

**Adverse events following Intensive Care discharge:
The contribution of system, clinician and patient factors**

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Glossary

Adverse event: any unintentional injury or complication that arises from health care management rather than patients' underlying disease and results in disability, death or prolonged hospital stay (Wilson et al., 1995).

Intensive Care Unit: A specially staffed and equipped hospital ward with advanced technologies, dedicated to the management of patients with life-threatening illness, injuries, and complications (Chan et al., 2009, p.297). An ICU can be further defined according to the exact level of care provided. The *Joint Faculty of Intensive Care Medicine* (2011) provides the following defining criteria:

Level I:

- A unit capable of providing immediate resuscitation and short term cardio-respiratory support for critically ill patients.
- It will also have a major role in monitoring and prevention of complications in 'at risk' medical and surgical patients.
- It must be capable of providing mechanical ventilation and simple invasive cardiovascular monitoring for a period of at least several hours.
- Patients admitted to the unit must be referred to the Medical Director of the unit or the specialist taking responsibility for the unit at the time of admission.

Level II:

- A unit capable of providing a high standard of general intensive care, including complex multi-system life support, which supports the hospital's delineated responsibilities.
- It should be capable of providing mechanical ventilation, renal replacement therapy and invasive cardiovascular monitoring for a period of at least several days.
- Patients admitted to the unit must be referred for management to the attending intensive care specialist.

Level III:

- A tertiary referral unit for intensive care patients, capable of providing comprehensive critical care including complex multi-system life support for an indefinite period.
- Patients admitted to the unit must be referred for management to the attending intensive care specialist.

ICU Liaison Nurse: A nurse whose major responsibilities are to facilitate ICU patient discharge, follow up, assess and support, manage unstable patients in ward areas, and provide a critical care resource for ward staff (Endacott et al., 2010).

ICU readmission: A second admission to Intensive Care during the same hospital stay (Campbell et al., 2008).

Post-ICU adverse event: An adverse event occurring after ICU discharge and before hospital discharge.

Statement of originality

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made. This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

I warrant that I have obtained where necessary, permission from the copyright owners to use any of my published work for which the copyright is held by another party. All research procedures reported in this thesis received the approval of the relevant ethics committee.

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Malcolm Elliott

March 2014

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Abstract

Background

An adverse medical event is any unintended injury or complication that arises from health care management rather than the patient's underlying disease, and results in disability, death or a prolonged hospital stay. Unfortunately, these events occur frequently across the care continuum including in patients recently discharged from Intensive Care Units (ICU). Currently there is limited understanding of adverse events in hospitalised post-ICU patients. Given the significant costs, consequences and preventability of these events, greater understanding of post-ICU adverse events is needed.

Aims

This research program aimed to further the understanding of post-ICU adverse events occurring before hospital discharge. Specifically, the research program: examined factors associated with ICU readmission; determined collective expert opinion of factors associated with in-hospital post-ICU adverse events; and prospectively validated factors associated with in-hospital post-ICU adverse events.

Methods

The research program was conducted in three phases using a mixed methods design. The program included interviews with nursing staff, an online survey of ICU Liaison Nurses, and a prospective, clinical validation study. Reason's accident causation model was used as a guiding conceptual framework, promoting a focus on factors associated with adverse events rather than simply blaming the individuals involved.

Results

Phase I of the research program, a qualitative study, involved interviews with 21 nursing staff who had cared for patients readmitted to ICU. Five key factors associated with readmission were identified: 1) premature ICU discharge; 2) delayed medical care on the wards; 3) heavy nursing workloads; 4) lack of adequately qualified staff; 5) clinically challenging patients.

In Phase II, an online quantitative survey, it was hypothesised that the findings of Phase I and key factors in the literature would be common to most in-hospital post-ICU adverse events. A questionnaire incorporating 25 factors was developed and pilot tested, and then used to survey Australian ICU Liaison Nurses. Thirty nine Liaison Nurses responded, representing approximately 93% of the Liaison Nurse population. Key factors associated with in-hospital post-ICU adverse events included a lack of experienced ward staff, patient co-morbidities and the clinically challenging nature of many patients.

Phase III of the research program, a clinical validation study, found the perceptions of ICU Liaison Nurses on the factors associated with post-ICU adverse events were accurate. Data were prospectively collected on a convenience sample of 52 post-ICU patients who experienced an adverse event prior to hospital discharge. All the factors identified by the Liaison Nurses in Phase II of the research program prospectively contributed to adverse events in post-ICU patients. Key factors related to patients such as illness complexity and co-morbidities.

Conclusion

This research program identified key factors, which have clinical significance for in-hospital post-ICU adverse events. Some of the factors are not easily modified as they are patient characteristics such as co-morbidities and illness severity. Other factors are modifiable and represent a unique opportunity to improve the way clinical care is delivered. These factors include time of ICU discharge, nurse to patient ratios and adherence to clinical guidelines. Clinical care and future research should focus on modifiable factors within care processes to improve post-ICU patient outcomes.

Statement of contribution to publications

In line with collaborative clinical research, a number of scholars contributed in part to the research and publications contained in this thesis. However the actual research undertaken and the preparation of the manuscripts for publication was solely my own work, except where acknowledged.

It is acknowledged that all co-authors of jointly published papers included in this thesis provide their consent for the inclusion of each publication in the thesis and that the co-authors accept my contribution to each publication. The contribution of each author is summarised at the commencement of relevant chapters.

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Malcolm Elliott

March 2014

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Professor Linda Worrall-Carter

March 2014

Scholarship

Conference presentations arising from the research program

Elliott, M., Page, K., Worrall-Carter, L., & Rolley, J. (2011). Examining adverse events after ICU discharge: development and testing of a questionnaire. Poster presented at St Vincent's Hospital Research Week, Melbourne, Australia.

Elliott, M., Page, K., & Worrall-Carter, L. (2008). Factors contributing to ICU readmissions: the nurses' perspective. St Vincent's Hospital Research Week, Melbourne, Australia.

Elliott, M., Crookes, P., Page, K., & Worrall-Carter, L. (2007). Factors contributing to ICU readmissions: the nurses' perspective. Poster presented at the Annual Scientific Meeting of the *Australian College of Critical Care Nurses*, Rotorua, New Zealand.

Awards and merits arising from the research program

Elliott, M., Page, K., Worrall-Carter, L., & Rolley, J. (2011). Examining adverse events after ICU discharge: development and testing of a questionnaire. Poster presented at St Vincent's Hospital Research Week, Melbourne. Chosen by peer review for moderated oral presentation.

Elliott, M. (2010). Improving outcomes of patients at risk of adverse events. Finalist - 3 Minute Thesis Competition, Australian Catholic University.

Elliott, M., Page, K., & Worrall-Carter, L. (2008). Factors contributing to ICU readmissions: the nurses' perspective. Presented at the St Vincent's Hospital Research Week, Melbourne. Nominated for Junior Investigator Award.

Additional output relating to the research program

Green, A., McIntyre, T., Taylor, C., **Elliott, M.**, Evans, S., Chaboyer, W., & Jones, D. (2011). ICU Liaison Nurse: an analysis of service delivery in seventeen hospitals. Poster presented at the Annual Scientific Meeting of the *Australian & New Zealand Intensive Care Society*, Brisbane, Australia.

Elliott, M. (2011). Mixed methods. In Richardson-Tench, M., Taylor, B., Kermode, S., & Roberts, K. *Research in nursing: evidence for best practice* (4th ed.). Melbourne: Cengage.

Pilcher, D., Bailey, M., Santamaria, J., Stow, P., Deshpande, K., George, C., Duke, G., **Elliott, M.**, & Hart, G. (2007). Factors associated with increasing risk of readmission to intensive care. Poster presented at the Annual Scientific Meeting of the *Australian & New Zealand Intensive Care Society*, Rotorua, New Zealand.

Elliott, M. (2006). Readmission to Intensive Care: a review of the literature. *Australian Critical Care*, 19(3), 94-103. (IF 0.95; 23 citations).

Elliott, M., Tate, R., & Page, K. (2006). Do clinicians know how to use pulse oximetry? A literature review and clinical implications. *Australian Critical Care*, 19(4), 139-144. (IF 0.95. Winner of the *Australian College of Critical Care Nurses'* best nursing review paper competition 2006; 29 citations).

Awarded *National Centre for Clinical Outcomes Research* secondment (six months) to the St Vincent's Centre for Nursing Research (Melbourne), 2010.

CHAPTER 1

Introduction and Background

Overview

The aim of the doctoral research program was to address a number of contemporary safety issues in the management of post-ICU patients. By better understanding adverse events that occur in these high-risk patients, processes of care can be modified to improve these patients' outcomes. This introductory chapter will establish the context of the research problem including an overview of seminal adverse event research and then introduce the research program's aim and design, and conclude by summarising the structure of the thesis.

Background

This section presents a definition of adverse events, highlights the contemporary increase in patient acuity and the role of Intensive Care Units, and outlines pioneering research on adverse events.

An adverse medical event is any unintended injury or complication that arises from health care management rather than the patient's underlying disease, and results in disability, death or a prolonged hospital stay (Wilson et al., 1995). This definition is comparable with the World Health Organization's (WHO) International Patient Safety Event Classification definition of a patient safety incident as an event or circumstance that could have resulted, or did result, in unnecessary harm to the patient (WHO, 2008, p. 15). Numerous definitions of an adverse event exist and they share three key characteristics: the events are undesirable; they have a negative impact on the patient; and they are a result of health care processes rather than the patient's underlying disease (Walshe, 2000). Clinical examples of adverse events include deep vein thrombosis, nosocomial infection and pulmonary oedema.

Some adverse events and their outcomes have been deemed nurse sensitive. These are defined as outcomes that are '... based on nurses' scope and domain of practice, and for which there is empirical evidence linking nursing inputs and interventions to the outcomes' (Doran, 2003, p. vii). Examples of these include pressure ulcers and falls (Given & Sherwood, 2005). Other adverse events relate to the quality of medical care delivered, for example, post-operative infections from poor surgical technique (Thomas et al., 2000). Many of these events reflect the challenging nature of acute clinical care such as increasing patient acuity.

Patient acuity

As health care delivery has become more complex, the risk of adverse events in acute health care settings has increased. This issue is very concerning and has a strong relationship to the increasing number of acutely ill ward patients - those who have deteriorated or are at risk of sudden clinical deterioration (Frost & Wise, 2012). There are many reasons for the growth in this patient population. These include the frequent use of advanced treatments, an ageing patient population, and the presence of co-morbidities, which may be exacerbated by an acute illness (DeVita et al., 2006; Massey et al., 2009). Advances in medical treatments and technologies have meant many critical illnesses and diseases are now reversible (Hillman, 2002). Improvements in surgical and anaesthetic techniques have also resulted in patients who once may have been too sick to be operated on, now undergoing complicated surgeries and surviving.

Recovery, for this group, can be prolonged with an increased risk of adverse events. Those aged 65 years and older have twice the risk of developing peri-operative complications and are more likely to undergo emergency surgery (Romano et al., 2003). Improved survival rates have resulted in a complex patient population that requires a greater level of monitoring and intervention than in the past (Hillman, 1999; James et al., 2010). The challenge created by complex ward patients is a global health care issue.

Research has found that many ward patients' illness acuity is greater than is normally catered for in a ward environment. A study in the United Kingdom for example, found that 12% of 1,873 general ward patients had care needs above those normally managed in a ward environment (Chellel et al., 2002). A Danish study conducted in five hospital wards found 20% of patients developed abnormal vital signs during their hospitalisation (Fuhrmann et al., 2008). This more than doubled the risk of 30-day mortality compared with patients whose vital signs were normal. A recent study in a 477 bed trauma hospital in North America similarly found that nearly a third of patients exhibited at least one clinically significant vital sign abnormality during their admission (Fagan et al., 2012). Of concern was that, of the 4,739 abnormal vital signs recorded, only 2.5% resulted in an emergency medical response. Other research has also highlighted the incidence of abnormal vital signs

in ward patients, as well as an absent or delayed response by clinical staff (Harrison et al., 2005; NPSA, 2007). Unfortunately clinical deterioration is often not recognised or acted upon promptly, and poor communication and delayed access to critical care expertise may add to this (National Institute for Health & Clinical Excellence, 2007).

Patient acuity and complexity in Australian hospitals is also increasing (Australian Institute of Health and Welfare, 2006; Massey et al., 2009). A retrospective analysis of 120,123 admissions to 57 ICUs found that the number patients aged 80 and older being admitted to ICU is increasing (Bagshaw et al., 2009). These patients had more co-morbidities and higher mortality rates than younger patients. Research has also found that the acuity and severity of patients presenting to Emergency Departments is also increasing (Hou et al., 2011).

Role of Intensive Care

An Intensive Care Unit (ICU) is a specialised department within a hospital that provides clinical expertise in critical care and a level of care not provided in other hospital areas. Patients admitted to ICU are of the highest acuity requiring management with life support technologies and aggressive interventions to sustain life and progress towards a clinically stable condition (Watts et al., 2007). Intensive care medicine is therefore resource and labour intensive, and its patients are often complex and at risk of adverse events (Duke et al., 2005).

The clinical support available to patients in ICU includes multi-disciplinary teams of health care providers such as doctors, nurses, pharmacists and physiotherapists (Vazirani et al., 2005). Globally, ICUs face many challenges such as having too few resources in relation to the number of patients requiring critical care and this is partly due to the costs associated with these services (Utzolino et al., 2010). In Australia, the annual cost of ICU services is \$US850 million, while in the United Kingdom the estimated cost is \$US872 million (ANZICS, 2002; Ridley & Morris, 2007). In North America, as much as \$US81.7 billion is spent each year funding critical care services (Halpern & Pastores, 2010).

ICU discharge

To justify these expenses, it is vital that patients admitted to ICU are those who are most likely to survive. Similarly, it is essential that quality of care continues when

patients are discharged from ICU to a ward. However, ICU discharge represents a large drop in the intensity of care with patients moving from a high acuity unit to a general care unit (Stelfox et al., 2013). Pressure for ICU beds may also mean that patients are discharged to a ward prematurely, and often at short notice (Forsberg et al., 2011). This may result in highly dependent patients with complex care needs being admitted to a ward environment.

Discharge from ICU typically also involves a change in health care providers, with most post-ICU patients being assigned new teams of doctors, nurses, pharmacists, physiotherapists and other allied care providers (Stelfox et al., 2013). Nurses in ICU and in general wards have identified a gap in clinical care during the transition period from ICU; the gap includes differences in the environment, nurses' competence levels and communication channels (Forsberg et al., 2011).

The problem of how to appropriately manage these more complex ward patients is exacerbated by a lack of ward resources, increased throughput and limited educational support for ward staff (Coombs & Dillon, 2002). Other factors that may compromise care relate to the organisation, for example, junior doctors with limited clinical experience (Royal College of Physicians, 2011). These issues and patient acuity place post-ICU patients at risk of an adverse event prior to hospital discharge. However despite what is known from studies of adverse events, little is known about these events in patients recently discharged from ICU (Williams et al., 2010). Attendance to risk and the associated issues of patient safety are therefore now more important than ever before (Rischbieth, 2006).

Seminal adverse event research

For some time, unintended patient harm or injury has been globally recognised as a significant health care problem. The emergence of global patient safety initiatives was partly due to the findings of seminal patient safety research. These pioneering and frequently cited studies brought the significance and impact of unintended patient harm to the attention of clinicians and hospital managers, who are under increasing pressure to demonstrate the quality of care they provide (Lagu & Lindenauer, 2010; Lindenauer et al., 2007). These studies demonstrated that the problem of unintended patient harm was not unique to one health care system globally; this suggests that common factors may contribute to, or be associated with,

adverse events in acute health care systems worldwide. The studies are summarised in Table 1.

The United States Institute of Medicine's frequently cited report, *To Err is Human*, was heavily based on patient safety research and found that between 44,000 and 98,000 deaths occurring in North American hospitals each year were due to medical errors (Kohn et al., 1999). This mortality rate is higher than for motor vehicle accidents, breast cancer and AIDS (Kohn et al., 1999). A similar report from the United Kingdom, *An Organisation with a Memory*, estimated that 10% of hospital admissions in Great Britain are associated with an adverse event (National Health Service, 2000).

A significant difference was found in the adverse event rate in two key studies, the Quality in Australian Health Care Study and the Utah Colorado Study (Thomas et al., 2000; Wilson et al., 1995). In the Australian Health Care Study adverse events affected 16.6% of patients but only 2.9% in the Utah Colorado Study. This difference was partly explained by some key methodological differences including the number of reviewers involved (two versus one) and the threshold used to define medical causation of an adverse event (Thomas et al., 2000a). It was also speculated that the quality of health care may have been worse in Australia and that there were differences in the medical record content and reviewer behaviour (Thomas et al., 2000a).

Another possible explanation for the differences was that the Utah Colorado Study used reviewers with a more general background while the Australian study used specialist reviewers (Thomas et al., 2000a). The differences may also have reflected under-reporting of certain types of adverse events in North America (Runciman et al., 2000). Due to the higher likelihood of litigation in North America, fewer details of adverse events may have been recorded in the medical records (Runciman et al., 2000). This difference highlights the broad range of rates of adverse events reported in clinical research.

Two common patient outcomes following an adverse event were identified in the pioneering studies - permanent disability and death. The incidence of permanent disability in these studies ranged from 2.6% to 33% of all patients who experienced an adverse event (Brennan et al., 1991; Vincent et al., 1991). Not all of the studies

reported the incidence of permanent disability; some studies cited a combined incidence of permanent disability and death. The mortality rate following an adverse event ranged from 4.9% to 33% of patients (Vincent et al., 1991; Wilson et al., 1995).

As well as the impact on patients, adverse events have a financial burden. In a study conducted in two hospitals in the United Kingdom, each adverse event resulted in an extra 8.7 days in hospital, with additional costs of £290,268 to the health care service involved (Vincent et al., 2001). Based on these findings, the researchers estimated that adverse events in British hospitals result in an extra three million hospital bed days per year. The extra bed days alone carried an additional cost of £1 billion per year (Vincent et al., 2001). The North American report, *To Err is Human*, estimated that the total cost of adverse events, including lost income and disability, was between \$US17 billion and \$US29 billion per year in North American hospitals (Institute of Medicine, 1999).

Litigation costs resulting from patient harm can also be significant. In 2009 to 2010, the National Health Service Litigation Authority in the United Kingdom paid out over £800 million in claims (NHS Litigation Authority, 2010). None of the other key studies reported the litigation costs of adverse events.

The aim of these seminal studies was to explore the nature and characteristics of adverse events, rather than to propose preventive strategies. However, in 2004, the World Health Organisation (WHO) launched the World Alliance for Patient Safety to advance the patient safety goal of 'first do no harm' and to reduce the adverse health and social consequences of unsafe health care (WHO, 2004). A recent initiative of the alliance is the 'High 5s project', which aims to reduce the frequency of five challenging patient safety problems in five countries over five years (WHO, 2012a). The problems being targeted relate to concentrated injectable medications, medication accuracy at transitions in care, correct procedure on the correct body site, communication failures during patient handovers and health care-associated infections (WHO, 2012b).

Table 1: Seminal adverse event studies

Author	Sample	Method	Key findings
Baker et al (2004)	3,745 medical records in 20 hospitals in five Canadian provinces	Retrospective chart review	Adverse event incidence 7.5%. The most common events were related to surgical procedures, followed by drug or fluid administration. More than a third of adverse events were deemed preventable.
Davis et al (2002)	6,579 medical records from 13 acute hospitals in New Zealand	Retrospective chart review	Adverse event incidence 12.9%. Adverse events were most common in patients aged 65 years or older (29.9%). Few (5%) adverse events were deemed preventable; these were related to system errors, such as inadequacies of equipment, training or staffing.
Vincent et al (2001)	1,014 randomly sampled medical records in two London hospitals	Retrospective chart review	Adverse event incidence 10.8%. Nearly half of the adverse events (46%) were deemed preventable with ordinary standards of care.
Thomas et al (2000)	15,000 randomly sampled medical records from 28 North American hospitals	Retrospective chart review	Adverse event incidence 2.9%. Nearly half (44.9%) of the adverse events were related to surgical procedures and were attributed to surgeons. Less than 2% of the adverse events were attributed to nursing staff.

Wilson et al (1995)	14,179 admissions to 28 hospitals in two Australian states	Retrospective chart review	Adverse event incidence 16.6%. More than half (51%) of the adverse events were deemed avoidable.
Brennan et al (1991)	30,195 randomly selected medical records from 51 acute hospitals in New York State	Retrospective chart review	Adverse event incidence 3.7%. The most common adverse events were related to medications (19%), wound infections (14%) and technical complications (13%). More than half of the adverse events were management errors resulting from substandard care and therefore deemed potentially preventable.

A similar initiative was undertaken in Australia in the last decade. In 2006, the Australian Commission on Safety and Quality in Health Care (ACSQHC) was launched by health ministers to lead and coordinate health care safety and quality improvements in Australia (ACSQHC, 2006). Six domains for developing patient safety and quality datasets in Australia were identified: core hospital-based outcome indicators; patient safety reporting for hospitals; hospital patient experience and satisfaction; practice-level indicators for safety and quality of primary health care; core outcome indicators for day procedure services; and whole system measures of health care quality (ACSQHC, *n.d.* a).

Guidelines for improvement

Recently, the ACSQHC developed national safety and quality health service standards to provide a nationally consistent set of measures of safety and quality for application across a variety of health care services (ACSQHC, 2011). The standards address ten key areas, including falls prevention, clinical handover, medication safety, nosocomial infection, and recognising and responding to clinical deterioration. Current outcomes include the development of an inpatient medication chart designed for national use. A national vital signs chart, based on heuristic principles, is also being developed (ACSQHC, *n.d.* b).

The North American Institute of Medicine outlined a four-tiered strategy by which government, health care providers, industry and consumers could reduce preventable medical errors (Institute of Medicine, 1999). The strategy involved: establishing a national focus to create leadership, research and protocols to enhance the knowledge base about safety; identifying and learning from errors by developing a nationwide mandatory reporting system; raising performance standards and expectations for improvements in safety through the actions of organisations and professional groups; and implementing safety systems in health care organisations to ensure safe practices at the delivery level (Institute of Medicine, 1999, p. 3-4).

More than a decade later, it has been suggested that the Institute of Medicine report has had little impact on clinical practice as the adverse event incident rate among hospitalised adult patients in three leading hospitals in North America has remained high (Landrigan et al., 2010; Classen et al., 2011). A longitudinal retrospective review of 11,883 medical records from 41 hospitals in the Netherlands found that the

adverse event incidence rate has actually increased in recent years (Baines et al., 2013). The study concluded that patient harm is a persistent problem that is hard to influence. Questions such as why has the incidence of medical harm not decreased with time are now being asked, although there are few evidence-based answers (Shojania & Thomas, 2013). A possible reason is that the key factors associated with patient harm have not yet been identified.

Other proposed reasons for the slow improvement in patient safety include: health care safety issues not being obvious to clinicians; discordance between the true extent of the problem and health professionals' perceived extent; inconclusive evidence of cause and effect; a culture of blaming individuals for poor patient outcomes rather than recognising systemic failures which contribute; debate and disagreement about which safety problem has the greatest priority; and a culture of reluctance to correct an erring colleague (Leistikow et al., 2011).

A key document from the United Kingdom, *An Organisation with a Memory*, highlighted the similarity of adverse events between hospitals, and emphasised that many events could have been avoided if lessons had been learned from earlier events (National Health Service, 2000). While the impact of negligence and human error was recognised, the contribution of the complex nature of health care was also emphasised. This included latent conditions that develop over time and combine with other factors to breach safety defences (National Health Service, 2000, p. ix). However strategies for avoiding future adverse events were not proposed.

Contemporary research has also highlighted the incidence and characteristics of adverse events in other countries including Spain, France, the Netherlands, Brazil and Sweden (Aranaz-Andres et al., 2008; Mendes et al., 2009; Michel et al., 2007; Soop et al., 2009; Zegers et al., 2009). A combined sample of 25,658 patients was included in these studies and the incidence of adverse events ranged from 5.7% to 12.3% of admissions. Between 2.3% and 70% of events were deemed avoidable. Permanent disability resulted from 5% to 22% of adverse events and patient mortality was the outcome in 3% to 10.5% of adverse events.

Summary of seminal studies

These seminal studies had some similarities including the research methods used and the struggle to identify causative factors of adverse events. Key differences included the nature of the characteristics of the common adverse events. In summary, it can be seen that adverse events are common in acute health care settings worldwide and are not confined to one unique health care system. The average adverse event incidence rate in these studies ranged from 2.9% to 16.6%. Whilst this might be considered low, seminal research has consistently concluded that up to half of all adverse events may be preventable with better standards of care. This is significant given that up to a third of patients die due to the adverse event experienced. While this figure is alarming, it also suggests that with changes or improvements to care processes, many patients may be spared the burden of these events.

Whilst these seminal studies are frequently cited and have highlighted the global problem of patient harm in acute health care settings, more research using unique methods is needed to find a contemporary solution. As some of the seminal studies are more than a decade old, their findings are less applicable to modern clinical practice. For example, a recent change to the Australian health care system is the evolution of ICU Liaison Nurses, who have a key role in patient care following ICU discharge.

Current research on adverse event in Australia has found these events continue to be a national problem in acute health care settings. A review of 979,834 in-patient episodes in Victoria for example, found that 6.8% involved at least one adverse event, adding 10 days to the hospital admission at a cost of \$6826 per episode (Ehsani et al., 2006). A study of 194 adverse events in an Australian Emergency Department found these events were either errors of commission (55%) or omission (45%), though some were due to events occurring prior to presentation (Hendre et al., 2007). Events occurring due to care in the Emergency Department were considered highly preventable. A recent study in an ICU in Victoria found that 26.1% of patients experienced an adverse event (Silas & Tibballs, 2010). A quarter of these events were labelled a major event, though few were considered catastrophic.

The greatest challenge to clinicians today is preventing adverse events in clinical care. This is not easily achieved because health care is a complex entity with many influencing variables. The patients themselves may contribute to the risk simply by being acutely ill and having co-morbidities. The ultimate goal of patient safety research is to develop evidence-based preventive strategies. This cannot occur without first identifying the factors contributing to or associated with the risk of adverse events. This is the ongoing challenge to health care researchers and clinicians. A possible reason that preventive strategies remain elusive is the limitations of methods used to examine these events.

Research methods

As with all studies, it is important to understand the strengths and limitations of the methods used, however it is particularly important in reporting adverse events. Historically, various research methods have been used to identify adverse events in acute clinical settings; these methods have implications for study outcomes. Factors influencing the choice of research method may relate to costs, time, available resources and the strengths and limitations of each method. The methods most commonly used for identifying adverse events in acute settings are presented in Table 2.

The most commonly used method in adverse event research is retrospective medical record analysis (see Table 1). However inter-observer agreement has been found to be poor when medical records are reviewed to determine if adverse events are due to error (Lilford et al., 2003, 2007). For example, nurse reviewers have been found to detect more errors than medical reviewers though the reasons are unclear (Silver et al., 2007). This has implications for interpreting the findings of studies using this research method. If an adverse event is detected by medical record review, the question of preventability rests with the subjective opinion of each reviewer (Scanlon et al., 2008). For example, the criteria used for determining adverse events in the Utah Colorado study heavily influenced the number of events identified; if all three reviewers had to agree that an error had occurred, the error rate was less than 10% of the rate when the opinion of only one reviewer was required (Thomas et al., 2002). Poor agreement has also been found between adverse events reported through patient surveys and medical record review, and between prospective data

collection by clinicians and medical record review (Michel et al., 2004; Weissman et al., 2008).

Table 2: Research methods

Method	Characteristics
Retrospective medical record analysis	<p>Strengths include the ease of planning data collection and the workload for staff involved (Michel et al., 2004).</p> <p>Relies heavily on the accuracy of clinical documentation, which is often vague, incomplete and subjective (Bogardus et al., 2001; DeVon et al., 2004). Furthermore, documentation in medical records often fails to capture the subtleties of health care or the context in which care is delivered (Brown et al., 2008). Clinical documentation may therefore provide little insight into strategies for avoiding future adverse events (Wald & Shojania, 2001).</p> <p>Due to their sensitive nature, adverse events are not always documented in medical records and will not always be detected by this method (de Vries et al., 2008; Kopp et al., 2006).</p>
Trigger tools	<p>Increasingly being used in studies in the United Kingdom and North America (Classen et al., 2011). These tools are designed for use when reviewing medical records (Griffin & Classen, 2008).</p> <p>Allow reviewers to scan medical records in a comprehensive manner, as they allow reviewers to systematically look at discharge codes and summaries, laboratory results, operation records, and nursing and medical notes to determine whether a trigger exists (Classen et al., 2011).</p> <p>Have been found to have high sensitivity and specificity; therefore, they may be able to identify far</p>

	<p>more adverse events than other methods (Classen et al., 2011).</p> <p>Less labour intensive than traditional methods of reviewing medical records (Griffin & Classen, 2008).</p> <p>Effectiveness is highly dependent on the quality of documentation in medical records.</p> <p>Although they may reduce reviewer subjectivity, a large variation in agreement has been found between teams of reviewers using them to assess adverse events (Schildmeijer et al., 2012).</p>
Retrospective analysis of clinical data	<p>Has been rated highly by the Agency for Healthcare Research and Quality because of its impact and effectiveness (Shojania et al., 2001).</p> <p>Data may be more readily available to care providers and patient safety personnel if they are recorded electronically (Tinoco et al., 2011).</p> <p>There is no guarantee that recorded clinical data will show evidence of an adverse event, even if the data are recorded electronically; data may simply reflect the underlying disease and medical treatment.</p>
Voluntary reporting	<p>Most common method used to detect and track adverse events in most hospitals in North America (Classen et al., 2011). Is relatively easy and cost-effective.</p> <p>Often fails to detect most adverse events and therefore fails to indicate the true incidence of these events (Aspden et al., 2004; Giles et al., 2006). Clinician-reported events are a more sensitive indicator of patient safety during hospitalisation and may therefore be a better indicator of poor quality care (Naessens et al., 2009).</p>

Due to these reasons, reviewer judgement of the presence of adverse events has only low to moderate reliability and face validity (Localio et al., 1996; Michel et al., 2004). Ideally patient safety research conducted using medical record review should be reliable and accurate without losing efficiency (Pavao et al., 2012). But retrospective reviews of medical records tend to significantly under report the incidence of adverse events (McCannon et al., 2007).

Summary of research methods

Accurate measurement of adverse events is important to establish research priorities, generate ideas for improvement and evaluate whether improvement efforts are effective (Classen et al., 2008). However, there is currently no accepted gold standard for detecting adverse events in hospitalised patients (Classen et al., 2011). One of the many challenges in trying to identify these events is that the levels of illness and fragility among patients make it difficult to identify errors and disentangle their effects from the progression of the patients' underlying diseases (Brennan et al., 2005). Different detection methods tend to identify different types of adverse events (Hogan et al., 2008; Naessens et al., 2009; Samore et al., 2004). A systematic review conducted by the WHO (2003, p. 4) concluded that the available methods for identifying adverse events have widely differing purposes, strengths and weaknesses and must be considered as complementing each other by providing different levels of qualitative and quantitative information.

Recently, there has been a call for more practical and less labour intensive approaches to assess patient safety than reviewing medical records (Classen et al., 2011). It has also been recommended that more than one method of detecting adverse events be used to provide an adequate assessment of these events (Olsen et al., 2007; Tinoco et al., 2011). More rigorous research methods or combinations of methods are needed to identify risk factors associated with adverse events and, in particular, to identify preventable or modifiable factors within patient care (Thomas & Peterson, 2003; Wetzels et al., 2008).

Research has been conducted on adverse events in a wide range of acute clinical settings including specialty areas such as emergency departments, operating theatres and Intensive Care Units (Calder et al., 2010; Forster et al., 2008; Pritchard et al., 2010). Clinical areas such as these are in high demand and require the

services of specialised staff and equipment. These areas are also resource and labour intensive and carry a large financial burden. It is therefore vital that patients presenting to and discharged from these areas are given the chance of the best possible outcomes, including the risk of adverse events being minimised.

Research program outline

The research program examined adverse events occurring in the acute clinical setting. The aim of the program was to add to the limited understanding of in-hospital post-Intensive Care adverse events by exploring factors associated with or contributing to these events. The program was conducted in three phases using a mixed methods design and guided by an accident causation model. The model promoted a focus on factors within the system or environment in which clinical care is delivered, the person delivering the care and the care recipient. Publications arising from the research program are included in five chapters (chapters, 2, 3, 5, 6, 7).

Through an original investigation involving a series of related studies, the program provides a unique contribution to the limited body of knowledge around the problem of post-Intensive Care adverse events. The findings of the research program are presented in eight manuscripts either published, in press or currently under review. The purpose was not to try to eliminate or resolve the problem of these events through an intervention but to make recommendations for clinical practice.

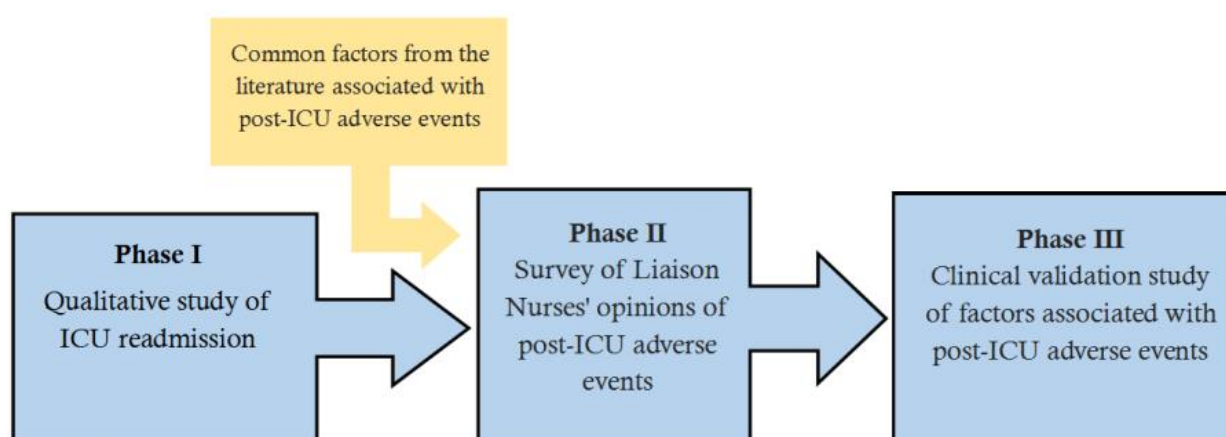


Figure 1: Overview of the research program

Research questions

The primary research question addressed by the research program was: What factors are associated with adverse events in patients discharged from ICU?

To address this question, a three-phased research program was designed. Each phase was informed by the preceding phase and addressed a specific question related to the overall aim of the program.

Phase I

What are nurses' perceptions and experiences of the factors associated with ICU readmission?

Phase II

What is the collective expert opinion of the factors associated with in-hospital post-ICU adverse events?

Phase III

When tested in real time, can factors believed to be associated with in-hospital post-ICU adverse events be validated?

Research aims

The overall aim of the research program was to improve the understanding of adverse events occurring in-hospital after ICU discharge. The specific aim was to identify factors associated with adverse events following ICU discharge to make recommendations for clinical care and research.

Study design

A mixed methods research design was used in the research program. This research method involves the collection, analysis and integration of quantitative and qualitative data in a single program of inquiry (Creswell & Plano Clark, 2007). Its core characteristics include the integration of quantitative and qualitative data sets by merging them or connecting them sequentially, with one building on or extending the other (Sweetman et al, 2010). The research program used an exploratory mixed methods design in which a qualitative phase is conducted first followed by a

quantitative phase. This mixed methods design is used to explore a phenomenon about which little is known.

Consistent with this method, phase I of the research program involved interviews with staff involved in the care of patients readmitted to ICU. The findings of Phase I along with key factors from the literature, informed Phase II. This was important, to determine if factors contributing to ICU readmission also contribute to other in-hospital post-ICU adverse events. Equally, the results of Phase II fed into the next stage and were clinically validated in Phase III. Chapter four provides an overview of mixed method research designs and how this design was used in the research program.

Conceptual framework

In recent years there have been calls to strengthen the theoretical underpinnings of patient safety research (Brazil et al, 2005). The research program was therefore guided by an accident causation model, which helped achieve a deep understanding of the clinical problem under investigation. The use of the model was important in avoiding simplistic conceptions of fault and blame and enabled the program's outcomes to be linked to the existing body of knowledge (Borbasi et al, 2008; Woloshynowych et al, 2005).

The model used in the research program, Reason's accident causation model (1997), guided data collection and analysis. The model acknowledges that whilst human error may contribute to adverse outcomes, humans are vulnerable to the conditions or environment in which they were working at the time of the event. Reason's model recognises that weaknesses in complex systems contribute to adverse outcomes; this is known as vulnerable system syndrome (Reason et al, 2001). An overview of the model is presented in chapter three.

Thesis structure

Consistent with the Australian Catholic University's policy on thesis by publication, this thesis is based on a program of research with a series of peer-reviewed publications (or manuscripts accepted for publication or currently under review). The candidate was the sole author of one of these publications and the primary author of the others. Each publication highlights the candidate's scholarly contribution to research in this area.

Each chapter is introduced within the context of the thesis. Each chapter also contains a concluding statement. Permission has been obtained from each publishing company to include a copy of the publications in this thesis. The only condition of this permission was that each publication be an exact copy of that which appeared in print. Hence there are some inconsistencies in referencing styles in the published manuscripts.

The final thesis chapter provides a list of references cited in each chapter; each published manuscript though has its own reference list. The thesis uses the referencing style prescribed by the School of Nursing Midwifery and Paramedicine at the Australian Catholic University, which is based on the sixth edition of the American Psychological Association's Publication Manual (2010, 6th ed.). The thesis is divided into eight key chapters (see Table 3).

Table 3: Thesis chapters

Chapter 1	Provides the background and significance of the research program. The purpose, aims, objectives and limitations of the program are also described.
Chapter 2	Consists of two published manuscripts reviewing research on ICU readmission and post-ICU mortality. The gaps in the literature are highlighted and a justification for the research program provided.
Chapter 3	Consists of a published manuscript describing the conceptual framework that guided the research program.
Chapter 4	Outlines the method used in the research program.
Chapter 5	Consists of a published paper reporting Phase I of the research program. The chapter also contains a published paper conceptualising the research problem addressed in Phase I.
Chapter 6	Consists of a published paper reporting Phase II of the research program. The chapter also contains a published paper describing the pilot study for Phase II.
Chapter 7	Consists of a published paper reporting the third and final phase of the research program.
Chapter 8	Provides a summary and discussion of the findings of the research program and conclusions.

Chapter summary

Adverse events are defined as any unintentional injury or complication that arises from health care management rather than patients' underlying disease and results in disability, death or prolonged hospital stay (Wilson et al., 1995). They are a global problem in many acute health care settings and not confined to one health care system. Of concern is that many adverse events are associated with poor patient outcomes such as permanent disability and death. Furthermore, more than half of all adverse events have been deemed preventable with better standards of care.

An Intensive Care Unit is a specially staffed and equipped hospital ward with advanced technologies, dedicated to the management of patients with life-threatening illness, injuries, and complications (Chan et al., 2009, p.297). Intensive Care Units provide a vital clinical service for critically ill patients; without these Units, many patients would die from their acute illness. Patients admitted to ICU are typically older and this, combined with a critical illness and co-morbidities, puts post-ICU patients at greater risk of an in-hospital adverse event than others.

Research has found that ward staff struggle with the care of these patients. Due to the challenging nature of critical illness and the complexities involved in delivering the requisite care, there is an inherent risk of adverse events following ICU discharge. Research to date on adverse events has been limited by the methods used and thus struggled to identify key causal factors. Currently, little is also known about the factors associated with these adverse events in the post-ICU population.

The purpose of the doctoral research program therefore was to add to the current limited understanding of in-hospital post-ICU adverse events by providing evidence of factors associated with their occurrence. The purpose was not to try to eliminate or resolve the problem of these events but to make recommendations for clinical practice.

To address the research problem, a mixed method three phased research programme was designed. Quantitative and qualitative methods were used. The research program was guided by an accident causation model which promoted a focus on system, clinician and patient factors; doing so avoided simplistic explanations of causality. Key findings from the research program were published

during the course of study. This had many benefits including making significant research findings available to key stake holders in a timely manner.

Chapter One has laid the foundations for this thesis. It provided justification for the research program and summarised the research program. Chapter Two provides a review of the literature on post-ICU adverse events and is divided into three sections: a review of studies on post-ICU mortality, a review of studies on ICU readmission and a review of other studies examining post-ICU adverse events.

CHAPTER 2

Literature Review

This chapter contains two manuscripts published in international, peer-reviewed critical care journals.

Elliott, M., Worrall-Carter, L. & Page, K. (2012). Factors associated with in-hospital mortality following ICU discharge: a comprehensive review. *British Journal of Intensive Care*, 22(4), 120-125.

- Malcolm Elliott – led the conception and design of the study; developed the literature search strategy; undertook the literature search, data extraction and analysis; and wrote and edited manuscript drafts.
- Prof Linda Worrall-Carter – contributed to the conception and design of the study; and edited manuscript drafts for key intellectual content.
- Dr Karen Page – contributed to the conception and design of the study; assisted with data analysis and interpretation; and edited manuscript drafts for key intellectual content.

Elliott, M., Worrall-Carter, L. & Page, K. (2014). Intensive Care readmission: a contemporary review of the literature. *Intensive & Critical Care Nursing* (in press).

- Malcolm Elliott – led the conception and design of the study; developed the literature search strategy; undertook the literature search, data extraction and analysis; and wrote and edited the manuscript drafts.
- Prof Linda Worrall-Carter – assisted with data analysis and interpretation; and edited manuscript drafts for key intellectual content.
- Dr Karen Page – assisted with data analysis and interpretation; and edited manuscript drafts for key intellectual content.

Introduction

Chapter One presented an overview of key research on adverse events and the global initiatives aimed at preventing them. The chapter outlined the three phases of the research program as well as the research problem being addressed. Chapter Two builds on the first by reviewing literature relevant to post-ICU adverse events. The reviews aim to synthesis research which has examined the two most common in-hospital post-ICU adverse events. The literature is divided into three themes: studies examining in-hospital post-ICU mortality; studies examining ICU readmission; and studies examining other in-hospital post-ICU adverse events. There are many clinical examples of adverse events, ranging from falls and pressure ulcers to medication errors and mortality. In conducting a search of the literature, however, it became apparent that research on post-ICU adverse events has predominately focused on two key events: mortality and readmission.

To date, the primary research approach to post-ICU adverse events has been retrospective review of medical records (see chapter one). This is probably due to ease and convenience of analysing data recorded in this way. However as the nature of intensive care has changed significantly in recent years along with ICU patient acuity and complexity, different or more innovative research methods are needed to provide further insight into the problem of post-ICU adverse events. Reliance upon the research methods used in the past may do nothing more than to replicate other studies' findings.

Two key studies were identified that aimed to examine a broad range of adverse events after ICU discharge rather than focusing on just one specific event (Chaboyer et al., 2008; McLaughlin et al., 2007). While these studies used the global definition of an adverse event, they did not attempt to focus on all possible adverse events following ICU discharge. The first study examined medical records using predefined criteria, to identify any abnormal clinical events; the criteria were those used to call a medical emergency team (McLaughlin et al., 2007). The second study conducted a review of medical records using an internationally accepted audit protocol (Chaboyer et al., 2008). These two studies are reviewed in the final section of this chapter.

Post-ICU mortality

Critically ill patients are admitted to ICU to reduce morbidity and mortality related to acute illness, trauma or surgical procedures (Braber & van Zanten, 2010). The majority of ICU patients survive their critical illness and are discharged to a step-down unit or ward environment. Up to 40% of patients will die soon after ICU discharge (Rellos et al., 2006); some of these deaths are expected and cannot be prevented (Campbell et al., 2008; Campos et al., 2011). However, the sudden death of post-ICU patients who are expected to survive may reflect a breakdown in care quality and a breach of safety processes. However, post-ICU patients often have complex care needs, which may be difficult to provide in a ward environment, resulting in poor patient outcomes (Green & Edmonds 2004).

Recent research has found that up to a third of post-ICU patients will experience preventable harm such as an adverse event; more than half of these events may be preventable with better standards of ward care (Chaboyer et al., 2008; McLaughlin et al 2007). Seminal research found that up to 20% of patients who died on a ward after ICU discharge were expected to survive; these patients tended to be older, have longer ICU lengths of stay and higher illness acuity scores (Goldhill & Sumner, 1998; Smith et al., 1999; Wallis et al., 1997). Research also concluded that some deaths may have been avoided with a better standard of ward care (Lawrence & Havill, 1999; Wallis et al., 1997). However, these studies are more than 10 years old and there have been many changes to acute care processes since then.

