School of Physiotherapy

Early mobilisation of mechanically ventilated adults in intensive care: implementation of practice change and benchmarking of practice

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Declaration

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

To the best of my knowledge and belief this thesis contains no material previously published by any person except where due acknowledgment has been made.

Signature:

Date:

"With a growing number of patients surviving critical illness, there is an urgent need to more fully address the long term consequences of intensive care for survivors and their families. This Society of Critical Care Medicine conference focused on improving these long term consequences and discussed three major issues in the field" one of which is "identifying barriers and solutions for comprehensive post-ICU rehabilitation". (Needham, Davidson et al. 2012) pg 507-508

The program of research in this thesis pre-dates this quote from 2012 by four years. The aim of the studies in this thesis was to evaluate an implementation of early mobilisation practices and record the barriers and work practices associated with early mobilisation at a local, national and international level.

Abstract

Introduction

Patients who are admitted to the intensive care unit (ICU) for the treatment of critical illness experience muscle loss greater than that experienced from bed rest alone. Muscle loss is thought to be due to a combination of factors involving inflammation, sedation and immobilisation. The exact pathophysiology is not yet understood. Mobilisation has been purported to slow or reverse the rate of muscle loss but as yet this has not been proven.

The literature that focuses on mobilisation in ICU is limited in both number and scope. The studies focus primarily on efficacy of the treatment and are not able to be generalised due to the restricted study populations included. Many of the studies include less than 10% of patients admitted to that ICU. The definition in the literature of what constitutes 'mobilisation' and what is defined as 'early' is highly variable. To date there is poor documentation of the work practices and variation of these for 'early' mobilisation in ICU. No studies exist that examine more than two ICUs and therefore no benchmarks of mobilisation practice exist for local, national or international populations.

The program of research undertaken in this thesis examines work practices associated with mobilisation in multiple ICUs. The three studies conducted analyse an introduction of systems change approach towards mobilisation practices as well as an examination of safety and barriers associated with mobilisation. This thesis forms the widest review of mobilisation practices in a local, national and international setting.

Methods

This thesis is comprised of three studies. The first study was conducted at a single, level III, tertiary ICU and utilised a before and after study design examining the ability to introduce an early mobilisation systems change in work practices. Adult patients admitted to ICU who received mechanical ventilation for three or more calendar days were included. The study had three timeframes: retrospective (n=500), current practice (n=102) and prospective (n=412). Auditing was

undertaken using a specific mobilisation form completed by ICU staff. The data was used to examine the influence of an early mobilisation program on the feasibility of implementation, safety and barriers to mobilisations within existing resources.

Study Two was a physiotherapy point prevalence study and was nested within the larger point prevalence study conducted by ANZICS CTG in 2010.This study was a prospective, observational epidemiological study carried out at a single time point across ICUs in Australia and New Zealand. Mobilisation practices and barriers were recorded using a scale derived from Study One.

Study Three aimed to evaluate baseline practice, safety and barriers to early mobilisation for adult patients who were mechanically ventilated during their stay in Australian and Scottish ICUs. This study was a series of prospective, observational bedside audits. The audits consisted of a four-week recruitment period and then a further four-week period of follow up auditing of those patients already recruited but not yet discharged from ICU. This was the first study to obtain full length of stay data for consecutive patients in an international setting.

Results

Study One: The proportion of patients who mobilised increased significantly after implementation of an early mobilisation program. Proportions rose from 53.9% to 64.6% (p=.047) of all patients and from 63.3% to 79.9% (p=.002) for patients who had the opportunity to mobilise. Mobilisation rates for patients with endotracheal tubes and vasopressor infusions increased significantly after implementation. Mobilisation rates for patients with renal replacement therapy increased but did not reach significance. Adverse event rates did not increase and remained low at 1.1% of episodes. Patients who mobilised were associated with better discharge destinations. The leading barrier to mobilisation was sedation.

Study Two: In 86% (n=33) of all level III ICUs in Australia and New Zealand, 40% of the 498 patients admitted to ICUs on the point prevalence day were mobilised. No patient on mechanical ventilation was mobilised. Adverse event rates were low (6.4%). Haemodynamic instability and sedation were the top barriers to mobilisation identified on the study day.

Study three: Ten Australian and nine Scottish ICUs participated in the study incorporating a total of 665 patients. The percentage of patients who mobilised during their ICU stay was 68.8% in Australian and 42.5% in Scottish sites. The adverse event rate in the Australian cohort was 3.2% and 6.2% in the Scottish cohort. The leading barrier to mobilisation in both cohorts was sedation.

Conclusions

The three studies provided a review of mobilisation work practices in ICU in Australia, New Zealand and Scotland. Mobilisation of mechanically ventilated adults is both safe and feasible in a heterogeneous ICU patient population. It was demonstrated that mobilisation can be conducted without significant adverse events for patients with ETTs, RRT and / or vasopressor infusions. This was true for a diverse range of settings across Australia and Scotland. This forms the basis of evidence to influence clinical guidelines on barriers to mobilisation.

The scope of these studies demonstrates that work practices vary greatly across all units and these are influenced by the admission diagnosis and the severity of illness of the patient. A systems change strategy (Study One) demonstrated that these practices and specifically the barriers to mobilisation can be modified.

Across the majority of settings, the primary barrier to mobilisation was sedation.

Implications

This is the first study to examine a heterogeneous ICU patient population in a local (Western Australia), national and international setting. Standard nomenclature of 'early mobilisation in ICU' should be adopted to establish a generalisable framework for future efficacy studies. Barriers to mobilisation are either modifiable or unavoidable. Modifiable barriers have been shown to have the capacity to be changed (Study One). The information gained in these studies can form the basis of future, more robust studies examining the influence of mobilisation on patient centred outcomes.

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First and foremost I would like to thank the patients that participated in the three studies, especially those at Royal Perth Hospital ICU who put their trust in the team to safely get them up when they were battling such difficult times. The bravery and effort shown by the patients in ICU continues to motivate me during tough times.

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Abbreviations

APACHE	acute physiological and chronic health evaluation
ANZICS	Australia and New Zealand and Intensive Care Society
ANZ	Australia and New Zealand
BP	blood pressure
CI	confidence interval
cmH2O	centimetres of water pressure
CNS	Central nervous system
CVC	central venous catheter
CVS	Cardiovascular system
ETT	endotracheal tube
FiO2	fraction of inspired oxygen
GCS	Glasgow Coma Score
HR	heart rate
Hrs	hours
ICU	intensive care unit
ICUAW	intensive care unit acquired weakness
ICU LOS	intensive care length of stay
LOS	length of stay
MAP	mean arterial pressure
min	minutes
MDT	Multidisciplinary team
N	the number of patients in the total cohort
n	the number of patients in the subgroup
NSW	New South Wales
NTT	nasotracheal tube
PEEP	positive end expiratory pressure
PaO2	partial pressure of oxygen
PaCO2	partial pressure of carbon dioxide
QLD	Queensland
RPH	Royal Perth Hospital
RR	respiratory rate
RRT	Renal replacement therapy
SD	standard deviation
SpO2	oxyhaemoglobin saturation measured by pulse oximetry
Tas	Tasmania
Trache	tracheostomy
VIC	Victoria
WA	Western Australia

Chapter 1 Introduction

1.1 Background

There has been progressive improvement in patient mortality for people who suffer a critical illness (Hodgin, Nordon Craft et al. 2009; Herridge, Tansey et al. 2011; Moran and Solomon 2012). The advancements in patient morbidity have not kept pace with those seen in mortality (Eddleston, White et al. 2000; Hodgin, Nordon Craft et al. 2009; Vincent and Norrenberg 2009; Griffiths and Hall 2010; Corner, Wood et al. 2013). Weakness is a common side effect experienced by patients in the ICU (Bolton, Gilbert et al. 1984; Bloomfield 1997; Greenleaf 1997; De Jonghe, Cook et al. 1998; de Letter, Schmitz et al. 2001; DeJonghe, Sharshar et al. 2002; Hudson and Lee 2003; Robson 2003; Winkelman 2004; DeJonghe, Lacherade et al. 2007; Johnson 2007; Stevens, Dowdy et al. 2007; Brower 2009; Chambers, Moylan et al. 2009; de Jonghe, Lacherade et al. 2009; Herridge 2009; Vincent and Norrenberg 2009; Griffiths and Hall 2010; Banerjee, Girard et al. 2011; Adler and Malone 2012; Bierbrauer, Koch et al. 2012). Muscle mass losses of between 2 and 6% per day have been reported in the ICU patient population (Bloomfield 1997; Topp, Ditmyer et al. 2002; Brower 2009; Truong, Fan et al. 2009). This rate is greater than that experienced with immobilisation alone and is thought to be due to the combination of inflammation, sedation and immobilisation that frequently occurs in the ICU (Monk, Plank et al. 1996; De Jonghe, Cook et al. 1998; de Letter, Schmitz et al. 2001; DeJonghe, Sharshar et al. 2002; Hudson and Lee 2003; Winkelman 2004; DeJonghe, Lacherade et al. 2007; Johnson 2007; Winkelman 2007; de Jonghe, Lacherade et al. 2009; Vincent and Norrenberg 2009; Griffiths and Hall 2010). This weakness is typically more prevalent in proximal muscles used for functional tasks such as transfers. Loss of function secondary to this weakness can last for up to five years in some patient populations (Herridge, Cheung et al. 2003; Cheung, Tansey et al. 2006; Herridge, Tansey et al. 2011).

Mobilisation is an attractive candidate intervention that may ameliorate weakness experienced in the ICU. Comparatively, it is an inexpensive therapy that if shown to improve an outcome has the potential to decrease the health care burden.

The term early mobilisation has been used loosely to describe a number of terms such as rehabilitation, passive and active range of movement ambulation and exercise. To date there has not been a clear definition of early mobilisation in reference to patients in intensive care. In order to progress this area of research a clear definition of the therapy is required. This thesis will endeavour to construct a definition from available literature and operationalise this definition in three studies.

Limited studies exist that examine mobilisation as a therapy. Those that do examine a limited scope of patients, predominantly patients admitted for respiratory failure. No study has evaluated early mobilisation practices in a heterogeneous patient population. It has not been established if mobilisation is able to be safely implemented to patients of a variety of admission diagnoses. Feasibility of implementing a change in practice using existing resources is not conducive to a randomised controlled trial design. Therefore a before and after design approach was taken to implement and measure the changes in practice that occurred.

Due to the ambiguity of the definition of what 'early' implies in reference to mobilisation practices in ICU, it is important to document current practice across a large sample of ICUs. It is proposed that this is necessary to progress this area of research (Needham, Davidson et al. 2012). This has subsequently (2012) been determined by the Society of Critical Care Medicine as a key priority for research in this area. Studies in this thesis pre-date this recommendation and have documented baseline practice around Australia and benchmarked this internationally with Scottish practices.

1.2 Thesis structure and aims

This thesis is comprised of three studies. These will be presented in chronological order as they were carried out. There are many common elements to the methods

of the studies. Therefore, a common methods chapter will precede the three studies with study specific methods included in the chapter outlining each study. Each study's specific methods and results will be presented within a chapter with an epilogue explaining the link from one study to the next. The discussion chapter will be structured according to the aims of the thesis and cover all three studies.

One site, Royal Perth Hospital Intensive Care Unit (RPH ICU), participated in all three studies. This allowed for comparison of mobilisation rates between studies which occurred across a four year period.

This thesis covers four domains and the aims for each are described below.

1) Mobilisation rates
    - To evaluate the effect of an early mobilisation program on mobilisation rates in a single centre with a heterogeneous patient population
    - To establish the prevalence and incidence of mobilisation of patients who also received an endotracheal tube (ETT), renal replacement therapy (RRT) and / or vasopressor infusions. This will be looked at in a single unit to assess capability of change as well as the prevalence and incidence of this practice nationally
    - To establish baseline levels of mobilisation for patients of different admission diagnoses in Australian ICUs
    - To benchmark mobilisation practices in Australia internationally with Scotland
2) Early mobilisation and discharge destination
    - To determine if there is an association between patients who mobilise and a more favourable outcome at the time of hospital discharge
3) Safety and feasibility of mobilisation
    - To evaluate the influence of implementing an early mobilisation program on adverse events in a single centre
    - To establish an adverse event rate for mobilisation of patients receiving an ETT, RRT and / or vasopressor infusions in a single centre, around Australia and internationally in Scotland.

- To establish an adverse event rate for mobilisation as a therapy for patients of different admission diagnoses in Australian ICUs and benchmark this internationally with Scottish ICUs.

4) Barriers to mobilisation
    - Identify barriers to mobilisation practices for patients in Australia and compare these internationally with barriers identified in Scottish ICUs.

1.3 Significance and originality

This is the first study to investigate mobilisation of mechanically ventilated adults in a heterogeneous patient population at a local, national and international level. More than 2100 patients have been examined across the three studies of this thesis. Numbers of this proportion have not been examined in any other program of research on this topic. This thesis describes national and international baseline practices for early mobilisation which have not previously been documented. This information will provide valuable information for clinical practice, future systems change research, and from the basis of larger, more robust trials investigating the effect of early mobilisation on patient centred outcomes.

Chapter 2 Literature review

2.1 Introduction

Over 118 000 people are admitted to ICU in Australia every year (ANZICS and CORE 2010). Care in the ICU is the most expensive common health care service available (Williams, Dobb et al. 2005). With technology, treatments have improved mortality with little thought to the quality of life and long term morbidity. Patients who are mechanically ventilated often have the legacy of weakness years after discharge from hospital (Herridge, Cheung et al. 2003; Cheung, Tansey et al. 2006; Herridge 2009). Mobilisation has been discussed as a potential therapy to counteract this weakness and improve outcomes (Bailey, Thomsen et al. 2007; Hopkins, Spuhler et al. 2007; Morris 2007; Morris and Herridge 2007; Dean 2008; Needham 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Truong, Fan et al. 2009; Garzon Serrano, Ryan et al. 2011; Adler and Malone 2012). The literature around this topic is limited.

This chapter will discuss the intensive care unit as an entity as well as the physiological consequences often experienced by patients whilst receiving care. Literature focussing on early mobilisation as a therapy will be synthesised to examine definitions used for this term. While limited by scientific rigor and low patient numbers, studies using early mobilisation as an intervention in ICU are discussed. Furthermore the barriers to early mobilisation as a therapy will be summarised.

2.2 Intensive care units

2.2.1 Historical context of intensive care

Intensive care is a relatively new division of medicine, evolving only in the last century (Judson and Fisher 2006). The first official general ICU in Australia was founded at St Vincent's Hospital, Melbourne in 1961 (Judson and Fisher 2006). Practical work and research into positive pressure mechanical ventilation saw the success of this unit and from this point there was a steep rise in the number of ICUs

around Australia (http://www.ncah.com.au/careers/brief-history-of-intensive-care/243/ http://www.sccm.org/AboutSCCM/History_of_Critical_Care/Pages/default.aspx) (both accessed September 2012).

2.2.2 Australian Intensive care units – classifications

The Australian institute of Health and Welfare have defined what qualifies as an intensive care unit in Australia as:

> "a designated ward of a hospital which is specially staffed and equipped to provide observation, care and treatment to patients with actual or potential life-threatening illnesses, injuries or complications, from which recovery is possible. The ICU provides special expertise and facilities for the support of vital functions and utilises the skills of medical, nursing and other staff trained and experienced in the management of these problems." ([accessed Aug 12 2012] http://meteor.aihw.gov.au/content/index.phtml/itemId/327234)

Intensive care units are ranked according to the care processes provided and the clinical standards delivered. The Australian Council on Healthcare Standards (ACHS) has developed a three level classification system. The highest classification is level III and the ACHS has defined this as:

> "must be capable of providing complex, multisystem life support for an indefinite period; be a tertiary referral centre for patients in need of intensive care services and have extensive backup laboratory and clinical service facilities to support the tertiary referral role. It must be capable of providing mechanical ventilation, extracorporeal renal support services and invasive cardiovascular monitoring for an indefinite period; or care of a similar nature." ([accessed Aug 12 2012] http://meteor.aihw.gov.au/content/index.phtml/itemId/327234)

In order to make best use of resources, technology and skills, certain specialties are often located in a limited number of units within each state. Specialties include, but are not limited to: cardiothoracic surgery, trauma, neurosurgery, spinal and organ transplantation. Many units will manage a number of different specialties. Population numbers as well as distribution determines how many specialist units

are required within each state ([accessed August 2012] http://meteor.aihw.gov.au/content/index.phtml/itemId/327234).

Adult long term ventilation units are not common in Australia and are not covered in this thesis.

2.2.3 Australian Intensive Care Units - staffing

In Australian hospitals, intensive care units are run by separate and specialised medical staff (http://www.cicm.org.au/intensivist.php)(Judson and Fisher 2006). Medical doctors with a background in internal medicine, anaesthesia or more recently, emergency medicine are able to specialise in intensive care medicine as a secondary specialty and are referred to as intensivists (http://www.cicm.org.au/intensivist.php). Doctors from other specialties are not allowed to admit patients directly to an ICU. Intensivists and/or their senior staff assess each case on an individual basis to determine the appropriateness of the admission ([accessed Aug 12 2012] http://www.cicm.org.au/intensivist.php).

The nursing to patient ratio is most commonly 1:1 in Australia due to the severity of illness of the patients (Martin and Mathisen 2005; Judson and Fisher 2006; Rose, Presneill et al. 2009). There is a significant allied health input into Australian ICUs. The majority of these professions have a permanent presence in ICU or a referral system in place to provide the service on an as needs basis (Skinner, Berney et al. 2008; ANZICS and CORE 2010).

2.2.4 Australian intensive care units - epidemiology

There are 29 level III adult ICUs in Australia and 129 other ICUs which are a combination of level I and level II ICUs (ANZICS and CORE 2010). The 2010 Annual Report ANZICS Centre for Outcome and Resource Evaluation (2010) state the average annual occupancy rate of ICU beds in Australia is 69.9% with approximately 120 000 adults admitted to the 1627 physical ICU beds in Australian ICUs in 2010. With the population of people greater than 16 years being over 17.8 million people in 2010, the incidence of admission to ICU in Australia is 1:150 (ANZICS and CORE 2010). Thirty eight percent of patients admitted are ventilated at some stage during

their ICU admission (ANZICS and CORE 2010). The characteristics of patients admitted to ICUs in Australia are listed in Table 1 below.

Table 1 Epidemiology of patients admitted to intensive care units in Australia

Descriptor	2010 statistics for Australian ICUs
Age – median years	64.7 (49.8-75.8)
Sex – Male	58%
Top 5 admission diagnoses	CABG surgery – 6.8% GI surgery for neoplasm – 4.5% Orthopaedic surgery - 4.1% Valvular heart surgery -3.6% Drug overdose - 3.3%
APACHE II* score – median	14 (10-19)
Mortality	6.4% in ICU 10.1% in hospital
Length of stay in ICU – median	1.8 (0.9-3.7)

*APACHE II – Acute Physiological and Chronic Health Evaluation score. See Appendix 1 (ANZICS and CORE 2010)

Of all Australian Level III ICU beds, two thirds are staffed and funded for ventilated patients (Judson and Fisher 2006; ANZICS and CORE 2010). Patients occupying 'non ventilator' beds are often patients admitted after surgery such as cardiothoracic surgery that require close monitoring but are not admitted for failing organs (Judson and Fisher 2006; ANZICS and CORE 2010). The dynamics of this group of patients differs as their expected recovery is much quicker and routine than patients admitted in an emergency situation. It would be considered standard practice for patients who have undergone major surgery such as an open abdominal aortic aneurysm repair or coronary artery bypass grafting to mobilise and be discharged from the ICU the day after surgery (Brasher, McClelland et al. 2003; Kirkeby-Garstad and Sellevold 2006) Kirkeby-Garstad and Sellevold, 2006). These patients typically have a lower APACHE score and lower mortality rate in comparison to patients admitted for non-surgical or emergency surgical procedures (Moran and Solomon 2012).

2.2.5 Australian Intensive Care Units – cost

The cost of providing care in an Australian ICU varies depending on what services are required. An average medical hospital admission costs AUD$4133 in total whereas some common diagnosis related groups utilising intensive care, cost on average AUD$63000. In 2005 the approximate cost per day of being in ICU was greater than AUD$3000 (Soloman and McLeod 1998; Brown and Lilford 2006). More current data on costs is not available.

The USA spends approximately one third of its total health budget on intensive care service delivery (Higgins, Pettila et al. 2010) and while it is not known what percentage Australia spends on intensive care, the total health budget for Australia is $121.4 billion or 9.4% of gross domestic product (2009 – 10). ([accessed 12 Sept 2012] www.aihw.gov.au)

2.2.6 International Intensive Care

There is little data available on international baseline practices. The classification of ICUs into Level I, II or III is consistent throughout the UK, the Americas and Australasia (Haupt, Bekes et al. 2003). However, variation in service delivery occurs between countries and units. Factors that often differ between countries are staffing ratios, sedation practices and presence of multidisciplinary team members in the ICU (Clarke 1999). Variations in one or all of these factors cause variation in care delivery patterns.

Nurse to patient ratios have an important influence on patient management. It has been shown that units with a nurse to patient ration of 1:2 have higher usage of sedation than those with a 1:1 ratio (Martin and Mathisen 2005). Australia, as previously mentioned, most commonly has a nurse to patient ratios of 1:1, as does the United Kingdom. However, in the USA where the majority of studies examining early mobilisation originate, nurse to patient ratio is more commonly 1:2 ([accessed 2012 Aug 12] http://www.aacn.org/WD/BeaconApps/Content/fall_08-09_recipients/CICU-COLO.content?menu=BeaconApps). Differences in care practices make comparison of outcomes from studies across countries and individual units difficult.

Medical staffing in British and American ICUs is moving towards a similar model adopted by Australia where consultant doctors have specific training in intensive care medicine as well as training in a medical specialty such as anaesthetics, respiratory medicine or emergency medicine (Gajic and Afessa 2009) ([accessed 2012 Nov 19] www.ics.ac.uk/professional/standards_safety_quality/standards_and_guidelines/standards_for_consultant_staffing_2007). Intensivists in the USA are in far shorter supply and therefore ICUs are often staffed by surgeons or pulmonologists (Haupt, Bekes et al. 2003; Gajic and Afessa 2009). Historically, ICUs in the UK were managed by anaesthetists and in contrast to Australian intensivists; British intensivists often continue to practice in both areas of medicine ([accessed 2012 Nov 19] http://www.ics.ac.uk/professional/standards_and_guidelines/standards_for_consultant_staffing_2007).

Variation in service delivery is also true for physiotherapy services internationally. Physiotherapy presence in Australian ICUs is reported as 100% in surveyed units (Skinner, Berney et al. 2008). Permanent ICU based physiotherapy staff are present in approximately 88% of Australian units (Skinner, Berney et al. 2008). Survey data from the UK state 38% of physiotherapy staff are full time in ICU but all ICUs received routine physiotherapy (Lewis 2003). Physical therapists had a high presence in US ICUs but frequently require a physician's referral to initiate therapy (Hodgin, Nordon Craft et al. 2009). Individual studies examining mobilisation in a US ICU comment that prior to the implementation of the study, physical therapy was uncommon unless mechanical ventilation was prolonged (Morris, Goad et al. 2008; Schweickert, Pohlman et al. 2009; Needham, Korupolu et al. 2010). In Australia, mobilisation practices in ICU are most commonly lead by physiotherapists (Skinner, Berney et al. 2008). In the UK, Lewis (2003) found that 100% of surveyed physiotherapists in the UK offer mobilisation and rehabilitation exercises.

No information could be found regarding other professions that may be involved in rehabilitation in ICUs in USA and UK. Suggestions of other professions that may be involved are respiratory therapists, exercise physiologists and nurse specialists. Respiratory therapists are an independent profession in the USA that have a major

role in managing respiratory care of patients ([accessed 12 February 2013] http://www/healthpronet.org/ahp_month/02_05.html) In Australia, this role is commonly adopted by physiotherapists. Exercise physiologists are currently not present in Australian ICUs (Skinner, Berney et al. 2008). The different professions and their differing roles within ICUs show how care delivery patterns vary internationally and make comparison of studies difficult.

2.3 Consequences of being in ICU

2.3.1 Immobility

Admission to ICU is associated with immobility. Immobility can be due to sedation, paralysis, treatment techniques, or the perceived need for the patient to rest (Hudson and Lee 2003; Robson 2003; Foster 2005; Winkelman 2007; Chambers, Moylan et al. 2009; Trivedi, Shelly et al. 2009; Vincent and Norrenberg 2009; Griffiths and Hall 2010; Banerjee, Girard et al. 2011). Bed rest and its effect on body systems has been investigated for more than 40 years via a number of experimental protocols that include study cohorts as well as cast immobilisation, space flight and enforced bed rest on healthy volunteers (Bamman, Hunter et al. 1997; Bloomfield 1997; Bamman, Clarke et al. 1998; Brower 2009; Truong, Fan et al. 2009). There are numerous well known negative effects on body systems associated with less than optimal mobilisation of biological tissues. These effects are summarised below in Table 2.

Muscle loss associated with immobility is due to the decrease in number and magnitude of muscle contractions. The rate of muscle loss related to strict bed rest has been reported as 1 - 1.5% per day while cast immobilisation showed losses of 1.3 – 6% per day (Bloomfield 1997; Topp, Ditmyer et al. 2002; Brower 2009; Truong, Fan et al. 2009). This indicates the more restricted the muscle is, the more muscle loss occurs. This muscle loss has shown to be attenuated by physical activity (Bamman, Hunter et al. 1997; Bamman, Clarke et al. 1998; Topp, Ditmyer et al. 2002; vanderSchaaf, Beelen et al. 2004; Winkelman 2007; de Jonghe, Lacherade et al. 2009).

Mechanical ventilation of critically ill patients involves resting the muscles of respiration. This rest results in weakness that is proportionate to skeletal muscle weakness (DeJonghe, Lacherade et al. 2007). Levine et al.(2008) conducted a rare human study showing convincing evidence of atrophy in human diaphragm myofibres after only 18-69 hours of complete diaphragmatic inactivity on mechanical ventilation. This work confirms results obtained from animal studies (Powers, Kavazis et al. 2009). The clinical significance of such losses of diaphragmatic and respiratory muscle strength is still unknown but hypothesised to increase mechanical ventilation time and hence increase duration of immobility and length of stay in ICU (Levine, Nguyen et al. 2008).

Table 2 Negative physiological effects associated with immobility

Body system	Impact of bed rest
Musculoskeletal	Loss of contractile strength – more evident in weight bearing extensor muscles Greater loss of Type II than Type I muscle fibres Bone loss (Wolff's law)
Cardiovascular	Micro vascular dysfunction Decreased total blood volume Orthostatic intolerance Increased heart rate Decreased stroke volume, cardiac output and peak oxygen uptake Increased risk of thromboembolic disease
Electrolyte and hormonal	Decreased protein synthesis Insulin resistance Depression Increased excretion of nitrogen and calcium
Skin	Pressure ulcers
Neural	Decreased neural drive to motor units

(Bamman, Hunter et al. 1997; Bloomfield 1997; Bamman, Clarke et al. 1998; Brower 2009; Truong, Fan et al. 2009)

2.3.2 Intensive care unit acquired weakness – definition, significance and incidence

Critical illness and immobility are often experienced simultaneously by patients in intensive care (Griffiths and Hall 2010). A proportion of these patients experience levels of weakness greater than that expected from bed rest alone (Stevens, Dowdy et al. 2007; de Jonghe, Lacherade et al. 2009; Truong, Fan et al. 2009; Vincent and Norrenberg 2009; Griffiths and Hall 2010). This condition was first described in 1984 by Bolton(1984) but to date the aetiology and pathogenesis remains unclear.

Weakness associated with critical illness has been described as a myopathy, a neuropathy and / or a combination of both (Stevens, Dowdy et al. 2007; de Jonghe, Lacherade et al. 2009; Truong, Fan et al. 2009; Vincent and Norrenberg 2009; Griffiths and Hall 2010). Critical illness myopathy is diagnosed by electromyography, critical illness polyneuropathy is diagnosed by nerve conduction studies and critical illness polyneuromyopathy is formally diagnosed by both but clinically is often diagnosed by physical examination (DeJonghe, Lacherade et al. 2007; Stevens, Dowdy et al. 2007; Bittner, Martyn et al. 2009; Hermans and Gosselink 2011).

The term intensive care unit acquired weakness (ICUAW) has been proposed and accepted by a panel of ICU experts at the Brussels Round Table Conference in 2009 (Stevens, Marshall et al. 2009). The term refers to “clinically detected weakness in critically ill patients in whom there is no plausible aetiology other than critical illness” and encompasses the three elements of critical illness myopathy, critical illness polyneuropathy and critical illness polyneuromyopathy. (Stevens, Marshall et al. 2009) It is important to note the adoption of this broad term focuses not on the physiology behind the condition but on the outcomes that result – which is predominantly weakness. The position described in the literature is a functional, patient focused term and outlines a complex and important condition requiring further investigation.

De Jonghe et al.(2007) comment that ICUAW is both “under recognised and under estimated”. The impact of ICUAW has shown to have lasting effects on function and quality of life up to five years after discharge from ICU in subgroups of the

population (Herridge, Cheung et al. 2003; Cheung, Tansey et al. 2006; Herridge, Tansey et al. 2011). The effect of ICUAW on a heterogeneous ICU patient population is not known.

Studies reporting the incidence of ICUAW vary depending on the patient population and the classification used for identification of ICUAW. A systematic review of 24 studies examining the effect of ICUAW on outcomes report nearly 50% of patients in ICU experiencing sepsis, multi organ failure or protracted mechanical ventilation will experience ICUAW (Stevens, Dowdy et al. 2007). For studies examining all patients who receive mechanical ventilation, incidence varies from 25 to 50% (De Jonghe, Cook et al. 1998; DeJonghe, Sharshar et al. 2002). However, no time frame was given for the period of ventilation received. For patients admitted to an ICU for longer than seven days, incidence of ICUAW is estimated to be from 33% to 57% (Johnson 2007). The highest incidence is reported in patients who experience sepsis and systemic inflammatory response syndrome (SIRS) who show rates between 50 and 100% (Johnson 2007; Griffiths and Hall 2010).

The impact of ICUAW also continues to impact on muscle strength after discharge from ICU (Herridge, Cheung et al. 2003; Cheung, Tansey et al. 2006; Herridge 2009; Herridge, Tansey et al. 2011). Loss of muscle strength in adulthood has been linked to increased risk of disability and morbidity (Bittner, Martyn et al. 2009). Detection and treatment techniques for patients with ICUAW have not yet been formalised but it is thought that early mobilisation may assist in attenuating the muscle loss (Winkelman 2007; Herridge 2008; Chambers, Moylan et al. 2009; de Jonghe, Lacherade et al. 2009; Herridge 2009; Truong, Fan et al. 2009; Vincent and Norrenberg 2009).

2.3.3 Physiology of weakness in ICU

The exact pathophysiology of weakness experienced by patients admitted to ICU is not known but there is a strong physiological rationale that identifies several contributing factors. These factors include: prolonged inactivity, inflammation, metabolic derangements, malnutrition and decreased micro vascular circulation to nerve and muscle tissue (de Letter, Schmitz et al. 2001; DeJonghe, Lacherade et al.

2007; Truong, Fan et al. 2009). The contribution of each factor in isolation is unknown and factors may be cumulative or synergistic and act on different timeframes (Brower 2009).

Prolonged bed rest results in primary muscle atrophy (Morris 2007). If muscle loss in the immobile person is partly due to less activation of muscle tissue and decreased exposure to mechanical load, then patients who are immobilised *and* sedated may experience less muscle contractions and mechanical load. Therefore it could be postulated that muscle atrophy is greater in patients who are immobile and sedated (Chambers, Moylan et al. 2009). No evidence is available to support this premise.

The addition of a pathological insult like inflammation results in secondary muscle atrophy (Morris 2007). Secondary atrophy leads to a loss of contractile proteins with a corresponding increase in non-contractile tissue content such as collagen (Morris 2007). The combination of inflammation and immobility leads to muscle damage more severe than that experienced by immobility alone (Morris 2007).

Electrolyte and metabolic disturbances are common in patients admitted to the ICU. Decreased phosphate, decreased or increased magnesium, decreased potassium and decreased calcium can precipitate or aggravate weakness (DeJonghe, Cook et al. 1998). Therefore, patients in intensive care battle weakness as a result of immobility as well as from electrolyte imbalances caused by critical illness.

The body's reaction to injury and illness results in increased blood glucose levels, inhibition of insulin and ultimately insulin resistance (Reid and Campbell 2004). Production of this glucose by gluconeogenesis results in breakdown of protein and lean tissue which increases with severity of illness (Reid and Campbell 2004). This loss of lean muscle tissue is a contributor to the higher rate of muscle loss experienced by patients with critical illness compared to subjects experiencing bed rest only. Muscle loss in this patient population is reported as 2% per day with a loss of 50% within three weeks (Robson 2003; Reid and Campbell 2004).

Malnutrition due to poor regulation of glucose as well as delayed feeding is a common issue in critically ill patients. It is known to be a catabolic process and

contributes to muscle loss and delayed healing and recovery (Robson 2003; Reid and Campbell 2004). Exercise on the other hand is anabolic and may help to ameliorate the negative effects of bed rest, malnutrition and critical illness.

2.3.4 Risk factors for ICUAW

Many elements of care have been proposed as potential risk factors for ICUAW. However, here has only been two studies conducted (de Letter, Schmitz et al. 2001; DeJonghe, Sharshar et al. 2002) where the primary focus was risk factors for critical illness polyneuromyopathy or intensive care unit acquired paresis. Both studies were observational in nature and lacked a comparative group (de Letter, Schmitz et al. 2001; DeJonghe, Sharshar et al. 2002). The weak study designs used and conflicting nature of the results in these two studies makes it difficult to draw definitive conclusions. Plausible physiological explanations can be given for many elements but results show association between risk factors not a causal link.

The most investigated factor considered in ICUAW is multiple organ failure. Patients with two or more failing organs for two or more days have shown a much higher rate of ICUAW (DeJonghe, Lacherade et al. 2007; Stevens, Dowdy et al. 2007; Stevens, Marshall et al. 2009). Interestingly, severity of illness as measured by APACHE score has not shown to be consistently associated with weakness in the ICU (de Letter, Schmitz et al. 2001; Johnson 2007; Stevens, Dowdy et al. 2007). It has therefore been hypothesised that multi organ failure is associated with weakness not due to the link with illness severity but because of the high rate of inflammation and systemic inflammatory response syndrome commonly associated with organ failure (Johnson 2007; Stevens, Dowdy et al. 2007).

Sepsis is also commonly associated with inflammation and ICUAW. In a meta-analysis, Johnson (2007) reported the odds ratio of being diagnosed with ICUAW if sepsis was present was 2.4 to 49. Inflammation has again been hypothesised as the link between these two factors. In the same study patients receiving RRT were 3.4 times more likely to experience ICUAW (Johnson 2007). Because patients with sepsis often receive RRT it is not clear if the association is due

to the treatment itself or the condition that is requiring the treatment, for example, sepsis. More research is needed to clarify this point.

The influence of hyperglycaemia has been examined in two large studies. One has shown to be associated with ICUAW and inversely associated with tight glycaemic control (van der Berg 2007). A more recent, large, pragmatic RCT demonstrated decreased 90-day survival with tight glycaemic control which brings previous results into question (Griesdale, de Souza et al. 2009; NICE-SUGARStudyInvestigators 2009). Reduction of weakness at the expense of mortality is clearly counterproductive and the role of hyperglycaemia in the development of ICUAW is far from established.

The mode of action of neuromuscular blockers has lead to strong suspicion that increased doses of neuromuscular blockers may affect nerve end plates long term and could therefore contribute to ICUAW (de Letter, Schmitz et al. 2001; DeJonghe, Lacherade et al. 2007; Johnson 2007; Stevens, Dowdy et al. 2007). A recent systematic review has shown no consistent relationship (Stevens, Dowdy et al. 2007).

Other medications that have had examination as a risk factor are: corticosteroids; catecholamine infusions; aminoglycosides and midazolam. There are currently inconclusive findings within the literature examining the relationship between these medications and ICUAW (Johnson 2007; de Jonghe, Lacherade et al. 2009; Hermans G 2009).

Physiological principles would suggest that patients with a lower muscle mass prior to admission to ICU may potentially suffer greater functional consequences and perhaps increased ICUAW. However, patients who are known to have a low muscle mass relative to others such as females compared to males and people of increased age have not shown definitively to be at higher risk of ICUAW or functional loss (Johnson 2007; Stevens, Dowdy et al. 2007).

The literature has indicated that mechanical ventilation time is associated with ICUAW (Stevens, Dowdy et al. 2007; de Jonghe, Lacherade et al. 2009; Hermans G

2009). However, it is difficult to test if this is due to mechanical ventilation itself or if it is related to the higher rate of immobilisation and sedation that occurs concurrently during mechanical ventilation. Differentiation between the effect of mechanical ventilation and immobilisation on ICUAW has not been studied.

Many ideas have been postulated for the risk factors for ICUAW without conclusive evidence. However, even if correctly identified, some risk factors are not able to be altered, for example gender, age and amount of failing organs. Isolation of factors such as sedation medication, bed rest and length of mechanical ventilation on ICUAW may remain indistinguishable. Awareness of the potential contributors to ICUAW may assist in the early identification of those patients who are at greater risk and allow therapists to optimise specific interventions for these individuals.

2.4 Definition of early mobilisation in the ICU

This section is currently under review for publication as a paper in the following format.

What is early mobilisation?

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Abstract

Objective: To provide a clear definition of early mobilisation in reference to mechanically ventilated adult patients in acute intensive care units. Specifically, what type of activity is practised for "mobilisation" and the timing of the intervention that classifies it as "early".

Data Sources: A literature search was conducted on Medline, PubMed and Cinhal using the key words – mobilisation, physical therapy, critical illness, ambulation, and intensive care and associated MESH headings.

Study Selection: Articles were included if they were written in English, between the years of 2001 and June 2012, examined adult patients who were mechanically ventilated, and included a protocol or guideline for mobilisation. Papers were excluded if participants were from long term ventilation units or had chronic critical illness only.

Data Extraction: The above keywords generated 9626 citations. After applying limits 2224 citations were identified. From here, two of the reviewers screened all citation titles and abstracts. Eighty seven articles were retained for evaluation by full text. Twenty articles were identified as appropriate for the review.

Data Synthesis: Articles were divided into three categories: opinion articles; non-randomised interventional studies; and randomised controlled studies.

Conclusions: The term early mobilisation is widely used to describe a single concept that is defined very differently in different studies. The term early mobilisation should not be abandoned but all studies should objectively report the activities, as well as the timing of initiation of mobilisation.

Key words: mobilisation; physical therapy; critical illness; ambulation; intensive care; ventilation, mechanical.

Introduction

There has been progressive improvement in case-fatality for patients with critical illness (1). This has led to an increasing focus on recovery as assessed by physical function, quality of life as well as long-term survival (2,3). Many critically ill patients develop muscular weakness during their illness (4,5). This weakness can arise as a specific consequence of critical illness neuropathy and myopathy or occur as a consequence of muscle atrophy associated with immobility (4,5). The combination of interest in recovery and the identification of weakness as a substantial barrier to recover, has led to increased interest in commencing rehabilitation while patients are still being treated in an intensive care unit (ICU), rather than waiting until patients are transferred to the ward (6-8).

Early mobilisation is an attractive candidate intervention that may be effective in improving quality of life, physical function, and long-term survival. However, a critical barrier in advancing programmes of research that would aim to determine the effectiveness and cost-effectiveness of early mobilisation is what is actually meant by 'early mobilisation'. Articles use the term early mobilisation but there has been no systematic review to determine if different studies use the term to describe the same intervention. The following review is aimed at defining more clearly what is meant by 'early mobilisation'.

The objectives of this review were to undertake a systematic review of the literature to determine:

1. the types of activity that are practised as "mobilisation"
2. the timing of mobilisation in the patient's journey that classifies it as "early"

Methods

Information sources

Databases used for identification of relevant studies were: Medline; CINHAL; Ovid and PubMed. Reference lists of articles found were inspected to identify related articles. In addition to this, the authors followed up with key researchers in the area to identify any missing sources of articles.

Search strategy

Keywords used in the search strategy were: intensive care; critical care; critical illness; physical therapy, physiotherapy; physical medicine; exercise therapy; early mobilisation; rehabilitation; ambulation; movement; respiration, artificial and ventilators, mechanical.

Using the above keywords, 9626 citations were identified. After limiting to English language only, humans only, adults and years 2001 to current, 2224 citations were identified. From here, two reviewers screened all citation titles and abstracts. Eighty seven articles were retained for evaluation by full text. This was refined to 22 articles of which two were in dispute. A third reviewer independently reviewed the articles and 20 articles were identified as appropriate for the review.

Study selection

We included only papers that related solely or predominantly to adult patients who were receiving mechanical ventilation in an ICU and received treatments or interventions aimed at improving mobility, physical function or both. Only manuscripts published after 2001 and written in English were included. Publications were excluded if patients were treated in long term ventilation units. The reviewed studies were then divided into three categories based on study design: 1) opinion 2) non-randomised interventional studies and 3) randomised controlled trials (RCTs).

Each manuscript was reviewed with respect to definitions of mobilisation that was

practiced and when in the patient's admission mobilisation was first commenced. The timing of activity had two aspects to the definition: the length of time from admission to ICU until mobilisation occurred; and the requirements for combinations of physiological status and degree of treatment-dependence that defined when activity commenced. We applied ordinal scales to both 'early' and 'mobilisation' which are outlined below.

Timing: 1) in ICU with mechanical ventilation further qualified by requirements for physiological stability; 2) in ICU without mechanical ventilation further qualified by requirements for physiological stability; 3) not in ICU further qualified by requirements for physiological stability

Type of Mobilisation: 1) in bed exercises (passive, active, active assisted range of motion exercises or strengthening exercises); 2) out of bed exercises (sitting over the edge of the bed, sitting in a chair or rehabilitation chair); 3) weight bearing exercises (axial loading of the spine and / or long bones, standing, or walking).

Results

Opinion articles

The 13 papers identified in this subgroup of the literature express opinion on or describe author's beliefs about the conduct of activities that they define as early mobilisation (6-18). Eleven of the studies state that early mobilisation is mobilisation that is conducted in the ICU, preferably whilst the patient is still on mechanical ventilation (see Table 1) (6, 9-18). The earliest paper in this group, by Stiller and Phillips in 2003 (16), comments that while mechanical ventilation is not a barrier to mobilisation, it is recommended to await extubation for mobilisation to be safe for most patients.

Table 2 outlines the criteria that constitute physiological stability for each of the 13 studies. Eleven of the papers (6-10, 12-17) state that these parameters are intended to be used as a guide and not an absolute rule from which to prescribe safe mobilisation whilst two encourage mobilisation but do not state safe parameters (11, 18). Cardiovascular stability was defined in detail in nine studies (6, 7, 10, 12-17). This included precise definitions for one or more of pulse, blood pressure and heart rhythm, whilst two studies (8, 9) state only 'cardiovascular stability' without defining it and another two provide no specific details (11, 18). Neurological stability was defined in eight articles (7, 8, 10, 12, 14-17). Seven of these states the patient must be able to respond or consent to be deemed neurologically stable (7, 8, 10, 12, 14-16). The absence of head trauma or intracranial bleeding was criteria for two articles (14, 17) while six articles state broadly 'no deterioration in neurology' as being stable without specific physiological parameters being mentioned (7, 8, 10, 12, 15, 16). Respiratory stability was defined in 11 of the articles (6-10, 12-17). Specific parameters for one or more of FiO_2, PEEP, respiratory rate or pattern, SpO_2 and PaO_2:FiO_2 ratio was given in nine of the articles but no information was given for how or why the specific details were chosen (6, 7, 10, 12-17). Other factors considered as measures for stability were the absence of fractures and spinal cord injuries where ambulation was contraindicated (7, 8, 12, 14-17); attachments such as arterial lines and vascular catheters, particularly where catheters are placed in femoral vessels (7, 14-17); and the absence of sepsis (6, 9).

Activities that are defined as mobilisation in these articles include passive range of movement (PROM) exercises, active range of movement (AROM) exercises, active assisted range of movement (A-AROM) exercises, strengthening exercises, sitting over the edge of the bed, sitting out in a chair, standing, using a tilt table and ambulation. Among the 13 papers, five classified exercises only carried out in the bed as mobilisation (see Table 1.) (7, 8, 11, 13, 17).

Non-randomised interventional studies

Five studies examining mobilisation in ICU as a defined and implemented intervention

were identified in this review (19-23). Three studies were prospective cohort (19-20) and two used before and after study designs (22, 23).

The mobilisation practices performed prior to implementation were described in only one study and were reported to involve PROM exercises and turning (21). Intervention protocols described the activities undertaken as early mobilisation and are listed in Table 3.

The time from admission to the first episode of early mobilisation was documented in three studies. Bailey et al (19) reported a mean of 6.6 days from admission to ICU until patients were sat on the edge of the bed; Bourdin et al (20) had a median of 5 days from ICU admission to the start of the rehabilitation protocol, of which the lowest level of activity was sitting out of bed; and Morris et al's (21) study reported a mean of 8.5 days from ICU admission until patients first sat out of bed.

Physiological stability was used to define readiness to mobilise in the intervention arm of all studies and was conveyed by specific inclusion and exclusion criteria and these are listed in Table 3.

Randomised controlled trials

There are two RCT's that compared early mobilisation with standard care (24, 25).

Schweickert et al (25) delivered early mobilisation by undertaking physical and occupational therapy that commenced during daily interruption of sedation in patients who were mechanically ventilated (see Table 3). The usual care arm of the study also received daily interruption of sedation but only passive range of motion exercises performed by the bedside nurse were undertaken, with physical and occupational therapy not commenced until patients had been mechanically ventilated for more than two weeks (see Table 3). The specific activities conducted in the intervention group were not described. Schweickert et al (25) reported that the duration from intubation to first mobilisation out of bed was a mean of 1.7 days in the intervention group and 6.6 days in the control group. Exclusion criteria for the study were listed (see Table 3) but no physiological criteria were reported to identify when patients were deemed ready to mobilise.

The intervention in Burtin et al's (24) study was cycle ergometry that was performed for 20 minutes per day. Passive and active range of movement exercises were considered standard care and were conducted in both groups. The intervention arm received cycle ergometry in addition to standard care once physiological stability was achieved (24). No weight bearing exercises were conducted as part of this study. Time to out of bed was not reported in this study but mean time until inclusion in the study was 14 days for the treatment group.

Discussion

There is substantial interest in early mobilisation as an intervention to influence patient centred outcomes. As for all new candidate interventions, RCTs are the best means to determine effectiveness and safety. However, to conduct trials that have internal and external validity the intervention must first be clearly defined. The major results of this review are, that at this time there is substantial variability in the published literature as to what is defined as early mobilisation with variation in both the timing that constitutes 'early' and the activities that constitute mobilisation. Variation in the baseline timing and activities that constitute existing mobilisation practices are likely to vary. As a consequence, our recommendation is that all future studies that investigate early mobilisation should report the planned and actual timing of initial mobilisation and report the actual activities undertaken. In studies with an intervention arm, it is important that all of these aspects are reported for both intervention and control arms.

This review has identified the list of activities that have been proposed as comprising early mobilisation. The activities employed vary between studies. The largest area of disparity is whether PROM and AROM exercises

constitute early mobilisation or if they are part of standard care or both. Defining the timing of early mobilisation is more difficult and it is insufficient to define 'early' as within ICU. Even when mobilisation commences within the ICU there can be substantial variation in timing of initiation. For example, in Burtin et al's (24) study, the mean time until patients received the intervention (14 days) was more than double the length of time to first mobilisation in the control group of the Schweickert et al (25) study (6.6 days).

The initiation of mobilisation in many studies was linked to achievement of physiological stability. This seems intuitively sensible but experience from conducting these studies is that it can be difficult to operationalise. Broad guidelines such as 'absence of significant neurological dysfunction' (12), provide little meaningful guidance to allow standardised delivery of an intervention, but do allow for the appropriate application of clinical judgement to play a part in decision making. More specific criteria such as "SpO2 greater than 90% with less than four percent recent decrease in SpO_2" (16) make standardisation of treatments much simpler but may prevent patients that could otherwise have been mobilised safely.

To operationalise guidelines in the future, one solution could be a three tiered traffic light system. Green indicates an accepted threshold for each physiologic criteria where there would be consensus agreement that mobilisation would virtually always be appropriate, red indicates criteria that there is consensus agreement that mobilisation is absolutely contraindicated, and amber is the zone where consensus is not possible. The amber criteria would allow for the use of contingent criteria combined with the application of clinical judgement. Here, mobilisation would occur under some circumstances on a trial basis with additional physiological criteria that would indicate suitability for ongoing mobilisation or that an additional period without mobilisation was appropriate. Such a system might be capable of defining a standardised protocol that allowed maximum safe mobilisation with the minimum amount of subjective clinical judgement, but still preserve appropriate clinical decision making.

This does not mean that in future trials the comparison groups should withhold mobilisation, only that the comparison group should always be standard care.

Limitations

There were several limitations to this review of early mobilisation. This study did not include paediatric patients or mechanically ventilated patients in long term ventilation units. The impact of functional electrical stimulation and inspiratory muscle training were beyond the scope of this review. The impact of early mobilisation 'culture' in individual ICUs appears to influence outcomes but is difficult to measure and has not been discussed. Similarly, variations between international standards were not discussed. The literature included in this review has a heavy bias towards patients with respiratory failure and hence there have been little examinations of sub groups of the population.

Conclusion

The term early mobilisation is widely used to describe a single concept that is defined very differently in different studies. The term early mobilisation should not be abandoned but all studies should objectively report the activities, as well as the timing of initiation of mobilisation.

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Table 1 Categorisation of early mobilisation definitions

Author (year of publication)	In bed exercises (PROM, AROM, A-AROM, strength)	Sitting (either over the edge of bed or in a chair or rehab chair)	Weight bearing (axial loading through spine and / or long bones)	In ICU with MV + physiological stability
Stiller and Phillips (2003)	Not clear #	Not clear	Not clear	Yes
Stiller (2007)	Not clear	Not clear	Not clear	Yes
Gosselink et al (2008)	✓	✓	✓	Not clear
Timmerman (2008)	✓	✓	✓	Yes
Dean (2008)	✓	✓	✓	Not clear
Perme and Chandrashekar (2008)	X	✓	✓	Yes
Dowds (2009)	X	✓	✓	Yes
Hopkins and Spuhler (2009)	X	✓	✓	Yes
O'Connor and Walsham (2009)	✓	✓	✓	Yes
Perme and Chandrashekar (2009)	✓	✓	✓	Yes
Rochester (2009)	Not clear	Not clear	Not clear	Yes
Vasilevskis et al (2010)	Not clear	Not clear	Not clear	Yes
Hanekom et al (2011)	X	✓	✓	Yes
Perme et al (2006)	X	✓	✓	Yes
Bailey eta l (2007)	X	✓	✓	Yes
Thomsen et al (2008)	X	✓	✓	Yes
Morris et al (2008)	✓	✓	✓	Yes
Bourdin et al (2010)	X	✓	✓	Yes (*) ETT
Needham et al (2010)	X	✓	✓	Yes
Schweickert (2009)	✓	✓	✓	Yes
Burtin (2009)	✓	X	X	Yes

not clear refers to the text not specifically stating these activities.
(*)but not ETT

Table 2 Definitions of physiological stability in opinion articles

Authors	Cardiovascular criteria	Neurological	Respiratory	Other
Stiller & Phillips 2003 # Stiller 2007 # Gosselink et al 2008	HR < 50% age predicted max HR BP <20% variability recently ECG normal Other major cardiac conditions excluded Hb stable & >7g/dL Platelet count stable & > 20000cells/mm^3 Medically stable if DVT &/or PE evident	Stable conscious state No neurological CI Patient consents	PaO_2/FiO_2 >300 SpO_2 >90% & <4% recent decrease in SpO_2 Satisfactory respiratory pattern Mechanical ventilation able to be maintained during treatment	WCC 4300 – 10800 cells/mm^3 Temp <38 C BGL 3.5 – 20 mmol/L No ortho CI No recent SSGs to LLs or trunk No attachments that CI mobilisation Patient not appearing in pain, fatigued, SOB or exceptionally emotional
Timmerman 2007	SBP >90mm Hg HR <130 b/min No unstable cardiac rhythms 1 vasopressor / inotrope max & no recent ↑ in usage No IABP No active bleeding	No acute TBI, ICH or SAH No ICP monitoring or drain in situ No unstable SCI No recent neurological deterioration No neuromuscular blockade medication	FiO_2 <0.6 PEEP <10 cm H_2O RR <35b/min PCV or HFO mode not in use	Absence of a femoral sheath, femoral arterial line &/or skeletal traction No vertebral fracture
Dean 2008	Haemodynamically stable	Patient is awake and cooperative ICP & perfusion clearance obtained	DO_2 exceeds VO_2 demand	SCI & / or fracture clearance has been obtained

Authors	Cardiovascular criteria	Neurological	Respiratory	Other
Perme and Chandrashekar 2008	No significant or symptomatic changes in resting ECG with hemodynamic compromise No unstable angina or uncontrolled heart failure Absence of high dose or multiple vasopressor drugs No known or suspected dissecting aneurysm	Patient is awake and responsive Controlled ICP Absence of significant neurological dysfunction	No acute pulmonary emboli FiO_2 <0.7	Absence of unstable fractures & / or musculoskeletal dysfunction
Dowds 2009	CVS is stable	Nil	Mechanical ventilation can maintain satisfactory ABG's and O_2 saturations	Underlying critical condition is stabilised The source of sepsis is eliminated
Hopkins and Spuhler 2009	No catecholamine drips No symptomatic orthostasis	Patient not comatose Follows commands & is cooperative	FiO_2 <0.6 and PEEP <10 cm H_2O	Nil
O'Connor and Walsham 2009	Nil	Nil	Nil	Nil
Perme and Chandrashekar 2009	HR <110beats/min at rest MAP 60 - 100 mm Hg No hypotension associated with dizziness, fainting & / or diaphoresis HR less than maximum age predicted HR No change in heart rhythm No significant chest pain	Nil	SpO_2 >88% on O_2 No change of breathing pattern or ↑ in acc. mm use, paradoxical pattern, nasal flaring & / or an appearance of facial distress No extreme fatigue or severe intolerable dyspnoea RR = baseline + <20 br/min	Have sufficient perfusion to maintain normal organ function No excessive pallor or flushing of skin Patient consent

Authors	Cardiovascular criteria	Neurological	Respiratory	Other
Rochester 2009	No orthostatic hypotension No catecholamine infusion SBP >90 & <200 mmHg MAP >65 mm Hg HR <130 b/min No unstable cardiac rhythm or new antiarrythmic medication	Alert & responsive to stimulation No acute ICH or SAH or TBI or ischemic stroke. No new neurological deterioration No ICP monitor drain	FiO2 ≤60% PEEP < 10 cm H_2O &/or ready to wean RR ≤35 No pressure control ventilation	No SCI No active bleeding No IABP, femoral sheath or femoral arterial line
Vasilevskis et al 2010	Nil	Nil	Nil	Nil
Hanekom et al 2011	No new cardiac arrhythmias on ECG Patient only on low dose inotrope support: Dopamine <10mcg/kg/min; Nor/adrenaline <1mcg/kg/min <20% variability in BP Absence of orthostatic hypotension HR <50% age predicted maximum rate at rest to allow mobilisation, <75% for in bed activity. No uncontrolled haemorrhage	Nil	SpO_2 >94% with <4% variation PaO_2:FiO_2 >300 Satisfactory respiratory pattern FiO_2 <60% in first 5 days & <50% for de-conditioned pts PEEP < 10cmH_2O in first 5 days & ≤5 cm H_2O for de-conditioned pts No sophisticated modes of ventilation Pt comfortable, no ↑ WOB or dyspnoea Stable and secure airway Min. aspiration Secretions manageable with infrequent suctioning	Sepsis controlled Secure parenteral line

as stated in Stiller & Phillips 2003 article; ABG's = arterial blood gas; b/min = beats per minute; BGL = blood glucose level; BP = blood pressure; br/min = breaths per minute; CI = contraindication; CVS = cardiovascular system; DO_2 = oxygen delivery; DVT = deep vein thrombosis; ECG = echocardiogram; FiO_2 = Fraction of inspired oxygen; Hb = haemoglobin; HFO = high frequency oscillation; HR = heart rate; IABP = intra aortic balloon pump; ICH = intra cerebral haemorrhage; ICP = intra cerebral pressure; LL = lower limb; MAP = mean arterial pressure; Min. = minimal; O_2 = oxygen; ortho = orthopaedic; PaO_2 = partial pressure of arterial oxygen; PCV = pressure controlled ventilation; PE = pulmonary embolus; PEEP = positive end expiratory pressure; RR = respiratory rate; SAH = subarachnoid haematoma; SBP = systolic blood pressure; SCI = spinal cord injury; SOB = shortness of breath; SpO_2 = saturation of oxygen measured peripherally; SSG = split skin grafts; TBI = traumatic brain injury; Temp = temperature; VO_2 = oxygen demand; WCC = white cell count; WOB = work of breathing;

Table 3 **Interventions, inclusion and exclusion criteria of reviewed randomised and non-randomised interventional studies**

Author Date	Intervention	Inclusion criteria	Exclusion criteria
Bailey et al 2007	Early activity protocol in RICU 3 activities SOEOB, SOOB in chair & ambulation	>4 days MV & admitted to RICU (usually pts had been transferred from another ICU)	FiO_2 >0.6; PEEP >10 cmH_2O; orthostatic hypotension; catecholamine drips
Bourdin et al 2010	Rehabilitation protocol Chair sitting, tilting-up (with arms supported or unsupported) and walking	>2 days MV and to stay in ICU >7days	Agitation; confusion; impaired or no response to simple orders; shock (defined as SBP <90 mm Hg or need for ongoing vasopressors); persistent resp failure (RR > 35 br/min &/or PaO_2:FiO_2 ratio < 200 mm Hg, $PaCo_2$ >50 mmHg &/or pH < 7.30); RRT; IV sedation; scheduled extubation; procedure out of ICU
Morris et al 2008	Introduced a mobility team (critical care nurse, nurse assist physical therapist)	Acute respiratory failure; requiring MV via ETT on admission; >18 yrs who survived to discharge from ICU	Inability to walk without assistance, cognitive impairment or immunocompromised before acute illness; neuromuscular disease impairing weaning; acute stroke; BMI >45; unstable cervical spine or pathologic or hip fracture; MV > 48 hours before transfer from an outside facility; hospitalisation or transferring hospital stay >72 hours; CPR or DNR at admission; hospitalization within 30 days before admission, cancer therapy within 6 months; re-admission to ICU within current hospitalisation
Needham et al 2010	MDT focused on reducing heavy sedation & increasing staffing to include PT and OT with new consultation guidelines	Pts who were cognitively intact without neuromuscular disease prior to MICU admission & required >4days MV	
Thomsen et al 2008	Transfer to a RICU where early activity is a priority	>4 days of mechanical ventilation and were transferred to RICU	Neurological disease that precluded activity such as stroke or paralysis; readmission to RICU; terminally ill

Author Date	Intervention	Inclusion criteria	Exclusion criteria
Schweickert et al 2009	Early exercise & mobilisation by PT & OT during periods of daily interruption of sedation	>18 yrs; MV for <72 hrs & expected to continue for >24 hrs; baseline independent functional independence 2 wks prior to admission	Rapidly developing neuromuscular disease; cardiopulmonary arrest; irreversible disorders with 6-month mortality estimated at <50%; raised ICP; absent limbs; enrolment in another trial
Burtin et al 2009	Bedside cycle ergometry for 20 mins at an individually adjusted intensity level	Patients with an expected prolonged stay of >7 days (judged on day 5); stable cardio respiratory system	Conditions impairing the cycling movement (trauma or surgery of the leg, pelvis, or lumbar spine; open abdominal wounds; extreme obesity (BMI >35); serious bedsore or venous ulcers); an anticipated fatal outcome; body length <1.5 m; pre-existing diagnosis causing neuromuscular weakness; acute stroke; status epilepticus; coagulation disorders (INR >1.5 or blood platelets <50000/mm^3); ICP >20 mm Hg; psychiatric disorders or severe agitation; cardio respiratory instability (FiO_2 >55%; PaO_2 <65 mm Hg; minute ventilation >150 mL/kg body weight; RR >30 br/min on adequate ventilator support; sig vasopressor support)

APACHE = acute physiological and chronic health evaluation; BMI = body mass index; br/min = breaths per minute; CPR = cardiopulmonary resuscitation; D/C = discharge; DNR = do not resuscitate; ETT = endotracheal tube; FiO_2 = fraction of inspired oxygen; hrs = hours; ICP = intracranial pressure; INR = international ratio; IV = intravenous; LOS = length of stay; MDT = multi-disciplinary team; MICU = medical intensive care unit; MV = mechanical ventilation; OR = odds ratio; OOB = out of bed; OT = occupational therapist; $PaCO_2$ = partial pressure or arterial carbon dioxide; PaO_2 = Partial pressure of oxygen in artery; PaO2:FiO_2 = partial pressure of arterial oxygen: Fraction of inspired oxygen; PEEP = positive end expiratory pressure; Pts = patients; PT = physical therapist; RICU= respiratory intensive care unit; RR= respiratory rate; RRT = renal replacement therapy; SBP = systolic blood pressure; sig = significant; SOEOB = sit over edge of bed; SOOB = sit out of bed; t/f = transferred; wks = weeks; yrs = years; ↓= decreased; ↑ = increased.

