IMPROVING THE QUALITY AND QUANTITY OF SLEEP FOR THE INTENSIVE CARE PATIENT

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Certificate of authorship/originality

I certify that the work in this thesis has not been previously submitted for a degree nor has it been submitted as part of the requirements for a degree except as fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help I have received in my research work and in the preparation of this thesis has been acknowledged. In addition, I certify that all the information sources and literature used are indicated in the thesis.

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Signature of candidate

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Abstract

Patients in intensive care units (ICUs) frequently experience sleep disruption. Few recent sleep studies using polysomnography (PSG) conducted in ICU are available. Interventional studies to improve sleep in ICU are rare and PSG is infrequently used to evaluate interventions designed to improve sleep in ICU.

The primary aim of the study was to explore ICU patients' quality and quantity of sleep, using 24-hour PSG recording, patient self-report and nurse nocturnal observation. Secondary aims included an assessment of 24-hour sound and illuminance levels; self-reported sleep quality on the Ward and at home two months after discharge from hospital; patients' psychological well-being at home two months after discharge from hospital; and the effect of the introduction of a 'rest and sleep' guideline.

An exploratory approach was taken in this quasi-experimental study. Thirty patients completed 24-hour PSG sleep recording before the introduction of the Guideline and 23 patients after. The Guideline was developed using a consultative approach in which research evidence and suggestions from ICU health care personnel were incorporated. Audits were conducted in the postintervention phase to assess guideline adoption.

The sample comprised 70% men and the mean age was 58 years. Diagnoses were mainly nonoperative (66%). Fifty-four percent received mechanical ventilation during PSG recording. Median duration of mechanical ventilation was six days and median length of ICU stay was 12 days.

Median total sleep time was five hours. The majority of sleep was stage 1 and 2. There was significant sleep fragmentation (median duration of sleep without waking: 3:15 min:sec). Forty-four per cent of sleep was during the day. There were concerns about the interrater reliability of the PSG data analysis using the Rechtshaffen and Kales criteria (Kappa values: 0.56 and 0.51). Patients' self-reported sleep in ICU using the Richards Campbell Sleep Questionnaire was poor (mean: 51 mm). Nurses' estimations of nocturnal

sleep were higher than the PSG derived value. Sound levels exceeded international standards for hospitals. Night-time illuminance levels were appropriately low. The introduction of the Guideline did not appear to result in an improvement in sleep however Guideline uptake was limited.

This investigation revealed the need for alternative methods of analysing ICU patients' PSG data. The study protocol demonstrates the feasibility of conducting further extensive investigations into potential relationships between patients' sleep disruption and outcomes. The method in which the Guideline was developed may be of interest to other clinicians wishing to develop guidelines when research evidence is limited.

1 Introduction

1.1 Background to the study

1.1.1 Introduction

Patients in the intensive care unit (ICU) are treated for critical illness which frequently requires invasive and intrusive devices and treatments. This, together with the effects of illness and a noisy environment, contributes to discomfort and in particular an inability to sleep well. International research indicates that patients treated in ICU often experience highly disrupted (fragmented) sleep. Their sleep comprises predominantly of short bouts of stage 1 and 2 with little or no rapid eye movement (REM) or slow wave sleep. Patients who are able to, comment on their inability to sleep well in ICU.

There is a growing understanding that sleep is vital for well-being. Epidemiological studies confirm the link between poor sleep and illness such as coronary artery disease. Intensive care patients experience poor quality sleep but are arguably in great need of good quality sleep in order to heal and recover from critical illness.

The nature and mechanisms of sleep disruption in ICU patients are not clearly understood. Many extrinsic and intrinsic sleep disruptive factors have been proposed, for example elevated environmental sound and illuminance levels, inflammatory mediators, discomfort and mechanical ventilator settings. Few recent studies using polysomnography (PSG) in ICU have been published and there is a lack of knowledge about patients' sleep in Australian ICUs, as there are no published data using PSG, the definitive method of measuring sleep. More significantly there are few recent studies examining patients' sleep alongside the measurement of factors with the potential to sleep disturb sleep in ICU.

1.1.2 Assessing sleep in ICU

A number of objective and subjective methods to assess sleep are available. Many have significant limitations when used in the intensive care context. Objective measures

include PSG, actigraphy and Bispectral Index. Subjective methods are patient self-reports and nurse observation.

Polysomnography is the definitive method of assessment allowing sleep staging and identification of arousals and awakenings. However it requires specific equipment and expertise to obtain data of sufficient quality and experienced personnel to analyse the data. Actigraphy involves the use of a movement sensor which is usually worn on the wrist. It is not used to assess sleep in ICU patients because immobility tends to lead to overestimations of sleep time. Bispectral Index is useful for monitoring levels of anaesthesia but has not yet been configured to detect sleep states with any accuracy. Therefore at present PSG remains the only option for objectively measuring sleep in ICU.

The most reliable subjective method of sleep assessment is patient self-report. A number of instruments are available for self-reporting sleep and a few have been specifically developed for assessment in the critically ill. However patients must have sufficient awareness and cognition to complete them. The Richards Campbell Sleep Questionnaire (RCSQ) (Richards et al., 2000) is a widely used self-report instrument in ICU. Nurse observation has often been shown to provide an overestimation of sleep time particularly when unstructured methods of assessment are performed. The two structured instruments consistently used in ICU are the Echols' Sleep Behaviour Tool (Echols, 1968) and the Nurses' Observation Checklist (Edwards and Schuring, 1993). Estimations of sleep time using these instruments correlate more closely with PSG measured sleep time than unstructured methods of nurse observation.

1.1.3 Strategies to improve sleep in ICU

A number of methods to improve sleep for ICU patients have been attempted with some success. They include noise and disturbance reduction programmes, eye masks and ear plugs, administration of nocturnal exogenous melatonin, nocturnal mechanical ventilator settings, massage and relaxation. As few studies have used PSG to evaluate the effectiveness of interventions to improve sleep the results are largely inconclusive.

1.2 The aim of the thesis

In summary evidence from international research suggests that ICU patients experience disrupted poor quality sleep. However there are few recent published studies which have measured sleep using PSG and there are no published studies from Australian ICUs. The purpose of this thesis is to report an exploratory study in which sleep was assessed using 24-hour PSG recording, patient self-report and nurse observation in patients in ICU. An account of environmental sound and illuminance levels and the treatment and care patients were exposed to during sleep recording is provided. The patients' self-reported sleep quality at several different time points, prehospital, in ICU, in the Ward and at home two months after discharge from hospital, is also presented. An additional objective is to describe the development and implementation of a rest and sleep guideline (containing sleep promoting activities) which was introduced in the study ICU.

1.3 Outline of the thesis

The background to the study described in this thesis has been briefly outlined in this chapter. A more thorough overview of the importance of sleep, its architecture and measurement is provided in Chapter two. In addition the findings of previously published studies investigating sleep in ICU patients are presented with particular emphasis on the review of studies conducted in ICU using 24-hour sleep recording. Factors known to affect sleep in ICU patients are presented along with the findings of interventional studies. Chapter two ends with the aims of the study.

In Chapter three the methods are outlined including descriptions of the instruments, protocol, data collection methods, data analysis and ethical considerations. Chapter four outlines the development and implementation of the Guideline ('rest and sleep for the intensive care patient'). Relevant literature regarding the development, implementation and adoption of clinical practice guidelines is presented along with diffusion of innovations theory.

The results including sample characteristics, sleep outcomes and environmental sound and illuminance levels are provided in Chapter five. An interpretation of the study findings in relation to existing knowledge are discussed in Chapter six. The effect of the introduction of the Guideline is explored together with the strengths and limitations of the study in this chapter. In addition recommendations arising from the study are made for future research and clinical practice. Finally Chapter seven, the conclusion, provides a summary of the research study, findings, and the contribution the thesis makes to knowledge and research.

2 Literature review

2.1 Introduction

Sleep is understood to be vital for health and well-being. The function of sleep is obscure, however the effects of disrupted sleep or sleep deprivation are well understood. Epidemiological studies have established that poor sleep is associated with increased risk of cancer and coronary artery disease and all cause mortality.

Critically ill patients frequently require invasive monitoring and intrusive treatments in intensive care units. Patients are dependent on ICU health care personnel and technology to sustain them. Frequently multi-organ treatment and support are required; assistance with breathing using mechanical ventilation via artificial airways and the administration of intravenous medications for haemodynamic stability and fluids for nutrition and hydration. The presence of several critically ill patients requiring care and treatment in ICU leads to high activity levels and intrusive noise levels. All of these factors contribute to discomfort and may lead to an inability to sleep. In fact published studies confirm that ICU patients commonly experience profound sleep disruption; in some cases total sleep time (TST) may be normal but the majority of sleep is stage 1 and 2 and little stage 3 and 4 (slow wave) or REM sleep. Patient self-reports of disrupted sleep in ICU support these findings. Arguably, critically ill patients are in great need of the benefits of restorative sleep, but are unlikely to experience it while in ICU. Larger observational studies and experimental investigations are required in order to improve sleep for patients treated in the ICU. Investigation of the amount and quality of ICU patients' sleep in Australia is warranted.

This chapter provides an overview of the background to the study described in this thesis. It begins with an overview of human sleep architecture during health, the function and control of sleep and the effects of sleep deprivation and disrupted sleep. The chapter also includes a review of the methods of quantifying and assessing the quality of sleep along with the advantages and disadvantages of their use in ICU. Studies which have quantified and assessed the quality of ICU patients' sleep are described together with

their strengths and weaknesses. The likely effects of various treatments, organ support, illness and the ICU environment on patients' sleep are discussed. Experimental studies conducted to improve sleep for ICU patients are also critically appraised. The chapter concludes with the study aims.

2.2 Human sleep architecture during health

Sleep in the adult human comprises one consolidated period--or TST--of six to eight hours in a 24 hour period at night (measured in the sleep investigation laboratory) (Ohayon et al., 2004). The sleep efficiency index (SEI) represents the proportion of time spent sleeping out of the time in bed / available to sleep and for a healthy adult is 85%. There are two main sleep states; REM sleep (approximately 25% of TST) and non-rapid eye movement (non-REM) sleep (approximately 75% of TST). Non-REM sleep is comprised of 4 stages: stages 1 and 2 and stages 3 and 4 or slow wave sleep (SWS) (newer sleep stage criteria, albeit not yet widely adopted, combine stage 3 and 4 into N3 (Iber et al., 2007)), which must be completed in sequence in order to enter REM sleep. Individuals become incrementally more difficult to wake from stage 1 to 4 so stages 1 and 2 are often referred to as 'light sleep' and stages 3 and 4 as 'deep sleep'. The consolidated sleep period consists of 4 to 6 sleep cycles; stages 1 to 4 followed by REM sleep, which last 60 to 90 minutes. During healthy nocturnal sleep the proportion of REM in each cycle increases towards the morning (Kryger et al., 2005). Time spent awake during the sleep period is less than five per cent of TST. Arousals (evidence of emergence into lighter stages of sleep on the electroencephalogram) are a feature of sleep; the population norm is approximately 10-25 per hour (Bonnet and Arand, 2007). The characteristics of normal sleep during health are provided in Table 1.

Table 1. Characteristics of normal sleep during health

Characteristic	Quantity/Description
Amount	
TST / SEI	Six to eight hours / 85%
Circadian nature	
Nocturnal	100% of sleep at night
Type of sleep	
Non-REM	75-80% of TST / slow frequency EEG* / reduced EMG† / little or no EOG‡ activity
REM	20-25% of TST / mixed frequency EEG / no EMG / EOG activity
Stages	
1	10-15% of TST / EEG slower than wake / little EMG / slow eye movements
2	40-50% of TST / EEG spindles and k complexes / little EMG and EOG
3 and 4	20-25% of TST / EEG slowest / no EMG and EOG
Organisation	Cycles of stages in sequence / five to six cycles per night/containing less stage 3 and 4 and more REM towards morning
Awakenings / arousals	Less than 5% of TST awake / 10-25 arousals per hour

*EEG = electroencephalography, †EMG = electromyography, ‡EOG = electrooculography

There are changes in sleep architecture over the adult lifespan which require consideration in the context of conducting sleep research in ICU patients. Total sleep time and percentage of SWS decline (TST by 10 minutes and SWS by two per cent per decade from childhood) and stage 1 and 2 sleep increases slightly (by five per cent between 20 and 70 years) with age (Ohayon et al., 2004). Rapid eye movement sleep remains fairly

constant with an approximate 0.6% decline per decade until age 70 when the proportion of REM increases with a simultaneous decrease in TST (Floyd et al., 2007). Time spent awake after sleep onset increases with age by ten minutes per decade after age 30 (Ohayon et al., 2004). Arousals increase during the adult lifespan from a mean of ten per hour during the second and third decade to approximately 25 per hour in the sixth decade (Bonnet and Arand, 2007).

The widely accepted method for defining sleep states and stages in adults are the Rechtschaffen and Kales (R and K) (1968) criteria which require sleep monitoring using a polysomnograph (outlined in the next section). The criteria describe waveform configurations and frequencies over 30 second intervals (or epochs). Criteria for relaxed wakefulness are: alpha or faster frequency electroencephalograph (EEG) for greater than 50% of the standard epoch, many eye movements and high electromyography (EMG) activity. Stage 1 criteria are: alpha or faster frequency EEG for less than 50% of the epoch (well defined rhythmic activity), increased theta and vertex wave activity on the EEG and slow rolling eye movements. In stage 2 there is low EMG activity combined with little eye movement, and sleep spindles or K complexes less than three minutes apart. The criteria for stage 3 are; little or no eye movements and EMG activity and distinctive delta-H waves for 20 to 50% of the epoch. Stage 4 is similar to stage 3 however there are delta-H waves present for more than 50% of the epoch. More recent sleep staging criteria defines stage 3 as '20% or more of an epoch contains waves of frequency 0.5 Hz-2 Hz and peak-to-peak amplitude greater than 75 μV, measured over the frontal regions' with additional rules related to reduced EMG and electrooculography (EOG) activity (Iber et al., 2007). Absence of EMG activity is characteristic of REM sleep along with rapid eye movements, sleep spindles or K complexes greater than three minutes apart, saw-tooth EEG and low-amplitude, mixed frequency EEG similar to stage 1 (Rechtschaffen and Kales, 1968). Arousals according to the American Academy of Sleep Medicine criteria are defined as 'an abrupt shift of EEG frequency including alpha, theta, and/or frequencies greater than 16 Hz (but not spindles) that lasts for at least three seconds, with at least 10 seconds of stable sleep preceding the change.' (Iber et al., 2007).

2.3 The function and control of sleep

The exact function of sleep is unclear. Fortunately, studies investigating partial and complete sleep deprivation and disruption provide some useful clues. However interpretation of the evidence is difficult. Studies into sleep deprivation and disruption have used different designs, are often dated and diverse techniques and times to measure outcomes such as immunological indicators were employed. Ethical concerns over deliberately preventing individuals from sleeping preclude further experimental research into complete sleep deprivation and prolonged sleep disruption in humans so that more recent research on the topic is predominantly performed in animals. For these reasons many of the effects of sleep deprivation and disruption (and consequently clues to the function of sleep) in humans are derived from observational (frequently epidemiological) study designs. To date, the most widely accepted theory of the function of sleep is that it restores the brain and body. The control and timing of sleep is explained by homeostatic and circadian theories.

Despite difficulties associated with research methodology used to investigate sleep deprivation and disruption, the evidence does suggest a vital role for sleep in psychological, cognitive and physical functions. Studies have highlighted changes in behaviour, mood and performance associated with sleep disruption (Luby et al., 1960, Taber and Hurley, 2006). Altered distribution of sleep stages, excessive daytime sleepiness, and decrements in mood and performance are some of the effects observed after a short period of sleep deprivation or disruption (Pilcher and Huffcutt, 1996, Zisapel, 2007). In prolonged sleep deprivation, temporary states resembling acute paranoid schizophrenia have been reported in healthy volunteers (Luby et al., 1960, Boonstra et al., 2007). There are no published studies confirming the association between delirium and sleep disruption in ICU, however anecdotal evidence suggests this is highly likely (Helton et al., 1980, Johns et al., 1974, Mistraletti et al., 2008, Weinhouse et al., 2009). A proposed mechanism for mood, cognitive and behavioural changes associated with sleep disruption is that repeated sleep disturbance prevents the repair and maturation of brain cells (particularly in the hypothalamus) and unconsolidated periods of REM sleep prevent the

reduction of levels of the brain neurotransmitter, monoamine (Meerlo et al., 2008). Monoamine reduction during REM is thought to be mood stabilising (Meerlo et al., 2008). It should also be noted that prolonged sleep deprivation and repeated episodes of sleep disruption increase sleep propensity, so many 'slowing' symptoms may be related to the desire and tendency to fall asleep. The resulting 'microsleeps' affect cognitive performance (in particular tasks requiring alertness) and provide an explanation for disturbances in perception (Durmer and Dinges, 2005).

Negative effects of sleep deprivation and disruption on the immune, respiratory, muscular and endocrine systems have also been described (Dinges et al., 1994, Meier-Ewert et al., 2004, Series et al., 1994, Vgontzas et al., 2004) indicating that sleep has a number of physical functions. Elucidating the exact nature of the adverse effects of sleep disruption on immune function is challenging for the reasons mentioned earlier; studies employ different techniques and times to measure immune function and are often conducted on animals. Despite this, evidence from epidemiological studies reporting chronic sleep deprivation or disruption comprising frequent periods of six hours or less of sleep in 24 hours in 'healthy' people have demonstrated long-term negative health effects and an increase in all-cause mortality (Gallicchio and Kalesan, 2009, Grandner et al., 2009). The adverse health effects are similar in character to an extended exposure to stress for example, coronary artery disease and cancer (Banks and Dinges, 2007). Increases in C-reactive protein during partial and complete sleep deprivation suggest a long-term immune inflammatory response may be to blame (Meier-Ewert et al., 2004, Patel et al., 2009). (Indeed sleep periods of greater than nine hours in 24 hours in the long-term have also been shown to increase propensity for chronic illness (Ferrie et al., 2007). The suggested mechanism here is that attempts to sleep for extended periods lead to fragmented and unrestorative sleep.) Sleep disruption studies highlight different reactions in terms of individuals' susceptibility and resistance to infection but recent results are a little less ambiguous suggesting sleep has an immunoprotective effect (Benedict et al., 2007, Cohen et al., 2009, Spiegel et al., 2002). The respiratory system has also been shown to be adversely affected by sleep deprivation (Series et al., 1994). In the

only study to investigate the effect of sleep disruption on clinical outcome in ICU, patients who experienced abnormal sleep were more likely to fail non-invasive ventilation (Roche Campo et al., 2010). Muscular dysfunction (premature fatigue) related to sleep disturbance is thought to be the result of increased insulin resistance and decreased glucose tolerance (VanHelder and Radomski, 1989). Endocrine derangements observed in sleep restriction are thought to increase appetite and contribute to unwanted weight gain, suggesting a role for sleep in metabolic control as well (Leproult and Van Cauter, 2010).

It should be highlighted that the presence of the effects of sleep loss vary from person to person and that partial and complete sleep deprivation studies merely provide a clue to the function of sleep and sleep stages. In regards to selective sleep deprivation, evidence of the relative importance of one sleep stage / state over another in adult humans is inconclusive (for example the role of REM sleep in assisting declarative memory) (Siegel, 2003). It would appear that all stages of sleep are important however non-REM appears to be preserved during adverse conditions more strongly than REM (suggesting that non-REM may be more important for health) (Siegel, 2005). Progression through sleep stages is normally required to experience slow wave and REM sleep, so sleep fragmentation is most likely to result in a significant reduction or elimination of slow wave and REM sleep (despite increased attempts to enter slow wave and REM sleep by individuals during prolonged sleep fragmentation). There is increasing evidence (from animal models) that prolonged REM reduction can result in inhibition of cell proliferation in the hippocampus (which arises independently of the associated stress hormones released as a consequence of sleep loss) (Meerlo et al., 2008). This mechanism may be responsible for poor health related to repeated REM sleep interruption and the relative increased feelings of fatigue and sleepiness associated with prolonged sleep fragmentation in comparison to short (restricted) sleep in which TST is identical. The impact of sleep fragmentation increases as the period between disruptive events decreases. Seminal work by Bonnet et al. in the 1980's, indicating that periods of consolidated sleep of 15 to 20 minutes are required for normal restoration (Bonnet,

1989), is still considered valid. Indeed high frequency sleep fragmentation is likely to be as detrimental to health as total sleep deprivation (Bonnet and Arand, 2003).

With regards to the time of day in which is preferable to sleep, it is generally considered that night-time sleep is more restorative (Zisapel, 2007). Sleep during the day is likely to be more fragmented (despite any increased propensity brought on by sleep restriction) as melatonin is released during darkness (at night) and human activity and interactions are higher during daylight hours. Despite this some sleep (whenever it is experienced) is better than none (Taber and Hurley, 2006).

The circadian clock and sleep homeostasis explain the timing of sleep and the propensity to sleep in humans. Briefly, the circadian (evolutionary) theory highlights the role of the suprachiasmatic nucleus, and an endogenous sleep promoting and maintaining hormone, melatonin, which is released from the evening to the early hours of the morning, in regulating circadian rhythm. The regulatory processes of the suprachiasmatic nucleus naturally promote a 24 to 25 hour sleep / wake cycle however exposure of the retina to light can phase shift the circadian rhythm. It is hypothesised that sleep ensures energy conservation by encouraging a period of inactivity in each 24-hour period. Since regulatory hormones promote sleep during darkness, when visual acuity is at its poorest, it reduces the risk of attack by predators. The homeostatic theory of sleep is based on the hypothesis that there is an increased propensity to sleep associated with high extracellular levels of adenosine which decrease cholinergic cell activity in the forebrain (Porkka-Heiskanen et al., 2002). Adenosine may also mediate other sleep promoting factors. Wakefulness increases brain extracellular adenosine levels and sleep reduces levels of adenosine.

2.4 **Measuring sleep**

There are many subjective and objective methods for measuring and recording sleep. Unfortunately most techniques have many limitations when used in the ICU context. This section outlines techniques for measuring sleep and their potential to accurately record sleep in ICU patients.

2.4.1 Objective measures

Polysomnography (PSG)

In order to score sleep states and stages using the R and K (1968) or American Academy of Sleep Medicine (Iber et al., 2007) criteria, three electrical waveforms are required: the EEG, the EOG and the surface EMG. These waveforms comprise the PSG and are the minimum requirement to stage the two sleep states, non-REM and REM. For this reason PSG is currently the definitive method for measuring and recording sleep for research and the diagnosis of sleep disorders and nocturnal respiratory insufficiency in clinical practice.

The first criterion on which staging is based are features of the EEG so the EEG comprises the core measurement of PSG. Electrodes are located according to the 10-20 international system (Jasper, 1958) of scalp EEG electrode placement. Given slight differences in the four cranial landmarks used for the 10-20 system between individuals, measurements for the exact placement of electrodes are made before each recording. The American Academy of Sleep Medicine recommends the placement of three EEG derivations to sample from the frontal, central and occipital regions referenced to the right and left mastoid processes for example, C4 (the right central location) referenced to M1 (the left mastoid process) (Iber et al., 2007). A minimum sampling rate of 200 Hz is recommended (the desirable rate is 500 Hz). A number of viable options are available to attach the electrodes and depend on the purpose and duration of the recording, however skin preparation is standardised; thorough cleansing and exfoliation is performed to remove oils and dead skin.

The EMG and EOG provide further information to allow sleep staging and arousal scoring. Reduced EMG activity is a feature of SWS and zero activity is detected during REM sleep in healthy individuals. Typically, the EMG is obtained from two electrodes (bipolar) placed over the mentalis / submentalis muscles but the masseter muscles may also be used. Electrooculography enables the recording of phasic rapid eye movements, a characteristic of REM sleep and the slow eye movements associated with sleep onset. Two

electrodes are required for the EOG: right and left. The left is placed one centimetre below the left outer canthus and the right one centimetre above the right outer canthus. The recommended minimum sampling rate for the EOG and EMG channels is 200 Hz (Iber et al., 2007).

Polysomnography offers the ability to record the quantity of sleep, sleep stages and sleep states, but a trained operator is required to ensure satisfactory signal quality and continuous recording. (Unattended PSG monitoring when the operator leaves after setup, typically results in 10-20% unusable data (Mykytyn et al., 1999, Redline et al., 1998)). This drawback precludes its routine use in clinical practice in the ICU. Potential problems for the researcher include the presence of 50 Hz interference and its elimination, space (for the electrodes on the patient and equipment beside the patient) and interpretation of sleep states from atypical EEG waveforms associated with critical illness (for example sepsis) (Cooper et al., 2000) and medications (for example, sedatives and hypnotics) (Freedman et al., 2001, Hardin et al., 2006). Despite these potential problems PSG, using at least two EEG channels, remains the most accurate option for quantifying ICU patients' sleep and providing an indication of sleep quality.

Actigraphy

Modern actigraphs are small wristwatch devices (which may also be located on the trunk or leg) containing accelerometers which detect motion in a single axis or multiple axes and memory capacity to record for many days (Ancoli-Israel et al., 2003). Motion is transformed into digital data using one or two of three methods, time above threshold, zero crossing or digital integration, and then stored. Typically movement is sampled several times a second (for example 32 Hz) and stored in one minute epochs. Band pass filtering is used to eliminate unwanted movements such as shivering and tremor (Ancoli-Israel et al., 2003, Bourne et al., 2007).

Actigraphy allows limited interpretation of sleep states therefore it currently has few clinical and research applications, for example it has no place in the diagnosis of sleep related respiratory insufficiency which is the main indication for sleep monitoring (Ancoli-

Israel et al., 2003). It is however well suited to the investigation of sleep disorders related to circadian rhythm derangements and in individuals who do not tolerate PSG, for example patients with dementia and children. Unfortunately this relatively simple device (which does not require a trained attendant) is unsuitable for research and clinical use in ICU patients. The data provide an overestimation of sleep time (ICU patients are generally immobile for long periods regardless of sleep state) and do not correlate well with PSG data (overall agreement between actigraphy and PSG is less than 65%) (Beecroft et al., 2008). This explains the small number of studies which have employed actigraphy in ICU.

Bispectral Index (BIS)

Acknowledging the technical difficulties with PSG and the inaccuracies associated with actigraphy recordings in the ICU setting, processed EEG monitoring devices, in particular the Bispectral Index (BIS), have been investigated as an alternative (Bourne et al., 2007, Nieuwenhuijs et al., 2002, Sleigh et al., 1999). Bispectral Index records frontal cortex EEG signals and processes this raw data using a specific algorithm. The device is routinely used to guide the administration of anaesthesia during surgery. Studies of sleep monitoring using BIS indicate that BIS values fall during sleep and rise during arousals (Sleigh et al., 1999, Tung et al., 2002). Sleigh et al. (1999), Benini et al. (2005) and Dahaba et al. (2011) investigated BIS values during sleep in healthy individuals and found BIS to be of value as a simple indicator of the depth of sleep. Nieuwenhuijs et al. (2002) noted considerable overlap in BIS values between sleep stages (simultaneous PSG recording was performed). An investigation conducted in ICU using BIS with an EMG channel, revealed good correlation between observed conscious level and BIS value but there was a wide variation in the data (Nicholson et al., 2001). The value of these results is further compromised by the small sample size and absence of PSG for comparisons and validation. The possibility of EMG interference (causing a concomitant rise in BIS) was a concern in the study by Dahaba et al. (2011) despite the use of the most recent version (BIS-VISTA). Allocating appropriate BIS values for REM sleep is another difficulty. Anyhow at present the algorithm on which BIS scores are derived is based on EEG raw data obtained from thousands of patients undergoing anaesthesia. Therefore considerable

algorithm development using comparisons with PSG data in healthy individuals is required before BIS is a viable option to measure sleep accurately in any setting.

Other objective methods

Few alternative objective methods to PSG other than actigraphy exist to measure sleep. For example, continuous recording of skin potentials has the potential to reliably indicate arousal level (Shiihara et al., 2001). Despite the possible utility in guiding sedation management, skin potential recording is unlikely ever to provide any more than a crude estimation of TST. Less sophisticated measures have also been developed for the purpose of measuring sleep. A recent review examined the sensitivity and specificity of a range of novel sleep 'detectors' for use in ambulatory settings including bed sensors and purpose made head caps for REM recording but none surpassed actigraphy as an alternative to PSG (Van de Water et al., 2010). The authors concluded that more research and development is required before these methods can be used to aid the diagnosis and treatment of sleep disorders or to research sleep in any setting.

2.4.2 Subjective measures

Subjective measures of sleep are common in descriptive and experimental studies conducted in ICU for reasons already provided: the potential technical problems associated with PSG and lack of an alternative objective measure. Despite the known disadvantages of self-reports (particularly for individuals with poor cognition or inattention), the patient's perception is an essential adjunct for any investigation aiming to promote or improve sleep quality. However observer assessment may be the only option when PSG or other technology is unavailable or the patient is unable to self-report.

Patient self-reports

Arguably the patient is best placed to judge the quantity and quality of their sleep. Patient perception or measures of quality of life are rated second only to mortality in importance as outcomes in health research. Therefore this and the relatively low complexity involved in administering sleep self-report instruments has lead patient perception of sleep to be the primary measure in many studies conducted in ICU. The

instruments used in these studies include visual analogue scales (VAS) and questionnaires. The mostly commonly used instruments in ICU sleep studies are the Verran and Snyder-Halpern (VSH) sleep scale (Snyder-Halpern and Verran, 1987) and the Richards Campbell Sleep Questionnaire (RCSQ) (Richards et al., 2000): both comprise multiple 100 mm VAS.

The VSH sleep scale (Snyder-Halpern and Verran, 1987) was specifically designed for use in hospital patients. It consists of 14 VAS attributes of sleep that measure three dimensions of sleep: disturbance, effectiveness and supplementation. Zero on each scale indicates the sleep attribute is absent and higher scores indicate increasing frequency of the attribute. The global VSH sleep scale score is the sum of all the VAS scores (three VAS scores are reversed). Higher scores indicate better sleep. The original VSH sleep scale (containing ten items) was validated in 69 healthy volunteers using two other methods of self-report (the St Mary's Hospital Sleep Questionnaire (Ellis et al., 1981) and the Baekeland Hoy Sleep Log (1971)) and showed moderate correlation, for example depth of sleep, $r = 0.69$ and quality of sleep, $r = 0.70$ ($p < 0.001$). Convergent reliability was satisfactory ($\theta = 0.82$). Inconsistent reliability was revealed in other studies; mean TST was comparable for actigraphy and VSH sleep score (308.1 versus 314.8 minutes, $p = 0.39$) in the study by Kroon & West (2000) but PSG and VSH sleep scale data showed poor correlation in the study by Fontaine (1987). Poor recall for shorter awakenings, misinterpretation of one of the VAS and a distorted sense of time were proposed as factors contributing to the disparity between PSG data and VSH sleep score (Fontaine, 1987).

Two self-report instruments have been specifically developed for use in ICU; the RCSQ and the Sleep in Intensive Care Questionnaire (SICQ). The RCSQ comprises five 100 mm VAS; sleep depth, latency, awakenings, time awake and quality of sleep. The total RCSQ score is the mean of the VAS scores. Higher individual VAS and total RCSQ scores indicate better sleep. The RCSQ was first developed for a study to compare the patients' and nurses' perceptions of patient sleep in ICU, however the thesis (by Campbell, C.) is unpublished with only a brief mention of the study in a review paper (Richards, 1987). The

RCSQ was pilot tested in a medical ICU (n = 9, all men) with PSG recordings over a total of 14 nights (Richards and Bairnsfather, 1988, Richards et al., 2000). After two amendments it was validated with PSG in a more extensive investigation involving 70 male patients (Richards et al., 2000). Despite correlations being low between the individual VAS and PSG sleep characteristics, there was a moderate correlation between total RCSQ score and SEI measured by PSG; $r = 0.58$ ($p < 0.001$). The total RCSQ score predicted 33% of the variance in the SEI (Richards et al., 2000).

The SICQ was developed in the 1990s in North America to investigate the patient's perspective of the quality of sleep with particular emphasis on the quality of sleep in ICU compared to 'at home' and the factors which contributed to sleep disruption while they were in ICU (Freedman et al., 1999). In addition, it was devised to provide an indication of the relative disruptive nature of environmental factors, for example alarm noises, X-rays and monitoring. It comprises seven items based on a Likert scale between one and ten (Freedman et al., 1999). A four factor model was proposed: sleep disruption secondary to interruptions by health care personnel and diagnostic tests, ICU sleep quality, daytime sleepiness and sleep disruption associated with environmental factors. The variance explained by the model was 54.9%. None of the factors were associated with age or gender. The authors performed pilot testing on 43 patients and as a consequence added question seven regarding noise disruption.

The SICQ is somewhat dated (some items currently have limited relevance for example, 'blood samples') however it offers a useful method of gaining the patient's perspective on specific potentially disruptive factors. It is also a helpful adjunct to other sleep measures to corroborate or refute the associations between environmental noise and care / treatment activities on sleep. The most appropriate use for the SICQ may be in quality improvement initiatives to gauge the adoption of organization / unit wide changes in clinical practice.

The RCSQ shows promise as a method of estimating sleep quantity (SEI) and the SICQ provides a gauge of environmental disturbance but there are limitations for their use

in ICU. The RCSQ, together with other self-report instruments, require a degree of cognitive acumen, sufficient memory and a reasonable perception of time in order to be completed accurately. Bourne et al. (2007) found 20% of patients were unable to complete the RCSQ mainly because they were delirious. Similarly, Frisk et al. (2003) estimated that 50% of patients were not sufficiently conscious or orientated to complete it. Fatigue and inattention are additional factors which reduce the ability of ICU patients to complete any instrument. It should also be noted that there are no data currently available from the healthy population on which to base comparisons or cut-off points for the RCSQ. This is a potential drawback when relying solely on it as a measure of sleep in the ICU for research and clinical practice.

Nurse assessment

Two validated instruments for nurse assessment of patient sleep state in ICU are currently available: the Echols' Patient Sleep Behavioural Observation Tool (EPSBOT) (Echols, 1968) and the Nurses' Observation Checklist (NOC) (Edwards and Schuring, 1993). Unfortunately only secondary information sources are available regarding the development of EPSBOT (Echols' thesis is unpublished) (Cureton-Lane and Fontaine, 1997, Fontaine, 1987, Kroon and West, 2000). The EPSBOT requires an assessment of the patient every five minutes with an evaluation of the patient's response to stimulation (torch light or calling the patient's name) every 30 minutes. (It is remarkable that an instrument designed to assess sleep requires a 'response to stimulation'.) An assignment of sleep / wake state: awake, drowsy, REM and non-REM sleep is made every five minutes. Criteria for eyelid, body, and respiratory muscle movement, are provided for each state. The EPSBOT was validated in a study conducted by Fontaine (1987) in a trauma ICU. A moderate to strong correlation between the nurse observer and PSG was noted (Sleep Latency ($r = 0.37$, $p < 0.05$), Mid Sleep Awakenings ($r = 0.46$, $p < 0.05$) and Wake After Sleep Onset ($r = 0.59$, $p < 0.01$)). Similarly the only other published study, which used the EPSBOT in an adult critical care setting, found that mean EPSBOT derived TST, actigraphy recorded TST and patient self-reported TST were comparable (270.0, 308.1 and 314.8 minutes ($p = 0.39$) respectively) (Kroon and West, 2000). However, in this study significant

differences were found between EPSBOT and the other sleep measures for midsleep awakenings and sleep latency data.

The NOC was used in a study to 'validate staff nurses' observations of sleep and wake states'. It is a relatively simple instrument which requires assessment and assignment of wake / sleep state: 'awake', 'asleep', 'could not tell' and 'no time to observe' every 15 minutes. Polysomnography recordings and nurse assessments occurred between 0100 and 0500 hours. No specific criteria were given for the assignment of wake / sleep state. Comparisons with PSG revealed that the nurses' assessment were correct 73.5% ($r = 0.385$, p value not provided) of the time. During sleep monitoring nurses were blinded to the PSG and no consultation was allowed between the PSG technician and the nurse.

Since evidence from studies using other instruments (or no instrument) suggest that nurses tend to overestimate sleep time (Beecroft et al., 2008, Bourne et al., 2007, Nicolás et al., 2008, Richardson et al., 2007b, Aurell and Elmqvist, 1985) it is perhaps surprising that the EPSBOT and NOC performed so well. (The worst concordance was reported by Aurell and Elmqvist (1985); mean TST estimated by the nurse was seven hours versus less than three hours for patient self-report.) There are a number of reasons that may account for the results. In the case of the EPSBOT, the principal investigator in the Fontaine (1987) study was a trained observer who performed all of the observations and was responsible for PSG recordings. It is unclear whether the PSG monitor was obscured from the observer; unintentional bias may have enhanced the results. In addition, the observer was solely responsible for sleep recording (mean duration: 6.25 hours). Likewise the nurse assessors in the Kroon and West (2000) study were responsible for one patient and sleep recording occurred between 2300 and 0600 hours. For the NOC, PSG recording occurred from 0100 to 0500 hours (four hours total) and 8.5% of nurse observations were 'no time to observe' and were subsequently classified as missing data (Edwards and Schuring, 1993). The conditions under which observations were made do not accurately depict a typical clinical workload and the likelihood of being able to closely and

continuously observe a patient for eight hours (the amount of missing data in the Edwards and Schuring (1993) study is evidence of this difficulty).

Notwithstanding the limitations associated with instruments like EPSBOT and NOC they may provide the most practical method of assessing the trend in a patient's TST, particularly if training on recognizing sleep / wake state behaviour is provided and when documented over a number of nights.

One other instrument, widely used for patient self-report, the RCSQ may provide an alternative method for observer assessment. It was first developed for this purpose. Frisk and Nordström (2003) administered the RCSQ to patients and the nurses caring for them to evaluate the competence of nurses to accurately assess ICU patients' sleep. The relationship between patients' and nurses' RCSQ scores was assessed. Nurses in this study were remarkably accurate in their assessments ($r = 0.869$, $p < 0.001$). This study is further discussed in the next section. In a similar study by Nicolás et al. (2008), nurses were correct about 40% of the time; in the majority of cases when they were incorrect they overestimated patients' sleep quality. Additional research is required to establish the validity of the RCSQ as a proxy assessment of patient sleep.

2.5 Sleep studies conducted in ICU

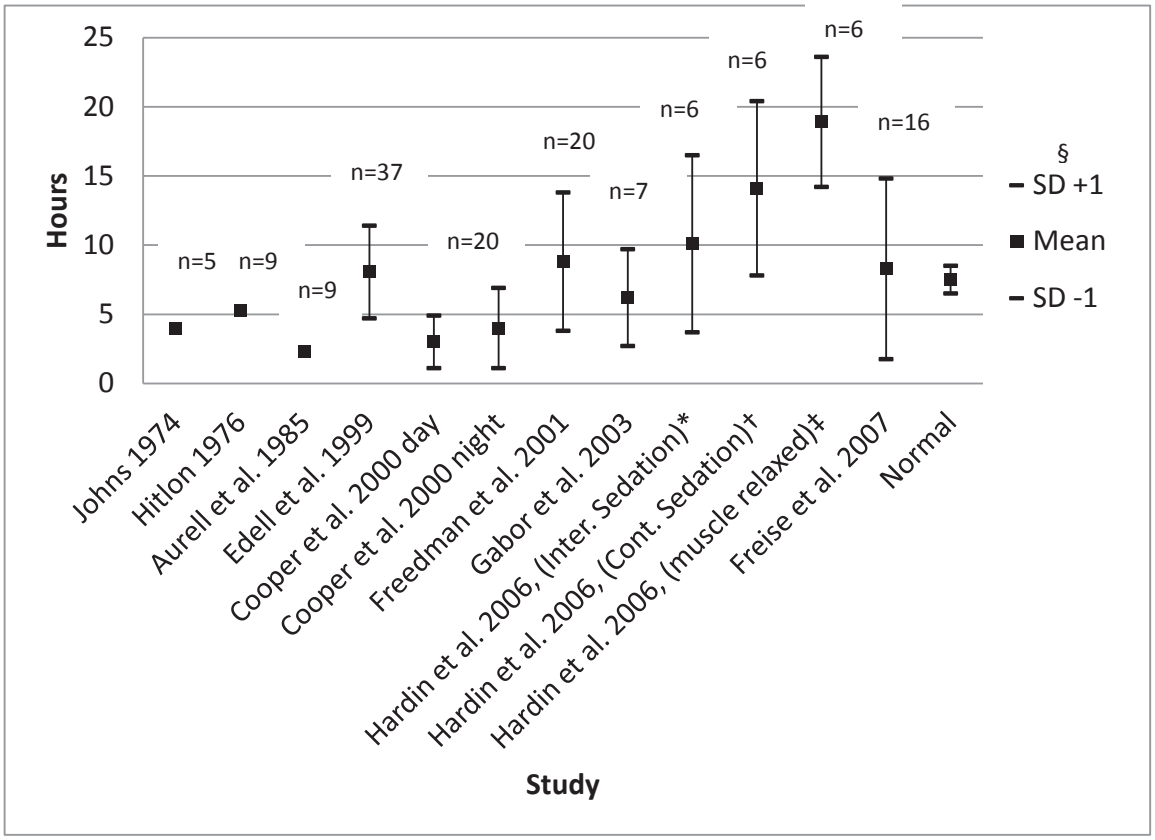
Studies conducted in ICU have used a variety of methods to measure sleep and employed a number of research designs; the descriptive study is the most prevalent. This, together with the diversity of patient demographics and small sample sizes makes summarizing the evidence challenging. However some similarities in the results can be identified. This section outlines the research conducted so far to elucidate the amount and quality of ICU patients' sleep and factors affecting their sleep. It begins with studies using PSG as the main method of measurement. Summary tables of the most frequently cited studies conducted in ICU are presented in Appendix A (published review paper).

2.5.1 Objective data

Studies using polysomnography (PSG)

The technical difficulties associated with undertaking PSG and atypical EEG waveforms frequently exhibited by ICU patients almost certainly accounts for the small number and size of studies conducted in ICU (sample sizes rarely exceed 20 patients). These factors, together with heterogeneous patient populations are a possible explanation for the wide variation in results between studies. In addition the dispersion of data within studies is wide (standard deviations commonly exceed 50% of the mean TST). However the methodology and results warrant careful consideration in order to develop research procedures and effective strategies to promote sleep. A summary of the findings of investigations using PSG conducted about sleep in ICU is provided in Table 2 at the end of this section.

Twenty-four hour sleep monitoring reveals that ICU patients' sleep is distributed approximately equally between day and night (Aurell and Elmqvist, 1985, Cooper et al., 2000, Edéll-Gustafsson et al., 1999, Freedman et al., 2001, Friese et al., 2007, Gabor et al., 2003, Hardin et al., 2006). The significant circadian rhythm disruption and sleep fragmentation experienced by patients in ICU are the most likely explanations. In studies that have employed 24-hour monitoring TST varies considerably between and within cohorts but the average may be normal or prolonged (Figure one).



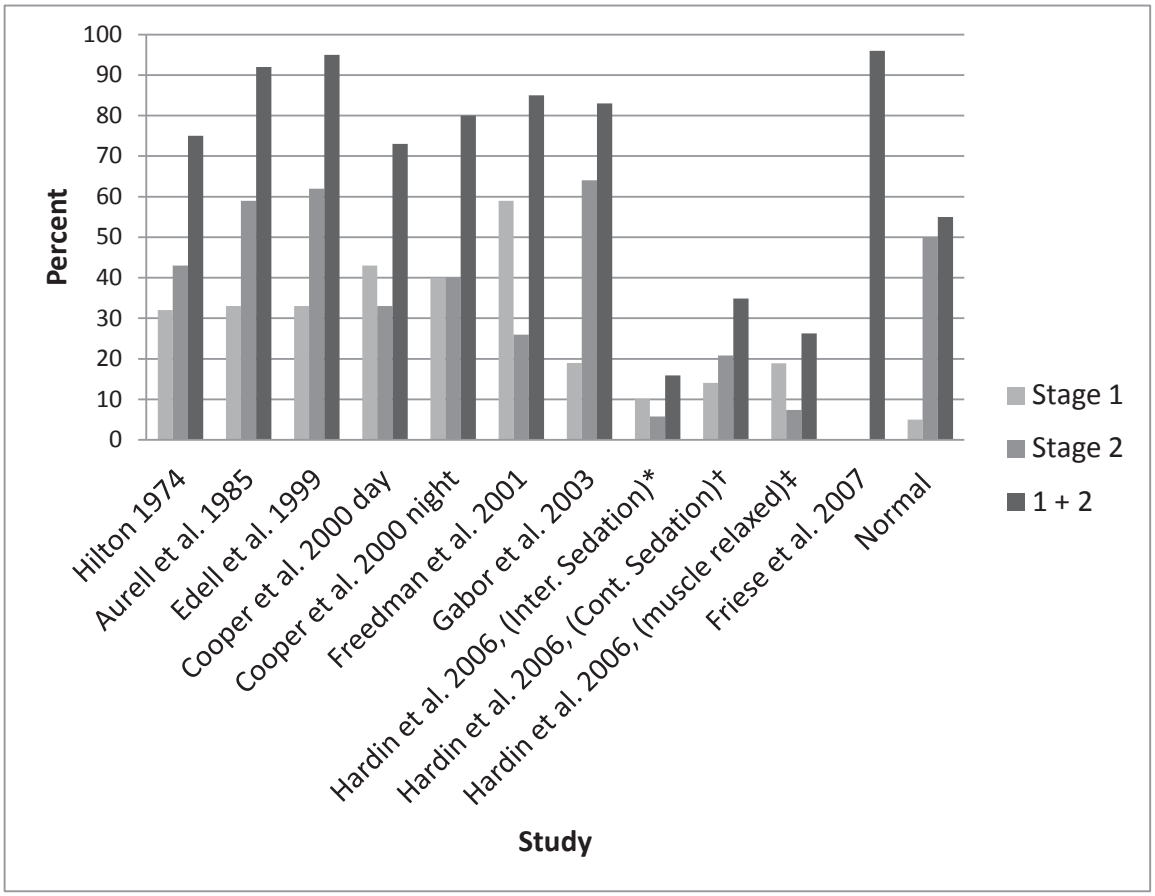
*Inter. sedation = patients were administered sedative medication intermittently, †Cont. sedation = patients were administered sedative medication using a continuous infusion, ‡Muscle relaxed = patients were administered neuromuscular blocking agents and sedative medication using a continuous infusion, §SD = standard deviation

Figure 1. Mean TST data (during 24-hour recordings in ICU)

A few studies reveal normal TST, however the standard deviations are wide and do not reflect expected healthy adult human values. In the study in which mean TST was prolonged, data from three groups of patients receiving moderate to large doses of sedative medications and neuromuscular blocking agents, intermittent sedation (n = 6), continuous sedation (n = 6) and neuromuscular blockade plus sedation (n = 6), were analysed separately (Hardin et al., 2006). Despite the obvious limitations of the small sample size and corresponding large standard deviations, this is the only study which has specifically investigated patients who are deeply sedated or muscle relaxed. It provides a further reminder of the methodological difficulties associated with using PSG in ICU. Large doses of sedatives and neuromuscular blocking agents reduce eye and muscle movement and likely caused an over calculation of TST using the R and K criteria. In addition sedatives

tend to prolong stage 1 and 2 sleep and reduce SWS, however this study revealed shorter stage 1 and 2 sleep and increased SWS (modified Delta criteria for SWS were used to compensate for the decrease in amplitude of delta waves associated with age and revealed similar results to the analysis using conventional amplitudes). This apparent anomaly may be explained by the small sample and the potential effect of underlying health conditions.

A predominance of stage 1 and 2 sleep is a feature common to all studies (other than Hardin et al. (2006)) using PSG in ICU. Data from 24-hour studies reveal that stage 1 and 2 sleep comprises a large proportion of TST, which is much higher than normal adult human values (measured in a sleep laboratory) (Figure two). The reduced amounts in the Hardin et al. (2006) study probably relate to difficulty interpreting EMG and EOG activity during deep sedation / muscle relaxation and increased slow wave EEG activity associated with underlying health conditions.