The first manuscript in this chapter is a review of contemporary research on post-ICU mortality. Many studies have examined this adverse event because iatrogenic and preventable mortality after ICU discharge are indicative of a deficiency in care quality (Duke et al., 2005). While many post-ICU deaths are expected, those which are preventable represent the greatest chance for improving patient outcomes. By identifying factors associated with or contributing to preventable post-ICU mortality, care processes can be modified to reduce the risk of this event in the future. In reviewing the literature on post-ICU adverse events, the first manuscript in this chapter highlights what is currently known about this clinical problem, as well as limitations of the research and gaps in current knowledge.

Factors associated with post-ICU mortality: a comprehensive review

REVIEW

Factors associated with in-hospital mortality following ICU discharge: a comprehensive review

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Critically ill patients are admitted to the Intensive Care Unit (ICU) to reduce morbidity and mortality associated with acute illness, trauma or surgical procedures. The objective of this review is to identify key factors associated with in-hospital mortality in adult patients discharged from the ICU. A search of CINAHL, MEDLINE, PubMed and Web of Knowledge databases was performed for the period 2006–2012. Key terms were used to identify relevant literature. Inclusion criteria were research studies examining in-hospital mortality in adult patients discharged from Intensive Care, peer-reviewed studies and those published in English. Data extraction and appraisal were performed. Twenty-two studies which examined in-hospital mortality following intensive care discharge and meeting the inclusion criteria were identified. Various methodological designs were used. Key factors associated with post-Intensive Care mortality were older age, illness acuity and time of discharge. Factors associated with post-ICU mortality have changed little over the past decade. The only modifiable factor in care processes is time of ICU discharge. Research needs to identify how best to articulate modifiable risk factors and deliver care to reduce the risk of preventable mortality in patients discharged from the ICU.

INTRODUCTION

Critically ill patients are admitted to the Intensive Care Unit (ICU) to reduce morbidity and mortality associated with acute illness, trauma or surgical procedures.¹ Up to a fifth of patients will die in the ICU.² The majority survive their ICU admission to be discharged to a step-down or ward environment. Some patients though will die soon after ICU discharge, and deaths such as these are predictable and cannot be avoided.^{3,4} However, other deaths occurring after ICU discharge are unexpected and may be preventable with better standards of care.^{5,6}

Seminal research^{7–9} has found that one out of every five patients who died on a ward after ICU discharge was expected to survive. These patients tended to be older, have longer ICU lengths of stay and higher illness acuity scores. Researchers^{9,10} concluded that some of these deaths may have been avoided with a better standard of ward care. These seminal studies though important are more than a decade old and many changes to acute care processes have occurred since then.

The introduction of ICU Liaison Nurses¹¹ and Medical Emergency Teams¹² in Australia and Critical Care Outreach Teams¹³ in the United Kingdom has influenced how post-ICU care is delivered on hospital wards today. In order to reduce the incidence of short-term mortality, more information on risk factors for and determinants of post-ICU mortality are needed.¹⁴ It is therefore timely to conduct further review of the literature to identify factors associated

with in-hospital mortality in post-ICU patients. Identifying these factors would allow the streamlining of care processes, thus reducing morbidity and mortality rates in this vulnerable patient population, as well as the associated healthcare costs.

Aim

The aim of this paper is to present a comprehensive review of current literature on in-hospital mortality in adult patients discharged from the ICU. The purpose of the review was to identify key factors associated with post-ICU mortality, rather than just describing causes of death such as malignant disease or respiratory failure.

METHODS

Search strategy

A systematic search was conducted of the electronic databases CINAHL, MEDLINE, PubMed and Web of Knowledge. A range of search terms and combinations was used: intensive OR critical care AND discharge OR transfer AND mortality OR death. The reference lists of retrieved studies were hand searched to locate further relevant studies not identified by the electronic search strategy. Inclusion and exclusion criteria were applied to aid in determining the final literature sample. Literature was included in the review if it was:

- Primary research (quantitative or qualitative) focusing on in-hospital mortality in adult patients discharged from the ICU
- Published in full text in a peer-reviewed journal, and
- Published between 2006 and 2012.

Studies on paediatric patients, cardiothoracic surgical patients and studies not reported in English were excluded. Studies on patients discharged from the ICU expected to die or made not for resuscitation were also excluded. A search for unpublished data was not conducted.

Data evaluation and synthesis

Once relevant studies were identified, data were extracted. Critical appraisal guidelines¹⁵ were used to critique the methodological quality of each study including design, sample size and data collection period. Research papers were read and re-read to identify aims, methods and findings. Other data extracted included ICU characteristics and study limitations.

RESULTS

Online searches identified 1566 publications relating to the review topic. When the inclusion criteria were applied to

Table 1. Studies examining post-ICU mortality

Author	Setting	Aim	Design	Sample	Key Findings
Utzolino <i>et al.</i> ¹⁶	20-bed surgical ICU in Germany	To assess if unplanned ICU discharge correlates with a worse outcome	Retrospective analysis	2558 ICU discharges during 1 year	2% of daytime ICU discharges and 3% of night time discharges died on the ward. Mortality rate increased by 4% in readmissions for each year of age ($p<0.05$; OR for death 1.04 for each year of age). Readmission correlates with a higher risk of death.
Singh <i>et al.</i> ¹⁷	20-bed Australian ICU	To assess effect of after-hours ICU discharge on in-hospital mortality	Observational cohort study	2300 patients admitted to ICU during 3-year period	34.7% of patients were discharged after hours; crude mortality of these patients was 13.7% (vs 10.1% in patients not discharged after hours). After-hours discharge was associated with a higher risk of in-hospital mortality (OR 1.38; $p<0.05$).
Braber & van Zanten ¹	12-bed medical-surgical ICU in the Netherlands	To study characteristics of patients dying in hospital after ICU discharge	Retrospective cohort study	405 ICU patients	10.3% of post-ICU patients died in hospital. Independent predictors of post-ICU death were: age (mean 73.9 years), number of co-morbidities (mean 1.05), ICU length of stay (mean 9.8 days), APACHE II score (mean 21).
Al-Subaie <i>et al.</i> ¹⁸	17 bed medical-surgical ICU in British university teaching hospital	To assess the value of CRP as a predictor of ICU readmission and post-ICU death	Prospective observational study	1185 ICU discharges during 12 month period	2.9% of post-ICU patients died unexpectedly. These patients were older (76 vs 59 yrs; $p<0.001$) and had a higher APACHE II score (21 vs 15; $p<0.001$).
Martinez <i>et al.</i> ¹⁹	26-bed medical-surgical ICU in 700-bed Spanish teaching hospital	To assess relationship between tracheostomy tube in situ at ICU discharge and hospital mortality	Prospective observational cohort study	118 patients tracheostomised in ICU	Ward mortality was 19% overall; 11% in decannulated patients and 26% with tracheostomy tube in situ. Three factors were significantly associated with ward mortality: lack of decannulation before ICU discharge (OR 0.14, 95% CI 0.03–0.83, $p=0.03$), body mass index $> 30 \text{ kg/m}^2$ (OR 5.81, $p=0.03$), tenacious sputum at ICU discharge (OR 7.27, $p=0.05$).
Chrusch <i>et al.</i> ²⁰	Single ICU in Canadian tertiary hospital	To determine whether a lack of ICU beds was leading to premature ICU discharge and subsequent death	Prospective cohort study	10,185 ICU admissions during 8-year period	5.5% of patients experienced an adverse event (readmission, death) within 7 days of ICU discharge. Adjusted risk factors for post-ICU death or readmission included: age > 35 years (OR 1.46), APACHE II score of 20–29 (OR 2.16), ICU length of stay 3–10 days (OR 1.72, 95% CI 1.35–2.18) and no ICU vacancy at the time of discharge (OR 1.16).
Bagshaw <i>et al.</i> ²¹	57 Australian and New Zealand ICUs	To assess rate, characteristics and outcomes of very old patients (> 80 yrs) admitted to ICU	Retrospective analysis of prospectively collected data	15,640 ICU admissions over 6-year period	Crude in-hospital mortality rate was higher for patients aged > 80 years (24% vs 13%, $p<0.001$). Factors associated with hospital mortality were: age > 80 years (OR 5.4), medical admission (OR 2.58, $p<0.001$), and ICU length of stay (per day) (OR 1.17, $p<0.001$).
Sakr <i>et al.</i> ²²	198 ICUs in 24 European countries	To investigate predictors of post-ICU mortality	Sub-analysis of data collected from larger study	3147 patients admitted to ICU	In-hospital mortality rate 4%; of these 20% died on first day after ICU discharge. Non-survivors were: older (70 years + 12.5 vs 59 + 18 years, $p<0.001$), had higher incidence of cancer (8.8% vs 1.5%, $p<0.001$) and cirrhosis (8.8% vs 2.7%, $p<0.001$), had greater SAPS II (45.5 + 14.7 vs 30.3 + 13, $p<0.001$) and SOFA scores (4.6 + 3.1 vs 2.5 + 2.1, $p<0.001$), and were more likely to be admitted for medical than surgical reasons (68% vs 48.6%, $p<0.001$).
Laupland <i>et al.</i> ²³	All ICUs in one Canadian health region.	To determine whether patients admitted to ICU on evenings or weekends have increased mortality rates.	Inception cohort design	20,466 ICU admissions	26% of patients were discharged on weekends; 41% at night and/or weekend. Post-ICU mortality rate 6%. The crude risk for post-ICU death was lowest in late morning and early afternoon and then increased gradually until midnight. Increased crude mortality rates were associated with discharge at night versus day time (12% vs 5%, $p<0.0001$).



REVIEW OF POST-ICU MORTALITY

Table 1. Studies examining post-ICU mortality (continued)					
Author	Setting	Aim	Design	Sample	Key Findings
Ho <i>et al.</i> ²⁴	22-bed ICU in Australian university hospital	To assess ability of clinical markers to predict ICU-discharge mortality	Prospective cohort study	603 consecutive ICU patients who survived their first admission	4.3% of post-ICU patients died in hospital; most deaths occurred within 2 weeks (mode 1 day, median 8.5 days). High CRP concentrations at ICU discharge were associated with in-hospital mortality (OR 1.09, $p=0.001$).
Fernandez <i>et al.</i> ²⁵	16-bed medical-surgical ICU	To determine the effect of ICU discharge with a tracheostomy on ward mortality	Retrospective cohort study	936 patients discharged from ICU	13.9% of patients were discharged with a tracheostomy; ward mortality was higher than those without a tracheostomy (26 vs 7%, $p<0.001$). Three factors were associated with ward mortality in multivariate analysis: age (OR 1.03, $p=0.009$), tracheostomy in situ (OR 2.2, $p=0.01$) and Sabadell score of 1 or higher (OR 4.6, $p=0.001$).
Campbell <i>et al.</i> ³	Single ICU in Scotland	To identify post-ICU patients at risk of death or readmission	Secondary analysis of clinical audit data	6208 admissions to ICU during 10-year period	11.2% of patients died in hospital after ICU discharge. Risk factors for post-ICU mortality included: increasing age (70 vs 59 years, OR 1.04, $p<0.001$), days in hospital before ICU admission (2 vs 1; OR 1.03, $p<0.001$), APACHE score (22 vs 17, OR 1.09, $p<0.001$), and CPR in 23 hours before ICU admission (OR 1.98, $p<0.001$).
Pilcher <i>et al.</i> ²⁶	ICUs in 40 Australian and New Zealand hospitals	To determine prevalence, trends and effect on patient outcomes of ICU discharge time	Retrospective analysis of data routinely recorded on ICU admission	76,690 ICU discharges	Post-ICU mortality rate 5.8%. After-hours discharges occurred in 18.2% of patients; mortality in these patients was higher than daytime discharges (8% vs 5.3%, $p<0.0001$). In multivariate analysis, factors associated with mortality were after-hours discharge (OR 1.42, $p<0.0001$) and emergency admission to ICU (OR 1.53, $p<0.001$).
Obel <i>et al.</i> ²⁷	Single ICU in Danish university hospital	To assess whether weekend ICU discharge is associated with mortality	Prospective, observational cohort study	783 patients admitted to ICU during 5-year period	Medical ICU patients discharged early in the weekends had increased mortality risk (adjusted OR 1.43).
Litton <i>et al.</i> ²⁸	22-bed multidisciplinary ICU of university hospital	To assess ability of clinical markers to predict in-hospital mortality post-ICU	Nested case-control study	1272 who survived their ICU admission	2.3% of ICU discharges died unexpectedly in hospital. CRP level at ICU discharge was associated with mortality.
Clec'h <i>et al.</i> ²⁹	12 French medical or surgical ICUs	To examine link between tracheostomy insertion in ICU and post-ICU mortality	Prospective, observational cohort study	177 patients who had a tracheostomy inserted whilst in ICU	Tracheostomy was associated with increased post-ICU mortality when left in situ (Model 1: OR 3.73, $p=0.008$; Model 2: OR 4.63, $p=0.003$).
Chen <i>et al.</i> ³⁰	Medical ICU in Taiwanese tertiary hospital	To examine the effects of severity of illness at ICU discharge on post-ICU mortality	Prospective observational study	203 patients discharged from ICU	In-hospital mortality 19%. Two independent risk factors for post-ICU mortality: discharge APACHE II score (OR 1.17, $p<0.0001$) and male gender (OR 3.24, $p=0.015$).
Tobin & Santamaria ³¹	Single ICU in Australian tertiary referral hospital	To examine ICU discharge patterns and impact of discharge time on mortality	Retrospective cohort study	10,903 patients discharged from ICU	In-hospital mortality 4.5%; 25% of deaths occurred within 3 days of discharge. Mortality after ICU discharge was increased by: higher APACHE II score, admission to ICU from ward or operating theatre, and discharge during afternoon and night shift.
Rellos <i>et al.</i> ³²	General ICU in Greek tertiary hospital in.	To compare outcomes of oldest ICU patients (> 90) with younger patients	Prospective cohort study	5505 consecutive ICU admissions	1.1% of patients were aged >90; in-hospital mortality was 40% (vs 8.9%). APACHE II score was independently associated with in-hospital mortality.
Priestap <i>et al.</i> ³³	31 Canadian hospitals	To determine impact of night time ICU discharge on post-ICU mortality	Multicentre retrospective observational cohort study	47,062 discharges from ICU to wards	10.1% of patients were discharged at night (9pm or later). OR of death for patients discharged at night was 1.35 ($p<0.05$). Mortality risk was increased 1.22 fold for night discharges ($p<0.05$).
Mayr <i>et al.</i> ³⁴	12-bed ICU in tertiary hospital in Austria	To evaluate causes of post-ICU in-hospital mortality.	Prospective cohort study	3700 ICU admissions	In-hospital post-ICU mortality was 4.3%; those patients had longer ICU length of stay. Most common causes of in-hospital post-ICU deaths were malignant tumour disease and chronic cardiovascular disease.
Alban <i>et al.</i> ³⁵	20-bed surgical ICU in tertiary hospital	To determine whether severity-adjusted outcomes are impacted by ICU readmission	Prospective observational study	10,840 patients admitted to ICU	Readmission rate 2.73%; these patients had higher APACHE II scores on day of discharge. ICU readmission significantly increased the risk of death beyond that predicted by APACHE II and SAPS scores.

the titles and abstracts, 126 were deemed relevant. Once inclusion and exclusion criteria were applied 22 studies were identified for review. Table 1 presents a summary of these. All reviewed studies used quantitative methods including prospective cohort and retrospective observational designs. The mean sample size was 10,040 with a range of 118 to 76,690 patients. Where reported, study findings are listed in Table 1 as odds ratios (ORs).

Study findings

Post-ICU mortality rates in 18 studies ranged between 2 and 12% of all patients (average 5.95%). Four studies reported higher rates. Two studies^{21,32} focused on patients aged over 80 years, reported mortality rates of 24 and 40%. In addition, a high mortality rate of 19% was reported in a small study¹⁹ (n=203) of patients discharged from the ICU with a tracheostomy, and in a study³⁰ conducted in a medical ICU, with non-surgical, non-cardiac and non-neurological patients.

Age

The patient's age was significantly associated with post-ICU mortality in nine studies.^{1,20–22,24,25,28,31,33} Age groups identified were age greater than 35 years, 70 years and 80 years.^{20–22} In three studies comparing survivors and non-survivors, patients who died following ICU discharge were older than survivors: 73 versus 60 years¹; 70 versus 58 years²⁵; and 65 versus 52 years.²⁴

Illness severity

Illness severity was significantly associated with post-ICU mortality in 11 studies.^{1,3,18,20,22,24,28,30–33} Scoring systems used were APACHE II, Simplified Acute Physiology Score (SAPS) and Sequential Organ Failure Assessment (SOFA). For each of these scoring systems, a higher score was associated with a greater risk of mortality.

Discharge time

Time of ICU discharge was significantly associated with post-ICU mortality in six studies.^{17,23,26,27,31,33} Higher mortality rates were associated with discharge from the ICU in the evenings and at night time/after hours. This involved ICU discharge between 6pm and 7am. Discharge from the ICU during the 'early weekend', Friday and Saturday, was associated with post-ICU mortality in one study.²⁷

Other factors

Other factors were found to be significantly associated with post-ICU mortality but only in single studies.^{25,28,31,33} These factors were: male gender, emergency ICU admission, admission from a general ward, mean white cell count, mean CRP concentration, requiring renal replacement therapy during ICU stay, mechanical ventilation greater than 96 hours, requiring parenteral nutrition or vasoactive drugs, being discharged from the ICU at a time of no vacancy, and body mass index greater than 30 kg/m².

DISCUSSION

Clinical outcomes research tends to focus on endpoints that are considered important for patients and society; survival is the primary endpoint.³⁶ A clinical outcome such as mortality is also easy to define and measure using empirical methods. Mortality following ICU discharge is a quality indicator and frequently an anticipated event.^{37,38} The sud-

den death of post-ICU patients who are expected to survive for example represents a waste of valuable healthcare resources³⁹ and a missed opportunity to save a life.

Safety and quality must be care priorities in patients discharged from the ICU. However, post-ICU patients often have complex care needs which may be difficult to provide in a ward environment,⁴⁰ resulting in poor outcomes.⁴¹ In part this may be because inexperienced nurses and doctors struggle to provide the necessary complex care.⁴² Up to a third of patients for example will experience an adverse event after ICU discharge.⁴³ Half of these events may be preventable with better standards of ward care.⁶

Despite recent changes in acute care processes such as the introduction of ICU Liaison Nurses and Critical Care Outreach Teams, factors associated with post-ICU mortality have changed little over time. In the time since seminal research^{9,10,39,44} was conducted, the need to better support ward patients with complex needs has been recognised.⁴¹ ICU Liaison Nurses and Critical Care Outreach teams have evolved in part, to help meet the needs of these challenging patients. A recent study⁴⁵ for example demonstrated the positive impact of ICU Liaison Nurses in preventing adverse events in post-ICU patients. Research⁴⁵ has also found that Outreach Teams can improve hospital mortality. However, none of the 22 studies in this review mentioned whether support roles such as Liaison Nurses and Outreach Teams existed in the study hospitals. Some researchers³ speculated that Outreach teams may influence the quality of care before ICU admission and thus post-ICU outcomes, but this was not an empirical finding.

Whilst this review has similar findings to seminal research,^{9,10,39,44} limited research focus has been given to potentially modifiable factors. One such factor is the time of ICU discharge. Research^{26,31} indicates that after hours ICU discharge is becoming more common. This may reflect an increasing demand for ICU beds or a lack of ward beds when an ICU patient is ready for discharge.⁴⁶ In one study³³ half of night time ICU discharges were preceded or followed by another admission, suggesting intense pressure for beds. As time of ICU discharge is the only modifiable factor identified which is associated with post-ICU mortality, this is key for future research and clinical care.

ICU discharge decision-making is often based on demand for ICU beds rather than patient readiness.⁴⁷ When faced with an urgent bed shortage, ICU staff are often forced to discharge the patient who is doing the best, even though he or she may not be doing particularly well.^{31,39} In one hospital,¹⁶ this was a frequent problem. A study⁴⁸ of 55 Swiss ICUs found marked heterogeneity in ICU discharge practices; less than a quarter of the responding ICUs used written discharge guidelines. This suggests an absence of evidence-based guidelines on ICU discharge.

The reviewed studies which demonstrated a relationship between after-hours discharge and mortality were not able to identify specific causes of mortality. However, numerous reasons were speculated^{17,23,26,27,31}: inconsistencies in care after hours, inferior medical care on the receiving ward, less surveillance on the ward, lower nurse:patient ratios, lower doctor:patient ratios, and less immediate access to experienced medical staff. Older research^{44,49,50} speculated similar reasons. One study⁴⁴ demonstrated lower mortality rates for ICU patients discharged to a high dependency unit compared with those discharged directly to a ward environment. Research^{8,39} also found that higher nursing dependence at



the time of ICU discharge is associated with a worse outcome. The factors speculated to be associated with after-hours ICU discharge and mortality may therefore be worth investigating.

A possible explanation for the similar findings of this review and seminal research is that research has not attempted to explore the influence of potentially modifiable factors such as organisational structure on post-ICU mortality. For example, research^{51,52} has demonstrated a relationship between patient outcomes and nurse:patient ratios and staff educational levels. A relationship has also been demonstrated⁵³ between patient mortality and the characteristics of the healthcare environment, such as staffing levels. The impact of factors such as these on post-ICU mortality needs exploration. A method of facilitating this is the use of an accident causation model.

Researchers and psychologists examining industrial errors have developed theoretical and conceptual models to help analyse error causation.⁵⁴ Conceptual frameworks such as these facilitate the examination of adverse events and enable outcomes to be linked to the existing body of knowledge.⁵⁵ Reason's accident causation model⁵⁶ for example proposes that within complex systems multiple layers or barriers exist to prevent accidents but these barriers contain weaknesses. Identifying these weaknesses is a step towards accident prevention.⁵⁷

Accident causation models such as Reason's⁵⁶ and Donabedian's structure/process/outcome model⁵⁸ promote the analysis of factors associated with accidents to help identify where remedial action should focus. Using these models allows factors associated with clinical adverse events to be categorised into either patient, clinician or system factors. Some researchers³ acknowledged they did not consider the impact of potentially relevant organisational factors such as ICU bed occupancy and level of ward care on post-ICU mortality. Others¹⁷ speculated that inadequate clinical handover or poor appraisal of patient needs may compromise the quality of ongoing care after ICU discharge; but these were not substantiated by research. Failing to identify the underlying causes of an adverse event does little to prevent the event from recurring. Future research on post-ICU adverse events may therefore benefit from the guidance of an accident causation model.

Practice implications

The findings of this review suggest that patients should not be discharged from the ICU after hours. If an older patient whose acute illness has not completely resolved is discharged after hours, their mortality risk is increased considerably. Whilst after hours ICU discharges should be avoided, resource limitations such as a shortage of ICU beds may prevent this. If a patient is discharged from the ICU after hours, staff on the receiving ward should be aware of the significant risk increase. Such patients may be best managed with the ongoing input of ICU staff and other support services such as ICU Liaison Nurses and Outreach Teams.

Limitations

This review has some limitations. A number of studies had methodological weaknesses such as a retrospective or single site design, small sample sizes and short data collection periods. There was a lack of homogeneity in the research methods used and patient characteristics. Some studies for example used prospective data collection methods whilst others

used retrospective methods. The research was conducted in different types of ICUs including medical and surgical, hence the differing patient characteristics. These differences prevented a full systematic review being conducted. Some studies though published since 2006, presented data that were over ten years old. Furthermore only English language publications were included in the review, limiting the generalisability of the findings to many countries.

CONCLUSIONS AND RECOMMENDATIONS

This review has identified key factors associated with in-hospital mortality following ICU discharge. Given the high costs associated with providing intensive care, preventable death must be avoided in patients expected to survive following ICU discharge. Patients at greatest risk of post-ICU mortality need to be targeted so that processes of care can be streamlined. Future research needs to identify modifiable factors within care process, to reduce the incidence of preventable in-hospital mortality following ICU discharge.

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Intensive care readmission

The second post-ICU adverse event to receive considerable research attention is Intensive Care readmission. This event is defined as a second admission to ICU during the same hospitalisation (Campbell et al., 2008). The first published study on this adverse event was conducted more than 30 years ago (Franklin et al., 1981). The study found that readmitted patients had an in-hospital mortality rate of 60%; nearly half were discharged from ICU prematurely; and recurrence of patients' original disease led to 50% of all readmissions (Franklin et al., 1981).

ICU readmissions have traditionally been used as a quality indicator of ICU care (Society of Critical Care Medicine, 1999). This is problematic given that these adverse events may reflect suboptimal care on the wards rather than care within ICU prior to discharge (Australian Council on Healthcare Standards, 2012). This highlights an inherent problem with the conventional definition of ICU readmission. By defining a readmission as a second admission during the same hospitalisation and then using readmissions as an ICU key performance indicator, ICU performance may be evaluated using factors independent of ICU care processes. Some professional bodies, therefore, only focus on readmissions occurring within 72 hours of ICU discharge as a clinical performance indicator (Australian Council on Healthcare Standards, 2009). This is an arbitrary measure that aims to identify deficiencies in patient management rather than complications or progression of the underlying disease process (Australian Council on Healthcare Standards, 2011).

Many studies have examined ICU readmissions since the first study was published 30 years ago, reflecting the contemporary problem this adverse event presents. The large number of studies is also indicative of the challenges researchers face in attempting to identify key causal factors in care processes contributing to readmissions. This may partly be attributed to the research methods used. Research using the same quantitative methods to examine ICU readmission has struggled to make recommendations for reducing the risk of this event. Most quantitative studies have found that readmissions are due to cardiorespiratory problems, but this is also the main reason for most primary ICU admissions.

A literature review published in 2006 examined 20 studies of ICU readmission (Elliott, 2006). The average readmission rate was 7.8%, and risk factors for

readmission included renal or gastrointestinal disease, longer ICU length of stay, and high respiratory rate, heart rate or oxygen requirements at the time of ICU discharge (Elliott, 2006). Patients readmitted to ICU also tended to be older (>70 years of age). Few of the reviewed studies provided insight into the specific factors contributing to readmissions and of those that did, no dominant themes emerged. A limitation of the reviewed studies is that most involved retrospective audits of medical records. This is a significant limitation, as documentation in medical records is often conducted retrospectively and therefore reliant on memory (Elliott, 2006).

As this published literature review was conducted seven years ago, the second manuscript contained in this chapter is a review of contemporary literature on ICU readmissions. The aim of the review was to identify contemporary factors associated with, or contributing to, this post-ICU adverse event. The review included studies published in English after 2005 and excluded those involving cardiac or paediatric patients.

Intensive care readmission: a contemporary review of the literature

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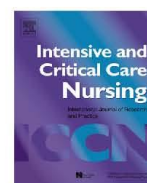
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REVIEW

Intensive care readmission: A contemporary review of the literature

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KEYWORDS

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Summary ICU readmissions are a commonly used quality measure but despite decades of research, these adverse events continue to occur. Of particular concern is that readmitted patients have much worse prognoses than those not readmitted. In recent years new clinical service roles have evolved to assist ward staff with the care of acutely ill patients, such as those discharged from ICU. Given the recent emergence of these service roles, a review of contemporary ICU readmission studies was warranted to determine their impact on this adverse event.

Reviewed studies indicated the incidence of readmissions and outcomes of these patients have changed little in recent years. Few studies mentioned whether clinical service roles existed to support ward staff caring for patients recently discharged from ICU. Future research needs to focus on identifying modifiable factors in care processes to reduce the incidence and outcomes of this adverse event and to determine how clinical service roles can best help prevent its occurrence.

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Introduction

Patients admitted to Intensive Care Units (ICU) are of the highest acuity, requiring management with life support technologies and aggressive interventions to sustain life and

progress towards a clinically stable condition (Watts et al., 2007). The demand for intensive care services is escalating worldwide and being driven by increasingly sophisticated technology, increasing numbers of older patients with comorbidities and increased consumer expectations (Williams et al., 2010a). Due to the costs associated with intensive care provision and the scarcity of these resources, in recent years significant attention has been given to ICU quality measures (de Vos et al., 2007; McMillan and Hyzy, 2007). These measures can be assessed in numerous ways including risk-adjusted outcomes, incident monitoring and access indicators (Hewson and Burrell, 2006).

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Implications for Clinical Practice

- Having survived a critical illness, many post-ICU patients are at risk of readmission to ICU.
- Older patients with co-morbidities are at greater risk of ICU readmission than others.
- The specific factors contributing to or associated with ICU readmission are not clear. Ward staff caring for post-ICU patients should monitor these patients closely to ensure progress towards desired clinical outcomes.

One of the more frequently cited ICU quality measures is readmission to ICU during the same hospitalisation. These events are a significant concern because they carry greater risk for adverse outcomes than other types of ICU admissions (Schorr, 2012). Furthermore as they are considered a marker of ICU and hospital care quality, ICU readmissions may be used for resource allocation or to compare performance between ICUs (Berenholtz et al., 2002; Halpern, 2011).

Two reviews of ICU readmission research were published in the last decade (Elliott, 2006; Rosenberg and Watts, 2000). The reviews found on average 7% of patients are readmitted to ICU and primarily for respiratory and cardiac reasons. Readmitted patients had poorer prognoses, were older and more acute on their first ICU admission than those not readmitted; they also had higher mortality rates than non-readmitted patients. Some of the reviewed studies suggested that abnormal vital signs at the time of ICU discharge may be predictive of readmission but it is unclear if ward staff act upon these. No clear causes or risk factors for readmission were identified in the two reviews and despite three decades of research, the factors leading to unplanned ICU readmission are still not clearly understood (Baker et al., 2009). This may be because risk factors for ICU readmission have not been well studied or are not reproducible (Zimmerman, 2008).

During the period in which the reviews were published, a number of clinical resources evolved to assist ward staff with the care of acutely challenging patients including those recently discharged from ICU. The new resources developed out of necessity as post-ICU patients are a high risk group for adverse events due to their complex care needs (Chaboyer et al., 2008). Ideally, ICU readmission is avoided by monitoring post-ICU discharge progress and promptly recognising when patients are unwell or in a deteriorating condition so as to permit appropriate interventions (Williams et al., 2010b).

The new clinical resources aim to achieve this and include ICU Liaison Nurses, Medical Emergency Teams and Critical Care Outreach Teams (Endacott and Chaboyer, 2006; Green and Edmonds, 2004; MERIT Study Investigators, 2005). A recent study found that ICU Liaison Nurses now exist in 27% of Australian hospitals which have an ICU and that these Nurses have a positive impact on patient outcomes (Athifa et al., 2011; Elliott et al., 2012; Endacott et al., 2010). There is also evidence of the positive impact of Medical Emergency and Critical Care Outreach Teams (Chen et al., 2009; Endacott et al., 2009).

Aim

Given the growing popularity of these new clinical support services and the impact they seem to have on patient

outcomes, a review of contemporary ICU readmission research is warranted. The aim of this review is to determine if the nature or characteristics of ICU readmissions have changed in recent years, in light of the new clinical support services. The specific questions addressed by the review are:

- I. What is the incidence of ICU readmission?
- II. What are the risk factors for ICU readmission?
- III. What are the characteristics and outcomes of patients readmitted to ICU?
- IV. Is there evidence in the literature of the new clinical support services influencing ICU readmissions?

Methods

A search was conducted of the electronic databases Medline, CINAHL, PubMed and Scopus for publications from 2006 onwards. Key search terms were: intensive or critical care; readmission; recidivism; and discharge. Inclusion criteria were research based publications on adult ICU readmission and published after 2005 in English language peer-reviewed journals. This date was chosen as the most recent review of ICU readmissions was published in 2006 and therefore included studies prior to this date (Elliott, 2006).

Abstracts from intensive care conferences were also searched via professional bodies' websites and publications. These included the Australian College of Critical Care Nurses, British Association of Critical Care Nurses and the Society of Critical Care Medicine. Some of these sites contained links to each organisation's professional journal; these were also searched for relevant publications. Reference lists of identified studies were also reviewed to locate further studies not found by the search strategy. Exclusion criteria were studies on paediatric or cardiac ICU patients and those not published in English.

Literature identified by the search strategy was appraised using guidelines for determining methodological quality; this helped to establish whether to include identified studies in the review (Greenhalgh, 2010; see Table 1). Studies were assessed by a single reviewer. Studies chosen for inclusion were then ranked using national guidelines, to rate their evidence level (NHMRC, 2008; see Table 2).

Findings

After inclusion and exclusion criteria were applied, thirty-five studies were identified for review. The research methods used included case control studies and prospective observational studies. The most popular method was retrospective review of prospectively collected clinical data. Sample sizes ranged from 205 to 263,082 patients (see Table 3). Varying definitions of ICU readmission were used

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Table 1 Summary of appraisal guidelines.

Quantitative studies	Qualitative studies
How were subjects recruited?	Was a qualitative approach appropriate for the research question?
Was the study design appropriate to the field of research addressed (e.g. prognosis, causation)?	How were the setting and subjects selected?
Were the inclusion and exclusion criteria appropriate?	What data collection methods were used? Are these described in enough detail?
How were outcomes defined and measured?	What data analysis methods were used?
For a cohort or case-control study, were the controls appropriate?	How was rigour of the research findings established?
Have <i>p</i> values been calculated and interpreted appropriately?	Were the conclusions justified by the findings?
Was the study large enough to make the findings credible?	Has the researcher's perspective been taken into account?
	Are the study findings transferable to other clinical settings?

(see Table 4). A narrative analysis was conducted as heterogeneity of research methods and study samples meant that neither systematic review nor meta-analysis were possible.

Readmission rate

The ICU readmission rate ranged from 1.3% to 13.7% of discharged patients. The lowest rate was in a nested case-control study of 1405 admissions to a 22 bed Australian ICU during a 12-month period (Ho et al., 2006). The purpose of the study was to assess the ability of potential clinical predictors to predict ICU readmission. The highest readmission rate was in a prospective observational cohort study of 546 patients discharged from a general medical-surgical ICU in an 801 bed hospital in Brazil (de Araujo et al., 2013).

Readmission risk factors

Eleven studies identified statistically significant risk factors for ICU readmission. These factors were: patient location

before ICU admission; acute physiology score at the time of ICU admission; APACHE II score, older age; co-morbidities; ICU length of stay; physiologic abnormalities at the time of ICU discharge or on the ward; ICU discharge at night or after hours; discharge to another critical care area or hospital; shock index (heart rate/systolic blood pressure), respiratory rate and Glasgow Coma Score; and higher Nursing Activity Score at the time of discharge.

Ten studies reported the disease processes of readmitted patients. The most common involved the cardiac and respiratory systems such as respiratory failure, arrhythmias and myocardial ischaemia. Sepsis was the next most common disease process resulting in ICU readmission. Some disease processes were associated with a statistically greater risk of ICU readmission. These included: ischaemic heart disease, cerebrovascular disease, pneumonia, sepsis, heart failure, chronic liver disease, diabetes mellitus and chronic obstructive pulmonary disease (COPD), viral hepatitis, subarachnoid haemorrhage, non-operative gastrointestinal disorders, haematological conditions, cervical spine injury and hepatic failure.

Table 2 NHMRC Evidence Hierarchy.

Level	Intervention
I	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudorandomized controlled trial
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> • non-randomised experimental trial • cohort study • case-control study • interrupted time series with a control group
III-	A comparative study without concurrent controls: <ul style="list-style-type: none"> • historical control study • two or more single arm study interrupted time series without a parallel control group
IV	Case series with either post-test or pre-test/post-test outcomes

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Table 3 ICU readmission studies.

Study	Design	Sample	Evidence level	Key findings
de Araujo et al. (2013). Brazil	Prospective observational cohort study	977 patients discharged from two ICUs	III-2	Readmission rate 13.7% in medical-surgical ICU; 9.3% in trauma/neurosurgical ICU. Readmissions resulted in increased morbidity, length of stay and total costs.
Kramer et al. (2013). North America	Retrospective cohort study	263,082 admissions to 105 ICUs in 46 hospitals	III-2	Readmission rate 6.3%. Readmitted patients had higher post-discharge mortality (21.3% vs 3.6%), longer initial ICU lengths of stay (4.9 vs 3.4 days) and longer hospital stays (13.3 vs 4.5 days); $p < .001$.
Kramer et al. (2012). North America	Retrospective cohort study	229,375 admissions to 97 ICUs in 35 hospitals	III-2	Readmission rate 6.1%. Risk factors included location before ICU admission, age, co-morbidities, diagnosis, ICU length of stay, physiologic abnormalities at time of discharge and discharge to a step-down unit ($p < .001$).
Ouanes et al. (2012). France	Retrospective analysis of prospective database	3462 patients admitted to four ICUs	Not ranked	Post-ICU mortality or readmission rate 7%. Independent risk factors for post-ICU mortality or readmission: age ($p < .002$), SAPS II score at ICU admission ($p < .0001$), use of a central venous catheter ($p < 0.0001$) and discharge at night ($p < .002$).
Laia et al. (2012). Taiwan	Retrospective analysis of prospective database	192,201 patients admitted to ICU	Not ranked	Readmission rate 13%. Risk factors for readmission ($p \leq .05$): age > 39 years, female gender, ischaemic heart disease, cerebrovascular disease, pneumonia, sepsis, heart failure, chronic liver disease, diabetes mellitus and COPD.
Brown et al. (2012). North America	Retrospective cohort study	196,202 patients admitted to 156 ICUs	III-2	2% of readmissions occurred within 48 hours of discharge; 3.7% within 120 hours. Median time to readmission was 3 days. Medical patients in tertiary hospitals had higher odds of 48 hour (OR 1.51; 95% CI 1.12–2.02) and 120 (OR 1.63; 95% CI 1.24–2.16) hour readmission than patients in community hospitals.

Study	Design	Sample	Evidence level	Key findings
Timmers et al. (2012). Netherlands	Prospective observational cohort study	1682 patients discharged from a surgical ICU	III-2	Readmission rate 8%; 20% were readmitted within 48 hours. Main causes of readmission were respiratory failure (48%), cardiac problems (16%) and sepsis (14%). Readmitted patients were older, mostly had vascular disease (39%) or gastrointestinal surgery (25%), had higher initial illness acuity scores ($p = .003$; $p = .007$) and more co-morbidities ($p = .005$). Long-term mortality rate was significantly higher in readmitted patients.
Abu-Awwad and Buran (2012). North America	Retrospective analysis	6194 patients discharged from medical ICU	Not ranked	3.6% of patients were readmitted or died within 72 hours of ICU discharge. Risk factors predicting readmission included heart rate/blood pressure index, temperature, respiratory rate, GCS, haemoglobin and lymphocyte count ($p < .015$ for all factors).
da Silva et al. (2011). Brazil	Longitudinal prospective study	600 patients admitted to ICU in 4 hospitals	III-2	Readmission rate 9.1%. Antecedents related to infectious or parasitic diseases increased the risk of readmission (OR 2.97; 95% CI 1.23–7.22, $p = .016$). Higher Nursing Activity Score at discharge decreased the readmission risk (OR 0.98; 95% CI 0.95–1.0, $p = .036$).
Renton et al. (2011). Australia	Retrospective longitudinal study	247,103 patients discharged from 38 ICUs	III-3	Readmission rate 5.5%. Factors increasing risk of readmission: admission source other than elective surgery; any chronic health issue; tertiary hospital ICU and discharge after hours (OR > 1.05; $p < .001$). Diagnoses associated with a greater risk of readmission: subarachnoid haemorrhage, non-operative gastrointestinal disorders, haematological conditions, isolated cervical spine injury and hepatic failure (OR > 2; $p < .001$). In-hospital mortality rate was nearly 5 times greater for readmitted patients (OR 5.4; 95% CI 5.1–5.7, $p < .001$).

Table 3 (Continued)

Study	Design	Sample	Evidence level	Key findings
Lone (2011). Scotland	Retrospective cohort study	8413 patients admitted to ICU	III-2	Readmission rate 9.6%. Independent predictors of readmission: out of hours discharge ($p < .007$); one or more co-morbidities ($< .002$); and discharge to another critical care area or hospital ($p < .001$).
Elliott et al. (2011). Australia	Qualitative analysis of clinicians' opinions.	21 clinical nurses, educators and managers	Not ranked	Key factors associated with readmission: premature ICU discharge, delayed medical care on the ward, heavy nursing workloads on the wards, lack of adequately qualified staff and clinically challenging patients.
Utzolino et al. (2010). Germany	Retrospective analysis	2558 patients discharged from a surgical ICU	Not ranked	Readmission rate 8.3% in elective discharges and 25.1% in unplanned discharges ($p < .001$). Half of all readmissions were for surgical complications. Half of all readmissions had initially been discharged electively. Hospital mortality rate was 5.8 times higher for readmitted patients ($p < .001$). Readmission for respiratory failure accounted for most of the mortality.
Miller et al. (2010). England.	Retrospective audit	2127 admissions to a medical-surgical ICU	Not ranked	Readmission rate 5.7%. 10.4% of readmitted patients were discharged out of hours. 28.7% of readmissions occurred between days 2 and 7.
Makris et al. (2010). Australia	Retrospective case-control study	205 patients readmitted to a medical-surgical ICU within 72 hours	III-2	Readmission rate 3.1%. Readmitted patients had significantly higher overall mortality (OR 4.7, 95% CI 2.1–10.7). Independent risk factors for readmission: chronic respiratory disease (OR 3.7, 95% CI 1.2–12, $p = .029$), pre-existing anxiety/depression (OR 3.3, 95% CI 1.7–6.6, $p < .001$), immobility (OR 2.3, 95% CI, 1.4–3.6, $p = 0.001$), enteral nutrition (OR 2.0, 95% CI 1.0–4.0, $p = 0.041$) and non-weekend ICU discharge (OR 1.9, 95% CI 1.1–3.5, $p = 0.029$). Physiological derangement on the ward strongly predicted readmission (OR 26, 95% CI 8.0–81, $p < 0.001$), though only 20% of patients meeting MET criteria had a MET call made.

Table 3 (Continued)

Study	Design	Sample	Evidence level	Key findings
Frost et al. (2010). Australia.	Inception cohort study	14,952 patients discharged from a single ICU	III-2	Readmission rate 6.6%. Readmitted patients were more likely to have an ICU stay of 7 days or more odds ratio (OR 2.2, 95% CI, 1.85–2.56, $p < .001$), been non-electively admitted initially (OR 1.7, 95% CI, 1.44–2.08, $p < .01$) and have acute renal failure (OR 1.6, 95% CI 0.97–2.47, $p < .001$). Patients initially admitted to ICU from general wards, the emergency department or other hospitals had a higher risk of readmission. 1.5% of patients were readmitted within 3 days.
Lee et al. (2009). South Korea	Prospective observational study	25,717 admissions to 8 ICUs	III-3	Respiratory and cardiovascular problems were most common reason for readmission. The risk of readmission increased when the APACHE II score at the time of discharge exceeded 8.5 (OR 1.16, CI 1.03–1.30, $p < .013$). A 1 point increase in the score was associated with a 21% increased risk of readmission (OR 1.21, 95% CI 1.108–1.325, $p < .05$)
Butler et al. (2009). North America	Retrospective cohort study	6511 patients discharged from ICU	III-2	Readmission rate 6%. Readmitted patients had higher APACHE II and SAPS II scores (16 vs 14; $p < 0.001$). Patients with gastrointestinal disorders were most likely to be readmitted, followed for gastrointestinal surgery for neoplasms and congestive cardiac failure.
Japiassul et al. (2009). Brazil	Prospective observational study	577 patients admitted to a mixed ICU	III-3	Readmission rate 10.7%. Average time to readmission was 9 days. Readmitted patients: tended to be older (75 vs 67 years; $p < .01$); were more likely to be admitted with respiratory insufficiency or sepsis (33 vs 13%, $p < .01$); admitted for medical reasons (49 vs 32%, $p < .05$); have first ICU stay longer than 3 days (35 vs 23%, $p < .01$) and have higher SAPS II scores (27 vs 23, $p < .01$). Older age, acute physiology score and admission for respiratory problems or sepsis were independently associated with readmission.