2.5 Early mobilisation

2.5.1 Measurement of early mobilisation outcomes

To date there is no valid, reliable measure developed that assesses function and is sensitive to change in the ICU period (Skinner, Berney et al. 2008). Due to this, surrogate measures from the chronic respiratory failure and gerontology specialties of medicine have been used. Examples include the six minute walk test (Burtin, Clerckx et al. 2009) and the Bartel index (Schweickert, Pohlman et al. 2009).

In the seven studies examining implementation of early mobilisation numerous outcome measures have been used or adapted. These are listed below in Table 3.

Table 3 Outcome measures used in studies of early mobilisation

	Bailey et al.(Bailey, Thomsen et al. 2007)	Morris et al.(Morris, Goad et al. 2008)	Bourdin et al.(Bourdin, Barbier et al. 2010)	Needham et al.(Needham and Korupolu 2010)	Thomsen et al(Thomsen, Snow et al. 2008)	Schweickert et al.(Schweickert, Pohlman et al. 2009)	Burtin et al.(Burtin, Clerckx et al. 2009)
Activities conducted	✓	✓	✓	✓	✓		
Activities on MV			✓		✓		
Time from adm^{n} to rehab (median days)	6.5	5	8.5			1.7	14
% of pts mobilised	✓	✓		✓(for each ex)	✓ (amb)	% of days mobilised	
Minutes mobilised			✓			✓	
Distance walked	✓		✓			✓	✓
Activity level prior to ICU D/C	✓	✓					
Duration of mechanical ventilation					✓	✓	

	Bailey et al.(Bailey, Thomsen et al. 2007)	Morris et al.(Morris, Goad et al. 2008)	Bourdin et al.(Bourdin, Barbier et al. 2010)	Needham et al.(Needham and Korupolu 2010)	Thomsen et al(Thomsen, Snow et al. 2008)	Schweickert et al.(Schweickert, Pohlman et al. 2009)	Burtin et al.(Burtin, Clerckx et al. 2009)
LOS – ICU & hospital		✓		✓	✓	✓	
Hospital D/C destination	✓	✓			✓	✓	✓
Hand grip strength						✓	✓
Quadriceps strength							✓
Independent function						✓ (Bartel index & N of ADLs)	Berg balance
MRC						✓	
6 MWT							✓
SF-36							✓

Adm^{n} = admission; D/C = discharge; LOS = length of stay; MRC = Medical Research Council score; MV = mechanical ventilation; SF-36 = short form 36; % = percent; 6 MWT = six minute walk test.

From these studies, the most commonly used outcome measures to evaluate early mobilisation have been: number of activities conducted; time from admission to ICU until activity; percentage of patients mobilised and hospital discharge destination (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). These are markers of exercise dosage and surrogate functional outcomes. None of these measures have been shown to be a valid measure of intensity or dosage of mobilisation or function in the intensive care patient population. This may reflect the difficulty of exercise prescription in the ICU setting.

New measures of function for the ICU patient population are emerging but as yet lack rigorous testing. For example, the PFIT (Physical Function in ICU Test) was developed in Australia and uses simple measures of strength, endurance and function in a 12-point scale (Skinner, Berney et al. 2008). While this measure is simple to perform and is reliable, it has shown to have a floor effect for debilitated patients (Adler and Malone 2012). The Chelsea Critical Care Physical Assessment Tool (CPAx) has recently been published and has shown content and face validity and has shown to be reliable in a small of physiotherapists (Corner, Wood et al. 2013). Neither tool has reported large usage in clinical trials.

The comparison of outcomes for patients in different ICUs is complicated. This is due to the lack of validated measures, but also because patients admitted to ICU vary considerably depending on factors such as age, sex, height, weight, pre-morbid conditions, admission diagnosis, and severity of illness on admission. The APACHE II score is widely used to give a numerical value to the severity of illness for patients admitted to intensive care and allows for comparison of patients with different conditions (Knaus, Draper et al. 1985). It uses a 71 point scale, with a greater score indicating a worse severity of illness. This score closely correlates with the risk of hospital death (Knaus, Draper et al. 1985). An updated version, the APACHE III has been developed (Knaus, Wagner et al. 1991) but the APACHE II continues to be the more widely utilised system. Six of the seven studies on early mobilisation in ICU utilised the APACHE II scoring system for patient comparison of severity of illness

(Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Needham and Korupolu 2010).

2.5.2 Previous studies utilising early mobilisation as an intervention

From the available literature the implementation of mobility teams or protocols in ICU resulted in increased mobilisation (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). Although patient numbers were low and limited diagnostic groups were examined, these results are encouraging and provide preparatory information for larger more robust trials looking at mobilisation as a safe and feasible treatment option that optimises outcomes for all ICU patients.

Activities undertaken by patients during ICU mobilisation studies have been described in four articles. Two studies reported the number of activities in total which were 1449 activities for 103 patients (Bailey, Thomsen et al. 2007) and 270 activities for 20 patients (Bourdin, Barbier et al. 2010). These figures are difficult to interpret as results are dependent on patients length of stay, admission diagnosis and co-morbid conditions. More commonly, the percentage of activities that involved ambulation or weight bearing were reported. The percentage of activities involving ambulation varied from 11% to 53% of activities (Bailey, Thomsen et al. 2007; Thomsen, Snow et al. 2008; Bourdin, Barbier et al. 2010) and one study reported 33% of activities were tilt tabling (Bourdin, Barbier et al. 2010).

The documentation of episodes of mobilisation was inconsistent and reported in a number of different ways. Two studies reported the number of sessions per patient which were 5.5 and 7 episodes per patient post implementation (Morris and Herridge 2007; Needham and Korupolu 2010). An alternative two studies reported the number of study days where therapy was conducted was 88% and 87% of study days (Bailey, Thomsen et al. 2007; Schweickert, Pohlman et al. 2009). What

constituted therapy was not discussed in either study. The remaining three studies did not comment on episodes of mobilisation.

Minutes of mobilisation was touched on by Bourdin et al.(2010) who reported the median time patients spent chair sitting was 150 minutes (IQR = 90 to 240 minutes). The six other studies did not refer to minutes of mobilisation as a focus area in their results (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Needham and Korupolu 2010).

Reports of patients mobilising with an ETT on mechanical ventilation, RRT and vasopressors is quite variable across the seven studies. Mobilisation with an ETT has seen the most support with three studies advocating this practice and reporting favourable outcomes (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008) and only one study excluded patients with an ETT (Bourdin, Barbier et al. 2010). The first study conducted on early mobilisation as an intervention in ICU, set out to remove non-physiologic barriers such as ETTs to allow mobilisation (Bailey, Thomsen et al. 2007). After this change, 40.9% of all activities recorded were conducted with an ETT of which 42% were ambulation (Bailey, Thomsen et al. 2007). All studies examining mobilisation with an ETT reported this practice as being safe in the respiratory failure patient population.

Mobilisation with RRT has not had significant discussion within the general literature. Schweickert et al(2009) allowed patients with continuous venovenous haemodiafiltration to mobilise, but patients on intermittent dialysis were excluded. No results regarding the number of episodes conducted with this therapy were reported. The study that excluded patients mobilising with ETTs also excluded patients with RRT (Bourdin, Barbier et al. 2010). The remaining studies did not comment on RRT. Therefore, there is little literature regarding the practice of mobilisation with RRT.

The literature is divided when it comes to mobilisation of patients on vasopressor infusions. Thomsen et al.(2008) did not allow mobilisation with vasopressor infusions, Burtin et al.(2009) allowed the practice but not with significant support

(this was not defined further) and Morris et al.(2008) did allow patients to mobilise with vasopressors. It was not reported how many activities were conducted with vasopressor infusions running in the two studies that allowed this practice.

Functional outcome measures were recorded in the only two RCTs (Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009). The results were improved independence measured using the Bartel index (Schweickert, Pohlman et al. 2009) and increase in six minute walk distance at hospital discharge (Burtin, Clerckx et al. 2009) (see Table 4). There was a trend towards more patients in the intervention group being discharged home in one study, but this was not statistically significant (Schweickert, Pohlman et al. 2009). The limitations of the results in both of these studies is that less than 10% of patients admitted to the units were recruited, patients were predominantly suffering respiratory failure and the patients in Burtin et al.'s (2009) study were only included if they received greater than five days of mechanical ventilation. Therefore, although these studies had rigorous design and positive results, the external validity of these findings is limited.

Currently, no data exist on the effect of early mobilisation on all patients admitted to acute Level III ICUs.

2.5.3 Safety

Safety in the ICU is considered paramount due to the severity of illness of the patients. Therefore, all treatments in intensive care must be evaluated in terms of the potential benefit provided versus the potential for harm to patients. Early mobilisation as a treatment must also have this evaluation completed. As yet, an adverse event rate for early mobilisation in a heterogeneous ICU population has not been established.

Subgroups of the population have had some investigation. Five studies investigating the implementation of early mobilisation for patients admitted to ICU with respiratory failure have reported adverse event rates. The classification criteria for an adverse event as well as the rate reported is listed in Table 4. The rates vary from 0.96% to 3% of sessions encountering an event, none of which resulted in reported increased mechanical ventilation time, increased length of stay or death (Bailey,

Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). For subgroups of the ICU population, early mobilisation, using the various definitions of early mobilisation, has shown to be a safe intervention.

Adverse event rates for physiotherapy practices, of which mobilisation was included has been described in one Australian study (Zeppos 2007). The overall adverse event rate was 0.2%, or 27 of the 12 287 episodes of physiotherapy carried out over three months across five sites in Australia (Zeppos 2007). The physiotherapy treatments included respiratory, neurological and musculoskeletal treatments. An increase in respiratory rate on one occasion was the only adverse event related to mobilisation (Zeppos 2007). Minimal data was available about the patient populations assessed and the intensity, dose and timing of the interventions. This limited data is difficult to extrapolate due to the constraints of the study.

The adverse event rate associated with mobilisation for all subgroups of the ICU population remains to be established for Australian ICUs

Table 4 Studies investigating early mobilisation: adverse events and outcomes

Authors Year	N	Patient diagnostics	Intervention	Outcomes	Adverse event classifications	AE rate
Bailey et al. 2007 (Bailey, Thomsen et al. 2007)	103	Respiratory failure Sepsis – 39.8%; Pneumonia – 19.4%; Cardiovascular disease – 9.7%; Aspiration – 6.8%; Trauma – 5.8%; GI bleed or liver failure – 5.8%; Surgery – 5.8%; COPD – 3.9%; Cancer – 1.9%; Asthma – 1.0%	Early activity protocol in RICU 3 activities SOEOB, SOOB in chair & ambulation	Time from ICU admission to SOEOB = 6.6 +/- 5.5 days (no comparison group available) On D/C, 69.4% of pts ambulated >100 feet	Fall to knees Tube removal SBP >200 mmHg SBP <90 mm Hg SpO2 <80% Extubation	0.96%
Bourdin et al. 2010 (Bourdin, Barbier et al. 2010)	225	Respiratory failure (more than 50% had chronic respiratory disease) and whose ICU stay was greater than 1 week.	Rehabilitation protocol Chair sitting, tilting-up (with arms supported or unsupported) and walking	Median time from ICU admission to the start of rehabilitation = 5 (1.5-9) Contraindication to rehab intervention on 15% of days	Drop in muscle tone Hypoxaemia (SpO2 <88% for > 1 min) Unplanned extubation Orthostatic arterial hypotension	3%

Authors Year	N	Patient diagnostics	Intervention	Outcomes	Adverse event classifications	AE rate
Morris et al 2008 (Morris, Goad et al. 2008)	330	Acute lung injury – 58.7%; Acute on chronic lung disease – 12.3%; Coma – 15.4%; Post-op – 4.3%; Congestive heart failure – 7.4%; Cardiac arrest – 1.9%;	Mobility team (critical care nurse, nurse assist physical therapist)	Time from ICU admission to OOB = 8.5 days*	SpO2 frequently <88% MAP <65 mm Hg Myocardial infarction Increase in PEEP or change to assist control mode once weaning commenced	N/A
Needham et al 2010 (Needham and Korupolu 2010)	57	Medical ICU patients (no further details provided)	MDT focused on reducing heavy sedation & increasing staffing to include PT and OT with new consultation guidelines	Number of PT and OT treatments increased 286%* MICU LOS ↓ 30%* Hospital LOS ↓18%*	Cardiopulmonary arrest Loss of consciousness Fall Removal of any medical device Oxygen desaturation <85% for >3 minutes	1.36%
Thomsen et al 2008 (Thomsen, Snow et al. 2008)	104	Respiratory failure only Sepsis – 38.5%; Pneumonia – 16.3%; Cardiovascular disease – 14.4%; Trauma – 9.6%; GI bleed or liver failure – 8.7%; Surgery – 4.8%; Aspiration - 1.9%; Cancer - 1.9%;	Transfer to a RICU where early activity is a priority	11% of pts ambulated 24 hours prior to t/f to RICU vs. 28% after t/f Predictors of ↑ ambulation = RICU transfer (OR 2.47)*; absence of	N/A	N/A

Authors Year	N	Patient diagnostics	Intervention	Outcomes	Adverse event classifications	AE rate
		COPD – 1.0%; Asthma - 1.0%; Pulmonary embolism - 1.0%; Renal disease - 1.0%		sedatives (OR 1.88)*; ↓ APACHE II (OR 1.06)*; female (OR 1.88)*		
Schweickert et al 2009 (Schweickert, Pohlman et al. 2009)	104	Respiratory failure Acute lung injury - 55%; COPD - 8%; Asthma - 10%; Sepsis - 14%; Haemorrhage – 2%; Malignancy – 4%; Other – 6%	Early exercise & mobilisation by PT & OT during periods of daily interruption of sedation	Time from admission to ICU to OOB = 1.7 days* Return to independent functional status at hospital D/C* Shorter duration of delirium*	Fall to knees ETT removal SBP > 200 mm Hg, SBP <90 mm Hg SpO2 < 80%.	0.2% (4% of sessions stopped due to instability)
Burtin et al 2009 (Burtin, Clerckx et al. 2009)	90	Surgical – 90% Cardiac surgery - 39%; transplant surgery - 24%; thoracic surgery - 16%; other – 10%	Bedside cycle ergometry for 20 mins at an individually adjusted intensity level	Time from admission to ICU till cycle ergometry commencement = 14 days Isometric quadriceps force* 6-min walking distance* and subjective feeling of functional well being at hospital D/C*	Malign arrhythmias Symptoms of myocardial ischaemia Respiratory distress leading to symptoms of intolerable dyspnoea	0

D/C = discharge; MICU = medical ICU; OOB = out of bed; OT = occupational therapist; PT = physiotherapist; RICU = respiratory ICU; SOEOB = sitting over edge of bed; SOOB = sitting out of bed; *= statistically significant result

2.5.4 Implementation and Feasibility

Assessment of the feasibility of a treatment technique in ICU should take into account the patients, the setting and the workforce. Studies examining early mobilisation in ICU (see Table 4) have reported that a specific interventional technique is feasible because the technique was self-evidently possible in a clinical trial (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). In each of these studies many factors were controlled or modified in order to remove experimental bias or concentrate on a clinical sub-cohort of patients. To date, no study has demonstrated that outside the experimental context these behaviours or work practices have been adopted or transferred into other settings using a systems change approach. Evidence of clinical efficacy can only be translated into clinical utility if the proposed systems change is able to be implemented within a specific setting. The feasibility and sustainability of changes in early mobilisation work practices in ICU is yet to be reported.

From the review of the literature, a major factor that impacts on the ability for an early mobilisation treatment strategy to be adopted in ICUs is the limited ability to be confident that the current evidence is generalisable. Overall, only a small proportion of the ICU patient population in any particular setting, in any particular timeframe has been the focus of clinical efficacy studies. Most feasibility studies have been limited to patients admitted to ICU with respiratory failure (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Burtin, Clerckx et al. 2009) thereby such findings have limited external validity for the broader ICU population. One of these studies (Bailey, Thomsen et al. 2007) did have a larger proportion of all patients in the specific setting available for recruitment, however on review this was undertaken in an ICU setting with a specific focus on respiratory care. It is unlikely that this ICU was the equivalent of a level III ICU since patients were only admitted after being stabilised in another acute ICU.

Results of studies examining early mobilisation are difficult to extrapolate to the Australian population for three reasons: the limited patient groups examined; the variation in settings and variation in workforce.

In the literature, clinical efficacy studies report the use of experimental protocols that altered the normal workforce arrangements. For example, three studies employed additional staffing to form specifically trained mobility teams where previously there had been no permanent rehabilitation staff (Morris, Goad et al. 2008; Schweickert, Pohlman et al. 2009; Needham and Korupolu 2010); three reported no increase in staffing (Bailey, Thomsen et al. 2007; Burtin, Clerckx et al. 2009; Bourdin, Barbier et al. 2010) and one did not comment (Thomsen, Snow et al. 2008). One study reported no additional staffing resources but did have additional equipment supplied to achieve the goal of cycle ergometry for ICU patients (Burtin, Clerckx et al. 2009).

Of the seven studies examining early mobilisation as an intervention, only Morris et al.(2008) commented on total costs of the program. Taking into account the increased cost of wages for the mobility team, it was demonstrated the average cost per patient decreased after the implementation of a mobility team (Morris, Goad et al. 2008). This is most likely due to the decrease in patient length of stay however, no breakdown of costs was provided.

The investigation into feasibility of early mobilisation of patients in the ICU is limited and therefore warrants further investigation with a specific focus on systems change in a heterogeneous patient population in Australian, level III ICUs.

2.6 Barriers to mobilisation

Barriers to early mobilisation of mechanically ventilated adults are largely unreported (Needham and Korupolu 2010; Adler and Malone 2012). Recently, Needham et al.(2012) has postulated that in order to progress the adoption of early mobilisation and determine its effect on patient centred outcomes, the barriers to its implementation need to be established. Barriers to new treatments in the ICU are influenced by country, unit culture and the admission diagnosis of the patient.

Reported barriers to mobilisation vary depending on how they were examined. Bedside data collection focuses on barriers for the individual patient, whereas interviews of staff opinion are more likely to reflect unit culture as a whole. The four studies examining barriers to mobilisation as an outcome differ in their study designs (Needham and Korupolu 2010; Winkelman and Peereboom 2010; Garzon Serrano, Ryan et al. 2011; Leditschke, Green et al. 2012). Two studies recorded barriers at the bedside during contemplation of patient mobilisation (Garzon Serrano, Ryan et al. 2011; Leditschke, Green et al. 2012) while the other studies conducted interviews of staff opinion (Needham and Korupolu 2010; Winkelman and Peereboom 2010). The disadvantage of interviews is that the identification of one primary barrier may prevent the exploration of other valid, but more individual barriers. For example, if sedation is discussed as a major barrier the fact that the patient is on RRT may not be considered. Cultural barriers need to be put into context with individual data in order to develop a more detailed picture of barriers to mobilisation.

Two papers that surveyed or presented clinician opinion found that safety was the primary concern when considering mobilisation of any patient in ICU, followed by the use of sedation (Morris 2007; Winkelman and Peereboom 2010). These findings contradict Leditschke et al.'s (2012) findings of vascular access in the femoral region; respiratory instability and timing of procedures which were the most frequently reported barriers during the four week audit. Cardiac, respiratory and neurological stability of the patient was of concern in all studies but varied in level of importance (Morris 2007; Needham, Korupolu et al. 2010; Winkelman and Peereboom 2010; Leditschke, Green et al. 2012). Tied into safety and stability was the concern for line and attachment patency, particularly ETTs and femorally inserted lines (Morris 2007; Winkelman and Peereboom 2010; Leditschke, Green et al. 2012). Reported barriers to mobilisation vary depending on whether data is collected on clinician opinion or collected at the patient bedside. The commonality between the two approaches is the concern for patient safety.

The variation in worldwide practice also plays an important part when interpreting articles. Areas where there is little physiotherapy input have reported lack of time

and staffing as barriers (Morris 2007; Needham, Korupolu et al. 2010). These barriers were not mentioned in the Australian study (Leditschke, Green et al. 2012) where physiotherapy presence is higher. Sedation was also listed as a higher concern in studies carried out in North American countries (Morris 2007; Needham, Korupolu et al. 2010). This correlates with the higher use of sedation in this region (Martin and Mathisen 2005). Barriers to mobilisation as reported in the literature therefore must be seen as context dependent.

The difference between patients of different diagnostic specific categories has not been investigated. Although the Leditschke et al.(2012) did report a mixed medical surgical population, no comment was made on whether there were differences within the diagnostic specific categories. Further research into barriers for patients admitted into different diagnostic specific categories needs to be conducted.

The culture of an ICU is very difficult to measure but plays an important part in mobilisation rates of mechanically ventilated patients. Attitudes of individual clinicians towards mobilisation and how these individuals interact with the MDT heavily influence the amount of activity patients receive. Winkleman and Peereboom (2010) commented that medical orders for mobilisation were positively associated with mobilisation. This study was conducted in the USA where physiotherapy is initiated by physician referral (Winkelman and Peereboom 2010). With greater understanding of the impact of weakness in patients admitted to ICU and with higher levels of evidence to support mobilisation therapy, physicians and MDTs may be influenced to adopt this therapy into their practice. The attitude of physicians working in ICU is therefore a potentially modifiable barrier to this treatment.

Deciding to mobilise a patient involves complex interpretation of clinical situations balancing the perceived risks and benefits (Hopkins, Spuhler et al. 2007; Stiller 2007; Timmerman 2007; Dean 2008; Gosselink, Bott et al. 2008; Perme and Chandrashekar 2008; Hanekom, Gosselink et al. 2011; Perme, Lettvin et al. 2011; Herridge, Batt et al. 2013). Early mobilisation is a relatively new therapy and it has not yet been established what the effect size of this therapy is. The nature of

adverse events that occur with early mobilisation has also not been confirmed. Without understanding what gains can come from this therapy it is difficult to know what an acceptable level of risk should be. Establishing an adverse event rate for early mobilisation will assist in understanding the barriers and their relative merit to the therapy (Morris 2007; Adler and Malone 2012; Needham, Davidson et al. 2012).

Many barriers to early mobilisation may be modifiable within the system while others will remain unmodifiable (e.g. unstable spinal fractures) and delineation between these within the ICU context could be an early step in change of practice. Leditschke et al.(2012) resolved that unavoidable barriers to mobilisation were respiratory, hemodynamic and neurological stability as well as medical orders to rest in bed. Avoidable barriers were vascular access catheters in a femoral position, timing of procedures, sedation management and early ward transfer. Definitions of these categories and strategies of how to overcome avoidable barriers were not provided. The literature shows that future studies need to be explicit in their definitions of barriers in order to progress this area of research.

2.7 Summary

Intensive care therapy is relatively new and is continuing to develop. Focus is now on improving function as well as mortality.

Intensive care often provides numerous therapies and is delivered in different ways in different units and countries, often dependent on the culture of the unit.

Immobility leads to muscle weakness. Immobility as well as critical illness combined with sedation results in more weakness. This is termed ICUAW and risk factors for this require further research and definition.

Early mobilisation is a loose term and for future studies should define both the baseline level as well as the change in mobilisation to determine what constitutes early. Mobilisation has been defined as moving against gravity and inducing axial loading of the spine and / or long bones. The activities that constitute mobilisation are sitting (either over the edge of the bed or in a chair), standing, using a tilt table

or ambulation. Baseline practice in Australia has not previously been documented or compared.

Few studies have been conducted in this area and no studies have examined the whole ICU patient population. Studies that have been conducted have had low adverse event rates. The effect of early mobilisation on outcomes for all patients in ICU remains unknown.

Few studies with low numbers have looked at barriers to early mobilisation. Results vary depending on study design. Barriers for all patients are unknown. Bedside data is important in establishing the complexity of barriers that exist at the local, national and international ICU level.

Chapter 3 Common methods

3.1 Introduction

The thesis consists of three studies. All studies were conducted independently but focus on mobilisation of mechanically ventilated adults admitted to intensive care. This section will describe the aims and hypotheses for the thesis as a whole as well as the methods that are common to all three studies. The definition of early mobilisation used for all three studies will be as described in the literature review.

3.2 Aims

The thesis examined early mobilisation of mechanically ventilated adults throughout their ICU stay and had four main areas of focus. These areas of focus and the associated aims for this thesis are described below.

1) Mobilisation rates
    - To evaluate the effect of an early mobilisation program on mobilisation rates in a single centre with a heterogeneous patient population.
    - To establish the prevalence and incidence of mobilisation of patients who also received an ETT while mechanically ventilated, RRT and / or vasopressor infusions. This will be looked at in a single unit to assess capability of change as well as the prevalence and incidence of this practice nationally.
    - To establish baseline levels of mobilisation for patients of different admission diagnoses in Australian ICUs
    - To benchmark mobilisation practices in Australia internationally with Scotland.
2) Early mobilisation and discharge destination
    - To determine if there is an association between a more favourable outcome at the time of hospital discharge and patients who mobilise in ICU

3) Safety and feasibility of early mobilisation
    - To evaluate the influence of implementing an early mobilisation program on adverse events in a single centre.
    - To establish an adverse event rate for early mobilisation of patients receiving an ETT and mechanical ventilation, RRT and / or vasopressor infusions in a single centre, around Australia and internationally in Scotland.
    - To establish an adverse event rate for early mobilisation as a therapy for patients of different admission diagnoses in Australian ICUs and benchmark this internationally with Scottish ICUs.
4) Barriers to early mobilisation
    - Identify barriers to early mobilisation practices for patients in Australia and compared these internationally with barriers identified in Scottish ICUs.

3.3 Design

The studies that constitute this thesis are described in chronological order. At the conclusion of each study there were questions left unanswered that led to the natural progression of the next study. The individual study designs are explained in the methods section for that study.

3.4 Hypotheses

Hypotheses were devised for each individual study and can be found in the methods section specific for that study.

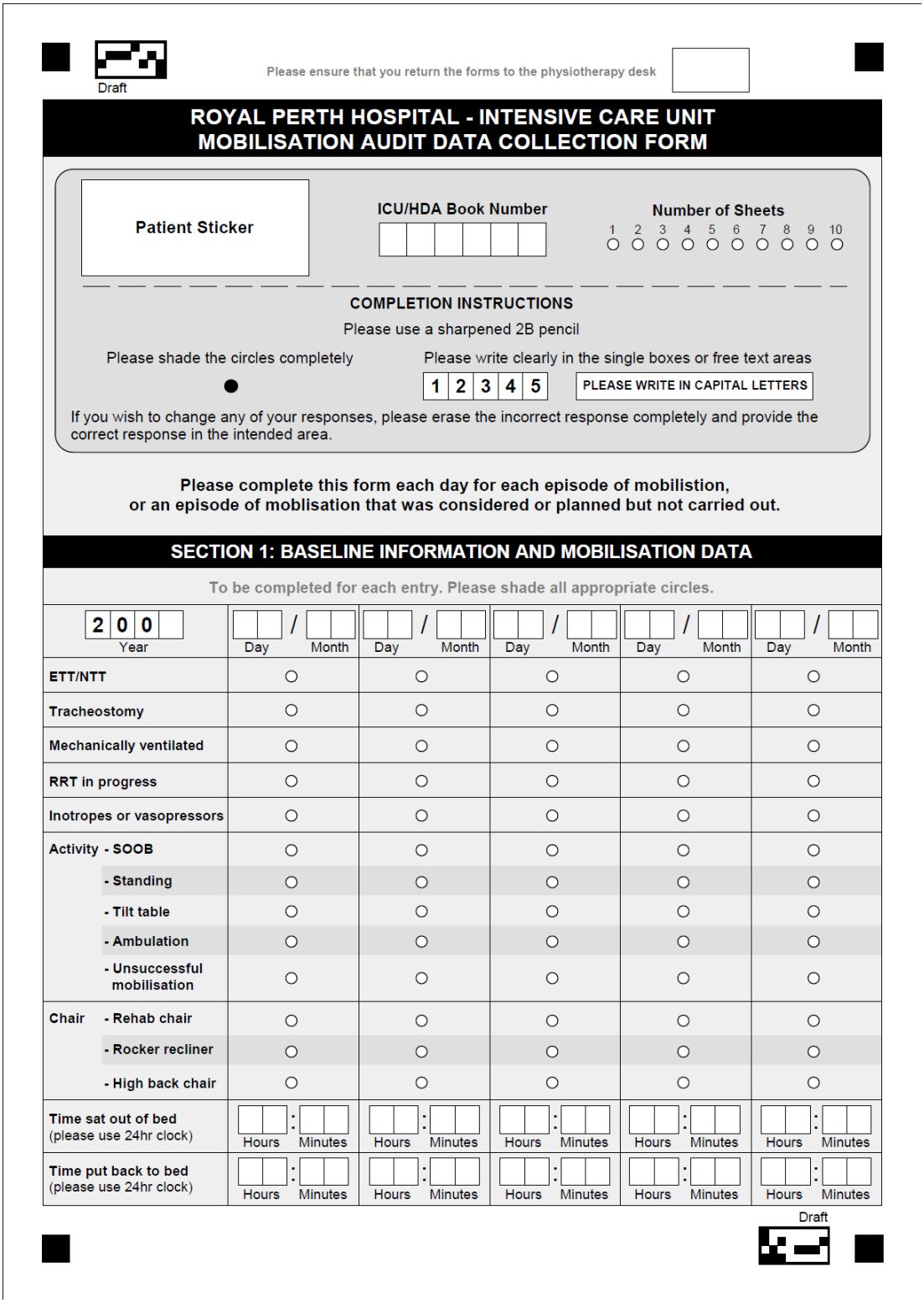
3.5 Research tools and variables collected

3.5.1 Mobilisation Data Collection Form

The Mobilisation Data Collection Form (MDCF) (see Figure 1) was developed for Study One. The MDCF collects data relating to mobilisation and changes associated with mobilisation. Study Two utilised aspects of the MDCF but was devised by a

unique group of researchers and therefore does not cover all aspects of the MDCF. Study Three made slight adjustments to section three of the MDCF but remained similar across all other sections.

Figure 1 Mobilisation data collection form



Draft

Please ensure that you return the forms to the physiotherapy desk

ROYAL PERTH HOSPITAL - INTENSIVE CARE UNIT
MOBILISATION AUDIT DATA COLLECTION FORM

Patient Sticker

ICU/HDA Book Number

Number of Sheets: 1 2 3 4 5 6 7 8 9 10

COMPLETION INSTRUCTIONS

Please use a sharpened 2B pencil

Please shade the circles completely ●

Please write clearly in the single boxes or free text areas: 1 2 3 4 5 PLEASE WRITE IN CAPITAL LETTERS

If you wish to change any of your responses, please erase the incorrect response completely and provide the correct response in the intended area.

Please complete this form each day for each episode of mobilistion, or an episode of moblisation that was considered or planned but not carried out.

SECTION 1: BASELINE INFORMATION AND MOBILISATION DATA

To be completed for each entry. Please shade all appropriate circles.

	Year 2 0 0	Day / Month	Day / Month	Day / Month	Day / Month	Day / Month
ETT/NTT		○	○	○	○	○
Tracheostomy		○	○	○	○	○
Mechanically ventilated		○	○	○	○	○
RRT in progress		○	○	○	○	○
Inotropes or vasopressors		○	○	○	○	○
Activity - SOOB		○	○	○	○	○
- Standing		○	○	○	○	○
- Tilt table		○	○	○	○	○
- Ambulation		○	○	○	○	○
- Unsuccessful mobilisation		○	○	○	○	○
Chair - Rehab chair		○	○	○	○	○
- Rocker recliner		○	○	○	○	○
- High back chair		○	○	○	○	○
Time sat out of bed (please use 24hr clock)		Hours : Minutes	Hours : Minutes	Hours : Minutes	Hours : Minutes	Hours : Minutes
Time put back to bed (please use 24hr clock)		Hours : Minutes	Hours : Minutes	Hours : Minutes	Hours : Minutes	Hours : Minutes

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Please ensure that you return the forms to the physiotherapy desk

SECTION 2: ADVERSE EVENTS OCCURRING DURING MOBILISATION

Please indicate if any of these adverse events occurred during mobilisation.

Unplanned removal art line	○	○	○	○	○
Unplanned removal CVC or Vascath	○	○	○	○	○
Unplanned removal peripheral line	○	○	○	○	○
Unplanned removal ETT	○	○	○	○	○
Unplanned removal trache	○	○	○	○	○
Unplanned removal NGT / OGT	○	○	○	○	○
Unplanned removal drain	○	○	○	○	○
Unplanned removal other - please specify					
Fall	○	○	○	○	○
Increased oxygen requirements (i.e.↑FiO2)	○	○	○	○	○
Increased inotropes / vasopressors	○	○	○	○	○
Inotropes / vasopressors started	○	○	○	○	○
Unexpected return to bed due to - CNS unstable	○	○	○	○	○
- CVS unstable	○	○	○	○	○
- ↓SpO2	○	○	○	○	○
- patient refused	○	○	○	○	○

SECTION 3: FOR PATIENTS NOT MOBILISED

Please indicate reason(s) why the patient was not mobilised.

Procedure required	○	○	○	○	○
CNS unstable	○	○	○	○	○
CVS unstable	○	○	○	○	○
Respiration unstable	○	○	○	○	○
Orthopaedic orders	○	○	○	○	○
Sedated	○	○	○	○	○
Patient refused	○	○	○	○	○
Lack of resources	○	○	○	○	○
ETT in situ	○	○	○	○	○
Diarrhoea	○	○	○	○	○
Craniectomy without helmet	○	○	○	○	○

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The construction of the MDCF clearly defined each variable in a data dictionary (see Appendix 2). This data table was then used as a reference for physiotherapists completing data collection. The form was trialled for seven days to establish ease of use and relevance. Alterations were then made accordingly.

The MDCF was divided into three sections.

1) Baseline information and mobilisation data
2) Adverse events occurring during mobilisation
3) For patients not mobilised what barriers existed

Ventilation data were divided into three separate rows; ETT/NTT, tracheostomy and mechanical ventilation. This was done intentionally to clarify whether patients with an ETT/NTT or a tracheostomy were on mechanical ventilation whilst an artificial airway was in situ at the time of mobilisation.

The activities constituting mobilisation are defined in the data dictionary (Appendix 2). The activities under the heading of early mobilisation were in accordance with the definition of early mobilisation. Mobilisation activities in the MDCF were: sitting (either over the edge of the bed or in a chair or rehabilitation chair) or weight bearing exercises involving axial loading of the spine and / or long bones (tilt table, standing, or walking). Passive range of movement exercises were considered to be part of standard care and not classified as mobilisation as they do not involve movement against gravity and have not shown to sufficiently contribute to whole body functional rehabilitation (Cook and Campbell 1979; Jadad 1998).

One column of the MDCF was used per episode of mobilisation. If more than one episode of mobilisation was carried out per day then an additional column was completed with the same date at the top of the new column.

The MDCF was specially formatted so completed forms were able to be scanned for data entry. This data was then linked with information routinely collected as part of the quality assurance data base of each ICU.

3.5.2 Quality assurance database variables

Variables from the quality assurance database were as follows:

- Age

  Age of all patients was recorded to ensure adequate matching of groups in each study

- Sex

  Sex of all patients was recorded to ensure adequate matching of groups in each study

- Admission diagnosis

  Admission diagnoses were recorded using the APACHE III diagnostic codes as used by ANZICS Centre for Outcome and Resource Evaluation database (see Appendix 3). There are 21 main groupings of diagnoses, 11 of which apply to non surgical admissions and 10 for surgical admissions.

- APACHE II score

  The APACHE II (acute physiological and chronic health evaluation, version two) is a prognostication system used to establish the risk of hospital mortality for critically ill adults (Knaus, Draper et al. 1985). Patients are scored on disease category, acute physiological abnormalities, age, pre-existing functional limits, major co-morbidities and treatment location prior to ICU (Knaus, Draper et al. 1985). The final score of between 0 and 71 then gives a risk estimate for hospital death. APACHE II has shown to have an accuracy of within 3% of the actual observed (Knaus, Draper et al. 1985)(www.anzics.com.au). The APACHE II scoring system is widely used in this area of research and recognized and therefore it is a useful comparative tool to include in this study (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Needham and Korupolu 2010). It gives an appreciation of the severity of illness of patients.

  APACHE II scores can be recorded at different time points during a patients stay in ICU. To portray the severity of illness of patients, the worst APACHE II score was recorded for all patients during their ICU stay was recorded for all

patients in all studies in accordance with protocol (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Needham and Korupolu 2010).

- Days where mechanical ventilation was present
  Mechanical ventilation was an entry criterion for Study One and Three and in order to ensure inclusion criteria were met and calculate capture rates; patients receiving mechanical ventilation were identified and cross referenced with all patients included in the study from quality assurance databases.
- Length of stay in ICU
  Length of stay in ICU was collected for all patients in Study One and Three to ensure groups were appropriately matched. Length of stay in ICU was observed as the time from admission to the time of discharge and was measured in hours and converted to days for reporting.
- Length of stay in hospital
  Length of stay in hospital was collected for all patients in Study One and Three. Length of stay in hospital was observed as the time of admission to any area of the hospital until discharge from any area of the same hospital and was recorded in either days or hours but reported in days only.
- Discharge destination from hospital
  The discharge destinations recorded for ANZICS Centre for Outcomes and Resource Evaluation database were used for all studies. The five locations identified for hospital discharge are: dead, home, another acute ICU, acute hospital, rehabilitation / nursing home (ANZICS and CORE 2010).

3.5.3 Questionnaire

In conjunction with Study One and Three, a questionnaire was sent to the senior physiotherapist in each unit to establish what resources were available in each unit and what the consensus position was on mobilisation of patients with an ETT, RRT and / or vasopressor infusions (See Appendix 4).

3.6 Evaluation measures

From the variables collected, measures were derived to assess the four focus areas of the thesis. Within these measures, the cohorts in each study were described as whole entities and then in sub groups. The sub groups were devised from APACHE III admission diagnostic codes and APACHE II scores in accordance with literature in this area (Judson and Fisher 2006). A final sub set of the population was also devised for Study One only. This population was 'patients who had the opportunity to mobilise'.

Categories within each of the sub groups did not overlap and were all mutually exclusive.

Diagnosis (sub group 1)

The categories in this sub group were: cardiac; respiratory; gastrointestinal; neurology; sepsis; orthotrauma and metabolic. The categories were based on the APACHE III diagnostic codes for each organ system and included both operative and non-operative codes in each category (see Appendix 3). This is similar to previous studies (Moran and Solomon 2012). The orthotrauma category is a combination of trauma, musculoskeletal and skin diagnostic codes and gastrointestinal category included genitourinary and gynaecological surgery codes.

In the literature there is considerable discussion surrounding patients admitted with respiratory conditions (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008). This diagnostic breakdown allows for the comparison of patients admitted with respiratory conditions with patients admitted with alternative organ dysfunction.

Classification (sub group 2)

The categories in this sub group were: medical; surgical and trauma. These categories were also devised from the APACHE III admission diagnostic codes. All non-operative diagnoses, except trauma were classified as medical; all operative diagnostic codes, except trauma were classified as surgical and both operative and

non-operative trauma and burns categories were classified under the trauma category.

Of the seven studies evaluating early mobilisation, six examined only medical patients (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). Anecdotal evidence only is available on the impact of early mobilisation on patients who undergo surgery. Trauma patients are often excluded from trials evaluating mobilisation due to the high prevalence of fractures that impact upon weight bearing (Bailey, Thomsen et al. 2007; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009) and have not previously been examined as a cohort.

Severity of illness (sub group 3)

A third sub group was created to examine the effect of severity of illness on mobilisation. Previous studies in this field have not examined patients according to the severity of illness of the patient. The categories of this sub group were five point increments of the APACHE II score starting from 0 - 4 and including the highest recorded APACHE II score of the studies (45 – 49).

Those who had the opportunity to mobilise

In certain conditions, mobilisation is contraindicated due to the risk of harm outweighing the benefits. These conditions include premature labour; unstable spinal or pelvic fractures; patients with written medical orders to rest in bed and patients where death is imminent.

In an effort to examine improvement in mobilisation rates the removal of these patient groups helps eliminate those who were never and should never mobilise and help identify those who weren't mobilised but could have been. Identification of this population was only possible in Study One.

3.6.1 Evaluation measures for mobilisation

Currently, there is no accepted definition of rate of mobilisation for patients in ICU. Therefore, mobilisation rate was measured in a number of ways to display intensity, duration and frequency of mobilisation amongst the cohorts.

The number of activities was calculated as the number of discreet tasks (sitting, standing, tilt tabling or ambulating) performed for the patient's length of stay. The activity performed is also a determinant of exercise intensity and has been dichotomised into weight bearing (standing, tilt tabling and ambulation) and non-weight bearing activities (sitting over the edge of the bed or in a chair).

An episode of mobilisation is defined as one session of mobilisation with substantial rest periods on either side of that session. An episode was indicated by one column on the MDCF. Patients may have completed more than one episode per day which would be indicated by more than one column of the MDCF being completed on the same date. The number of episodes of mobilisation is a measure of frequency. The numbers of activities conducted during each episode were also recorded.

The number of minutes of mobilisation was recorded on the MDCF by the treating physiotherapist and is a measure of duration of exercise. Minutes of mobilisation was measured for each episode of mobilisation, not each activity and commenced when the patient began one of the mobilisation activities and ended on return to bed.

The proportion of patients mobilising with an ETT and mechanical ventilation, RRT and / or vasopressor infusions was recorded from data points on the MDCF. These measures gave an indication of the safety of mobilising patients who still required invasive support and what intensity of exercise could be safely achieved with these therapies.

3.6.2 Evaluation of early mobilisation and discharge destination

At this time there is no valid and reliable functional outcome measure appropriate for use in this patient population that is sensitive enough to detect change within ICU length of stay (Skinner, Berney et al. 2008). In the absence of this, a surrogate

measure of function is hospital discharge destination. This has been used in four previous studies (Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009). The location of discharge from hospital gives a gross indication of the patient's abilities needed in order to achieve that destination. Discharge destination after *ICU* is not being used as a measure because function is often considered a criterion for discharge destination from ICU, therefore functional level on discharge from ICU would be unlikely to vary significantly pre and post intervention.

3.6.3 Evaluation measures for safety and feasibility

The adverse events listed on the MDCF were chosen after extensive review of the literature (see Table 4), consultation with the multi-disciplinary team and clinical experience. A *serious* adverse event was defined in line with Bailey et al. and Schweickert et al.'s studies as myocardial ischaemia, fall to the knees and / or removal of an ETT. Adverse events were defined as: removal of a line (arterial line, vascular catheter, intravenous (IV) line, tracheostomy tube, nasogastric tube, drain or other); fall; increase in FiO_2, increase or commencement of vasopressor infusions; return to bed unstable CNS; return to bed due to unstable CVS; return to bed due to unstable respiratory system and patient refusal to continue. This more extended list of possible adverse events was chosen by an iterative process involving medical, nursing and physiotherapy staff to ensure all aspects of safety were examined.

Study One involved a change in practice and in accordance with the ethics board's recommendations a safety committee was established prior to commencement of the study involving two intensive care physicians and one clinical nurse specialist. Any serious adverse event was reported to this committee for further evaluation. As Study Two and Three were observational in nature, such study specific committees were not required.

3.6.4 Evaluation measures for barriers to mobilisation

Barriers to mobilisation were recorded in the third section of the MDCF and definitions for each barrier are provided in the data dictionary (Appendix 2). The

criteria were then divided into two groups: avoidable or partially modifiable barriers and unavoidable barriers. These groups were centred on those described in previous literature (Leditschke, Green et al. 2012) with adaptation to our specific cohort needs.

The barriers deemed to be avoidable or partially modifiable were: sedation; ETT in situ; lack of resources; craniectomy without helmet; patient refused and procedure required. Barriers that were thought to be unavoidable were primarily physiological in nature and included: CNS unstable; CVS unstable; respiration unstable; orthopaedic orders to rest in bed and diarrhoea.

3.7 Statistics

A unique patient reference number was recorded at the top of the MDCF to allow linking of the mobilisation data with the physiological data recorded in quality assurance databases. The MDCF tool was printed in a scannable form for ease of data entry. On completion of the study, the forms were sent for scanning and results collated into SPSS format. The SPSS version 21.0 for Windows (SPSS; Chicago, IL) was used to analyse the data.

Statistical analysis incorporated full demographics of each of the cohorts to maximise the external validity of the findings. The descriptive data was reported using mean and standard deviation or median and inter-quartile ranges where applicable in cases where the data did not fit parametric models. Cohort comparisons on demographic data were made using unpaired comparisons and all tests of significance were 2-sided. Statistical significance was set at 0.05 level of confidence. No alpha level adjustments were made for multiple comparisons as all hypotheses were established apriori and the magnitude of differences are interpreted in the clinical context.

The number of episodes of mobilisation and activities of mobilisation were not normally distributed therefore the median number of episodes and activities per patient was reported.

Patients who mobilised and carried out weight bearing activities were recorded as a percentage of the whole group. Patients who mobilised with ETTs, RRT, vasopressor infusions or mechanical ventilation were also reported in this way.

The day a patient first mobilised was the calendar day where any activity of mobilisation was carried out and the day of admission to ICU was considered to be calendar day 1. This data was not normally distributed and therefore the median and inter-quartile range was reported.

Discharge destination as an evaluation tool described the percentage of patients in each of the five discharge locations. This was reported for the whole group as well as those who mobilised and did not mobilise.

Adverse events were reported by description of the adverse event itself; the number of events per episode of mobilisation as well as the number of patients that experienced an adverse event as a proportion of the total population in question.

Barriers were stated as the percentage of patients affected by this barrier at any time in their ICU stay as well as the number of episodes the barrier was present per patient in that cohort.

For group comparisons, in general, where parametric assumptions were met, tests were used for independent and dependent two group comparisons. For non-parametric paired comparisons Mann Whitney U tests were used.

Specific statistical methods are described in each study.

Chapter 4 Study One

4.1 Introduction

Prior to the commencement of this study, mobilisation activities and associated adverse events were not recorded at RPH ICU. Patients with ETTs, RRT and / or vasopressor infusions were not mobilised. Furthermore, there were no formal communication strategies focussing on mobilisation as a form of rehabilitation among the members of the multidisciplinary team. This study involved the development of a program of early mobilisation designed to overcome these issues and identify barriers to mobilisation.

Methods

4.2 Aim

The aim of this study was to implement a systems change that supported safe increases in mobilisation rates of all intensive care patients who were mechanically ventilated for three or more calendar days. Systems change was defined as a multi-disciplinary approach that aims to improve the system as a whole from one of low mobilisation activity to higher activity. Particular focus was placed on increasing mobilisation in patients with ETTs, RRT and vasopressor infusions and identify modifiable barriers to mobilisation.

4.3 Design

The study used a before and after design comparing prospective and retrospective cohort data sets. This research examined a change in practice, therefore a before / after study design was the most appropriate in this health service context.

4.4 Hypothesis

From the review of the related literature the following global research hypotheses were generated:

4.4.1 Primary hypothesis

- That the introduction of an ICU wide, early mobilisation protocol will be safe and feasible.

4.4.2 Secondary hypotheses

- That the introduction of an early mobilisation ICU wide protocol will not be associated with an increase in adverse events
- That the introduction of an early mobilisation ICU wide program will increase mobilisation rates for all patients mechanically ventilated for three or more calendar days
- That the introduction of an early mobilisation ICU wide program will increase mobilisation rates for patients with ETTs, RRT and/or vasopressor infusions
- That the introduction of an early mobilisation ICU program will increase the percentage of patients discharged home and a decrease in percentage of patients who die at the time of hospital discharge.
- Barriers to early mobilisation will be able to be identified and divided into two categories: barriers that are potentially manageable and barriers that are unable to be overcome.

4.5 Study setting

4.5.1 Location

Royal Perth Hospital is a Level III, tertiary teaching hospital and an accredited trauma centre with approximately 900 hospital beds of which there are 23 ICU beds. Royal Perth Hospital ICU accepts admissions from a range of specialty areas including spinal injuries, trauma, heart and lung transplantation, general surgery and multi-organ failure. It does not provide paediatric or long term ventilation services.

4.5.2 Workforce

The RPH ICU is managed by specialist trained intensivists as well as senior registrars, registrars and resident doctors. Physiotherapist cover is provided 24 hours per day, 7 days per week. There is a complex staffing regimen for physiotherapists in this unit. For the majority of daytime working hours (0800 – 1630 hours) there are two physiotherapists present for 22 funded beds. This includes some overlap during change of shift. This overlap period is shorter on weekends (30 minutes) than during the week (two to two and a half hours). Evening shifts during the week have two staff members and on weekends have one staff member present in the unit. One physiotherapist is present in the hospital overnight on all days of the week. However, physiotherapists working evening or night shift are also responsible for all out of hours treatments and non-invasive ventilation service calls on the wards as well as all patients in the ICU. Nurse staffing ratios were predominantly one nurse to one patient.

4.5.3 Patient population

This study was examining a systems change for early mobilisation and aimed to be as inclusive as possible. However, a large proportion of patients are admitted to ICU for observation only or acute management after cardiac surgery. These patients often follow a routine pathway and have less chance of exhibiting consequences of bed rest. Patients admitted to the ICU and mechanically ventilated for three or more calendar days make up one third of admissions at RPH ICU and are likely to suffer greater muscle and function loss. The early mobilisation program was applied to all patients admitted to the ICU, for their entire stay in ICU but study data was recorded only for those patients admitted for three or more calendar days.

Length of stay for ICU and hospital, age, sex, severity of illness and admission diagnosis were recorded for all patients as an assurance measure that the cohorts were matched. All of these measures are routinely recorded for the RPH ICU quality assurance database.

4.6 Study criteria

4.6.1 Inclusion Criteria

Patients aged 18 years and older admitted to RPH ICU and who received mechanical ventilation on three or more calendar days were included in the study.

4.6.2 Exclusion Criteria

The study aimed to evaluate a change in practice within RPH ICU therefore there were no specific exclusion criteria.

4.6.3 Withdrawal Criteria

Patients who were readmitted to the ICU during their hospital journey were withdrawn from analysis of results due to difficulty in statistical management of this event.

In the event of a major trauma episode such as a bombing or chemical disaster, interruption of data collection would occur as these events fall outside the normal characteristics of the referral pattern relative to the retrospective cohort.

4.7 Sample size expectations

As this study was an analysis of a systems change, formal power calculations were not conducted. A 12 month period was chosen to examine influences of seasonal variation. Approximation of study numbers was based on RPH ICU 2007 admission rates. There were 1542 admissions in the 12 month period, of which less than one third were mechanically ventilated for three or more calendar days (<500). Aiming for a conservative 85% capture rate, the expected sample for the prospective phase of the study was approximately 425 patients prior to analysis.

4.8 Outcome measures

All definitions for outcome measures and their respective derived variables are as previously described in Chapter 3.

4.8.1 Safety

Safety of the intervention was determined by adverse event rates as described in Chapter 3.6.3. Adverse events will be reported for all patients and all sub groups listed in 3.6.

4.8.2 Mobilisation

Mobilisation details were derived from data recorded using the MDCF. Mobilisation derived variables are listed in item 3.6.1. Mobilisation rates are reported for all patients and all sub groups as listed in clause 3.6.

4.8.3 Function

As described in section 3.6.2, discharge destination at time of hospital discharge were used as a surrogate measure for functional outcome. This measure was recorded for all patients and all sub groups listed in section 3.6

4.8.4 Barriers to mobilisation

Perceived barriers to mobilisation were recorded on the MDCF and were reported on for the following:

- Barriers for
    - All patients
    - Patients who never mobilised

4.9 Research Process

4.9.1 Phase 1 - Retrospective

Retrospective data was obtained from the RPH ICU QA database to establish an historical control. Patients included in the retrospective analysis were those meeting inclusion criteria of the study admitted in the 12 months prior to the current practice audit.

4.9.2 Phase 2 - Current practice audit

Mobilisation practices and associated physiological responses and adverse events were not recorded prior to this study at RPH ICU. To establish baseline practice, a 10 week 'current practice' audit was conducted using the MDCF for all patients

meeting study inclusion criteria. This data was combined with interventional and physiological data from the RPH QA database.

4.9.3 Phase 3 - Implementation

Following a 10 week period of auditing there was a two week education block. Medical, nursing and physiotherapy staff all received presentations during their allocated education timeslots. For nursing staff this included morning and evening shifts both weekdays and weekends. An opportunity for discussion of concerns was provided with senior physiotherapists, senior nursing staff and senior medical staff in attendance to show support for the study and to answer queries.

A multidisciplinary approach was the basis of the programme of early mobilisation. It was agreed to by all disciplines that mobility was to be a priority in patient's daily schedules where appropriate. Communication opportunities were increased to help with coordination of all professions in achieving this goal. Prior to medical handover the Senior Physiotherapist and the Clinical Nurse Specialist met at each patient's bedside to co-ordinate mobility events for that day. This was then followed by the medical handover where the Senior Physiotherapist or CNS discussed any patients who met the predetermined criteria requiring discussion with the medical team.

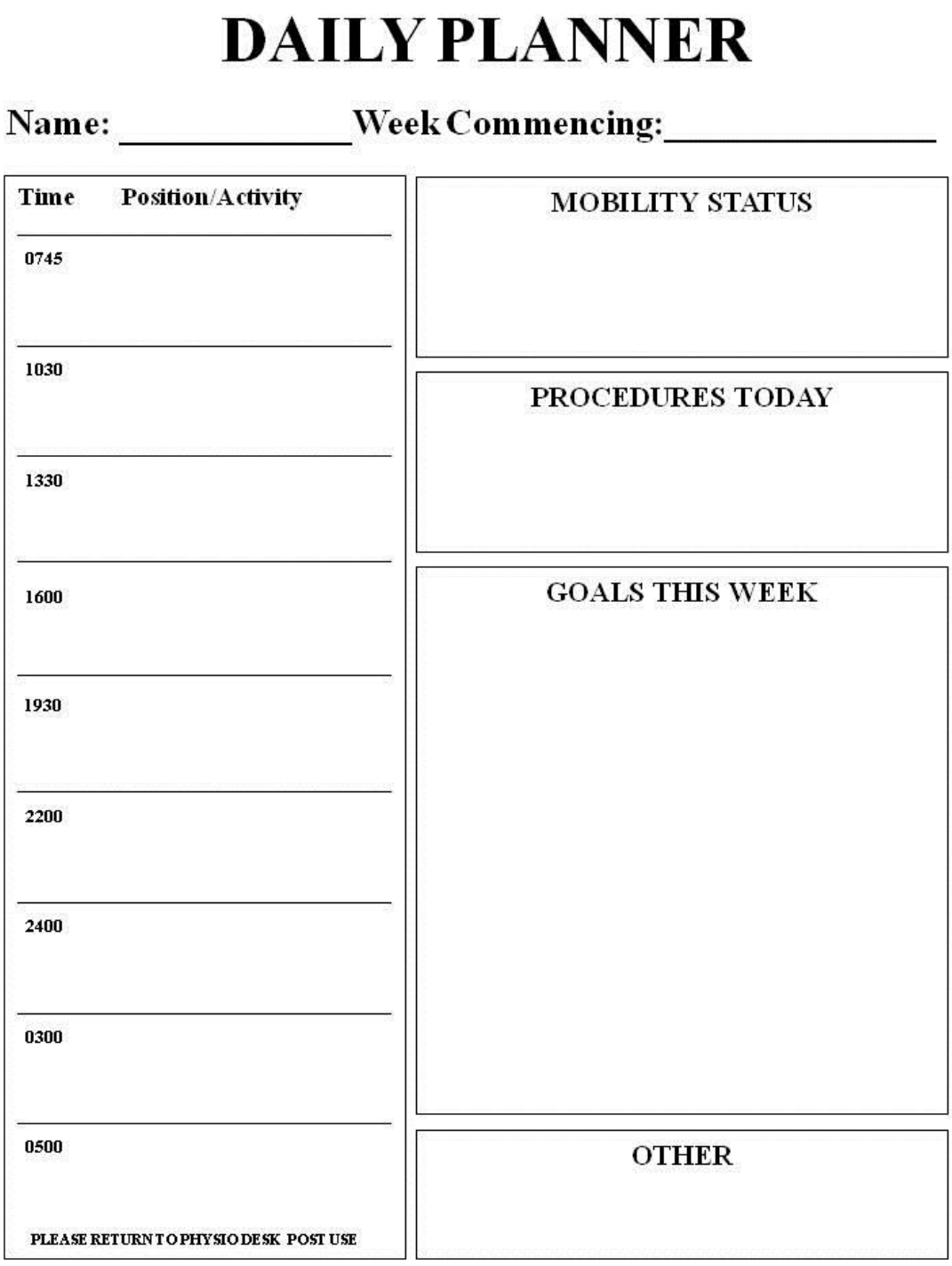
Predetermined criteria for discussion were: 1) patients with an endotracheal tube in situ; 2) patients with vasopressor infusion(s) running at greater than 5mL/hour; 3) patients with an extra ventricular drain in situ.

As well as allowing patients with ETTs, RRT and vasoactive infusions to mobilise, other strategies to improve mobilisation at RPH involved early communication with medical teams to identify accurate mobilisation restrictions and early ordering of helmets for patients who had undergone a craniectomy to minimise the risk of this being a barrier to mobilisation.

All patients meeting study inclusion criteria had a mobility planner (see Figure 2) to help communicate daily and weekly goals to all team members, assist with motivation of the patient and assist in establishing a day/night routine.

Non-urgent procedures were encouraged to be worked around mobility wherever possible. If staff shortage or skill shortage was experienced, there was commitment from senior staff of all members of the MDT to assist with mobilisation as a priority.

Figure 2 Daily planner



DAILY PLANNER

Name: _____ Week Commencing: _____

Time	Position/Activity
0745	
1030	
1330	
1600	
1930	
2200	
2400	
0300	
0500	

PLEASE RETURN TO PHYSIO DESK POST USE

MOBILITY STATUS

PROCEDURES TODAY

GOALS THIS WEEK

OTHER

4.10 Statistical Analysis

Baseline statistical analyses used for this study were outlined in Chapter 3. Measures pertaining to demographic data involved comparison of Phase 1, 2 and 3. Measures pertaining to mobilisation in this study involved comparison of Phase 2 and Phase 3.

In addition to demographic analysis, length of stay in ICU and hospital were analysed using log transformation of the data and ANCOVA statistics. Covariates were age, sex and APACHE II scores.

The student's t-test was used for pair wise comparison of parametric data. Proportional data was analysed using Fisher's exact test. Data pertaining to activities, episodes and minutes of mobilisation were all non-parametric in distribution and were analysed using Mann Whitney U test.

4.11 Ethical Considerations

Mobilisation of patients admitted to RPH ICU who required an ETT, RRT and / or vasopressor infusions had not been practiced prior to this study. In order for the culture of the unit to change and allow these practices, discussions were conducted at a variety of levels of management. Physiotherapists at RPH with an interest in this area were involved in a round table discussion about familiarity with these practices and experience of conducting these practices in other hospitals. A literature search was conducted to gain evidence of adverse event rates associated with these practices. This combined information formed a proposed set of guidelines for practice at RPH ICU. This proposal was taken to the medical consultant meeting for evaluation. The medical consultants discussed all points in detail and the issues of governance and communication were deliberated. An iterative process was undertaken until consensus was obtained by all members. The new practices were thought to be in accordance with best practice and there was unanimous support that the ethics application request a waiver of consent.

On approval of all components of the guidelines, ethics approval was sought and approved with reciprocal approval from Curtin University Human Research Ethics Committee (HREC 2008/099).

Results

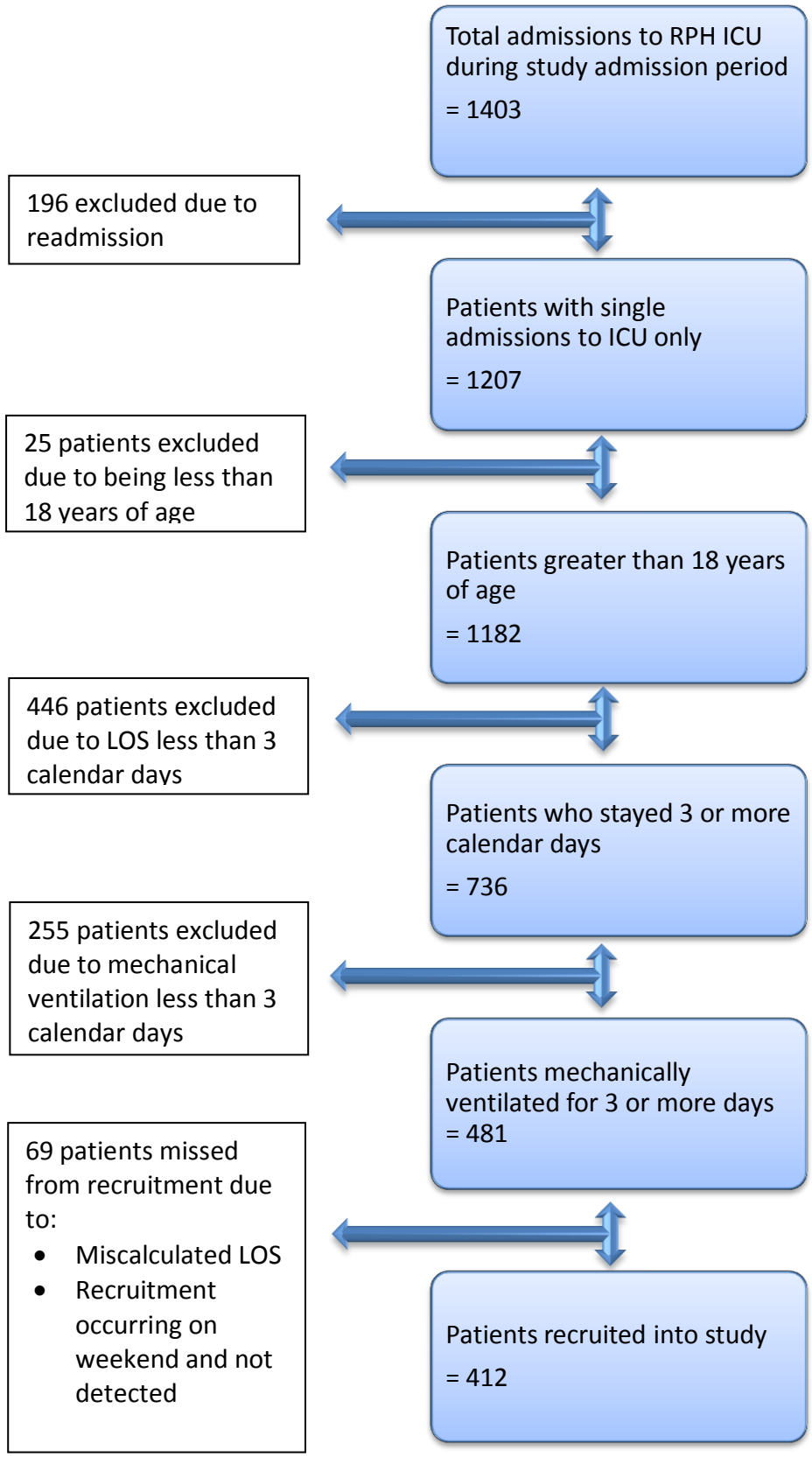
4.12 Baseline results

Phase 1 data was obtained retrospectively from the RPH ICU QA database. Demographic data from 500 consecutive patients meeting inclusion criteria prior to the current practice audit were obtained. The dates of admission of these patients were from 17/6/2007 to 30/7/2008. Phase 2 of the study ran from 4/8/2008 to 12/10/2008. There were 270 admissions to RPH ICU during this time and 113 met inclusion criteria. Of these patients, mobility data were collected on 102 patients (90.3% captured).

