to go to their line manager.

When incident types were independently categorised by two independent coders, clinical management incidents were not consistently coded on nearly 50% of occasions. Because of the multi-factorial elements of many reports, it was often difficult to know whether clinical management should be the principal or secondary incident type. There were many more reports generated by intervention units during the study period for which clinical management was implicated, but this is not reflected in our statistics which only report principal incident types.

Communication errors, which underpin most clinical management incidents, contribute to approximately 65% of the adverse events which result in serious outcomes in health care[174, 177] and are the most common cause of preventable disability or death according to results of the Quality in Australian Health Care Study.[20] They often provide greater insight into the vulnerabilities of a hospital than other types of incidents, because they often involve system

failures. It was encouraging to see these types of incidents reported by both doctors and nurses.

5.1.9.1.5. Other incident types

Incident related to falls, medication, documentation and clinical management accounted for 75% of all incidents lodged during the study period in the intervention units and 82% of all incidents lodged in control units. Other important incident types included medical devices and equipment and accidents/occupational health and safety events, which each accounted for a further 5% of the incidents reported in both intervention and control units. In control units during the study period 6% of reports related to organisational management, which was higher than the 3% recorded in intervention units.

A change in types of incidents reported during the study period enabled many errors previously not widely recognised to be identified. More importantly, these errors led to a number of changes being made in hospitals. Faulty electrocardiograph machines were replaced, out of office hours security arrangements were modified, and labelling of intravenous lines with stickers was introduced.

Despite encouraging a diversity of reports, the intervention was not successful in improving the reporting of pressure ulcers, infections, and nutrition-related incidents. The following explanations may account for the lack of ability to improve reporting of pressure ulcers, infections and nutrition-related incidents:

1. **Incidents detected over a period of time:** Incidents which are immediate, dramatic, often witnessed and habitually reported are better reported than incidents which occurred gradually and are often not attributable to a single event, or regarded not so much as incidents as complications of prolonged hospitalisation.[9] One reason for this practice is outlined in the work of Charles Perrow, a sociologist who has written extensively on why incidents and accidents occur in high risk industries, and how organisations can be designed to prevent them.[350] Many errors in healthcare are complex in nature, due largely to the patient's disease and the number and diversity of healthcare professionals working with the patient while they are hospitalised[351] When incidents evolve gradually, it is not surprising that each member of the healthcare team looking after the patient assumes that somebody else has reported the incident.
2. **Duplication of effort:** It may be that reporters believe this information is already captured elsewhere, and that to write an incident report would duplicate data and

increase workload. At the time that this intervention was undertaken, a number of other projects were occurring to address pressure ulcers in hospitals throughout South Australia. A point prevalence study on pressure ulcers was performed during the study period, and mattresses on beds were being upgraded as part of a statewide initiative. With regard to infection-related reports, there are a number of other processes to capture information about infections already available, including microbiology culture results and through a patient care management system which is used in public hospitals throughout South Australia (Exelcare).[352] The incident reports received from intervention units during the study period relating to infection related to cross transmission of head lice and scabies. This information is less likely to be captured through existing systems.

3. **Not habitual:** As mentioned in Triandis' Theory of Social Behaviour, habit is the most important predictor of behaviour.[271] Staff may be more likely to habitually report falls and some medication incidents compared with pressure ulcers and infections. A study by Benbow et al[353] investigating the accuracy of incident reporting data relating to pressure ulcers found that pressure ulcers were more likely to be reported in medical and orthopaedic wards than surgical and rehabilitation wards, indicating that in some areas they are more habitually reported.

Even though the number of reports increased in the control unit during the study period by sixty percent, proportionately the types of incidents reported altered very little. A literature review has revealed one other study where changes in incident reports were demonstrated following an intervention.[61] This study involved the introduction of a web-based reporting system and was conducted over a three month period in a US hospital. Incidents reported online during the study period (January to March 2002) were compared with paper-based incident reports generated in the previous year (January to March 2001). Kivlahan et al's study[61] identified that reporting of incident types changed marginally, with a decline in fall-related reports (15% to 9% of all reports) and medication incidents (36% to 26% of all reports) with an increase in equipment-related reports (4% to 6%), therapeutics/diagnostic reports (6% to 11%) and miscellaneous reports (39% to 47%).

Comparing the results of Kivlahan et al's study to ours, it can be seen that in our study in intervention units we had a much higher proportion of reports relating to falls at baseline than at the end of the study (36.1% to 23.8%), but lower rates relating to medication incidents (26.8% to 27.9%). As with Kivlahan et al's study, our study also saw a decline in medical device related incidents during the study period (6.9% to 4.8%). Other categories

reviewed by Kivlahan are not comparable with any used in our study. Kivlahan et al's study involved reporting by a wider range of people and there is no sub-group analysis by reporter designation. Additionally, there was no mention in the article of how incidents were classified and so it is difficult to interpret these findings.

5.1.9.2. Limitations in addressing aim 4 (to improve the reporting rate and change the types of incidents reported)

In addressing aim 4 of the study; to increase the reporting rate and change the types of incidents reported, a number of limitations must be considered when interpreting the results.

With regard to the increase in reporting:

1. **Contamination**: There was likely contamination of the control units by staff who had been exposed to the intervention. As discussed previously, this would serve to reduce the impact of the study in improving reporting rates in intervention units. In addition to the intervention, there were also a number of activities being implemented in South Australia at the time of the study, which would likely have impacted on reporting rates in control units. These included three Root Cause Analysis workshops and preliminary work towards the rollout of a statewide reporting system.

2. **Non-random study design:** The fact that we did not randomly assign departments to control and intervention groups increases the likelihood that we have introduced selection bias. Baseline comparisons of groups show that there was heterogeneity in reporting among control and intervention groups. However, we have no reason to suspect that the design of the study would favour reporting more in one unit than another. Departments in the study were matched in a stratified sampling frame to make the study more rigorous. Had we randomly allocated units, it is likely that contamination would have resulted in poor quality results. This is discussed in section 3.6.4.1 of the Methods section.

3. **Limited ability to promote the project:** We were unable to widely promote various aspects of the intervention such as the call centre, because of recognition that this might introduce contamination into control units. If the call centre was implemented throughout the hospital, a wider education and promotional campaign would have been undertaken and this may have had an impact on uptake of reporting.

4. **Limited resources to establish call centre:** When we introduced the Call Centre, we had few resources to train call centre nurses. With the benefit of hindsight, more preparation time should have been spent providing nurses with simulated incidents to improve skills. Had we had a more concentrated and rigorous training schedule, we may not have experienced the problems faced in the rural medical intervention unit. Future dissemination of the call centre option for reporting in other South Australian hospitals would likely be easier, as the groundwork has been laid for education of call centre operators.

5. **Limited time to achieve change:** This intervention was assessed over a 40 week period. Reporting rates in Appendix 28 indicated that reporting was still trending upwards in some intervention units. Many changes in healthcare, particularly those requiring culture changes, take time to be incorporated into routine practice. Had the intervention run for a longer time period, we may have seen even greater improvement in reporting.

6. **Inability to access anonymous reports sent to the APSF:** Incidents written anonymously at baseline and in control units during the study period were either sent to the NUM or were sent directly to the APSF. The baseline staff survey identified that less than two percent of staff from intervention and control units had ever made an anonymous report directly to the APSF. It was therefore likely that during this study few reports were submitted anonymously to the APSF, and that if anonymous reports were made to the APSF, this would have occurred in both intervention and control units. However, caution should be used when interpreting anonymous reporting data because we do not know the actual number of anonymous reports sent from either the control or intervention units at baseline and during the study period.

With regard to limitations in types of incidents reported, the following aspects of the study design should be considered:

1. **Non-blinding of coder in one hospital:** To compare baseline incident types with those identified during the study we used independent coders who were blinded to whether the report was generated by control or intervention units during the baseline or study period for most clinical areas (see section 4.6.8.2). Unfortunately, for one hospital it was not possible to independently classify incidents using the form itself, because permission was not granted for the form to leave the hospital. In this case, the coder was provided with incident details over the telephone and asked to classify the incident. Although this technique was different to that undertaken in other

hospitals, it would have been unlikely to have resulted in different categorisation of incident data.

2. **Inadequate sample size to do effective sub-group analysis**: Given that there were fifteen incidents types, it was not possible to do subgroup analysis on many of the incident types because they were reported infrequently.

5.1.9.3. Significance of the findings with regard to aim 4 (to improve reporting rates and change the types of incidents reported)

Our study has demonstrated that it is possible to improve reporting rates by making changes to the way in which reports are completed and processed, educating staff about the ability to report anonymously and ensuring that feedback is given. However, it also demonstrates that this is not always successful; ICU appears to be the most difficult area to infiltrate and some doctors (particularly GPs) did not support the study.

By comparing the approach taken in this study with other successful incident reporting studies and by comparing units within the study which reported well with those that did not, a number of key findings have been identified:

Finding 1: Incident reporting during the study period increased in inpatient areas from 83 to 190 reports per 10,000 OBD in intervention units, and from 54 to 101 reports per 10,000 OBD in control units. Reporting in the ED stayed constant in the control units at 22 reports per 10,000 ED attendances but increased from 6 to 46 reports per 10,000 ED attendances in intervention units. In the intervention units there were an additional 854 incidents reported during the forty week study period compared with baseline while in control units there were an additional 220 reports submitted during the study period compared with baseline.

Finding 2: Reporting rates improved and were sustained over the study period in most intervention units. Most other studies aimed at improving reporting were conducted over a shorter study period.

Finding 3: There was heterogeneity in reporting in intervention units at the end of study period, with some units reporting in excess of 400 reports per 10,000 occupied bed days and others reporting less than 100 reports per 10,000 occupied bed days.

Finding 4: Reasons for increased reporting by staff incontrol units during the study period might include contamination by staff working in the intervention units, and the fact that other quality and safety activities were occurring at the same time as this study.

Finding 5: It is difficult to compare reporting rates obtained in this study with rates obtained by others for a number of reasons: the lack of a consistent outcome being measured, the lack of standard definitions even when the same outcome is being measured, the different patient population and target group being studied, and differences in the length of time of the intervention. It was not possible to know what the underlying incidence of adverse incidents was in study areas.

Finding 6: It was difficult to improve reporting by medical staff. In isolated pockets it worked well, however in most areas there were less than five doctor-initiated reports per department over the study period. This suggests that the way in which the report was presented i.e. on a single page or multiple pages, had little overall impact on whether or not doctors report incidents. The information gleamed from doctors during this intervention showed that it may have been more effective if it was "owned" by doctors, if they were given more constant prompting, if there were stronger clinical champions working in the departments and if reports had gone to the professional College of the reporter, rather than the hospital.

Finding 7: In spite of the effort made to entice GPs to attend education sessions and participate in the project, this was not forthcoming. Some strategies employed included having members of the project team individually visit GPs to explain the project, and offer professional incentives to attend a workshop and departmental meetings. These made little impact. The intervention may have been more effective had GPs been consulted regarding the project design and if reports were sent to their professional Colleges.

Finding 8: It was difficult for project staff to present feedback and education to medical staff. Despite being given assurances that this would occur on a three-monthly basis, in some units we were not provided with the time to do so. In areas where feedback occurred more often and meetings were of a longer duration, there appeared to be a greater reporting culture among medical staff. Unlike other studies, incident reporting in our study was not incorporated into daily clinical practice. Staff were not reminded to report at morning rounds and Project Officers were not part of the teams.

Finding 9: Nurses contributed to 73% of all incidents reported in intervention units during the study period. This compares with 88% of all reports generated by nurses in control units during the study period and a baseline of approximately 91% on both control and intervention units.

Finding 10: Reporting did not improve as much in areas where a Project Officer was not based. In these hospitals, Project Officers had limited ability to work with NUMs to action reports in the early stages of the project. It may have been the case that staff felt less comfortable discussing and reporting in a system where reports would be seen by people outside their organisation.

Finding 11: It is possible to improve incident reporting, even in departments with very poor reporting culture at baseline. Reporting increased by doctors most substantially in the ED where baseline reporting was very low. Reasons for improvement may include the fact that the Head of Unit attended the Root Cause Analysis course, had access to the AIMS reporting database, actively discussed incidents in an informal setting on a regular basis with staff and motivated staff to report.

Finding 12: Techniques used in this study in intervention units resulted in significantly more incident reports by allied health professionals. This provides some confidence that the methodology will be transferable and generalisable to other populations. Increased reporting by allied health professionals may have resulted from their exposure to the project though departmental meetings, increased prominence of report forms, visual cues to report on telephones, promotional material distributed throughout intervention units, and through being given individual feedback if they reported an incident on intervention units.

Finding 13: Given the two reporting options available to all staff in intervention units, the majority of staff preferred to use the single page form. However, a fifth of all reports were lodged via the call centre and in one department the call centre was used to report 85% of incidents. Staff in rural hospitals rarely used the call centre. These findings reinforce the need to provide choices in methods to report incidents.

Finding 14: In hospitals with more than one intervention unit, anonymous reporting was used significantly more in the study period than in the baseline period. In one hospital one quarter of all reports were submitted anonymously. When reporters identified their profession but not the location of the incident, more doctors reported anonymously than nurses. When comparing the types of incidents reported anonymously, reports implicating the line manager were more likely to be reported anonymously than with identified reports. Anonymous reports were as likely to be reported through the call centre as on a paper form. Reasons for the increase in anonymous reports are likely multi-factorial; bypassing the line manager may have been appealing.

Finding 15: In its current format, it is unlikely that online reporting will be well utilised in large metropolitan ICUs. For it to be used, a number of strategies should be considered; generic logins without need for individual passwords and making the interface generally more user-friendly and robust.

Finding 16: The intervention did result in a change in the types of incidents reported, with proportionately fewer falls, and more documentation and clinical management incidents during the study period. Proportionately more incidents related to documentation were reported on the single page paper forms compared with the call centre (13.1% vs. 4.9% RR=2.7).

Finding 17: Reporting resulted in some important changes to hospital systems.

5.1.9.4. Future research with regard to aim 4 (to improve reporting rates and change the types of incidents reported)

This study has demonstrated that a number of strategies increased reporting and changed the types of incidents reported. Future research should be directed towards:

Undertaking longer term studies: Longer term studies are required to assess sustainability of reporting when the project team is no longer providing assistance to clinical areas. Difficulty lies in maintaining the reporting culture after the project concludes and human resources have been removed. Sustainability of all projects aimed at improving reporting is of paramount importance, and has been shown to be difficult to achieve.[56] This has been highlighted in a study aimed at improving reporting of adverse drug events by doctors.[354] Despite achieving a five-fold increase in reporting of adverse drug events by placing report cards in each patient's chart on admission, having forms available in clinical areas and sending reminders to doctors, when reminders ceased after three months, the reporting also dropped off. Despite maintaining availability of forms, reporting returned to its baseline level at six months.

We were cognisant of the need to provide staff with skills and infrastructure to establish a reporting system, and progressively withdrew Project Officers from offering assistance to NUMs, Heads of Units and Patient Safety Managers. The next phase of evaluation is to assess whether withdrawing Project Officers entirely from assisting in the project impacts on reporting rates and staff's perception of feedback and usefulness of the project in achieving system change. Alternatively, it needs to be considered that having Project Officers assist in the management of incidents needs to be permanently funded as are positions such as infection control consultants. While cost-benefit analysis should be

undertaken, unlike the more defined field of infection control, it is often difficult to assess the financial impact of what might have happened had incidents not been detected and had changes not been made. .

Undertaking hospital-wide studies: There were few anonymous reports submitted in hospitals with only one intervention unit. It would be interesting to see whether the rate of anonymous reporting would increase if the system was adopted throughout the hospital (therefore making it less easy to identify individuals). Also of interest if the system was rolled out hospital-wide is whether there would be less heterogeneity in reporting rates between departments. Consideration would need to be given to ensuring that resources were provided to enable timely entry of incident data into the database and to follow up incidents in a systematic and thorough manner. Using the SAC score to assist in prioritising how quickly reports were seen and feedback was provided appeared to work well.

Further developing telephone-based reporting: Future research is required to investigate how to further improve reporting through the call centre, particularly reducing the time required to submit a report. Our results indicate that staff prefer to use the single page form, however improvements in the capacity of the call centre to take reports quickly and more effectively may see more people using this service. Different strategies for achieving this need to be researched. For example, it may be that only a minimum dataset is obtained for certain types of events or those with little or no outcome. A cognitive engineer or human factors expert might provide important advice in redesigning the screen to assist call centre nurses receive and enter information more effectively. We shortened the disclaimer required to be read out for each report, but ideally, it would be best not to have to read it out to those who make multiple reports. When we sought legal advice on this matter, we were advised that the disclaimer was required to be read out with each report lodged.

Other forms of telephone based reporting should also be considered. The use of telephone reporting using a computer-based voicemail systems has been trialled in Western Australia,[355] however a literature review failed to retrieve any results on its effectiveness in improving incident reporting. It would be interesting to compare types of incidents and costs associated with the establishment and ongoing running of both systems.

Improving useability of online reporting: Online reporting was not well used in our study. Future endeavours to improve online reporting should include ability for staff to access the database without requiring access authorisation. When staff in control units at the end of the study period were asked what innovations would encourage them to report incidents, more than 50% of respondents thought that online reporting would have little or

no impact on whether they would report incidents. Conversely, 90% of staff thought that shortening the form would motivate them to report. In this climate, uptake of online reporting may be difficult to achieve, particularly if staff are given the choice to report using paper forms as well as having the option to report online. As mentioned to improve the call centre, having the interface reviewed by a cognitive engineer or human factors expert might improve useability.

Trialling profession-based reporting in Australian hospitals: With regard to reporting by doctors, it would be interesting to assess if reporting rates would have increased if reports were submitted to professional Colleges rather than to the Safety Unit within each hospital. Future research could involve using techniques employed in this study to increase reporting, (education, call centre, single-page form, online reporting, and feedback) but having reports sent to the College instead of the hospital. Issues such as how hospitals could then obtain vital information to enable them to initiate system changes need to be addressed.

Encouraging ownership by profession: As a means of further encouraging reporting by doctors, discussion of incidents at departmental meeting should be facilitated by staff from within the unit. The use in this study of a person not assigned to the Unit might have contributed to the lack of reports by doctors. As seen in the metropolitan ED, champions from amongst the profession can play a significant role in fostering reporting.

Seeking GP involvement in hospital-based reporting systems: The lack of reporting by rural GPs was disappointing. Although they participated in the staff survey, GPs were not invited to participate in focus groups. Focus groups should be undertaken to determine attitudes towards incident reporting and barriers to reporting so that efforts can be made to ensure that the reporting system is both relevant to and supported by them. This may explain why academic detailing, which has been demonstrated to be effective in changing physician behaviour,[356] had no impact in this population.

Using experts from other industries to encourage reporters at the coalface: It would be interesting to look specifically at the impact that a person external to the organisation undertaking quality activities or providing consultancy to staff at a clinical level would make on changing behaviour towards incident reporting, particularly medical staff. It may be that experts in aviation, nuclear power and aeronautical sciences would have more success in improving reporting by doctors.

Undertaking further work with allied health professionals: This study demonstrated that there were more allied health professional reports during the study period compared to

baseline. Future work might involve determining the needs of this group further to ensure that the reporting processes meets their demands. There is a paucity of information detailing the types of incidents reported by allied health professionals and how these have been used to initiate change in organisations. More needs to be published in this field.

Identifying effective strategies to provide feedback: This study demonstrated that distributing feedback to staff via newsletters likely had limited impact. Newsletters are time consuming to produce and expensive if they are distributed on paper rather than electronically. It would be worthwhile exploring other ways of distributing newsletters and information in general. For example, newsletters may have had greater impact if they were attached to pay slips. Feedback may have been more effective if it was given in a more interactive way as occurred in the ED, rather than in a didactic lecture format. The use of a hand held computer where individual performance is assessed may hold more value to clinicians than contributing to a system which may not be able to be individually responsive to reporting.[238]

Identifying the impact that reporting has on improving patient outcomes: Even though this project has increased the number of incidents reported and has led to a number of Root Cause Analysis and Quality Improvement activities (see some outcomes in the newsletters attached as Appendix 27), it was not within the scope of this project to measure the impact the intervention had on improving patient care. Future research should be directed towards establishing the value of incident reporting on improving patient outcomes.

Further clarifying types of incidents to be reported: The use of a pre-defined list of reportable incidents might be considered for different specialties. For example, a Respiratory Medicine unit might be particularly interested in determining errors resulting from intercostal catheters, while an Orthopaedic Unit might be more concerned about pressure ulcers. The identification of key types of events to report underpins sentinel event registries[177] however by limiting the types of incidents reported to a pre-defined list there is the likelihood that a vast amount of information about errors will not be collected.

The use of reporting prompts, as used in other studies[139] might help to clarify incidents to be reported. For example, this might include having a drop-down list of incident types on the report form as used by others.[45 48 49 139 147] We did not do this because we wanted to keep the report form to a single page in length.

Reporting minimum dataset: It is easy for incidents which occur often, such as falls, to "fall beneath the radar". Capturing this information on incident reports may seem time-

consuming, particularly when the contributing factors are well established. A compromise may be to capture a minimum dataset of information, which is not overly burdensome on the reporter.

Identifying why staff do report: This study focussed on identifying barriers to reporting, and neglected to identify in depth what motivates staff to report. Focus group data provided some clues but this should be further explored.

5.1.10. To improve knowledge of the reporting system (aim 5.1)

In this section, findings from the baseline study and focus groups will be discussed and compared with findings from the end of study survey with respect to the following questions:

- Q1 Does this hospital have a reporting system?
- Q2 Do you know how to make a report?

It was hypothesised that, by addressing barriers to reporting, there would be greater understanding of the reporting system. Because the intervention consisted of reporting using the call centre, a paper form or on-line reporting, at the end of the study staff were asked if they knew how to make a report. At baseline, because only paper forms were used, staff were asked if they knew how to locate or access the incident report form. Both were surrogate markers for being able to report an incident.

Does this hospital have a reporting system?

The intervention made no significant impact in improving awareness of the reporting system. However, baseline knowledge was high with 99% of control unit staff and 98% of intervention unit staff knowing that the hospital had a reporting system.

Do you know how to make a report?

Doctors knowledge of how to make a report increased between baseline and the end of the study period in intervention units and also in control units (control units 42% to 59% vs intervention units 42% to 81%, RR 1.38 95% confidence interval 0.9-2.1) (Table 4-32). While it was encouraging that 81% of doctors at the end of the study in the intervention unit knew how to make a report, nonetheless there were still 19% who, despite education and feedback sessions, did not know how to report incidents.

Staff working in rural intervention hospitals and in surgical intervention departments were significantly more likely at the end of study to know how to report an incident compared with at baseline (Table 4-33).

The reasons why knowledge of how to make a report increased significantly in rural hospitals compared to metropolitan hospitals might be due to:

- **Less transient population:** Rural doctors consisted almost exclusively of GPs, who were less transient that junior doctors in metropolitan hospitals. Compared to metropolitan doctors, it was easier to distribute promotional material to GPs, and it was easier for the Project Officer to meet individually with them.
- **More nurses than doctors in rural hospitals:** Doctors contributed to 26% of responses in metropolitan hospitals and only 15% in rural hospitals. Results may therefore reflect the differences between doctors and nurses.
- **Greater exposure to the study:** Nurses had greater contact with the rural Project Officer in hospital 4 than in any other hospital, largely because of the location of her office within the hospital. The amount of formal education provided to staff in this hospital was comparable to that provided in other hospitals, but there was likely more informal discussion in this hospital. Because of the comparative smaller size of the rural hospitals and the fact that in one hospital the majority of inpatient areas were part of the study (with the exception of the mental health unit and the Women's and Children's Unit), there was likely greater exposure to the project. In contrast, nursing staff in metropolitan hospitals were more likely to have moved through intervention units with little exposure to the project. Programs such as the Graduate Nurse Program mean that in most metropolitan hospitals junior nurses rotate on a six to eight week basis through departments.

In surgical intervention units, staff awareness of how to access or locate a form increased from 75% to 92% during the study. In control units understanding increased only marginally, from 81% to 84%.

Reasons for the significant improvement in understanding of how to report an incident in surgical intervention units include the following:

- **Fewer staff to educate:** There were fewer staff in the surgical units than the medical units (53 vs. 149 staff members), making it easier to disseminate education.

- **Greater exposure to the study:** Surgical intervention units were based in hospitals where a Project Officer was based. In contrast, two medical intervention units were located in hospitals where Project Officers had limited ability to access staff. One metropolitan medical unit only enabled staff to present to medical staff on two occasions throughout the intervention and only for ten minute periods.
- **Higher baseline reporting rate**: Staff in the surgical intervention units were starting from a lower baseline than most units.

Results of the intervention component of the study showed that reporting did improve significantly at the end of the study in surgical units; however the actual reporting rate was less in surgical units than in other types of units at the end of the study (Table 4-22). We found that in areas where significant improvement in knowledge occurred (rural hospitals and surgical units) there was also significant improvement in reporting.

5.1.11. To change views on reporting practices (aim 5.2)

In this section, survey findings from the baseline study will be compared with findings from the end of study survey. To compare reporting practices, the end of study staff survey will be compared with actual reporting data.

We had hypothesized that staff in intervention units would believe they reported more incidents than staff in control units at the end of the study period; however in most cases this did not occur. We also hypothesised that staff in intervention units would believe they should report more incidents than staff in control units at the end of the study period. For most incidents this was also not the case.

5.1.11.1. Comparison of staff who believed they did report incident types on more than 50% of occasions

When asked about incident reports they do report, intervention unit staff at the end of the study period were *less* likely than control unit respondents to report that they do report a medication error that required corrective treatment and problems with machinery resulting in patient harm. The survey identified that intervention unit staff were *more* likely to report when a patient did not receive a necessary treatment or procedure.

The findings of the staff survey did not corroborate with data from the AIMS database, which demonstrated that intervention unit staff reported more incidents than control unit staff in all incident type categories. With regard to problems with machinery, staff in control units reported seven incidents related to medical devices and equipment during the study

period compared to sixty one reports submitted by intervention unit staff during the same period. Many incidents relating to equipment reported in intervention units related to equipment which was used across a range of areas. Examples of faulty medical devices included infusion pumps from a central repository, ECG machines, breathing circuits and faulty commodes.

In attempting to understand why control unit staff were more likely than intervention unit staff to believe they reported medication errors requiring corrective treatment and problems with machinery, the following reasons were considered:

1. **Improve recognition of what is an incident in intervention units:** Compared to control unit staff, intervention unit staff may have been more attuned to recognising incidents at the end of the study following the intense education campaign and therefore were more aware of what they were not reporting.

2. **Higher quality care delivered in control units:** It may be that care provided by staff in control units was of a higher standard than that provided in intervention units. In designing the study with matched control an intervention units, we could not adjust for individual performance of staff within units. If there were clinicians operating at a sub-optimal standard then incident rates would be expected to be higher in this area.

3. **More individual staff members in control units were submitting reports** Even though intervention units reported more incidents, these may have been submitted by only a few dedicated staff members.

With regard to reporting acts of omission; staff in intervention units were significantly more likely than staff in control units to believe they reported when a patient did not receive necessary treatment or procedures. Even after the study, in intervention units only 51% of staff felt they reported these incidents on 50% or more of occasions. During the education campaign, reporting of omissions was encouraged by Project Officers, largely as a result of baseline survey results which indicated that the majority of staff felt they did and should report acts of commission more than acts of omission.

In a paper by Cook et al[357] the point was raised that acts of omission were more pervasive and more difficult to identify than acts of commission. Examples cited included failing to use preventive strategies against complications associated with central venous line insertion, failing to use medic alerts for people with known penicillin allergy and failing to provide warfarin to people with atrial fibrillation. Results of the end of study survey indicate that

while this education campaign made a significant impact, there remains considerable room for improvement in convincing doctors and nurses to report acts of omission.

5.1.11.2. Comparison of staff who believed they should report incident types more than 50% of occasions

Staff in the intervention units at the end of the study were more likely to believe that they *should* report drug near misses and infections compared to staff in control units. There was a lack of significant change in perception of how often people did and felt they should report falls, pressure ulcers, DVTs resulting from inadequate prophylaxis, wrong treatment, breach in confidentiality and medication errors.