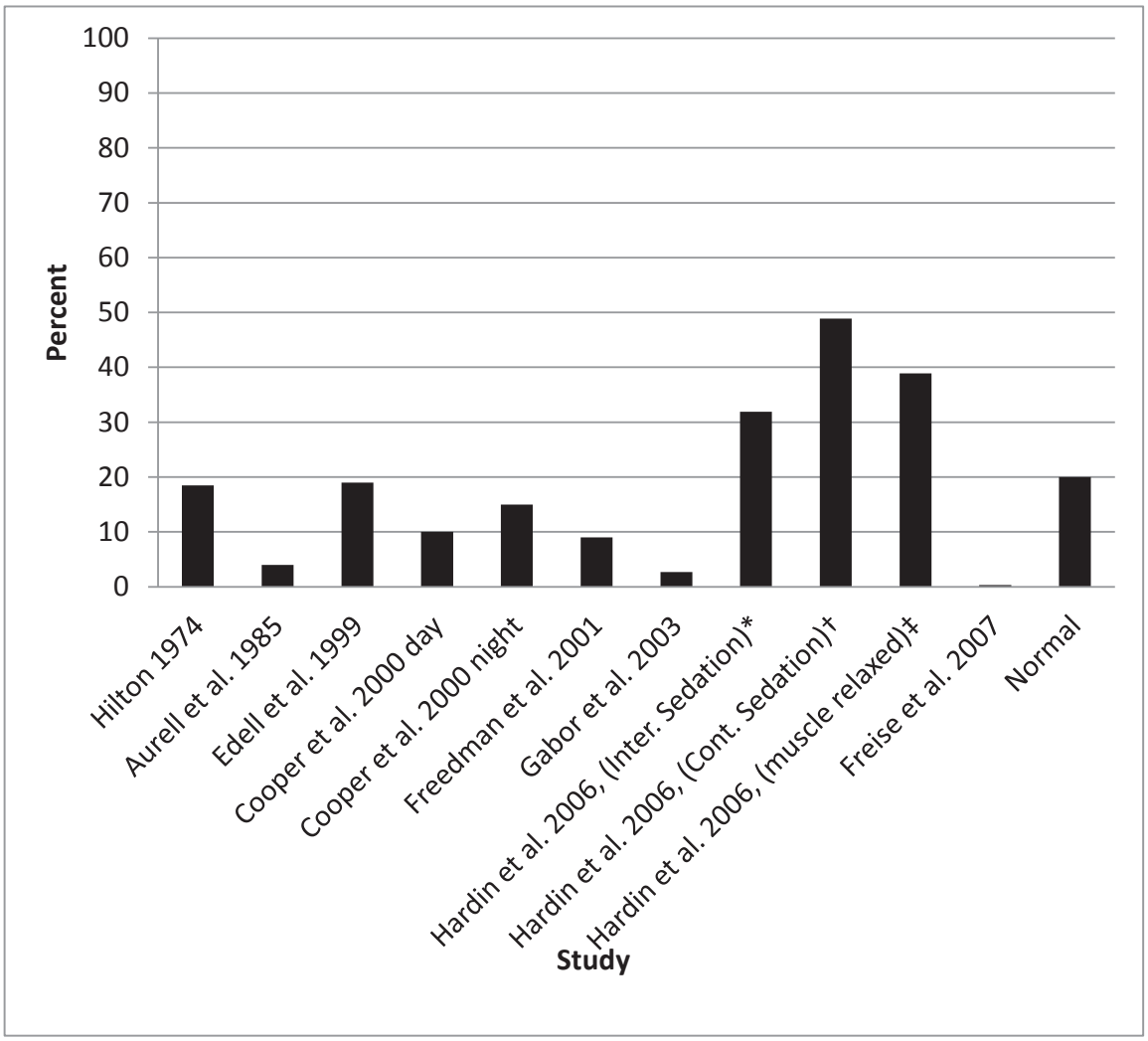
*Inter. sedation = patients were administered sedative medication intermittently, †Cont. sedation = patients were administered sedative medication using a continuous infusion, ‡Muscle relaxed = patients were administered neuromuscular blocking agents and sedative medication using a continuous infusion

Figure 2. Proportion of stage 1 and 2 sleep (mean percentage of TST during 24-hour recordings in ICU)

In a study comparing the effect of two modes of ventilation on nocturnal sleep (n = 17), patients experienced 80 to 100% stage 1 and 2 sleep (Alexopoulou et al., 2007). In fact, the majority of studies measuring nocturnal sleep reveal similar proportions of stage 1 and 2 (Beecroft et al., 2008, Cabello et al., 2008, Fontaine, 1987, Richards, 1998, Roche Campo et al., 2010).

Reduced proportion of SWS is a common feature of most sleep studies performed in ICU (except Hardin et al. (2006)) (Figure three). It is noteworthy that advanced patient age did not account for the reduced SWS in these studies. For example mean patient age reported by Aurell and Elmqvist (1985) was 49 years; 61 years by Edéll-Gustafsson et al.

(1999); 56 years by Gabor et al. (2003) and the median reported age reported by Friese et al. (2007) was 38 years.

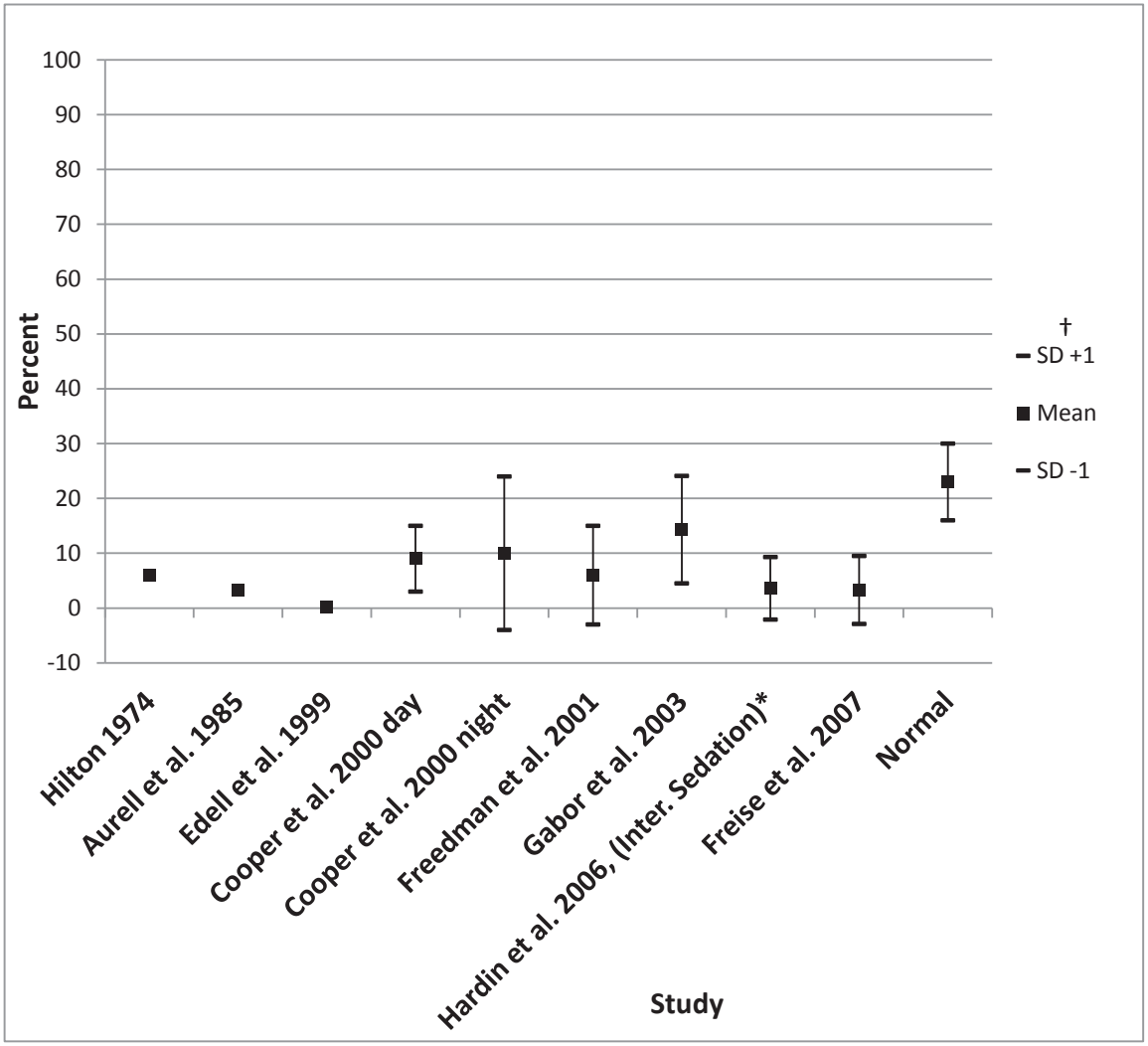


*Inter. sedation = patients were administered sedative medication intermittently, †Cont. sedation = patients were administered sedative medication using a continuous infusion, ‡Muscle relaxed = patients were administered neuromuscular blocking agents and sedative medication using a continuous infusion

Figure 3. Proportion of slow wave sleep (mean percentage of TST during 24-hour recordings in ICU)

In addition, few ICU patients are found to experience more than 15% of TST as REM sleep and in many studies it is absent (Figure four). The most likely explanation for the virtual absence of REM sleep and small proportions of SWS is sleep fragmentation. In one study the mean sleep bout duration was 15±9 minutes (range 5.5 to 40.0) (Freedman

et al., 2001). Thus patients never progress beyond stages 1 and 2 to slow wave and REM sleep. In addition, interpretation of REM stage may be complicated by increased muscle tone (atonia is a feature of normal REM sleep). Increased muscle tone is interpreted as 'awake' despite the presence of EOG and EEG features of REM sleep (Cochen et al., 2005).



*Inter. sedation= patients were administered sedative medication intermittently, †SD=standard deviation

Figure 4. Proportion of REM sleep (mean±SD percentage of TST during 24-hour recordings in ICU)

Intensive care patients experience disproportionately large amounts of stage 1 and 2 sleep and a lack of slow wave and REM sleep. Further evidence of excessive disturbance is provided by the substantial number of awakenings and arousals as well as unconsolidated sleep. Mean arousal indices between 20 and 56 (Cooper et al., 2000, Edéll-

Gustafsson et al., 1999, Hardin et al., 2006, Roche Campo et al., 2010) with awakenings as frequent as three to 32 per hour of sleep are not unusual (Broughton and Baron, 1978, Fontaine, 1987, Gabor et al., 2003, Richards, 1998). It should be noted there are differences in sleep staging, and in particular arousal scoring, between sleep investigation units and sleep technologists (Bonnet et al., 2007, Whitney et al., 1998). Furthermore few studies report on the number of interventions and nursing care activities during sleep monitoring so that the intrinsic arousal and awakening rate is difficult to ascertain. Even when arousal indices and awakenings are reliably captured or within expected limits, evidence of fragmentation is clear; numerous short sleep bouts are reported. The mean number of sleep bouts during 24-hour monitoring in one study was 41 (range: five to 100) with a mean duration of only 15 minutes (Freedman et al., 2001). Intensive care patients do not move through sleep stages conventionally. REM sleep has been observed to follow stages 1, 2 or 3 and some stages may be absent (Cooper et al., 2000, Friese et al., 2007, Richards, 1998) or occur sooner after sleep onset than in healthy individuals (Cochen et al., 2005). In a group of nine patients treated in a respiratory ICU, only one was observed to complete a sleep cycle (96 minutes) (Hilton, 1976).

Although some sleep is certainly better than none, there is no doubt that ICU patients are at increased risk of the consequences of fragmented sleep. The effect of the lack of slow wave and REM sleep is a matter of conjecture but may affect patient recovery and ability to engage in rehabilitation at the very least. The consequences of experiencing a high proportion of daytime sleep in this population are unclear.

A summary of the findings of the investigations into patients' sleep while treated in the ICU are described in Table 2.

Table 2. Summary of the nature of the quality and duration of sleep patients experience while treated in ICU (measured using PSG)

Parameter	Deviation from expected population norm
Total sleep time (TST)	Normal / reduced / prolonged (wide variation)
Time at which sleep occurs	Frequently 50 / 50% night / day
Non-REM stage 1 and 2	Disproportionately large
Non-REM stage 3 and 4	Reduced
REM	Reduced
Sleep fragmentation	Severe, little evidence of consolidated sleep

Other objective methods including actigraphy and BIS

Notwithstanding the potential lower reliability associated with objective measures such as BIS and actigraphy, studies using these methods do corroborate evidence from both PSG and patient self-report studies (Bourne et al., 2008, Nicholson et al., 2001, Shilo et al., 2000). In an exploration of the use of BIS to monitor sleep in ICU, mean TST was 1.6 hours (Nicholson et al., 2001). In a clinical trial of the effect of melatonin on ICU patients' sleep, mean TST did not exceed 3.5 hours during nocturnal recordings using actigraphy in either control or treatment group (Bourne et al., 2008). Conversely Shilo et al. (2000), in their before and after investigation of melatonin in ICU patients (n = 8), found mean nocturnal TST measured with actigraphy increased to 6.3 hours after treatment. However awakenings (mean duration of 12 minutes) still occurred each hour (awakenings were similar for the control group which comprised ward patients (n = 6)).

2.5.2 Subjective data

Patient reports

Subjective patient reports confirm the results from investigations using PSG. A summary of the findings of studies using patients' self-reports is located in Table 3 at the end of this section. Patients rate the overall quality of their sleep as poor and more specifically they report light sleep with frequent awakenings and considerable difficulty falling and returning to sleep. For example, in a study conducted in a Swedish ICU (n = 31)

comparing patients' and nurses' assessment using the RCSQ, patient self-report of mean sleep depth was 40.2 mm (range: zero to 98) and quality of sleep 39.0 mm (range: zero to 96). The overall total sleep score was 45.5 mm (range: zero to 97) (Frisk and Nordström, 2003). Contrary to other studies such as Nicolás et al. (2008) and Richardson, Crow et al. (2007b), there was a strong correlation between nurse and patient assessment ($r = 0.869$, $p < 0.001$) but only 13 patients and nurses were included in this analysis. Interestingly, even though there are no published RCSQ scores from the healthy population, the authors allocated ranges of scores to categorise the quality of sleep; zero to 25 indicated very poor sleep, 26 to 50 was a sign of poor sleep, 51 to 75 was classified as good sleep and 76 to 100 was considered very good sleep. There was a wide variation in sleep scores, four patients had a total sleep score of 25 mm (very poor) or less and three patients had a score above 75 mm (very good). These results are confirmed by patient self-report data obtained in other studies and countries (Knapp-Spooner and Yarcheski, 1992, Kroon and West, 2000, Nicolás et al., 2008, Richardson et al., 2007a).

In a study (n = 62) conducted in a cardiothoracic ICU in Britain to improve patients' sleep, 70% of patients reported sleeping less than eight hours and over 50% less than four hours (range: zero to 8 hours) (Richardson et al., 2007a). Freedman et al. (1999) reported that sleep quality at home was rated seven compared to five in ICU (SICQ, Likert scale: 1 to 10) by a group of patients who were ready for discharge from several ICUs in a hospital in North America. Patients (n = 104) treated in a surgical ICU in Spain had a mean RCSQ total score of 52±27 mm (range: zero to 100) with 28% scoring over 66 mm (optimal sleep) and 23% 'attained low scores' (poor sleep) (Nicolás et al., 2008). (In a similar way to Frisk and Nordström (2003), the authors allocated categories to denote sleep quality.) Forty-eight per cent of patients asked about their experiences in a study conducted in an ICU in the Netherlands said they had sleep problems in ICU even though they were not specifically asked to rate the quality of their sleep (Hofhuis et al., 2008).

Former ICU patients, who remember their ICU experience, recall difficulties sleeping and significant disruptions from noise and interventions. In a comprehensive

survey of former patients (n = 100) who could remember ICU, Rotondi et al. (2002) found 39% could recall 'not being able to sleep', 35% remembered 'having trouble falling asleep' and 40% recalled 'wakening in the night'. Fifty-one per cent remembered noise. Again the results of this investigation conducted in North America are comparable to the results of studies performed in other countries. For example, 'Not being able to sleep' was ranked as third most stressful (after 'having tubes in your nose or mouth' and 'being in pain') by Jordanian former ICU patients (Hweidi, 2007), second after 'having pain' by patients in a Brazilian ICU (Novaes et al., 1997) and patients interviewed three days after discharge from an ICU in Hong Kong ranked their 'inability to sleep' third most stressful (So and Chan, 2004).

The large number of former ICU patients who recall unreal memories and nightmares while treated in the ICU also provides evidence of sleep disruption (Jones et al., 2001, Roberts et al., 2007, van de Leur et al., 2004). The dissociated state described by former patients is a feature of the administration of sedative and hypnotic agents and delirium; both are associated with sleep disruption (Sanders and Maze, 2011).

Two survey studies suggest that 33% and 38% of former ICU patients experience sleep disruption during recovery after ICU (Eddleston et al., 2000, Orwelius et al., 2008). In a large (n = 1625) survey conducted in Sweden using the Basic Nordic Sleep Questionnaire, patients reported that quality of sleep was the same before the critical illness (measured at six and 12 months during recovery). Severity of illness and length of ICU stay did not appear to affect sleep during recovery. However the presence of concurrent diseases was strongly associated with sleep disruption suggesting that disease and not the ICU experience itself contributed to quality of sleep during recovery (Orwelius et al., 2008). Similarly Edéll-Gustafsson (1999) in a study of cardiac surgery patients, found PSG sleep quality data had almost returned to baseline levels at one month after hospital discharge. However in a survey conducted in Britain, 44% of women and 25% of men reported sleep disturbances at three months after ICU discharge but this improved to 28% and 19% at 12 months (Eddleston et al., 2000). No comparison was made in this study between pre-ICU

sleep quality and sleep during recovery. A possible mechanism for the poorer quality of sleep at three months in this sample may be continued disrupted melatonin secretion which is evident up to four weeks after discharge in patients who have experienced sepsis (Mundigler et al., 2002). (A large proportion of patients in the study had medical diagnoses which are more likely to be associated with sepsis.) A case series of former patients (n = 7) who were treated for acute respiratory distress syndrome in ICU and experienced sleep problems six months or more after recovery, suggested that self-reported and PSG sleep abnormalities may have been associated with critical illness in ICU (Lee et al., 2009). Most had PSG evidence of insomnia and all patients rated their sleep using the Insomnia Severity Index (ISI) (Bastien et al., 2001) as significantly worse after their illness. The cause of insomnia, suggested by the authors, was the persisting increase in physiological arousal associated with lying in bed, which was 'learned' during illness. Regardless of the mechanism underlying sleep disruption during recovery from critical illness (and whether it is pre-existing), there is no doubt sleep should be addressed in the same way other quality of life matters are considered.

Table 3. Summary of the quality and quantity of sleep in patients while treated in ICU (subjective patient reports)

Construct	**Details**
Duration of sleep	Little or no sleep
Quality of sleep	Poor
Awakenings	Frequent
Daytime sleepiness	Evident
Themes emerging from patient reports	Attribute sleep disruption to noise, intrusive treatments, thirst, neurological assessments
	Approximately 30% of recovering ICU patients remember not being able to sleep

Nurse reports

Despite their propensity to overestimate the amount and quality of ICU patients' sleep, evidence suggests that nurses generally give low ratings and at the very least reflect the evidence provided by PSG and patient reports, that is patient sleep is less than optimal (Bourne et al., 2008, Fontaine, 1987, Frisk and Nordström, 2003, Ibrahim et al., 2006, Nicolás et al., 2008, Richardson et al., 2007b).

2.5.3 Factors adversely affecting sleep in the critically ill

Treatment and organ support for critical illness often involves invasive monitoring and intrusive treatments delivered via intravascular catheters and artificial airways; mechanical ventilation is commonplace. Patients also contend with the symptoms of illness and the side effects of medications. In addition patients may present with significant co-morbidities and health histories that negatively affect sleep. Finally the ICU environment which is typically busy, noisy and technological is another source of distress. Therefore a number of interrelated intrinsic and extrinsic factors contribute to adversely affect sleep in ICU patients. Extrinsic factors are noise, non-circadian light, unsuitable ambient temperature, frequent interventions and nursing care activities and treatment (for example, medications such as opioids and benzodiazepines, mechanical ventilation settings) and intrinsic factors relate to the presence of pre-existing sleep disorders, illness (for example, systemic inflammatory response, circadian rhythm disruption) and psychological distress (for example, anxiety and pain). These extrinsic and intrinsic factors are listed in Table 4 at the end of this section.

It is conceivable that ICU patients might become acclimatised to the high sound and activity levels. However evidence suggests that intrusive sound, in particular increased peak sound levels, does adversely affect their sleep in ICU (Aaron et al., 1996, Freedman et al., 2001, Gabor et al., 2003). Overall elevated sound levels and frequent loud sound peaks account for approximately one-third of arousals and awakenings (Gabor et al., 2003). The addition of 'white noise' to ameliorate the effect of peak noise has been shown to reduce arousal indices in healthy volunteers exposed to ICU noise (Stanchina et

al., 2005) suggesting that the deviation from baseline rather than the peak sound level itself is the determinant of sleep disruption. The effect of particularly high baseline sound levels (71 (A)dB, equivalent to noise levels in a busy shop) and an illumination level of 100 lux (equivalent to the illuminance level of an overcast day) in one ICU were not appreciably ameliorated by ear plugs and eye masks in healthy volunteers (Hu et al., 2010). In a recent study patients (n = 88) who wore ear plugs reported significantly better sleep ($p = 0.002$) than patients in the control group (Scotto et al., 2009), suggesting that noise is responsible for sleep disruption. Patient reports often contain reference to noise levels and the associated annoyance. In the study by Frisk and Nordström (2003), an open ended question was posed in which patients were asked what had adversely affected their sleep. Approximately 50% of patients cited various discomforts and a few remarked on the noise and in particular conversations by health care personnel and spontaneously breathing patients' snoring. More recently in an interventional study to reduce night-time sound levels and care activities to improve sleep, noise was cited as the most disruptive sleep environmental factor in both interventional and control groups (Li et al., 2011).

Given that it is known that light is a powerful 'zietgeber' (time giver) in health (Czeisler et al., 1986) it is likely that non-circadian light levels may negatively impact sleep in ICU patients. However patients rarely highlight inappropriate lighting as sleep disruptive (Freedman et al., 1999). The reason for this could be that illuminance levels are appropriate (recent data suggest this may be the case that is 12 to 20 lux (Perras et al., 2007) and mean 9 lux at night (Bourne et al., 2008)) or that illuminance levels are perceived by patients as innocuous compared to the many other annoyances they contend with such as artificial airways, mechanical ventilation and intravascular devices (Adamson et al., 2004, Rotondi et al., 2002, So and Chan, 2004).

Investigators of studies conducted in ICU do not remark on the ambient temperature, making it difficult to ascertain the extent of any effect on patient sleep. Ambient temperature has an important influence on both the quality and quantity of sleep and is a vital zietgeber for individuals who are isolated from other time cues (Zisapel,

2007). A thermoneutral external temperature (29 °C) (achieved with heating / cooling or clothing) results in the greatest TST with decreases noted above and below (Haskell et al., 1981). Cold is more sleep disruptive than heat (Haskell et al., 1981). Given that there is little scope to regulate the ambient temperature in the open plan ICU (an ambient temperature of 29°C would be too warm for health care personnel and activity) it is perhaps surprising that these data are not presented in published studies.

Critically ill patients are dependent on health care personnel for almost of their needs therefore interventions, such as repositioning, tracheal suction and neurological assessments are frequently performed. Studies do not always report the number and type of interventions during PSG sleep recording however investigations based on self-reports provide further insight into the degree of disturbance ICU patients contend with. A study in which events were thoroughly documented during PSG recording revealed that therapeutic interventions, personal care and assessment procedures comprised 22%, 18% and 11% of sleep disturbances respectively (Hilton, 1976). The mean number of interventions per hour was three; day and night rates were similar. In another study, the use of simultaneous infrared video recording synchronised with PSG revealed a higher intervention rate (7.8±4.2 per hour) of which 17% resulted in sleep disturbance (Gabor et al., 2003). One further study in which events were recorded with 'paper and pen' revealed a mean 150 interventions in 24 hours for the most severely ill patients (Hardin et al., 2006). Patient self-reports provide further evidence of high intervention rates. Neurological assessment was cited as problematic by 40% of patients questioned about sleep in a neurosurgical ICU (Uğraş and Öztekin, 2007). A chart review complemented by patient (n = 104) comments revealed approximately 10% of patients were disturbed by nursing care; the maximum number of nocturnal interventions was nine (Nicolás et al., 2008).

Medications such as sedatives and analgesics are administered to ameliorate some of the discomfort associated with illness and treatment in ICU. PSG data from healthy volunteers and EEG data during anaesthesia and sleep research reveal that these and

many other medications that cross the blood brain barrier are potentially sleep disruptive. Despite their general acceptance and perceived usefulness by people experiencing insomnia in the community benzodiazepines (Siriwardena et al., 2008) are known to have adverse effects on sleep. They reduce SWS and REM sleep and increase sleep quantity by prolonging stage 1 and 2 sleep (Borbely et al., 1985) with concomitant increases in daytime sleepiness (Siriwardena et al., 2008). Opioid medications reduce SWS and increase stage 2 sleep (Dimsdale et al., 2007). Propofol increases slow wave brain activity but suppresses REM sleep (Rabelo et al., 2010). Medications administered to support the cardiovascular system, such as vasopressors and beta antagonists, may also adversely affect sleep architecture. Vasopressors such as noradrenaline and adrenaline are likely to reduce slow wave and REM sleep through alpha-1 receptor stimulation. Some beta antagonists prolong sleep latency and reduce REM sleep (but this is dependent on their lipid solubility) (McAinsh and Cruickshank, 1990).

In the only study to specifically examine the effect of neuromuscular blocking agents and 'sedative dosage' on sleep architecture in ICU patients, significant differences in sleep were reported between types and doses of these medications (Hardin et al., 2006). Intermittent sedation appeared to increase the occurrence of sleep spindles (stage 2 sleep) but interestingly patients who received continuous sedation had more SWS (Hardin et al., 2006). In another study, patients receiving higher doses of sedation were reported to have less SWS than patients receiving lower doses of sedation (Cooper et al., 2000). It is worth highlighting that subjective data support the hypothesis that hypnotics adversely affect sleep quality. Patients who received hypnotics had significantly poorer sleep rated on the RCSQ (mean 31.6 mm) compared to those who did not (mean 54.3 mm, $p = 0.037$) (Frisk and Nordström, 2003). Despite the paucity of objective (and conflicting) data from the ICU population to confirm or refute sleep research findings regarding sedative and other medications, it is likely that ICU patients' sleep is adversely affected by medications and given that ICU patients often experience renal and hepatic impairment, the effects may even be magnified.

Mode of mechanical ventilation has been implicated in sleep disruption in ICU patients. Some ventilator modes and settings lead to central apnoeas and associated arousals and awakenings. During an investigation to compare the effect of three ventilator modes on nocturnal sleep, low expired carbon dioxide levels associated with clinically controlled pressure support ventilation (PSV) lead to hypoapnoeas and a trend to lower TST (Parthasarathy and Tobin, 2002). A further investigation to compare the effect of two modes of ventilation on sleep by Bosma et al. (2007) reported a correlation between patient-ventilator asynchrony and number of arousals, however repeated measures in the same patients were used so the results are intercorrelated and must be interpreted with caution. More recent data suggests that alkalosis in the presence of low levels of plasma carbon dioxide is most likely the cause of sleep disruption (Fanfulla et al., 2011). However yet again sample sizes were small in the studies investigating the effect of ventilator mode on sleep, making the results more useful for the generation of theory than radical changes to practice (Alexopoulou et al., 2007, Bosma et al., 2007, Parthasarathy and Tobin, 2002, Toublanc et al., 2007). Ventilator related sleep disturbance may be minimised, as indicated in the evidence discussed below.

Arousals, awakenings and sleep fragmentation cannot always be explained by environmental and treatment related factors. They may be attributable to the critical illness itself, for example non-circadian secretion of melatonin and the inflammatory response (cytokines such as interleukin-1 and tumour necrosis factor). Disrupted circadian rhythm is a potential factor affecting ICU patients' sleep. Serum melatonin and urinary melatonin metabolite levels have been reported to be low (Frisk et al., 2004, Perras et al., 2007) and do not follow the diurnal pattern present in health (Mundigler et al., 2002, Perras et al., 2007, Shilo et al., 1999, Olofsson et al., 2004, Frisk et al., 2004). In addition, body temperature acrophase (the time at which temperature is at its highest in the 24-hour period) was found to occur at varying times in the 24-hour period (normally expected in the late afternoon / early evening) and shifted six to 12 hours in one retrospective study (Tweedie et al., 1989). However the association between melatonin level or body temperature with sleep disruption in ICU have yet to be specifically investigated. Similarly

acute brain dysfunction, specifically delirium, has been implicated in sleep disruption in ICU patients. However until the exact mechanism is elucidated it is impossible to differentiate whether sleep disruption leads to brain dysfunction or vice versa (Roche Campo et al., 2010, Cochen et al., 2005).

To date little attention has been paid to the incidence of pre-existing sleep disorders in ICU patients in the health care literature. The presence of pre-existing sleep disorders obviously impacts on the amount and quality of sleep while patients are in ICU. The incidence of sleep disorders (symptoms of insomnia) in the general population may be as high as 30% (LeBlanc et al., 2009, Monti and Monti, 2006). Pharmaceutical prescribing data from Medicare Australia and private providers reveals that 2.4% of the Australian population are regularly prescribed hypnotics, anxiolytics and sedatives, many of which are used to ameliorate the symptoms of insomnia. These data exclude severe disorders such as obstructive sleep apnoea (OSA) which are rising with increasing rates of obesity (Lee and Mokhlesi, 2008). Given their age and co-morbidities, the incidence of all sleep disorders is likely to be higher in ICU patients than in the general population (Glerant et al., 1999, Lee and Mokhlesi, 2008). An indication of the problem was provided in a group of ICU patients (n = 20) with undiagnosed sleep behaviour disorders (parasomnias) in whom it was noted that the condition was pre-existing in 75% of cases. In an ICU follow up study, approximately 8% of patients questioned rated their pre-ICU sleep as ‘bad’ (Orwelius et al., 2008). Furthermore in recognition of the potential confounding effect of existing sleep disorders, ICU sleep investigators either attempt to exclude patients with sleep disorders or record their presence (Lee et al., 2009, Orwelius et al., 2008).

Self-reports by patients confirm not only that noise, interventions and nursing activities, disturb sleep in ICU, but that discomfort and anxiety adversely affect its quality. Pain and discomfort from invasive devices for example, endotracheal tube and drains were cited as problematic by patients invited to comment after completing the RCSQ (Nicolás et al., 2008). Furthermore patients who received non-opioid analgesics reported poorer quality sleep compared to those who received opioid analgesia on the RCSQ

(47.01±23.17 versus 60.11±15.97 mm), illustrating the need for adequate analgesia and careful dosing to avoid the adverse effects of pain and opioids on sleep. Thirst was also a significant stressor reported by ICU patients and is likely to contribute to sleep disruption (Cornock, 1998, Hweidi, 2007, Nelson et al., 2001). Anxiety is a psychological factor which is likely under recognised (McKinley and Madronio, 2008) and potentially deleterious to sleep (Nicolás et al., 2008).

Table 4. Factors affecting sleep in ICU patients

Intrinsic	Extrinsic
Pre-existing sleep disorder	Intrusive sound levels
Systemic inflammatory response	Frequent interventions and care activities
Deranged circadian rhythm	Noncircadian light levels
Discomfort (for example, intrusive devices, thirst)	Suboptimal ventilator settings (particularly nocturnal)
Psychological distress (for example, anxiety)	Medications (for example, sedative agents, opioids, beta blockers)

2.5.4 Potential strategies to improve sleep in ICU patients

Recognising the need to improve the quality and quantity of sleep, a number of interventions have been tested in several investigations including environmental improvements, patient focused approaches, pharmaceuticals and mechanical ventilator mode. Guidelines to reduce the number of disturbances, such as noise reduction, instigation of appropriate illuminance levels and clustering care have been successfully implemented. Few published studies provide PSG evidence of the effect of these interventions however improvements in sleep promoting practices have been noted.

Noise reduction and behaviour modification programs have been successful in reducing noise and changing behaviour but their long-term sustainability has not been confirmed. In a preintervention-postintervention study, health care personnel in a surgical ICU developed nocturnal environmental guidelines which included a commitment to

minimise patient disturbance, reduce noise and ensure the patients' rooms were dark (Walder et al., 2000). Noise levels improved from an average 48.3 to 41.3 dB(A) and a peak of 74.9 to 70.8 dB(A). There were also appreciable reductions in the number of sound peaks and number of alarms as a result of the intervention but patient sleep (estimated by nurses) did not improve. Illuminance levels were low throughout (Walder et al., 2000). Kahn et al. (1998), using a similarly designed study, reduced the number of sound peaks higher than 80 dB(A) over 24 hours from 1,363 before the implementation of a behaviour modification program to 976 after the program ($p = 0.0001$). More recently in a comparable preintervention-postintervention study Li et al. (2011) reduced mean peak sound levels from 59.2 dB to 51.3 dB ($p < 0.001$) and 'average' noise levels from 57.7 dB to 50.1 dB ($p < 0.001$) after implementing a guideline to control nocturnal noise and care activity. Interpretation of the results is complicated by a lack of technical detail regarding sound recording for example, sampling rates and the use of weighting scales in the published report and increased sleep disruption ratings by patients in the postintervention phase. Positive results were achieved in an investigation with the aim of reducing noise, providing specific rest periods and clustering care in a neurointensive care unit (Monsén and Edéll-Gustafsson, 2005). Behaviour modification lead to an overall trend to lower sound levels, a reduction in the number of times patients were approached for nursing activities from an average 356 to 304 per day, and patients were not disturbed during rest periods. The behaviour modification program consisted of education about sleep disturbances and group work (73% of the ICU staff attended) (Monsén and Edéll-Gustafsson, 2005). Cmiel et al. (2004) reduced the average and peak noise level during shift change (from 113 to 86 dB(A)).

Behaviour modification to reduce noise is preferable to attempting to ameliorate intrusive sound levels using an additional device or technology such as earplugs or 'white' noise. However such devices have been used with varying success. In a study, in which healthy volunteers underwent sleep monitoring using PSG while exposed to ICU sounds, an increase in REM sleep was noted while earplugs were worn (Wallace et al., 1999). Likewise Hu et al. (2010) found that the REM sleep of healthy volunteers increased

however TST did not appreciably increase with the use of earplugs during exposure to ICU noise (70 dB(A)). In a clinical trial (n = 88) of the effectiveness of earplugs on subjective sleep quality, self-reports of the amount and quality of sleep using the VSH were significantly better ($p = 0.002$) for patients wearing ear plugs (Scotto et al., 2009). Earplug associated discomfort caused seven patients to discontinue. In another trial, patients who were able to self select earplug and eye mask use (n = 64) also said earplugs helped them to sleep (the sample size precluded statistical analysis) (Richardson et al., 2007a). Again there were individual differences in comfort and tolerance levels.

Once more healthy volunteers (n = 8) were used to test the use of 'white noise' to ameliorate the effect of peak noise in simulated ICU sound (Stanchina et al., 2005). In this cross-over study, sleep arousals were comparable to baseline levels when 'white' noise was played during simulated ICU sound: sleep architecture was less fragmented. The strategy has yet to be tested on ICU patients.

There are few studies investigating the instigation of appropriate illuminance levels in ICU. Walder et al. (2000) found that night illuminance levels were 4.6±7.9 lux before a behaviour modification program and 1.6±4.8 lux afterwards. There were greater variations in maximum illuminance levels (none exceeded 100 lux) in the postintervention program data, leading to concern that this might be more sleep disturbing. In their eagerness to reduce illuminance levels health care personnel reduced illumination levels but switched lights on during procedures and observations. During a campaign to improve sleep conditions in ICU Olson et al. (2001) achieved similar results; mean lux level during designated sleep times was greater than 25 lux before the instigation of the sleep promoting intervention and less than 10 lux postintervention. Patients were also more likely to be assessed as sleeping during these times; however nurses working in the same neurocritical care unit performed sleep assessments using the NOC, so bias may have been a confounder.

Patient focused approaches to improve sleep include the use of massage, music, and relaxation. Most studies are small pilot investigations using subjective sleep

measures. However in a randomised study, Richards (1998) compared the effect of relaxation and back massage on sleep in critically ill patients using PSG (the control group received a six minute rest period before bedtime). There was a trend towards improved SEI in the massage group but analysis of variance was not statistically significant; massage 77.32%, relaxation 73.13% and control 62.84%, $p = 0.06$. The use of relaxation and imagery did not improve subjective nocturnal sleep reports when critically ill patients were provided with relaxation and imagery on two evenings (Richardson, 2003). Zimmerman et al. (1996) tested the efficacy of music and a music video to reduce pain and promote sleep in postoperative cardiothoracic patients. Total sleep scores on the RCSQ were significantly higher in the music video group (72.0±20.2 versus 56.3±24.3 mm ($p < 0.05$) than in the resting group. There were no differences for pain intensity between groups. In a controlled trial investigating the effectiveness of ocean sounds in ICU patients discharged to the hospital ward, the group exposed to ocean sounds slept more deeply and the overall total RCSQ score was 66 versus 48 mm in the control group ($p = 0.002$) (Williamson, 1992). Music has been shown to reduce state anxiety in mechanically ventilated patients (Wong et al., 2001). This offers a possible mechanism for improvements in sleep reported by patients exposed to music and ocean sounds.

There are very few studies investigating pharmaceutical interventions. Recently, in the light of knowledge about disrupted melatonin circadian rhythm in ICU patients, the effect of exogenous melatonin administration and the application of light and darkness to stimulate appropriate endogenous secretion have been investigated. Exogenous melatonin administration did not result in an increase in TST in three small studies which used actigraphy and nurse observation to measure sleep; however the safety of melatonin was confirmed (Bourne et al., 2008, Ibrahim et al., 2006, Shilo et al., 2000). The application of bright light and darkness did not result in appropriate melatonin secretion in one group of ICU patients (Perras et al., 2007).

As discussed above, results from the studies in ICU investigating the effect of medications known to promote sleep are inconclusive (Cooper et al., 2000, Frisk and

Nordström, 2003). The few experimental studies that have been performed do not provide any additional suggestions for practice. The introduction of a sedation algorithm did not result in any improvements in the quantity or quality of sleep assessed using nurse observation (Brown and Scott, 1998). In the only study to compare medications for sleep promotion in ICU there was no difference in the quality and quantity of sleep between continuous infusions of propofol and midazolam (Treggiari-Venzi et al., 1996). Evidence from the treatment of 'healthy' insomniacs revealed no health benefit to merely prolonging TST by administering benzodiazepines and many hypnotics (Monti and Monti, 2006) but subjective ratings of sleep improve (Siriwardena et al., 2008). However recently a low dose propofol regimen was used in a randomised controlled trial to treat chronic insomnia and resulted in significant improvements in insomnia symptoms which persisted for six months (Xu et al., 2011). The drug dexmedetomidine is a promising sedative, analgesic and hypnotic. One animal study suggests that it activates sleep pathways (Nelson et al., 2003). A recent study, using EEG, confirmed that the administration of dexmedetomidine produces sleep spindles similar to electrical activity found in stage 2 sleep in healthy volunteers (Huupponen et al., 2008). The efficacy of dexmedetomidine to promote quality sleep has not yet been investigated. Some newer antipsychotics may prolong SWS and REM sleep but again their efficacy has not yet been confirmed (Gimenez et al., 2007).

Given the evidence that some mechanical ventilator modes and settings lead to arousals and awakenings, investigations have been performed to compare different modes and settings. In an experimental study, Parthasarathy and Tobin (2002) randomised patients to receive assist control (AC), pressure support (PS) alone or PS with dead space for at least two hours each from 2200 hours to 0600 hours. Sleep consolidation was significantly better during AC (54±7 versus 79±7 arousals and awakenings per hour during PS ($p = 0.02$)). The addition of dead space to PS ventilation reduced hypocapnia and decreased arousals and awakenings. A randomised cross over study using AC versus low levels of PS revealed similar results; AC was associated with better sleep quality (more SWS and REM sleep in the later part of the night) (Toublanc et

al., 2007). In another comparison, proportional assist ventilation appeared to provide a better match for respiratory effort during sleep than PS ventilation and resulted in better sleep (Bosma et al., 2007). However in a more recent study, no difference was found in sleep quality between AC, clinically adjusted PS and automatically adjusted PS modes of ventilation (Cabello et al., 2008). The likely explanation for this conflicting result is that high inspiratory pressure settings result in hyperventilation and hypocapnia and central apnoeas but more conservative settings prevent hyperventilation. Therefore existing evidence suggests that an adjustment of inspiratory settings, which are sympathetic to respiratory physiology during sleep, should be considered.

2.6 Summary of findings in the literature

Intensive care patients frequently experience significant sleep disruption. In general, investigations into the quality and quantity of sleep in ICU have small samples and heterogeneous populations and use a variety of methods to measure sleep. In large part this explains the inconsistency in published results. However it is reasonable to summarise PSG data as follows: there may be near normal TST but slow wave and REM sleep are less than the expected values in the healthy population. Also of note, and perhaps more concerning is the degree of sleep fragmentation; frequent arousals, awakenings and multiple short sleep bouts are common. These objective data are supported by subjective reports from ICU patients.

Evidence suggests that factors affecting sleep in this population are both extrinsic (ICU environment and treatment related) and intrinsic (patient psychological distress, discomfort and physiological state). A few experimental studies have been conducted to improve sleep in ICU with some success. Trends towards more sleep have been noted with reduced sound and illuminance levels (including the use of ear plugs and eye masks and staff behaviour modification): massage, music and relaxation show some promise and certain mechanical ventilator settings may reduce sleep fragmentation; results for melatonin are inconclusive and investigations comparing other sleep promoting medications have yet to be conducted.

2.7 Rationale for the current study

Restorative sleep is vital for health and a feeling of well-being. Evidence of its importance to health is growing. Consequently, the quality and quantity of sleep are recognised as important health outcomes in their own right. Arguably, ICU patients are in great need of undisturbed sleep but they are less likely to experience it than healthy individuals. There is a need for more research to promote sleep in the critically ill using PSG as a measure of sleep. Furthermore interventional studies to improve environmental conditions and reduce the number of disturbances have not reported the use of sustainable approaches to implementation.

Given changes over the past decade in patient care and treatment, a more contemporaneous study is warranted to assess ICU patients' sleep using PSG along with measurement of potentially sleep disruptive factors. There is a need to investigate sleep with PSG in Australia because many studies reporting sleep outcomes in ICU were conducted in North America. Recent evidence suggests that the outcomes of interventional groups in many ICU trials conducted in North America (and internationally) are no better than standard care in Australia (Bellomo et al., 2007). For example in two investigations into the effectiveness of a sedation guideline, first used in North America (Brook et al., 1999), to reduce duration of mechanical ventilation in Australia revealed poorer outcomes in the patient groups whose sedation was managed according to the sedation guideline (Elliott et al., 2006b, Bucknall et al., 2008). Outcomes in the group that did not receive the intervention in both studies were better than in the study by Brook et al. (1999). Potential explanations are the higher registered nurse to patient ratios and the overall management of patients by an intensive care staff specialist in a 'closed' unit rather than an 'open' ICU, in Australia (Bucknall et al., 2008). Sleep in an Australian ICU requires assessment with the exploration of sleep promoting interventions, if required. Investigations have identified that former ICU patients experience sleep disturbance at home but the specifics have not been reported in the Australian population.

In addition there is a need for large interventional studies in which extrinsic and intrinsic factors known to affect sleep are measured alongside sleep. Broad inclusion criteria are required in order to increase the likelihood of generalising the results.

2.8 Study aims

The broad aim of the current study was to describe the quality and quantity of sleep experienced by patients.

2.8.1 Primary aim

The primary aim of the study reported in this thesis was to assess the

- Quality and amount of patients' sleep while they were treated in the intensive care unit using
    - Twenty-four hour PSG
    - Patients' and nurses' subjective reports

2.8.2 Secondary aims

One of the secondary aims was to assess the 24-hour environmental sound pressure and illuminance levels and treatment and care activities (events) patients were exposed to. Other aims were to assess subjective self-reported quality of sleep while patients were treated in the Hospital ward and during recovery at home two months after hospital discharge and the psychological well-being of ICU patients two months into their recovery at home. An additional aim was to determine the effectiveness of sleep promoting activities suggested by ICU health care personnel.

3 Methods

3.1 Introduction

In this chapter the study design is described and the methods in which the study was conducted are outlined. It details the participants and setting, instruments, data collection and procedure. Data analysis in relation to each of the study aims is also summarised.

3.2 Research design

To address all of the aims of the study, an exploratory approach was taken during the conducting of this quasi-experimental preintervention and postintervention unrelated samples study. Intensive care patients' sleep was compared before and after the introduction of a guideline. The study was conducted in two phases, a 12 month (January 2009 to December 2009) preintervention phase in which data were collected from a series of patients before the development and implementation of the Guideline (a five month process) and again in another series of patients in a nine month postintervention phase (September 2010 to April 2011). Extensive feasibility work was undertaken during 2008 to increase the probability of successfully meeting the broad aim of the main study which was to collect 24-hour PSG data from ICU patients. Appendix B (Preliminary work) contains an overview of this work.

3.3 Study outcomes

The main outcomes measured were the quality and quantity of patients' sleep in ICU, environmental illuminance and sound levels, minimum and maximum ambient temperature, patient events (treatment and care activities) and subjective sleep quality and quantity in ICU for one 24-hour period. Subjective sleep quality on the Hospital ward and after discharge from hospital during recovery, and psychological well-being after discharge from hospital during recovery, were also measured. The adoption of the sleep and rest guideline was monitored in the postintervention phase (this is described in detail in Chapter four).

3.4 Definitions of key terms

Sleep terms

Quantity of sleep: An objective measure of the amount of time asleep. Two methods of quantifying the amount of sleep were used:

Total sleep time (TST): The sum of the total amount of time in all of the sleep stages during PSG recording.

Sleep Efficiency Index (SEI): The percentage of total time asleep during PSG recording. The SEI was calculated by dividing the TST by the total recording time multiplied by one hundred. Based on overnight SEI in health of 85% (TST divided by time in bed), the expected SEI for a 24-hour PSG recording is approximately 27%.

Per cent daytime sleep: The percentage of the PSG derived TST during the period 2100 to 0600 hours, excluding all periods of wakefulness.

Nocturnal sleep efficiency: The percentage of sleep during the period 2100 to 0600 hours.

Quality of sleep: A complicated construct which includes many sleep related factors: perceived sleep duration, time in each sleep stage, disturbances, sleep disorders, degree of daytime sleepiness, satisfaction with sleep and degree of difficulty falling and staying asleep. In the current study quality of sleep was operationalised in a number of ways including: the percentage of time spent in each sleep stage, and perceived difficulty going to sleep and staying asleep, the number of arousals and awakenings, number of discrete sleep episodes (degree of fragmentation).

Sleep stages: The definitions used in the study for sleep stages were based on the R and K criteria (1968). Using these criteria, five sleep stages; non-REM (stages 1 to 4) and REM were classified within 30 second epochs for each PSG recording. A brief description of each follows:

Stage 1: Well defined rhythmic alpha and mixed frequency low-voltage EEG for more than 50% of the epoch together with increased theta and vertex wave activity, slow rolling eyes on the EOG and low-voltage EMG activity.