Phase 3 ran from 27/10/2008 to 1/10/2009. During this time there were 1403 admissions of which 481 met inclusion criteria. Final mobility data was collected on 412 patients equating to an 85.7% capture rate (see Figure 3). Demographic data were obtained for all patients who met inclusion criteria regardless of whether mobility data was captured.

During the study there were no major state or national disasters resulting in an alteration of normal referral patterns to RPH ICU and as such there were no interruptions in the data collection periods.

Figure 3 Recruitment process for Phase 3 of RPH study



4.12.1 Baseline results - setting

Summary statistics for RPH ICU across all phases of the study are presented in Table 5.

Table 5 Descriptive statistics for Phase 1, 2 and 3 of RPH study

Royal Perth Hospital	Phase 1&2	Phase 3
Level III ICU beds	23	23
Specialties included in unit		
- Cardiothoracic surgery	✓	✓
- Neurosurgery	✓	✓
- Trauma	✓	✓
- Spinal	✓	✓
- Transplantation	✓	✓
PT attend medical handover	✓	✓
Culture		
- Mobilisation with ETT	X	✓
- Mobilisation with RRT	X	✓
- Mobilisation with vasopressors	X	✓
Equipment in unit		
- High back chair	5	5
- Rocker recliner	3	3
- Rehabilitation chair	4	4
- Tilt table	1	1
- Standing lifter	0	0

X = not part of workforce practice. ✓ = considered in current practice.

4.12.2 Baseline results – workforce

Physiotherapy staffing remained consistent during all phases of the study. On average across the week, physiotherapist to ICU bed ratio was 1:4.6. There was a one hour per week increase (from 10 to 11 hours) in physiotherapy assistant staffing which commenced midway through Phase 3 of the study. This was not thought to have impacted heavily upon results. Medical and nursing staff ratios remained the same throughout.

4.12.3 Baseline results – patients

Baseline summary demographic statistics for patients in all three phases of the study are outlined in Table 6. As this study examined a systems change, data for all patients who met inclusion criteria was analysed, not just those for whom mobility

data was recorded. No differences were seen in length of stay after adjustment for age, sex and APACHE II scores.

Of note, the patients in Phase 3 have a higher severity of illness (as assessed by APACHE II) than both Phase 1 and Phase 2 (see Table 6). The difference in severity of illness between phases was investigated in an attempt to discover any alterations in admission patterns or state wide changes to health delivery. No such explanation was identified.

Table 6 Summary demographic statistics for all patients meeting inclusion criteria in Phase 1, 2 and 3

	Phase 1	Phase 2	Phase 3	*p*-value
N of pts	500	113	481	
Age (mean)	50.56 (SD 19.46)	48.78 (SD 18.14)	51.43 (SD19.42)	>.187[#]
Sex (% Male)	65.8%	66.4%	64.9%	>.754[#,†]
APACHE II (mean)	21.66 (SD 7.76)	20.37 (SD 8.02)	23.83 (SD 7.98)	Phase 1&2 = .858 Phase 1&3; 2&3 <.001
LOS – ICU (median)	6.08 (3.92 to 10.61)	6.00 (4.06 to 10.46)	6.79 (3.96 to 12.65)	>.106[#]
LOS – hospital (median)	18.92 10.88 to 33.96	20.83 (9.90 to 37.79)	22.58 (10.89 to 39.59)	>.107[#]

[#]pair wise comparison, independent t-tests
LOS ICU and LOS Hospital analysis was done with log transformation and ANCOVA. Covariates were: age, sex, APACHE II.

Baseline statistics for patients who had the opportunity to mobilise are shown in Table 7.

Table 7 Summary demographic statistics for patients who had the opportunity to mobilise

	Phase 2	Phase 3	*p*-value
N of pts	79	293	
Age (mean)	48.75 (SD16.84)	52.69 (SD 18.78)	.092
Sex (% Male)	60.8	60.4	.995[§]
APACHE II – mean	19.70 (SD 7.90)	23.79 (SD 7.71)	<.001
LOS – ICU (median)	6.25 (4.67 to 10.58)	7.50 (4.83 to 12.44)	.332
LOS – hospital (median)	20.38 (11.12 to 37.5)	23.08 (13.02 to 42.33)	.446

LOS ICU and LOS Hospital analysis was done with log transformation and ANCOVA. Covariates were: age, sex, APACHE II.

[§] Chi square test

4.12.3.1 Baseline results – patient sub groups

As described in section 3.6 of the methods, patients were divided into three different sub groups for diagnosis. Figures 4, 5 and 6 shows the breakdowns of these sub groups for all patients who met study inclusion criteria. In general, the subgroups of the three phases were relatively stable with the dominance of medical (orthotrauma and respiratory) diagnoses.

Figure 4 Diagnosis (sub group 1) - breakdown of all patients meeting inclusion criteria in Phase 1, 2 and 3

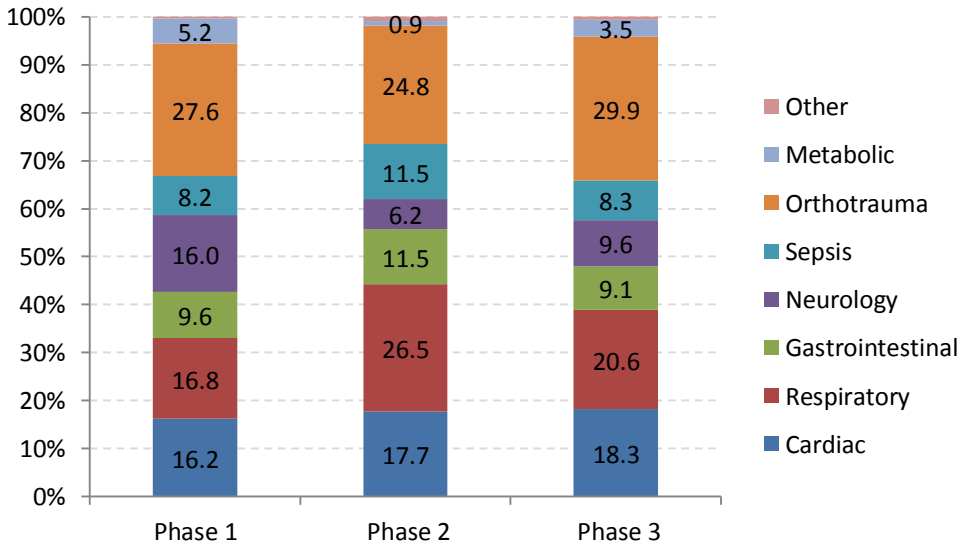


Figure 5 Classification (sub group 2) - breakdown of all patients meeting inclusion criteria in Phase 1, 2 and 3

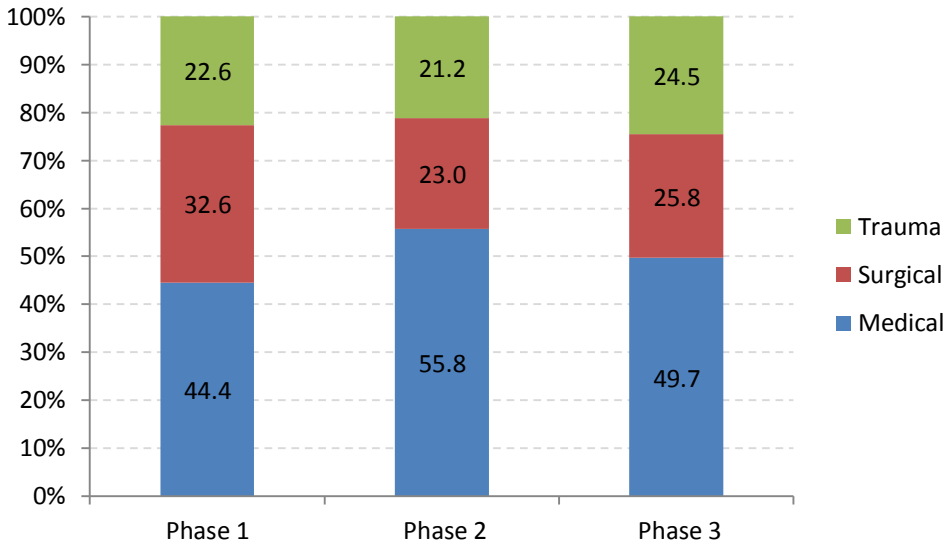
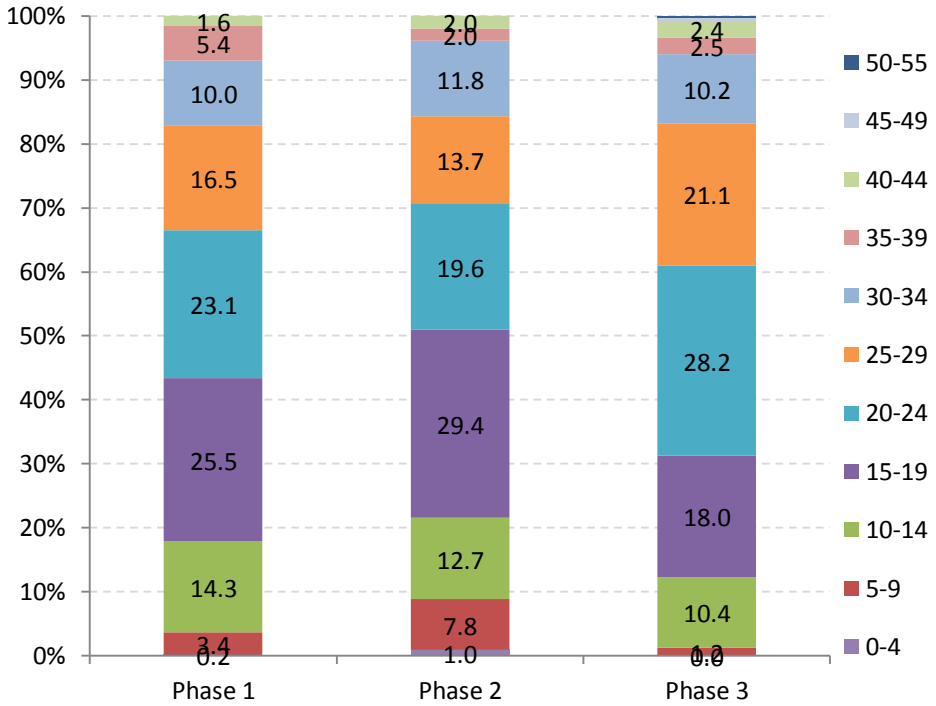


Figure 6 Severity of illness (sub group 3) – APACHE II category breakdown for all patients meeting inclusion criteria in Phase 1, 2 and 3



The breakdowns of each subcategory for patients who had the opportunity to mobilise are displayed in Figures 7, 8 and 9. For patients who had the opportunity to mobilise, no statistical difference was found between the proportion of each diagnostic specific category in Phase 2 and Phase 3 (see Appendix 5).

Figure 7 **Diagnosis (sub group 1) - breakdown of patients who had the opportunity to mobilise in Phase 2 and 3**

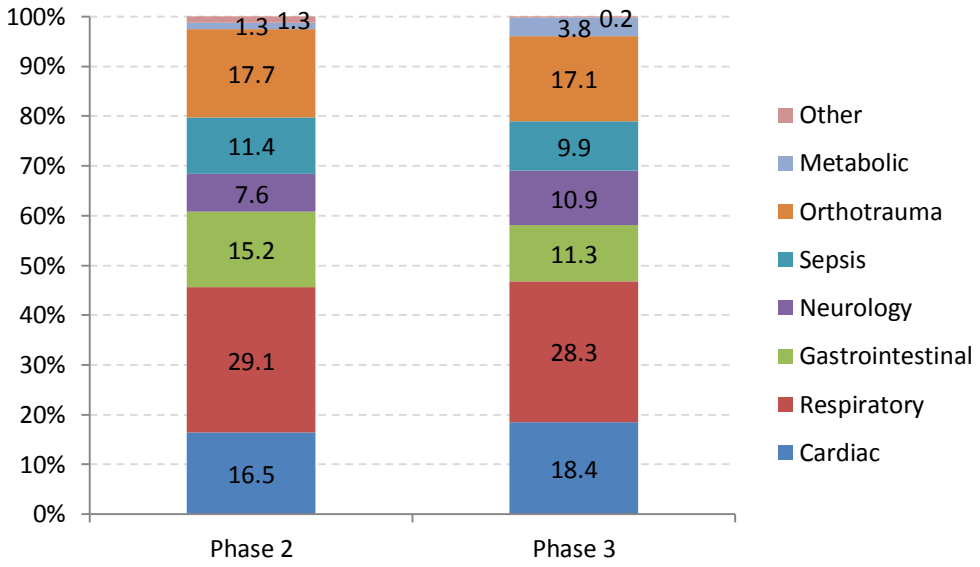


Figure 8 **Classification (sub group 2) - breakdown of patients who had the opportunity to mobilise in Phase 2 and 3**

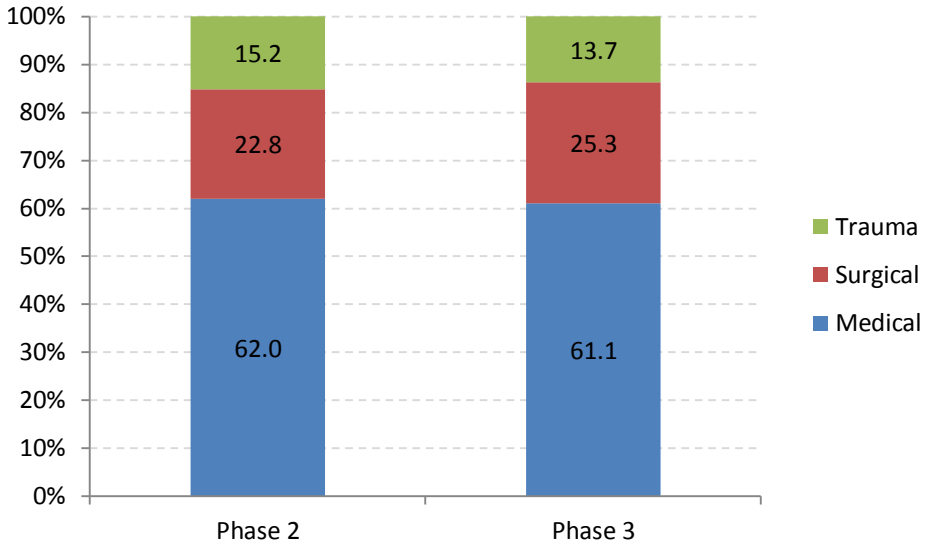
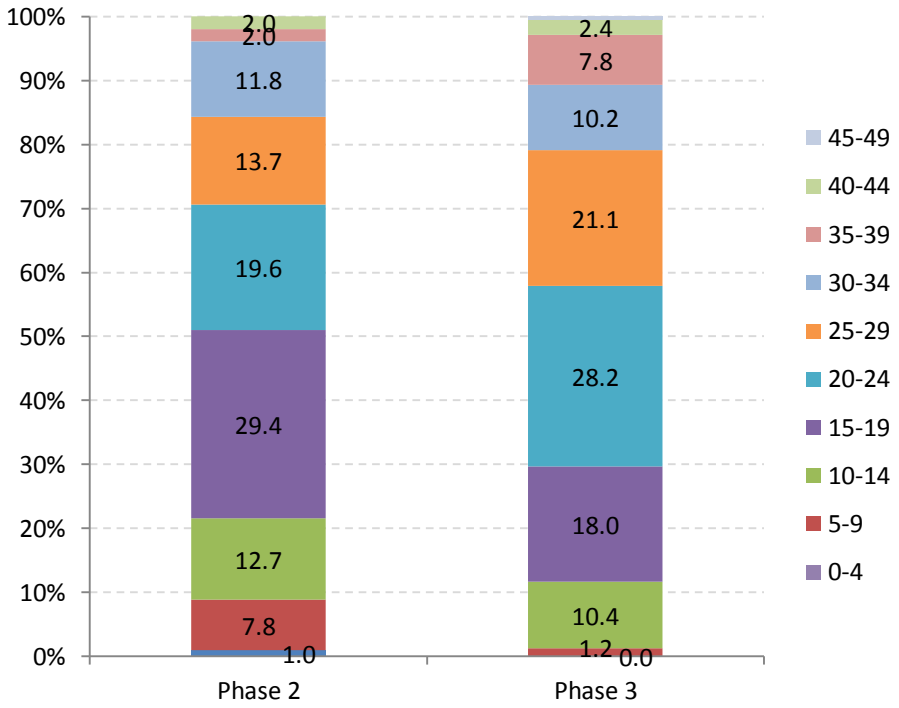


Figure 9 Severity of illness (sub group 3) – APACHE II category breakdown for patients who had the opportunity to mobilise in Phase 2 and 3



4.13 Mobilisation rates

Mobilisation rates were not recorded prior to study commencement. Therefore results presented are for both prospective Phases (2 and 3) of the study.

4.13.1 Overall

Measures of mobilisation for all patients recruited in Phase 2 and 3 are listed in Table 8. After implementation of the early mobilisation protocol, the percentage of patients mobilised rose significantly (p=.047). The increase in proportion of patients mobilised was not at the expense of the number of activities or episodes of mobilisation per patient which did not differ significantly between phases (p=.790 and p=.483 respectively).

Table 8 Mobilisation rates for all patients recruited into Phase 2 and 3

	Phase 2	Phase 3	p value
% of patients who mobilised	53.9	64.6	.047*
^N of activities per pt	1 (0 to 5)	2 (0 to 5)	.246
^N of activities per pt mobilised	4(2 to 8.75)	4 (2 to 8)	.790
^N of episodes per pt	1 (0 to 3)	1 (0 to 3)	.076
^N of episodes per pt mobilised	2.5 (1 to 4.75)	2 (1 to 6)	.483
% patients who wt bear	34.31	36.89	.648
^Mins spent mobilising per pt	315 (75 to 815)	352.5 (150 to 813.8)	.432
% of total activities on MV	48.9	49.3	1.00

Fisher's exact test was used in the comparison of percentages
Mann Whitney U test was used in the comparison of activities, episodes and minutes
*statistically significant ^median (IQR) recorded for this statistic

Mobilisation rates for patients who had the opportunity to mobilise are displayed in Table 9. The overall percentage of patients mobilised rose significantly (p=.002) as did the number of episodes of mobilisation per patient (p=.017). No other variables were found to have a systematic statistically significance difference however there was a trend towards increased number of activities, percentage of patients' weight bearing and minutes of mobilisation in Phase 3.

Table 9 Mobilisation rates for those who had the opportunity to mobilise in Phase 2 and 3 of RPH study

	Phase 2	Phase 3	p value
N of pts	79	293	
% of patients who mobilised	63.3	79.9	.002*
^N of activities per pt	2 (0 to 5)	3 (1 to 7)	.072
^N of activities per pt mobilised	5 (2 to 9)	4 (2 to 8)	.734
^N of episodes per pt	1 (1 to 3)	2 (1 to 5)	.017*
^N of episodes per pt mobilised	2 (1 to 5)	2 (1 to 6)	.666
% patients who wt bear	41.77	47.78	.375
^Mins spent mobilising per pt	322.5 (80.25 – 873.75)	365 (173.75 – 781.50)	.191

*statistically significant; ^median (IQR) recorded for this analysis

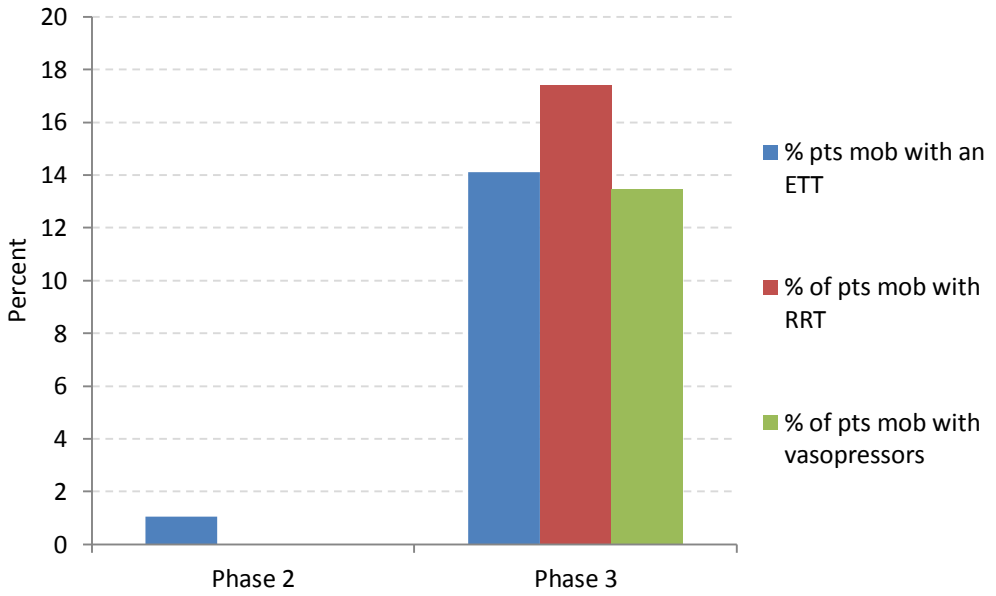
From this point onwards, analysis of mobilisation rates were calculated only on patients who had the opportunity to mobilise unless otherwise stated.

4.13.1.1 Overall mobilisation rates in the presence of ETT, RRT and vasopressors

All patients who were recorded as mobilising with an ETT were, at the same time, receiving mechanical ventilation. For patients who received ETTs and vasopressors, there was a noticeable increase in mobilisation rates ($p<0.001$; $p=0.003$ respectively). Mobilisation of patients receiving RRT increased between phases but did not reach statistical significance ($p=.185$) in the presence of very low numbers (see Figure 10).

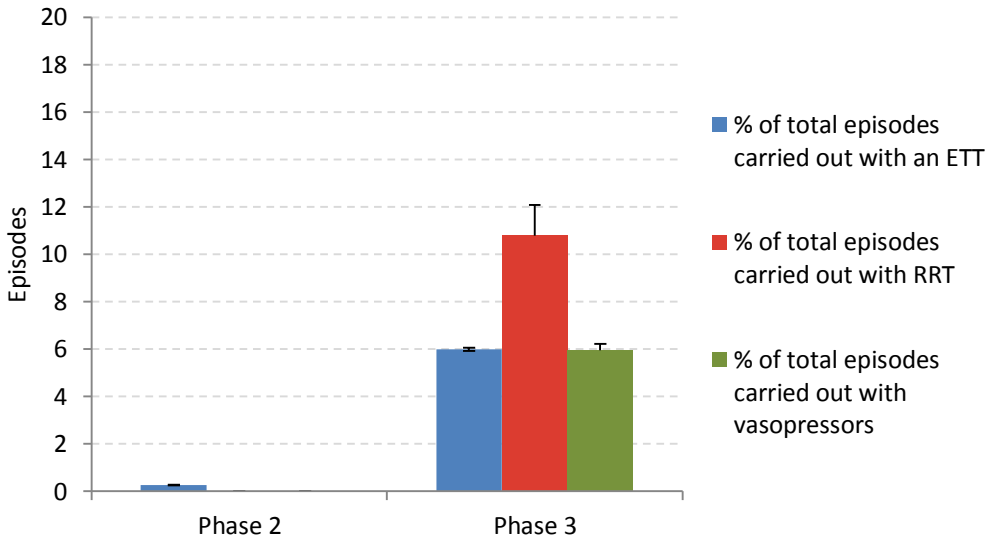
The number of episodes of mobilisation showed a corresponding increase (Fisher's exact test) for ETTs ($p<0.001$) and vasopressors ($p<0.001$). Episodes of mobilisation with RRT increased but again only approached statistical significance ($p=0.055$) (see Figure 11).

Figure 10 Percentage of patients mobilised with ETT, RRT and vasopressors in situ during Phase 2 and 3



Note: the minimal data seen for Phase 2 reflects that the work practices of mobilising with ETTs, RRT and vasopressor infusions was new.

Figure 11 Percentage of episodes carried out with ETT, RRT and/or vasopressors in situ during Phase 2 and 3



Error bars represent standard error for each variable
Note: the minimal data seen for Phase 2 reflects that the work practices of mobilising with ETTs, RRT and vasopressor infusions was new.

4.13.1.2 Day first mobilised

For patients admitted to RPH ICU for 3 or more calendar days and who had the opportunity to mobilise, the median time till first mobilisation was 5.1 days in Phase 2 and 4.9 days in Phase 3 (p=.413).

4.13.2 Sub group analysis

Using the three sub groupings described in 3.6 of the methods, mobilisation rates were compared across diagnoses.

4.13.2.1 Sub group analysis – diagnosis (sub group 1)

The comparison of diagnostic specific categories in the first sub group showed an increase in the percentage of patients mobilised in the orthotrauma category (p=.001). No other category showed statistically significant improvements despite an overall increase in percentage of patients mobilised in Phase 3 of the RPH study (see Appendix 6).

Numbers of activities, episodes, minutes, weight bearing activities and activities on mechanical ventilation per patient were not significantly different between categories in this breakdown (see Appendix 7).

As previously stated, overall increases were seen in patients mobilising with ETTs and vasopressors. Diagnostic sub groups that also showed increases in number of episodes of mobilisation with an ETT were respiratory, gastrointestinal and sepsis and for episodes of mobilisation with vasopressor infusions, the respiratory sub group increased statistically (see Tables 10 and 11). No change was observed in sub groups for episodes of mobilisation with RRT (see Table 12).

Table 10 Diagnosis (sub group 1): number of episodes of mobilisation with an ETT present for each category

	Phase 2 Episodes of mob with ETT /episodes ETT present	Phase 3 Episodes of mob with ETT /episodes ETT present	p value
Cardiac	0/37	8/190	.360
Respiratory	1/74	38/368	.011*
Gastrointestinal	0/55	19/135	.002*
Neurology	0/15	6/104	1.00
Sepsis	0/42	15/140	.024*
Orthotrauma	0/65	7/236	.353
Metabolic	0/2	1/33	1.00
Total	1/290	97/1211	<.001

Analysis using Fisher's exact test

Table 11 Diagnosis (sub group 1): number of episodes of mobilisation with vasopressor infusion present within each category

	Phase 2 Episodes of mob / episodes vasopressors present	Phase 3 Episodes of mob / episodes vasopressors present	p value
Cardiac	0/22	16/139	.131
Respiratory	0/38	17/176	.047*
Gastrointestinal	0/36	6/81	.175
Neurology	0/4	0/19	1.00
Sepsis	0/14	10/82	.349
Orthotrauma	0/20	7/133	.595
Metabolic	0/1	0/18	1.00
Total	0/135	56/648	<.001

Analysis using Fisher's exact test

Table 12 Diagnosis (sub group 1): number of episodes of mobilisation where RRT was present within each category

	Phase 2 Episodes of mob / episodes where RRT present	Phase 3 Episodes of mob / episodes where RRT present	p value
Cardiac	0/5	1/18	1.00
Respiratory	0/1	16/58	1.00
Gastrointestinal	0/11	6/29	.162
Neurology	0/0	1/2	1.00
Sepsis	0/9	0/25	1.000
Orthotrauma	0/0	2/46	1.000
Metabolic	0/0	0/5	1.000
Total	0/26	26/183	.051

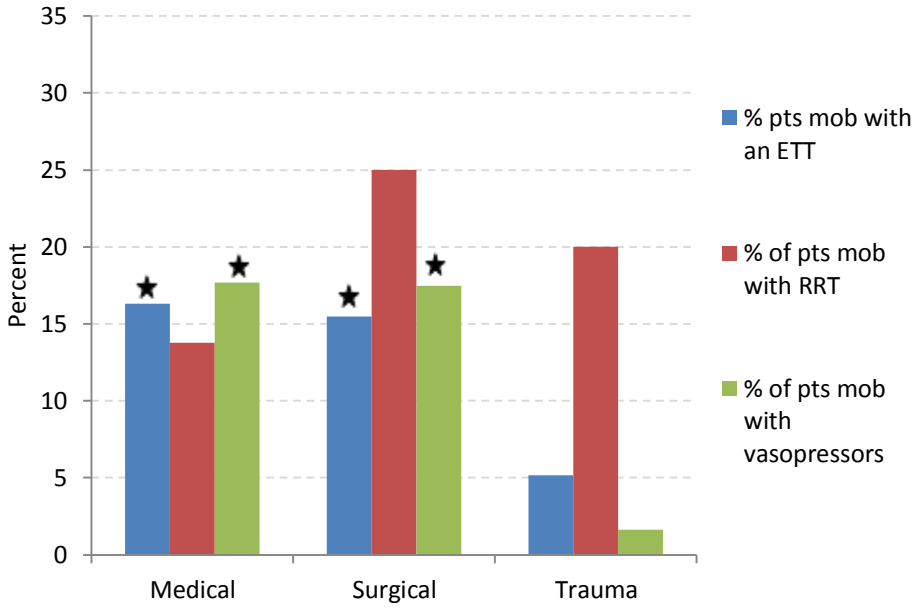
Analysis using Fishers exact test

4.13.2.2 Sub group analysis – classification (sub group 2)

The percentage of patients who mobilised rose significantly in the surgical (p=.048) and trauma (p=.001) categories of this sub group. No difference was seen in the medical category (p=.342). The average number of minutes of mobilisation per patient increased in the trauma sub group (p=.015). All other results for activities, episodes, activities of weight bearing and mobilisation with mechanical ventilation were not significantly different between Phase 2 and Phase 3 for these diagnostic specific categories (see Appendix 8).

The percentage of patients who mobilised with ETTs and vasopressors increased in the medical and surgical categories but not in the trauma category. The low numbers of patients receiving RRT explains how the larger change in percentage seen in Figure 12 does not achieve statistical significance. Only data for Phase 3 is shown graphically in Figure 12. Phase 2 data is not presented as only one patient mobilised with an ETT in the medical diagnostic group. No other episodes of mobilisation with ETTs, RRT or vasopressor infusions were recorded during Phase 2.

Figure 12 Classification (sub group 2): percentage of patients mobilised with an ETT, RRT or vasopressors within each category of Phase 3



★ Statistically significant increase occurred in this diagnostic specific category when compared with Phase 2

Medical and surgical patients saw increases in episodes of mobilisation with ETTs (see Table 13) and with vasopressor infusions (see Table 14). No change was detected for the number of episodes of mobilisation with RRT in any category (See Tables 13, 14 and 15).

Table 13 Classification (sub group 2): number of episodes of mobilisation with an ETT present for each category

	Phase 2 Episodes of mob with ETT /episodes ETT present	Phase 3 Episodes of mob with ETT /episodes ETT present	p value
Medical	1/159	70/722	<.001*
Surgical	0/72	22/282	.011*
Trauma	0/59	5/207	.590
Total	1/290	97/1211	<.001*

Analysis using Fisher's exact test

Table 14 Classification (sub group 2): number of episodes of mobilisation with vasopressor infusion present within each category

	Phase 2 Episodes of mob / episodes vasopressors present	Phase 3 Episodes of mob / episodes vasopressors present	p value
Medical	0/64	34/356	.005*
Surgical	0/54	17/175	.015*
Trauma	0/17	5/117	1.00
Total	0/135	56/648	<.001*

Analysis using Fisher's exact test

Table 15 Classification (sub group 2): number of episodes of mobilisation where RRT was present within each category

	Phase 2 Episodes of mob / episodes where RRT present	Phase 3 Episodes of mob / episodes where RRT present	p value
Medical	0/16	17/94	.126
Surgical	0/10	7/51	.587
Trauma	0/0	2/38	1.00
Total	0/26	26/183	.051

Analysis using Fisher's exact test

4.13.2.3 Sub group analysis – severity of illness (sub group 3)

Results for activities, episodes, and minutes of mobilisation, weight bearing activities and activities of mobilisation on mechanical ventilation within each APACHE II grouping were all non-significant. Graphing of the percentage of each group mobilised as well as the number of activities, episodes and minutes of mobilisation are shown in Figures 13 to 16. These figures show a trend towards increased mobilisation in each of the APACHE groupings. The p-values for each APACHE II grouping in each variable can be found in Appendix 9. Statistical comparison of APACHE II groups is difficult due to low numbers in each grouping.

Figure 13 Percentage of each APACHE II grouping that was mobilised in Phase 2 and Phase 3

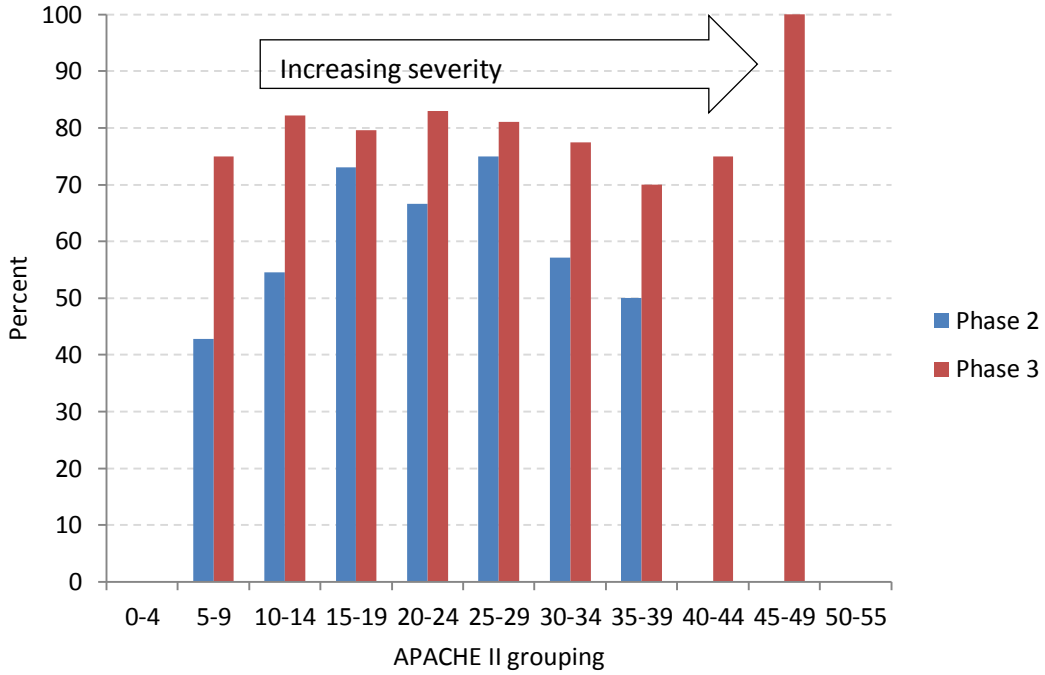
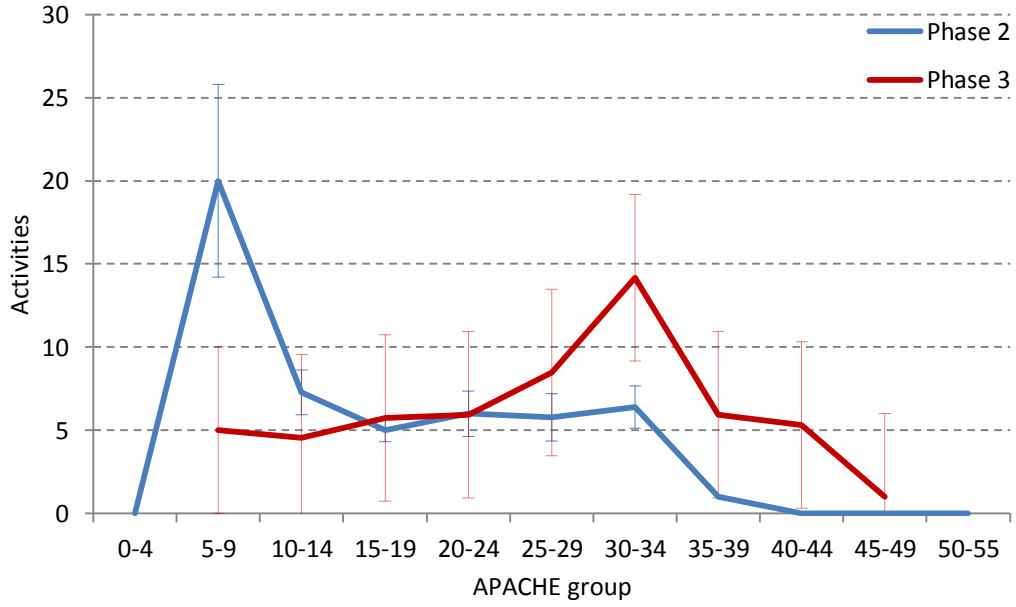
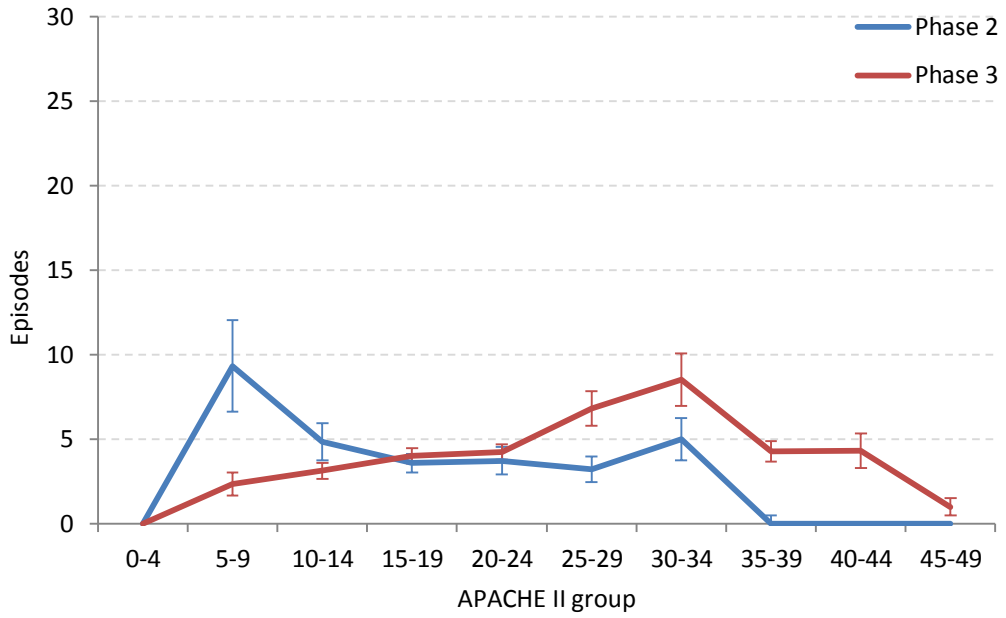


Figure 14 Number of activities carried out per patient mobilised in each APACHE II group during Phase 2 and Phase 3



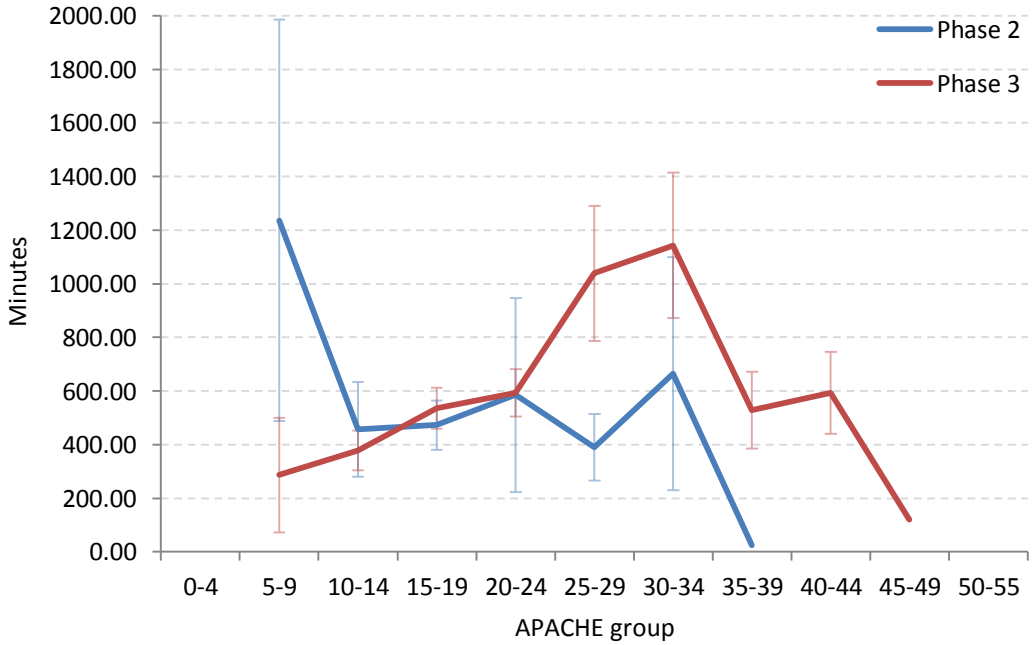
Note: Error bars represent the standard error for each variable

Figure 15 Number of episodes of mobilisation per patient mobilised in each APACHE II group during Phase 2 and Phase 3



Note: Error bars represent the standard error for each variable

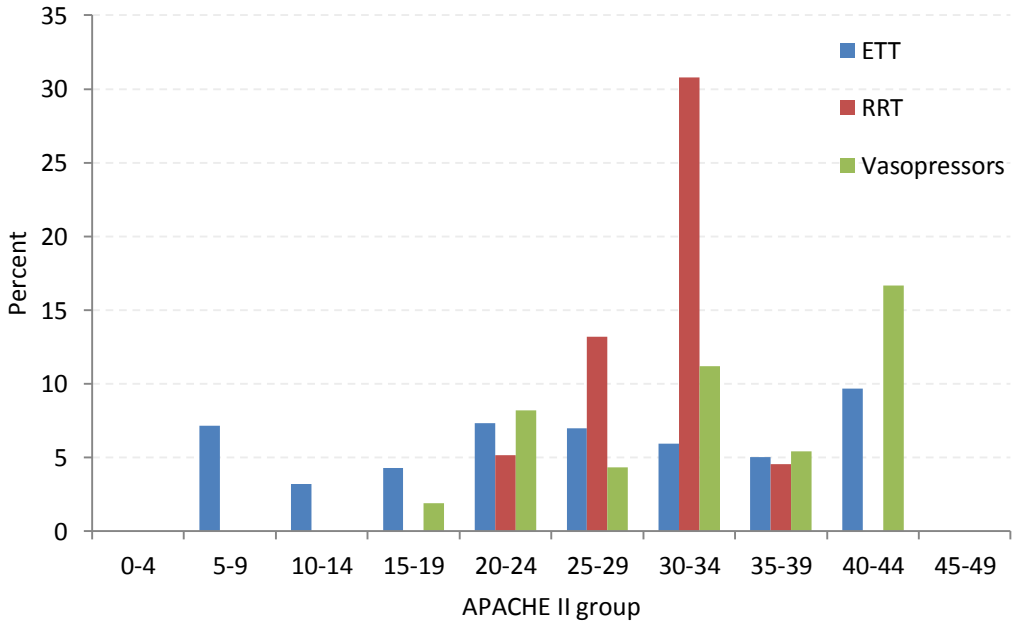
Figure 16 Number of minutes of mobilisation per patient mobilised in each APACHE II group during Phase 2 and Phase 3



Note: Error bars represent the standard error for each variable

There was a significant increase in patients mobilising with an ETT in APACHE groups 15-19 (p=.014) and 20-24 (p=.049) during Phase 3 of the study. No other significant results were found when examining patients treated with RRT or vasopressors (see Appendix 10). While statistical significance was not achieved, clinically there was an increase in occurrence of these practices. Figure 17 shows the percentage of episodes of mobilisation carried out in the presence of an ETT, RRT or vasopressors. Phase 2 data is not shown in this graph as only one episode of mobilisation with an ETT occurred during this phase of the study. This patient was in the APACHE II group 20-24. No mobilisation with RRT or vasopressor infusions occurred during Phase 2.

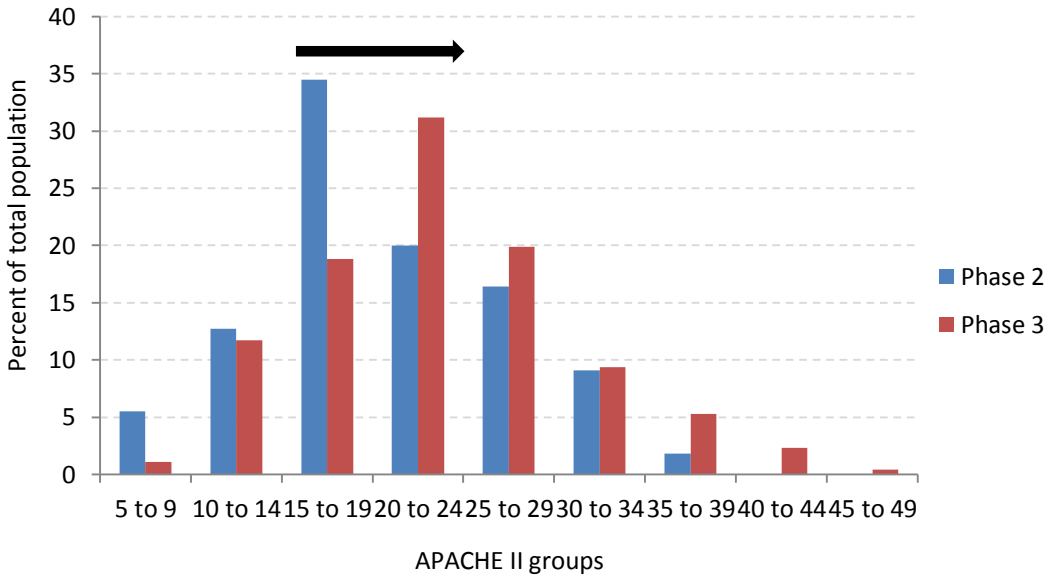
Figure 17 The percentage of episodes of mobilisation within each APACHE II category carried out with ETT, RRT and vasopressors in situ in Phase 3



4.14 Change in practice

Figure 18 relates to workforce activity. It shows the percentage of the whole mobilised population that is in each APACHE II grouping for Phase 2 and Phase 3. There is a clear shift to the right indicating patients who were more severely ill were more likely to be mobilised after introduction of the protocol.

Figure 18 The percentage of the whole population mobilised during Phase 2 and Phase 3



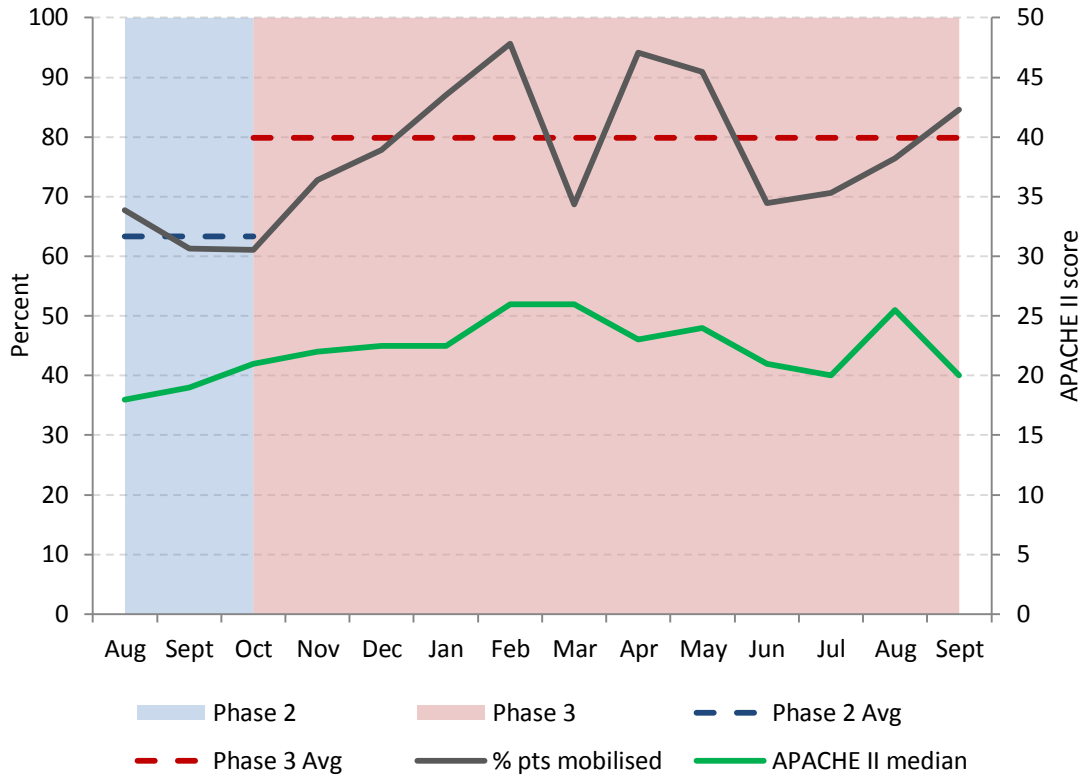
After implementation of the early mobilisation protocol, mobilisation rates increased (p=.002) for those who had the opportunity to mobilise. Using odds ratio, it was calculated that patients were OR 3.0 (95% CI: 1.7 to 5.3) times more likely to mobilise in Phase 3. The increase in number of patients mobilised did not come at the expense of the number of activities or episodes of mobilisation per patient did not change systematically between phases (p=.734; p=.666).

Mobilisation within diagnostic specific categories showed a significant increase in the orthotrauma category only. The lack of significance in all other categories in the presence of an overall increase in mobilisation is suggestive of an across the board improvement rather than individual category focus.

Mobilisation practices were graphed in monthly increments to examine levels of variability across a 12 month period. Figure 19 shows the percentage of patients mobilised in Phase 2 and Phase 3 each month. The decrease in percentage of patients mobilised during March coincides with an increased number of patients admitted with neurological trauma injuries.

The target areas for change in practice were patients with ETTs, RRT and vasopressor infusions. This change in practice was successful with overall increases in mobilisation in the presence of these therapies (see Figure 10 and Figure 11)

Figure 19 Percentage of patients mobilised per month who had the opportunity to mobilise with corresponding median APACHE II score during Phase 2 and Phase 3



4.15 Discharge destination

Discharge destination was chosen as a surrogate measure to examine function. Figure 20 shows the hospital discharge location for all patients in Phase 2 and Phase 3. There was a slight increase in the number of patients who were discharged home in Phase 3 but this was not statistically significant.

Figure 21 outlines hospital discharge locations for patients who did and did not mobilise in Phase 2 and Phase 3. Patients who were mobilised in both Phase 2 and Phase 3 were more likely to go home than patients who did not mobilise.

Figure 20 Discharge destinations of patients in Phase 2 and Phase 3

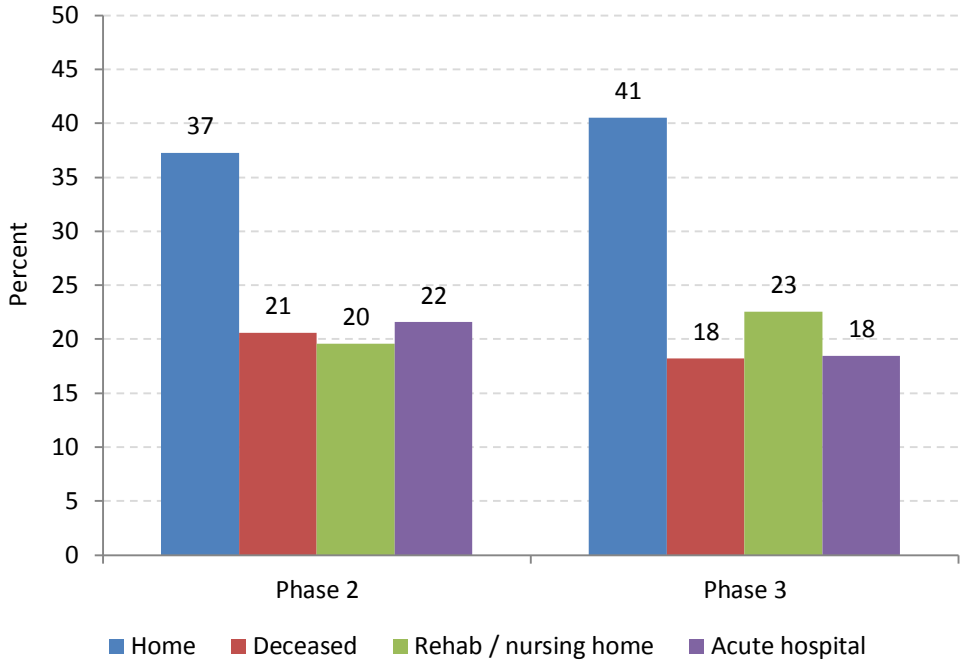
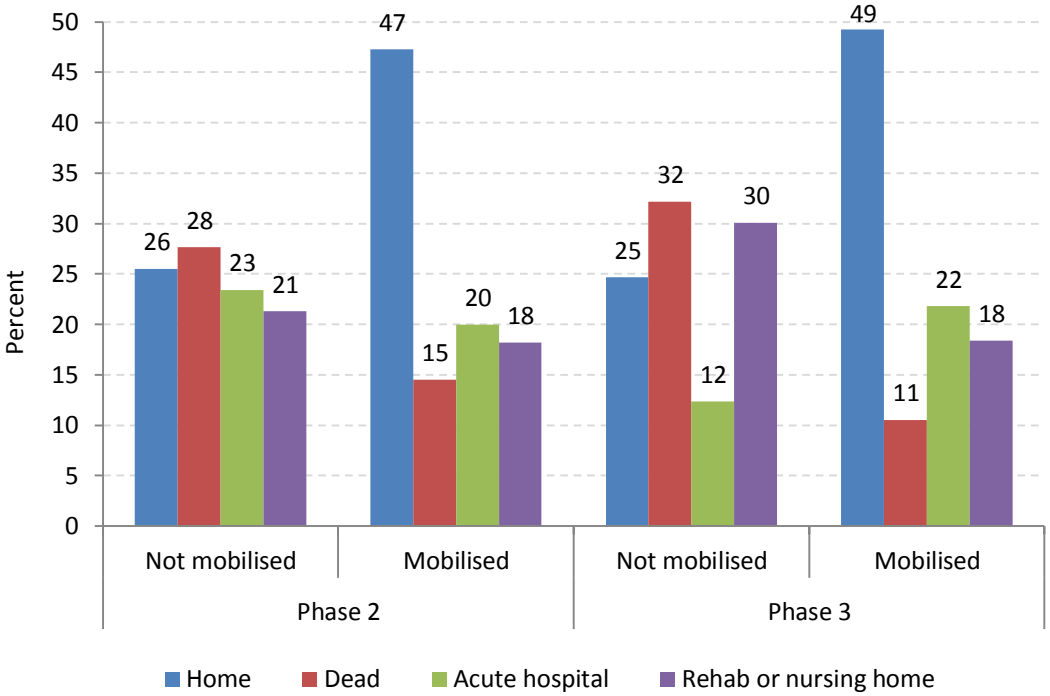


Figure 21 Discharge destinations of patients in Phase 2 and Phase 3 who did and did not mobilise



4.16 Safety

Adverse events related to mobilisation were not recorded prior to this study therefore only prospective data from Phase 2 and Phase 3 is presented in this section.

4.16.1 Overall safety

There were no serious adverse events during this study. Three adverse events were recorded in Phase 2 and 15 in Phase 3; one of which required an increase in inotrope dose from the bedside nurse. This patient did not need to return to bed and remained in the chair. It was the opinion of the treating teams that no adverse event resulted in an increase in the patient's length of stay. The natures of all adverse events are listed in Table 16.

Table 16 Description of adverse events for patients in Phase 2 and Phase 3

Adverse event	Phase 2 n (% of total)	Phase 3 n (% of total)
IV line removed	1 (33.3)	1 (6.7)
Withdrawal of participation	2 (66.7)	5 (33.3)
NGT removed		1 (6.7)
CNS unstable		2 (13.3)
CVS unstable		5 (33.3)
Increase dose of inotropes		1 (6.67)
Total	3 (100)	15 (100)

Note: Values in brackets are the percentage of the total adverse events in that phase of the study.

Adverse event rates are expressed as a percentage of the total number of episodes conducted. The number of patients who experienced these events was also recorded in alignment with previous studies definitions and recording formats.(Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Schweickert, Pohlman et al. 2009) For this study, the adverse event rate is 1.3% (3 out of 226 episodes in 3 patients) for Phase 2 and 1.1% (15 out of 1318 activities in 13 patients) for Phase 3 (p=1.000).

Of interest, 60% of adverse events in Phase 3 occurred greater than one week after admission to ICU.

4.16.2 Safety within each sub group

The patients who experienced adverse events had a variety of diagnoses and classifications (see Table 17 and 18). Numbers were low throughout all sub groups resulting in descriptive reporting of the data. Patients with sepsis and trauma diagnoses in Phase 2 had the highest adverse event rates.

Adverse events for all APACHE II groupings are listed in Table 19. Patients in the APACHE grouping of 30-34 had the highest rate of adverse events during Phase 3. The natures of these events were: three episodes of CVS instability; three withdrawals of participation by the patient and one removal of an IV line.

Table 17 Diagnosis (sub group 1): patients who experienced an adverse event in Phase 2 and Phase 3

	Phase 2			Phase 3		
Diagnostic specific category	N of pts	N of episodes	Rate - AE/total episodes (%)	N of pts	N of episodes	Rate - AE/total episodes (%)
Cardiac				3	3	1.9
Respiratory	1	1	1.2	4	5	1.0
Gastrointestinal				2	2	1.3
Neurology				2	2	3.2
Sepsis	1	1	5.9	2	3	2.3
Orthotrauma	1	1	4.0			
Metabolic						
Total	3	3	1.3	13	15	1.1

AE = adverse event

Table 18 Classification (sub group 2): patients who experienced an adverse event in Phase 2 and Phase 3

	Phase 2			Phase 3		
Diagnostic specific category	N of pts	N of episodes	Rate - AE/total episodes (%)	N of pts	N of episodes	Rate - AE/total episodes (%)
Medical	2	2	1.4	11	12	1.5
Surgical				2	3	0.9
Trauma	1	1	5.0			
Total	3	3	1.3	13	15	1.1

AE = adverse event

Table 19 Severity of illness (sub group 3): adverse events within each APACHE grouping for Phase 2 and Phase 3

	Phase 2			Phase 3		
APACHE group	N of pts	N of episodes	Rate AE/episode (%)	N of pts	N of episodes	Rate AE/episode (%)
15-19	2	2	2.9	2	2	1.0
20-24	1	1	2.4	2	2	0.6
25-29	0			3	3	0.8
30-34	0			5	7	3.3
35-39	0			0		
40-44	0			1	1	3.8
Total	3	3	1.3	13	15	1.1

4.16.3 Safety of patients receiving ETT, RRT and / or vasopressors

The focus areas of change during this study were mobilisation of patients with ETTs, RRT and / or vasopressor infusions. Patients in Phase 2 did not mobilise with these three therapies on a routine basis and there were no adverse events related to these therapies during Phase 2. There were 3 recorded adverse events in Phase 3. Two were due to cardiovascular instability during RRT and one was withdrawal of patient participation whilst an ETT was in situ.

4.17 Barriers to mobilisation

Table 20 outlines the individual barriers that were identified. The barriers that significantly decreased were: sedation; lack of resources; ETT in situ and craniectomy with no helmet. The barriers that had an increased incidence was procedures (p=.007) and respiratory instability (p=.024). The barriers that remained unchanged were physiological in nature.