Because at baseline 57% of doctors and 51% of nurses reported that they did not think they should report medication near misses, the education campaign focused heavily on the advantages of reporting near misses. When discussing how to change systems, Berwick[358] commented that a precondition to change is that people identify the gap between current performance and desired performance. The gap between what people felt they *should* report compared with what they *did* report in relation to near misses narrowed as a result of the intervention, however this was due only to an increased number of staff recognizing that they should report near misses. There was no improvement in perception of how often they did report near misses. The change in attitude towards reporting of near misses is significant, even if it did not result in more staff believing that they were reporting incidents. It is hoped that this will translate to a change in reporting practices over time.

In investigating changes in views on the reporting system, it is interesting that so few significant changes in perceptions were achieved during the study period. It may be that staff did not feel they should report certain incidents even after the intervention because information could be captured elsewhere. It may be that the increase in perception of how often staff in control units felt incidents should be reported diminished the effect in the intervention units. This might have resulted from contamination in the control units or as a result of other strategies employed during the same time period as this study.

5.1.12. To reduce barriers to reporting (aim 5.3) and introduce a reporting system which is well accepted by staff (aim 5.4)

The end of study staff survey was designed to gauge whether the intervention was successful in breaking down some barriers to reporting and whether staff found it acceptable. End of study survey results indicated that staff in intervention units were more likely to believe that it was worthwhile reporting near misses, that incident reporting could

result in system change and that they should do more than just discuss the incident with the person directly involved in the event. They were however, more likely to identify the fact that when they were busy they could forget to report. This might demonstrate heightened awareness.

Subgroup analysis by professional designation of reporter indicated that doctors in intervention units at the end of the study were less likely than control unit doctors to believe that the incident was too trivial to report and that if the issues were discussed with the person involved nothing else needed to be done (Appendix 35). Nurses were more likely at the end of the study to believe that when the ward is busy they forget to report, that the form takes too long to complete, and that they don't have the time (Appendix 35).

5.1.12.1.1. Significant barriers to reporting

When it's a near miss, I don't see any point in reporting it.

More staff in intervention units at the end of the study period believed they should report medication near misses, and conversely significantly fewer at the end of the study period stated that they saw no point in reporting near misses. This suggests that staff were more likely at the end of the study period to see that there was value in reporting near misses. Even though subgroup analysis by doctors and nurses was unable to demonstrate a significant difference between intervention and control units at the end of the study period, the trend was towards more people seeing value in reporting near misses (Appendix 35).

Incident reporting is unlikely to lead to system change

At the end of the study period staff in the intervention units were more likely to believe that reporting led to system changes (Table 4-36). As with the reporting of near misses, subgroup analysis by doctors and nurses did not demonstrate a significant difference, likely because of insufficient sample size.

In attempting to understand why intervention unit staff were more likely than control unit staff to believe system changes occurred as a result of reporting, the most obvious reason is that feedback via departmental meetings and newsletters was successful in disseminating system changes following reports. However, 25% of intervention unit staff at the end of the study stated on the survey that they had received not enough or no information about the project and 51% stated they received not enough or no information about outcomes arising from reports. This suggests that even if staff receive only a little bit of information about outcomes this can change the pervasive belief[196-199 201] that reporting serves no purpose.

If I discuss the case with the person involved nothing further needs to be done.

It was encouraging to see that staff (and in particular doctors) in intervention units were significantly less likely than control unit staff at the end of the study to believe that if they discussed the incident with the person involved nothing else needed to be done, with 12% and 14% agreeing respectively. At baseline 15% of staff in intervention units agreed with this statement compared with 12% in control units.

The implication is that more staff are recognising the benefit of sharing information about error. It suggests that staff are beginning to recognise that mistakes are not due so much to individual failings as to system errors. This may have occurred as a result of staff listening to details of errors that were presented at departmental meetings or in newsletters. More than 80% of doctors and nurses working in intervention units during the study period stated that they felt comfortable having incidents discussed with others. There is no indication of why 20% of staff in intervention units did not feel comfortable and whether this impacted on subsequent reporting practice.

When the ward is busy, I forget to make a report

The ward being busy and this causing staff to forget to report was more of a barrier to reporting at the end of the study in intervention units compared to baseline. It was not within the scope of this project to reduce the workload of nurses and doctors. The shorter form and call centre was simply designed to make the reporting process quicker. Strategies such as allocating time at the end of the shift for reporting incidents, improving staff ratios and reducing nurse-patient ratios might all improve the likelihood that staff will report incidents.

The incident was too trivial

Significantly fewer doctors in intervention units at the end of the study believed that the incident was too trivial to report compared to control units (Appendix 35). This was opposite to the trend for doctors in control units, where more doctors believed this to be the case at the end of the study compared with baseline.

This finding indicates a change in perception by doctors. Unfortunately it translated to only fifty four more reports being lodged in intervention units during the study compared with the baseline of 3 reports. However, as a potential precursor to change it is encouraging. It indicates increased recognition that minor events with no immediate consequence can still hold valuable messages for staff.

5.1.12.1.2. Non-significant barriers to reporting

There were many components of the intervention designed specifically to reduce barriers to reporting; however survey results indicated that many had no effect on doctors and nurses. Some of these barriers will be discussed to understand why they may not have been successful.

The incident form takes too long and I just don't have the time

It was hoped that the study would address this barrier through the single-page form. Fewer people in both the intervention and control units thought that the form was too long at the end of the study period compared to baseline (control unit 47% to 34%; intervention unit 46% to 37%). Given that in the control unit the form did not change over this time, this difference is difficult to explain.

Reducing the time taken to complete a report requires that information be removed or that it be captured by another method. In a study in primary practice, only a minimum dataset of information was obtained in the first instance to reduce the reporting burden, however it was often necessary for staff to be contacted at a later stage to gather additional information.[62] The subsequent follow up telephone conversation took between five and fifteen minutes. In a similar format, another study used hand held computers to collect a minimum dataset[359] and staff were often contacted later to gather additional data. It did not allow for information to be collected about contributing factors. This creates the following potential problems with the completeness and quality of the data:

- If information is not collected immediately following an incident, it is more likely to be affected by recall bias
- Re-contacting staff in acute hospitals can be very difficult due to shift work and rosters which often have staff rotating through departments on a short-term basis.
- If staff report anonymously, there is no subsequent opportunity to gather additional information.

When the study design was implemented it was hypothesised that provision of a shorter form and the call centre would diminish the reporting burden on staff, however this was not perceived to be the case by those using the system. When staff in control units were asked at the end of the study what would motivate them to report incidents, the most popular strategy was to remove the traditional AIMS report form and introduce the singe page form (Table 4-44). Eighty percent of staff felt that this would motivate them a lot or a moderate

amount. However, this survey suggests that many staff would still feel that the form was too long and that there was insufficient time to complete it.

I never get feedback on what action is taken

Overall results of the end of study survey indicate that even though there was a reduction in staff believing they never got feedback following a reported incidents by 23%, this did not reach statistical significance (Table 4-36) (control unit; 60% at both baseline and end of study vs intervention unit; 61% to 38% agreeing they never got feedback). However, when this barrier was examined by type of unit, more staff in the ED, medical and surgical units felt they got feedback at the end of the study compared with baseline. The reason why there was not an overall change was because staff in ICUs did not significantly change their views and this group had the most numbers (Table 4-38).

With regard to the feedback provided to intervention unit staff during the study period, less than 50% thought that the amount of exposure to outcomes arising from reports was about right. Of the 60% of staff in the intervention unit at the end of the study period who claimed that they had reported an incident in the last nine months, 80% believed that reporting had been worthwhile, despite the fact that half did not know how it was followed up and whether they would receive feedback.

Only 40% of staff in intervention units were aware they would get feedback following a report. When asked whether they were aware of the timeframe for this feedback, again only 40% were aware of when this was expected to occur. Strategies used to transmit this information including documenting it on the single page form and having call centre staff state this to reporters when a report was lodged had limited success. Those least likely to know whether they would get feedback and when that should occur were staff working in the ICU. This is not surprising given that:

- the unit was much larger than all other units making it more difficult to disseminate information,
- only nine percent of reports were lodged through the call centre in this area,
- staff in ICU were more likely than other areas to believe they had not enough or no exposure and to outcomes
- they were least likely to understand how the incident was followed up.

While considerable effort has gone into identifying barriers to reporting and methods to improve reporting practices, surprisingly little effort has been directed at how incident data

should be presented when it is fed back to clinical areas. In some hospitals, staff are provided with paper-based reports[245] while in others, feedback is in an open forum.[168 239]

One program aimed at improving incident reporting introduced seminars in which feedback of outcomes following reports was given to staff in an entire hospital.[168] Attendance at seminars increased by a factor of 14 in a two year period demonstrating a desire for staff to learn from error. We found that the vast majority of staff in intervention units were not uncomfortable discussing incidents with others and for this reason would advocate that feedback continue to be provided in departmental meetings.

Disciplinary action

This study has indicated that with regard to all barriers associated with disciplinary action (I don't want to get into trouble; I am worried about disciplinary action; even if I don't give my details, I'm sure they'll track me down; junior staff are often blamed unfairly for adverse incidents; my co-workers may be unsupportive) the intervention made no significant impact.

In addition to the lack of effect with regard to the questions associated with barriers, 33% of staff who submitted a report felt that the incident was managed in a blameworthy manner. Only 50% of staff working in the ICU were of the opinion that the report was handled in a non-punitive manner. It is likely that staff were worried about disciplinary action by their line manager, as PSMs only actioned anonymous reports, for which individual feedback was not possible. These findings indicate a need for more work to be done in this area with those investigating incidents.

All staff in the intervention units were asked to identify barriers to reporting at the end of the study regardless of whether they had lodged a report. When data were analysed based on whether a person had lodged a report in the intervention units during the study period, there was no difference in perception of fear of disciplinary action between the two groups.

The lack of effect in reducing feelings of fear by doctors and nurses may be due to the following factors:

- **Insufficient training of those responsible for actioning incidents**: Although tools such as Root Cause Analysis were offered to all managers during the study, this was not taken up by some. In the ICU, where staff were more likely to believe they faced punitive action following a report, it is likely that staff were not given adequate training in how best to manage reports.

- **Entrenched cultural behaviour:** It is difficult to change managers' work practice. Even with training, it is not always possible to improve the way in which reports are managed. In this situation, it may be necessary to remove that person from the position of investigating incidents.

5.1.12.2. Limitations in addressing aim 5 (to improve knowledge of the reporting system, to change views on the reporting system, to reduce barriers to reporting and introduce a well accepted reporting system)

The following limitations should be considered when interpreting results of the study with regard to its ability to improve knowledge of the reporting system, change views on the reporting system and reduce barriers to reporting:

1. **Limitation of study design:** The most important limitation when comparing baseline and end of study data is that this was not a cohort study; it was a repeated cross sectional study. Therefore, it may be that staff interviewed at baseline were not the same as those interviewed at the end of the study. In hindsight, we should have asked respondents in the end of study survey whether they had filled out the baseline survey. This study therefore investigates change in attitude and knowledge among the two groups, but will not measure individual changes. Because the study was anonymous, we have no way of linking the baseline and end of study results by individual reporter. In a clinical setting, it would be very difficult to design such a cohort study, and its relevance would be questionable when in reality, staff move across units.

2. **Limited ability to promote the project:** We were unable to provide intense hospital-wide education about the incident reporting system, because we did not want to contaminate control units with the intervention. It mat be that had we been able to provide education to a broader audience knowledge of the reporting system, including incidents which should be reported may have been further enhanced.

3. **Change to questions being asked:** Section 5.1.10 discussed why a question that staff were asked at the end of the study with regard to knowledge of the reporting system differed slightly to the question asked at baseline. It may be that there was a greater tendency for staff to answer in the affirmative when asked whether they knew how to make a report compared with knowing how to access or locate a form.

4. **Perception does not equal reality:** With regard to knowledge of the reporting system, this study gathered self-reported knowledge. We do not know whether those

who answered in the affirmative really did know how to make a report, as this was not formally tested. As stated by Cook et al[357] "The universal caveat of all surveys, however, is that stated practice might not represent actual practice". We attempted to minimize this potential bias by making the survey anonymous and providing the ability to return the survey without having contact with Project Officers.

With regard to self-perceived reporting practices, it seems likely that staff did not report as often as they thought they did. However, in some instances it may be that staff who stated that they had reported incidents may have just commenced working in intervention units, but incidents may have been logged in other units. This information was not collected.

5. **Delayed survey response:** At the end of the study period, some respondents were slow in returning their surveys. As outlined in section 3.7.4.5, in some units recruitment for the staff survey was extended to six weeks after the project concluded. If staff had reported an incident in the six week period after the project concluded this would explain the disparity. This delayed response would likely have the effect of diminishing the effect of the study as over time staff were less likely to remember details of the intervention, including information about how to access the report.

5.1.12.3. Significance of the findings with regard to aim 5 (to improve knowledge of the reporting system, to change views on the reporting system, to reduce barriers to reporting and introduce a well accepted reporting system)

Finding 1: With regard to improving knowledge of the reporting system, no published studies were identified which directly measured knowledge of the reporting system before and after an intervention and whether improved knowledge translated to a better reporting culture. This is significant because it signals that strategies such as providing education at baseline and through departmental meetings and the use of promotional and educational aids can improve knowledge of the reporting system in limited areas. Increased knowledge of how to report did not always correlate with more reports being written. For example, even though more GPs knew how to report incidents at the end of the study, only a few reported incidents during the study period.

Finding 2: The intervention was generally well accepted by staff, with 80% of staff believing it was worthwhile to report and 70% of respondents believing that the amount of exposure they had to the intervention was about right.

Finding 3: With regard to being able to provide feedback to staff, the study identified that newsletters had limited effectiveness, with only half of the staff in intervention units stating that they had seen any newsletters during the study period. This indicates that distribution of outcomes using a newsletter is unlikely to be sufficient in providing feedback of outcomes to doctors and nurses. A systematic review of the effectiveness of strategies to change physician behaviour revealed that a combination of approaches is most effective.[356] Given our results, we would support using a multi-pronged approach.

Finding 4: Strategies used in this study appear to have resulted in cultural shift amongst doctors towards considering minor incidents as being important to learn from, and that there was increased recognition that others can learn from discussion of incidents. The finding that significantly more staff felt that incident reporting can lead to system change is encouraging. Although this has largely not translated to change in practice amongst doctors, it may be that the project was not of sufficient duration to measure this change. Changing practice often takes time, and is usually preceded by a change in attitude.[272] This study suggests some precursors to change are occurring in intervention units.

Finding 5: Even though there is evidence that there is a gap between perception of what doctors believe they report and actual practice,[360] we identified no studies where staff self-perception of reporting practice and actual reporting rates were compared. The finding that AIMS data suggests that staff do not report as often as they think they do, and that staff survey findings indicate that staff do not report as often as they think they should, is important. This needs to be reiterated to staff in education sessions as a way of encouraging staff to report incidents.

Finding 6: Strategies to improve incident reporting have rarely assessed changes in attitudes. No identified studies have compared self-perceived reporting rates and barriers to incident reporting in a large population at baseline and following an intervention aimed at addressing barriers to improve reporting practice. Although studies have shown increased reporting of incidents following introduction of interventions such as web-based reporting and anonymous reporting, none have assessed change in perception of the experience from baseline. By assessing its acceptability by staff, the intervention can be modified and improved. By using control units, the effect of the intervention over and above other activities occurring at the time of the intervention can be measured.

Finding 7: Some strategies seem to have been successful in changing attitude towards the reporting system. Education focussing on near misses likely improved perception of the importance of reporting near misses. Feedback likely improved perception that reporting can lead to system changes.

Finding 8: Some strategies had no measurable impact on reducing barriers to reporting. For example, staff were as concerned at the end of the study about getting into trouble following a report as at baseline, even though some managers had attended workshops to learn how to effectively manage reports in a non-punitive manner. Secondly, because the study asked staff to report more incidents yet did not provide resources to reduce workload in other areas, it is not surprising that at the end of the study staff felt that when the ward was busy they forgot to report.

5.1.12.4. Future research with regard to aim 5 (to improve knowledge of the reporting system, to change views on the reporting system, to reduce barriers to reporting and introduce a well accepted reporting system)

Future research to improve knowledge of the reporting system, change views of what should be reported and reduce barriers to reporting need to explore methods to:

1. **Provide education about the reporting system:** It would be worthwhile investigating other possible ways in which information about the reporting system could be given to staff, and the impact that this would have on reporting rates. Strategies should focus on medical staff. Other approaches may involve (a) the Head of Unit or a Registrar providing information to staff, (b) didactic and interactive learning tools such as videos and simulation provided to all medical and nursing staff, in which human factors engineering is outlined and support for the reporting system is given by senior personnel and opinion leaders.
2. **Reduce time taken to lodge a report:** This study has demonstrated that it is possible to change the often held belief that incident reporting has little purpose. However, much work remains to be done to address the belief by staff that they do not have time to report incidents. We do not understand why, despite provision of easy reporting options, this remains an ongoing concern for both doctors and nurses. In another study designed to elicit incident reports, interviews to collect incident details took between 5 and 15 minutes to complete, depending on the complexity of the report.[62] Shortening the time required to lodge a report will necessitate that not all information is collected. It may be that an extensive report is only collected for

certain types of events, or is dependent on the severity of the event. Innovative techniques such as having designated staff on rounds to write reports, and having time set aside at the end of the shift specifically for the purpose of completing incident forms might be worth investigating in future studies to improve reporting rates.

3. **Assess whether strategies designed to improve reporting also affect the severity of the incidents reported:** While it is possible to collect data on the severity of the incident, this was not reported in the thesis because of difficulty in comparing baseline data which was entered into an earlier version of the AIMS database and had a different severity scale. Future work should be undertaken to examine whether more near misses are being reported, as has been demonstrated in others' studies.[51 245 276]

4. **Reduce the perception that incidents in ICU were managed in a punitive manner:** Staff investigating incidents in ICU need to receive education and counselling in how to use non-punitive techniques so that staff can feel confident to report incidents. Attitude by staff towards management of incidents needs to be re-evaluated following this training. If staff still fear punitive consequences, then more appropriate staff should complete this task.

5. **Remove line managers entirely from the process of investigating incidents:** Although this would necessitate that other processes be put in place, it would be worthwhile investigating the impact of removing line managers from the investigative process. In other industries, such as aviation and nautical incidents, the investigative team would not include the person "in charge", but rather an independent third party. The impartiality of this independent person might be advantageous in identifying and rectifying problems identified on incident reports.

6. **Identify other methods of providing feedback:** Because only 50% of staff reported receiving any feedback on outcomes, other strategies need to be explored. Combining didactic and interactive measures of feedback has been shown to be more effective than simply using didactic measures in changing physician behaviour.[361] Even though we made the session interactive by having staff members make mock phone calls to the call centre, other approaches to providing outcome information need to be considered.

7. **Reward reporting:** Greater emphasis needs to be placed on encouraging reporting. Strategies such as providing financial incentives and comparative data between like departments might improve incident reporting. This must be pre-empted with education to explain that the more reports the better. More reports demonstrate a good safety culture and not poor performance.

6. CONCLUSION

This thesis was designed to gain a better understanding of incident reporting in healthcare from the perspective of consumers, doctors and nurses. From a consumer perspective views on hospital safety, the experience of an adverse event and reporting of error was gathered. It determined that seven percent of people admitted to hospital experienced an adverse event, half of which they deemed were serious. Those who either themselves suffered from an adverse event or had a household member who experienced one were twice as likely as those who did not, to feel unsafe being admitted to hospital. It also determined that most people feel healthcare workers should report errors and be required to identify themselves, even if it leads to a reprimand.

From the perspective of doctors and nurses, the study gathered views on reporting of error and barriers to reporting. It determined that, even though most people knew that their hospital had an incident reporting system, there were many types of incidents which staff felt should be reported yet were not. Some important barriers to reporting were lack of feedback, a lack of knowledge about who should report and what should be reported, a lack of time and a feeling of persecution of junior staff by senior staff.

Based on this information an intervention was tested to determine whether incident reporting rates could be improved, types of incidents reported diversified, and attitudes changed towards incident reporting. Strategies included providing individual feedback for serious events and via departmental meetings and newsletters for interesting incidents; providing education via departmental meetings and an aide memoire about how to report the types of incidents staff should report and the ability to report anonymously; introducing a call centre, online reporting and shortening the form to make it quick and easy to report; and altering the reporting process so that reports initially bypassed the line manager.

The intervention successfully improved incident reporting in all types of units other than intensive care units. It led to a more diverse range of incidents being reported by doctors, nurses and allied health professionals. Even though it did not result in staff believing that they were reporting incidents more often than before the intervention, it did result in more staff believing they should report near misses and nosocomial infections.

It is important that we build on the work undertaken in this study. We identified strategies which improved incident reporting, and we identified reasons why the intervention was not successful in one area. Strategies such as having effective champions actively involved in

follow up and discussion of incidents, managing reports in a non-punitive manner and conducting regular meetings to discuss incidents are suggestive of whether reporting will increase in units. We have identified areas for future research, of which there are many. Issues still not properly addressed included improving reporting by GPs and staff in ICUs, and reducing the punitive approach to managing incidents in ICUs.

Even though the call centre was introduced to reduce reporting burden, for many it was still time consuming. On-line reporting requires much attention before it will be accepted. If it were not for the fact that staff had the ability to choose a tool to report incidents, online reporting rates may have improved. The heterogeneity in the way in which people lodged reports (call centre, online, paper form) demonstrates the importance of offering choices to reporters.

It is important that incident reporting is not relegated to the status of a 'nursing tool'. If managed well, it can empower staff to be able to make changes in their clinical setting and help to foster an open and fair culture in hospitals. Voluntary reporting relies on altruism of doctors and nurses to do the right thing and report when things go wrong. If staff are not supported in this process by their organisation, then a source of valuable information is lost. The consequence of not identifying incidents is that they will continue to occur, and not only cause injury to patients but also have detrimental consequences for those who make them.[209]

This study has identified that it is possible to make inroads into improving reporting rates and changing types of incidents reported by both doctors and nurses, but the widespread solution is not as simple as introducing education, feedback and a variety of reporting options. Entrenched cultural barriers to reporting, as seen in general practice and more widely among doctors are difficult to overcome. It is possible that developing a reporting system which is managed exclusively by doctors for doctors will improve reporting rates in this group. However, this introverted approach neglects to acknowledge that doctors do not act in isolation in delivering health care, and that others would benefit from (a) learning about factors contributing to incidents, and (b) the development of preventive strategies to prevent recurrence of incidents.

Hope, I believe, lies in identifying and harnessing effective champions and continuing to explore other ways in which reports can be managed, perhaps even outside the hospital. I like to imagine a ripple effect, in which those using it to constructively drive change influence those who see no value in it. This is going to take time.

"Physicians will always make mistakes. The decisive factor will be how we handle them. Patient safety and physician welfare will be well served if we can be more honest about our mistakes to our patients, our colleagues, and ourselves."

Albert Wu[209]

7. REFERENCE LIST

1. Berwick DM, Leape LL. Reducing errors in medicine. BMJ 1999; 319(7203):136-7.

2. Brennan TA, Leape LL, Laird NM *et al.* Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med 1991; 324(6):370-6.

3. Reason J. Human Error. Cambridge: Cambridge University Press, 1990.

4. Barach P, Small SD. How the NHS can improve safety and learning. By learning free lessons from near misses. BMJ 2000; 320(7251):1683-4.

5. University of Queensland. Key Centre for Human Factors and Applied Cognitive Psychology [Web Page]. Available at http://www.humanfactors.uq.edu.au/. (Accessed 3 January 2006).

6. Australian Council for Safety and Quality in Health Care. Definitions of Safety and Quality in Health Care [Web Page]. 2005; Available at www.safetandquality.org. (Accessed 3 January 2006).

7. Kohn LT, Corrigan JM, Donaldson MS. To Err is Human: Building a safer health system. Washington, DC: National Academy Press, 2000: 1-16.

8. Rasmussen J, Pedersen OM. Operational Safety of Nuclear Power Plants (vol 1). Human Factors in probabilistic risk analysis and risk management. Vienna: International Atomic Energy Agency, 1984.

9. Runciman WB, Moller J. Iatrogenic Injury in Australia. A report prepared by the Australian Patient Safety Foundation for the National Health Priorities and Quality Branch of the Department of Health and Aged Care of the Commonwealth Government of Australia. Adelaide, South Australia: Australian Patient Safety Foundation, 2001.

10. Human Resources Unit Department of Health. Patient Safety Manager- Job and Person Description. 2003.

11. Macquarie University (Ed). 3rd edition. Macquarie University NSW : The Macquarie Library Pty Ltd, 1997.

12. Dunn D. Incident reports--correcting processes and reducing errors. AORN Journal 214; 78(2):212.

13. Australian Council for Safety and Quality in Health Care. Sentinel events [Web Page]. Available at http://www.safetyandquality.org/sentnlevnt31305.pdf. (Accessed 3 January 2006).

14. Schimmel EM. The hazards of hospitalization. 1964. Quality & Safety in Health Care 2003; 12(1):58-63; discussion 63-4.

15. Mills D. Report on the Medical Insurance Feasibility Study. San Fransisco: California Medical Association, 1977.

16. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ 2001; 322(7285):517-9.

17. Davis P, Lay-Yee R, Schug S *et al.* Adverse events regional feasibility study: indicative findings. New Zealand Medical Journal 2001; 114(1131):203-5.

18. Baker GR, Norton PG, Flintoft V *et al.* The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. CMAJ Canadian Medical Association Journal 2004; 170(11):1678-86.

19. Schioler T, Lipczak H, Pedersen BL *et al.* Incidence of adverse events in hospitals. A retrospective study of medical records. Ugeskr Laeger 2001; 163(39):5370-8.

20. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The Quality in Australian Health Care Study. Med J Aust 1995; 163(9):458-71.

21. Runciman WB, Webb RK, Helps SC *et al.* A comparison of iatrogenic injury studies in Australia and the USA: Reviewer behaviour and quality of care. International Journal for Quality in Health Care 2000; 12(5):379-88.

22. Thomas EJ, Studdert DM, Runciman WB *et al.* A comparison of iatrogenic injury studies in Australia and the USA. I: Context, methods, casemix, population, patient and hospital characteristics. International Journal for Quality in Health Care 2000; 12(5):371-8.

23. Hayward R, Hofer T. Estimating Hospital Deaths Due to Medical Errors: Preventability Is in the Eye of the Reviewer. JAMA 2001; 286(4):415-20.

24. McNeil JJ, Leeder SR. How safe are Australian hospitals? Med J Aust 1995; 163(9):472-5.

25. Thomas EJ, Studdert DM, Burstin HR *et al.* Incidence and types of adverse events and negligent care in Utah and Colorado. Medical Care 2000; 38(3):261-71.

26. Australian Council for Safety and Quality in Health Care. Safety First: Report to the Australian Health Ministers' Conference. Canberra, ACT: Department of Health and Ageing, Commonwealth of Australia, 2000.

27. Expert Group on Learning from Adverse Events in the NHS. An Organisation with a Memory. London: Stationary Office, 2000.

28. Australian Council for Safety and Quality in Health Care . Safety Innovations In Practice (SIIP) Program Mark II Compendium of project reports. Canberra: Safety and Quality Council, 2004.

29. University of California at San Francisco (UCSF)-Stanford University Evidence-based Practice Center. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Rockville, MD: Agency for Healthcare Research and Quality, 2001; Evidence Report/Technology Assessment: Number 43. AHRQ Publication No. 01-E058. Available at http://www.ahrq.gov/clinic/ptsafety/ (accessed 3rd January 2006).

30. Leape LL, Berwick DM, Bates DW. What practices will most improve safety? Evidence-based medicine meets patient safety. JAMA 2002; 288(4):501-7.

31. Ioannidis J, Lau J. Evidence on interventions to reduce medical errors: an overview and recommendations for future research. Journal of General Internal Medicine 2001; 16(5):325-34.

32. Easterbrook P, Berlin J, Gopalan R, Matthews D. Publication bias in clinical research. Lancet 1991; 337:867-72.

33. Montori VM, Smieja M, Guyatt GH. Publication bias: a brief review for clinicians. Mayo Clinic Proceedings 2000; 75(12):1284-8.