Stage 2: Mixed frequency low-voltage EEG activity interspersed with sporadic 'K complex' and sleep spindles less than three minutes apart, low-voltage EMG activity combined with little eye movement.

Stage 3: Distinctive high-voltage (greater than 75 μV) delta waves for 20 to 50% of the epoch, no eye movements and tonic EMG activity.

Stage 4: Distinctive high-voltage (greater than 75 μV) delta waves for more than 50% of the epoch, no eye movements and tonic EMG activity.

REM sleep: Absent EMG activity along with rapid eye movements, sleep spindles or K complexes more than 3 minutes apart, saw-tooth EEG and low-amplitude, mixed frequency EEG similar to stage 1.

The most recent American Academy of Sleep Medicine (Iber et al., 2007) classification system for sleep staging combines stages 3 and 4 (that is N3) so that there are four stages of sleep (N1, N2, N3 and R) instead of the R and K five stage system. The R and K system was predominately used to report the results in the current study because the American Academy of Sleep Medicine has not yet been widely adopted and to allow comparisons to made with the results of previously published studies.

Arousal: 'An abrupt shift in EEG frequency which may include theta, alpha and/or frequencies greater than 16 Hz (but not spindles)' (Iber et al., 2007) with the following characteristics: the EEG frequency change lasts three seconds or more, a minimum of 10 continuous seconds of sleep precedes the arousal and occurs between arousals, concurrent submental EMG amplitude increases in REM but not in non-REM. The number of arousals per hour of sleep (arousal index) was recorded in the current study. The arousal index range in healthy adults (measured in the sleep investigation laboratory) is

between 10 to 22 arousals per hour (Bonnet and Arand, 2007). An example of an arousal in stage 1 sleep is provided in Figure five.

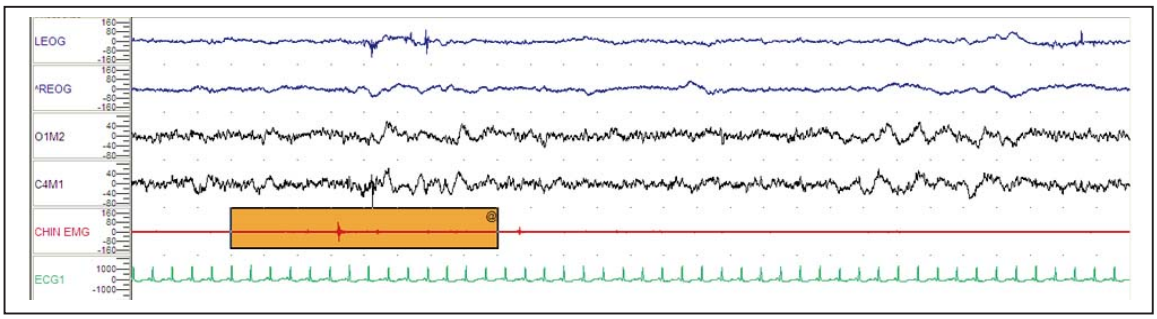


Figure 5. Hypnogram showing an arousal in Stage 1 sleep

Awakening: An EEG wave frequency activity faster than alpha for greater than 50% of the standard epoch, many eye movements and high EMG activity on the PSG. Alternatively the patient's self-report of awakenings at night.

Sleep episode: A discrete time period in which the patient met the criteria to be asleep (regardless of stage) during sleep recording with PSG.

Event: A treatment, care procedure or activity which had the potential to cause an arousal or awakening while sleep monitoring in ICU, that is touching, moving or communicating with the patient.

Acoustic terminology

Equivalent continuous sound pressure level (LA_{eq}): The LA_{eq} was used to describe broadband sound pressure levels to which patients were exposed. The LA_{eq} is the time averaged sound level using the 'A' frequency weighting (which corresponds closely to the response of the human ear at low sound pressure levels). Technically this is twenty times the logarithm to base ten of the ratio of a root-mean-square sound pressure during a specified time interval. LA_{eq} is commonly used in occupational health assessments of sound pressure exposure.

Background sound level (LAF_{90}): The LAF_{90} is the time averaged sound pressure level (using the 'A' frequency filter weighting) which is exceeded 90% of the recording time. It is colloquially known as the 'background sound level'.

Peak sound level (LC_{peak}): LC_{peak} was used to describe the greatest absolute sound levels during sleep monitoring. Technically this is twenty times the logarithm to base ten of the ratio of the greatest absolute instantaneous sound pressure level using the 'C' weighting frequency filter (which is responsive to sound signals at higher sound pressure levels than 100 dB) during a specified time period.

Noise: An unwanted sound of sufficiently intrusive quality to prevent, disturb or disrupt sleep.

Light terminology

Lux: The SI unit used to measure illuminance (the concentration of light falling on a surface) and in which illuminance levels were reported in the current study. Reference and recommended illuminance values are provided in Figure six.

Reference and recommended values Sunlight = 10,000	lux value >1,400
	1,300
	1,200
	1,100
Full daylight	1,000
	800
	700
	600
Office/library	500
	300
	200
Over cast day	100
Bathroom = 80 Living room = 50 Very overcast day = 10 Twilight = 1	0

Figure 6. Reference and recommended illuminance levels and their corresponding lux values

3.5 **Setting**

The setting for the study was a 36 bed general, neurosurgical and cardiothoracic adult ICU in a 600 bed metropolitan hospital in Sydney, Australia. This hospital was a tertiary referral facility for specialty services such as cardiac, spinal, renal, neuroscience and burns. The ICU was a closed unit where an accredited ICU staff specialist was ultimately responsible for the admission and management of all patients. During the time in which the study was performed the Registered Nurse (RN) to patient ratio was one to one for mechanically ventilated patients and one to two or three for patients requiring high dependency care. The RN performed all the care for the patient. Additional clinical support was available during the day, Monday to Friday, including Clinical Nurse

Educators, a Clinical Nurse Consultant and a Nursing Unit Manager (NUM). 'After hours' assistance was available from the after-hours NUM and patient service assistants.

The building in which the study ICU was situated was a solid brick and concrete 13 floor structure. The ICU was located three floors from ground level (two floors of the building were subterranean). During the study, a roof helicopter landing pad was located on the same level approximately 150 metres from the ICU on another building within the Hospital campus. There were infrequent external loud noises when the Air Ambulance landed or took off.

Twenty-four hour PSG sleep data and illuminance and sound level data collection took place in five of the eight patient rooms in the study ICU (data collection did not occur in the neurosurgical or isolation areas). Each room had one external brick wall with large windows. Few modern building acoustic features were present. However the ceiling tiles were wet-formed mineral fibre covered with a vinyl latex paint, with acoustic properties: noise reduction coefficient of 0.55 and weighted sound absorption coefficient, alpha w of 0.5 (Armstrong ceilings, 2008). Most interior walls were solid brick. The floor was solid concrete with an overlay of polished vinyl tiles. The five open plan six bedded spaces in which many 24-hour data collection episodes were performed were divided by a four metre long solid brick wall extending from the exterior wall, with the other three bedded area being a mirror image (Figure seven). The sluice room was open to the main room. The other area of the study ICU used for 24-hour data collection was a larger open planned five bedded area with one solid brick (30 cm thick) half wall divider and another plaster board (12 cm thick) half wall divider extending from an external wall between two beds (Figure eight). In this area the sluice room which had a door and was situated further from the nearest patient bed space than in the six bedded area. All the rooms in which sleep recording occurred were open to sound throughout.

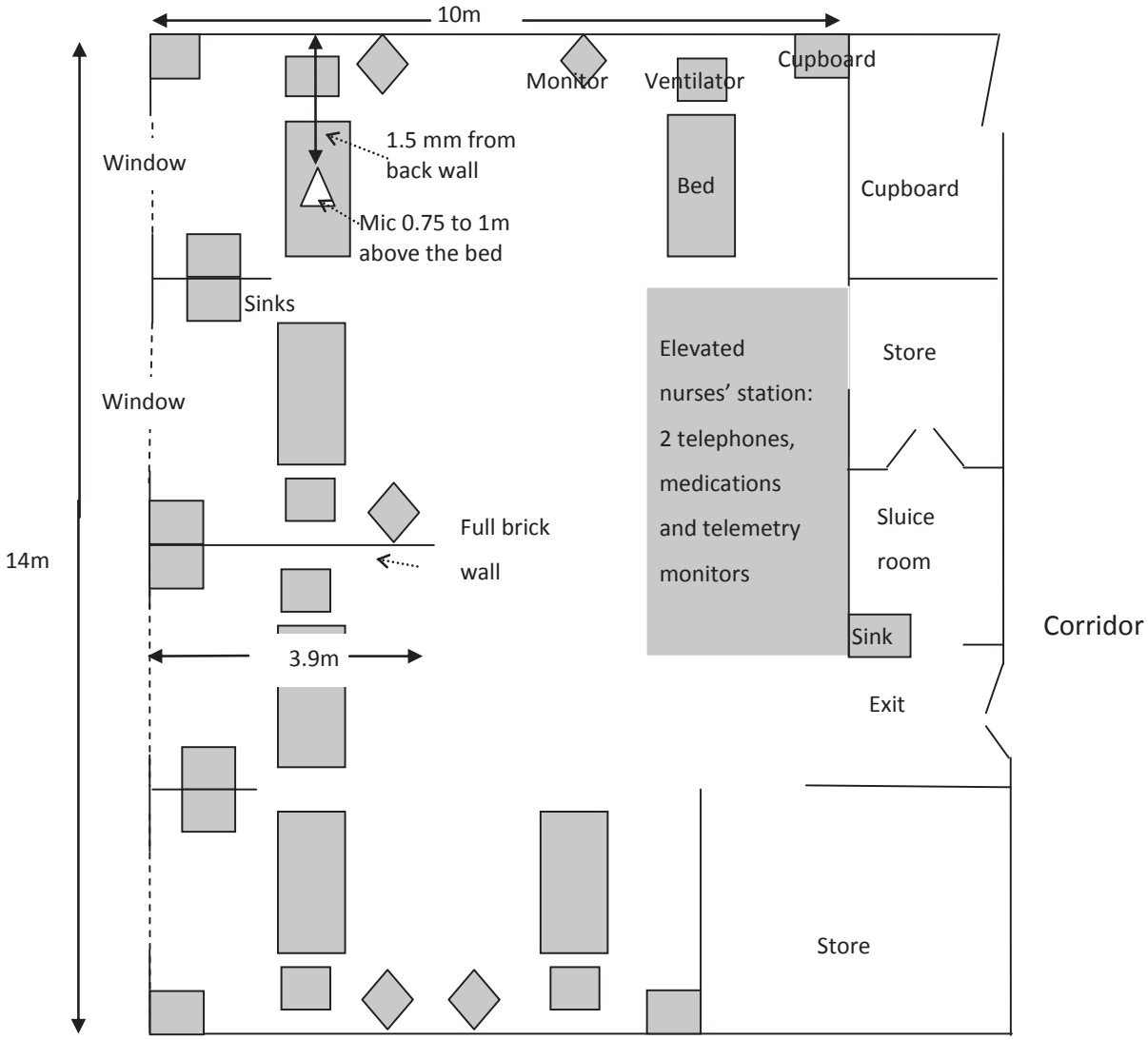


Figure 7. Plan of one of the four patient areas (six bedded rooms: H, G, N and R) in which 24-hour PSG sleep data and illuminance and sound level data collection took place (outline to scale).

Position of microphone shown relative to the patient's bed.

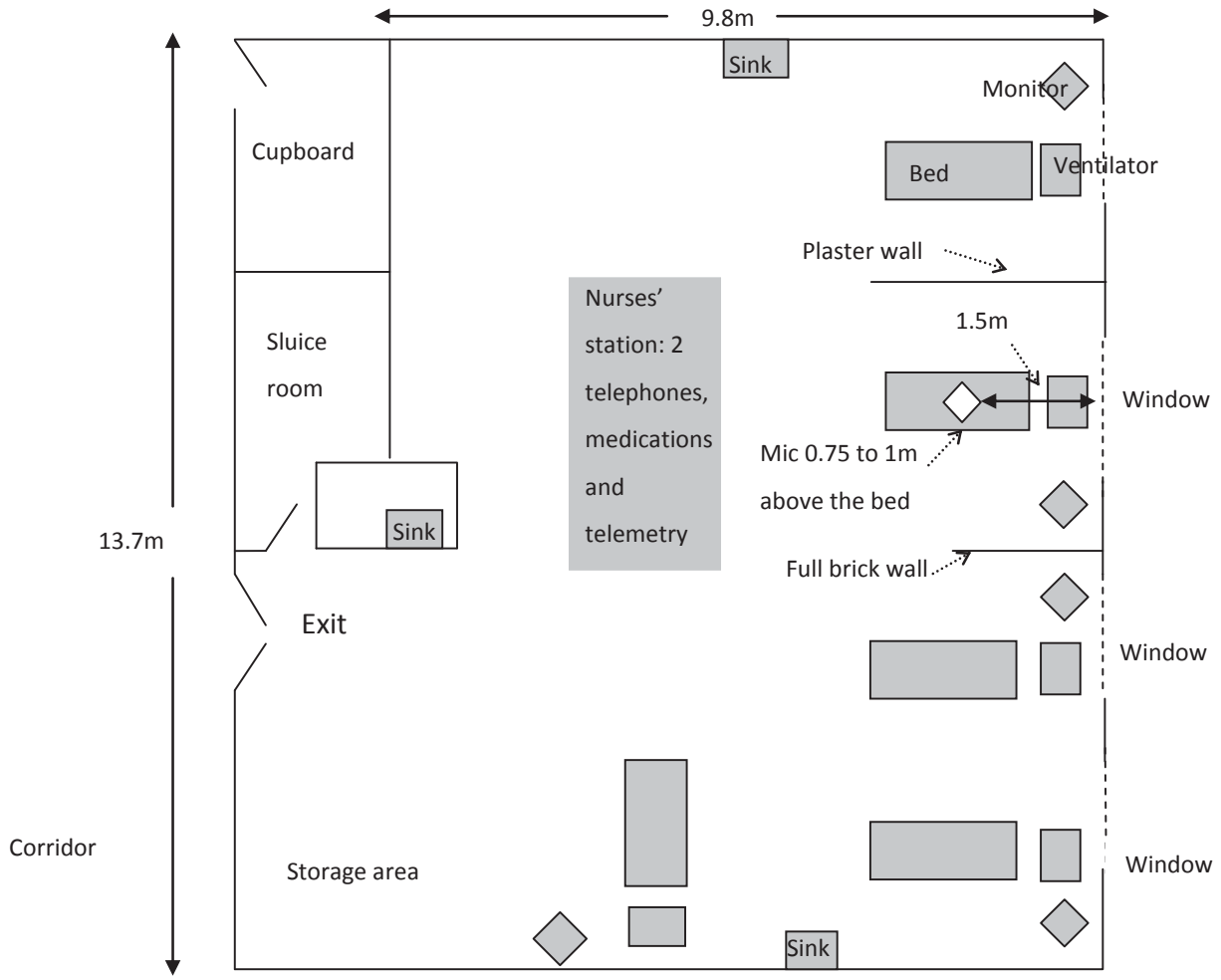


Figure 8. Plan of the five bedded room (J) in which 24-hour PSG sleep and illuminance and sound level data collection took place (outline to scale).

Position of microphone shown relative to the patient's bed

3.6 Participants

Participants were volunteers who received no remuneration for participating. Critically ill adults treated in the study ICU were invited to participate if they met the eligibility criteria.

3.7 Sampling

Convenience sampling was used. In the case that more than one patient was eligible to participate at once, the patient who was most suitable for sleep monitoring was invited to participate (for example, face and head clear of wounds). There were 25 to 45 patients who satisfied the inclusion criteria during screening each month.

3.8 Method in which patients were recruited

Prospective participants were identified in the ICU. Screening occurred only when the PSG was not in use and when 24-hour data collection was possible. Each patient was enrolled only once.

3.8.1 Eligibility criteria

Patients were eligible to participate if they were:

- in ICU for 24 hours or more and had an expected ICU stay of a further 24 hours or more (after enrolment)
- older than 16 years

There was no upper age limit for inclusion in the study.

3.8.2 Exclusion criteria

Efforts were made to recruit patients who had sufficient cognitive capacity to give informed consent, co-operate with the placement and maintenance of PSG electrodes and provide appropriate responses to the research questionnaires. Otherwise eligible patients were excluded if they had:

- a history or evidence / suspicion of sleep disorders (for example obstructive sleep apnoea, body mass index (BMI) greater than 30 kg/m^2 (Lee and Mokhlesi, 2008) or pre-existing insomnia)
- a history or evidence of psychiatric illness requiring medication
- a known diagnosis of dementia
- drug or alcohol withdrawal at time of screening
- a recent history (within four weeks) of long term alcohol dependency (more than four standard drinks for men and more than three for women per day for more than one year)
- a central neurological impairment (Glasgow Coma Score less than 12 without endotracheal / tracheostomy or less than 10 with) for example, brain trauma confirmed by radiological scan, anoxic brain injury, suspected encephalopathy, seizure disorder or drug overdose
- injuries that prevented the correct placement of electrodes for PSG
- previous and known complete permanent hearing or sight loss
- insufficient understanding of the English language to complete the study instruments
- liver failure (Childs-Pugh class B or C disease / Childs-Pugh score greater than seven)
- significant treatment limitations in place or receiving palliative care
- a multiresistant organism colonisation or infection

3.9 **Obtaining informed consent**

Prospective patients' sedation level was assessed using the Vancouver Interaction and Calmness Scale (VICS) (de Lemos et al., 2000) (Appendix C). If the interaction score was greater than 20 and calmness score was greater than 24, that is opened eyes spontaneously to voice and were able to respond to questions appropriately, they were approached. If the patient was willing to participate, their ability to give informed consent

was assessed using a predetermined method (adapted from Fan et al. (2008) and Higgins & Daly (1999)):

1. The patient's ability to give informed consent was subjectively advised by the bedside nurse. Their cognition was discussed including orientation to time and place and ability to follow simple instructions.

2. The patient was approached and asked to state their name (or mouth the words). If the patient was able to perform this instruction a further check was made, step three below.

3. The patient's understanding and ability to follow instructions was checked by asking them to nod when the correct colour card was held up from a selection of three.

The study was explained to the patient. Written informed consent (Appendix D contains the participant information statement and consent form) was obtained if the patient was willing to participate. If the patient was unable to sign the consent form the closest proxy / next of kin was contacted to sign the form after confirming for themselves that the patient had given informed consent. In practice the patient's decision to participate was corroborated by the person closest to them in most cases. All participants received a study information sheet and a copy of the signed consent form to keep.

3.10 **Instrumentation**

The outcomes and other variables and the instruments used to measure them are outlined in Table 5. Further details are provided in the text.

Table 5. Outcomes assessed and corresponding instruments used in the ICU Sleep Study

	Variable assessed	**Instrument / technique**	**Time administered / collected**
Pain	Pain intensity	Numerical pain scale	On enrolment
Anxiety	State anxiety	Faces Anxiety Scale (FAS)	On enrolment
Quality and quantity of sleep in the intensive care unit	TST	PSG	For 24 hours following enrolment
	SEI		
	Number and duration of sleep episodes		
	Sleep stages		
	Arousals and awakenings		
Noise / environmental sound levels	Sound pressure level	Sound level meter	For 24 hours during sleep monitoring
Environmental illuminance levels	Illuminance level	Illuminance level meter	For 24 hours during sleep monitoring
Ambient temperature	Maximum and minimum temperatures	Minimum / maximum environmental ambient thermometer	For 24 hours during sleep monitoring
Frequency of potential interruption for patient care activities	Events (treatment and care procedures)	Computer recorded event form (Access database)	For 24 hours during sleep monitoring by bedside nurses

	Variables assessed	Instrument / technique	Time administered / collected
Subjective sleep quality and quantity	Patients' self-reported quality of sleep prior to hospitalisation	Insomnia Sleep Index (ISI)	On enrolment (patient / proxy)
		Sleep in Intensive Care Questionnaire (SICQ)	First question on enrolment
	Patients' self-reported subjective quality and quantity of their sleep overnight in ICU and on the Ward	Richards Campbell Sleep Questionnaire (RCSQ)	Immediately after 24-hour sleep monitoring and on the Ward two days after ICU discharge
	Patients' perception of sleep disturbances in ICU	Sleep in Intensive Care Questionnaire (SICQ)	On the Hospital ward two days after ICU discharge
	Patients' subjective assessment of their sleep during recovery at home.	Pittsburgh Sleep Quality Index (PSQI)	Two months after hospital discharge
	Nurses' subjective assessment of the quantity of the patients' sleep.	Nurses' Observation Checklist (NOC)	Completed by bedside nurses during the night (2000 to 0800 hours) of 24-hour sleep monitoring

	Variables assessed	Instrument / technique	Time administered / collected
Psychological well-being	Symptoms of depression, anxiety and stress	Depression Anxiety Stress Scales (DASS)-21	Two months after hospital discharge
	Symptoms of Posttraumatic Stress Disorder	Posttraumatic Symptoms Checklist for a specific event (PCL-S)	Two months after hospital discharge
	Recall and perception of the experience of being an intensive care patient	Intensive Care Experience Questionnaire (ICEQ)	Two months after hospital discharge

3.10.1 Technical instrumentation

Quality and quantity of sleep in the intensive care unit

Two portable PSGs were used, the PS-2™ (Compumedics, Melbourne, Australia) and from patient number 23 in the preintervention phase and all patients in the postintervention phase, the ALICE® LE (Philips Respironics, Amsterdam, the Netherlands). The ALICE LE was purchased because data collected using the PS-2 were increasingly difficult to manage as the software was not compatible with recent computer operating systems. 'Gold' cup electrodes with EC2™ conduction paste were used for the EEG, EOG and facial EMG channels and 'snap on' paediatric size electrodes were used for the limb (ALICE) and ECG channels. The following montage was used (see also Figure nine):

- two EEG channels; O1 / M2 and C4 / M1 placed according to the 10-20 International system (Jasper, 1958) of EEG electrode placement

- one bipolar submental EMG channel over the masseter muscles
- EOG channels right and left over the canthuses
- two peripheral limb electrodes to detect position changes
- one position sensor placed on the chest to detect position changes
- one ECG heart rate bipolar channel (lead II)

Sampling rates and filters used during PSG recording

PS-2 Compumedics portable PSG

The following sampling rates were used: EEG channels 256 Hz, EMG channel and ECG 128 Hz, EOG channels 64 Hz, right and left limb movement channels 8 Hz and position sensor, sound and light channels 8 Hz.

The filters were not used during recording. However the following filters were applied during analysis of the PSG recordings by the sleep technologist: EEG (both channels) high-pass 0.48 Hz - 3 dB and low pass 30 Hz - 3 dB, EMG high-pass 7 Hz - 3 dB and low-pass 70 Hz - 3 dB and EOG (left and right) high-pass 0.48 Hz - 3 dB and low-pass 30 Hz - 3 dB. Filters were not used for the limb channels. The notch setting was 50 Hz.

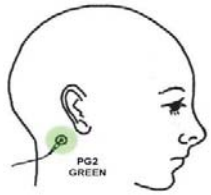
ALICE LE PSG

The same montage was used with the exception of the limb electrodes (only one bipolar channel was used for limb movement). (Sound and light channels were not available on the ALICE LE). An initial sampling rate of 2,000 Hz with a storage rate of 200 Hz was used except for the position sensor which was 1 Hz.

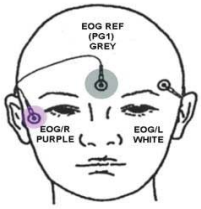
Filters were used during recording and analysis for data obtained using the ALICE LE: EEG and EOG channels high pass 0.3 Hz - 3 dB and low pass 15 Hz - 3 dB, ECG high pass 0.5 Hz - 3 dB and low pass 30 Hz - 3 dB and no filters for the limb and EMG channels. QRS

filters were switched on during data acquisition for the EOG and EEG channels. The notch setting was 50 Hz.

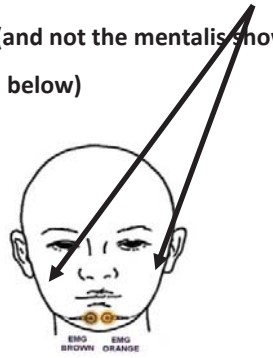
1. Patient reference electrode



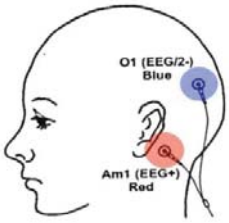
2. EOG electrodes

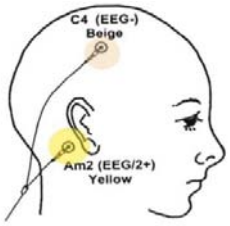


3. EMG electrodes –over the masseter muscle (and not the mentalis shown in the diagram below)



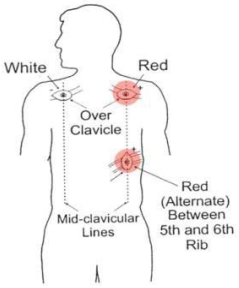
4. EEG electrodes



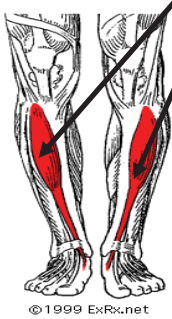


7. Position sensor

5. ECG electrodes



6. Leg electrodes -over the anterior tibialis on each limb for PS-2 and one limb for ALICE LE



Source: PS-2 user guide (September 2001), Compumedics Limited, Abbotsford, VIC, Australia

Figure 9. Position of electrodes used during continuous 24-hour sleep monitoring

Environmental sound pressure levels

A portable sound level meter (SLM) and analyser (Model 2250) (meeting international standard IEC 61672-1), microphone (Model 4189) attached to a 3.0 metre extension lead and calibrator (Model 4231) (Brüel and Kjaer™, Denmark) were used. Sound level meter software BZ7222 ver 1.5, frequency analysis software BZ7223 ver 1.5 and logging software BZ7224 ver 1.4.1 were used (Brüel and Kjaer™, Denmark).

The SLM was programmed to record sound pressure broadband parameters along with LZ spectra at a sampling and logging frequency of one sample per second for 24 hours. Maximum input level was 141.07 dB and 1/3 octave bandwidth was used for the sound spectra. The 'Logging' mode was used. Calibration was performed prior to each recording at 1,000 Hz, 94 dB as a reference output.

Environmental illuminance levels

The T-10 illuminance meter (Minolta™) was used to record illuminance levels throughout the 24-hour data collection period. The T-10 is an illuminance meter used by light engineers. It was attached to the laptop computer via a serial port to USB port converter. Automatic calibration occurred when the meter was switched on. A one minute sampling and recording period was used.

Ambient temperature

A minimum / maximum thermometer was placed within two meters of the patient's bed to provide information about the ambient temperature. An analogue thermometer was used in the preintervention phase (manufacturer unknown) and a digital thermometer (Model 40102 F/C, Extech® Instruments Corp, MA, US) in the postintervention phase.

Patient care activities

The bedside nurse was requested to log an event whenever the patient received treatment or care in order to assess potential disturbances. The event log was created using Microsoft Access™ software. A form located in the main study database remained open (Appendix E shows a 'screen dump' of the event log form) on the screen of a laptop

computer (Compaq™ / Hewlett Packard™ compaq 8510 with Windows XP Professional™ Version 2002 service pack 2 operating system) located on a trolley at the bedside within reach of the nurse. The event log contained the following items: clinical assessment; tracheal suctioning; pressure area care; physiotherapy; mouth/eye care; blood test (sampling); wash; non-invasive blood pressure; eating and drinking; dressing; pain; line insertion; X-ray; clinical crisis; agitation/anxiety/confusion; electrode replacement and other (for example placing an extra blanket on the patient).

The internal clocks on the laptop computer, SLM and PSG were manually synchronised during the study set-up. The resulting concordance between the clocks was within one second before the study began.

3.10.2 Non-technical instrumentation

Patient demographics

The data collection sheet was designed for the collection of relevant demographic and clinical information, for example age, gender, severity of illness and duration of mechanical ventilation. The data collection form was stored separately from the patient information form. Appendix F contains the patient information and data collection forms.

Diagnosis. The Acute Physiology and Chronic Health Evaluation III ANZICS modified diagnostic codes (ANZICS, 2004) were used to classify the diagnosis of patients in the study. In the development of the original APACHE II prognostic system 18 sub-categories were used which contained a total of 79 disease categories (Knaus et al., 1991). This classification system was modified by the Australian and New Zealand Intensive Care Society and is used during routine data collection in Australian ICUs and widely used to assign patients to diagnostic groups for ICU research (ANZICS, 2004).

Severity of illness. The Acute Physiology and Chronic Health Evaluation II (APACHE II) (Knaus et al., 1985) and APACHE III severity of illness scores on admission to ICU (Knaus et al., 1991) were used to describe the sample. The APACHE II and III classification system is designed to predict risk of in-hospital death for ICU patients. Higher APACHE II and III

scores indicate greater severity of illness. APACHE II scores range from zero to 77 and APACHE III scores range from zero to 299. Both scoring systems were developed and validated in ICU patient populations and found to be reliable in investigations predicting prognosis (Gunning and Rowan, 1999). More importantly they are used extensively to describe ICU patients in studies and provide information which assists the reader with assessment of the generalisability of results to their patients. The APACHE II and III instruments are located in Appendix F in the data collection form.

Pain intensity. Pain was assessed using a zero to ten numerical pain intensity scale, where 10 is the worst pain possible.

State anxiety level. Anxiety level was assessed using the Faces Anxiety Scale (FAS) (McKinley and Madronio, 2008). The FAS contains five faces representing different levels of anxiety. The respondent is required to point at the face that best describes how they feel. The FAS was specifically developed for use in the ICU. It correlated well with the Spielberger State-Trait Anxiety Inventory ($r = 0.7$, $p < 0.0005$) during testing for criterion validity.

Patients' dependency and likely care activity levels during sleep monitoring. The Modified Sequential Organ Failure Assessment (SOFA) score (Vincent et al., 1996) and the Nursing Activities Score (NAS) (Reis Miranda et al., 2003) were used to describe patients' dependency levels during sleep monitoring, as well as an indication of care activity levels (and the potential for disturbance). Higher scores on both of these instruments were postulated to be associated with higher patient care activity levels in the current study. The SOFA and NAS are contained in Appendix F.

The SOFA provides an alternative method of quantifying severity of illness. The higher the score the higher the dysfunction of the organ system (range: zero to 20). The initial SOFA instrument, the Sepsis-Related Organ Failure Assessment was developed by the working group on Sepsis-Related Problems of the European Society of Intensive Care Medicine in 1994 (Vincent et al., 1996) to quantify severity of illness and describe organ dysfunction over time. Since then the renamed Sequential Organ Failure Assessment has

been published in various modified versions (Finfer et al., 2009, Andrews, 2010, Finfer et al., 2004, Park et al., 2011). The modified SOFA score used by Finfer et al. (2009) was used in the current study.

The NAS comprises twenty-three nursing activities and interventions weighted according to time required by nurses' to undertake them and independent of the severity of illness (Reis Miranda et al., 2003). Each activity/intervention is allotted a score. The greatest possible total score is 177% which equates to about 1.8 Registered Nurses' time over 24 hours and lowest possible score is 0%.

The NAS is an instrument based on the Therapeutic Intervention Scoring System (TISS)-28 to assist decision makers about workforce planning and resource allocation (Reis Miranda et al., 1997). It was developed to better describe nursing time required rather than severity of illness (Padilha et al., 2008). The NAS was selected as a surrogate measure of dependency level and intensity of nursing care (relative disturbance level) during 24-hour sleep data collection in the current study. The use of NAS is free of charge but permission was sought from the author to use the NAS for this purpose (Appendix G).

Subjective sleep reports

Patients' quality of sleep prior to admission to the intensive care unit. The Insomnia Severity Index (ISI) (Bastien et al., 2001) (Appendix H) was administered to assess the patient's quality of sleep prior to their critical illness. The ISI comprises seven items based on the symptoms and severity of sleep disturbance and its effect on daily life. Each item is scored from zero (not at all) to four (extremely) and the total score ranges from zero to 28. The cut-off score for the diagnosis of clinical insomnia is 15. Scores of 22 and above indicate severe clinical insomnia.

The ISI was developed to identify clinically significant insomnia (based on Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV) (American Psychiatric Association, 1994) diagnostic criteria for the condition). Concurrent validity was investigated in unpublished work by Morin and reported by Bastien, Vallières et al. (2001) (r = 0.65). Further testing of the psychometric properties in two studies (the

assessment of insomnia and a randomised controlled trial of pharmacological and behavioural therapies for insomnia in a sleep disorder clinic) revealed good internal consistency and moderate concurrent validity.

In the current study, respondents or their proxy (a person who had known the patient for more than five years and who, prior to this hospital admission, was in their company for four or more hours per week as described by Pisani et al. (2003)) were requested to report on the severity of each item over the past two weeks. The ISI has been previously administered via a proxy (usually the spouse) and permission was granted from the author (Charles Morin) to administer the instrument via the patient's proxy for the current study (Appendix I).

Patients' subjective assessment of their sleep in the intensive care unit and on the ward. The Richards Campbell Sleep Questionnaire (RCSQ) (Richards et al., 2000) (Appendix J) was used to assess the patient's perception of the quality and quantity of their overnight sleep in ICU and on the Hospital ward. The RCSQ comprises five 100 mm visual analogue scales: sleep depth, latency, awakenings, time awake and quality of sleep. Responses are scored by measuring the distance from the low end of the scale to the mark made by the patient. The total score for the RCSQ is the mean of the five VAS scores. High scores indicate good quality sleep.

The RCSQ was pilot tested in a medical ICU (n = 9, 100% male, 14 nights) (Richards and Bairnsfather, 1988) and validated in a more extensive investigation involving 70 male patients (Richards et al., 2000). The correlation between total RCSQ score and PSG SEI was moderate, $r = 0.58$ ($p < 0.001$); the total RCSQ score was able to predict 33% of the variance in the SEI. (Richards et al., 2000). There are no published RCSQ data for healthy individuals on which to base a comparison or provide cut off scores for poor, moderate or good sleep.

Nurses' subjective assessment of the quantity of the patients' sleep. The Nurses' Observation Checklist (NOC) (Edwards and Schuring, 1993) (Appendix K) was used to obtain the bedside nurses' assessment of the quantity of the patient's sleep. It is a

relatively simple instrument which requires assessment and assignment of a category; ‘awake’, ‘asleep’, ‘could not tell’ and ‘no time to observe’ to each patient every 15 minutes.

The NOC was first used to validate critical care nurses’ ability to assess the patients’ sleep / wake state (Edwards and Schuring, 1993). Nurses (n = 15) using the NOC in a sample of 21 patients (20 were mechanically ventilated) correctly assessed the patients’ sleep / wake state 73.5% of the time according to PSG recordings. Assessment occurred between 0100 hours and 0500 hours during which attempts were made to ensure the environment was conducive to rest.

In the current study data derived from the NOC provided an evaluation of the accuracy of nurses’ routine assessment of patient sleep states during the night relative to PSG. No specific criteria or training were provided so that the data were as reflective of routine ‘assessment’ as possible. Nurses were not required to assess sleep status at a specific time within the 15 minute time frame; they were asked to assess whether they thought the patient had been asleep over the previous 15 minutes. The NOC was used to assist discussions about the preintervention phase data and to explore its utility for routine assessment of sleep in ICU patients.

Patients’ perception of sleep disturbances in the intensive care unit. The Sleep in Intensive Care Questionnaire (SICQ) (Freedman et al., 1999) (Appendix L) was administered to assess the patients’ perception of sleep disturbances and their sleep in the ICU. The SICQ contains seven questions, some with more than one item. Responders are requested to rate their overall sleep quality at home and in the ICU (and at three different times during their ICU stay) using the SICQ. In addition, ratings on daytime sleepiness are included, along with sources of perceived sleep disruption and noise. Items are rated on a scale one to 10. Ten is the most desirable score for items contained in questions one to five and one is the most desirable score for items in questions six to seven.

During the preintervention phase in the current study many patients added other comments about the ICU environment and many felt that there were items in the last two sections which were not relevant. Therefore two open ended items (six and seven) were added to the SICQ for the postintervention phase (Appendix M). They were added in order to allow a better understanding of former ICU patients' perception of sleep disturbance while treated in a current ICU setting in Australia.

Patients' subjective assessment of their sleep during recovery at home. The Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989) (Appendix N) was administered to assess the quality and quantity of the patients' sleep at home during recovery from critical illness. This 19 item instrument contains seven components (subscales): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication and daytime dysfunction. Each component has a possible score of zero to three and the global PSQI score is zero to 21. Global PSQI scores greater than five indicate the presence of severe difficulties in at least two components or moderate difficulties in more than three. Responders are required to report on their sleep over the 'past month'.

The PSQI was designed to provide a reliable and valid measure of sleep quality, have sufficient sensitivity to differentiate 'poor' sleepers from 'good' sleepers, be brief and simple for responders and researchers / clinicians to use and provide a useful assessment of factors which disturb sleep (Buysse et al., 1989). The items were identified during clinical work with sleep disorder patients and a review of existing sleep quality questionnaires. The PSQI was used for clinical and research purposes for many years before being formally evaluated for 'its clinimetric properties'. The seven PSQI components demonstrated good internal consistency (Cronbach's alpha = 0.83) and correlations between the global PSQI score and each component were moderate to strong, the strongest being habitual sleep efficiency ($r = 0.85$, $p = 0.001$). Test-retest reliability was also confirmed ($r = 0.85$, $p < 0.001$). A global PSQI cut off score of five

correctly identified 88.5% (Kappa = 0.75, $p < 0.001$) of sleep disorder patients ('poor' sleepers) (giving an overall sensitivity 89.6% and specificity 86.5%).

Psychological outcomes

The short version of the Depression Anxiety Stress Scales (DASS-21) (Lovibond and Lovibond, 1995), Intensive Care Experience Questionnaire (ICEQ) (Rattray et al., 2004) and the Posttraumatic Stress Disorder Checklist for a specific event (PCL-S) (Weathers et al., 1993) were administered during follow up at two months after discharge from hospital (Appendix O).

The DASS-21, ICEQ and PCL-S were selected to assess perceptions of the ICU experience and psychological well-being, that is the symptoms of depression, anxiety, stress and posttraumatic stress disorder (PTSD) during recovery from critical illness. They were also selected for the potential to examine associations between these outcomes and quality of sleep while in ICU in a future research program. A brief description of their development and psychometric properties follows.

Symptoms of depression, anxiety and stress. The DASS-21 (Lovibond and Lovibond, 1995) consists of three subscales (depression, anxiety and stress) containing seven items each taken from the original 42-item DASS. The scores for each item are doubled so that the subscale and global scores can be compared to data collected using the 42-item DASS and corresponding normative values (Lovibond and Lovibond, 1995).

Lovibond and Lovibond's (1995) 42-item DASS is a self administered questionnaire used to measure depression, anxiety and stress for research and clinical purposes. The DASS was developed using healthy and clinical populations including insomniacs in extensive investigations of many thousands of people. Since its development the DASS has been validated in numerous studies and the shorter DASS-21 has shown adequate reliability (the anxiety subscale is less robust) and construct validity (Henry and Crawford, 2005).

Posttraumatic stress disorder symptoms. The PCL-S (Weathers et al., 1993) is a 17 item self-report for assessing PTSD symptoms (based on DSM-III-R (American Psychiatric Association, 1987) diagnostic criteria)and reactions to a specific event. There are three subscales 'reexperiencing' (items one to five), 'avoidance' (items six to 12) and 'hyperarousal' (items 13 to 17). Each item corresponds to a PTSD symptom and respondents are requested to indicate how much they were bothered by each symptom over the past month using a five point Likert scale (1 = 'not at all' and 5 = 'extremely').

Initial psychometric testing on the PCL-M (developed for military experiences) revealed a test-retest reliability of 0.96 and scale/item correlations from 0.67 to 0.87. There are now three versions of the PCL: PCL-M, the PCL-C, developed for generic civilian use were created in 1993 at the National Centre for PTSD (US) and PCL-S developed for a specific event. There are very slight differences in wording of the items in each version. Both Blanchard et al. (1996) and Ruggiero et al. (2003) demonstrated that the PCL-C had high sensitivity, specificity and internal consistency when administered to survivors of trauma. PCL-S is used exclusively in health research. It has been shown to correlate highly with the Clinician-Administered PTSD scale (incorporating DSM-IV criteria (American Psychiatric Association, 1994)) (sensitivity 0.97 and specificity 0.87) and demonstrate high internal consistency (Cronbach's α = 0.86) and test-retest reliability (Pearson's r = 0.8) in trauma survivors (Ventureyra et al., 2002).

Recall and perception of the experience of being an intensive care patient. The ICEQ (Rattray et al., 2004) contains 24 items relating to the perception, feelings and sensations of being in ICU. Each answer is allocated to one of four domains 'awareness of surroundings' (scores: nine to 45), 'frightening experiences' (scores: six to 35), 'satisfaction with care' (scores: four to 20) and 'recall of experience' (score: five to 25). There are two types of response formats, a Likert scale ('strongly agree' to 'strongly disagree') for items one to 12 and a frequency scale ('all of the time' to 'never') for items 13 to 24 with scores of one to five on each item. Fourteen items are negatively worded and 10 are positively / neutrally worded. Three are reverse scored. There are three further open questions. High

scores represent greater perceived ‘awareness’ and ‘frightening experiences’ in ICU and ‘greater satisfaction with care’ whereas a low score in the ‘recall of experience’ component indicates poorer recollection of the experience.

The ICEQ was designed to describe and quantify the patient’s experience of ICU and predict short and long-term emotional outcome during recovery (Rattray et al., 2004). The ICEQ was administered, to assess its concurrent and predictive validity, with the Hospital Anxiety Depression Scales (HADS) (Zigmond and Snaith, 1983) and IES (Horowitz et al., 1979) at hospital discharge and six and 12 months after hospital discharge. Moderate and statistically significant correlations were discovered between the ‘frightening experiences’ component and the HADS anxiety and depression scales at hospital discharge and at six months ($r = 0.258$ to 0.483, $p \leq 0.05$) and 12 months for the HADS anxiety ($r = 0.444$, $p \leq 0.01$). In addition there were moderate to strong statistically significant correlations between ‘frightening experiences’ and the avoidance and intrusion scales of the IES ($r = 0.413$ to 0.6, $p < 0.01$) (Rattray et al., 2004). The authors have performed two additional studies to further investigate the psychometric properties of the ICEQ. Thus content and construct validity (Rattray et al., 2010) and internal consistency (Rattray et al., 2005) have been confirmed and the potential for the instrument to predict short and long term emotional outcomes is beginning to be demonstrated (Rattray et al., 2005, Rattray et al., 2010).

3.11 **Study procedure and data collection**

On enrolment patients were asked to rate their pain intensity and state anxiety. They were also requested to rate the quality of their sleep at home. The patient or their proxy provided information about any symptoms of insomnia prior to critical illness. Twenty-four hour sleep data collection with environmental sound and illuminance levels and maximum and minimum temperature recording within ICU was performed immediately after enrolment. Bedside nurses completed the event log during sleep monitoring. During the night period (between 2000 and 0800 hours) nurses were

requested to assess whether the patient was sleeping. Immediately after the PSG was removed the patient was asked to provide a self-report of the quality of their sleep.

Two days after transfer to the Hospital ward patients were requested to self-report their sleep quality while on the Ward. At this time they were also asked to give their perspective of sleep disruptions while in ICU.

Two months following discharge from the Hospital patients were contacted by the postal service (and again later by telephone if the questionnaires were not returned) to complete questionnaires regarding their psychological well-being and quality and quantity of sleep during recovery at home. This timeline was selected in order to capture the patients' perceptions of the ICU experience sufficiently close to the ICU discharge but in a time when the patient had had time to reflect and complete the questionnaires. Figure 10 shows the procedure for patient recruitment and data collection.

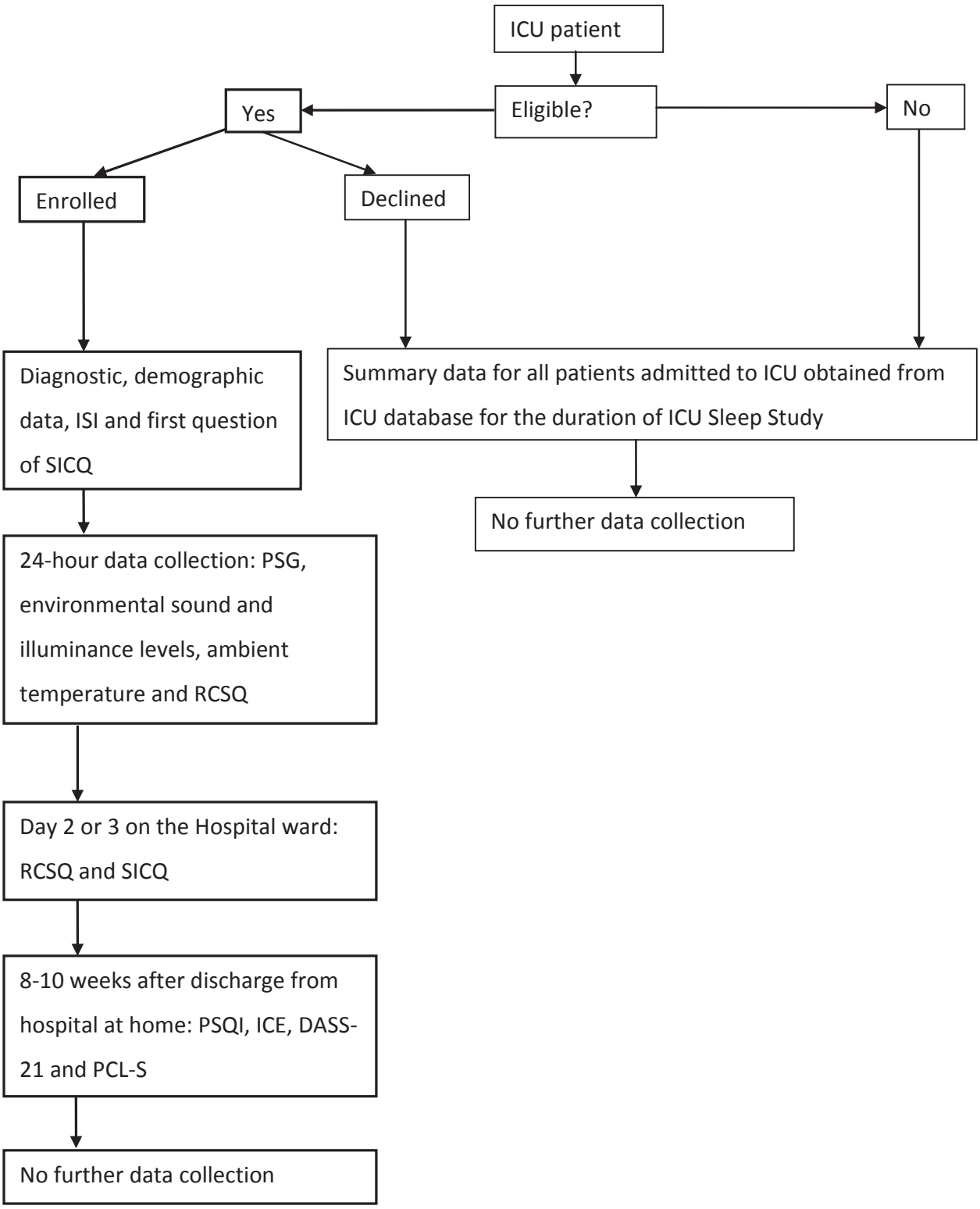


Figure 10. The procedure for patient recruitment and data collection.