Table 20 Number of patients and number of episodes of mobilization where barriers to mobilisation were present for all patients during Phase 2 and Phase 3

Barrier	Phase 2		Phase 3		p-value (for Total N of barriers/ pts)
	No of pts (%)	Total N of barriers/pt	No of pts (%)	Total N of barriers/pt	
Sedation	91 (89.2)	3.7	327 (79.4)	3.3	0.023*
ETT in situ	92 (90.2)	3.6	11 (2.7)	0.1	<.001*
Lack of	20 (19.6)		48 (11.6)		0.049*
resources		0.5		0.2	
Craniectomy	6 (5.9)	0.3	6 (1.5)	0.0	0.017*
Procedures	29 (28.4)	0.4	177 (43.0)	0.7	0.007*
Respiratory	18 (17.7)		118 (28.6)		0.024*
unstable		0.5		1.0	
CVS unstable	62 (60.8)	2.1	214 (51.9)	1.9	0.121
Orthopaedic	15 (14.7)		89 (21.6)		0.132
orders		0.7		1.8	
CNS unstable	31 (30.4)	1.2	156 (37.9)	1.5	0.170
Decline	7 (6.9)	0.2	16 (3.9)	0.1	0.446
Diarrhoea	5 (4.9)	0.1	23 (5.6)	0.1	1.000
Total	102 (100)	13.2	412(100)	10.7	

*statistically significant result using Mann Whitney U test

The most common barriers recorded for all patients in Phase 2 were: ETT in situ, sedation and CVS instability. The top five barriers affecting patients after implementation of a mobility protocol were: sedation, CVS instability, procedures, CNS instability and respiratory instability (see Figure 22).

The number of barriers to mobilisation per patient overall decreased from 13.23 in Phase 2 to 10.67 in Phase 3 (p=.023). Individual barriers per patient are displayed in Figure 23.

Figure 22 The percentage of patients in Phase 2 and Phase 3 who experienced each barrier at any stage during their ICU admission

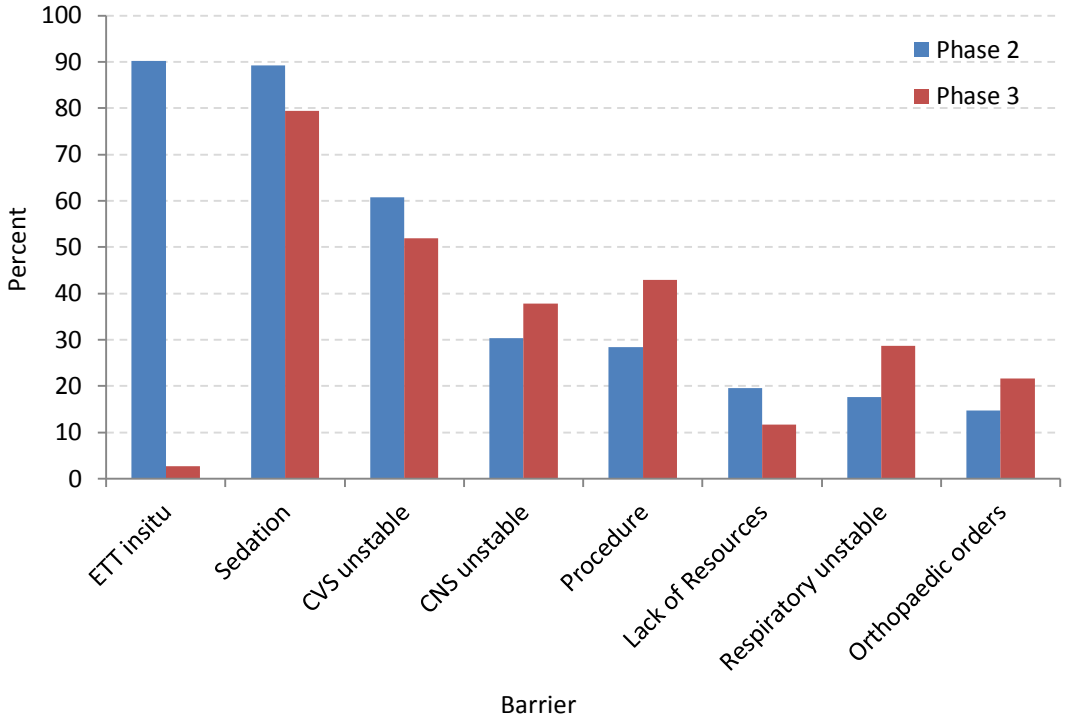
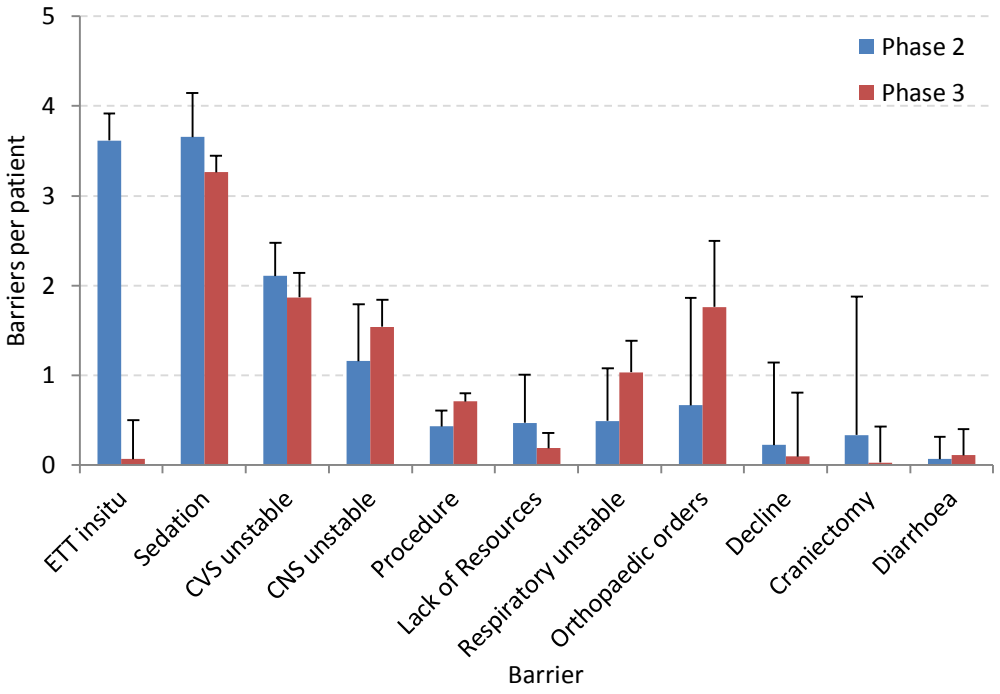


Figure 23 The number of barriers per patient that were present during Phase 2 and Phase 3



Note: Error bars represent standard error for each variable

For patients that never mobilised the number of barriers per patient did not differ between Phase 2 and 3 (p=0.307). The barriers ETT in situ and craniectomy without a helmet were reduced in Phase 3 (p<.001 and p=.013). All other barriers remained similar between (see Table 21).

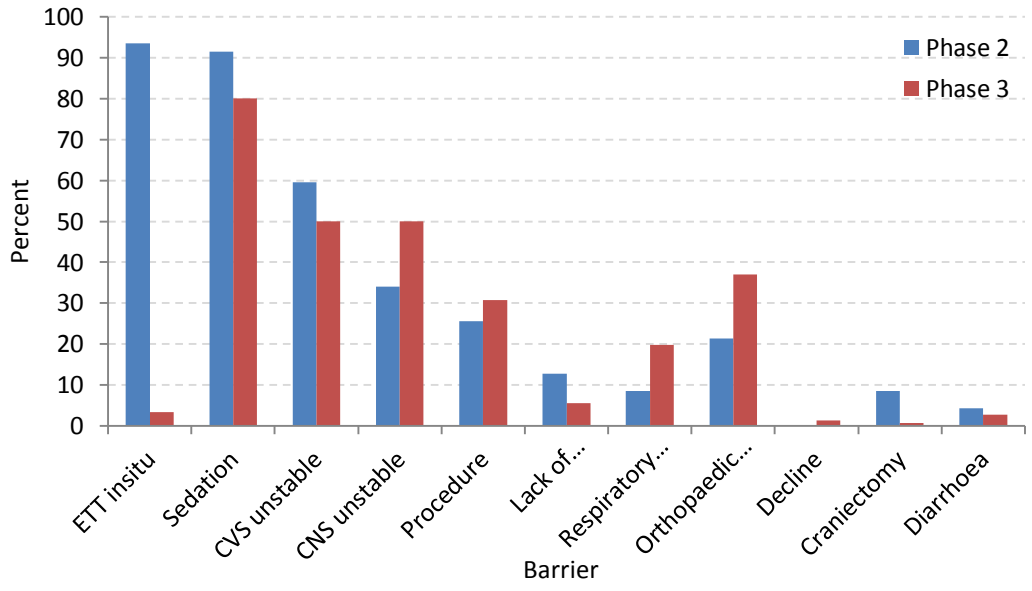
The top three barriers for patients who never mobilised during Phase 2 were the same as those for all patients: ETT in situ, sedation and CVS instability. For Phase 3, barriers for patients who never mobilised differed slightly and were: sedation, CVS instability and CNS instability (see Figure 22).

Table 21 Barriers for patients that never mobilised during Phase 2 and Phase 3

Barrier	Phase 2		Phase 3		p-value (for N of pts
	N of pts (%)	Total N of barriers / pt	N of pts (%)	Total N of barriers / pt	
Sedation	43 (91.5)	3.19	117 (80.1)	3.01	0.079
ETT in situ	44 (93.6)	3.26	5 (3.4)	0.06	<.001*
Lack of resources	6 (12.8)	0.34	8 (5.5)	0.09	0.110
Craniectomy	4 (8.5)	0.45	1 (0.7)	0.01	0.013*
Procedures	12 (25.5)	0.30	45 (30.8)	0.47	0.347
Respiratory unstable	4 (8.5)	0.38	29 (19.9)	0.72	0.079
CVS unstable	28 (59.6)	1.83	73 (50.0)	1.57	0.314
Orthopaedic orders	10 (21.3)	0.98	54 (37.0)	3.73	0.051
CNS unstable	16 (34.0)	1.43	73 (50.0)	2.03	0.065
Decline	0 (0.0)	0.00	2 (1.4)	0.01	1.000
Diarrhoea	2 (4.3)	0.04	4 (2.7)	0.04	0.635
Total	47 (100)	12.19	146 (100)	11.73	

*statistically significant result using Mann Whitney U test

Figure 24 The percentage of patients who never mobilised in Phase 2 and Phase 3 who experienced each barrier during their ICU admission



4.18 Summary

This study is the first study to examine early mobilisation of a heterogeneous ICU patient population. A total of 1014 patients were examined in the three phases of

the study. The percentage of patients successfully mobilised after implementation of an early mobilisation program increased significantly when looking at all patients as well as when examining patients who had the opportunity to mobilise. This did not come at the expense of the number of episodes and activities conducted for each patient. Mobilisation rates can be increased for all patients in a unit that was positive towards mobilisation prior to implementation.

Workforce behaviour changed with the introduction of the program. There was a marked increase in the number of patients mobilised with ETT, RRT and vasopressor infusions across diagnostic groups and APACHE II groups. Patients with medical and surgical diagnoses showed greater improvement than those with trauma diagnoses. Workforce mobilisation activity also shifted from being concentrated on patients with low APACHE II scores to those with higher APACHE II scores.

The proportion of patients discharged home on hospital discharge was higher for patients who mobilised in both prospective phases of the study. Although there was no significant increase in the percentage of patients who were discharged home at hospital discharge overall between phases, there was a 20% increase in the number of patients who were mobilised in Phase 3. Therefore this additional 20% of patients who mobilised achieved similar rates of discharge home.

There were no serious adverse events recorded during the study. The adverse event rate for mobilisation of patients in the ICU remained low and consistent between phases of the study. This rate was similar to other studies conducted in this field (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). Adverse event rates did not change significantly between diagnostic groups. Early mobilisation of a heterogeneous patient population in a single centre is safe.

Sedation was the most common barrier to mobilisation across all diagnostic and APACHE II sub groups. Areas that were targeted in the mobilisation protocol such as. ETTs, lack of resources, helmets for patients with a craniectomy, patient declining intervention and cardiovascular instability all decreased as barriers in

Phase 3. Despite sedation not being a target of the protocol, it also decreased significantly as a barrier after introduction of early mobilisation practices.

The successful introduction of an early mobilisation program into a single ICU created further interest in mobilisation practices around the country. No study had previously recorded baseline mobilisation levels for patients in the ICU in Australia. To adequately define 'early' mobilisation and evaluate its effect as a therapy on patient centred outcomes, knowledge of baseline practice is required. This thought process assisted in the construction of Study Two.

Chapter 5 Study Two

5.1 Introduction

The Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG) is a collaborative group of clinicians interested in quality research in the area of critical care. For the past five years (2007 to 2012) this group has conducted point prevalence studies in adult ICUs around Australia and New Zealand. This collaboration prevents duplication of efforts and funding to obtain epidemiological data on patients in intensive care. Data from the 10 previous ANZICS CTG point prevalence studies has resulted in two publications (Group 1987; Lilford 1994).

The point prevalence study in 2010 was co-ordinated by the ANZICS CTG and had endorsement by their management team. Prior to the 2010 point prevalence study, mobilisation data had not been collected in Australia or New Zealand. The growing interest in early mobilisation and discussion of preliminary results of the PhD candidate's first study at an annual CTG meeting (May 2009) resulted in the idea of nesting a sub study examining baseline mobilisation practices within the overall point prevalence program. Collaboration occurred between interested physiotherapists on data points required. Definitions of mobilisation activities were taken from Study One of the candidates thesis. Due to financial constraints, the amount of barriers and adverse events able to be reported was condensed.

This study was carried out chronologically between Study One and Study Three of this thesis and forms a bridge between the two studies. The candidate played an integral part in the study but was not the lead investigator of the point prevalence study. Permission to present this data was obtained from all other investigators. The key staff involved in the construction of the physiotherapy aspect of point prevalence study were (in alphabetical order): Dr Sue Berney, Associate Professor Linda Denehy, Hon Professor Ian Seppelt, Professor Steve Webb and the PhD candidate Meg Harrold. Mobilisation data collected from this study has not previously been reported.

Methods

5.2 Aim

The aim of this study was to establish a snapshot of mobilisation practices of patients in ICUs around Australia and New Zealand.

For the candidate's program of research, the following new information was added to the point prevalence data collection:

- Mobilisation rates for mechanically ventilated adults in Australian and New Zealand ICUs
- Adverse event rate around Australia and New Zealand
- Barriers to mobilisation for patients in Australian and New Zealand ICUS

5.3 Design

The point prevalence study is a prospective, observational epidemiological study carried out at a single time point for all units involved. The physiotherapy point prevalence study was nested within the larger point prevalence study conducted by ANZICS CTG in 2010.

5.4 Study setting

5.4.1 Location

All 182 (35 level III and 147 level I and II) Australian and New Zealand ICUs who admit adult patients were invited to participate in this study.

5.4.2 Data collectors

The demographic data was obtained by research coordinators. Mobility data was collected by physiotherapy staff in each unit with the assistance of the research coordinators.

5.5 Study criteria

5.5.1 Inclusion criteria

All adult patients admitted to the participating units at any time during the study day were included.

5.5.2 Exclusion criteria

There were no specific exclusion criteria for this study

5.6 Raw data collection

The physiotherapy point prevalence data collection sheet consisted of 25 items: two related to service provision; two to respiratory care (did they receive treatment, if so, what technique); 10 relating to mobilisation practices and barriers to mobilisation; 11 relating to factors interfering to physiotherapy and two items related to unplanned or adverse events occurring during physiotherapy (see Appendix 11). The adverse events section applied to both respiratory treatment and mobility treatment. Separation of these two types of treatment was not possible.

Definitions for the mobility sections of the form were based on the candidate's first study and the candidate was responsible for these aspects of the data dictionary (see Appendix 12). All definitions were decided upon a priori. The final physiotherapy data collection sheet was constructed by consensus of the investigators involved in the physiotherapy point prevalence.

The raw data provided information which formed the derived variables relating to mobilisation rates, safety and barriers to mobilisation.

5.6.1 Mobilisation rates

Raw data collected that relate to this program of research were:

- The time patients spent out of bed and ambulating. These were both measured categorically for ease of data collection and organised into the following categories: <5 mins; 5to < 15 mins; 15 to < 30 mins; 30 to < 60 mins; 1 to < 2 hours; 2 to <4 hours; 4+ hours

- Activities conducted. These included: exercises; tilt table; sitting over edge of bed; standing; sitting out of bed; ambulation.

To align with Study One and Three of this programme of research, reported mobilisation activities did not include 'exercises' but did include all other categories measured. Weight bearing was classified as using a tilt table, standing or ambulating.

5.6.2 Safety

To examine safety, adverse events associated with physiotherapy were recorded. An adverse event was defined a priori as:

- Fall: Patient descends to knees or buttocks In an uncontrolled manner during a mobilization activity
- Deterioration in gas exchange: During the process of mobilization (i.e. not prior to commencement), the patients oxygenation deteriorates sufficiently to warrant a sustained PEEP ≥10 cm H2O OR if was PEEP ≥10 cm H2O at commencement, an increase of 20% from PEEP at initiation of mobilization was required
- Reduction in blood pressure: During the process of mobilization the patient's blood pressure falls sufficiently to require return to bed, whether or not this also necessitated a commencement or increase in vasoactive medication
- Deterioration in mental state: During the process of mobilization, there is a drop in Glasgow Coma Scale by one point or more, a clear and sustained change in mentation compared with prior to mobilisation, or a sustained increase in the patient's intracranial pressure above 20 mmHg, if monitored
- Arrhythmias: During the process of mobilization, the patient experiences an abnormal heart rhythm that requires return to bed or medical attention
- Unplanned extubation / decannulation: During the process of mobilization the patient's endotracheal tube, nasotracheal tube or tracheostomy tube was dislodged or removed and was then unable to be used in its intended capacity

- Unplanned removal of lines: During the process of mobilization, a line (e.g. NGT, IV line, ICC) was dislodged or removed and was then unable to be used in its intended capacity.

Adverse event rates were described as the number of adverse events divided by the number of activities carried out. The number of patients who experienced adverse events was also recorded.

5.6.3 Barriers to mobilisation

Barriers to mobilisation were agreed upon by consensus. The categories are limited in number and therefore broad in nature due to budget limitations of the study. The following seven categories of barriers to mobilisation were as follows:

- Unconscious / unresponsive (neurological injury, metabolic coma, drug intoxication)
- Agitation or deep sedation
- Haemodynamically unstable
- Severe respiratory failure
- Unstable trauma (spine, spinal cord or pelvis)
- Severe neuromuscular weakness (e.g. unable to support own head despite being conscious)
- Other

Due to the broad nature of the categories it was not possible to divide these into modifiable and non-modifiable barriers. Barriers to mobilisation are therefore expressed as the total number in each category.

5.7 Research process

Data regarding all mobility and rehabilitation activities undertaken by patients in the previous 24 hours were collected from the nursing or physiotherapy notes and / or from the daily observation chart.

5.8 Ethical considerations

Ethics approval, when required, was approved by the ethics committee of each participating hospital with the need for participant consent waived. Data were de-identified before submission to the co-ordinating centre.

Results

5.9 Baseline results

5.9.1 Baseline results – setting

In total, 38 of 182 ICUs participated in the study (33 Australian, 5 New Zealand). Thirty units were Level III accredited units (86% of all Level III ANZ units); eight were Level I and II accredited units (5.4% of all ANZ Level I and II units).

5.9.2 Baseline results – patients

Data was collected on 513 patients but complete data collection was only obtained in 498 patients (97.1%). The number of patients, average age, sex and median APACHE II score for each site is listed in Table 22.

Table 22 Number of patients and percentage of patients who mobilised at each site in Study Two

Site	N of patients	% mobilised	Sex (%Male)	Age – mean (SD)	APACHE II median(IQR)
203	11	72.7	70.0	55.1 (22.6)	15 (10 to 20)
204	7	14.3	57.1	61.7 (15.2)	22 (16 to 29)
205	18	33.3	44.4	57.5 (17.3)	16 (8.5 to 21)
206	26	26.9	65.4	61.3 (16.1)	20 (13 to 23)
207	12	66.7	58.3	61.4 (16.0)	14.5 (9.2 to 22)
208	9	66.7	77.8	67.6 (14.3)	13 (12 to 15)
209	14	35.7	57.1	60.1 (20.6)	13 (9.2 to 19.2)
210	27	37.0	63.0	58.8 (19.1)	14 (8 to 18)
211	44	38.6	58.1	56.5 (15.9)	17.5 (12.7 to 23.5)
212	9	22.2	88.9	62.4 (20.7)	21 (12 to 23)
213	13	38.5	69.2	59.0 (12.1)	19 (12 to 33)
215	16	43.8	62.5	67.6 (14.0)	20 (12 to 33)
301	10	20.0	90.0	51.9 (12.6)	23 (9 to 34)
401	11	36.4	80.0	70.1 (8.8)	15 (9 to 20)
402	13	46.2	53.8	51.4 (22.6)	21 (14.5 to 25)
403	12	33.3	66.7	64.1 (10.1)	19.5 (16 to 25.2)
407	14	50.0	50.0	59.7 (14.1)	16.5 (11.2 to 23.2)
409	8	50.0	50.0	55.0 (16.7)	16.5 (7.7 to 21)
501	8	50.0	50.0	63.8 (7.2)	14.5 (12.5 to 23.5)
502	12	50.0	41.7	58.0 (18.3)	18 (7.7 to 29.7)
503	8	12.5	100	42.9 (13.3)	17.5 (16 to 20.5)
504	24	33.3	52.2	58.3 (17.7)	15 (12 to 21)
506	8	62.5	62.5	58.9 (19.8)	15.5 (13.2 to 23.5)
507	4	50.0	66.7	74.5 (6.0)	23 (16.7 to 27)
602	7	28.6	71.4	54.9 (9.5)	N/A
603	7	42.9	57.1	68.9 (13.4)	28 (26 to 32)
701	12	16.7	83.3	57.5 (12.7)	20 (15.2 to 32.7)
801	31	41.9	67.7	58.9 (14.8)	16 (12 to 19)
802	17	23.5	64.7	61.1 (16.4)	18.5 (15 to 24.7)
803	6	83.3	66.7	72.0 (6.4)	18 (14.7 to 24)
804	7	42.9	57.1	61.1 (13.0)	31 (21 to 33)
808	10	80.0	80.0	64.6 (14.3)	19 (14.7 to 24.2)
810	6	16.7	33.3	59.7 (23.6)	20 (18 to 25.2)
811	18	27.8	55.6	59.3 (17.0)	19 (14.7 to 29.5)
812	12	33.3	45.5	70.0 (14.9)	17.5 (15 to 20.7)
813	9	44.4	88.9	54.4 (19.9)	16 (12 to 24)
903	20	40.0	80.0	42.7 (18.5)	N/A
904	13	35.7	38.5	59.4 (14.9)	22 (13.5 to 25)
Total	513	39.3	62.9%	59.2 (16.8)	18 (13 to 23)

N/A = not available

RPH ICU

5.10 Mobilisation

5.10.1 Overall

Of the 513 patients, 202 patients were mobilised in the preceding 24 hours (39.3%). The total number of activities conducted was 412, of which 216 were weight bearing. This equated to a median of two activities per patient mobilised, one of which was a weight bearing activity.

The time spent mobilising in the 24 hour period was recorded for sitting activities and weight bearing activities. For all patients the mode for sitting activities was two to four hours and for weight bearing activities it was less than five minutes.

No patients were recorded to have mobilised on mechanical ventilation however three patients mobilised with an ETT and supplemental oxygen in situ. One of these patients was extubated later that day. These three patients carried out six activities of mobilisation. All patients were from the one hospital and no adverse events occurred during these activities.

Thirteen patients who received RRT on the day of auditing were also recorded as having mobilised. It is not known if mobilisation occurred simultaneously with RRT or if it occurred during a break in the circuit. With this limitation in mind, 21 activities of mobilisation were conducted in these 13 patients. Two adverse events occurred: one reduced blood pressure and one deterioration of mental state.

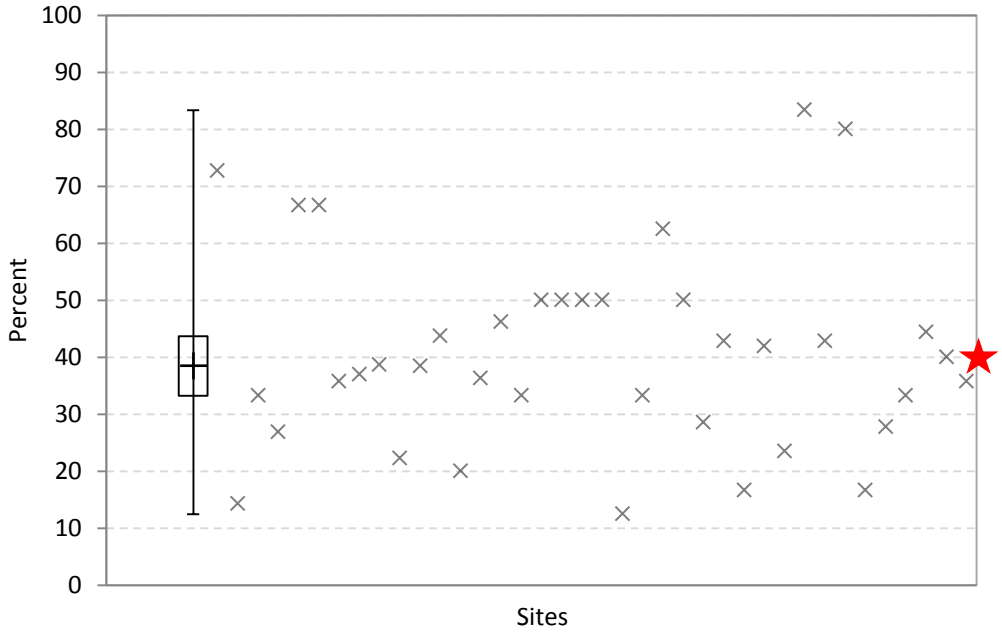
Vasopressor infusions were present at some stage during the audit day for 147 patients. Of these, 30 patients mobilised and carried out 61 activities, 30 of which were weight bearing activities. This equates to a total of 14.8% of the total activities were carried out on patients who received vasopressors at some stage that day. Two patients experienced adverse events (decrease in blood pressure and decrease in mental state); the second patient also received RRT.

5.10.2 Mobilisation - sites

Mobilisation rates varied between sites. Figure 25 shows a box plot of percent of patients mobilised at all sites with error bars representing the maximum and

minimum percent of patients mobilised, as well as the individual result for all sites included in the study. The percentage of patients who completed weight bearing activities is displayed in a similar graph in Figure 26. Of those that mobilised the percentage that then participated in weight bearing activities is displayed in Figure 27.

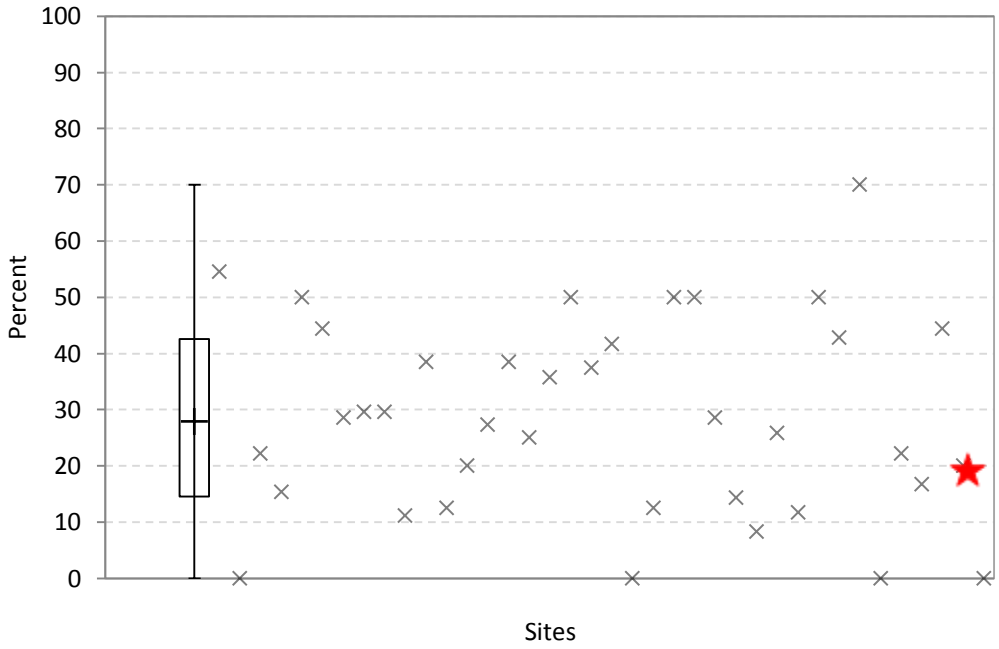
Figure 25 Percentage of patients mobilised at each site in Study Two



Note: box plot represents the median and middle 50% of sites and the error bars are the minimum and maximum. Each cross represents one site.

★ RPH ICU

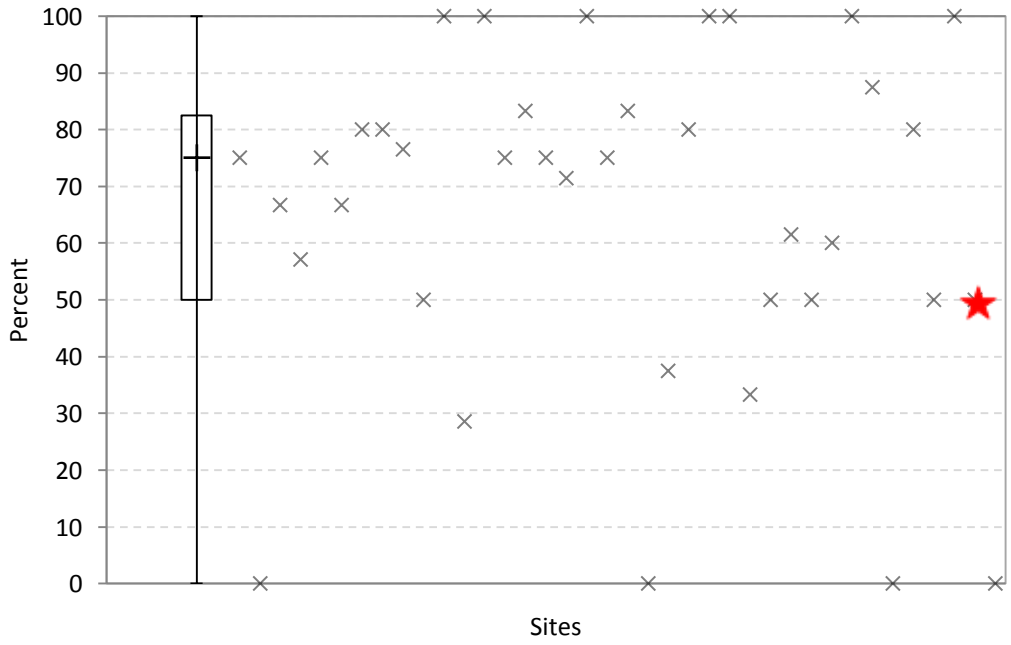
Figure 26 Percentage of patients who weight bear at each site in Study Two



Note: box plot represents the median and middle 50% of sites and the error bars are the minimum and maximum. Each cross represents one site.

★ RPH ICU

Figure 27 Percentage of patients that were mobilised who also weight bear in Study Two



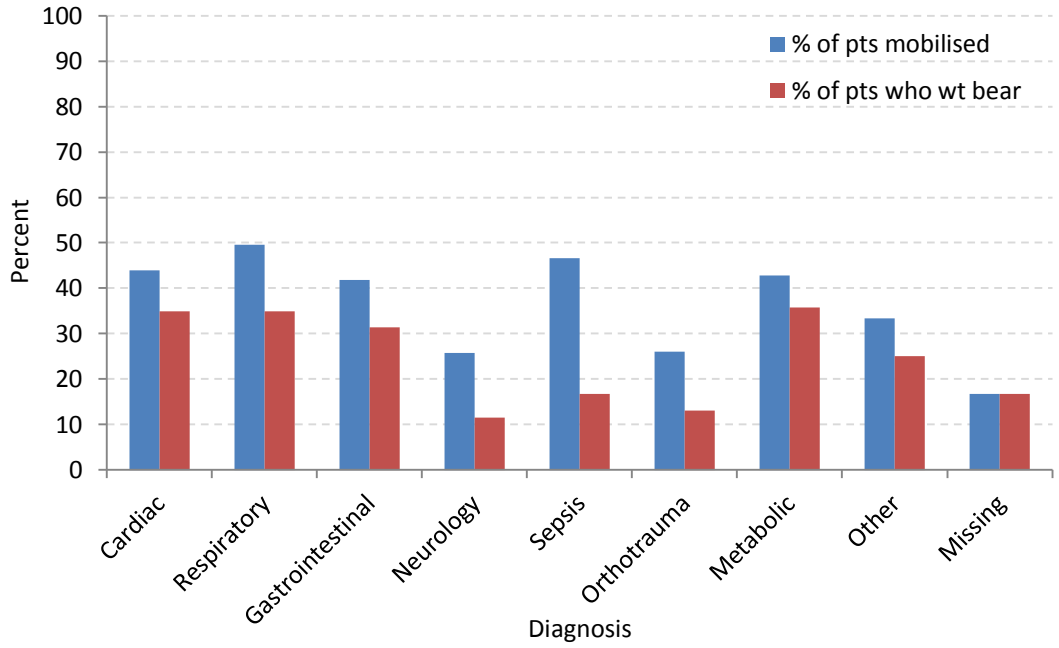
Note: box plot represents the median and middle 50% of sites and the error bars are the minimum and maximum. Each cross represents one site.

★ RPH ICU

5.10.3 Sub group analysis – diagnosis (subgroup 1)

Patients admitted with a respiratory diagnosis had the highest percentage of patients who mobilised, closely followed by patients with sepsis diagnoses. Patients with respiratory diagnoses who carried out weight bearing activities again recorded the highest rate; however patients with sepsis diagnoses had one of the lowest rates of weight bearing. Patients with neurological and trauma conditions show low rates of both mobilisation and weight bearing (See Figure 28).

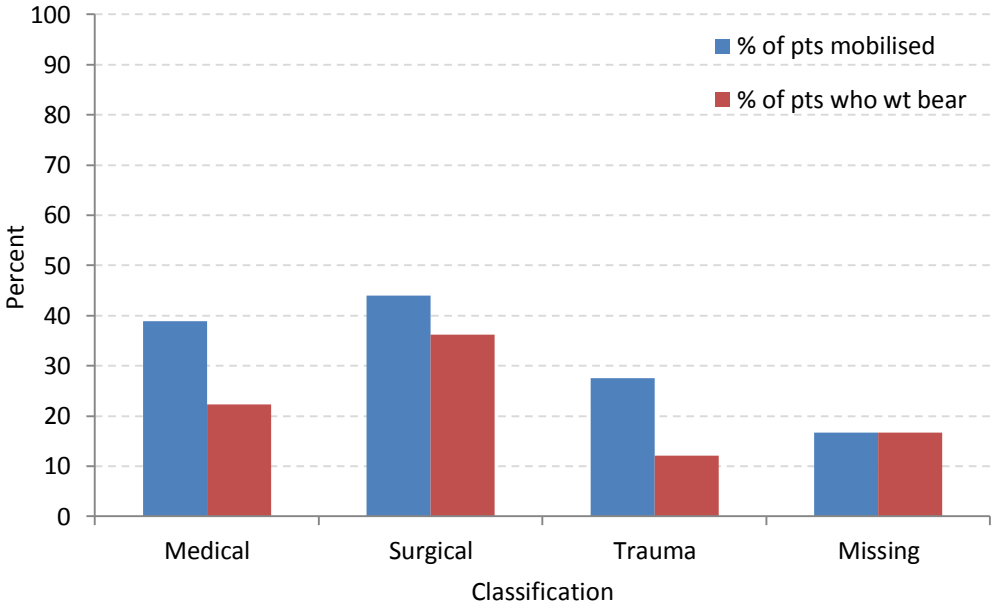
Figure 28 Diagnosis (sub group 1): the percentage of patients who mobilised and who weight bear in each diagnostic specific category



5.10.4 Sub group analysis – classification (sub group 2)

Patients admitted for surgical reasons had the highest percentage of patients who mobilised and carried out weight bearing activities. Weight bearing activities were proportionately less in patients admitted with medical conditions compared with surgical conditions (see Figure 29).

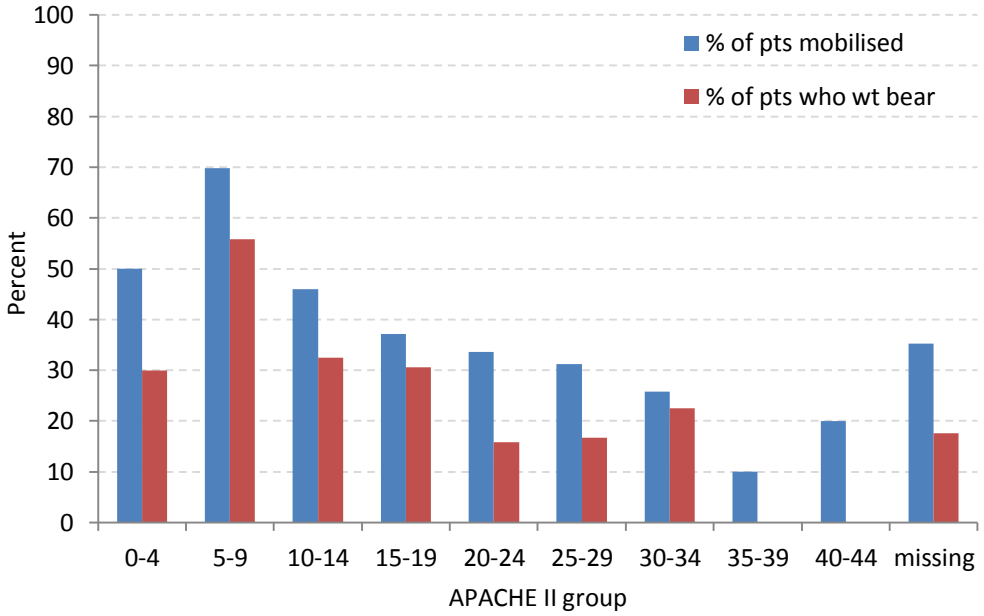
Figure 29 Classification (sub group 2): the percentage of patients who mobilised and who weight bear in each diagnostic specific category



5.10.5 Subgroup analysis – severity of illness (sub group 3)

As severity of illness scores increased, the percentage of patients who mobilised decreased apart from the APACHE II grouping of 40 – 44 which did have a higher percentage of patients mobilised than the 35 – 39 grouping (see Figure 30). Percentage of patients who carried out weight bearing activities followed a similar trend with a slight increase in rate in the 30 – 34 APACHE II grouping in comparison to the previous group. No patients in the 35-39 or 40 – 44 APACHE II grouping participated in weight bearing activities (see Figure 30).

Figure 30 Severity of illness (sub group 3): percentage of each APACHE II group who mobilised and weight bear

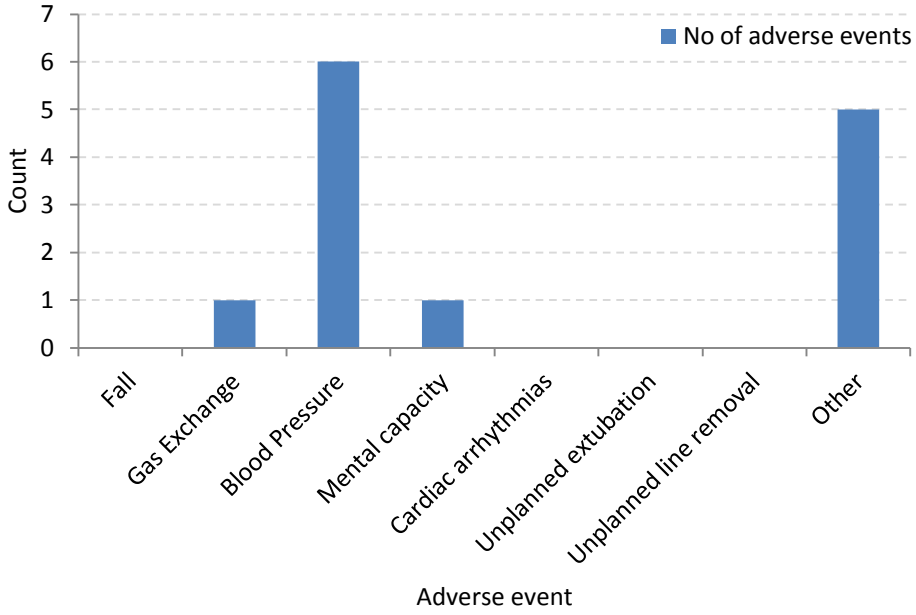


5.11 Safety

For patients who did mobilise, 13 adverse events occurred during respiratory, mobility therapy or both, in 11 patients. This equates to an adverse event rate of 6.4% (13 adverse events / 202 episodes).

Figure 31 is a graphical representation of the adverse events in this study. The adverse events listed as 'other' include three episodes of dizziness, one of increased blood pressure and one of shortness of breath.

Figure 31 Number of adverse events overall for Study Two

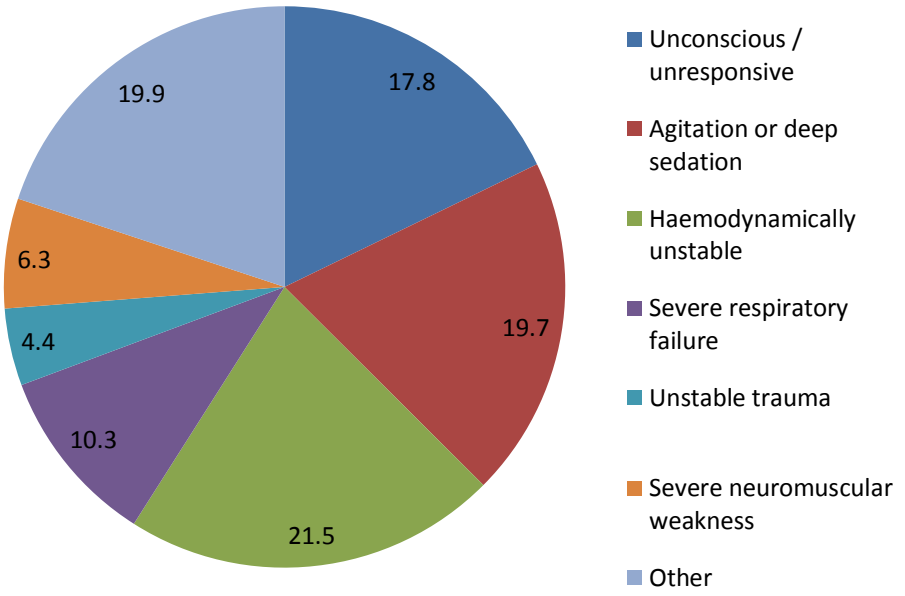


5.12 Barriers

The largest barrier to mobilisation was reported as haemodynamic instability. This was closely followed by agitation or deep sedation. Unstable trauma and severe neurological weakness were the least recorded barriers (see Figure 32).

Nearly 20% of barriers were classified as ‘other’. There were 15 different types of barriers mentioned in this section. Patient drowsiness and fatigue was the most commonly stated barrier in the ‘other’ section, followed by patient refusal.

Figure 32 Barriers to mobilisation for all patients in Study Two



5.13 Summary

This study captured mobilisation activity on one day in 38 ICUs across Australia and New Zealand which represented 86% of all level III ICUs in the area.

Of the 497 patients with complete data, 39.3% mobilised. The percentage of patients mobilised at each individual site varied considerably from 12.5% to 83.3%. However, if the patients did mobilise, a median of 75% of patients also carried out weight bearing activities.

No patients were mobilised with mechanical ventilation. Two patients did mobilise with an ETT in situ but were not connected to mechanical ventilation. Due to wording of the questionnaire, it was not possible to determine accurately the number of patients who mobilised with vasopressor infusions and RRT. It can be shown that 13 out of the 58 patients who received RRT at some stage during that day mobilised and 30 out of the 147 patients who had vasopressor infusions running at some stage during that day mobilised.

Patients admitted for respiratory or sepsis conditions had the highest proportion of patients carry out mobilisation. Analysis of APACHE II subgroups showed that prevalence of mobilisation was higher in patients with lower APACHE II scores than in patients with higher groupings.

Haemodynamic instability was the largest barrier to mobilisation, followed closely by sedation. These results are difficult to interpret due to the broad nature of the categories available on the questionnaire.

Adverse event rates across all patients were low and there were no serious adverse events.

This study showed low levels of mobilisation on any one day for patients admitted to Australian and New Zealand ICUs. It is not clear if this is an accurate representation of daily mobilisation levels or if this is due to the weak study design. One day of data does not provide enough information about patterns of mobilisation throughout patients' length of stay and how barriers to mobilisation change with time.

Results from Study Two revealed a need to conduct a study capturing patients' total length of stay to establish base line practice of mobilisation as well as what barriers exist to conducting mobilisation. This was in line with what would subsequently be decided upon at the Society of Critical Care Medicine conference as one of the key priorities for the area of early mobilisation in ICU research (Needham 2012). In 2010, two years prior to these conference proceedings, a third study was designed to examine mobilisation activity and barriers to mobilisation in Australia and to benchmark this internationally.

The ambiguities of the results from Study Two were the motivation for a more robust assessment of baseline mobilisation practice in Australia and lead to Study three.

Chapter 6 Study Three

6.1 Introduction

This chapter covers the third and final study of this program of research. The need for a more comprehensive examination of baseline practice came after review of the many limitations of the point prevalence study. The study was conducted across two countries, Australia and Scotland, and examined baseline mobility practice.

Results of this study are predominantly descriptive and comparison between countries will be performed on baseline results to show differences in demographics between the two countries. In many instances statistical comparison is not possible due to differences in patient populations, workforce and settings.

Methods

6.2 Aim

The aims of this study were:

1) To quantify baseline levels of mobilisation in Australian and Scottish ICUs
2) To establish an adverse event rate for mobilisation in Australian and Scottish ICUs
3) To benchmark Australian practices internationally with Scottish practices

6.3 Design

The study was a series of eight-week prospective observational studies looking at mobility practices carried out around Australia and Scotland. The audits consisted of a four-week recruitment period and then a further four-week period of follow up auditing of those patients already recruited but not yet discharged from ICU.

6.4 Hypothesis

From the related literature and previous studies conducted, the following hypotheses were generated:

- The proportion of patients who mobilise during their ICU stay will be above 40% in both Australia and Scotland
- Adverse event rates in both Scotland and Australia will occur in less than 6% of activities conducted
- Barriers to mobilisation within Australian and Scottish ICUs will be similar and can be divided into avoidable and non-avoidable barriers

6.5 Study setting

6.5.1 Locations and recruitment

A research collaboration was formed between the PhD candidate and senior researchers in Scotland after discussion of common research interests at ICU conferences and on line networks. The lead researcher in the Scottish Physiotherapy group is Dr Lisa Salisbury. Through this collaboration, invitation was made to senior physiotherapists of all Scottish ICUs to participate in Study three.

Australian sites were recruited through collaboration and presentations with the intensive care network at ANZICS and ANZICS CTG conferences as well as word of mouth.

Sites were enrolled if they had established quality assurance databases that collected the necessary demographic patient information required for this study and the physiotherapist on site was able to access this information. Involvement in the study was voluntary and under the premise that data recorded would be available for use by the original site after publication by the chief investigator.

6.5.2 Workforce

The candidate made initial contact with the senior physiotherapist working in the ICU of each site and in all cases this person remained the primary contact for the

study. Junior physiotherapists assisted with daily data collection and data was validated on patient discharge by the senior physiotherapist at each site.

6.6 Study population

6.6.1 Inclusion criteria

Patients aged over 18 years admitted to ICU and received mechanical ventilation in the ICU.

6.6.2 Exclusion Criteria

There were no exclusion criteria.

6.6.3 Withdrawal Criteria

Patients whose total length of stay was not captured at the study census date were withdrawn from analysis. Census date was put at eight weeks after commencement of the study to capture as many patients total length of stay as possible.

6.7 Sample size expectations

It was anticipated that 8 sites around Australia and 8 sites around Scotland would be recruited. The sample size was one of convenience as it required an eight week commitment to data collection with no remuneration offered. The aim was to include approximately 25% of all 29 Level III ICUs in Australia (the six tertiary Level III ICUs in New Zealand were not included) and have a comparable number of sites in Scotland.

Census dates were decided upon using Australian data from previous years and results from Study One. The median length of stay for Australian patients admitted to ICU in 2010 was 1.8 days (0.9 to 3.7) (ANZICS and CORE 2010) and approximately two thirds of patients were mechanically ventilated (Judson and Fisher 2006). Data from Study One showed patients who were mechanically ventilated for three or more calendar days had an average length of stay of 25 days (SD 26 days). In order to capture as many patients total length of stay in ICU it was decided that there be a recruitment phase of four weeks (28 days) and an audit period of another

four weeks (28 days). The audit period was to ensure patients recruited towards the end of the recruitment four weeks had their total length of stay captured.

6.8 Outcome measures

6.8.1 Mobilisation rate

Mobilisation details were recorded using the MDCF2 (see Appendix 13) and from this information, mobilisation rates were derived as described in section 3.6.1 and were recorded for:

- All patients
- Patients at each site
- Patients within each sub group

6.8.2 Safety

Safety levels were determined by adverse event rates (as previously defined in section 3.6.3) for the following groupings of patients:

- All patients
- Patients at each sites
- Patients receiving an ETT, RRT and/or vasopressor infusions
- Patients within each sub group

6.8.3 Barriers to mobilisation

Barriers to mobilisation for this study were recorded on the MDCF2 (see Appendix 13). From this information, barriers to mobilisation were expressed as unavoidable or avoidable / partially modifiable.

6.9 Research process

After initial agreement to participate in the study, ethics applications specific to each sites requirements were obtained as well as formal approval of access to the quality assurance patient database.

Sites began data collection at a time convenient to their unit. Ethics approval for 19 hospitals necessitated this staggered approach. However, once data collection had commenced, recruitment occurred on all consecutive patients meeting inclusion criteria for a four week period. Patients who were recruited in this four week period but whom had not yet been discharged continued to be audited until they were discharged from the ICU or until the census date was reached, whichever came first. The aim of this was to capture as many patients total lengths of stay as possible.

A standardised, scannable data collection form was used across all sites and labelled the MDCF2 (see Appendix 13). This form was constructed from the MDCF used in Study One with an additional four categories added to Section 3 'for patients not mobilised'. These categories were: 'Sedated', 'Comatosed', 'RRT in progress' and 'Imminent death'. The data dictionary was updated accordingly (see Appendix 14).

The one page questionnaire used in Study One was also given to the lead physiotherapists at each site in this study (Appendix 14). This was to establish the size of the unit and the resources available to staff at each unit.

Data were collected by physiotherapists working at each site. While this does potentially introduce bias, feasibly it represented the best possible way of collecting all mobilisation data.

6.9.1 Data linkage

The MDCF2 was specially designed with a perforated edge for easy removal of the top section of the form. This top section recorded the patient name or identifier as well as the unique study number to be written on it for easy identification by the collecting therapist. This top section could then be removed prior to transfer of data outside the ICU. On completion of the audit, the top sections of all forms are kept on site in a locked cupboard in accordance with ethics applications. The main section of the forms included the unique study number to allow data linkage whilst maintaining confidentiality.

Data linkage of mobilisation data and demographic data from the quality assurance database was performed by the senior physiotherapist at each site as they were the only person with access to both the patient identifier and the unique study number.

6.10 Statistical analysis

Statistics for this study were predominantly descriptive in nature. Where there were two independent groups with data that was normally distributed, student t-tests were used in analysis to compare means. For non-parametric data, two independent groups were analysed using Mann Whitney U tests.

6.11 Ethics

This study was observational in nature and did not pose substantial ethical risk. Permission to access demographic, physiological and length of stay data was obtained from participating sites' management committee. This information is obtained on a routine basis for individual patients as a matter of quality assurance. Ethics approval was obtained from all 10 Australian hospitals (see Appendix 15). Permission to access quality assurance data bases for each site was also gained prior to commencement of the study. The hospitals involved were:

Australia

The Alfred Hospital - Victoria

The Austin Hospital - Victoria

Fremantle Hospital – Western Australia

Princess Alexandra Hospital - Queensland

Prince Charles Hospital - Queensland

Royal Hobart Hospital - Tasmania

Royal Perth Hospital – Western Australia

Sir Charles Gairdner Hospital – Western Australia

St Vincent's Private Hospital – New South Wales

Wollongong Hospital – New South Wales

A waiver of ethics was granted for Scotland (Appendix 16). However, Caldicott guardianship was still required for each National Health System (NHS) region. Cauldicott approval was obtained for all nine hospitals which were located in six NHS regions (see Appendix 16). The hospitals and NHS regions are listed below.

Scotland

Aberdeen Royal Infirmary – NHS Grampian

Forth Valley Royal Hospital – NHS Forth Valley

Royal Infirmary of Edinburgh – NHS Lothian

Ninewells Hospital – NHS Tayside

Perth Royal Infirmary – NHS Tayside

Queen Margaret Hospital – NHS Fife

Raigmore Hospital – NHS Highland

St John's Hospital – NHS Lothian

Western General Hospital – NHS Lothian

Results

6.12 Baseline results

Baseline results for both Australian and Scottish cohorts will be compared statistically.

6.12.1 Baseline results – setting: Australia

Ten sites were involved in data collection in the Australian arm of the study. This consisted of one rural ICU and nine metropolitan ICUs, one of which was in a private hospital. All units only admitted level III ICU patients. The sites were spread over five states of Australia: three in Western Australia, two in Victoria; two in New South Wales; two in Queensland and one in Tasmania.

Descriptive statistics are outlined in Table 23. The average number of beds across all 10 sites was 19.4 (SD 7.17). Specialties covered at each ICU varied with all sites having at least one specialty area.

Attitudes towards mobilisation with ETTs, RRT and or vasopressor infusions varied across sites. Half of sites stated that as a general rule they did mobilise patients with an ETT and the same sites also allowed mobilisation of patients with vasopressor infusions. Mobilisation with RRT in situ was allowed in six of the 10 sites but these sites did not correlate with the acceptance of mobilisation with ETTs and vasopressor infusions.

Table 23 Descriptive statistics for Australian sites

Site	1	2	3	4	5	6	7	8	9	10
Level III ICU beds	34	18	12	24	20	10	23	23	12	18
Specialties included in unit										
- Cardiothoracic surgery	✓	✓	✓	✓	✓	✓	✓	✓	✓	X
- Neurosurgery	✓	✓	X	✓	X	✓	✓	✓	✓	✓
- Trauma	✓	X	X	✓	X	✓	✓	✓	✓	X
- Spinal	✓	✓	X	✓	X	✓	✓	✓	✓	X
- Transplantation	✓	✓	X	✓	✓	X	✓	✓	✓	X
PT attend medical handover	X	✓	✓	X	✓	✓	✓	✓	X	X
Culture										
- Mobilisation with ETT	✓	✓	X	X	X	✓	✓	X	X	✓
- Mobilisation with RRT	✓	✓	✓	X	X	X	✓	✓	✓	X
- Mobilisation with vasopressors	✓	✓	X	X	X	✓	✓	X	X	✓
Equipment in unit										
- High back chair	10	0	4	4	10	3	5	0	6	4
- Rocker recliner	0	8	3	0	6	0	3	0	2	2
- Rehabilitation chair	8	0	0	4	2	2	4	5	0	3
- Tilt table	1	1	0	1	1	1	1	2	1	1
- Standing lifter	1	1	0	0	0	0	0	1	1	0

6.12.1 Baseline results – setting: Scotland

Nine sites participated in data collection for the Scottish arm of the study, all of which had a combination of level II and level III operational ICU beds. Only patients mechanically ventilated and admitted to Level III ICU beds were admitted into the study.

Descriptive statistics are listed in Table 24. On average the number of beds in each unit was 9.0 (SD 4.18) which was significantly less (p=.001) that those ICUs audited in Australia (19.4 (SD 7.17)).

No Scottish site covered cardiothoracic surgery or transplantation specialties.

Mobilisation with an ETT and vasopressor infusions was permitted at eight out of the nine sites compared with mobilisation of patients with RRT which was allowed at six sites.

Table 24 Descriptive statistics for Scottish sites

Site	1	2	3	4	5	6	7	8	9
Level III ICU beds	13	7	12	9	3	9	8	4	16
Specialties included in unit									
- Cardiothoracic surgery	X	X	X	X	X	X	X	X	X
- Neurosurgery	✓	X	X	✓	X	X	X	X	✓
- Trauma	✓	✓	✓	✓	X	✓	✓	✓	✓
- Spinal	✓	X	X	X	X	X	X	X	✓
- Transplantation	X	X	X	X	X	X	X	X	X
PT attend medical handover	✓	X	X	X	✓	✓	✓	✓	✓
Culture									
- Mobilisation with ETT	✓	✓	✓	✓	✓	✓	✓	✓	X
- Mobilisation with RRT	✓	✓	✓	X	X	✓	X	✓	✓
- Mobilisation with vasopressors	✓	✓	X	✓	✓	✓	✓	✓	✓
Equipment in unit									
- High back chair	0	3	4	0	1	3	1	2	2
- Rocker recliner	5	16	4	0	0	0	2	2	5
- Rehabilitation chair	0	0	0	1	1	3	1	0	2
- Tilt table	1	1	1	1	1	1	1	1	1
- Standing lifter	0	1	0	1	0	1	1	0	0

6.12.2 Baseline results – workforce

Data for the study was collected by physiotherapists in each unit. Staffing levels varied at each site. The mean ratio of physiotherapists to ICU beds for Australia was 1:5.6 (SD 1.82) and for Scotland it was 1:6.7 (SD 2.36) which were not statistically different (p=.298).

6.12.3 Baseline results – patients in Australia and Scotland

The number of patients in the Australian cohort was more than 3.7 times that of the Scottish cohort. The mean APACHE II scores for the Scottish population was higher but not statistically different (p=.069). The length of stay in both ICU and hospital was longer for patients in Scotland (see Table 25).

Table 25 Baseline demographic results for Australian and Scottish cohorts of Study three

	Australia	Scotland	*p*-value
N of pts	665	179	
Age (mean)	59.7 (SD 17.07)	N/A	
Sex (% Male)	66.6	N/A	
APACHE II (mean)	16.81 (SD 7.30)	17.96 (SD 7.16)	.069
LOS – ICU (median)	2.00 (1.00 to 4.17)	3.85 (1.98 to 8.67)	<.001*
LOS – hospital (median)	10.58 (6.58 to 18.02)	16.00 (6.00 to 33.00)	.002*

Note: Due to ethics board requirements, age and sex was not allowed to be collected for patients in the Scottish arm of the study.
*statistically significant result. Comparison of mean values was analysed with t-test. Comparison of median values was analysed with Mann-Whitney test

6.12.4 Baseline results – Australian and Scottish patient sub groups

Patients meeting inclusion criteria in the Australian and Scottish cohorts were pooled and divided into the three previously described sub groups. The breakdown of each sub group for both Australia and Scotland are displayed in Figures 33, 34 and 35. These three graphs show clear differences in admission diagnoses and severity of illness patterns between the two countries.