34. Olson CM, Rennie D, Cook D *et al.* Publication bias in editorial decision making. JAMA 2002; 287(21):2825-8.

35. Australian Council for Safety and Quality in Health Care. Lessons from the Inquiry into Obstetrics and Gynaecological Services at the King Edward Memorial 1999-2000. Canberra: Commonwealth of Australia, 2002.

36. Health Care Complaints Commission. Investigation Report: Cambelltown and Camden Hospitals Macarthur Health Service [Web Page]. December 2003; Available at http://www.health.nsw.gov.au/pubs/i/pdf/invstign_hccc_2.pdf . (Accessed 3 January 2006).

37. Department of Health. Learning from Bristol: The DH Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995.

38. Toft B. External Inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham, 4th January 2001. London: Department of Health, 2001.

39. Department of Health. The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: Final Report. London: Bristol Royal Infirmary Inquiry, 2001.

40. Department of Health. Committee of inquiry to investigate how the NHS handled allegations about the performance and conduct of Richard Neale. London: Department of Health, 2004.

41. Australian Council for Safety and Quality in Health Care. Safety in Practice Making Health Care Safer. Second Report to the Australian Health Ministers' Conference. Canberra: Safety and Quality Council, 2001.

42. Beckmann U, West LF, Groombridge GJ *et al.* The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. The development and evaluation of an incident reporting system in intensive care. Anaesth Intensive Care 1996; 24(3):314-9.

43. Beckmann U, Bohringer C, Carless R *et al.* Evaluation of two methods for quality improvement in intensive care: facilitated incident monitoring and retrospective medical chart review. Critical Care Medicine 2003; 31(4):1006-11.

44. Gaba DM. Anaesthesiology as a model for patient safety in health care. BMJ 2000; 320(7237):785-8.

45. Jayasuriya JP, Anandaciva S. Compliance with an incident report scheme in anaesthesia. Anaesthesia 1995; 50(10):846-9.

46. Runciman WB, Sellen A, Webb RK *et al.* The Australian Incident Monitoring Study. Errors, incidents and accidents in anaesthetic practice. Anaesthesia & Intensive Care 1993; 21(5):506-19.

47. Staender S, Davies J, Helmreich B, Sexton B, Kaufmann M. The anaesthesia critical incident reporting system: an experience based database. International Journal of Medical Informatics 1997; 47(1-2):87-90.

48. Vinen J. Incident monitoring in emergency departments: an Australian model. Academic Emergency Medicine 2000; 7(11):1290-7.

49. Fordyce J, Blank FSL, Pekow P *et al.* Errors in a busy Emergency Department. Annals of Emergency Medicine 2003; 42(3):324-33.

50. Welsh CH, Pedot R, Anderson RJ. Use of morning report to enhance adverse event detection. J Gen Intern Med 1996; 11(8):454-60.

51. O'Neil AC, Petersen LA, Cook EF, Bates DW, Lee TH, Brennan TA. Physician reporting compared with medical-record review to identify adverse medical events. Ann Intern Med 1993; 119(5):370-6.

52. Wanzel K, Jamieson G, Bohnen J. Complications on a General Surgery Service: incidence and reporting. Can J Surg 2000; 43(2):113-7.

53. Battles JB, Kaplan HS, Van der Schaaf TW, Shea CE. The attributes of medical event-reporting systems: experience with a prototype medical event-reporting system for transfusion medicine.[comment]. Archives of Pathology & Laboratory Medicine. 1998; 122(3):231-8.

54. Fernald DH, Pace WD, Harris DM, West DR, Main DS, Westfall JM. Event reporting to a primary care patient safety reporting system: a report from the ASIPS collaborative. Annals Fam Med 2004; 2(4):327.

55. Bhasale AL, Miller GC, Reid SE, Britt HC. Analysing potential harm in Australian general practice: an incident- monitoring study. Med J Aust 1998; 169(2):73-6.

56. Flynn EA, Barker KN, Pepper GA, Bates DW, Mikeal RL. Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. Am J Health-Syst Pharm 2002; 59(5):436-46.

57. Stanhope N, Crowley-Murphy M, Vincent C, O'Connor AM, Taylor-Adams SE. An evaluation of adverse incident reporting. J Eval Clin Pract 1999; 5(1):5-12.

58. Jha AK, Kuperman GJ, Teich JM *et al.* Identifying adverse drug events: development of a computer-based monitor and comparison with chart review and stimulated voluntary report. Journal of the American Medical Informatics Association 1998; 5(3):305-14.

59. Classen D. Description of a computerized adverse event monitoring system using a hospital information system. Hospital Pharmacist 1992; 27 :774-83.

60. Sutton J, Standen P, Wallace A. Unreported accidents to patients in hospital. Nursing Times 1994; 90(39):46-9.

61. Kivlahan C, Sangster W, Nelson K, Buddenbaum J, Lobenstein K. Developing a comprehensive electronic adverse event reporting system in an academic Health Center. Joint Commission Journal on Quality Improvement. 2002; 28(11):583-94.

62. Westfall JM, Fernald DH, Staton EW, VanVorst R, West D, Pace WD. Applied strategies for improving patient safety: a comprehensive process to improve care in rural and frontier communities. Journal of Rural Health 2004; 20(4):355-62.

63. Sucov A, Shapiro MJ, Jay G, Suner S, Simon R. Anonymous error reporting as an adjunct to traditional incident reporting improves error detection. Acad Emerg Med 2001; 8(5):498-9.

64. Taylor JA, Brownstein D, Christakis DA *et al.* Use of incident reports by physicians and nurses to document medical errors in pediatric patients. Pediatrics 2004; 114(3):729-35.

65. Institute of Medicine. To Err is Human: Building a Safer Health System. Washington, D.C.: National Academy Press, 1999.

66. Wilson R, Gibberd R, Hamilton J, Harrison B. Safety of healthcare in Australia: adverse events to hospitalized patients. Rosenthal MM, Mulcahy L, Lloyd-Bostock SE. Medical Mishaps: Pieces of the Puzzle. Buckingham: Open University Press, 1999.

67. Clark RB. Australian Patient Safety Survey: Final Report to the Commonwealth Department of Health and Aged Care. Canberra, Australia: Commonwealth of Australia, 2001.

68. Andrews LB, Stocking C, Krizek T *et al.* An alternative strategy for studying adverse events in medical care. Lancet 1997; 349(9048):309-13.

69. Chang A, Schyve PM, Croteau RJ, O'Leary DS, Loeb JM. The JCAHO Patient Safety Event taxonomy: a standardized terminology and classification schema for near misses and adverse events. Int J Qual in Health Care 2005; 17(2):95-105.

70. Jamtvedt G, Young JM, Kristoffersen DT, Thomson O'Brien MA , Oxman AD. Audit and feedback: effects on professional practice and health care outcomes. Cochrane Database of Systematic Reviews 2003; (3): CD000259.

71. Hargreaves J. Reporting of adverse events in routinely collected data sets in Australia. Canberra, Australia: Australian Institute of Health and Welfare, 2001; Health Division Working Paper no. 3.

72. Ansari MZ, Costello AJ, Jolley DJ, Ackland MJ, Carson N, McDonald IG. Adverse events after prostatectomy in Victorian public hospitals. Australian & New Zealand Journal of Surgery 1998; 68(12):830-6.

73. Roughead EE. The nature and extent of drug-related hospitalisations in Australia. J Qual Clin Pract 1999; 19(1):19-22.

74. O'Hara DA, Carson NJ. Reporting of adverse events in hospitals in Victoria, 1994-1995. Medical Journal of Australia 1997; 166(9):460-3.

75. Runciman WB, Roughead EE, Semple SJ, Adams RJ. Adverse drug events and medication errors in Australia. International Journal for Quality in Health Care. 15 Suppl 1:I49-59, 2003 Dec.

76. Hargraves J, Maddern R. Measuring adverse events: problems and potential. National Summit on Quality and Efficiency in Medicine. Australian Medical Association.

77. Bates DW, Spell N, Cullen DJ *et al.* The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group. JAMA 1997; 277(4):307-11.

78. Bates DW, Cullen DJ, Laird N *et al.* Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 1995; 274(1):29-34.

79. Braithwaite RS, DeVita MA, Mahidhara R *et al.* Use of medical emergency team (met) responses to detect medical errors. Quality & Safety in Health Care 2004; 13(4):255-9.

80. Vincent C, Young M, Phillips A. Why do people sue doctors? A study of patients and relatives taking legal action. Lancet 1994; 343(8913):1609-13.

81. Levinson W, Roter DL, Mullooly JP, Dull VT, Frankel RM. Physician-patient communication. The relationship with malpractice claims among primary care physicians and surgeons. JAMA 1997; 277(7):553-9.

82. Rothman KJ, Greenland S. Modern Epidemiology. 2nd edition. Philadelphia: Lippincott-Raven Publishers, 1998.

83. Runciman WB. Iatrogenic harm and anaesthesia in Australia. Anaesthesia and Intensive Care 2005; 33(3):297-300.

84. Studdert DM, Thomas EJ, Burstin HR, Zbar BI, Orav EJ, Brennan TA. Negligent care and malpractice claiming behavior in Utah and Colorado. Med Care 2000; 38(3):250-60.

85. Localio AR, Lawthers AG, Brennan TA *et al.* Relation between malpractice claims and adverse events due to negligence. Results of the Harvard Medical Practice Study III. N Engl J Med 1991; 325(4):245-51.

86. Brennan TA, Sox CM, Burstin HR. Relation between negligent adverse events and the outcomes of medical- malpractice litigation. N Engl J Med 1996; 335(26):1963-7.

87. Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. JAMA 2003; 290(14):1868-74.

88. MacIntyre CR, Ackland MJ, Chandraraj EJ, Pilla JE. Accuracy of ICD-9-cm codes in hospital morbidity data, Victoria: implications for public health research. Australian & New Zealand Journal of Public Health 1997; 21(5):477-82.

89. Henriksen K, Kaplan H. Hindsight bias, outcome knowledge and adaptive learning. Qual Saf Health Care. 2003; 12 (Suppl 2:ii 46-50).

90. Caplan RA, Posner KL, Cheney FW. Effect of outcome on physician judgments of appropriateness of care. JAMA 1991 Apr 17; 265(15):1957-60.

91. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. JAMA Jul 5; 284(1):93-5.

92. Dixon-Woods M. What can ethnography do for quality and safety in health care? Qual Saf Health Care 2003; 12(5):326-27.

93. Byrne M. Ethnography as a qualitative research method. AORN Journal 2001; 74(1):82-4.

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

95. Bellomo R, Goldsmith D, Russell S, Uchino S. Postoperative serious adverse events in a teaching hospital: a prospective study. Medical Journal of Australia 2002; 176(5):216-8.

96. Taxis K, Barber N. Incidence and severity of intravenous drug errors in a German hospital. Eur J Clin Pharmacology 2004; 59(11):815-7.

97. Wirtz V, Taxis K, Barber ND. An observational study of intravenous medication errors in the United Kingdom and in Germany. Pharmacy World & Science 2003; 25(3):104-11.

98. Taxis K, Barber N. Ethnographic study of incidence and severity of intravenous drug errors. BMJ 2003; 326(7391):684.

99. Dean B, Schachter M, Vincent C, Barber N. Prescribing errors in hospital inpatients: their incidence and clinical significance. Qual Saf Health Care 2002; 11(4):340-4.

100. Taxis K, Barber N. Causes of intravenous medication errors: an ethnographic study. Qual Saf Health Care 2003; 12(5):343-7.

101. Coiera EW, Jayasuriya RA, Hardy J, Bannan A, Thorpe ME. Communication loads on clinical staff in the emergency department. Medical Journal of Australia 2002; 176(9):415-8.

102. Savage J. Ethnography and health care. BMJ 2000; 321(7273):1400-2.

103. De Amici D, Klersy C, Ramajoli F, Brustia L, Politi P. Impact of the hawthorne effect in a longitudinal clinical study: the case of anesthesia.[See comment]. Controlled Clinical Trials 2000; 21(2):103-14.

104. Bark P, Vincent C, Jones A, Savory J. Clinical complaints: a means of improving quality of care. Quality in Health Care 1994; 3(3):123-32.

105. Allsop J, Mulcahy L. Doctors' responses to patient complaints. Rosenthal MM, Mulcahy L, Lloyd-Bostock S. Medical Mishaps: Pieces of the Puzzle. Buckingham, UK: Open University Press, 1999.

106. Draper M, Cohen P, Buchan H. Seeking consumer views: what use are results of hospital patient satisfaction surveys?. International Journal for Quality in Health Care. 2001; 13(6):463-8.

107. National Patient Safety Foundation at the AMA. Public Opinion of Patient Safety Issues Research Findings. 1997; Available at www.npsf.org/download/1997survey.pdf (accessed 3rd January 2006).

108. Kaiser Family Foundation/Agency for Healthcare Research and Quality. National Survey on Americans as Health Care Consumers: An update on the role of quality information. Rockville, MD: Henry J Kaiser Family Foundation, 2000; Available at http://www.kff.org/content/2000/3093/AHRQToplines.pdf (accessed 3rd January 2006).

109. Kaiser Family Foundation/Agency for Healthcare Research and Quality/Harvard School of Public Health. National Survey on Consumers' Experiences with Patient Safety and Quality Information. Rockville, MD: Henry J Kaiser Family Foundation, 2004; Available at http://www.kff.org/kaiserpolls (accessed 3rd January 2006).

110. Kaiser Family Foundation/Agency for Healthcare Research and Quality. Americans as Health Care Consumers: The role of quality information. Rockville, MD: Henry J Kaiser Family Foundation, 1996; Available at http://www.kff.org/kaiserpolls (accessed 3rd January 2006).

111. Blendon RJ, DesRoches CM, Brodie M *et al.* Views of practicing physicians and the public on medical errors. N Engl J Med 2002; 347(24):1933-40.

112. Kuzel AJ, Woolf SH, Gilchrist VJ *et al.* Patient reports of preventable problems and harms in primary health care. Annals of Family Medicine 2004; 2(4):333-40.

113. Greenhalgh T. Assessing the methodological quality of published papers. BMJ 1997; 315(7103):305-8.

114. Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. BMJ 2000; 320(7237):741-4.

115. Allsop J, Mulcahy L. Dealing with clinical complaints. Vincent CE. Clinical Risk Management. London: BMJ Publishing Group, 2001.

116. Coughlin SS. Recall bias in epidemiologic studies. Journal of Clinical Epidemiology 1990; 43(1):87-91.

117. Leape LL. Error in medicine. JAMA 1994; 272(23):1851-7.

118. McIntyre N, Popper K. The critical attitude in medicine: the need for a new ethics. British Medical Journal Clinical Research Ed. 1983; 287(6409):1919-23.

119. Murtagh J. General Practice. 3rd edition. New South Wales: McGraw-Hill Australia Pty Ltd, 2003.

120. Phillips RLJ, Bartholomew LA, Dovey SM, Fryer GE Jr, Miyoshi TJ, Green LA. Learning from malpractice claims about negligent, adverse events in primary care in the United States. Quality & Safety in Health Care 2004; 13(2):121-6.

121. Pegram R. General Practice in Australia: Introduction. Commonwealth Department of Health and Aged Care. General Practice in Australia: 2000 . Canberra: Commonwealth of Australia, 2000.

122. Britt H, Sayer GP, Miller G *et al.* General Practice Activity in Australia 1998-1999. Canberra, Australia: AIHW, 1999; Cat.No.GEP 5 (General Practice Series).

123. Makeham MA, Dovey SM, County M, Kidd MR. An international taxonomy for errors in general practice: a pilot study. Med J Aust 2002; 177(2):68-72.

124. McKean-Cowdin R, Feigelson HS, Ross RK, Pike MC, Henderson BE. Declining cancer rates in the 1990s. Journal of Clinical Oncology 2000; 18(11):2258-68.

125. Rubin G, George A, Chinn DJ, Richardson C. Errors in general practice: development of an error classification and pilot study of a method for detecting errors. Qual Saf Health Care 2003; 12(6):443-7.

126. Shah S, Aslam M, Avery AJ. A survey of prescription errors in general practice. Pharm J 2001; 267:860-2.

127. Flanagan JC. The critical incident technique. Psycho Bull 1954; 51:327-58.

128. Helmreich RL. On error management: lessons from aviation. BMJ 2000; 320(7237):781-5.

129. Barach P, Small SD. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. BMJ 2000; 320(7237):759-63.

130. Helmreich RL. Culture at Work in Aviation and Medicine. Hants, England: Ashgate Publishing Limited, 1998.

131. Aviation Safety Reporting System. 6 April 2005; Available at http://asrs.arc.nasa.gov/overview_nf.htm. (Accessed 3 January 2006).

132. Federal Aviation Administration (FAA). Aviation Safety Reporting Program (ASRP) [Web Page]. Available at http://asrs.arc.nasa.gov/overview.htm. (Accessed 3 January 2006).

133. Brennan TA. Hospital peer review and clinical privileges actions: to report or not report. JAMA. 1999; 282(4):381-2.

134. Australian Transport Safety Bureau- Australian Government. Aviation Safety [Web Page]. 5 May 1905; Available at http://www.atsb.gov.au/aviation/index.cfm. (Accessed 3 January 2006).

135. Randell O, owen.randell@atsb.gov.au. CASA aviation reporting system. [E-mail to Sue Evans, Susan.evans@adelaide.edu.au]. 4 May 2005.

136. Acott C, Sutherland A, Williamson J. Anonymous reporting of diving incidents: a pilot study. SPUMS Journal 1989; 19:18-22.

137. Organizational factors affecting the incident reporting of train drivers. Work & Stress, 12(1):6-16, 1998 Jan-Mar.(31 Ref) .

138. Cooper JB, Newbower R, Long C. Preventable anaesthesia mishaps: a study of human factors. Anesthesiology 1978; 49:399-406.

139. Beckmann U, Baldwin I, Hart GK, Runciman WB. The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. An analysis of the first year of reporting. Anaesth Intensive Care 1996; 24(3):320-9.

140. Australian Council for Safety and Quality in Health Care. Safety in Numbers. A technical options paper for a national approach to the use of data for safer health care. Canberra: Commonwealth of Australia, 2001.

141. Australian Council for Safety and Quality in Health Care. Maximising national effectiveness to reduce harm and improve care: Fifth report to the Australian Health Ministers' Conference. Canberra: Safety and Quality Council, 2004.

142. Wolff AM, Bourke J. Detecting and reducing adverse events in an Australian rural base hospital emergency department using medical record screening and review. Emerg Med J 2002; 19(1):35-40.

143. Osmon S, Harris CB, Dunagan WC, Prentice D, Fraser VJ, Kollef MH. Reporting of medical errors: an intensive care unit experience. Critical Care Medicine 2004; 32(3):727-33.

144. Buckley TA, Short TG, Rowbottom YM, Oh TE. Critical incident reporting in the intensive care unit. Anaesthesia 1997; 52(5):403-9.

145. Flaatten H, Hevroy O. Errors in the intensive care unit (ICU). Experiences with an anonymous registration. Acta Anaesthesiologica Scandinavica. 1999; 43(6):614-7.

146. Thomas AN, Pilkington CE, Greer R. Critical incident reporting in UK Intensive Care Units: a postal survey. Journal of Evaluation in Clinical Practice 2003; 9(1):59-68.

147. Wright M, Parker G. Incident monitoring in psychiatry. Journal of Quality in Clinical Practice 1998; 18(4):249-61.

148. Hamadeh RR, Al Alaiwat B, Al Ansari A. Assaults and nonpatient-induced injuries among psychiatric nursing staff in Bahrain. Issues in Mental Health Nursing 2003; 24(4):409-17.

149. Van der Walt JH, Sweeney DB, Runciman WB, Webb RK. The Australian Incident Monitoring Study. Paediatric incidents in anaesthesia: an analysis of 2000 incident reports. Anaesthesia & Intensive Care 1993; 21(5):655-8.

150. Van der Walt JH, Webb RK, Osborne GA, Morgan C, Mackay P. The Australian Incident Monitoring Study. Recovery room incidents in the first 2000 incident reports. Anaesthesia & Intensive Care. 1993; 21(5):650-2.

151. Short TG, O'Regan A, Jayasuriya JP, Rowbottom M, Buckley TA, Oh TE. Improvements in anaesthetic care resulting from a critical incident reporting programme. Anaesthesia. 1996; 51(7):615-21.

152. Cooper JB, Newbower R, Kitz R. An analysis of major errors and equipment failures in anesthesia management: considerations for prevention and detection. Anesthesiology 1984; 60:34-42.

153. Abeysekera A, Bergman IJ, Kluger MT, Short TG. Drug errors in anaesthetic practice: a review of 896 reports from the Australian Incident Monitoring Study database. Anaesthesia 2005; 60:220-27.

154. Bhasale A, Miller G, Britt H, Reid S. Clinical incidents in general practice. Keeping on track with test results. Aust Fam Physician 1996; 25(12):1861-3.

155. Bhasale A, Miller G, Britt H, Reid S. Clinical incidents in general practice. Communication between casualty departments and general practitioners. Aust Fam Physician 1996; 25(8):1293-5.

156. Morris GP, Morris RW. Anaesthesia and fatigue: an analysis of the first 10 years of the Australian Incident Monitoring Study 1987-1997. Anaesthesia & Intensive Care 2000; 28(3):300-4.

157. Beckmann U, Baldwin I, Durie M, Morrison A, Shaw L. Problems associated with nursing staff shortage: an analysis of the first 3600 incident reports submitted to the Australian Incident Monitoring Study (AIMS-ICU). Anaesthesia & Intensive Care 1998; 26(4):396-400.

158. Webb RK, Russell WJ, Klepper I, Runciman WB. The Australian Incident Monitoring Study. Equipment failure: an analysis of 2000 incident reports. Anaesthesia & Intensive Care. 1993; 21(5):673-7.

159. Morrison AL, Beckmann U, Durie M *et al.* The effects of nursing staff inexperience (NSI) on the occurrence of adverse patient experiences in ICUs. Australian Critical Care 2001; 14(3):116-21.

160. Runciman WB, Webb RK, Lee R, Holland R. The Australian Incident Monitoring Study. System failure: an analysis of 2000 incident reports. Anaesthesia & Intensive Care. 1993; 21(5):684-95.

161. Wolff AM, Bourke J, Campbell IA, Leembruggen DW. Detecting and reducing hospital adverse events: outcomes of the Wimmera clinical risk management program. Med J Aust 2001; 174(12):621-5.

162. Weingart SN, Callanan LD, Ship AN, Aronson MD. A physician-based voluntary reporting system for adverse events and medical errors. Journal of General Internal Medicine 2001; 16(12):809-14.

163. Kluger MT, Tham EJ, Coleman NA, Runciman WB, Bullock MF. Inadequate pre-operative evaluation and preparation: a review of 197 reports from the Australian Incident Monitoring Study. Anaesthesia 2000; 55(12):1173-8.

164. Amoore J, Ingram P. Learning from adverse incidents involving medical devices. BMJ 2002; 325(7358):272-75.

165. Meurier CE. Understanding the nature of errors in nursing: using a model to analyse critical incident reports of errors which had resulted in an adverse or potentially adverse event. J Adv Nurs 2000; 32(1):202-7.

166. Miller G, Britt H, Steven I, Bhasale A, Reid S. Clinical incident monitoring. Aust Fam Physician 1996; 25(6):821.

167. Williamson JA, Webb RK, Sellen A, Runciman WB, Van der Walt JH. The Australian Incident Monitoring Study. Human failure: an analysis of 2000 incident reports. Anaesthesia & Intensive Care 1993; 21(5):678-83.

168. Nakajima K, Kurata Y, Takeda H. A web-based incident reporting system and multidisciplinary collaborative projects for patient safety in a Japanese hospital. Qual Saf Health Care 2005; 14(2):123-9.

169. Marang-van de Mheen P, van Hanegem N, Kievit J. Effectiveness of routine reporting to identify minor and serious adverse outcomes in surgical patients. Qual Saf Health Care 2005; 14:378-82.

170. Sharpe V. Promoting Patient Safety: An Ethical Basis for Policy Deliberation. Hastings Center Report Special Supplement 33. 2003; No. 5 S1-S20.

171. Shannon, D, Taylor, C, Lloyd. D. Mandatory Reporting and Child Sexual Abuse: Contextualising Beliefs and Attitudes [Web Page]. 2001; Available at http://www.aare.edu.au/01pap/tay01411.htm (Accessed 3 January 2006).

172. Courts Administration Authority-Coroners Court. When must a death be reported to the Coroner [Web Page]. Available at http://www.courts.sa.gov.au/courts/coroner/. (Accessed 3 January 2006).

173. Victorian Consultative Council on Anaesthetic Mortality and Morbidity. (Accessed 30 April 2005).

174. Joint Commission on Accreditation of Healthcare Organisations. Sentinel Event Statistics - December 5, 2002 [Web Page]. Available at http://www.jcaho.org. (Accessed 3 January 2006).

175. New South Wales Department of Health. Patient Safety and Clinical Quality Program: First report on incident management in the NSW public health system 2003-2004. NSW, Australia: NSW Department of Health, 2005.

176. Department of Human Services. Sentinel Events Program Annual Report 2002-03. Victoria, Australia: Department of Human Services, 2004.

177. Department of Human Services. Sentinel Events Program Annual Report 2003-04. Victoria, Australia: Department of Human Services, 2004.

178. Flink E, Chevalier L, Ruperto A, Dameron P, Heigel FJ, Leslie R. Lessons learned from the evolution of a mandatory adverse event reporting system. Rockville, MD: Agency for Healthcare Research and Quality, 2005.

179. Australian Council for Safety and Quality in Health Care. .Patient Safety: Towards Sustainable Improvement. Fourth Report to the Australian Health Ministers. Canberra, Australia: Safety and Quality Council, 2003.

180. Wilson R. How safe are our hospitals? Australia Talks Back Australian Broadcasting Commission, 2005.

181. Weissman JS, Annas CL, Epstein AM *et al.* Error reporting and disclosure systems: views from hospital leaders. JAMA 2005; 293(11):1359-66.

182. Department of Health and Human Services Food and Drug Administration. Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules; Final Rule. 1995; 21 CFR Part 20 [Docket No. 93N–0334].

183. Cohen MR. Why error reporting systems should be voluntary. BMJ 2000; 320(7237):728-9.

184. Andrus CH, Villasenor EG, Kettelle JB, Roth R, Sweeney AM, Matolo NM. "To err is human": uniformly reporting medical errors and near misses, a naive, costly, and misdirected goal. Journal of the American College of Surgeons 2003; 196(6):911-8.

185. Weeks WB, Bagian JP. Developing a culture of safety in the Veterans Health Administration. Eff Clin Pract 2000; 3(6):270-6.

186. Webster CS, Anderson DJ. A practical guide to the implementation of an effective incident reporting scheme to reduce medication error on the hospital ward. International Journal of Nursing Practice 2002; 8(4):176-83.

187. Runciman B, Merry A, Smith AM. Improving patients' safety by gathering information. Anonymous reporting has an important role. BMJ 2001; 323(7308):298.

188. Ostergaard DHN, Anderson H, Madsen MD, Schiřler T. A study of the views of doctors and nurses on adverse event reporting. 8th European Forum on Quality Improvement in Health Care. Bergen: BMJ, 2003.

189. Bagnall G. What about the victims of medical error ? BMJ 323(7307):280.

190. Kaplan H, Barach P. Incident reporting: science or protoscience? Ten years later. Qual Saf Health Care 2002; 11(2):144-5.

191. Roberts K, Professor of Business Administration, Haas School of Business. Creating a Culture of Safety. Enhancing Patient Safety and Reducing Errors in Health Care. Chicago: National Patient Safety Foundation, 1999.

192. Wilson LL, Fulton M. Risk management: how doctors, hospitals and MDOs can limit the costs of malpractice litigation. Med J Aust 2000; 172(2):77-80.

193. Cullen DJ, Bates DW, Small SD, Cooper JB, Nemeskal AR, Leape LL. The incident reporting system does not detect adverse drug events: a problem for quality improvement. Jt Comm J Qual Improv 1995; 21(10):541-8.

194. Schmidek JM , Weeks WB. Relationship between tort claims and patient incident reports in the Veterans Health Administration. Qual Saf Health Care 2005; 14(2):117-22.

195. Weingart SN, Ship AN, Aronson MD. Confidential clinician-reported surveillance of adverse events among medical inpatients. Journal of General Internal Medicine 2000; 15(7):470-7.