Table 3 (Continued)

Study	Design	Sample	Evidence level	Key findings
Ho et al. (2009). Australia	Linked data cohort study	16,926 admissions to a single ICU	III-2	Readmission rate 3.9%. Readmitted patients were older, were more likely to be originally admitted from the ward or operating theatre, had higher acute physiology scores and more co-morbidities. Early readmissions (≤ 72 hours) were associated with an increased risk of hospital mortality (OR 1.68, 95% CI 1.18–2.39, $p = .004$).
Chrusch et al. (2009). Canada	Prospective cohort study	8693 admissions to 1 medical and 1 surgical ICU	III-2	Readmission rate 5.3%. There was a positive correlation between ICU readmission and average ICU occupancy. Significant risk factors for readmission or post-ICU death: age > 35 years (OR 1.46, CI 1.02–2.07, $p < .05$), respiratory diagnosis (OR 1.73, CI 1.11–2.68, $p < .05$), sepsis (OR 1.66, CI 1.08–2.55, $p < .05$), gastroenterology diagnosis (OR 2.55, CI 1.54–4.25, $p < .05$), thoracic surgery (OR 2.79, CI 1.64–4.73, $p < .05$), neurosurgery (OR 1.95, CI 1.14–3.33, $p < .05$), APACHE II score 10–19 (OR 1.5, CI 1.0–2.24, $p < .05$), ICU length of stay 3–10 days (OR 1.72, CI 1.35–2.18, $p < .05$) and ICU discharge at a time of no vacancy (OR 1.56, CI 1.05–2.31, $p < .05$).
Chan et al. (2009). Taiwan	Retrospective medical chart audit	945 discharges from 4 surgical ICUs	Not ranked	Readmission rate 11.6%. Readmitted patients were older, had a longer initial ICU stay (8.05 vs 5.22 days, $p < .001$) were sicker during their initial admission and had higher mortality rates (40% vs 3.6%, $p < .001$). Nearly half of the patients (46.4%) were readmitted with the same diagnosis. Respiratory disease was the most common diagnosis for patients readmitted with a new problem.
Baker et al. (2009). North America	Retrospective comparative analysis	3233 patients discharged from a neuroscience ICU	Not ranked	Readmission rate 3% (39% within 24 hours; 78% within 48 hours). The odds of a patient being readmitted within 72 hours were 2.5 times higher on days when ≥ 9 patients were admitted to ICU (OR 2.43, 95% CI 1.39–4.26, $p < .05$). The odds of readmission were nearly 5 times higher when ≥ 10 patients were admitted (OR 4.99, CI 2.45–10.17, $p < .05$).

Table 3 (Continued)

Study	Design	Sample	Evidence level	Key findings
Matsuoka et al. (2008). Japan	Retrospective cohort	1835 patients admitted to a single ICU	III-2	Readmission rate 7.7%. In 14.9% of patients, the reason for readmission was lung oedema or atelectasis.
Kaben et al. (2008). Germany	Logistic regression analysis	2852 patients discharged from a surgical ICU	Not ranked	Readmission rate 13.4%. Readmitted patients had higher SAPS II scores (37 vs 33, $p < .001$) on initial ICU admission, high in-hospital mortality rates (17.1% vs 2.9%, $p < .001$). Higher risk of readmission was associated with: age (OR 1.13; 95% CI 1.03–1.24; $p = .04$), maximum sequential organ failure score (OR 1.04 per point; 95% CI 1.01–1.08; $p = .04$) and C-reactive protein level on the day of discharge (OR 1.02; 95% CI 1.01–1.04; $p = .035$).
Gajic et al. (2008). North America	Prospective cohort study	1131 patients admitted to one medical and one medical-surgical ICU	III-2	Readmission rate 8.8%. Reasons for readmission included respiratory failure, haemorrhage, infection, arrhythmia and myocardial ischaemia. Predictors of readmission: ICU admission source (OR 2.256, 95% CI 1.437–3.540, $p < .01$), ICU length of stay (OR 1.404, 95% CI 1.098–1.795, $p < .01$) and requirement for complex pulmonary management (OR 2.149, 95% CI 1.010–4.576, $p < .05$).
Conlon et al. (2008). Ireland	Retrospective review of prospectively collected data	1061 patients discharged from a medical-surgical ICU	Not ranked	Readmission rate 7.4%. Common diagnoses leading to readmission were categorised as respiratory, cardiovascular and septic shock. The most common cause of readmission was respiratory infection.

Study	Design	Sample	Evidence level	Key findings
Campbell et al. (2008). Scotland	Secondary analysis of clinical audit data	475 patients discharged from a medical-surgical ICU	Not ranked	Readmitted patients were older 66.9 vs 61.7 yrs, $p < .005$), more likely to have been an emergency ICU admission (60% vs 31.7%, $p < .001$) and had higher APACHE II scores (14.4 vs 10.2, $p < .001$). Readmitted patients had double the incidence of death in ICU (19.2% vs 9.1%, $p = .005$). Readmission rate 8.8%.
Song et al. (2007). Korea	Retrospective review of prospectively collected data	1087 patients admitted post-operatively to ICU	Not ranked	Independent risk factors for readmission: surgical admitting specialty (OR 1.27, 95% CI 0.97–1.64, $p < .078$), APACHE II score (OR 1.05, CI 1.03–1.06, $p < .001$) and mean TISS (OR 1.04, CI 1.02–1.05, $p < .001$). Readmission rate 8.6%.
Pilcher et al. (2007). Australia	Retrospective analysis of prospectively collected data	76,690 patients discharged from multiple ICUs	Not ranked	Most common reason for readmission was pulmonary complications such as acute respiratory distress syndrome (60% of patients). Readmission was associated with a higher risk of in-hospital mortality. A third of patients died in ICU after readmission. Readmission rate 5.3%.
Klimasauskas and Kekstas (2007). Lithuania	Retrospective cohort study	13,343 patients admitted to 3 ICUs	III-2	Patients discharged after hours (>1800 hours) had a higher readmission (6.3% vs 5.1%, $p \leq .0001$) and mortality rates (8% vs 5.3%, $p \leq .0001$). Readmission rate 6.4%. Patients readmitted within 48 hours had higher mortality than those readmitted later (25.1% vs 20.1%, $p = .045$ and $p = .097$).

Table 3 (Continued)

Study	Design	Sample	Evidence level	Key findings
Boudesteyn et al. (2007). Netherlands	Retrospective case-control study	1393 patients admitted to a medical-surgical ICU	III-2	Readmission rate 1.8%. Most common reason for readmission (68%) was respiratory deterioration. 39% of readmitted patients died. In multivariate analysis, significant predictors of readmission were: age (OR 1.1, 95% CI 1.0–1.3, $p = .03$) ventilator time during first admission (OR 1.1, CI 1.0–1.1, $p = .03$). Readmitted patients had a significantly longer ventilation times (during both admissions) and total ICU length of stay. Readmission rate 1.3%.
Ho et al. (2006). Australia	Nested case-control study	1405 admissions to a single ICU	III-2	C-reactive protein concentration within 24 hours before ICU discharge was associated with a higher risk of readmission ($p < .0001$).
Frankel et al. (2006). North America	Retrospective analysis of prospectively collected routine clinical data	4956 patients admitted to a surgical ICU	Not ranked	Readmission rate 1.8%. Most common reason for readmission was respiratory problems: 46% of readmissions before, 51% during and 80% after implementation of accreditation council staffing guidelines.
Alban et al. (2006). North America	Prospective observational study	10,840 patients admitted to a surgical ICU	III-3	Readmission rate 2.7%. Readmitted patients had higher APACHE II scores on the day of original ICU discharge (15.7 vs 13.8, $p < .001$). Initial ICU length of stay was longer for readmitted patients (4.9 vs 3.2 days, $p < .001$). Readmission significantly increases the risk of mortality independent of the admission severity score.

OR = Odds Ratio; CI = Confidence Interval; APACHE = Acute Physiology and Chronic Health Evaluation; TISS = Therapeutic Intervention Scoring System; MET = Medical Emergency Team; SAPS = Simplified Acute Physiology Score.

Table 4 Definitions of ICU readmission.

Definition	Citing studies	
Returning to ICU during the same hospitalisation	de Araujo et al. (2013) Ouanes et al. (2012) da Silva et al. (2011) Renton et al. (2011) Miller et al. (2010) Frost et al. (2010) Butler et al. (2009) Ho et al. (2009)	Chan et al. (2009) Kaben et al. (2008) Conlon et al. (2008) Campbell et al. (2008) Pilcher et al. (2007) Ho et al. (2006) Alban et al. (2006)
Returning to the same or different ICU after discharge to an area that provided a lower level of care during the same hospitalisation	Kramer et al. (2012, 2013)	
Returning to the same ICU during a single hospitalisation	Brown et al. (2012) Lone (2011)	
More than one admission to ICU during a 12 month period	Laia et al. (2012)	
A return to ICU within 48 hours	Boudesteijn et al. (2007)	
A return to ICU within 72 hours	Makris et al. (2010) Baker et al. (2009)	
A return to ICU within 7 days	Chrusch et al. (2009) Gajic et al., 2008	
A return to ICU within 30 days	Timmers et al. (2012) Matsuoka et al. (2008)	
Returning to ICU during the same hospitalisation or within 3 months of ICU discharge	Japiassul et al. (2009)	
None provided	Abu-Awwad and Buran (2012) Elliott et al. (2011) Utzolino et al. (2010) Lee et al. (2009)	Song et al. (2007) Klimasauskas and Kekstas (2007) Frankel et al. (2006)

Patient characteristics

Many studies described the characteristics of patients readmitted to ICU. Compared with those who were not readmitted, readmitted patients: tended to be older; had more co-morbidities; had more non-surgical diagnoses; had undergone emergency instead of elective surgery; had higher illness severity scores (e.g. APACHE); and had longer initial ICU lengths of stay. In one study of 977 patients, those readmitted had lower Glasgow Coma Scores on the day of ICU discharge than those not readmitted (de Araujo et al., 2013).

Mortality

Five studies reported readmitted patients have much higher mortality rates than those not readmitted. In two studies for example, the in-hospital mortality rate was five times greater for readmitted than non-readmitted patients (Renton et al., 2011; Utzolino et al., 2010). One of these

was a retrospective longitudinal study of 247,103 patients discharged alive from 30 Australian ICUs. Similarly, up to a third of readmitted patients died in ICU in a Korean study of post-operative ICU patients (Song et al., 2007).

The highest reported mortality rate for readmitted patients was 41.9% (de Araujo et al., 2013). This was a prospective observational cohort study based on data from a medical-surgical ICU. Of the patients who survived their readmission and were discharged to a ward, another 21% died (de Araujo et al., 2013). The causes of death of readmitted patients were not reported in most reviewed studies.

Discussion

This literature review included studies on ICU readmission published after 2005. The aim was to determine if the nature or characteristics of ICU readmissions have changed in recent years, particularly in light of new clinical support services such as Liaison Nurses. Thirty-five studies were

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identified for review, suggesting that ICU readmissions continue to be a substantial clinical problem. This is noteworthy as ICU beds are a significant cost driver for tertiary hospitals (Williams et al., 2010a).

Compared with studies published before 2006, the review found the average ICU readmission rate has changed little in recent years. This is not surprising, as a widely cited study conducted in 10 hospitals in North America found that adverse events such as patient harm continue to occur, despite being highlighted as an acute clinical problem more than a decade ago (Kohn et al., 2000; Landrigan et al., 2010). This may simply be because there are few known effective patient safety interventions or that the gold standard instrument for measuring patient safety problems is too blunt to detect changes with time (Shojania and Thomas, 2013).

There are a number of possible reasons the readmission rate remains unchanged. Firstly the key factors associated with ICU readmission may not be modifiable or amenable to better standards of care. The reviewed studies found for example that readmitted patients tend to be older than those not readmitted. With the ageing process comes an increased incidence of co-morbidities and functional impairment (Mitniski et al., 2007; Song et al., 2007). Elderly patients are therefore less able to meet the physiological demands of critical illness (Vosylius et al., 2005). As age is not a modifiable factor in care processes, there will always be a risk of older post-ICU patients needing further ICU care, thus sustaining the readmission rate.

A second possible reason for the lack of recent change in the readmission rate is that the research methods used may not have been sensitive enough to identify key contributing factors (Zimmerman, 2008). Many of the reviewed studies involved retrospectively collected data and thus represent a weaker form of evidence. There are inherent problems with using retrospectively collected data. For example key data may not have been collected and thus would not appear in research analyses. Alternate methods of data collection and analysis may need to be considered in future research on ICU readmission.

A further reason the readmission rate remains unchanged is the heterogeneity of ICUs in which research was conducted. Local organisational factors which influence care processes may be a significant contributor to ICU readmissions and these factors may differ between hospitals (Maia et al., 2012). For example, a study of 55 ICUs in Switzerland found marked heterogeneity in ICU discharge processes (Heidegger et al., 2005). A recent review also found that only a small number of ICUs used written patient discharge guidelines, a crucial part of the discharge process (Lin et al., 2009).

Factors associated with the transfer of a patient from ICU include limited resources within the health care system, ICU and ward bed availability, ward nursing practices, conflicting objectives of clinical staff and the need for follow-up services (Chaboyer et al., 2012; James et al., 2013; Lin et al., 2013; Wu and Coyer, 2007). Faced with the pressure for an ICU bed, staff may choose to discharge the least acute ICU patient to free a bed for a more acute patient (Chalfin et al., 2007; Chan et al., 2012). The habit of discharging ICU patients to the ward quicker and sicker though is not new (Chaboyer et al., 2002). The increased

stress and workload ward staff experience when caring for these complex patients have therefore been described (Whittaker and Ball, 2000).

Post-ICU patients are at particular risk for adverse events because of the severity of their illness and complexity of care required (Williams et al., 2010c). Discharging patients from ICU before they are ready further increases the risk of readmission because wards may not be resourced to provide the higher level of care post-ICU patients still require. The need for ward staff to develop the unique skills needed to care for post-ICU patients has been previously highlighted as an important strategy to help minimise the readmission rate (Russell, 1999). Involving ICU and ward staff in the ICU discharge process may help improve patient outcomes and avoid adverse events such as readmission (Chaboyer et al., 2012; Perren et al., 2008).

The time of ICU discharge has also been found to affect some patients' outcomes. Research has demonstrated that being discharged from ICU after hours increases the risk of readmission and post-ICU mortality (Gopal et al., 2010; Pilcher et al., 2007). Key reasons for this may include lower staffing levels on the wards at night time combined with inadequate clinical handover or poor appraisal of patient needs (Obel et al., 2007; Singh et al., 2010).

Whilst some of the reviewed studies demonstrated a link between after hours discharge and ICU readmission, it was not a common finding. Again this may reflect limitations of the research methods used, rather than this not being the case in clinical practice. It could also be that clinicians today are more aware of the risks associated with the timing of ICU discharge and therefore try to avoid certain discharge times.

The definition of an ICU readmission may also influence data collection and any conclusions reached. Most studies defined readmission as a return to ICU during the same hospitalisation, although six other definitions were also used. The limitations of this popular definition have been highlighted previously (Elliott, 2012). The most significant is that readmissions occurring many days or weeks after first ICU discharge may be due to care processes on the ward unrelated to ICU care or the discharge process. Four studies overcame this limitation by focussing only on readmissions within 72 hours or seven days of discharge. These studies' findings may be the most important for making recommendations about how to modify ICU care to avoid future readmissions.

There is also the challenge of distinguishing between risks and causes of ICU readmission. Most patients are admitted to ICU because of the need for respiratory and/or cardiovascular support. Regardless of whether a patient is admitted two, three or more times to ICU, the need for respiratory or cardiovascular support is the main reason for the admission. Stating this as the cause or reason for readmission fails to identify the actual factors contributing to this adverse event.

Isolating the root causes of ICU readmissions is therefore extremely important for improving future patient outcomes. Stating that a patient was readmitted because of respiratory failure for example does not highlight the true cause of the respiratory failure or the readmission. The respiratory failure for example may have developed because the patient was discharged from ICU prematurely, because of discontinuity of care between ICU and the ward, or because of

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inexperienced ward staff not having the knowledge and skills needed to provide essential care. Important questions to ask about readmitted patients therefore include, was there adequate resolution of the primary health problem at the time of discharge or an underestimation of the risk of deterioration after ICU discharge (Russell, 2012). Asking these questions may be a starting point in isolating the root causes of readmissions.

This review found the mortality rates of readmitted patients have also changed little over time compared with previous research. The factors associated with post-ICU mortality have also changed little (Elliott et al., 2013). Given that readmitted patients tend to be older and sicker on first admission, as evidenced by acute physiology scores, it is not surprising contemporary research has found little change in these mortality rates.

A recent meta-analysis demonstrated a relationship between increasing ICU severity of illness scores and the risk of ICU readmission (Frost et al., 2009). This would seem an important point and relationship to consider when caring for these patients. Post-ICU patients who had higher severity of illness scores may therefore be the cohort to benefit the most from the input of clinical support services such as Liaison Nurses and Critical Care Outreach Teams. This is an area requiring further research.

As few studies commented on whether the study hospitals utilised ICU Liaison Nurses, Medical Emergency or Critical Care Outreach Teams, a link between these clinical services and ICU readmissions cannot be established in this review. However, this does not mean these new services do not improve patient outcomes. ICU Liaison Nurses for example have been shown to have a role in preventing major adverse events such as unexpected death, and promoting more efficient ICU discharge such as reducing ICU discharge delay (Chaboyer et al., 2006; Elliott et al., 2008; Endacott et al., 2010). Critical Care Outreach Teams have been demonstrated to decrease the proportion of patients admitted to ICU who received cardiopulmonary resuscitation prior to admission (Harrison et al., 2004). Medical Emergency Teams have been associated with an independent reduction in hospital mortality (Tobin and Santamaria, 2012).

A methodological challenge in trying to establish a relationship between these services and ICU readmissions is that readmission may not be sensitive enough or an appropriate outcome measure to use for service evaluation. It may also be that data currently collected on readmitted patients are not sensitive enough. This may be why some studies were unable to demonstrate a positive impact of ICU Liaison Nurses or Critical Care Outreach Teams (Williams et al., 2010b). The complexities in evaluating the efficacy of Outreach Teams have been noted by others (Esmonde et al., 2006; McGaughey et al., 2007). Alternate data may therefore need to be collected or other data collection methods used.

Recently there has been a call for critical care professional groups to proactively address issues such as ICU discharge processes, enhanced ward coverage of patients at increased risk of ICU readmission and increased use of Medical Emergency Teams (Russell, 2012). Whilst it is likely new clinical services such as Critical Care Outreach Teams and ICU Liaison Nurses positively influence the care of post-ICU

patients and their outcomes, more research using appropriate quality measures is needed to determine this.

Recognising and managing patients at high risk of ICU readmission is important for maximising patient outcomes and minimising ICU admission costs (Fialho et al., 2012). This emphasises a key role for clinical support services such as Liaison Nurses. Contemporary research examining ICU readmissions though has not investigated the impact of these services. Research designs such as prospective multi-centre follow-up studies are needed to determine the impact of these services on ICU readmissions.

Limitations

This literature review has a number of limitations. Whilst it reviewed contemporary research on ICU readmission, some of the studies used data that were collected prior to 2005. For example, a study published in 2009 used data collected before the year 2000 (Chrusch et al., 2009). As clinical support services such as ICU Liaison Nurses are relatively new, it is possible they did not exist in some hospitals during the data collection periods.

A further limitation is the validity of comparing studies involving heterogenous populations and those involving single and multiple sites. Whilst the review only included studies on adult patients discharged from non-cardiac ICUs, criteria for admission, discharge and readmission likely varied dramatically between ICUs and between countries (Russell, 2012). Although it is important to apply inclusion and exclusion criteria in a review, such criteria are not able to take into account differing clinical practices such as these.

Finally, heterogeneity of reviewed studies prevented a systematic review or meta-analysis being conducted. Hence most of the studies represent weaker forms of clinical evidence as indicated by the NHMRC criteria. It should be noted though that criteria for evaluating evidence, such as those proposed by the NHMRC, are often biased in favour of quantitative methods and in particular, randomised controlled trials. Studies using qualitative methods receive no ranking. The failure of some of the reviewed studies to be ranked as higher levels of evidence (or to receive any ranking) is also very much due to the nature of the research problem being investigated and that an intervention was not being trialled. All the reviewed studies instead focussed on a clinical outcome.

Conclusion

This review highlighted that despite three decades of research on ICU readmissions and the emergence of new clinical service roles to improve acute patients' outcomes, the readmission rate and outcomes of readmitted patients have changed little over time. Due to limitations of published studies it has not been possible to demonstrate if the new service roles, as important clinical resources, make a difference to ICU readmissions.

Future research needs to focus on identifying modifiable factors in care processes to reduce the incidence and outcomes of this chronic clinical problem. Given the administrative and patient care frustrations associated with ICU

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readmissions, clinicians are faced with finding a solution to decrease or prevent these adverse events (Schorr, 2012). Decades of research exist on ICU readmissions but a contemporary solution remains elusive.

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Studies on other post-ICU adverse events

There are few published studies which have examined post-ICU adverse events other than readmission and mortality. These events have received the most research attention. An extensive search of the literature identified only two studies that aimed to examine other post-ICU adverse events (Chaboyer et al., 2008; McLaughlin et al., 2007). These studies used the globally accepted definition an adverse event: unintentional injury or harm to a patient that arises from the health care provided (Wilson et al., 1995). Both studies examined adverse events occurring within 72 hours of ICU discharge and did so via chart review. The time period of 72 hours was chosen because events occurring within this period are recognised as being linked to care within ICU (Australian Council on Healthcare Standards, 2007).

One of these studies was conducted in a 580 bed Australian hospital with 12 ICU beds and no high-dependency unit (Chaboyer et al., 2008). The study period was eight months and included 507 patients discharged from ICU. Two experienced ICU nurses used an internationally accepted chart audit protocol to review the medical records of patients discharged from ICU; these auditors were looking for documented evidence of adverse events. A total of 147 adverse events were identified, of which 11% were considered major (occurring in a third of the sample). The most common events were nosocomial infection or sepsis, and other complications such as deep vein thrombosis, pulmonary oedema or myocardial infarction (Chaboyer et al., 2008).

Two statistically significant independent predictors of an adverse event were identified by this study: respiratory rate less than 10 breaths/minute or greater than or equal to 25 breaths/minute and heart rate greater than 110/min (Chaboyer et al., 2008). In univariate analysis, high nursing care requirements at the time of discharge was predictive of an adverse event (although not in multivariate analysis); this was recommended as an area for further research. A limitation of this study was that because data were collected retrospectively, the influence of staffing levels and skill mix at the time of the event was unable to be examined. Furthermore, despite being a common research method, retrospective chart review is not ranked as a form of evidence for causation (NHMRC, 2008).

The second study examining post-ICU adverse events was conducted in a 708 bed Australian hospital with a 22 bed general ICU (McLaughlin et al., 2007). All patients discharged from ICU to the wards during a 12-week period were included (n=157). Patients' medical records were reviewed within 24 hours of ICU discharge and then every 24 hours up to 72 hours after discharge. Identification of adverse events was guided by a list of predefined vital signs and criteria for calling the Medical Emergency Team (e.g., pulse less than 40 per minute). A consensus panel then rated the preventability of each event.

Seventeen (10%) ICU discharges were associated with an adverse event; 52% of these were deemed probably preventable and 12% definitely preventable. Patients experiencing an adverse event were older (mean age 66 years). They also had higher Acute Physiology and Chronic Health Evaluation scores during their first 24 hours in ICU. These patients were mainly admitted to ICU with gastrointestinal, neurological or respiratory conditions, or with renal, trauma and septic conditions. Most of the adverse events in this study occurred in patients admitted to ICU from the operating theatre or discharged from ICU in the evening or night. Nearly half of the adverse events were related to fluid management (i.e., inadequate hydration or fluid overload).

One of these two key studies found an inappropriate level of care and attention on the wards, discontinuities of care, and care delivery interrupted by transfer to the ward (though inappropriate care was not defined; McLaughlin et al., 2007). Some patients had not had their vital signs recorded on admission to the ward; infrequent measuring of vital signs was also a common finding. Other patients had signs of deterioration documented but not acted upon. It was concluded that a review of support systems and processes is needed for patients discharged from ICU. Limitations of the study were that it was conducted at a single site and the study period was only 12 weeks. The study also relied upon documentation in patients' medical records (not ranked as a level of evidence).

Chapter summary

This chapter has provided a contemporary review of research focused on post-ICU adverse events. The chapter highlighted the adverse events which have been given the greatest attention in the literature, ICU readmission and post-ICU mortality.

Although Intensive Care Medicine has existed as a clinical specialty for many decades, the factors associated with post-ICU adverse events are still not well understood. Some factors that contribute to these events, such as older age and co-morbidities, have been identified in the literature. These factors, however, are not modifiable.

An increased understanding is needed of modifiable factors within care processes that contribute to the risk of post-ICU adverse events. By identifying and describing how these factors contribute to adverse events, the delivery of post-ICU care can be modified to reduce the risk of future events and thus improve patient outcomes. This research program therefore has wide-spanning implications, not just for ICU patients locally, but also for those in countries with similar health care systems.

While research has been conducted on ICU readmission for the last 30 years, the research methods used have some significant limitations. As such, there is thorough understanding of the characteristics of readmitted patients and the associated medical diagnoses but not of the factors contributing to, or associated with, these post-ICU adverse events. Furthermore, scant research attention has been given to the experiences and opinions of clinicians involved in the care of readmitted patients. This previously unexplored data has the potential to further the understanding of ICU readmission. The first phase of the research program was therefore an exploratory study that investigated nurses' perceptions and experiences of the factors associated with ICU readmission.

The literature reviews presented in this chapter have highlighted numerous unresolved issues related to post-ICU adverse events. The research program contained in this thesis helps address some of those issues. The next chapter provides an overview of the conceptual framework that guided data collection and analysis in the research program.

CHAPTER 3

Conceptual Framework

This chapter contains a manuscript published in a peer-reviewed nursing journal.

Elliott, M., Page, K., & Worrall-Carter, L. (2012). Reason's accident causation model: application to adverse events in acute care. *Contemporary Nurse*, 43(1), 22-28. (IF 0.44)

- Malcolm Elliott – led the conception of the key intellectual content; and wrote and edited the manuscript drafts.
- Dr Karen Page – edited manuscript drafts for key intellectual content.
- Prof Linda Worrall-Carter – edited manuscript drafts for key intellectual content.

Introduction

Contemporary adverse event analysis has shifted the focus from legal consequences and personal blame to a more constructive approach focused on solutions (de Vries et al., 2008). It has been argued that safety interventions should be developed in light of the casual chain, through which interventions may have an impact on an organisation and its patients (Brown et al., 2008). To date, no studies on in-hospital post-ICU adverse events have used an accident causation model to guide data collection and analysis. An overview of the model which guided the research program is presented in this chapter.

Various accident causation models have been developed by researchers and psychologists to help investigate error causation (Dean et al., 2002). These models aim to identify the root cause of accidents to prevent their recurrence. Accident causation models have been used for many years in high-risk industries, such as chemical processing plants and the rail and airline industries. Examples of popular accident causation models are Reason's Swiss cheese model (Reason, 1997) and Donabedian's structure/process/outcome model (Donabedian, 2003).

After reviewing numerous accident causation models, Reason's model was chosen as the guiding conceptual framework for the research program. The model was chosen because it recognises that adverse events rarely have a single cause and are typically due to many factors; the model also promotes the concept of a causal chain (Brown et al., 2008; Cox, 2008). For example, how an individual clinician exercises his or her skills can have a profound effect on the safety of the care delivered; surgeons, physicians and nurses have to rely heavily on their own skills in order to protect patients from harm (Reason, 2004).

Adverse events in health care typically involve a complex interaction between a variety of elements, including: human behaviour; technological aspects of the system; socio-cultural factors; and a range of organisational and procedural weaknesses. Reason's model is therefore considered the most appropriate model to apply to the complex health care environment (DoH, 2000). Although popular for event analysis however, little guidance exists on the use and application of Reason's model. The publication included in this chapter outlines the theoretical underpinnings

of the model and demonstrates its application to adverse events in the acute care setting.

Reason's accident causation model: application to adverse events in acute care

Reason's accident causation model: Application to adverse events in acute care

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ABSTRACT: *Adverse events are unintended harm to a patient caused by the health care provided; more than half of all these events have been deemed avoidable. Adverse events are a common problem in acute care and represent a breach in care quality and safety. They are generally not caused by a single mistake or error and although safety barriers exist in health care, patients today are still harmed. Using an accident causation model is a constructive way of identifying the underlying causes of adverse events and to strengthen a study's theoretical underpinnings. Reason's model is recommended as a useful framework for adverse event analysis as it promotes a focus on the conditions or situation in which the clinician was trying to perform, rather than apportioning blame.*

KEYWORDS: adverse events, accident causation, quality and safety

Adverse events are a widely researched problem in health care. Three factors characterise these events. The patient suffers harm, an injury, disability or complication. The event is unintended and is associated with health care management rather than the patient's illness itself (Vincent, Neale, & Woloshynowych, 2001). Adverse events are not a new clinical phenomenon and the severity of their consequences has been recognised for some time. In North America for example, they are the fifth leading cause of death, causing more mortality than motor vehicle accidents and breast cancer (Kohn, Corrigan, & Donaldson, 2000).

Unfortunately adverse events are common in the clinical setting, affecting up to one third of hospitalised patients (Fowler et al., 2008; Griffin & Classen, 2008). Of these patients up to 20% will die as a result and 13% will suffer permanent disability (Baker et al., 2004; De Vries, Ramrattan, Smorenburg, Gouma, & Boermeester, 2008). This incidence rate is high, particularly given that up to 80% of all adverse events are considered preventable (Sharek et al., 2006; Sinopoli et al., 2007). Adverse events also carry a huge financial burden. For example a recent Australian study on patients undergoing cardiac surgery found that 36% of patients experienced at least one adverse, at a total cost of \$42.5 million (Ehsani, Duckett, & Jackson, 2007).

Clinical care today is complex, team based and reliant on technology (Woloshynowych, Rogers, Taylor-Adams, & Vincent, 2005). Patients discharged from Intensive Care (ICU) for example often have unique care needs, which may be difficult to provide in a ward environment (Green & Edmonds, 2004). Various factors influence the quality of care and thus the incidence of adverse events. The analysis of these events therefore needs to move beyond simplistic conceptions of human error, fault and blame (Woloshynowych et al., 2005). This is because humans, be they novice or expert, do not deliberately try to cause harm or make a mistake. Instead their decisions or actions are based on information available at the time and the environment in which they were working. System and human factors, such as skill mix and fatigue, have been found to play a role in 70–80% of all accidents (Runciman, Webb, Lee, & Holland, 1993). This is one reason why many adverse events are deemed preventable.

Researchers and psychologists examining industrial errors have developed theoretical and conceptual models to help analyse error causation (Dean, Schachter, Vincent, & Barber, 2002). These theoretical frameworks are important as they facilitate the examination of an adverse event and enable outcomes to be linked to the existing body of knowledge (Borbasi, Jackson, & Langford, 2008). Without reference to existing knowledge, a

study and its findings exist in isolation from other similar studies, and the theoretical significance of the investigation remains unclear (Parahoo, 2006; Polgar & Thomas, 2008).

Progress in science is best advanced when the researcher identifies the theoretical notions underpinning the research and attempts to formalise the link between theory and all phases of the research (Moody, 1990). For these reasons there have been calls in recent years to strengthen the theoretical underpinnings of patient safety research (Brazil, Ozer, Cloutier, Levine, & Stryer, 2005; Mark, Hughes & Jones, 2004). One of the most popular theoretical models for adverse event analysis in health care is Reason's accident causation model.

AIMS

Although a popular framework for adverse event analyses, little formal guidance exists on the use of Reason's accident causation model and its clinical application. This paper therefore aims to discuss the theoretical underpinnings of Reason's model and describe its application to adverse event analyses via clinical exemplars. This paper serves as a guide to researchers and clinicians considering using Reason's model as a conceptual framework for event analysis, by demonstrating how it has been applied. The use of the model in a current programme of research on adverse events will also be described.

ACCIDENT CAUSATION MODEL

Reason's (2000) model proposes that within complex systems such as hospitals, multiple barriers or layers exist to prevent accidents or errors. In health care these layers may include hospital policies, protocols or clinical guidelines. However, Reason (2000) suggests that each of these safety barriers has random holes or weaknesses and when these holes align, the patient is able to 'pass straight through' the barrier resulting in an adverse event. These holes are labelled latent conditions and the adverse event which occurs, an active failure (Reason, 2000).

Reason (2001) describes two simple ways in which failure can occur: The plan is adequate but the associated actions do not proceed as intended, or the actions go as intended but the original

plan was flawed. These failures may be labelled as either an error or a violation. Errors are defined as the failure of a planned sequence of actions to achieve the desired goal (Reason, 2001). They can be further categorised as slips, lapses or mistakes.

Slips are actions in which there are recognition or selection failures such as confusing the dose of two drugs. Lapses are a failure of memory or attention, such as failing to cease a drug on a medication chart. Mistakes include the incorrect choice of objective, or choice of an incorrect path to achieve it (Dean et al., 2002). Errors may therefore be a skill-based slip or memory-based lapse, or rule-based or knowledge-based mistakes. A violation is an instance in which rules of correct behaviour such as clinical guidelines are consciously ignored by the clinician (Dean et al., 2002).

MODEL DEVELOPMENT

Reason's (1997) model classifies factors contributing to accidents into three domains: Organisational/systems, local workplace and unsafe acts. In doing so, the model moves the blame from human error to the environment in which humans work. In other words, the model promotes a focus on the conditions or situation in which the person is trying to perform, conditions which might be designed to create an incident or error.

Reason et al. (2001) label these conditions vulnerable system syndrome – a cluster of organisational pathologies that renders some systems more liable to adverse events. Examples of these pathologies include: Blaming front line individuals for adverse events, such as the clinicians at the bedside involved in the event; denying the existence of systemic error provoking weaknesses, such as a chronic shortage of experienced staff; and the blind pursuit of key performance indicators, such as patient throughput.

The strength of Reason's (2000) model is its focus on the system or environment in which the event occurred, rather than the individual involved as the cause of the event, and to randomness rather than deliberate action, in medical errors (Perneger, 2005). This is because when an accident occurs it is usually due to a specific trigger

which has influenced the long-term failures in the design of the system (Johnson & Botting, 1999). Examples of such triggers include staffing levels or staff workloads (Dean et al., 2002).

It has been hypothesised that accidents are the end result of long chains of events that start with decisions at the managerial level, suggesting that accidents are built into an organisation's infrastructure rather than being deliberately caused (Wagenaar, Hudson, & Reason, 1990). Five key ingredients of accident scenarios have been described: Management decisions, such as reducing the number of maintenance staff; general failure types, such as inadequate time to complete a task; psychological precursors, such as a wrong habit which worked well in the past; unsafe acts, such as touching a loose electrical wire; and missing defences, such as no triggering of an alarm if a drug cupboard is forcibly opened (Wagenaar et al., 1990).

This approach to error classification and analysis is reinforced by Johnson, McCarthy, and Wright (1995) who stated that an accident investigation must identify the starting point or initial circumstances, the anticipated behaviour of the system and the abnormal events that led to system failures or human error. The organisational or situational context in which the adverse event occurred is described by Reason (2000) as latent failures because these are conditions which are present in a complex system but may not be obvious and thus easily contribute to an error or patient harm. Examples of these are poor design, inadequate supervision, manufacturing defects or maintenance failures, unworkable procedures, clumsy automation, shortfalls in training, and less than adequate tools and equipment (Reason, 1997).

Reason attributed latent failures to decisions made by designers, builders, policy writers and top level management. It is these decisions which set up the employee for failure or fail to protect them from foreseeable errors or omissions (Perin, 2005). An example is two medications with similar names but differing actions being contained in similar shaped, sized and coloured ampoules. The clinical nurse at the bedside is not responsible for labelling these drugs, nor their packaging design.

However, it is the bedside nurse administering the medications who could easily confuse these drugs and thus be a victim of the poor design along with the patient.

MODEL LIMITATIONS

Reason's model is one of the most frequently cited accident causation models. Despite this, little formal guidance exists on its use and application. Perneger (2005) therefore conducted a study to explore healthcare quality improvement professionals' understanding of the model. A convenience sample of 85 delegates at an international conference on quality in health care completed a questionnaire on Reason's model.

Opinion on the meaning and significance of the model was far from univocal. For example there was varying opinion among these professionals about what the various parts of Reason's model represent (Perneger, 2005). This finding may reflect these professionals' misunderstanding of the model; but if experts have trouble understanding and/or applying it, then perhaps the model is too complex to be easily and usefully applied by those investigating adverse events. It was also suggested that the model places too much emphasis on systemic causes of patient harm, as opposed to an individual's failure (Perneger, 2005). This is probably because according to Reason (1997) we cannot change the human condition, but we can change the conditions under which people work.

Reason's (2000) model is only a framework for adverse event analysis. As with any theoretical framework it is not designed to deliver answers to those using it but rather to act as a guide to the investigation and analysis of an incident. Reason's model is a framework not a research method and clinicians or researchers using it for incident analysis must be cognisant of this.

MODEL IN PRACTICE

Reason's model can guide data collection and analysis when examining adverse events in clinical practice. Data collected on factors contributing to adverse events can be framed as organisational or systems factors, rather than mistakes made by clinicians. Examples of these factors may include staffing levels, time of patient discharge or bed

shortages. These organisational or systems factors can be included in adverse event reporting tools used by hospitals. Mark et al. (2008) for example recently established the influence of contextual factors such as hospital size, structural factors such as skill mix, and safety climate factors such as communication culture, on medication errors and patient falls. They concluded that future research may benefit from the use of theoretical models which are focussed on the explanation of particular types of adverse events (Mark et al., 2008).

Using Reason's model, researchers can classify data into latent conditions or as acute work conditions, such as local workplace conditions occurring only at the time of the event. The acute conditions for example could include nurse: patient ratios or staff skill mix. Other conditions could be the premature discharge of a patient from ICU to a hospital ward because of a system factor such as bed shortages. Prompting clinicians to isolate organisational factors which contribute to adverse events will highlight system changes needed to reduce the incidence of adverse events in the future, as classifying errors is pivotal to any process of change (Johnson & Young, 2011). To highlight the application of Reason's model, examples of adverse event analysis will now be described.

MEDICATION ERRORS

Medication errors are one of the most common types of adverse events. The landmark report, *To Err is Human* revealed that more than one million medical mishaps occur in North America each year, resulting in 100,000 deaths, of which 75% are adverse drug events (Kohn et al., 2000). Bates and Schiller (2007) therefore applied Reason's model to the case of a 15 year old boy who presented to an Emergency Department with slurred speech, pallor, unsteady gait, confusion and headache. On questioning the patient's mother, it was found that she had refilled his medication prescription 2 days prior and that the patient's physician had changed the Clonidine prescription from three times daily to once nightly. The patient had been receiving one 75 mcg tablet three times a day but to simplify the medication

regime, the physician changed the order to one nightly extended-release tablet.

This within itself was not an unreasonable change to make and may have improved compliance with the medication by reducing the number of tablets the patient needed to swallow. The pharmacist however, noticed that the dose had been written incorrectly: 2.25 mg/night instead of 225 mcg/night. Despite this the pharmacist supplied the drug as prescribed, and the patient received a daily dose that was ten times greater than was intended. Using Reason's framework, this would be labelled an active failure.

When investigating this case a number of errors or holes were identified: An incorrect dose was prescribed; it was detected but not queried by the pharmacist; the boy's parents did not understand the change on the drug label (it was not clear if they had been informed); and two doctors in the Emergency Department and the admitting medical team failed to check the correct paediatric dose of Clonidine or the common signs of overdose of this drug (Bates & Schiller, 2007). Reason's framework would label all these issues as latent failures. The pharmacist and medical staff involved could be considered 'safety barriers' in Reason's model because these clinicians are educated, skilled health professionals. However, for whatever reason, perhaps because they are human, they all made mistakes or judgement errors.

The prescribing physician could easily have been reprimanded for making an error but such action would not guarantee that a similar error would not occur again. The pharmacist could also be asked why he/she detected a dose error but still dispensed the incorrect dose. The factors contributing to the prescription error were not reported but using Reason's model promoted the recognition of how the error occurred and focus on how it could be prevented in the future such as by educating parents.

RIGHT DRUG, WRONG ROUTE

Another example of adverse event analysis using Reason's model is an incident involving a drug administered via the incorrect route (Cohen, 2006). An oral cough medication was ordered for a patient but the route was not specified on the

medication chart, a human error. The drug was dispensed in a syringe for oral administration, but the nurse was not familiar with 'oral syringes'. This lack of familiarity is not strictly a human error but could be considered a system error due to lack of staff education.

As the drug was dispensed in a syringe and the patient had an intravenous cannula insitu, the nurse assumed the drug was to be administered intravenously, another human error. The pharmacy label on the syringe covered the manufacturer's instructions, 'for oral route only', another human error. Fortunately the patient was not harmed when the drug was administered via the incorrect route.

The nurse involved in this incident could have been disciplined for placing the patient at risk. Using Reason's model though, it can be seen that human error was a factor – the errors of the nurse and the person who covered the manufacturer's instructions. The nurse's assumption to administer the drug intravenously is though understandable. However, as it is uncommon for liquids intended for oral administration to be contained in a syringe, the lack of clear guidance on the administration route is a system error. If the nurse administering the medication had been disciplined and no further action taken, then the specific factors which contributed to the error would remain, potentially causing the error to recur. Applying Reason's model to this event encourages the analysis of underlying factors, rather than simply blaming the clinician involved.

ADVERSE EVENTS

Reason's model is currently being used by the authors in a large programme of research examining adverse events following discharge from ICU. The aim of the research programme is to improve post-ICU patient outcomes through the examination of key factors contributing to adverse events in this unique population. The research programme also aims to promote the development of corrective action to reduce the risk and severity of future adverse events in this patient cohort.

The first phase of the programme was a qualitative analysis of ICU readmission (Elliott, Crookes, Worrall-Carter, & Page, 2011). This

clinical adverse event was examined as previous research on the topic has not isolated contributing factors, only the associated disease processes (Elliott, 2006). The first phase identified five key factors believed by respondents to contribute to ICU readmission. A literature review was also conducted to identify factors which contribute to adverse events in all acute settings. It was hypothesised that the findings of the first phase and those in the literature would contribute to most adverse events following ICU discharge.

Using Reason's model, these factors were categorised into three domains: Those relating to the system or environment in which care is delivered; those relating to clinicians; and those relating to patients. These were formatted into a questionnaire which was used to explore nurses' opinions of factors contributing to adverse events following ICU discharge (Elliott et al., in press). Categorising factors contributing to adverse events using Reason's model encouraged nurses completing the questionnaire to think beyond superficial causes such as 'nurses don't know how to care for these patients'. Instead it prompted them to view an adverse event as an outcome or result of flaws or limitations within clinical care. Conceptualising adverse events this way allows processes of care to be modified thus reducing the risk of future adverse events.

SUMMARY

Adverse events are a common problem in health care and represent a breach in care quality and patient safety. These events carry a high cost for the patient, staff and organisation involved. Adverse events are generally not caused by a single mistake or error and although preventive barriers or safety mechanisms exist in health care organisations, patients are still harmed. These barriers are not perfect and contain weaknesses that may be bypassed if the right conditions exist. The investigation and analysis of adverse events must focus on identifying these conditions and the weaknesses in safety barriers.

There is always the likelihood of errors occurring in health care due to the human factor. However, often it is factors external to clinicians, such as the environment in which they work, which lead to errors. Unfortunately the historical

approach to error investigation has focussed solely on the clinicians involved and this fails to correct the weaknesses within the system which allow errors to occur (Kohn et al., 2000).

Bedside clinicians respond to the environment they are working in at the time, but do not 'create' the environment. For example they have little control over staff: patient ratios or equipment availability. This is why it is so important to examine the conditions or environment the clinician was working in at the time to identify causative factors, rather than the easier option of apportioning blame (Reason, 1990).

Using an accident causation model is a constructive way of identifying the underlying causes of adverse events and to strengthen a study's theoretical underpinnings. Reason's model is recommended as a useful framework for adverse event analysis. It prompts the researcher to identify specific causes of an adverse event rather than blaming the clinician involved. It promotes an examination of the organisational or system factors which contributed to the event including failure of safety barriers.

By using an accident causation framework such as Reason's model, adverse events may be analysed in a way that allows for the underlying causes to be isolated thus helping to improve care quality and patient safety, and prevent future adverse events. Despite having had a major impact on the way accidents are conceptualised, there is little published guidance on the practical application of Reason's model (O'Hare, 2000). There is also disagreement among safety experts about how the model should be applied to medical adverse events (Perneger, 2005). This paper describes the theoretical underpinnings of Reason's accident causation model and its application to clinical adverse event analyses.