Figure 33 Diagnosis (sub group 1): breakdowns for all patients meeting inclusion criteria in Australian and Scottish cohorts

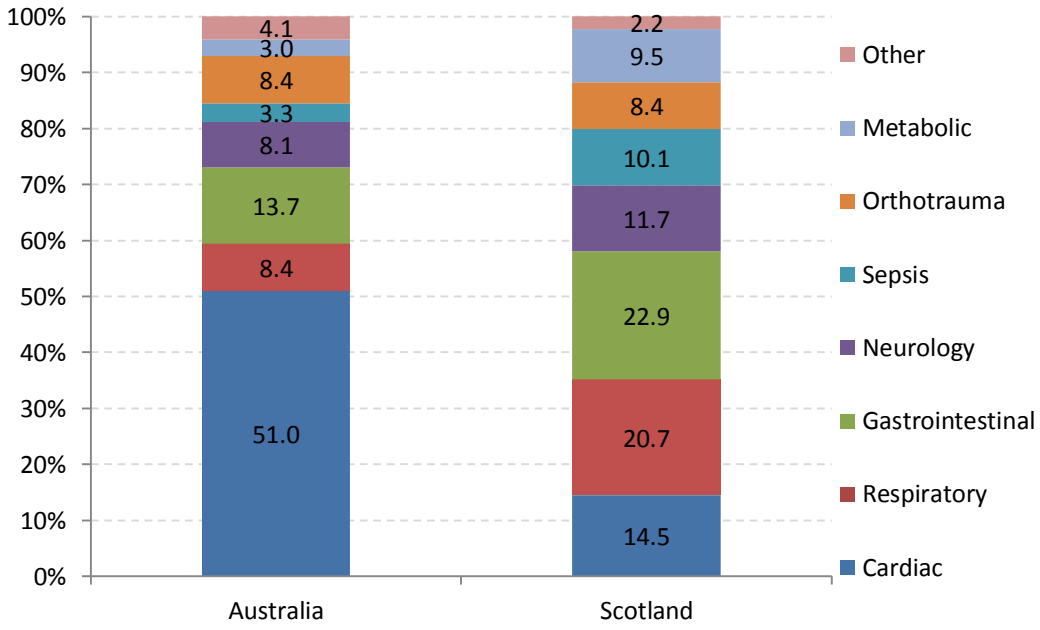


Figure 34 Classification (sub group 2): breakdowns for all patients meeting inclusion criteria in Australian and Scottish cohorts

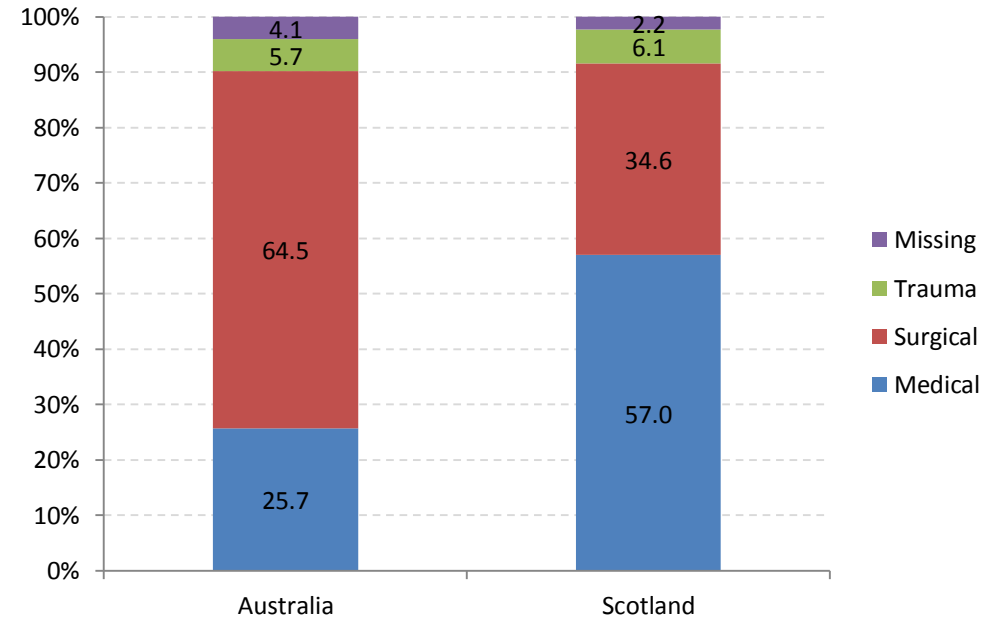
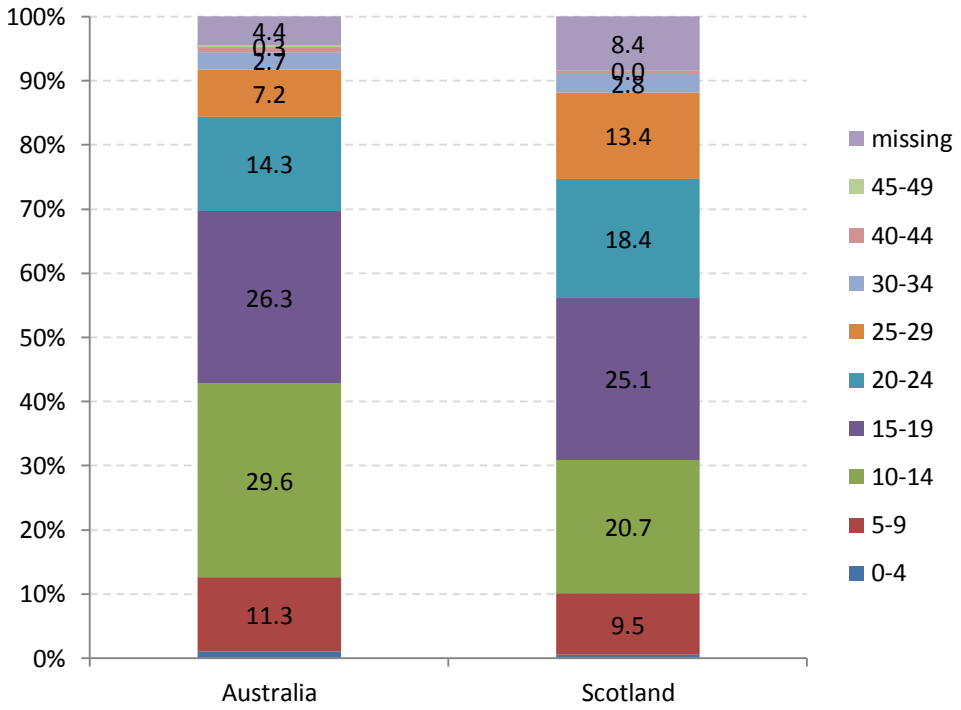


Figure 35 Severity of illness (sub group 3): breakdowns for all patients meeting inclusion criteria in Australian and Scottish cohorts



6.12.5 Baseline results – sites

Breakdowns of diagnosis and classification sub groups for each Australian site are shown in Figure 36 and Figure 37 and in Figure 38 and Figure 39 for Scottish sites. Numbers in each severity of illness category were too small to graph meaningfully. Results for RPH ICU are singled out in Figure 36 and Figure 37 as this unit is the only unit common to all three studies in this thesis.

Figure 36 Diagnosis (sub group 1): baseline results for each Australian site in Study Three

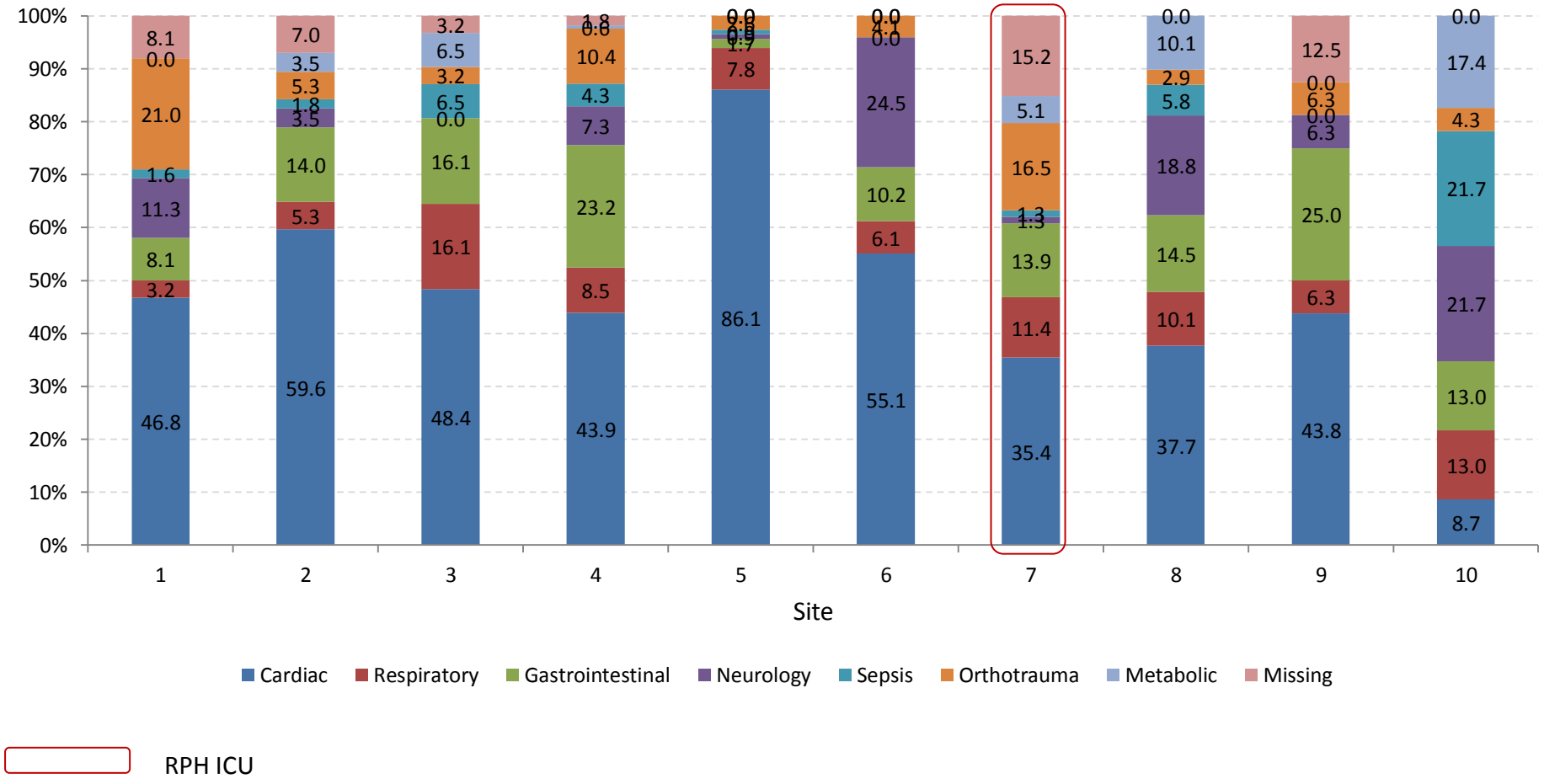


Figure 37 Classification (sub group 2) baseline results for each Australian site in Study Three

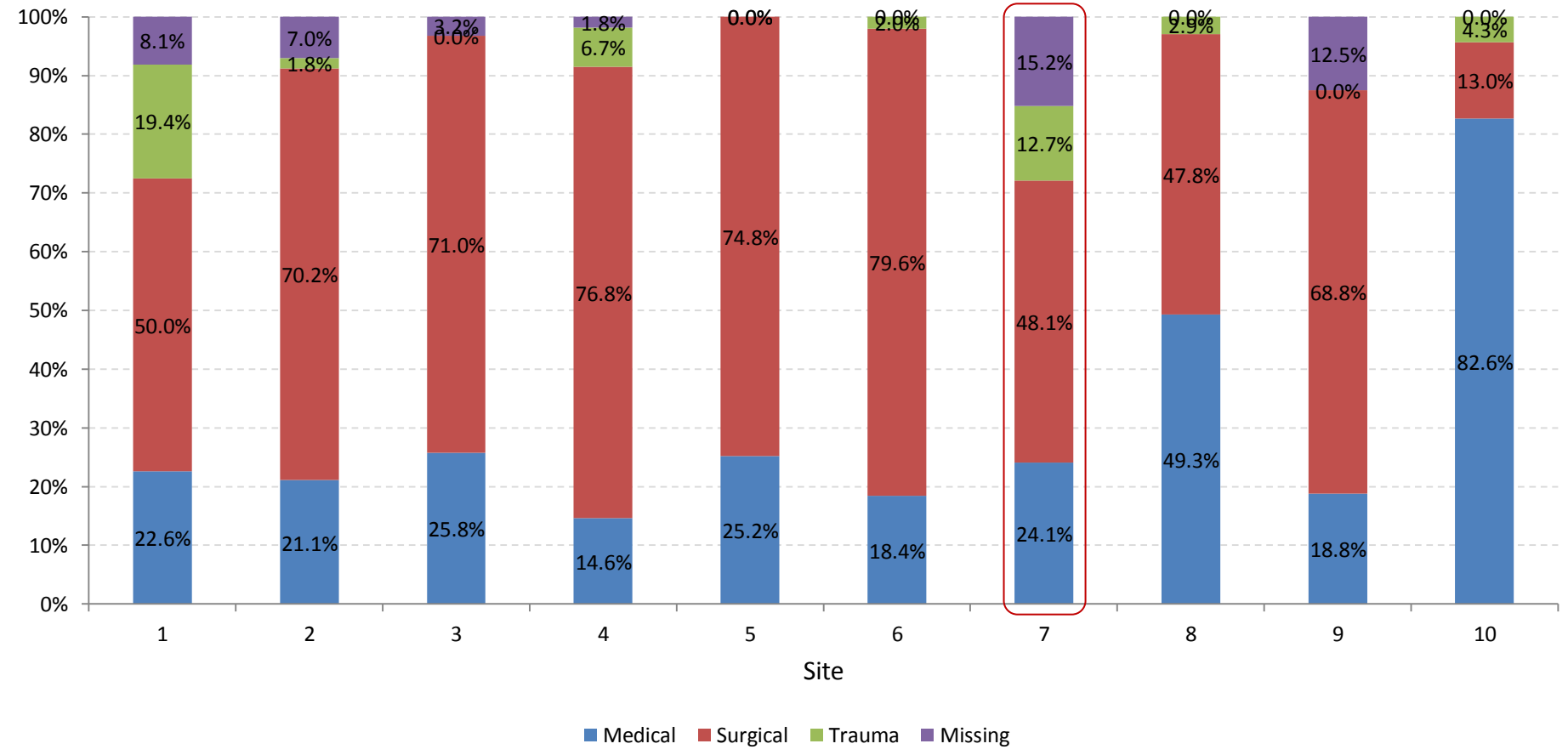


Figure 38 Diagnosis (sub group 1): baseline results for each Scottish site in Study Three

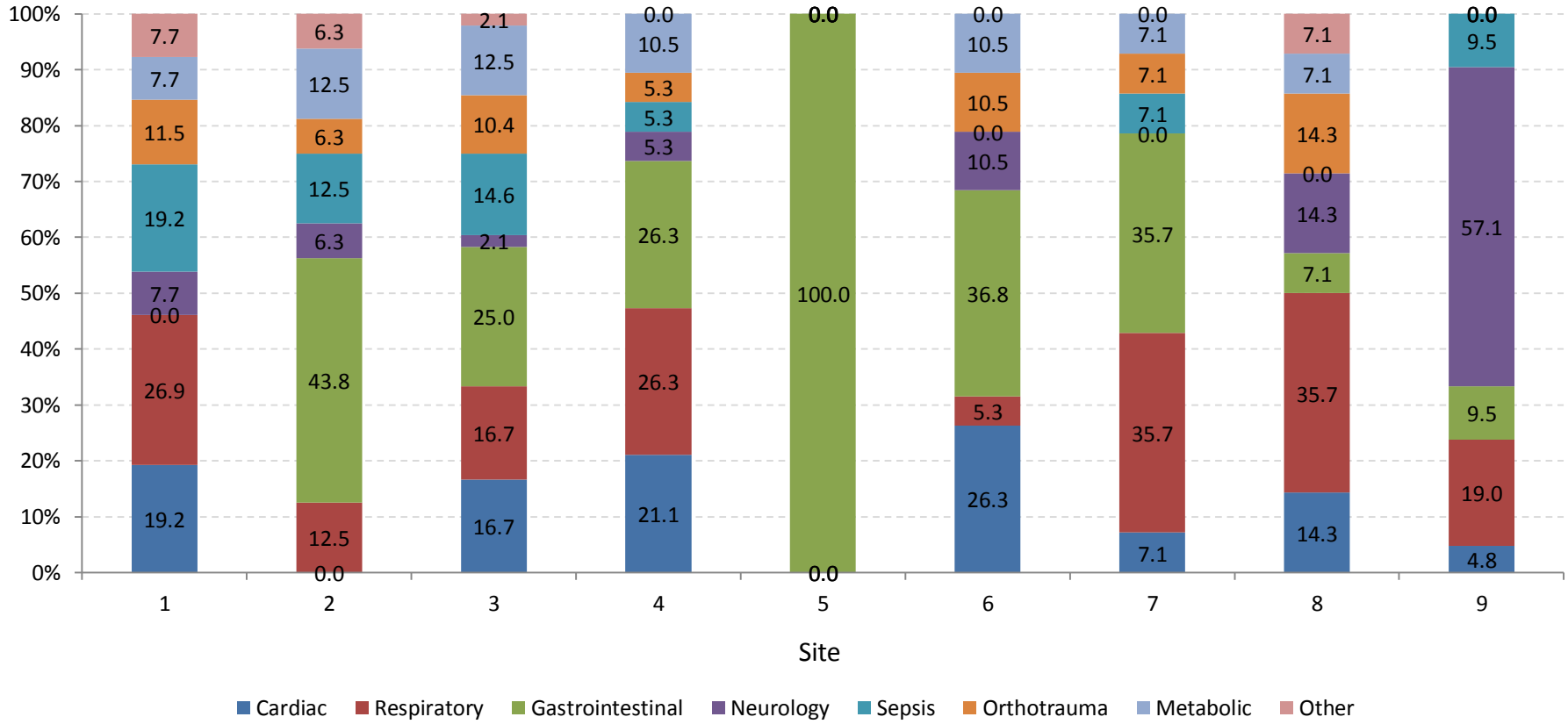
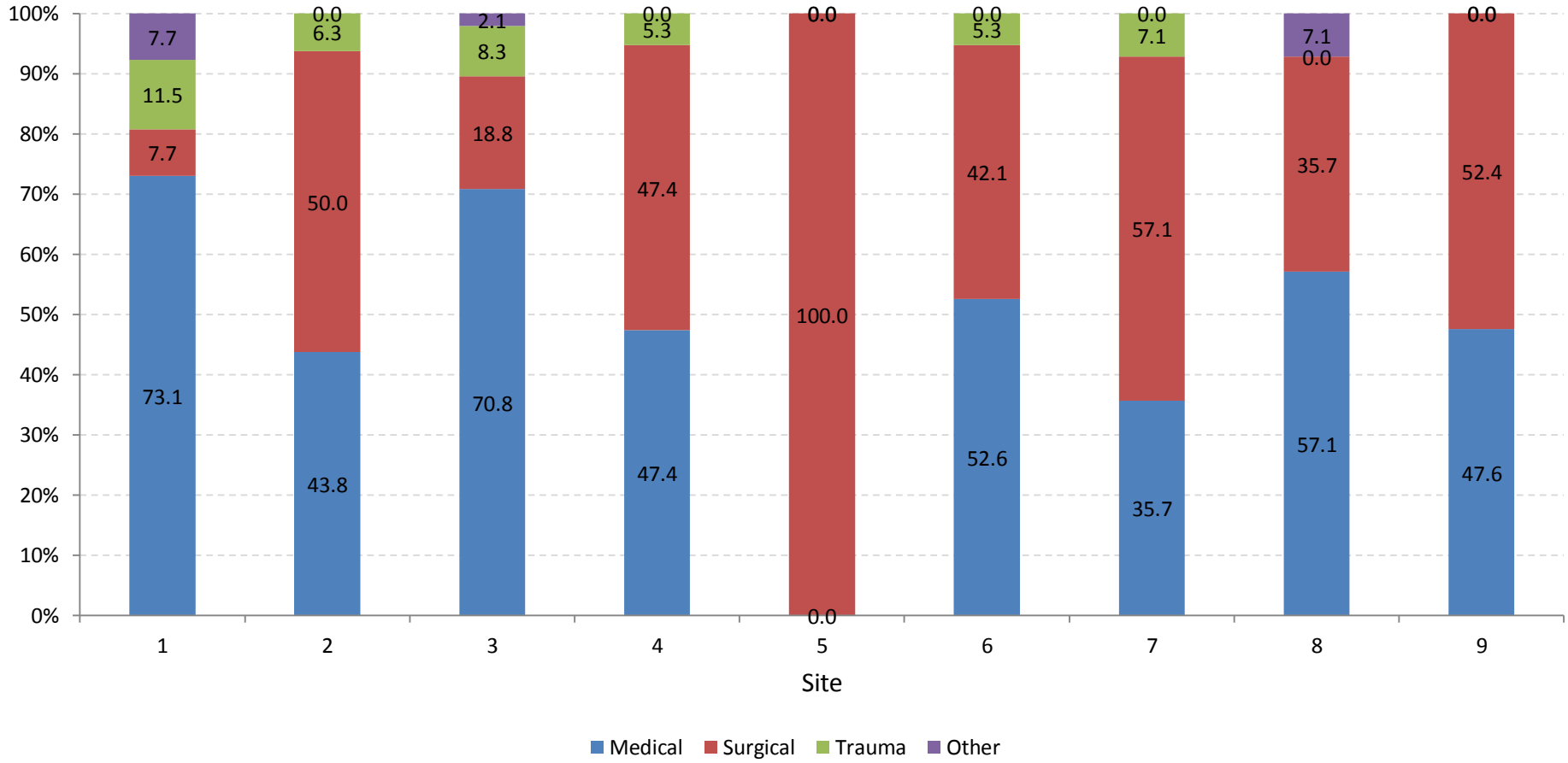


Figure 39 Classification (sub group 2): baseline results for each Scottish site in Study Three



6.13 Mobilisation rates

6.13.1 Overall

The variation between Australia and Scotland in baseline demographics makes the comparison of mobilisation statistics clinically unsound. The mobilisation results for the Australian and Scottish cohorts are shown in Table 26 and 27. Although the proportion of patients who mobilised in Scotland was lower (42.5%), the number of activities and episodes conducted per patient mobilised was higher (6.3 and 3.8). The percentage of patients who weight bear was markedly higher in the Australian cohort (57.1% compared with 29.1%).

Table 26 Overall mobilisation results for the Australian cohort of Study three

	Australia
% of patients who mobilised	68.8
^N of activities per pt	2.9
^N of activities per pt mobilised	4.2
^N of episodes per pt	1.4
^N of episodes per pt mobilised	2.1
% patients who wt bear	57.1
^Mins spent mobilising per pt	193
% of activities carried out on MV	9.3
Day first mobilised	2 (1 to 3)

^ median

Table 27 Overall mobilisation results for the Scottish cohort of Study three

	Scotland
% of patients who mobilised	42.5
^N of activities per pt	2.7
^N of activities per pt mobilised	6.3
^N of episodes per pt	1.6
^N of episodes per pt mobilised	3.8
% patients who wt bear	29.1
^Mins spent mobilising per pt	692
% of activities carried out on MV	34.4
Day first mobilised	4.5 (2 to 10.8)

^ median

Overall mobilisation rates in the presence of ETT, RRT and vasopressors

Out of the three therapies, mobilisation with vasopressor infusions was the most common to occur. For the Australian population of the study, mobilisation with

vasopressor infusions occurred in 17.1% of episodes (152 episodes) where vasopressor infusions were running. Mobilisation with RRT was present during 8.5% (12 episodes) of possible episodes and 2.0% (40 episodes) of episodes were carried out where an ETT was present. All episodes of mobilisation where the patient had an ETT in situ were also receiving mechanical ventilation.

In the Scottish population mobilisation with these therapies was lower. Mobilisation in the presence of an ETT occurred in 1.1% (7 episodes) of episodes possible. Mobilisation with RRT or vasopressor infusions occurred in 1.1% (1 episode) and 2.8% (8 episodes) of episodes respectively.

Day first mobilised

The median time to patients first getting out of bed was day 2 (1 to 3) for Australian patients and day 4.5 (2 to 10.8) (p=.003) for Scottish patients. Statistical comparison of these results is of limited validity due to the differences in diagnostic makeup of the populations.

6.13.2 Mobilisation results for individual sites.

Mobilisation results for individual Australian sites are shown in Table 28. Site seven is highlighted as this represents RPH ICU, the one site common to all three studies. The proportion of patients mobilised at each site varies between 28.6% and 92.2%.

Scottish mobilisation results are displayed in Table 29. The proportion of patients mobilised at individual sites varied from 21.1% to 68.8%.

The percentage of patients who mobilise and the percentage of patients who weight bear are displayed in Figure 40 and Figure 41 for Australian and Scottish cohorts. The difference between those who mobilise and those who weight bear are the proportion of patients who sat only.

6.13.3 Mobilisation results in sub groups

Results of mobilisation in each of the three sub groups for both Australia and Scotland populations are shown in Tables 30 through to 35.

For the diagnosis sub group, patients in the respiratory category had the highest percentage of patients mobilised in both cohorts. The category that experienced the greatest number of activities, episodes and minutes of mobilisation was sepsis for Australian and Scottish patients. Mobilisation with ETTs, RRT and vasopressors did not have the same consistency. For Australia, patients in the respiratory category were most likely to mobilise with an ETT or RRT and cardiac patients were most likely to mobilise with vasopressor infusions. In the Scottish cohort, the patients who mobilised most with an ETT were those in the metabolic category. Only patients in the gastrointestinal category mobilised with RRT and patients with sepsis had the highest rate of mobilisation with vasopressor infusions.

Patients in the surgical category of the classification sub group had the highest proportion of patients mobilised in both the Scottish and Australian cohorts. Medical patients recorded the most amounts of activities, episodes and minutes of mobilisation per patient in Australia in contrast to Scotland where patients in the trauma category recorded the highest values in these areas. Mobilisation of patients with RRT was most common in medical patients in Australia and Scotland. Mobilisation with an ETT was seen most commonly in medical patients for Australian cohort and in surgical patients in the Scottish cohort. Surgical patients in the Australian population and medical patients in the Scottish population saw the highest rate of mobilisation with vasopressor infusions.

Patterns of mobilisation in the severity of illness sub group for Australian patients showed the day first mobilised got progressively higher with increasing APACHE II groupings. This was not observed in the Scottish cohort.

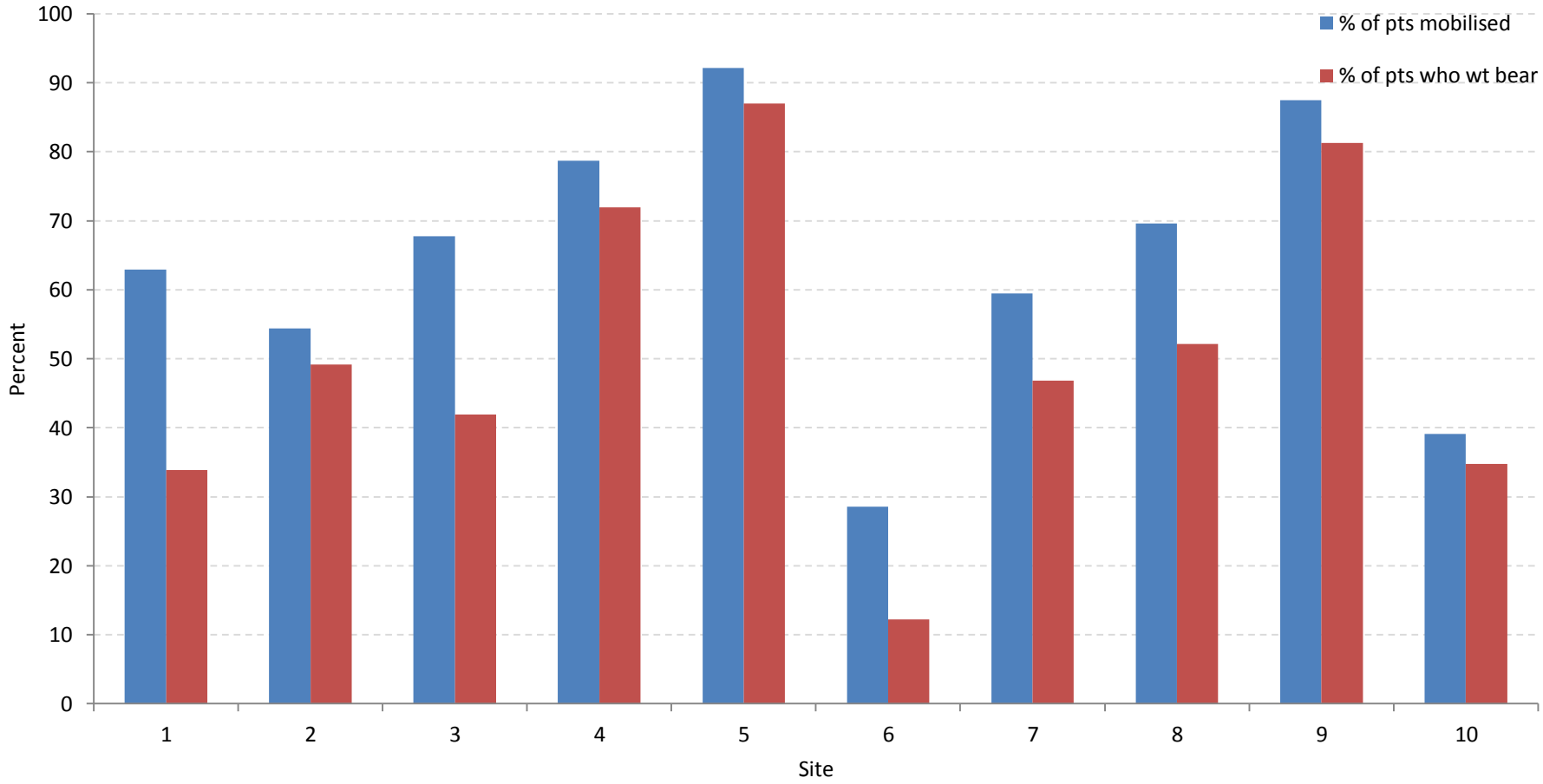
Table 28 Mobilisation rates for individual Australian sites in Study three

	1	2	3	4	5	6	7	8	9	10
N of pts	62	57	31	**164**	115	49	79	69	16	23
% pts mobilised	62.9	54.4	67.7	78.7	**92.2**	28.6	59.5	69.6	87.5	39.1
% pts who weight bear	33.9	49.1	41.9	72.0	**87.0**	12.2	46.8	52.2	81.3	34.8
N of activities per pt mobilised	3.9	5.0	2.5	1.7	6.8	4.4	5.4	3.2	4.3	**8.6**
N of episodes per pt mobilised	2.4	2.5	2.1	0.9	2.8	**3.2**	2.6	2.1	1.8	4.2
N mins per pt mobilised	347	404	208	75	718	263	**430**	312	300	712
% of episodes with ETT	1.4	0.0	2.0	0.0	2.9	0.0	2.9	0.5	**20.0**	5.2
% of episodes with RRT	0	0	0	0	14.3	0	**18.2**	13.0	0	0
% of episodes with vasopressors	2.1	7.1	7.4	5.4	**45.4**	3.9	12.2	0.0	8.3	0.0
Day first mobilised	3 (2 to 5)	2 (2 to 4)	2 (2 to 3)	1 (1 to 2)	2 (2 to 2)	3.5(1.8 to 8.5)	2 (2 to 5)	2(2 to 3.8)	2(1 to 2.2)	5(3 to 8.2)

RPH ICU

Note: Highlighted numbers represent the highest value for that criterion

Figure 40 The proportion of patients who mobilised and the proportion who weight bear in Australian sites for Study three



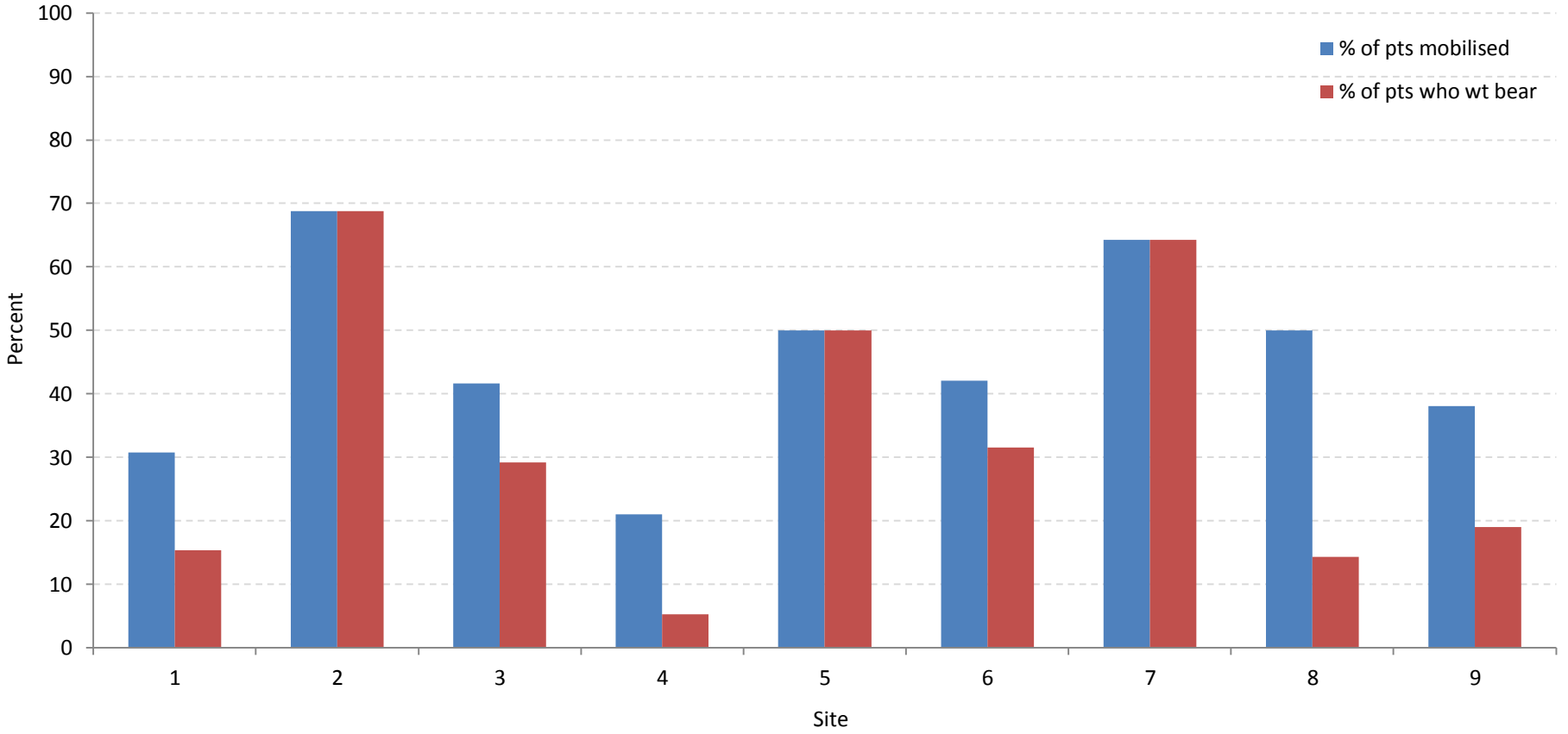
Note: The difference between the blue and red bars of the graph highlights those patients who sat only.

Table 29 Mobilisation rates for individual Scottish sites in Study three

	1	2	3	4	5	6	7	8	9
N of pts	26	16	**48**	19	2	19	14	14	21
% pts mobilised	30.8	**68.8**	41.7	21.1	50.0	42.1	64.3	50.0	38.1
% pts who weight bear	15.4	**68.8**	29.2	5.3	50.0	31.6	64.3	14.3	19.0
N of activities per pt mobilised	5.3	**9.9**	8.4	3.8	4.0	3.6	7.6	3.3	3.1
N of episodes per pt mobilised	4.6	4.7	4.5	**4.8**	2.0	2.3	3.9	2.9	2.4
N mins per pt mobilised	579	619	1022	**1144**	295	244	627	493	596
% of episodes with ETT	0.0	**4.9**	0.6	3.0	0.0	1.1	0.0	0.0	1.7
% of episodes with RRT	0.0	0.0	**1.8**	0.0	0.0	0.0	0.0	0.0	0.0
% of episodes with vasopressors	0.0	**8.7**	4.7	5.7	0.0	0.0	0.0	0.0	0.0
Day first mobilised	6(2 to 13.2)	**2(1 to 8)**	8.5(2.2 to 12)	11.5(4 to 31.8)	1	2(1 to 10.8)	3(2 to 8)	3(2 to 10)	5(2 to 7.5)

Note: Highlighted numbers represent the highest value for that criterion

Figure 41 The proportion of patients who mobilised and the proportion who weight bear in Scottish sites for Study Three



Note: The difference between the red and blue bars of the graph highlights those patients who sat only.

Table 30 Diagnosis (sub group 1): mobilisation rates for patients of different diagnostic specific categories in the Australian cohort of Study Three

Diagnostic specific category	Cardiac	Respiratory	Gastrointestinal	Neurology	Sepsis	Orthotrauma	Metabolic	Other
N of pts	**339**	56	91	54	22	56	20	27
% pts mobilised	74.9	**85.7**	75.8	46.3	59.1	41.1	50.0	59.3
% pts who weight bear	67.0	**69.6**	59.3	31.5	50.0	26.8	40.0	33.3
N of activities per pt mobilised	4.1	6.0	3.2	2.7	**9.5**	3.0	2.4	4.6
N of episodes per pt mobilised	1.9	2.9	2.0	1.9	**4.6**	2.1	1.3	3.4
N mins per pt mobilised	358	626	214	189	**893**	186	156	488
% of episodes with ETT	2.1	**6.2**	1.6	1.3	0.0	0.0	0.0	0.0
% of episodes with RRT	0	**18.4**	0	0	8.6	0	0	0
% of episodes with vasopressors	**29.9**	12.4	7.5	1.8	3.1	0.0	0.0	2.2
Day first mobilised	**2** (1 to 2)	**2.5** (1 to 5)	**1** (1 to 3)	**2** (1 to 4)	**4** (3 to 6)	**4** (2 to 7)	**2** (1 to 2.2)	**2** (1.2 to 5)

Note: Highlighted numbers represent the highest value for that criterion

Table 31 Diagnosis (sub group 1): mobilisation rates for patients of different diagnostic specific categories in the Scottish cohort of Study Three

Diagnostic specific category	Cardiac	Respiratory	Gastrointestinal	Neurology	Sepsis	Orthotrauma	Metabolic	Other
N of pts	26	37	**41**	21	18	15	17	4
% pts mobilised	38.5	**54.1**	51.2	19.0	38.9	33.3	41.2	50.0
% pts who weight bear	23.1	32.4	**46.3**	14.3	27.8	6.7	35.3	0
N of activities per pt mobilised	9.8	4.7	5.4	8.3	**12.7**	5.0	3.9	1.0
N of episodes per pt mobilised	5.6	3.4	2.9	6.0	**6.4**	5.0	1.7	1.0
N mins per pt mobilised	1156	681	460	841	**1236**	568	325	333
% of episodes with ETT	1.4	0	2.5	1.9	0	0	**3.4**	0
% of episodes with RRT	0	0	**5.3**	0	0.0	0	0.0	0
% of episodes with vasopressors	3.0	5.8	0	0	**6.5**	0	6.3	0
Day first mobilised	8.5 (3 to 19)	5 (2.2 to 10.2)	3 (2 to 9)	2 (2 to 9.5)	8 (1 to 14)	8 (4 to 14.5)	**2 (1 to 4)**	

Note: Highlighted numbers represent the highest value for that criterion

Table 32 Classification (sub group 2): mobilisation rates for patients of different classification categories in the Australian cohort of Study Three

Diagnostic specific category	Medical	Surgical	Trauma	Missing
N of pts	171	**429**	38	27
% pts mobilised	59.6	**76.0**	36.8	59.3
% pts who weight bear	45.6	**66.7**	18.4	33.3
N of activities per pt mobilised	**6.0**	3.6	3.8	4.6
N of episodes per pt mobilised	**3.1**	1.8	2.6	**3.4**
N mins per pt mobilised	**626**	279	233	488
% of episodes with ETT	**3.1**	1.6	0.0	0.0
% of episodes with RRT	**12.1**	0.0	0.0	0.0
% of episodes with vasopressors	11.6	**25.3**	0.0	2.2
Day first mobilised	3 (2 to 5)	**2 (1 to 2)**	5 (3.5 to 8)	2 (1.2 to 5)

Note: Highlighted numbers represent the highest value for that criterion

Table 33 Classification (sub group 2): mobilisation rates for patients of different classification categories in the Scottish cohort of Study Three

Diagnostic specific category	Medical	Surgical	Trauma	Missing
N of pts	**102**	62	11	4
% pts mobilised	43.1	**45.2**	18.2	50.0
% pts who weight bear	26.5	**38.7**	9.1	0.0
N of activities per pt mobilised	5.9	7.3	**9.5**	1.0
N of episodes per pt mobilised	3.7	3.9	**9.0**	1.0
N mins per pt mobilised	702	688	**919**	333
% of episodes with ETT	0.5	**2.5**	0.0	0.0
% of episodes with RRT	**1.4**	0.0	0.0	0.0
% of episodes with vasopressors	**3.6**	2.0	0.0	0.0
Day first mobilised	5 (2 to 12)	4.5 (2 to 9.8)	4 (1 to 4)	1.5 (1 to 1.5)

Note: Highlighted numbers represent the highest value for that criterion

Table 34 Severity of illness (sub group 3): mobilisation rates for patients of different APACHE II categories in the Australian cohort of Study Three

APACHE grouping	0-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	Missing
N of pts	7	75	**197**	175	95	48	18	14	5	2	29
% pts mobilised	71.4	73.3	**77.7**	70.9	71.6	43.8	55.6	28.6	0.0	0.0	62.1
% pts who weight bear	**71.4**	58.7	68.5	60.0	58.9	31.3	16.7	28.6	0.0	0.0	44.8
N of activities per pt mobilised	1.6	2.2	3.3	4.4	6.2	8.0	2.0	**9.8**	0.0	0.0	4.6
N of episodes per pt mobilised	1	1.4	1.7	2.2	3.0	**4.4**	1.8	3.8	0.0	0.0	3.1
N mins per pt mobilised	12	189	273	369	550	**839**	208	744	0	0	429
% of episodes with ETT	0.0	0.0	2.1	2.6	1.1	1.6	1.4	**4.7**	0.0	0.0	2.7
% of episodes with RRT	0.0	0.0	0.0	3.7	17.2	**19.4**	0.0	0.0	0.0	0.0	0.0
% of episodes with vasopressors	0.0	18.0	21.3	**23.7**	21.7	6.6	0.0	0.0	0.0	0.0	3.5
Day first mobilised	**1(1 to 2)**	**1(1 to 2)**	2(1 to 2)	2(1 to 3)	2.5(2 to 4.8)	4(2 to 5)	5.5(3.8 to 8)	9(5 to 13)			2(1 to 5)

Note: Highlighted numbers represent the highest value for that criterion

Table 35 Severity of illness (sub group 3): mobilisation rates for patients of different APACHE II categories in the Scottish cohort of Study Three

APACHE grouping	0-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	Missing
N of pts	1	17	37	**45**	33	24	5	1	1	0	15
% pts mobilised	0.0	35.3	45.9	46.7	36.4	**54.2**	40.0	0.0	0.0		33.3
% pts who weight bear	0.0	29.4	27.0	33.3	30.3	33.3	**40.0**	0.0	0.0		13.3
N of activities per pt mobilised	0.0	5.2	6.5	4.6	6.5	7.3	**22.0**	0.0	0.0		5.2
N of episodes per pt mobilised	0.0	2.5	4.0	3.6	3.7	3.5	**12.0**	0.0	0.0		4.2
N mins per pt mobilised	0.0	408	762	552	625	885	**1643**	0.0	0.0		675
% of episodes with ETT	0.0	**8.0**	0.0	2.3	0.7	1.9	0.0	0.0	0.0		0.0
% of episodes with RRT	0.0	0.0	0.0	0.0	0.0	**10.0**	0.0	0.0	0.0		0.0
% of episodes with vasopressors	0.0	25.0	1.9	2.9	1.7	9.4	0.0	0.0	0.0		0.0
Day first mobilised		**1.5(1 to 3.5)**	8(2 to 14)	5(2.5 to 8.5)	7(4 to 14)	2(1 to 3)	15(14 to 15)				3(2 to 21)

Note: Highlighted numbers represent the highest value for that criterion

6.14 Discharge destination

6.14.1 Overall

For all patients in the Australian cohort, 66.0% of patients were discharged home from hospital. The mortality rate for this group was 10.7% which is slightly lower than the national average (ANZICS CORE). Patients discharged to rehabilitation / nursing home facilities, another acute hospital, another ICU or data were missing accounted for 23.3% (7.7%, 11.4%, 0.3% and 3.9% respectively).

The discharge destinations for patients in Scotland did not follow the same pattern of Australia. Patients were discharged home in 54.7% of cases and mortality was 22.9% at hospital discharge. However, patients going to other destinations accounted for 22.4% of patients which is consistent with the Australian cohort (rehabilitation / nursing home – 14.0%; acute hospital – 1.1% and missing data – 7.3%).

6.14.2 Discharge destination for individual sites

The discharge destinations for each site in the Australian and Scottish cohorts are displayed in Figure 42 and Figure 43. The proportion of patients being discharged home at each site ranged from 40.3% to 82.6% for Australian sites and from 0% to 73.7% in Scottish sites.

Figure 42 Discharge destination for all Australian sites

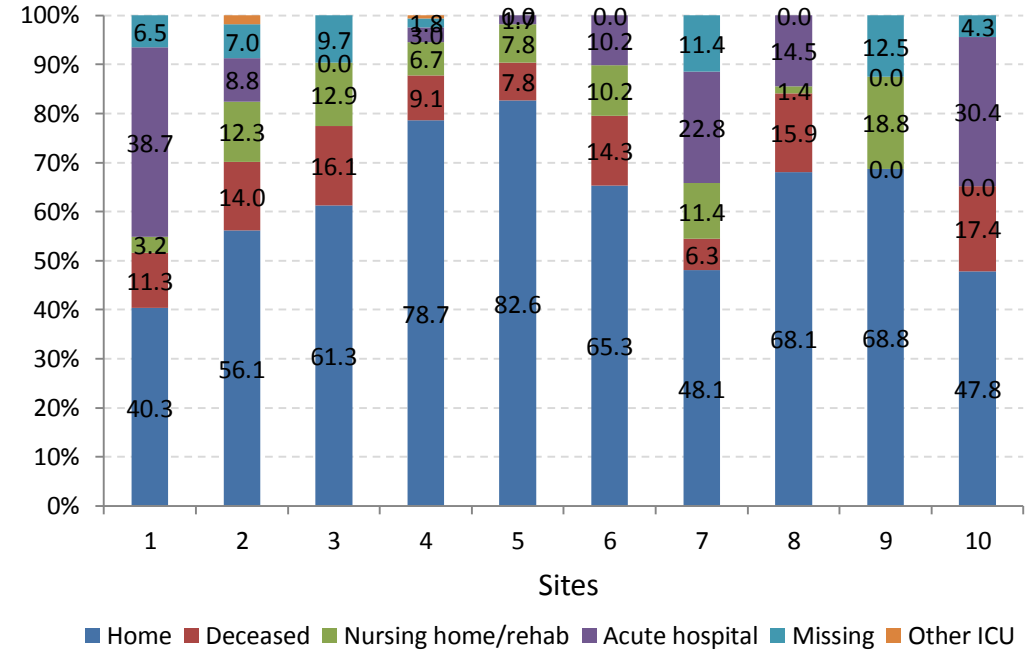
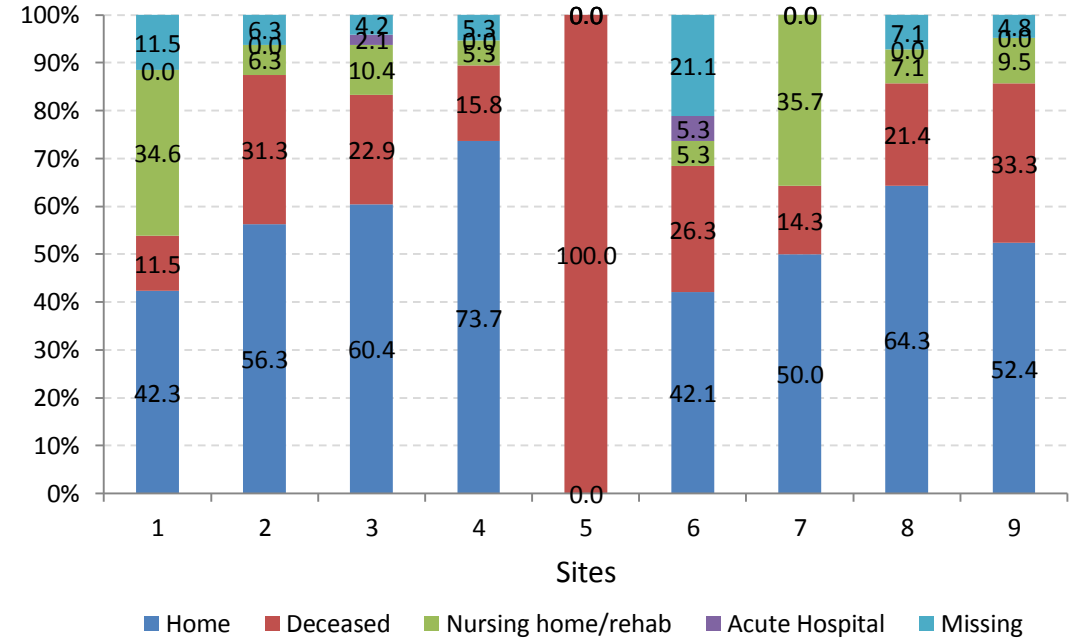


Figure 43 Discharge destination for all Scottish sites



Note: Site 5 had a cohort of two patients.

6.14.3 Discharge destination for patients who mobilised and did not mobilise

Discharge destination was analysed for patients who did and did not mobilise and results are shown in Figure 44 and Figure 45 for Australian and Scottish cohorts.

Australian patients had a higher likelihood of being discharged to an acute hospital than Scottish patients (p<.001). In both cohorts discharge to another ICU was rare. The difference between the mobilised and non-mobilised cohorts was more noticeable in the Australian population than in the Scottish.

Figure 44 Discharge destination for Australian patients who mobilised and did not mobilise

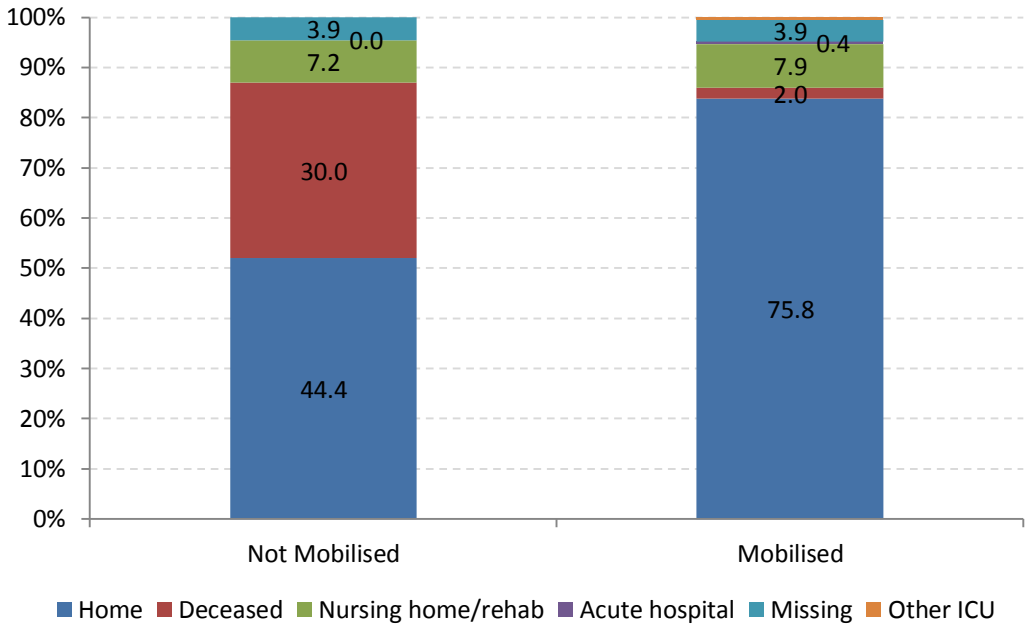
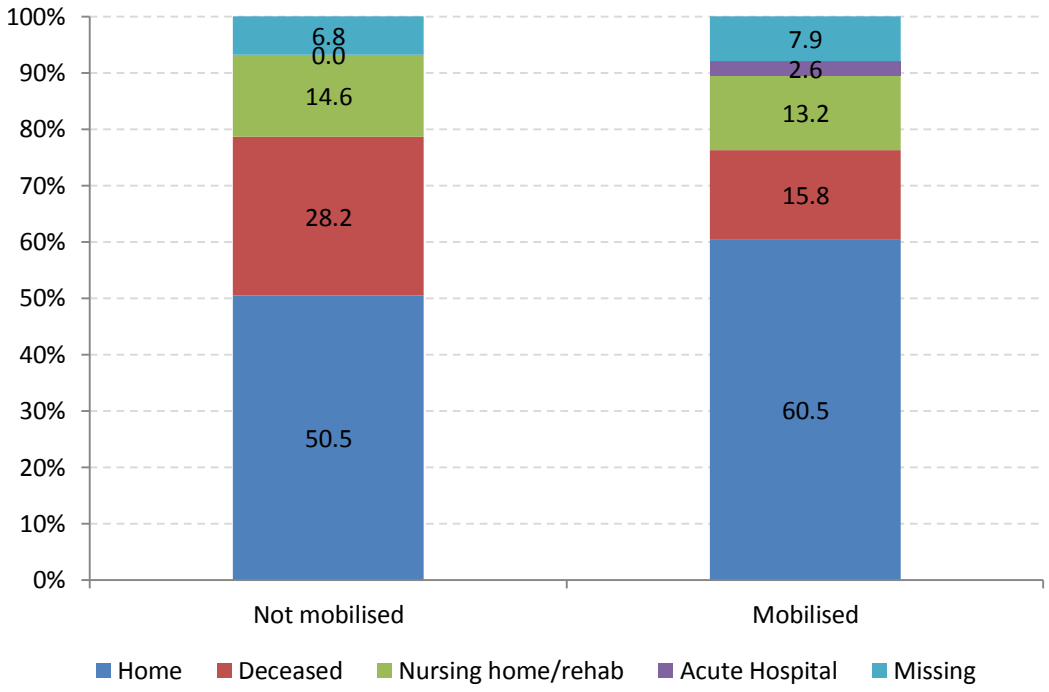


Figure 45 Discharge destination for Scottish patients who mobilised and did not mobilise



6.14.4 Sub groups

The discharge destinations for patients in each of the three sub groups for both Australian and Scottish cohorts are displayed in Figure 46 through to Figure 51.

For the diagnostic sub group (sub group 1), patients in the sepsis category for the Australian population showed the highest mortality and lowest rate of discharge home out of all Australian categories. For the Scottish cohort, patients with sepsis also had the highest mortality rate but the proportion of patients discharged home was second lowest, with patients in the cardiac category having the lowest rate of discharge home. Patients in the cardiac categories of Australia and Scotland behaved very differently. In Australia, these patients had the highest rate of discharge home and the lowest mortality in comparison to Scottish patients in the same category where the rate of discharge home was the lowest and mortality was the third highest.

For sub group 2, the proportion of patients discharged home from hospital was quite consistent between categories in the Scottish population. There was greater disparity between categories in the Australian cohort. Mortality for patients in

trauma categories was divergent with the rate for Australian trauma patients being 21.5% and Scottish trauma patients being zero.

APACHE II scores are used to predict outcome therefore it is to be expected that mortality rates increased as the APACHE II score increased. This was true in the Australian cohort. Small numbers in the APACHE II groupings for the Scottish cohort make results less meaningful; however they do follow the same general trend.

Figure 46 Diagnosis (sub group 1): discharge destination for each category of the Australian cohort in Study Three

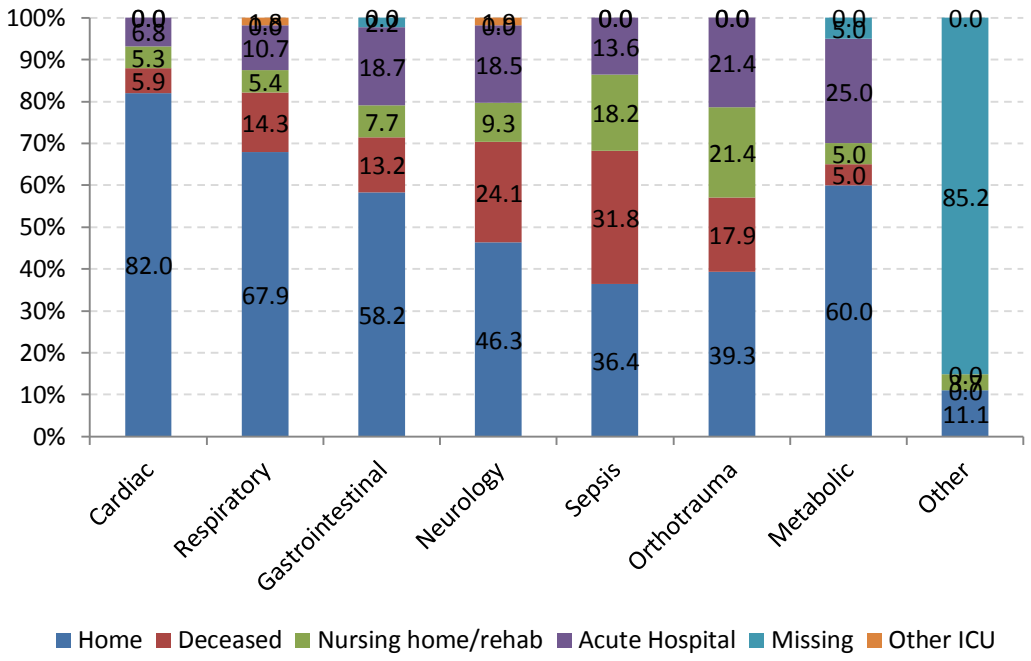


Figure 47 Diagnosis (sub group 1): discharge destination for each category of the Scottish cohort in Study Three

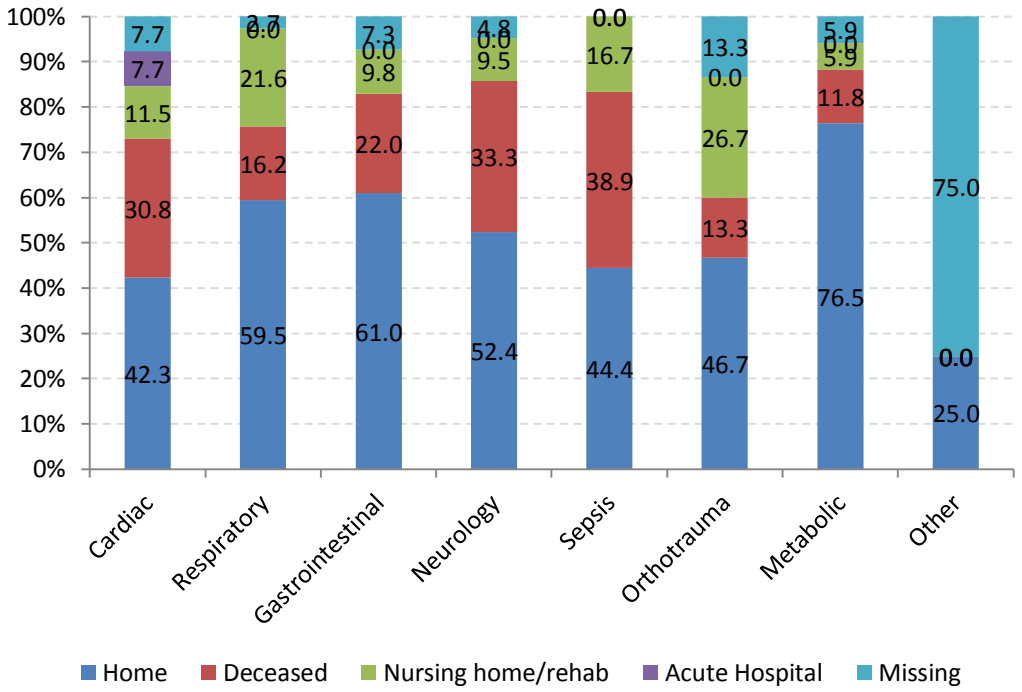


Figure 48 Classification (sub group 2): discharge destination for each category of the Australian cohort in Study Three

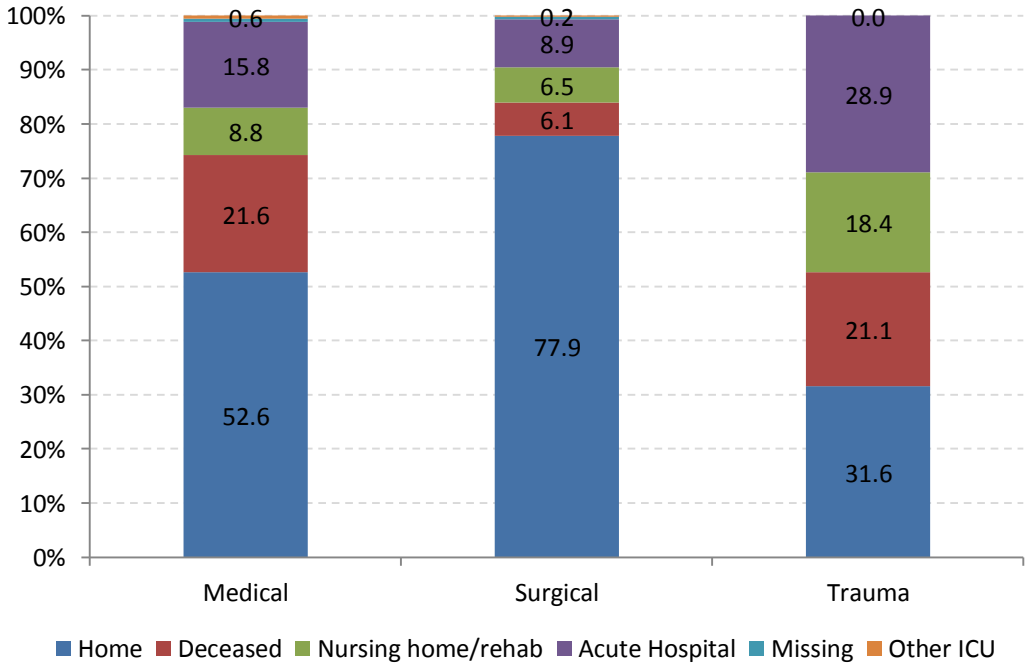


Figure 49 Classification (sub group 2): discharge destination for each category of the Scottish cohort in Study Three

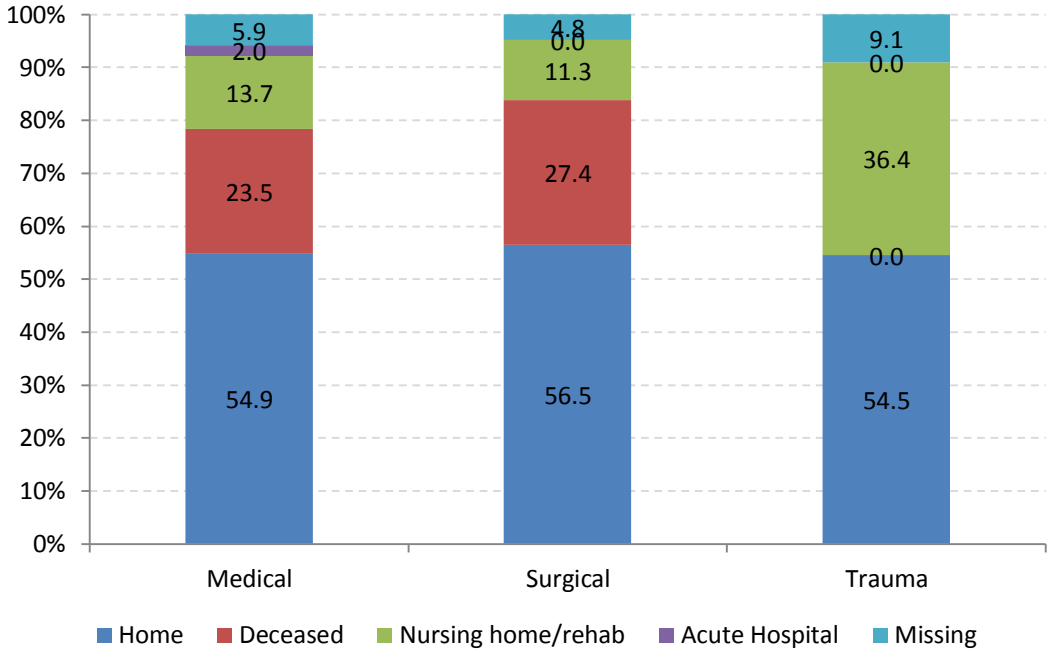


Figure 50 Severity of illness (sub group 3): discharge destination for each category of the Australian cohort in Study Three

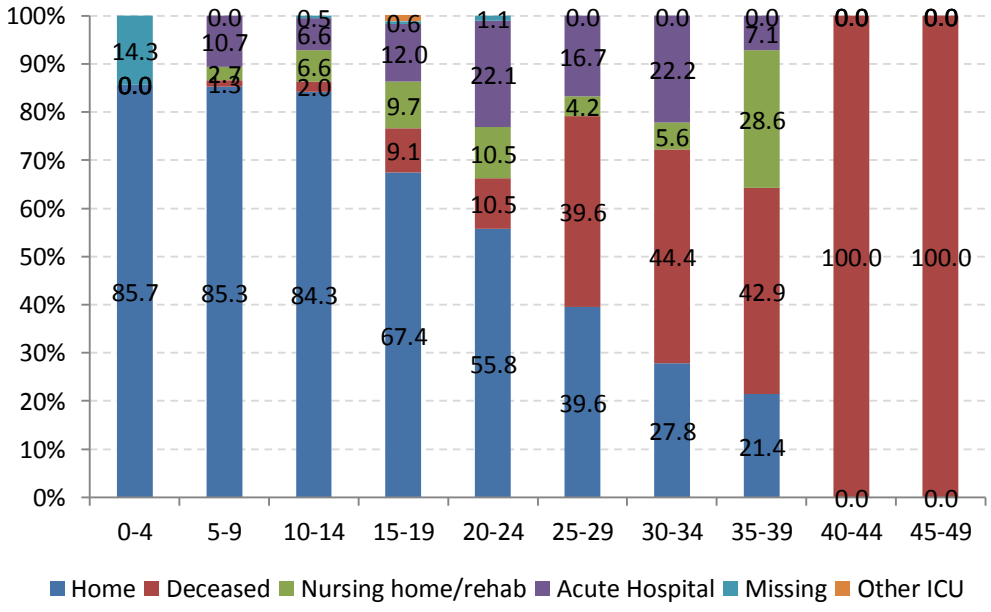
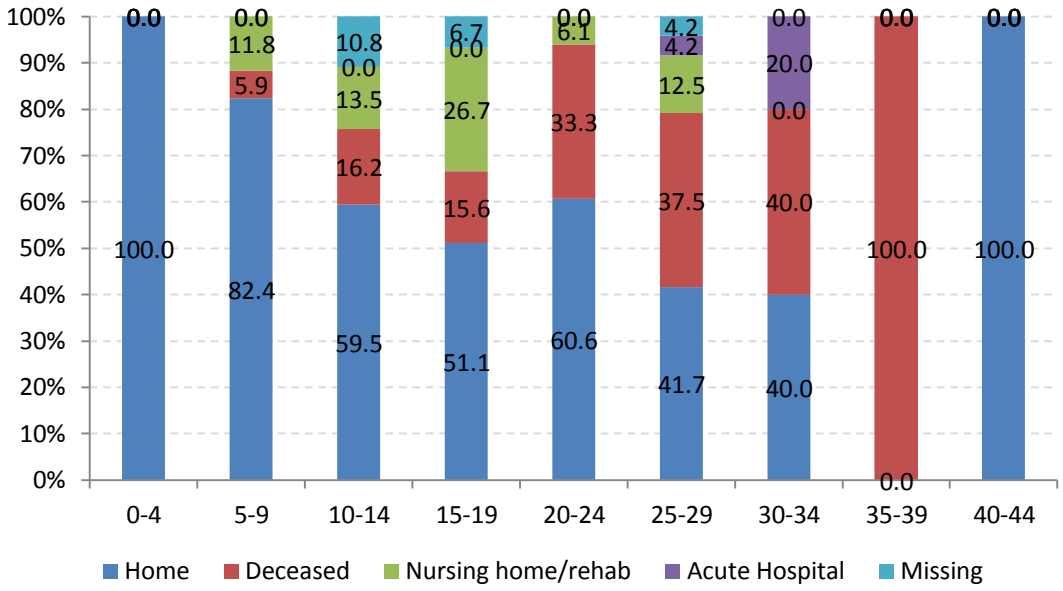


Figure 51 Severity of illness (sub group 3): discharge destination for each category of the Scottish cohort in Study Three



6.15 Safety

6.15.1 Overall safety

For this study, there were 50 adverse events recorded, 32 in the Australian population and 18 in the Scottish population. The adverse event rate for Australia equates to 3.2% (32 events / 996 episodes) and for Scotland is 6.2% (18 events / 292 episodes). These rates were found to be significantly different (p=.040).