3.11.1 Data collection in ICU

After informed consent was obtained the patient (if able) or patient's proxy was requested to complete the ISI. The ISI was mostly administered prior to 24-hour sleep data collection or shortly after PSG monitoring began. If a relative was not available and the patient did feel able, occasionally administration was postponed until the following day (if I was confident that the patient did not have a pre-existing sleep disorder which was an exclusion criterion). The first item of the SICQ (Freedman et al. 1999) ('rate the overall quality of your sleep at home') was also administered to the patient. At this time sedation, pain intensity and state anxiety levels were also assessed. Twenty-four hour sleep, ambient temperature and environmental sound and illuminance data collection began at the same time just after enrolment. A researcher was continuously available during data acquisition. Nurses were requested to assess the patient's sleep state during the night. Other demographic and clinical data were collected during the patient's ICU stay.

During the postintervention phase, the Guideline was audited on days when sleep monitoring was not conducted (described in detail in Chapter four).

Sleep data acquisition: PSG and event log

Skin preparation and electrode placement

The patient's head was marked according to the conventional International 10 / 20 system (Jasper, 1958) in which specific measurements ensure that EEG electrodes are placed over the correct corresponding anatomical area of the brain. The skin was thoroughly cleaned before electrode placement using standard procedures including; skin exfoliation using a specific product (Nu-Prep™) and oil removal using an alcohol wipe. Occasionally antiperspirant was applied at the end of skin preparation to counteract excessive sweatiness.

Starting sleep data collection

Polysomnograph recording was started once the electrodes were in place, the leads were plugged into the PSG, all connections checked and the electrode wires lightly

tied and placed over the patient's shoulder (Appendix P contains a photograph of the set up in progress).

Impedance checks were performed at the start of recording. Values of less than nine Ohms for each electrode in the case of the PS-2 was advised as acceptable but in practice recording did not begin until values were stable and less than six Ohms. On occasions this required multiple electrode changes. In the case of the ALICE LE, which provides the sum of the impedance values for each channel (both electrodes), a value less than nine Ohms was accepted.

On a few occasions impedance values for some electrodes were persistently high despite multiple electrode changes. After three changes per electrode no more attempts were made to improve the impedance value until the patient was due to be disturbed again for repositioning. In addition, I made a note of any channels with suboptimal impedance values and notified the sleep technologist later. In practice all PSG recordings of over 15 hours were of sufficient signal quality to allow the sleep technologists to analyse them.

Event log

As described previously, the event log was a form created in a password protected Access database. Before recording started the form was set up for the new study patient. The bedside nurse was requested to record any event which involved touching the patient immediately prior to or after an intervention or procedure by selecting the appropriate event from a list on the form (Appendix E). No other action was required by the nurse to save the record of the event in the database.

Protocol during sleep monitoring

Every effort was made to reduce bias (the Hawthorne effect) during the preintervention phase. The researchers remained in an office on the same floor as the ICU and were contactable by mobile telephone to assist throughout 24-hour data collection. Visual checks of the equipment and impedance checks were performed every hour during

daylight hours and every hour and half at night (this did not involve touching or disturbing the patient). Electrode impedance values were monitored and electrodes were changed during scheduled pressure area care and hygiene procedures. When impedance values were seen to consistently increase above six Ohms for individual electrodes, in the case of the PS-2 and nine Ohms for each channel in the case of the ALICE LE, electrodes were changed. Bedside nurses were requested to call a researcher before repositioning or moving the patient, to avoid waking the patient to check electrode placement and to reattach any electrode that had become loose during movement.

Patients were not restricted from mobilising or participating in physiotherapy at any time. Clinicians were requested to continue treatment and care as planned throughout. In order to accurately capture the quality and quantity of sleep experienced by ICU patients' in the preintervention phase, the researchers attempted to reduce the chance of directly changing the environment or behaviour of health care personnel during sleep PSG data collection and only intervened as directed by the ICU health care personnel. For example we did not intervene if clinicians spoke in loud voices near the patient who was being monitored. Regular checks of the equipment were required and the researchers attended during patient mobilisation but we left the immediate clinical area and spent the recording time in an office nearby. Clinical personnel were able to call the researchers by mobile telephone at anytime for assistance.

Nurses were requested to assess the patient's sleep state using the NOC during the night (2000 to 0800 hours). The screen displaying the PSG was not displayed during monitoring to ensure nurses' assessments were based on their observation of the patient alone.

Completion of sleep data acquisition

Sleep data acquisition was stopped at 24 hours or earlier if the patient was required to leave the ICU for a procedure or if the patient or the clinician requested it, for example if a clinical crisis occurred (preintervention phase n = 2, and postintervention

phase n = 4). The electrodes were removed and the skin was inspected for signs of irritation or injury.

After the equipment was removed the RCSQ was administered. The patient was requested to mark the five visual analogue scales. In the case that a patient was unable to write the researcher passed a pen slowly above each line and the patient was requested to indicate when the pen was at the correct point on the line (patients were asked to nod if they were unable to communicate verbally).

The equipment was thoroughly cleaned later in an unused patient care area. All study equipment was stored on a trolley covered with a dust sheet in a locked office between 24-hour data collection episodes. Standard infection control practices were adhered to at all times by all members of the research team.

Sleep data analysis and staging

Three experienced accredited sleep technologists staged the sleep data. The first 22 patients' sleep data from the preintervention phase were staged by one technologist and a second technologist staged the remainder and all of the postintervention phase sleep data (and performed reliability checks on seven studies analysed by the first sleep technologist). A third technologist performed the interrater reliability checks for the second sleep technologist (three studies from the preintervention phase and seven studies from the postintervention phase). Sleep technologists were remunerated. Two performed the analysis as an addition to their substantive work roles and the other was a self-employed sleep technologist. Data were sent on a USB memory stick or uploaded to a web based electronic file sharing service (DropBox™) within two weeks of acquiring the data. The R and K criteria were used to stage sleep and the American Academy of Sleep Medicine definition to identify arousals (as described earlier in section 3.4 Definitions of key terms).

Reliability checks were performed on the sleep analysis. Intrarater checks were performed by providing a random selection of 20% (n = 4) of the original electronic sleep

data files to sleep technologist number one who analysed them, many months later. The Kappa coefficients were high for sleep technologist one and similar to concordance for analyses performed in the sleep investigation unit. As intrarater concordance for PSG data analysis (performed in the sleep investigation unit) was similar for the other sleep technologists, further intrarater analyses were not performed in the current study. The sleep technologist remained 'blind' to the initial report and staging.

Interrater checks were made by providing studies to the technologist who was 'blind' to the report and staging performed by the other sleep technologist. Thirty per cent of studies in the preintervention phase and 26% in the postintervention phase were rescored by a different sleep technologist.

To examine the specifics of intra / interrater reliability of sleep data analysis calculations were performed for several groupings of sleep states and individual sleep stages. The groupings for the intrarater reliability calculations were: six (stages 1, 2, 3, 4 and REM and wake), five (stages 1, 2, 3 and REM and wake), four (stages 2, 3 and REM and wake) and three (non-REM, REM and wake) (according to Ambrogio et al. (2008)). Groups of sleep states and individual sleep stages were also examined for interrater reliability. The groupings were different to those used for the intrarater calculations as only one sleep technologist identified stage 4 sleep (equal numbers of categories are required for calculation of the Kappa statistic). Therefore stages 3 and 4 were combined in order to calculate the Kappa statistic.

Sound pressure data acquisition

The SLM was calibrated by the company at the factory prior to the start of the study. The SLM was pre-programmed with broadband parameters to record for 24 hours. The microphone was calibrated prior to each 24-hour data collection period. The microphone was placed 1.0 to 0.75 metre above the patient's head and bed (this varied as the bed height and angle of the patient backrest were adjusted from time-to-time), 1.75 metres above the ground and 1.0 metre below the ceiling, with the nearest wall 1.5 metres behind the patient (Appendix P). This set up was used to avoid reverberation but

occasionally slight deviation occurred in order to accommodate other equipment needs of the patient. Health care personnel were advised of the presence of the microphone and informed that sound pressure levels were monitored and recordings were not being made of activity and speech. They were requested to avoid knocking the microphone. Sound pressure recording was started and terminated at the same time as sleep data collection.

Visual checks were made every hour during the day and every hour and half at night. This was to ensure that the microphone was still in place, any buttons had not been accidentally activated and the mains power was still switched on.

Illuminance level data acquisition

The illuminance level meter (ILM) (and sensor head) was placed within three metres of the monitored patient on a trolley near the study laptop computer from patient one to 15 and on the pillow near the patient's head from patient 16. Clinicians were requested to avoid placing items over the illuminance detector head. During data acquisition the connection between the ILM and the laptop computer were checked at the same time as other equipment checks were made.

Minimum and maximum ambient temperature measurements

The thermometer was reset before use. It was placed close to the patient (usually hanging from an intravenous fluid stand) but sufficiently distant from electronic devices that might emit heat. At the completion of 24-hour sleep monitoring the minimum and maximum ambient temperatures were recorded.

3.11.2 Data collection on the Hospital ward

Patients were tracked on the Hospital electronic records database. One to two days (at least one night) after ICU discharge they were approached on the Ward to complete the entire SICQ and RCSQ. In the case that a patient was too fatigued the researcher read the questions out loud and used the same technique described earlier for patients who were unable to write. Permission to approach the patient at home was requested again and contact details were rechecked.

3.11.3 Data collection after discharge from the Hospital

Patients were continuously tracked on the Hospital electronic records database in order to follow them up two months after the hospital discharge date. At two months after hospital discharge patients were posted four questionnaires at home: PSQI, DASS-21, PCL-S and ICEQ with a cover letter (Appendix Q) and self addressed postage paid envelope for their return. Patients who remained in long-term rehabilitation facilities beyond two months received the ICEQ and PCL-S at two months and the PSQI and DASS-21 were sent just after their return home. A telephone call was made two to three weeks after the questionnaires were sent if they had not been returned. At this time patients were invited to respond to the questionnaires by telephone. If the patient expressed an intention to return the questionnaires by post and did not return them within three weeks a further set of questionnaires were sent out with a hand written note. If the patient still did not return the questionnaires no further contact was attempted.

3.12 Data entry and management

3.12.1 Demographic details and questionnaire data

All paper data collection sheets and questionnaires were coded with a study number but no other personal identification details were included. They were stored in a locked filing cabinet inside a locked office. Personal details of patients with study codes were stored in another locked filing cabinet inside a different locked office. Data were entered into the computer database by the researcher. A password protected Access® (Microsoft, California, 2007) database was used for storage of data and the management of multiple data entries. Data were transferred to PASW® version 18 (IBM®, Chicago, Illinois) for analysis.

A copy of the database file was made regularly and stored on a separate computer as backup. Visual checks of all data in the database for data entry inaccuracies were made. Errors were corrected before data analysis by systematically filtering the data and inspecting the data for values which were outside of a predetermined range.

3.12.2 Sleep (PSG) data

After the electrodes were removed from the patient and the equipment cleaned, data were transferred to the laptop computer for storage and the files copied and stored on another computer as a backup. In the case of the PS-2 the data were converted using Compumedics software (Portable Manager) but in the case of the ALICE LE the data were directly saved to a folder on the laptop computer during recording.

Sleep data were analysed manually by a sleep technologist using ProFusion PSG2 and ProFusion PSG3 software (Compumedics, Melbourne, Australia) and, from patient number 23, ALICE Sleepware software version 2.7.43 (Philips Respironics Australia). The R and K criteria for sleep staging and American Academy of Sleep Medicine criteria for arousals were used (as previously described in section 3.4 Definitions of key terms). Individual reports were generated for each patient and the main sleep parameters were entered into the Access™ database described previously. For all patients the duration of each individual episode of sleep was identified manually from the analysed PSG and recorded on an Excel™ spreadsheet. The arousals and awakenings were identified from the PSG log.

3.12.3 Event log

As the event log was a form in the study Access™ database, no further action was required to save it at the end of sleep monitoring. However, a copy of the database file was made at the completion of each patient's sleep monitoring period.

3.12.4 Sound pressure level data

Sound pressure level data were sampled at one second intervals and saved to the memory card of the SLM. The data were transferred on completion of 24-hour data collection to the laptop computer (Compaq™/Hewlett Packard Compaq 8510p, Windows XP Professional™ Version 2002 service pack 2 operating system) using the data management software BZ 5503 Utility Software for Hand Held Analyzers, version 2.00.0002 (Brüel and Kjaer™). The Noise Explorer™ Software version 4.15.1 (Brüel and

Kjaer™) was used to view and manage the data before exporting each individual recording into Excel™ (Microsoft®, California 2007) files and then aggregating the recordings from each phase into one PASW® file for data analysis. A copy was made of each of the sound level data files.

3.12.5 Illuminance level

Illuminance level data were acquired at one minute intervals using Minolta T-10 illuminance meter and saved directly to the hard drive of a laptop using a serial port to USB port converter from the illuminance level meter to the laptop. Data were saved in the T-A30 version 1.30 software (Minolta™) and as text files before being exported to Excel™ (Microsoft®, California 2007) for data analysis.

3.12.6 Ambient temperature

On completion of the sleep monitoring period the minimum and maximum temperatures were read from the thermometer and recorded on the patient's data collection sheet. These data were entered into the study Access™ database.

3.13 **Missing data**

The data from patients who were lost to follow up was treated as missing. However, missing responses to individual questions on the questionnaires were substituted as suggested by the developers of the respective instruments. For missing PSQI values every effort was made to contact the participant to obtain a valid response as the PSQI cannot be scored if it is incomplete. For the DASS-21, if there were more than two missing values in one subscale the participant was contacted. Where instructions were not available for an instrument, for example ICEQ the median or mean value for that subscale was used. However in the case of the SICQ no attempt was made to impute missing values. Patients were often unable to complete some items of the SICQ as they had no memory or were not exposed to some sounds named in the questionnaire. One of the researchers was present to administer the SICQ and clarify and account for missing values.

Analyses of quantity and quality of sleep were only performed for PSG sleep recordings greater than 15 hours duration. Therefore data from patients who revoked consent or for whom monitoring was terminated early were not used. Data collection continued until sleep recordings of analysable quality (and longer than 15 hours) for 30 patients in the preintervention phase were obtained. Twenty-four hour sleep data collection in the postintervention was discontinued after 27 patients were enrolled in order to meet the University deadline for thesis submission.

3.14 **Sample size estimation**

As few studies with substantial numbers of ICU patients using 24-hour PSG have been performed, this study was not powered to test a hypothesis. The sample size of 20 to 30 per phase at the outset was based on the standard deviations (SD) of TST over 24 hours in previously reported sleep studies in ICU patients that have coefficients of variation (CV) in the range of 40-70%. Examples include, 8.8±5.0 hours (CV 0.56), range 1.7 to 19.4 hours, n = 17, (Freedman et al., 2001), 8.28±6.53 hours (CV 0.78), range 0.63 to 20.7 hours, n = 16 (Friese et al., 2007), 6.2±2.5 hours (CV 0.4), n = 7 (Gabor et al., 2003) and 10.09±6.4 hours (CV 0.58), n = 6 (intermittent sedation group) (Hardin et al., 2006). Most previous studies performed in ICU had sample sizes of 20 or less. Given the wide range of CVs in previously conducted studies and the small sample sizes, the SD and CV in the current study sample were examined after each group of 15 patients. The CV was 0.76 for the TST and 0.74 for the SEI for the first 15 patients enrolled in the preintervention phase. The variation between patients for all sleep parameters, for example arousal index, median sleep period without waking, led to the decision to collect data for a further 15 patients in this phase. Twenty-seven patients were enrolled in the postintervention phase (sleep data for 23 were analysed).

3.15 **Baseline characteristics**

Univariate analyses were performed in order to characterise the entire sample. Means, medians, modes and standard deviations were used for continuous data and frequencies and percentages for categorical data. Equivalence of the two groups'

(preintervention and postintervention) baseline characteristics was tested using Student's t-tests (two-sided, α level of 5%) for continuous data that is, age APACHE II/III severity of illness scores, and Chi-square (X^2) tests for categorical data, that is gender and diagnosis.

3.15.1 Primary aim

The primary aim of the study was to assess the quality and quantity of sleep of patients while they were treated in the ICU. This was achieved by objectively measuring sleep using PSG and subjectively using patient and nurse reports. The distribution of data was first assessed for normality using frequency plots in the statistical software package PASW® (version 18). Appropriate descriptive statistics were used in order to describe the data.

3.15.2 Secondary aims

The secondary aims of the study were to assess the: 24-hour sound and illuminance levels and care and treatment activities ICU patients were exposed to, the quality of sleep and psychological well-being of former ICU patients during recovery. Descriptive statistics were used in order to describe the data along with frequency plots. Means, medians, modes and standard deviations were used for continuous data that is, sound levels and frequencies and percentages for categorical data that is, number / type of care / treatment activity. In order to allow comparisons to be made between medications administered to patients in the two study phases, the amount of opioid and benzodiazepine medications administered to each patient was converted into mean equivalent doses; micrograms per kilogram per hour of recording for morphine (Ballantyne et al., 2009) and micrograms per kilogram per hour of recording for midazolam (Ashton, 1994) using accepted conversion factors (Appendix R) and the dose of propofol milligrams per kilogram per hour of recording was also recorded for each patient. (The body weight on admission to ICU was used.) Likewise the number of patients administered corticosteroids, beta-blockers and adrenergics in each phase was recorded.

The number of completed PSQI, DASS-21, PCL-S and ICEQ instruments was considered to be insufficient for inferential statistical testing (that is to compare outcomes

between phases) however descriptive statistics were used to describe the data and content analysis was used to summarise the open ended questions. A further aim was to evaluate the introduction of sleep promoting activities that is, the rest and sleep guideline, suggested by ICU health care personnel. However the interrater reliability of the sleep data analysis using the R and K method was later found to be less than would be expected in a sleep investigation unit so comparisons of sleep parameters between the groups were not performed. Concordance (intrarater and interrater reliability) was checked for the analysis of PSG sleep data by the sleep technologists using Cohen's Kappa statistic. Kappa coefficients were calculated for several groupings of sleep stages (for example stages 2, 3/4 and REM and awake) and each stage according to Ambrogio et al. (2008).

Sound levels were compared between the two groups using Student's t tests (two-sided, α level of 5%). Illuminance levels were compared by examining the intensity of illuminance during the day and night. The data for each time of the day were then compared using the Mann-Whitney U test.

3.16 **Ethical considerations**

Ethics approval was provided by the Northern Sydney Central Coast Area Health Service Human Research Ethics Committee (HREC) (Harbour) with ratification by the HREC of University of Technology, Sydney (Appendix S).

Sleep monitoring with a PSG is not routinely performed in the ICU but was carried out in this investigation. Minimal discomfort was experienced with the placement of extra electrodes on the patients' face and head and no skin irritation was detected. However patients' were frequently informed that they could decline to participate at any time without explanation. Patients who were unable to speak were asked this question whenever they were repositioned by the nurse and therefore awake: 'Are you prepared to continue to have your sleep monitored using the equipment I attached to you earlier?' The question was posed in order to elicit a 'yes' or 'no' response and patients were instructed to provide their response by nodding or shaking their head or blinking

(whichever communication strategy they had adopted at that time). One patient revoked consent prior to electrode placement in the preintervention phase and three patients (one revoked consent) requested removal of electrodes six hours after enrolment in the postintervention phase. One patient said she was disturbed by a patient in a bed nearby (the patient was intellectually disabled and could not be persuaded to stop shouting) and could not tolerate the extra monitoring. She later revoked consent and died seven days later in the study ICU. The other patients stated that the PSG electrodes were uncomfortable (both said that they were content to continue to be enrolled so chose not to revoke consent). Also in the postintervention phase, a patient's condition deteriorated to the degree that palliation was considered. In this case I elected to cease monitoring and removed the PSG equipment nine hours after enrolment. This patient survived to be discharged from ICU and later died in another hospital. He was keen to continue in the study at the time he was a patient in the study ICU and Hospital.

It was anticipated that the quality of patients' sleep would be poor and this proved to be the case, however the researchers did not intervene in individual cases when evidence from the PSG indicated that a patient was not sleeping well. The researchers' presence was as unobtrusive as possible to reduce the possibility of bias. The aim of this investigation was to intervene and initiate long term global improvements in care in the postintervention phase.

The researchers did not witness unsafe or unethical practice; however procedures to intervene were established a priori for this eventuality. In addition existing protocols to support any patient who became distressed during follow up telephone data collection would have been employed. Follow up interviews were conducted in a quiet private office away from other patients and members of the public.

Patients who reported very high scores on any of the instruments measuring psychological distress were asked permission to refer them to the ICU Social Worker (preintervention phase, n = 2 and n = 1 postintervention phase). The ICU Social Worker followed up patients who gave their permission. The researchers telephoned patients who

had moderate scores on the psychological instruments and advised them to talk to their own General Practitioner regarding referral to a psychologist (preintervention phase, n = 2 and n = 2 postintervention phase).

Confidentiality was maintained for all data. The data collection sheets were coded and stored in a locked filing cabinet in a locked office only accessible to the researchers. Polysomnographic sleep data files were coded and no identifiable patient details were attached. The study databases were password protected. The study was registered with the Australian New Zealand clinical trial registry (ANZCTR) on 20th August 2010. The ANZCTR trial number is ACTRN12610000688088.

3.17 **Funding**

The primary sources of funding for the study were an Australian Postgraduate Award (an Australian federal government postgraduate research student stipend of A$20,000 per year for 3.5 years), the Intensive Care Foundation grant ($A15,000), the Australian College of Critical Care Nurses ($A15,000) and the Royal North Shore Hospital Nursing Research Scholarship (a stipend of A$10,000 per year for 3 years). Additional funds were provided by Northcare (a locally based philanthropic organisation supporting ICU nurses' postgraduate education and research) and the Pink Ladies Committee (volunteer Hospital fund raisers). The existing research infrastructure of the ICU and UTS professorial critical care nursing office was used for assistance during data collection and development and implementation of the Guideline. The sound pressure level meter was loaned free of charge for the duration of the study from the Faculty of Engineering, University of Technology Sydney.

4 The rest and sleep guideline

4.1 Introduction

Clinical practice guidelines are frequently used in acute health care settings, such as ICU to assist decision making and facilitate evidence based practice. Arguably, clinical practice guidelines are particularly useful when the condition or area of health care requires a number of interventions (or a complex intervention) in order to be effective, for example providing comfort or improving sleep for ICU patients.

The theory of Everett Rogers, the diffusion of innovations, has strongly influenced strategies to implement evidence based health care, in particular clinical practice guidelines (Greenhalgh et al., 2004) and quality improvement (Titler et al., 2001). High level evidence for the adoption of clinical practice guidelines is lacking, however two extensive systematic reviews revealed that the use of local consensus to inform guideline content together with multifaceted methods of encouraging adoption is a commonly used clinical practice guideline implementation strategy (Grimshaw et al., 2004, Greenhalgh et al., 2004). This comprehensive approach embraces many of the principles underpinning diffusion of innovation theory, namely awareness raising, reinvention and dissemination through social influence.

This chapter describes the development and implementation a clinical practice guideline, 'rest and sleep for the intensive care patient', designed to improve the sleep of patients in the ICU in the current study. Firstly, clinical practice guidelines and their adoption are explained. Secondly, the methods used to consult and engage health care personnel during guideline development are described. Information about the creative process is then presented. The chapter also contains information about strategies used to encourage adoption and attempts made to sustain changes in practice. The results section contains audit (process of care) data regarding guideline adoption. The chapter concludes with a discussion about the audit findings and insights into the development and implementation process.

4.2 Background

4.2.1 Clinical practice guidelines

Clinical practice guidelines are 'systematically developed statements to assist practitioner decisions about appropriate health care for specific clinical circumstances' (Davis and Taylor-Vaisey, 1997) . They assist clinicians' decision making and provide a convenient method by which to facilitate evidence based practice. They are principle based and distinctive from policies and protocols which are not designed to be adapted or reinvented. Clinical practice guidelines are particularly useful when a complex intervention is required to care for or treat patients more effectively (Craig et al., 2008a). For example to provide comfort for the ICU patient, assessment and treatment strategies must focus on several areas including pain management, anxiolysis and sedation. Likewise many areas require attention such as noise reduction, comfort and pharmacology to improve sleep for ICU patients.

The development of clinical practice guidelines

Ideally clinical practice guidelines are systematically developed statements based on high level research evidence, for example randomised controlled trials (RCT). However the lack of research (and RCTs) conducted for many conditions and evidence for the treatment and care of patients leads to difficulties adhering to this ideal (Forbes and Griffiths, 2002, Titler et al., 2001). This together with indications that clinical practice guideline acceptance and adoption are increased by content that is specific to the local context leads to the conclusion that a more pragmatic approach may be appropriate.

The adoption of clinical practice guidelines

Evidence is lacking for effective implementation and adoption strategies for clinical practice guidelines, with few studies reporting process of care data together with patient and cost outcomes (Grimshaw et al., 2004). However, it is likely that multifaceted inclusive approaches incorporating educational input and reminders have a moderate effect on clinical practice guideline adoption (Greenhalgh et al., 2004, Grimshaw et al., 2001,

Grimshaw et al., 2004, Simpson and Doig, 2007). In addition, audit and feedback have been shown to improve adoption in some studies (Grimshaw et al., 2004, Hysong et al., 2006). The adoption of clinical practice guidelines and evidence based practice have been heavily informed by diffusion of innovation theory (Greenhalgh et al., 2004).

The diffusion of innovations is a theory originating from research conducted into the uptake of new agricultural methods (Rogers, 2004). Rogers described diffusion as communication of an innovation between individuals in a social group. The innovation may not actually be 'new'; the important point is that the individual / group perceive it as novel. The six attributes of adopter friendliness of an innovation described by Rogers are: perceived relative advantage, compatibility with existing norms, observability, trialability, degree of complexity and ability to be reinvented, and can be applied to clinical practice guidelines. For example, evidence that a guideline contributes to better patient outcomes is likely to be persuasive for clinicians. Practices that hold little perceived advantage may not be pursued any further by the clinician (Dirksen et al., 1996). In addition guidelines designed to increase cost effectiveness may be less attractive to clinicians who are motivated to provide 'best' patient care. Accordingly audit and feedback of patient related data may counteract incompatibility issues (Foy et al., 2002). Arguably, observability is the adopter attribute most lacking in many clinical practice guidelines so that feed back of process of care and outcome data is vital. An example is the use of early feeding guidelines for ICU patients whose observable effects are reduced mortality at hospital discharge, an outcome not immediately obvious to the bedside clinician. The ease in which potential adopters can experiment with the guideline before taking it up more permanently (trialability) is linked to the perceived difficulty using the clinical practice guideline. Principle based plain language clinical practice guidelines are recommended (Grilli and Lomas, 1994, Lia-Hoagberg et al., 1999). The ability to add context specific content to a principle based clinical practice guideline or a clinical practice guideline developed by a professional organisation (ability to be reinvented) enables clinicians to adapt the interventions to the situation (Gagliardi et al., 2011).

Rogers also used categories to describe an individual's propensity to adopt: innovators, early adopters, early majority, late majority and laggards. Controversy exists about the accuracy of these categories with some diffusion of innovation researchers suggesting that the propensity to adopt is not stable, but rather is dependent on the characteristics of the innovation and the needs of the potential adopter (Greenhalgh et al., 2004, Wejnert, 2002). Despite this the categories do provide a schema of potential adopter characteristics for change agents to consider when planning an implementation campaign. For example, early adopters are often cited as potential opinion leaders who can influence adopters (Rogers, 2003). Unlike innovators who may be viewed by other members of the group as 'too keen' to take on new ideas, early adopters are considered experts capable of impartial decision making. Their engagement at the inception of the process is regarded as fundamental to the progress of adoption (Rogers, 2003).

The potential adopter's decision to adopt is described in terms of a five step process which is similar to the innovation process within an organisation: 1) agenda-setting (awareness of the need for change), 2) matching (potential solution to a problem is identified), 3) restructuring (the innovation is modified and reinvented and the organisation is adapted to accommodate the innovation), 4) clarifying (unwanted effects of the innovation are resolved) and 5) routinising (the innovation is incorporated in everyday work) (Rogers, 2003).

The rate of adoption (number of members of the social group adopting over time) is a Sigmoid curve. Typically adoption increases slowly until adoption rates are around 20 to 30% when adoption accelerates (described as 'take off') and tails off when very few individuals who have not adopted the innovation remain (called 'saturation') (Rogers, 2003). In terms of adopter groups, innovators and early adopters are the first to take up the innovation, followed by the other adopter groups. The laggards are the last to adopt (or may never adopt). Again some researchers have challenged early observations of Rogers about adoption rates, arguing that it is an overly simplistic view of the process which does not account for rapidly changing social group membership (so that adoption

rates fluctuate and routinisation is prolonged or may never occur) (Greenhalgh et al., 2004). Notwithstanding these valid concerns the Sigmoid curve is still a useful guide for clinical practice guideline implementation. In particular extensive dissemination of information to the entire health care team early encourages uptake by most of the influential members increasing the likelihood of 'take off'. This may counteract the slowing effect of clinician turnover.

4.3 Methods

This section outlines the development of the 'rest and sleep for the intensive care patient' guideline and the strategies used to implement and sustain the Guideline. An outline of the stages in the process is provided in Table 6.

Table 6. Stages in the development and implementation of the Guideline

Stage	*Activities*
Development	Examination of the evidence: search of international literature and analysis of preintervention data
	Consultation and discussions with health care personnel
	Iterative process including checking and rechecking
Implementation	Multifaceted approaches including academic detailing, presentations, reminders and sleep champion role models
Sustaining adoption	Continued use of multifaceted approaches (as above) together with audit and feed back.

4.3.1 Guideline development

In the current study a pragmatic approach to guideline development was undertaken in which all types of evidence were examined. Firstly, an integrative literature review was performed in which observational and interventional research about sleep in

ICU patients was examined and the results summarised (Elliott et al., 2011) (Appendix A). Secondly, data collected during the preintervention phase were examined. The data suggested that there were many opportunities to improve the environment and the way in which clinical care and treatment were delivered. Thirdly, ICU health care personnel were consulted about the data and their suggestions recorded. Finally evidence from all of these sources was integrated to create a multifaceted clinical practice guideline ('rest and sleep for the intensive care patient' Appendix T).

A clinical practice guideline was selected because there were interrelated facets of the environment, delivery of care and treatment which required improvement. The areas for improvement were arguably better combined in a clinical practice guideline than delivered individually. In addition, evidence from recent quality improvement initiatives ('care bundles') in ICU indicates that the sum of several actions can be highly effective in improving patient outcomes (Jain et al., 2006, Levy et al., 2010). In the study ICU, clinical practice guidelines were an accepted part of clinical practice therefore the selection of a clinical practice guideline was anticipated to encourage behavioural and organisational change beyond the time in which the study was conducted.

Examination of the evidence

Review of the international literature

An accepted checklist for performing literature reviews (MOOSE) was used (Stroup et al., 2000). However recommendations for combining study data in the MOOSE guidelines were not applicable as sleep research in ICU patients comprises small heterogeneous observational studies. Clear objectives were set out a priori. An inclusive selection process was used in order that important evidence for improving sleep in ICU patients was not excluded. The search procedure is described in detail in the review paper which is located in Appendix A.

Original observational and interventional investigations of sleep in adult ICU patients containing sleep data derived from PSG or patient self-reports while the patient

was treated in ICU, were selected. All studies reporting sleep outcomes, using PSG and patient self-reports, in ICU patients were examined. Studies with broader aims of examining the 'patient experience' of ICU were not considered as they were found to contain information which was not specific enough for guideline development.

The published reports were organised into groups: '24-hour PSG recording', 'overnight PSG recording' and 'methods other than PSG'. The data were summarised and presented in tables (see published journal paper: Appendix A). All evidence related to improving sleep for ICU patients was noted. Interventions with relatively little or low evidence were considered for inclusion in the Guideline if they had a reasonable physiological explanation, for example nocturnal mandatory ventilator respiratory rate settings.

Examination of the preintervention phase data

Conventional sleep staging analysis was performed on the sleep studies up to and including patient 22. (The interrater reliability of this staging was later found to be low however we were confident that overall patients sleep was highly fragmented and poor). The preintervention phase data were cleaned and univariate analyses were performed. The main findings were: short TST, significant sleep fragmentation and little or no slow wave or REM sleep, intrusive sound levels, poor quality sleep reported by ICU patients and illuminance levels that were appropriate at night. In addition patients' comments about their sleep in ICU and the factors that disrupted sleep were noted. The main finding here pertained to discomfort and intrusive noise levels.

Consultation with health care personnel

Consultation with health care personnel was used to build consensus about the Guideline and to contextualise recommendations from international research on sleep in ICU. In terms of diffusion of innovation theory, consultation comprised step one and two of the innovation process: agenda setting and matching. Sleep, sound and illuminance level and event data were fed back to the ICU health care personnel working in all areas of the ICU during May to July 2010.

The process used to begin guideline development in the current study was based on a solution focused technique of group engagement described by Walsh et al. (2005). It was selected not only to engage ICU health care personnel in discussions about the preintervention data but to also achieve consensus during the early phase of guideline development. The approach has been used in action research or practice development in health care settings (Moss and Walsh, 2009, Walsh et al., 2008). It assists facilitators to direct groups to select strategies to develop and implement changes for quality improvement and treatment. The key to the approach described by Walsh et al. (2005) is the choice of language; the word 'puzzle' is used rather than 'problem'. Thus a problem orientated approach is discouraged; puzzles require workable solutions and the causes of problems become less crucial. There are seven sequential steps in the process: naming the issue, identifying the puzzle, identifying stakeholders and considering the context, identifying the purpose, presenting the evidence, and visualising the future and generating new strategies for action (Walsh et al., 2005).

A presentation was developed to facilitate discussions about the preintervention data with ICU health care personnel. The presentation was a series of Power Point slides in which the preintervention summarised sleep, illuminance, sound and event data were displayed. The presentation was designed to enable ICU health care personnel to appreciate the main findings within 15 minutes, allowing time for discussion (Appendix U). The presentation was delivered to groups of health care personnel (predominately nurses) at the usual daily education time in the ICU conference room or in ICU to individuals or groups of two or three using laminated slides. At the conclusion of the presentation ICU health care personnel were requested to solve several 'puzzles'. The wording on the slide was deliberately solution focused on the main priorities, that is

'The puzzles that need solving

- Intrusive sound levels
- Significant sleep fragmentation

- Reduced slow wave/deep and REM sleep
- Poor quality sleep reported by patients'

In addition, solution focused questions were posed:

- 'How best can we give ICU patients the opportunity to rest and experience restorative sleep while in ICU?'
- 'How can we do more of what is done well now?'

The health care personnel appeared concerned about the poor quality of ICU patients' sleep and the need to reduce noise. Considerable discussion was generated and more than 320 suggestions to improve rest and sleep were provided. Suggestions were welcomed from all health care personnel regardless of role (clinical or nonclinical) or level of seniority. Seven group discussions and more than 60 academic detailing sessions were conducted, resulting in consultations with over 130 ICU health care personnel.

During discussions about the data, three nurses volunteered to be sleep champions. Each nurse worked in a different area of the ICU (neurosurgery, cardiothoracic and general). They were informal leaders within their social groups. During this phase an ICU Staff Specialist (identified by me as an opinion leader and innovator) was approached to assist by encouraging medical doctors to review the data and later to adopt the interventions.

During consultations about the preintervention data ICU health care personnel suggested that the need to improve patients' sleep should be an item regularly discussed at the ICU Quality Forum. The ICU Quality Forum is an open meeting in which ICU clinicians (regardless of role) may raise any global aspect of ICU patients' care and treatment which requires improvement in the study ICU. Areas of improvement are acted on using the well known quality cycle, 'plan, act, do'. Intensive care clinicians work on solutions and feed back audit data and progress at the Forum.

The creative process

All suggestions to improve rest and promote sleep during discussions were documented. The first iteration of the rest and sleep guideline involved a process akin to content analysis in which the most frequently cited interventions were included together with information from the integrative review. Comments made by patients after discharge from ICU on the ward and at home were also considered. The most frequent comments related to intrusive noise levels and an inability to sleep while in ICU.

Subsequent iterations comprised small adjustments after consultation with health care personnel who had most expertise or responsibility for a particular area of the Guideline. For example, removing bins to the corridor in order to change the clinical waste bin liners (considerable noise is associated with changing clinical waste bags) required further consultation with the environmental cleaning team to check feasibility. In this instance I joined the environmental cleaning team on a 'rubbish bin round' to trial this change in practice. The ICU pharmacist was requested to check the medication section of the Guideline. The ICU social workers, chaplain, ICU nurses, medical doctors, dieticians and physiotherapists were consulted regarding other aspects of the Guideline. The sleep champions were also requested to verify the content of the Guideline and ensure it was true to discussions with health care personnel. Small adjustments in the order of content in the Guideline were made as a consequence.

The final version of the Guideline comprised two main themes: 'Optimise the environment' and 'Rest and sleep interventions'. There were a number of sections within these themes. 'Optimise the environment' comprised 'Report faulty equipment and fittings', 'Quiet shoe rule', 'Environmental cleaning during daylight hours only', 'Quiet conversation' and 'Lighting is appropriate for the time of day'. The sections, 'Manage pain well', 'Optimise normal circadian rhythm', 'Rest period during daytime hours' and 'Provide optimal conditions for night-time sleep' (including the provision of ear plugs and eye shades) comprised the 'Rest and sleep interventions' theme. However recognising that non-pharmacological practices are not always effective against the myriad of potential

sleep disruptions critically ill patients must endure, an additional section was added which contained information for ICU clinicians about medications. Non-pharmacological practices were emphasised throughout the Guideline. The clinical practice guideline was developed over a two month period (July and August 2010). When the Guideline was complete and it had been endorsed by the nursing and medical directors of the study ICU, it was disseminated amongst the ICU health care personnel.

A supplier of ear plugs and eye shades was located. I personally trialled a number of ear plugs to select the most suitable for ease of use and comfort. Details of the products were given to health care personnel responsible for ordering stores in each area of the study ICU.

4.3.2 Guideline implementation

Strategies used to encourage adoption

Multifaceted strategies previously shown to be successful for the adoption of guidelines in the study ICU (Elliott et al., 2006a) and based on diffusion of innovation theory were used to introduce the Guideline. Arguably, implementation began when data from the preintervention phase were fed back to health care personnel (as described earlier). The full guideline was introduced over a two month period (September and October 2010).

Methods designed to reach as many health care personnel as possible as quickly as possible were used to raise awareness. These included: academic detailing, discussions at ICU meetings, the Guideline was located in a place accessible to all ICU health care personnel (the study ICU intranet), reminders were provided in the study ICU newsletter, the launch was announced on the social networking website Facebook© (FB), and signage was displayed. Before the daily rest period began signs were placed in the ICU visitors' waiting room outlining the proposed time (1330 to 1500 hours) and rationale for the rest period.

The aim was to reach 80% of bedside clinicians in one month in order to thoroughly inform the social group (ensure 'early adopter' exposure and early acceleration in adoption rates). To this end I contacted a total of 130 ICU health care personnel (approximately 40% of the ICU workforce) in face to face group sessions or through academic detailing. The sleep champions reached an additional 30% of the workforce using academic detailing. Many more health care personnel were made aware of aspects of the Guideline through more passive methods such as the ICU newsletter, signage and FB announcements.

4.3.3 Strategies to sustain adoption and routinise the Guideline

Many of the strategies used to disseminate the Guideline continued throughout the postintervention data collection phase. In particular academic detailing continued for temporary and new ICU health care personnel. Strategies were employed to continue raising awareness and to increase guideline use, including: reminders, the use of a visual sound level meter, feed back of audit data, 'Sleep rounds' (specific academic detailing following audits), academic detailing during patient simulation education sessions, identity badge reminders, announcements on FB and via email and the use of volunteer sleep champions.

Daily reminders (verbal) were provided for several weeks during the introduction of the daily rest period and at intervals thereafter. Signage about the rest period was placed in prominent places on the doors to each of the ICU areas. The ICU Chaplain and Social Workers continued to monitor visitors' attitudes to the rest period and any access difficulties (an open visiting policy persisted throughout).

Reminders about many aspects of the Guideline and awareness raising 'advertising' were displayed on signs placed on the wall in areas of the study ICU regularly frequented by clinical ICU health care personnel. The signs were colourful and succinct. The topic was often light-hearted. Examples of the signs are provided in Appendix V. Signage was changed weekly to maintain interest.

A visual sound level meter, the SoundEAR 2000® (Appendix W) was incorporated in the campaign to reduce noise levels. The SoundEAR 2000® is an adjustable visual sound level meter, in which a warning light provides a cue when sound exceeds the set level. Sound levels from 40 to 115 dB(A) can be selected in increments of five dB(A). An ear shaped light illuminates yellow if the sound level approaches the setting and a red light "warning" flashes when the sound level is exceeded. It was attached to a mobile stand. Each week it was placed in a different area of the study ICU. The sound level was adjusted to reflect the fluctuations in activity level of the 24-hour period. During the day (approximately 0700 to 1900 hours) the sound level was set at 70 dB(A) and at the lower level of 60 at night (approximately 1900 to 0700 hours). A sign was placed on the SoundEAR 2000® displaying the current setting. ICU health care personnel were encouraged to use the device to politely inform colleagues if their voices were loud.

Audits were conducted twice a month during the postintervention phase to monitor Guideline use. The audit data were fed back to clinicians at the ICU Quality Forum, on reminders and after presentations during the nurses' education time.

Approximately every two weeks 'Sleep rounds' were conducted. The round often followed an audit so that advice and discussions were relevant to the ICU health care personnel and the patients treated in ICU on that day. Patients were asked about the quantity and quality of their sleep at home if they were able to communicate. Otherwise the bedside nurse was requested to ask the patient's proxy or person closest when convenient. The information about usual sleeping patterns was written in the patient's records. If a sleep disorder was suspected the possibility of a referral to the sleep medicine team was discussed with the ICU Staff specialist. The patient was asked about their sleep in ICU. The bedside nurses and the health care records were consulted if patients were unable to communicate. If the patient experienced poor sleep they were asked about the potential cause. Eye shades and ear plugs were offered if they had not already been suggested (when appropriate). Other reasons for poor sleep were also explored such as nocturnal ventilator settings. If the patient was receiving pressure

support ventilation, the logbook on the ventilator was checked for apnoea alarms. If there were several apnoea alarms per hour, the bedside nurse was encouraged to discuss with the ICU Staff specialist the possibility of setting a mandatory mode or respiratory rate at night. Patients who were able to communicate were encouraged to express their concerns and, in cases when they could not be reassured, the ICU Chaplain or Social worker was consulted.

'Sleep' presentations were conducted regularly during the daily education time which is accessible to all ICU health personnel (Appendix X contains two examples of the presentations provided). The presentations included a number of sleep related topics such as 'Sleep and shift work' and 'Sleep architecture'. At the conclusion of each presentation, an outline of the Guideline was provided and its location highlighted.

Patient simulation (ICU Simulation in Training At the Royal North Shore (ICU STAR)) is one of the many educational strategies used in the study ICU. It was used to increase awareness and use of the rest and sleep guideline in the current study. ICU STAR comprises a realistic patient scenario in which a resuscitation training manikin is prepared to be reviewed on the ward round in a dedicated area of the ICU. The aim of this education strategy is to address everyday aspects of care and treatment rather than team performance during emergencies. A scenario is developed in which the multidisciplinary clinical team is involved in assessing, diagnosing and managing the patient. New clinical practice guidelines are promoted and practice areas which require improvement addressed. Consideration of the patient's sleep requirements and interventions to increase the opportunity to improve rest and sleep were discussed. A different component of the rest and sleep guideline was presented during the debriefing for each ICU STAR which took place once a month during the postintervention phase.

Facebook was again used for occasional announcements. Regular broadcasts via FB were avoided to reduce the likelihood of over saturating users with guideline information and reducing the effectiveness of this communication method. Examples of announcements made on FB were the requisition of a new type of eye shade, the arrival

of the EAR and positive audit results. Emails were also sent to ICU nurses containing these announcements.

A summary of the Guideline was placed on small cards which attached to the identity badges worn by health care personnel. The reminder cards were designed to offer a quick reference reducing the need to access the ICU intranet website. In addition the principal researcher wrote a letter to all the nurses working in ICU at three and six months into the postintervention phase. The letter contained information about the study design, protocol and progress to date. In this way nurses who started work in the ICU in the postintervention phase were informed about the background to the study. In addition the letter was accessible for nurses who did not use electronic communication media and who worked infrequently, for example at weekends.

The sleep champions continued to reach ICU health care personnel who worked temporarily or infrequently in the ICU. For example, the champions assisted in informing environmental cleaners working at weekends and during the night about the regimen for waste bin liner changes. They also participated in audits from month three of the postintervention phase and distributed Guideline cards for attachment to identity badges. They were guideline experts and encouraged colleagues by demonstrating best practice in this area. The medical opinion leader was influential during simulation teaching (ICU STAR) when the importance of sleep and aspects of the Guideline were discussed.

Measurement of adoption

The implementation of complex interventions requires the collection of process of care and outcome data (Craig et al., 2008b). In the current study the goals were also to provide a measurement of adoption (verify guideline use) and target areas of the Guideline that required more emphasis. A summative index was developed and used during process of care audits.

The method of measuring adoption was adapted from the summative index for pain management described by Titler et al. (2009). The summative index for pain management provided a quantitative evaluation of the quality of this aspect of care in older patients

(Titler et al., 2009). The aim in the current study was to develop a reliable method of assessing the extent to which the Guideline was in use. The rest and sleep summative index comprised four practices within the Guideline that were measurable across all areas of the study ICU and thought to be fundamental to the principles of the Guideline:

1. Provide optimal conditions for night-time sleep
2. Optimise circadian rhythm
3. Manage pain well
4. Provide a daytime rest period

The extent and use of each practice was assessed using predetermined criteria. The level of care at which they were delivered was determined as 'minimal' (score = 1), 'good' (score = 2) or 'excellent' (score = 3). To be assigned a score of 2 the patient had to have received all aspects of that practice at the 'minimal' level as well as the 'good' level. If a patient received care which did not meet the specified minimum standard a score of zero was assigned.

Auditing began three months after the introduction of the Guideline and continued every two weeks until the completion of 24-hour sleep data collection in the postintervention phase. A random day between Monday and Friday was chosen on which to perform the audit (when sleep monitoring was not taking place). Intensive care personnel were unaware that the audit was to be conducted. Each audit was an assessment of the use of the Guideline over a 24-hour period for all patients currently treated in each area of the ICU and who had been admitted before 1900 hours in the evening prior to audit day. The sleep champions in each area of the ICU noted the time at which the main lights were switched off at night and turned on again in the morning and when window blinds were shut and opened again. I noted which areas adhered to the daytime rest period that is closing the blinds, switching off the lights and reducing noise. Patient documentation was used to assess evidence of 'clustering' interventions and care. Data were collected in paper form and entered into an Excel™ spreadsheet. Audit data

informed the selection of the content of weekly reminders and emphasis of discussions during ‘sleep rounds’.

Analysis and presentation of audit (process of care) data

Data were aggregated and descriptive analysis performed in Excel™. The summative indices for all patients and an overall mean value for the entire ICU were calculated. Indices were also produced for each of the practices in the Guideline that were audited. As it happened, summative indices were not used to present to ICU health care personnel because the sleep champions recommended that a more accessible method be used to communicate audit data. Results were summarised and interpreted before the trends were placed on signs, in the newsletter and presented at the ICU Quality Forum. The content was designed to be concise and factual; punitive statements were avoided.

4.4 Results: process of care audit data

Ten audits were conducted during data collection in the postintervention phase. Audits were conducted twice a month in November and December, 2010 and January, March and April, 2011. The use of the Guideline was assessed in 264 patients in these audits. Six patients had their care audited more than once and one patient’s care was assessed in all ten audits. The summative index ranged from 3.4 to 6.6. The average summative index for all ten audits was 5.2. Average score for each practice in the Guideline ‘Provide optimal conditions for night-time sleep’, ‘Optimise circadian rhythm’, ‘Manage pain well’, and ‘Provide a daytime rest period’, together with the summative index for each audit are graphically presented in Figure 11. The practice that consistently scored highest was ‘Optimise circadian rhythm’ and the lowest was ‘Provide a daytime rest period’. Seventeen patients received care that rated ‘good’ or better in each practice. Patients with scores above eight were long term ICU patients with ICU length of stay greater than one month. Often these patients had a dedicated team of nurses caring for them to enhance continuity of care. An individualised care plan containing information about daily routines and patient preferences was in use, including sleep hygiene.