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Chapter summary

This chapter outlined the conceptual framework that guided the research program. The publication included in this chapter describes the theoretical underpinnings of the accident causation model; development of the model; limitations of the model; and concludes with a clinical case study demonstrating the model's application.

Acute care delivery is complex and is influenced by many variables ranging from government funding, bed availability and staff fatigue to equipment faults and waiting times. The analysis of adverse events therefore needs to move beyond simplistic conceptions of fault and blame because many events may be an outcome of the conditions staff were working under at the time (Woloshynowych et al., 2005). Blaming staff for patient harm and neglecting to consider the many variables influencing care delivery fails to address the underlying causes of harm and cannot prevent future adverse events.

Using a framework such as Reason's accident causation model to guide the research program was important because it promoted a focus on several factors of post-ICU adverse events rather than attributing superficial explanations. No published studies that used an accident causation model to examine post-ICU adverse events were identified in the research program. This makes the findings of the research program unique. The use of conceptual frameworks in patient safety research is important due to the complex nature of acute care delivery. Conceptual frameworks facilitate the examination of adverse events and enable outcomes to be linked to the existing body of knowledge (Borbasi et al., 2008). Using Reason's model to guide the research program helped identify modifiable factors within care processes which contribute to post-ICU adverse events.

The preceding chapters have set the scene for the research program. Chapter One provided the background to adverse events, Chapter Two reviewed the literature on post-ICU adverse events and Chapter Three outlined the conceptual framework which guided the research program. The next chapter presents the method used in the research program.

CHAPTER 4

Research Method

This chapter presents the method used in the research program. It contains a book chapter written by the candidate on mixed method research.

Elliott, M. Mixed methods; in Richardson-Tench M, Taylor B, Kermode S & Roberts K. (2011). *Research in nursing: evidence for best practice* (4th ed.). Melbourne: Cengage.

- Malcolm Elliott – conceived the key intellectual content, and wrote and edited manuscript drafts.

Introduction

This chapter presents an overview of the method used in the research program, a mixed methods design. The philosophical basis of mixed methods research is described, as well as the strengths and limitations of this method. Data collection and analysis techniques of the individual phases of the research program are also summarised.

The content of chapter 4 is presented as a book chapter written by the candidate. Chapter four concludes with an overview of the method used in each phase of the research program.

Mixed methods

Chapter learning objectives

The material presented in this chapter will assist you to

- define mixed methods research
- describe the reasons for using a mixed method design
- describe the different types of mixed method designs
- understand how mixing of research methods can be achieved
- outline the strengths and limitations of mixed methods research
- identify issues to consider when designing a mixed methods study
- understand how to critique a mixed methods study.

Introduction

Earlier in this text you were introduced to the two main research designs – quantitative and qualitative. Every so often debate rages about which of these designs is the best or on the differences between them (though not the apparent similarities). Any such argument about which is superior is flawed as neither is the best. Instead, each serves a specific purpose or function and the researcher chooses one based on the aims of their study.

Every research project also has limitations, which could be a reflection of the research design. A quantitative design might, for example, be used to determine the incidence of prostate cancer but it cannot uncover how men feel about receiving such a diagnosis. Similarly, a qualitative design can describe how it feels to be paraplegic but not the risk of injury when drink driving.

While a mixed methods design enables the researcher to explore quantitative and qualitative data it also does so much more. A **mixed method design**, as its name implies, involves mixing two methodological approaches within the one study. The two methodological approaches used are typically quantitative and qualitative, though they could be just one of these (Morse & Niehaus 2009) with the mixing coming from data collection and analysis or the interpretation phases of the study. It is important to distinguish a mixed method design from a **multimethod design**, which involves various combinations of field, survey and experimental methods to address the research question (Brewer & Hunter 2006) (note the absence of any reference to mixing in this definition). These two are sometimes – incorrectly – referred to interchangeably.

Mixing research methods enables the researcher to achieve a greater depth of understanding of the phenomenon under investigation than either approach alone and to challenge the either/or debate. Some researchers believe that mixed methods produce new knowledge not through the complementarity of different data types and analysis techniques but through the integration of different methods at the analytical, interpretive or epistemological levels (Elwood 2009).

Why might a researcher want to mix research methods? Consider the example of a nurse performing a patient assessment. The nurse can collect qualitative data – by asking how a patient is feeling, and quantitative data – by taking a patient's pulse, blood pressure and temperature. By themselves each individual piece of assessment data is meaningless, but when the qualitative and quantitative data are collated the nurse can reach rigorous conclusions about the patient's condition (e.g. hypotovaemia, shock) that are far more sound and which the nurse can have confidence in. The same can be said for conclusions arising from a mixed methods study.

Mixed methods research typically involves integrating quantitative and qualitative data collection and/or analysis in a single study or program of enquiry. The emphasis must be on integrating, as simply adding a quantitative phase to a qualitative study (or vice versa) is not a new concept and does not constitute a mixed methods approach (Creswell & Tashakkori 2008). Newer conceptualisations of mixed methods research acknowledge that a study is not considered mixed if there is no integration across research stages (Teddle & Tashakkori 2006). Nevertheless, the process of mixing different components of the study can be quite challenging.

As the mixing of research methods is not yet widely accepted by the scientific community study findings could be ignored or heavily scrutinised. The hard scientists, those who favour only a quantitative approach and scoff at the softer qualitative methods, could, in their ignorance, suggest that mixing of these two methods is impossible. The idea of mixing methods has started to appear in the quantitatively focused medical literature (see, for example, Donovan et al. 2002; Malterud 2001). Mixed methods research is not a new research design.

Denzin (1978), for example, described mixed methods research more than three decades ago. Furthermore, many research topics have been rigorously examined within nursing and outside the health professions using this approach.

TIP

Just because a quantitative phase and a qualitative phase were used within the one study do not consider a study that involves these two methods to be a mixed study.

Philosophical basis

Researchers are expected to position their research within a selected paradigm. A paradigm is a way of looking at natural phenomena that encompasses a set of philosophical assumptions and that guide one's approach to inquiry (Polit & Beck 2006). Examples of paradigms include pragmatism, constructivism and postpositivism. Paradigms are sometimes referred to as 'world views' or as a 'theoretical lens'. Quantitative research is influenced by the positivist paradigm, while qualitative research is influenced by the naturalistic or constructivist paradigms. These differing paradigms tend to imply that quantitative and qualitative research are not compatible, but the researcher undertaking a mixed methods study is not trying to make them compatible but rather gain from the strengths of each method while minimising their inherent limitations.

A number of worldviews (paradigms) can be assumed by the research that uses a mixed method design. Creswell and Plano Clark (2007) highlight the three philosophical stances on mixed methods research.

- 1 There is one best paradigm that fits mixed methods research.
- 2 Researchers who use mixed methods can use multiple paradigms.
- 3 Worldviews relate to the type of mixed method design and vary depending on the type of design.

The researcher using mixed methods may find themselves in a conundrum because of the differing worldviews associated with qualitative and quantitative research.

Tashakkori and Teddlie (2003) argue that the research question is of prime importance more so than the method or philosophical underpinnings of the method. This is consistent with the **pragmatism** paradigm. Researchers using this approach ask what works to determine the best method for answering a research question, a method that rejects the either/or approach of the postpositive and constructivist paradigms (Mertens 2005). As such, the values or beliefs of the researcher may have significant influence on how the study is conducted or the data interpreted. Pragmatism has a number of other characteristics:

- a lack of commitment to any one philosophy or view of the world
- value of both subjective and objective knowledge
- the belief that knowledge is constructed and based on the reality of the world one experiences and lives in
- the problem (and its solution) is of prime importance
- methods for solving the problem are of lesser importance.

Method or methodology?

Methods and methodology are important parts of any study. These terms are sometimes used interchangeably but they do not refer to the same concept. The method (or methods) of a

study refers to the tools the researcher uses to complete the study (i.e. to collect and analyse data), which could involve the use of a survey, interviews with participants or a software program (e.g. SPSS) for data analysis. The choice of methods could also include issues regarding timeframes, financial support or other resources. There are no rules about which tools should or should not be used, but a justifiable reason for their choice, such as people's opinions may be acquired more easily by an interview than a questionnaire provided the researcher has enough time to conduct interviews, must be evident.

Methodology refers to the theoretical assumptions and values that underpin a particular research approach (Giddings & Grant 2007). Consider, by way of analogy, how different religions view issues such as birth, death or illness. None of these views are right or wrong; they are just opinions or beliefs that dictate how believers of the particular religion live their lives. The same could be said of a methodology in that it dictates how each part of the study is conducted because methodologies contain assumptions about knowledge (e.g. whether it is generated inductively or deductively). Methods of data collection and analysis are often chosen based on the assumptions the overriding methodology makes about the nature of knowledge generation and validation (for a further discussion see chapters 6 and 8). Hence the methodology has the greatest influence on the conduct of the study.

Some authors view mixed methods as a method because of its focus on collecting, analysing and interpreting qualitative and quantitative data (Creswell & Tashakkori 2007a). Those who view mixed methods as a methodology argue that a method cannot stand alone or separate itself from the other parts of the research process, such as the philosophical assumptions and data collection strategies (Creswell & Tashakkori 2007a). Irrespective of the researcher's view, clear and transparent decisions need to be made about the methods used in the study and it must be obvious which theoretical assumptions are guiding it.

Why use a mixed methods approach?

There is a variety of reasons for using a mixed method design, but it should not be assumed that mixed methods are inherently a better choice than a single method. Some of the common reasons for using a mixed method design include that

- it enables the researcher to acquire a much greater understanding of the problem under investigation than could be acquired by a single method alone
- it is a way of capitalising on the strengths of quantitative and qualitative methods while minimising the limitations of each single approach
- it is a way of adding strength to any study and of increasing rigour in the research process (Creswell, Fetters & Ivankova 2004)
- it enables the researcher to answer important questions such as what is happening (quantitative data) and why it is happening (qualitative data) within the one study
- any conclusions reached are based on these two types of data rather than just one.

The main assumption underpinning mixed methods research is that using quantitative and qualitative approaches in the same study results in complementary strengths. Furthermore, the limitations of one approach may be corrected or balanced by the other approach. The philosophy of pragmatism advances the notion that the consequences are more important than the process and therefore the end justifies the means (Doyle, Brady & Byrne 2009). So even though each method's strengths might complement each other, it is what this combination produces that is of greatest benefit.

Brewer and Hunter (2006) argued that many explanatory theories do not respect conventional methodological boundaries. As such it may be difficult to test a theory by traditional research methods. A combination of methods potentially allows the researcher to overcome this hurdle by providing more than one option to assess the validity or rigour of a theory. If

more than one method confirms the rigour of a theory, then the validity of the theory is stronger than if tested by a single method alone.

Why might a nurse researcher want to conduct a mixed methods study? Over the last two decades nurses have increasingly been expected to engage in evidence-based practice. While randomised controlled trials are considered by many to be the best form of evidence, the context and experience of providing nursing care unfortunately do not lend themselves to be easily evaluated by such a trial (Flemming 2007). It has even been argued that the knowledge generated by these trials merely serves to restrict or devalue other forms of knowledge and ultimately stifle nursing scholarship (Rolfe 2009). A mixed methods design enables the researcher to evaluate nursing care using quantitative and qualitative methods, thereby creating a greater depth of understanding than could a randomised controlled trial alone.

In summary, mixed method designs are usually used in the following three circumstances (Morse & Niehaus 2009).

- 1 If the research question does not completely encompass the phenomena of interest
- 2 If during the course of inquiry, interesting or unexpected phenomena are revealed. A mixed method design would allow the researcher to incorporate the new phenomena into the study while the present one is ongoing.
- 3 Unexpected findings are revealed in a quantitatively-driven study. A mixed method design would allow the researchers to qualitatively explore quantitative data which is puzzling.

TIP

Using more than one method does not by itself make a study more rigorous or the results more significant.

Designing a mixed methods study

Obtaining an accurate answer to the research question and one that the researcher has confidence in is the ultimate goal or outcome of the study. The accuracy of the answer can be influenced by many variables during the course of the study, such as the amount of time or financial support the researcher has or the willingness of subjects to be interviewed.

Because answering the research question is the primary focus the question strongly determines the method that the researcher will use. The following suggestions for writing research questions for a mixed methods study may be helpful.

- Write separate quantitative and qualitative questions followed by an explicit mixed methods question
- Write an overarching mixed research question later broken down into separate quantitative and qualitative sub-questions to answer in each strand or phase of the study
- Write research questions for each phase of a study as the study evolves.

Tashakkori & Creswell 2007, p. 208.



ACTIVITY

Discuss what the basic characteristics of qualitative and quantitative research questions are and how they differ. How might mixed methods questions differ from qualitative and quantitative research questions?

Decisions about the method need to be given careful consideration before data collection commences, although this may not always be the easy. A nurse might, for example, decide to survey all the wards of a hospital to determine the number of patients who experience an adverse event (e.g. pressure areas, falls). If one ward is found to have a much higher incidence than other wards, the researcher might want to identify the reasons why. However, if staff know their ward has a much higher incidence of adverse events they might provide false or misleading answers when interviewed by the researcher (**Hawthorne effect**). But if the quantitative (incidence of adverse events) and qualitative data (staff opinions of causes of adverse events) were collected concurrently, staff might provide more truthful and honest answers, particularly if they are blinded to the quantitative results.

Also decide which phase (qualitative or quantitative) is exploratory and which confirmatory: is the purpose of the study to confirm what is already known or suspected (that adverse events occur or how many)? Or is it to explore previously uncovered areas and identify what has previously not been known (nurses' opinions of the causes of adverse events)? In a mixed methods study the qualitative phase is typically exploratory and the quantitative phase is confirmatory but the researcher must decide the role of each phase of their study.

Perhaps the most important decision to be made is how the qualitative and quantitative phases of the study will be mixed, because if no mixing occurs then a mixed method study has not been conducted. This tends to be the greatest challenge to the researcher and many may struggle to articulate exactly how their study is mixed. This problem might exist because of debate about what actually constitutes a mixed methods study. Again, there are no right or wrong answers but researchers must be able to justify the decisions they made about their study.

Different kinds of **research objectives** lend themselves to being addressed by a mixed methods design. Some common examples are

- to develop conclusions that are well substantiated by quantitative and qualitative data
- to validate quantitative data (e.g. collected via survey)
- to generate and test hypotheses
- to build, test and refine theories
- to enhance an experimental design
- to test the efficacy and effectiveness of nursing interventions
- to understand why specific relationships exist within a correlational design
- to explain certain aspects of quantitative results (i.e. explication)
- to select participants for an in-depth qualitative study
- to help develop a quantitative data collection tool (i.e. instrumentation)
- to help generalise qualitative findings with quantitative data.

Plano Clark, Creswell, O'Neil Green & Shope 2008, pp. 367–71.

Table 10.1 provides some guidelines for integrating quantitative and qualitative results. Creswell and Plano Clark (2007) suggest some additional strategies.

- *Merging data sets*: the researcher explicitly brings the data sets together or integrates them in the interpretation or analysis phases.
- *Embedding data sets at the design level*: data from one phase are embedded in the design of the other phase. This may occur concurrently or sequentially.
- *Connecting from data analysis to data collection*: this occurs when analysis of one data set leads to the need for the other type of data.

A final important decision the researcher needs to make is how each phase of the study is weighted. Are the qualitative and quantitative phases weighted equally so they play an equal role in answering the research question or does one phase have greater weighting and thus more influence on the research process?

1	Selection of research methods needs to be made after the research questions are formulated
2	Some methods work well in some domains and not in others
3	There is no model of integration that is better than another
4	When there are results that support each other, it is possible that both the qualitative and quantitative results are biased and both are not valid
5	The main function of integration is to provide additional information when information obtained from one method only was insufficient
6	If the results lead to divergent results, then more than one explanation is possible.

TABLE 10.1
Guidelines for
integrating
quantitative
and
qualitative
results

Wurtz, K. (n.d.). *Using Mixed Methods Research to Analyze Surveys*, Chaffey College, retrieved from <http://rpgroup.org/documents/UsingMixedMethodsResearchToAnalyzeSurveys.ppt>

Other issues also need to be considered. If, for instance, the phases are given equal weighting, more resources (time, financial support) may be necessary (Creswell & Plano Clark 2007). If the research is being conducted for a Masters or doctoral thesis, then the resources available could influence the weighting decision far more than any other factors. The choice of weighting might also reflect the researcher's experience or expertise in one method (Creswell & Plano Clark 2007). The method the researcher has the greater understanding of and experience using may be the dominant method.

Finally, the researcher may need to consider the target audience (Creswell & Plano Clark 2007). A quantitative research journal with little history of publishing mixed methods studies may be less willing to publish a study where the qualitative method was dominant. Similarly, a thesis examiner with a qualitative background might be more favourable to a mixed methods thesis in which the qualitative phase was dominant.

Ethical issues

Obtaining ethics approval for a mixed method study can pose unique challenges. Although ethics committees are familiar with qualitative and quantitative research they may not be familiar with the concept of mixed methods due to it being a relatively new research method.

There are a number of issues that need consideration when a researcher is submitting an application for ethics approval, including these.

- Has the way in which mixing will occur been stated?
- Has a rationale for the design been included in the application (including strengths and limitations)?
- Have the ethical issues created by the particular mixed method design been addressed (Creswell & Plano Clark 2007)?
- Should the ethical issues arising from each phase of the study be addressed separately in the application?
- Have the ethical issues for the participants been stated, such as consent, privacy or level of risk (including how these issues will be addressed)?



ACTIVITY

Identify a mixed methods study of interest to you and consider how, if you had to conduct this study, you would address the following practical issues as suggested by Halcomb and Andrew (2009):

- time
- financial cost
- skill
- supervision
- managing more than one data set
- ethics approval.

Typology of mixed methods

The mixed method approach to research offers a variety of designs or frameworks; there is no single approach to undertaking a mixed method study (Bazeley 2006). There are differing schools of thought about the types or classification of mixed method designs (see tables 10.2 and 10.3). It is not the intention of this chapter to provide an overview of each of them, particularly as they have much in common (for an explanation of each of these, see the cited references). The common theme of the different classifications is the sequence in which data are collected. Creswell (2002) suggests that the researcher has three choices:

- 1 to collect quantitative and qualitative data at the same time
- 2 to collect quantitative data first, and then collect qualitative data
- 3 to collect qualitative data first, and then collect quantitative data.

TABLE 10.2
Classifications
of mixed
method
designs

Sequential <ul style="list-style-type: none"> • <i>Explanatory</i> • <i>Exploratory</i> • <i>Transformative</i> Concurrent <ul style="list-style-type: none"> • <i>Triangulation</i> • <i>Nested</i> • <i>Transformative</i> <p>Creswell, Plano Clark, Guttman & Hanson 2003</p>	Concurrent <ul style="list-style-type: none"> • <i>Triangulation</i> • <i>Concurrent embedded</i> Sequential <ul style="list-style-type: none"> • <i>Explanatory</i> • <i>Exploratory</i> • <i>Sequential embedded</i> <p>Creswell & Plano Clark 2007</p>
Concurrent <ul style="list-style-type: none"> QUAL + QUANT QUAL + quant QUANT + qual Sequential <ul style="list-style-type: none"> QUANT → QUAL QUAL → QUANT QUAL → quant qual → QUANT QUANT → qual Quant → QUAL <p>Andrew & Halcomb 2007</p>	Simultaneous <ul style="list-style-type: none"> QUAL + <i>quant</i> QUAL + <i>qual</i> QUANT + <i>quant</i> QUANT + <i>qual</i> Sequential <ul style="list-style-type: none"> QUANT → <i>qual</i> QUAL → <i>qual</i> QUAL → <i>quant</i> QUANT → <i>quant</i> <p>Morse & Niehaus 2009, pp. 28–9</p>

Concurrent mixed method designs

Concurrent mixed method designs (also referred to as 'mixed method simultaneous design') (Morse & Niehaus 2009) are so called because the qualitative and quantitative methods are used at the same time, which means that careful planning is needed at the start of the study before data collection commences. The purpose of a concurrent design is to confirm, crossvalidate or corroborate findings from one research method with those from another

(Wilkins & Woodgate 2008). Findings from each method are integrated in the interpretation phase of the study.

A concurrent design may be considered by the researcher if, during the planning phase of a study, the research question or problem is considered rather complex. Morse and Niehaus (2009, pp. 16–17) suggest that a concurrent design could be used when

- a study has multiple groups of participants
- a study has several types of variables that do not fit well together in the analytical scheme
- the phenomenon under investigation changes over time
- different components of interest require different types of data be collected
- complex concepts are combined with concrete phenomena
- a theory has various concepts and different types of outcome variables
- there is a broad, encompassing question rather than a narrow targeted question.

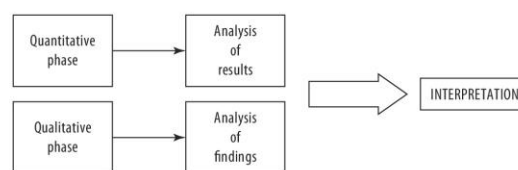


FIGURE 10.1
Concurrent
mixed methods
design

Concurrent embedded

Also referred to as the 'embedded experimental' model or 'concurrent nested design', this mixed method approach involves collecting quantitative and qualitative data at the same time but one of these methods is dominant and guides the study (mixing occurs at the design phase of the study). The second, less dominant, method is embedded (nested) within the dominant method. Typically, the dominant method is quantitative and the less dominant is qualitative.

This nesting means that the embedded method can address different questions or seek information from different participants. Within this design the qualitative and quantitative data sets can first be analysed separately and the findings then integrated in a final analysis or interpretation stage. The embedded design simultaneously provides the opportunity to look for consistency in findings between the two methods used, and at the same time to identify any inconsistencies. The qualitative findings can be used to explain the quantitative result.

One of the advantages of using an embedded mixed method design is that it enables the researcher to use a research method they are familiar with as the dominant method, so the researcher does not have to spend vast amounts of time developing expertise in a less familiar method (as it is less dominant). This choice of design is attractive if limited resources and time are available, as may be the case in tertiary projects (Plano Clark, Creswell, O'Neill & Shope 2008). The challenge, as with any mixed method study, is that competence in a new method still needs to be developed.

for example

Jordan, Philpin, Warring, Cheung & Williams (2006) used a concurrent embedded mixed method design in their study of patients' experiences of percutaneous endoscopic gastrostomies (PEGs). The aim of the study was to develop the understanding of patients' experiences of PEGs. Twenty patients with long-term PEGs were interviewed via structured and semistructured interviews. Quantitative data were then collected using a symptom rating scale. The quantitative data were compared with data from the qualitative interviews in the analysis phase of the study.

Triangulation

Triangulation typically involves the use of two methods (data collection), methodologies, theoretical frameworks or data analysis techniques within the one study. Triangulation may be used to overcome some of the intrinsic weaknesses within a method or methodology and provides the researcher with a different perspective of the data than does a single method alone.

The concurrent triangulation mixed method approach involves the use of a qualitative and quantitative phase to confirm, cross validate or corroborate findings within the one study (Creswell 2009). The qualitative and quantitative data are collected concurrently. Each phase may be given equal priority or one phase may dominate. The findings of each phase are integrated during the interpretation phase. There are four variants of a triangulation design: the convergence model, the data transformation model, the validating quantitative data model and the multilevel model (Creswell & Plano Clark 2007).

A strength of the concurrent triangulation design when compared with a sequential design is that less data collection time may be needed. A sequential design is not appropriate for triangulation because the data collected first may influence or bias the data collected sequentially (Onwuegbuzie & Collins 2007).

for example

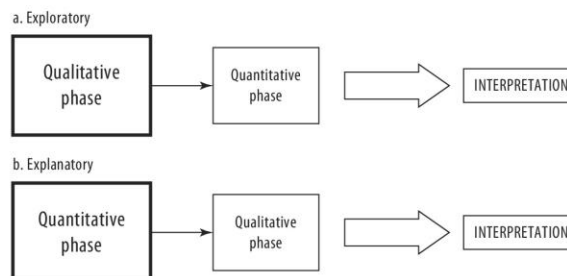
Benoit, Westfall, Treloar, Phillips and Jansson (2007) used a concurrent triangulation mixed methods design to explore the social factors linked to postpartum depression. Their aims were to investigate the link between social factors, maternity services and the incidence of depression among a sample of new mothers at 3–4 weeks and 4–6 months post partum. Quantitative data were collected using a validated depression scale. Qualitative data were collected by interviewing the participants and using open-ended questions. Both types of data were triangulated, which enabled the researchers to elaborate on the meaning and experiences identified by the survey.

Sequential mixed method designs

Sequential mixed method designs are so called because the qualitative and quantitative methods are used in a sequence or linear approach. The purpose of this approach is for the data from one method to build on the other (Wilkins & Woodgate 2008). Data analysis occurs after each phase but interpretation does not occur until the end of the study. Typically, results from the first phase of the study inform the design of the second (Teddlie & Tashakkori 2009).

The strength of a sequential design is that it is a relatively simple method for the researcher to implement. This may be an advantage for novice researchers. The simplicity of the method also makes it easier to report or describe the study. The main limitation of this design is that, as the phases do not occur concurrently, a lot of time may be needed for data collection, particularly if the phases are assigned equal weighting. There are three types of sequential designs.

FIGURE 10.2
Sequential
mixed methods
design



Exploratory

The purpose of an exploratory mixed methods design is to explore a particular phenomenon about which little is known. To do so involves conducting a qualitative study, followed by a quantitative study. The methods are mixed by the second quantitative phase building on or connecting to the results of the first qualitative phase; the quantitative data are used to measure, generalise, test or interpret the qualitative findings (Plano Clark et al. 2008). Such an approach is used to identify important variables to study quantitatively when those variables are unknown (Creswell & Plano Clark 2007). Creswell (2009) emphasised that the data are mixed through being connected between qualitative data analysis and the quantitative data collection.

Exploratory mixed methods research has two main variants:

- the instrument development model
- the taxonomy development model.

The former is used when researchers want to develop a quantitative research instrument based on qualitative findings (Creswell & Plano Clark 2007), the latter when a qualitative study is necessary to identify variables, develop a classification system or an emergent theory that is then tested quantitatively (Creswell & Plano Clark 2007).

for example

One study that used a sequential exploratory design is the research by Stoller et al. (2009), the aim of which was to determine whether factors influencing alcohol consumption decisions among heavy drinkers reflected consumption decisions among non-heavy drinkers who were advised to stop drinking for medical reasons. The qualitative phase of their project provided insight into drinking patterns of heavy drinkers; the quantitative phase provided estimates of the decision-making factors (about drinking) identified in the qualitative phase.

Explanatory

Previously called the 'sequential explanatory mixed method design', the main aim of the explanatory design is to explore a particular phenomenon. To do so involves the initial collection and analysis of quantitative data, which results then feed the second, qualitative phase of the study. The qualitative findings assist in the interpretation of the quantitative results by examining them in greater detail. Greater weight or attention is typically given to the quantitative data as they are collected first. This design may be preferred by researchers who favour quantitative designs (Creswell 2009).

Performing the qualitative phase second enables the researcher to examine in more detail unexpected or unusual results from the quantitative phase. Another strength is that it is easy to implement because of its simple nature, which also makes it easy to describe the method and report the results. The explanatory design also readily lends itself to multiphase investigations and single mixed methods studies (Creswell & Plano Clark 2007). Challenges faced by the researcher include having to decide how and when to connect the quantitative and qualitative phases of the study and how to integrate the results of these phases to answer the research question (Ivankova, Creswell & Stick 2006).

for example

Igo, Kiewra and Bruning (2008) used a sequential explanatory approach in their study of college students' notetaking habits. The purpose of the study was to examine the impact of different levels of copy and paste notetaking restriction on learning from Internet-based text. The first phase, in which

Research in nursing

students took notes under one of four experimentally designed conditions, was quantitative. Students were then tested to determine the effectiveness of the notes they made. The findings of the tests and those from previous research informed the data collection and analysis of the qualitative phase. Analysis of the students' notes and interviews helped explain the findings of the first phase of the study.

Sequential embedded

The sequential embedded design usually involves the collection of qualitative data before or after an intervention. Creswell, Plano Clark and Garrett (2008) note that, when collected before the intervention, the qualitative data can be used to

- help recruit participants
- help test the treatment before the actual experiment
- select participants that are best suited for the experimental or control conditions.

When collected after the intervention, the qualitative data can be used to help explain why different outcomes resulted (Creswell, Plano Clark & Garrett 2008).

TABLE 10.3
Character-
istics of
mixed
method
designs

Design	Characteristics
Embedded	Concurrent quantitative/qualitative data collection phase within which one dominant method guides the project. The second less dominant method is embedded, or nested, within the dominant method.
Triangulation	Qualitative and quantitative phases implemented at the same time and given equal weighting.
Exploratory	Qualitative data collected first. Quantitative data collected to provide a greater understanding of the qualitative findings. Often used for research problem about which little is known.
Explanatory	Quantitative data collected first and may be used as sampling frame or for coding of qualitative data. Qualitative data collected to provide a greater understanding of the quantitative results.

Regardless of how the designs are classified decide which of the designs is most appropriate for your study based on the study's aims and the chosen method's strengths and weaknesses. Also decide whether the two research methods will be used to collect data at the same time (concurrently) or one after the other (sequentially).

Strengths and limitations of mixed methods

Strengths

The strengths and benefits of combining research methods are widely described. Some of the main strengths include the following.

- Qualitative and quantitative research methods have innate strengths and weaknesses. Mixing two research methods enables the researcher to use one method to offset or balance the weaknesses of the other. Doing so adds to the rigour of the study's findings by limiting the impact of one method's weaknesses on the research process.

- Mixed methods enable the researcher to simultaneously ask confirmatory and exploratory questions and thereby verify and generate theory in the same program of enquiry (Teddle & Tashakkori 2006).
- Using a mixed methods approach enables the researcher to explore the data more deeply to acquire a greater understanding of the phenomenon under investigation.
- Using quantitative and qualitative data enables the researcher to simultaneously generalise results from a sample to a population and to gain a deeper understanding of the phenomenon of interest (Hanson, Creswell, J.W., Plano Clark, Petska and Creswell, J. 2005).
- Using mixed methods creates the ability to be inclusive of multiple approaches to a problem so there is more certainty in the results (Giddings 2006).
- Using mixed methods enables researchers to use all possible methods to explore research questions (Creswell & Plano Clark 2007). Doing so produces a better, more complete understanding of the problem under investigation than would looking at the problem from only one perspective (Plano Clark et al. 2008).
- The validity of a study's conclusions is enhanced if the conclusions have been confirmed by more than one data set or method.

Limitations

There are numerous limitations to combining research methods within a single study.

- Combining two methods requires a lot of time to complete both data collection phases, even if the phases are conducted concurrently.
- Mixed methods research can be more resource or labour intensive and require greater financial support.
- There are possible unintentional effects of combining data collection methods in a single study (Vitale, Armenakis & Field 2008). A limitation or weakness of a method could be enhanced if, for example, two methods are mixed (as opposed to enhancing the strengths of both methods by mixing within the one study).
- Using two methods creates twice the amount of a data as a single method, so requires even more time for analysis and interpretation.
- Sound knowledge of each method is needed.
- If the results of both phases of the study are published together, the journal in which they are to be published must be willing to accept a manuscript that could be much lengthier than their recommended guidelines. If they are not willing to do so the researcher might be tempted to salami slice their study, but doing so fails to present the integrated whole and the reader may fail to comprehend the significance of the study.

TIP

In exploring and answering the research question the goal is to see that the different methods complement each other.

Rigour in mixed methods research

Every researcher is expected to provide evidence that their findings are accurate and represent the truth. In quantitative research this is known as **reliability** and **validity**, while in qualitative research it is called trustworthiness (four criteria can be used to determine the trustworthiness of a study: credibility, dependability, confirmability and transferability) (Polit & Beck 2006).

These concepts differ because of the differing paradigms these two methods are associated with. Debates have been and continue to be conducted over the use and application of these terms. Although mixed methods research is a relatively new way of collecting the truth, researchers using this method are not exempt from providing evidence that their results are genuine and credible.

In quantitative research establishing the truth can be much easier than in qualitative research. Quantitative researchers can provide their data for independent analysis: numbers are entered into an equation giving an indisputable answer. Although rigour in quantitative research is a bit more complex than this, it can be even more challenging in qualitative research. After all, how can you demonstrate that a participant's opinions represent the truth? How can a researcher make generalisations from a sample of only three or four participants?

Rigour is initially established by the researcher providing sound justification for choosing to use a mixed methods approach. As mentioned earlier a mixed methods design should not be used simply because it can provide a deeper level of understanding than the use of a single method. The research problem under investigation must lend itself to quantitative and qualitative examination within the one study.

Consider the example of a nurse who wants to know how effective a new wound care product is. Such a problem could be addressed quantitatively. A qualitative question could be to ask patients how they feel about having a pressure ulcer, but this question does not flow logically from the first. A more appropriate question to ask as part of a mixed methods study would be to ask patients if their pain was increased by the new product, because if the new product increases patients' pain, then it should be considered to be ineffective. Or nurses could be asked if using the new product increased the amount of time they spent performing wound dressings as this limitation might outweigh any obvious benefits.

Critiquing mixed methods studies

As a mixed methods approach to research has only recently become popular, research students might struggle to determine the best way to critique studies that have used it. While numerous guidelines exist for critiquing quantitative and qualitative studies (e.g. Polit & Beck 2006; Sandelowski & Barroso 2007), these guidelines cannot simply be combined and used as a tool for evaluating mixed methods studies. Other factors must be considered. Some of these criteria could be used to evaluate a qualitative or quantitative study, but a mixed methods approach must have a distinct and justifiable mixing of research methods.

Mertens (2005) suggests the following guidelines for critiquing the rigour of mixed methods research.

- What are the multiple purposes and questions that justify the use of a mixed methods design?
- Has the researcher matched the purposes and questions to appropriate methods?
- To what extent has the researcher adhered to the criteria that define quality for the quantitative portion of the study?
- To what extent has the researcher adhered to the criteria that define quality for the qualitative portion of the study?
- How has the researcher addressed the tension between potentially conflicting demands of paradigms in the design and implementation of the study?
- Has the researcher appropriately acknowledged the limitations associated with data that were collected to supplement the main data collection of the study?
- Has the researcher integrated the results from the mixed methods? If necessary, how has the researcher explained conflicting findings that resulted from different methods?

- What evidence is there that the researcher developed the design to be responsive to the practical and cultural needs of specific subgroups on the basis of such dimensions as disability, culture, language, reading levels, gender, class, race or ethnicity?

Mertens 2005, p. 304

Creswell and Plano Clark (2007, pp. 163–5) propose additional evaluation standards.

- Does the study meet the common definition of a mixed method study?
- Does the study demonstrate purposeful and intentional collection of both qualitative and quantitative data?
- Do the researchers report the specific type of mixed method design used?
- Does the study demonstrate an awareness of the challenges and limitations of the chosen design?



ACTIVITY

Identify a qualitative or quantitative study of interest to you. Based on its findings use a mixed methods approach (if the study is qualitative, try to conceptualise a study using a quantitative approach and vice versa) to consider what other research questions might be worth exploring. Which of the main mixed methods approaches would be most suitable for your study? Why?

Summary

In this chapter you have learnt the meaning of mixed methods research and its associated characteristics. You have learnt the philosophical basis of this method as well as the different types of mixed method designs. You have learnt how to design and critique a mixed methods study.

Objective 1: Define mixed methods research.

Mixed methods research involves integrating quantitative and qualitative data collection and analysis into a single study.

Objective 2: Describe the reasons for using a mixed methods design.

There are many reasons for using a mixed methods design, the main one being to add strength to a study's conclusions.

Objective 3: Describe the different types of mixed methods research designs.

There are two main mixed method designs: sequential and concurrent. Within each of these are different types.

Objective 4: Understand how mixing research methods can be achieved.

Mixing research methods can be achieved in a number of ways. It may be at the design phase, the data collection phase or the interpretation phase.

Objective 5: Outline the strengths and limitations of mixed methods research.

Mixed methods research has inherent strengths and limitations. The researcher needs to consider all of these before deciding to use this method.

Objective 6: Identify issues to consider when designing a mixed methods study.

When designing a mixed methods study, there are many factors to consider, including how mixing will occur and whether data will be collected sequentially or concurrently.

Objective 7: Understand how to critique a mixed methods study.

When critiquing a mixed methods study, many factors can be evaluated, including the justification for the choice of method and how the methods were mixed.



CASE STUDY

Donna is a registered nurse with 15 years critical care experience. She is employed at a 600 bed hospital that has a very busy emergency department, two intensive care units and a high dependency unit. She is very interested in studying the short-term outcomes of patients discharged from the unit in which she works. She is not sure whether to conduct a qualitative study (e.g. What do ward nurses think affects these patients' outcomes?) or a quantitative study (e.g. How many patients experience an adverse

event? Does time of discharge affect their outcomes?). Donna has heard that mixed methods studies are becoming more commonly used.

What should you tell Donna in relation to

- using a mixed method design
- factors to consider in using this design
- the benefits of using a mixed method design
- the limitations to using a mixed methods design?

Review topics

- 1 What is the difference between mixed methods research and triangulation?
- 2 What is the difference between a method and a methodology?
- 3 What are the philosophical assumptions that underpin a mixed methods approach to research?
- 4 List three benefits of using a mixed methods approach.
- 5 List three limitations of a mixed methods approach. How might these be avoided or minimised?
- 6 What criteria can be used to critique a mixed methods study?

Search me! nursing



Explore Search me! nursing for relevant articles on mixed methods. Search me! is an online library of world-class journals, ebooks and newspapers, including *The Australian* and *The New York Times*, and is updated daily. Log in to Search me! through www.cengage.com/sso using the access card in the front of this book.

Locate the following two articles in the Search me! nursing database, and then critique each of them using the questions below.

Alonso-Coello, P., et al. (2009). Perceptions, attitudes and knowledge of evidence-based medicine in primary care in Spain: a study protocol. *BMC Health Services Research*, 9, p. 80; and Starzomski, R. & Hilton, A. (2000). Patient and family adjustment to kidney transplantation with and without an interim period of dialysis. *Nephrology Nursing Journal*, 27(1), 17–32.

- Does the title of the study refer to mixed methods? If not does it reflect the type of design?
- Does the introduction or background justify the use of a mixed method design?
- Having read the literature review, did you find the gap in the literature obvious?
- Is the aim of the study clearly stated?
- Have ethical issues relevant to the design been addressed?
- Is it clear what mixing has occurred (e.g. data collection, analysis, etc.) and why the researchers did the mix they did?

Search tip: Search me! nursing contains information from both local and international sources. To get the greatest number of results, try using both Australian and American spellings in your searches, e.g. 'globalisation' and 'globalization'; 'organisation' and 'organization'.

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Research in nursing

Further reading

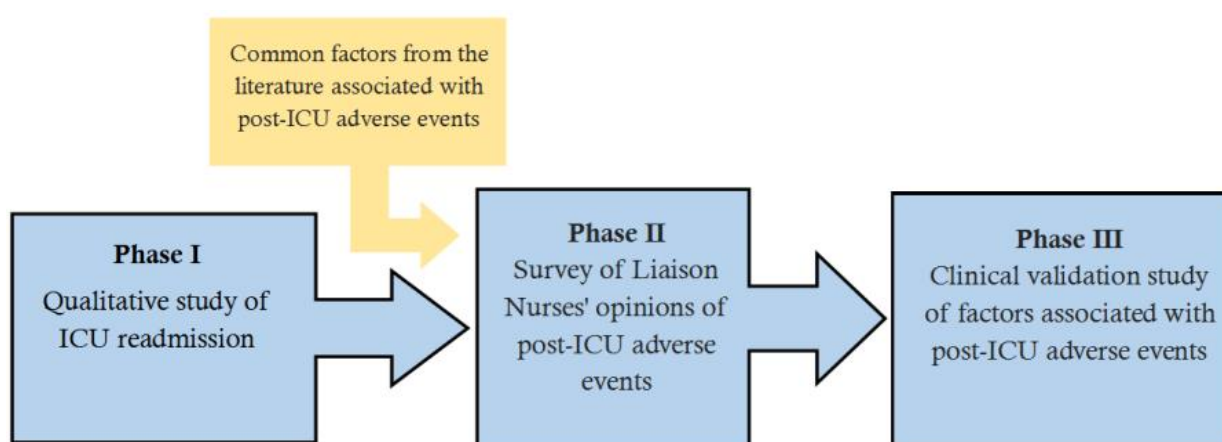
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Research program

The research program presented in this thesis was conducted in three phases (see Figure 1). A mixed method research design was used in the program and differing methods used in each phase. The primary research question addressed by the research program was: What factors are associated with adverse events in patients discharged from ICU? To help answer this question, each phase of the research program addressed a different question.

Figure 1: Overview of the research program



Phase I (Chapter 5)

Studies on readmission have consistently found that most patients are readmitted for cardio-respiratory reasons, but the causes of the clinical deterioration are not clear in the literature (Elliott, 2006). Is it because wards are not resourced to provide the level of respiratory care most post-ICU patients require? If so, is this because lower nurse to patient ratios on the wards do not allow staff the time to provide post-ICU patients with the care and attention they need?

With questions such as these unanswered and with other contributing variables such as systems or organisational factors given little attention in previous research, Phase I of the research program was conceptualised. Phase I was a qualitative, exploratory study which aimed to provide a deeper understanding of the factors associated with ICU readmission.

The first phase of the research program was one of the first published studies to use qualitative methods and provides new insights into post-ICU adverse events (Chapter 5). The perceptions and experiences of nurses were not previously identified in the literature. The findings of Phase I demonstrated that ICU readmission is a complex problem involving system or environment factors as well as the patient's age and or disease processes. The findings also represent potentially modifiable factors within care processes.

Phase II (Chapter 6)

Consistent with a mixed methods research design, the findings from Phase I informed the design of Phase II. Factors identified from a literature review and Phase I were hypothesised to contribute to most adverse events following ICU discharge. The factors were formatted into an online questionnaire and pilot tested; the development and testing are described in a publication in Chapter Six (Elliott et al., 2013).

ICU Liaison Nurses were asked to rate, based on their experience, the extent to which they believed 25 factors contribute to post-ICU adverse events. A five-point Likert scale was used to achieve this (see Appendices). Phase II of the research program was the first study to explore ICU Liaison Nurses' opinions on factors associated with post-ICU adverse events. The findings provide unique insight into the nature of these events and add to the existing body of literature on this acute clinical problem. A limitation of Phase II is that the findings reflect collective expert opinion. The findings of Phase II were therefore validated in the third and final phase of the research program.

Phase III (Chapter 7)

Phase III of the research program was designed to clinically validate the findings of Phase II in real time. A convenience sample of ICU Liaison Nurses from four hospitals in a metropolitan Australian city was recruited to collect data. The findings of Phase II were developed into a paper-based data collection tool. The ICU Liaison Nurses were asked to use the tool to rank 25 factors as to their contribution to actual adverse events following ICU discharge. Data collection also involved the Nurses providing a brief description of each patient, including their medical diagnosis. The

Nurses were also asked to describe any others factors not listed on the tool, which contributed to each adverse event in the patients they encountered.

Chapter summary

This chapter provided an overview of mixed methods research. This design was used in the research program for its inherent ability to provide a deeper understanding of the problem under investigation than a single method alone. The chapter described the philosophical underpinnings of mixed methods research and highlighted this method's strengths and limitations. The way in which a mixed methods design was conducted in the research program to identify factors associated with post-ICU adverse events and to develop an understanding of how these factors interrelate and contribute to this unique clinical problem, was also described.

The preceding chapters have set the scene for the research program. Chapter One provided the background to adverse events, Chapter Two reviewed the literature on post-ICU adverse events, and Chapter Three outlined the conceptual framework which guided the research program. The next chapter describes Phase I of the research program, a qualitative study exploring nurses' opinions and experiences of ICU readmission.

CHAPTER 5

Phase I ICU readmission: nurses' perspective

This chapter contains two manuscripts published in international peer-reviewed critical care journals.

Elliott, M. (2012). Using ICU readmissions as a marker of care quality: time for a rethink? *British Journal of Intensive Care*, 22(3), 86-89.

- Malcolm Elliott – conceived the key intellectual content; and wrote and edited the manuscript drafts.

Elliott, M., Crookes, P., Worrall-Carter, L., & Page, K. (2011). Readmission to intensive care: a qualitative analysis of nurses' perceptions and experiences. *Heart & Lung*, 40(4), 299-309. (IF 1.40)

- Malcolm Elliott – led the conception and design of the project; collected data; led the data analysis; and wrote and edited manuscript drafts.
- Professor Patrick Crookes – advised on the research plan and analysis; assisted with data interpretation.
- Prof Linda Worrall-Carter – advised on data analysis and interpretation; and edited manuscript drafts for key intellectual content.
- Dr Karen Page – assisted with data analysis and interpretation; and edited manuscript drafts for key intellectual content.