196. Coyle Y, Mercer S, Murphy-Cullen C, Schneider G, Hynan L. Effectiveness of a graduate medical education program for improving medical event reporting attitude and behavior. Quality & Safety in Health Care 2005; 14:383-87.

197. Uribe CL, Schweikhart SB, Pathak DS, Dow M, Marsh GB. Perceived barriers to medical-error reporting: an exploratory investigation. Journal of Healthcare Management 2002; 47(4):263-79.

198. Vincent C, Stanhope N, Crowley-Murphy M. Reasons for not reporting adverse incidents: an empirical study. J Eval Clin Pract 1999; 5(1):13-21.

199. Eland IA, Belton KJ, van Grootheest AC, Meiners AP, Rawlins MD, Stricker BH. Attitudinal survey of voluntary reporting of adverse drug reactions. Br J Clin Pharmacol 1999; 48(4):623-7.

200. Kingston MJ , Evans SM, Smith BJ, Berry JG. Attitudes of doctors and nurses towards incident reporting: a qualitative analysis. Med J Aust 2004; 181(1):36-9.

201. Firth-Cozens J, Redfern N, Moss F. Confronting Errors in Patient Care: Report of Focus Groups. University of Birmingham, 2001; ISBN 1 861 352 689.

202. Walker SB, Lowe MJ. Nurses' views on reporting medication incidents. Int J Nurs Pract 1998; 4(2):97-102.

203. Elnitsky C, Nichols B, Palmer K. Are hospital incidents being reported? Journal of Nursing Administration 1997; 27(11):40-6.

204. Kaplan HS, Fastman BR. Organization of event reporting data for sense making and system improvement. Quality & Safety in Health Care. 12 Suppl 2:Ii68-72, 2003 Dec.

205. Jeffe DB, Dunagan WC, Garbutt J *et al.* Using focus groups to understand physicians' and nurses' perspectives on error reporting in hospitals. Joint Commission Journal on Quality & Safety 2004; 30(9):471-9.

206. Rosenthal MM. How doctors think about medical mishap. Rosenthal MM, Mulcahy L, Lloyd-Bostock Se. Medical Mishaps: pieces of the puzzle. Philadelphia: Open University Press, 1999.

207. Wu AW, Folkman S, McPhee SJ, Lo B. Do house officers learn from their mistakes? JAMA 1991; 265(16):2089-94.

208. Sexton JB, Thomas EJ, Helmreich RL. Error, stress, and teamwork in medicine and aviation: cross sectional surveys. BMJ 2000; 320(7237):745-9.

209. Wu AW. Medical error: the second victim. The doctor who makes the mistake needs help too. BMJ 2000; 320(7237):726-7.

210. Leape LL. Why should we report adverse incidents? J Eval Clin Pract 1999; 5(1):1-4.

211. Creswell J. Research Design: Qualitative, Quantitative and Mixed Methods Approaches. 2nd edition. California, US: Sage Publication, Inc., 2003.

212. Stewart D, Shamdesani P. Focus Groups: Theory and practice. Newbury Park: Sage, 1991.

213. Kitzinger J. Qualitative research. Introducing focus groups. BMJ 1995; 311(7000):299-302.

214. Jackson CJ, Furnham A. Designing and Analysing Questionnaires and Surveys: A manual for health professionals and administrators. London, England: Whurr Publishers, 2000.

215. Lawton R, Parker D. Barriers to incident reporting in a healthcare system. Qual Saf Health Care 2002; 11(1):15-8.

216. Billings CE. The NASA Aviation Safety Reporting System: Lessons learned from voluntary incident reporting. Enhancing Patient Safety and Reducing Errors in Health Care. Chicago, Illinois: National Patient Safety Foundation, 1999.

217. Lindgren OH, Christensen R, Harper Mills D. Medical malpractice risk management warning systems. Law and Contemporary Problems 1991; 54(2):23-41.

218. Runciman WB, Sellen A/Webb RK, Barker L. Errors, incidents and accidents in anaesthetic practise. Anaesthetic Intensive Care 1993; 21:506-19.

219. Runciman WB. Qualitative versus quantitative research - balancing cost, yield and feasibility. Anaesthesia and Intensive Care 1993; 21:502-5.

220. Frey B, Buettiker V, Hug MI *et al.* Does critical incident reporting contribute to medication error prevention?. European Journal of Pediatrics 2002; 161(11):594-9.

221. Runciman W, Merry A, Smith AM. Improving patients' safety by gathering information. Anonymous reporting has an important role. BMJ 2001; 323(298):7308.

222. Runciman WB, Edmonds MJ, Pradhan M. Setting priorities for patient safety. Quality & Safety in Health Care 2002; 11(3):224-9.

223. Sivaram C. Impact of a quality improvement model on ADR reporting. Pharm Ther 1994; 235-47.

224. Johnson CW. How will we get the data and what will we do with it then? Issues in the reporting of adverse healthcare events. Quality Safety Health Care 2003; 12(Supplement 11):ii64-ii67.

225. Wald H, Shojania K. Incident reporting. Shojania KG DBMKWRM. Making Health Care Safer: a Critical Analysis of Patient Safety Practices . Evid Rep Technol Assess (Summ).AHRQ publication 01-E058 edition. Rockville, MD: Agency for Healthcare Research and Quality, 2001.

226. Zhang J, Patel VL, Johnson TR, Shortliffe EH. A cognitive taxonomy of medical errors. Journal of Biomedical Informatics 2004; 37(3):193-204.

227. Zhang J, Patel VL, Johnson TR, Shortliffe EH. Toward a cognitive taxonomy of medical errors. Proceedings of the AMIA Annual Symposium. 2002; 934-8.

228. Sullivan P. Failure to study GPs' medical errors a mistake. CMAJ Canadian Medical Association Journal 2001; 165(7):939.

229. Kumar V, Barcellos WA, Mehta MP, Carter JG. An analysis of critical incidents in a teaching department for quality assurance. A survey of mishaps during anaesthesia. Anaesthesia 1988; 43(10):879-83.

230. Australian Incident Monitoring System (AIMS) Australian Patient Safety Foundation. Adelaide, SA: Australian Patient Safety Foundation; 2003.

231. Busse DK, Wright DJ. Classification and analysis of incidents in complex medical environments. Topics in Health Information Management, 20(4):1-11, 2000 May.(29 Ref) .

232. Degeling P, Kennedy J, Hill M. Mediating the cultural boundaries between medicine, nursing and management--the central challenge in hospital reform. Health Services Management Research 2001; 14(1):36-48.

233. Auditor General's Office. Is patient safety performance monitoring and reporting effective? Managing patient safety in public hospitals. Melbourne: Government of Victoria, 2005; 2005:3 Available at http://www.audit.vic.gov.au/reports_par/agp102cv.html (accessed 3rd January 2006).

234. Yong H, Kluger MT. Incident reporting in anaesthesia: a survey of practice in New Zealand. Anaesthesia & Intensive Care 2003; 31(5):555-9.

235. Feely J, Moriarty S, O'Connor P. Stimulating reporting of adverse drug reactions by using a fee. BMJ 1990; 300(6716):22-3.

236. Benson M, Junger A, Fuchs C *et al.* Using an anesthesia information management system to prove a deficit in voluntary reporting of adverse events in a quality assurance program. Journal of Clinical Monitoring & Computing 2000; 16(3):211-7.

237. Atherton T. Implementing a stronger patient safety program using the internet takes step-by-step planning. Quality Letter for Healthcare Leaders 2001; 13(11):10-1.

238. Bent PD, Bolsin SN, Creati BJ, Patrick AJ, Colson ME. Professional monitoring and critical incident reporting using personal digital assistants. Med J Aust 2002; 177(9):496-9.

239. Baldwin I, Beckman U, Shaw L, Morrison A. Australian incident monitoring study in intensive care: local unit review meetings and report management. Anaesthesia & Intensive Care 1998; 26(3):294-7.

240. Kizer K, Under Secretary for Health . Large system change and a culture of safety. Enhancing Patient Safety and Reducing Errors in Health Care. Chicago: National Patient Safety Foundation, 1999.

241. Moore A. The ethics of payment for research participants. Monash Bioethics Rev 1996; 15 (3):10-3.

242. Dickey B. Are financial incentives and best practice compatible? Psychiatric Services 2004; 55(2):130-31.

243. Jick H. Adverse drug reactions: the magnitude of the problem. Journal of Allergy & Clinical Immunology 1984; 74(4 Pt 2):555-7.

244. Maass G, Cortezzo M. Computerizing incident reporting at a community hospital. Joint Commission Journal on Quality Improvement 2000; 26(6):361-73.

245. Wu AW, Pronovost P, Morlock L. ICU Incident Reporting systems. Journal of Critical Care 2002; 17(2):86-94.

246. Greengold NL. A web-based program for implementing evidence-based patient safety recommendations. Joint Commission Journal on Quality Improvement. 2002; 28(6):340-8.

247. Lubomski LH, Pronovost PJ, Thompson DA. *et al.* Building a better incident reporting system: perspectives from a multisite project. Journal of Clinical Outcomes Management. 2004; 11(5):275-80.

248. Kempe A, Luberti AA, Hertz AR *et al.* Delivery of pediatric after-hours care by call centers: a multicenter study of parental perceptions and compliance. Pediatrics 2001; 108(6):E111.

249. St George IM, Cullen MJ. The Healthline pilot: call centre triage in New Zealand. New Zealand Medical Journal 2001; 114(1140):429-30.

250. Anonymous. 'Dial-A-Doc' puts physicians on the line of 24-hour telephone info and triage system. Healthcare Demand & Disease Management 1997; 3(3):42-6.

251. Moherman LJ, Kolar MM. Complication rates for a telephone-based anticoagulation service. American Journal of Health-System Pharmacy 1999; 56(15):1540-2.

252. Australian Council for Safety and Quality in Health Care. Adverse Medicine Events Line [Web Page]. Available at http://www.safetyandquality.org/articles/ACTION/amehomepg2.pdf. (Accessed 3 January 2006).

253. Gordon NF, Salmon RD, Mitchell BS *et al.* Innovative approaches to comprehensive cardiovascular disease risk reduction in clinical and community-based settings. Current Atherosclerosis Reports 2001; 3(6):498-506.

254. US Food and Drug Administration. The FDA Safety Information and Adverse Event Reporting Program [Web Page]. April 2004; Available at http://www.fda.gov/medwatch/report/hcp.htm . (Accessed 3 January 2006).

255. Soumerai SB. Principles and uses of academic detailing to improve the management of psychiatric disorders. International Journal of Psychiatry in Medicine 1998; 28(1):81-96.

256. Avorn J, Soumerai S. Improving drug therapy decisions through educational outreach: A randomised controlled trial of academically based 'detailing'. New Engl J Med 1983; 308:457-63.

257. Del Mar CB, Mitchell GK. Feedback of evidence into practice. Med J Aust 2004; 180(6 Suppl):S63-5.

258. National Health Data Committee. National Health Data Dictionary Summary edition . National Health Labour Force. Canberra: AIHW, 2002; AIHW Cat. No. HWI 36.

259. Australian Bureau of Statistics. Population by Age and Sex in Statistical Local Areas, South Australia. Canberra, Australia: Australian Bureau of Statistics (Catalogue no. 3235.4.55.001), 2004.

260. Babbie E. Survey Research Methods. 2nd edition. Belmont, Calif: Wadsworth Pub. Co, 1990.

261. Anastasi A, Urbina S. Psychological Testing. 7th edition. New Jersey: Prentice Hall, 1997.

262. Fink A, Kosecoff J. How to Conduct Surveys- a Step-by-Step Guide. California: Sage Publications, Inc., 1985.

263. Mueller D. Reliability and Validity of Attitude Measures. Measuring Social Attitudes: A Handbook for Researchers and Practitioners. New York: Teachers College Press, 1986: 57-75.

264. Edwards P, Roberts I, Clarke M *et al.* Increasing response rates to postal questionnaires: systematic review. British Medical Journal 2002; 324(7347):1183.

265. McCracken G. The long interview. Sage university paper series on qualitative research methods. Vol. 13. Beverly Hills, CA: Sage Publications, 1988: 9-49.

266. Patton M. Sampling and triangulation. Qualitative evaluation and research methods. Newbury Park: Sage Publications, 1990: 165-98.

267. Kidd PS, Parshall MB. Getting the focus and the group: enhancing analytical rigor in focus group research. Qualitative Health Research 2000; 10(3):293-308.

268. Mays N, Pope C. Qualitative research in health care. Assessing quality in qualitative research. BMJ 2000; 320(7226):50-2.

269. NU*DIST qualitative analysis software, Version Release 4.0. Victoria, Australia: QSR International Pty Ltd, 2000.

270. Tones K, Tilford S. Health education: effectiveness, efficiency and equity. 2nd edition. London: Chapman and Hall, 1994.

271. Triandis H. Values, attitudes, and interpersonal behaviour. Nebr Symp Motiv 1979; 27:195-259.

272. Triandis HC. Attitude and attitude change. New York: John Wiley and Sons, 1971.

273. Australian Industrial Relations Commission. Nurses (ANF-South Australian Private Sector) Award 2003. South Australia: Commonwealth Government Printer AW825646, 2004.

274. Better Service Delivery Program. Available at http://bsdp.hsnet.nsw.gov.au/. (Accessed 3 January 2006).

275. Bagian JP, Lee C, Gosbee J *et al.* 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 2001; 27(10):522-32.

276. Bagian J. VA Hospitals. Australian Patient Safety Foundation National Summit on Patient Safety. Adelaide, South Australia: Australian Patient Safety Foundation, 2003.

277. Australian/New Zealand Standard. Risk Management (AS/NZS 4360:1999). New South Wales, Australia: Standards Australia, 1999.

278. Australian Teleservices Association. Available at http://www.ata.asn.au/. (Accessed 3 January 2006).

279. Australian Communications Authority. Telecommunicatons (Emergency Services) Determination . Telecommunications (Consumer Protection and Service Standards) Act 1999. Subsection 147 (1) .

280. Palmer E, eloise@vivaz.com.au. Call Centre key performance indicators. [E-mail to, susan.evans@adelaide.edu.au]. 15 April 2005.

281. Leape LL, Cullen DJ, Clapp MD *et al.* Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. JAMA 1999; 282(3):267-70.

282. Royal Australasian College of Surgeons. Guide to Continuing Medical Education [Web Page]. Available at www.surgeons.org/Content/NavigationMenu/FellowshipandStandards/ProfessionalStandards/ApprovedCMEactivities/cme_guide.pdf. (Accessed 3 January 2006).

283. Royal Australasian College of Physicians. Maintenance of Professional Standards [Web Page]. October 2005; Available at http://www.racp.edu.au/public/mops_whatis.htm. (Accessed 3 January 2006).

284. Royal Australian College of General Practitioners. Quality Assurance and Continuing Medical Education [Web Page]. 23 February 1995; Available at http://www.racgp.org.au/document.asp?id=868. (Accessed 3 January 2006).

285. Therapeutics Goods Administration, Department of Health and Aged Care. Australian Therapeutic Device Bulletin [Web Page]. Available at http://www.tga.gov.au/docs/html/atdb/tdbindex.htm. (Accessed 3 January 2006).

286. Berwick DM. Disseminating innovations in health care. JAMA 2003; 289(15):1969-75.

287. Stata statistical software. Version Release 8.0. College Station, TX: Stata Corporation; 2003.

288. Australian Bureau of Statistics (ABS). Estimated Resident Population by Age and Sex in Statistical Local Areas, South Australia. Canberra, Australia: Australian Bureau of Statistics (Catalogue no. 3235.4), 2001.

289. Triandis H. Interpersonal behaviour. California: Brooks/Cole Publishing Company, 1977.

290. Rogers AS. Adverse drug events: identification and attribution. Drug Intell Clin Pharm 1987; 21(11):915-20.

291. Australian Bureau of Statistics (ABS) and the Australian Institute for Health and Welfare (AIHW). The health and welfare of Australia's Aboriginal and Torres Strait Islander peoples. Canberra, ACT: ABS, 2001; Cat. No. 4704.0.

292. Office for Aboriginal and Torres Strait Islander Health Division CDoHaAC. Better Health Care Studies in the Successful Delivery of Primary Health Care Services for Aboriginal and Torres Strait Islander Australians . Canberra, Australia, 2001.

293. Cleary PD. The increasing importance of patient surveys. Now that sound methods exist, patient surveys can facilitate improvement. BMJ 1999; 319(7212):720-1.

294. Hebert PC, Levin AV, Robertson G. Bioethics for clinicians: 23. Disclosure of medical error. CMAJ. 2001; 164(4):509-13.

295. Ali NY, Lo TY, Auvache VL, White PD. Bad press for doctors: 21 year survey of three national newspapers. BMJ 2001; 323(7316):782-3.

296. Knox R. Doctor's Orders Killed Cancer Patient Dana-Farber Admits Drug Overdose Caused Death Of Globe Columnist, Damage To Second Woman. *Boston Globe.* 23 March 1995.

297. Anon. Cancer patient, 18, critical after drug injection blunder. Daily Mail. 24 Jan: 2001 (p11,col 1-3).

298. Lateline - late night news & current affairs. Record payout sparks concern in medical circles [Web Page]. 11 May 2001; Available at http://www.abc.net.au/lateline/content/2001/s409179.htm . (Accessed 3 January 2006).

299. Australian Council for Safety and Quality in Health Care. Safety through Action: Improving Patient Safety in Australia. Third report to the Australasian Health Ministers' Conference. Canberra: Commonwealth of Australia, 2002.

300. British Broadcasting Commission- UK edition. Harold Shipman found dead in cell [Web Page]. 13 January 2004; (Accessed June 2005).

301. British Broadcasting Commission- UK edition. Australia's Doctor Death [Web Page]. 10 June 2005; Available at http://news.bbc.co.uk/go/pr/fr/-/2/hi/asia-pacific/4080164.stm. (Accessed 3 January 2006).

302. Australian Medical Association. Media Release- AMA welcomes Federal Government intervention to ease medical indemnity crisis [Web Page]. 28 March 2002; Available at http://www.ama.com.au/web.nsf/doc/WEEN-5GB4AN. (Accessed 3 January 2006).

303. Wakefield DS. Understanding the costs of nosocomial infections. Wenzel RPE. Prevention and Control of Nosocomial Infections. 2nd edition. Baltimore, Maryland: Williams and Wilkins, 1993.

304. Miller RR. Interpretation of studies on adverse drug reactions. Am J Hosp Pharm 1977; 34:753-4.

305. Talley RB, Laventuruer MF. Drug-induced illness. JAMA 1974; 229(1043).

306. Kingston M, Evans SM, Smith B. Attitudes towards incident reporting: qualitative analysis of healthcare focus groups. Health and Social Care Modelling Seminar. Adelaide, South Australia: 2002.

307. Aron DC, Headrick LA. Educating physicians prepared to improve care and safety is no accident: it requires a systematic approach. Qual Saf Health Care 2002; 11(2):168-73.

308. Stevens DP. Finding safety in medical education. Qual Saf Health Care 2002; 11(2):109-10.

309. Branch W, Pels RJ, Lawrence RS, Arky R. Becoming a doctor. Critical-incident reports from third-year medical students. NEJM 1993; 329(15):1130-2.

310. Commonwealth Department of Health and Ageing. Should you pack your bag for weeks or days? [Web Page]. 2 August 2005; Available at http://www.seniors.gov.au./internet/wcms/Publishing.nsf/Content/health-ahca-sooph05-ins_pack.htm. (Accessed 3 January 2006).

311. Australian Institute of Health and Welfare. Nursing and Midwifery Labour Force 2003. Canberra: AIHW 2005; Catalogue number HWL 31.

312. Australian Institute of Health and Welfare. Medical Labour Force 2002. Canberra: AIHW 2004; Catalogue number HWL 30.

313. Degeling P, Sorenson R, Maxwell S, Aisbett C, Xang K, Coile B. Organisation of Hospital Care and its Effect. NSW, Australia: University of New South Wales, 2001.

314. Firth-Cozens J. Barriers to incident reporting. Quality in Health Care 2002; 11(1):7.

315. Farrell G. From tall poppies to squashed weeds: why don't nurses pull together more? J Adv Nurs 2001; 35(1):26-33.

316. Kitzinger J. Introducing focus groups. Mays EN, Pope C. Qualitative Research in Health Care. London: BMJ Publishing Group, 1996: 36-45.

317. Krauss M, Evanoff B, Hitcho Eea. Risk factors for falls. J Intern Med 2005; 20:116-22.

318. Mintzberg H. Mintzberg on Management: inside our strange world of organisations. New York: Free Press, 1989.

319. Robbins SP. Organizational Behaviour: concepts, controversies, and applications. 5th edition. London: Prentice-Hall, International (UK) Limited, 1991.

320. Salvage J, Smith R. Doctors and nurses: doing it differently. BMJ 2000; 320(7241):1019-20.

321. Soumerai SB, McLaughlin TJ, Gurwitz JH *et al.* Effect of local medical opinion leaders on quality of care for acute myocardial infarction: a randomized controlled trial. JAMA 1998; 279(17):1358-63.

322. Rogers FM. Diffusion of Innovations. 4th edition. New York, NY: Free Press, 1995.

323. Borenstein J, Chiou CF, Henning JM *et al.* Physician attitudes toward strategies to promote the adoption of medical evidence into clinical practice. American Journal of Managed Care 2003; 9(3):225-34.

324. Grimshaw JM , Eccles MP, Walker AE, Thomas RE. Changing physicians' behavior: what works and thoughts on getting more things to work. Journal of Continuing Education in the Health Professions 2002; 22(4):237-43.

325. Britt H, Miller GC, Steven ID *et al.* Collecting data on potentially harmful events: a method for monitoring incidents in general practice. Fam Pract 1997; 14(2):101-6.

326. Bhasale A, Norton KJ, Britt H. Tests and investigations. Indicators for better utilisation. Australian Family Physician 683-1996; 25(5):680-1.

327. Bhasale A, Miller G, Britt H, Reid S. Warfarin prescribing. Australian Family Physician 1996; 25(7):1119-20.

328. Bhasale A. The wrong diagnosis: identifying causes of potentially adverse events in general practice using incident monitoring. Fam Pract 1998; 15(4):308-18.

329. Britt H, Reid S, Bhasale A, Miller G. Clinical incidents in general practice. Prescription errors. Aust Fam Physician 1996; 25(10):1609-10.

330. Zivin JG, Pfaff AS. To err on humans is not benign. Incentives for adoption of medical error-reporting systems. Journal of Health Economics 2004; 23(5):935-49.

331. Waring JJ. A qualitative study of the intra-hospital variations in incident reporting.[See comment]. International Journal for Quality in Health Care 2004; 16(5):347-52.

332. Sorenson L. Computerized incident reporting: an example of healthcare IT for the 21st century. Journal of Healthcare Risk Management 2001; 21(2):15-20.

333. Weingart SN, Toth M, Eneman J *et al.* Lessons from a patient partnership intervention to prevent adverse drug events. International Journal for Quality in Health Care 2004; 16(6):499-507.

334. France DJ, Cartwright J, Jones V, Thompson V, Whitlock JA. Improving pediatric chemotherapy safety through voluntary incident reporting: lessons from the field. Journal of Pediatric Oncology Nursing 2004; 21(4):200-6.

335. Haines T, Bennell KL, Osborne R, Hill KD. Effectiveness of targeted falls prevention programme in subacute hospital setting: randomised controlled trial. BMJ. 2004; 328(7441):676-9.

336. Kivlahan C, Nelson K, Buddenbaum J. The development of an electronic voluntary adverse event reporting system [Web Page]. 2002; Available at http://www.wmrc.com/businessbriefing/pdf/health3_2002/reference/Ref24.pdf. (Accessed 3 January 2006).

337. Sleigh A. Uses of error: systemic causes. Lancet 2001; (358):1364.

338. Larson EB. Measuring, monitoring, and reducing medical harm from a systems perspective: a medical director's personal reflections. Academic Medicine 2002; 77(10):993-1000.

339. Flaatten H. Effects of major structural change to the intensive care unit. Qual Saf Health Care 2005; 14:270-2.

340. Witham MD, Kendall PA. A prospective, physician self-reported adverse incident audit on a general medical unit. Journal of Quality in Clinical Practice 2001; 21(3):61-5.

341. Gawande AA, Thomas EJ, Zinner MJ, Brennan TA. The incidence and nature of surgical adverse events in Colorado and Utah in 1992. Surgery 1999; 126(1):66-75.

342. Wolff AM, Bourke J. Reducing medical errors: a practical guide. Med J Aust 2000; 173(5):247-51.

343. Steven ID, Malpass A, Moller J, Runciman WB, Helps SC. Towards safer drug use in general practice. Journal of Quality in Clinical Practice 1999; 19(1):47-50.

344. Khare R, Uren B, Wears R. Capturing more emergency department errors via an anonymous web-based reporting system. Q Manage Health Care 2005; 14(2):91-4.

345. Siwicki B. Biometric and single-sign-on technologies cure the passwords 'haddock'. Health Data Management 2004; 12(9):8.

346. Adelaide West and National Ageing Research Insistute. Commonwealth Department of Health and Ageing. Stay on your feet; a guide to prevent falls for older people. Adelaide, SA: State Government of South Australia, 2004.

347. Mahoney J. Immobility and Falls. Clinics in Geriatric Medicine 1998; 14(4):699-726.

348. Queensland Health. Falls prevention on older people. Statewide action plan 2002 - 2006. Brisbane: Queensland Government, 2002.

349. Carroll AE, Tarczy-Hornoch P, O'Reilly E, Christakis DA. Resident documentation discrepancies in a neonatal intensive care unit. Pediatrics 2003; 111(5 Pt 1):976-80.

350. Perrow C. Normal Accidents: Living with High Risk Technologies. New York: Basic Books, 1984.

351. West E. Organisational sources of safety and danger: sociological contributions to the study of adverse events. Qual Health Care 2000; 9(2):120-6.

352. Jenkins-Clark S, Carr-Hill R. Marking time. Health Service Journal 1992; 102(5297):24-5.

353. Benbow M. Pressure ulcer incidence reporting. Nursing Standard 2004; 18(32):57-66.

354. McGettigan P, Golden J, Conroy RM, Arthur N, Feely J. Reporting of adverse drug reactions by hospital doctors and the response to intervention. Br J Clin Pharmacol 1997; 44(1):98-100.

355. Australian Patient Safety Foundation. APSF newsletter [Web Page] June 2002; Available at http://www.apsf.net.au/Newsletter_2002_06.pdf. (Accessed 3 January 2006).

356. Davis DA, Thomson MA, Oxman AD, Haynes RB. Changing physician performance. A systematic review of the effect of continuing medical education strategies. JAMA 1995; 274(9):700-5.

357. Cook DJ, Montori VM, McMullin JP, Finfer SR, Rocker GM. Improving patients' safety locally: changing clinician behaviour. Lancet 2004; 363(9416):1224-30.

358. Berwick DM. Improvement, trust, and the healthcare workforce. Qual Saf Health Care 2003; 12(6):448-52.

359. Bolsin S. Use of PDA technology to improve reporting of error by anaesthetists. Bristol Ten Years On- What's Changed? Monash University.

360. Rosser WW. Using the perception-reality gap to alter prescribing patterns. Journal of Medical Education 1983; 58(9):728-32.

361. Davis DA, O'Brian M, Thomson MA *et al.* Impact of formal continuing medical education: do conferences, workshops, rounds and other traditional continuing education activities change physician behaviour or health care outcomes? JAMA 1999; 282(9):867-74.

An intervention to improve voluntary incident reporting in South Australian public hospitals

Susan Margaret Evans

BN (Deakin), Grad Dip Clinical Epidemiology (Monash)

Volume II

Appendices

to a thesis submitted in 2006 for the degree of Doctorate of Philosophy

Department of Medicine

University of Adelaide

APPENDICES

Appendix 1: Baseline staff survey information sheet and survey tool.

Incident Reporting to Improve Systems

Staff Information Sheet

The Clinical Epidemiology and Health Outcome Unit (NWAHS) in collaboration with the Department of Anaesthesia and Intensive Care (RAH) invite you to participate in a research project which we believe is of relevance to all healthcare workers.

Why do this study?