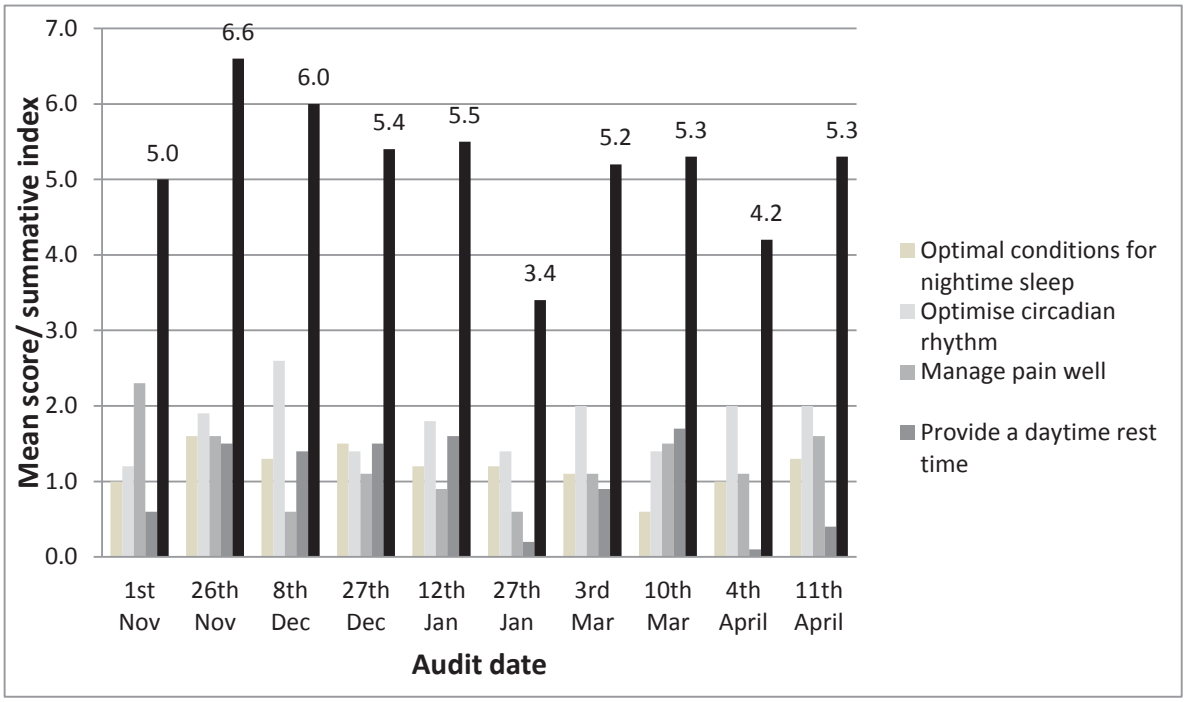


Figure 11. Mean process of care audit scores for each practice in the Guideline and the summative index for each audit

4.5 Discussion

4.5.1 Summary of the audit findings

In the ten audits of clinical practice guideline adoption that were performed during data collection in the postintervention phase (six months) there was evidence of uptake of some of the practices, in particular 'Optimise circadian rhythm'. The average summative indices did not increase during the time in which audits were conducted.

4.5.2 Insights into the development and implementation process

Extensive multifaceted approaches to implementation and continuous and sustained efforts to maximise guideline uptake were used. However there appeared to be little evidence of progression past steps one and two of the innovation process, agenda setting and matching. Evidence of a lack of any appreciable improvement in patient sleep and intrusive sound levels (Chapter five) may provide confirmation that this was the case but there may also be other factors contributing to the lack of measurable improvement.

The apparent low adoption rates could be related to the prolonged time over which the data were collected and fed back to clinicians (16 months from the first patient) and the comparatively short time over which the Guideline was introduced (two months), plus the need for a larger more diverse group of sleep champions. Other potential contributory factors are the timeliness of audit (process of care) and outcome (sleep) data feed back during the postintervention phase, the workload in the study ICU and prevailing workplace culture.

Anecdotally there was widespread interest amongst health care personnel during the preintervention phase. This phase took 12 months for a range of reasons, including the presence of many patients with H1N1 influenza which decreased recruitment rates. There was also difficulty engaging sleep technologists to analyse all sleep recordings. A decision was made to feed back analysed PSG data for the first 22 patients five months after the completion of data collection in the preintervention phase. Interest amongst health care personnel may have diminished in the time lag and the impact of the feed back was less potent than it might have been if it had been delivered sooner after data collection. There was willingness amongst health care personnel to comment on the data and suggest sleep promoting activities but the delay may have contributed to low adoption rates.

The time during which the Guideline was developed and implemented before sleep data collection began again was relatively short (five months). Published data about the time required in which to implement clinical practice guidelines are not available. However given that it has been suggested that evidence takes more than a decade to be translated into practice, the time frame for guideline implementation in the current study may have been overly short. It is likely that the adoption rate had not reached the critical threshold (‘take off’) of 20 to 30% of health care personnel before the conclusion of the study. Alternatively, adoption may not have followed the classic Sigmoid curve in this case. The Sigmoid curve occurs if the turnover of potential adopters is not too high and

adopters' perceived value of the innovation remains constant (Greenhalgh et al., 2004). In the absence of additional data either explanation is possible.

The selection process, social standing and number of sleep champions may also have been a factor in the observed guideline adoption rates. There was no external peer review or selection process for the identification of the sleep champions. It is possible they were not considered to be opinion leaders by their peers. Regardless of this they were passionate and role modelled the Guideline in their practice. More importantly more sleep champions (three nurses and one medical doctor were insufficient for the complexity of the Guideline and size of the ICU, in which over 200 nurses, approximately 25 medical doctors and in excess of 40 other health care personnel regularly work) would have been beneficial.

Feed back of process of care and outcome data during the postintervention phase was limited by the time and resources available. The competing priorities of patient recruitment and follow up and data management meant that sleep and sound level (outcome) data were not available until late in the postintervention phase. It was also challenging to reach a critical mass of health care personnel in a timely manner with process of care data. Timeliness of patient data feed back is a factor highlighted by some implementation investigators (Axt-Adam et al., 1993, Hysong et al., 2006, Mugford et al., 1991) however a recent Cochrane review was equivocal about the matter (Jamtvedt et al., 2010).

In an investigation about strategies, barriers and facilitators of guideline implementation in health care facilities four effective characteristics of audit data were highlighted: timeliness, non punitiveness, 'individualisability' and customisability (Hysong et al., 2006). The investigators postulate that the underlying consideration is whether the feed back is actionable. More specifically, aggregated (non-individualised) audit data which is fed back in a punitive manner more than one month after collection is less likely to be acted upon. Despite the limitation of the use of self-report in the Hysong et al. (2006) study the supposition is plausible. In addition their conclusions have relevance for

the current study in which the observability of the effect of the Guideline and 'perceived advantage' were not immediate so that actionable feed back was important.

The work load in the study ICU may have also have had an impact on guideline uptake. In the postintervention phase the number of patients admitted to the study ICU was higher than in any other period since the ICU opened. For example, there were almost twice as many patients admitted to ICU from September to December 2010 compared to the same period in 2009. This inevitably impacted on the ability and willingness of health care personnel to engage in change. Practically speaking, it was also difficult for clinicians to minimise noise when there were constant patient transfers in and out of the ICU. Anecdotally, some futility was noted in the attitudes of some health care personnel towards positively impacting on the quality of patients' sleep while there were such high activity levels. A number of clinicians remarked on the constant pressure of 'patient flow' (making space for new patients) and the overwhelming demands on them to work 'faster and harder'.

Another likely explanation for the lower than expected uptake in guideline use was the prevailing workplace culture in the ICU during the time the study was conducted. A workplace survey conducted during 2009 in the Hospital revealed that the prevailing culture was one of blame with an accompanying perception that 'nothing can be changed' (Best Practice Australia, 2009). A breakdown of the organisation wide results reveals that the prevailing culture in the ICU was similar.

4.5.3 Strengths and limitations of the Guideline and implementation strategies

There are a number of strengths of the Guideline and implementation strategies, which warrant consideration. These include the use of all types of evidence to inform the development and implementation of the Guideline and the inclusive method in which the Guideline was developed. Another strength was the collection and use of audit data.

In the absence of high level research evidence to inform the development of the Guideline, an extensive integrative review, results of the preintervention phase, suggestions from health care personnel and feed back from former ICU patients (study

participants) were all considered. A number of iterations occurred after checking with health care personnel including the sleep champions. The process was akin to the verification strategies suggested by qualitative researchers to ensure reliability and validity of data (Morse et al., 2002). This was likely to have ensured that not only were all important aspects of improving sleep for ICU patients included but also that the Guideline was context specific and therefore relevant to the study ICU.

Evidence from diffusion of innovation theory and guideline implementation research was used to increase the potential for guideline adoption. A multifaceted approach incorporating innovative practices such as simulation (ICU STAR) was used. One commonly cited systematic review on the effectiveness of guideline implementation strategies suggested that multifaceted approaches are no more effective than single strategies (Grimshaw et al., 2004) however this review did not include the context in which the Guideline was to be implemented. The approach adopted had previously been shown to be effective in the study ICU and was context specific.

Engagement techniques were used to increase potential adoption and sustainability. A solution focused approach was selected as it was nonpunitive and de-emphasised orientation towards identifying and fixing problems and thus was more likely to enhance health care personnel interest and commitment.

This study utilised process of care audits to gauge adoption and inform the content of guideline reminders. Process of care data were also collected in order to interpret the results of the entire study. It would be difficult to attribute changes in patient outcomes to the Guideline if use of the new practice was not measured.

The Guideline and implementation strategies had several limitations which should be considered. Arguably the Guideline was too complex (a result of being too inclusive during development) and the underpinning evidence base may not have been persuasive enough for some clinicians. Complexity is highlighted in implementation and diffusion of innovation research as a potential barrier to adoption (Denis et al., 2002, Grilli and Lomas,

1994, Rogers, 2003) and high level evidence for a guideline is more likely to lead to adoption (Denis et al., 2002).

The implementation strategy may have been improved by greater numbers of sleep champions, a more refined auditing process and a longer time period for the introduction of the Guideline. In addition, the audit was complex and summative indices were not readily interpretable by busy clinicians. The reliance on chart review for such items as clustering care and the time patients' hygiene needs were met was also a limitation. When documentation was missing or unclear there were difficulties auditing if the patient was unable to communicate verbally. Auditing was also dependent on the champions' ability to surreptitiously record lights 'on' and 'off' times in each area of the ICU at night. Preintervention phase audits to gauge current practices around promoting rest and sleep before the implementation of the Guideline would have provided a baseline and enabled comparisons to be made for the process of care between the study phases.

Finally, the time over which the implementation was conducted may have been too short to impact on such a large group of health care personnel. A longer run in time for initial dissemination followed by several weeks of reminders before measuring adoption and outcome data may have been more appropriate.

4.6 **Conclusion**

The 'rest and sleep for the intensive care patient' guideline used in the current study was developed in consultation with ICU health care personnel, based on data collected within the study ICU, and informed by an integrative literature review and patient feed back. Strategies used to implement the Guideline were based on diffusion of innovation theory and implementation evidence. A multifaceted approach was used to implement and sustain adoption including: academic detailing, discussions at ICU meetings, presentations, reminders, announcements on FB, and process of care audits and feed back. Adoption of the Guideline did not increase (and environmental conditions support this). There are several possible explanations for this including: the complexity of the Guideline, the number of champions, the complexity of audit process and the implementation timeframe.

5 Results: clinical outcomes

5.1 Introduction

This chapter describes the sample and the results of the study. The prevalence of eligible patients and characteristics of patients who declined to participate are also presented. The characteristics of the sample and descriptive statistics for gender, age, diagnosis and severity of illness on admission to the study ICU are provided. Equivalence of the preintervention and postintervention groups for gender, age, diagnosis and severity of illness on admission to the study ICU is presented.

The primary aim of the study was to assess the quantity and quality of sleep experienced by patients in ICU. Accordingly, descriptive statistics are presented for a number of parameters of sleep derived from PSG. The patients' self-report of nocturnal sleep quality and the nurses' estimation of patients' nocturnal TST in ICU is also described. Content analysis was used to explore patients' responses to the open ended questions about sleep disturbance in ICU added to the SICQ (Freedman et al., 1999) in the postintervention phase and the themes which emerged are presented. Patient self-reports of their sleep at home two months after discharge from hospital are also reported as descriptive statistics.

The secondary study aims included the assessment of sound and illuminance levels and the number of treatment and care activities patients experienced during 24-hour sleep recording. Comparisons between the phases for the average and peak sound level were performed. The phases were also compared for the number of peak sound levels. The results of lux level comparisons for the study phases and time of day are presented.

Other factors known to affect sleep quality such as ambient temperature, medications and Systemic Inflammatory Response Syndrome (SIRS) were also explored. Doses of opioid, benzodiazepine and propofol medications are provided and differences between the groups presented. The numbers of patients administered beta-blocker, corticosteroid and adrenergic medications are described.

Another secondary aim was to assess the effectiveness of the sleep promoting activities suggested by ICU health care personnel. Therefore sleep outcomes for the preintervention and postintervention groups are presented. The results of reliability checks of the sleep data analysis are provided. Descriptive statistics are presented for the quality of sleep at home and psychological outcomes two months after discharge from hospital.

5.2 Prevalence of eligible patients

5.2.1 Preintervention phase

There were 1,247 patients admitted to the study ICU in the preintervention phase (January to April, June to July and October to December, 2009). Screening occurred on a total of 70 days in the preintervention phase resulting in the identification of 299 patients who satisfied the inclusion criteria. Of these patients 154 were excluded. A further 115 patients were 'eligible not enrolled' (34 declined and 81 were discharged before they could be enrolled). Thirty patients were enrolled in this phase of the study, all of whom completed 24-hour sleep monitoring. Figure 12 presents the number of patients screened and enrolled for the preintervention phase.

5.2.2 Postintervention phase

During the postintervention phase (September 2010 to April 2011), 1,186 patients were admitted to the study ICU and screening occurred on 78 days. Three hundred and fifty-seven patients satisfied the inclusion criteria of whom 236 were excluded. Of these patients 121 were eligible however 94 were 'eligible not enrolled' (40 declined and 54 were discharged before they could be enrolled). Twenty-seven patients started 24-hour sleep monitoring; two discontinued within 12 hours, one experienced an acute clinical deterioration and the EEG sleep data for another patient were unable to be analysed because of 'alpha wave intrusion'. Details of the numbers of patients screened and enrolled in the postintervention phase are presented in Figure 13.

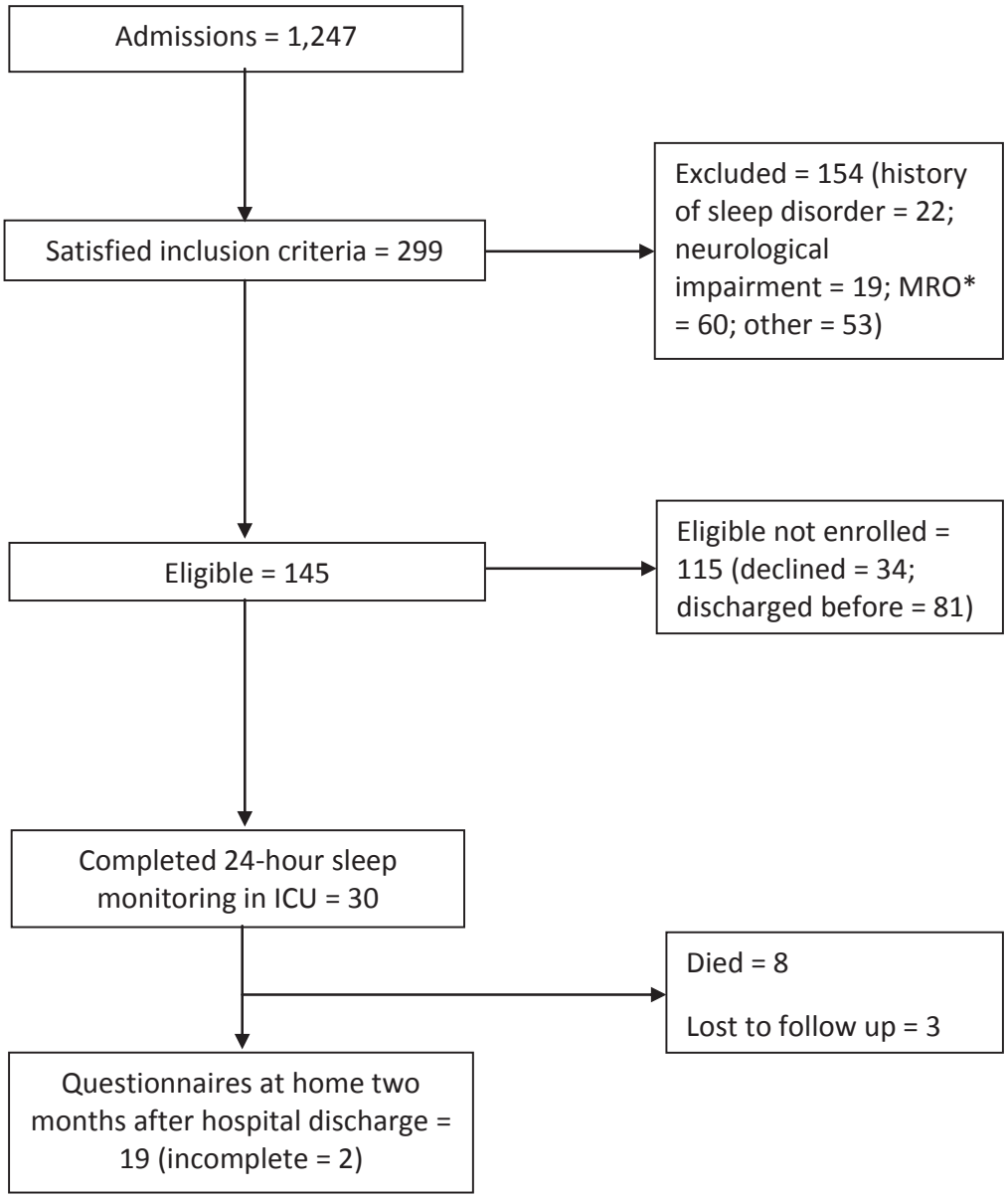


Figure 12. Flow diagram number of patients admitted to the study ICU, screened for the study, declined to participate and enrolled in the preintervention phase

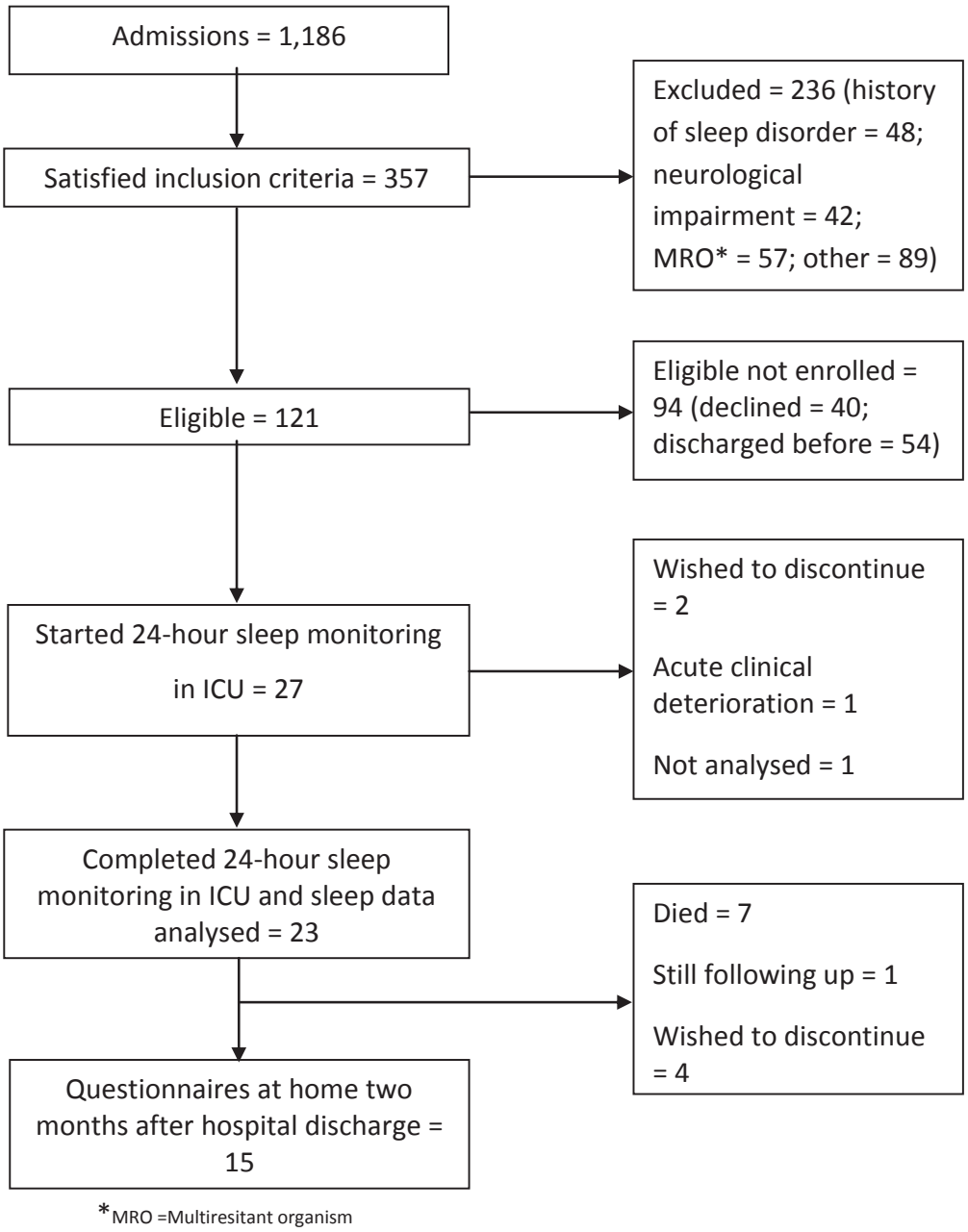


Figure 13. Flow diagram number of patients admitted to the study ICU, screened for the study, declined to participate and enrolled in the postintervention phase

5.3 Characteristics of all patients treated in the study ICU during the study

Data from the patient database in the study ICU (used for routine quality assurance) were obtained to describe the characteristics of all patients treated in ICU during the two phases of the study. Summary statistics are provided in Table 7 for patients treated in ICU before and after the introduction of the Guideline.

Table 7. Characteristics of all patients treated in the ICU during the study

		Pre (n = 1,247)	**Post (n = 1,186)**
Number of females (%)		456 (37)	428 (36)
Number of patients mechanically ventilated (%)		791 (63)	615 (52)
Number of deaths in ICU (%)		81 (6)	94 (8)
APACHE* II score	Mean±SD†	16.53±1.77	14.50±6.50
ICU length of stay, in days	Median‡	2.34	2.28

*APACHE = Acute Physiology and Chronic Health Evaluation, †SD = standard deviation, ‡interquartile range is not provided as the calculation is based on the median length of stay for several time periods for each area of the ICU and not the entire data set

5.4 Characteristics of patients who declined to participate

The characteristics of patients who declined to participate in both the preintervention and postintervention phase are provided in Table 8. More than half of the patients who declined to participate in both phases of the study were female. Their mean age was similar to the patients who agreed to participate. Duration of mechanical ventilation and length of ICU stay was shorter for patients who declined. Severity of illness scores were slightly lower for patients who declined to participate.

Table 8. Characteristics of patients who declined to participate

		Pre (n = 34)*	**Post (n = 40)***
Number of females (%)		21 (66)	20 (54)
Age, in years	Mean±SD†	60.71±19.27	57.62±20.89
	Range	19.00-87.00	18.00-87.00
Diagnosis, number of patients (%)‡			
Operative		15 (52)	8 (22)
Nonoperative		14 (48)	28 (78)
APACHE§ II score	Mean±SD	16.41±8.01	16.00±8.22
	Range	5.00-33.00	0.00-37.00
Duration of mechanical	Median	0.95	1.50
ventilation, in days	IQR	0.00-7.62	1.00-5.25
ICU length of stay, in days	Median	6.00	6.00
	IQR	3.00-27.25	3.50-8.00

*Data missing for two patients in the preintervention phase and three patients in the postintervention phase, †SD = standard deviation, ‡diagnostic information missing for three patients in the preintervention phase and one patient in the postintervention phase, §APACHE = Acute Physiology and Chronic Health Evaluation

5.5 Sample characteristics

There were more men (70%) than women in the sample and the mean age of the patients was 58.74 years (range 19 to 85 years). Thirty-three per cent of patients were admitted postoperatively and 67% were admitted for other nonoperative medical diagnoses. The mean APACHE II score (Knaus et al., 1985) on ICU admission was 18.04 (range five to 37) and mean SOFA score (Vincent et al., 1996) on enrolment was 4.09 (range zero to 9) (Table 9). The median duration of mechanical ventilation during the patients' ICU stay was 6.00 days. Patients were treated in the ICU for a median 12.00 days

and the median Hospital stay was 29.00 days. Sleep recording occurred 5.00 days (median) into the patients' ICU stay (Table 10).

5.6 **Group characteristics**

A total of 57 patients were included in the analysis. The preintervention group and the postintervention group contained 30 and 27 respectively. The groups were equivalent for most characteristics except there were higher nursing dependency levels in the postintervention group (Tables 9 and 10).

Table 9. Sample and group characteristics: gender, age, diagnosis, severity of illness, BMI and deaths during enrolment

		Sample (n = 57)	**Pre (n = 30)**	**Post (n = 27)**	***p***
Number of females (%)		17 (29.81)	10 (33.32)	7 (25.92)	0.542[||]
Age in years	Mean±SD[*]	58.74±20.67	59.97±20.14	57.37±21.58	0.640[¶]
	Range	19.00-85.00	22.00-85.00	19.00-83.00	
Diagnosis, number (%)					
	Operative	17 (33.32)	12 (40.00)	7 (25.92)	0.260[||]
	Nonoperative	38 (66.68)	18 (60.00)	20 (74.08)	
APACHE[†] II	Mean±SD	18.04±8.39	19.33±7.74	16.59±8.95	0.221[¶]
score	Range	5.00-37.00	6.00-37.00	5.00-35.00	
SOFA[‡] score	Mean±SD	4.09±2.53	4.57±2.70	3.56±2.26	0.133[¶]
	Range	0.00-9.00	0.00-9.00	0.00-8.00	
Nursing	Mean±SD	65.83±12.86	61.48±12.70	70.68±11.37	0.006[¶]
Activities	Range	34.00-91.50	36.30-87.50	34.00-91.50	
Score					
BMI[§] in Kg/m^2	Mean±SD	24.44±4.81	24.18±4.76	24.73±4.94	0.673[¶]
	Range	17.00-38.10	17.00-38.10	17.20-37.10	
Number of deaths in ICU during enrolment (%)		3 (5.26)	1 (3.32)	2 (7.31)	-

[*]SD = standard deviation, [†]APACHE = Acute Physiology and Chronic Health Evaluation, [‡]SOFA = Sequential Organ Failure Assessment, [§]BMI = Body Mass Index, [||]Chi-square test, [¶]Student's t-test

Table 10. Sample and group characteristics: duration of mechanical ventilation, ICU and hospital length of stay and day on which sleep monitoring occurred

		Sample (n = 57)	**Pre (n = 30)**	**Post (n = 27)**	***p***
Number receiving mechanical ventilation during sleep monitoring (%)		31 (54.37)	17 (56.67)	14 (51.84)	0.716[†]
Duration of ventilation in days	Median	6.00	8.50	4.50	0.598[‡]
	IQR[*]	1.86-21.50	1.59-22.50	2.00-13.00	
Length of ICU stay in days	Median	12.00	12.00	11.00	0.854[‡]
	IQR	5.50-26.00	5.00-28.25	6.00-19.00	
Length of hospital stay in days	Median	29.00	36.50	27.00	0.284[‡]
	IQR	17.00-51.50	16.75-60.00	17.00-46.00	
ICU admission day on which sleep monitoring occurred	Median	5.00	4.50	5.00	0.699[‡]
	IQR	2.50-11.00	2.00-13.25	3.00-8.00	

[*] IQR = Interquartile range, [†] Chi-square test, [‡] Mann-Whitney U test

5.6.1 Pain, anxiety, sedation and conscious level on enrolment

Patients were requested to rate their pain (zero to 10) and state anxiety using the Faces Anxiety Scale (McKinley and Madronio, 2008)) (one to five) on enrolment. Sedation (assessed using the Vancouver Interaction and Calmness Scales) and conscious levels (assessed using the Glasgow Coma Scale) were assessed by the researcher at this time. While every attempt was made to encourage patients to rate their pain intensity and anxiety level some patients were unable to use the rating scales. Overall there were 10 missing responses for anxiety level and two for pain intensity. There were no missing data for sedation and conscious level.

The mean pain level was 1.87 and mean FAS score was 2.83 for the entire sample. The median VICS sedation levels indicated that patients were interactive (30.00) and calm (30.00). The median Glasgow Coma Scale score was 15.00.

There was a statistically significant difference in anxiety level between the groups; anxiety levels were higher in the preintervention group. Other differences between the groups such as Glasgow Coma Scale scores did not reach statistical significance at a p value of 0.05 (Table 11).

Table 11. Pain intensity and anxiety, sedation and conscious level on enrolment

		Sample (n = 54)	**Pre (n = 29)**	**Post (n= 26)**	***p***
Pain intensity score	Median	0.00	0.00	0.00	0.213[†]
	IQR	0.00-4.00	0.00-6.00	0.00-3.00	
	Mean±SD[*]	1.87±2.66	2.34±2.94	1.35±2.25	
			Pre (n = 25)	**Post (n = 22)**	
FAS score	Mean±SD	2.83±1.31	3.20±1.29	2.41±1.26	0.040[‡]
	Range	1.00-5.00	1.00-5.00	1.00-5.00	
			Pre (n = 30)	**Post (n = 27)**	
Vancouver Interaction score	Median	30.00	26.50	30.00	0.139[†]
	IQR	24.50-30.00	22.75-30.00	27.00-30.00	
Vancouver Calmness score	Median	30.00	30.00	30.00	0.141[†]
	IQR	30.00-30.00	30.00-30.00	27.00-30.00	
Glasgow Coma Scale score	Median	15.00	11.00	15.00	0.063[†]
	IQR	11.00-15.00	11.00-15.00	11.00-15.00	

[*]SD = standard deviation, [†]Mann-Whitney U test, [‡]Student's test

5.7 Sleep outcomes

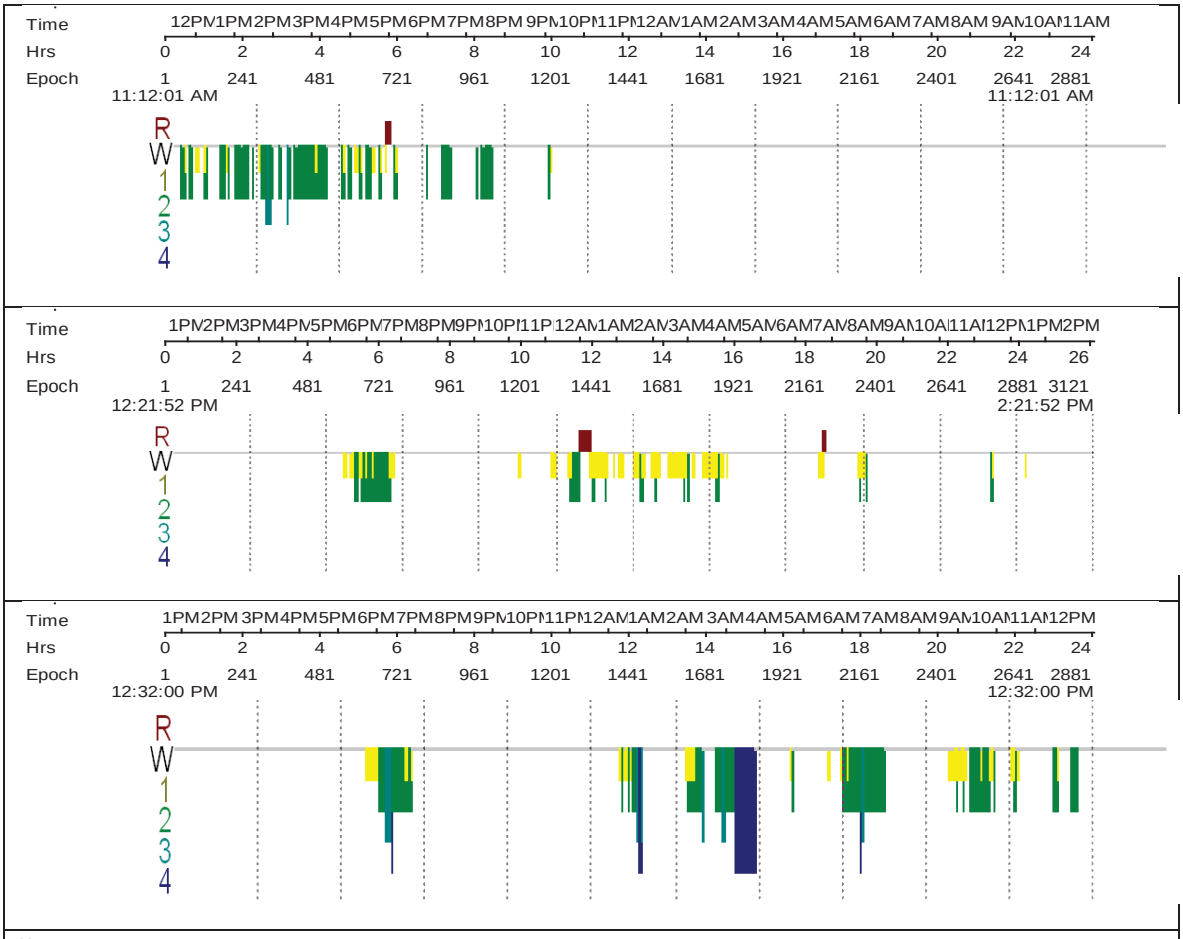
The sleep outcomes for the study groups are presented in this section. Objective sleep (PSG) data were summarised but inferential statistical tests to compare groups were not performed because of concerns about the reliability of the analysis of sleep data using the R and K (1968) criteria. Accordingly interrater reliability (Cohen's Kappa statistic) is provided.

Patient subjective reports of the quality of their sleep at home prior to enrolment, in ICU, on the Hospital ward and at home after hospital discharge are presented in the form of descriptive statistics. In addition the descriptive statistics are presented for sleep data based on nurse observation.

5.7.1 Objective sleep outcomes: PSG data

Fifty-three sleep recordings were analysed: 30 in the preintervention phase and 23 in the postintervention phase. Data from four patients' in the postintervention phase were not analysed: two patients requested discontinuation of monitoring six hours into recording, monitoring was removed from another as their clinical status deteriorated and one patient had significant 'alpha intrusion' which made analysis of the PSG impossible using R and K criteria.

The mean PSG recording time was 23 hours 22 minutes and the range was 17 to 24 hours. The mean TST for the recording time was five hours and 40 minutes, TST at night was three hours and nine minutes and TST during daytime hours was two hours and thirty-six minutes for the entire sample size. Mean nocturnal SEI was 34% for the sample. Sleep was highly fragmented resulting in a median 38 sleep periods for the sleep recording and a median sleep period of three minutes fifteen seconds without waking. Results of the descriptive analyses for PSG data for the sample and the preintervention and postintervention groups are provided in Tables 12 to 14. Further evidence of the degree of sleep fragmentation and unconventional sleep architecture is provided in the hypnograms (summaries of the sleep states and stages over the entire recording period). Hypnograms are provided for three patients in Figure 14.



Key:
R: Rapid Eye Movement (REM) sleep (burgundy)
W: Wake (grey line)
1: stage 1- light sleep (yellow)
2: stage 2 - light sleep (green)
3: stage 3- deep/slow wave sleep (blue/green)
4: stage 4- deep/slow wave sleep (dark blue)

Figure 14. Hypnograms for three patients (study number one, three and five)

Table 12. Total sleep time (hours) and time in sleep stages (minutes)

		Sample (n = 53)	Pre (n = 30)	Post (n = 23)
TST in	Median	05:00:00	05:12:00	04:03:00
hr:min:sec	IQR[*]	02:52:30-07:14:30	02:47:00-10:14:00	02:50:30-05:24:30
	Range	00:06:30-17:20:00	00:06:30-17:20:00	00:42:00-08:29:30
Stage 1	Median	60.50	79.75	34.50
	IQR	22.75-91.50	25.25-140.75	17.50-63.50
	Range	1.50-295.50	1.50-295.5	4.50-116.50
Stage 2	Median	183.50	206.75	170.00
	IQR	96.50-319.25	76.61-491.36	97.00-239.50
	Range	0.00-911.50	0-911.50	23.5-439
Stage 3	Median	0.00	0.00	0.00
	(mean±SD[†])	(6.16±14.95)[‡]	(4.00±11.00)[‡]	(9.12±19.04)[‡]
	IQR	0.00-3.00	0-0.63	0.00-11.50
	Range	0.00-82.00	0.00-47.00	0.00-82.00
Stage 4	Median	0.00	0.00	0.00
	(mean ±SD)	(2.12±12.15)[‡]	(0.92±5.10)[‡]	(3.66±17.62)[‡]
	IQR	0.00-0.00	0.00	0.00
	Range	0.00-84.50	0.00-28	0.00-84.5
REM[§]	Median	0.00	0.00	4.50
	(mean ±SD)	(13.54±23.74)[‡]	(11.77±24.10)[‡]	(15.87±23.58)[‡]
	IQR	0.00-21.00	0.00-16.00	0.00-23.00
	Range	0.00-112.50	0.00-112.50	0.00-89.00

[*]IQR = interquartile range, [†]SD = standard deviation, [‡]Mean and SD provided as medians were zero, [§]REM = rapid eye movement.

Table 13. Percentage of total sleep time in each stage and percentage of daytime sleep

		Sample (n = 53)	Pre (n = 30)	Post (n = 23)
Stage 1	Median	19.20	19.35	19.20
	IQR*	8.80-31.30	8.95-34.33	7.80-30.40
	Range	1.80-100.00	3.80-100.00	1.80-57.90
Stage 2	Median	73.20	77.45	67.20
	IQR	58.05-87.15	60.37-87.62	58.00-86.60
	Range	0.00-95.00	0.00-92.70	32.7-95.00
Stage 3	Median (mean±SD†)	0.00 (1.95±4.52)‡	0.00 (1.10±2.60)‡	0.00 (3.07±6.08)‡
	IQR	0.00-1.05	0.00-0.15	0.00-4.70
	Range	0.00-25.50	0.00-9.50	0.00-25.50
Stage 4	Median (mean±SD)	0.00 (0.70±4.07)‡	0.00 (0.28±1.60)‡	0.00 (1.22±5.93)‡
	IQR	0.00-0.00	0.00-0.00	0.00-0.00
	Range	0.00-28.50	0.00-8.80	0.00-28.50
REM§	Median (mean±SD)	0.00 (3.53±5.52)‡	0.00 (2.16±3.87)‡	2.00 (5.32±6.81)‡
	IQR	0.00-6.00	0.00-3.12	0.00-8.00
	Range	0.00-22.90	0.00-17.30	0.00-22.90
Sleep during daytime	Median	41.00	48.50	32.00
	IQR	24.00-55.50	33.75-64.00	12.00-50.00
	Range	0.00-100.00	0.00-100.00	0.00-75.00

*IQR = interquartile range, †SD = standard deviation ‡Mean and SD provided as medians were zero, §REM = rapid eye movement.

Table 14. Sleep fragmentation (arousal indices and number of awakenings, stage shifts, sleep periods and median sleep period without waking and sleep efficiency at night)

		Sample (n = 53)	Pre (n = 30)	Post (n = 23)
Arousal index	Median	27.00	23.50	27.00
	IQR*	14.00-37.50	12.75-38.00	21.00-38.00
	Range	2.90-82.00	2.90-82.00	6.00-72.60
Awakenings	Median	25.00	40.50	16.00
	IQR	12.50-51.00	14.00-67.00	11.00-25.00
	Range	1.00-149.00	1.00-149.00	2.00-96.00
Stage shifts	Median	117.00	145.50	96.00
	IQR	84.00-181.50	93.75-281.50	82.00-174.00
	Range	10.00-575.00	10.00-575.00	26.00-273.00
Sleep periods	Median	38.00	50.00	25.00
	IQR	19.00-56.50	27.50-86.25	19.00-36.00
	Range	3.00-164.00	3.00-164.00	7.00-86.00
Median sleep	Median	3.25	2.50	5.00
period in	IQR	2.12-5.12	2.00-4.00	2.50-8.50
minutes	Range	1.00-50.00	1.00-50.00	1.00-23.50
Sleep	Median	34.00	35.50	32.00
efficiency at	IQR	21.00-51.50	12.75-58.75	25.00-40.00
night	Range	0.00-84.00	0.00-84.00	3.00-55.00

*IQR = interquartile range

5.7.2 Sleep (PSG) data analysis: intrarater and interrater reliability between the sleep technologists

Intrarater reliability checks were performed on four recordings (11,142 epochs) analysed by sleep technologist number one. Interrater reliability checks were performed on 10 recordings in the preintervention phase (30%) and six in the postintervention phase (26%). Concordance of intra / interrater reliability was tested using Cohen's Kappa statistic. The Kappa coefficients for intrarater reliability are given in Table 15; coefficients for interrater reliability are provided in Table 16.

Table 15: Concordance (intrarater) for sleep technologist one (four recordings)

	Kappa (11,142 epochs)	**95 % confidence intervals**
Six groups: stages 1, 2, 3, 4 and REM* and wake	0.813	0.798-0.827
Five groups: stages 1, 2, 3 and REM* and wake	0.817	0.802-0.831
Four groups: stages 2, 3 and REM and wake	0.859	0.846-0.871
Three groups: non-REM†, REM and wake	0.876	0.863-0.888
Stage 1	0.680	0.651-0.708
Stage 2	0.806	0.787-0.824
Stage 3	0.585	0.501-0.668
Stage 4	0.873	0.810-0.936
REM	1.000	N/A‡
Sleep / wake	0.876	0.863-0.888

*REM = rapid eye movement, †non-REM = non-rapid eye movement, ‡standard error < 0.005

Table 16. Concordance (interrater) for sleep technologists one and two and two and three (16 sleep recordings)

	Technologists one and two (18,644 epochs)	Technologists two and three (25,908 epochs)
Five groups: stages 1, 2, 3/4, REM and wake (± 95% CI)	0.572 (0.5502, 0.5818)	0.508 (0.4982, 0.5178)
Four groups: stages 2, 3/4, REM and wake (± 95% CI)	0.662 (0.6522, 0.6718)	0.542 (0.5322, 0.5518)
Three groups: non-REM[‡], REM and wake (± 95% CI)	0.665 (0.6552, 0.6748)	0.561 (0.5512, 0.5708)
Stage 1 (± 95% CI)	0.123 (0.1014, 0.1445)	0.078 (0.0603, 0.0956)
Stage 2 (± 95% CI)	0.593 (0.4558,0.7302)	0.560 (0.5482, 0.5717)
Stage 3/4 (± 95% CI)	0.757 (0.6962, 0.8177)	0.197 (0.1519, 0.2420)
REM[†] (± 95% CI)	0.439 (0.3880, 0.4899)	0.409 (0.3717, 0.4462)
Sleep/wake (± 95% CI[*])	0.677 (0.6652, 0.6887)	0.576 (0.5642, 0.5877)

[*] CI = confidence interval, [†]REM = rapid eye movement, [‡]non-REM = non-rapid eye movement

5.7.3 Subjective sleep outcomes: Patient subjective reports of sleep quality and nurse estimation of nocturnal sleep time in ICU

Patients' prehospital subjective sleep quality was assessed on enrolment using the Insomnia Severity Index (ISI) (Bastien et al., 2001) and the first question of the SICQ (Freedman et al., 1999). The mean ISI score for the entire sample was 8.02 and 21% of the sample had a cut off ISI score (15) indicating a clinical diagnosis of insomnia. The median score for the first question of the SICQ was 8.00. Three patients in the preintervention group and two patients in the postintervention group were unable to rate their sleep using the ISI. There were five missing responses for the first question of the SICQ in the preintervention group and none in the postintervention group. Descriptive statistics and group comparisons are presented in Table 17.

Table 17. Patients' subjective sleep quality prior to hospital admission

		Sample (n = 52)	**Pre (n = 27)**	**Post (n = 25)**	***p***
ISI total score	Mean± SD[*]	8.02±7.98	9.44±8.23	6.48±7.57	0.429[‡]
	Range	0.00-24.00	0.00-24.00	0.00-24.00	
ISI score ≥15	n (%)	11 (21)	6 (22)	5 (20)	0.844[§]
		Sample (n = 52)	**Pre (n = 25)**	**Post (n = 27)**	
Question one SICQ (sleep quality at home)	Median	8.00	8.00	8.00	0.712[‖]
	IQR[†]	5.00-9.00	4.50-8.50	5.00-9.00	
	Range	1.00-10.00	1.00-10.00	2.00-10.00	

[*]SD = standard deviation, [†]IQR = interquartile range, [‡]Independent samples t-test, [§]Chi square test, [‖]Mann-Whitney U test

Table 18 provides descriptive statistics for patients' self-report of sleep in the ICU and Hospital ward. There were nine missing RCSQ in the preintervention group and six in the postintervention group. The range for the total RCSQ score for the sample in ICU was 0.00 to 88.00 mm and the range on the Ward was 0.18 to 100.00 mm. There was no statistical difference (assessed with a related samples Wilcoxon Signed Ranks test) between the self-reported quality of sleep in ICU and on the Hospital ward measured on the RCSQ (p = 0.606).

Table 18. Patients' self-report of sleep quality in ICU and the Hospital ward

		Sample	**Pre**	**Post**	***p***
		(n = 42)	**(n = 21)**	**(n = 21)**	
Total **RCSQ**	Median	57.50	59.00	56.00	0.928[†]
score **ICU**	IQR[*]	34.00-70.00	20.50-72.50	44.50-64.00	
	Mean±SD[‡]	51.36±24.43	48.90±28.46	53.81± 20.02	
Depth	Mean±SD	48.83±29.34	49.86±30.77	47.81±28.55	-
Latency	Mean±SD	53.00±30.81	53.14±36.80	52.86±24.34	-
Awakenings	Mean±SD	47.62±28.03	39.33±29.62	55.90±24.29	-
Back to sleep	Mean±SD	55.59±32.70	51.70±37.82	59.29±27.39	-
Quality	Mean±SD	51.55±31.79	49.71±36.51	53.38±27.04	-
		Sample	**Pre**	**Post**	
		(n = 47)	**(n = 26)**	**(n = 21)**	
Total **RCSQ**	Median	57.40	59.30	52.60	0.313[†]
score **ward**	IQR	37.40-75.40	37.55-70.25	35.70-76.40	
	Mean±SD	53.88±23.96	53.90±24.35	53.86±24.07	
Depth	Mean±SD	52.12±28.44	51.34±27.37	53.09±30.38	-
Latency	Mean±SD	61.47±29.27	61.53±27.87	62.00±31.62	-
Awakenings	Mean±SD	54.49±28.26	52.93±27.30	56.42±29.97	-
Back to sleep	Mean±SD	49.43±31.94	53.62±31.44	44.23±32.54	-
Quality	Mean±SD	51.62±29.27	50.12±30.44	53.47±28.38	-
		Sample	**Pre**	**Post**	
		(n = 47)	**(n = 25)**	**(n = 22)**	
Question two	Mean±SD	4.51±2.14	4.47±2.20	4.54±2.12	0.918[§]
SICQ (sleep	range	1.00-9.00	1.00-9.00	1.00-9.00	
quality in ICU)					

[*] IQR = interquartile range, [†] Mann Whitney U test, [‡] SD = Standard deviation, [§] Student's t-test

Noise was rated the most sleep disruptive (5.67±2.77) on the SICQ by the entire sample and the highest rated noise was talking (4.64±2.90) (Tables 19 and 20).