Introduction

While much is known about the occurrence of adverse events within acute settings such as Intensive Care, less is known about adverse events in patients recently discharged from ICU. One of the few post-ICU adverse events that have been empirically examined is ICU readmission. This event has received significant research attention for many reasons including its use as a key indicator of ICU performance (Drennan et al., 2010). There are, however, numerous limitations in using readmissions in this way.

Care is delivered in general hospital wards independent of care delivered within ICU. As such, readmissions may be a reflection of suboptimal ward care and not of care within an Intensive Care Unit. For example, ward staff could fail to adequately supervise a post-ICU patient resulting in the patient falling and suffering a cerebral haemorrhage necessitating a second ICU admission. For this reason, some researchers have focused only on readmissions occurring within 72 hours of ICU discharge (Makris et al., 2010). This, however, represents the minority of studies.

Most research on ICU readmission has focused on any second admission to Intensive Care during the same hospitalisation. Quality of care delivered on hospital wards though is not a reliable measure or reflection of ICU performance. The first publication in this chapter highlights this issue; it also challenges the traditional definition of readmission. The methodological characteristics of studies examining ICU readmissions are also critiqued.

The publication also outlines the many variables influencing ICU readmission. For example, advances in medical and surgical techniques mean that patients who would once not have survived their critical illness are now surviving to ICU discharge. Improvements in clinical care also mean that many patients are living longer and with that comes associated co-morbidities. Ward staff today therefore have to care for a much more acute and complex patient population than in the past, many whom will become seriously ill during their hospital admission (Bright et al., 2004; Ryan et al., 2004). If staff skill mix on general wards is not adequate to meet care needs, patients are placed at risk of adverse outcomes and for some this may mean a return to ICU.

Outcomes measures such as readmissions must allow for the contribution of care breakdown or discontinuity between ICU and the wards. Poor communication including inadequate patient handover has been recognised and may be a contributor to readmission (Boutilier, 2007). This problem though is not unique to ICU and the wards. The quality of communication between health professionals including patient handover is currently a priority area for the Australian Commission on Safety and Quality in Health Care. Although ICU staff are responsible for the quality of handover they deliver to ward staff, they are not responsible for care delivered once the patient is admitted to a ward. This is another factor that must be considered when interpreting readmission data.

Research on ICU readmissions found that 5% to 10% of patients are readmitted to ICU and mainly for cardio-respiratory reasons (Elliott, 2006). Research has not identified the causes of readmissions or the associated factors. The primary focus of medical care in ICU is support of the cardiovascular and respiratory systems; most ICU readmissions therefore reflect the need for advanced cardio-respiratory support. However, most primary admissions to ICU, regardless of the primary diagnosis, reflect a need for advanced cardio-respiratory support. The research finding that most ICU readmissions are cardio-respiratory in nature provides little insight into the true causes or characteristics of this adverse event.

The intention of Phase I of the research program was to identify factors which warrant further investigation. Nursing staff were chosen as the key informants for Phase I because they spend more time at the bedside involved in direct patient care than other health professionals. They are therefore ideally positioned to observe and thus comment on care delivered by other clinicians.

Within the context of the research program, Phase I explored the following question: what are nurses' perceptions and experiences of the factors contributing to ICU readmission? Unstructured one-on-one in-depth interviews were conducted of nurses who had worked in ICU and on hospital wards and had cared for patients readmitted to ICU. Nurses who provided support for these staff such as nurse educators, were also interviewed. Data were gathered until saturation was reached; this occurred after interviews with 21 nurses. Phase I of the research program identified five key factors associated with ICU readmissions: premature discharge

from ICU; heavy workloads on the wards; delayed medical care on the wards; lack of adequately qualified ward staff; and patients whom ward staff found to be clinically challenging.

The first publication in this chapter is a conceptual paper on ICU readmission. The second publication presents Phase I of the research program. Both papers have been published in international peer-reviewed journals.

Using ICU readmissions as a marker of care quality: time for a rethink?

REVIEW

Using ICU readmissions as a marker of care quality: time for a rethink?

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Providing quality care to patients in intensive care units (ICUs) is vital, as these units are expensive and in limited supply. Preventable deaths in ICU patients represent not only a human cost, but also a waste of valuable resources. As such, the outcomes of patients admitted to ICUs are often closely examined to ensure these expensive resources have been utilised appropriately. ICU readmission rates are commonly used as a marker of care quality, but this creates significant problems. For example, readmission rates may reflect care delivered after ICU discharge and not before. Furthermore readmission rates may highlight that resources aimed at improving patient outcomes, such as critical care outreach teams, are actually working. This paper describes the limitations of using ICU readmission rates as a marker of care quality.

The quality of care delivered to intensive care unit (ICU) patients and their outcomes are of significant interest to researchers, clinicians and policy-makers. There are many reasons for this; one is the global and chronic shortage of ICU beds, while another is the huge expense associated with providing ICU services. In the UK, for example, an estimated £719 million is spent funding ICU services every year.¹ It is therefore essential that quality care and safety be maintained during the care continuum, as preventable deaths in ICU patients represent, among other things, a significant human cost and a waste of expensive healthcare resources.²

Quality of care and patient safety underpin many health-related policies and professional codes of conduct, as well as being major determinants of patient outcomes. These outcomes are frequently used as key performance indicators or to determine the distribution of healthcare funds. Measuring the performance of ICUs is challenging, however, as these units are dynamic systems and some of the most complex environments of all healthcare facilities.³

One of the most commonly cited ICU outcome measures is the readmission rate. This may be used as an indicator of ICU quality or of the processes of care between ICUs and hospital wards. Numerous professional bodies cite readmission rates as a clinical indicator, including the Intensive Care Society, the Society of Critical Care Medicine, and the Australian and New Zealand Intensive Care Society.⁴⁻⁶ The definition of ICU readmission varies though between these professional groups, ranging from readmission within 48 hours of discharge to a second or subsequent ICU admission during the same hospitalisation. The Australian Council on Healthcare Standards, for example, states that adverse events occurring within 72 hours of ICU discharge are linked to care within ICU, while events occurring after this time are considered to reflect care on the wards or other factors.⁷ If ICU readmissions are to be used as a measure of care quality, it is essential that a rigorous, transparent definition be used. This will allow deficits in clinical care to be easily identified and strategies implemented to prevent their recurrence.

As with any measure of care quality, ICU readmissions have distinct limitations. The aim of this paper is to highlight the conceptual problems inherent in examining ICU readmissions and using them as a key performance indicator. This paper serves to inform clinicians, researchers and policy-makers of issues to consider when using ICU readmission rates as a measure of care quality, and proposes an alternate definition of ICU readmission.

READMISSION DEFINITION

Numerous studies examining ICU readmissions have been conducted over the past three decades. The common definition of ICU readmission in these studies is a second admission to ICU during the same hospitalisation.⁸ This definition is problematic, however, and should be used with caution. The main limitation is that subsequent (or second) admissions to ICU are often elective and planned, such as the second stage of a major surgical procedure. For example, an Australian study of more than 76,000 ICU admissions found that nearly a third of ICU readmissions were elective surgical patients undergoing second-stage procedures.⁹ These readmissions are not the result of suboptimal care, but are instead a continuation of planned surgical treatment and may thus give a false or misleading view of care delivery. The inclusion of these readmissions in outcomes data is therefore questionable.

The importance of differentiating between elective and emergency postoperative patients when reviewing the outcomes of ICU patients has been highlighted. In a prospective observational study of more than 1800 ICU admissions in Israel, patients undergoing emergency admission had greater acuity of illness, required longer postoperative mechanical ventilation and experienced longer ICU lengths of stay.¹⁰ ICU readmissions may therefore not reflect care quality if factors unique to individual patients (e.g. illness acuity, age, presence of comorbidities) influence their outcomes, independent of the care given; a number of studies have shown this to be the case.^{11,12} These factors must be considered when reviewing ICU readmission data in the context of care quality.

To overcome the confounding influence of comorbidities, some researchers have classified ICU readmissions as being either due to the same problem (i.e. the issue that caused the first ICU admission) or the development of a new problem.¹³ In a study of 2352 readmissions to 28 hospitals in North America, for example, the diagnosis responsible for the first ICU admission and the subsequent readmission was identical in less than 20% of patients.¹⁴

If a patient develops a new clinical problem requiring a second ICU admission, the development of this problem may not be due to care quality during the first ICU admission. The new problem could simply be a natural progression of the disease, such as hydrocephalus following subarachnoid haemorrhage. But if the patient is readmitted to the ICU for the same reason as the first admission,

this may be due to a breakdown in continuity of care between the ICU and the wards. It is these readmissions that may be the most sensitive marker of care quality, as they may be a more accurate reflection of care delivery.

ILLNESS ACUITY

A patient may survive a critical illness with the support of an ICU admission, but die soon after on a ward because of a natural progression of their disease process. An outcome such as this could be interpreted as poor post-ICU care, given that disease progression is difficult to quantify. Similarly, if such a patient does not die on the ward but is readmitted to the ICU, the specific cause of the readmission may be difficult to determine. For example, was the patient readmitted because of the natural development of respiratory failure or because of a breakdown in continuity of care? If an ICU readmission is due to a new clinical problem, factors specific to the patient may also contribute.

Patients admitted to acute-care hospitals (and ICUs) are likely to become seriously ill during their admission because of the complexity of their condition.^{15,16} Patients are also often elderly, with associated comorbidities and a decline in physiologic reserves. In addition, advances in medical techniques mean that patients who once would not have survived a critical illness now survive to ICU discharge. All of these factors mean that patients on hospital wards (particularly those just discharged from the ICU) are challenging to care for and require more complex levels of care than patients in the past. If the skill mix of ward staff does not meet patients' care needs then patients may not receive the care required, resulting in clinical deterioration and a return to intensive care. However, the staff skill mix on the wards is beyond the control of ICU staff, as is the quality of ward care delivered. This is an example of an issue unique to the ward environment that must be considered when reviewing readmission rates, particularly if readmissions are assumed to reflect care delivered in the ICU.

CARE CONTINUITY

An examination of the use of outcomes for ICU evaluation and improvement emphasised that ICU outcome measures must account for effects caused by continuity (or discontinuity) of care.¹⁷ Communication or handover problems have been identified between ICUs and general wards, and may be a significant contributor to discontinuity of care and thus readmissions.¹⁸ A study of more than 10,000 patients admitted to a surgical ICU in North America found that some ICU readmissions were caused by a delay in initiating respiratory care on the ward immediately after ICU discharge.¹⁹ These readmissions may reflect care quality on the wards, but they not reflect care delivered in the ICU – although they may be indicative of the quality of the patient handover.

It can be argued that patients readmitted to the ICU after a certain timeframe should be excluded from ICU outcome data.²⁰ For example, a patient could experience a fall while in the ward 10 days after ICU discharge, resulting in an acute subdural haematoma necessitating a second ICU admission. If the patient's first ICU admission was due to respiratory failure or sepsis then there will be no clear relationship between the two ICU admissions. This is the limitation to defining readmissions as any subsequent admission to ICU during the same hospitalisation. If ICU readmissions are going to be considered a marker of care quality, then it must be clear where the care has been sub-optimal (or fallen below acceptable standards).

An ICU readmission can therefore reflect poor care on the wards rather than poor care before ICU discharge. In addition, readmissions can reflect ICU discharge processes, as the discharge of some high-risk ICU patients to a ward (instead of a high-dependency unit) increases the chance of clinical deterioration for these patients.²¹ In a study conducted in a 14-bed ICU in the UK, only 15% of ICU readmissions were related to the pathology of the first ICU admission, confirming the belief that the patients' initial discharge from the ICU was appropriate.²²

TIME OF READMISSION

A study of 1613 cardiac surgery patients admitted to the ICU in a tertiary hospital in Israel found that nearly half of all ICU readmissions occurred within 24 hours of discharge.²³ ICU readmissions that occur this quickly can have numerous causes, including disease progression (rather than poor quality care), incomplete resolution of a critical illness and premature ICU discharge because of a bed shortage. Premature discharge from the ICU may expose patients to inadequate levels of care and place them at risk of clinical deterioration.¹⁴ It is possible, however, that such deterioration would occur even if the patient remained in the ICU for longer. In another study of 95,000 ICU patients in 22 Australian hospitals, 75% of readmissions occurred within 7 days of ICU discharge.⁹ These readmissions could be due to the development of a new disease process independent of the care provided. If the ICU discharge was deemed premature, however, this could reflect poor bed management rather than poor care in the ICU or on the wards.

TIME OF DISCHARGE

Some discharges from ICU are premature or unplanned, and this is commonly due to the high demand for ICU beds.^{24,25} Premature ICU discharge implies patients were discharged before they should have been or were well enough to no longer require intensive care. If a patient is discharged prematurely from an ICU, it is easy to apportion the blame for this to ICU staff. ICU staff could be questioned as to why some ICU discharges occur after hours (e.g. after 20:00 hours), given that these patients have poorer outcomes than those discharged during daylight hours.^{26,27}

It is unlikely, though, that ICU staff willingly discharge patients prematurely. Senior ICU staff are undoubtedly aware that premature or after-hours ICU discharge places the patient at risk of readmission and other adverse events, particularly if the patient's critical illness has not completely resolved. However, if an ICU bed is needed for a more acutely ill patient then ICU staff may have little choice than to discharge another patient after hours or prematurely.²⁸ Later readmission of these patients to the ICU may not reflect poor clinical care, but poor bed management at the higher administrative level. It may also reflect the limited resources available to clinicians at the bedside.

Pilcher *et al.* have suggested that after-hours discharges may be reduced (and outcomes improved) by providing more ICU beds.²⁶ This is a simple solution and an obvious one. It confirms the hypothesis that after-hours ICU discharges are an economic or administrative issue, rather than being down to poor clinical care. ICU staff should not be blamed for a shortage of ICU beds or other resources, and may struggle to provide quality care with the limited resources available to them. But a shortage of resources is not apparent when ICU readmission rates are cited.



Because of the increasing acuity of hospitalised patients in tertiary-care hospitals, many resources have been developed to help ward staff in providing acute care. These resources also provide assistance to ward staff when caring for patients discharged from ICUs. Examples include outreach teams, patient-at-risk teams and ICU liaison nurses.^{29–31} The main goal of these resources is to improve patient outcomes and provide support to ward staff when caring for post-ICU patients. However, some of these resources may actually increase ICU readmission rates by ensuring they occur in a timely fashion (i.e. before the patient dies on the ward) rather than preventing them entirely.³² An increase in readmission rates after these resources are implemented locally may therefore reflect better care rather than worse.

METHODOLOGICAL ISSUES

For a clinical problem to be examined, a clear definition of the issue under investigation needs to be articulated. A research question should clearly identify the variables under investigation, specify the population being studied and imply the possibility of empirical testing.³³ More than 20 studies examining ICU readmissions have been published over the last three decades, highlighting the importance given to this clinical problem as an outcome measure and area of clinical concern.⁸ Many of these studies have used the same data-collection method: retrospective review of medical records. But this research method has significant limitations.

Although medical records are commonly used as a source of research data, the documentation within them is widely recognised as being vague, incomplete and subjective.^{34,35} Medical records may therefore contain little useful information about why the patient deteriorated or required a second ICU admission. These records may also provide little insight into the quality of care delivered. Readmission data based on information extracted from medical records alone should therefore not be considered in isolation, as these rates may reflect nothing more than the quality of documentation (as opposed to the quality of care). Other data should be collected (or other methods used) to confirm what is contained (or implied) in medical records.

A further limitation of studies on ICU readmission is that many cite the medical diagnosis on readmission, but not the underlying cause of the patient's deterioration. This may be because the actual cause is very difficult to identify due to the complexity of care delivery and its many influencing variables. To assume that ICU readmission rates reflect care quality places clinicians in a vulnerable position: ICU staff cannot be responsible for care provided on the wards, while ward staff cannot be responsible for care provided in the ICU.

Patients discharged from ICUs should ideally be sent to a high-dependency area rather than a ward environment, particularly if their critical illness has not completely resolved. This allows an increased level of care (that the patient still requires), which wards are not resourced to provide. A hospital that does not have a high-dependency unit may therefore have higher ICU readmission rates than one that does.^{21,36} ICU readmission data may therefore reflect only resource availability, not care quality. This issue must be taken into account when reviewing ICU readmission rates.

CLINICAL SIGNIFICANCE

Intensive care medicine is both resource- and labour-intensive, and patients are often complex and at high risk of adverse

events.³⁷ Patients are often admitted to the ICU in a moribund state, providing a unique challenge for the clinicians attempting resuscitation. Some deaths in the ICU are thus inevitable and, as such, ICU mortality rates may not be a valid reflection of care quality. But when as many as 9% of patients die after ICU care but before hospital discharge, questions may be raised about the quality of care provided or the benefit of the ICU admission in the first instance.³⁸ A 5-year study in one British hospital found that of 153 patients who died on wards after ICU discharge, 20% were expected to survive.³⁹

Quality indicators are increasingly being used in healthcare to support and guide improvements in care quality.⁴⁰ But quality in healthcare is difficult to define and quantify.³⁷ Patient outcomes after ICU discharge are often cited as markers of care quality. If these outcomes are poor then the validity of spending vast healthcare funds on critically ill patients may be challenged. But if this occurs, an examination of post-ICU care must also be conducted to identify where the true cause of the problem exists.

An ICU readmission should not necessarily be considered an adverse event or marker of poor care quality. ICU readmissions may actually indicate that safety systems (e.g. critical care outreach teams) are working effectively. It is known that patients readmitted to ICUs have worse outcomes than those not readmitted, although currently this is only reflected in statistical data.⁴¹ It is not clear whether there is a clinical difference in outcomes between these two groups; after all, some patients may die on the ward after ICU discharge without being readmitted. These patients may have received better care, as the question of whether to resuscitate may have been asked of the patient or his or her family.

Some patients readmitted to ICUs who later die may have received a more dignified death if they had been asked the same question. ICU readmissions may therefore reflect a patient cohort that should have received better care – but, as they did not, a return to the ICU was inevitable. Further research is needed to confirm whether this is true, but such research will need a rigorous definition of ICU readmission. If these patients die despite their readmission and it is speculated they would have survived with better care, then those patients should be identified and targeted on the wards (e.g. followed closely by outreach teams). If these deaths were considered inevitable despite the care received then this also represents a group of patients worth identifying, as such patients can be spared the expense of a second ICU readmission (and the bed can be used for a patient with a better prognosis).

One of the current definitions of ICU readmission is a second admission to the ICU within 72 hours of the initial discharge. Any subsequent admissions to the ICU after this time that are labelled a readmission should be challenged. Furthermore, patients who have a planned subsequent admission to the ICU during the same hospital stay for the second stage of a surgical procedure should not be included in outcomes data; these admissions are not caused by a breakdown in care quality. Only ICU readmissions that are due to inadequate care should be labelled as readmissions. If the inadequate care was on a hospital ward then these readmissions should be included in data reflecting ward care, not care within the ICU.

CONCLUSION

Intensive care is one of the most costly areas of hospital care today.⁴² As such, it is vital that ICU patients receive quality care both during their ICU admission and following dis-



charge to a ward. ICU readmissions are commonly used as a marker of care quality. This is inherently problematic, as the validity of the commonly used definition of ICU readmission is questionable. There is also the problem of who is actually responsible for, or what causes, readmissions. If ICU readmissions are going to be used as an outcome measure then a more reliable definition is needed, as well as more rigorous ways of determining where the cause of the problem truly exists. If readmission rates reflect care quality then the natural question to ask is: who is to blame for poor care?

Blaming staff contributes little towards resolving the actual problem. ICU readmission rates and many studies of this problem fail to reflect the challenging conditions under which staff deliver care. Readmission rates do not reveal the many factors that influence patient care, such as staff shortages or workloads, although they are quite likely to be caused by them. This must be considered when reviewing ICU readmission data.

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Readmission to intensive care: a qualitative analysis of nurses' perceptions and experiences



HEART & LUNG

Readmission to intensive care: A qualitative analysis of nurses' perceptions and experiences

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ABSTRACT

OBJECTIVE: The purpose of this study was to identify and describe the experiences and perceptions of nurses regarding the factors that contribute to the readmission of patients to intensive care.

METHODS: Twenty-one nurses participated in the study. Unstructured interviews were conducted to ascertain participants' perceptions and experiences. Interview transcripts were analyzed using a constant comparison method to identify major conceptual categories.

RESULTS: Five main themes were identified that contributed to the readmission of patients to intensive care: premature discharge from intensive care, delayed medical care at the ward level, heavy nursing workloads, lack of adequately qualified staff, and clinically "challenging" patients who demanded a different skill set from the nurses.

CONCLUSION: Discharging patients early from the intensive care unit when they are clinically unstable creates issues around workload and significantly challenges ward staff. It also increases the likelihood of patients being readmitted to the intensive care unit. Hospital managers need to look at ways of increasing the knowledge and skills of ward staff or identify more appropriate environments for managing these acutely ill patients.

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Unplanned readmissions to the intensive care unit (ICU) impose a significant burden on patients and the healthcare system. Readmissions are costly and place considerable pressure on a system with finite resources. It is not surprising that research indicates that patients readmitted to ICU within the same hospital stay

experience poorer outcomes than those not readmitted. What is notable is that these patients' overall mortality rates are up to 6 times higher,^{1,2} they have lengths of stay twice as long as non-readmitted patients, and they are 11 times more likely to die in hospital.³ To date, only one study⁴ has examined ICU readmissions using

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a qualitative perspective. This study was conducted 17 years ago collecting mainly quantitative data. Clinicians were interviewed, but it was unclear how many and whether data saturation was attained. Identifying the factors contributing to ICU readmissions could improve health outcomes and facilitate the optimal use of limited health resources.

BACKGROUND

A search of CINAHL, Medline, Embase, and Psycinfo databases identified 42 published studies that have examined readmissions to ICU. Search terms used were *intensive/critical care*, *readmission*, and *recidivism*. Readmission is defined in these studies as “a second admission to ICU during the same hospitalization.” There has been heightened interest in ICU readmissions in the last 7 years, with 23 of these studies being published since 2003. This recent interest probably reflects the increased demand for ICU beds and the resulting pressure on clinicians to use ICU resources more efficiently.

All but 1 of the 42 studies used a quantitative approach. The readmission rate in these studies ranged from .1% to 19.4%.^{5,6} Eleven studies conducted a retrospective analysis of data routinely recorded on patients admitted to ICU, the largest analyzing a dataset of 4684 admissions; this did not include analysis of medical records. The main findings were that readmissions were more common among patients who responded poorly to treatment (eg, a patient remaining septic despite receiving antibiotics). Readmission risk was increased when patients were transferred to the ICU from another hospital or general medicine ward. A delay in readmission was also found to affect prognosis.⁶ Although the issue is controversial, Russell⁴ speculates that improved care on wards (rather than admission to a high-dependency unit [HDU]) after initial ICU discharge may reduce readmission rates and improve outcomes.

Nineteen of the readmission studies conducted between 1999 and 2009 were prospective observational studies. The largest sample size was 136,161 patients.⁷ Readmission rates in these studies ranged from 1.3% to 19.4%.^{8,9} These studies found that respiratory complications were the main reason for readmission. Residual organ dysfunction at discharge increased the chance of a readmission, and comorbidities were a risk factor for ICU readmission 3 or more days after discharge. It was suggested that quality of care in the ICU and on the wards is likely to be associated with readmission.

Twelve studies conducted a retrospective analysis of the medical records of patients discharged from the ICU. The largest sample was 25,717 patients,¹⁰ and readmission rates ranged from .89% to 12%.^{11,12} The main findings were that respiratory and cardiac deterioration were the main reasons for readmission, inadequate respiratory care on the wards contributed

to patients' deterioration, and ICU readmission was associated with substantial resource consumption.

The only study that included a qualitative approach described the opinions of patients and their family members regarding their experience of an ICU readmission.⁴ This Australian study was situated in a metropolitan, tertiary referral hospital with a 14-bed ICU. The study was conducted for 6 months, and during this time there were 639 ICU admissions. A total of 298 patients consented to participate; of these, 18 underwent an in-depth interview, 68 underwent a structured interview, and 212 completed a self-reported questionnaire. Staff were also interviewed, but the number who participated was not mentioned in the article.

The readmission rate in this study was 10.5%; 46 patients were admitted to the ICU twice, 7 patients were admitted 3 times, 1 patient was admitted 4 times, and 1 patient was admitted 5 times. Of the first admissions to ICU, 35% were postoperative, 27% were cardiac related, and 14% were respiratory related. Of the second admissions, 38% were respiratory related, 25% were cardiac related, and 22% were postoperative. During the in-depth interviews, 2 key themes emerged: a lack of resources on general wards and a lack of communication between ICU and the ward staff.⁴ Data from the questionnaires and other interviews also identified progression of the patient's illness, postoperative care requirements, and inadequate care on the wards after ICU discharge (eg, not aspirating a nasogastric tube).

Quantitative studies have used a variety of methods to develop the understanding of ICU readmissions. Some of these studies analyzed datasets of more than 100,000 patients.⁷ The disease processes commonly associated with these readmissions have been described in these studies, although the factors resulting in the development of these acute illnesses have not. A combination of qualitative and quantitative data provides a more complete picture by noting trends and generalizations, as well as in-depth knowledge of participants' perspectives.¹³ The purpose of this qualitative, descriptive study therefore was to provide a deeper understanding of factors contributing to the readmission of patients to the ICU from the nurses' perspective. The aim was to ascertain nurses' perceptions and experiences of the factors that contribute to the readmission of patients to the ICU.

SETTING

The study was conducted in a 500-bed tertiary referral hospital in New South Wales, Australia, that serves a population of 250,000 and admits 50,000 patients per year. The hospital's clinical specialties include critical care, surgery, and cancer care. The 12-bed general ICU is managed by medical staff with specialist intensive care training. Admission and discharge of patients are

dependent on approval by an ICU consultant or senior registrar.

Once it is determined that a patient in ICU can be discharged, the hospital's bed manager is contacted to arrange a bed on the appropriate ward. If a bed is available immediately, the patient will be discharged to the ward. If not, the patient remains in the ICU until a vacant bed is found on one of the wards. The hospital also uses an ICU liaison nurse whose role is to help ensure continuity of care after patients are discharged from the ICU. This role was created in response to the increasing acuity of patients being discharged from the ICU to general wards and the desire to provide these patients with access to some of the resources of the ICU without having to send the patient back to the ICU.

The study hospital did not employ respiratory therapists. Medical officers order the patients' treatment (eg, oxygen therapy), which is then implemented by the nursing staff. Once a patient has been discharged from the ICU, the ICU staff (medical and nursing) are no longer involved in the patient's care. Instead, ward staff provide the nursing care while the primary admitting medical team (eg, cardiology) provide the ongoing medical care. If the primary medical team thinks a patient should be admitted (or readmitted) to the ICU, they contact the ICU medical staff for a consultation.

Care on the wards is also influenced by other variables, such as skill mix and nurse:patient ratios. In this study, the nurses would have a case load of 4 to 6 patients, irrespective of acuity. Furthermore, patients are admitted to the hospital on the basis of diagnosis and not nursing acuity. For example, patients requiring care of a neurologist are admitted to the neurology ward; this could result in several highly dependent patients with stroke being admitted to that ward in the same timeframe, without any change in numbers or skill mix of the nurses.

In terms of nursing care, specialist or postgraduate qualifications were not required for the nurses to work in the ICU, which meant that some of the nurses had only 1 or 2 years of postgraduate experience. Similarly, postgraduate qualifications were not required to work on the specialist wards of the hospital. Participant demographics resembled the general nursing population who cared for patients during or after their ICU admission in the study hospital. This point is useful to consider in terms of transferability of the findings. Polit and Beck¹⁴ discuss the degree to which one can transfer across samples depends on the similarities and the people to whom the findings might be applied.

MATERIALS AND METHODS

Participant Recruitment

To gain a complete picture of the readmission phenomenon, participants were recruited from 3 practice

domains: the ICU, hospital wards, and nurses in education and managerial positions. Information sessions about the study were conducted in the ICU and on the hospital wards. During these sessions, nurses were invited to participate in the study if they had been involved in the care process of a patient who had been readmitted to the ICU. Some participants volunteered because of the "snow balling" effect of nurses either speaking with each other about the study or recommending another nurse to participate.

Consent

The study was approved by university and health service ethics committees. The ethical principles highlighted in the Declaration of Helsinki¹⁵ were followed in the study. During the information sessions, potential participants were informed that participation was voluntary and that their decision to participate (or refuse to) would not affect their employment in any way. Participants were also informed that the interviewer was not a hospital employee and that all information provided would be de-identified and anonymity maintained. They were also informed of the researcher's intention to publish the results of the study but that neither their name nor the hospital's name would appear in any publication. This was done to help establish trust with the participants and encourage them to respond freely and honestly. All participants gave written informed consent before their interview.

Data Gathering

Data were gathered by unstructured one-to-one interviews. To encourage participants to speak freely, each interview was conducted in a private office in the hospital and lasted approximately 40 minutes. To ensure anonymity, confidentiality, and privacy,¹⁶ participants' names were not used during each interview and participants were allocated a code name for the study (eg, "nurse 2b"). All participants consented to their interview being audiotaped. Interview transcripts and tapes were kept in a locked filing cabinet in a locked office, as required by the ethics committee. If any sensitive issues arose during an interview, the participant was encouraged to discuss it with his/her unit manager or educator.

At the start of the interviews, participants were told that the interviewer would ask about their experiences of caring for patients who had been readmitted to the ICU and use further questions to explore their responses in detail. This was done to gain a thorough understanding of contributing factors from the participant's perspective. It also provided the participant with an understanding of the interviewer's role during the interview. Each interview commenced with the same statement ("tell me your experiences of caring for patients who have been readmitted to ICU"). This consistent approach to data collection helped ensure

trustworthiness.¹⁷ Participants were asked to provide a detailed and honest account in response to the interviewer's questions. They were informed that they did not have to provide any information that they felt uncomfortable providing or that was particularly sensitive. The interview tapes were professionally transcribed.

Field notes were made during and immediately after each interview. These were used to help the interviewer synthesize and understand the data that had just been collected and to make memos about significant concepts that were mentioned and worthy of exploration in future interviews. This also helped establish a decision trail. Memos have been described as a way of capturing and preserving conceptual analysis, promoting ongoing inquiry and stimulating the researcher's theoretic creativity.¹⁸

Data Analysis

Participants from the 3 practice domains were recruited and interviewed until data saturation occurred. Consistent with constant, comparative analysis, data were analyzed before the next participant was interviewed. Saturation was reached when no new themes were identified during analysis. Data saturation was achieved within similar numbers for each of the groups of nurses; from the perspective of the ICU nurses, ward nurses, and educators and managers, this occurred after 8, 6, and 7 nurses had been interviewed, respectively (Table 1). Participants had between 2 and 20 years of postgraduate experience. Nineteen of the nurses were female, and 2 of the nurses were male. All volunteered and gave informed consent to participate in the study.

Constant, comparative analysis¹⁹ was used to identify conceptual categories (Figure 1). The first stage involved "open coding." During this initial coding process, data were broken down into discrete parts, closely examined, and compared for similarities and differences. Each line of the transcribed interviews was read, and a label was applied to each theme or process that related to ICU readmissions. The second stage of coding involved "axial coding." The purpose of this stage of coding was to reassemble data that were broken down during open coding.¹⁹ Data codes that emerged during the open coding process were compared to identify themes. Data were managed using the qualitative software program N-Vivo.²⁰

Findings

Themes emerging from the data related to the patient, staff, or working conditions. The 5 key themes were premature discharge, challenging patients, lack of skilled staff, heavy workloads, and delayed care.

Table 1 – Participant demographics

Role	Years of experience in role		
	<2	2-5	>5
ICU nurse (n = 8)	2	5	1
Wards nurse (n = 6)	0	4	2
Other (n = 7)			
After hours' clinical support nurse (n = 1)		1	
Nurse educators (n = 2)		2	
Ward manager (n = 1)		1	
Manager of the surgical/critical care division (n = 1)			1
Manager of the quality care division (n = 1)	1		
ICU liaison nurse (n = 1)		1	

ICU, intensive care unit.

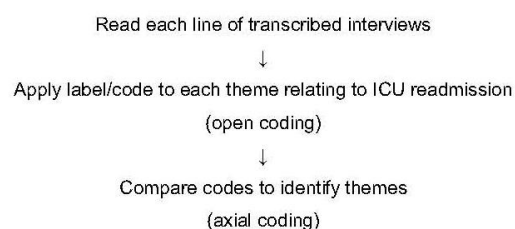


Figure 1 – Constant, comparative analysis. ICU, intensive care unit.

Premature Discharge

The premature discharge of patients from the ICU was a factor cited by participants. Premature discharge was defined as a patient being discharged from the ICU to a general ward before he/she was ready to be discharged. The most common reason cited for this was a shortage of ICU beds. Participants reported that this mainly occurred because a patient on the hospital wards was more critically ill than a patient in the ICU, such as a patient having a cardiac arrest on one of the wards. When asked why patients were being discharged prematurely from the ICU, an experienced ward nurse stated:

"They've got a certain amount of ICU beds, HDU beds, and they have a certain amount of staff, and if you've got someone sicker that needs a bed, they need to get someone out of the unit, and this has been the situation previously. But in the past sometimes you know you got told 'well we've got to get someone out of ICU because there's a ventilated patient in A&E,' and so you know and they sort of move along and I guess probably the staff down there would assist the patient and say 'OK you know

um this patient could be ready for the ward and send them out.” (quote from participant 3a)

A senior nurse manager in charge of the hospital's surgical and critical care division suggested that patients are often sent out of ICU prematurely because of necessity. She cited the demand for ICU beds, elective postoperative admissions, or patient transfers from other hospitals as the common reasons.

Participants also defined premature discharge from the ICU as patients being discharged and sent to a ward on the same day they are extubated. A ward nurse (participant 3a) stated:

“On this ward it's the fact that they're sent out too soon, and they are not ready for the care that we offer on the ward. Nothing to do with the level of care that we can offer, it is adequate, but you know not for that patient, not for that kind of patient you know that's sort of been sent out too soon, they are still quite ill and so of course they tend to deteriorate and go back.”

Many participants thought that if patients had remained in ICU a bit longer, any deterioration would have been detected earlier because of the higher nurse-to-patient ratios. They believed this would have prevented ICU readmissions. One ICU nurse provided a reason for this:

“So they will shift that patient out maybe only a couple of hours early, but those couple of hours might have made the difference between one more treatment of continuous positive airway pressure, something that they won't receive on the ward, and if the source of their sepsis is in their chest, that extra hour of expansion might be the kick to help them along.” (quote from participant 2a)

Clinically Challenging Patients

Participants indicated that compared with previous years, caring for general ward patients was more challenging because they were sicker and therefore required a higher level of care. When asked, an experienced ward nurse provided the following example of this type of patient:

“... needing hourly obs (observations) or they've got antibiotic after antibiotic after antibiotic. They've got to be sponged in bed, they may be needing nasogastric stuff or percutaneous endoscopic gastrostomy feeds and things like that. Lots of drains, they may have 2 underwater sealed drains, 2 sump drains, a redivac, 3 antibiotics as well.” (quote from participant 8c)

The premature discharge of patients from the ICU meant that patients who were still needing ICU level

care were being admitted to general wards. Participants thought this put these patients at risk of ICU readmission because they perceived the wards were not resourced to provide the care patients needed. Participants described these patients as being clinically unstable, such as having fluctuating blood pressure. Because of this instability, patients required more monitoring by nursing staff, which was not normally possible in a general ward staffing allocation or part of these nurses' skill base. Participants also indicated that some patients on general wards were too sick to be there because of the severity of their condition and the high level and intensity of their care needs.

Another reason why nurses described their patients as challenging is that the healthier (ie, less sick or dependent) patients were being cared for elsewhere. Participants reported that surgical patients who might have previously required a 5- or 7-day hospital admission were now day-surgery or short-stay cases. A nurse educator said that in the past, these patients tended to “offset” the more challenging ones, making the workload more manageable for ward staff. However, this type of patient was now admitted to other areas of the hospital. This meant that ward nurses were not able to spend as much time with more dependent patients, such as those who had been recently discharged from the ICU. These patients were therefore not able to receive the care they needed, often resulting in a readmission to the ICU. A senior ward nurse reported that some of the patients who come to the ward from the ICU still required one-on-one nursing, which the wards were not resourced to provide. The nurse (participant 7e) in charge of the hospital's clinical practice unit provided an example:

“...you've got a patient who has had, you know Whipple's (pancreaticoduodenectomy) or something, and they're receiving total parenteral nutrition with titrated insulin infusion. They've got 4 sump drains in. They're on massive fluid replacement. They're on fourth hourly antibiotics. The dressings, some of them will come back with open abdomens with the mesh, so it takes a few of you to do the dressing, you're replacing the sump fluid every hour let alone a colostomy bag, a nasogastric tube, aspirates, the whole thing. They are incredibly sick, high acuity surgical patients.”

She reported that when she started working on the ward many years earlier, the nurses would care for 6 or more patients, but they were not as busy with that workload as staff currently were with fewer patients. This was due to patients being more dependent than patients in previous years. This was reinforced by another ward nurse (participant 9a) who stated:

“Wards are equipped to nurse ward patients, not ICU patients. If patients deteriorate, it may not be due to inadequate care but rather inappropriate admission to a unit that is not designed to care for

that type of patient, just as ICU is not designed for long-term care.”

The nurse in charge of the hospital’s clinical practice improvement unit said that many ward patients today were the high-dependency patients of 6 months ago. By this she meant that the types of patients who were dependent enough to require admission to a HDU 6 months ago now met the criteria for admission to a general ward:

“You see some patients walk through the door, and they really don’t look like they’d last more than a couple of weeks. They’re that sick that you don’t know how they could possibly operate on them.” (quote from participant 7e)

Ward staff therefore obviously struggled to provide the care needed because they may not have the skills to care for patients who are so clinically unstable, and even if they did, there probably would not be enough staff to do so.

Lack of Skilled Staff

Several participants thought that many nurses, particularly those on general wards, did not have the knowledge or skills required to care for acutely ill patients. This was a particular problem among new graduate nurses, with one senior ward nurse (participant 7b) saying, “we’ve got new graduates that...really don’t have a clue.” Another ward nurse (participant 8d) made a similar comment:

“There is a lack of senior nurses; having one on a shift may not be enough if the other staff are junior, inexperienced or enrolled nurses, particularly as senior staff will have their own patient load; less experienced staff may not be able to detect subtle patient changes.”

In contrast, a nurse educator said that some new graduates can determine that a patient’s condition is deteriorating and might contact a doctor, but these nurses did not know what care the patient might need and therefore could not determine if the care prescribed was appropriate. For example, a ward nurse educator highlighted the problem posed by employing new graduate nurses:

“There’s certainly some new grads out there that I wouldn’t be happy with them looking after a patient straight out of ICU or HDU, but um, the ones that we have at the moment I have real bad problems with.” (quote from participant 7c)

One participant (8b) had worked on a general ward for 1 year and ICU for 2 years. He commented on what he knew now with what he knew when he was a new graduate on the wards: “There are a lot of things

I wouldn’t have picked up on.” Conversely, another nurse educator said that new graduates often called a doctor as soon as they had identified a change in a patient’s condition. However, these nurses often failed to collect the relevant information the doctor needed to treat the patient.

Participants reported that many experienced ward nurses were also not able to recognize that a patient had deteriorated or was acutely ill. This meant that many patients did not receive appropriate care until they had deteriorated significantly, by which time an ICU readmission was inevitable. One of the hospital’s ICU liaison nurses thought that many ICU readmissions and subsequent deaths could have been prevented with more thorough patient assessment than those she had witnessed. She had encountered patients who had their deterioration on a ward clearly documented, but no action was instigated. She thought this was primarily due to a lack of recognition of the change in the patient’s condition by ward staff:

“...early intervention, I think, is of vital importance, and with that is being able to identify your signs and symptoms, and all that comes back to knowledge and unless the nurses go and do postgraduate qualifications. I think it’s, it’s just like a bad cycle, and I think people don’t realize how much they don’t know until they actually go and do a course.” (quote from participant 8e)

The lack of skilled staff was said to have contributed to ICU readmissions in other ways. A ward nurse educator suggested that if nurses see a particular medical device only 1 or 2 times per year, it is difficult for them to maintain their competence in caring for a patient with such a device. An example was changing the inner cannula of tracheostomy tubes, which one ward nurse (participant 9a) said at times did not get done because staff “...just don’t know, so they don’t touch it.” This situation would also occur if nurses had to care for patients outside their area of specialization. A nurse educator on the wards for example stated that “if the orthopedic ward gets something out of their specialty, they seem to have problems.” This lack of skills or knowledge meant that patient care was often delayed or inadequate, also resulting in an ICU readmission.

Heavy Workloads

Having to care for patients who were sicker than others significantly affected ward nurses’ workloads and thus the time they had to provide care. An experienced ward nurse highlighted this problem:

“...I had 6 to 7 patients when I started on this ward, 6 to 7 years ago, and I didn’t find that was extremely hard or frustrating, but now I can have 4 patients and be run off my feet. (quote from participant 8c)

An ICU nurse who had worked on the wards of the hospital made the following comment:

“...that ward is atrocious, and I’ve been deployed there and it’s awful because they have patients with 5 pigtail drains who are bed bound with you know 2 nasogastric tubes, and you know are just in a terrible condition. They have been there for 3 months. It’s really heavy nursing, and I can understand how it’s difficult.” (quote from participant 8f)

The nurse in charge of the hospital’s clinical practice improvement unit described the nurses on one ward as highly skilled surgical nurses, but despite this said that workloads were always a problem. The workload of senior staff on the general wards was further increased if they were the staff member in charge of the shift and had to supervise nurses who were new or inexperienced, while also having their own patient load.

Although ward nurses were supposed to only be allocated 3 or 4 patients to care for in a shift, typically they cared for a lot more because of staff shortages. If 1 or more of these patients were acutely unwell or just been discharged from ICU, some patients were neglected or received what one ward nurse referred to as minimal care. Even having less than 4 patients was problematic if 1 of these patients was acutely unwell or had just been discharged from ICU. An experienced ward nurse (participant 7b) provided the following example:

“We did everything up here that you could possibly do, electrocardiograms, but...you know you’ve got 1 nurse to 6 patients, and looking after this patient was, it would have been too much to keep up regular monitoring...you know to see if she was going to become tachycardic, and then later on she went back to the operating room and had 1.5 liters evacuated from her gallbladder bed.”

Some ICU nurses thought that once patients were admitted to a general ward, they did not receive the same nursing care they had received in the ICU. The main reason for this was the nurse/patient ratios, which was often because of a lack of staff. When a ward was understaffed, each nurse was forced to care for more patients than usual. One ward nurse highlighted this problem:

“...if you’ve got enough staff on, I feel adequately safe to look after the patients that are quite sick. If there’s not enough staff on, then you’re really not spending enough time with them.” (quote from participant 8c)

An ICU nurse expressed similar concerns about sending patients with a lot of airway secretions to the wards, fearing they would not receive the frequent airway suctioning required. Another ICU nurse (participant 8j) who had recently worked on a general

ward suggested the reason this type of patient is readmitted to ICU is “...because they haven’t been cared for properly respiratory wise.” She said that this was because ward nurses are not able to provide frequent suctioning of the upper airways because of their heavy workloads. These workloads often resulted in essential patient care being delayed or even omitted. A nurse educator employed as a resource for ward staff stated that nurses on the wards

“... don’t have the time to spend with the patients to ensure they do their physio and that...sometimes on days...they’re hard pushed to get through the basic stuff they need to do to get through a shift.” (quote from participant 7c)

Delayed Care

The delay in providing care to acutely ill patients on general wards was commonly cited by participants as a major factor contributing to ICU readmissions. This delay could occur for a number of different reasons. In a teaching hospital, each medical team usually consists of junior and senior members. As the junior member of this team, the intern is generally the first medical officer to review or treat patients. Ward nurses described the knowledge and skills of many interns as lacking or being inadequate, for example, a nurse described an intern who mistook hypervolemia for a pulmonary embolus.

Participants reported that because of their inexperience, interns were often unsure about the care patients needed and frequently had to refer to their senior medical colleagues for guidance or advice. However, participants reported that these senior clinicians were also often unsure of the appropriate care needed and would often ask for advice from other medical teams, such as ICU. All of this would take time, during which patients would continue to deteriorate.