- Mistakes happen frequently in hospitals and often go undetected. We are trying to find out why under-reporting happens.
- It is likely that most healthcare workers will, at some stage in their career, inadvertedly cause harm to a patient. Open acknowledgment that even the most conscientious and clever person can make a mistake is slow in coming in health.
- Mistakes will continue to happen unless we find a way to make the system robust enough to cope with individual errors, rather than just blaming the individual.

What do I have to contribute?

- You have been chosen to participate because you are a doctor, nurse, pharmacist or dietician working on one of the 10 wards involved in this study.
- By filling in this questionnaire, which will take 5-10 minutes, you will help us identify (1) barriers to reporting and (2) what you think constitutes an incident worthy of reporting.

What do we hope to achieve?

- Your responses will help us set up an incident monitoring system that best meets your needs. The outcome, we hope, is to improve the quality of care received by patients by reducing preventable harm. This will be achieved by:
  - Identifying risks through a reporting process
  - Open discussion of incidents in a 'blame-free' environment by staff at the clinical level
  - Identifying system changes which will reduce the likelihood of individual error

What does consent involve?

- By filling in the questionnaire you are consenting solely to providing information about the barriers to reporting and what you believe constitutes an incident worthy of reporting.
- The questionnaire has no individual identifiers and your consent is voluntary.

Any queries about this project can be directed to:	
Chief Investigators	Associate Professor Brian Smith (82226670) Professor Bill Runciman (82224000) Dr Robert Adams (82226000)
Project Officers	Sue Evans (82226387) Jesia Berry (82226897)

This study has been approved by the North Western Adelaide Health Service Ethics of Human Research Committee. Should you wish to speak to a person not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study or your rights as a participant, or should you wish to make a confidential complaint, you may contact the Executive Officer of this Committee Mr Paul Miller on (08) 8222 6841.

Incident Reporting Questionnaire

1. Does this hospital have an incident reporting system?
   - ☐ 1 Yes
   - ☐ 2 No — Go to Question 11
   - ☐ 3 I don't know — Go to Question 11
2. Have you ever filled in an incident form?
   - ☐ 1 Yes
   - ☐ 2 No
3. Do you know how to locate or access the incident form?
   - ☐ 1 Yes
   - ☐ 2 No
   - ☐ 3 I'm not quite sure
4. Have you filled in an incident form in the last month?
   - ☐ 1 Yes
   - ☐ 2 No
   - ☐ 3 I'm not quite sure
5. Do you know what to do with the completed incident form?
   - ☐ 1 Yes
   - ☐ 2 No
   - ☐ 3 I'm not quite sure
5. For each incident that you report, do you :
   - ☐ 1 Use only a hospital incident form (eg. WorkCover, Accident/Incident, OH&S, Exposure to Body Fluids form)
   - ☐ 2 Use only the AIMS+ form
   - ☐ 3 Use both a hospital incident form and AIMS+ form
   - ☐ 4 Use one or the other, whichever I feel is more appropriate
   - ☐ 5 Never know which form to use
7. Have you ever posted an anonymous AIMS+ form directly to the Australian Patient Safety Foundation (APSF)?
   - ☐ 1 Yes
   - ☐ 2 No
3. We are interested in what sort of incidents and how often various types of incidents are captured on either the AIMS+ form or the hospital incident form.

Please comment on your reporting practices for the following incidents:		Never	Less than 50% of occasions	50% or more of occasions	Always	N/A
8.1 Patient sustained a pressure sore whilst in hospital.	How often do you report this incident?					
	How often do you think you should report it?					
8.2 Patient sustained an injury due to a fall in hospital.	How often do you report this incident?					
	How often do you think you should report it?					
8.3 Patient sustained a hospital-acquired infection eg infected wound site, phlebitis due to infected IV site.	How often do you report this incident?					
	How often do you think you should report it?					

		Never	Less than 50% of occasions	50% or more of occasions	Always	N/A
8.4 Patient sustained a DVT post-operatively due to inadequate prophylaxis.	How often do you report this incident?					
	How often do you think you **should** report it?					
8.5 Patient received wrong treatment or procedure.	How often do you report this incident?					
	How often do you think you **should** report it?					
8.6 Patient did not receive necessary treatment or procedure.	How often do you report this incident?					
	How often do you think you **should** report it?					
8.7 Staff made a drug error but it was not actually given (near miss).	How often do you report this incident?					
	How often do you think you **should** report it?					
8.8 Staff made a drug error where no corrective treatment was necessary.	How often do you report this incident?					
	How often do you think you **should** report it?					
8.9 Staff made a drug error resulting in corrective treatment being given.	How often do you report this incident?					
	How often do you think you **should** report it?					
8.10 Problems with equipment or machinery resulting in patient harm eg. faulty pump / bed.	How often do you report this incident?					
	How often do you think you **should** report it?					
8.11 Breach in confidentiality eg. Information given without authority.	How often do you report this incident?					
	How often do you think you **should** report it?					

9. I DON'T REPORT INCIDENTS BECAUSE:	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
9.1 I am worried about disciplinary action.	1	2	3	4	5
9.2 When the ward is busy I forget to make a report.	1	2	3	4	5
9.3 I am worried about litigation.	1	2	3	4	5
9.4 The incident form takes too long to fill out and I just don't have time.	1	2	3	4	5
9.5 My co-workers may be unsupportive.	1	2	3	4	5
9.6 I don't know whose responsibility it is to make a report.	1	2	3	4	5
9.7 I don't want the case discussed in meetings.	1	2	3	4	5
9.8 I don't feel confident that the form is kept anonymous.	1	2	3	4	5
9.9 Adverse incident reporting is unlikely to lead to system changes that will improve the quality of care.	1	2	3	4	5
9.10 I don't want to get into trouble.	1	2	3	4	5
9.11 Junior staff are often blamed unfairly for adverse incidents.	1	2	3	4	5

PTO →

(CONTINUED) I DON'T REPORT INCIDENTS BECAUSE:	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
9.12 When the incident does not eventuate or a correction was made (a near miss) then I don't see any point in reporting it.	1	2	3	4	5
9.13 If I report something, I never get any feedback on what action is taken.	1	2	3	4	5
9.14 The AIMS+ form is too complicated and requires too much detail.	1	2	3	4	5
9.15 I feel that if I discuss the case with the person involved nothing else needs to be done.	1	2	3	4	5
9.16 I worry about who else is privy to the information that I disclose.	1	2	3	4	5
9.17 The incident was too trivial.	1	2	3	4	5
9.18 It's not my responsibility to report somebody else's mistakes.	1	2	3	4	5
9.19 Even if I don't give my details I'm sure that they'll track me down.	1	2	3	4	5

10 Please give any other comments / reason(s) for not reporting incidents _____

_____

_____

11 What is your gender?

- ☐ 1 Male
- ☐ 2 Female

12 What is your age?

- ☐ 1 19-29 years
- ☐ 2 30-39 years
- ☐ 3 40-49 years
- ☐ 4 50-59 years
- ☐ 5 Greater than 60 years

13. What is your profession?

☐ 1 Intern ☐ 2 Resident ☐ 3 Registrar ☐ 4 Consultant

☐ 5 CNM or Clinical Nurse ☐ 6 Registered Nurse ☐ 7 Enrolled Nurse

☐ 8 Pharmacist ☐ 9 Dietician ☐ 10 Other (please specify) _____

14. How many years post entry-level qualification have you spent in the acute health sector?

- ☐ 1 Less than 1 yr
- ☐ 2 1–3 years
- ☐ 3 4-5 years
- ☐ 4 6-10 years
- ☐ 5 Greater than 10 years

Thank you very much for sparing us your time.

_____

Appendix 2: Ethics of Human Research Committee approval

NORTH WESTERN ADELAIDE HEALTH SERVICE

Ethics of Human Research Committee

29 July 2003

Dr B Smith
Epidemiology Unit
The Queen Elizabeth Hospital

Dear Dr Smith Application Number 107/2001

The Ethics of Human Research Committee Chairman has considered amendment to your protocol entitled:

"Evaluation of a focus group driven intervention to improve incident reporting in hospitals

The amendments as submitted 7 July 2003 have been reviewed and approved

Approval Status Final

*Where conditions require documents to be changed or submitted, final approval will not be given until sighting by the Chairman.

Protocols are approved for up to twelve months only and a report is required at the end of the study or 12 month period. Extensions will not be granted without a report to the Committee.

The Ethics of Human Research Committee must be notified should there be significant changes to a protocol.

Yours sincerely

Paul F Miller
Executive Officer

Dr M Hoby
Chairman
Ethics of Human Research Committee

ROYAL ADELAIDE HOSPITAL
Medical Administration & Services
[redacted]

8222 4139

12 September 2001

Level 5
Margaret Graham Building
TELEPHONE
(08) 8222 5543
FACSIMILE
(08) 8222 5936
WEBSITE
http://www.rah.sa.gov.au

Prof W B Runciman
ANAESTHESIA & INTENSIVE CARE UNIT
ROYAL ADELAIDE HOSPITAL

Dear Prof Runciman,

Re: "Evaluation of a focus group driven intervention to improve incident reporting in hospitals." RAH Protocol No: 010902

I am writing to advise that ethical approval has been given to the above project. Please note that the approval is ethical only, and does not imply an approval for funding of the project.

Human Ethics Committee deliberations are guided by the Declaration of Helsinki and N.H. and M.R.C. Guidelines on Human Experimentation. Copies of these can be forwarded at your request

Adequate record-keeping is important and you should retain at least the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them if necessary, in the future. The Committee will seek a progress report on this project at regular intervals and would like a brief report upon its conclusion.

If the results of your project are to be published, an appropriate acknowledgment of the Hospital should be contained in the article.

Yours sincerely,

DR M JAMES
CHAIRMAN
RESEARCH ETHICS COMMITTEE

WHYALLA HOSPITAL & HEALTH SERVICES INC.

24 September 2002

Ms Sue Evans
Clinical Epidemiology and Health Outcomes Unit
The Queen Elizabeth Hospital
28 Woodville Rd
WOODVILLE SOUTH SA 5011

Re: Adverse Events project Whyalla Hospital & Health Services Inc.

Dear Sue

I am pleased to provide a formal statement in writing regarding the Whyalla Hospital & Health Services Inc.'s agreement to and approval for participation in this project. The project has resolute support from the Executive and Board of Directors. Incident reporting and the functional analysis and learning from the data supplied is a significant issue for all organisations especially HealthCare. I look forward to our successful partnership in this venture and to contributing to the development of meaningful, robust and systematic incident reporting systems that will reduce preventable patient harm and improve the safety and quality of our HealthCare services.

Yours faithfully

MARGARET NIHILL
CHIEF EXECUTIVE OFFICER

Government

Hospital
PO Box 267
Whyalla 5600
Tel (08) 8648 8300
Fax (08) 8648 8399

Community Health Centre
PO Box 2488
Whyalla Norrie 5608
Tel (08) 8648 8930

Domiciliary Care
PO Box 267
Whyalla 5600
Tel (08) 8648 8500
Fax (08) 8648 8594

'Oronga' Day Care Centre
PO Box 267
Whyalla 5600
Tel (08) 8645 8025

23 October 2002

Ms Sue Evans
Clinical Epidemiology & Health Outcomes Unit
Queen Elizabeth Hospital
Floor 8
Basil Hetzel Institute
28 Woodville Road
WOODVILLE SOUTH SA 5011

Re: IRIS Reporting Project

This letter advises that **MOUNT GAMBIER AND DISTRICTS HEALTH SERVICE INC.** is willing to participate in this project, with the appointment of a .2 coordinator position in the Emergency Department.

We understand that funding/resources will be made available for the training and payment of the person appointed to this position as well as the associated expenses incurred in monitoring, tracking, dealing with adverse clinical events and making appropriate reports required under the terms of the project.

Yours sincerely

Trena Mullan
MANAGER QUALITY IMPROVEMENT AND CUSTOMER LIAISON

for

Sue Thomson
DIRECTOR OF NURSING AND PATIENT SERVICES

Accredited by the Australian Council on Healthcare Standards until March 2003.

276-300 Wehl Street North, PO Box 267 Mount Gambier, 5290

Telephone: (08) 8721 1200 Facsimile: (08) 8721 1579 ABN: 32 874 272 262

Appendix 3: AIMS Incident Form

NOTE:
This appendix is included on pages 15-17 of volume 2 of the print copy of the thesis held in the University of Adelaide Library.

Appendix 4: Incident severity categories- AIMS+

Incident outcomes as categorised in the AIMS+ reporting system

Incident Level	Description of incident level
1	Potential incident: Dangerous state/ potential for harm/ no event occurred (eg understaffed ICU/ torn floor covering where no fall occurred)
2	Potential incident: Dangerous state/ potential for harm/ event occurred but intercepted (eg wrong drug drawn up but not given/ drug prescribed for patient with an allergy but not dispensed or administered)
3	Actual incident: No outcome. Event ran to completion/ no harm occurred (eg harmless drug given to wrong patient)
4	Actual incident: Minor outcome. Extra observations or monitoring/ reviewed by doctor/ no harm occurred or minor harm not requiring treatment.
5	Actual incident: Moderate outcome: Extra observations or monitoring/ reviewed by doctor/ minor diagnostic investigations (eg blood test or urinalysis)/ minor treatment (bandage, cold pack, analgesia)
6	Actual outcome: Moderate to significant outcome. Extra observations or monitoring/ reviewed by doctor/ diagnostic investigations (eg radiological procedures)/ need for treatment with another drug/ surgical intervention/ cancellation or postponement of treatment/ transfer to another area which does not require increased length of stay.
7	Actual outcome: Significant outcome. Hospital admission or increased length of stay/ morbidity which continues at discharge
8	Actual outcome: Severe outcome. Permanent disability/ contributed to death.

Appendix 5: Part VC- Commonwealth of Australia Health Insurance Commission Act

Commonwealth of Australia Health Insurance Commission Act

Section 124X of Part VC of the Act

SECT 124V
Object of this Part

(1) The object of this Part is to encourage efficient quality assurance activities in connection with the provision of certain health services.

(2) For the purpose of achieving that object, this Part contains provisions:

(a) Prohibiting:

(i) the disclosure of information that became known solely as a result of those activities; or

(ii) the production to a court of a document that was brought into existence solely for the purposes of those activities; and

(b) protecting certain persons engaging in those activities in good faith from civil liability in respect of the activities.

SECT 124W
Interpretation

(1) In this Part, unless the contrary intention appears:

authority, in relation to the disclosure of information, means an authority given by the Minister under section 124Z that is in force when the disclosure takes place.

court includes a tribunal, authority or person having power to require the production of documents or the answering of questions.

declared quality assurance activity means a quality assurance activity in respect of which a declaration by the Minister under section 124X is in force when the activity is engaged in.

disclose, in relation to information, means give, reveal, or communicate in any way.

health service includes any administrative or other service related to a health service.

person, except in the reference to another person in section 124ZB, includes a committee or other body of persons, whether incorporated or unincorporated, and includes a member of such a committee or other body.

produce includes permit access to.

quality, in relation to health services provided by a person, includes the practices of the person in providing the services or the competence of the person to provide the services.

quality assurance activity means:

(a) an assessment or evaluation of the quality, or a study of the incidence or causes of conditions or circumstances that may affect the quality, of health services provided by a person, whether before or after the commencement of this Part, being:

(i) services in respect of which payments were made, or that are or would be eligible for payments, under Part II, III or IV; or

(ii) services relating to the prescribing of pharmaceutical products in respect of which payments were made, or that are or would be eligible for payments, under Division 3 of Part VII of the *National Health Act 1953*; or

(iii) services in respect of which payments were made under the Health Care (Appropriation) Act 1998, or that are or would be eligible for such payments; or

(b) the making of a recommendation about the provision of those services as a result of such an assessment, evaluation or study; or

(c) the monitoring of the implementation of such a recommendation.

serious offence means an offence punishable by imprisonment for a period of more than one year.

(2) For the purposes of this Part:

(a) Information about a matter is not taken to have become known merely because of the existence or dissemination of suspicions, allegations or rumours about that matter; and

(b) Information may be taken to have become known solely as a result of a declared quality assurance activity even though it was previously known to a person whose actions have been or are being investigated by the persons engaging in the quality assurance activity.

SECT 124X
Minister may declare quality assurance activity to be an activity to which this Part applies

(1) The Minister may, by signed writing, declare a quality assurance activity described in the declaration to be a quality assurance activity to which this Part applies.

(2) A declaration may describe a quality assurance activity in any way, including any one or more of the following ways:

(a) by reference to the nature of the activity;

(b) by reference to a person who is engaging or proposes to engage in the activity;

(c) by reference to circumstances in which the activity is being, or is proposed to be, engaged in.

(3) The Minister must not make a declaration in respect of a quality assurance activity unless the Minister is satisfied that:

(a) any person who is engaging, or proposes to engage, in the activity is authorised to do so:

(i) under a law of the Commonwealth, of a State or of a Territory; or

(ii) by, or by an authority of, the Commonwealth, a State or a Territory; or

(iii) by a body that provides health care; or

(iv) by an educational institution; or

(v) by a body established wholly or partly for the purposes of research; or

(vi) by an association of health professionals; or

(vii) by any other prescribed body; and

(b) it is in the public interest, having regard to such criteria as are prescribed by the regulations, that this Part should apply to the activity.

(4) A declaration, unless sooner revoked, ceases to be in force at the end of 5 years after the instrument of declaration was signed, but this subsection does not prevent the Minister from making a further declaration in respect of the same activity.

SECT 124Y
Information about declared quality assurance activity not to be disclosed

(1) Subject to this section, a person who acquires any information that became known solely as a result of a declared quality assurance activity, whether the person acquired the information in the course of engaging in that activity, as a result of a disclosure under section 124Z or in any other way, must not, except for the purposes of that activity or in accordance with an authority given by

the Minister, directly or indirectly make a record of that information or disclose that information to another person or to a court.

Penalty: Imprisonment for 2 years.

(2) Subject to this section, a person cannot be required:

(a) to produce to a court a document that was brought into existence solely for the purposes of a declared quality assurance activity; or

(b) to disclose to a court any information that became known solely as a result of such an activity;

except when it is necessary to produce the document or disclose the information for the purposes of this Part.

(3) Subsections (1) and (2) do not apply to information that does not identify, expressly or by implication, a particular individual or particular individuals.

(4) Subsection (2) does not apply to a document that does not identify, either expressly or by implication, a particular individual or particular individuals.

(5) This section does not prohibit a disclosure of information if the person, or each of the persons, who would be directly or indirectly identified by the disclosure consents to that disclosure of the information.

(6) This section does not prohibit the disclosure of information to the Minister for the purpose of enabling the Minister to decide whether to authorise the disclosure of the information under section 124Z.

(7) If a quality assurance activity ceases to be a declared quality assurance activity, this section nevertheless continues to apply in respect of information that became known, or a document that was brought into existence, at a time when the activity was a declared quality assurance activity.

SECT 124Z
Minister may authorise disclosure of information about a serious offence

(1) If it appears to the Minister that information that became known after the commencement of this Part solely as a result of a declared quality assurance activity relates to conduct, whether the conduct took place before or after that commencement, that may have been a serious offence against a law (whether written or unwritten) in force in any State or Territory, the Minister may, by signed writing, authorise the information to be disclosed in a way stated in the instrument of authority for the purposes of law enforcement, a Royal Commission or any other prescribed purpose.

(2) Subsection (1) does not permit the Minister to authorise the disclosure of information of a non-factual nature (such as statements of opinion) unless the information consists only of matter contained in a report prepared by a person who engaged in the quality assurance activity.

Appendix 6: Principal Incident types- AIMS+ and Advanced AIMS

Comparison between fields in the AIMS+ and Advanced AIMS reporting system.

AIMS + database Principal Incident Type categories	Advanced AIMS Principal Incident Type categories
Fall	Fall
Security	Security
Medication	Medication
Documentation	Documentation
Behaviour	Behaviour/ human performance
Injury	Aggression
	Accident/ Occupational Health and Safety
	Pressure ulcer
Therapeutic: device or equipment or property	Medical device, equipment, property
	Buildings, fittings, fixtures, surrounds
Blood or blood products and oxygen	Blood or blood products
	Oxygen and gases
Other	Clinical Management
	Hospital-acquired infection
	Organisational management

Appendix 7: Risk matrices used in the single-page incident report form

Risk Matrix taken from that used in VA hospitals and implemented for four months- 4X4

Consequence / Likelihood	Catastrophic Death or permanent loss of function	Major Permanent lessening of body function	Moderate Increased length of stay or increased level of care	Minor No increased length of stay or level of care
Frequently Several times in one year	3	3	2	1
Occasionally Several times in 1-2 years	3	2	1	1
Uncommonly Sometime in 2-5 years	3	2	1	1
Remotely Sometime in 5-30 years	3	2	1	1

Risk Matrix adopted four months after commencement of intervention- 5x 5

Consequence / Likelihood	Extreme Death	Major Permanent loss of function	Moderate Permanent lessening of function, additional surgery, increased length of stay	Minor Required review and evaluation, extra investigation or referral to clinician	Insignificant No increased level of care or length of stay
Frequent (almost certain) Within a few weeks	1	1	2	3	3
Probable (likely) Several times a year	1	1	2	3	3
Occasional (possible) Sometime in 1-2 years	1	2	2	3	4
Uncommon (unlikely) Sometime in 2-5 years	1	2	3	4	4
Remote (rare) In exceptional circumstances	2	3	3	4	4

Appendix 8: IRIS Form

NOTE:
This appendix is included on page 29 of volume 2 of the print copy of the thesis held in the University of Adelaide Library.

Appendix 9: Terms of Reference for the IRIS Committee

South Australian Collaborative

Incident Reporting to Improve Systems (IRIS) Committee

Terms of Reference

General Scope and Authority

The Incident Reporting to Improve Systems (IRIS) project addresses the following standards from within the Australian Council on Healthcare Standards (ACHS) Evaluation and Quality Improvement Program (EQuIP):

Standard 1.5 Implementation of Care

- Care is coordinated to ensure the best possible outcomes for the patient/consumer.

Standard 1.6 Evaluation of Care

- The health care team evaluates the effectiveness and efficiency of care delivered to patients/consumers.

Criterion 5.1.5 Safe Practice and Environment

- An incident reporting system identifies potential harm, evaluates causal and contributing factors and corrective and preventive action is taken.

Purpose and function

The purpose of this committee is to work as a collaborative group to achieve (1) improvement in incident reporting and (2) a reduction in patient harm in public hospitals.

The IRIS Committee is a multi-disciplinary body functioning to:

- Work together as a multi-agency Committee to provide consistency of approach for project intervention across rural and metropolitan hospitals
- Ensure that the project achieves its goals within an acceptable timeframe
- Discuss problems that arise during the intervention period, so that advice can be sought and information shared to enable the best possible outcomes to be achieved.
- Discuss system changes implemented over the study period to improve patient care in acute public hospitals.

Composition

The Committee shall consist of representatives from each of the hospitals participating in the project, the Department of Human Services (DHS) as well as a project sponsor

Membership of the Committee as at 20th September 2003 is:

- Director, Clinical Epidemiology and Health Outcomes Unit, The Queen Elizabeth Hospital (TQEH) (Chair)
- Director Anaesthesiology and Intensive Care Unit, Royal Adelaide Hospital (RAH)

- Director of Research and Head, Division of Surgery and Upper Gastrointestinal Unit, TQEH
- Manager, Quality Improvement & Customer Liaison, Mt Gambier and Districts Health Service Inc. (MGDHS)
- Regional Risk Manager, Northern and Far Western Health Service
- Executive Director, Clinical Systems, Department of Human Services (DHS)
- Chair, South Australian Hospitals Metropolitan Clinical Sub-Committee
- Quality and Safety Manager, Lyell McEwin Health Service (LHMS)
- Patient Safety Manager, TQEH
- Clinical Risk Manager, LMHS
- Quality Manager, RAH
- IRIS Project Officers, MGDHS, Whyalla Hospital and Health Service, RAH, TQEH and LMHS
- IRIS Project Coordinator
- Specialist Clinical Pharmacist, TQEH
- Principal Consultant - Safety and Quality Clinical Systems, DHS
- Principal Project Officer Performance Measurement and Outcomes Metropolitan Health Division, DHS
- Executive Director Medical Services, TQEH
- Principal Consultant, Clinical Governance Mental Health Unit, DHS
- Quality Manager, Flinders Medical Centre
- Senior Project Officer Safety & Quality, Clinical Systems DHS

Meetings

Meetings will be held each alternate month. Any person may be invited to attend meetings of the Committee, but not necessarily for the full duration of the meeting.

A notice of each meeting confirming the date, time, venue and agenda shall be forwarded to each member of the Committee in the week prior to the date of the meeting.

Minutes of proceedings and resolutions of Committee meetings shall be kept by the Secretary. Minutes shall be distributed to all Committee members after the Committee Chairman has given preliminary approval.

Quorum

A quorum will comprise any four Committee members. In the absence of the Committee Chairman or appointed delegate, the members shall elect one of their number as Chairman for that meeting.

Appendix 10: Process for managing specific incident types

Incident types managed or reviewed by personnel other than the line manager (for identifiable reports)

Hospital number	Medication incidents reviewed by pharmacist	Falls incidents reviewed falls (multi-disciplinary) working group	Security incident reviewed by security officer	Accident incident reviewed by OH&S manager*	Infection incident reviewed by ICP†
1	X	X	X	X‡	X
2	X	X			
3					
4	X	X			X
5					
6		X			

* Occupational Health and Safety Manager † Infection Control Practitioner ‡ de-identified report

Appendix 11: Staff Education Folder

NOTE:
This appendix is included on pages 36-68 of volume 2 of the print copy of the thesis held in the University of Adelaide Library.

Appendix 12: Section 64D- South Australian Health Act and authorisation of the IRIS Committee by The Governor, South Australia

South Australian Health Act

Section 64D:

1. This section applies to a person, or the members from time to time of a specified group or body, authorised by the Governor, by instrument in writing, to have access to confidential information for the purpose of-

(a) conducting research into the causes of mortality or morbidity or

(b) assessing and improving the quality of specified health services

and to any person providing technical, administrative or secretarial assistance in the performance of such functions.

2. Confidential information may be disclosed to a person to whom this section applies without breach of any law or any principle of professional ethics.

3. Subject to this section, a person must not in any circumstances include proceedings before any court, tribunal or board), divulge confidential information obtained directly or indirectly as a result of a disclosure made pursuant to this section

4. Subsection (3) does not prevent a person to whom this section applies disclosing information to another person to whom this section applies.

5. A person must not, when appearing as a witness in any proceeding before a court, tribunal or board, be asked, and, if asked, is not required to answer, any question directed at obtaining confidential information obtained by that person directly or indirectly as a result of disclosure made pursuant to this section and any such information volunteered by such a person is not admissible in any proceedings.

6. In this section-

confidential information means information relating to a health service in which the identity of the patient or person providing the service is revealed.

DEPART[illegible]NT OF HUMAN SERVICES

Contact Person: **Diane Carter**

Phone: (08) 82266178
Facsimile: (08) 82266955

Project Officer (Para-legal) & FOI Liaison Officer (Health)
Parliamentary & Legal Unit
P.O. Box 65, Rundle Mall
ADELAIDE SA 5000

FACSIMILE TRANSMISSION

TO: The Queen Elizabeth Hospital, North Western Adelaide Health Service

FAX NO: 8222 6121

ATTENTION: Ms Sue Evans

DATE: 9 November 2001

TOTAL PAGES: 2
(including cover sheet)

I write to advise that the **North Western Adelaide Health Service/Royal Adelaide Hospital Incident Monitoring Committee** was, on 8 November, 2001, authorized by His Excellency The Governor, under section 64D of the *South Australian Health Commission Act 1976*

Please find herewith a copy of the authorization which appeared in the Government Gazette.

THE SOUTH AUSTRALIAN GOVERNMENT GAZETTE [8 November 2001

Department of the Premier and Cabinet
Adelaide, 8 November 2001

HER Excellency the Governor in Executive Council has been pleased to approve the changes set out to the list of persons and groups authorised to access confidential information, pursuant to section 64D of the South Australian Health Commission Act 1976.

SOUTH AUSTRALIAN HEALTH COMMISSION ACT 1976.
SECTION 64D

AUTHORISATION OF ACCESS TO CONFIDENTIAL INFORMATION

Authorisation by the Governor

Pursuant to section 64D of the South Australian Health Commission Act 1976 and with the advice and consent of the Executive Council, I authorise the members from time to time of a group or body listed below to have access to confidential information in accordance with that section.