Table 19: Sleep in intensive care questionnaire (sleep disruptive activities in rank order)

		Sample	Pre	Post
Noise	Mean±SD*	5.67± 2.77	5.95±2.48	5.32±3.10
	Range (n†)	1.00-10.00 (46)	1.00-10.00 (25)	1.00-9.00 (21)
Nursing	Mean±SD	5.02±2.63	5.20±2.74	4.81±2.53
interventions	Range (n)	1.00-10.00 (46)	1.00-10.00 (25)	1.00-9.00 (21)
Light	Mean±SD	4.95± 2.43	5.07±2.11	4.81±2.79
	Range (n)	1.00-10.00 (45)	1.00-10.00 (24)	1.00-10.00 (21)
Diagnostic	Mean±SD	4.26±2.72	4.57±2.45	3.98±3.01
testing	Range (n)	1.00-10.00 (46)	1.00-10.00 (24)	1.00-9.00 (22)
Vital signs	Mean±SD	4.08±2.17	4.07±2.10	4.08±2.30
	Range (n)	1.00-10.00 (45)	1.00-10.00 (24)	1.00-8.00 (21)
Blood samples	Mean±SD	3.90±2.21	3.90±2.16	3.90±2.31
	Range (n)	1.00-8.00 (44)	1.00-8.00 (23)	1.00-8.00 (21)
Administration	Mean±SD	3.88±2.84	3.96±2.23	3.37±2.04
of medications	Range (n)	1.00-8.00 (44)	1.00-8.00 (23)	1.00-7.00 (21)

*SD = standard deviation, †number of responses

Table 20: Sleep in intensive care questionnaire (noise disruptions in rank order)

		Sample	Pre	Post
Talking	Mean±SD*	4.64±2.90	4.92±2.80	4.32±3.04
	Range (n†)	1.00-10.00 (45)	1.00-10.00 (24)	1.00-10.00 (21)
Suctioning	Mean±SD	3.92±2.57	4.28±2.44	3.54±2.70
	Range (n)	1.00-9.00 (41)	1.00-8.00 (21)	1.00-9.00 (20)
IV pump alarm	Mean±SD	3.90±2.61	4.00±2.45	3.81±2.84
	Range (n)	1.00-9.00 (43)	1.00-8.00 (22)	1.00-9.00 (21)
Heart rate	Mean±SD	3.88±2.84	4.21±2.89	3.51±2.81
monitor alarm	Range (n)	1.00-9.00 (45)	1.00-9.00 (24)	1.00-9.00 (21)
Oxygen finger	Mean±SD	3.88±2.72	4.09±2.83	3.67±2.62
probe	Range (n)	1.00-10.00 (44)	1.00-10.00 (23)	1.00-10.00 (21)
Nebulizer	Mean±SD	2.97±2.26	2.80±1.90	3.09±2.55
	Range (n)	1.00-10.00 (37)	1.00-7.00 (16)	1.00-10.00 (21)
Doctors' pages	Mean±SD	2.15±1.67	1.88±1.56	2.37±1.76
	Range (n)	1.00-7.00 (40)	1.00-7.00 (19)	1.00-6.00 (21)
Telephone	Mean±SD	1.74±1.39	1.88±1.58	1.60±1.19
	Range (n)	1.00-7.00 (39)	1.00-7.00 (19)	1.00-5.00 (20)
Television	Mean±SD	1.73±1.39	1.77±1.62	1.70±1.25
	Range (n)	1.00-7.00 (34)	1.00-7.00 (14)	1.00-4.00 (20)

*SD=standard deviation, †number of responses

Content analysis of the two open ended questions added to the SICQ in the postintervention phase revealed that discomfort and noise were the most commonly cited factors that disrupted sleep (Table 21). The noise from ICU machines and equipment were most commonly cited as sleep disruptive (n = 5) (Table 22).

Table 21. Content analysis for the SICQ open ended question (6)

"What factors or activities were disruptive to your sleep in ICU?" (postintervention group only, n = 17)

Content	Number of comments
Discomfort	10
Noise	9
Light	3
Procedures	3

Table 22. Content analysis for the SICQ open ended item (7)

"If you found noise to be disruptive to your sleep in ICU, please list or describe which noises you found disruptive" (postintervention group only, n = 17)

Content	Number of comments
Machines/equipment	5
Talking	3
Movement/coughing	3

Nurses' observation of patients' nocturnal (2000 to 0800 hours using the NOC) TST was missing on two occasions in the preintervention phase but no data were missing for the postintervention phase. The mean TST observation for the entire sample was 5.67 hours. Nurses' observations were similar for the two study phases (Table 23).

Table 23. Nurses' observation of patients' nocturnal (2000 to 0800 hours) TST in ICU

		Sample (n = 52)	**Pre (n = 27)**	**Post (n = 25)**	***p*** [†]
TST in hours	Mean±SD[*]	5.67±2.35	5.30±2.60	6.07±2.02	0.2
	Range	0.25-10.25	0.25-10.25	2.00-9.25	41

[*]SD=standard deviation, [†]Student's t-test

Patient self-reports at home two months after discharge from hospital

There were 17 completed PSQI (Buysse et al., 1989) instruments returned in the preintervention phase and 14 in the postintervention phase. Twenty-five patients in the entire sample had global PSQI scores of five or more (19 had scores higher than five). (A global score of five is the recommended cut off score indicating the need for referral to sleep investigation services.) The mean global PSQI score was 7.71 and median 6.00. Group comparisons were not performed however descriptive statistics are provided in Table 24. There were only two comments for the free text question ten therefore content analysis was only performed for question five (j). The content analysis of the 12 responses is presented in Table 25.

Table 24. Self-reported sleep quality at home two months after hospital discharge (PSQI total and component scores)

		Sample (n = 31)	**Pre (n = 17)**	**Post (n = 14)**
Patients with a total PSQI score ≥5 (%)	Number (%)	25 (81)	14 (82)	11 (79)
Total PSQI	Mean±SD*	7.90±4.68	8.06±4.71	7.70±4.83
	Range	2.00-21.00	2.00-18.00	4.00-21.00
'subjective sleep quality'	Mean±SD	1.19±1.25	1.06±0.75	1.36±1.68
	Range	0.00-6.00	0.00-2.00	0.00-6.00
'sleep latency'	Mean±SD	1.38±0.91	1.46±0.93	1.27±0.90
	Range	0.00-3.00	0.00-3.00	0.00-3.00
'sleep duration'	Mean±SD	0.77±1.08	0.93±1.18	0.56±0.94
	Range	0.00-3.00	0.00-3.00	0.00-3.00
'habitual sleep efficiency'	Mean±SD	1.20±1.12	1.05±1.11	1.36±0.62
	Range	0.00-3.00	0.00-3.00	0.00-3.00
'sleep disturbances'	Mean±SD	1.45±0.67	1.53±0.72	1.36±0.62
	Range	0.00-3.00	0.00-3.00	1.00-3.00
'use of sleep medication'	Mean±SD	0.73±1.17	0.75±1.24	0.71±1.14
	Range	0.00-3.00	0.00-3.00	0.00-3.00
'daytime dysfunction'	Mean±SD	1.40±0.97	1.50±0.97	1.27±0.98
	Range	0.00-3.00	0.00-3.00	0.00-3.00

*SD = standard deviation

Table 25. Content analysis: PSQI question five

"During the past month, how often have you had trouble sleeping because you... other reason(s), please describe" (n = 12, 13 comments)

Content	Number of comments
Discomfort / pain	6
Worry / anxiety	4
Bad memories of illness	1
Attend to continuing treatment (that is enteral feeding)	1
Other	1

5.8 Sound outcomes

Descriptive statistics of environmental sound pressure levels are presented in Table 26. (Technical difficulties resulted in three missing data sets for the preintervention phase and two for the postintervention phase.) Comparisons were performed for the broadband parameters: continuous equivalent sound level (LA_{eq}), background sound level (LAF_{90}) and peak sound level (LC_{peak}) in decibels (dB). No statistically significant differences were found between the phases for daytime and night-time hours or the whole sleep recording period.

Table 26. Broadband sound levels (dB(A))

		Sample (n = 52)	Pre (n=27)	Post (n=25)	*p*[‡]
Continuous equivalent sound level during **daytime**[*] hours	Mean±SD[†]	53.95±2.33	53.54±1.61	54.47±2.95	0.160
	Range	50.61-66.23	50.61-56.76	51.86-66.23	
Continuous equivalent sound level during **night-time**[§] hours	Mean±SD	50.20±3.21	49.65±2.34	50.86±3.87	0.191
	Range	45.72-64.04	45.72-53.84	47.00-64.04	
Continuous equivalent sound level during sleep recording	Mean±SD	56.60±2.16	56.40±1.60	56.80±2.70	0.431
	Range	51.70-66.50	52.70-59.50	51.70-66.50	
Background sound level during **daytime** hours	Mean±SD	51.01±2.85	50.36±2.03	51.70±3.41	0.114
	Range	46.51-65.70	46.51-54.55	48.39-65.70	
Background sound level during **night-time** hours	Mean±SD	48.39±3.53	47.37±2.60	49.40±4.07	0.055
	Range	43.34-64.29	43.34-52.88	45.66-64.29	
Background sound level during sleep recording[‖]	Mean±SD	47.20±3.41	46.80±2.90	47.60±3.90	0.436
	Range	42.00-63.30	42.00-53.00	44.10-63.30	
Peak sound level (**dB(C)**) during sleep recording	Mean±SD	107.33±10.33	106.50±11.60	108.40±8.70	0.509
	Range	63.00-121.40	63.00-121.40	74.50-120.90	

[*]Daytime = 0600-2100 hours, [†]SD = standard deviation, [‡]Student's t-test, [§] Night-time = 2100-0600 hours for sound and illuminance recordings, [‖]Explanation for the lower mean background sound level for the entire recording. Every sample of sound data (each second) for the daytime and night-time hours were exported from the sound level meter software and the mean for each recording was calculated. However the LAF_{90} for the entire 24-hour recording was taken from the sound level meter software to calculate the mean 'during sound recording'. Since LAF_{90} is the level exceeded for 90% of the measurement time (the 10^{th} percentile) there is an apparent discrepancy between the mean for sleep recording and the daytime and night-time level. However the analysis allows quantification of the background sound level for times of day and comparisons between the groups.

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For the entire sample there were a median of 416 sound peaks greater than 80 dB(C) per hour during the daytime and a median of 90 during night-time hours. The range for the sample was 31 to 1,436 per hour. The number of sound peaks above 80 dB(C), 90 dB(C) and 100 dB(C) per hour were compared between study phases and no statistically significant differences were found (Table 27).

Table 27. Number of sound peaks (LC_{peak}) per hour

		Sample (n = 52)	**Pre (n=27)**	**Post (n=25)**	***p*** [‡]
>**80** dB(C) during **daytime** [*] hours	Median IQR [†]	416.60 366.14-502.50	416.60 376.20-498.80	421.20 342.45-504.85	0.809
>**80** dB(C) during **night-time** [§] hours	Median IQR	90.14 65.02-141.75	83.10 60.48-127.05	95.80 67.57-153.13	0.203
>**90** dB(C) during **daytime** hours	Median IQR	22.81 18.20-26.50	23.10 17.80-28.10	22.23 18.30-25.68	0.587
>**90** dB(C) during **night-time** hours	Median IQR	7.28 4.92-10.78	6.43 3.80-9.70	8.17 5.42-11.40	0.392
>**100** dB(C) during **daytime** hours	Median IQR	0.78 0.57-1.24	0.80 0.41-1.28	0.78 0.58-1.25	0.976
>**100** dB(C) during **night-time** hours	Median IQR	0.09 0.063-0.13	0.08 0.05-0.15	0.07 0.06-0.14	0.860

[*] Daytime = 0600-2100 hours, [†] IQR = Interquartile range, [‡] Mann-Whitney U test, [§] Night-time = 2100-0600 hours

5.9 Illuminance level outcomes

Technical difficulties resulted in eleven missing illuminance level data sets, five in the preintervention phase and six in the postintervention phase. Illuminance levels were considerably lower at night with a median of 1.74 (range: 0.00 to 285.30) lux versus 74.20

(range: 0.06 to 3,230.00) lux during the daytime for the entire sample. The mean illuminance level for the whole recording in the preintervention phase was 70.28±103.24 lux and in the postintervention phase it was 87.24±179.01 lux. Daytime and night-time median illuminance levels were compared between phases. No statistically significant differences were found between the groups. Illuminance levels were lower at night in both study phases (Table 28).

Table 28. Median illuminance levels (lux)

		Sample (n = 46)	**Pre (n = 25)**	**Post (n = 21)**	***p***
Daytime[*] hours	Median	74.20	74.20	72.05	0.468[‡]
	IQR[†]	43.54-139.80	44.55-114.15	39.55-154.65	
Night-time[§] hours	Median	1.74	1.86	1.50	0.268[||]
	IQR	1.13-2.51	1.22-2.81	0.82-2.46	

[*]Daytime = 0600-2100 hours, [†]IQR = interquartile range, [‡]Student's t-test, [§]Night-time = 2100-0600 hours, [||]Mann-Whitney U test

5.10 **Frequency of treatment and care activities during sleep recording**

There was one missing event log (record of treatment and care activities) in the preintervention phase and none in the postintervention phase. The mean number of events during sleep recording was 40.58±13.63 (1.74±0.55 per hour). The mean number of events was lowest between 0200 and 0500 hours (0.00 to 1.00 per hour). There were no differences between the groups for the total number of care or treatment activities (events) during sleep recording (Table 29). The mean number of events for each hour of sleep recording was similar for the groups except the hour between 1300 and 1400 hours, when the mean number of events was higher in the preintervention group (2.36 versus 1.16, p = 0.005) (Figure 15).

Table 29. Number of events (patients' treatment and care activities during sleep recording)

		Sample (n = 52)	**Pre (n=29)**	**Post (n=23)**	***p*** [†]
Total number during sleep recording	Mean±SD[*]	40.58±13.63	40.65±11.17	40.51±16.47	0.972
	Range	20.00-92.00	21.00-64.00	20.00-92.00	
Number ***per hour*** of sleep recording	Mean±SD	1.74±0.55	1.76±0.42	1.70±0.70	0.713
	Range	0.82-3.82	1.00-2.67	0.82-3.82	

[*]SD = standard deviation, [†]Student's t-test

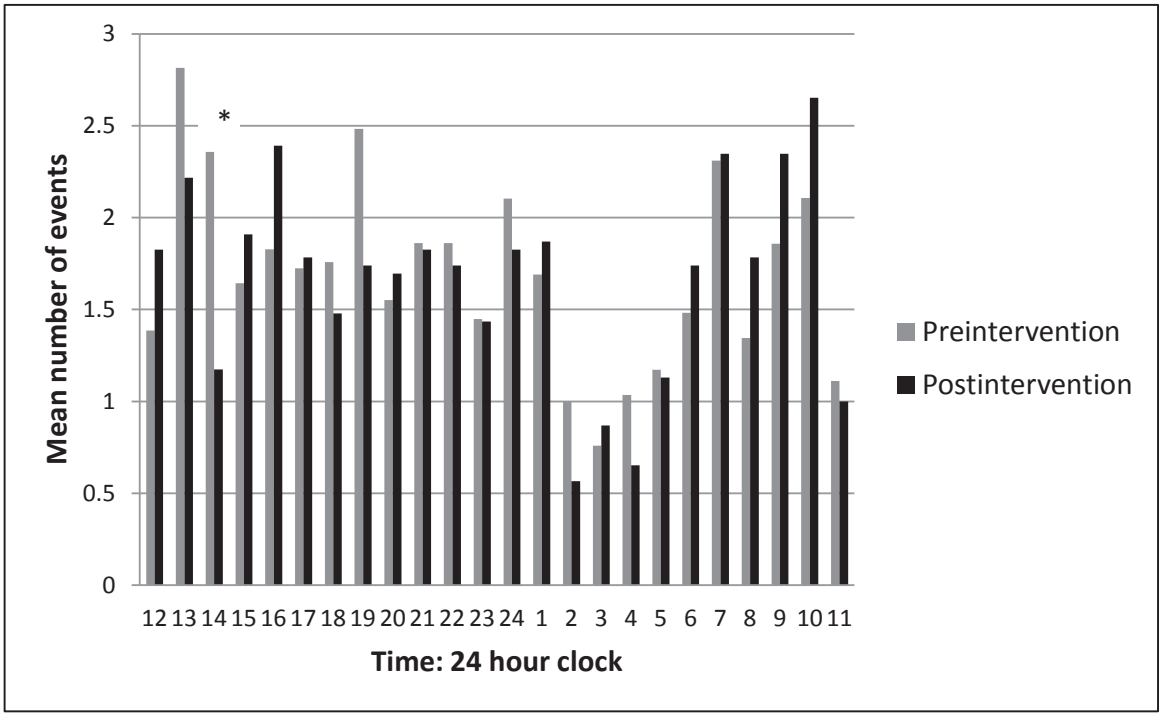

Figure 15. Mean number of events during each hour of sleep recording (*p = 0.005)

5.11 Prevalence of other factors known to affect sleep quality

5.11.1 Ambient temperature during sleep recording

The mean maximum ambient temperature was 23.98±2.00 °C and the mean minimum temperature was 22.60±1.27 °C for the sample. There were statistically significant differences between the groups for the mean maximum and minimum ambient temperature during sleep recording. The temperatures recorded during the postintervention phase were higher. Descriptive statistics and results of the independent Student's t tests are presented in Table 30.

Table 30. Maximum and minimum ambient temperature during sleep recording in degrees centigrade (°C)

		Sample (n = 53)	**Pre (n = 30)**	**Post (n = 23)**	***p*†**
Maximum temperature	Mean±SD*	23.98±2.00	22.42±0.74	25.70±1.42	<0.005
	Range	21.00-28.50	21.00-24.00	23.50-28.50	
Minimum temperature	Mean±SD	22.60±1.28	22.27±0.64	22.92±1.67	0.004
	Range	21.00-28.00	21.00-23.50	21.00-28.00	

*SD = standard deviation, †Student's t-test

5.11.2 Prevalence of Systemic Inflammatory Response Syndrome (SIRS) in the sample

A total of 18 (31.58%) patients in the sample had evidence of SIRS at enrolment. There was no difference in the prevalence of SIRS between the study groups. The number of patients in each group with evidence of SIRS and the results of the Chi-test are provided in Table 31.

Table 31. Number of patients with evidence of SIRS

	Sample (n = 57)	Pre (n = 30)	Post (n = 27)	*p*[*]
Number of patients (%)	18 (31.58)	7 (23.3)	11 (40.7)	0.158[*]

[*]Chi-square-test

5.11.3 Medications administered during sleep recording

Descriptive statistics are provided for the number of patients administered opioids, benzodiazepines and propofol in Table 32. Sixty per cent of the sample received opioid medications and 26 per cent received both an opioid and a benzodiazepine / propofol medication. Analyses were also performed for the mean equivalent doses administered per hour during sleep recording. The mean equivalent dose of morphine was 29.15±66.11 mcg/kg/hour and the equivalent dose of midazolam was 2.15±11.58 mcg/kg/hour for the sample. There were no statistically significant differences between the preintervention and postintervention groups for the numbers of patients administered these medications or their mean equivalent doses.

Inferential statistical analyses and calculations of mean equivalent doses were not performed for beta-blocker, corticosteroid and adrenergic medications. The number of patients administered these medications in each group are presented in Table 33.

Table 32. Medications administered during sleep recording: opioids, benzodiazepines and propofol

		Sample (n = 53)	**Pre (n = 30)**	**Post (n = 23)**	***p***
Number of patients administered opioids (%)		32 (60.00)	19 (63.33)	13 (56.52)	0.311*
Number of patients administered a benzodiazepine medication (%)		17 (32.06)	12 (40.00)	5 (21.74)	0.158*
Number of patients administered propofol (%)		13 (24.53)	7 (23.33)	6 (26.09)	0.817*
Number of patients administered opioids and midazolam or propofol (%)		14 (26.40)	9 (30.00)	5 (21.74)	0.413*
Equivalent dose of **morphine** in mcg/kg/h	Median (Mean±SD†) IQR	4.30 (29.15±66.11) 0.00-17.35	5.25 (22.21±37.44) 0.00-19.77	4.30 (38.21±91.27) 0.00-17.50	0.825‡
Equivalent dose of **midazolam** in mcg/kg/h	Median (Mean±SD) IQR	0.00 (2.15±11.58) 0.00-0.99	0.00 (3.56±15.34) 0.00-1.13	0.00 (0.33±0.80) 0.00-0.00	0.135‡
Dose of **propofol** in mg/kg/h	Median (Mean±SD) IQR	0.00 (0.098±0.22) 0.00-0.01	0.00 (0.06±0.16) 0.00-0.01	0.00 (0.10±0.26) 0.00-0.24	0.577‡

*Chi-square-test, †SD = standard deviation, ‡Mann-Whitney U test

Table 33. The number of patients administered beta-blocker[*], corticosteroid[†] and adrenergic[‡] medications during sleep recording:

		Sample (n = 53)	Pre (n = 30)	Post (n = 23)
Beta-blockers	Number (%)	6 (11.32)	4 (13.32)	1 (4.35)
Corticosteroids	Number (%)	10 (18.86)	3 (10.00)	7 (30.42)
Adrenergics	Number (%)	12 (22.64)	6 (20.00)	6 (26.09)

[*]Beta-blocker = metoprolol, [†]Corticosteriods = prednisolone, dexamethasone, hydrocortisone, [‡]Adrenergics = noradrenaline, adrenaline or dopamine. The small frequencies precluded comparative statistical analyses.

5.12 **Psychological outcomes during recovery**

The DASS-21, PCL-S and ICEQ were mailed to former ICU patients enrolled in the study two months after hospital discharge. To maximise the response rate the protocol included three telephone calls and resending the instruments if necessary. This resulted in 17 complete responses in the preintervention phase (two patients failed to complete the ICEQ and DASS-21) and 14 in the postintervention phase (the PSQI and DASS-21 were yet to be received for one patient at the time of writing).

The mean global DASS-21 score for the sample was 33.44±32.07. Nineteen per cent of the sample reported depression subscale scores greater than 20 and anxiety subscale scores greater than 14 and nine per cent had Stress subscale scores greater than 26. The mean (and SD) and range of DASS-21 scores are provided in Table 34.

Table 34. Global and subscale DASS-21 scores

		Sample (n=31)	Pre (n=17)	Post (n=14)
DASS-21 global	Mean±SD*	33.44±32.07	35.22±37.55	31.27±25.04
	Range	00.00-122.00	0.00-122.00	2.00-84.00
Depression	Mean±SD	12.78±13.20	13.40±14.80	12.00±11.46
	Range	0.00-42.00	0.00-42.00	0.00-38.00
Anxiety	Mean±SD	9.86±10.30	10.00±11.60	9.70±8.90
	Range	0.00-38.00	0.00-38.00	0.00-28.00
Stress	Mean±SD	11.39±11.68	11.81±13.20	10.86±10.00
	Range	0.00-42.00	0.00-42.00	0.00-36.00

* SD = standard deviation

A total PCL-S score of less than 41 was reported by 75% of the sample (seven patients reported scores of 44 or more). Other descriptive statistics of PCL-S total and subscale scores are provided in Table 35. Again comparisons between the study groups were not performed for PCL-S scores.

Table 35. Total and subscale PCL-S scores

		Sample (n=32)	Pre (n=19)	Post (n=13)
PCL-S total	Mean±SD*	33.75±13.90	34.30±15.08	32.47±11.68
	Range	17.00-67.00	17.00-67.00	20.00-60.00
Reexperiencing	Mean±SD	9.00±4.41	8.83±4.72	9.00±3.86
	Range	5.00-20.00	5.00-20.00	5.00-18.00
Avoidance	Mean±SD	14.91±7.17	15.16±7.60	14.60±6.53
	Range	6.00-31.00	7.00-31.00	6.00-24.00
Hyperarousal	Mean±SD	10.16±4.70	10.83±5.34	8.87±3.43
	Range	5.00-21.00	5.00-21.00	5.00-19.00

*SD = standard deviation

Comparisons for ICEQ responses were not performed between the study groups, however descriptive statistics and content analyses (for the ICEQ open ended questions) are provided in Figures 16 and 17 and Tables 36 and 37.

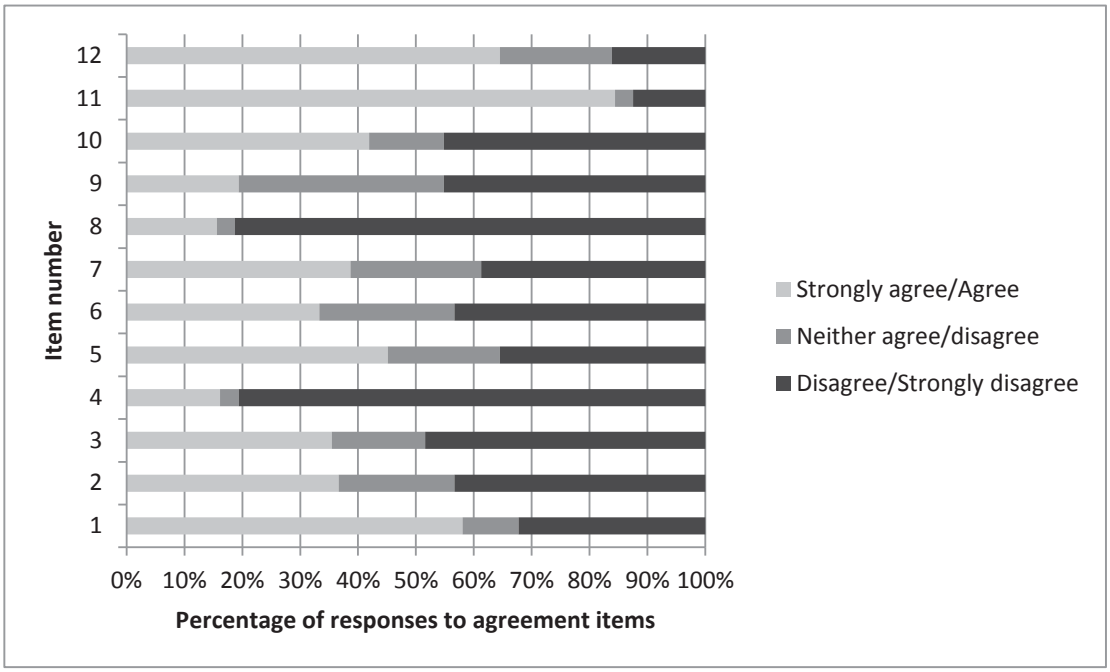

Figure 16. The percentage of responses to agreement items on the ICEQ

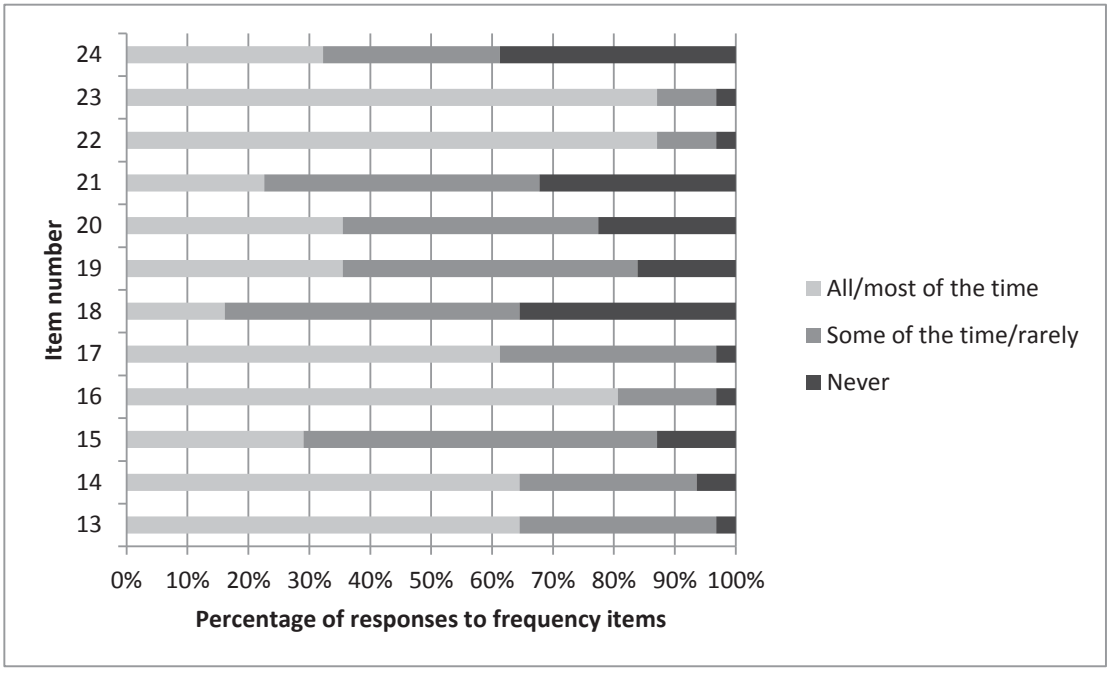

Figure 17. The percentage of responses to frequency items on the ICEQ

Table 36. Total and domain ICEQ scores

		Sample (n=30)	Pre (n = 17)	Post (n = 13)
Total ICEQ	Mean±SD*	79.70±10.55	77.23±11.38	82.07±8.96
	Range	46.00-95.00	46.00-95.00	60.00-92.00
'awareness of	Mean±SD	34.20±7.39	33.16±4.71	34.87±6.37
surroundings'	Range	12.00-45.00	12.00-41.00	24.00-45.00
'frightening	Mean±SD	16.40±6.27	15.81±6.35	16.87±5.93
experiences'	Range	6.00-30.00	6.00-30.00	8.00-28.00
'recall of	Mean±SD	14.87±4.40	14.87±4.73	15.00±4.10
experience'	Range	8.00-21.00	8.00-21.00	9.00-20.00
'satisfaction with	Mean±SD	14.10±3.32	14.87±3.04	13.32±3.34
care'	Range	5.00-20.00	10.00-20.00	5.00-18.00

* SD = standard deviation

Table 37. Content analysis for ICEQ open ended questions

"What was best about intensive care?" (31 comments)

Content	Number of comments
Nurses / Doctors helpful / kind	11
Level of care / treatment	10
Surviving / being liberated from ventilator	2
Close monitoring / supervision	2
Leaving ICU	2
Nothing	2
Opportunity to rest and sleep	1
No memory of ICU	1

Content analysis for ICEQ open questions continued

"What was worst about intensive care?" (34 comments)

Content	**Number of comments**
Noise	11
Helplessness / dependence on others	5
Sleep disturbance	3
Nothing	3
Infection	2
Worry	2
Being there	2
Other	6

"Is there anything else you'd like to tell me about intensive care?" (22 comments)

Content	**Number of comments**
Grateful / 'thank you' / kind staff	6
High level of care	6
Disorientated at times in ICU	2
No / little memory of ICU	2
Nothing	2
Other	4

5.13 **Summary of main findings**

A large proportion of the sample in this study was male (70%) and the mean age was 58 years. The diagnoses were mostly nonoperative and over half of the sample were receiving mechanical ventilation during sleep monitoring. The preintervention and postintervention groups were equivalent in most respects at enrolment including age, gender, diagnosis, severity of illness and self-reported prehospital sleep quality. The differences noted were statistically significant higher nursing dependency levels and lower anxiety scores and a trend towards higher Glasgow Coma Scores in the postintervention group.

Analysis using conventional R and K criteria indicated that patients had reduced median TST, a predominance of stage 1 and 2 and reduced slow wave and REM sleep. It was also noted that there were few consolidated sleep periods with numerous arousals and awakenings. A large proportion of patients' sleep was experienced during daytime hours. Patients' subjective self-reports were that the quality of their sleep in ICU and in the Hospital ward was poor. Noise was the most highly rated sleep disruptive 'activity' and talking was the highest rated sleep disruptive noise in ICU. Nurses' observations indicated that patients' TST in ICU was low but higher than the PSG derived value.

Sound levels were elevated and exceeded noise standards for hospitals. There were many sound level peaks throughout sound recording. There was a trend towards higher background sound levels at night in the postintervention phase.

Illuminance levels were appropriate for the time of day with very low illuminance levels evident at night. No differences were detected between the study phases. The mean number of events (care and procedures) the patients were subjected to was significantly higher in the preintervention group during one hour of the day (1300 to 1400 hours). The minimum and maximum ambient temperatures during sleep recording were appropriate for the ICU setting. Ambient temperatures were significantly higher in the postintervention phase.

The patients' subjective self-report of sleep quality at home two months after hospital discharge was lower than population norms. More than half the patients who returned the completed PSQI had global scores greater than five. The former ICU patients' scores on the DASS-21, PCL-S and ICEQ at two months after discharge from hospital were moderate for most of the scales.

The effect of the introduction of the Guideline was inconclusive. Comparisons of the PSG sleep data were not performed between the preintervention and postintervention groups as there were concerns about the overall interrater reliability of the sleep data analysis using R and K criteria. However the results from comparisons for sound outcomes and data from audits of the use of the Guideline indicates that the intervention was not extensively adopted.

6 Discussion

6.1 Introduction

This study described the quality and quantity of patients' sleep in ICU using PSG, patient subjective self-report and nurse observation. It also investigated the introduction of a rest and sleep guideline, on patients' sleep. The study provides insights into the challenge of measuring sleep in ICU patients, in particular the analysis of PSG data using the conventional R and K criteria. In this chapter the major findings of the study are summarised and discussed in relation to previous published research reports. The strengths and limitations of the study are acknowledged and the recommendations for research and clinical practice outlined.

6.2 Summary of major findings

Polysomnography data analysed using conventional R and K criteria revealed that TST was less than would be expected (median five hours) for healthy adults and the quality of patients' sleep was poor. There was a predominance of stage 1 and 2 sleep and reduced stage 3 and 4 and REM sleep. Sleep appeared to be highly fragmented resulting in multiple short non-contiguous sleep periods, many stage shifts and numerous arousals and awakenings. A large proportion of sleep was experienced during daylight hours. Patients' subjective self-reports of sleep in ICU were poor and they rated noise as the most sleep disruptive factor and talking the most sleep disruptive noise. Patients' nocturnal TST derived from nurses' observations appeared to be greater than the PSG derived value (05:40 versus 03:09 hours) but inferential analyses were not performed.

The introduction of the Guideline did not appear to result in an improvement in sleep quality or an increase in the amount of sleep within the first four months of the postintervention phase. However group comparisons were not performed because of concerns about the validity and reliability of PSG data analysis using the conventional R and K criteria in the study sample of ICU patients. This study highlights the barriers to

conducting valid measurements of sleep in this patient population and the need for alternative methods to analyse or measure ICU patients' sleep.

6.3 Sample characteristics

The mean age of participants was 58 years and the majority (70%) were men. A large percentage of the sample was admitted to ICU with nonoperative diagnoses (66%), the mean severity of illness (APACHE II) score was 18 and the mean organ failure (SOFA) score was four. In addition 54 % of the sample was receiving mechanical ventilation during PSG sleep recording. These characteristics together with the median duration of mechanical ventilation (six days) and median ICU and hospital length of stay (12 and 29 days), suggest that the sample was representative of patients undergoing medium to long term treatment in ICU. Sleep recording took place approximately half way through the patients' stay in ICU.

There was group equivalence in most characteristics including diagnosis, severity of illness on ICU admission and self-reported prehospital sleep quality. Slight differences noted were statistically significant higher nursing activity levels and lower anxiety scores and a trend towards higher Glasgow Coma Scores in the postintervention group.

6.4 Primary outcome

6.4.1 The quality and quantity of sleep experienced by patients in ICU

The TST experienced by patients' measured by PSG and analysed using R and K criteria (median: five hours and 40 minutes) was below the TST experienced by healthy adults but similar to reports in previous published studies of patients' sleep in ICU measured over 24 hours (Cooper et al., 2000, Edéll-Gustafsson et al., 1999, Freedman et al., 2001, Friese et al., 2007, Gabor et al., 2003, Hilton, 1976, Johns et al., 1974). Polysomnography also revealed that the quality of sleep was poor. Over 90% of patients' sleep was stage 1 and 2. Again these results reflect evidence from previous studies using 24-hour sleep recording in ICU; few report more than 10% of either slow wave or REM sleep (Aurell and Elmqvist, 1985, Edéll-Gustafsson et al., 1999, Freedman et al., 2001, Friese et al., 2007, Hilton, 1976). In addition significant sleep fragmentation and

unconventional architecture was evident in the current study with multiple short (median duration: 03:15 minutes) non-contiguous sleep periods (median number: 38), many awakenings (median number: 25) and numerous stage shifts (median number: 117). Freedman et al. (2001) reported comparable findings; a mean sleep period of 15 minutes and an average of 41 sleep periods during 24-hour sleep recording but arousal indices were within normal limits (mean: 11). Arousals and awakenings reported in most studies are frequent. In the current study sleep fragmentation was significant resulting in a number of unconventional stage changes including REM following stage 1 sleep and stage 4 following stage 1 sleep. Non-sequential stage changes are described in previously published ICU sleep studies (Cooper et al., 2000, Friese et al., 2007, Richards, 1998).

A large percentage of TST was experienced during daytime hours in the current study (median 41%). Again this outcome is reflective of results from other studies in which it is common for up to half of TST to be experienced during daytime hours (Freedman et al., 2001, Gabor et al., 2003, Hardin et al., 2006, Hilton, 1976).

The potential pathological consequences of the degree of sleep fragmentation and SW and REM deprivation experienced by patients in our study are many and they are far reaching. For example given that growth hormone (GH) is preferentially excreted at the beginning of SWS (Obal and Krueger, 2004) it is likely that the circadian rhythmicity of GH secretion and therefore wound healing is adversely affected. In addition as partial sleep deprivation (four hours of sleep for six nights) has been shown to adversely affect cellular glucose uptake and glucose tolerance to a level similar to gestational diabetes (Spiegel et al., 1999) many ICU patients may be affected in this way. Furthermore both animal and human studies indicate that total sleep deprivation and sleep fragmentation lead to measureable reductions in pulmonary function, particularly in the presence of an existing pulmonary disorder, namely decreased forced vital capacity (Phillips et al., 1987) and lengthening in time to arousal in response to hypoxia and hypercapnia (Phillipson et al., 1980).

Nurses' observation of the patient's nocturnal TST was low (median: five hours forty minutes) but appeared to greater than the PSG derived value (median: three hours and nine minutes). The study protocol did not specify a time frame within the fifteen minutes when the nurses should make their observations, so inferential analyses were not performed to test the correlation between the PSG and nurse derived TST. Concerns about the reliability of the PSG R and K analysis also contributed to the decision not to compare the NOC observations against the PSG data statistically.

The difficulty scoring PSG sleep data in ICU patients using the established R and K criteria used in sleep investigation unit studies was reinforced in this study. Interrater reliability of the PSG analysis using R and K criteria in the current study was below typical values for sleep technologists. Overall interrater reliability (epoch by epoch) for sleep technologists' analysis, using R and K criteria, in sleep investigation units is good, with reported Kappa values of 0.72 (Danker-Hopfe et al., 2009) and 0.81 (Whitney et al., 1998), and intrarater reliability of 0.79 (Whitney et al., 1998). Given the technical challenges involved with using PSG to measure sleep in ICU it is surprising that the reliability of PSG analysis of ICU patients' sleep has been infrequently reported in other PSG studies in ICU patients. When reliability of the analysis is performed often only one or two recordings are reported and statistical analyses are rarely provided. In the two studies in which interrater reliability was reported it was high (Kappa = 0.82 (Fontaine, 1989); Kappa = 0.83 (Richards et al., 2002)). However in a comparison of four methods of analysing ICU patients' PSG data, Ambrogio et al. (2008) found that the interrater reliability for 200 epochs from 14 recordings was poor (Kappa = 0.19) but intrarater reliability was high (Kappa = 0.68). In the current study interrater reliability was moderate; 0.56 for sleep technologists one and two (18,644 epochs) and 0.51 for sleep technologists two and three (25,908 epochs) and intrarater reliability was high for sleep technologist one (Kappa = 0.80, 11,142 epochs).

Interrater reliability for each stage was low using the conventional R and K criteria in this study, but higher than the results reported in a similar population by Ambrogio et al.

(2008) except for REM sleep. In the current study the interrater reliability Kappa statistics for stage one were 0.11 and 0.08. Ambrogio et al. (2008) reported a Kappa of 0.01. The Kappa statistics for REM were 0.44 and 0.41 in contrast to a Kappa statistic of 0.70 in the Ambrogio et al. (2008) study. Given the evident problems in the reliability of the PSG analysis using conventional R and K criteria in the current study, statistical inferential testing for differences in sleep parameters between the preintervention and postintervention groups was not reported, nor potential associations between PSG measurements and environmental factors which could disrupt sleep.

Self-reports of sleep by patients in ICU were poor but comparable to reports in previous published studies of ICU patients' sleep. The mean total RCSQ score in ICU was 51.36 mm for the sample. The mean total RCSQ score from (n = 222) patients who were ready for discharge to the Hospital ward (n=222) in the same ICU was 47.18 mm (McKinley et al., 2011). In a study investigating the utility of the RCSQ and the concordance of nurse and patient sleep assessment the mean total RCSQ score was 45.50 mm (Frisk and Nordström, 2003). In a similar study Nicolás et al. (2008) reported a mean total RCSQ score of 51.42 mm. Mean values for the individual RCSQ VAS ranged from 47.62 to 55.59 mm and were also similar to previous reports in the literature. In addition the mean sleep quality rating in ICU using question two of the SICQ was 4.51 which is almost identical to the value reported in the study in which the SICQ was developed (Freedman et al., 1999) but a little lower than patient reports in another study (5.5) (Gabor et al., 2003).

Patient reports of sources of sleep disruption were similar to previous studies. Noise was rated the most disruptive to sleep and talking was the most disruptive noise on the SICQ which was also the case for patients in the study conducted by Gabor et al. (2003). However patient ratings of disruption were higher compared to the current study (noise: 7.6 versus 5.67 and talking 7.5 versus 4.64). In the development of the SICQ patients' ratings of disruptive activities were lower and noise (4.5) was less disruptive than vital signs (5.5) and phlebotomy (5.5) but talking (3.5) was rated the most disruptive noise (Freedman et al., 1999). Notwithstanding the concerns with the reliability of the PSG

analysis in the current study, it would appear that the amount and quality of patients' sleep while in ICU assessed using both objective and subjective methods is not dissimilar (that is poor) to reports in the international health care literature.

6.5 Secondary outcomes

Sound pressure and illuminance levels, together with patient care and treatment activities (events) were recorded during sleep monitoring in order to assess their effect on patients' sleep. Both average (continuous equivalent: L_{eq}) and background (ninety percentile: LAF_{90}) sound pressure levels were elevated throughout the 24-hour sleep recording period and exceeded international standards for sound pressure levels in hospital. The World Health Organisation (WHO) standards for sound pressure levels in hospitals stipulate that continuous equivalent sound levels should not exceed L_{eq} 35 dB(A) in patient areas and LAF_{max} should be below 40 dB(A) at night (Berglund and Lindvall, 1999). In the current study, L_{eq} was greater than 49 dB(A) and LAF_{90} was greater than 46 dB(A), exceeding the LAF_{max} WHO standard. (LAF_{max} is the highest level of sound occurring during the recording period.) Continuous equivalent (L_{eq}) and background (LAF_{90}) sound pressure levels were 10 dB(A) lower than in many previously published reports of sound level recordings in ICU (Balogh et al., 1993, Freedman et al., 2001, Hilton, 1985, Hu et al., 2010, Tsiou et al., 1998, Wallace et al., 1999) and similar to others (Blomkvist et al., 2005, Buemi et al., 1995, Gabor et al., 2003, Ryherd et al., 2008).

The peak sound pressure levels are difficult to assess against reports in other studies measuring sound levels in ICU. Many previously published studies report mean peak sound pressure levels whereas in the current study the absolute peak sound level for each recording was used to calculate the overall study mean peak sound level. However given that the range was 63.00 to 120.90 dB(C) and previously published studies report mean values of 80 to 90 dB(C) it is likely that they are similar. The frequent sound peaks above 80 dB(C) was a concern (range: 31 to 1,436 per hour). Again it is difficult to contrast this result with reports in previously published studies as few report the number of peaks and when they are reported there is variability in the sampling frequency. Some studies report

sampling rates of 15 to 60 seconds (Kahn et al., 1998, Meyer et al., 1994) whereas a one second sampling period was used for the current study. Despite this difficulty it would appear that the number of sound peaks above 80 dB(C) was high in contrast to other studies. Kahn et al. (1998) reported a mean rate of 56 per hour before a noise reduction behaviour modification programme and 40 afterwards, while the most frequent mean rate reported by Meyer et al. (1994) was 60 per hour. This contrasts with mean daytime hourly rates of 456 and night-time rates of 106 for the recordings in the current study. The source of these frequent sound peaks is not obvious but investigations during pilot work revealed that simply placing a pair of metal scissors on a metal dressing trolley near to the bedside could result in a peak sound greater than 80 dB(C) (Appendix B). Associations between peak sounds and sleep disruption were not explored for several reasons. Firstly there was concern about the reliability of the sleep data analysis, as discussed above. Secondly it was found after data collection that the manual synchronisation between the PSG and SLM was not absolutely precise (more than a five second discrepancy). It is also notable that the frequency of the sound peaks (456 per hour during the day and 106 per hour at night) was higher than the sleep arousal rate (27 per hour). Thus while statistically analysis might be significant, there was a risk of spurious chance association.

In contrast to the potentially sleep disrupting sound levels, illuminance levels were appropriate at night with median night-time levels of less than two lux. However daytime median illuminance levels of 74 lux may have been too low to adequately encourage a 24-hour circadian rhythm. In contrast a higher median daytime illuminance level of 200 lux with a range of 47 to 630 lux was reported in a previous published study (Perras et al., 2007). Likewise Frisk et al. (2004) report illumination levels between 250 and 500 lux at midday (night-time levels were approximately 50 lux). Data from investigations of endogenous melatonin secretion in healthy participants indicate that illuminance levels of less than 100 lux may not be sufficiently bright to suppress melatonin secretion in some individuals (Gronfier et al., 2007). Thus patients in the current study may have been subjected to the sleep promoting and maintaining properties of melatonin during the day and this may in part explain the proportion of sleep experienced during daytime hours.

The number of recorded events (treatment and care) patients were subjected to during sleep recording was lower than reports in previously published studies. The mean number of events per sleep recording was 40 events (1.7 per hour). This contrasts with hourly event rates reported by Hilton (1976), Gabor et al. (2003) and Hardin et al. (2006) which were three, seven and six respectively. Encouragingly activity levels were considerably lower in both study phases from 0200 to 0500 hours when the mean number of events per hour was zero to one. However as the bedside nurses were responsible for recording care and treatment events there remains the possibility that some events were not recorded and that the number of events throughout sleep recording was under reported. A previously published ICU sleep study which performed video recording to capture care and treatment interactions (in a sample with some similar characteristics) the event rate was much higher (seven per hour) (Gabor et al., 2003). In a more recent study which had the aim of capturing the 24-hour ICU events patients were exposed to, digital camera recording revealed an hourly event rate of 3.5 (Merilainen et al., 2010). The event rates in these studies suggest that nurse under recording may be responsible for the lower event rate.