Participants also described a reluctance by other staff to seek help where needed. When describing some of the delays in patient care, the nurse manager (participant 7d) for surgical and critical care said the following:

“...oftentimes, the nurses in the HDU especially were too intimidated to approach the medical staff in ICU and they had to go through the primary medical team.”

Unlike some hospitals, the ICU staff in the study hospital did not provide care for patients also in the HDU. The primary medical team caring for the patient would intervene initially. Again this meant that medical teams with no ICU experience would manage patients when they first deteriorated, and most of the patients in HDU were quite sick to begin with. Unfortunately, the ICU in this study did not have the

resources to assess HDU or ward patients on a regular basis.

Some participants reported that many nurses lacked assertiveness and the ability to clearly articulate how sick patients actually are. This resulted in some nursing staff being ignored by medical staff or not being taken seriously, and the patient therefore not receiving the appropriate care. The nurse (participant 7e) in charge of the hospital's clinical practice improvement unit, for example, described the following incident:

"I had a patient who was clinically deteriorating. He had been unwell for a few days postoperatively. I think getting a bit septic, getting a bit confused, hypoxic, and the nursing staff had written an incident form saying 'I have this patient who is deteriorating, they are really sick, and I rang the registrar and the registrar ordered some Serenace, and this was completely inappropriate.' So I thought 'well I think it was possibly inappropriate as well.' So I went to the registrar and I said, 'I was just wondering why with this pattern of clinical deterioration you would order Serenace over the phone?' He said 'I didn't know the patient was sick.' 'The nurse said to me this man is really going off,' and he said 'and I thought going off' because he had been confused, that he was going off and getting agro so I ordered some Serenace."

Similarly, another ward nurse (participant 8d) reported that doctors want to hear "something concrete" and that they do not tend to recognize or appreciate nurses' gut instincts. These communication issues between medical and nursing staff delayed patients' care, which resulted in ICU readmissions.

DISCUSSION

This study used unstructured interviews to ascertain a small cohort of nurses' perceptions and experiences of the readmission of patients to ICU. Five key themes emerged from the data: premature discharge from intensive care, delayed medical care at the ward level, heavy nursing workloads, lack of adequately qualified staff, and clinically "challenging" patients who demanded a different skill set from the nurses.

The nurses in this study highlighted that premature discharge was frequent in patients readmitted to the ICU. Premature discharge was defined by participants as a patient being discharged from ICU to a general ward before he or she was ready to be discharged (or on the same day he or she was extubated). This has been recognized as a risk factor for ICU readmission.^{11,12,21}

The ICU nurses in this study perceived that ward nurses did not possess the acute care knowledge

or skills for high acuity patients with associated complex technologies (eg, continuous positive airway pressure). This is consistent with the hypotheses of others^{6,22,23} that suboptimal or inadequate care is responsible for many patients' deterioration. Suboptimal care has been defined as a lack of knowledge regarding the significance of clinical findings relating to dysfunction of airway, breathing, and circulation.^{22,23} The nurses identified that because some patients were discharged prematurely from ICU in the current study, they needed a level of care that would not normally be provided in a general ward environment but rather in an ICU or HDU. This included, for example, patients needing their vital signs measured more than 4 times per hour, which was the general norm for ward-based patients. They also required frequent tracheal suctioning, again an uncommon occurrence on the ward.

The nurses in the current study thought that many patients' deterioration (eg, decreasing blood pressure) may have been detected and treated earlier, thus avoiding ICU readmission (as speculated above). In addition, it was perceived that appropriate patient care was further delayed because medical staff also did not have the necessary acute care skills. This is consistent with the findings of previous research²⁴ examining junior doctors' ability to manage unstable patients.

The current study suggests that medical and nursing staff working on general hospital wards need to possess advanced knowledge and skills (eg, caring for a patient with a tracheostomy). A number of other studies^{25–27} have highlighted the frequent prolonged periods of instability experienced by patients before their admission to intensive care. Similar periods of instability have also been found^{28–30} in patients before cardiac arrest, with clinicians often documenting but not acting on the physiologic deterioration. If patients are going to be discharged early from the ICU, it is essential that they continue to get the care they need (eg, frequent airway suctioning, repositioning, mobilizing), and that their condition continues to be closely monitored (eg, visualized regularly and vital signs measured frequently, eg, once or twice per hour). Discharging acutely ill patients from the ICU to general wards may adversely affect their outcome, and the findings of this study suggest one possible outcome is readmission to the ICU.

The presence of acutely ill patients on general wards significantly increased staff workloads, reducing the time nurses have to spend with their patients. This is consistent with the suggestion of Goldhill³¹ that increased medical and nursing workloads leads to reduced continuity of care, which results in suboptimal care. Admitting an acutely ill patient from the ICU to a ward environment almost guarantees that essential care will be omitted because patients will have complex and competing needs. Goldhill et al³² found that 25% of patients admitted to the ICU die soon after discharge to a ward and that many of these patients experience adverse incidents. It would seem that

placing acutely ill patients who are at risk of deterioration on general wards will result in poor outcomes for at least some of them.

Russell⁴ found that decreased resources on general wards contributed to ICU readmissions. Other research has also demonstrated the impact of resource availability on care delivery.^{33,34} Findings of the current study suggest that appropriate resources (eg, adequately skilled staff) to provide the care needed by patients on general wards are still lacking on a day-to-day basis. Ward staff struggled to provide the care needed, because they did not have the knowledge, skills, time, or resources required. However, this does not mean that staff are incompetent but rather that they were placed in a situation above their level of expertise and capacity. Several of the nurses in the current study reported that medical staff also struggled when patients were much sicker than those they usually encountered. This is consistent with the findings of another study³⁵ in which 9% of nurses commented on poor response from medical staff when patients were referred with signs of being unwell. Future research therefore needs to examine the systemic or organizational factors that influence the care patients receive after discharge from ICU.

Many studies have examined the discharge process from the ICU to the wards. A Swiss survey³⁶ of 55 ICUs identified significant heterogeneity in ICU discharge practices. Written discharge guidelines, for example, were not widely used, and there was a lack of agreement in clinical decision-making about the discharge process. Furthermore, a recent study³⁷ in Sweden found that nurses struggled with the gap in care between the ICU and the wards during the transition period. The ward nurses interviewed wanted access to the necessary resources for patient care, questioned their own competence, and sought assurance of the patients' ability to be transferred from the ICU. Differences in the level of care were seen in the nurses' competence and focus. The ICU nurses interviewed tended to be "medically focused" (eg, saving the patients' lives), whereas the ward nurses focused on the patients' strengths and less on monitoring. The nurses sought improved collaboration between the ICU and the wards and desired routines that facilitated patient focused care. Nurses in Haggstrom et al's study³⁷ felt overwhelmed when they were receiving a patient from the ICU because of the extra workload involved, similar to the experiences of nurses in the current study.

Several other studies have found that ICU patients often could not be discharged to a ward because of the ward staff's lack of knowledge and skills.^{38–40} Poor communication between the ICU and the wards has also been identified as a variable contributing to the efficacy of the ICU discharge process.^{41,42} Research also found that the ICU discharge process was conducted poorly because of the urgent need to vacate the bed for an urgent ICU admission.^{43–45}

LIMITATIONS

This study has one main limitation. The findings reflect the experiences of nurses at one publicly funded, tertiary referral hospital in Australia. The results of the study must be interpreted within this context. Nurses in other hospitals (eg, private hospitals) or those without an ICU liaison nurse or critical care outreach team might have different experiences. Similarly, the nurses' experiences in this study reflect the public health care system in Australia. Nurses in countries with health care systems different than the system in Australia may not have the same experiences.

IMPLICATIONS FOR CLINICAL PRACTICE AND FURTHER RESEARCH

In this study, nurses described 5 main factors that the participants perceived as contributing to the readmission of patients to the ICU. Previously published research has not actively sought the perceptions of clinicians caring for readmitted patients in this specialist area. The findings highlight key factors that clinicians and managers can examine and modify to improve the care and thus the outcomes of patients at risk of ICU readmission. These factors relate to the way direct patient care is provided and the way care is managed at the organizational level.

Future research needs to examine how these system factors contribute to other adverse outcomes in patients discharged from the ICU. The issues in ward care might be ameliorated by nurses with different levels of expertise undertaking to deliver team-based care, rather than as "individuals" with their own case-load. Research has demonstrated that team-based nursing is effective in improving patients' outcomes in acute care settings.⁴⁶ The impact of team nursing on ICU patients' outcomes is an area for further research. Other researchers⁴⁷ speculated that the current deficiencies in ward care may be due to the absence of senior and experienced clinical decision-making at the bedside and that at present, only the symptoms, not the causes, of suboptimal ward care are being treated.

The Intensive Care Society⁴⁸ stated that the ability to recognize and treat critically ill patients is central in preventing and recognizing admissions and readmissions to ICU. However, research^{49,50} and the findings in this study suggest that ward staff are poor at recognizing these patients and that at least half of all adverse events involving patients are avoidable with correct standards of care.⁵¹ In addition to previous research, the findings of this study provide clinicians and hospital managers with a starting point by identifying the key issues related to ICU readmission. The next step would be for a larger-scale study to be carried

out on the basis of these outcomes to develop strategies to reduce the risk or occurrence of ICU readmissions.

CONCLUSIONS

Discharging patients from the ICU to the wards requires planning and consideration of ward-based knowledge and skills, especially because some of these patients are clinically unstable and require frequent monitoring. This creates issues around workload and significantly challenges ward staff. Although ward staff might possess knowledge and skills relevant to their own specialty, it is unreasonable to expect them to be competent in critical care (although they should have sound assessment skills). Hospital managers need to look at ways of increasing the knowledge and skills of ward staff and identifying more appropriate environments for managing these acutely ill patients. Further investigation of the effect of skill-mix or different models of care provision on patients' outcomes is warranted.

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Chapter summary

This chapter presented Phase I of the research program, an exploratory study describing nurses' perceptions and experiences of ICU readmissions. The study is innovative because it is one of two published studies to use qualitative methods to explore factors associated with this post-ICU adverse event; the other was older work by Russell (1999). Most research on ICU readmissions has been quantitative in nature, primarily examining medical records or retrospectively analysing clinical data. Previous studies have found that most ICU readmissions are due to cardiorespiratory illnesses but did not identify key factors such as those in care processes, which contribute to this adverse event.

Phase I identified five key factors associated with ICU readmissions: premature ICU discharge, complex patient care needs, lack of skilled staff, heavy workloads and delayed care. Phase I of the research program was one of the first studies to identify these specific factors and to do so using a qualitative research method. These findings represent unique factors in care processes which clinicians can target to help reduce the risk of future ICU readmissions. The findings relate to the way patient care is delivered at the bedside and the way it is managed at the organisational level. Phase I had a number of key recommendations:

- Hospital managers explore ways of improving the acute care knowledge and skills of ward staff
- Hospital managers identify more appropriate environments other than general wards for managing post-ICU patients
- Further investigation into the effects of skill mix and different models of care on post-ICU patient outcomes
 - For example, the impact of team-nursing nursing rather than individual patient allocation
- Further research examining how system factors contribute to other adverse outcomes in post-ICU patients.

As the overall aim of the research program was to add to the limited understanding of post-ICU adverse events and not just ICU readmission, Phase II of the research

program was designed to build on the findings of Phase I. It was speculated that the factors identified in Phase I that contribute to ICU readmissions would be common to most post-ICU adverse events. These findings, along with those identified in the literature, were therefore explored further in Phase II of the research program, which is presented in the next chapter.

CHAPTER 6

Phase II

Factors associated with post-ICU adverse events: the perspective of ICU Liaison Nurses

This chapter contains two manuscripts published in peer-reviewed journals.

Elliott, M., Page, K., Worrall-Carter, L., & Rolley, J. (2013). Examining adverse events after intensive care unit discharge: outcomes from a pilot questionnaire. *International Journal of Nursing Practice*, 19(5), 479 - 486. (IF 0.88)

- Malcolm Elliott – led the conception and design of the project; led the questionnaire development; collected data; led the data analysis; and wrote and edited the manuscript drafts.
- Dr Karen Page – advised on the conception and design of the project; assisted with questionnaire development; contributed to data interpretation; and edited manuscript drafts for key intellectual content.
- Prof Linda Worrall-Carter – assisted with questionnaire development; and contributed to data interpretation.
- Dr John Rolley – assisted with questionnaire formatting and data interpretation; and edited manuscript drafts for key intellectual content.

Elliott, M., Page, K. & Worrall-Carter, L. (2013). Factors contributing to adverse events after ICU discharge: a survey of liaison nurses. *Australian Critical Care*, 26(2), 76 - 80. (IF 0.95)

- Malcolm Elliott – led the conception and design of the project; collected data; led the data analysis; and wrote and edited the manuscript drafts.
- Prof Linda Worrall-Carter – advised on the research plan; and edited manuscript drafts for key intellectual content.
- Dr Karen Page – advised on the conception of the project; assisted with data interpretation; and edited manuscript drafts for key intellectual content.

Introduction

The previous chapter presented Phase I of the research program which identified five key factors associated with ICU readmissions. No previous research on ICU readmission identified these factors, possibly because few studies have interviewed staff involved in the care of readmitted patients. Instead, most research on ICU readmission has used quantitative methods such as retrospective medical record review. Studies using this method have a major limitation because documentation in medical records is often recorded at the end of a shift and is reliant on memory. Furthermore, medical records fail to capture the many factors that influence characteristics of care processes, such as nurse to patient ratios and the conditions under which patient care was delivered.

Because ICU readmission is one of the most common post-ICU adverse events, it was hypothesised that the five factors identified in Phase I, along with other factors reported in the literature, would be common to most adverse events following ICU discharge. The factors identified in the literature include failing to deliver what is considered standard care and failure to act upon clinical findings.

Phase II of the research program was designed to test the hypothesis that factors common to other adverse events would also be associated with post-ICU adverse events. Phase II of the research program tested this hypothesis by capitalising on the experience of a group of specialist clinicians, ICU Liaison Nurses. These specialist clinicians were key informants for Phase II because they are actively involved in the care of patients before and after ICU discharge and are a valuable resource for ward staff caring for acutely ill patients including those recently discharged from ICU.

To explore these nurses' opinions, a questionnaire was developed for data collection. Consistent with a mixed methods research design, the preliminary draft of the questionnaire was informed by the findings of Phase I and the literature. This process involved obtaining input from an expert panel to appraise the questionnaire's reliability and validity. Some of the expert panel members were ICU Liaison Nurses and thus also contributed data to phase II. The development and testing of the questionnaire are reported in the first publication in this chapter.

Once the reliability and validity of the questionnaire were established, Australian ICU Liaison Nurses were invited to complete the questionnaire online. Invitation to participate in the survey was sent via the Australian College of Critical Care Nurses' (ACCCN) Liaison Nurse Special Interest Group email list. This Group is a sub-branch of the ACCCN and is for College members with an interest in the ICU Liaison Nurse role. The email invitation contained a hyperlink to the questionnaire which was contained in Survey Monkey. It was anticipated that some members of the Liaison Nurse Special Interest Group would not be working in the role of an ICU Liaison Nurse. The first question of the questionnaire therefore asked if the respondent was an ICU Liaison Nurse (see Appendices). If a response of 'no' was provided, the respondent was exited from the questionnaire.

Likert scales were used throughout the questionnaire. There is debate in the literature about whether Likert scale data should be treated as interval rather than ordinal. Likert scales fall within the ordinal level of measurement (Hansen, 2003); the response categories have a rank order, but the intervals between values cannot be presumed equal (Jamieson, 2004). Some argue that it is 'illegitimate' to infer that the intensity of feeling between 'strongly disagree' and 'agree' is equivalent to the intensity of feeling between other data categories (Cohen et al., 2000). The results of phase II were analysed quantitatively and the argument has been made for using parametric methods to analyse Likert scale data (Norman, 2010). The decision was therefore made to treat the Likert scale data as interval data.

The specific question addressed by this second phase of the research program was: based on the opinions and experiences of ICU Liaison Nurses, what factors contribute to adverse events following discharge from ICU? The opinions of these Nurses were important because of the Nurses' unique clinical role in facilitating ICU discharge and patient follow up in ward areas (Endacott et al., 2010).

Within the context of the thesis and the aim of the research program overall, this chapter provides greater understanding of the clinical problem of adverse events following ICU discharge. The second publication in this chapter highlights the many factors contributing to post-ICU adverse events and provides a strong argument for these factors to be explored in greater depth.

Examining adverse events after intensive care unit discharge: outcomes from a pilot questionnaire

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✧ RESEARCH PAPER ✧

Examining adverse events after intensive care unit discharge: Outcomes from a pilot questionnaire

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Elliott M, Page K, Worrall-Carter L, Rolley J. *International Journal of Nursing Practice* 2013; **22**: 114–120
Examining adverse events after ICU discharge: Outcomes from a pilot questionnaire

Adverse events are common in acute clinical settings but little is known about these events occurring after Intensive Care discharge. This study aimed to develop a reliable and valid tool for exploring clinicians' opinions of factors associated with post-Intensive Care adverse events. A convenience sample of Australian Intensive Care Liaison Nurses was invited to complete and appraise a questionnaire using structured guidelines. Content validity and internal consistency were assessed.

Twelve Intensive Care Liaison Nurses completed the questionnaire. Cronbach's alpha coefficient showed high internal consistency for the questionnaire; all 24 items on the questionnaire had coefficients greater than 0.852. The content validity index of the questionnaire overall was 0.76.

The post-Intensive Care adverse events questionnaire demonstrated reliability and validity. It is a tool that can be used to explore clinicians' opinions of factors associated with these events. The tool is important as it facilitates further insight into the causes of post-Intensive Care adverse events.

Key words: adverse events, Intensive Care, patient safety.

INTRODUCTION

An adverse event is any unintended harm or injury to a patient, including temporary or permanent disability, which is caused by the health care provided rather than the patient's disease or illness.¹ These events are not

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uncommon, with nearly a quarter of patients experiencing an adverse event during their hospital admission.² Of these patients, one fifth die as a result and another 13% suffer permanent disability; half of these events could be preventable with better standards of care.^{3,4}

Adverse events occur in many clinical settings including intensive care units (ICUs). These units provide a vital service for critically ill patients but at a high cost; as much as \$81.7 billion US dollars is spent each year funding critical care services in North America.⁵ In Australia,⁶ the annual cost of ICU services is \$850 million US dollars, whereas in the United Kingdom⁷ the estimated cost is \$872 million US dollars. In order to justify this expense, it is essential that continuity of care occurs after ICU discharge, as preventable deaths in the post-ICU population represent, among other things, a high human cost and a significant investment of expensive health-care resources.⁸

The high demand for ICU beds often results in patients being discharged prematurely from ICU, before they are ready for ward level care.⁹ Ward staff can find it challenging to care for these patients as their care needs are often complex.¹⁰ This places vulnerable post-ICU patients at high risk for an adverse event as they might not continue to receive the care required. Research¹¹ has therefore found that up to a third of patients will experience an adverse event soon after ICU discharge. Consistent with adverse events in other patient populations, half or more of adverse events occurring after ICU discharge could be preventable with better standards of care.¹²

To date, most research on short-term adverse outcomes after ICU discharge has focussed on mortality, as it is an outcome which is easy to define and measure clinically. Seminal research^{13–15} found that up to 20% of patients who died on a ward after ICU discharge were expected to survive; these patients tended to be older, have longer ICU lengths of stay and higher illness acuity scores. Research^{15,16} also concluded that some deaths might have been avoided with better standards of ward care. However, various changes to contemporary clinical practice mean that the findings of these studies, though seminal, are less applicable today.

Two recent Australian studies^{11,12} identified factors contributing to adverse events in the post-ICU population. Patients who experienced an adverse event were older and required a high level of nursing care at the time of ICU discharge.¹¹ Delays in taking action for abnormal physiological signs and infrequent charting were evident¹²

in post-ICU patients. Data collection in these studies occurred via medical chart review which, although a common method, has limitations. Documentation in medical records is often subjective and ad hoc and could therefore provide limited insight into care processes.¹⁷ Other research designs are therefore needed to further the understanding of adverse events occurring post-ICU discharge.

Limited data are currently available on the incidence, characteristics and outcomes of adverse events in the post-ICU population.¹⁸ A contemporary understanding of the factors contributing to these events is lacking. The clinicians best positioned to fill this knowledge gap are ICU Liaison Nurses. These Nurses represent a new clinical service role in Australia which evolved due to the increasing number of critically ill patients on hospital wards. Important tasks performed by these Nurses include facilitating patient transition from ICU and assisting ward staff with the management of patients with complex care needs.^{19,20} ICU Liaison Nurses are very similar to Patient-At-Risk²¹ and Critical Care Outreach Teams²² in the United Kingdom. These teams were developed to improve the care and outcomes of critically ill ward patients, support ICU discharges and ensure timely ICU admission.

As the ICU Liaison Nurse is a new clinical role in Australia, to date no research has capitalized on these Nurses' knowledge of adverse events in the post-ICU population. To capitalize on these Nurses' unique experience and to help fill the knowledge gap on factors contributing to adverse events following ICU discharge, a valid and reliable data collection tool was developed.

AIM

This pilot study informs the second phase of a larger programme of research which aims to improve post-ICU patient outcomes through the identification of key factors associated with adverse events in this unique patient cohort. The research programme aims to promote the development of corrective action to reduce the risk and severity of future adverse events in these high-risk patients.

The aim of the second phase of the programme was to explore ICU Liaison Nurses' opinions of adverse events occurring after ICU discharge. This paper reports the development and testing of the post-ICU adverse events questionnaire, to be used for exploring ICU Liaison Nurses' opinions.

ETHICS

Approval for this study was obtained from a university Human Research Ethics Committee and deemed negligible risk. Consent was implied through completion of the questionnaire. All data were stored on security protected hardware. The ethical principles of the Declaration of Helsinki were adhered to.

METHODS

Reason's accident causation model²³ was used as the framework to guide questionnaire development. The model proposes that accidents such as adverse events are the end point of failures in the system or environment in which humans work. When exploring the causes of accidents, Reason's model²³ encourages a proactive approach by focussing on the conditions in which the individual was working, rather than blaming the individual for the error.

Item development

Guidelines^{24–26} for questionnaire development were followed. These guidelines described the essential steps for questionnaire development, including formulating conceptual definitions of the variables to be measured, deciding whether variables are categorical or continuous, and pilot testing the preliminary questionnaire. In the absence of any survey tool for exploring clinicians' opinions of factors contributing to adverse events after ICU discharge, the research team developed the preliminary questionnaire draft.

The preliminary draft was informed by an extensive review of the literature and the findings of an earlier qualitative study²⁷ of ICU readmissions undertaken by the research team. The literature suggested three key domains of factors contributing to adverse events in acute care settings: factors relating to the system or environment in which care is delivered, the person delivering care (i.e. human factors) and the care recipient (i.e. patient factors).

The qualitative study of ICU readmissions which informed the questionnaire was one of few which have attempted to describe clinicians' opinions and experiences of ICU readmission. As ICU readmission is a common adverse event following ICU discharge, it was hypothesized that factors contributing to readmissions would be common to most adverse events after ICU discharge. These factors were therefore included in the preliminary questionnaire draft. Although some of these factors were

similar, they were not identical. For example, staff skill mix referred to the experience of staff whereas nurse to patient ratios reflect numbers not skill base.

Response format

The questionnaire contained five-point Likert scales which measured the respondent's level of agreement with the questionnaire items (*never, seldom, sometimes, often, always*). A Likert scale was used because of its sensitivity and ability to produce interval level data.²⁸ A five-point scale was chosen as reliability increases when the number of rating points increases, with the maximum benefit achieved with five or seven points.^{29,30} Respondents were asked to use the Likert scale to rate the extent to which they believed each of the questionnaire's items contributes to adverse events in patients discharged from ICU.

The preliminary questionnaire draft contained two sections:

1. A demographics section with 17 questions. This included questions on the number of hours worked by the respondent, their qualifications, the number of hospital beds where they work, including ICU and high-dependency beds, and the type of nursing care delivery on their hospital's wards (e.g. team nursing).
2. A 24-item questionnaire of causal factors contributing to adverse events after ICU discharge. These factors were divided into three domains: system, human and patient factors, based on the conceptual framework.

Validity

Once the items were generated, three nurses were asked to assess the face and content validities of the preliminary draft. These nurses were experienced critical care nurses with at least 6 years experience in senior clinical roles. Their opinions were therefore important as the goal of the preliminary draft was to capture key factors associated with adverse events.

Although face validity has limitations, it is a useful procedure in the early phase of instrument development as the readability and clarity of content are examined.³¹ Minor changes to the wording of some items were made based on face validity assessment by the nurses. Clarifying examples were also added to each of the 24 items.

Expert panel

Questionnaire development involves tool validation by a panel of experts. Experts in the content area are often called on to analyse a tool's adequacy in representing the

concept being measured.³² A convenience sample of Australian ICU Liaison Nurses was therefore invited to participate in the study. These nurses had an existing professional relationship with the Chief Investigator (ME) through common membership of the Australian College of Critical Care Nurses Liaison Nurse Interest Group. The nurses were invited to participate in the study at a quarterly meeting of this Group.

Fifteen ICU Liaison Nurses volunteered to participate. These Nurses were emailed an electronic copy of the questionnaire. They were asked to complete the questionnaire and then comment on the comprehensiveness and readability of the questionnaire and the relevance of the questionnaire's items to adverse events after ICU discharge. A list of instructions for providing this feedback was provided based on De Vellis²⁵ (see Table 1). They were then asked to email their feedback to the Chief Investigator.

Statistical analyses

Data were analysed in PASW Statistics 18.³³ All data were cleaned and checked before analysis. Analyses included determining the reliability and content validity of the questionnaire. For reliability analysis (i.e. internal consistency), Cronbach's alpha coefficient for the questionnaire overall and item-total correlation were calculated. To establish content validity, the expert panel of nurses was asked to rate each item in terms of its relevance to adverse events following ICU discharge. A four-point Likert scale was provided: 1 = *not relevant*, 2 = *somewhat relevant*, 3 = *quite relevant*, 4 = *highly relevant*. This allowed calculation of the content validity index (CVI). The CVI indicates the extent to which a panel of experts agree that instrument items relate to or measure the desired construct (i.e. adverse events).

Two types of CVI can be calculated; one for each individual item and one for the instrument overall.³⁴ An

instrument has good content validity if its overall CVI is 0.8 or higher.³⁵ The CVI for the questionnaire overall was calculated by averaging the CVIs for the 24 items. For individual items, a CVI between 0.7 and 0.9 is optimal.³⁶ The CVI for each item was determined by calculating the proportion of experts giving a rating of either 3 or 4 for that item.

RESULTS

Of the 15 nurses invited to participate, complete data were provided by 12 nurses. Incomplete data were not analysed. The 12 nurses were employed in eight tertiary referral hospitals across three Australian states. These hospitals had between 140 and 470 beds (mean 372) and between 6 and 45 ICU beds (mean 16). The ICU Liaison Nurse services were available between 8 and 23 h per day within these hospitals (mean 11 h). All the Liaison Nurses were experienced ICU nurses and had between 1 and 10 years experience (mean 3) in their Liaison Nurse role. All but one had a postgraduate intensive care qualification.

The alpha coefficient for the questionnaire overall was 0.872 (an alpha between 0.7 and 0.8 is considered acceptable³⁷). The mean, standard deviation of each item and correct item-total correlation are provided in Table 2. Floor and ceiling effects were not observed for any of the 24 items.

The CVI for the questionnaire overall was 0.76, suggesting that the expert panel felt that the questionnaire is relevant to adverse events following ICU discharge. However, 8 of the 24 items (see Table 2) had individual CVIs of less than 0.7. Four of these eight items were removed from the final questionnaire due to their low CVI (equipment problems; care omission; the patient's age; impaired ability to communicate). Four were retained as they were deemed by the researchers to be clinically relevant to adverse events based on the literature. Removing

Table 1 Guiding instructions for expert panel

- The 24 items are grouped under three headings (system/human/patient factors). Please comment on whether the items listed under each heading fit appropriately under that heading.
- Please comment on the clarity and conciseness (i.e. wording) of each item. Is it clear? Could it be better worded? If so, please make a suggestion.
- Are any of the items awkward or confusing? If so, please suggest alternate wording.
- Are there other items (i.e. factors which contribute to adverse events in patients discharged from ICU) not listed which should be in the questionnaire? Please feel free to make a suggestion.

Table 2 Item mean, standard deviation, CVI and correlation

Item	Mean	Standard deviation	CVI	Item-total correlation
System factors				
Lack of inadequate supervision of medical/nursing staff	3.50	0.79	0.84	0.31
Lack of experienced staff (or lack of input from experienced staff)	3.41	0.67	0.92	0.67
Equipment problems	2.25	0.62	0.33	0.87
Ward staffing levels below normal requirements	2.75	0.96	0.58	0.86
Heavy workloads on the wards	3.58	0.67	0.92	0.53
Ward nursing staff skill mix not usual ratio	3.00	1.19	0.75	0.67
Nurse : patient ratios	2.92	1.31	0.67	0.79
ICU discharge process	3.00	0.95	0.77	0.214
Patient discharged from ICU before they are ready	3.75	0.45	1	0.10
Patient admitted to inappropriate ward	2.92	0.7	0.67	0.34
Lack of adequately qualified ward staff	3.33	0.65	0.92	0.45
Human factors				
Failure of staff to follow a rule or policy	2.75	0.62	0.67	0.39
Delay in providing care	3.25	0.75	0.84	0.437
Poor communication between staff	3.25	0.75	0.84	0.31
Care omission	2.83	0.83	0.54	0.39
Inadequate patient monitoring or assessment	3.67	0.49	1	0.70
Failure to deliver what is considered standard care	3.41	0.79	0.84	0.50
Failure to follow advice from senior clinician	2.92	0.79	0.84	0.36
Delayed medical care on the ward	3.17	0.83	0.75	0.473
Patient factors				
Increased illness acuity	3.5	0.52	1	0.49
Presence of co-morbidities	3.17	0.72	0.84	0.25
Impaired ability to communicate	2.42	0.79	0.25	0.62
Clinically challenging patients	3.41	0.79	0.84	0.69
The patient's age	2.58	0.79	0.58	−0.85

CVI, content validity index; ICU, intensive care unit.

the four items with a low CVI increased the CVI of the questionnaire overall to 0.825.

Qualitative feedback from the expert panel also resulted in changes to the questionnaire. The changes are summarized in Table 3.

DISCUSSION

Many factors contribute to adverse events in acute care settings. These include factors unique to the patient (e.g. co-morbidities), the environment in which care is delivered (e.g. staffing levels) and to the staff delivering care (e.g. qualifications). In unique patient populations such as those recently discharged from ICU, these and other factors might contribute to the development of adverse events. The post-ICU adverse events questionnaire was

developed to obtain a better understanding of those factors and is the first questionnaire designed to do so. It was felt that a questionnaire was optimal as it offered a mechanism to collect the unique opinions of ICU Liaison Nurses in a validated, timely and cost-effective manner. It could therefore be superior to other data collection techniques such as chart review.

The content validity of the questionnaire is sound as its content was informed by a literature review of adverse events following ICU discharge and a qualitative study of ICU readmission. The questionnaire's items were validated by an expert panel of 12 experienced ICU Liaison Nurses, employed in eight tertiary referral hospitals across Australia. The pilot study also indicates that the post-ICU adverse events questionnaire is a reliable and

Table 3 Changes to questionnaire based on qualitative feedback

-
- System Factor 'lack of/inadequate supervision of medical/nursing staff' split into two factors; one for medical staff and one for nursing staff
 - System Factor 'lack of experienced staff' split into two factors; one for medical staff and one for nursing staff
 - System Factor 'patient discharged from ICU before they are ready' split into two factors—premature ICU discharge and after hours discharge
 - System Factor added: 'fragmentation of patient management due to multiple medical teams'
 - Human Factor added: 'lack of recognition of (or response to) patient deterioration'
 - Human Factor added: 'Inadequate patient handover from ICU to ward staff (e.g. patient care needs not obvious from ICU documentation or verbal handover)'
 - Clarifying example ('omitting observations') added to Human Factor 'inadequate patient monitoring or assessment'
-

internally consistent tool as evidenced by a high Cronbach's alpha score.

Four factors were retained in the questionnaire despite having a low CVI. These factors were deemed by the researchers to be clinically relevant to adverse events following ICU discharge. Based on quantitative analysis and qualitative feedback from the expert panel, the final version of the post-ICU adverse events questionnaire contained 25 items: 14 items in the System Factors domain; 8 items in the Human Factors domain; and 3 items in the Patient Factors domain.

Limited data are currently available on adverse events in patients discharged from ICU.¹⁸ Plans for future research therefore include using the questionnaire to determine Australian ICU Liaison Nurses' perceptions of factors contributing to adverse events in post-ICU patients. Identifying factors associated with adverse events in this high-risk population has the potential to improve outcomes by streamlining care processes. Although the ICU Liaison Nurse's role is unique to the Australian health-care setting, the questionnaire could also be used to explore opinions of clinicians who perform a similar role in other comparable health-care settings. Examples include Patient-At-Risk Teams²¹ and Critical Care Outreach Teams²² in the United Kingdom.

Limitations

This study has some limitations. ICU Liaison Nurses are unique to the Australian health-care system. If the expert panel had consisted of clinicians from other health-care systems, the results of the study might have differed. The United Kingdom, for example, has a health-care system comparable with Australia, but North America does not. A further limitation is that the pilot data reflect collective

expert opinion. Although the first-hand experience of experts is valuable, it is only opinion and thus subjective and reliant upon memory.

Little formal guidance exists in the literature on the sample size for a pilot study; few epidemiology or research textbooks cover the topic with the necessary detail.³⁸ Seminal research texts^{32,39} offer no guidance; other advice⁴⁰ is that no set number is needed for a pilot study. Others⁴¹ state that usually a small group of colleagues can be an appropriate sample to perform a pilot study. For a pilot clinical trial, a minimum of 12 subjects per group is recommended,⁴² based on feasibility and the precision around estimates to be used to design future studies.

For pilot samples of 24 to 40 members, the observed Cronbach's alpha should be at least 0.75, in order to have confidence that the population value is at least 0.70; samples having fewer than 25 participants need the observed alpha to be close to 0.80 to achieve this.⁴³ The observed alpha for the post-ICU adverse events questionnaire overall was 0.872.

As with any statistical test, CVI has limitations. It has been said that expert judgements about the relevance of an instrument's content should not be construed as validity and that expert opinion is merely a mechanism for obtaining an estimate of an item's relevance.⁴⁴ Furthermore, an expert panel might agree on an item's relevance purely by chance. Content validity is based mainly on the judgement, logic and reasoning of the researcher, with validation from a panel of judges holding expertise in the domain of content.³⁴ Content validity is thus a subjective entity even though attempts are made to quantify it. Recommendations⁴⁵ to overcome this limitation include using an expert panel of at least five members and four-level

Likert scale. Both these recommendations were followed in this study.

The accuracy of pilot study results becomes questionable when unrepresentative samples are used.⁴⁶ As this pilot captured one out of every three Australian ICU Liaison Nurses,⁴⁷ it would not truly be representative; however, the homogeneity of the responses suggests good representation.

A final limitation is that panel members were recruited through the Australian College of Critical Care Nurses ICU Liaison Special Interest Group. One of the researchers (ME) is also a member of the Group. This could have influenced panel members' responses to the questionnaire due to the lack of confidentiality. Although a valid concern, the researchers felt that this would not impact significantly, given that this group of clinicians are very autonomous.

CONCLUSION

The post-ICU adverse events questionnaire is a structured measure of factors contributing to adverse events following ICU discharge. The findings of this pilot study demonstrate that the questionnaire is a reliable and valid tool. It could therefore be a useful tool for better understanding adverse events following ICU discharge.

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Factors contributing to adverse events after ICU discharge: a survey of Liaison Nurses

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Factors contributing to adverse events after ICU discharge: A survey of liaison nurses

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ABSTRACT

Background: A significant number of patients experience an adverse event when discharged from intensive care to a ward. More than half of these events may be preventable with better standards of care.

Aim: To explore the opinions of an expert group of clinicians around factors contributing to adverse events in patients discharged from ICU.

Method: Online survey of Australian ICU Liaison Nurses (n = 39) using a validated questionnaire of 25 items.

Results: The response rate was 92.8%. Key contributing factors included a lack of experienced ward staff, patient co-morbidities and the clinically challenging nature of many patients.

Conclusion: Modifying processes of care may decrease the risk or impact of adverse events in this high risk patient population.

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Introduction

Many patients experience an adverse event when discharged from intensive care (ICU).¹ These events are defined² as unintended injury or an event that results in disability, which is caused by the health care provided rather than the patient's disease or illness. Research³ suggests that half or more of all adverse events following ICU discharge may be preventable with better standards of care.

Currently limited data are available on the incidence, characteristics and outcomes of patients who experience an adverse event following ICU discharge.⁴ The specific factors which contribute to adverse events in this high risk population are unclear. Identifying these factors has the potential to improve patient outcomes by streamlining care processes, thus preventing avoidable death and injury as well as reducing health care costs.

Over the last decade a new clinical service role has evolved in Australia to assist ward staff caring for patients discharged from ICU through various mechanisms. The ICU liaison service is generally staffed by an experienced critical care nurse who provides advanced clinical consultancy to ward staff and assists them with the management of patients following ICU discharge.^{5,6} As the ICU Liaison Nurse is a relatively new clinical role, little research has been conducted on this role, such as exploring the unique knowledge these nurses possess. This study utilises a key informant process. Due to their specialised role, ICU Liaison Nurses are in a unique position to provide an informed opinion of the care processes associated with patients discharged from ICU.

Aim

This study builds on earlier qualitative research⁷, which identified key factors contributing to ICU readmission. The aim of the current study was to survey ICU Liaison Nurses to explore the contribution that these and other factors identified in the literature make towards adverse events following ICU discharge.

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Methods

Ethics

Ethics approval was obtained from a university human research ethics committee (approval number V2011 132). There were no anticipated risks to the nurses participating in the study. Non-identifiable data were collected.

Survey instrument

In the absence of a tool to explore nurses' opinions of factors contributing to adverse events following ICU discharge, a questionnaire was developed. The questionnaire was informed by a literature review of studies examining adverse events following ICU discharge and earlier research on ICU readmission.⁷ Tool development guidelines^{8–10} were followed to ensure the questionnaire's rigour, reliability and validity. The questionnaire was piloted amongst 12 ICU Liaison Nurses and its reliability and validity established (alpha coefficient 0.852, content validity index 0.76). The questionnaire consisted of two parts.

The first part contained 16 questions and collected demographic data such as the hours per day the liaison services operated. The second part used five point Likert scales (*never, seldom, sometimes, often, always*) to assess the extent to which respondents believed 25 factors contributed to adverse events after ICU discharge. These factors were categorised into three domains based on Reason's Accident Causation Model¹¹: system or organisation, such as staff skill mix (14 factors); human, such as failure to follow a guideline (8 factors); and patient factors, such as a complex patient with a central venous catheter, tracheostomy and chest drain (3 factors). Reason's model¹¹ proposes that people involved in accidents do not deliberately cause them, and that these events are often due to the characteristics of the environment in which the accident occurs. These characteristics may include weaknesses within the safety systems which are actually designed to prevent harm.

Target population and recruitment

The target population for the survey was Australian ICU Liaison Nurses. This group of specialist nurses has representation through the Australian College of Critical Care Nurses (ACCCN) ICU Liaison Special Interest Group which has 656 members. The ACCCN agreed to contact group members via the email list and invite them to complete the questionnaire. The invitation outlined the background and aim of the survey and contained a hyperlink to the survey website.

To ensure the survey only captured the Special Interest Group members who are practising as ICU Liaison Nurses, recipients were instructed to complete the questionnaire only if their current role involved following up patients after ICU discharge. The survey

was conducted via Survey Monkey which is secured using Secure Socket Layer encryption. Responses were received during a six week period in April and May 2011. Response to the survey implied consent.

Data management and analysis

Data were downloaded and analysed in PASW Statistics 18.¹² Demographic data are reported as descriptive statistics. No assumptions were made about missing data. For the section of the questionnaire on factors contributing to adverse events, Likert scale items are summarised and reported in frequency tables. Strength of relationship between the 25 factors was assessed using Spearman's correlation coefficient, with number of hours per day the service was provided as the dependent variable ($P < 0.05$ was considered statistically significant). These relationships were explored because of all the demographic data, the number of hours per day the service was provided was hypothesised to have the greatest influence on adverse events.

Results

Sixty-seven members of the ICU Liaison Special Interest Group commenced the online questionnaire. Of these 39 completed the questionnaire and indicated their clinical role involved following up patients after ICU discharge. A recent survey¹³ found that 27% of 113 Australian ICUs have a Liaison Nurse service, with a mean of 1.4 full time equivalent positions (i.e. population = 42). Based on this, our study had a response rate of 92.8% (39/42) of the Australian ICU Liaison Nurse population.

The Liaison Nurses worked in hospitals with bed numbers ranging from 100 to 700 (mean 391). ICU bed numbers ranged from five to 48 (mean 17.5). Of the ICUs, 15% were level I, 22% were level II and 63% level III. Most of the Liaison Nurses (82.1%) had a Graduate Certificate or Diploma in intensive care nursing. The length of time the Liaison Nurse services had been available ranged from two months to more than 13 years. The operation times of the Liaison Nurse service ranged from one to 24 h (mean 9.5, SD 5.01) per day. Sixty percent provided the service during business hours (08:00–18:30); eight percent after hours (18:30–23:00); with the remaining 32 percent offering services in and out of business hours (08:00–22:00).

System factors contributing to adverse events

Of the 14 system factors hypothesised to contribute to adverse events, most were deemed by half or more of the Liaison Nurses to sometimes or often contribute to these events. These are summarised in Table 1.

Table 1
System factors.

Factor	Never/seldom (%)	Sometimes (%)	Often/always (%)
Heavy workloads on the wards	2.6	21.1	76.3
Lack of experienced nursing staff on the wards	5.3	42.1	52.6
Lack of/inadequate supervision of ward medical staff	7.9	42.1	50
Lack of/inadequate supervision of ward nursing staff	7.9	44.7	47.3
Lack of experienced medical staff on the wards	5.3	47.4	47.3
Patient discharged from ICU after hours	23.7	39.5	36.8
Ward nursing staff skill mix not usual ratio	28.9	36.8	34.2
Lack of adequately qualified ward staff	13.2	52.6	34.2
Ward staffing levels below normal requirements	39.5	28.9	31.5
Nurse to patient ratios	42.1	28.9	28.9
ICU discharge process	36.8	34.2	28.9
Patient admitted to inappropriate ward	44.7	28.9	26.3
Patient discharged from ICU prematurely	28.9	52.6	18.4
Fragmentation of patient management due to input of multiple medical teams	10.5	73.7	15.8

Table 2
Human factors.

Factor	Never/seldom (%)	Sometimes (%)	Often/always (%)
Delayed medical care on the ward	0	31.6	68.4
Lack of recognition of (or response to) patient deterioration	5.3	42.1	52.7
Inadequate patient monitoring or assessment	7.9	42.1	50
Failure to deliver what is considered standard care	13.2	39.5	47.4
Delay in providing nursing care	10.5	52.6	36.9
Failure of staff to follow a rule or policy	28.9	50	21
Failure to follow advice from a senior clinician	21.1	57.9	21
Inadequate patient handover from ICU to ward staff	29.7	51.4	18.9

Table 3
Patient factors.

Factor	Never/seldom (%)	Sometimes (%)	Often/always (%)
Clinically challenging patients	0	31.6	68.4
Increased illness acuity	5.3	36.8	57.9
Presence of co-morbidities	0	42.1	57.9

Table 4
Factors associated with number of hours per day the Liaison service was available.

Factor	Spearman's correlation coefficient	P value	Coefficient of determination
Nurse:patient ratios	−0.354	0.017	12.5%
Inadequate patient handover from ICU staff	0.308	0.036	9.4%
Inadequate patient monitoring	0.285	0.046	8.1%
Ward staffing levels below normal requirements	−0.279	0.049	7.8%

Human factors contributing to adverse events

All eight human factors were deemed by the majority of respondents to sometimes or often contribute to adverse events. These are summarised in Table 2.

Patient factors contributing to adverse events

All three patient factors were believed to be major contributors to adverse events following ICU discharge; these are reported in Table 3.

Correlation

Strength of relationships between the number of hours per day the Liaison Nurse service was provided and the 25 systems, human and patient factors are summarised in Table 4. Only factors which demonstrated correlation are listed (i.e. those reaching statistical significance). Two factors, 'lack of experienced nursing staff on wards' and 'failure to deliver what is considered standard care' did not reach significance but had *P* values <0.6.