Additions

North Western Adelaide Health Service and Royal Adelaide Hospital

- North Western Adelaide Health Service/Royal Adelaide Hospital Incident Monitoring Committee

Appendix 13: End of study staff survey- Intervention Units.

NOTE:
This appendix is included on pages 73-76 of volume 2 of the print copy of the thesis held in the University of Adelaide Library.

Appendix 14: End of study staff survey- Control Units

NOTE:
This appendix is included on pages 78-80 of volume 2 of the print copy of the thesis held in the University of Adelaide Library.

Appendix 15: Consumer survey 1 country of birth categories

Country of birth categories for Consumer survey 1

1. Unweighted sample:

z1 in which country were you born?	gender male	female	Total
Australia	895	1,252	2,147
UK and Ireland	168	228	396
Italy	27	31	58
Greece	12	7	19
Holland	15	9	24
Germany	17	30	47
Other European	25	29	54
New Zealand	12	18	30
African country	4	9	13
Asian country	23	29	52
South America	1	1	2
North America	1	4	5
Other	47	50	97

COB_cat	gender male	female	Total
Australia	895	1,252	2,147
Europe - UK&Ireland	168	228	396
Europe - Other	96	106	202
Asia	23	29	52
Other	65	82	147

2. Weighted sample:

COB_cat	gender male	female	Total
Australia	1,030.6	1,110.94	2,141.54
Europe - UK&Ireland	171.2727	183.1192	354.3919
Europe - other	96.5446	91.61178	188.1564
Asia	30.02909	28.12036	58.14945
Other	72.08192	68.29189	140.3738

z1 in which country were you born?	gender male	female	Total
Australia	1,030.6	1,110.94	2,141.54
UK and Ireland	171.2727	183.1192	354.3919
Italy	30.72194	30.79138	61.51332
Greece	12.31906	110302	18.42937
Holland	12.19726	10.09675	22.294
Germany	16.61711	20.80363	37.42074
Other European	24.68923	23.80972	48.49894
New Zealand	15.93716	15.05103	30.9882
African country	5.009436	6.711388	11.72082
Asian country	30.02909	28.12036	58.14945
South America	1.125199	2.750053	3.875252
North America	1.436246	3.072473	4.508719
Other	48.57387	40.70695	89.28082

Appendix 16: Consumer survey 2 country of birth categories

Country of birth categories for Consumer survey 2

1. Unweighted sample:

country of birth	gender female	male	Total
Australia	867	677	1,544
Europe - UK/Ireland	144	108	252
Europe - Other	42	60	102
Asia	11	8	19
Other	44	44	88

z.4 what is your country of birth?	gender female	male	Total
Australia	867	677	1,544
Austria	2	2	4
Bosnia-Herzegovina	2		2
Canada	2	3	5
Croatia		3	3
Germany	9	13	22
Greece	5	3	8
Holland/ Netherlands	8	9	17
Hong Kong	1	1	2
Italy	12	22	34
Malaysia	1	3	4
New Zealand	9	8	17
Philippines	6	3	9
Poland	2	4	6
Slovenia		1	1
Spain		2	2
UK and Ireland	144	108	252
USA		2	2
Vietnam	3	1	4
Former Yugoslav Republics			

2. Weighted sample:

country of birth	gender female	male	Total
Australia	814.5315	762.9511	1,577.48
Europe - UK/Ireland	117.7221	105.8172	223.5392
Europe - Other	36.17744	57.10691	93.28435
Asia	12.26871	9.462375	21.73109
Other	43.69479	45.26779	88.96258

z.4 what is your country of birth?	gender female	male	Total
Australia	814.5315	762.9511	1,577.48
Austria	1.212767	2.033653	3.246421
Bosnia-herzegovina	2.597511		2.597511
Canada	8587434	3.631904	4.490648
Croatia		2.92905	2.92905
Germany	6.680821	11.83984	18.52066
Greece	4.65824	4.21631	8.87455
Holland/ Netherlands	5.586987	8.44662	14.03361
Hong Kong	7226184	7272671	1.449885
Italy	11.55183	20.55204	32.10388
Malaysia	8593122	3.645683	4.504996
New Zealand	9.865942	7.543552	17.40949
Philippines	4.998553	3.918606	8.917158
Poland	2.518506	2.627473	5.145979
Slovenia		.8791155	.8791155
Spain		2.855539	2.855539
UK and Ireland	117.7221	105.8172	223.5392
USA	1.756228		1.756228
Vietnam	5.68823	1.170819	6.859049
Former Yugoslav Republics of Serbia & Mo	1.370778	7272671	2.098045
Other country	32.9701	32.33611	65.30621

Appendix 17: Baseline staff survey Q-test categories

Q sort categories into which barriers to reporting were allocated

	Disciplinary Legal, Privacy, Peer-related	**Peer-related**	**Practical**	**Unnecessary, Ineffective, Communication**
I am worried about disciplinary action.	X			
When the ward is busy I forget to make a report.			X	
I am worried about litigation.	X			
The incident form takes too long to fill out and I just don't have time			X	
I don't know whose responsibility it is to make a report.				X
My colleagues may be unsupportive.		X		
I do not want the case discussed in meetings.	X			
I do not know which incidents should be reported.				X
The circumstances of the case often make reporting unnecessary.				X
As long as the staff involved learn from incidents it is unnecessary to discuss them further.				X
Adverse incident reporting is unlikely to lead to system changes that will improve quality of care.				X
When the incident does not eventuate or a correction was made I don't see any point in reporting it.				X
If I do report, my supervisor may think that I am stepping out of my place.	X			
I don't want my colleague to get into trouble or be offended.		X		
Even if I do report I don't get any feedback on what action is being taken, if any.				X
Junior staff are often blamed unfairly for adverse incidents.	X			
The AIMS form is too complicated and requires too much detail.			X	
The 'incident' was too trivial.				X

Table 0-1 Q sort categories into which pre-defined incident reports were allocated

	Act of commission	**Hospital acquired infection / injury**	**Act of omission**	**Near miss**
Patient sustained an injury due to a fall in hospital		X		
Patient sustained a hospital-acquired infection eg infected wound site, phlebitis due to infected IV site		X		
Patient sustained a DVT post-operatively due to inadequate prophylaxis	X			
Patient received wrong treatment or procedure.	X			
Patient did not receive necessary treatment or procedure			X	
Staff made a drug error but it was not actually given				X
Staff made a drug error where no corrective treatment was necessary				X
Staff made a drug error resulting in corrective treatment being given.	X			
Staff did not follow procedure or 'order' resulting in harm to patient	X			
Breach in confidentiality eg. Information given without authority	X			

Appendix 18: Baseline staff survey reliability test

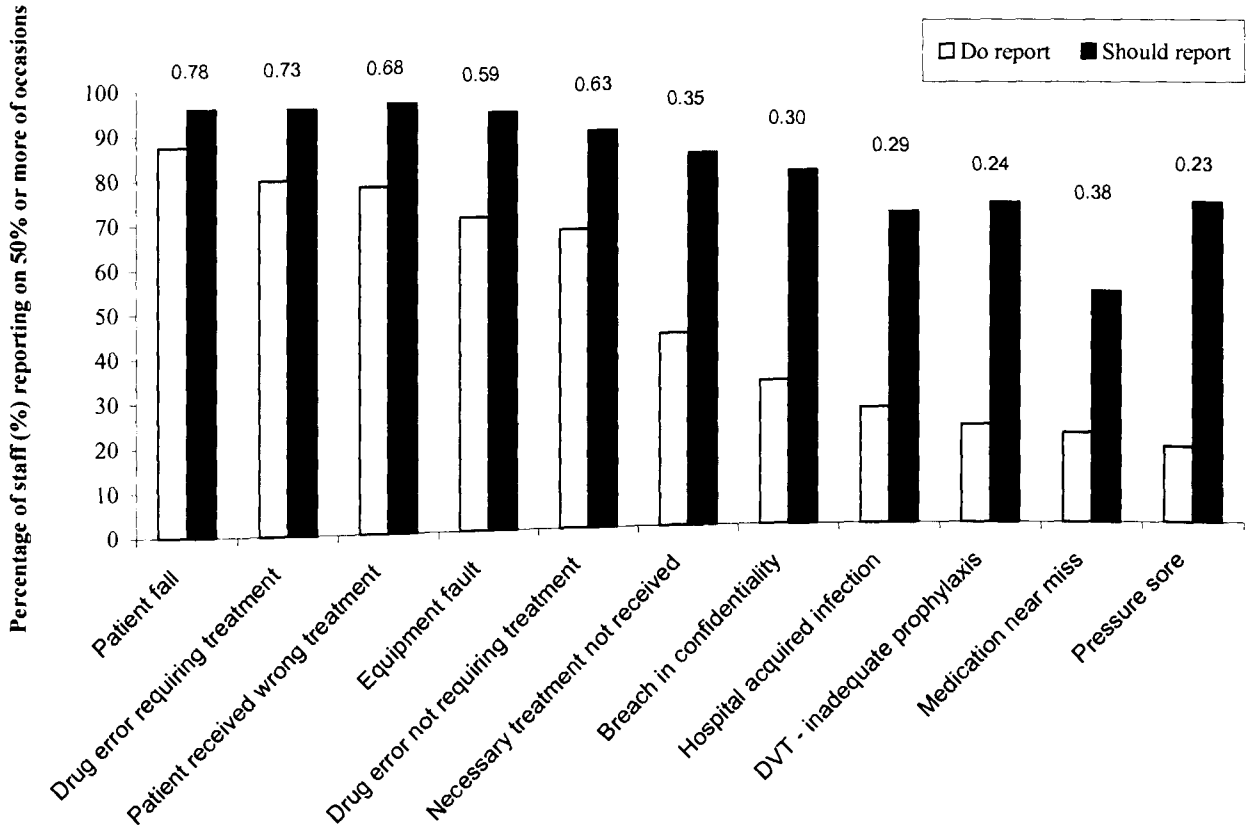
Test-retest reliability for knowledge of the reporting system -staff survey

Baseline survey question	Kappa (κ)
Is there an IR system?	1.0
Have you ever filled in an IR	1.0
Do you know how to locate IR?	0.5
Do you know what to do with completed IR?	0.6
Which form do you use?	0.5
Anonymous report to the APSF?	1.0
Barriers to reporting	
I am worried about disciplinary action	0.6
When the ward is busy, I forget	0.6
I am worried about litigation.	0.6
The incident form takes too long to fill out and I just don't have time	0.4
My colleagues may be unsupportive.	0.7
I don't know whose responsibility it is to make a report	0.6
I do not want the case discussed in meetings	0.6
I don't feel confident that the form is kept anonymous.	0.8
I do not know which incidents should be reported.	0.0
Adverse incident reporting is unlikely to lead to system changes that will improve the quality of care	0.8
I don't want my colleague to get into trouble or be offended	0.7
I don't want to get into trouble	1.0
Junior staff are often blamed unfairly for adverse incidents.	0.5
When the incident does not eventuate or a correction was made (a near miss) I don't see any point in reporting it.	0.6
If I do report, my supervisor may think that I am stepping out of my place.	0.2
Even if I do report I don't get any feedback on what action is being taken, if an	0.4
The AIMS form is too complicated and requires too much detail.	0.8
As long as the staff involved learn from incidents it is unnecessary to discuss them further	0.7
I worry about who else is privy to the information that I disclose.	1.0
The incident was too trivial.	0.5
It's not my responsibility to report somebody else's mistakes.	1.0
Even if I don't give my details I'm sure that they'll track me down	0.8

Baseline survey question	Do report (κ)	Should report (κ)
The incident was too trivial.	0.6	0.7
It's not my responsibility to report somebody else's mistakes.	0.8	0.6
Even if I don't give my details I'm sure that they'll track me down	1.0	0.7
Reporting practices		
Patient developed a DVV due to inadequate prophylaxis	1.0	0.6
Patient received wrong treatment or procedure	0.6	1.0
Patient did not receive necessary treatment or procedure	0.4	1.0
Staff made a drug error but it was not given (near miss)	0.6	1.0
Staff made a drug error but it did not requiring corrective treatment	0.5	1.0
Staff made a drug error requiring corrective treatment	0.6	1.0
Staff did not follow correct procedure	0.2	1.0
Problem with equipment or machinery resulting in patient harm	0.6	0.6
Breach in confidentiality	1.0	0.6
Staff made a drug error but it was not given (near miss)	0.6	1.0
Staff made a drug error but it did not requiring corrective treatment	0.5	1.0
Staff made a drug error requiring corrective treatment	0.6	1.0
Staff made a drug error requiring corrective treatment	0.6	1.0
Staff did not follow correct procedure	0.2	1.0
Problem with equipment or machinery resulting in patient harm	0.6	0.6
Breach in confidentiality	1.0	0.6

Appendix 19: Baseline staff survey intraclass correlation between should and did reporting categories

Baseline staff survey intraclass correlation between should and did reporting categories



Appendix 20: Focus group report- Harrison Health Research

IRIS STUDY

Overview Report on Focus Groups with Medical and Nursing Personnel

1. Introduction

The Clinical Epidemiology Unit based at The Queen Elizabeth Hospital is undertaking a study which has four aims namely:

- To improve incident reporting
- To identify barriers to incident reporting so that appropriate issues can be addressed to encourage reporting
- To develop a clearly defined process for handling incidents
- To identify changes in pattern of reporting over the study period

Over two days - 21st and 22nd March 2002 – a series of focus groups was held at the Harrison Research Centre, Gilles Street, Adelaide. The purpose of the groups was to understand attitudes toward incident reporting and to explore a number of issues about the process, obstacles and reactions to the proposed intervention.

The five groups were moderated by Ross Harrison and were structured as follows:

- Junior nursing personnel – Junior RNs/ENs
- Senior nursing – Clinical nurses/Clinical nurse managers
- Junior medical – RMO's/Interns
- Senior medical – Registrars
- Senior medical – Consultants

The plan is that the project leader will now analyse and report in detail about the findings and outcomes from the groups having observed the groups and with the assistance of tape recordings of the proceedings. However, it was requested that Ross Harrison prepare a brief overview document of the key findings and observations as interpreted by him.

2. Key Findings and Observations

2.1 A Huge Cultural Divide Between Medical and Nursing Personnel

All nursing personnel were aware of the incident form whereas perhaps only slightly more than half of the doctors had ever seen the form, which is surprising in itself, given that they were attending a discussion session about incident reporting.

Nurses at all levels felt that incident reporting is an important part of their role even though there was significant disenchantment with the actual process, principally in relation to how time consuming it is. Despite a lack of feedback, nurses felt that it is important to keep a good record of patient falls and other untoward events. After all, from their perspective, that is the right and proper thing to do.

There was even a degree of optimism that this may assist (even though they had seen no evidence to support this) in making a case for more nursing staff. (It was suggested that there must be a fairly direct relationship between the quantum of mistakes/problems/errors occurring and the number of staff on duty at any point in time)

The view was also expressed that completion of an incident form can be a good way to "cover one's arse" and a couple of people had direct experience of a situation where this had in fact helped. Another benefit of the reporting of incidents is the opportunity to learn from that particular mistake by carefully documenting what went wrong and why.

Doctors on the other hand were particularly scathing about the concept. Although there were a couple of "pockets" of optimism and positive feedback, by and large doctors thought that incident

reporting was a good record of trivial events and, at the extreme, the sentiment expressed was to the effect "the patient didn't die did they?".

With only one or two exceptions none of the doctors had ever completed an incident form. They were almost all nurse initiated "Nurses are good at that sort of thing".

From the perspective of medical staff the completion of an incident form which duplicates other information already recorded is not only time consuming but irrelevant.

Doctors, it was said, handle incidents in a different way because in some instances it is important to effect change straight away. Therefore, according to them, they seek out their peers or seniors to discuss any problem areas.

Given the lack of feedback from the completion of AIMS forms such a course of action has little to recommend it.

But it was also obvious that fear of repercussions, in particular litigation, dampens any enthusiasm that doctors may have for incident reporting. Whilst they don't seem too opposed to the principle involved they very much dislike what would be required of them.

The view was even expressed by a doctor that the more serious the incident the less likely that they would be to complete an incident report. Protection of one's own back and that of colleagues appears to be the order of the day.

One of the major issues that was raised by people in all groups concerned the question of "What is an incident?" Medical staff expect that complications will arise in many medical circumstances and procedures. This is what they have been trained to handle. Hence their view that the incident reporting process collects a great deal of information about incidents that are largely unimportant and irrelevant.

2.2 The Proposed Intervention

The plan involving a Project Officer working with the intervention units, then collecting and analysing the incident forms with subsequent feedback to the units, was generally well received.

The single best aspect of the intervention is the fact that, for the first time, some feedback will be forthcoming.

3. Conclusions

If incident reporting were only a matter of having the nursing profession embrace the concept then the task would be 80% done already. The form itself, in the opinion of nurses, requires a significant re-work and what they believe is required seems logical and appropriate to us. The main objective is to reduce the time requirement from 15 to 20 minutes down to a few minutes. The other very grey area is "what is an incident?" This needs a lot more thought and discussion.

However, in our view there is a large question mark over whether doctors will ever embrace the concept. Our rather negative assessment is that the chances of this happening will be slight indeed. They see the whole issue as having some merit as long as someone else does it. Completion of incident report forms is perceived to be the role and function of nurses and doctors are more than happy for it to remain that way.

ROSS HARRISON

27th March 2002

Appendix 21: Focus group summary of barriers to reporting and strategies to facilitate incident reporting.

Barriers to reporting and strategies to facilitate incident reporting as identified by focus group participants

Barriers	ID	Facilitating Conditions	Motivation	Intention & Habit
Lack of process knowledge	*ι	Education at orientation 'Aide memoir' to give examples of adverse events Reinforcement through feedback of incident data on a regular basis	Knowledge of process	Consequences perceived as positive
Poor visibility & access to forms	*†	3 reporting options- Call Centre, computer or form	Accessibility through choice of reporting systems	
'Nursing Form' by association	*	Change form, simplify it to provide a new look. Change the reporting process so that it does not go through nursing division only	Relevant to doctors & nurses	
Time constraints	*†	1 page format. Incorporate into ward rounds	Quick to fill in Supported by leaders	
Form complexity	*ι	Simple, user friendly and easy to read	Simplified system	Increased positive affect - trust, confidence, security, less hostility & anxiety
Duplication	*†	Phone call option	Decreases paperwork	
No feedback	*†	Risk matrix and feedback loop according to priority	Improved communication Knowledge that reports are being used to effect change	
Statistics from report analysis are meaningless	†	Find out from staff what sort of statistics they want. Enable staff to get real-time reports	Data available and meaningful to staff	
No guarantee of protection	*	Confidentiality guaranteed	Security	
Culture of blame	†	Anonymous option/education	Reduced personal threat Reports do not go though line manager in the first instance.	Culture change (beliefs, norms, roles, ideals, values) - leading to **habit**
No value	*†	Feedback processes through risk management Use the reports in meetings to discuss way of preventing recurrence	Improved quality (patient safety and work conditions)	

Professional ID: * = Doctors; † = Nurses

Appendix 22: Comparison between fields in AIMS+ and the single-page incident form

Comparison of fields in the AIMS+ incident form and the single-page incident form

Field	AIMS +	Advanced AIMS-IRIS database	Rationale for not including field in one-page form
Institution name	✓	✓	
Subject details: last name, first name, date, of birth/age, ward/unit	✓	✓	
Mental health clients: detained/voluntary unknown	✓		Evaluation of AIMS+ data showed only 0.2% of all fields in AIMS+ having this field completed. There was no evidence that knowing the patient's detention status would affect investigation of event, and whether reports based on this would be useful to managers.
Reporter details: professional designation	✓	✓	
1sr witness name, contact number	✓		Relevance of having a person 'witness' an incident was felt to have punitive connotations and undermined the ability of staff to recognize and accurately report an incident.
2nd witness name, contact number	✓		
Place of incident, date of incident	✓	✓	
Current and relevant diagnoses/problems	✓		Although seen as important, space consideration precluded inclusion of this field, and it was felt that this would come out in the narrative when describing what happened and why the incident occurred.
Was next of kin notified?	✓		Incident reports were written as soon as possible after the event. By putting this in the reporter section, it was felt that it might delay submission of the report. This section removed and placed in the Management section.
Medical practitioner's examination of subject	✓		By having this in the reporter section, it implied that all incidents reported via the AIMS form needed to be validated by a doctor. In many cases, it was not necessary/relevant to have a doctor comment on contents of the report. Where incidents occurred which required medical attention, doctors should write comments in the medical history, as this is a legal document. Requiring doctors to write on the AIMS form

Field	AIMS +	Advanced AIMS-IRIS database	Rationale for not including field in one-page form
			perpetuates the "nursing form" image of the report, results in duplication of information, often delays submission of the report for extended periods of time, and hence causes frustration to doctors and nurses.
Description of what happened	✓	✓	
Contributing factors	✓		It was thought that this would be captured in "Why did the incident occur?"
Describe why the incident occurred	✓	✓	
Treatment/investigations ordered	✓		At the time of the report, tests and treatments (e.g. x-rays, pathology) ordered might not be known. These often become apparent after reports have been submitted and would be available in medical records and through information management databases. If incident reports were to be used to trigger further investigation, then this data could easily be collected then.
What factors minimized the outcome?	✓		Audit of previous reports showed that this yielded little meaningful information. The majority of reporters wrote "good luck".
How could incident have been prevented?	✓	✓	
Why do you think this incident is important?		✓	This was inserted to enable reporters to discuss why they wrote the report. This was not thought to be captured in any other field. It was inserted because, when piloting the form, doctors felt that the form provided no avenue for discussing potential for error.

Appendix 23: Location of single page incident forms

Location of incident report forms in intervention units

Dept. number	Location where incident reports were placed in the Department.
4	• In each of the four bays with medical paperwork (progress report sheets of paper, discharge summary, pathology/radiology request slips/consent forms). • In Perspex boxes, attached to the wall in each of the three bays.
5	• In each of the four bays with medical paperwork (progress report sheets of paper, discharge summary, pathology/radiology request slips/consent forms). • In Perspex boxes, attached to the wall in each of the three bays.
6	• In Perspex boxes, attached to the wall in two areas in the work station in ED
9	• Originally kept in a bookshelf underneath the allocation board as well as extras in the filling cabinet. Later permission was granted to have one Perspex box in nurses station, near where the nurses tended to write reports, the other was in the alcove on the other side of the room where the Doctors sat.
11	• In the filing cabinet where the old AIMS forms were kept. A Perspex box was placed in the Doctors room (where medical staff wrote the notes).
13, 14, 15	• In Perspex boxes attached to the wall in the nurses station. • Ten one-page forms were posted to each of the GPs in the intervention units.
19	• In a Perspex box on the bench top in ED office which was shared by doctors and nurses.
20	• In a filing cabinet where all medical and nursing forms were kept. A filing cabinet was housed in each of the three bays in the ICU.

Appendix 24: Call Centre performance based upon key performance indicators

Call Centre performance based on key performance indicators

Key performance indicator	Call Centre performance based on weekly aggregate report statistics
90% of calls answered within 20 seconds. The remaining 10% will be answered within 1 minute	Achieved on 94.23% of weekly reports. Grade of service as low as 68% during week commencing 26th October 2003. Subsequently detected fault in switchboard operation.
Less than 2% of calls will leave the Call Centre unanswered (Incomplete Calls)	Achieved on 94.23% of weekly reports. Abandonment rate exceeded the KPI on three weekly reports with rate as high as 25% during week commencing 25/12/03
Less than 10% of calls will be placed on hold and that this will not be for longer than 30 seconds.	Achieved on 100% of weekly reports.
Greater than 90% of calls will be completed within 10 minutes. The remaining 10% will be completed within 20 minutes.	Achieved on 84.62% of weekly reports. Reasons for not achieving KPI on eight weekly reports included database issues, and reporter preference to make a long report.
Greater than 90% of incidents will be forwarded within 30 minutes of a completed call (remaining 10% will be forwarded within 1 hour of the report being generated, unless IT problems occur, in which case, reports will be forwarded within 1 hour of the system being operational).	Achieved on 100% of weekly reports
IRIS Project Officers, through an audit process, will assess quality assurance of information entered into the database. It is expected that there be a less than 10% error rate in data entered	5.68% of all Call Centre generated reports (15 reports) was associated with inaccurate coding, as assessed by independents coder. Update of the manual and education subsequently lowered the classification error rate.
Less than 5% of callers will complain about the service. A complaint is any expression of dissatisfaction with the provision of a telephone service.	1.51% of calls associated with a complaint. All complaints were in regard to the protracted length of time it took to complete a report.

Appendix 25: RDNS Education folder

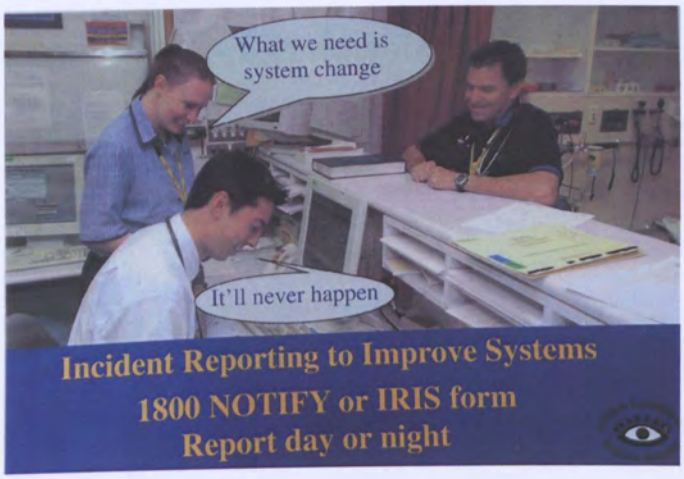
NOTE:
This appendix is included on pages 106-117 of volume 2 of the print copy of the thesis held in the University of Adelaide Library.

Appendix 26: Promotional material

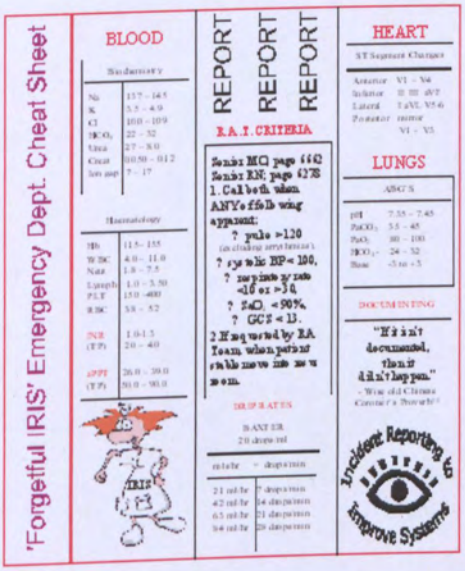
Promotional pens distributed to doctors and nurses in intervention units.