6.15.2 Safety at each site

Adverse event rates ranged from 1.9% to 6.3% of episodes in Australian sites. A much larger range was seen in Scottish sites with rates ranging between 0% and 27.0% of episodes (Table 36 and 37).

Table 36 Adverse event rates for each Australian site in Study three

Site	N of patients	N of episodes an AE occurred	Adverse event rate%
1	2	2	2.1
2	3	3	3.9
3	2	2	4.4
4	7	7	6.3
5	6	7	2.4
6	1	1	2.2
7	5	5	4.1
8	2	2	1.9
9	1	1	4.0
10	2	2	5.3
Total	31	32	3.2

Table 37 Adverse event rates for each Scottish site in Study three

Site	N of patients	N of episodes an AE occurred	Adverse event rate%
1	2	10	27.0
2	1	2	3.8
3	3	3	3.3
4	0	0	0.0
5	0	0	0.0
6	1	1	5.6
7	1	1	2.9
8	1	1	5.0
9	0	0	0.0
Total	9	18	6.2

6.15.3 Safety within each sub group

Adverse event rates were calculated for each diagnostic specific category within sub group 1. The results for the Australian population are displayed in Table 38 and for the Scottish population in Table 39. Patients in the gastrointestinal category had the

highest adverse event rate (3.6%) and patients in the metabolic category had no adverse events.

The adverse event rate for the Scottish orthotrauma category appears disproportionately high at 20.0%. Both the number of events (five) and total numbers of episodes of mobilisation (25) were low in this category and therefore this rate is not likely to be an accurate representation.

Table 38 Diagnosis (sub group 1): adverse events in each category for the Australian cohort of Study Three

Diagnostic specific category	N of patients	N of episodes an AE occurred	Adverse event rate%
Cardiac	11	12	1.2
Respiratory	5	5	1.7
Gastrointestinal	8	8	3.6
Neurology	2	2	3.0
Sepsis	3	3	2.4
Orthotrauma	1	1	1.4
Metabolic	0	0	0
Missing	1	1	1.4

Table 39 Diagnosis (sub group 1): adverse events in each category for the Scottish cohort of Study Three

Diagnostic specific category	N of patients	N of episodes an AE occurred	Adverse event rate
Cardiac	1	1	1.0
Respiratory	2	2	2.1
Gastrointestinal	2	2	1.8
Neurology	1	2	6.1
Sepsis	1	6	6.7
Orthotrauma	2	5	20.0
Metabolic	0	0	0
Missing	0	0	0

Adverse events for Australian patients in sub group 2 were relatively consistent between categories. The trauma category of the Scottish cohort recorded a high adverse event rate once again due to low overall numbers (see Table 40 and 41).

Table 40 Classification (sub group 2): adverse events in each category for the Australian cohort of Study Three

Diagnostic specific category	N of patients	N of episodes an AE occurred	Adverse event rate
Medical	8	8	1.3
Surgical	21	22	1.9
Trauma	1	1	1.9
Missing	1	1	1.4

Table 41 Classification (sub group 2): adverse events in each category for the Scottish cohort of Study Three

Diagnostic specific category	N of patients	N of episodes an AE occurred	Adverse event rate
Medical	3	8	3.1
Surgical	5	6	3.0
Trauma	1	4	21.0
Missing	0	0	0

Adverse events for severity of illness groupings were low and consistent across categories in the Australian population. For Scottish patients, a higher adverse event rate was seen in the 20-24 category. The adverse event rate for the higher APACHE II category was considerably lower at 2.1% showing no relationship between APACHE II score and adverse event rate (see Table 42 and 43).

Table 42 Severity of illness (sub group 3): adverse events within each category for the Australian cohort of Study Three

APACHE II group	N of patients	N of episodes an AE occurred	Adverse event rate
5-9	2	2	1.6
10-14	10	10	2.0
15-19	6	7	1.3
20-24	7	7	1.7
25-29	3	3	1.8
30-34	1	1	5.0
35-39	1	1	2.6
Missing	1	1	1.2

Table 43 Severity of illness (sub group 3): adverse events within each category for the Scottish cohort of Study Three

APACHE II group	N of patients	N of episodes an AE occurred	Adverse event rate
10-14	3	4	3.60
15-19	1	4	4.12
20-24	3	8	10.26
25-29	2	2	2.11

6.15.4 Safety of patients receiving ETT, RRT and / or vasopressors

Adverse events in the presence of an ETT, RRT or vasopressor infusions were rare and are therefore reported descriptively. There were no adverse events in the Australian and one in the Scottish population for patients mobilising with an ETT (patient refused to participate in mobilisation). For patients with RRT, the Australian cohort recorded one adverse event (patient refusal) and no events occurred in the Scotland cohort. Patients treated with vasopressor infusions mobilised more frequently and had slightly higher numbers of adverse events. Scotland reported two episodes where the patient's vasopressor infusions needed to be increased. Australian patients reported eight episodes. These were: two episodes of increased vasopressor requirements, three episodes where the patient returned to bed due to cardiovascular system instability, one increase in fraction of inspired oxygen, one dislodgement (but not removal of) a vascular catheter, one episode where the patient returned to bed due to central nervous system instability and one episode where the patient returned to bed due to low oxygen saturations.

6.16 Barriers to mobilisation

Barriers to mobilisation for all patients in Study Three are shown in Table 44 for Australian patients and Table 45 for Scottish patients. The number of barriers reported per patient was higher in the Scottish population at 8.9 barriers per patient than in the Australian population (5.2 barriers/patient p=.012).

The most common barrier in both cohorts was sedation. This barrier affected a much larger percentage of patients than other barriers. After sedation, cardiovascular instability was the next largest barrier affecting patients in Scotland

and the third largest barrier in Australian patients. The presence of an ETT was a noticeable barrier for Australian patients (second largest) but less so in Scottish populations (sixth largest).

Table 44 Barriers to mobilisation for all Australian patients in Study three

Barrier	N of Pts (%)	Barriers/pt
Procedure	81 (12.2)	0.2
Sedation	408 (61.4)	1.6
CNS unstable	103 (15.5)	0.5
CVS unstable	239 (35.9)	0.8
Respiratory unstable	61 (9.2)	0.3
Orthopaedic orders	48 (7.2)	0.3
Decline	14 (2.1)	0.0
Lack of resources	37 (5.6)	0.1
ETT in situ	243 (36.5)	1.0
Diarrhoea	7 (1.1)	0.0
Coma	44 (6.6)	0.2
Imminent death	44 (6.6)	0.1
Dialysis	29 (4.4)	0.2
Transfer to ward	6 (0.9)	0.0
Fatigue	1 (0.2)	0.0
Total	665 (100)	5.2

Table 45 Barriers to mobilisation for all Scottish patients in Study three

Barrier	N of Pts (%)	Barriers/pt
Procedure	59 (33.0)	1.7
Sedation	135 (75.4)	3.5
CNS unstable	53 (29.6)	2.4
CVS unstable	80 (44.7)	3.2
Respiratory unstable	52 (29.1)	3.2
Orthopaedic orders	11 (6.1)	7.0
Decline	10 (5.6)	1.2
Lack of resources	24 (13.4)	2.5
ETT in situ	33 (18.4)	2.5
Diarrhoea	4 (2.2)	1.5
Coma	25 (14.0)	2.7
Imminent death	25 (14.0)	1.5
Dialysis	16 (8.9)	4.5
Transfer to ward	23 (12.8)	1.2
Fatigue	10 (5.6)	2.1
Total	179 (100)	8.9

Barriers for patients who never mobilised during their ICU stay are outlined in Table 46 for Australian patients and in Table 47 for Scottish patients. The number of barriers per patient for Australian patients was 7.8 barriers per patient which is higher than that found for all patients in the Australian cohort and was 6.7 barriers per patient for Scottish patients which is lower than that found for all patients in the Scottish cohort.

The top three barriers to mobilisation for Australian patients were similar to the whole population with slightly different order (Sedation, cardiovascular instability and ETT in situ). The top two barriers for Scottish patients who did not mobilise were the same as for the whole population and affected a similar proportion of patients. The third largest barrier for patients who did not mobilise was CNS instability affecting 28.2% of patients.

Table 46 Barriers to mobilisation for Australian patients not mobilised in Study three

Barrier	N of Pts (%)	Barriers/pt
Procedure	34 (16.4)	0.3
Sedation	129 (62.3)	1.9
CNS unstable	55 (26.6)	0.8
CVS unstable	80 (38.6)	1.2
Respiratory unstable	20 (9.7)	0.3
Orthopaedic orders	33 (15.9)	0.8
Decline	8 (3.9)	0.0
Lack of resources	23 (11.1)	0.1
ETT in all	68 (32.9)	1.3
Diarrhoea	2 (1.0)	0.0
Coma	29 (14.0)	0.5
Imminent death	39 (18.8)	0.3
Dialysis	16 (7.7)	0.3
Transfer to ward	4 (1.9)	0.0
Fatigue	0 (0.0)	0.0
Total	207 (100)	7.8

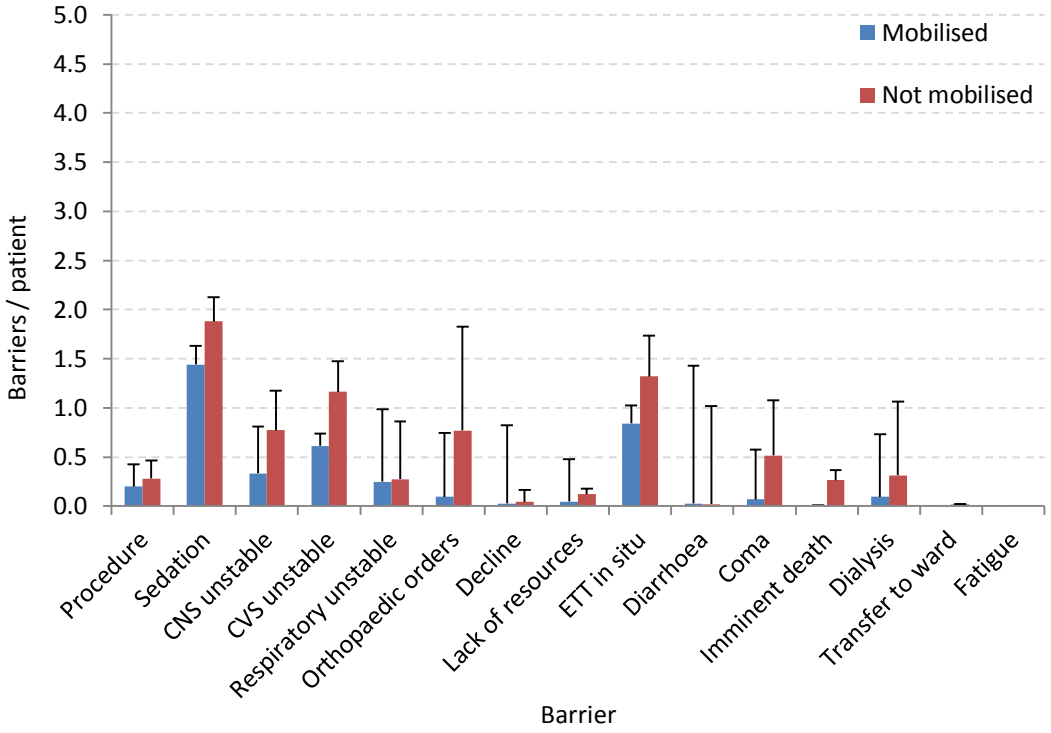
Table 47 Barriers to mobilisation for Scottish patients not mobilised in Study three

Barrier	N of Pts (%)	Barriers/pt
Procedure	25 (24.3)	1.6
Sedation	75 (72.8)	2.7
CNS unstable	29 (28.2)	2.0
CVS unstable	44 (42.7)	2.5
Respiratory unstable	26 (25.2)	2.5
Orthopaedic orders	9 (8.7)	6.4
Decline	2 (1.9)	1.0
Lack of resources	9 (8.7)	1.1
ETT in all	20 (19.4)	1.9
Diarrhoea	0	0
Coma	15 (14.6)	1.9
Imminent death	22 (21.4)	1.4
Dialysis	11 (10.7)	2.7
Transfer to ward	18 (17.5)	1.1
Fatigue	1 (1.0)	1.0
Total	103 (100)	6.7

To compare barriers per patient in those who did and did not mobilise, results were graphed for the Australian and Scottish cohorts in Figure 52 and Figure 53. Note the differences in axis.

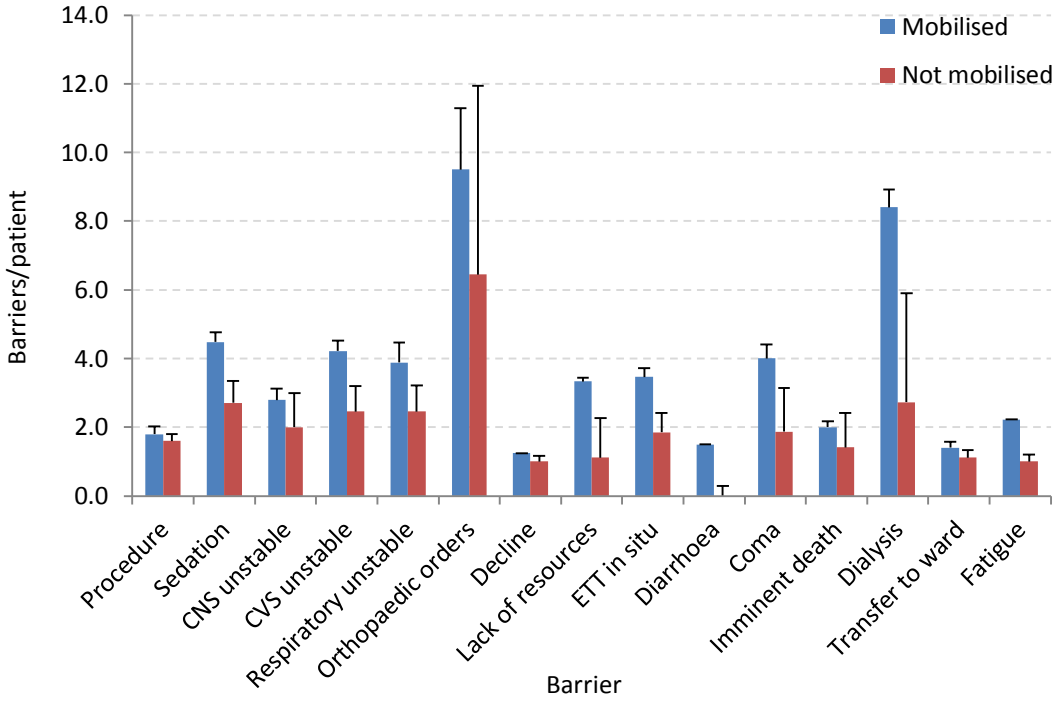
Patients who did mobilise in Scotland had more barriers per patient (11.8) than those who did not mobilise (6.7). This is opposite to that experienced in the Australian cohort. For Australia, patients who did mobilise recorded 4.1 barriers per patient and those who didn't mobilise had 7.8 barriers per patient.

Figure 52 Barriers per patient for Australian patients who did and did not mobilise in Study three



Note: error bars represent standard error

Figure 53 Barriers per patient for Scottish patients who did and did not mobilise in Study three



Note: error bars represent standard error

Avoidable or partly modifiable barriers constituted 60.2% of barriers in the Australian population and 53.2% in the Scottish population. Barriers seen to be unavoidable therefore made up 39.2% of barriers in the Australian population and 47.8% in Scottish populations.

6.17 Summary

At the conclusion of this study, data was collected on 665 patients across 10 Australian ICUs and nine Scottish ICUs. This is the first study to examine baseline practice of early mobilisation nationally and benchmark it internationally.

Patients in the Australian cohort were more likely to mobilise than patients in the Scottish cohort. However, the number of activities and episodes of mobilisation per patient that mobilised was higher in the Scottish cohort. With finite resources available to both cohorts, there appears to be different approaches in how to distribute these. In the Australian cohort there appears to be more patients

mobilised, but at a lower rate and in the Scottish cohort less patients mobilise but those who do, work at a higher rate.

The overwhelming observation from this study is that while there are common themes in mobilisation work practices, patients of different diagnoses, classification and severity of illness vary in the frequency and duration of mobilisation activities carried out in ICU.

Results from this study are in alignment with those from Study One that shows an association between patients who mobilise and better discharge destination from hospital.

Adverse event rates were low in both the Scottish and Australian cohorts. Adverse events that were recorded rarely required medical intervention. Patients who did experience an adverse event continued to mobilise on subsequent days which leads to the belief that the adverse events recorded were in fact transient instability rather than harmful events.

Sedation remained the most commonly reported barrier in both the Scottish and Australian cohort. A higher percentage of patients experienced sedation as a barrier in the Scottish cohort. Physiological instability and the presence of an ETT were also frequently reported barriers.

Chapter 7 Discussion

This chapter will focus on the results of all studies in this program of research. The thesis aims outlined in Chapter 3 will form the sub headings of this chapter and help guide the discussion.

7.1 Introduction

Mortality rates in ICU have been progressively improving and with this there has been an increased focus on improving functional ability of those who survive (Eddleston, White et al. 2000; Hodgin, Nordon Craft et al. 2009; Herridge, Tansey et al. 2011; Adler and Malone 2012; Needham, Davidson et al. 2012). Muscle weakness heavily impacts upon function and is a serious side effect of critical illness (Carson, Bach et al. 1999; Eddleston, White et al. 2000; Rubenfeld 2002; Herridge, Cheung et al. 2003; Dowdy, Eid et al. 2005; Cheung, Tansey et al. 2006; Herridge 2009; Herridge, Tansey et al. 2011). Early mobilisation as an intervention in intensive care is an evolving therapy aimed to attenuate weakness often experienced by patients admitted to intensive care. The extent of the direct and indirect impacts of early mobilisation has not yet been established. The majority of studies examining early mobilisation as an intervention in ICU have been published in the past 10 years (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). Indeed, four of the seven studies on efficacy were published after the start of data collection for this thesis (Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010).

To date there have been very few studies examining early mobilisation in acute critically ill patients. The studies that have been conducted focus primarily on patients with respiratory failure (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Schweickert, Pohlman et al. 2009; Needham and Korupolu 2010). The program of research described in this thesis is the first to describe early mobilisation in a heterogeneous patient population. It examines a

systems change in a single ICU that allowed improved mobilisation levels for all mechanically ventilated patients. As well, there is reporting of baseline levels of mobilisation nationally in Australia. Finally, benchmarking of these rates internationally with Scottish ICUs was achieved. Previously there has been no reporting of baseline mobilisation levels for all mechanically ventilated patients in ICUs nationally or internationally.

Results from this thesis will assist in two areas. Firstly, to inform future system changes in ICU involving whole of workforce practices and secondly to provide a basis from which to design a valid and generalizable randomised controlled trial examining the influence of mobilisation on patient centred outcomes.

Early mobilisation has evolved during the time taken to conduct this program of research. Through formal ethics applications and conference presentations to informal meetings with clinicians, knowledge of what is involved in early mobilisation of mechanically ventilated patients has improved. Conducting two studies around Australia, one with the ANZICS CTG, which measured early mobilisation levels, may have inadvertently altered work practices in Australia. There is now a raised level of awareness among the workforce regarding mobilisation in the ICU and a questioning of the parameters required to safely conduct this therapy.

7.2 Definition of early mobilisation

The term ‘early mobilisation’ has been used in the literature quite broadly and is often used interchangeably with terms such as rehabilitation, ambulation and exercise in ICU. To progress this area of research, a clear definition was required. The two key aspects to the definition are what timing constitutes mobilisation as being ‘early’, and what activities come under the umbrella of mobilisation. After review of the literature, ‘early’ was defined as within ICU when the patient is physiologically stable. The definition of physiological stability is more complex and should involve collaboration with members of the MDT at the unit level to determine what parameters are deemed acceptable.

Activities that constitute mobilisation included those where movement was against gravity and involved axial loading of the spine and / or long bones. These activities, in hierarchical order of difficulty from lowest to highest were: sitting over the edge of the bed, sitting in a chair, utilisation of a tilt table to 40 degrees or greater, standing and ambulating. Patients can utilise anything from no assistance to maximal assistance to achieve these activities.

The definition of early mobilisation outlined above was used for all studies in this thesis. Both aspects of 'early' and 'mobilisation' in the control and intervention arms of the study were documented in Study One. The importance of documenting standard care for future trials formed the basis of Study Two and study three.

7.2.1 Change in mobilisation practice

Loss of muscle mass in patients requiring care in ICU is noticeable within days of admission (Hudson and Lee 2003; Robson 2003; Winkelman 2004; Foster 2005; Winkelman 2007; Chambers, Moylan et al. 2009; Vincent and Norrenberg 2009; Griffiths and Hall 2010). Patients in ICU experience a decrease in the number and size of muscle contractions whilst critically unwell due to a combination of sedation and bed rest (Bloomfield 1997; Bamman, Clarke et al. 1998; de Letter, Schmitz et al. 2001; Topp, Ditmyer et al. 2002; Levine, Nguyen et al. 2008; Powers, Kavazis et al. 2009). There is a physiological rationale for why mobilisation may reverse or slow the rate of this muscle loss (Brower 2009). As yet there is no definitive proof of this or even if mobilisation of mechanically ventilated patients can be achieved outside the respiratory failure patient population. Study One is the first study to report mobilisation rates before and after implementation of a targeted early mobilisation program for patients in a heterogeneous patient population. Intensive care units are complex workplace settings and it is critical to demonstrate that implementation strategies can change practice.

At the conclusion of Study One a significant increase in the percentage of patients mobilised was achieved. Proportions of patients who mobilised rose from 53.9% to 64.6% of all patients and from 63.3% to 79.9% for patients that had the opportunity to mobilise. Processes that were implemented during the systems change involved

clarification of communication channels and acceptance of mobilisation of patients with ETTs, RRT and vasopressor infusions. Improved communication has been a common element in previous studies that have implemented a change in practice (Bailey, Thomsen et al. 2007; Thomsen, Snow et al. 2008; Bailey, Miller et al. 2009; Needham and Korupolu 2010). Mobilisation of patients with ETTs, RRT and vasopressor infusions has not specifically been targeted in prior research. However, Needham et al.(2010) described their technique to achieve improved mobilisation rates was to first identify areas in need of improvement and address them formally. This was a key component to the success of their study. Importantly, Study One was conducted prior to this study being reported and also validates these findings. Mobilisation with ETTs, RRT and vasopressor infusions had been identified as an area for improvement at RPH and hence it was a target of the early mobilisation program.

In previous ICU studies, culture has been shown in previous studies to influence mobilisation practices (Thomsen, Snow et al. 2008; Needham and Korupolu 2010). High levels of enthusiasm towards this study in the three key professions within the MDT at RPH ICU is thought to have positively influenced work practices but the size of this influence is difficult to measure. Consensus of the different focus points of each profession within the MDT gave a more patient focused approach to mobilisation. The increase in the percentage of patients mobilised is likely to be due to a combination of changes to process and culture but also an unknown proportion must be apportioned to a Hawthorne effect of conducting a study with no blinding. Future studies examining sustained changes in work practices will verify this.

Although attitudes towards mobilisation among staff were positive prior to the study, practice at RPH ICU changed with the implementation of an early mobilisation program in two ways. First, there was an increase in the volume of mobilisation conducted seen by the significant rise in the proportion of patients mobilised (20%) as well as a non-significant rise in the number of minutes of mobilisation for this increased proportion of patients. The second change seen was a trend towards mobilisation of patients with a higher severity of illness. Graphing of the proportion of patients mobilised in each APACHE II category for Phase 2

resulted in a bell shaped curve where patients at either end of the APACHE II spectrum were mobilised less than the middle categories (Figure 13). Graphing of the same proportions for Phase 3 showed increases in all categories as well as more consistent rates across all APACHE II categories. After implementation, the average APACHE II score of patients who mobilised increased. This may reflect the fact that there is a specific limited capacity of the workforce and therapists may preferentially mobilise patients with greater illness severity. Future studies examining mobilisation will need to consider controlling for severity of illness and diagnosis.

Examination of the workload as a total entity showed a shift of activity towards the higher APACHE II categories (see Figure 18) which was sustained over a 12 month period. Thomsen et al.(2008) conducted the only other study of similar time period (12 months) that examined a systems change targeting increased mobilisation levels. Mobilisation rates in Thomsen et al.'s (2008) study were sustained at a higher level however, patients were of a single diagnostic category (respiratory) only. Study One of this thesis is the first study to document sustained change in mobilisation practices for all patients mechanically ventilated for more than three calendar days.

Increases in mobilisation rates of selected ICU patient populations have previously been achieved by increases in staffing (Morris, Goad et al. 2008; Schweickert, Pohlman et al. 2009; Needham and Korupolu 2010). Study One was conducted with no increase in staffing or resources and managed to increase the proportion of patients mobilised and increase, although not significantly, the number of episodes (frequency), activities (intensity) and minutes (duration) of mobilisation per patient. With no increase in staffing, it appears that workforce efforts of the MDT were directed towards increasing the number of patients who achieved mobilisation and maintaining the frequency and intensity of the exercise prescribed to all patients. Alternative aspects of physiotherapy were not measured during this study. Therefore, it is difficult to know if the increase in mobilisation came at the cost of other treatments such as respiratory care. Proportions of patients mobilised post

implementation in Study One are comparable with results seen at the conclusion of Morris et al.'s (2008) study.

Mobilisation with ETTs, RRT and vasopressor infusions

No guidelines or evidence exists for safe mobilisation of patients with ETTs, RRT and / or vasopressors. Studies frequently refrain from mentioning these practices. Opinion articles have previously documented 'readiness' criteria for mobilisation within the ICU and included statements about mobilisation with each therapy (Stiller and Phillips 2003; Hopkins, Spuhler et al. 2007; Stiller 2007; Timmerman 2007; Perme and Chandrashekar 2008; Hanekom, Gosselink et al. 2011; Herridge, Batt et al. 2013). However, there is no consensus view. Even if consensus of guidelines was present, the implementation of mobilisation with these therapies would not be uniform as each patient in ICU is its own case.

Patients mobilising with ETTs increased significantly in Study one. After implementation of the early mobilisation program, 14.1% of patients mobilised with an ETT where only one patient (1.0%) mobilised with an ETT prior to implementation. Achieving safe increases in the proportion of patients mobilising with an ETT is in line with literature for the respiratory failure patient population (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008). Results from Study One show that ETTs are not a contraindication to mobilisation. This does not mean all patients with an ETT in situ can be safely mobilised, it merely shows that if a therapist chooses to mobilise a patient who has an ETT in situ, it is associated with a low rate of adverse events. Further investigation into how therapists chose who is appropriate to be mobilised needs to be conducted.

Mobilisation with vasopressor infusions has had the most documentation in previous papers and views range from supporting the practice (Morris, Goad et al. 2008; Schweickert, Pohlman et al. 2009), supporting the practice but with constraints on the dose of vasopressors (Timmerman 2007; Perme and Chandrashekar 2008; Burtin, Clerckx et al. 2009), to not supporting the practice at all (Bailey, Thomsen et al. 2007; Hopkins, Spuhler et al. 2007; Bourdin, Barbier et al. 2010). Study One showed a significant increase in the proportion of patients who

mobilised with vasopressor infusions (13.4%). Previously this practice had not occurred at RPH ICU. This is the first study we are aware of to describe the achievement of this in a heterogeneous ICU patient population. This change in practice allowed patients to be mobilised sooner and more often.

Schweickert et al.(2009) supported mobilisation with continuous RRT but not intermittent haemodialysis and neglected to document rates of mobilisation with RRT. Patients in Study One who mobilised with RRT increased after study implementation but this did not reach statistical significance due to low numbers of patients receiving this therapy. Comparative studies in this field cannot be found and further research is required to document mobilisation practices of patients with RRT.

This thesis is the first to document mobilisation levels in the presence of ETTs, RRT and vasopressor infusions. The fact that not all patients with these therapies did mobilise suggests there are additional factors in why patients being treated with these therapies are not mobilised. This is raises the issue of barriers to mobilisation and indicates why it is vital that barriers are identified and quantified.

Day first mobilised

Exercise prescription is one of the most common forms of rehabilitation. The safe dose of mobilisation resulting in the optimal outcome for patients will rely on the known principles of prescription: type, frequency, intensity and duration (http://www.ncwc.edu/academics/divisions/math-sci/ex-sci/prescription.php). What is fundamental to exercise prescription in *ICU* is the more temporal element of prescribing exercise which is when can it be initiated and how soon can it be progressed. For example, sitting out of bed at day 4 of a patient's ICU stay is likely to produce different outcomes to the same activity being carried out at day 14.

Previous literature has reported when mobilisation was initiated for patients in the respiratory failure population but not in a heterogeneous patient population (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Schweickert, Pohlman et al. 2009). Study One showed for patients who were mechanically ventilated for 3 or more calendar days the median times to

mobilisation were 5.1 days in Phase 2 and 4.9 days in Phase 3 of the study. With the systems change this meant an additional 20% of patients, who were of a higher severity of illness, safely mobilised at approximately the fifth day of their admission. This information will help to inform future clinical practice to determine safe timing of early mobilisation.

7.2.2 Sub groups

One of the difficulties of interpreting the thematic elements of the limited literature on mobilisation in ICU is that there are different sub-groups of focus represented in the literature. This thesis has not only recognised these issues but has analysed mobilisation in the context of three of the most common sub-group breakdowns: diagnosis; classification and illness severity.

Diagnosis (sub group 1)

Statistically significant increases in the percentage of patients mobilised were noted in sub group 1 for patients in the orthotrauma category. Patients admitted with orthopaedic or traumatic injuries are frequently excluded from studies examining early mobilisation (Bailey, Thomsen et al. 2007; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009). The increase in percentage of patients mobilised in the orthotrauma category was unexpected but opens up new possibilities for research in this area. It is unclear as to what specific change helped to achieve this result, but may be due to improved communication between medical staff and surgeons on deciding the appropriateness of rest in bed orders and the MDT working together to achieve rehabilitation that involves more than one discipline of the team.

Patients in the respiratory category experienced the highest number of episodes, activities, weight bearing activities and minutes per patient mobilised. This category also saw the highest proportion of patients mobilised (84.3% of all patients, 89.2% of those who had the opportunity to mobilise). The high rates in the respiratory category are not solely due to an above average length of stay but more likely due to the change in guidelines that allowed patients with ETTs, RRT and vasopressors

to mobilise. This is supported by the large number of patients who mobilised with these three therapies.

The proportion of patients in the respiratory category of this study who mobilised is comparable with those described in Morris et al.'s (2008) study (80%) and Needham et al.'s (2010) study (93%) who had similar or higher APACHE II scores. Clearly, the respiratory category of the ICU population, in which the majority of the early mobilisation research has been undertaken, has the highest rate of mobilisation. Therefore, change in practice within this category is not likely to appear as dramatic as in other categories.

Patients admitted for gastrointestinal or sepsis concerns experienced the next highest number of episodes, activities, weight bearing activities and minutes of mobilisation per patient. This category of patients had a higher than average length of stay in ICU but high activity levels witnessed are likely to be due to physiotherapy staff perceiving these two groups of patients required early mobilisation as a high priority due to knowledge of the pathological processes involved with sepsis and muscle wasting. Patients with sepsis had the highest rate of patients mobilising on mechanical ventilation, closely followed by patients in the respiratory and gastrointestinal categories. Currently, no literature is available that examines these two sub groups of patients. The potential for improvement in mobilisation rates in these patients is large and warrants further attention in future studies.

Patients admitted for neurological reasons showed a decrease in patients who mobilised. Severity of illness was markedly higher for patients in Phase 3 of the study (Phase 2 APACHE II score – 16; Phase 3 APACHE II score – 22). This increase in severity of illness may account for the decrease in patients able to safely mobilise.

Mobilisation with ETTs, RRT and vasopressor infusions in this sub group mirrored those of the whole group. Significant increases in the proportion of patients who mobilised with ETTs were seen in patients in the respiratory, sepsis and gastrointestinal categories. Only patients in the respiratory category showed significant increase in proportion of patients mobilised with vasopressor infusions. The small number of patients receiving vasopressor infusions in Phase 2 of the study

may have influenced this result. Low numbers in Phase 2 is again likely to explain the non-significance of the increases in proportion of patients mobilised with RRT.

The safe mobilisation of patients with ETTs and vasopressor infusions in the respiratory category is consistent with existing literature in this area (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Schweickert, Pohlman et al. 2009). What has not previously been shown is the safe and feasible practice of mobilisation of patients with ETTs and vasopressor infusions in patients admitted with sepsis and gastrointestinal concerns. This success can assist in informing future clinical practice.

Classification (sub group 2)

The surgical and trauma categories of this sub group saw a significant increase in the proportion of patients mobilised. The ICU surgical patient population as a whole has not been examined previously. Of the seven studies in this area, six were conducted in respiratory or medical ICUs or did not have any surgical admissions during the study period (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). The remaining study (Burtin, Clerckx et al. 2009) focused on in bed cycle ergometry and did not aim to mobilise patients out of bed. Therefore, there is little data with which to compare these results to. It is probable that the increase seen in the percentage of surgical patients mobilised in Phase 3 was achieved by allowing patients with vasoactive infusions in situ to mobilise given the large number of patients requiring these medications.

As discussed for patients in the orthotrauma category of the diagnostic sub group, patients in the trauma category of the classification sub group showed a surprising increase in proportion of patients mobilised. Patients admitted with traumatic injuries have not previously been examined in robust trials but this should not rule them out for assessment of readiness to mobilise in a clinical setting.

In this study, the proportion of medical patients who mobilised did not increase significantly. This fails to confer with previous results described in the literature (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008;

Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). The percentage of patients mobilised in the medical category was above the average of the whole group prior to implementation of change. It may be that patients in this category were already achieving positive results and significant change above this level was difficult to achieve.

Patients in the medical category of this sub group experienced the highest number of episodes, activities, weight bearing activities, episodes on mechanical ventilation and minutes of mobilisation per patient. This was closely followed by the surgical category.

Significant increases were seen in the percentage of patients mobilised and number of episodes of mobilisation with ETTs and vasopressor infusions in situ for the medical and surgical categories. The practice of mobilising patients with ETTs and vasopressor infusions has been shown possible in medical patients (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008; Schweickert, Pohlman et al. 2009) but this study is the first to show feasibility and significant improvement in rates among patients admitted for surgical reasons. Larger studies are required to determine practice of mobilisation with RRT in these categories.

Severity of illness (sub group 3)

The APACHE II score is a commonly used measure of severity of illness and correlates closely with mortality (Knaus, Draper et al. 1985). The pattern of mobilisation for APACHE II categories differed between Phase 2 and 3. The proportion of patients mobilised within each category for Phase 2 appeared bell shaped with the highest proportion of patients mobilised in category 25-29 and lower percentages of mobilisation for categories either side of this. A relatively consistent proportion of patients were mobilised for all categories in Phase 3. The average APACHE II score of patients who mobilised increased from 20.2 to 23.1 in Phase 3. This result demonstrates the change in practice towards mobilisation of more severely ill patients that occurred with implementation of the study.

Substantial increases in the number of episodes, activities, weight bearing activities and minutes of mobilisation were seen in higher APACHE II groupings of Phase 3.

The prevalence of RRT and vasopressor infusions increased in the higher APACHE II categories. The change in policies surrounding these therapies at RPH allowed mobilisation rates to improve in the higher categories more so than in the lower categories. Previous studies have not examined the influence of severity of illness on mobilisation rates in mechanically ventilated patients. Future studies should observe and document if these changes are influenced by policy change, additional staffing or changes in culture.

7.2.3 Change across the three studies

Royal Perth Hospital ICU was the only unit to participate in all three studies. This provides a unique opportunity to compare rates of mobilisation recorded using different study designs. Chronologically, Study One was concluded approximately six months prior to Study Two and two years prior to Study three. The overall percentage of RPH patients who mobilised varied between all studies from 53.9% in phase 2 and 64.6% in phase 3 of Study One, 40.0% in Study 2 and 59.5% in Study three.

Study One aimed to implement a systems change with regard to mobilisation practices. At the conclusion of the study mobilisation rates were increased. The carry over effect of Study One can be seen two years later in the results of Study three. The proportion of patients mobilised was mid-way between Phase 2 and Phase 3 rates. After the intense period of change was over at the conclusion of Study One, it is positive to see that although rates dropped, the proportion of patients mobilised did not return to baseline. The number of activities and episodes each patient received did not alter significantly between Study One and Study Three but the percentage of patients who participated in weight bearing activities did rise in Study three. The influence of case mix changes must be taken into account, but from these results it appears workforce efforts were directed towards increasing intensity of mobilisation activities for those patients who were mobilised rather than the proportion of patients mobilised. With a finite amount of resources there will always be a compromise between the numbers of patients mobilised and the intensity of activity conducted.

The point prevalence design indicates the proportion of patients mobilised on one day. Per day rates will always be lower than rates seen across a patient's total length of stay. The proportion of patients mobilised at RPH in Study Two was 40.0%. This was comparable with the median rate of all sites in Study Two. Rates for RPH in Study Three were also comparable with the median of all sites. So capture of the percentage of patients who mobilised on one day or the percentage of patients who mobilised at any stage during their whole length of stay varied but the relative position of the workforce practices when compared to other ICUs remained consistent. The point prevalence study design may not be strong enough to draw many other conclusions from.

The number of activities, episodes and minutes of mobilisation recorded at RPH ICU in Study 3 were above average in comparison to other sites. Case mix is an obvious variable that influences which patients are able to mobilise, but once it is decided a patient is safe to mobilise, case mix plays less of an influence on the frequency and intensity of mobilisation delivered. Length of stay of patients will influence the number of opportunities for mobilisation, however if this is comparable between sites, intensity and frequency of activities can be compared. When comparing sites with similar lengths of stay in ICU, RPH has one of the highest rates of activities, episodes and minutes of mobilisation, second only to site 10.

Mobilisation of patients with RRT and vasopressor infusions remained consistent and high between Phase 3 of Study One, Study 2 and Study three. However, mobilisation of patients with ETTs decreased substantially from 14.1% in Study One to 0% in Study 2 and to 2.9% in Study three. The practice of mobilisation of patients with ETTs clearly did not embed into standard practice at RPH ICU.

7.3 Baseline practice of mobilisation: Australia and Scotland

7.3.1 Introduction

Mobilisation rates for patients admitted to Australian ICUs were measured in Study Two and three using different study designs. The point prevalence study measured mobilisation events for all patients regardless of whether they had received

mechanical ventilation. This data was collected for one day and represents the prevalence of mobilisation but not incidence. Study Three examined patients in intensive care who had received mechanical ventilation at any stage and whose whole length of stay was captured during the study period. Capturing patient's total length of stay allows for the reporting of both prevalence and incidence of mobilisation.

Mobilisation practices in Scottish ICUs were observed in Study 3 only.

7.3.2 Overall mobilisation rates

Overall, the percentage of patients who mobilised in the 10 Australian ICUs studied was 68.9% and in the nine Scottish ICUs studied was 42.5%. The disparity between these results could potentially be explained by the difference in diagnostic mix. The Australian cohort had a large percentage of patients admitted post cardiothoracic surgery. The majority of these patients are routine and are admitted to ICU overnight for monitoring and are able to be mobilised the next morning. With just under half of the Australian cohort being made up of patients admitted for cardiothoracic surgery, the overall mobilisation rate is likely to be positively skewed as a result.

Study Two had a more balanced group in terms of admission diagnoses and APACHE II groups. The proportion of patients mobilised on the study day was 39.2%. This fraction represents the prevalence of patients mobilised on any one day rather than if a patient mobilised at any stage of their total ICU stay. This information alone cannot be directly compared with Study One and Three.

Episodes, activities, activities of weight bearing, minutes and activities on mechanical ventilation

Patients mobilised in Scottish units had higher numbers of median activities (6.3), median episodes (3.8) and median minutes (692 minutes) of mobilisation during their ICU stay than patients in Australian units (4.2 activities, 2.2 episodes and 362 minutes). One possible explanation for this is the significantly longer length of stay experienced by Scottish patients compared with Australian patients (median 3.8

days vs. 2 days p<.001). Interestingly, when looking at activities and episodes per patient rather than per patient mobilised, the rates between Australia and Scotland cohorts are similar. This infers that workforce efforts are similar but in the Scotland cohort these efforts are directed towards fewer patients. This is the first study to clearly demonstrate how workforce practices are different in terms of dose of mobilisation as a therapy.

The high proportion of Australian patients who participated in weight bearing activities in Study Three may reflect the high proportion of patients admitted for cardiothoracic surgery. A high proportion of these patients would ambulate the day after surgery. This is re-confirmed in Study Two where 84.2% of surgical patients who mobilised participated in weight bearing activities. Literature describing the rate of muscle loss in ICU patients after less than one day suggests it may not be significant enough to affect functional activities such as standing and walking.

A longer length of stay potentially provides more opportunity for mobilisation to occur. However, a longer length of stay in ICU may also equate to longer periods of inactivity, muscle wasting and time on mechanical ventilation. Although length of mechanical ventilation data was not collected, longer ventilation time in the Scottish cohort seems likely given 34.4% of activities in Scottish ICUs were conducted on mechanical ventilation. In contrast only 9.3% of Australian patients mobilised on mechanical ventilation at some stage during their stay in Study Three and no Australian patients mobilised on mechanical ventilation in Study Two. With ten sites in Study Three and 38 sites in Study One, albeit only on one day, it is unlikely that Australia's low rate of mobilisation on mechanical ventilation is a random occurrence. More likely an explanation is that patients admitted to Australian ICUs rarely mobilise on mechanical ventilation.

The quantification of these elements of mobilisation can contribute to future models of research that examine dose of mobilisation in mechanically ventilated adults. Baseline results of episodes, activities and minutes of mobilisation will assist in power analysis estimates for sample size and effect size changes.

ETTs, RRT and vasopressor infusions

Results of the questionnaire given to the senior physiotherapist in each unit suggest that mobilisation with these therapies is more commonly accepted in Scottish ICUs. Eight out of nine Scottish units accepted mobilisation with ETTs and vasopressor infusions and six out of nine units accepted mobilisation with RRT in comparison to five out of ten Australian units accepting mobilisation with ETTs and vasopressors and six out of ten units accepting mobilisation with RRT. As a percentage, more patients were admitted to Scottish units where these practices were an option. However, rates of mobilisation with ETTs, RRT and vasopressor infusions were lower in Scotland than in Australia. There is a discrepancy between agreeing in principle to mobilisation with these therapies and actually conducting the practices.

The percentage of mobilisation episodes where an ETT and mechanical ventilation was present was low in both Australian (2.0%) and Scottish (1.1%) cohorts. Mobilising with ETTs has been reported in two studies. Bailey et al.(2007) found 40.9% of the 103 study patients mobilised with an ETT and Thomsen et al.(2008) observed 60% of the 10 subjects mobilised with this therapy. The discrepancy between previous studies conducted in America and this current program of research could be explained by differences in tracheostomy insertion practices. The timing of tracheostomy insertion varies depending on clinician preference and prediction of a patient's ICU length of stay. Although a tracheostomy is viewed as a more secure airway it is a surgical procedure and not without risk. On close examination of the data, patients in the American cohorts continued to have ETTs in situ at day 14 (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Thomsen, Snow et al. 2008) in comparison to Australian and Scottish data showing ETTs in situ commonly for less than 7 days. The lower number of days with an ETT gives less opportunity to mobilise with one in situ. Observed practice in Scotland shows a large percentage of patients mobilised with mechanical ventilation but not with ETTs. Therefore, mobilisation occurred with ventilation delivered via a tracheostomy. Overall, mobilisation of patients where an ETT was present was an infrequent occurrence in both Australia and Scotland.

Mobilisation in the presence of RRT was higher in the Australian cohort at 8.5% but remained low in Scottish ICUs at 1.1% of episodes. Study Two also showed high prevalence of mobilisation on RRT in an Australian cohort with 22.4% of patients receiving RRT undergoing mobilisation. Schweickert et al.(2009) allowed patients with RRT to mobilise but did not make specific comment on the percentage of episodes where this therapy was being used. Baseline levels of mobilisation with RRT are unknown around the world. Study Three is the first study to document the prevalence and incidence of mobilisation in the presence of RRT in the Australian cohort and benchmark it internationally. Mobilisation of patients receiving RRT is common in Australian ICUs and rare in Scottish ICUs.

Of all three therapies, patients mobilised with vasopressor infusions most frequently with 17.1% and 20.4% of episodes of mobilisation being carried out with this therapy in situ in the Australian population of Study Three and Study Two respectively and 2.8% in the Scottish population. Reporting of mobilisation with vasopressor infusions in the literature is poor. No baseline rates have been described for any country. Morris et al.'s (2008) study was the only study to mention patients had mobilised with vasopressors but did not state a percentage of the patients who mobilised with this therapy. The findings in Study Two and Three show a high rate of mobilisation in the presence of vasopressor infusions for Australian patients admitted to ICU but low in the Scottish equivalents.

Reporting of comparable dosages of different vasopressor medications is a challenge for research in this area (Morris and Herridge 2007; Morris, Goad et al. 2008). Recording of the type and dose of vasopressors delivered to patients during mobilisation did not occur for this study. However, it is likely that the dose of vasopressor delivered to a patient at the time of deciding whether or not to mobilise the patient will impact upon the decision made. This should be taken into consideration for future studies examining the influence of vasopressors on mobilisation of patients in the ICU.

The average rate of mobilisation with ETTs, RRT and vasopressor infusions for each country does not reflect practice at the individual unit level. For all three therapies

there were extremes of scores at individual sites. Commonly an individual ICU would record no episodes of mobilisation with a particular therapy and therefore the remaining units had above average episodes of mobilisation with that particular therapy. If a unit regularly has patients admitted for example post operatively with vasopressor infusions, clinicians gain familiarity with this therapy and mobilisation of patients on this is accepted and is carried over to medical and trauma patients. Units that do not come into regular contact with the therapies may not have the same level of confidence and therefore mobilisation never occurs in these instances. The prevalence of mobilisation with these three therapies in some units gives a positive indication that there is room for increases in both Australian and Scottish cohorts. It also highlights the need for education and up skilling of staff for future studies attempting to implement these practices.

Diagnosis (sub group 1)

Literature examining early mobilisation focuses heavily on patients admitted for respiratory illnesses. Results of these studies show between 80% and 100% of patients mobilised after the addition of extra staffing (Morris, Goad et al. 2008; Schweickert, Pohlman et al. 2009) or changes in process (Bailey, Thomsen et al. 2007; Thomsen, Snow et al. 2008; Needham and Korupolu 2010). In both the Australian and Scottish cohorts of Study three, baseline practice was recorded with no additional staff or resources. In both cohorts, the respiratory category recorded the highest percentage of patients mobilised (85.7% of Australian and 54.1% of Scottish patients). Scottish rates of mobilisation in the respiratory category are at a similar level to reported pre-implementation cohorts in Morris et al.'s (2008) study (47%) and Needham et al.'s (2010) study (59%). The proportion of respiratory patients mobilised in the Australian cohort (Study Three) is comparable with post implementation cohorts of patients in previous studies conducted.

Patients in the neurological and orthotrauma category in both Australian and Scottish cohorts recorded low proportions of patients being mobilised and even less patients carried out weight bearing activities. With no comparative literature on this category of patients, a physiological approach is used to understand mobilisation rates in these categories. Given the potential for fractures and lack of innervation to

the lower limbs is high in both diagnostic populations, low rates of mobilisation would be expected. None of the studies in this thesis collected data that documented the physiological contraindications to weight bearing in this or other diagnostic specific categories. Rates in the Scottish cohort (neurology: 19.0%; orthotrauma 33.3%) were lower than those recorded in the Australian cohorts (neurology: 46.3%; orthotrauma: 41.1%) which is consistent with overall mobilisation rates of the Scottish cohort.

Patients in the gastrointestinal category in both Australia and Scotland recorded high rates of mobilisation (Australia: 75.8%; Scotland: 51.2%) and weight bearing (Australia: 59.3%; Scotland: 46.3%). This category of patient has been neglected in the literature and warrants further investigation on the benefits and feasibility of mobilisation.

Patients in the sepsis category in both the Australian and Scottish cohorts recorded the highest number of activities per patient of any of the sub groups but the proportion of patients mobilised was less than that of the respiratory cohorts. Given the severity of illness and increased mortality rate of patients in this category, it is not surprising that fewer patients mobilised. However, for those who do mobilise, the longer average length of stay these patients experience provides more opportunity for mobilisation and hence why these patients experience the highest number of activities per patient mobilised. Future research could examine the impact of temporally earlier mobilisation in this cohort in a randomised controlled trial to determine its influence on outcomes.

The cardiac category contains patients admitted with both medical and surgical cardiac diagnoses. Mobilisation rates in centres heavily weighted with patients admitted post cardiothoracic surgery (Australian site 4 and 5) were extremely high (78.7% and 92.2%). The overall mobilisation rate of the cardiac category for Australia is 75% which is somewhat lower due to the combination of medical and surgical admission diagnoses in this category. In the Scottish cohort, no patient was admitted post cardiothoracic surgery in the Scottish cohort and therefore had a high proportion of patients admitted with medical cardiac problems such as

myocardial infarction. Patients admitted for medical cardiac conditions can potentially have a more tumultuous course than patients admitted for cardiac surgery. Therefore it is not unexpected that the proportion of patients mobilised was 38.5% which is considerably lower than the Australian counterpart.

Classification (sub group 2)

Mobilisation rates for medical patients have been reported in two papers (Schweickert, Pohlman et al. 2009; Needham and Korupolu 2010). Both populations were predominantly made up of patients with respiratory illnesses and therefore rates may be increased due to admission diagnoses. Rates of 94% and 93% respectively were recorded after implementation of changes to process. These rates are higher than reported in Australian and Scottish practice (59.6% and 43.1% respectively). No mention was made in either paper on the sustainability of this increase in activity.

The surgical population in the Australian cohort is heavily weighted with elective post operative cardiothoracic surgery patients. This group is much larger than any other of the groups and the proportion of patients mobilised was high at 76.0% in comparison with the much smaller Scottish group where 45.2% of patients mobilised. The median time to first mobilisation was also markedly different between the groups at day 2 (1 to 2) for Australian surgical patients and day 4.5 (2 to 9.8) for Scottish patients. Disparity between these values does not necessarily reflect differences in practice, it may be that there are significant differences in the type of surgery performed.

Patients admitted with trauma injuries have been discussed in previous sections (orthotrauma). The low rate of mobilisation in this category of patients is to be expected due to the nature of injuries experienced. Low patient numbers in both the Australian and Scottish cohorts makes interpretation of this data difficult. However, it must be noted that not all patients admitted under trauma need to be excluded from mobilisation. Patients must be assessed individually to identify potential for mobilisation.

Severity of illness (sub group 3)

The connection between mobilisation and severity of illness has not yet been reported for the Australian population. On examination of data in Study three, the Australian cohort had similar proportions of patients mobilised in the categories from 0 to 24 but steadily decreased in the higher APACHE II categories. Scotland does not show the same consistency with the proportion of patients mobilised varying between categories. No Scottish patients were mobilised in APACHE II categories over 30. The lack of consistency in the Scottish cohort suggests the decision to mobilise a patient has little to do with severity of illness and more to do with diagnosis or perceived need. This differs from Australian ICUs where there is a clear drop in activity for patients who are more severely ill. Given that APACHE II scores are not known by physiotherapists at the time of treatment, the score itself would not be a factor in mobilisation decisions. Future research into mobilisation in ICU should consider illness severity as a stratification variable in any randomisation process.

7.4 Mobilisation and discharge destination

Discharge destination is used as a surrogate measure of function (Schweickert, Pohlman et al. 2009). This measure was chosen due to the lack of availability of a valid and reliable measure for the heterogeneous ICU patient population. Discharge destination is indicative of what functional level has been attained by the time the patient is due to be discharged from hospital. Although this measure is broad in nature it is none the less patient focussed.

The before / after study design used in Study One does not allow for causality to be attributed to mobilisation. The intervention delivered in Study One cannot be separated from the therapists' patient selection of who should be mobilised. It is likely that both aspects play a role in the discharge location. Despite these limitations, associations can be examined. Establishing an association between patients who are mobilised and the destination to which they are discharged helps establish grounds for future more robust trials.

Study One examined discharge destination before and after the implementation of an early mobilisation program. The percentage of patients discharged home did rise from 37% to 41% but was not significant. Mortality trended down from 21% to 18% after implementation but again was not significant. These results are similar to those found in Schweickert et al.'s (2009) randomised controlled trial where there was a trend towards better discharge locations but significance was not achieved. Study One had a large sample size and was not able to detect a significant change. Alternative study designs with discharge destination as the primary outcome may need to be examined in order to evaluate the impact of early mobilisation on outcomes.

After dividing patients of Phase 2 and 3 into those who mobilised and those who did not mobilise there was a clear pattern. Irrespective of what phase of the study patients were in, the patients who were mobilised showed better discharge destinations. There are many reasons why patients who mobilise are more likely to be discharged home and less likely to die. Firstly, the therapists may consciously or unconsciously select to mobilise patients who they perceive have the potential to be discharged home or at least less likely to die. Alternatively, patients who are mobilised may be less severely ill than those who do not. Finally, mobilisation may impact on discharge destination.

Phase 3 saw a 20% increase in the number of patients mobilised and as a group, the patients who mobilised achieved the same or better discharge destination. So despite there being additional patients in the mobilisation group, the same standard of discharge location was maintained. With APACHE II scores remaining similar in the mobilised and not mobilised groups, an association can be made that patients who were chosen and mobilised in ICU, for whatever reason, are more likely to be discharged home and less likely to die.

Australia and Scotland

In Study Three, the mortality rate for patients in Australia was similar to the national average recorded by ANZICS CORE data. Although mortality rates for Scotland appear high, they are not unexpected (Moran and Solomon 2012). The

Scottish population had very low percentages of patients admitted for elective surgery, who typically have a low mortality rate and results were not adjusted for severity of illness. Mortality rates for the Australian cohort are similar to those seen in Morris et al.(2008) and Thomsen et al.'s (2008) studies which were conducted in the USA. Scottish cohorts are more in line with Schweickert et al.(2009) and Burtin et al.'s (2009) studies conducted in USA and Belgium respectively.

There is a large variation in discharge destinations at each site for both Australia and Scotland cohorts. Variation between units can be influenced by the medical specialties available in the unit, socioeconomic status of the catchment area and practice standards of the area and / or country. The variability seen at individual sites and between countries reinforces the need for early mobilisation in ICU to be compared with standard practice at each site rather than between sites of different demographic makeup.

The difference in discharge location seen between patients who mobilised and did not mobilise is not as stark in the Scottish population as it is in the Australian population. While some of this difference must be attributed to the larger amount of patients admitted for elective surgery in the Australian cohort, this is unlikely to be the only contributor. Mobilisation practices may help to explain these differences. In Study three, mobilisation occurred later and in fewer patients in the Scottish cohort than the Australian cohort. The effect of this on discharge destination requires further investigation.

The discharge locations for different diagnostic specific categories showed respiratory and gastrointestinal patients were more likely to be discharged home than patients in the neurology or sepsis categories for both Australia and Scotland. Previous data focuses on mortality of these patient groups and shows inverse but similar trends. Patients admitted into the cardiac category behave differently in Australia and Scotland due to the Australian population being constructed predominantly of patients admitted for elective surgery.

The discharge location of patients who mobilise has had limited investigation. So far studies have not been designed or powered to detect differences in this measure

(Schweickert, Pohlman et al. 2009). An association has been shown in Study One and three between mobilisation and better discharge destination but further studies are required to substantiate the link.