Discussion

This study aimed to explore ICU Liaison Nurses' opinions of factors contributing to adverse events following ICU discharge. Numerous factors were identified, by expert opinion, as sometimes or often contributing to adverse events.

Two recent studies^{1,3} identified factors contributing to adverse events in the post-ICU population; this was achieved primarily via chart review. Contributing factors in these studies included delay in taking action for abnormal vital signs and infrequent charting. Results from our study were similar, though obtained via a different method. The majority of Liaison Nurses believed that inadequate patient monitoring or assessment sometimes or often contributed to adverse events; most also believed that a lack of recognition (or response to) patient deterioration sometimes or often contributed.

Research^{14–16} similarly found that deterioration in other patient cohorts is often documented but not acted upon. Our findings, though only expert opinion, reinforce the importance of measuring, recording and reporting of abnormal vital signs in patients discharged from ICU. They also emphasise an essential role for ICU Liaison Nurses – ensuring that ward staff understand the significance of vital sign measurement and interpretation in post-ICU patients. These findings also raise the broader question of why this crucial assessment is not occurring in the first instance. This is an area for further research and may relate to staff skill mix, qualifications, experience or staff supervision, which were also identified as key contributors in our study. The choice (or lack of choice) of post-ICU discharge destination may also be a factor.

Over half the ICU Liaison Nurses believed that admitting patients to an inappropriate ward sometimes or often contributed to adverse events. If a patient requires high dependency care, it cannot be assumed they will receive it in an environment not resourced to do so; similarly it cannot be assumed that a patient will receive specialised care in a general ward. The challenge of caring for multiple patients who require highly skilled care compounded by rapid unpredictable changes in care has been recognised.^{17–19}

It is surprising that a patient would be discharged from ICU to an inappropriate environment given that many post-ICU patients still require close observation and comparatively more complex care than routinely provided at ward level.⁶ However in the current era of resource limitations such as a shortage of ICU beds,²⁰ remaining in ICU may not always be feasible given competing priorities. It is often difficult to identify indicators that define the right discharge destination for high-risk ICU patients.²¹ Decisions on when to discharge patients from ICU and the ideal discharge location are complex and influenced by many factors. Heterogeneity in ICU discharge practices has therefore been identified.²² The complexity of ICU discharge decision making and its impact on patients' outcomes has also been demonstrated.²³

ICU bed availability and associated step-down bed availability (HDU) may be the factor most likely to have the greatest impact on ICU discharge decisions, resulting in an admission to a ward environment with lower nurse to patient ratios and differing staff

skill mix and staff expertise than found in a high-dependency unit.

In our correlation analysis, a significant negative relationship was found between ward staffing levels and the number of hours per day Liaison Nurses work. A negative relationship was also found between nurse:patient ratios and the number of hours per worked. Given the relationship which has been established^{24–26} between nurse staffing, workload, patient dependency and outcomes, these are expected findings. Our results also highlight the important clinical contribution of ICU Liaison Nurses when hospital beds are in short supply.

Nearly three quarters of the Liaison Nurses believed that after hours discharge from ICU sometimes or often contributed to adverse events. The detrimental impact of after-hours ICU discharge on patients' outcomes has been previously demonstrated.^{27–29} In our study, Liaison Nurses were available 24 h/day at only three sites; these respondents believed that after hours ICU discharge is seldom a factor contributing to adverse events. A study comparing patient outcomes in hospitals with and without a 24 h Liaison Nurse service may therefore be worth conducting.

More than half of the Liaison Nurses surveyed believed that inadequate patient handover from ICU to ward staff sometimes contributed to adverse events. Given the links identified^{30,31} between handover, care quality and patient outcomes, we expected this factor to be rated more highly. Quality of clinical handover is currently a priority area for the Australian Commission on Safety and Quality in Health Care³² and research³ has found that care needs are not always communicated to ward staff when a patient is discharged from ICU.

In correlation analysis, a positive relationship was found between inadequate patient handover from ICU to ward staff and the number of hours per day Liaison Nurses worked. This is an unexpected finding and might be explained by an ICU nurse's need to give a rushed handover due to an impending new ICU admission; this might also occur if he or she knew that a Liaison Nurse was available to assist ward staff with patient care. Unplanned discharge from ICU after hours is often rushed to accommodate an emergency ICU admission.^{3,33} It is unclear if this also occurs during business hours.

Attempts⁴ are currently being made to improve the quality of handover from ICU staff such as the adoption of a discharge plan. If ward staff are not informed of the care required following ICU discharge particularly if the patient is admitted to a general ward area, then it is quite likely continuity of care will not occur. This highlights another key role for ICU Liaison Nurses – ensuring ward staff are aware of essential patient care and have the skills or resources to deliver it.

Research^{34,35} has found that undergraduate medical and nursing education often lacks a critical care component, possibly explaining why important care is missed in post-ICU or acutely ill patients. Attempts³⁶ have been made to address this problem, such as the development of core competencies in acute care for undergraduates. Not surprisingly more than half the Liaison Nurses in the current survey indicated a lack of adequately qualified ward staff was sometimes a contributing factor to adverse events and a third indicated it was often a contributing factor. Other data support this. For example most Liaison Nurses believed that delays in providing nursing care on the wards, such as not sitting a patient out of bed for two days following ICU discharge, sometimes or often contributed to adverse events.

All three patient factors were rated highly in terms of their contribution to adverse events. This is consistent with previous research^{37,38} which found that risk factors for ICU readmission include older age (e.g. >65 years) and the presence of comorbidities. ICU readmission was also shown to increase the risk of in-hospital mortality in these studies. Patient characteristics

however are not factors which clinicians can modify or alter but they highlight patients who are at greater risk of an adverse event.

Strengths and limitations

This study builds on earlier qualitative research on ICU readmission.⁷ By doing so it adds to the understanding of adverse events in patients recently discharged from ICU. It is also the first study to explore and utilise the in-depth knowledge and experience that Australian ICU Liaison Nurses have of this clinical problem.

The size of the ICU Liaison Nurse population is estimated to be 42; 39 of these Nurses contributed data to this study. It is not known what true portion of the ICU Liaison Nurse population this actually represents however and it is likely that the actual population is greater than estimated. This study's findings may therefore have differed if a larger portion of ICU Liaison Nurse population completed the questionnaire, or if the factors contributing to adverse events were able to be captured in real time. Furthermore the number of factors used in the correlation analysis is potentially a methodological limitation.

Although ICU Liaison Nurses were uniquely positioned to inform this study, the results only represent collective expert opinion. These factors require prospective clinical validation. Further research is also needed to explore how or why key factors influence quality of care and patient outcomes following ICU discharge.

Clinical implications

The findings of this study may have implications for patient safety and quality of care following ICU discharge. ICU and ward staff need to understand the risks and implement processes to manage patients discharged directly from ICU to a ward. Medical and nursing staff caring for post-ICU patients on hospital wards should also be educated on the importance of ongoing assessment of these high risk patients. There is also a strong argument for post-ICU patients' care being delivered by the most qualified staff. Where possible ward managers should assess staff skill mix when an admission from ICU is expected; however given that some of these admissions occur after hours or at short notice, this may not be possible.

Conclusion

There is consensus among ICU Liaison Nurses in this study regarding the factors contributing to adverse events following ICU discharge. Establishing expert opinion about these factors is a step towards minimising the incidence and impact of these events, and thus improving patient outcomes. Future research needs to examine exactly how these and other factors influence patient outcomes so that processes of care can be streamlined hopefully reducing the incidence and impact of future adverse events in patients discharged from ICU.

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Chapter summary

This chapter contains two publications, representing Phase II of the research program. The first publication reports a pilot study of the development and testing of the questionnaire used for data collection. The second publication is a research paper describing the aim, methods, results, clinical implications and conclusions of Phase II of the research program. The study reported in this chapter is unique because it is the first published study to explore ICU Liaison Nurses' opinions of adverse events following ICU discharge. The findings of the study highlight the many factors contributing to post-ICU adverse events; these are categorised into system, clinician and patient factors.

The findings of Phase II illustrate the complexity of post-ICU adverse events, by highlighting the many interrelated factors that contribute. It is not surprising that numerous factors contribute to post-ICU adverse events as clinical health care is multifaceted and its outcomes are influenced by many variables, including characteristics of the patients themselves. ICU and ward staff should be aware of the factors contributing to post-ICU adverse events, and where possible, try to minimise their impact. For example, patients identified as being at risk of a post-ICU adverse event may have better outcomes if admitted to a high-dependency unit, where they may be closer monitored than in a ward environment. Resource limitations, however, may prevent this.

If patients are discharged directly from ICU to a ward environment, ward staff should be aware of the factors identified in Phase II that are associated with post-ICU adverse events. Being cognisant of these factors may be the first step towards adverse event prevention. Based on the findings of Phase II, modification of the way clinical care is delivered may also reduce the risk. For example, allocating the care of post-ICU patients to the most senior or experienced ward staff may help provide the patient with the best chance of a positive outcome or avoiding an adverse event.

In summary, the key recommendations of Phase II were:

- ICU and ward staff be aware of the key factors associated with post-ICU adverse events
- Ward staff be educated on the importance of ongoing assessment of patients recently discharged from ICU
- Post-ICU patient care be delivered by the most qualified ward staff
- Ward managers assess staff skill mix when a patient is admitted to a ward from ICU.

The findings of Phase II of the research program represent collective expert opinion. It was considered important to explore expert opinion on post-ICU adverse events due to the lack of literature and understanding on this unique clinical problem, and the essential role served by these Nurses. The third and final phase of the research program was informed by the findings of Phase II. Phase III was designed to clinically validate the Phase II findings and is presented in the next chapter.

CHAPTER 7

Phase III

Adverse events on the ward after ICU discharge: a clinical validation study

The manuscript contained in this chapter has been accepted for publication in an international peer-reviewed critical care nursing journal.

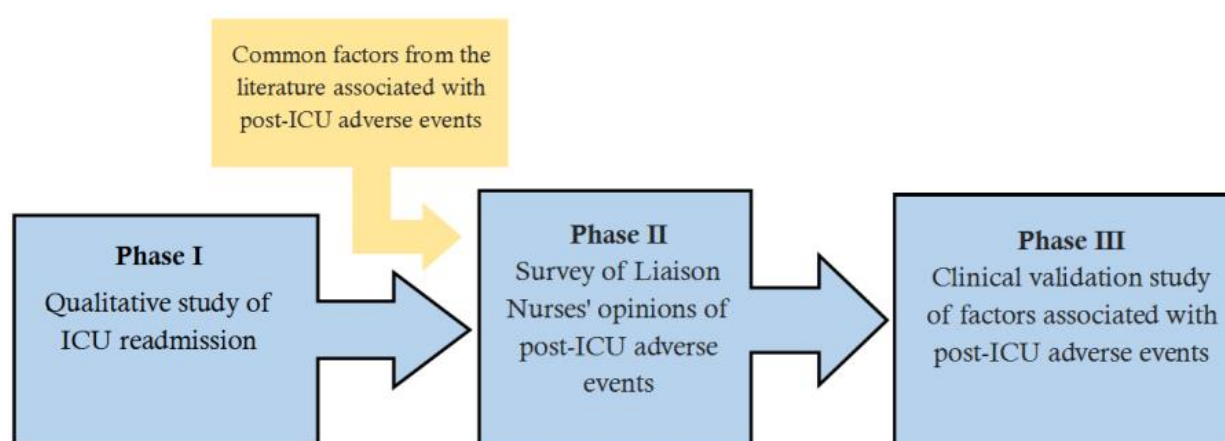
Elliott, M., Page, K. & Worrall-Carter, L. (2014). Factors associated with post-ICU adverse events: a clinical validation study. *Nursing in Critical Care*. (IF 0.95)

- Malcolm Elliott – led the conception and design of the project; collected data; led the data analysis; and wrote and edited the manuscript drafts.
- Dr Karen Page – advised on the conception of the project; assisted with data analysis; and edited the final manuscript for key intellectual content.
- Prof Linda Worrall-Carter – advised on the research plan; and edited the final manuscript for key intellectual content.

Introduction

The previous chapter described Phase II of the research program, an online survey of Australian ICU Liaison Nurses. The survey explored these Nurses' opinions of factors associated with post-ICU adverse events. Phase II of the research program contributed unique knowledge to the limited understanding of these adverse events by describing these previously unreported expert opinions. The findings highlight the complex nature of post-ICU adverse events and demonstrate that these events are a combination of system, clinician and patient factors. Based on the findings, Phase II of the research program made key recommendations for clinical practice.

Figure 1: Overview of the research program



As the majority of the Australian ICU Liaison Nurse population completed the survey, the findings of Phase II represent collective expert opinion on post-ICU adverse events. These findings are important because the development of clinical recommendations always requires the opinions of experts (Balshem et al., 2011). These opinions add to the limited understanding of post-ICU adverse events and are a step towards minimising the risk of these events in the future.

It is however important to uncover and clarify the evidence that underlies experts' opinions (Balshem et al., 2011). The third and final phase of the research program was therefore designed to prospectively validate the findings of Phase II. By validating these findings, Phase III aimed to determine their relevance to clinical practice and make recommendations for clinical care. The recommendations of this phase are based on the study's findings.

A number of ethical issues needed to be considered prior to study commencement. Data on adverse events reflect care quality and safety processes within the hospital setting. As a key role of ICU Liaison Nurses involves the co-ordination of post-ICU care, these nurses had to be willing to report data on poor outcomes of patients they are directly responsible for. Numerous ICU Liaison Nurses volunteered to do this. To ensure anonymity all data were de-identified. The participating hospitals were also not named in the resulting publication.

The manuscript contained in this chapter reports Phase III of the research program and has been accepted for publication in an international peer-reviewed critical care nursing journal.

Factors associated with post-ICU adverse events: a clinical validation study

RESEARCH

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Factors associated with post-intensive care unit adverse events: a clinical validation study

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ABSTRACT

Background: Many patients discharged from intensive care units (ICU) have complex care needs, placing them at risk of an adverse event in a ward environment. Currently, there is limited understanding of factors associated with these events in the post-intensive care population. A recent study explored intensive care liaison nurses' opinions on factors associated with these events; 25 factors were identified, highlighting the multifaceted nature of post-intensive care adverse events.

Aim: This study aimed to clinically validate 25 factors intensive care liaison nurses believe are associated with post-intensive care adverse events, to determine the factors' relevance and importance to clinical practice.

Design: Prospective, clinical validation study.

Method: Data were prospectively collected on a convenience sample of 52 patients at 4 tertiary referral hospitals in an Australian capital city. All patients had experienced an adverse event after intensive care discharge.

Results: Each of the 25 factors contributed to adverse events in at least 6 patients. The factors associated with the most adverse events were those that related to the patient such as illness severity and co-morbidities.

Conclusion: Clinical care and research should focus on modifiable factors in care processes to reduce the risk of future adverse events in post-intensive care patients.

Relevance to clinical practice: Many patients are at risk of post-ICU adverse events due to the contribution of non-modifiable factors. However, by focusing on modifiable factors in care processes, the risk of post-ICU adverse events may be reduced.

Key words: Adverse event • Discharge • Quality • Safety

INTRODUCTION

An adverse event is any unintended injury or complication that arises from health care management rather than the patient's underlying disease, and which results in disability, death or a prolonged hospital stay (Wilson *et al.*, 1995). Examples of these events include nosocomial infection, deep vein thrombosis and medication error. Adverse events are not uncommon, and up to a third of patients experience an event during their hospital admission (Fowler *et al.*, 2008). Of these patients, 20% will die and 13% will suffer a permanent

disability (Baker *et al.*, 2004; de Vries *et al.*, 2008). Of greatest importance to care providers, hospital managers and researchers is that up to 80% of all adverse events are considered avoidable (Sinopoli *et al.*, 2007).

Patients admitted to intensive care units (ICU) are at high risk of adverse events because of the critical nature of their illness and the complex care they require (Kane-Gill *et al.*, 2010). Many patients discharged from ICU continue to have complex care needs, sustaining the risk of adverse events in a ward environment (Green and Edmonds, 2004). Up to one third of post-ICU patients for example will experience an adverse event, more than half of which may be preventable with better standards of care (Chaboyer *et al.*, 2008; McLaughlin *et al.*, 2007).

Previous research on post-ICU adverse events has focused primarily on mortality and readmission because these events are easier to quantify than others (Elliott *et al.*, 2012a, 2013a). Contemporary and seminal research found that key factors associated with these two events included older age, illness severity, length

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of ICU stay, residual organ dysfunction and time of ICU discharge (Wallis *et al.*, 1997; Moreno *et al.*, 2001; Singh *et al.*, 2010). Patients readmitted to ICU also had poorer prognoses than those not readmitted including a higher mortality risk (Chrusch *et al.*, 2009; Utzolino *et al.*, 2010).

A recent study surveyed Australian ICU liaison nurses to determine their opinions of 25 factors believed to be associated with post-ICU adverse events (Elliott *et al.*, 2013b). These factors were identified from the literature and research on ICU readmission (Elliott *et al.*, 2011, 2012a, 2013a). In this study, the 25 factors were categorised into 3 domains: system, clinician and patient factors, consistent with an accident causation model (Elliott *et al.*, 2012b). Examples of these factors include staff workloads, nurse:patient ratios, failure to follow a rule or policy and co-morbidities. The ICU liaison nurses rated most of the 25 factors highly in terms of their contribution to post-ICU adverse events (Elliott *et al.*, 2013b).

While the findings of the survey represent important factors associated with post-ICU adverse events, it is crucial when making recommendations for clinical practice to uncover and clarify the empirical evidence that underlies experts' opinions (Balshem *et al.*, 2011). Clinical validation of the 25 factors would allow the streamlining of care processes in order to reduce the mortality and morbidity related to post-ICU adverse events as well as associated health care costs.

AIM

This study aimed to clinically validate intensive care liaison nurses' opinions of factors associated with in-hospital post-ICU adverse events. The study represents the third and final phase of a larger programme of research that aims to improve post-ICU patient outcomes by exploring factors associated with adverse events. Phase I of the research programme, a qualitative study, identified five key factors associated with ICU readmission (Elliott *et al.*, 2011). The second phase explored ICU liaison nurses' opinions of factors associated with post-ICU adverse events (Elliott *et al.*, 2013b).

METHODS

Design

A prospective clinical validation study was conducted, to test in real time, 25 factors believed to contribute to post-ICU adverse events. Validation is the independent determination of data accuracy and is necessary to ensure the data's scientific credibility (McCoubrey *et al.*, 2005). Validation also helps establish the relevance of a study's findings to clinical practice. A

limitation of validation studies is that the results may only reflect the environment in which the research is conducted.

Setting

Data were collected at four tertiary referral hospitals in an Australian capital city. The hospitals had between 300 and 850 ward beds and between 10 and 30 ICU beds. Each hospital was serviced by ICU liaison nurses.

Population

The study included a convenience sample of adult patients recently discharged from one of the four ICUs. Some of the patients had been electively admitted to ICU for care following routine surgery such as thoracic lobectomy and craniotomy. Others were emergency ICU admissions for conditions such as septic shock and necrotising pancreatitis. Data were not collected on paediatric patients. All patients experienced an adverse event on a ward following ICU discharge.

Data collection

A data collection tool incorporating the 25 factors believed to contribute to post-ICU adverse events was developed. The ICU liaison nurses who agreed to act as data collectors were instructed to complete the tool whenever they encountered a patient who experienced an adverse event following ICU discharge. Whenever such a patient was identified, the Nurses were asked to speak with the staff involved in the patient's care and to review the medical records to determine the factors contributing to the adverse events. Once the factors were identified, the Nurse ranked the factors in order of their contribution to the event. Factors having the greatest contribution were ranked as 1 and those contributing less given a lower ranking (e.g. 2, 3 or 4).

The clinicians best positioned to collect data were ICU liaison nurses due to their unique role in pre- and post-ICU patient care. Key responsibilities of ICU liaison nurses include facilitating ICU patient discharge, following up and managing unstable patients in ward areas, and providing a critical care resource for ward staff (Endacott *et al.*, 2010). These Nurses were recruited through the Australian College of Critical Care Nurses ICU Liaison Special Interest Group. The Group meets four times a year and communicates via an email list. At one of the group's meetings, a presentation of the research proposal was delivered by the Chief Investigator (M. E.). Following the presentation, Nurses at four Australian tertiary referral hospitals volunteered to act as data collectors.

Data analysis

Descriptive statistics were used for data analyses. To estimate the extent to which each of the 25 factors is present in post-ICU patients experiencing an adverse event, confidence intervals (CI) were calculated. CIs estimate the extent to which a given factor exists within a population based on the sample studied (Clarke, 2012). A method for estimating sample size in a study designed to measure prevalence in a single group is to nominate the level of precision that is required around the prevalence estimate and then to calculate the sample size needed to attain this (Peat *et al.*, 2001). A sample size of 70 was required to report 95% CI with $\pm 10\%$ precision (Peat *et al.*, 2001). 95% CIs are associated with a significance level (*p* value) of 0.05 (Cadeddu *et al.*, 2012; Connelly, 2013).

No assumptions or sampling techniques were used in the sample size estimation. Descriptive summaries of the frequency and 95% CI for reporting of each of the factors associated with post-ICU adverse events were calculated. For data analysis, factors having the

greatest contribution were grouped together (a ranking of 1 or 2), as were those contributing the least (a ranking of 3 or 4). The tool included a section to describe the patient's diagnosis and a section to list any other factors which also contributed to each adverse event.

Ethics approval for this study was obtained from a university Human Research Ethics Committee. The study was deemed negligible risk. Ethics Committees at participating hospitals also gave approval. No identifiable patient data were collected. All data were stored on security protected hardware. The ethical principles highlighted in the Declaration of Helsinki were followed.

RESULTS

Data were collected during an 18-month period in 2012 and 2013. A final sample size of 52 was obtained. This allowed reporting of 95% CI with $\pm 12\%$ precision. The factors associated with post-ICU adverse events were categorised into three domains: system, clinician and patient (Table 1).

Table 1 Factors associated with post-ICU adverse events

Factor	Percentage of patients in whom factor was present	95% Confidence interval	
		Ranking1 or 2	Ranking3 or 4
System factors			
Lack of/inadequate supervision of ward nursing staff	21	4.0–21.9	4.0–21.9
Lack of/inadequate supervision of ward medical staff	21	7.6–28.3	1.1–14.8
Lack of experienced nursing staff on the wards	16	2.9–19.6	1.9–17.3
Lack of experienced medical staff on the wards	27	11.5–34.4	1.1–14.8
Ward staffing levels below normal requirements	13	—	5.4–24.1
Heavy workloads on the wards	23	6.4–26.2	2.9–19.6
Ward nursing staff skill mix not usual ratio	13	1.1–14.8	1.9–17.3
ICU discharge process	23	5.2–24.1	4.0–21.9
Premature ICU discharge	32	7.6–28.3	7.6–28.3
After hours ICU discharge	21	2.9–19.6	5.2–24.1
Patient admitted to inappropriate ward	14	0.4–12.3	4.0–21.9
Lack of adequately qualified ward staff	13	1.1–14.8	1.9–17.3
Fragmentation of patient management due to input of multiple medical teams	20	4.0–21.9	2.9–19.6
Clinician factors			
Failure of staff to follow a rule or policy	21	4.0–21.9	4.0–21.9
Delay in providing nursing care	16	5.2–24.1	0.4–12.3
Inadequate patient handover from ICU to ward staff	11	0.04–9.5	2.9–19.6
Inadequate patient monitoring or assessment	23	10.2–32.4	0.4–12.3
Lack of recognition of or response to patient deterioration	38	15.8–40.3	2.9–19.6
Failure to deliver what is considered standard care	18	7.6–24.1	0.04–9.5
Failure to follow advice from a senior clinician	16	2.9–19.6	1.9–17.3
Delayed medical care on the ward	27	10.2–32.4	1.9–17.3
Patient factors			
Increased illness acuity	70	50.4–76.6	1.1–14.8
Presence of co-morbidities	57	32.9–60.3	4.0–21.9
Clinically challenging patients	46	21.8–47.8	4.0–21.9

ICU, intensive care unit.

Table 2 Other factors contributing to adverse events

- Incorrect choice of discharge ward
- Poor medical follow-up of patient on weekend
- Patient placed in room out of view of ward nurses' station
- High nurse to patient ratios on ward overnight
- Multiple doses of narcotic causing drowsiness
- Hypervolaemia
- Rapid clinical deterioration
- Delayed response to clinical deterioration on ward
- Clinical deterioration due to combination of acute and chronic co-morbidities
- Incorrect choice of medical treatment
- Tracheostomy patient being given oral fluid despite being nil by mouth
- Patient not adherent to ward nursing care due to delirium
- Lack of evidence-based guidelines for medical care
- Patient at high risk of aspiration

Additional factors were identified by the data collectors that were not on the data collection tool but also contributed to the adverse events. Fourteen factors were described (Table 2), and each of these factors was present in only one or two patients.

DISCUSSION

Limited data are available on the incidence, characteristics and outcomes of patients who experience an adverse event following ICU discharge (Williams *et al.*, 2010). Little is also known about the quality of patient care during the transition from ICU (Stelfox *et al.*, 2013). To be able to provide post-ICU patients with the best possible outcomes, more needs to be known about factors associated with adverse events in this high-risk population.

This study therefore aimed to clinically validate 25 factors ICU liaison nurses believe are associated with post-ICU adverse events. Seven factors contributed to adverse events in 25% or more of the study sample. Three factors contributed to adverse events in nearly half or more of the sample. These three factors were unique to the patients themselves: illness severity, co-morbidities and patients whom ward staff found to be clinically challenging.

Apart from readmission and mortality, post-ICU adverse events have received scant attention in the research literature. This is probably because these two events are easier to quantify than others. Furthermore, post-ICU mortality, as a potentially preventable and undesirable event, represents the worst of all possible adverse outcomes. However, while much is known about post-ICU mortality and readmission, less is

known about other post-ICU adverse events and their associated factors.

Two recent Australian studies examined post-ICU adverse events primarily using chart review (McLaughlin *et al.*, 2007; Chaboyer *et al.*, 2008). In one of these, patients who experienced an adverse event were more frequently discharged in the evening or night (McLaughlin *et al.*, 2007). In this study, after-hours ICU discharge contributed to adverse events in nearly a quarter of patients. The ICU discharge process and premature ICU discharge were also key factors, contributing to events in 23% and 32% of patients, respectively. Other studies also identified the negative consequences of discharging patients from ICU prematurely (Chrusch *et al.*, 2009; Barker and Flint, 2010).

The ICU discharge process may therefore be a key area where strategies to reduce the risk of post-ICU adverse events could be most effective. The ICU discharge process is, however, influenced by many factors such as hospital bed management activity and competing priorities on the receiving ward (Lin *et al.*, 2013). Standardising the ICU discharge process could improve the safety, quality and efficacy of post-ICU care (Stelfox *et al.*, 2013). Research is attempting to identify the best ways to achieve this (Watts *et al.*, 2005; Lin *et al.*, 2009). Proposed strategies include reducing invasive technology prior to ICU discharge (Haggstrom *et al.*, 2012).

An inappropriate level of care on the wards, breakdown in care continuity and failure to record, or infrequent measurement of, vital signs have also been associated with post-ICU adverse events (McLaughlin *et al.*, 2007). Similar factors were identified in this study; these included delayed medical care on the ward and failure to deliver standard care. Other studies have highlighted suboptimal care delivery on hospital wards (Goldhill *et al.*, 1999; Hodgetts *et al.*, 2002).

The landmark inquiry into care before ICU admission found the management of airway, breathing, circulation and oxygen therapy on the wards to frequently be suboptimal (McQuillan *et al.*, 1998). The main causes of suboptimal care were lack of knowledge, lack of supervision, failure to appreciate clinical urgency and failure to seek advice (McQuillan *et al.*, 1998). A failure to measure vital signs has also been observed before emergency ICU admission (Jonsson *et al.*, 2011). A lack of, or inadequate, supervision of ward nursing and medical staff, failure of staff to follow a rule or policy, and lack of experienced medical and nursing staff on the wards similarly contributed to adverse events in this study.

These findings, and those of other studies, highlight the challenges ward staff face when caring for acute patients, and suggest that general wards are not the

ideal environment for post-ICU patients who are at risk. Ward staff have described a sense of dread and feeling of depression when informed that a patient was to be transferred from ICU (Whittaker and Ball, 2000). Providing ward staff with the knowledge and skills needed to care for these patients may be another strategy for limiting the frequency or severity of post-ICU adverse events. Education of ward staff may be a key role of Critical Care Outreach Teams and ICU liaison nurses.

In another Australian study, univariate and multivariate predictors of post-ICU adverse events included respiratory rate less than 10 or greater than 25 and a pulse rate greater than 110/min at the time of ICU discharge (Chaboyer *et al.*, 2008). The recording and reporting of vital signs were concluded as being important to post-ICU outcomes (Chaboyer *et al.*, 2008). This would seem self-evident, as simple physiological observations can identify high-risk patients (Goldhill and McNarry, 2004). However, delays in taking action for abnormal vital signs and infrequent charting have been identified in patients experiencing a post-ICU adverse event (McLaughlin *et al.*, 2007). This study validated the contribution of similar factors including inadequate patient monitoring or assessment and lack of recognition or response to patient deterioration. Other research similarly found that ward patients do not have their vital signs measured as often as they should and that patient deterioration often goes unrecognised (Fuhrmann *et al.*, 2008; Leuven and Mitchell, 2008; Chen *et al.*, 2009). Unfortunately this is not a new clinical problem, suggesting that little progress is being made on this issue (Smith and Wood 1998).

In a retrospective audit of post-operative patients' medical records, ward documentation of vital signs became less frequent as the number of post-operative days increased, possibly suggesting a perception that the patient was stable (McGain *et al.*, 2008). If this is the case with post-ICU patients, it may explain the inadequate monitoring and assessment validated in this study. Ward staff might assume that if numerous days have passed since a patient was discharged from ICU, then the critical illness has resolved and less observation and assessment are needed. This is an important care issue requiring further investigation, particularly if these beliefs or assumptions reflect local practices. If a culture of limited documentation is applied to high-risk patients, it may have appreciable negative consequences (McGain *et al.*, 2008).

Hospital and patient factors can increase the frequency of the measurement and documentation of vital signs. The presence of epidural or patient-controlled analgesia for example has been shown to increase the incidence of vital sign measurement

(McGain *et al.*, 2008). The reasons for this are unclear, but it may be due to a mandatory requirement for more frequent documentation in those patients (McGain *et al.*, 2008). The increased frequency may also be due to nurses' perception of the importance of vital signs assessment in certain high-risk patients. Again, this is an area in need of further investigation, particularly to determine the type of post-ICU patient that ward staff perceive to be at greatest risk.

In this study, the three factors contributing to the most adverse events reflected patients' characteristics: illness acuity, co-morbidities and the challenging nature of many patients. The presence of co-morbidities has been previously shown to contribute to other adverse events, although is not a factor which can be modified (Thomas and Brennan 2000). Clinicians should be mindful that post-ICU patients with co-morbidities are at greater risk of an adverse event than other patients. Given that co-morbidities often reflect the ageing process and that many patients admitted to ICU are aged 60 years and over, there will always be a risk of some patients experiencing an adverse event following ICU discharge (Song *et al.*, 2007).

Other factors not previously reported by ICU liaison nurses to be associated with post-ICU adverse events were identified in this study. However, each of these only contributed to adverse events in one or two patients. Some of these factors have been identified in other research and include poor medical follow-up of the patient, fluid mismanagement and nurse to patient ratios (Neale *et al.*, 2001; Rothberg *et al.*, 2005; McGain *et al.*, 2008). Although these factors were not validated by this study, because they have been identified in other research, their impact on post-ICU patient outcomes is worthy of further investigation.

Practice implications

The results of this study allow patients at risk of post-ICU adverse events to be more easily identified at the ward level. While it remains unclear what preventative action should be taken for those patients, this study is a starting point in that process. Ward staff caring for post-ICU patients should be aware that these patients are at higher risk of adverse events than other patients. They should also be mindful of the factors highlighted in this study which contribute to adverse events in post-ICU patients.

In particular, clinicians who help to coordinate post-ICU care such as Critical Care Outreach Teams and ICU liaison nurses should be alert to the potential impact that these factors have on post-ICU patients' outcomes. Factors such as the frequency with which ward staff perform assessments of post-ICU patients for example may be modified through staff education,

and therefore prevent some patients experiencing an adverse event post-ICU discharge.

Research implications

This study has identified numerous issues requiring further investigation. These include staff perceptions of what a high-risk post-ICU patient is; the knowledge and skills ward staff need to care for these at-risk patients; and ward staff perceptions of how high-risk patients should be assessed. The impact of other factors identified by the ICU liaison nurses, which also contributed to the adverse events in this study, is also worthy of further exploration.

Limitations

The method used for data validation in this study has a number of limitations. The study results may reflect each liaison nurse's interpretation or analysis of the adverse events they encountered in clinical practice. Each Nurse's analysis may have been based on clinical data and documentation in medical records. As such, there is a degree of subjectivity to the data collected and the results of this study. This, however, is a limitation common to any study with clinician involvement in the interpretation or documentation of adverse events. The results of this study also reflect adverse events

occurring in post-ICU patients in the Australian health care system. It is recommended that the 25 factors be further validated in other health care systems round the world.

Some of the study's findings may also reflect inadequate communication between health professionals. The contribution of poor communication, however, is difficult to identify and measure; this should be considered when interpreting the study's findings.

The 25 factors validated in this study originated from the literature and other research. It is possible, however, that factors other than these 25, contribute to post-ICU adverse events. Some for example, may be those in Table 2, which require further validation.

CONCLUSION

Little is currently known about factors associated with post-ICU adverse events. This study validated 25 factors clinical experts believe to be associated with adverse events in the post-ICU population. Key factors were those unique to patients, and as such are not easily modified. Future research should focus on how clinical care should be streamlined in light of factors which are modifiable. Changing the way in which clinical care is delivered may help reduce the risk of future adverse events in post-ICU patients.

WHAT IS KNOWN ABOUT THIS TOPIC

- Patients admitted to ICU are at high risk of adverse events.
- Many patients discharged from ICU continue to have complex care needs, sustaining the risk of adverse events in a ward environment.
- Research on post-ICU adverse events has focused primarily on mortality and readmission.

WHAT THIS PAPER ADDS

- Factors associated with the most post-ICU adverse events are those related to the patient.
- By focusing on modifiable factors in care processes, the risk of post-ICU adverse events may be reduced.

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Chapter summary

This chapter presented the third and final phase of the research program. Phase III, a clinical validation study of factors believed to contribute to post-ICU adverse events is unique in both its method and findings. To date, ICU Liaison Nurses' and other clinicians' opinions of factors associated with post-ICU adverse events have been unknown and thus not reported. Phase III of the research program aimed to validate those Nurses' opinions.

Consistent with the findings of Phase II, some of the factors validated in Phase III are not modifiable, such as the presence of co-morbidities. Other factors though, such as ICU discharge processes, may be modified. Care processes and future research should focus on these factors to help reduce the risk of future post-ICU adverse events. Phase III of the research program made a number of key recommendations for clinical practice.

Ward staff need be educated on the importance of thorough and ongoing assessment of post-ICU patients. While this might seem self-evident, Phase III validated the contribution of inadequate patient assessment to post-ICU adverse events. Other studies have similarly identified suboptimal assessment of ward patients. Failing to adequately assess high-risk patients, such as those recently discharged from ICU, increases the likelihood of poor outcomes.

Patients should only be discharged from ICU when their critical illness has resolved and they are ready for the lower intensity care delivered at the ward level. The premature discharge of ICU patients, including discharge after hours, typically reflects an urgent need for an ICU bed rather than an ICU patient's readiness for ward care. The contribution of premature discharge and after hours discharge was validated in Phase III of the research program. Patients discharged from ICU under these conditions create a unique challenge for ward staff because wards are not sufficiently resourced to provide the higher level care these patients need.

Admitting patients to a ward when they are not yet ready to be discharged from ICU increases the risk of an adverse event. This practice partly explains why some post-ICU patients may receive suboptimal care. Nurse to patient ratios on general wards are not the same as in ICU because ward patients are of lower acuity. However,

when a higher acuity patient is admitted to a ward, competing priorities will prevent one or more patients receiving the necessary care.

Phase III also recommended areas for further research. These included exploring reasons for the inadequate monitoring and assessment of post-ICU patients. Ward staff perceptions of what a high risk patient is and the skills needed to care for these patients need to be identified. Evidence-based methods for improving the ICU discharge process to reduce the risk of post-ICU adverse event need to be established. Strategies for ICU Liaison Nurses to reduce the risk of post-ICU adverse events are also worthy of investigation.

The next chapter summarises the key findings of each phase of the research program, describes how each phase is linked and discusses the findings of the program overall. Chapter Eight highlights the strengths and limitations of the research program, and concludes by making recommendations for clinical practice and areas for future research.

CHAPTER 8

Discussion, future research and conclusion

Introduction

This final chapter summarises the findings of each research phase, and highlights the important contribution of the research program within the context of the existing body of literature on in-hospital post-ICU adverse events. This chapter also demonstrates how the questions guiding each phase of the research program were linked. Finally, the limitations and conclusions of the research program are discussed, as are areas for future research.

Background

For many years, adverse events have been recognised as a significant problem in acute health care settings. However despite decades of research, adverse events continue to occur with enormous cost to both health and economic outcomes. Chapter One outlined seminal research on adverse events and the associated responses of health care organisations around the world. Because of the complex nature of these events, the investigation and analysis of adverse events is challenging. Adverse events rarely have a single cause and typically, factors related to systems, clinicians and patients contribute. These factors include poorly designed equipment, poor supervision of junior staff, lack of knowledge or experience and poor communication (Bion & Hefner, 2004; Vincent, 2003).

There are also a variety of conceptual issues in the literature regarding adverse events. These include sentinel event, never event, near miss, failure to rescue and medical error. The use of these terms creates challenges when comparing studies, identifying common themes and making recommendations for practice. For example, many studies on post-ICU mortality and ICU readmission do not use the term adverse event. Researchers have also acknowledged that difficulties in identifying the true incidence of adverse events are related to the limitations of the research methods used; these are summarised in Chapter One. In recent years, there has therefore been a shift away from research focused on the incidence of adverse events to research focused on preventability and patient outcomes (Bion & Hefner, 2004).

Consistent with this contemporary focus, the research program examined adverse events occurring in patients discharged from Intensive Care. The objective of the

program was to add to the current understanding of these events. Specifically, the research program aimed to: explore the opinions and experiences of nurses who cared for patients readmitted to ICU; explore Liaison Nurses' opinions of factors associated with in-hospital post-ICU adverse events; and clinically validate these Nurses' opinions. The objective of the research program was achieved through a series of discrete studies using a mixed methods design and guided by an accident causation model.

Research question

The primary question that drove the research program was, what factors are associated with adverse events in patients discharged from ICU? Chapter Two presented two reviews of research on post-ICU adverse events. Contemporary literature primarily focuses on two specific events: ICU readmission and mortality. The reviews contained in Chapter Two showed that a variety of factors are associated with these two events, including those related to the patient. Other factors identified in the literature that contribute to in-hospital post-ICU events include the time of ICU discharge and the patient's readiness for discharge to a step-down environment.

Only two studies were identified in the literature that focused on a broader range of post-ICU adverse events (Chaboyer et al., 2008; McLaughlin et al., 2007). These Australian studies used the globally accepted definition of an adverse event: unintended patient harm or injury caused by medical treatment (Wilson et al., 1995). Adverse events identified by these studies included nosocomial infection, deep vein thrombosis, fluid overload and airway obstruction. Key factors found to contribute to post-ICU adverse events included delay in taking action for abnormal vital signs, discontinuity of care and nursing care requirements at the time of discharge. Vital signs at the time of ICU discharge were also found to predict a post-ICU adverse event occurring before hospital discharge.

These two studies were limited by their sample size, data collection period and number of sites involved. Both studies were conducted at single hospitals, limiting the ability to generalise their findings to other health care environments. One of the studies collected data for a 12-week period (McLaughlin et al., 2007). The studies' recommendations for future research included capitalising on the input of nurses

involved in the ICU discharge process (Chaboyer et al., 2008; McLaughlin et al., 2007).

As the majority of research on in-hospital post-ICU adverse events has primarily focused on two specific events, current knowledge and understanding of this unique clinical problem are limited. Little is known for example about the incidence, characteristics and outcomes of patients who experience an adverse event following ICU discharge (Williams et al., 2010a). The potential impact of factors related to the environment in which care is delivered, such as staffing levels and nurse to patient ratios, is also unclear. The research program was therefore conceptualised to help address this gap in the current understanding of in-hospital post-ICU adverse events.

Key findings of the program

Overall, the research program has provided new insight into the nature and characteristics of post-ICU adverse events, and has added to the limited understanding of this unique clinical problem. Key findings of each research phase are summarised in Tables 1, 2 and 3.

Table 1: Phase I key findings

Factors associated with ICU readmission:

- Premature ICU discharge
- Delayed medical care on the ward
- Heavy nursing workloads on the wards
- Lack of adequately qualified staff
- Clinically challenging patients who required staff to have a unique skill set.

Table 2: Phase II key findings

Key factors associated with post-ICU adverse events:

- System factors
 - Heavy ward workloads
 - Lack of experienced ward nursing staff
 - Lack of experienced ward medical staff
 - Lack of/inadequate supervision of nursing and medical staff on the ward
 - Lack of adequately qualified ward staff
- Clinician factors
 - Delayed medical care on the ward
 - Delayed nursing care on the ward
 - Lack of recognition or response to patient deterioration
 - Inadequate patient monitoring or assessment
 - Failure to deliver standard care
- Patient factors
 - Co-morbidities
 - Clinically challenging patients
 - Increased illness acuity

Table 3: Phase III key findings

Key factors associated with post-ICU adverse events:

- System factors
 - Premature ICU discharge
 - ICU discharge process
 - Lack of experienced medical staff on the wards
 - Lack of/inadequate supervision of nursing and medical staff on the wards
 - Heavy workloads on the wards
- Clinician factors
 - Lack of recognition or response to deterioration
 - Delayed medical care on the ward
 - Inadequate patient monitoring or assessment
 - Failure of staff to follow a rule or policy
- Patient factors
 - Co-morbidities
 - Clinically challenging patients
 - Increased illness acuity

Accident causation model

The research program has gone beyond mere descriptions of the medical diagnoses of patients experiencing in-hospital post-ICU adverse events and instead, identified and validated the contribution of numerous system, clinician and patient factors. The identification of these factors was guided by an accident causation model (Reason, 1995). The model is based on the premise that adverse events occurring within complex systems, such as health care, are due to either active or latent failures (Reason, 1990, 1995). Active failures refer to the action or inaction of a clinician, such as failure to follow a rule or policy. Latent failures are factors within a complex

system, which are less obvious but also contribute to adverse events; examples include nurse to patient ratios and an organisation's bed management culture.

Active failures

Consistent with the accident causation model, the active failures identified by the research program which contribute to post-ICU adverse events are: premature ICU discharge; delayed medical care on the ward; lack of recognition or response to deterioration; inadequate patient monitoring or assessment; and failure of staff to follow a rule or policy. As these factors reflect the behaviour or decisions of clinicians, they are factors which may be able to be eliminated with further education.

Latent failures

Latent failures identified by the research program which contribute to post-ICU adverse events are: heavy nursing workloads on the wards; lack of adequately qualified staff; lack of experienced ward nursing staff; lack of experienced ward medical staff; lack of/inadequate supervision of nursing and medical staff on the ward; and ICU discharge processes. Clinical staff may be aware that these factors reflect the less than ideal conditions in which clinical care is often delivered. However as these are tacit conditions as per Reason's model, their contribution to post-ICU adverse events may not be obvious.

Two of the factors identified by the research program, illness acuity and co-morbidities, cannot be easily modified; these two factors were identified in Phase II of the research program and validated in Phase III. There will therefore always be a risk of some post-ICU patients experiencing an adverse event before hospital discharge. The complex care needs of post-ICU patients place them at high risk for an adverse event (Chaboyer et al., 2008). Ward staff who care for these patients following ICU discharge should be alert to this inherent risk.

Research has found that the quality of pre-ICU care has an impact on post-ICU outcomes and that many ICU admissions are preventable (Goldhill & Sumner 1998; McGloin et al., 1999; McQuillan et al., 1998). For example, a study involving an audit of patient records at a 220 bed regional hospital found that 76% of patients had clinical markers prior to ICU admission (Endacott et al., 2007). Other research has

had a similar finding (Goldhill et al., 1999). If these clinical markers were acted upon, it is possible that some ICU admissions could have been avoided.