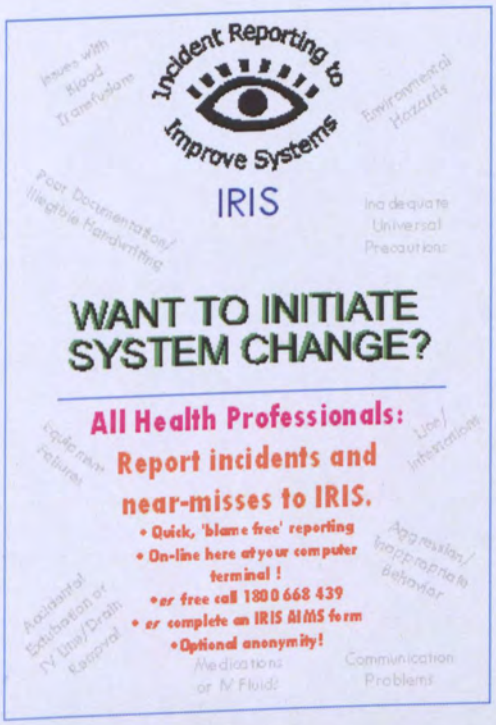
Stickers to promote project placed on telephones throughout intervention units

Posters used in intervention units to promote project



Promotional cheat sheets and charts used by staff in the ED and ICU



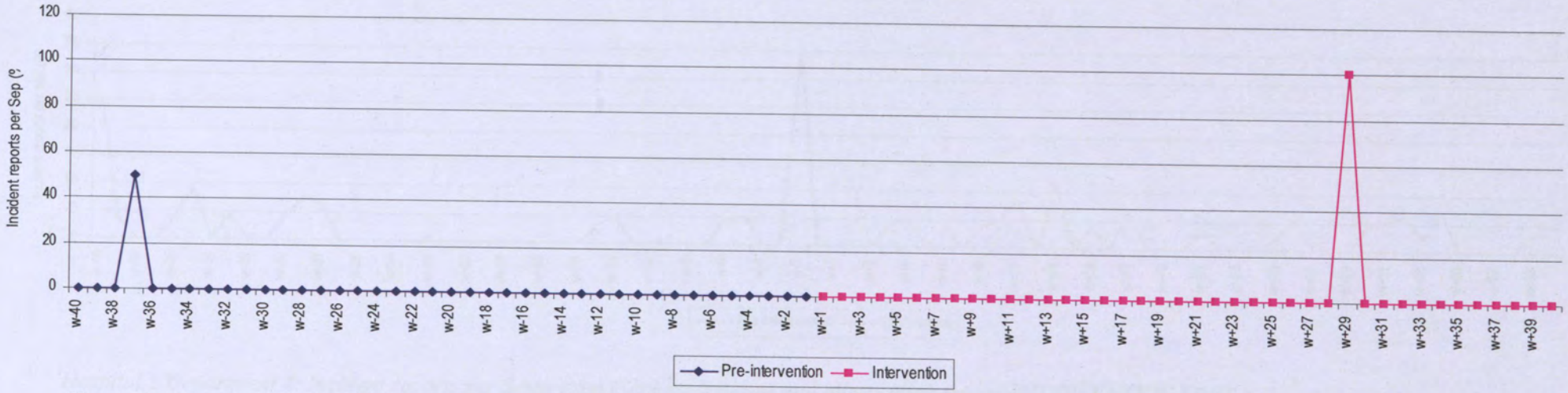


Appendix 27: Incident report newsletters

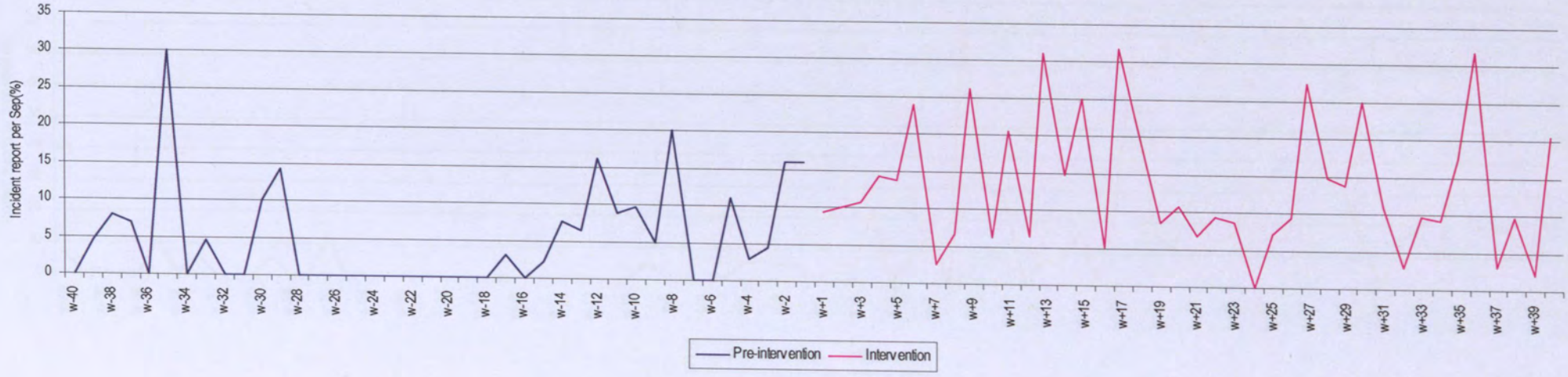
NOTE:
This appendix is included on pages 122-133 of volume 2 of the print copy of the thesis held in the University of Adelaide Library.

Appendix 28: Incident reporting rates- timeline

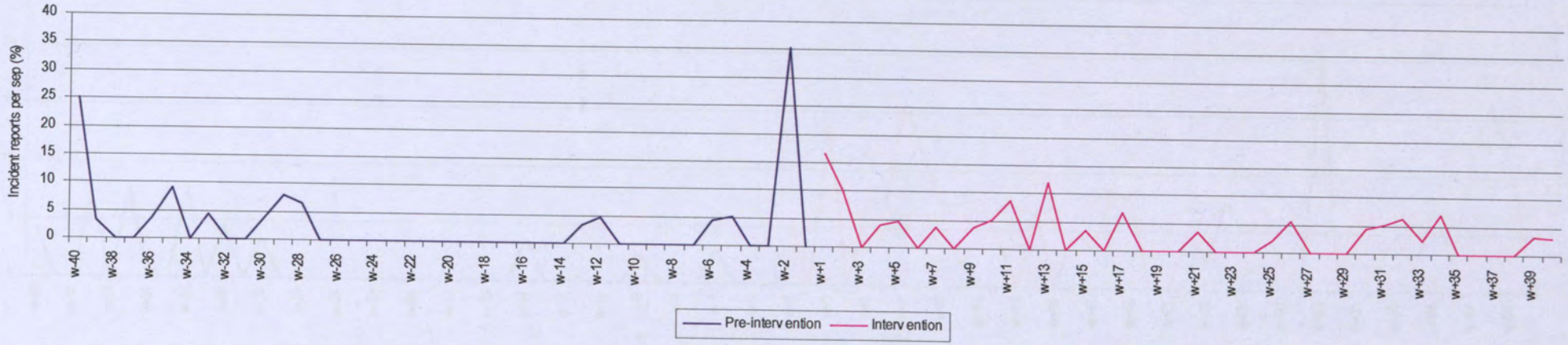
Hospital 1 Department 1: Incident reports per Separation (Sep) for baseline and intervention period- CONTROL UNIT



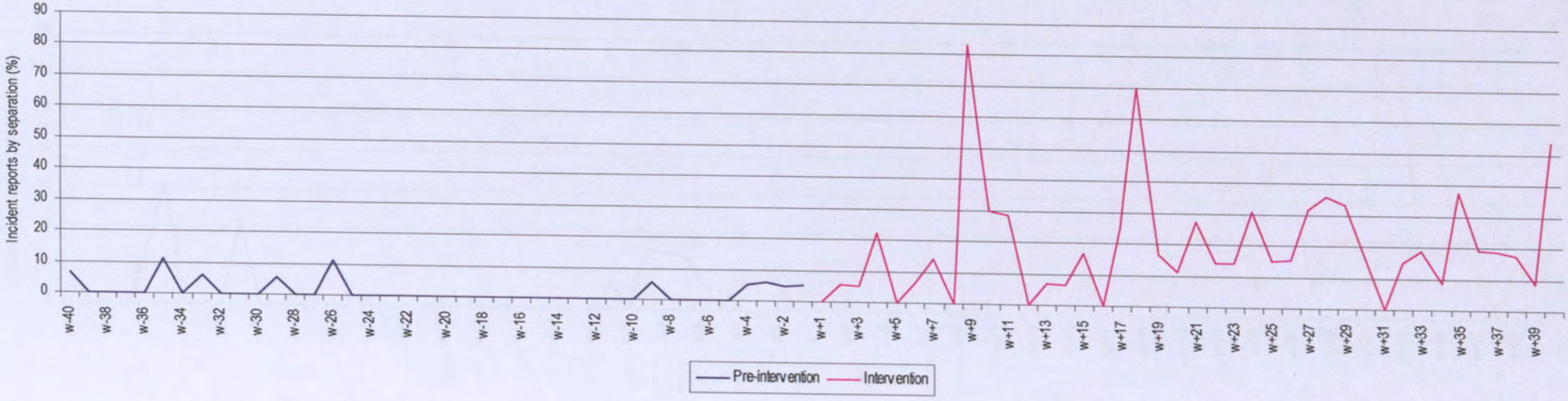
Hospital 1 Department 2: Incident reports per Separation (Sep) for baseline and intervention period-CONTROL UNIT



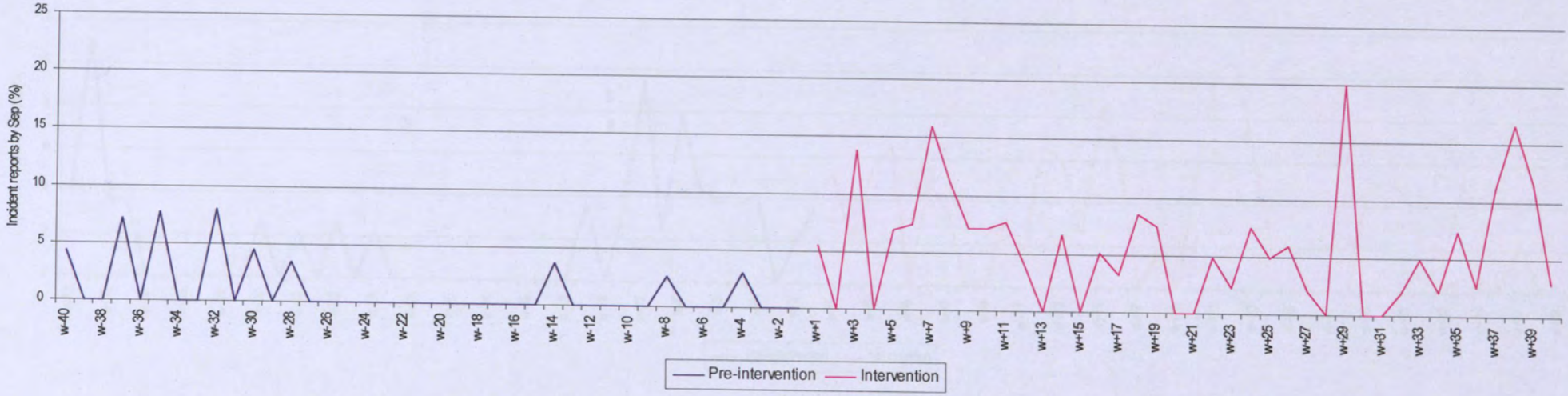
Hospital 1 Department 3: Incident reports per Separation (Sep) for baseline and intervention period-CONTROL UNIT



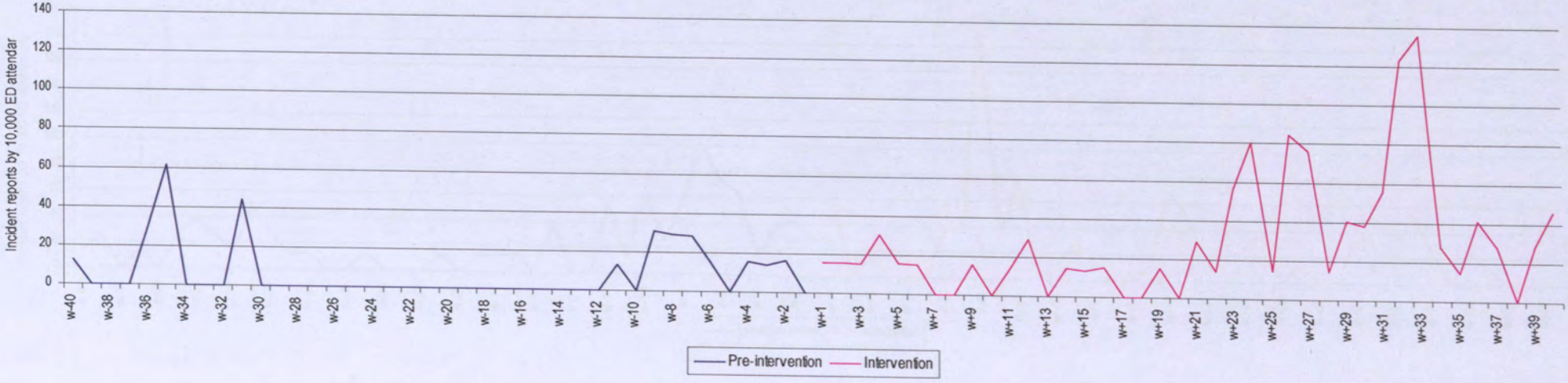
Hospital 1 Department 4: Incident reports per Separation (Sep) for baseline and intervention period-INTERVENTION UNIT



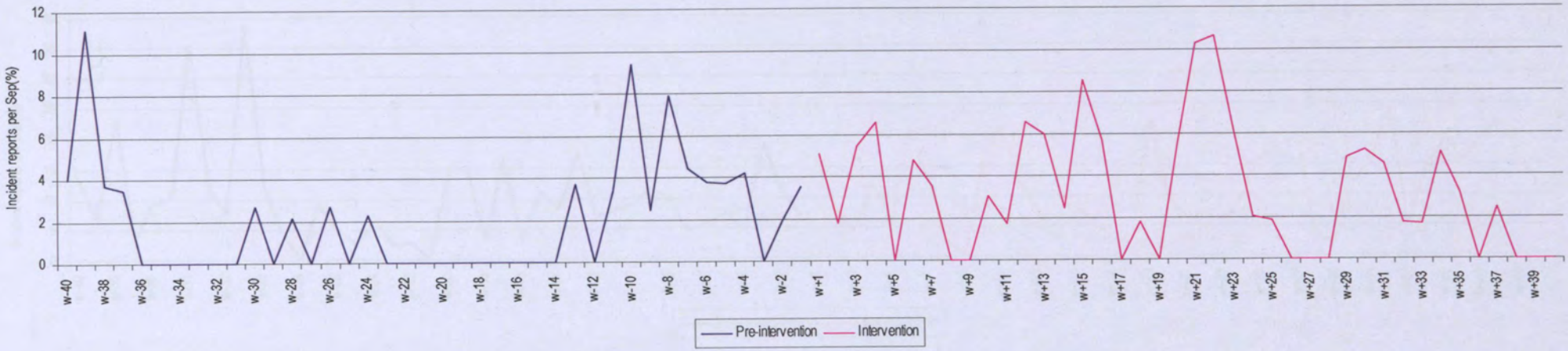
Hospital 1 Department 5: Incident reports per Separation (Sep) for baseline and intervention period-INTERVENTION UNIT



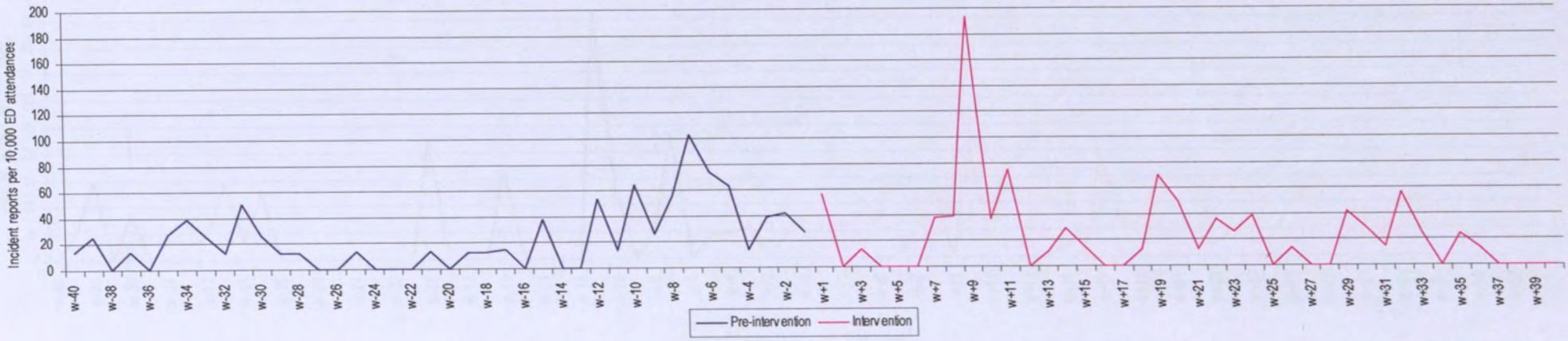
Hospital 1Department 6. Incident reports per 10,000 ED attendances for baseline and intervention period-INTERVENTION UNIT



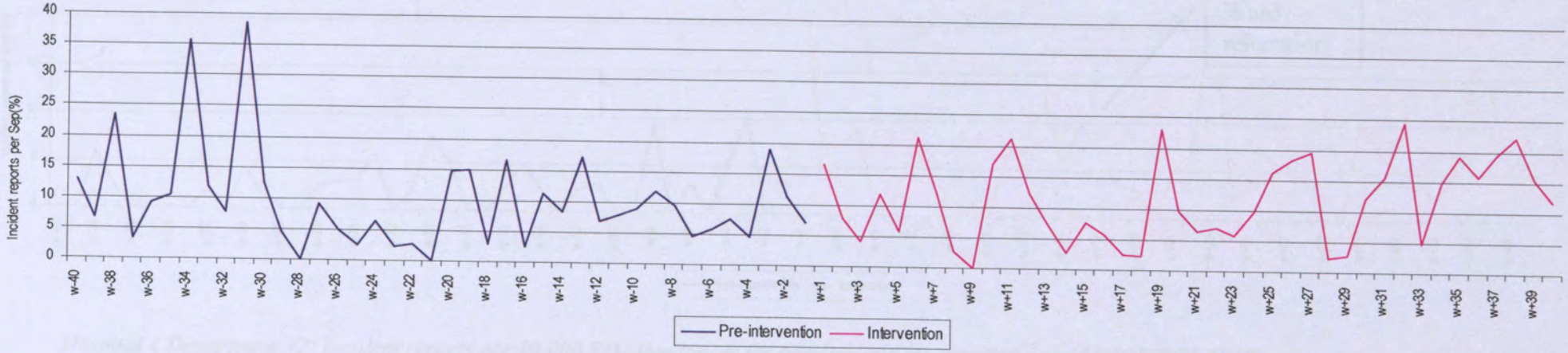
Hospital 2 Department 7: Incident reports per Separation (Sep) for baseline and intervention period-CONTROL UNIT



Hospital 2 Department 8: Incident reports per 10,000 ED attendances for baseline and intervention period-CONTROL UNIT

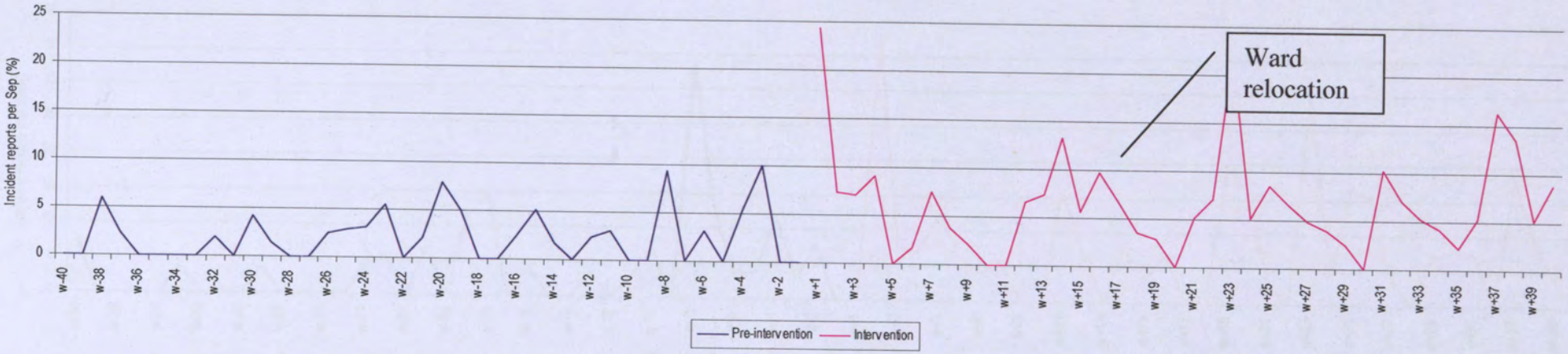


Hospital 2 Department 9: Incident reports per Separation (Sep) for baseline and intervention period-INTERVENTION UNIT

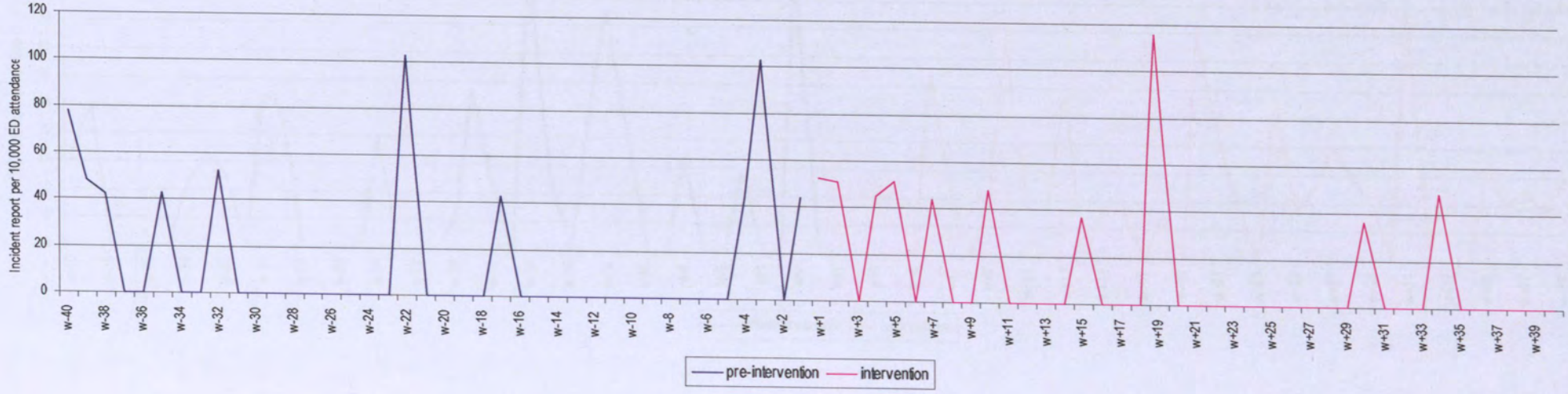


Hospital 3 Department 10 Incident reports per Separation (Sep) for baseline and intervention period-CONTROL UNIT

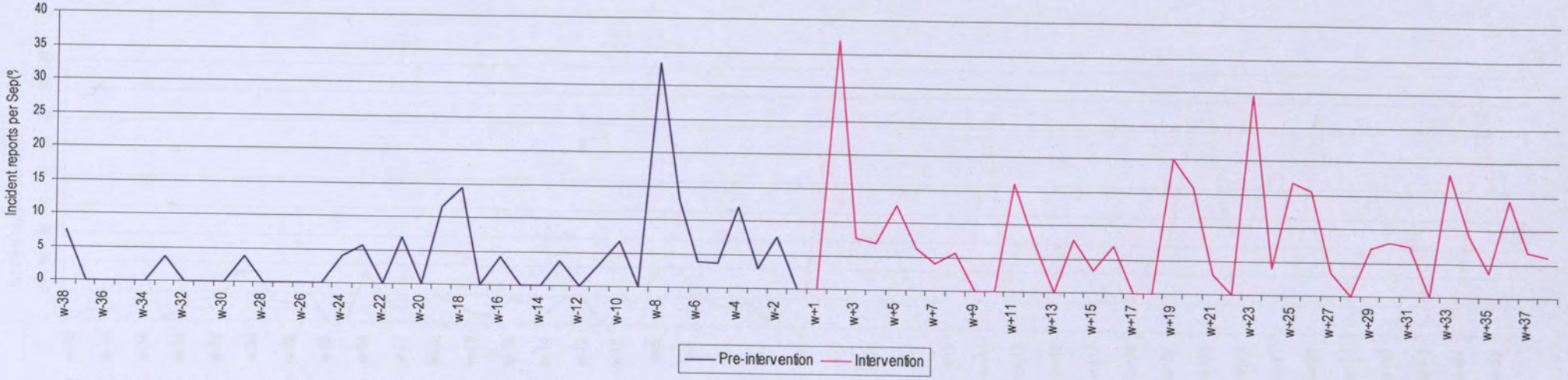
Hospital 3 Department 11 Incident reports per Separation (Sep) for baseline and intervention period-INTERVENTION UNIT



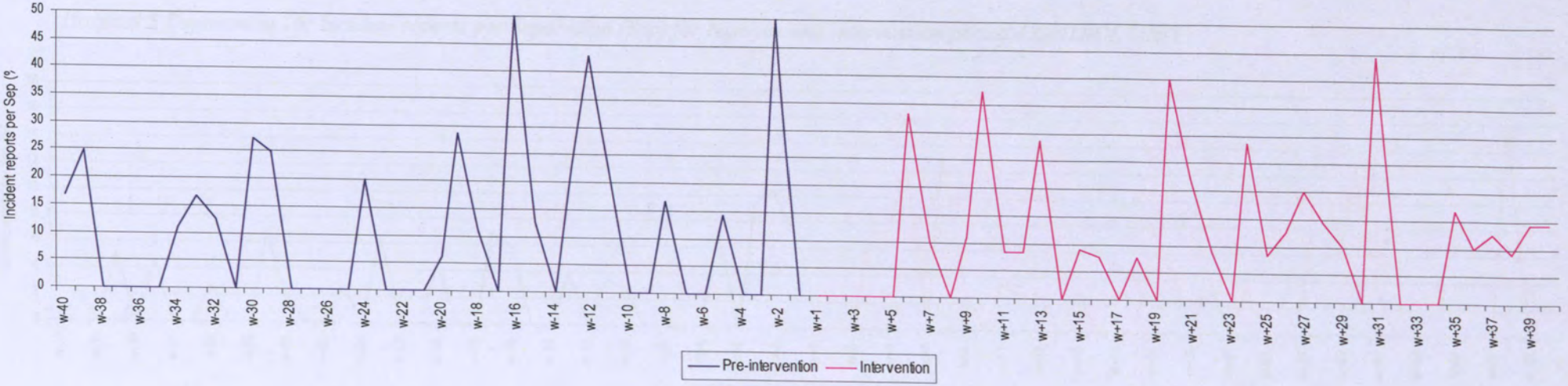
Hospital 4 Department 12: Incident reports per 10,000 ED attendances for baseline and intervention period-CONTROL UNIT



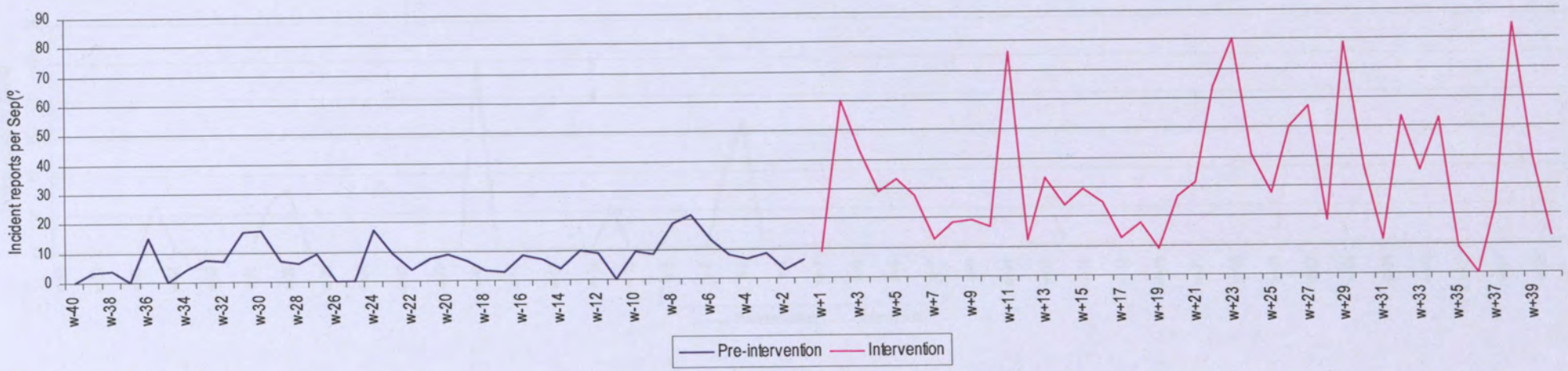
Hospital 4 Department 13: Incident reports per Separation (Sep) for baseline and intervention period-INTERVENTION UNIT