A number of other factors known to affect sleep quality were also measured during sleep recording including minimum and maximum ambient temperature, evidence of SIRS and medication administered during sleep recording. The maximum and minimum ambient temperature was recorded for each sleep recording. The mean maximum ambient temperature was 23.98 °C and the minimum 22.60 °C in ICU during sleep recording for the entire sample. There was a statistically significant difference in both the maximum and minimum ambient temperatures between the study phases. A possible explanation for this was that data collection occurred at different times during the year in the study phases that is, January to April, June to July and October to December, 2009 for the preintervention phase and September 2010 to April 2011 for the postintervention phase. However since the study ICU had a thermostatically controlled ambient temperature throughout and there was no change in the Hospital air conditioning or heating systems during the study, a possible explanation is the use of different ambient

thermometers in the study phases; an analogue thermometer for the preintervention phase and a digital thermometer for the postintervention phase. The difference in ambient temperature was statistically significant between the study phases however the difference was probably not clinically significant (the mean maximum temperature difference was 3.28 °C and mean minimum temperature difference was 0.65 °C). Reports of ambient temperature could not be found in previously published studies about sleep in ICU.

The signs of SIRS were recorded as evidence of the presence of elevated levels of cytokines as they are thought to affect sleep. Both animal and human research indicates that beta interleukin-1 and alpha tumour necrosis factor promote slow wave EEG activity (Opp, 2005). Evidence of an association between elevated levels of inflammatory mediators and ICU patients' sleep, and more specifically EEG activity was highlighted by Freedman et al. (2001) who noted mixed frequency waveform activity superimposed on delta and theta waves in the EEG up to eight hours prior to the onset of sepsis. Thirty-one percent of the sample in the current study had evidence of SIRS. There was no statistical difference in the number of patients with evidence of SIRS between the study groups. Statistical examination of an association between symptoms of SIRS was not conducted in this study because of the reliability of the PSG staging using R and K criteria.

The main types and doses of medications administered to patients and considered to have the potential to affect sleep were noted during sleep recording. A large proportion (60%) of the sample received opioid medications. The mean equivalent dose of morphine was 29.15±66.11mcg/kg/hour which is higher than the dose administered to mechanically ventilated patients who experienced 'atypical' sleep (12.30±18.10) (Cooper et al. 2000) but lower than the mean dose administered to a group of patients receiving intermittent sedation (40.33 mcg/kg/hour) (Hardin et al., 2006). The majority of previously published studies do not report doses so other comparisons are difficult to make. It is highly likely that many patients' sleep in the current study was affected by opioid medications. In an investigation of the effect of two opioid medications (15 mg sustained release morphine

and 10 mg methadone administered at bedtime) on 42 healthy volunteers' sleep, it was found that slow wave sleep was significantly reduced with a concomitant increase in stage 2 sleep (Dimsdale et al., 2007).

A similar proportion of the patients in the current study received benzodiazepine medication or / and propofol (50%). This offers another potential explanation for the high proportion of stage 2 and lack of REM sleep in the sample. Associations between type and dose of medication and sleep disruption were not explored. There were no statistically significant differences between the preintervention and postintervention groups for the number of patients administered opioids, benzodiazepines and propofol and the doses. As only a small percentage of patients were administered beta-blocker, corticosteroid and adrenergic medications, group comparisons were not performed.

Additional secondary aims of the study were to explore patients' self-reported quality of sleep on the Hospital ward and at home two months after discharge from hospital. The mean total RCSQ score on the Hospital ward was 53.88 mm. There was no difference between the patients' self-reported sleep quality, measured with the RCSQ, in the ICU and on the Hospital ward. The lack of difference may be explained to some extent by the time frame in which the patients were requested to report on their sleep (two to three days after transfer to the Ward). It is likely that the effects of their critical illness and treatment related activities had not declined sufficiently to detect an improvement in sleep quality. However the possibility also remains that the Ward environment was not conducive to rest and sleep for this group of patients. Patient reports of quality sleep on the Hospital ward in the current study are reflective of scores obtained from patients in a larger study (n = 222) in the same hospital (mean 54.33 mm) (McKinley et al., 2011), patient reports in high dependency units and are often similar to quality of sleep reported by ICU patients (Edéll-Gustafsson et al., 1999, Zimmerman et al., 1996). Sleep quality tends to progressively improve in the ward during recovery (Broughton and Baron, 1978, Edéll-Gustafsson et al., 1999).

Patients' self-reported quality of sleep at home using the PSQI (Buysse et al., 1989) demonstrated that there were significant signs of poor quality sleep at two months after discharge from hospital in the sample. The suggested cut-off score for poor quality sleep and trigger for clinical intervention on the PSQI is a global score of five (Buysse et al., 1989). Eighty-one percent of the sample had a score of five or more and the mean global score was 7.71. The PSQI components which contributed most to the global score were 'sleep disruption' and 'daytime sleepiness'. The most frequently cited factors causing patients 'trouble sleeping' (question five of the PSQI), were discomfort and anxiety. Direct comparisons cannot be made with the results of previously published ICU patient follow up studies as there are differences in time to follow up and sleep assessment instruments however there are similarities in patients' reports. It would appear that in the immediate (up to three months) recovery period self-reported sleep quality is poor but improves to pre-illness values by six months. For example patient reports of sleep quality on the sleep component of the Nottingham Health Profile were worse than prehospital values one month after cardiac surgery in one investigation (even though sleep quality measured with PSG had almost returned to prehospital values) but returned to self-reported prehospital sleep quality six months after hospital discharge (Edéll-Gustafsson et al., 1999). Likewise 44% of women and 25% of men in a study of the quality of life of former ICU patients had sleep disturbance at three months after discharge from ICU but this improved to 28% of women and 18% of men by six months (pre-illness sleep quality was not reported) (Eddleston et al., 2000). In the current study patients were followed up on one occasion at two months after discharge from hospital so it is not possible to report longer term follow up in the study in this thesis. In view of previous evidence suggesting the temporary nature of sleep disturbance in the majority of former ICU patients, the occurrence of more persistent 'conditioned insomnia' in a few (Lee et al., 2009) and on the advice of a clinical psychologist sleep specialist, patients with global PSQI scores of nine or higher were followed up and offered information about sleep investigation services (in practice these patients had high scores on the PCL-S and were followed up anyway).

Exploration of the psychological well-being of former ICU patients at two months after hospital discharge was a further aim of the study. Patients were administered three instruments measuring psychological well-being; DASS-21, PCL-S and ICEQ. The DASS-21 (Lovibond and Lovibond, 1995) was administered to detect signs of psychological distress in the sample. The mean global DASS-21 score was 33.44±32.07 which is much higher than the population norm reported by Henry and Crawford (2005) (18.86±19.32). The subscale scores were also higher than the scores for the normative sample used in the development of the DASS (Lovibond and Lovibond, 1995). However the percentage of patients in the sample whose subscale scores exceeded the 'severe' category was similar to the proportion reported in a study specifically designed to examine the performance of the DASS in an ICU population (Sukantarat et al., 2007). Nineteen per cent of the sample reported scores greater than 20 on the depression and 14 on the anxiety subscales and nine per cent reported scores greater than 26 on the stress subscale.

The PCL-S (Weathers et al., 1993) was used to identify the presence of symptoms of PTSD. A total score of less than 41 was reported by 75% of the sample. The mean total score was 33.75±13.90. This result and the mean scores for each of the subscales are very similar to reports from healthy volunteers who comprised the control groups in previously published studies validating the PCL-S (Ventureyra et al., 2002, Weathers et al., 1993). The developers of the PCL-S originally suggested a cut-off score of 50 to trigger referral for treatment (Weathers et al., 1993). They later revised this to a range of 28 to 56, depending on the nature of trauma, as evidence came to light from validation studies performed with motor trauma and sexual assault patients (VA National Center for PTSD, 2010). In practice only seven patients in the current study reported scores of 44 or more and they were contacted by telephone and either were advised to speak to their General Practitioner about referral to a psychologist or asked permission to refer them to the ICU Social Worker. In summary the prevalence of symptoms likely to indicate PTSD diagnosis was low in the sample (approximately 20%). This is a higher prevalence rate than reports in follow up studies of former ICU studies (approximately 14%) (Weinert and Sprenkle, 2008, Cuthbertson et al., 2004) and much higher than the estimated population

prevalence rate (3 to 6%) (Terhakopian et al., 2008). However it should be highlighted that different instruments have been used to identify PTSD symptoms in ICU patients, which may contribute to the prevalence rate of PTSD given that PCL-S scores compared favourably with those of healthy individuals in investigations using the PCL-S. The small sample size in this study could also have led to an overestimation of the prevalence.

The ICEQ (Rattray et al., 2004) was administered specifically to assess the patients' perceptions of the ICU experience. Responses to most items of the ICEQ were analogous to the results reported by Rattray et al.(2010), in particular there was high agreement in the responses for three items (one, 11 and 12), 'Most of my memories of intensive care are blurred', 'I thought the care was as good as it could have been' and 'I was able to let people know what I wanted', in both studies. Responses to the frequency items were less comparable. In general, patients in the current study reported better awareness of where they were and what was happening in ICU than in the study by Rattray et al. (2010).

The study was exploratory in nature however an additional aim of the current study was to determine the effectiveness of sleep promoting activities (a rest and sleep guideline) suggested by the ICU health care personnel. Despite an inability to assess differences in PSG sleep data between the study groups (because of the reliability of the analysis) other evidence (for example patient self-reports of sleep quality) suggests that the Guideline either did not result in a change in sleep quality or quantity or that guideline adoption was limited. Evidence from environmental sound recording that is, persisting high sound pressure levels and frequent sound peaks above 80 dB(C), together with low guideline adoption rates in the postintervention phase (Chapter four) suggest that there was limited implementation of the practices contained in the Guideline. It should also be recognised that a number of factors may have potentially confounded any possibility of detecting a true difference in sleep quality and quantity between the groups including heterogeneity in patient characteristics (even though the groups were equivalent for the selected demographics), variations in patients' usual sleep prior to hospitalisation,

variations in clinicians' practices and differences in the PSG equipment and sleep technologists.

6.6 Adoption of the rest and sleep guideline

A rest and sleep guideline was developed using a consultative iterative approach in which data from the preintervention phase were presented to the ICU health care personnel. The Guideline was then implemented using multifaceted strategies including academic detailing, presentations and reminders which were previously found to be successful in the study ICU. Reminders, audit and feedback comprised the majority of the on-going efforts at sustaining adoption. Adoption of the Guideline was monitored throughout the postintervention phase.

Adoption was assessed using a predetermined method in which 'minimal', 'good' and 'excellent' criteria were nominated for the degree each section of the Guideline was in use. Adoption rates for all sections were low and did not increase through the postintervention phase. There was evidence of a limited uptake of 'Optimise circadian rhythm'. The most likely explanation for the lack of evidence of guideline uptake was the restricted time over which it was implemented. Another limitation was that audits were not conducted in the preintervention phase so it is possible that there were important improvements in sleep promoting practices between the study phases which were not assessed. Chapter four contains a more detailed discussion about the development and implementation of the guideline and auditing process.

6.7 Strengths and limitations of the study

There are a number of strengths of this study which warrant consideration. These include the use of PSG to perform 24-hour sleep recording in ICU patients: simultaneous collection of potentially sleep disruptive environmental and patient factors; collection of data related to the patients' perspective at several different time points; the consultative approach to guideline development and implementation; and the collection of process and outcome data in the postintervention phase.

Twenty-four hour PSG recordings of patients' sleep in ICU are rarely performed and previously published studies report much smaller sample sizes compared to the current study in which data were collected and analysed for 53 patients. (Twenty-four hour PSG recording is required to allow a thorough assessment of the nature of sleep disruption in a population known to experience circadian rhythm anomalies.) This study contributes to the understanding of sleep disturbance in an Australian ICU population as there are no previously published studies using 24-hour PSG recording in an ICU in Australia (at the time of writing).

The simultaneous data collection of many potentially sleep disruptive environmental and patient factors together with PSG, performed in the current study, is infrequently performed or not thoroughly reported in published ICU studies. In the most comprehensive published study an infrared camera along with a sound level meter were used and patient related data were collected including positive blood cultures and sedative, opioid and vasoactive medications but illuminance levels were not reported (Gabor et al., 2003). Many of the ICU studies reporting 24-hour PSG recording only contain accounts of the types of medications administered (and occasionally the doses) (Aurell and Elmqvist, 1985, Cooper et al., 2000, Friese et al., 2007, Johns et al., 1974) and the number of events (Hardin et al., 2006, Hilton, 1976, Freedman et al., 2001). The presence of positive blood cultures was reported by Freedman et al. (2001), Gabor et al. (2003) and Hardin et al. (2006). Freedman et al. (2001) also reported sound pressure levels. In the current study, sound pressure and illuminance level, patient care and treatment event, medications including dose, evidence of the signs of SIRS, minimum and maximum ambient temperature and prehospital sleep quality data were collected making it one of the most comprehensive investigations into ICU patients' sleep to date.

The collection of patients' self-reported sleep quality and perceptions of sleep disruption in ICU was a further strength of the study. Patient reported outcomes are considered second only to mortality in importance in clinical research. Furthermore sleep is a highly subjective experience so any study seeking to investigate the quality of sleep

arguably requires concomitant self-report from the participants. Patients were asked to report on their sleep in the Hospital ward and at home during recovery. This unique approach has the potential to allow inferences to be made about the effect of sleep disturbance in ICU on sleep during recovery in future investigations using larger sample sizes.

A consultative approach to guideline development and implementation was used out of respect for health care personnel and to increase the likelihood of adoption and long term sustainability of the Guideline. The development of the Guideline was based on a specific solution focused approach which has been shown to progress practice development in several different health care contexts including the emergency department (Moss and Walsh, 2009), cardiology (Walsh et al., 2008) and aged care (Walsh et al., 2006). To date no published reports of the use of this uniquely solution focused method of engaging clinicians in ICU are available. In the current study the approach was highly effective at eliciting suggestions from and encouraging constructive discussions among ICU health care personnel resulting in consensus about the content of the rest and sleep guideline.

The selection of multifaceted methodology for guideline implementation was based on research evidence and previous experience of effectively implementing a sedation guideline in the study ICU (Elliott et al., 2006a). This evidence based approach is discussed in detail in Chapter four.

The collection of process and outcome data provided a measure of guideline usage and adoption rates and strengthened the implementation process by revealing areas within the Guideline which required more promotion. The collection of process data also overcame the potential weakness of the preintervention-postintervention study when there may be uncertainty about whether an intervention is actually used. In fact other comparative research designs such as the randomised control trial were considered but the randomisation of patients to an intervention or control group would have been impractical in this study in which the aim was to change ICU health care personnel

behaviour and work practices. The geographical layout and work organisation would have lead to contamination of a control group.

The study had several limitations which should be considered. Major limitations include the low reliability of the R and K analysis of the PSG data, use of different PSG equipment between phases, engagement of different sleep technologists to analyse data for the study phases, insufficient accuracy of the synchronisation of the PSG with the illuminance and sound pressure level meters and brief guideline implementation phase. Minor limitations and areas for improvement were the omission of audits of sleep practices in the preintervention phase and the use of different ambient thermometers in the study phases.

The uncertain reliability of the R and K analysis limited the ability to explore associations between sleep quality and quantity and potentially sleep disruptive factors. Interpretation of the descriptive statistics was also constrained as a consequence. However it would appear that the results are not too dissimilar to those published in previous ICU sleep studies suggesting that the reliability of the PSG analysis was adequate for reporting descriptive statistics as has been done in other studies in which the R and K criteria were used.

The switch to more up to date PSG equipment was unavoidable (the software for the Compumedics PS2 was no longer compatible with current computer operating systems), however it would have been better to collect all the data using the same equipment. There were differences in the sensitivity to electrical interference between the equipment. There was reduced clarity of the waveforms for data acquired using the ALICE LE. In addition it was decided, after extensive discussions with sleep technologist one, that a further sleep technologist who was familiar with the ALICE system should be engaged to analyse data obtained using the ALICE LE. These changes in equipment and sleep technologists may have contributed to the observed results but were unavoidable.

Regardless of concerns over the PSG analysis, exploration of potential associations between arousals and awakenings and environmental events would have been suboptimal

because the synchronisation between the internal clocks of the equipment was not absolutely precise. Manual synchronisation was performed before the study began and was accurate to within one second. However large discrepancies in time keeping by the internal clocks of the electronic devices developed over the duration of study (for example there was a discrepancy of five seconds for the data obtained between the laptop and the SLM). As there was uncertainty about the rate at which the discrepancies occurred, estimations could not be confidently made to adjust the time in order to test for associations.

An important limitation of the evaluation of the effect of the Guideline was the relatively brief guideline implementation and follow up measurement periods, dictated by duration of PhD candidature and the requirement to complete the thesis. On the basis of a previous successful experience implementing a sedation guideline in the study ICU it is highly likely that more prolonged implementation would have improved guideline adoption rates. This issue is discussed in detail in Chapter four.

Audits of ICU sleep practices were not conducted in the preintervention phase, meaning that any observed improvements in sleep practices between the phases could not be attributed to the Guideline. Also differences in the use of sleep practices by clinical personnel between the phases could not be detected.

Different thermometers were used to measure ambient temperature between the two study phases. However this limitation was unavoidable; the analogue thermometer used in the preintervention phase was broken and an identical replacement could not be found. Had there been sufficient confidence in the R and K analysis of the PSG data to report an association with ambient temperature, the use of the different thermometers might have limited interpretations.

6.8 Recommendations for future research

Notwithstanding considerable efforts to investigate sleep in the critically ill, major gaps in knowledge persist. Several areas requiring further research have emerged from

this thesis. There is little doubt that ICU patients experience highly fragmented sleep comprising mostly of stage 1 and 2, however the precise mechanisms of sleep disruption remain unclear. In addition difficulties analysing and interpreting PSG (the definitive method of measuring sleep) data compound the problem of exploring sleep disruptive mechanisms. There is a need for more reliable measurement and analysis of sleep data in ICU patients and investigations to thoroughly understand the mechanisms of sleep disruption so that interventions including pharmaceuticals can be evaluated. In addition there is a need to further investigate any effect of sleep disruption on sleep during recovery in order to maximise functional outcomes for former ICU patients.

The current study and the investigation by Ambrogio et al. (2008) have highlighted the potential difficulty of analysing PSG data of ICU patients using R and K criteria. Possible solutions to this are either a different method of sleep measurement and / or another approach to PSG data analysis. To date there is no alternative to PSG as a reliable objective method of assessing sleep in ICU patients however there is the immediate possibility of using non-manual methods of PSG analysis. In comparisons of four methods of analysing sleep in ICU patients; R and K criteria, power spectral density, EEG burst suppression and sleep-wakefulness organization pattern, power spectral density analysis of the EEG was shown to have superior reliability (Ambrogio et al., 2008). In fact power spectral density analysis (which has greater ability to detect EEG slow wave activity than manual methods (Martin et al., 1972)) with simultaneous examination of EMG activity may be a more suitable method of analysing PSG sleep data than conventional R and K sleep staging in the ICU population. This approach warrants further investigation and is part of our future ICU sleep research program.

Recognising the need to first solve the problem of improving reliability of sleep measurement and analysis, the precise mechanisms of sleep disruption in ICU patients require further exploration. There remains the need for comprehensive studies in which continuous sleep recording and environmental data are integrated with patient related sleep disturbance factors (for example melatonin metabolism, plasma inflammatory

mediators, medications) to ascertain the most appropriate and efficacious way of intervening to improve ICU patients' sleep. In addition more extensive research is required to elucidate the causes and solutions to circadian rhythm anomalies in this population.

Pharmaceutical interventions, either administration strategy or medication type, have not yet been extensively investigated. For example recent investigations into the effect of daily interruption of sedation on sleep, indicate that the nocturnal titration of sedative medication (in this case midazolam) to effect (Ramsay sedation score of four or five) produces more slow wave and REM sleep than the use of a continuous infusion using the same sedation target level (Oto et al., 2011). It remains to be seen if the same result can be achieved using a lower sedation level target, that is Ramsay score of two (patient responsive and calm), which is the goal in many Australia ICUs (Elliott et al., 2006b, O'Connor et al., 2010). Medications that show promise at increasing the likelihood of restorative sleep, including propofol and dexmedetomidine, require investigation. Propofol has been shown to produce slow wave EEG activity at low doses (plasma concentrations of 1.3 to 3.5 mcg / mL) (Rabelo et al., 2010) and prolonged sedation with propofol in animal models did not induce sleep deprivation (Tung et al., 2001). Sedation with propofol resulted in the same functional recovery as natural sleep after a bout of sleep deprivation in the same animal models (Tung et al., 2004) suggesting some restorative effect. Two investigations suggest propofol could potentially be used to promote and maintain sleep in ICU patients. In an experiment to explore the safety of propofol induced sleep (an infusion administered over two hours at bed time) as a treatment for chronic insomnia, there were significant improvements in reports of all aspects of sleep quality and daytime symptoms which persisted for months after the five day treatment regimen (Xu et al., 2011). There were a few minor adverse effects associated with the use of propofol, including dizziness, but the dose was not reported. In another study, propofol was used to produce artificial sleep in patients with obstructive sleep apnea in order to relax the pharynx, to a state representative of sleep, for nasoendoscopy examination (Rabelo et al., 2010). The low doses of propofol (previously stated) resulted in significant amounts of stage 2 and slow wave (however REM was

completely eliminated) sleep in both control and experimental groups (Rabelo et al., 2010). Importantly snoring (that is signs of airway obstruction) did not occur in healthy individuals who comprised the control group. The sleep promoting potential of dexmedetomidine an alpha-2 agonist with sedative, analgesic and hypnotic properties (discussed in the literature review, Chapter two) have not yet been investigated in ICU. Research is required to test the safety and efficacy of both dexmedetomidine and propofol to promote and maintain restorative sleep in ICU patients.

Finally, further investigation is required to explore associations between sleep quality in ICU with sleep and functional outcomes in former ICU patients (in particular sleep disruption and poor outcomes). To date this important area of practice and research has been largely overlooked in the follow up and recovery of ICU patients. Given the known physiological effects of sleep fragmentation (effects not dissimilar to a systemic stress response) (Bonnet and Arand, 2003, Zisapel, 2007) outcomes for healing and physical recovery would be potential measures for this area of research.

6.9 Recommendations for clinical practice

Sleep is a fundamental need for human health and according to current evidence is not afforded the priority it requires in the care and treatment of the critically ill. Likewise this was the case for early feeding in ICU patients two decades ago. Significant efforts were made by researchers and clinicians to promote early feeding until it became embedded in practice. It is understood that the adoption of early feeding has resulted in significant improvements in ICU patient outcomes. The ill effects of poor or limited sleep quality and quantity are not as immediately obvious as nutritional deficiencies, however long-term effects of poor sleep reported in epidemiological studies in healthy populations suggest there is an imperative to improve ICU clinical practice.

In the absence of conclusive evidence for interventions to improve ICU patients' sleep, recommendations for practice include low risk activities which are heavily based on sleep promotion advice during health. The major recommendations include the use of routine sleep assessment, noise and disturbance reduction strategies, illuminance levels

that are conducive to circadian rhythm and nocturnal mechanical ventilator modes and settings which are conducive to sleep. In addition given variations in genetics and sleep hygiene practices (for example settling and getting up times and body position) an approach to sleep promotion and maintenance which recognises and meets individual needs is recommended.

In order to intervene clinically to improve sleep an assessment is advised. In the absence of the facilities for PSG recording and analysis, patient self-report using an instrument like the RCSQ is probably the most practical and useful. Nurse assessment is an alternative when the patient is unable to self-report and may be helpful if a structured approach is taken such as the NOC. Either of these sleep assessment methods provides the potential to monitor the effectiveness of efforts to improve sleep.

Strategies to reduce noise and disturbances are necessary to create an environment conducive to rest and sleep. Despite evidence that many arousals and awakenings are induced by factors other than elevated sound pressure levels there remains the possibility of increasing the opportunity for sleep if noise is minimized. Illuminance level is a powerful zeitgeber. The current study suggests that night-time illuminance levels were conducive to sleep but daytime levels may have been too low (dim) to suppress melatonin secretion and thus lead to circadian rhythm disturbance. Great attention should be paid to ensuring that main room lights are turned on (as they emit adequate proportions of short wave length light to suppress melatonin secretion) and blinds opened during daytime outside of rest time periods.

Patients receiving spontaneous modes of mechanical ventilation should be carefully monitored for signs of hypocapnia (and serum alkalosis). Mechanical ventilation modes and settings conducive to normocapnia may lead to less sleep disturbance and should therefore be considered at night.

Finally individual approaches to care and treatment have been recommended in many nursing contexts despite limited evidence of their effectiveness (Suhonen et al., 2008). However given slight genetic variations in the homeostatic control of human sleep

(for example circadian rhythm differences) (Dijk and Archer, 2010) and personal preferences for settling, getting up times and body position, it seems logical that an individualised approach to promoting and maintaining sleep will at the very least increase the opportunity for ICU patients to sleep better.

7 Conclusion

7.1 Introduction

This thesis reports the findings of an exploratory study investigating the quality and quantity of patients' sleep over 24 hours in an Australian ICU. Data concerning environmental, patient and illness related sleep disruptive factors which were simultaneously collected are described. The quality of patients' sleep assessed using self-report, in the Hospital ward and at home two months after discharge from hospital is also presented. An additional secondary outcome, the effect of the introduction of a rest and sleep guideline, was examined. Accordingly, the extent of the adoption of the Guideline by health care personnel was described.

As described in Chapter two, ICU patients typically experience highly fragmented sleep comprised predominantly of stage 1 and 2 with little or no slow wave or REM sleep. The mechanisms of sleep disruption are not clearly understood because only a minority of studies have simultaneously recorded sleep disruptive factors during sleep recording. It is likely that they are multifaceted and interrelated. They include both extrinsic (for example noise and care and treatment such as mechanical ventilation) and intrinsic (for example illness related pathophysiology such as the presence of inflammatory mediators, preexisting sleep disorders and discomfort) factors. Attempts have been made to ameliorate these factors with some success however often the results of interventional studies to improve sleep for ICU patients are inconclusive because evaluation is rarely performed using PSG.

The clinical practice guideline has been used to improve care and treatment in a number of health care settings. Guidelines incorporate recommendations based on the best evidence available in order to provide clinicians with standard approaches to treatment and care. Improvements in patient outcomes are dependent on their effective implementation and consequent widespread adoption. The Guideline described in Chapter four incorporated recommendations based on the best evidence available. Consultative approaches based on solution focused methods of team engagement were

used to achieve consensus about the content of the Guideline. Furthermore diffusion of innovation theory informed the multifaceted strategies used to encourage uptake and adoption of the Guideline.

7.2 Summary of findings

An exploratory approach was taken in this preintervention and postintervention study in which 24-hour PSG sleep data were collected in ICU. Convenience sampling was used. Fifty-seven patients were enrolled and sleep data were collected from 53 adult ICU patients. There was equivalence between the preintervention (n = 30) and postintervention (n = 27) groups for most sample characteristics including diagnosis, severity of illness and self-reported prehospital sleep quality. Slight differences in nursing activity and anxiety levels between the groups were noted.

7.2.1 Sleep outcomes

Patients' sleep was highly fragmented and comprised predominately of stage 1 and 2 with no or little slow wave and REM sleep. Self-reported sleep in ICU was poor. Noise was rated as the most sleep disruptive with talking rated the most disruptive sound. The nurses' observation of ICU patients' total sleep time was low and the PSG derived TST value were not compared using statistical analysis. The interrater reliability of the R and K analysis of the PSG data was lower than values obtained from sleep investigation units.

7.2.2 Secondary outcomes

Sound pressure and illuminance levels were continuously recorded during PSG sleep data collection. Sound pressure levels were elevated throughout but levels during the night-time were lower than during daylight hours. Levels were reflective of many reports in previously published studies and exceeded international standards for hospitals. While illuminance levels were low at night they were probably not high (bright) enough during daylight hours to suppress melatonin secretion. The number of patient treatment and care activities recorded during sleep recording was lower than reports in previously published international studies. Self-reported sleep quality on the Hospital ward was similar to self-reports in ICU. Patients also self-reported their sleep quality at home two

months after hospital discharge. The data indicates that there was significant sleep disruption during the early part of patients' recovery from critical illness.

Psychological well-being was assessed at home two months after discharge from hospital. It would appear that patients experienced some difficulty with symptoms of depression, anxiety and posttraumatic stress disorder. In parallel with previous evidence, patients in this study reported blurred memories of ICU.

The effect of the introduction of the Guideline was inconclusive primarily because of the inability to assess differences in the quality and quantity of sleep, measured using PSG, between the study groups. However patient self-reports, elevated sound levels in both study phases and low adoption rates suggest that there was limited uptake of the practices recommended in the Guideline.

7.3 The contribution this thesis makes to research and knowledge

In conclusion the content presented in this thesis contributes to the understanding of sleep in patients treated in an Australian ICU. To date this study is the largest and most comprehensive of its kind to record sleep using PSG for 24 hours in ICU. Polysomnography recording together with nocturnal nurse observation and patient self-reported sleep data collection and simultaneous data collection of a number of potentially sleep disruptive factors was performed.

In addition the study highlights the significant challenges associated with PSG measurement and analysis in the ICU population. Only one other investigation has reported intrarater and interrater reliability for the R and K analysis of the PSG data in ICU to the same extent as this study. The results emphasize the need for either alternative techniques for measuring sleep in ICU patients or other methods of analysing PSG data.

Measurement of sleep included patients' perspectives of the quality of their sleep at several time points in their illness trajectory: prehospital, in ICU, on the Ward and two months following hospital discharge. The demonstrated feasibility of the protocol in the current study provides a framework on which to base future larger studies in order to

better understand the effect of critical illness / ICU sleep disturbance on sleep and well-being during recovery.

Finally the consultative iterative approach to Guideline development using a solution focused method resulted in consensus and the creation of a comprehensive context specific guideline. This method may be of interest to other ICU clinicians wishing to develop or adapt guidelines specific to their context particularly when the research evidence for the area of practice is limited.

APPENDIX A: Published review containing summary tables

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Review

The quality and duration of sleep in the intensive care setting: An integrative review

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ABSTRACT

Background: Sleep is essential for well-being and recovery from illness. The critically ill are in significant need of sleep but at increased risk of sleep loss and disruption.
Objectives: To determine the quality and duration of sleep experienced by adults who are patients in intensive care units and factors affecting their sleep.
Design: An integrative approach was used for this literature review in order to explore the available evidence on this topic, which has yet to be fully investigated.
Data sources: PubMed, CINAHL, Psychinfo, the Australian Digital Theses Program and ProQuest Dissertations and Theses (Interdisciplinary) databases were searched for studies conducted about sleep in adult intensive care units. Manual searches of papers identified from this search were performed to find additional studies.
Review methods: Data related to the quality and duration of sleep along with study design, sample size and intensive care context were extracted, evaluated and summarised.
Results: Total sleep time is normal or reduced with significant fragmentation. Light sleep is prolonged and deep and rapid eye movement sleep are reduced. The most likely factors affecting sleep quality are high sound levels, frequent interventions and medications. Data obtained from polysomnography are supported by patient self reports. Considerable variation in data exists between patients and studies affecting generalizability. Existing criteria for staging sleep may be inadequate for quantifying sleep in intensive care patients.
Conclusions: There is evidence that intensive care patients' sleep is significantly disrupted. Alternative methods of quantifying sleep for intensive care patients may be required. Few large observational or interventional studies have used polysomnography and simultaneous recordings of intrinsic and extrinsic disruptive factors. These studies are required in order to improve sleep for intensive care patients.

What is already known about the topic?

- Sleep is understood to be essential for physical and psychological well-being.
- Critically ill adults in intensive care units experience significant sleep disruption.

What this paper adds

- Considerable variation in sleep data exists between patients and studies.
- Generalizability and reliability of results from investigations about sleep in ICU are limited by small sample sizes related to technical challenges associated with polysomnography, EEG abnormalities and heterogeneous research populations.

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- Alternative approaches to quantifying sleep in ICU patients may be required.
- There is a need for large detailed multicentre studies using serial polysomnography to investigate sleep in ICU patients.

1. Background

Intensive care units (ICU) provide treatment to critically ill patients. Intensive care monitoring and treatments involve intrusive and invasive devices such as artificial airways and intravascular catheters. These, together with symptoms of illness and the noisy environment may lead to discomfort, including the inability to sleep. Sleep is considered to be physically and psychologically restorative and essential for healing and recovery from illness. The adverse health effects of poor sleep are understood and have short and long-term sequelae including poor cognition, susceptibility to infection and even cancer and cardiovascular disease (Ferrie et al., 2007; Gallicchio and Kalesan, 2009). Arguably, critically ill people are in greater need of undisturbed sleep but are at higher risk of sleep loss and poor sleep quality. Published studies confirm that ICU patients frequently experience profound sleep disruption (Freedman et al., 2001; Frisk and Nordström, 2003; Gabor et al., 2003). This review is a comprehensive summary of studies investigating the quality and duration of sleep together with factors affecting sleep within the ICU setting. It provides important information for clinicians working in intensive care and other acute care settings.

Sleep in the adult comprises one consolidated period of 6–8 h of total sleep time (TST) in each 24 h period occurring at night. The Sleep Efficiency Index (SEI), an alternative method of representing the quantity of sleep, is the fraction of time spent asleep during the duration of sleep monitoring (or the TST divided by the total time in bed after all lights are turned off to time of awakening). The expected SEI for a healthy adult is approximately 80–85% (Ohayon et al., 2004). Sleep duration declines with advancing age (that is from an expected TST of 7.5 h and SEI of 80% at 25 years to 5–6 h and 77% at 85 years) (Ohayon et al., 2004).

There are two main sleep states, rapid eye movement sleep (REM), which comprises approximately 25% of TST, and non-rapid eye movement sleep (non-REM) (75% of TST) (Ohayon et al., 2004). REM sleep declines slightly with aging from 25% in early adulthood to 16–18% at 85 years. The proportion of non-REM sleep does not decline with age but the proportion of light sleep, particularly stage 2 sleep, increases and slow wave sleep decreases (Ohayon et al., 2004). There are four stages of non-REM sleep: stages 1 and 2 or light sleep; stages 3 and 4 or slow wave sleep (SWS). These represent increasing depths of sleep and are usually completed in sequence in order to enter REM sleep (Kryger et al., 2005). The consolidated sleep period consists of four to six sleep cycles – stages 1–4 followed by REM sleep – which last 60–90 min. Time spent awake during the sleep period is less than 5% of TST. Arousals (emergence into lighter stages of sleep on the electroencephalograph (EEG)) are also a feature of sleep; an adult population norm (measured in the sleep investigation laboratory) is 10–22 arousals per hour (Bonnet and Arand, 2007). Published data from sleep studies in ICU are presented using the older Rechtschaffen and Kales (R and K) criteria (1968) as the recent American Academy of Sleep Medicine (AASM) criteria (Iber et al., 2007), which merge stages 3 and 4, have not yet been widely adopted. The R and K and AASM criteria describe waveform configurations and frequencies and arousals over 30 s intervals (standard epochs).

Both R and K and AASM criteria require sleep monitoring using a polysomnograph (PSG) (EEG, electro-oculography (EOG) and electromyography (EMG)). Sleep data derived from PSG provide measures of TST/SEI, time in Stages 1–4 and REM sleep, and arousals and arousal indices (number per hour of sleep). Despite being technically challenging and presenting limitations when assessing sleep in ICU patients, PSG remains the 'gold standard' of measuring sleep in this context.

Other objective methods of measuring sleep include actigraphy and Bispectral index (BIS) monitoring. Actigraphy utilises a movement sensor incorporated in a device usually worn on the wrist. Actigraphy tends to overestimate the quantity of sleep in ICU patients as they are often immobile and it provides little information about the quality of sleep (i.e. sleep stages) (Bourne et al., 2007). BIS monitoring (commonly used to assess the depth of anaesthesia) has also been used to attempt to record sleep in the ICU patient, but specific algorithms for sleep have not yet been developed and sleep data derived from the BIS have limited value (Bourne et al., 2007).

Subjective measures of sleep include questionnaires incorporating visual analogue and likert scales, for example the Richards Campbell Sleep Questionnaire (RCSQ), the Sleep in the Intensive Care Unit Questionnaire (SICQ) and the Verran/Snyder Halpern (VSH) Sleep Scale (Snyder-Halpern and Verran, 1987). The RCSQ and VSH were validated against the PSG showing a moderate correlation of $r = 0.58$ between total RCSQ score and PSG (Richards et al., 2000) and patients were shown to be able to reliably report mid-sleep awakenings >4 min using the VSH (when compared to PSG) (Fontaine, 1989). However self report instruments have limitations for ICU patients: they require a degree of cognitive acumen and sufficient memory to be completed accurately. For example Bourne et al. (2007) reported that 20% of patients were unable to complete the RCSQ mainly because they were delirious and Frisk and Nordström (2003) estimated that 50% of ICU patients were not sufficiently conscious or orientated to complete the RCSQ.

Nurse assessment instruments have also been validated against PSG, for example the Echols Sleep Behaviour Observation Tool (EBOT) (Echols, 1968) and the Nurses' Observation Checklist (Edwards and Schuring, 1993). Although nurses in the Edwards and Schuring (1993) study correctly assessed the sleep/wake state 82% of the time, others report that nurse assessment overestimates the quantity of sleep and provides limited information regarding sleep quality (Aurell and Elmqvist, 1985; Beecroft et al., 2008; Bourne et al., 2007; Richardson et al., 2007b).

2. Objectives

This review was performed to assess what is already known about the sleep experienced by adult intensive care

patients with the specific aims of addressing four questions:

- How much sleep do intensive care patients experience?
- What is the quality of intensive care patients' sleep?
- What factors affect the sleep of intensive care patients?
- What are the priorities for future research?

3. Design and methods

3.1. Design

An accepted checklist for performing literature reviews reported in the healthcare literature (MOOSE) was used to conduct this review (Stroup et al., 2000). As sleep research in ICU patients to date consists of very small heterogeneous observational studies, the statistical approaches for combined study data recommended for reporting of systematic reviews in the MOOSE guidelines were not applicable in this review. Clear objectives for the review were set out a priori. An inclusive selection process was used in order that important theory generating studies were not excluded, and an integrative rather than a systematic review was performed. There were insufficient published studies to perform a systematic review (that is a review based on a single focused clinical question using a thorough identification, analysis and synthesis of all randomised control trials). An integrative review is used to determine the comprehensive knowledge on a topic. It involves the identification, analysis and synthesis of empirical data and examination of theory from all methodological research approaches (Whittemore and Knafl, 2005). Arguably the integrative review is more suited to nursing practice as often nursing interventions are not easily investigated using randomised control trials.

3.2. Data sources

The following databases were searched: PubMed, Psychinfo, CINAHL, the Australian Digital Theses Program and ProQuest Dissertations and Theses (Interdisciplinary). The search terms used in the all of the databases were 'sleep' and 'intensive care'. The term 'intensive care' was used rather than 'critical care' because it is subordinate to 'critical care' in the MeSH hierarchy in Medline (i.e. is more specific) and its use yields many studies not relevant to the ICU study population of this review. Searches were limited to studies (i.e. clinical trial, RCT, clinical trial phase I–IV, comparative study and validation) performed with human adults (>19 years) and published in English from 1966 to May 2010 in the PubMed and CINAHL databases and human adults (>18 years) in the PsychINFO database (with no date limits). No limits were applied to the other databases. A manual search of the reference lists in the papers identified was performed.

3.3. Study selection

Original observational and interventional investigations of sleep in adult ICU patients containing sleep data derived from PSG or patient self reports while the patient was in ICU were included in the review. Given the paucity of studies published on this topic all studies reporting sleep outcomes using PSG and patient self reports in ICU patients were included. Limitations of the studies were noted and are reported. Studies with broader aims of examining the 'patient experience' of ICU were not reviewed as they were found to contain information which was not specific enough to meet the objectives of this review. However reference is made to a number of these studies as they add further information to the studies reviewed exploring patients' self reports of sleep in ICU.

The first author, a registered nurse with Bachelors and Masters degrees in nursing, together with expertise in ICU nursing and sleep, reviewed the research reports. Specific emphasis was given to abstracting the data which described the quality (i.e. proportion of each sleep stage) and duration of sleep and factors affecting sleep. In addition study design, setting and sample size were extracted and evaluated.

The published reports included in the review were organised into groups: '24 h PSG recording', 'overnight PSG recording' and 'methods other than PSG'. The data were summarised and presented in tables (Tables 1–3). Commonalities and patterns in sleep outcomes according to accepted sleep definitions were noted and are discussed in the text.

4. Results

Of the 650 records retrieved from the search of the databases, 140 were found to be potentially relevant. Records of abstracts were searched for duplicates and papers not likely to be relevant, leaving 53 which were obtained as full text papers. Forty-two studies were selected for review (Fig. 1). The majority of included studies were observational ($n = 26$), while the remaining 16 studies were clinical trials (there were three cross-over studies). Ten studies reported data from 24 h PSG monitoring; only five studies using PSG to assess sleep reported a final sample size of 20 or more patients (Table 1).

The international research suggests that ICU patients frequently experience sleep disruption (Freedman et al., 2001; Frisk and Nordström, 2003; Richardson et al., 2007a). The quality and duration of sleep varies between cohorts of ICU patients, however commonalities exist and the data may be summarised.

4.1. The quantity of sleep: data derived from polysomnography

Twenty-four hour monitoring, when achieved, reveals that patients' sleep was distributed approximately equally between day and night (Freedman et al., 2001; Friese et al., 2007; Hardin et al., 2006). Because ICU patients' sleep was distributed across 24 h, TST data from 24 h sleep investigations are discussed in detail here. The TST observed varies considerably between and within cohorts but the average may be within normal limits (i.e. 6.5–7.5 h). A summary of the nature of the quality and duration of ICU patients' sleep is summarised in Table 4.

Table 1
24 h polysomnograph recordings in ICU patients.

Author (s) (Year) Design	Number of patients and ICU context	Total sleep time (h)	Stage 1 and 2 (approx. %)	Stage 3 and 4 (approx. %)	REM (approx. %)	Factors affecting sleep and other results	Details/comments
Aurell and Elmqvist (1985) Descriptive	9, surgical	(Stage 1 excluded) 00:58–03:48	37–99	0–4	<1–6	Poor correspondence between nurses and PSG TST (7 h versus 2.7 h, $p < 0.001$)	Recording started within 2 h postoperatively and continued until ICU discharge or 83 h (24 h monitoring) Nurses rated sleep every 5 min Isolation room
Cooper et al. (2000) Descriptive	20, medical and surgical	Disrupted sleep: night; 3.0 ± 1.9, day; 4.0 ± 2.9 Atypical sleep: night; 4.0 ± 2, day; 6 ± 3	Disrupted sleep: stage 1: 40, Stage 2: 30 Atypical sleep: stage 1: 35, stage 2: 15	Disrupted sleep: 10–15 Atypical sleep: 45	Disrupted sleep: 10 Atypical sleep: 4	Mean arousals/hour Disrupted sleep: 20–25 Atypical sleep: 5–8 Risk of sleep disruption associated with lower doses of morphine and lorazepam, lower severity of illness and GCS $\geq$10	Muscle relaxants, sedatives and opioids used. Some patients comatose All mechanically ventilated Patients divided into groups; atypical sleep ($n = 5$), disrupted sleep ($n = 8$) and coma ($n = 7$). No recognisable sleep data for coma group
Edéll-Gustafsson et al. (1999) Descriptive	38, cardiothoracic (pre-op, $n = 37$, post-op, $n = 36$, home, $n = 34$)	Pre-op 07:01 Post-op 08:03 Home 7:28	Night: Stage 1: 11–30 Stage 2: 55–62 Day: Stage 1: 15–38 Stage 2: 47–62	Night: Stage 3 and 4 7–18 Day: Stage 3 and 4 6–13	Night: 0–17 Day: 0–10	Mean arousals; 31–56/h Significant sleep disruption in postoperative period. Factors affecting sleep not reported	Light sedation only Comparison of sleep of 38 patients at three time points; 24 h pre-operatively, 48 h 3 h after surgery and for 24 h 1 month after surgery (at home)
Freedman et al. (2001) Descriptive	22 (final 17), medical	08:48 (1:42–19:24)	Stage 1: 59 Stage 2 26	9	6	Mean sleep periods 41 (5–100); mean length of sleep bout 15 min 26% (0–75%) of awakenings related to environmental noise	Mechanically ventilated patients ($n = 20$). Intermittent sedation used in eight patients (14 none) Unscorable data for five with/prior to developing sepsis. Fourteen 24 h recordings; eight patients studied for 48 h. No patients had consolidated sleep
Friese et al. (2007) Descriptive	16, surgical	8:16	Stage 1 and 2: 96	Stage 3 and 4: 1	3	No correlation between sedation and sleep disruption.	Five mechanically ventilated patients, 13 received opioids and 3 sedatives Sleep was significantly disrupted
Gabor et al. (2003) Descriptive	Seven patients, (six healthy volunteers), Med/surg	Patients 6:12	Patients Stage 1: 19 Stage 2: 64	Patients Stage 3 and 4 3	Patients 14	Arousals 10/h Awakenings 11/h 50% of sleep during day	All patients mechanically ventilated six received benzodiazepines

Table 1 (*Continued*)

Author (s) (Year) Design	Number of patients and ICU context	Total sleep time (h)	Stage 1 and 2 (approx. %)	Stage 3 and 4 (approx. %)	REM (approx. %)	Factors affecting sleep and other results	Details/comments
Hardin et al. (2006) Descriptive	18; medical	10–18	Stage 1: 5–20 Stage 2: 28–57	Stages 3 and 4: 31–49	IS: 3, NMBA/CS: (not detectable)	Arousals/h: <population norm. Increased delta wave activity associated with sedation. Sleep architecture abnormal for all patients. > 50% sleep during the day	All mechanically ventilated, three groups: intermittent sedation (IS), continuous sedation (CS) and neuromuscular blocking agent (NMBA/CS). More ARDS and higher severity of illness NMBA/CS group
Hilton (1976) Descriptive	9, respiratory	First 24 h: 05:20 Second 24 h: 05:48 (00:06–13:20)	First 24 h: Stage 1: 49 Stage 2: 41 Second 24 h: Stage 1: 32 Stage 2: 43	First 24 h: Stage 3: 0.7 Stage 4: 0.1 Second 24 h: Stage 3: 14 Stage 4: 4.5	First 24 h: 3.6 Second 24 h: 6.0	22% of sleep disturbances caused by therapeutic interventions, 13% staff noise. Confirmed in interviews. 40–50% sleep during the day	No. of patients receiving mechanical ventilation and sedative agents not provided. Observation and interview over a 48 h period
Johns et al. (1974) Descriptive	5, surgical (cardiothoracic)	24 h postoperative 1–4	Not stated	Not stated	Four patients had none, one patient had nine	Large variability between and within patients Opioid/barbiturate medications and frequent interventions postulated as most likely to cause sleep disruption	Four patients mechanically ventilated. Sleep recorded pre-op and several weeks post-op. Used palmar skin resistance instead of EMG with EOG and EEG. R and K criteria not used—counted no. of EEG waves exceeding 40 μV

Table 2
Overnight polysomnography (PSG) in ICU patients.