7.5 Safety and feasibility

Early mobilisation of mechanically ventilated patients as a therapy is being carried out at varying intensities in ICUs internationally. Currently, there has not been an assessment of the safety of this therapy in a heterogeneous Australian population.

Baseline adverse event rates were established in Study One at RPH ICU, in Study Two at 38 units across ANZ and in Study Three in 10 Australian sites and benchmarked with nine Scottish sites.

7.5.1 Safety

Safety of early mobilisation was measured in this thesis by the number of adverse events experienced. Adverse event rates will vary depending on what criteria are used to classify an adverse event. There have not been clear criteria for the classification of an adverse event for early mobilisation in ICU. For the studies comprising this thesis, there were no serious adverse events. Overall, adverse event rates for the three studies were 1.1% (Phase 3 of Study One) 6.4% (Study Two), 3.2% (Australia, Study three) and 6.2% (Scotland, Study three) respectively. These results are comparable or slightly higher than those previously reported for mobilisation in ICU which is between 0.96% and 4.2% (Bailey, Thomsen et al. 2007; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010).

The studies in this thesis listed 16 criteria as possible adverse events. The number of categories in our studies far exceeded previous studies where no more than five criteria were listed (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). Schweickert et al.(2009) reported 4 criteria (fall to knees, ETT removal, SBP >200mmHg or <90 mmHg and SpO2 <80%) and had an adverse event rate of 0.2%. However, this was prefaced with the fact that 4% of

therapy sessions were discontinued due to instability. What classifies as an adverse event in studies in this thesis would have classified as merely instability in another study. The definition of an adverse event impacts on the reported rate. The criteria in this thesis were perhaps overly conservative in comparison to other studies (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010). Despite this, adverse event rates remained low.

One of the adverse event criteria was: 'patient withdraws consent to participate after mobilisation has commenced'. This had not previously been a criterion in other studies but it was felt that in order to be patient focussed, it would be helpful to understand what proportion of mobilisation episodes were terminated not due to physiological criteria but patient's wishes. Interestingly, this formed a large component of all adverse events in Study One and Three. In Study One it contributed to two thirds of the events in Phase 2 and one third of the events in Phase 3. The percentage was less in the Scottish cohort (3/18) but remained high in the Australian cohort of Study 3 (10/32). The point prevalence study did not have this as a criterion. For future studies implementing a change in culture, this criterion will continue to be important. It may provide insight into whether patients are in fact capable of and should be able to judge the intensity of their mobilisation session or it may be that the therapist is not able to explain the benefits of the session adequately to the patient due to communication issues on either side. However, if studies are evaluating mobilisation only as a technique this may increase adverse event rates unnecessarily and should therefore only be acknowledged or even abandoned altogether in reporting.

Study One measured adverse events at RPH ICU in the two prospective phases. The recorded adverse event rates were similar at 1.3% prior to implementation and 1.1% after implementation of the mobility protocol. RPH ICU also participated in Study Two and three where the adverse event rate during the point prevalence study was zero and in the eight week audit there were five events in 121 episodes of mobilisation equating to a 4.1% adverse event rate. Three of the five events were a withdrawal of participation by the patient and no event required medical

intervention. Across the three studies which span three years, adverse event rates at RPH ICU were low and consistent with other studies conducted in this area (Bailey, Thomsen et al. 2007; Morris, Goad et al. 2008; Burtin, Clerckx et al. 2009; Schweickert, Pohlman et al. 2009; Bourdin, Barbier et al. 2010; Needham and Korupolu 2010).

Study Two is the first study to report on adverse events for early mobilisation therapy across Australia and New Zealand. The adverse event rate of 6.4% is likely to be an overestimation of the true rate as this rate represents events connected with both mobilisation and respiratory treatments delivered. Although analyses of adverse events for this study were only examined if the patient did mobilise, it is still unclear if the adverse event was related to mobilisation or respiratory treatment. The majority of the events (54%) were related to blood pressure fluctuations. It is unclear as to whether any of these events required medical intervention.

Study Three examined all patients who received mechanical ventilation. Overall, Australia had an adverse event rate of 3.2% which was significantly lower than Scotland's rate of 6.2%. Closer analysis of this data shows an uneven distribution of events in the Scottish data. One patient at one site experienced six of the nation's 18 adverse events, five of which were a reduction in oxygen saturation. The patient did not have to return to bed because of the decrease in oxygen saturation in any episode. The repeated nature of this event may suggest a misinterpretation of the criteria which did allow for an increase in oxygen requirements prior to commencement of mobilisation and reporting only when oxygen needed to be increased during mobilisation. Alternatively, perhaps oxygen desaturation is not seen as an adverse event and does not impact upon subsequent mobilisation practices in the same patient.

The adverse events in the Australian arm of the study occurred earlier in patient's ICU stay than in the Scottish arm. Fifty three percent of the adverse events occurred within the first week of admission in the Australian population in comparison to 11% of Scotland's events. The timing of events may be due to the slightly earlier

timing of mobilisation in the Australian cohort when patients are often experiencing more cardiovascular instability. This is plausible given one third of the Australian cohort's adverse events were related to cardiovascular instability.

Study One examined consecutive patients of all diagnostic specific categories for greater than 12 months and showed adverse events were consistent across groups and remained low. Study Two recorded adverse events in only three of the eight diagnostic specific categories (cardiac, respiratory and gastrointestinal) and again, these rates were low.

In the Australian cohort of Study three, patients in the gastrointestinal category recorded the highest adverse event rate at 5.7%. These events were not concentrated at any particular site and events were across four criteria suggesting this is an accurate representation. In the Scottish cohort, the orthotrauma category showed an abnormally high adverse event rate of 20%. This is likely to be due to the low number of episodes of mobilisation in this sub group rather than a true representation of harm.

Examination of patients in the classification sub group showed low adverse event rates for patients admitted for trauma in all studies. There was minimal difference in adverse event rates between medical, surgical and trauma diagnostic specific categories. Classification of admission does not appear to influence adverse event rates.

The adverse event rates were higher in the higher APACHE II groupings. With many of the adverse events being related to cardiovascular instability, it is not surprising that these occurred in patients who were more severely ill and likely had more labile cardiovascular stability. Despite this slight increase, rates remained low. However, the influence of therapist's selection of which patients are mobilised should not be underestimated in the instance of mobilising patients who are severely ill.

In clinician surveys regarding concerns about or barriers to early mobilisation, patient safety was the number one concern (Morris 2007; Winkelman and

Peereboom 2010). The studies in this thesis assessed adverse events related to early mobilisation of critically ill patients who received mechanical ventilation. These studies spanned a number of ICUs over an extended period of time and reported no serious adverse events. Adverse event rates in all categories were low. From this data, it appears that patient selection and mobilisation carried out by physiotherapists within a MDT is safe.

This program of research is the first to examine adverse event rates associated with early mobilisation in a heterogeneous ICU patient population and found the therapy, when applied by physiotherapists to chosen patients to be safe.

7.5.2 Feasibility

Study One is the first study we are aware of to use a systems change approach to early mobilisation in a level III heterogeneous ICU. An across the board increase in the percentage of patients mobilised was safely achieved and maintained for a one year period. The feasibility of implementing an early mobilisation program focussed on three areas: the setting, the workforce and the patient population.

The culture surrounding early mobilisation at RPH ICU was positive prior to implementation of the study. It was a setting receptive to change of policy and practice with a MDT already established. The influence of this on the success of the program is difficult to measure but felt to be extremely important.

The majority of previously conducted studies utilised additional staff to achieve increases in mobilisation rates (Morris, Goad et al. 2008; Schweickert, Pohlman et al. 2009; Needham and Korupolu 2010). This increase in staffing may have been due to there being no physical therapist or low physical therapist presence in these units prior to the study commencement. The exact staffing ratios prior to commencement of data collection in prior studies were not reported. No additional staffing was employed to implement the systems change carried out in Study One. The increase in mobilisation was achieved by altering policies and improving communication opportunities between disciplines and between shift changes. Study One shows changes in process can be safely achieved with current staffing levels. The cost per day of staying in intensive care is the most expensive of any hospital

bed (Williams, Dobb et al. 2005) therefore feasible implementation of a therapy utilising existing staffing levels is an attractive concept. It is not yet known if this approach can be translated into multiple ICUs internationally.

Previous studies have examined patients predominantly admitted for respiratory conditions only, leaving a gap in the literature on feasibility of early mobilisation in all ICU patients. Morris et al.(2008) is the only study to report the *feasibility* of introducing an early mobilisation program for respiratory patients. Study One examined all mechanically ventilated patients regardless of diagnosis. Within this study, patients in the respiratory category showed high levels of mobilisation both pre and post implementation. The percentage of patients mobilised prior to the early mobilisation program was at a similar rate to those achieved at the conclusion of Morris et al.'s (2008) study. After implementation, the percentage of respiratory patients at RPH ICU who mobilised increased (78.3% to 89.2%). This data shows even in an ICU that is already positive towards early mobilisation, it is feasible to increase rates of mobilisation.

Feasibility of early mobilisation in all diagnostic specific categories is demonstrated by safe increases in the proportion of patients mobilised in each of the categories. Significant increases in the proportion of patients mobilised were seen in the orthotrauma, surgical and trauma categories with meaningful increases seen in the remaining categories. The exception to this was the neurology group who showed a decrease which is likely to be explained by the increase in severity of illness of these patients in Phase 3 (median APACHE II score rose from 16 to 22). These results show that early mobilisation can feasibly and safely achieved with existing staffing and resources for patients in all diagnostic specific categories except neurology.

Mobilisation levels and adverse events for RPH ICU were also assessed in Study Three, two years later. Study Three reported the percentage of patients mobilised at RPH ICU as 59.5% which was half way between rates recorded in the pre and post implementation periods of Study One (53.9%, 64.6%). After two years, there was a decrease in the percentage of patients mobilised which was to be expected after the decrease in attention early mobilisation was given after completion of the

study. However, meaningful change in mobilisation activity was maintained above the rate seen pre implementation in Study One.

The results of Study One and Study Three at RPH ICU show that implementation of early mobilisation is feasible for patients with a variety of diagnostic specific categories and an increase in rate can be maintained over a two year period.

7.6 Barriers to mobilisation

Establishing barriers to mobilisation of patients in intensive care has been purported as a key priority for future research in this industry (Adler and Malone 2012; Needham, Davidson et al. 2012). Patient safety has previously been a large concern among clinicians and has been a barrier to mobilisation of patients early in their ICU stay (Needham, Korupolu et al. 2010; Winkelman and Peereboom 2010). The low adverse event rate associated with early mobilisation at RPH has shown this to be a falsely held belief for this cohort.

In previous research, barriers to mobilisation have been divided into two categories: avoidable barriers and unavoidable barriers (Leditschke, Green et al. 2012). These formed the basis for categorisation of barriers in Study One. Barriers that were deemed to be avoidable or partially modifiable in Study One were: presence of an ETT; lack of resources; patients with a craniectomy and no helmet; presence of sedation; patient declined to participate; procedures and cardiovascular instability.

In all studies of this thesis barriers were recorded at the patient's bedside at the end of treatment by the treating physiotherapist. Responses will therefore reflect individual clinician's beliefs regarding why a patient should not mobilise. While responses may be subjective in nature, it is an accurate reflection of currently held beliefs on what is stopping patients from being mobilised early. This data will assist in the design of future studies to understand the challenges required to be overcome at the ground level.

7.6.1 Barriers to mobilisation in a single centre

Study One measured barriers to mobilisation prospectively before and after implementation of the early mobilisation program. The program targeted a number of long standing barriers to mobilisation that were present at RPH ICU. The main message of the program was 'to make mobilisation a priority in every patient's day'. Target changes were: allowing patients with ETTs, RRT and vasoactive infusions to mobilise; early communication and coordination of staff to ensure mobilisation was not hindered by lack of resources or procedures; early communication with medical teams to identify accurate mobilisation restrictions; early ordering of helmets for patients who had undergone a craniectomy to ensure this was not a barrier to mobilisation and daily planners in patients rooms to establish a routine of activities and expectations for both the patient and the staff to prevent patient refusal.

7.6.1.1 Barriers at baseline

Prior research conducted prospectively at patients' bedsides revealed attachments, such as ETTs and femorally inserted lines, and procedures were commonly reported barriers to mobilisation (Garzon Serrano, Ryan et al. 2011; Leditschke, Green et al. 2012). For patients in Phase 2 of Study One, the presence of an ETT was the biggest barrier to mobilisation and affected 90.2% of the patients. Procedures on the other hand were not as prominent a barrier and were experienced by 28.4% of patients.

The presence of sedation affected 89.2% of patients in Phase 2 which confirms the thoughts of surveyed clinicians in prior studies (Needham, Korupolu et al. 2010; Winkelman and Peereboom 2010). Cardiovascular stability was the third biggest barrier prior to implementation of the early mobilisation program and affected 60.8% of patients at any one time during their length of stay. The remaining barriers were far less frequent but included in descending order, central nervous system instability, lack of resources, respiratory instability and orthopaedic orders. Barriers that affected less than 10% of patients were: patient declined intervention; the presence of a craniectomy without a helmet and the presence of uncontrollable diarrhoea.

For patients that never mobilised while in RPH ICU, the top five barriers to mobilisation remained the same and the proportion of patients affected by each also remained similar. The barrier that was more prevalent in this group was orthopaedic orders. This rose from 14.7% for the whole group to 21.3% for patients that never mobilised. In other words, 10 of the 47 patients who never mobilised had injuries that required them to remain in bed for longer than their ICU length of stay. Previous studies did not specifically examine patients who never mobilised. For future studies in this area it is vital to understand the factors that are limiting patients from mobilising.

7.6.1.2 Barriers after implementation of early mobilisation program

Of the seven barriers deemed to be avoidable or partially modifiable, four were significantly decreased after the implementation of the early mobilisation program, two barriers were reduced but not significantly and one increased. The areas of improvement correlated with the objectives of the early mobilisation program.

The most significant barrier to change was the presence of an ETT. Prior to the early mobilisation program, an ETT was a barrier to 90.2% of patients at some stage during their ICU stay in comparison to only 2.7% of patients after implementation ($p<.001$). In the literature, the patency of lines such as ETTs has been a concern for clinicians that has limited mobilisation (Needham, Korupolu et al. 2010; Winkelman and Peereboom 2010). Changing clinician's perceptions of ETTs as being a hindrance to mobilisation to being a manageable attachment was a focus area of the study and was successfully achieved.

Communication and coordination of members of the MDT was considered a key area for improvement in Study One. The significant reduction in the barrier 'lack of resources' from 19.6% to 11.6% ($p=.049$) represents achievement of this goal with implementation of systems change and not by increasing staff time or resources. Considerable effort from all staff, and particularly senior staff ensured mobilisation was a priority and adequate staff and equipment were available to carry this out as well as complete all other usual aspects of patient care. Communication between

members of the MDT is possible and central to the accomplishment of system changes.

Patients who undergo a craniectomy must have a helmet to mobilise as a matter of policy at RPH. Delays in referral for helmets were common prior to the introduction of the early mobilisation program. Although this was not an overwhelming issue, the reduction in this barrier from 5.9% to 1.9% (p=.017) shows how simple changes can impact on the process of care for patients.

Sedation as a barrier decreased significantly after implementation of the early mobilisation program from 89.2% to 79.4% (p=.023). It has been purported in the literature that sedation is a barrier to mobilisation and in order to improve mobilisation rates, sedation minimisation should occur prior to any mobilisation program (Schweickert, Pohlman et al. 2009; Needham and Korupolu 2010; Needham, Korupolu et al. 2010; Winkelman and Peereboom 2010). Results of this study suggest that early mobilisation of patients in fact influences delivery of sedation patterns. What is not clear is whether the sedation was decreased prior to mobilisation to ensure maximum participation or if after mobilisation the patient required less sedation due to being more settled and physically tired. Sedation was not a focus area of this study but may have decreased as a consequence of the early mobilisation program. Further research is needed into the interplay between mobilisation and sedation

The barrier 'declined to participate in mobilisation' affected only 6.9% of patients in Phase 2 but was viewed by investigators prior to commencement of the study to be a result of poor planning and communication of the benefits of mobilisation and was therefore targeted in the early mobilisation program. This barrier did decrease to 3.9% but did not reach statistical significance. The decrease in patients declining mobilisation is encouraging but needs further attention in order to limit this as a barrier in the future.

Patients who did not mobilise due to the presence of vasopressor infusions came under the barrier 'cardiovascular instability'. This category also covered patients experiencing new or uncontrolled abnormal cardiac rhythms, a haemoglobin level

lower than 70 d/L or a systolic blood pressure of less than or equal to 80 mm Hg. Due to the array of situations that met this criteria, it is not surprising that a statistically significant decrease in the number of patients experiencing this barrier was not found. There was a decrease from 60.8% to 51.9% and this may be partly attributed to the allowing of patients with vasopressor infusions to mobilise. In future the presence of any vasopressor infusions should be separated out as an individual barrier to more clearly determine change in practice.

The higher APACHE II scores seen in Phase 3 could perhaps have equated to patients requiring an increased number of procedures. If so, it is reasonable to assume that the number of occasions where procedures were a barrier to mobilisation would also increase. Procedures as a barrier increased from 28.4% to 43.0% (p=.007) after implementation of the program. Leditschke et al (2012) found the timing of procedures one of the top barriers to mobilisation in their study conducted at patient bedsides. For Study One, it was thought that if mobilisation was made a priority in the patients' day that it would still be possible to achieve it even when multiple procedures were required. This was perhaps overly ambitious given the time and physical effort required of patients to participate in these. As a barrier, procedures are not always a modifiable barrier.

The percentage of patients where respiratory instability was a barrier increased from 17.7% to 28.6% in Phase 3. The cause for this rise is unknown but rates are consistent with other studies in this field (Garzon Serrano, Ryan et al. 2011; Leditschke, Green et al. 2012). The change in policy regarding mobilisation of patients with an ETT at RPH may have removed this attachment as a barrier in the minds of the clinician and allowed them to look more closely at the respiratory system as a whole and therefore the reduction in ETTs as a barrier has equated to a rise in respiratory instability being a barrier.

Central nervous system instability, uncontrollable diarrhoea and orthopaedic orders to rest in bed were not focussed on in the early mobilisation program as they were thought to be unable to be modified. This is confirmed in the results of the study as

the percentage of patients where these criteria were barriers did not change significantly between Phase 2 and 3.

Results of barriers for patients who never mobilised reinforce the achievement of systems change with the introduction of the early mobilisation program. The presence of an ETT was no longer a major barrier in this population, nor was a craniectomy without a helmet. Cardiovascular instability as a barrier decreased at a similar rate to the whole population. Orthopaedic orders to rest in bed and procedures increased which was to be expected for patients who never mobilised. The target areas of the study were achieved in all patients and unavoidable barriers remain high for patients who never mobilised.

7.6.2 Current barriers to mobilisation in Australia and Scotland

Study Three measured baseline practice for Australia and Scotland. As with Study One, barriers were reported by clinicians at the patient bedside. For the Australian cohort of Study three, the top five barriers reported were: sedation (61.4%); presence of an ETT (36.5%); cardiovascular instability (35.9%); central nervous system instability (15.5%) and procedures (12.2%). All other barriers affected less than ten percent of the population. The Scottish cohort reported more barriers per patient overall (8.5 per patient compared with 5.5 per patient in Australian cohort) but the number one barrier for Scotland was common with Australia. Sedation affected 75.4% of patients in the Scottish cohort. Endotracheal tubes were not reported to be a major barrier in the Scottish cohort despite a very low incidence of patients mobilising with an ETT being recorded in the audit.

The literature on barriers to mobilisation found femorally inserted lines were a common barrier (Leditschke, Green et al. 2012). The safety of these lines did not feature in the Scottish or Australian cohorts of this study. Procedures were a prevalent barrier in the Scottish cohort (33.0%) which may reflect the diagnostic make-up of the group being slightly higher in severity of illness and less routine surgery patients being present when compared with Australia. Stability of the cardiovascular, central nervous system and respiratory systems is mentioned in all four previous studies as a barrier to mobilisation (Needham, Korupolu et al. 2010;

Winkelman and Peereboom 2010; Garzon Serrano, Ryan et al. 2011; Leditschke, Green et al. 2012). Results for both the Australian and Scottish cohorts confirmed these as barriers to mobilisation with cardiovascular and central nervous system instability being one of the top five barriers in both Australia and Scotland and respiratory system instability being a barrier in the Scottish cohort.

Examination of patients that never mobilised revealed similar results when compared with the whole cohort in both Australia and Scotland. Barriers that increased were unavoidable barriers that were expected to increase for patients that never mobilised. For example, the barrier of imminent death increased from 1.1% and 3.9% of patients in the mobilised category to 18.1% and 21.4% in the not mobilised category for Australia and Scotland. Central nervous system instability increased as a barrier from 15.5% to 26.6% for Australian patients which was also an unavoidable barrier.

Barriers that are deemed to be unavoidable contributed to 39.8% of the total barriers for Australia and 46.7% of barriers for Scotland. The barriers that increase when examining patients who never mobilise are orders to rest in bed, patients in whom death is inevitable and patients with central nervous system disturbances. These patients are not likely to be able to mobilise in future studies.

In contrast, barriers that have been deemed avoidable or partially modifiable contributed to 60.2% of total barriers for Australia and 53.3% for Scotland. For future studies, the barrier requiring most attention is sedation. It has been found to be the number one barrier in Study One and Study Three for all cohorts. This supports previous studies which surveyed clinician opinions on barriers to mobilisation (Needham, Korupolu et al. 2010; Winkelman and Peereboom 2010). This program of research did not target sedation reduction but did show a reduction in sedation as a barrier in Study One after introduction of an early mobilisation program. Sedation as a barrier is not unique to Australian ICUs and was reported more frequently in the Scottish cohort in Study Three. Although barriers to early mobilisation of mechanically ventilated patients in intensive care will continue to

exist, a large proportion of the barriers are able to partially or completely overcome.

7.6.3 Study limitations

The studies in this thesis have several limitations. Firstly, Study One used a before and after study design. This design was chosen to evaluate the incidence and prevalence of mobilisation activities across the spectrum of patients admitted to the ICU. While study designs such as randomised controlled trials and stepped-wedge designs may have statistical advantages, they do not allow for change management at a single site to adequately occur. Given the aim of the study was to change behaviour, the before and after study design was the most appropriate.

The use of physiotherapists as data collectors for all studies in this thesis may have been a source of bias. Feasibly, this represented the best possible way of collecting all mobilisation data in a prospective manner.

The APACHE II scoring system as a measure of severity of illness may be limited in its descriptiveness of how the severity of each patient's illness will present over time clinically. However, it is the most widely used and reported risk stratification tool used in Australian and Scottish ICUs and widely recognised in the literature.

The use of discharge destination as a surrogate measure of function is crude and is a limitation of the studies in this thesis. At the time of conducting these studies, there was no validated and reliable measure of function available for patients in the ICU setting. In the absence of a more scientifically robust measure, discharge destination was used. Hopefully, development of an appropriate tool for this patient population is an area of future research.

"With a growing number of patients surviving critical illness, there is an urgent need to more fully address the long term consequences of intensive care for survivors and their families. This Society of Critical Care Medicine conference focused on improving these long term consequences and discussed three major issues in the field" one of which is "identifying barriers and solutions for comprehensive post-ICU rehabilitation". (Needham, Davidson et al. 2012) pg 507 - 508

The program of research in this thesis pre-dates this quote from 2012 by four years. This research examined mobilisation and the barriers to it at a local, national and international level.

Chapter 8 Conclusion and future research

8.1 Conclusion

From the thesis outcomes the following conclusions have been drawn:

- The definition of early mobilisation in ICU has previously lacked clarity. In this thesis, the term has been broken down and defined. Activities that constitute mobilisation are those that are performed against gravity and involve axial loading of the spine and / or long bones which are: sitting (either over the edge of the bed or in a chair); using a tilt table; standing and ambulation. The timing of mobilisation that classifies it as early involves the patient being in the ICU and physiologically ready. Physiological readiness or stability is difficult to define and will vary between units as to what parameters are acceptable for patients to mobilise with. Consequently, early mobilisation should always be discussed in relation to standard practice. Given the variability of patient admission diagnosis and therapies that are available and practiced, comparison of early mobilisation results between countries and units should be made cautiously and only when there is a clear definition of standard practice.

- It is possible to change work practice behaviours in a long term and sustainable way in a heterogeneous level III ICU with the implementation of an early mobilisation program that changes the focus and goals of the MDT. This can be achieved with little increase in resources or staffing.

- Baseline mobilisation practices vary greatly. This variation can be partly explained by workforce practice as well as differences in patient diagnosis, classification and severity of illness. To establish generalizable clinical pathways for the mobilisation of patients in the ICU, future research should take into consideration the large degree of patient variation.

- Adult patients who received mechanical ventilation in the ICU and who mobilised showed an association with better discharge destination. This association requires investigation in more robust trials.

- Reporting of adverse events related to early mobilisation has not yet been standardised. Future research should nominate adverse events as events where harm has occurred rather than transient instability. This thesis has documented a very low rate of adverse events associated with early mobilisation. While this is promising, until the true efficacy of mobilisation (both the dose and timing) is validated there will be a continued conservative approach to the use of mobilisation in the ICU.

- Barriers to early mobilisation of mechanically ventilated adults in intensive care are multidimensional and often not independent of one another. Barriers vary as to how modifiable they are in clinical practice. Some barriers have previously been thought to be contraindications to mobilisation such as the presence of an ETT. This thesis has shown that therapists are able to appropriately select patients who have an ETT in situ for mobilisation and that this practice is associated with a low adverse event rate and it is not a contraindication to mobilisation.

- Sedation was consistently reported as the most frequently occurring barrier to mobilisation for patients locally, nationally and internationally. Modification of sedation delivery and its impact on early mobilisation warrants further investigation.

Early mobilisation of patients in ICU is an area of growing research. This thesis is the first to report safety and feasibility of implementing an early mobilisation program in a large heterogeneous patient population. This thesis is the first program of research to report baseline mobilisation levels at a local, national and international level. Barriers to early mobilisation have been identified in Australia and benchmarked internationally to guide future systems change studies as well as more robust randomised controlled trials focussing on the effect early mobilisation has on patient centred outcomes.

8.2 Future research

The aims and objectives of this program of research have been met and answered. However, results from this research have also identified further questions that are relevant to the field and it is recommended that these be investigated in future studies.

The primary question that remains unanswered in this field of research is - what, if any, effect does early mobilisation have on patient centred outcomes. To date this has not been established. Several preliminary questions require answering before this can be established. Suggestions for future research which aim to resolve this primary question have been identified by this thesis. These are outlined below.

- Early mobilisation should be clearly defined in studies as a relative concept that is in comparison to baseline practice. Both the control and intervention arms of studies must be clearly defined in terms of activities that constitute 'mobilisation' and the timing that constitutes it as 'early'.

- Early mobilisation of all patients in a heterogeneous patient population has safely and feasibly been achieved. Future studies investigating early mobilisation as a therapy should consider the inclusion of patients of all admission diagnoses.

- The impact of clinician's attitudes towards mobilisation and their selection of who receives mobilisation in ICU has not yet been investigated. The impact of this on rates of mobilisation in the ICU requires further investigation to allow changes of practice to occur.

- Patients admitted into the gastrointestinal and sepsis diagnostic categories have shown that an increased level of mobilisation is possible and was not associated with an increase in the adverse event rate. Patients in these categories have previously lacked attention and should be included in future research that examines the impact early mobilisation has on patient centred outcomes.

- Safe increases in mobilisation rates of patients with RRT did not show statistical significance in this study. Studies with larger numbers of patients receiving this therapy are required to determine if it is clinically viable.
- The impact of early mobilisation on the patients discharge destination from hospital needs to be established in more robust trials.
- Adverse event criteria related to early mobilisation in the ICU have not been agreed upon across studies. A consensus of what constitutes an adverse event should be formed and implemented for future research examining early mobilisation of mechanically ventilated adults in ICU.
- The relationship between sedation and early mobilisation has not yet been clarified and requires further research.

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Appendix 1 APACHE II scoring system

APACHE II Severity Of Disease Classification

A. ACUTE PHYSIOLOGY SCORE (APS)

PHYSIOLOGIC VARIABLE	High Abnormal Range					Low Abnormal Range				APS Scores
	+4	+3	+2	+1	0	+1	+2	+3	+4	
Temperature – rectal (°C)	≥41	39 – 40.9		38.5 – 38.9	36 – 38.4	34 - 35.9	32 – 33.9	30 – 31.9	≤29.9	
Mean arterial pressure (mmHg) (kPa)	≥160 ≥21.3	130 – 159 17.3 - 21.2	110 – 129 14.6– 17.2		70 – 109 9.3 – 14.5		50 – 69 6.6 - 9.2		≤49 ≤6.5	
Heart rate (ventricular response)	≥160	140 – 179	110 – 139		70 - 109		55 - 69	40 - 54	≤39	
Respiratory rate (non-ventilated or ventilated)	≥50	35 – 49		25 - 34	12 - 24	10 - 11	6 - 9		≤5	
Oxygenation: A - aDO_2 or PaO_2 a. if $FIO_2 \geq 0.5$ record A - aDO_2 (mmHg) (kPa)	> 500 >66.5	350 – 499 46.6-66.4	200 – 349 26.6-46.5		< 200 <26.6					
b. if $FIO_2 < 0.5$ record only PaO_2 (mmHg) (kPa)					PO_2 > 70 PO_2 > 9.3	PO_2 61-70 PO_2 8.1-9.3		PO_2 55-60 PO_2 7.3-8.0	PO_2 < 55 PO_2 <7.3	
Arterial pH	≥7.7	7.6 – 7.69		7.5 – 7.59	7.33 – 7.49		7.25– 7.32	7.15–7.24	< 7.15	
Serum sodium (mmol/L or mEq/L)	≥160	160 – 179	155 – 159	150 - 154	130 - 149		120 - 129	111 - 119	≤110	
Serum potassium (mmol/L or mEq/L)	≥7	6 – 6.9		5.5 – 5.9	3.5 – 5.4	3 – 3.4	2.5 – 2.9		≤2.5	
Serum creatinine (double point score for acute renal failure#) (μmol/L) (mg/dl)	≥300 ≥3.39	171-299 1.93-3.38	121-170 1.37-1.92		50-120 0.57-1.36		< 50 < 0.57			
Haematocrit (%)	≥60		50 – 59.9	46 – 49.9	30 – 45.9		20 – 29.9		< 20	
White blood count (total/mm^3) (in 1,000s)	≥40		20 – 39.9	15 – 19.9	3 – 14.9		1 – 2.9		< 1	
Glasgow Coma Score (GCS) (Score = 15 minus actual GCS) – see Appendix 2 for GCS calculation										
Serum HCO_3 (venous – mMol/L) (Only use this if no ABGs available)	≥52	41 – 51.9		32 – 40.9	22 – 31.9		18 – 21.9	15 – 17.9	<15	

#Acute renal failure: *"If abnormal serum creatinine values reflect acute renal failure as opposed to chronic renal failure then the points assigned to the creatinine values should be doubled. Acute renal failure is defined as any creatinine value that is not within the normal range designated by the APACHE II system."*

Thus for the purposes of this study if your patient has **any points for an increased creatinine and they are not documented to have chronic renal failure then the**

Assign points to age as follows:

Age (yrs)	Points
☐ ≤ 44	0
☐ 45–54	2
☐ 55–64	3
☐ 65–74	5
☐ ≥ 75	6

If patient has history of severe organ system insufficiency or is immuno–compromised, assign points as follows:

	Points
☐ a. for non-operative or emergency post-operative patients	5
☐ b. for elective post-operative patients	2

DEFINITIONS: Organ insufficiency or immuno-compromised state must have been evident prior to this hospital admission and conform to the following criteria:

LIVER	Biopsy proven cirrhosis & documented portal hypertension (PH); episodes of upper GI bleeding due to PH; or prior episodes of hepatic failure/encephalopathy/coma
RENAL	Receiving chronic dialysis
CARDIOVASCULAR	New York Heart Association Class IV - Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.
RESPIRATORY	Chronic restrictive, obstructive or vascular disease resulting in severe exercise restriction (i.e. unable to climb stairs, perform household duties); or documented chronic hypoxia, hypercapnia, 2° polycythemia, severe pulmonary hypertension (>40mmHg) or respiratory dependency
IMMUNOCOMPROMISED	Patient has received therapy that suppresses resistance to infection, eg. immuno-suppression, chemotherapy, radiotherapy, long term or recent high dose steroids, or has a disease sufficiently advanced to suppress resistance to infection (eg leukaemia, lymphoma, AIDS)

APACHE II SCORE - a sum of:	A. APS points =____	B. Age points =____	C. Chronic Health points = ____	Sum of A + B + C = _____ (0 to 71)

Appendix 2 Data Dictionary

Variable	Definition
ETT / NTT	An endotracheal or nasotracheal tube is in situ at the time of mobilization
Tracheostomy	A tracheostomy is in situ at the time of mobilization
Mechanically ventilated	The patient is receiving mechanical ventilation at the time of mobilization
RRT in progress	The patient is receiving renal replacement therapy (dialysis) at the time of mobilization
Inotropes or vasopressors	The patient is receiving one or more of noradrenaline, adrenaline, dobutamine or dopamine intravenously for the purpose of supporting blood pressure at the time of mobilization.
SOOB	This includes sitting over the edge of the bed or sitting in a chair with anything from maximal to no support from others
Standing	Patient is required to weight bear through lower limb/s with or without assistance from others +/- the use of an aid for a minimum of 2 seconds
Tilt table	Patient has been placed on the tilt table and inclined to greater than 40 degree angle
Ambulation	Patient has taken more than 3 steps with or without assistance of others +/- the use of an aid. These steps may be on the spot or in a forward direction
Unsuccessful mobilisation	
Rehab chair	Includes chairs that have the ability to be flattened to allow patient to be slid across and then passively sat up
Rocker recliner	An arm chair with the ability to elevate legs and recline the back rest
High back chair	A solid, supportive chair without moving parts
Time sat out of bed	Using a 24 hour clock, the time the patient was successfully and safely seated out of bed or on the edge of the bed
Time put back to bed	Using a 24 hour clock, the time the patient was successfully and safely returned to bed
Unplanned removal art line	During the process of mobilization the patient's arterial line was dislodged or removed and was then unable to be used in its intended capacity

Variable	Definition
Unplanned removal CVC or Vascath	During the process of mobilization the patient's central venous catheter or vascath was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal peripheral line	During the process of mobilization the patient's peripheral line was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal ETT / NTT	During the process of mobilization the patient's endotracheal tube or nasotracheal tube was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal trache	During the process of mobilization the patient's tracheostomy tube was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal NGT / OGT	During the process of mobilization the patient's nasogastric or orogastric tube was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal drain	During the process of mobilization the patient's drain was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal other – please specify	During the process of mobilization, an attachment not otherwise stated (e.g. intercostals catheter) was dislodged or removed and was then unable to be used in its intended capacity
Fall	In an uncontrolled manner, the patient descends to their knees or buttocks during a mobilization activity
Increased oxygen requirements (i.e. FiO2)	During the process of mobilization (i.e. not prior to commencement), the patients oxygen level drops sufficiently to warrant a sustained increase in FiO2 of 0.1 or more
Increased inotropes / vasopressors	During the process of mobilization the patient's blood pressure falls requiring a sustained increase of vasoactive medication intravenously
CNS unstable	During the process of mobilization, there is a drop in Glasgow Coma Scale by one or more, or a sustained increase in the patient's intracranial pressure above 20 mmHg
CVS unstable	During the process of mobilization, the patient experiences abnormal heart rhythm, heart rate, or blood pressure that requires return to bed

Variable	Definition
↓SpO2	During the process of mobilization, the patient's oxygen saturation levels drop to 84% or less for greater than 10 seconds
Patient refused	During the process of mobilization, the patient declines to participate in mobilization despite explanation of the benefits of mobilization, appropriate pain cover and encouragement
Procedure required	Despite best efforts to co-ordinate with all team members, the requirement of a procedure must take precedence over mobilization
CNS unstable	Patient's intracranial pressures have been discussed with senior medical staff and deemed to be too high or too labile to allow safe mobilization
CVS unstable	Patient is requiring high levels of vasoactive medication, is having new or uncontrolled abnormal cardiac rhythms, has a haemoglobin level lower than 70 or a systolic blood pressure of ≤ 80 mm Hg
Respiratory unstable	Patient's ventilation requirements are deemed to great by medical staff to allow mobilization +/- patient is requiring nitric oxide.
Orthopaedic orders	Due to orthopaedic restrictions, patient is not allowed to mobilize in order to allow healing of bony fractures.
Sedated	Patient is unable to co-operate with staff due to high level of sedation – this does NOT include unsedated patients who have a low GCS
Patient refused	Prior to the commencement of mobilization the patient refuses to participate despite adequate pain cover, explanation of the benefits of mobilization and encouragement
Lack of resources	Mobilisation is not carried out due to the lack of availability of staff or equipment (e.g. chairs, tilt table)
ETT in situ	Mobilisation is not carried out due to the presence of an ETT/NTT
Diarrhoea	Mobilisation is unable to be carried out due to patient suffering from uncontrolled diarrhoea
Comatosed	Mobilisation is not carried out due to the patient having a low GCS. The low GCS must NOT be related to the influence of sedatives

Variable	Definition
Procedure required	Despite best efforts to co-ordinate with all team members, the requirement of a procedure must take precedence over mobilization
ETT in situ	Mobilisation is not carried out due to the presence of an ETT/NTT
Diarrhoea	Mobilisation is unable to be carried out due to patient suffering from uncontrolled diarrhoea
Craniectomy without a helmet	Mobilisation is unable to be carried out due to the lack of protective head gear over a craniectomy site

Appendix 3 APACHE III diagnostic codes

Table B.3: Detailed APACHE III-J code description

Non operative
Cardiovascular

101 Cardiogenic Shock
Shock, cardiogenic
Papillary muscle rupture
102 Cardiac Arrest
Cardiac Arrest with or without respiratory arrest; for respiratory arrest see Respiratory System)
Poisoning, carbon monoxide, arsenic and cyanide; non-traumatic coma due to anoxia/ischemia
103 AORTIC Aneurysm
Aneurysm, dissecting aortic
104 Congestive Heart Failure
Congestive Heart Failure
105 Peripheral Vascular Disease
Aneurysm/pseudoaneurysm, other
Thrombus, arterial
106 Rhythm Disturbance
Rhythm disturbance (primary, i.e., conduction defect)
107 Acute Myocardial Infarction
Infarction, acute myocardial (MI)
108 Hypertension
Hypertension, uncontrolled (for cerebrovascular accident- see Neurological System
109 Other Cardiovascular Disease
Anaphylaxis
Angina, stable (asymp or stable pattern of symptoms w/meds)
Cardiovascular medical, other
Chest pain, atypical (noncardiac chest pain)
Efffusion, pericardial
Endocarditis
Haematomas
Haemorrhage (for gastrointestinal bleeding GI-see GI system) (for trauma see Trauma)
Hypovolemia (including dehydration. Do NOT include shock states.
MI admitted > 24hrs after onset of ischemia
Monitoring, hemodynamic (pre-operative evaluation)
Pericarditis
Tamponade, pericardial
Thrombosis, vascular (deep vein)
Toxicity, drug (i.e., digoxin, theophylline, dilantin, etc.)
Vascular medical, other
110 Cardiomyopathy
Cardiomyopathy
111 Unstable Angina
Angina, unstable (angina interferes w/quality of life or meds are tolerated poorly.

Non operative
Respiratory

201 Aspiration Pneumonia
Pneumonia, aspiration, toxic, chemical pneumonitis
202 Resp. Neoplasm incl. larynx/trachea
Cancer of the following: laryngeal, lung, oral, tracheal,
203 Respiratory Arrest
Arrest, respiratory (without cardiac arrest)
204 Pulmonary Oedema non cardiac.
ARDS-adult respiratory distress syndrome, non-cardiogenic pulmonary edema
206 COPD
Emphysema/bronchitis
207 Pulmonary Embolism
Embolus, pulmonary
208 Mechanical Airway Obstruction
Obstruction-airway (i.e. acute epiglottitis, post-extubation edema, foreign body, etc.)
209 Asthma
Asthma
210 Parasitic Pneumonia
Pneumonia, fungal
Pneumonia, parasitic (i.e. Pneumocystis pneumonia)
211 Other Respiratory Diseases
Apnoea, sleep
Atelectasis
Effusions, pleural
Haemorrhage/haemoptysis, pulmonary
Hemothorax
Hypertension-pulmonary, primary/idiopathic
Near drowning accident
Pneumothorax
Respiratory- medical, other
Restrictive lung disease (i.e. sarcoidosis, pulmonary fibrosis)
Smoke inhalation
Weaning from mechanical ventilation (transfer from other unit or hospital only)
212 Bacterial Pneumonia
Pneumonia, bacterial
Pneumonia, other
213 Viral Pneumonia
Pneumonia, viral

Non Operative
Gastrointestinal

301 Hepatic Failure
Acute hepatic failure
Hepatic Encephalopathy
Hepato-renal syndrome
Liver transplant rejection
303 GI Bleeding -varices
Bleeding, GI from oesophageal varices/portal hypertension
305 GI Bleeding -ulcer/laceration
Bleeding, GI-location unknown
Bleeding, upper GI
306 GI Bleeding -diverticulosis
Bleeding, lower GI
307 Other GI Disease
GI medical, other
Haemorrhage, intra/retroperitoneal
Ulcer disease, peptic
Adrenal neoplasm (including pheochromocytoma
Chest pain, epigastric
308 GI Perforation
GI Perforation/rupture
309 GI Obstruction
GI Obstruction
310 GI Vascular Insufficiency
GI Vascular Insufficiency
311 Pancreatitis
Pancreatitis
312 GI cancer
Cancer of the following: colon/rectal; oesophagous; other GI; pancreas; stomach;
313 Other GI Inflammatory Disease
Cholangitis
Diverticular disease
GI Abscess/cyst
Inflammatory bowel disease
Peritonitis

Non Operative
Neurological

401 Intracerebral Haemorrhage
Haemorrhage/haematoma, intracranial
402 Subarachnoid Haemorrhage
Subarachnoid haemorrhage/arteriovenous malformation
Subarachnoid haemorrhage/intracranial aneurysm
403 Stroke
CVA, cerebrovascular accident/stroke
404 Neurologic Infection
Abscess, neurologic
Encephalitis
Meningitis
405 Neurologic Neoplasm
Neoplasm, neurologic

Non Operative
Metabolic

701 Metabolic coma
Diabetic hyperglycaemic hyperosmolar nonketotic coma (HHNC)
Encephalopathies (excluding hepatic)
702 Diabetic ketoacidosis
Diabetic ketoacidosis
703 Drug overdose
Alcoholic withdrawal
Drug withdrawal
Over dose, self inflicted
704 Other metabolic disease
Acid-base electrolyte disturbance
Addisons disease/hypoadrenal crisis
Cushing's Syndrome/disease
Heat exhaustion/stroke
Hyperthermia
Hyperthyroid storm/crisis
Hypoglycaemia
Hypothermia
Hypothyroid/myxedema
Metabolic/endocrine medical, other
Thyroid neoplasm

Non Operative
Haematological

801 Coagulopathy/Neutropenia/Thrombocytopenia
Coagulopathy
Neutropenia
Pancytopenia
Thrombocytopenia
802 Other Haematologic Disease
Anaemia
Blood transfusion reaction
Leukaemia: ALL;AML; CLL; CML
Lymphoma: Hodgkins; Non-Hodgkins
Sickle cell crisis

Non Operative
Genitourinary

901 Renal disease
Genitourinary medical, other
Renal bleeding
Renal failure, acute
Renal infection/abscess
Renal neoplasm, cancer
Renal obstruction
Kidney transplant
902 Pre-eclampsia
Pre-eclampsia/eclampsia (female only)
903 Haemorrhage postpartum
Haemorrhage, postpartum (female only)

406 Neuromuscular Disease
Amyotrophic lateral sclerosis
Guillian-Barre syndrome
Myasthenia gravis
Neuromuscular medical, other
408 Other Neurologic Disease
Hydrocephalus, obstructive
Neurologic medical, other
Palsy, cranial nerve
407 Seizure
Seizures (primary-no structural brain disease)
409 Epidural haematoma
Hematoma, epidural
Hematoma, subdural
410 Coma
Coma/change in level of consciousness (for hepatic see GI, for diabetic see Endocrine, if related to cardiac arrest, see CV)

Non Operative
Sepsis

501 Sepsis other than urinary
Sepsis, cutaneous/soft tissue
Sepsis, GI
Sepsis, gynaecologic
Sepsis, other
Sepsis, pulmonary
Sepsis, unknown
502 Sepsis of Urinary Tract Origin
Sepsis, renal/UTI (including bladder)
503 Sepsis with shock other than urinary tract [ANZICS addition]
504 Sepsis of Urinary tract origin with shock [ANZICS addition]

Non Operative
Trauma
601 Head Trauma +/- multi trauma
Head (CNS) only trauma
Head/abdomen trauma
Head/chest trauma
Head/extremity trauma
Head/face trauma
Head/multiple trauma
Head/pelvis trauma
Head/spinal trauma
602 Multiple trauma excluding head
603 Burns [ANZICS addition]
604 Multi trauma with spinal injury [ANZICS addition]
605 Isolated cervical spine injury [ANZICS addition]

Non Operative
Musculoskeletal/Skin

1101 Musculoskeletal/Skin disease
Arthritis, rheumatoid
Arthritis, septic
Connective tissue disease (mixed)
Musculoskeletal medical, other
Lupus, systemic
Myositis, viral
Rhabdomyolysis without acute renal failure
Scleroderma
Vasculitis
1102 Cellulitis/ soft tissue infection
Cellulitis and localized soft tissue infections

Non Operative
Other
1002 Other medical diseases : nos
Other medical diseases not otherwise specified

Appendix 4 Questionnaire

Trial of Early Activity and Mobilisation
TEAM

The intensive care unit

Number of operational beds in the intensive care unit _____

Number of operational level III beds in the intensive care unit _____

Does your intensive care unit treat one or more of the following patient categories? If so please tick all appropriate boxes below

Cardiothoracic ☐ Neurosurgery ☐ Trauma ☐ Spinal ☐ Transplantation ☐

Number of full time equivalent physiotherapists in the unit _____

Equipment

These questions refer to equipment for use predominantly in the intensive care unit

Number of rocker recliner chairs _____

Number of high back chairs _____

Number of rehabilitation chairs (i.e. transform from flat plinth to chair) _____

Number of tilt tables _____

Number of standing frames _____

Physiotherapy practices

As a general rule are patients in your unit allowed to:

- Mobilise out of bed with an endotracheal tube in situ Y / N
- Mobilise out of bed with renal replacement therapy in progress Y / N
- Mobilise out of bed if vasopressors are being infused Y / N

Do physiotherapy staff attend a medical or multidisciplinary handover session or meeting on a daily basis Y / N

Other comments:

_____

_____

_____

Appendix 5 Diagnostic breakdown of sub group 1 in Phase 2 and Phase 3

	Phase 2	Phase 3	p-value
Cardiac	16.5	18.4	0.744
Respiratory	29.1	28.3	0.889
Gastrointestinal	15.2	11.3	0.856
Neurology	7.6	10.9	0.530
Sepsis	11.4	9.9	0.678
Orthotrauma	17.7	17.1	0.868
Metabolic	1.3	3.8	0.437
Other	1.3	0.3	0.868

Appendix 6 Study One: for those who had the opportunity to mobilise the proportion of patients who mobilised in each diagnostic specific category in Phase 2 and Phase 3

	Phase 2	Phase 3	p
Cardio	53.85	74.07	.185
Resp	78.26	89.16	.179
GI	58.33	84.85	.058
Neuro	83.33	68.75	.650
Sepsis	66.67	72.41	1.00
Orthotrauma	35.71	84.00	.001*
Metabolic	100	54.55	1.000

Analysis using Fischer's exact test

Appendix 7 Diagnosis (sub group 1): statistical difference between the activities, episodes, minutes, weight bearing activities and activities on mechanical ventilation between Phase 2 and Phase 3

Average number of activities per patient within each diagnostic specific category

	Phase 2	Phase 3	p
Cardio	9.14	5.69	.828
Resp	7.78	10.04	.513
GI	4.38	6.72	.361
Neuro	8.17	3.40	.044*
Sepsis	3.50	7.83	.367
Orthotrauma	3.88	5.74	.866
Metabolic	5.00	3.67	.445
Total	6.47	6.97	.513

Analysis using Mann Whitney test

The average number of episodes of mobilisation per patient within each diagnostic specific category

	Phase 2	Phase 3	p
Cardio	4.43	3.62	.529
Resp	4.61	6.89	.855
GI	3.38	5.48	.275
Neuro	6.00	2.52	.235
Sepsis	2.83	5.65	.271
Orthotrauma	3.13	4.26	.865
Metabolic	2.00	1.67	.403
Total	4.11	4.95	.762

Analysis using Mann Whitney test

Average number of minutes per patient within each diagnostic specific category

	Phase 2	Phase 3	p
Cardio	499.43	524.05	.209
Resp	782.67	960.89	.630
GI	310.25	815.97	.108
Neuro	771.17	369.00	.395
Sepsis	284.50	757.04	.112
Orthotrauma	182.25	549.31	.069
Metabolic	330.00	313.67	.617
Total	531.42	689.38	.172

Analysis using Mann Whitney test

The average number of weight bearing activities carried out per patient who mobilised in each diagnostic specific category.

	Phase 2	Phase 3	p
Cardio	5.14	2.55	.460
Resp	3.72	3.49	.378
GI	1.13	2.14	.660
Neuro	2.83	1.04	.095
Sepsis	0.67	2.57	.310
Orthotrauma	1.13	1.77	.442
Metabolic	3.00	2.00	.546
Total	2.75	2.44	.346

Analysis using Mann Whitney test

Number of activities of mobilisation carried out on mechanical ventilation per patient that mobilised within each diagnostic specific category

	Phase 2	Phase 3	p
Cardio	5.71	2.36	.622
Resp	4.06	5.75	.798
GI	2.38	3.52	.648
Neuro	3.50	1.12	.819
Sepsis	1.83	4.91	.535
Orthotrauma	1.25	2.05	.894
Metabolic	0	0.50	.533
Total	3.16	3.44	.596

Analysis using Mann Whitney test

Appendix 8 Classification (sub group 2): statistical difference between the percentage of patients mobilised, activities, episodes, minutes, weight bearing activities and activities on mechanical ventilation between Phase 2 and Phase 3

Percentage of patients mobilised within each diagnostic specific category

	Phase 2	Phase 3	p
Medical	71.43	78.21	.342
Surgical	55.56	78.38	.048
Trauma	41.67	90.00	.001

Analysis using Mann Whitney test

Average number of activities per patient within each diagnostic specific category for those who did mobilise

	Phase 2	Phase 3	p
Medical	6.08	7.73	.807
Surgical	9.25	6.61	.421
Trauma	3.71	5.30	.902
Total	6.47	6.97	.513

Analysis using Mann Whitney test

The average number of episodes of mobilisation per patient within each diagnostic specific category

	Phase 2	Phase 3	p
Medical	4.06	5.39	.592
Surgical	5.00	4.77	.760
Trauma	2.86	3.94	.785
Total	4.11	4.95	.762

Analysis using Mann Whitney test

Average number of minutes per patient within each diagnostic specific category

	Phase 2	Phase 3	p
Medical	624.19	759.53	.674
Surgical	497.83	669.48	.501
Trauma	111.86	514.18	.018
Total	531.42	689.38	.172

Analysis using Mann Whitney test

The average number of weight bearing activities carried out per patient who mobilised in each diagnostic specific category.

	Phase 2	Phase 3	p
Medical	2.47	2.64	.346
Surgical	4.42	2.48	.073
Trauma	1.29	1.68	.402
Total	2.75	2.44	.346

Analysis using Mann Whitney test

Number of activities of mobilisation carried out on mechanical ventilation per patient that mobilised within each diagnostic specific category

	Phase 2	Phase 3	p
Medical	3.06	4.10	.696
Surgical	4.75	3.23	.635
Trauma	1.00	1.82	.861
Total	3.16	3.44	.596

Analysis using Mann Whitney test

Appendix 9 Severity of illness (sub group 3): statistical differences between activities, episodes, minutes, weight bearing activities and activities on mechanical ventilation in Phase 2 and Phase 3

Activities per patient

APACHE group	Phase 2	Phase 3	p-value
0-4	0	0.0	
5-9	20.0	5.0	0.507
10-14	7.3	4.5	0.209
15-19	5.0	5.7	0.424
20-24	6.0	5.9	0.910
25-29	5.8	8.5	0.849
30-34	6.4	14.2	1.000
35-39	1.0	5.9	0.103
40-44	0	5.3	
45-49	0	1.0	
50-54	0	0.0	

Analysis using Mann Whitney test

Episodes per patient

APACHE group	Phase 2	Phase 3	p-value
0-4	0	0	
5-9	9.3	2.3	0.369
10-14	4.9	3.1	0.574
15-19	3.6	4.0	0.602
20-24	3.7	4.2	0.691
25-29	3.2	6.8	0.339
30-34	5.0	8.5	0.501
35-39	0	4.3	0.195
40-44	0	4.3	
45-49	0	1.0	
50-54	0	0	

Analysis using Mann Whitney test

Minutes per patient

APACHE group	Phase 2	Phase 3	p-value
0-4	0	0	
5-9	1236.7	286.7	0.513
10-14	457.9	379.0	0.692
15-19	473.7	536.9	0.835
20-24	585.7	592.6	0.230
25-29	390.9	1039.1	0.215
30-34	665.2	1143.0	0.211
35-39	25.0	528.9	0.165
40-44	0	593.3	
45-49	0	120.0	
50-54	0	0	

Analysis using Mann Whitney test

Weight bearing activities

APACHE group	Phase 2	Phase 3	p-value
0-4	0	0	
5-9	11.0	2.7	0.767
10-14	3.4	1.6	0.096
15-19	1.8	2.0	0.822
20-24	2.5	2.2	0.674
25-29	2.7	2.0	0.872
30-34	1.6	6.2	1.000
35-39	0	1.9	
40-44	0	1.5	
45-49	0	0	
50-54	0	0	

Analysis using Mann Whitney test

Activities on mechanical ventilation

APACHE group	Phase 2	Phase 3	p-value
0-4			
5-9	66.7	6.7	<.001
10-14	31.4	36.2	0.609
15-19	40.0	43.2	0.633
20-24	57.6	45.6	0.087
25-29	48.1	59.7	0.087
30-34	53.1	56.5	0.714
35-39	0	43.4	1.000
40-44	0	31.3	
45-49	0	0	
50-54	0	0	

Analysis using Mann Whitney test

Appendix 10 Severity of illness (sub group 3): statistical differences between number of patients who mobilise with ETTs, RRT or vasopressors in Phase 2 and Phase 3

Percent of patients who mobilise with an ETT

APACHE group	Phase 2	Phase 3	p-value
0-4	0	0	
5-9	0	7.1	0.400
10-14	0	3.2	0.597
15-19	0	4.3	0.014
20-24	1.2	7.3	0.049
25-29	0	7.0	0.095
30-34	0	5.9	0.206
35-39	0	5.0	1.000
40-44	0	9.7	1.000
45-49	0	0	
50-54	0	0	

Analysis using Fisher's exact test

Percent of patients who mobilise with RTT

APACHE group	Phase 2	Phase 3	p-value
0-4	0	0	
5-9	0	0	
10-14	0	0	
15-19	0	0	
20-24	0	5.2	1.000
25-29	0	13.2	0.579
30-34	0	30.8	0.321
35-39	0	4.5	1.000
40-44	0	0	
45-49	0	0	
50-54	0	0	

Analysis using Fisher's exact test

Percent of patients who mobilise with vasopressor infusions

APACHE group	Phase 2	Phase 3	p-value
0-4	0	0	
5-9	0	0	
10-14	0	0	
15-19	0	1.9	0.557
20-24	0	8.2	0.059
25-29	0	4.3	1.000
30-34	0	11.2	0.122
35-39	0	5.4	1.000
40-44	0	16.7	1.000
45-49	0	0	
50-54	0	0	

Analysis using Fisher's exact test

Appendix 11 Point prevalence data collection sheet

CTG POINT PREVALENCE	PHYSIOTHERAPY IN ICU – ALL PATIENTS FORM 2	Hospital ID: I__ı__ı__I Patient ID: I__ı__I

IMPORTANT INFORMATION

Complete Form 2 for **EVERY** patient present in the ICU at 10am on the study day. Almost all questions relate to **the study day**. Importantly, this study is not an audit of documentation. The aim is to determine whether certain aspects of care have been **delivered**, rather than whether they have been documented, but generally physiotherapy documentation is good so it is reasonable to assume that a treatment is a documented treatment

This form is best completed at the end of the study day.

PHYSIOTHERAPY TREATMENT SESSIONS

2.1 How many discrete physiotherapy sessions were provided on the study day? _____

If none, go to question **2.3** otherwise continue to Question **2.2**

2.2 What specific services were provided by the physiotherapist? [Tick all that apply]

- [Y] Assessment only
- [Y] Mobility treatment (with or without assessment)
- [Y] Respiratory care treatment (with or without assessment)

MOBILISATION AND REHABILITATION

2.3 [Y] [N] Did the patient have any mobilisation exercises on the study day (includes sitting out of bed)?

If no, go to question **2.7**

2.4 By whom was the mobilisation performed? [Tick all that apply]

- [Y] Nursing Staff
- [Y] Physiotherapist
- [Y] Physiotherapy assistant / student

2.5 Which techniques were used for mobilisation? [Tick all that apply]

- [Y] Exercises
- [Y] Tilt Table
- [Y] Sitting over edge of bed
- [Y] Standing
- [Y] Sitting out of bed - if **Y** please also answer question **2.5.1**
- [Y] Ambulation (walking) – if **Y** please go to question **2.6** otherwise go to question **2.7**

2.5.1 What was the time spent sitting out of bed on the study day?

- [Y] none
- [Y] < 5 minutes
- [Y] 5 to < 15 minutes
- [Y] 15 to < 30 minutes
- [Y] 30 to < 60 minutes
- [Y] 1 to < 2 hours
- [Y] 2 to < 4 hours
- [Y] 4 hours or more

If the patient spent time ambulating (walking) on the study day please answer questions **2.6 and 2.6.1**

2.6 What was the time spent walking or walking on the spot?

- [ ] < 5 minutes
- [ ] 5 to < 15 minutes
- [ ] 15 to < 30 minutes
- [ ] 30 to < 60 minutes
- [ ] 1 hour or more

2.6.1 What respiratory support was needed during ambulation? [Tick all that apply]

- [ ] Endotracheal tube *in situ* (oral or nasal)
- [ ] Tracheostomy tube *in situ*
- [ ] Face mask or nasal prongs
- [ ] Non invasive ventilation (CPAP or BiPAP) during ambulation
- [ ] Mechanical ventilation during ambulation

2.7 [ ] Y [ ] N Was there a contraindication to sitting out of bed on the study day?

If no, go to question **2.8** otherwise continue to Question **2.7.1**

2.7.1 What was the contraindication to sitting out of bed? [Tick all that apply]

- [ ] Unconscious / unresponsive (neurological injury, metabolic coma, drug intoxication)
- [ ] Agitation or deep sedation
- [ ] Haemodynamically unstable
- [ ] Severe respiratory failure
- [ ] Unstable trauma (spine, spinal cord or pelvis)
- [ ] Severe neuromuscular weakness (eg unable to support own head despite being conscious)
- [ ] Other – please describe _____

If contraindication to sitting out of bed (yes to question **2.5**) then go now to question **2.7**. If no contraindication then go to question **2.6**

2.8 [ ] Y [ ] N If the patient could sit out of bed, was there a contraindication to ambulating (standing, walking) on the study day?

If no, go to question **2.9** otherwise continue to Question **2.8.1**

2.8.1 What was the contraindication to ambulation? [Tick all that apply]

- [ ] Haemodynamically or autonomically unstable
- [ ] Severe respiratory failure
- [ ] Severe neuromuscular weakness
- [ ] Unstable trauma (spine, spinal cord or pelvis)
- [ ] Severe diarrhoea
- [ ] Other – please describe _____

CTG POINT PREVALENCE	PHYSIOTHERAPY IN ICU – ALL PATIENTS FORM 2	Hospital ID: I__I__I Patient ID: I__I__I

RESPIRATORY CARE

2.9 Y N Did the patient receive respiratory physiotherapy on the study day?

If no, go to question **2.11** otherwise continue to Question **2.10**

2.10 What respiratory physiotherapy techniques were used by the physiotherapist? [Tick all that apply]

- Y Hyperinflation
- Y Suctioning
- Y Saline lavage
- Y Breathing exercises
- Y Non invasive ventilation (CPAP, BiPAP, IPPB - Bird) applied by physiotherapist

ADVERSE EVENTS DURING PHYSIOTHERAPY

2.11 Y N Was physiotherapy associated with any unplanned or adverse events on the study day?

If no, go to question **2.13** otherwise continue to Question **2.12**

2.12 What unplanned or adverse events took place? [Tick all that apply]

- Y Fall
- Y Significant deterioration in gas exchange
- Y Significant reduction in blood pressure
- Y Deterioration in mental state
- Y Cardiac arrhythmias
- Y Unplanned extubation or decannulation of tracheostomy
- Y Unplanned / unexpected removal of lines(s)
- Y Other – please describe _____

PATIENT FACTORS WHICH MIGHT INTERFERE WITH PHYSIOTHERAPY

2.13 Y N Did the patient have an endotracheal tube (oral or nasal) at any time on the study day?

If no, go to question **2.14** otherwise continue to Question **2.13.1**

2.13.1 Y N Was the patient extubated at any time on the study day?

2.14 Y N Did the patient have a tracheostomy tube at any time on the study day?

If no, go to question **2.15** otherwise continue to Question **2.14.1**

2.14.1 Y N Was the patient's tracheostomy decannulated at any time on the study day?

2.15 Y N Did the patient have non invasive ventilation (CPAP or BiPAP) via a tight fitting facemask at any time on the study day?