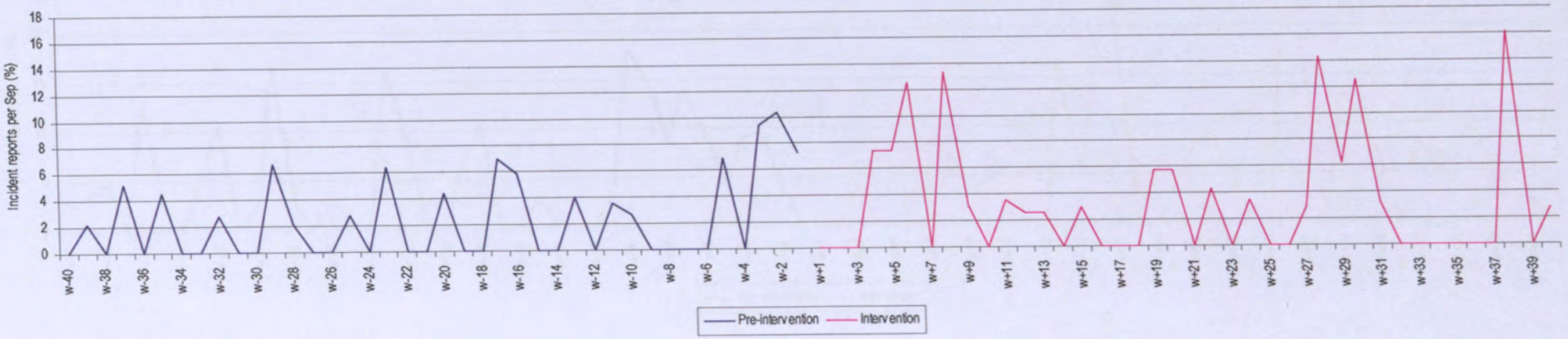
Hospital 4 Department 14: Incident reports per Separation (Sep) for baseline and intervention period-INTERVENTION UNIT



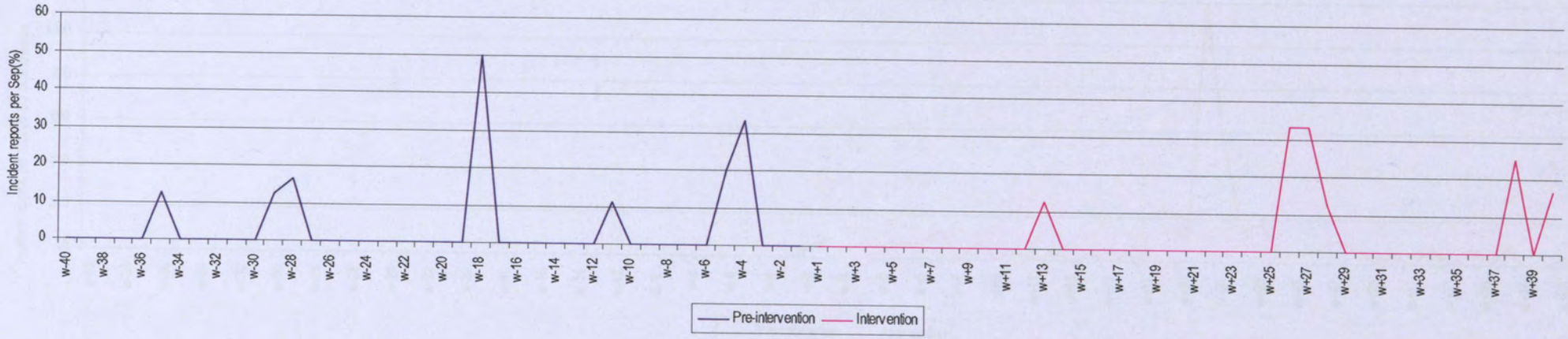
Hospital 4 Department 15 Incident reports per Separation (Sep) for baseline and intervention period-INTERVENTION UNIT



Hospital 5 Department 16: Incident reports per Separation (Sep) for baseline and intervention period-CONTROL UNIT

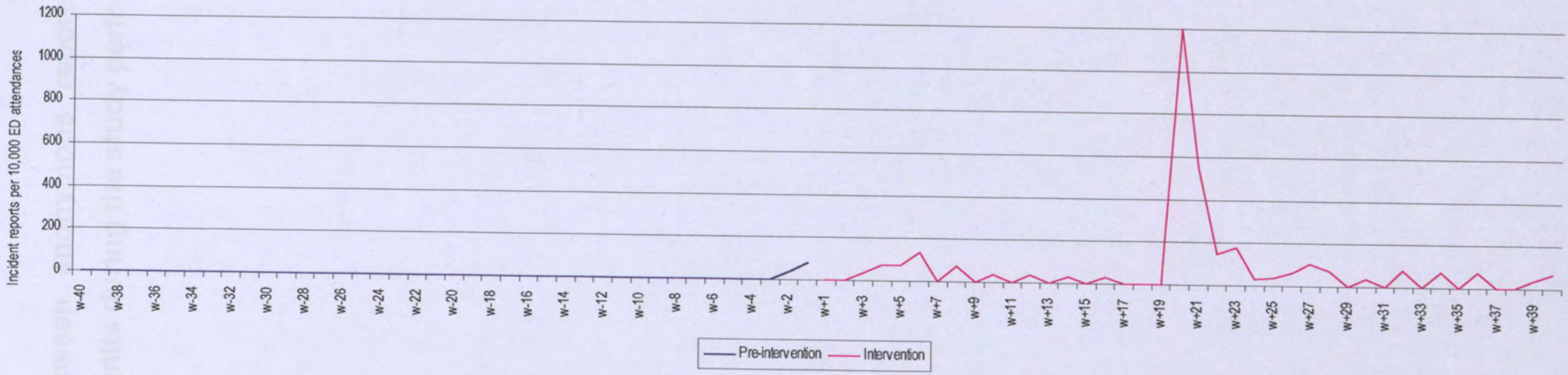


Hospital 5 Department 17: Incident reports per Separation (Sep) for baseline and intervention period-CONTROL UNIT



Hospital 5 Department 18: Incident reports per Separation (Sep) for baseline and intervention period-CONTROL UNIT

Hospital 5 Department 19: Incident reports per 10,000 Emergency attendances for baseline and intervention period-INTERVENTION UNIT



Hospital 6 Department 20: Incident reports per Separation (Sep) for baseline and intervention period-INTERVENTION UNIT

Appendix 29: Comparison between anonymous reports and identified reports in intervention units during the study period

Comparison of anonymous reports and identified reports made by staff in the intervention unit during the study period

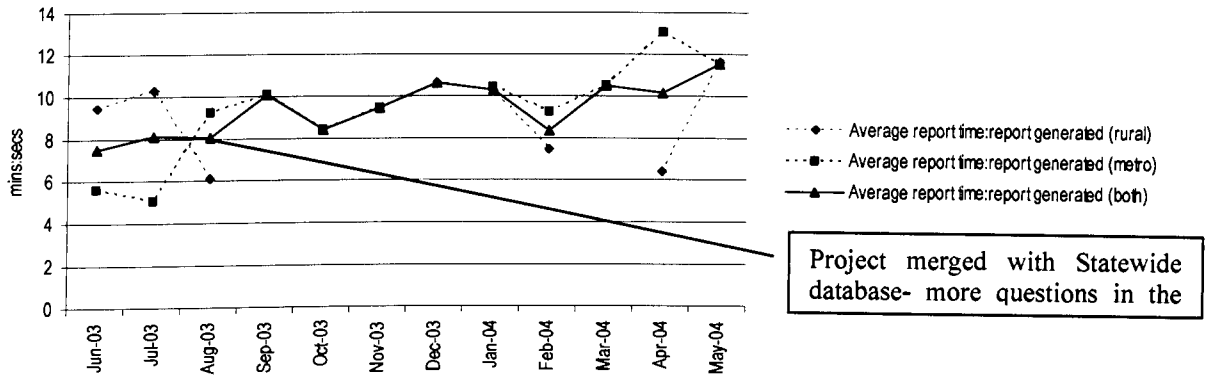
	Anonymous reports % (n)	N	Identified reports % (n)	N	P *
Profession†	**6.2%**	**1017**	**93.8%**	**1017**	**0.011**
Doctor	14.0%	57	86.0%	57	
Nurse	5.7%	960	94.3%	960	
Hospital	**12.9%**	**1275**	**87.1%**	**1275**	**<0.001**
Hospital 1	23%	350	67%		
Hospital 2	7.3%	165	92.7%		
Hospital 3	-		100%	102	
Hospital 4	11.3%	417			
Hospital 5	-		100%	101	
Hospital 6	17.1%	140			
Incident type	**12.9%**	**1275**	**87.1%**	**1275**	**0.009**
Reports often implicating line manager (Clinical management/ organisational management/ behaviour & human performance)	17.9%	240	82.1%	1035	
Reports rarely implicating line manager (Fall/ medication/ documentation/ accident OH&S/ aggression/ medical device, equipment)	11.7%	240	88.3%	1035	
Report method ‡	**12.9%**	**1269**	**87.1%**	**1269**	**0.142**
One-page form	13.6%	164	86.4%	1105	
Call Centre	10.2%	164	89.8%	1105	

* Chi squared test † 101 reports lodged anonymously did not state the professional designation of the reporter

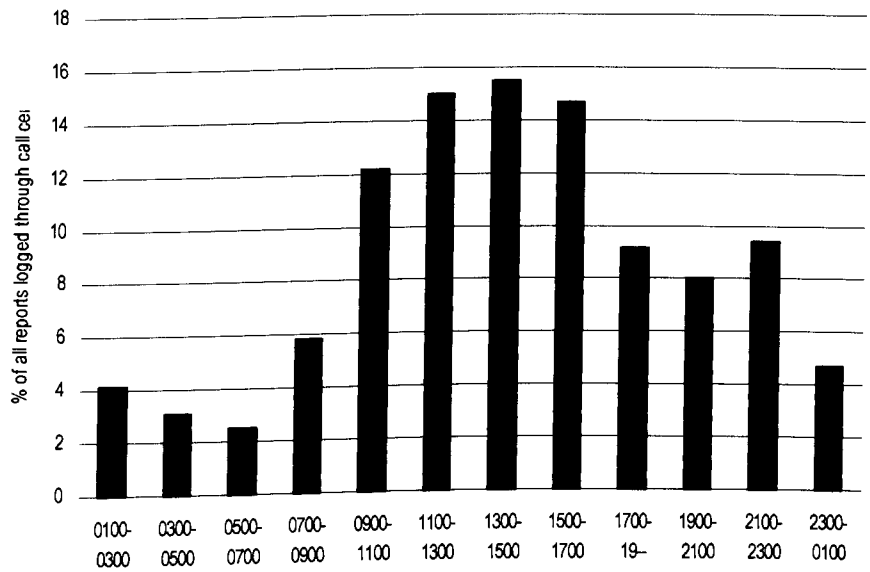
‡ 6 reports lodged using on-line reporting were not included in analysis

Appendix 30: Call Centre reports- by time of day, day of the week and length of time to submit a report

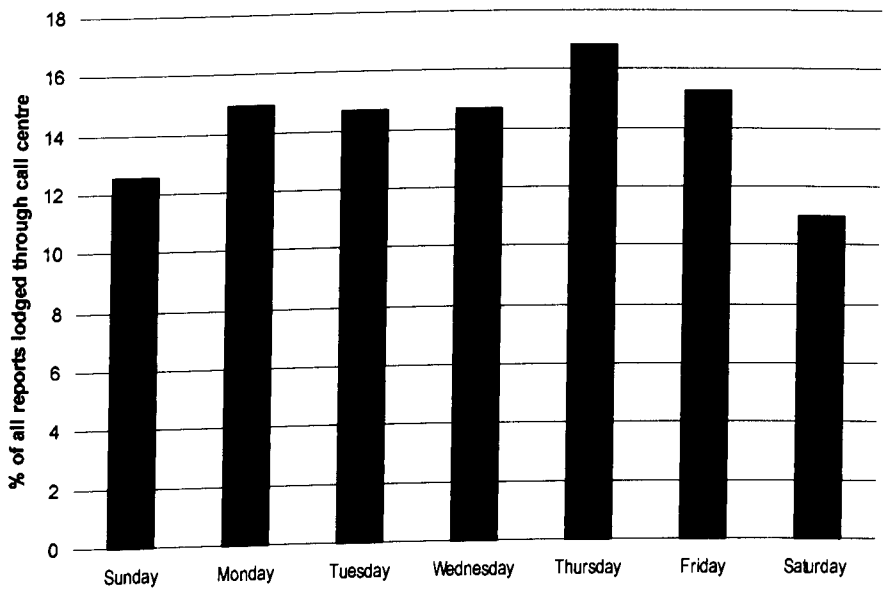
Call Centre- average reporting time for rural and metropolitan hospitals



Call Centre- reports received by time of day



Call Centre- reports received by day of week



Appendix 31: Agreement in classification of Principal Incident Types (PIT) categories between staff and an independent coder

Agreement in classification of 20 incident reports from each Principal Incident Types (PIT) category between staff and an independent coder

PIT allocated by staff *	% agreement	N	Differential categories classified by coder
Falls	100%	15	
Hospital-acquired infection	86%	14	Behaviour/human performance (14%),
Medication	85%	15	Fall (5%), Documentation (10%),
Occupational Health & Safety	79%	14	Medical devices, equipment, property (7%), Fall (14%)
Behaviour/human performance	73%	15	Fall (7%). Medication (7%), Security (7%), Clinical Management (6%)
Aggression-victim	73%	15	Aggression-aggressor (27%)
Medical device, equipment, property	53%	15	Fall (20%), OH&S (14%), Organisation Management (7%), Medication (7%),
Documentation	67%	15	Medication (27%), Behaviour/human performance (6%)
Aggression-aggressor	53%	15	Aggression-victim (47%)
Organisational management	53%	15	Clinical management (27%), Medication (13%), Behaviour/human performance (7%)
Clinical management	47%	15	Organisational Management (13%), Medication (20%), Documentation (13%), Behaviour/human performance (7%)

* Staff = Call Centre personnel, NUMs, Project Officers, Patient Safety Managers, or hospital employees

Appendix 32: Number of incidents classified into the AIMS+ and Advanced AIMS database- Hospital 5

Number of incidents classified into the AIMS+ and Advanced AIMS database in hospital 5 during the baseline and study period

Department	Baseline	End	
	AIMS+	AIMS +	Advanced AIMS
Dept. 16	34 incidents (16 falls, 11 med* 1 doc† 1 cm‡, 1 bhp§, 1 accident, 1 medical device and 2 aggression)	28 incidents (11 falls, 13 med, 1 doc, 1 cm, 1 bhp, 1 blood)	11
Dept 17	8 incidents (1 fall, 3 med, 1 doc, 2 accident, 1medical device	4 incidents (3 falls, 1 doc)	2
Dept 18	57 incidents (42 falls, 3 med, 2cm, 6 bhp, 1 medical device, 3 aggression, 1 nutrition)	36 incidents (27 falls. 8 med, 1 bhp)	20
Dept 19	3 incidents (3 falls)		101

* medication †documentation ‡ clinical management §behaviour/human performance

Appendix 33: End of study survey test-retest reliability

Test-retest reliability for knowledge of the reporting system -staff survey

Survey question	kappa
Do you think there is an appropriate place to phone through a report	0.7
Have you reported an incident in the last 9 months?	1.0
Which method did you use?	1.0
I felt it was worth my while making a report	1.0
I understood I would get feedback	*
I was unaware of the timeframe for getting feedback	0.8
I understood how the incident was followed up	0.4
I felt apprehensive about the person investigating the incident	*
I felt that the incident was managed in a blame-free way	1.0
I felt uncomfortable having adverse events discussed with others	1.0
I never got feedback	*
I was happy with the time it took to make a report-CC	1.0
I was worried that the report would not accurately reflect what I was trying to say	1.0
The CC nurse remained objective when taking a report	1.0
I prefer the CC to the IRIS form	0.8
There was insufficient room to write all I wanted	0.7
I had difficulty locating the form	1.0
I prefer the IRIS form to the 4 page AIMS form	1.0
I prefer the IRIS form to the CC	0.8
How much information have you seen about IRIS	*
How much have you been informed about outcomes	*
How much exposure have you had to IRIS in meetings etc	*
Did you receive newsletter	1.0
Was it useful in informing you of outcomes	0.6
Have you seen previous newsletters	1.0
Where did you see newsletter?	
• Communication book	0.7
• Tearoom	1.0
• Posted	0.7
In last nine months, are you aware of situation where a patient was harmed?	*

agreed+expected same did not calculate kappa

Appendix 34: End of study survey comparison of doctors and nurses who believe they DO report incident types more than 50% of the time

Staff who believe they DO report incident types more than 50% of the time in Control and Intervention Units

	Baseline				End				Comparison at End adjusted for Baseline†	
	Control	Intervention			Control	Intervention				
	Do report >50% of the time (%)	Do report >50% of the time (%)	RR *	95% CI	Do report >50% of the time (%)	Do report >50% of the time (%)	RR	95% CI	RR	95% CI
Doctors										
Hospital-acquired infection	14.5% (55)	17.9% (95)	1.23	0.56, 2.66	32.0% (75)	18.7% (96)	0.59	0.22 - 1.57	0.48	0.34 - 0.67
Staff made a medication error but it was not given to the patient (near miss)	15.8% (57)	18.1% (94)	1.15	0.69, 1.89	37.3% (75)	16.1% (93)	0.43	0.22 - 0.85	0.38	0.21 - 0.67
Staff made a drug error which did not require corrective treatment	36.8% (57)	29.5% (95)	0.80	0.60, 1.07	51.9% (77)	27.2% (92)	0.52	0.36 - 0.75	0.65	0.51 - 0.85
Staff made a medication error requiring corrective treatment	47.3% (55)	47.3% (93)	1.00	0.87, 1.15	66.2% (77)	37.2% (94)	0.56	0.45 - 0.71	0.56	0.45 - 0.70
Problem with equipment/machinery resulting in patient harm	34.5% (55)	43.5% (92)	1.26	0.82, 1.93	70.8% (72)	48.9% (94)	0.69	0.55 - 0.87	0.55	0.41 - 0.73
Nurses										
Staff made a medication error but it was not given to the patient (near miss)	24.3% (222)	18.9% (301)	0.78	0.53, 1.13	29.0% (262)	33.1% (311)	1.14	0.74 - 1.75	1.47	1.23 - 1.74

* log binomial generalized linear models adjusting for clustering by hospitals. † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalized linear models.

Appendix 35: Comparison of barriers to reporting between baseline and end of study by doctors and nurses

Comparison of barriers to reporting by Doctors

	Baseline				End				Comparison at End adjusted for Baseline †	
	Control	Intervention			Control	Intervention				
	% agree (n)	% agree(n)	RR *	95% CI	% agree (n)	% agree (n)	RR *	95% CI	RR*	95% CI
I never get any feedback on what action is taken	65.0 (60)	52.0 (102)	0.80	0.54-1.18	59.6 (89)	40.0 (105)	0.67	0.49-0.91	0.84	0.45-1.57
When it's a near miss, I don't see any point in reporting	32.8 (61)	35.9 (103)	0.87	0.58-1.31	30.7 (88)	29.2 (106)	0.95	0.51-1.76	0.87	0.24-3.13
When the ward is busy I forget to make a report	50.0 (60)	47.5 (101)	0.95	0.73-1.24	53.5 (86)	56.1 (107)	1.05	0.85-1.29	1.10	0.84-1.45
The incident form takes too long /I don't have the time	59.0 (61)	50.0 (100)	0.85	0.57-1.25	59.8 (87)	48.6 (107)	0.81	0.52-1.26	0.96	0.7-1.31
The incident was too trivial	43.3 (60)	55.3 (103)	1.28	0.96-1.69	49.4 (87)	36.8 (106)	0.74	0.56-0.98	0.58	0.50-0.68
I worry about who is privy to information I disclose	31.7 (60)	22.5 (102)	0.71	0.34-1.49	31.5 (89)	35.5 (107)	1.13	0.63-2.01	1.56	0.49-5.18
I don't feel confident the form is kept anonymous	23.7 (59)	19.8 (101)	0.83	0.5-1.4	40.4 (89)	20.7 (106)	0.51	0.28-0.91	0.61	0.22-1.69
Incident reporting is unlikely to lead to system changes	28.3 (60)	25.2 (103)	0.89	0.41-1.96	25.6 (90)	20.6 (107)	0.80	0.56-1.17	0.90	0.42-1.94
Junior staff are blamed unfairly for adverse incidents	33.3 (60)	29.1 (103)	0.87	0.58-1.31	43.3 (90)	34.3 (108)	0.79	0.42-1.48	0.90	0.36-2.25

	Baseline				End				Comparison at End adjusted for Baseline †	
	Control	Intervention			Control	Intervention				
	% agree (n)	% agree(n)	RR *	95% CI	% agree (n)	% agree (n)	RR *	95% CI	RR*	95% CI
I am worried about litigation	23.3 (60)	18.8 (101)	0.81	0.47-1.39	23.6 (89)	29.2 (106)	1.24	0.73-2.11	0.93	0.59-14.8
I don't want to get into trouble	11.7 (60)	10.9 (101)	0.93	0.4-2.2	15.9 (88)	14.1 (106)	0.89	0.65-1.22	0.95	0.34-2.64
My co-workers may be unsupportive	13.3 (60)	13.9 (101)	1.04	0.60-1.79	16.1 (87)	15.6 (109)	0.97	0.62-1.51	0.93	0.38-2.3
Even if I don't give my details, they'll track me down	11.9 (59)	6.9 (102)	0.86	0.49-1.50	19.3 (88)	10.2 (108)	0.53	0.33-0.85	0.91	0.33-2.54
It's not my responsibility to report somebody else's mistake	18.3 (60)	15.7 (102)	0.86	0.49-1.50	22.2 (90)	16.0 (106)	0.72	0.52-1.0	0.84	0.54-1.32
I am worried about disciplinary action	6.7 (60)	7.9 (101)	1.19	0.30-4.78	11.4 (88)	11.1 (108)	0.98	0.58-1.65	0.82	0.19-3.48
I don't know whose responsibility it is to make a report	38.3 (60)	38.6 (101)	1.0	0.78-1.31	34.1 (88)	34.6 (107)	1.01	0.72-1.43	1.0	0.59-1.73
I don't want the case discussed in meetings	6.8 (59)	6.9 (101)	1.02	0.17-6.00	11.5 (87)	12.4 (105)	1.08	0.92-1.25	1.05	0.19-5.80
If I discuss the case with the person nothing else needs to be done	13.6 (59)	28.4 (102)	2.1	1.72-2.55	28.9 (90)	21.5 (107)	0.74	0.36-1.52	0.35	0.18-0.72

* log binomial generalized linear models adjusting for clustering by hospitals. † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalised linear models

Table 0-2 Comparison of barriers to reporting by Nurses

	Baseline				End				Comparison at End adjusted for Baseline†	
	Control	Intervention			Control	Intervention				
	% agree (n)	% agree (n)	RR *	95% CI	% agree (n)	% agree (n)	RR *	95% CI	RR	95% CI
I never get any feedback on what action is taken	58.4 (238)	35.9 (331)	1.10	1.02- 1.18	60.1 (276)	38.3 (337)	0.63	0.35-1.15	0.58	0.33-1.00
When it is a near miss, I don't see any point in reporting it	52.1 (236)	46.7 (332)	0.90	0.75-1.06	38.5 (275)	25.8 (337)	0.67	0.46-0.96	0.75	0.55-1.01
When the ward is busy I forget to make a report	47.5% 238)	48.4 (335)	1.02	0.91-1.14	42.7 (276)	59.6 (339)	1.40	1.18-1.6	1.37	1.20-1.57
The incident form takes too long / I just don't have the time	43.3 (238)	44.6 (332)	1.28	0.76-1.39	25.7 (276)	33.1 (335)	1.28	0.99-1.68	1.25	1.06-1.48
The incident was too trivial	43.2 (234)	39.7 (330)	0.92	0.70-1.20	35.0 (274)	34.4 (334)	0.98	0.76-1.27	1.07	0.86-1.32
I worry about who is privy to the information that I disclose	32.5 (237)	34.7 (331)	1.07	0.84-1.37	28.5 (277)	25.9 (336)	0.91	0.66-1.26	0.85	0.69-1.12
I don't feel confident the form is kept anonymous	29.4 (238)	30.4 (335)	1.04	0.78-1.38	23.1 (277)	23.3 (334)	1.01	0.61-1.65	0.98	0.75-1.26
Incident reporting is unlikely to lead to system changes	27.7 (235)	31.7 (332)	1.14	0.98-1.33	20.9 (277)	17.6 (336)	0.83	0.55-1.26	0.73	0.45-1.20

	Baseline				End				Comparison at End adjusted for Baseline†	
	Control	Intervention			Control	Intervention				
	% agree (n)	% agree (n)	RR *	95% CI	% agree (n)	% agree (n)	RR *	95% CI	RR	95% CI
Junior staff are often blamed unfairly for adverse incidents	24.8 (238)	26.2 (332)	1.06	0.77-1.44	19.2 (276)	21.4 (337)	1.11	0.76-1.62	1.05	0.74-1.49
I am worried about litigation	20.2 (238)	20.9 (335)	1.04	0.77-1.40	15.0 (273)	17.3 (335)	1.15	0.70-1.86	1.11	0.70-1.77
I don't want to get into trouble	19.3 (238)	18.1 (331)	0.94	0.68-1.29	16.7 9276)	13.9 (332)	0.83	0.63-1.10	0.88	0.60-1.30
My co-workers may be unsupportive	18.1 (238)	22.7 (334)	1.26	0.74-2.13	15.6 (276)	23.4 (337)	1.50	0.89-2.53	1.19	0.86-1.66
Even if I don't give my details, they'll track me down	18.1 (237)	16.3 (326)	0.90	0.63-1.27	10.5 (277)	13.6 (337)	1.30	0.85-2.00	1.45	0.85-2.50
I am worried about disciplinary action	19.0 (237)	17.5 (332)	0.92	0.62-1.36	12.6 (278)	11.9 (335)	0.95	0.63-1.43	1.03	0.60-1.78
It's not my responsibility to report somebody else's mistakes	14.8 (237)	17.6 (329)	1.19	0.73-1.95	12.0 (275)	13.1 (336)	1.09	0.66-1.80	0.91	0.45-1.81
I don't know whose responsibility it is to make a report	9.2 (238)	12.0 (334)	1.30	0.88-1.89	5.8 (278)	7.5 (335)	1.30	0.74-2.25	1.00	0.55-1.83
I don't want the case discussed in meetings	16.0 (238)	15.2 (335)	0.95	0.70-1.29	13.0 (276)	10.1 (336)	0.78	0.44-1.37	0.81	0.55-1.21
If I discuss the case with the person nothing needs to be done	11.8 (276)	11.3 (338)	0.95	0.52-1.77	9.4 (276)	9.0 (334)	0.95	0.56-1.63	1.00	0.59-1.68

* log binomial generalized linear models adjusting for clustering by hospitals. † End of study comparisons between intervention and control units were undertaken by formally testing the interaction term between period and study group in the generalised linear models

Appendix 36: Attitudes of doctors and nurses towards changes in the reporting system- control unit

Views of doctors and nurses in the control unit on whether changes to the reporting processes would impact on reporting behaviour

Reporting process	**Doctor** % to which it would impact a moderate amount or a lot (N)	**Nurse** % to which it would impact a moderate amount or a lot (N).	**P value** *
A one page form instead of the 4 page AIMS form	84.4% (90)	78.3% (277)	0.164
A process existed where de-identified reports could be discussed amongst peer.	69.8% (86)	68.7% (275)	0.929
Feedback was given via departmental meetings/handovers	62.3% (85)	63.9% (269)	0.836
Feedback was given via newsletters	63.1% (84)	62.9% (259)	0.988
Ability to report on-line	52.8% (89)	46.7% (276)	0.332
Reports bypassed the line manager in the first instance, going directly to the PSM*	55.2% (87)	50.7% (278)	0.430
The form did not require medical officers to countersign	56.4% (78)	50.0% (270)	<0.001
A confidential Call Centre operated by Registered Nurses was available	41.1% (90)	42.0% (276)	0.908

Log binomial generalized linear model