Improving the quality of pre-ICU care may not prevent all ICU admissions, but improving pre-ICU care may mean that some patients are admitted to ICU not as critically ill. Improving the quality of pre-ICU care may be the key to modifying ICU patients' illness acuity and may help reduce the risk of a post-ICU adverse event. However, because many patients are admitted to ICU unexpectedly, improving these patients' pre-ICU care potentially means improving the care of all acute hospitalised patients. Research is currently attempting to improve ICU patients' outcomes by early detection and intervention of at risk patients (Alvarez et al, 2013).

Modifiable factors

Several factors identified by the research program which are associated with in-hospital post-ICU adverse events are modifiable. These findings represent areas in care processes that provide the greatest opportunity for improving post-ICU patient outcomes. Phase I of the research program found that premature ICU discharge is associated with ICU readmission. Phases II and III similarly found that premature discharge is a key factor associated with post-ICU adverse events. Patients who are discharged from ICU prematurely may not receive the appropriate level of care in ward areas simply because the ward environment is not resourced to provide the level of care needed. As a result, these patients may deteriorate, resulting in an adverse outcome (Scottish Intensive Care Society Audit Group, 2012).

Premature discharge

More than half of the ICU Liaison Nurses in Phase II indicated that premature ICU discharge sometimes contributes to post-ICU adverse events; nearly 20% said it often or always contributes. The association of premature ICU discharge with post-ICU adverse events was validated in Phase III. If patients are discharged from ICU to an area of lower care intensity before they are clinically ready, they are placed at risk of an adverse event. Premature discharge from ICU is therefore considered to be a quality indicator (Duke et al., 2005).

The premature discharge of patients from ICU may be a reflection of the pressure ICU staff are under and the limited resources available to them. Although it is

unlikely ICU staff willingly discharge patients from ICU before the patients are ready, doing so would obviously create a risk of an adverse event. In addition, due to finite clinical resources, ICU discharge decisions are often based on clinical judgement by considering which patients need an ICU bed the most (Yoon et al., 2004). If the ICU is full and staff are under pressure to admit another patient, then the lowest acuity patient may need to be discharged to an area of lesser care intensity, even though the patient is still unwell (Moreno et al., 2001). The habit of discharging ICU patients quicker and sicker is not new (Chaboyer et al., 2002).

Discharging patients from ICU before they are considered ready has been shown to double the risk of in-hospital post-ICU mortality (Blunt & Burchett, 2001). More than half of the ICU Liaison Nurses in Phase II believed that premature ICU discharge sometimes contributes to post-ICU adverse events, and nearly 20% indicated it often or always contributes. A recommendation has been made that for ICU patients with unresolved organ failure, discharge be delayed unless adequate monitoring and therapeutic resources are available on the ward (Moreno et al., 2001). High ICU occupancy and its impact on discharge practices are also associated with increased risk of ICU readmission (Chrusch et al., 2009). The practice of discharging ICU patients before they are ready has been described as a frequent problem in some clinical areas (Utzolino et al., 2010).

Patients discharged prematurely from ICU may need their vital signs to be measured more frequently than is the norm in a ward environment. But research has found that many ward patients often do not have their vital signs measured as frequently as they should and that vital sign derangements are often not noticed or acted upon (McGain et al., 2008; Oliver et al., 2010; Smith, 2008). In one Australian study involving an audit of 1,597 vital sign recordings in 62 ward patients, respiratory rate was documented an average of only once per day (Leuvan & Mitchell, 2008). This may be one reason why patients discharged from ICU prematurely have increased mortality rates (Daly et al., 2001; Goldfrad & Rowan, 2000); a failure of staff to recognise or act upon clinical deterioration.

The high demand for ICU beds is one explanation for the practice of discharging patients from ICU after hours. In Phase II of the research program, more than a third of ICU Liaison Nurses indicated that after-hours ICU discharge sometimes

contributes to post-ICU adverse events and a third said it often or always contributes. Discharge from ICU to a ward is most safely performed during the day when parent ward teams are still accessible (Scottish Intensive Care Society Audit Group, 2012). Research has demonstrated a negative impact of after-hours discharge on patient outcomes (Pilcher et al., 2006; Priestap & Martin, 2006; Singh et al., 2010).

ICU discharge process

The ICU discharge process may be a key area where strategies to reduce the risk of in-hospital post-ICU adverse events could be the most effective. Evidence-based guidelines may be one way to achieve this. Currently there is marked heterogeneity in ICU discharge processes and only a small number of ICUs use written patient discharge guidelines (Heidegger et al., 2005; Lin et al., 2009). The use of critical pathways has been shown to enhance the ICU discharge process (Watts et al., 2005). The effectiveness of Critical Care Outreach Services for facilitating ICU discharge though is yet to be demonstrated (Williams et al., 2010b).

A seminal study conducted in 20 ICUs in the United Kingdom found the post-discharge mortality rate of at risk patients may be reduced by 39% if these patients remain in ICU for another 48 hours (Daly et al., 2001), though demand for ICU beds may prevent this. A recent review found that ICU discharge 'by triage' still occurs, even though there is evidence that this practice and other factors increase the mortality risk (Lin et al., 2009). One such risk factor is staff workloads; even if staff on the receiving ward recognise the higher level of care a post-ICU patient requires, it may be difficult for them to provide the required care due to the care demands of other patients. It is therefore not surprising that ward staff have described a sense of dread and felt depressed when informed that a patient was to be transferred from ICU (Whittaker & Ball, 2000).

Workloads

Heavy workloads on the wards were identified by Phase I as a key contributor to ICU readmission. Workloads were also identified in Phase II as being a key factor contributing to other post-ICU adverse events. The premature discharge of patients from ICU may also be a key contributor to staff workloads on the wards. This

combined with the clinically challenging nature of many post-ICU patients, another Phase I finding, adds to ward staff workloads.

Three patient factors were also identified in Phase III as being key contributors to post-ICU adverse events. These factors were: the clinically challenging nature of many patients, increased illness acuity and the presence of co-morbidities. These factors increase patient complexity and care needs and thus the workloads of staff caring for them. Phase III validated the contribution of these three factors to post-ICU adverse events.

Care quality

Quality of post-ICU ward care was a key factor contributing to adverse events in the research program. Significant factors identified in Phase II included: lack of recognition or response to patient deterioration, inadequate patient monitoring or assessment, failure to deliver standard care and delay in providing nursing care. There are a variety of explanations for these findings. As described, if a patient is discharged from ICU prematurely, it is unrealistic to expect ICU level care to be delivered in another environment, particularly one with lower nurse to patient ratios.

Seminal research has speculated that some post-ICU deaths could have been prevented with improved care on the wards (Wallis et al., 1997). While improved care was not defined and some deaths were expected, most of the mortality occurred in patients who were expected to survive (Wallis et al., 1997). Suboptimal care has been attributed to delays in recognising and reporting deterioration, inappropriate clinical treatment, lack of knowledge and skills, poor communication and organisational issues (McQuillan et al., 1998; NCEPOD, 2005; NPSA, 2007).

A further explanation for inadequate care of post-ICU patients is the limited knowledge and skills ward staff may have related to resuscitation. A survey of nearly 500 ward nurses in Korea found that less than half had recent experience caring for patients with chest pain, arrhythmias or cardiac arrest (Roh et al., 2012). This may simply have been because these nurses worked on hospital wards and not in high acuity areas such as ICU where patients are more likely to have these clinical conditions. However, only a third of the nurses in the Korean study had received simulation-based resuscitation training. Insufficient training, lack of competence and

lack of confidence were found to be barriers to optimal resuscitation performance (Roh et al., 2012).

In Phase II of the research program, more than half of the ICU Liaison Nurses similarly felt that a lack of adequately qualified ward staff sometimes contributes to post-ICU adverse events and more than one third felt it often or always contributes. Nearly half the Nurses felt that a failure to deliver standard care often or always contributes to post-ICU adverse events.

Communication

Quality of care is also influenced by communication between clinicians caring for patients on the ward. Communication breakdown has been identified as a factor contributing to sub-optimal or inadequate care and is a current focus of the Australian Commission on Safety and Quality in Health Care (ACSQHC, *n.d.* c). Delayed medical care on the ward was identified in Phase II of the research program as a key contributor to post-ICU adverse events; some delays may have been due to inadequate communication between nursing and medical staff. Other key research has also identified communication as being a factor contributing to inadequate care of critically ill patients (Goldhill et al., 1999; McQuillan et al., 1998).

Many factors contribute to delayed medical care on the wards, and one is the failure of nursing staff to inform medical staff of a patient's deterioration in a timely manner. A recent qualitative study involving nurses who had managed a patient referred to an ICU outreach team found that junior medical staff were often reluctant to seek assistance from senior colleagues (Donohue & Endacott, 2010). Not surprisingly, research has found that undergraduate medical curricula often lack a critical care component (Frakel et al., 2004). This may contribute to the absence of acute care skills found amongst junior doctors and explain why they struggle to care for acutely ill patients (Buist et al., 2001; Smith & Poplett, 2002). It has also been recommended that nursing curricula emphasise the importance of identifying clinical trends and acting upon clinical deterioration (Endacott et al., 2010).

Staff issues

Other factors identified by the research program that contribute to staff workloads are nurse to patient ratios, staff skill mix, ward staffing levels, lack of qualified ward

staff and lack of or inadequate supervision of nursing staff. These are latent factors and were identified in Phases I and II of the research program. Other research has found that nurse to patient ratios influence patient outcomes. In one North American study involving 232,342 patients, each additional patient per nurse was associated with a 7% increase in the risk of death and a 7% increase in the risk of failure to rescue (Aiken et al., 2002). Other studies had similar findings (Blegen et al., 2011; Needleman et al., 2011; Rothberg et al., 2005). A recent systematic review also demonstrated an associated between increased registered nurse staffing and lower risk of hospital mortality and adverse events (Kane et al., 2007).

This suggests that the type of nurse or the knowledge and skills of the bedside nurse influences the incidence of adverse events. It is no surprise that the research program found that a lack of appropriately qualified ward staff contributes to post-ICU adverse events. The implication of this is that the most knowledgeable or skilled nurse on the ward should be caring for the most at risk patients, such as those recently discharged from Intensive Care.

Given that the ICU Liaison Nurses' opinions from Phase II of the research program were validated in Phase III, it is possible that experienced ICU staff may be able to accurately predict which patients are most likely to experience a post-ICU adverse event. This may be another strategy for improving the ICU discharge process. If ICU staff could predict patients who are likely to experience a post-ICU adverse event, these patients' discharge could be delayed, or if that is not possible, action could be taken to decrease the risk (such as admitting the patient to a high-dependency unit instead of a ward).

In a recent pilot study, ICU nurses could accurately identify patients' post-acute care needs; influential factors included the reason for the hospital admission and the patient's current functional status (Holland et al., 2012). Future research needs to determine if ICU staff can accurately predict which patients will experience an adverse event post-ICU discharge. The findings of such a study, along with the findings of this research program, may help reduce the incidence of in-hospital post-ICU adverse events by identifying which patients to target.

One of the key components of the ICU discharge process is communication between ICU and ward staff; deficits in this area may also contribute to post-ICU adverse

events. For example, an audit of 123 ICU medical transfer reports found that 64% contained at least one error, and of these, 28% were considered potentially harmful (Perrens et al., 2008). In Phase II of the research program, more than 70% of the ICU Liaison Nurses felt that the ICU discharge process sometimes or always contributes to post-ICU adverse events. Similarly, nearly 70% of the Liaison Nurses felt that inadequate handover from ICU to ward staff sometimes or always contributes.

A study of the recognition and communication of patient deterioration also highlighted the contribution of staffing issues to patient care (Endacott et al., 2007). The study involved interviews with nurses and doctors who had been involved in the care of patients unexpectedly admitted to ICU. Staffing issues reported to influence patient care included: staff shortages; wide variation in staff skill mix from shift to shift; frequent use of casual and part time staff; and demands on the time of medical staff (Endacott et al., 2007). Reduced staffing after hours and the use of 'covering' doctors who were not familiar with the patients, were also reported to contribute.

Scholarly contribution

This research program has made a number of contributions to the scholarly literature. The program explored the perceptions and experiences of nurses involved in the care of patients readmitted to ICU. Five key factors contributing to this unique in-hospital post-ICU adverse event were identified. Much of the research to date on ICU readmissions has focused on disease processes of readmitted patients and has done so via medical chart review. The findings of Phase I represent key areas in care processes worth targeting to reduce the risk of ICU readmission.

Phase II of the research program was informed by Phase I. It capitalised on a group of clinical experts' experience and identified key factors associated with post-ICU adverse events. Previous research has primarily focused on ICU readmission and mortality. The findings of Phase II demonstrated that many of the factors associated with adverse events in other acute settings contribute to these events following ICU discharge. However, unique factors associated with post-ICU adverse events were also identified.

The third and final phase of the research program clinically validated the findings of the earlier research phases. When data were prospectively collected on a sample of post-ICU patients who experienced an adverse event, the findings of Phases I and II of the program were substantiated. These findings represent new insight into the nature and characteristics of post-ICU adverse events: the contribution of system, clinician and patient factors. The findings add to the current understanding of this clinical problem and represent important areas for clinical care and research target to reduce the risk of future post-ICU adverse events.

The research program has a number of strengths. First, the program was guided by an accident causation model and is the first study on post-ICU adverse events to do so. Research on post-ICU adverse events occurring before hospital discharge has neither cited the use of an accident causation model nor commented on the contribution to current theory. The characteristics of the model that guided the research program are described in the publication in Chapter Three. Accident causation models have been used for many years in other high risk industries, such as the airline industry and nuclear power plants. Their application encourages a focus on key causative factors rather than superficially blaming those involved in adverse events. By identifying factors contributing to adverse events in acute health care, the way in which care is delivered can be modified and improved, which helps to avoid similar events in future.

Second, the research program used a mixed methods design. This design provides a more thorough understanding of the problem under investigation than use of a single method. Using a mixed methods design, the strengths of one method may compensate for the limitations of the other method, enhancing the rigour of the overall findings. Given the complex nature of adverse events and the numerous strengths of mixed method research designs, this method has been recommended for patient safety research (Brown et al., 2008a).

Finally, the research program capitalised on the experience and expertise of nurses involved in the discharge and care of post-ICU patients. Recent research on in-hospital post-ICU adverse events recommended that these nurses be used to understand these events further (Chaboyer et al., 2008). The findings of this program have helped to build research capacity through the expert opinion of key informants.

Limitations

As with any study, the research program has some limitations. Phase I was initial exploratory work and conducted in an Australian tertiary referral hospital. Although the hospital serves a large geographical population and contains a level III ICU, the findings of Phase I can only be generalised to similar hospitals within the Australian health care system. The findings may have differed if the study was conducted in a smaller Australian hospital, a hospital with a different level ICU or a hospital overseas. A further limitation of Phase I is that only the opinions and experiences of nurses were explored. Although this was an intended feature of the research design, the findings may have differed if medical staff were also interviewed. The unexplored opinions of medical staff involved in the care of patients readmitted to ICU are an area for further research.

The second phase of the research program was an online survey of ICU Liaison Nurses. They were asked to comment on 25 factors hypothesised to contribute to adverse events following ICU discharge. Although the findings are important they only represent collective expert opinion. While a good response rate was achieved, it is not clear as to the true percentage because the exact population of Australian ICU Liaison Nurses is unknown.

A further limitation is that the survey results were not analysed according to the type of hospital each respondent worked in. The results may have been strengthened if data were analysed according to hospital type. For example, ICU Liaison Nurses employed in a metropolitan tertiary referral hospital may have differing roles, responsibilities and experiences to those employed in smaller regional hospitals. Another limitation is that the sample for the pilot and main study may have had a few identical members.

The final phase of the research program involved clinical validation of the findings of Phase II. A tool was used to prospectively collect data on the factors contributing to adverse events in patients discharged from ICU. Although Phase III data were collected at four tertiary referral hospitals in a metropolitan city, similar to Phase II, the findings may have differed if data were collected at differing hospitals. The findings of Phase III only reflect post-ICU patients who experience an adverse event

in a metropolitan hospital with a level III ICU. Furthermore, without adjusting for potential confounders, the contribution of each factor is unknown.

A data dictionary was not used for phase III. Although the data collection tool included the international definition of an adverse event, individual data collectors determined whether or not a post-ICU patient experienced an adverse event. This may have affected the validation of some factors in this phase of the research program. The findings also only reflect nurses' perspectives.

Recommendations for practice

There are a number of recommendations for clinical practice arising from this research program. Given that up to a third of post-ICU patients may experience an adverse event prior to hospital discharge, and that many of these events have been deemed avoidable, it is imperative that the outcomes of this research program be translated into clinical practice.

Patients at risk of in-hospital post-ICU adverse events should be identified before ICU discharge. While this may not be possible for every patient at risk, the findings of this research program allow many at-risk patients to be more easily identified. Factors identified by the research program which ICU staff may be able to influence include the ICU discharge process (e.g., premature discharge, after hours discharge) and the quality of handover given to ward staff. Once a patient about to be discharged from ICU is identified as being at risk, action should be taken to reduce or eliminate the risk. Currently though, there are no evidence-based strategies for reducing the risk of in-hospital post-ICU adverse events. However, many of the findings of this research program represent modifiable factors within care processes, such as the time of ICU discharge.

When a patient discharged from ICU is determined to be at risk of an adverse event, staff on the receiving ward should be informed of this. Some patients though are discharged from ICU quickly to free a bed for an urgent case and ICU staff may not have time to assess a patient's risk of a post-ICU adverse event. Ward staff should therefore be aware of the factors associated with post-ICU adverse events and assess post-ICU patients to determine their risk. It is possible though that staff are

already aware of these factors but system factors inhibit them from taking preventative action.

When ward staff identify a patient at risk, or are informed by ICU staff that a patient is at risk of a post-ICU adverse event, steps should be taken to eliminate or reduce the impact of the risk factors. Ward staff though can only focus on factors which are modifiable. For example, ward staff may have little or no influence over the time a patient is discharged from ICU, or if the discharge is premature. However, if a patient is discharged from ICU prematurely, ward staff should be aware of the associated risks in order to manage them.

A lack of experienced medical staff and delayed medical care on the wards also contributes to post-ICU adverse events. Ward nursing staff have little influence over these factors, but ward staff should be aware of the contribution of these factors to post-ICU adverse events. If nursing staff are concerned that the medical advice they are given about a post-ICU patient is incorrect, or that a post-ICU patient is not receiving medical care in a timely manner, clinical care should be escalated. For example, it may be appropriate to request the input of an ICU Liaison Nurse or Medical Emergency Team. Factors which ward staff have control over include the frequency of vital sign measurements and the interpretation of these signs.

Ward staff should also be aware of the impact of less obvious factors on the risk of post-ICU adverse events. These include failure to follow a rule or policy, failure to follow advice from a senior clinician, and lack of recognition or response to patient deterioration. Being aware of these factors requires staff to reflect on their own clinical practice. While failing to follow a clinical guideline may have few consequences for some patients, the risk of doing this with post-ICU patients is significant. Less experienced or qualified ward staff in particular should be aware of this.

Similarly, ward staff must be aware of the importance of measuring and interpreting the vital signs of post-ICU patients. Research has demonstrated the consequences of failing to act upon clinical deterioration of general ward patients. Failing to deliver standard care such as the frequent measurement of vital signs, has far greater consequences for post-ICU patients.

Future research

There are a number of recommendations for future research arising from the research program. These may help to confirm, support or challenge the findings of the program.

1. The findings of the research program provide a good basis for future research to develop a clinical tool for assessing the risk of in-hospital post-ICU adverse events.
2. Inadequate patient assessment was found by the research program and previous research to contribute to post-ICU adverse events. More research needs to be conducted on the clinical assessment of post-ICU patients. Research is needed to explore why this important component of clinical care is often neglected on the wards.
3. Identifying these factors is step towards addressing a modifiable factor in care processes which contribute to adverse events.
 - i. Attention should also be given to why the measurement of respiratory care is often neglected in ward patients. This could be achieved via a qualitative study of ward nurses.
4. The factors associated with post-ICU adverse events may differ between hospitals. While some factors may be common in similar hospitals (e.g., tertiary referral hospitals), it is worth exploring if contributing factors differ between hospitals (e.g., regional vs. metropolitan).
5. Numerous factors associated with in-hospital post-ICU adverse events are modifiable. Future research needs to identify the best way to eliminate these factors from care processes or minimise their impact.
6. A prospective observational study comparing ICU staff's predictions of which patients will experience an in-hospital post-ICU adverse event with those who actually do, is worth conducting. If staff predictions are accurate then patients at risk could be targeted. While it remains

unclear what the best strategies are for reducing the risk of post-ICU adverse events, identifying at risk patients is a starting point.

7. A randomised controlled trial to examine the impact of specific interventions to reduce or eliminate in-hospital post-ICU adverse events is needed. Evidence for example, is inconclusive about the benefits of High Dependency Units. A trial comparing the outcomes of post-ICU patients admitted to these Units with those admitted directly to a ward would be beneficial.

Conclusion

This research program is a continuation of contemporary research and provides further insight into the problem of in-hospital post-ICU adverse events. The research program reveals that post-ICU adverse events are a complex, multi-factorial problem with a causal chain that goes beyond acute disease processes. It appears that factors relating to system, clinician and patient issues contribute to the development of post-ICU adverse events. Future research should explore key findings of this research program.

CHAPTER 9

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APPENDICES

Appendix I: Phase II questionnaire

1. Welcome

Whilst adverse events in ICU have been widely researched, little is known about the factors which contribute to adverse events in patients recently discharged from ICU. The purpose of this survey is to investigate those factors.

What is an adverse event? Unintended injury or an event that results in temporary or permanent disability, and is caused by health care management rather than the patient's disease or illness (Wilson et al, 1995).

Examples include (but are not limited to): falls, pressure areas, DVT/PE, infection (chest, wound, blood), ICU readmission, unexpected cardiac arrest or death.

This survey has two parts. Section 1 asks some demographic questions (17 in total) about your role and the hospital in which you work. Section 2 asks you to rate the impact of various factors (24 in total) which may contribute to adverse events in patients discharged from ICU.

Only complete this survey if your job/role (or part of your role) involves following up patients after they are discharged from ICU.

*** 1. Does your role involve following up patients after they are discharged from ICU?**

☐ Yes

☐ No

2.

Thank you for taking the time to consider the survey. However at this time you do not qualify to complete the survey.

Kind regards,

The research team

3. Demographics

* 1. Approximately how many beds does your hospital have?

* 2. How many ICU beds does your hospital have?

4. Type of ICU

The College of Intensive Care Medicine's Minimum Standards for Intensive Care are as follows:

Level I ICU

- capable of providing immediate resuscitation and short term cardio-respiratory support for critically ill patients
- major role in monitoring and prevention of complications in 'at risk' patients
- capable of providing mechanical ventilation and simple invasive cardiovascular monitoring for at least several hours
- unit has a medical director who is experienced in intensive care medicine

Level II ICU

- capable of providing a high standard of general intensive care, including complex multi-system life support
- capable of providing mechanical ventilation, renal replacement therapy and cardiovascular monitoring for at least several days
- medical care is provided by an ICU specialist
- at least four staffed and equipped beds

Level III ICU

- tertiary referral unit capable of providing comprehensive critical care including complex multi-system life support
- medical care is provided by an ICU specialist
- at least six staffed and equipped beds

*** 1. Using the above criteria, please indicate the level of the ICU(s) in your hospital**

- ☐ I
- ☐ II
- ☐ III

5. Demographics (cont)

*** 1. Does your hospital have a specialty ICU? eg neurosurgical ICU, cardiothoracic ICU**

☐ No

☐ Yes

If yes please specify types (including general ICU)

*** 2. Does your hospital have step-down or high-dependency beds? High-dependency beds are beds in a specifically staffed and equipped unit that provide a level of care intermediate between intensive care and general ward care. Typically patients in these beds have single organ failure and are at risk of developing complications (College of Intensive Care Medicine, 2010).**

☐ Yes

☐ No

If they are specialty beds (eg cardiac), please state the type

3. If your hospital has high-dependency beds, how many does it have?

4. If your hospital has high-dependency beds, are they physically located within your ICU or another area?

☐ In ICU

☐ Another area (eg dedicated HDU)

☐ Both

*** 5. What type of ward(s) are the majority of patients sent to when discharged from your ICU?**

☐ Step-down or HDU

☐ General ward (eg medical, surgical)

☐ Specialty ward (eg orthopaedics, neurology)

Other (please specify)

*** 6. What model of nursing care delivery is mainly used on your hospital's wards?**

- ☐ Primary nursing (eg one nurse providing all care for specific patients)
- ☐ Team nursing (eg two nurses caring for many patients)
- ☐ Other (please specify)

*** 7. Does your role (or part of your role) involve following up patients after they are discharged from ICU?**

- ☐ Yes
- ☐ No

8. If yes, how long have you worked in this role?

*** 9. What are your post-graduate intensive/critical care qualifications?**

- ☐ ICU certificate (hospital based)
- ☐ Graduate Certificate (intensive/critical care nursing)
- ☐ Graduate Diploma (intensive/critical care nursing)
- ☐ Masters degree (please specify specialty)

Other (please specify)

*** 10. How many hours per day on average do ICU Liaison Nurses (or someone providing this service) work in your hospital?**

*** 11. Which hours of the day is this service available in your hospital?**

- ☐ 0700 - 1700hrs
- ☐ 0800 - 1700hrs
- ☐ 0800 - 1830hrs
- ☐ 0800 - 2000hrs
- ☐ 1700 - 0500hrs

Other (please specify)

*** 12. If this service is not available 24hrs/day in your hospital, what support is available to ward staff at other times (eg "call ICU Registrar")?**

*** 13. How long has the ICU Liaison Nurse role (or a similar service) existed in your hospital?**

6. Factors contributing to adverse events - System Factors

1. Please rate the extent to which you believe the following system factors influence the development of adverse events in patients discharged from ICU

	Never	Seldom	Sometimes	Often	Always
Lack of/inadequate supervision of ward medical/nursing staff (eg little input from medical registrar)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of experienced ward staff (or lack of input of experienced staff)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Equipment problems (eg not available; not working)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ward staffing levels below normal requirements (eg 1 nurse sick on a shift and unable to be replaced)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Heavy workloads on the wards (eg numerous patients with complex care needs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ward nursing staff skill mix not usual ratio (eg too few Registered Nurses on a shift)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nurse:patient ratios (ie ward staff allocated more patients than usual)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ICU discharge process (eg patient handed over quickly due to new ICU admission)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient discharged from ICU before they are ready (ie needing more than ward-level care or discharged on night shift)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient admitted to inappropriate ward (eg neurosurgical patient admitted to cardiac ward)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of adequately qualified ward staff (eg ward staffed by many graduate nurses)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Too many experienced ward staff	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

7. Factors contributing to adverse events - Human Factors

1. Please rate the extent to which you believe the following human factors influence the development of adverse events in patients discharged from ICU

	Never	Seldom	Sometimes	Often	Always
Failure of staff to follow a rule or policy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Delay in providing care (eg not sitting patient out of bed for 2 days post-ICU discharge)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Poor communication between staff (eg ICU staff not handing over vital patient information)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Care omission (eg failing to apply TED stockings)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Inadequate patient monitoring/assessment (eg not recording fluid balance)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Failure to deliver what is considered standard care (eg suctioning a tracheostomy prn)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Failure to follow advice from senior clinician (eg "suction patient more frequently")	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Delayed medical care on the ward (eg unable to contact doctor or doctor not reviewing patient promptly)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

8. Factors contributing to adverse events - Patient Factors

1. Please rate the extent to which you believe the following patient factors influence the development of adverse events in patients discharged from ICU

	Never	Seldom	Sometimes	Often	Always
Increased illness acuity (eg patient much sicker than the typical ward patient)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Presence of co-morbidities (eg diabetes)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Impaired ability to communicate (eg language barrier, tracheostomy)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Clinically challenging patients (eg confused patient; patient with central venous catheter, tracheostomy and chest drain)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The patient's age	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

9. Conclusion

1. Please describe any other factors, not mentioned previously, which relate to adverse events in patients discharged from ICU.

10. Thank you

Thank you for taking the time to complete this questionnaire.

We would like as many Liaison Nurses as possible to complete the questionnaire. Please forward the original email (with the link to this survey) to other staff at your hospital who also perform the ICU liaison nurse role.

The research team

Appendix II: Phase III data collection tool

Adverse Events following ICU Discharge - Data Collection Tool

Briefly describe the patient and adverse event (see guidelines on the back):

Please indicate the factors which contributed to the above event by ranking in order the relevant contributing factors below (eg 1 = greatest impact, 4 = least impact).

System Factors	
<input type="checkbox"/>	Lack of/inadequate supervision of ward nursing staff (by senior staff)
<input type="checkbox"/>	Lack of/inadequate supervision of ward medical staff (by senior staff)
<input type="checkbox"/>	Lack of experienced nursing staff on the ward
<input type="checkbox"/>	Lack of adequately qualified ward staff (eg post-graduate qualifications)
<input type="checkbox"/>	Ward staffing levels below normal requirements
<input type="checkbox"/>	Heavy workloads on the ward
<input type="checkbox"/>	Ward nursing skill mix not usual ratio
<input type="checkbox"/>	Lack of experienced medical staff on the ward
<input type="checkbox"/>	Fragmentation of patient management due to multiple medical teams
<input type="checkbox"/>	ICU discharge process (eg rushed to accommodate emergency admission)
<input type="checkbox"/>	Patient discharged from ICU prematurely (eg acute illness not completely resolved)
<input type="checkbox"/>	Patient discharged from ICU after hours (≥ 1800 hrs)
<input type="checkbox"/>	Patient admitted to different specialty ward (eg surgical patient on medical ward)
Human Factors	
<input type="checkbox"/>	Failure of staff to follow a rule or policy
<input type="checkbox"/>	Delay in providing nursing care on the ward
<input type="checkbox"/>	Delay in providing medical care on the ward
<input type="checkbox"/>	Inadequate handover from ICU
<input type="checkbox"/>	Inadequate patient monitoring or assessment
<input type="checkbox"/>	Lack of recognition or response to patient deterioration
<input type="checkbox"/>	Failure to deliver what is considered standard care
<input type="checkbox"/>	Failure to follow advice from a senior clinician
Patient Factors	
<input type="checkbox"/>	Increased illness acuity
<input type="checkbox"/>	Presence of co-morbidities
<input type="checkbox"/>	Clinically challenging patient (eg tracheostomy, chest drain, central venous catheter)

List any other relevant factors here

Guidelines for Tool completion

What is an adverse event?

“Any unintended harm or injury to a patient which is due to their health care but not their disease process or illness”. Examples include (but not limited to):

- medication errors; pressure areas; DVT/PE
- pulmonary oedema
- fluid mismanagement such as fluid overload (including poor documentation on Fluid Balance Chart)
- nosocomial infection e.g. UTI, wound infection, chest infection
- patient deterioration documented but no action taken despite deterioration being documented (e.g. on Observation Chart)
- unplanned ICU readmission or HDU admission
- unexpected death (cardiac or respiratory arrest)

Briefly describe the patient and adverse event - EXAMPLE

Details should include age, gender, co-morbidities, reason for ICU admission, ICU length of stay, number of days on ward, details of event.

*[do **NOT** provide identifiable data]*

54 year old male, type 2 diabetic; admitted to ICU following a high speed MVA. Was ventilated for 8 days. Discharged to a ward 4 days ago and developed pneumonia.

List any other relevant factors here - EXAMPLE

Patient was not sat out of bed for 4 days following ICU discharge despite this being ordered in the patient's medical file. The patient was also not frequently repositioned when in bed. No documentation of tracheostomy care.

Ethics approval letters



Illawarra Area Health Service

Address all correspondence:
Chief Executive Officer
Private Mail Bag 3
Port Kembla N.S.W. 2505

Telephone (02) 4275 5111

Ext ~~(02)~~ 4253 4800.....

YOUR REF:

OUR REF: *HE03/029*
AMENDMENT

1 October 2003

Mr M Elliott
5/2 Liddle Street
WOONONA NSW 2517

Dear Mr Elliott

ETHICS No: HE03/029

TITLE: "An exploration of the factors contributing to the readmission of patients to Intensive Care"

Approved Amendments:

* *To conduct interviews with nurses by telephone*

We have received notification dated 30 September 2003 from the Joint University of Wollongong/Illawarra Area Health Service Human Research Ethics Committee that these amendments have been approved.

The Illawarra Area Health Service notes and approves these amendments.

Yours sincerely

Tineke Robinson
Acting Chief Executive Officer

cc Dr Frances Phillips, Ethics Officer, University of Wollongong
Professor Anthony Hodgson, Joint Director of Health Research, IAHS/UOW

"Better Health, Better Service"

Human Research Ethics Committee

Committee Approval Form

Principal Investigator/Supervisor: A/Prof. Karen Page Melbourne Campus

Co-Investigators: Prof Linda Worrall-Carter Melbourne Campus

Student Researcher: Malcolm Elliott Melbourne Campus

Ethics approval has been granted for the following project:

Adverse events following discharge from intensive care

for the period: 4/10/2010 - 30/06/2011

Human Research Ethics Committee (HREC) Register Number: V2010 102

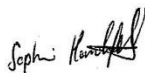
The following standard conditions as stipulated in the *National Statement on Ethical Conduct in Research Involving Humans* (2007) apply:

- (i) that Principal Investigators / Supervisors provide, on the form supplied by the Human Research Ethics Committee, annual reports on matters such as:
 - security of records
 - compliance with approved consent procedures and documentation
 - compliance with special conditions, and
- (ii) that researchers report to the HREC immediately any matter that might affect the ethical acceptability of the protocol, such as:
 - proposed changes to the protocol
 - unforeseen circumstances or events
 - adverse effects on participants

The HREC will conduct an audit each year of all projects deemed to be of more than low risk. There will also be random audits of a sample of projects considered to be of negligible risk and low risk on all campuses each year.

Within one month of the conclusion of the project, researchers are required to complete a *Final Report Form* and submit it to the local Research Services Officer.

If the project continues for more than one year, researchers are required to complete an *Annual Progress Report Form* and submit it to the local Research Services Officer within one month of the anniversary date of the ethics approval.



Signed: Date:04.10.2010.....
(Research Services Officer, Melbourne Campus)



Human Research Ethics Committee
Committee Approval Form

Principal Investigator/Supervisor: Linda Worrall-Carter Melbourne Campus
Co-Investigators: Melbourne Campus
Student Researcher: Malcolm Elliott Melbourne Campus

Ethics approval has been granted for the following project:
Determinants of adverse events after ICU discharge - a clinical validation study
for the period: 30/11/2011-1/06/2012
Human Research Ethics Committee (HREC) Register Number: V2011 132

Special Condition/s of Approval

Prior to commencement of your research, the following permissions are required to be submitted to the ACU HREC:
Approval letters from hospital HRECs

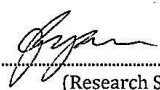
The following standard conditions as stipulated in the *National Statement on Ethical Conduct in Research Involving Humans* (2007) apply:

- (i) that Principal Investigators / Supervisors provide, on the form supplied by the Human Research Ethics Committee, annual reports on matters such as:
 - security of records
 - compliance with approved consent procedures and documentation
 - compliance with special conditions, and
- (ii) that researchers report to the HREC immediately any matter that might affect the ethical acceptability of the protocol, such as:
 - proposed changes to the protocol
 - unforeseen circumstances or events
 - adverse effects on participants

The HREC will conduct an audit each year of all projects deemed to be of more than low risk. There will also be random audits of a sample of projects considered to be of negligible risk and low risk on all campuses each year.

Within one month of the conclusion of the project, researchers are required to complete a *Final Report Form* and submit it to the local Research Services Officer.

If the project continues for more than one year, researchers are required to complete an *Annual Progress Report Form* and submit it to the local Research Services Officer within one month of the anniversary date of the ethics approval.

Signed:  Date:30/11/2011.....
(Research Services Officer, Melbourne Campus)

X:\Ethics Matters\Victoria\Ethics Applications\V2011\V2011 132 WorrallCarter Elliott\V2011 132 Approval Form.doc



Human Research Ethics Committee
Research Ethics Unit
Henry Buck Building
Austin Hospital

Austin Hospital

145 Studley Road
PO Box 5555 Heidelberg
Victoria Australia 3084
Telephone 03 9496 5000
Facsimile 03 9458 4779
www.austin.org.au

Phone: (03) 9496 4090

E-mail: ethics@austin.org.au

TO: Mr Malcolm Elliot
St Vincent's Centre for Nursing Research
Locked Bag 4115
FITZROY VIC 3065

PROJECT: Determinants of adverse events after ICU discharge - clinical validation study

PROJECT No: H2012/04547

Date: 8 May 2012

Approval Period: 2 May 2012 to 2 May 2015

Re: Ratification of Expedited Ethical Review

(1) Application version 2 dated 28 April 2012

(2) Protocol version 2 dated 28 April 2012

Thank you for submitting the above research project for ethical review. I am writing to inform you that your study was reviewed by several members of our Austin Health Human Research Ethics Committee, and your protocol, detailed above, was approved. This project now has full ethical approval for the approval period detailed above.

Austin Health HREC approval is granted from 2 May 2012 providing the following conditions being met:

1. Conditions

- The Austin Health HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
- The Principal Investigator will provide an annual report to the Austin Health HREC and at completion of the study in the specified format.
- Should your study not commence twelve (12) months from the date of this letter this approval will lapse. A resubmission to the Human Research Ethics Committee would then be necessary before you could commence.

2. Reporting

The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including any unforeseen events that might affect continued ethical acceptability of the project. Serious Adverse Events must be notified to the Committee **within 48 hours of the event** by the Principal Investigator. In addition the Principal Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Participant Information Sheet and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.


3. Amendments

If there is an event requiring amendments to be submitted you should follow the instructions found on the following website:
<http://www.austin.org.au/Page.aspx?ID=416>

Should you have any queries about the Austin Health HREC's consideration of your project please contact Research Ethics Unit on (03) 9496 4090 or email ethics@austin.org.au. The Austin Health HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from <http://www.austin.org.au/Page.aspx?ID=416> or from the Research Ethics Unit.

The Austin Health HREC wishes you every success in your research.

Yours Sincerely,


pp **Jill Davis** Heidi Aounke
Manager, Research Ethics Unit

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice annotated with TGA comments (July 2008)* and the applicable laws and regulations; and the *Health Privacy Principles in The Health Record Act 2001*. The process this HREC uses to review multi-centre research proposals has been certified by the NHMRC.

Human Research Ethics Committee - Scientific and Ethical Review

Ethical Approval – Granted

Commencement of Research at Eastern Health
has been authorised

16 July 2012

Mr Malcolm Elliott
C/o ACU/St Vincent's Centre for Nursing Research
Locked Bag 4115
Fitzroy MDC
Fitzroy VIC 3065

Eastern Health Research and
Ethics Committee
Ph: 03 9895 3398
Fax: 03 9094 9610
Email:
ethics@easternhealth.org.au
Website:
www.easternhealth.org.au/ethics

Dear Mr Elliott

LR86/1112 Determinants of adverse events after ICU discharge – a clinical validation study

Principal Investigator: Mr Malcolm Elliott

Associate Investigators: Professor Linda Worrall-Carter & Dr Karen Page

Eastern Health contact person: Ms Renata Mistarz

Eastern Health Site: Box Hill Hospital

Approval Period: On-going - subject to a satisfactory progress report being submitted annually

Thank you for the submission of the above project for review. Project has been reviewed by the Eastern Health Research and Ethics Committee. The project is considered of negligible risk/low risk in accordance with definitions given in the National Statement (2007). All queries have now been addressed and the project is accordingly **APPROVED**.

Documents submitted for review:

- Low Risk & Negligible Risk Research Application Form – Revised Sections 5.4 & 5.5
- Research proposal version 1 dated 26 January 2012
- Participant Information and consent Form version 2 dated 03 June 2012
- Adverse Events following ICU Discharge - Data Collection Tool version 1 dated 26 January 2012
- Curriculum Vitae – Malcolm Elliot, Linda Worrall-Carter & Karen Page
- Response to ethics queries dated 16 June 2012

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Correspondence from EH\LR86-1112 Final Approval 16Jul12.doc
Page 1 of 2

Members of Eastern Health

Angliss Hospital
Tel (03) 9764 6111

Box Hill Hospital
Tel (03) 9895 3333

Healesville & District
Hospital
Tel (03) 5962 4300

Maroondah Hospital
Tel (03) 9871 3333

Peter James Centre
Tel (03) 9881 1888

Wantirna Health
Tel (03) 9955 1200

Yarra Ranges Health
Tel (03) 9091 8888

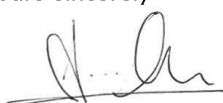
Yarra Valley
Community Health Service
Tel 1300 130 381

IMPORTANT: A final progress report should be submitted on project completion. If the project continues beyond 12 months an annual progress report should be submitted in **July 2013**. Continuing approval is subject to the submission of satisfactory progress reports. Progress report template can be downloaded from our web-page:

<http://www.easternhealth.org.au/research/ethics/progressreports.aspx>

Please quote our reference number **LR86/1112** in all future correspondence.

Yours sincerely



Ms Virginia Ma
Administrative Assistant
Eastern Health Office of Research and Ethics
(Signed on behalf of the Eastern Health Research and Ethics Committee)

Copy to:

- Ms Renata Mistarz, Professor Linda Worrall-Carter & Dr Karen Page

Confidentiality, Privacy & Research

Research data stored on personal computers, USBs and other portable electronic devices must not be identifiable. No patients' names or UR numbers must be stored on these devices.

Electronic storage devices must be password protected or encrypted.

The conduct of research must be compliant with the conditions of ethics approval and Eastern Health policies.

Publications

Whilst the Eastern Health Research and Ethics Committee is an independent committee, the committee and Eastern Health management encourage the publication of the results of research in a discipline appropriate manner. Publications provide evidence of the contribution that participants, researchers and funding sources make.

It is very important that the role of Eastern Health is acknowledged in publications.



11 January 2012

Malcolm Elliott
PhD Candidate
Australian Catholic University
c/o School of Nursing
Locked Bag 4115
Fitzroy MDC 3065

PO Box 2900
Fitzroy Victoria 3065 Australia
Telephone 03 9288 2211
www.svhm.org.au

St. Vincent's Hospital
(Melbourne) Limited
Incorporating:
Caritas Christi Hospice Limited
St. George's Health Service Limited
Prague House Limited
ABN 22 052 110 755

Dear Malcolm,

Thank you for your follow up letter regarding your proposed research in the Intensive Care Unit at St.Vincent's Hospital as part of your PhD.

I am pleased to note that the concerns raised by the ICU team have been addressed and on behalf of Cynthia Dowell, I am happy to now endorse the work to proceed.

I wish you all the best as you undertake your study and if I can be of any assistance, please do not hesitate to contact me.

Yours Sincerely,

Claire Hurstfield
Acting Director, Surgery & Specialist Services



Western Health

Low Risk Human Research Ethics Panel

Office for Research

3rd Floor, Western Centre for Health
Research and Education Sunshine
Hospital

Furlong Rd. St Albans VIC 3021

Tel. +61 3 895 8074

Fax. +61 3 895 8259

ABN 61 166 735 672

17 January 2012

Mr. Malcolm Elliott
St Vincent's Centre for Nursing Research
Australian Catholic University

Dear Mr Elliott,

QA Number: 2011.51

Project Title: Adverse Events Following ICU discharge- a clinical validation study.

I write in reply to your request for approval of the above-named project via the Quality Assurance review process.

It is noted that the aim of this project is to clinically validate 24 factors believed to contribute to adverse events in patients discharged from Intensive Care. Data will be collected in a non-identifiable manner using a paper based data collection tool. Data will then be entered onto an electronic database. The data will be stored on the researchers USB drive in a secure area for the duration of the study.

The Western Health Low Risk Ethics Panel reviewed this project against the criteria outlined in the NHMRC publication "When does quality assurance in healthcare require independent ethical review?" We are satisfied that it meets the criteria for a QA project that does not require the review of a HREC.

Accordingly your project was approved on the 12 January 2012. Your project number is QA2011.51. Please use this number in future correspondence.

Please note that documentation for this project must be kept for 12 months from completion. However if you intend to publish your results, documentation must be kept for 5 years post publication or 5 years from the decision not to publish.

Please provide a final report to the Office for Research when your project is complete.

Yours sincerely,

Dr Tam Nguyen
Manager
Office for Research

Ph: 61 3 839 58073

Email: tam.nguyen@wh.org.au

www.westernhealth.org.au