CTG POINT PREVALENCE	PHYSIOTHERAPY IN ICU – ALL PATIENTS FORM 2	Hospital ID: I__I__I Patient ID: I__I

2.16 What was the mode of ventilation at 10am on the study day?

- ☐ None (nasal prongs or simple mask)
- ☐ Non-invasive (CPAP OR BiPAP) via a tight fitting mask
- ☐ Predominantly spontaneous supported ventilation via ETT or trachy (eg CPAP, PSV, SIMV with >50% spontaneous breaths)
- ☐ Predominantly controlled ventilation (eg PCV, APRV, PRVC or SIMV with ≤ 50% spontaneous breaths)
- ☐ T-piece or HME via tracheostomy

2.17 ☐ Y ☐ N Did the patient have dialysis, CRRT, haemofiltration, plasma exchange or any other extracorporeal circuit in use at any time on the study day?

If no, go to question **2.18** otherwise continue to Question **2.17.1**

2.17.1 What was the location of the vascular access catheter / cannula? [Tick all that apply]

- ☐ Jugular / neck
- ☐ Subclavian
- ☐ Femoral
- ☐ Chronic AV fistula (eg forearm)
- ☐ Peritoneal
- ☐ Other, please specify _____

2.18 ☐ Y ☐ N Did the patient have a procedure in ICU or transport outside ICU that might have interfered with physiotherapy on the study day?

If **no,** this form is finished. If yes please continue to Question **2.18.1**

2.18.1 What was the procedure or purpose of transport? [Tick all that apply]

- ☐ Surgery or other procedure in operating theatres
- ☐ Medical imaging (CT, MRI, angiography etc)
- ☐ Procedure in ICU
- ☐ Other, please specify _____

THANK YOU – PLEASE GO TO FORM 3

Appendix 12 Point prevalence study data dictionary

CTG PPP

FORM 2 – PHYSIOTHERAPY IN ICU	
General tips	• Complete Form 2 for **EVERY** patient present in the ICU at 10am on the study day • Almost all questions relate to **the whole study day** Importantly, this study is not an audit of documentation. The aim is to determine whether certain aspects of care have been **delivered**, rather than whether they have been documented, but generally physiotherapy documentation is good so it is reasonable to assume that a treatment is a documented treatment Please don't show this to your physiotherapists before the study day, to avoid bias, but you are free to ask their assistance with data collection on the day This form is best completed at the end of the study day.

No.	Question	Definition or explanation of question	Comments
2.1	Physio today	For how many sessions was the physiotherapist in attendance for ≥10 minutes in the 24 hr study day?	Even if there were no specific physiotherapy sessions today, a lot of physio treatment is provided by other people eg nurses, so go to question 2.3 and continue
2.2	Physio services	1. Assessment only: The physiotherapist carried out a physical assessment of the patient to determine if physiotherapy treatment was indicated but no treatment was conducted 2. Mobility treatment: Mobility treatment was carried out by physiotherapist, eg sit out of bed, stand, walk on spot, walk, tilt-table, (see question 2.5 for example) 3. Respiratory care: Respiratory care treatment was carried out by physiotherapist	

CTG PPP

No.	Question	Definition or explanation of question	Comments
2.3 2.4	Mobilisation	Mobilisation performed by nursing staff: A member of the nursing team was involved in assisting the patient +/- patient associated attachments in achieving mobilization that is defined as sitting up with legs over the edge of the bed or moving the patient away from the bed eg. Sitting on a chair, standing or walking. Mobilisation performed by physiotherapy staff: A physiotherapist was involved in assisting the patient +/- patient associated attachments in achieving mobilization that is defined as sitting up with legs over the edge of the bed or moving the patient away from the bed eg. Sitting on a chair, standing or walking. Mobilisation performed by physiotherapy assistant: A physiotherapy assistant or physiotherapy student was involved in assisting the patient +/- patient associated attachments in achieving mobilization that is defined as sitting up with legs over the edge of the bed or moving the patient away from the bed eg. Sitting on a chair, standing or walking.	
2.5	Techniques for Mobilisation	1. Exercises: Formal arm or leg exercises prescribed for the purposes of increasing strength for future mobilisation 2. Tilt Table: Actual or attempted placement of the patient on a tilt table with an inclination of 40 degrees or more 3. Sitting over edge of bed: bed-side nurse or notes indicate that patient sat over edge of bed, irrespective of amount of assistance necessary to achieve this. 4. Standing: bed-side nurse or notes indicate that patient stood for a minimum of 2 seconds 5. Sit out of bed: bed-side nurse or notes indicate that patient sat out of bed in a chair, including high back, rocker recliner, wheelchair, rehabilitation chairs 6. Ambulation (walking): bed-side nurse or notes indicate that patient walked or that an attempt to ambulate occurred. To distinguish from standing, ambulation requires at least three steps, which may be on the spot.	
2.7	Contraindication to sitting out of bed	If the patient did **not** sit out of bed on the study day, was there a valid reason?	If there was a contraindication, please give the reason in 2.7.1 If no actual contraindication, tick 'No' to question 2.7
2.8	Contraindication to ambulation	Likewise, if the patient did not ambulate, what was the reason?	If there was a contraindication, please give the reason in 2.8.1 If no actual contraindication, tick 'No' to question 2.8
2.10	Respiratory physiotherapy	Definition of techniques: 1. Hyperinflation: Larger than tidal volume breaths were delivered by either a manual resuscitation bag or a ventilator for the purpose of physiotherapy 2. Suctioning: Refers to a specific suctioning treatment by the physiotherapist, not just endotracheal suctioning by the nurse 3. Saline lavage: Saline instillation of >2mLs via the artificial airway was performed with the intent of sputum removal 4. Breathing exercises: performed with a physiotherapist 5. Non-invasive ventilation: Either continuous or intermittent application of a non-invasive device was performed by a physiotherapist. This includes CPAP, BiPAP, IPPB (bird).	

CTG PPP

No.	Question	Definition or explanation of question	Comments
2.12	Unplanned or adverse events	Definition of adverse events: 1. Fall: Patient descends to knees or buttocks In an uncontrolled manner during a mobilization activity 2. Deterioration in gas exchange: During the process of mobilization (ie not prior to commencement), the patients oxygenation deteriorates sufficiently to warrant a sustained PEEP ≥10 cm H2O OR if was PEEP ≥10 cm H2O at commencement, an increase of 20% from PEEP at initiation of mobilization was required 3. Reduction in blood pressure: During the process of mobilization the patient's blood pressure falls sufficiently to require return to bed, whether or not this also necessitated a commencement or increase in vasoactive medication 4. Deterioration in mental state: During the process of mobilization, there is a drop in Glasgow Coma Scale by one point or more, a clear and sustained change in mentation compared with prior to mobilisation, or a sustained increase in the patient's intracranial pressure above 20 mmHg, if monitored 5. Arrhythmias: During the process of mobilization, the patient experiences an abnormal heart rhythm that requires return to bed or medical attention 6. Unplanned extubation / decannulation: During the process of mobilization the patient's endotracheal tube, nasotracheal tube or tracheostomy tube was dislodged or removed and was then unable to be used in its intended capacity 7. Unplanned removal of lines: During the process of mobilization, a line (eg NGT, IV line, ICC) was dislodged or removed and was then unable to be used in its intended capacity.	
2.14.1	Decannulation of tracheostomy	Removal of tracheostomy tube leaving no artificial airway inserted through the tracheostoma	
2.15	NIV	Includes any external positive pressure via a tight fitting facemask, in a patient who does not have an endotracheal tube or tracheostomy tube. Can include CPAP, BiPAP, VPAP, NIPPV…	'
2.16	Mode of ventilation at 10am	1. NIV defined as above (2.15) 2. Predominantly spontaneous ventilation via ETT or tracheostomy. This can include a variety of modes on the ICU ventilator, but the defining feature is that the 'spontaneous triggered' respiratory rate is 50% or more of the total respiratory rate 3. Predominantly controlled ventilation is the opposite of no 2, where the 'spontaneous triggered' respiratory rate is <50% of the total respiratory rate 4. T-piece or HME (heat and moisture exchanger) refers to a simple device attached to ETT or tracheostomy where the patient does all the work of breathing and no machine provides assistance [gas flow can still come from an ICU ventilator eg in'oxygen therapy' mode, but there is no positive pressure]	

Appendix 13 Mobilisation data collection Form 2

MOBILISATION DATA COLLECTION FORM

Patient Name: | **Patient Number:**

29317

Please ensure this form is returned to the physiotherapist

MOBILISATION DATA COLLECTION FORM

Site ID: | **Patient Number:** | **Number of Sheets** 1 2 3 4 5 6 7 8 9

COMPLETION INSTRUCTIONS

Please use a sharpened 2B pencil

Please shade the circles completely ●

Please write clearly in the single boxes or free text areas 1 2 3 4 5 PLEASE WRITE IN CAPITAL LETTERS

If you wish to change any of your responses, please erase the incorrect response completely and provide the correct response in the intended area.

Please complete this form each day of the patients stay in intensive care.
If mobilisation occurred more than once per day please enter each episode on a new column.

SECTION 1: BASELINE INFORMATION AND MOBILISATION DATA

To be completed for each entry. Please shade ALL appropriate circles.

	2 0 1 Year	Day / Month	Day / Month	Day / Month	Day / Month	Day / Month
ETT / NTT		○	○	○	○	○
Tracheostomy		○	○	○	○	○
Mechanically ventilated		○	○	○	○	○
RRT in progress		○	○	○	○	○
Inotropes or vasopressors		○	○	○	○	○
Activity - SOOB		○	○	○	○	○
- Standing		○	○	○	○	○
- Tilt table		○	○	○	○	○
- Ambulation		○	○	○	○	○
Chair - Rehab chair		○	○	○	○	○
- Rocker recliner		○	○	○	○	○
- High back chair		○	○	○	○	○
Time sat out of bed (please use 24hr clock)		Hours : Minutes	Hours : Minutes	Hours : Minutes	Hours : Minutes	Hours : Minutes
Time put back to bed (please use 24hr clock)		Hours : Minutes	Hours : Minutes	Hours : Minutes	Hours : Minutes	Hours : Minutes

29317

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Please ensure this form is returned to the physiotherapist

SECTION 2: ADVERSE EVENTS OCCURRING DURING MOBILISATION

Please indicate if any of these adverse events occurred during mobilisation by shading the relevant circle.

Unplanned removal art line	○	○	○	○	○
Unplanned removal CVC or Vascath	○	○	○	○	○
Unplanned removal peripheral line	○	○	○	○	○
Unplanned removal ETT / NTT	○	○	○	○	○
Unplanned removal trache	○	○	○	○	○
Unplanned removal NGT / OGT	○	○	○	○	○
Unplanned removal drain	○	○	○	○	○
Unplanned removal other - please specify					
Fall	○	○	○	○	○
Increased oxygen requirements (i.e.↑FiO2)	○	○	○	○	○
Increased inotropes / vasopressors	○	○	○	○	○
Commencement of inotropes / vasopressors	○	○	○	○	○
Unexpected return to bed due to:					
- CNS unstable	○	○	○	○	○
- CVS unstable	○	○	○	○	○
- ↓SpO2	○	○	○	○	○
- Patient refused	○	○	○	○	○
Nil	○	○	○	○	○

SECTION 3: FOR PATIENTS NOT MOBILISED

Please indicate the reason(s) the patient was not mobilised.

Sedated	○	○	○	○	○
Comatosed	○	○	○	○	○
Procedure required	○	○	○	○	○
ETT insitu	○	○	○	○	○
RRT in progress	○	○	○	○	○
Lack of resources	○	○	○	○	○
Patient refused	○	○	○	○	○
Orthopaedic orders	○	○	○	○	○
Imminent death	○	○	○	○	○
Diarrhoea	○	○	○	○	○
CVS unstable	○	○	○	○	○
CNS unstable	○	○	○	○	○
Respiratory unstable	○	○	○	○	○
Other - please specify					

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Appendix 14 Data dictionary for MDCF2

Variable	Definition
ETT / NTT	An endotracheal or nasotracheal tube is in situ at the time of mobilization
Tracheostomy	A tracheostomy is in situ at the time of mobilization
Mechanically ventilated	The patient is receiving mechanical ventilation at the time of mobilization
RRT in progress	The patient is receiving renal replacement therapy (dialysis) at the time of mobilization
Inotropes or vasopressors	The patient is receiving one or more of noradrenaline, adrenaline, dobutamine or dopamine intravenously for the purpose of supporting blood pressure at the time of mobilization.
SOOB	This includes sitting over the edge of the bed or sitting in a chair with anything from maximal to no support from others
Standing	Patient is required to weight bear through lower limb/s with or without assistance from others +/- the use of an aid for a minimum of 2 seconds
Tilt table	Patient has been placed on the tilt table and inclined to greater than 40 degree angle
Ambulation	Patient has taken more than 3 steps with or without assistance of others +/- the use of an aid. These steps may be on the spot or in a forward direction
Rehab chair	Includes chairs that have the ability to be flattened to allow patient to be slid across and then passively sat up
Rocker recliner	An arm chair with the ability to elevate legs and recline the back rest
High back chair	A solid, supportive chair without moving parts
Time sat out of bed	Using a 24 hour clock, the time the patient was successfully and safely seated out of bed or on the edge of the bed
Time put back to bed	Using a 24 hour clock, the time the patient was successfully and safely returned to bed
Unplanned removal art line	During the process of mobilization the patient's arterial line was dislodged or removed and was then unable to be used in its intended capacity

Variable	Definition
Unplanned removal CVC or Vascath	During the process of mobilization the patient's central venous catheter or vascath was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal peripheral line	During the process of mobilization the patient's peripheral line was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal ETT / NTT	During the process of mobilization the patient's endotracheal tube or nasotracheal tube was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal trache	During the process of mobilization the patient's tracheostomy tube was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal NGT / OGT	During the process of mobilization the patient's nasogastric or orogastric tube was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal drain	During the process of mobilization the patient's drain was dislodged or removed and was then unable to be used in its intended capacity
Unplanned removal other – please specify	During the process of mobilization, an attachment not otherwise stated (e.g. intercostals catheter) was dislodged or removed and was then unable to be used in its intended capacity
Fall	In an uncontrolled manner, the patient descends to their knees or buttocks during a mobilization activity
Increased oxygen requirements (i.e. FiO2)	During the process of mobilization (i.e. not prior to commencement), the patients oxygen level drops sufficiently to warrant a sustained increase in FiO2 of 0.1 or more
Increased inotropes / vasopressors	During the process of mobilization the patient's blood pressure falls requiring a sustained increase of vasoactive medication intravenously
Commencement of inotropes / vasopressors	During the process of mobilization the patient's blood pressure falls requiring the commencement of vasoactive medication intravenously
CNS unstable	During the process of mobilization, there is a drop in Glasgow Coma Scale by one or more, or a sustained increase in the patient's intracranial pressure above 20 mmHg

Variable	Definition
CVS unstable	During the process of mobilization, the patient experiences abnormal heart rhythm, heart rate, or blood pressure that requires return to bed
SpO2	During the process of mobilization, the patient's oxygen saturation levels drop to 84% or less for greater than 10 seconds
Patient refused	During the process of mobilization, the patient declines to participate in mobilization despite explanation of the benefits of mobilization, appropriate pain cover and encouragement
Nil	No adverse events occurred during mobilization
Sedated	Patient is unable to co-operate with staff due to high level of sedation – this does NOT include unsedated patients who have a low GCS
Comatosed	Mobilisation is not carried out due to the patient having a low GCS. The low GCS must NOT be related to the influence of sedatives
Procedure required	Despite best efforts to co-ordinate with all team members, the requirement of a procedure must take precedence over mobilization
ETT in situ	Mobilisation is not carried out due to the presence of an ETT/NTT
RRT in progress	Mobilisation is not carried out due to the presence of renal replacement therapy (dialysis)
Lack of resources	Mobilisation is not carried out due to the lack of availability of staff or equipment (e.g. chairs, tilt table)
Patient refused	Prior to the commencement of mobilization the patient refuses to participate despite adequate pain cover, explanation of the benefits of mobilization and encouragement
Orthopaedic orders	Due to orthopaedic restrictions, patient is not allowed to mobilize in order to allow healing of bony fractures.
Imminent Death	Mobilisation is not carried out due to medical staff's prediction that the patient's condition is not compatible with life and death is imminent in the next 48 hours.
Diarrhoea	Mobilisation is unable to be carried out due to patient suffering from uncontrolled diarrhoea

Variable	Definition
CVS unstable	Patient is requiring high levels of vasoactive medication, is having new or uncontrolled abnormal cardiac rhythms, has a haemoglobin level lower than 70 or a systolic blood pressure of ≤ 80 mm Hg
CNS unstable	Patient's intracranial pressures have been discussed with senior medical staff and deemed to be too high or too labile to allow safe mobilization
Respiratory unstable	Patient's ventilation requirements are deemed to great by medical staff to allow mobilization +/- patient is requiring nitric oxide.
Other – please specify	

Appendix 15 Ethics approvals

TheAlfred

ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 228/11

Project Title: Trial of Early Activity and Mobilisation

Principal Researcher: Dr Carol Hodgson

was considered for Low Risk Review and ***APPROVED*** *on* **07-Jun-2011**

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report on the anniversary of approval and on completion of the project.

Approval covers the project as described in the application (including any modifications made prior to approval). Low Risk projects are subject to audit and ethical approval may be withdrawn if the project deviates from that proposed and approved.

SPECIAL CONDITIONS

None

SIGNED: _____
Chair, Ethics Committee (or delegate)

R. FREW
SECRETARY
ETHICS COMMITTEE

Please quote Project No and Title in all correspondence

Austin Health

Austin Hospital

145 Studley Road
PO Box 5555 Heidelberg
Victoria Australia 3084
Telephone 03 9496 5000
Facsimile 03 9458 4779
www.austin.org.au

Human Research Ethics Committee
Research Ethics Unit
Henry Buck Building
Austin Hospital

TO:	**Dr Sue Berney** **ICU** **Austin Health**
PROJECT:	An audit of mobility practices in ICU
PROJECT NO:	H2011/04371
FROM:	**Jill Davis Research Ethics Unit Manager**
DATE:	**14th July 2011**
RE:	Audit application
Approval Period:	**14 July 2011 to 14 July 2012**

I wish to inform you that the audit named above has been reviewed and approved by the Austin Health Research Ethics Unit on behalf of the Austin Health Human Research Ethics Committee.

Should your audit not commence twelve (12) months from the date of this letter this approval will lapse. A resubmission to the Research Ethics Unit would then be necessary before you could commence.

Should you plan for your audit to go beyond the 1-year ethics approval, please request in writing an extension of ethics approval prior to its lapsing.

Please note a final report or publication must be submitted for all audits.

Jill Davis

FREMANTLE HOSPITAL & HEALTH SERVICE
Clinical Audit & Quality Improvement

Registration Form

Date Received:	29/10/10
QI Ref Number:	CAU1025

Refer to the Clinical Audit & Quality Improvement Registration Form Guideline before completing this form.

1	Project Title
	Project Title: TEAM - Trial of Early Activity and Mobilisation

2	Project Principal Investigator Details
	Name: Megan Harrold/ Jade Flindell **Job Title:** Senior Physiotherapist/ Acting Section Head - Cardiorespiratory Physiotherapy **Directorate/Department:** South Metro Physiotherapy **Internal Post Address:** Physiotherapy Department, Fremantle Hospital, B Block **Telephone and email:** 0421515074; harroldm@hotmail.com ▪ List Project Team Co-investigators in the typed Project Proposal.

3	Project Background
	Patients who have life threatening conditions and are treated in the intensive care unit (ICU) often experience muscle weakness beyond that expected from bed rest alone. The exact mechanisms behind this are not fully understood. An intervention purported to improve outcomes of these patients is mobilisation. As yet the optimal form, duration, intensity and frequency of exercise programs in ICU are yet to be established. In order to conduct a large trial to examine this intervention in detail, thorough baseline information must be established. This is the purpose of the current audit.

4	Project Objectives & Standards
	State Project Objective/s: Establish mobility levels of patients who are mechanically ventilated and admitted to ICU Establish adverse event rates associated with mobility of mechanically ventilated patients in ICU Establish reason why mechanically ventilated patients in ICU are not mobilised **List Project Standards:** (standards/policies/literature etc) ☒ None a) b) c) d)

5	Methodology
	Note: more than one method may be applicable

	☒ Clinical Audit ☐ Practice Review	☐ Satisfaction/ knowledge Survey ☐ Service Improvement	☐ Program Evaluation

6	**Data Collection Tool/s**
	Will the Project include data collection? ☒Yes ☐No ▪ If **Yes:** Will the Data Collection be: ☐ Retrospective ☒ Prospective ☐ Both Is the Data Collection Tool attached: ☒Yes ☐No ▪ Proceed to section 7 ▪ If **No:** ▪ Proceed to section 9

Registration Form – Continued

7	**Data Collection Details**
	Population group & sample size: Mechanically ventilated patients admitted to intensive care unit over a four week period for the duration of the patients stay in intensive care or until eight weeks from commencement of the audit - which ever occures first. **Data source/s:** APACHE database, Intensive Care Unit patient observation charts
8	**Data Analysis**
	Who will be analysing data? ☒ Project Principal Investigator and/or ☐ Other: state who **Method:** quanitative and descriptive data analysis
9	**Information Management**
	Where will the project paper and/or electronic files be stored? School of Physiotherapy, Curtin University, Perth Western Australia **How will the project paper and/or electronic files be secured?** All electronic data will be stored on password protected computers and paper files will be stored in locked filing cabinets.
10	**Ethical Assurance**
	Have you answered YES to any of the 5 questions for ethical assurance? ☐Yes ☒No ▪ If **Yes:** discuss the QI Project with QI Contact before submitting form. ▪ Do you intend to publish the outcomes of this project? ☒Yes ☐No
11	**Project Sign-off**
	Intended Project Start Date: 01/11/10 **Anticipated Project End Date:** 24/12/10 **Please specify who/where you intend to report your findings to:** As part of the principal investigator's (Megan Harrold) Doctorate of Philosophy; peer reviewed scientific journal

I agree to conduct this QI Project as specified by this Registration Form: ☒

Project Principal Investigator Signature: Megan Harrold
Printed Name & Job Title: Megan Harrold Senior Physiotherapist.
Date signed : 29/10/10

12	**Head of Department Sign-off**
	I am aware of the conduct of the QI Project as specified by this Registration Form: ☒ I agree to support this proposed QI Project on behalf of the Project Principal Investigator: ☒ **HOD/Manager Signature:** **Printed Name & Job Title:** MERCEDES ELLIOTT SECTION HEAD PHYSIOTHERAP **Date signed:** 29/10/10.

FHHS Clinical Audit Approval

CGU Manager

Print Name Jodie McNamara

Director Clinical Services

Print Name DAVID BLYTHE

Date Approved 5/11/10

This QI Project is approved on the proviso that results will not be published without the FHHS DCS permission.

Queensland Government

Queensland Health

Ms Meg Harrold
C/- Oystein Tronstad
Physiotherapy Department
The Prince Charles Hospital

Human Research Ethics Committee
The Prince Charles Hospital
Metro North Health Service District
Administration Building, Lower Ground
Rode Road, Chermside QLD 4032

Enquiries to: Jacqui_Hayward@health.qld.gov.au
Philip_Lee@health.qld.gov.au
Office Ph: (07) 3139 4691
(07) 3139 4500
Our Ref: PL/JI/Approval Amendments

28 July 2011

Dear Ms Harrold,

Re: HREC/11/QPCH/92: T.E.A.M Trial of early ambulation and mobilisation

I am pleased to advise that The Prince Charles Hospital Human Research Ethics Committee reviewed the amendments submitted and upon recommendation, the Chair has granted approval for the following:

- Additional site – Princess Alexandra Hospital

This information will be tabled at the next HREC meeting held 11 August 2011, for noting.

Documents reviewed and approved on 1 June 2011 pertaining to the above study include:

Document	Version	Date
Low Risk Application		25 May 2011
Low Risk Site Specific Assessment (TPCH)		25 May 2011
Protocol	1	25 May 2011
Data Collection Form	1	25 May 2011
Data Dictionary	1	25 May 2011
Questionnaire	1	25 May 2011

Sites included under this approval are:

No.	Principal Investigator	Site
1	Mr Oystein Tronstad	The Prince Charles Hospital
2	Mr Marc Nickels	The Princess Alexandra Hospital

A copy of this approval must be submitted to the District Research Governance Officer/Delegated Personnel with a completed Site Specific Assessment (SSA) Form for authorisation from the CEO or Delegate to conduct this research at The Princess Alexandra Hospital Health Service District.

Please complete the Notification of Commencement Form once commencement of this protocol has occurred at each site (http://www.health.qld.gov.au/northside/documents/form_notification.dot) and return to the office of The Prince Charles Hospital Human Research Ethics Committee.

Patient information collected and distributed as part of the previously approved research has been approved in accordance with Section 62 of the Health Services Act and the recent amendments to the Public Health Act Sections 282 and 284. Any change to the collection and or distribution will need to be reviewed by the HREC.

On behalf of the Human Research Ethics Committee, I would like to wish you every success with your research endeavour.

Yours truly,

Philip Lee, MBA (UQ); BAppSc (QUT); FRCNA; AFAIM
Executive Officer – Research, Ethics and Governance Unit
Email: Philip_Lee@health.qld.gov.au

Metro South
Human Research Ethics Committee

Enquiries to: Governance Department
Phone: (07) 3176 7722
Fax: (07) 3176 7667
Our Ref: HREC/11/QPCH/92 – SSA/11/QPAH/456
E-mail PAH-Research@health.qld.gov.au

Mr Marc Nickels
Physiotherapy Department
Princess Alexandra Hospital
Ipswich Road
Woolloongabba QLD 4102

SSA AUTHORISATION – PRINCESS ALEXANDRA HOSPITAL
METRO SOUTH HEALTH SERVICE DISTRICT

Dear Mr Nickels,

HREC reference number: HREC/11/QPCH/92
SSA reference number: SSA/11/QPAH/456
Project title: Trial of Early Ambulation and Mobilisation.

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to take place at the Princess Alexandra Hospital.

The following conditions apply to this research proposal. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval.

1. Problems and SAEs: The Research Governance Office must be informed of any problems that arise during the course of the study which may have ethical implications. Where serious adverse events (SAEs) are encountered, the events must be notified as soon as possible. http://www.health.qld.gov.au/pahospital/research/adverse_events.asp
2. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project are to be submitted to the HREC for review. A copy of the HREC approval/rejection letter must be submitted to the RGO;
3. Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project, are to be submitted to the research governance officer;
4. Proposed amendments to the research protocol or conduct of the research which may affect both the going ethical acceptability of the project and the site acceptability of the project are to be submitted firstly to the HREC for review and then to the research governance officer after a HREC decision is made.

If this research involves the recruitment of patients from the Metro South Health Service District (MSHSD), it is my responsibility to remind you of your ongoing duty of care for all people recruited into projects or clinical trials whilst public patients. All conditions and requirements regarding confidentiality of public information and patient privacy apply.

You are required to comply at all times with any application requirements of Australian and Queensland Laws including the Health Services Act, the Privacy Act, Public Health Act (2005) and other relevant legislation, ethics obligations and guidelines which may be applicable to the MSHSD from time to time including, without limitation, any requirement in respect of the maintenance, preservation or destruction of patient records.

When the study involves patient contact, it is your responsibility as the principal investigator to notify the relevant consultant and request their approval.

We wish you every success in undertaking this research.

Yours sincerely,

Dr David Theile Snr
DISTRICT CHIEF EXECUTIVE OFFICER
METRO SOUTH

27/1/12

Office
Centres for Health Research
Princess Alexandra Hospital
Metro South Health Service District

Postal
Ipswich Road
Woolloongabba Q 4102

Phone
61 7 3176 7722

Fax
61 7 3176 7667

Queensland Government

Queensland Health

Ms Meg Harrold
C/- Oystein Tronstad
Physiotherapy Department
The Prince Charles Hospital

Human Research Ethics Committee
The Prince Charles Hospital
Metro North Health Service District
Rode Road,
Chermside QLD 4032
Executive Officer Research & Ethics Ph: (07) 3139 4500
Office Ph: (07) 3139 4691
Fax:: (07) 3139 6907
Our Ref: AC/JL/Final Approval – Multi-site Low Risk

2 June 2011

Dear Ms Harrold,

Re: **HREC/11/QPCH/92: T.E.A.M Trial of early ambulation and mobilisation**

Thank you for submitting your Low Risk project for ethical and scientific review under the Single Ethical Review Process (SERP). I am pleased to advise that The Prince Charles Hospital Human Research Ethics Committee reviewed your submission and upon recommendation, the Chair has granted final approval for your low risk project.

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.

I am pleased to advise that the Human Research Ethics Committee has granted approval of this research project. The documents reviewed and approved on 1 June 2011 include:

Document	Version	Date
Low Risk Application		25 May 2011
Low Risk Site Specific Assessment		25 May 2011
Protocol	1	25 May 2011
Data Collection Form	1	25 May 2011
Data Dictionary	1	25 May 2011
Questionnaire	1	25 May 2011

This information will be tabled at the next HREC meeting held 9 June 2011, for noting.

Please note the following conditions of approval:

1. 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.

2. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major

amendments should be reflected in revised documents. Further advice on submitting amendments is available from http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf

3. Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r (by-passing the HREC).

4. Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly the HREC for review and, once HREC approval has been granted, then submit to the RGO.

5. The HREC is notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

6. The Principal Investigator will provide a report to the HREC at the completion of the study in the specified format.

7. The Human Research Ethics Committee or Health Service District Administration may inquire into the conduct of any research it approves for a specific site; or which the Committee has approved when conducted outside at multiple Health Service District sites.

HREC approval is valid for the duration of the project.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer on 3139 4500. The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp.

Please complete the Notification of Commencement Form once commencement of this protocol has occurred at this site (http://www.health.qld.gov.au/northside/documents/form_notification.dot) and return to the office of the Human Research Ethics Committee.

The HREC wishes you every success in your research.

Yours faithfully

Dr Russell Denman
Chair
HUMAN RESEARCH ETHICS COMMITTEE
METRO NORTH HEALTH SERVICE DISTRICT

Appendix:
List of Principal Investigators and Sites:

No.	Principal Investigator	Site
1	Mr Oystein Tronstad	The Prince Charles Hospital

Ethics approval for Royal Hobart Hospital

Office of Research Services
University of Tasmania
Private Bag 1
Hobart Tasmania 7001
Telephone + 61 3 6226 7479
Facsimile + 61 3 6226 7148
Email Human.Ethics@utas.edu.au
www.research.utas.edu.au/human_ethics/

HUMAN RESEARCH ETHICS COMMITTEE (TASMANIA) NETWORK

UTAS

25 October 2011

Prof Garry Allison
C/- Elisabeth Pilgrim
Physiotherapy Services
Royal Hobart Hospital
GPO Box 1061
Hobart TAS 7001

Dear Professor Allison,

REF NO: H12076
TITLE: TEAM (Trial of Early Activity and Mobilisation) – auditing current mobilisation practice in intensive care

- *Application Form Tasmania Health and Medical HREC- Prior Approval*
- *Application Form- Fremantle Hospital and Health Service*
- *Data dictionary*
- *Data collection Form*
- *Application approval letters: The Alfred Hospital HREC; Prince Charles Hospital HREC; St Vincent's Hospital HREC*
- *Protocol*
- *Human Research Ethics (Tas) Network Privacy Form*

The Tasmania Health and Medical Human Research Ethics Committee considered and approved the above documentation following its meeting on **26 September 2011.**

All committees operating under the Human Research Ethics Committee (Tasmania) Network are registered and required to comply with the *National Statement on the Ethical Conduct Human Research* (NHMRC 2007).

Therefore, the Chief Investigator's responsibility is to ensure that:

(1) The individual researcher's protocol complies with the HREC approved protocol.

(2) Modifications to the protocol do not proceed until **approval** is obtained in writing from the HREC.

(3) Section 5.5.3 of the National Statement states:

Researchers have a significant responsibility in monitoring approved research as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the relevant institution/s and ethical review body/ies and take prompt steps to deal with any unexpected risks.

Tasmania
Explore the possibilities

The appropriate forms for reporting such events in relation to clinical and non-clinical trials and innovations can be located at the website below. All adverse events must be reported regardless of whether or not the event, in your opinion, is a direct effect of the therapeutic goods being tested. http://www.research.utas.edu.au/human_ethics/medical_forms.htm

(4) All research participants must be provided with the current Patient Information Sheet and Consent Form, unless otherwise approved by the Committee.

(5) The Committee is notified if any investigators are added to, or cease involvement with, the project.

(6) This study has approval for 4 years contingent upon annual review. A *Progress Report* is to be provided on the anniversary date of your approval. Your first report is due **25 September 2012.** You will be sent a courtesy reminder closer to this due date.

(7) A *Final Report* and a copy of the published material, either in full or abstract, must be provided at the end of the project.

Should you have any queries please do not hesitate to contact me on (03) 6226 1956.

Yours sincerely

Adele Kay
Acting Executive Officer
Health and Medical Human Research Ethics Committee
Human Research Ethics Committee (Tas) Network

Ethics approval for Royal Perth Hospital

Department of Health
Government of Western Australia
South Metropolitan Area Health Service

Royal Perth Hospital

ETHICS COMMITTEE

A/Prof F M van Bockxmeer PhD MHGSA, ARPCA, FAHA
PathWest Laboratory Medicine
Tel: 9224 2322 Fax: 9224 2491
Email Frank.VB@health.wa.gov.au

Room 4112 Level 4, Kirkman House
Tel: 9224 2292

EC 2008/099
(This number must be quoted on all correspondence)

8th August 2008

A/Prof S Webb
Department of Intensive Care Unit
Royal Perth Hospital

Dear Steve

EC 2008/099 – The effect on outcomes of introducing an early mobilisation protocol for patients admitted to ICU and mechanically ventilated longer than 48 hours

Thank you for your detailed responses to the Committee's queries re the above study. I am pleased to advise the study is now **APPROVED.**

The following general conditions apply to all approvals by this Committee, and starting a trial or research project following the issue of ethics approval will be deemed to be an acceptance of them by all investigators:

1. The submission of an application for Ethics Committee approval will be deemed to indicate that the investigator and any sponsor recognises the Committee as a registered (with AHEC) Health Research Ethics Committee and that it complies in all respects with the National Statement on Ethical Conduct Research Involving Humans and all other national and international ethical requirements. **The Committee will not enter into further correspondence on this point.**

2. All income arising from the study must be lodged in a hospital special purposes account. Performance of a clinical trial for a sponsor is a service for tax purposes and all GST obligations must be met.

3. The investigator will report adverse events accompanied by a statement as to whether or not the trial should continue. The Committee reserves the right to not receive reports whose complexity or level of detail requires the expenditure of unreasonable time and effort. The Committee receives voluminous paperwork relating to adverse event reporting. From time to time the Committee chairman may require these reports to be summarised and approval is granted subject to the agreement of the investigator that he or she will prepare such a summary on request.

4. The Committee has decided that, as the responsibility for the conduct of trials lies with the investigator, all correspondence should be signed by the investigator.

5. All trial drugs must be dispensed by the Pharmacy Department. A fee is levied for this service and investigators must regard this fee as an item requiring a budget allocation. Alternatively, if a sponsor agrees, separate direct funding of pharmacy services may be undertaken. There are provisions for this fee to be waived for locally-inspired unfunded studies not having an external sponsor.

6. Though state institutions are outside the jurisdiction of the Privacy Act and related legislation, the Committee will assume that the privacy provisions of that Act will be the minimum standards applying during the conduct of a trial at Royal Perth Hospital. Traditional standards of patient confidentiality will apply.

7. The Committee will not acknowledge trial communications as a matter of course, unless they relate to a matter requiring Committee approval. Evidence of dispatch of a letter will be deemed to be evidence of receipt. This rule may be waived at the Committee's discretion on provision of a *pro forma* receipt by the investigator for the Chairman's signature and return. However, trivial correspondence (as judged by the Committee) will not be acknowledged even if a *pro forma* receipt is provided. Where an investigator requests written approval or written record of a matter for special purposes (say at the request of a sponsor), the investigator should prepare the required letter for the chairman's signature rather than expect the Committee secretary to prepare it. This mechanism increases the probability that the trial details in the letter are correct.

8. The Committee will provide the names and representative affiliation of members on request, but will not provide personal details or voting records.

9. A brief annual report on each project approved will be required at the end of each fiscal year, in default of which approval for the study may be suspended. Ethics approvals at RPH do not carry an expiry date so the annual report is an important part of Ethics Committee procedure.

10. The Committee has the authority to audit the conduct of any trial without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred or if a complaint is received from a third party, or the Committee wishes to undertake an audit for QA purposes.

11. Complaints relating to the conduct of a clinical trial should be directed to the Chairman and will be promptly investigated. Complaints about the Ethics Committee decisions or policies that cannot be resolved by discussion with the Chairman or about any actions of a particular member including the Chairman, should be directed to the Director of Clinical Services. Only written complaints (not e-mail) will be accepted for investigation.

Investigators of sponsored studies are advised to draw the above conditions to the attention of the sponsor. Investigators are reminded that records of consent or authorisation for participation in special studies (including clinical trials) form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA *Health Patient Information Retention and Disposal Schedule (Version 2) 2000.* A copy of the 'Patient Information Sheet' should also be included in the medical records as part of informed consent documentation.

Yours sincerely

Frank M van Bockxmeer
Chairman, Royal Perth Hospital Ethics Committee

The Royal Perth Hospital Ethics Committee is constituted and operates in accordance with NH&MRC Guidelines.

Copy: Julien Harris (Business Manager)

Government of **Western Australia**
Department of Health
Ethics Ref: 2011-094 approval SCGG
Ext 2999

Sir Charles
Gairdner Hospital

28 September 2011

Ms Diane Dennis
Intensive Care Unit
4th Floor G Block
Sir Charles Gairdner Hospital
Hospital Ave
NEDLANDS WA 6009

Dear Ms Dennis

APPLICATION TO CONDUCT HUMAN RESEARCH AT SCGH:
TRIAL No: 2011-094
TRIAL TITLE: Trial of Early Activity and Mobilisation

On behalf of the Sir Charles Gairdner Group Executive I give approval to conduct your research project at Sir Charles Gairdner Hospital based on the favourable reviews provided to me by Research Governance and the Sir Charles Gairdner Group Human Research Ethics Committee. This approval is granted until 28 September 2015, and on the basis of compliance with all requirements laid out in your application and with the provision of reports as required by the Research Governance and the approving HREC in giving their favourable opinion (attached).

The responsibility for the conduct of this study remains with you as the Principal Site Investigator. You must notify the HREC Office of any relevant issues arising during the conduct of the study that may affect continued favourable opinions by the hospital or by an HREC.

Please quote Study number 2011-094 on all correspondence associated with this study.

Yours sincerely

Dr Robyn Lawrence
EXECUTIVE DIRECTOR
SIR CHARLES GAIRDNER GROUP

Sir Charles Gairdner Group Human Research Ethics Committee, Level 2 A Block, Hospital Ave, Nedlands, WA 6009
Telephone (08) 9346 2999 Fax (08) 9346 3307 ABN: 13 993 250 709
email HREC.SCGH@health.wa.gov.au Website www.scgh.health.wa.gov.au

St Vincent's Hospital

A facility of
St. Vincents & Mater Health Sydney

St. Vincent's Hospital Sydney Ltd
ABN 77 054 038 872
390 Victoria Street
Darlinghurst NSW 2010 Australia

T +61 2 8382 1111
F +61 2 9332 4142
www.stvincents.com.au

5 August 2011

Meg Harrold
18 Morphett Cres
Bateman WA 6150

Dear Meg

SVH File Number: 11/085
Project Title: Trial of early ambulation and mobilisation

Thank you for submitting responses to issues raised by the HREC Executive Committee at a meeting on 21 June 2011 relating to the above project. Based on the information you have provided and in accordance with the NHMRC National Statement 2007 and NSW Health Policy Directive PD2010_055 Ethical and Scientific Review of Human Research in NSW Public Health Organisations, this project has been assessed as low/negligible risk and is therefore exempt from full HREC review.

This Lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the HREC Executive at a meeting on 4 August 2011 has granted ethical and scientific approval of the above **multi centre** project.

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The project is approved to be conducted at:

- St Vincent's Hospital
- St Vincent's Private Hospital
- Wollongong Hospital

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documents have been approved:

Protocol version 2: 20 July 2011

The Low and Negligible Risk Research Form (LNRF) reviewed by the HREC was LNRF AU/6/FFF903.

Please note the following conditions of approval:

- This approval is valid for five years.
- The Co-ordinating Investigator will provide an annual progress report beginning in **August 2012**, to the HREC as well as a final study report at the completion of the project in the specified format.

- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by participants regarding the conduct of the project.

- Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the HREC Executive for review, in the specified format.

- The HREC Executive will be notified, giving reasons, if the project is discontinued before the expected date of completion.

- Projects that are undertaken by Investigators holding an academic appointment (including conjoint appointments) or by students as part of a University course are also required to notify the relevant University HREC.

Should you have any queries about your project please contact the Research Office, Tel: 8382-2075, email research@stvincents.com.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website: www.stvincents.com.au/researchoffice or internal at http://exwwwsvh.stvincents.com.au/researchoffice

Please quote **SVH File Number: 11/085** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely

Sarah Charlton
HREC Executive Officer
Research Office
L6 deLacy Building
D/2011/11428

Health
Illawarra Shoalhaven
Local Health District

Research Directorate
Telephone: 02 4253 4800
Facsimile: 02 4253 4803

TRIM NO: D11/55222
Ref: 11/085
APPROVAL

Ms Anne Poulton
Physiotherapy Department
Level 5 – Block C
Wollongong Hospital

Dear Ms Poulton

HREC multi-centre project number: 11/085
Project title: Trial of Early Ambulation and Mobilisation

Thank you for submitting a Site-Specific Assessment application for authorisation of the above project. I am pleased to inform you that authorisation has been granted for this study to take place at the following site:

- Physiotherapy Department – Wollongong Hospital
- Intensive Care Unit – Wollongong Hospital

The following conditions apply to this research project. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval:

1. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the lead HREC for review, are copied to the research governance officer;
2. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing site acceptability of the project, are to be submitted to the research governance officer.

Yours faithfully

KRISTY PIERCE
Research Governance Officer

12 September 2011

Research Directorate
Level 8, Block C, Wollongong Hospital
(LMB 8808, SCMC NSW 2521)

Appendix 16 Scotland ethics requirements

Waiver of ethics for Scotland

South East Scotland Research Ethics Service

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000

NHS Lothian

Name: Lisa Salisbury
Address: Fourth Floor,
Medical School
(Doorway 6)
Teviot Place
Edinburgh

Date: 14/10/2010
Your Ref:
Our Ref: NR/109/AB17
Enquiries to: Alex Bailey
Direct Line: 0131 536 9050
Email: alex.bailey@nhslothian.scot.nhs.uk

Dear Lisa,

Full title of project: A Service Evaluation of Early Mobilisation in the Intensive Care Unit

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer and you are advised that, based on the submitted documentation (Mobilisation form Oct 2010.pdf, TEAM protocol version 3 12th Oct 2010.doc, Study questionnaire Oct 2010.doc), it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees in the UK. The advice is based on the following:

- *The project is a service evaluation using only data obtained as part of usual care, but note the requirement for Caldicott Guardian approval for the use or transfer of person-identifiable information within or from an organisation*

If this project is being conducted within NHS Lothian you should inform the relevant local Quality Improvement Team(s).

This letter should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that ethical approval is not required under NHS research governance arrangements. However, if you, your sponsor/funder or any NHS organisation feels that the project should be managed as research and/or that ethical review by a NHS REC is essential, please write setting out your reasons and we will be pleased to consider further. Where NHS organisations have clarified that a project is not to be managed as research, the Research Governance Framework states that it should not be presented as research within the NHS.

You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

Alex Bailey
Scientific Officer
South East Scotland Research Ethics Service

Caldicott guardianship for Aberdeen Royal Infirmary, Aberdeen (NHS Grampian)

From: Dijkhuizen Roelf (NHS GRAMPIAN) [mailto:roelf.dijkhuizen@nhs.net]
Sent: 18 August 2011 14:26
To: Lisa Salisbury
Cc: Cassie Lyndsay (NHS GRAMPIAN)
Subject: RE: Caldicott Guardian Approval

Dear Lisa

With this email I would like to confirm that NHS Grampian has no objections to the data flow as proposed in the documentation attached. Please ensure that electronic data is held in encrypted format and paper data is held behind lock and key. Any publication or presentation on the study should not contain patient identifiable data.

Best wishes

Roelf

Caldicott guardianship for Forth Valley Royal Hospital, Larbert (NHS Forth Valley)

CAL00000009

NHS FORTH VALLEY
CALDICOTT / DATA PROTECTION CONSENT FORM

NHS Forth Valley

APPROVAL FOR THE RELEASE OF NON-ANONYMISED INFORMATION WITHOUT CONSENT

Data Source [enter details of system]: **There will be 2 sources of data.**

MOBILISATION DATA COLLECTION FORM. A pre-printed mobilisation data collection form will be used to collect information on a daily basis about individuals ventilated in the intensive care unit (during a 2 month period of time). Information will include their daily need for ventilatory; renal & cardiovascular support; the type of activity & length of any episodes of mobilisation; any adverse events during mobilisation and reasons for patients not being mobilised. This will be completed by the Intensive Care Physiotherapist. This form will be sent to Australia, using a courier, for data analysis.

WARDWATCHER DATABASE. The wardwatcher number of each patient will be collected on a separate sheet (early mobilisation recording form). This wardwatcher number will be collected by the intensive care physiotherapist and passed to Lisa Salisbury (NHS Lothian). Wardwatcher is a national database of patients admitted to adult general Intensive Care Units (ICU) in Scotland since 1995. Detailed information is produced on the management of critically ill or injured patients. Using individual wardwatcher numbers an application will be made to the audit group managing the wardwatcher database to collect demographic details about the whole cohort of patients included in the service evaluation including age, gender, admission diagnosis, APACHE II, length of ICU stay, length of hospital stay.

Reason for Request:

This service evaluation is part of a Scotland wide service evaluation of early mobilisation in intensive care. The Scottish dataset will be compared with data collected in the same manner across intensive care units in Australia to provide an international baseline and comparison of mobilisation practice in intensive care. Data analysis of non-identifiable patient data will take place in Australia (Mobilisation Data Collection Form) and data analysis of patient-identifiable data will take place in Scotland by Lisa Salisbury.

Intended Recipients Details	
Name:	Lisa Salisbury
Position:	Research Physiotherapist
Organisation:	The University Of Edinburgh
Address:	Critical Care Research Office GU309 Chancellors Building 49 Little France Crescent EH16 4SB
Tel. No:	0131 242 9453
Email Address:	Lisa.Salisbury@ed.ac.uk
Data Protection Registration No.	Z6426984

Name(s) of any co-user(s):	Meg Harrold Garry Allison Steve Webb
Data Remaining within UK:	**Yes** ☐ **No** ☒

Will the Data be transferred out with the European Economic Area (EEA) at any time:

Yes ☒ **No** ☐

Give Reason for transfer out with EEA:

This service evaluation is part of an international comparison of mobilisation in intensive care units in Australia and Scotland.

The co-ordinating centre is in Perth, Australia and therefore data will need to be transferred from Scotland to Australia.

The data collection forms will be transferred to Australia by courier for data analysis (these forms will include no patient-identifiable data).

All demographic details (including all patient identifiable data) will be obtained by a request to SICSAG (Scottish Intensive Care Audit Group) from the wardwatcher database for the patients included in the service evaluation. The analysis of patient-identifiable data will take place in Scotland and be transferred to Australia as summary data only electronically using encrypted password protected files.

Nature of Information

Information Requested (specific details required):

On the mobilisation data collection form information relating to baseline information, mobilisation data, adverse events and reasons for any patients not mobilised will be collected. Please find attached a copy of the mobilisation data collection form.

Demographic details that will be requested from the wardwatcher database will include

1. Age
2. Gender
3. Admission Diagnosis (Surgical or Medical only)
4. Intensive care length of stay
5. Hospital length of stay
6. APACHE II score

Intended use of data (include publications): Journal publications, conference presentations and inclusion in the PhD thesis of Meg Harrold.

Name of Person & Department responsible for the data gathering:
Carol Grant, Physiotherapy Department.

Detail how the shared data will be transferred, during storage and destruction

The mobilisation data collection forms and early mobilisation recording forms will be completed by clinical staff working on the intensive care unit (Carol Grant).

All forms will be passed directly in person to Lisa Salisbury (Edinburgh University/NHS Lothian) who will collate all wardwatcher numbers from the early mobilisation recording form and apply to the wardwatcher database for the demographic and other data (age, gender, admission diagnosis, ICU length of stay, hospital length of stay, and APACHE). All paper held information will be kept in a locked cupboard in a room that is kept locked.

The mobilisation data collection forms (with no patient identifiable data) will be sent by courier from Scotland to Meg Harrold at Curtin University, Perth, Australia. The forms will be analysed electronically and then subsequently destroyed.

The database of information classified as non-identifiable (ICU length of stay, hospital length of stay, APACHE) obtained from the wardwatcher database will be sent to Meg Harrold at Curtin University, Perth, Australia. This will be sent electronically in an encrypted file which will be password protected.

The database of information classified as identifiable (age, gender and admission diagnosis) will remain in Scotland. This will be analysed by Lisa Salisbury and summary data only will be sent to Meg Harrold at Curtin University, Perth, Australia. This will be send electronically in an encrypted file which will be password protected.

The research team undertaking the service evaluation will have access to all the summarised data (Lisa Salisbury, Meg Harrold, Garry Allison, Steve Webb). Only Lisa Salisbury will have access to the databases that include patient-identifiable data. All the research team will have access to the databases of non-identifiable data.

In both countries all paper-based data (both patient identifiable and non-identifiable) will be kept in a locked cupboard. All data both patient-identifiable and non-identifiable data held electronically will be stored on the university network in preference to the hard drive and held in an area that can only be accessed by Lisa Salisbury (Scotland) or Meg Harrold (Australia) and which is password protected. Any electronic transfer of data between Australia and Scotland will be encrypted and password protected. The encryption tool will either be Bitlocker encryption or Truecrypt.

Caldicott Guardian Details (*see over for appropriate Guardian*)	
Name:	Dr Iain Wallace
Position:	Medical Director/Caldicott Guardian
Organisation:	NHS Forth Valley
Address:	Carseview House, Castle Business Park, Stirling FK9 4SW
Tel. No.	01786 463031
Data Protection Registration No:	**Z6175671**

Please return this form to:-

Information Governance Department
Central Supplies
Colquhoun Street
STIRLING, FK7 7PX

Telephone No: (01786) 433285

Fax No: **(01786) 451156**
(non secure)

Confidentiality Statement

For users of NHS patient data

Recipient's Declaration:

I declare that I understand and undertake to abide by the rule for confidentiality, security and release of data received from Forth Valley , as specified in points 1 - 7 on page 4 of this document.

Signature: [redacted] **Date:** 26th July 2011

Name: (Print) LISA SALISBURY

Caldicott Guardian's Declaration:

I declare that LISA SALISBURY (named above as the recipient of the data requested), is engaged in a reputable research/audit project and that the data requested can be entrusted to him/her in the knowledge that (s)he will conscientiously discharge his/her obligations in regard to confidentiality of the data, as stated in paragraph 1 - 7 on page 3 of this document. I am happy for him/her to receive this data.

Signature: A M Wallace **Date:** 27.7.11

(on behalf of NHS Forth Valley)

Name: (Print) AM WALLACE

Caldicott guardianship for Royal Infirmary of Edinburgh – Edinburgh; Western General Hospital – Edinburgh; St John's Hospital – Livingston (NHS Lothian)

Lothian NHS Board

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 465 5461
Fax 0131 536 465 5494

www.nhslothian.scot.nhs.uk

NHS Lothian

Lisa Salisbury
Research Fellow
Edinburgh University

Date 11TH October 2011
Your Ref
Our Ref JMS/fb/1183
Enquiries to Jim Sherval
Extension
Direct Line 0131 465 5461
Email jim.sherval@nhslothian.scot.nhs.uk

Dear Ms Salisbury

CALDICOTT APPLICATION 1183
A Service Evaluation of Early Mobilisation in the Intensive Care Unit

Thank you for the information supplied

Request received from	Lisa Salisbury, Research Fellow, Edinburgh University
Summary of proposal	A Service Evaluation of Early Mobilisation in the Intensive Care Unit
Patient identifiable information requested	Age, Gender, Wardwatcher Number, Admission Diagnosis
Approved	YES
Advice	

Yours sincerely

Dr Alison McCallum
Director of Public Health & Health Policy

Caldicott guardianship for Ninewells Hospital – Dundee; Perth Royal Infirmary - Perth (NHS Tayside)

Information Governance Team
Ashludie Hospital
Monifieth
Angus
DD5 4HQ
T. 01382 527920
F. 01382 527808
www.nhstayside.scot.nhs.uk

NHS Tayside

Date 28 September 2011
Your Ref
Our Ref Caldicott/CSAppLS280911
Enquiries To Sender
Extension 27920
Direct 01382 527920
Email peter.mckenzie@nhs.net

Lisa Salisbury, Research Fellow,
GU309
The University of Edinburgh
49 Little France Crescent
Edinburgh
EH16 4SB

Dear Ms Salisbury

Caldicott Approval –Data Extract from Wardwatcher Database

Attached to this letter is a copy of the completed Confidentiality Statement giving Caldicott Guardian approval to provision of the specified data held in Wardwatcher Database as described in your statement.

Thank you for your co-operation in providing us with the information requested by us in this process.

Please contact me should any queries arise from the application of this approval.

Peter McKenzie
Information Governance Manager

Cc: Dr Edward Wilson, Clinical Director for Critical Care, Dept of Anaesthetics, Ninewells Hospital
File

Caldicott guardianship for Queen Margaret Hospital – Dunfermline (NHS Fife)

NHS
Fife

APPLICATION FOR CALDICOTT APPROVAL FOR USE OF PATIENT IDENTIFIABLE DATA

User Details

Name: Lisa Salisbury

Position: Research Fellow

Organisation: The University of Edinburgh

Address: GU309, Chancellors Building, 49 Little France Crescent, Edinburgh

Postcode: EH16 4SB

Tel. No.: 0131 242 9453

E-mail: Lisa.Salisbury@ed.ac.uk

Name(s) of any co-user(s): Meg Harrold, Garry Allison, Steve Webb

NHS
Fife

Telephone Number: 01383 627032 ext ~~2288~~ 22288

Signature: ..... Date: 15/08/11

Counter-signature by Line Manager

Name: AMANDA WONG

Job Title: OPERATIONAL LEAD PHYSIOTHERAPIST

Signature: Amanda Wong Date: 24/08/11

Please forward to:
Una Hill
Data Protection & Caldicott Coordinator
NHS Fife
Information Services Department
Lynebank Hospital
Dunfermline KY11 8JH

Counter-signature by Operational Division/Primary Care Caldicott Guardian

Name: DR GORDON BIRNIE

Job Title: MEDICAL DIRECTOR, OPERATIONAL DIVISION

Signature: ..... Date: 12/10/11

I authorise access to the data as noted above:

Signature: ..... Date: 18/10/11

DR EDWARD COYLE
Caldicott Guardian for NHS Fife

Caldicott guardianship for Raigmore Hospital – Inverness (NHS Highland)

NHS Highland

CALDICOTT APPROVAL FORM FOR USE OF PATIENT IDENTIFIABLE DATA

Please return this form to

Christine Robinson, Office Manager, Public Health, Assynt House, Beechwood Park, Inverness IV2 3BW
Email: christine.robinson7@nhs.net

Project Title

A Service Evaluation of Early Mobilisation in the Intensive Care Unit

Name of Applicant: Lisa Salisbury

Address: GU309, Chancellors Building, The University of Edinburgh, 49 Little France Crescent, Edinburgh, EH16 4SB

Tel No 0131 242 9453

Email address: Lisa.Salisbury@ed.ac.uk

Name of organisation receiving data: The University of Edinburgh

and their Data Protection Registration Number: Z6426984

What patient identifiable information are you looking to use?

CHI Number	
Forename	
Surname	
Initials	
Date of Birth	
Address	
Postcode	
Other, please specify	1. Wardwatcher number

Application Number .....(for office use only) 1

NHS Highland

	2. Admission Diagnosis
Age	X
Gender	X

Purpose for which data are to be used (principle 1)

This service evaluation of early mobilisation in intensive care (ICU) is being carried out in Scotland and Australasia to provide an international comparison of clinical practice. This data will provide baseline information about the current practice of early mobilisation in intensive care. The data will be analysed both collectively and for individual units. Data will be fed back to individual units and will be used to inform a possible future trial.

A standard mobilisation data collection form will be used to collect information about mobilisation for each patient included in the service evaluation. The site ID will refer to the site of data collection. The patient number will be numbered consecutively for each patient on each site. The mobilisation data collection form will not contain any patient-identifiable data to ensure they are anonymous.

Requirement to use identifiable data (principle 2)

The wardwatcher number (database managed by the Scottish Intenisive Care Society Audit Group) is required to retrospectively obtain age, gender, admission diagnosis and other none patient identifiable data (ICU length of stay, hospital length of stay and APACHE) from the wardwatcher database. The wardwatcher number for each individual patient will be collected by the clinical physiotherapist on a sheet separate from the mobilisation data collection form.

Why is each data field required? (principle 3)

The age, gender and admission diagnosis are required to describe the patient populations and allow a comparison between the populations in Scotland and those in Australasia. While a specific diagnosis e.g. Liver Transplant may result in a patient being identified it is proposed in this service evaluation that admission diagnosis will be described as either surgical or medical and elective or non-elective.

The wardwatcher number is required to obtain data from the wardwatcher database. Access to the wardwatcher database is accessible only through an application.

Application Number .....(for office use only) 2

NHS Highland

Outline access to information (principle 4)

The mobilisation data collection forms and early mobilisation recording forms will be completed by clinical staff working on the intensive care units.

All forms will be passed to Lisa Salisbury (Edinburgh University/NHS Lothian) who will collate all wardwatcher numbers and apply to the wardwatcher database for the demographic and other data (age, gender, admission diagnosis, ICU length of stay, hospital length of stay, and APACHE).

The mobilisation data collection forms (with no patient identifiable data) will be sent by courier from Scotland to Meg Harrold at Curtin University, Perth, Australia. The forms will be analysed electronically and subsequently destroyed.

The database of information classified as non-identifiable (ICU length of stay, hospital length of stay, APACHE) obtained from the wardwatcher database will be sent to Meg Harrold at Curtin University, Perth, Australia. This will be send electronically in an encrypted file which will be password protected.

The database of information classified as identifiable (age, gender and admission diagnosis) will remain in Scotland. This will be analysed by Lisa Salisbury and summary data only will be sent to Meg Harrold at Curtin University, Perth, Australia. This will be send electronically in an encrypted file which will be password protected.

The research team undertaking the service evaluation will have access to all the summarised data (Lisa Salisbury, Meg Harrold, Garry Allison, Steve Webb). Only Lisa Salisbury will have access to the databases that include patient-identifiable data. All the research team will have access to the databases of non-identifiable data.

Outline action taken to ensure compliance with responsibilities and obligations to respect patient confidentiality (principle 5)

All clinical staff will already deal with patient-identifiable information and on an ongoing basis will maintain patient confidentiality in line with professional standards and the data protection act.

All university based staff will be required to adhere to data protection of research data and will hence maintain patient confidentiality.

Outline organisational compliance with legal requirements (principle 6)

Each organisation has somebody responsible for handling identifiable information and ensuring this is legal.

At Edinburgh University Data Protection is overseen by the Records Management Section. The Data Protection Officer is Susan Graham (Susan.Graham@ed.ac.uk), although other members of the team can advise on any data protection issues.

Application Number .....(for office use only)

NHS Highland

At Curtin University, Perth, Australia, Linda Teasdale is the manager of research ethics phone: (+618) 9266 2784 Fax: (+618) 9266 3793 email: L.Teasdale@curtin.edu.au and Assoc Prof Stephan Milett is Chairman of Human Research Ethics phone: (+618) 9266 1009 fax: (+618) 9266 3658 email: S.Millett@exchange.curtin.edu.au who have responsibility for data protection.

What have you done to establish whether anyone else has the data you require?

There are no other studies at this time that we know of that are collecting the same/similar data.

Please note: Copies of completed Approval Forms will be forwarded to NHS Highland's Area Information Security Manager and, if the project falls into non-research category, the Clinical Effectiveness Manager for comments.

Applicant: Lisa Salisbury

Job Title: Research Fellow

Signature: Lisa Salisbury **Date: 8th August, 2011**

Authorisation Granted **Yes** ☑ **No** ☐

Comments:

Caldicott Guardian: Dr Margaret Somerville, Director of Public Health, NHS Highland

Signature ..... **Date:** 12.9.11

Principle 1 – Justify the purpose(s)
Every proposed use or transfer of patient-identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian.

Principle 2 – Don't use patient-identifiable information unless it is absolutely necessary
Patient-identifiable information items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).

Application Number .....(for office use only) 4