Author (s) (Year) Design	Number of patients and ICU context	Total sleep time (h)	Stages 1 and 2 (approx. %)	Stages 3 and 4 (approx. %)	REM (approx. %)	Factors affecting sleep and other results	Details/comments
Aaron et al. (1996) Descriptive	6 Respiratory	05:25	Stage 1: 14 Stage 2: 43	5	6	Mean arousals 19/h mean sound peaks (>80 dB)/h 19	One patient received non-invasive ventilation. Three patients received light sedation/analgesia Environmental noise an important determinant of sleep disruption
Alexopoulou et al. (2007) Clinical trial (cross-over study)	17 Medical	Not stated	Protocol A: PAV_{high}: 87 PS_{high} 90 Protocol B: PAV_{high}: 94 PS_{high}: 78	Protocol A: PAV_{high}: 12 PS_{high} 10 Protocol B: PAV_{high}: 4 PS_{high}: 2	Protocol A: PAV_{high}: 1 PS_{high} none Protocol B: PAV_{high}: 2 PS_{high} 20	Arousals Protocol A: 4–7/h Protocol B: 8–12/h Periodic breathing associated with increased sleep disruption	PAV+ versus PS (cross-over in three patients) Protocol A: sedated with propofol 21:00–07:00 h Protocol B: non-sedated 23:00–06:00 Level of support/settings affects sleep
Beecroft et al. (2008) Descriptive	12 Med/surg	03:06 (medians reported)	Stage 1: 20 Stage 2: 74	Stage 3 and 4: 0.15	0.4	Arousals 12/h Actigraphy/nurse assessment grossly overestimated TST. Correlation poor between PSG and act/nurse	Lightly sedated and mechanically ventilated Simultaneous PSG and actigraphy recording. Nurses blinded to PSG Overnight 19:00–06:00 h (8–12 h recording)

Bosma et al. (2007) Clinical trial (cross-over study)	13, Med/surg	PAV: 05:34 PSV: 05:14	Not stated	Not stated	Not stated	Arousals PAV: 16/h PSV: 9/h Patient-ventilator asynchrony associated with arousals	Patients not sedated Cross-over PS versus PAV (2 nights; 22:00–08:00 h) Timing/relationship of ventilator pressure and patient generated pressures influence the quality of sleep not the ventilator mode
Broughton and Baron (1978) Descriptive	12, Cardiology	05:39	45	26	10	Awakenings 20, SEI 78 Angina lead to sleep disruption	Nocturnal recordings up to nine nights following myocardial infarction (light sedation with diazepam, respiratory status not stated)
Cabello et al. (2008) Clinical trial (18 h recording)	15, medical	05:14 (Medians reported)	Stage 1: 8 Stage 2: 63	19	10	Arousals and awakenings: 29/h Respiratory events <10% of sleep fragmentation Ventilator mode was not a primary influencing factor sleep disruption. SEI 43	Patients not sedated. Compared three ventilator modes
Cochen et al. (2005) Descriptive	19, general	GBS group during hallucinations 03:40 (controls 04:56)	GBS group: stage 1: 25 stage 2: 49 Controls stage 1: 14 stage 2: 43	GBS group: 14 Controls: 29	GBS group: 12 Controls: 14	Hallucinations and vivid dreams associated with increased muscle tone during REM sleep. Alternative methods of staging REM sleep were used	Guillian-Barre syndrome ($n = 13$) and other injuries ($n = 6$) were sleep monitored (8–24 h but mostly at night). Specific aim of examining the association of vivid dreams and hallucination with REM sleep
Fontaine (1989) Descriptive	20, Trauma	04:05	77	13	10	Mean awakenings 32 moderate to strong correlation between nurse observer and PSG. Care activities disturbed sleep although the association was not investigated	Examined relationships among measures of observed sleep, PSG, patient perception
Parthasarathy and Tobin (2002) Clinical trial	11, medical	AC: 01:30 PSA: 01:15 PSD: 01:12	Actual values not stated Stage 1 observed in all patients Only 5 patients experienced stage 2	Not observed in any patients	Observed in four patients Only 1 patient achieved REM in all three modes	Six patients developed apnoeas during PSV but none during assist-control (ACV or PSD better than PSV alone). Frequency of arousals similar for modes Hypocapnia during PSV lead to apnoea and sleep fragmentation	Mechanically ventilated patients assigned to receive at least two hours of each mode of ventilation: assist-control (AC), pressure support alone (PSA) or PS with 100 cm^3 dead space (PSD)
Richards et al. (2000) Descriptive: see also Richards and Bairnsfather (1988) (data from 14 nights)	Pilot: 9, medical Main study: 70, medical	04:43	41	9	7	SEI: 70% good correlation between sleep efficiency and total RCSQ score. Reliability good (Cronbach's $\alpha = 0.90$) correlation of the SEI and total RCSQ* score: $r = 0.58$ ($p < 0.05$)	Study to validate RCSQ* against PSG Main study: patient perception of nocturnal sleep (22:00–05:00 h) using the Richard Campbell Sleep Questionnaire (RCSQ) compared with PSG data Patients not ventilated or sedated. Sample comprised all males >50 years who were alert and orientated
Richards (1998) Clinical trial	17, cardiac	$C = 04:17$ $R = 04:32$ BM = 05:19	54–62	8–11	5–9	Awakenings: 18–21 Trend to better sleep for BM and R	Patients assigned to three groups; 6-minute back massage (BM), combined relaxation (R) or control (C). Patients were not mechanically ventilated, 21% received sedative medications. Variance between groups too large, results were N/S
Richards and Bairnsfather (1988) Descriptive	10, medical	04:45	Stage 1: 16 Stage 2: 35	Stage 3: 3 Stage 4: <1	3	Mean awakenings: 50, time awake: 42% Large standard deviations in sleep data. Possible explanation: patients located near supply cupboard were exposed to more light and noise	Ten patients not receiving mechanical ventilation or sedation were monitored for the first three nights after admission Sleep stage results based on sleep period (not TST)

Table 2 (*Continued*)

Author (s) (Year) Design	Number of patients and ICU context	Total sleep time (h)	Stages 1 and 2 (approx. %)	Stages 3 and 4 (approx. %)	REM (approx. %)	Factors affecting sleep and other results	Details/comments
Roche Campo et al. (2010) Descriptive	27, medical (8 had abnormal PSG)	05:48 (Medians reported on 19 patients)	Stage 1 and 2: 71	22	7	Strong association between NIV failure and abnormal sleep pattern PSGs for 8 patients unable to be staged	Patients admitted with hypercapnic respiratory failure were monitored for 17 h (15:00–08:00 h) to determine whether sleep disturbances occurred shortly after the initiation of NIV
Toublanc et al. (2007) Clinical trial	20, Medical	AC: 03:37 PS: 03:48 (% total recording time shown)	Both groups: 51	Both groups: 4	Both groups: 2 trend towards more in ACV group in later part of night	Awakenings: 7/h patients' perceived quality of sleep low. Ventilator settings that lead to central apnoeas were sleep disruptive. Patients awake for up to 40% of night	Patients were randomly assigned to receive either AC from 22:00 to 0:200 h and low level PS ventilation from 02:00 to 06:00 h or low level PS from 22:00 to 02:00 h and AC ventilation from 02:00 to 06:00 h (i.e. cross-over) No sedation was administered

* Richards Campbell Sleep Questionnaire (RCSQ) is an instrument specifically developed to allow critical care patients to subjectively report on their sleep. The RCSQ comprises 5 visual analogue scales 100 mm in length (0 is poor and 100 excellent). Patients are required to mark the lines. The total score is the average of the measurements of the 5 scales.

Table 3
Methods other than PSG used to record sleep in ICU patients.

Author(s) (Year) Design	Number of patients and ICU context	Method of sleep measurement and time frame	Results	Factors affecting sleep and other results	Comments
Bourne et al. (2008) Clinical trial	24, general	BIS monitoring/actigraphy/hourly nurse observation/Richards Campbell (RCSQ)* over night (22:00–07:00 h)	Total sleep time (SEI) based on analysis of BIS from nights 3 and 4: Placebo: 02:30 h (26) Placebo: 02:30 h (26) Melatonin: 03:30 h (39, $p = >0.05$) Results from other sleep measures inconclusive	One patient experienced a possible side effect (headache on one night)	Mechanically ventilated no sedatives during sleep recording (four nights). Randomised double-blind controlled trial (melatonin versus placebo). Dose of 10 mg likely too high (effects evident following day)
Brown and Scott, 1998 Clinical trial	37 patients over 204 nights preintervention and 41 patients over 193 nights postintervention, general	Nurse observation of sedation level (a sedation scale developed for the purpose of the study) and patients' nocturnal sleep.	Maximum amount of continuous sleep did not change. No change in the number of patient interruptions	No improvement in the achievement of the target sedation level	Ventilation/respiratory status not stated. Lorazepam and methotrimeprazine administered. Use of the algorithm was not assessed. No statistical inferential testing performed. Application of the findings to practice difficult
Dlin et al. (1971) Descriptive	24 (approximately), cardiac	Researcher observation 24 h (on eight occasions), structured interview with patient and questionnaires administered to nurses and doctors	Average no. of interruptions ranged from 4–12/h. Patients had little opportunity for sleep as they were interrupted frequently	Top three factors adversely affecting sleep; 1. Activity and noise, 2. Pain and physical condition, and 3. Nursing procedures	Ventilation/respiratory status not stated. TST not reported. No results from patient interviews or questionnaires administered to nurses and doctors. No sleep data provided

Freedman et al. (1999) Descriptive	203, general	Sleep in the ICU Questionnaire (SICQ) including multiple items rated using a likert scale 1–10 Administered to patients scheduled for discharge from ICU (overall perceptions of their sleep while in ICU)	Patients rated sleep at home better 7 versus 5 (1 = poor, 10 = excellent) ($p = <0.05$). Sleep quality and daytime sleepiness did not change ($p > 0.05$). Sleep quality not different for mechanically ventilated. Ventilated patients more daytime sleepiness	Top 3 disruptive factors, 1. Vital signs, 2. Phlebotomy, 3. Noise. Talking and telemetry alarms most annoying	Mechanical ventilation ($n = 30$). Sedative agents not stated. SICQ useful instrument for the assessment of environmental disturbances in ICU/ organisational change
Frisk and Nordström (2003) Descriptive	31, surgical	Patients' perception of their nocturnal sleep while in ICU using the RCSQ. Comparison of the patients' and nurses' perceptions of the patients' sleep using the RCSQ*	Mean total sleep score 45; range 0–97, mean quality of sleep 39; range 5–99, second night: no difference between patients' and the nurses' assessment (mean 53 versus 59, $p = >0.05$). Good correlation between the assessments ($r = 0.869$ $p = <0.05$)	Most common factor to disturb sleep was discomfort (e.g. pain, worry)	Number mechanically ventilated patients were not stated. Twelve patients had hypnotics or sedative agents only. 50% of patients judged capable of completing the RSCQ
Ibrahim et al. (2006) Clinical trial	32, general	24 h nurse observation (descriptors provided to bedside nurse but no formal instrument to guide their assessment)	Daytime median sleep duration; melatonin group 02:18 (00:50–03:50) versus placebo group: 01:44 (00:00–08:05) ($p = >0.05$) Nocturnal median sleep duration Melatonin group 04:00 (range 01:15–05:31) versus placebo group 04:03 (range 00:00–04:04) ($p = >0.05$)	Median procedures performed overnight; Melatonin group: 3 versus placebo group 4 No correlation between no. of procedures and TST	Trial of melatonin All patients tracheostomised and weaning from mechanical ventilation. Sedatives discontinued 12 h prior to sleep monitoring. Polysomnography would have strengthened this study
Knapp-Spooner and Yarcheski (1992) Descriptive	24, cardiac (coronary by-pass surgery)	Verran/Snyder Halpern (VSH)† Sleep Scale administered preadmission to hospital and on day three and six postoperatively to assess nocturnal sleep	Mean VSH scores (3rd day) (mm): disturbance 360 (26–602); effectiveness 256 (114–474); supplementation 236 (31–292) Mean TST (items 1 and 2) (3rd day) 06:00 (02:00–09:24)	Illness related stress did not predict sleep disturbance in this study.	Not mechanically ventilated. Temazepam ($n = 3$) and codeine administered ($n = 15$). Perceived sleep quality to near preadmission level on 6th postop day
Nicolás et al. (2008) Descriptive	104, surgical	Patients' perception of nocturnal sleep while in ICU using RCSQ* and reasons for poor sleep. Comparison with nursing records	RCSQ TST: 51 (0–94), depth: 50 (0–100), falling asleep: 55 (0–100), awakenings: 42 (0–90), ease at going back to sleep: 56 (0–100), quality of sleep: 52 (0–94)	43% agreement between nurses and patients. Nurses overestimated TST 40 times and underestimated 14 times. Procedures, noise and discomfort disrupted sleep	Not mechanically ventilated. RCSQ completed after first or second postoperative night. Sleep was light, difficulty returning to sleep and noise often cited as a disturbing factor
Nicholson et al. (2001) Descriptive	27, general	Nocturnal Bispectral Index and submental EMG recording	TST 01:38 (SWS 3.7 and REM 3.7). Normal sleep patterns in 12 patients. Three no recognisable sleep activity. Abnormal sleep patterns in 12	Trend towards more sleep disruption in renal impairment and high dose morphine	Nine patients mechanically ventilated; 12 patients received sedatives (moderate doses of midazolam, propofol and morphine). Unconventional method of sleep scoring. REM artefacts in the frontal EEG. May have underestimated the amount of REM
Olson et al. (2001) Clinical trial	379 (patients observed), neurocritical care	Nurse observation using the Nurse Observation Checklist (Edwards and Schuring 1993) at 8 time points/24 h. Predetermined 'rest' times i.e. 02:00–04:00 h and 14:00–16:00 h. Baseline data collected for 2 months 7/7. Data again collected postintervention (introduction of a quiet-time policy including light and noise reduction)	Light and noise reduction effective Intervention group 1.6× likely more than the control group to be asleep ($p < 0.05$). Higher proportion of patients appeared to be sleep during the 1400–1600 h rest time (not significant for night time observations)	Lower light and sound levels were associated with increased likelihood of being asleep	Ventilation/respiratory status not stated. Sedative agents not stated. Excluded patients with GCS < 10

Table 3 (*Continued*)

Author(s) (Year) Design	Number of patients and ICU context	Method of sleep measurement and time frame	Results	Factors affecting sleep and other results	Comments
Richardson et al. (2007a) Clinical trial	64, high dependency/ cardiothoracic ICU	Tested the effectiveness of ear plugs and eye masks. Two patient self assessment rating scales, number of hours slept and average sleep duration, were provided for nocturnal sleep. See Richardson et al. (2007b) for rating scale development	Self reported TST similar for intervention and non-intervention group. Trend towards longer sleep in the intervention group. (65% in non-intervention group slept <4 h versus 56% in intervention group)	Mixed reports for the comfort of the eye masks and ear plugs. Noise frequently cited as sleep disrupting (in both groups); staff talking and alarms	No mechanical ventilation or sedative agents during sleep assessments (16 patients were tracheostomised) Patients self selected intervention (i.e. eye masks and/or earplugs) or non-intervention. No inferential statistics provided i.e. sleep duration (sample size inadequate)
Richardson et al. (2007b) Clinical trial	82 patients and 82 nurses, general Neurosurgical Cardiothoracic	Three different rating instruments used to assess nocturnal sleep on one occasion: duration (banded in hours), comparison with normal/ average sleep and numerical scale 1–10 (1 = no sleep and 10 = slept well)	Slight association between patients' and nurses' assessment of the patients' sleep; $\gamma = 0.334$; 0.452 and 0.345 for the three items/scales	Patients preferred the rating scale: number of hours slept	Ventilation/respiratory status not stated. 27.8% tracheostomised and two intubated. Sedative agents discontinued 24 h before sleep assessment. Rating scales not validated with PSG
Richardson (2003) Clinical trial	36, medical, surgical and cardiac	Effectiveness of guided imagery and relaxation. Two dimensions (sleep fragmentation and depth) on the VSH Sleep Scale† to assess nocturnal sleep quality on three occasions in both groups	Trend towards improvement with intervention for males. Large variability in response to intervention. Sleep scores improved for all participants with time	Strong correlation between gender, time and intervention. Females slept less well	Ventilation/respiratory status not stated. Sedative agents not stated. Intervention repeated on two occasions
Scotto et al. (2009) Clinical trial	88, general (mostly cardiac)	Tested the effectiveness of ear plugs. VSH† used to assess nocturnal sleep quality after one night's sleep	Overall sleep significantly better in the intervention group ($p < 0.05$) and all dimensions except satisfaction with the amount of time to fall asleep		Exclusion criteria included mechanical ventilation and anaesthesia or sedation within the last 12 h. Actual VSH scores not stated
Shiihara et al. (2001) Descriptive	Not stated (results for two patients), Not stated	Skin potentials were recorded continuously for 9 days	Sleep duration and quality not stated. Skin potentials provided evidence of arousals rather than sleep	Potential use in detecting the on-set of delirium (the skin potential increased even in absence of stimulation prior to delirium in one patient)	No reference to sleep data
Shilo et al. (1999) Descriptive	14, respiratory (And six ward patients)	Quantity of sleep was assessed actigraphy over 72 h	Patients in ICU did not have consolidated sleep for the entire 72 h (short naps of up to 1 h). Control (ward patients) group slept 07:27 h	6-SMT excretion abnormal in all ICU patients and lower than hospital patients ($p < 0.05$)	Ventilation/respiratory status not stated. Sedative agents not stated. Actigraphy highlighted short sleep duration
Shilo et al. (2000) Clinical trial	8, respiratory (And six ward patients)	Nocturnal sleep duration was assessed using actigraphy (22:30–06:30 h)	Before melatonin mean TST 03:07 and mean awakening episodes 7. After melatonin TST was 06:24 and 1awakening episodes) versus 07:24 in ward patients (control) (statistical significant not stated)	No adverse events associated with melatonin	Double-blind study: melatonin (3 mg) or placebo at 22:00 h. Four were mechanically ventilated (six ward patients matched for age and diagnosis comprised the control group). None received sedative agents
Treggiari-Venzi et al. (1996) Clinical trial	40, surgical	Trial (comparison): effects of propofol versus midazolam on overnight sleep quality, anxiety and depression The first five items on the Hospital Anxiety and Depression Scale (HADS) used to assess the quality of nocturnal sleep on three occasions (administered 2 days apart). 0 = bad sleep and 10 = good sleep	Mean sleep scores similar; midazolam 6–7 and propofol 6–7 and improved slightly over time	Anxiety and depression levels remained high and similar. 1/3rd of patients recorded a pathological score	Patients not mechanically ventilated and only received the study sedatives. Items related to sleep the HADS have not been used in other studies measuring sleep in the ICU population

Uğraş and Öztekin (2007) Descriptive	84, neurosurgical	Face to face interviews on the ward on the day they were transferred conducted using a questionnaire developed by the investigators. Questionnaire contained items relating to sleep problems and factors affecting sleep such as noise and nursing interventions	66 (78%) patients experienced sleep problems during ICU	'Being kept immobile' (63.6%) and noisy environment (57.6%) rated most sleep disrupting. Repeatedly being asked questions to assess neurological function also rated highly sleep disruptive	Exclusion criteria included patients receiving sedative or opioid agents and patients who had been intubated

* Richards Campbell Sleep Questionnaire (RCSQ) is an instrument specifically developed to allow critical care patients to subjectively report on their sleep. The RCSQ comprises 5 visual analogue scales 100 mm in length (0 is poor and 100 excellent). Patients are required to mark the lines. The total score is the average of the measurements of the 5 scales.

† The Verran/Snyder Halpern (VSH) Sleep Scale contained 15 Visual analogue items (100 mm line) measuring three concepts; sleep disturbance, effectiveness and supplementation. Patients are required to mark the lines. The range of scores are; 0–700 for disturbance, 0–600 for effectiveness and 0–400 for supplementation. Higher scores reflect higher disturbance, effectiveness and supplementation.

The TST was of normal duration in four of the studies reviewed: 7–10 h (range) (Cooper et al., 2000); 7–8 h (range) (Edéll-Gustafsson et al., 1999); 8.8 ± 5.0 h (Freedman et al., 2001) and 8.2 ± 6.53 h (Friese et al., 2007). However the standard deviations (SDs) are much larger than those expected in a healthy adult human (1.5 h) and sleep is severely fragmented. One study revealed a prolonged mean TST of 10.9–18.9 h (Hardin et al., 2006). Twenty-four hour sleep data obtained from three groups of patients receiving moderate to large doses of sedation with or without neuromuscular blocking agents were analysed separately, intermittent sedation (low doses of benzodiazepine and opioid) ($n = 6$), continuous sedation (moderate doses of benzodiazepine and opioid) ($n = 6$) or sedation (moderate dose of benzodiazepine and low dose of opioid) plus neuromuscular blockade (vecuronium) ($n = 6$) (Hardin et al., 2006). Recognising that only limited conclusions can be made from this small study, this is the only investigation which has specifically examined sleep in patients who were administered high doses of sedative and/or neuromuscular medication. Occasionally a single patient in a study displayed a rebound phenomenon in which TST is excessively prolonged, for example 11 h and 50 min (Aurell and Elmqvist, 1985). Five studies revealed reduced mean TST ranging from 1 to 6 h (Aurell and Elmqvist, 1985; Gabor et al., 2003; Hilton, 1976; Johns et al., 1974). Reduced TST is universal in studies reporting only overnight PSG data.

Prolonged light sleep (stages 1 and 2) is also a feature common to studies using 24 h monitoring (other than Hardin et al. (2006) in which the proportion of light sleep approached normal values expected in a healthy adult) or overnight monitoring in ICU. Light sleep comprises a large proportion of TST, much higher than normal. Stage 1 and 2 sleep comprised 96–99% of TST in surgical ICU patients (Aurell and Elmqvist, 1985; Edéll-Gustafsson et al., 1999; Friese et al., 2007), and 76% and 83% in medical/trauma patients (Cooper et al., 2000; Gabor et al., 2003). Prolonged light sleep is a common finding across contexts and study designs (i.e. descriptive and interventional). In a small study ($n = 17$) comparing the effect of two modes of ventilation on nocturnal sleep, light sleep comprised 80–100% of TST (Alexopoulou et al., 2007). The majority of studies measuring nocturnal sleep reveal prolonged light sleep of similar proportion (Beecroft et al., 2008; Fontaine, 1989; Parthasarathy and Tobin, 2002; Richards, 1998). Reduced light sleep, for example 44% is a rare finding (Broughton and Baron, 1978).

Reduced stage 3 and 4 (SWS) is a common feature although values vary, for example <1% (Friese et al., 2007), <5% (with the exception of one of nine patients) (Aurell and Elmqvist, 1985), and 9 ± 18% of TST (Freedman et al., 2001), all lower than the proportion experienced by a healthy adult (20%). Interestingly SWS was prolonged in one study investigating overnight sleep in patients immediately after myocardial infarction (25%) (Broughton and Baron, 1978). In a further study of long-term ventilated medical patients (mean duration of ventilation 22 days), overnight median SWS was normal (19%) (Cabello et al., 2008).

It appears that few ICU patients experience more than 15% of TST as REM sleep. In some studies REM sleep is virtually absent (0.36 ± 0.95%) (Friese et al., 2007), with a

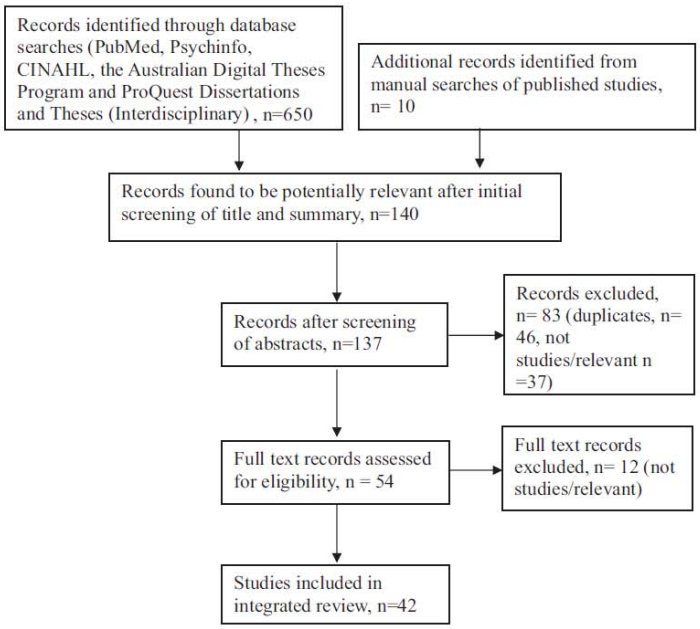

Fig. 1. MOOSE flowchart for the integrated review.

large proportion of patients not experiencing any (Freedman et al., 2001) despite efforts to reduce interruptions (<5% of TST) (Aurell and Elmqvist, 1985). Yet again values vary between individual patients and cohorts. In an interventional study comparing mechanical ventilatory modes during an 18 h recording period, median REM sleep was 10% (Interquartile range (IQR): 2–13) (Cabello et al., 2008). In 24 h recordings from respiratory/trauma patients REM was 14 ± 9% (Gabor et al., 2003), and in an overnight study involving patients after myocardial infarction it was 10 ± 6% (Broughton and Baron, 1978). Further interpretation of stage REM may be complicated by increased muscle tone. Increased muscle tone leads to the conclusion that the patient is awake despite the presence of EOG and EEG features of REM sleep (Cochen et al., 2005).

Arousal indices also differ although this may be related to interrater variability. It is well known that there are slight differences in arousal scoring and sleep staging between sleep investigation units and sleep technologists (Bonnet et al., 2007). For example Cabello et al. (2008) reported a median of 29 arousals per hour (IQR: 19–41) and Edéll-Gustafsson et al. (1999) 56.6 ± 32.6. Importantly few studies report on the number of interventions and nursing care activities during sleep monitoring so that the intrinsic arousal and awakening rate is difficult to ascertain. In addition ICU patients do not appear to transition through

Table 4
Summary of the nature of the quality and duration of sleep in ICU patients (measured with polysomnography).

Parameter	Deviation from expected population norm
Total sleep time (TST)	Normal/reduced/prolonged (wide variation)
Time at which sleep occurs	Approximately 50/50% night/day
Non-REM stage 1	Prolonged
Non-REM stage 2	Prolonged
Non-REM stage 3	Reduced
Non-REM stage 4	Reduced
REM	Reduced
Sleep fragmentation	Severe
Major factors thought to adversely affect sleep	High sound levels
	Non-circadian light levels
	Frequent interventions and care activities
	Critical illness (e.g. inflammatory response, deranged circadian rhythm)
	Medications (e.g. sedative agents, opioids, beta blockers)
	Inappropriate ventilator settings (particular nocturnal)

Table 5
Summary of the nature of the quality and duration of sleep in ICU patients (subjective patient reports).

Construct	Details
Duration of sleep	Little or no sleep
Quality of sleep	Poor
Awakenings	Frequent
Daytime sleepiness	Evident
Themes emerging from patient reports	Attribute sleep disruption to noise, intrusive treatments, thirst etc.
	Approximately 30% of recovering ICU patients remember not being able to sleep

the sleep stages conventionally. REM sleep has been observed to follow stages 1, 2 or 3 and some stages may be absent (Cooper et al., 2000; Friese et al., 2007; Richards, 1998) or occur sooner after sleep onset than in healthy individuals (Cochen et al., 2005). In a group of nine patients within a respiratory ICU, only one was observed to complete a sleep cycle (96 min) (Hilton, 1976). Mean sleep bout duration has been reported as low as 15 ± 9 min (range 5.5–40) (Freedman et al., 2001).

4.2. The quality of sleep: patient self reports

Patient self reports confirm the results from investigations using PSG. A summary of the quality and duration of sleep reported by ICU patients is in Table 5. Patients rate the overall quality of their sleep as poor (Freedman et al., 1999; Frisk and Nordström, 2003; Richardson et al., 2007a). More specifically they report light sleep with frequent awakenings, as well as considerable difficulty falling asleep and returning to sleep (Frisk and Nordström, 2003; Rotondi et al., 2002). For example, in a study conducted in a Swedish ICU ($n = 31$) comparing patients' and nurses' assessment of patients' sleep using the RCSQ, mean sleep depth reported by patients was 40.2 mm on the 100 mm scale and quality of sleep 39 mm (range 0–96). Scores on the other scales were slightly better, but the overall total sleep score was 45.5 mm, indicating poor sleep quality (Frisk and Nordström, 2003). Of note patients who received hypnotics had significantly poorer sleep (mean 31.6 mm) compared to those who did not (mean 54.3 mm, $p < 0.5$). Contrary to other studies such as Nicolás et al. (2008) and Richardson et al. (2007b), there was a strong correlation between nurse and patient assessment using the RCSQ ($r = 0.869$) but only 13 patients and nurses were included in this analysis. Patients in these studies remarked on the noise levels and in particular the disruption they experienced as a result of conversations by health care personnel.

The findings of Frisk and Nordström (2003), together with the wide variation in sleep scores (29% of patients had a total sleep score of 25 mm or below – very poor sleep – and 26% had a score above 75 mm – very good sleep), are confirmed in data obtained in other studies and countries (Freedman et al., 1999; Hofhuis et al., 2008; Nicolás et al., 2008; Richardson, 2003). In a study ($n = 62$) conducted in a cardiothoracic ICU in Britain to improve patients' sleep, 70% of patients reported sleeping less than 8 h and over 50% less than 4 h (range:0–8 h) (Richardson et al., 2007a). Freedman et al. (1999) reported that sleep quality at home was rated seven compared to five in ICU (Likert scale: 1–10) using the SICQ by a group of patients who were ready for discharge from several ICUs in a hospital in North America. Patients ($n = 104$) treated in a surgical ICU in Spain had a mean score of 52 ± 27 mm (range 0–100) on the RCSQ with 28% scoring over 66 mm and 23% 'attained low scores' (Richardson et al., 2007a). Although not specifically asked to rate the quality of their sleep, 48% of patients asked about their experiences in an ICU in the Netherlands said they had sleep problems in ICU (Hofhuis et al., 2008).

Self reports by patients confirm noise, interventions, nursing activities, discomfort and anxiety adversely impact on their sleep. A recent study revealed that patients ($n = 88$) who wore ear plugs reported significantly better sleep ($p = 0.002$) than patients in the control group (Scotto et al., 2009), suggesting that noise may have been responsible for sleep disruption. In a study ($n = 104$) to describe the perception of surgical patients' night-time sleep, participants were invited to comment after completing the RCSQ (Nicolás et al., 2008). Pain and discomfort from invasive devices e.g. endotracheal tube and drains were cited as problematic. Furthermore patients who received non-opioid analgesics had poorer quality sleep compared to those who received opioid analgesia (47.01 ± 23.17 versus 60.11 ± 15.97 mm). Thirst was also a significant stressor reported by ICU patients and is likely to contribute to sleep disruption (Cornock, 1998; Hweidi, 2007; Nelson et al., 2001). Anxiety is another patient factor which is likely under recognised (McKinley and Madronio, 2008) and potentially deleterious to sleep (Nicolás et al., 2008).

A comprehensive survey of former patients ($n = 100$) who could remember ICU, Rotondi et al. (2002) found that 39% could recall 'not being able to sleep', 35% remembered 'having trouble falling asleep' and 40% recalled 'wakening in the night'. Fifty-one percent remembered noise. Again the results of this investigation conducted in North America are comparable to the results of studies performed in other countries. For example, 'Not being able to sleep' was ranked as third most stressful by Jordanian former ICU patients (Hweidi, 2007); second after 'having pain' by patients in a Brazilian ICU (Novaes et al., 1997); and patients interviewed 3 days after discharge from an ICU in Hong Kong ranked their 'inability to sleep' third most stressful (So and Chan, 2004).

4.3. Factors adversely affecting sleep

A number of extrinsic and intrinsic factors, many of which are interrelated, adversely affect sleep in ICU patients. Extrinsic factors include noise, non-circadian light, ambient temperature and interventions and nursing care activities and treatment (e.g. medications such as opioids and benzodiazepines, mechanical ventilation settings). Intrinsic factors relate to the patient's usual sleep pattern, illness (e.g. presence of systemic inflammatory response, circadian rhythm disruption) and psychology (e.g. anxiety).

It is conceivable that ICU patients might become acclimatised to the high sound and activity levels.

However evidence suggests that noise, in particular increased peak sound levels, may adversely affect their sleep in ICU (Aaron et al., 1996; Freedman et al., 2001; Gabor et al., 2003). Overall elevated/peak sound levels account for approximately one-third of arousals and awakenings (Gabor et al., 2003). The addition of 'white noise' to ameliorate the effect of peak noise has been shown to reduce arousal indices in healthy volunteers exposed to ICU noise (Stanchina et al., 2005) suggesting that the deviation from baseline rather than the peak sound level itself is the determinant of sleep disruption. However caution must be exercised in applying this to practice and further work is required to assess the effect of 'white noise' especially since particularly high baseline sound levels (71(A)dB, equivalent to noise levels in a busy shop) and an illumination level of 100 lux (equivalent to the light level of an overcast day) in one ICU were found to disrupt sleep in healthy volunteers (Hu et al., 2010).

Given that it is well known that light is a powerful 'zietgeber' (time giver) in health (Czeisler et al., 1986) it is likely that non-circadian light levels adversely affect sleep in ICU patients. However patients rarely highlight inappropriate lighting as sleep disruptive (Freedman et al., 1999). The reason for this may be that light levels are appropriate (recent data suggest this is the case i.e. 12–20 lux at night) (Perras et al., 2007) or that light levels are perceived by patients as innocuous compared to the many other annoyances they contend with such as artificial airways, mechanical ventilation and intravascular devices (Adamson et al., 2004; Rotondi et al., 2002; So and Chan, 2004).

Medications such as sedatives and analgesics are administered to ameliorate some of the discomfort associated with illness and treatment in ICU. PSG data from healthy volunteers and EEG data during anaesthesia and sleep research reveal that these and many other medications that cross the blood–brain barrier are potentially sleep disruptive. Benzodiazepines are known to reduce SWS and REM sleep and prolong light sleep (Borbely et al., 1985). Opioid medications reduce SWS and increase stage 2 sleep (Dimsdale et al., 2007). Propofol increases slow wave brain activity but suppresses REM sleep (Rabelo et al., 2010). Medications administered to affect the cardiovascular system, such as vasopressors and beta antagonists, may also adversely affect sleep architecture. Vasopressors such as noradrenaline and adrenaline likely reduce SWS and REM sleep through alpha-1 receptor stimulation. Some beta antagonists prolong sleep latency and reduce REM sleep (but this is dependent on their lipid solubility) (McAinsh and Cruickshank, 1990). Despite the lack of objective data from the ICU population to confirm or refute these findings it is likely that ICU patients' sleep is similarly affected and the effects may even be magnified.

Mode of mechanical ventilation has also been implicated in sleep disruption in ICU patients. During an investigation to compare the effect of three modes on nocturnal sleep, low expired carbon dioxide levels associated with clinically controlled pressure support ventilation (PSV) lead to hypoapnoeas and a trend to decreased TST (Parthasarathy and Tobin, 2002). A further investigation to compare the effect of two modes of ventilation on sleep by Bosma et al. (2007) reported a correlation between patient-ventilator asynchrony and number of arousals, however repeated measures of the same patients were used so the results must be interpreted with caution. Sample sizes were small ($n \leq 20$) in the three studies investigating the effect of ventilator mode on sleep making the results more useful for the generation of theory than for changes to practice (Alexopoulou et al., 2007; Parthasarathy and Tobin, 2002; Toublanc et al., 2007). The current hypothesis is that ventilator settings which reduce the likelihood of hypocapnia lead to fewer hypoapnoeas and improved sleep (Ozsancak et al., 2008; Parthasarathy and Tobin, 2002).

Arousals, awakenings and sleep fragmentation cannot always be explained by external factors and may be attributable to the critical illness itself e.g. non-circadian melatonin secretion (a sleep promoting and maintaining hormone) and the inflammatory response. Disrupted circadian rhythm is another potential factor affecting ICU patients' sleep. Serum melatonin and urinary melatonin metabolite levels have been reported to be low (Frisk et al., 2004; Perras et al., 2007) and do not follow the diurnal pattern present in health (Frisk et al., 2004; Mundigler et al., 2002; Olofsson et al., 2004; Perras et al., 2007; Shilo et al., 1999). In addition body temperature acrophase (time at which temperature is at its highest in the 24 h period) occurred at varying times in the 24 h period (normally expected in the late afternoon/early evening) and shifted 6–12 h in one retrospective study (Tweedie et al., 1989). However the association between melatonin level or body temperature with sleep disruption in ICU have yet to be investigated. Similarly acute brain dysfunction, specifically delirium, has been implicated in sleep disruption in ICU patients however until the exact mechanism is identified it is impossible to differentiate whether sleep disruption leads to brain dysfunction or vice versa (Cochen et al., 2005; Roche Campo et al., 2010).

4.4. Summary of data derived from other objective measures of sleep

Few studies have used other objective instruments of measuring sleep, such as actigraphy and BIS monitoring, and although the validity and reliability of data derived from these instruments is questioned in the ICU context (as discussed in the introduction), they are similar to the results of studies discussed previously. For example in a randomised trial of the effectiveness of administered exogenous melatonin on nocturnal sleep in ICU patients using BIS monitoring, actigraphy and nurse observation ($n = 24$) Bourne et al. (2008) reported a low SEI, although there was a trend towards a greater SEI in the group administered melatonin as measured by BIS (26% versus 39%, $p = 0.09$). Of note SEI derived from actigraphy and nurse observation were similar between groups but were much higher than those obtained by BIS (75% and 51% versus 26% for the control group). (SEI during health is 80–85%). In a descriptive study using BIS, Nicholson et al. (2001) revealed a mean TST of 98 min with correspondingly low levels of SWS and REM sleep.

4.5. Priorities for future research

To date no published study has used PSG monitoring with data collection of potentially sleep disruptive factors in ICU patients. There is a need to simultaneously make recordings of environmental and intrinsic factors in real time; continuous light and sound data; ambient temperature; the frequency and nature of patient care interruptions; patient factors such as indicators of circadian rhythm, presence of inflammatory mediators, acute brain dysfunction and medications. In addition multicentre studies using this protocol incorporating serial PSG monitoring with alternative criteria for quantifying sleep would arguably better describe the nature of sleep architecture and factors associated with sleep disruption in the highly heterogeneous ICU population. An investigation of this complexity lends itself to a multidisciplinary approach in which collaboration with sleep medicine experts, sound engineers, laboratory scientists and pharmacists is recommended.

Given the current evidence of sleep disruption in ICU patients (albeit limited) and epidemiological evidence of the long-term adverse health consequences of poor sleep, there is a need to perform well designed interventional studies. Comparative studies are needed to evaluate complex interventions, such as behavioural and organisational change to make the ICU environment more conducive to rest and sleep. Larger trials of alternative mechanical ventilation settings, particularly at night, have not yet been performed. In addition research in ICU informed by evidence from studies performed to improve sleep for 'healthy' individuals is required. Examples of these studies are trials of medications such as antidepressants and atypical antipsychotics.

5. Discussion

The technical difficulties associated with undertaking PSG and interpreting unconventional EEG data almost certainly account for the small number and size of studies in which it has been used in ICU. The most commonly used PSG montage involves the use of a minimum of nine electrodes. Correct electrode placement and maintenance of low impedance values is vital to good quality signals. Not surprisingly several studies report missing data due to poor signal quality/artifact and resulting smaller sample sizes (Cooper et al., 2000).

In addition, EEG anomalies observed in ICU patients lead to difficulties in interpreting PSG data. In fact in one study sleep data from five patients could not be scored according to conventional methods as there was sustained EEG delta wave activity accompanied by EOG and EMG signs of wakefulness (Freedman et al., 2001), leaving sleep data from only 17 patients available for interpretation. In another investigation EEG activity was either absent, atypical or representative of coma in 12 of the 20 enrolled patients (Cooper et al., 2000). Freedman et al. (2001) noted the occurrence of this polysomnographic activity 8 h prior to the onset of sepsis in five patients. It is likely that this activity is reflective of brain dysfunction since the phenomenon is also observed in delirium (Jacobson and Jerrier, 2000). Thirty percent of the patients in a recent investigation to determine whether sleep disturbances that occurred shortly after the initiation of NIV were associated with NIV failure were found to have abnormal sleep. EEG activity was a mix of theta and continuous polymorphic waves in the presence of no eye movements and low EMG activity. The investigators devised alternative definitions for sleep, wakefulness and NREM sleep but NREM stages could not be differentiated (Roche Campo et al., 2010). A study designed to test the inter-observer reliability between four methods of sleep analysis (conventional R and K staging, sleep–wakefulness organisation pattern, number of burst suppressions and spectral analysis) highlighted the difficulty of analysing the EEG of ICU patients using the R and K criteria (Ambrogio et al., 2008). Inter-observer reliability for staging sleep and identifying sleep/wake state was much higher for R and K criteria in ambulatory patients than ICU patients ($k = 0.74$ versus $k = 0.19$) (Ambrogio et al., 2008).

These factors and the heterogeneous patient populations (diagnosis, severity of illness and age vary greatly) are likely explanations for the wide variation reported in the quality and duration of sleep between studies (study exclusion criteria reduce the effect of existing sleep disorders). In addition recent genomic research indicates that genetic factors affect sleep timing, duration and structure and hence the propensity to sleep disruption (Dijk and Archer, 2010). For example the genetic phenotype associated with the 'morning type' (present in approximately 10% of the population) leads to a preference for early sleep and a shorter circadian period (23.5 h) (Dijk and Archer, 2010). It is therefore conceivable that exposure to the unique adverse conditions associated with critical illness and ICU, which are largely beyond the control of the individual leads to large variation in the quality and quantity of sleep. The dispersion of data within studies is wide (SDs commonly exceed 50% of the mean TST) giving coefficients of variation (CV) in the range of 40–70%; this presents difficulties for generalisation and we acknowledge this as a limitation of this review. For example, TST values of 8.8 ± 5 h (CV 0.56), range 1.7–19.4 h, $n = 17$ (Freedman et al., 2001) and 8.28 ± 6.53 h (CV 0.78), range 0.63–20.7 h, $n = 16$ (Friese et al., 2007) have been reported. Despite this, the methods and results warrant careful consideration in order to develop research procedures and effective strategies to promote sleep.

Regardless of the small sample sizes and dispersion of data, it is evident that ICU patients experience poor sleep quality. Further evidence to suggest that sleep quality is poor is the large number of former patients who recall sleep disturbances, nightmares and unreal memories in ICU (Freedman et al., 1999; Jones et al., 2001; Nelson et al., 2001; Nicolás et al., 2008; Roberts et al., 2007; van de Leur et al., 2004).

Sleep duration may be observed to be normal but sleep is light and highly fragmented. The data suggest that the most probable reason for prolonged light sleep is sleep fragmentation; patients experience frequent arousals and awakenings which limit their ability to progress further into a natural sleep cycle before the next interruption or arousal. Perhaps the strongest evidence to support this

supposition is the length of the longest median sleep episode reported by Freedman et al. (2001) as 15 min. Associations between the number of interventions and sleep disruption require investigation.

The critical illness itself also plays a role as arousals are often, although not always, related to environmental noise (Aaron et al., 1996; Cabello et al., 2008; Freedman et al., 2001; Gabor et al., 2003) or patient care activities (Hardin et al., 2006). The effect of an overall systemic inflammatory response during illness has been postulated as a mechanism responsible for spontaneous arousals and reduced REM sleep. Many animal studies suggest that immune activation from infection leads to increased NREM sleep and decreased REM sleep. The effect is less clear in humans and may be dose dependent. One small study ($n = 19$) revealed that low doses of injected endotoxins lead to increased NREM and higher doses appeared to disrupt sleep in healthy volunteers (Mullington et al., 2000). However cytokine levels are also altered during sleep deprivation (Vgontzas et al., 2004). Alternative explanations are the rebound phenomenon resulting from sleep deprivation or acclimatisation (Kryger et al., 2005) to the ICU environment, but in the absence of studies using continuous serial PSG monitoring and serum cytokine levels any or all of these explanations are possible.

The large variability in sleep data in the ICU population may also be attributed to disrupted circadian rhythm and acute brain dysfunction. Melatonin secretion has not been investigated in large numbers of ICU patients, although four small studies suggest melatonin secretion may be non-circadian and low in this population (Frisk et al., 2004; Mundigler et al., 2002; Olofsson et al., 2004; Perras et al., 2007). Variations in the acrophase of the core body temperature from day to day in ICU patients also suggests that circadian rhythm may be irregular/abnormal in some people treated in ICU (Tweedie et al., 1989). However trials of exogenous melatonin in ICU have been largely inconclusive (Bourne et al., 2008; Ibrahim et al., 2006; Shilo et al., 2000). Possible explanations are that objective measures of sleep were not used so it is unclear whether the patients were asleep. In addition supraphysiological doses were administered once at the beginning of the night to overcome the short half life of melatonin; the high doses required to achieve an adequate plasma level overnight likely persist in the body and may affect circadian rhythm. The effectiveness of exogenous melatonin as a sleep medication for insomnia is yet to be clearly elucidated (Buscemi et al., 2005, 2006) although it has shown promise in the over 55 years as there is an age related decrease in endogenous melatonin (Brzezinski et al., 2005).

Possible causal association between acute brain dysfunction and sleep disruption has not been thoroughly investigated. As the behavioural manifestations of sleep disruption and acute brain dysfunction (specifically delirium) involve similar anatomical structures and chemical substances, it is likely that the two are inextricably linked and cannot be differentiated (Weinhouse et al., 2009).

Patients heavily sedated with medications are often excluded from studies as sedative, opioid and hypnotic medications change the configuration of the EEG waveform and affect sleep architecture. In the only study to specifically investigate sleep in patients who were receiving sedative medications intermittently or continuously or with or without neuromuscular blocking agents, Hardin et al. (2006) revealed that there were considerable technical problems; large doses of sedatives and neuromuscular blocking agents reduce eye and muscle movement, affecting EMG and EOG activity, and likely caused an over estimation of TST using the R and K criteria. However PSG recordings corresponded to shorter light sleep and increased SWS. Notwithstanding the small sample size this study demonstrates that medications (sedatives, hypnotics and neuromuscular blocking agents are only a few of the many groups of medications which affect sleep) are yet another complicating factor during data interpretation derived from all forms of sleep measurement.

6. Conclusion

Despite difficulties analysing PSG sleep data and the great variability in sleep data obtained from ICU patients, there is evidence from studies using both objective PSG and patient self reports that ICU patients' sleep requires improvement. Total sleep time may be normal but the quality is poor. The deeper sleep stages 3 and 4 and REM sleep are severely lacking. Sleep architecture is unconventional and associated with significant fragmentation. Fifty percent of sleep occurs during daylight hours. Many factors are thought to be responsible for ICU patients' poor sleep. They include intrinsic (patient and illness) and extrinsic (adverse environmental) related factors.

Generalisation of results may be improved by more detailed large multicentre studies incorporating serial PSG monitoring with alternative criteria for quantifying sleep (described previously).

In the absence of conclusive evidence to support sleep promoting interventions in ICU, recommendations are based on practices that would likely improve sleep in health that is, noise reduction, limiting the number of interruptions to which patients are subjected and maintenance of an environment that is generally conducive to normal night-time sleep.

Conflict of interest

None declared.

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APPENDIX B: Preliminary work

Introduction

One calendar year (2008) was dedicated to preliminary work in which the investigator: mastered set-up and use of the polysomnograph (PSG); sourced, purchased and mastered the operation of an illuminance level meter (ILM); obtained by loan and mastered the use of an environmental sound level meter (SLM); selected appropriate questionnaire instruments; designed data collection forms and the data dictionary; successfully received HREC approval and performed pilot data collection of simultaneous sleep and environmental sound and illuminance levels from a series of ICU patients. This appendix outlines the preliminary work performed to increase the likelihood of successfully undertaking and meeting the aims of the study, 'Improving the amount and quality of sleep for the intensive care patient'. In addition a brief summary of analysed pilot data is presented. More extensive information about the instruments and equipment is provided in the Methods, Chapter three.

Polysomnograph (PSG) data acquisition training

The investigator undertook a self-directed training programme in the set-up and use of the PSG (approximately 80 hours in duration). This involved: reading relevant chapters in a respected sleep medicine text, Kryger et al. (2005) and the PSG operating manual (Compumedics PS2 model); consulting published studies on sleep conducted in ICU; practicing the 10/20 international system (Jasper, 1958) head measurements on a polystyrene model; practicing ten PSG set-ups and recordings on herself and healthy volunteers; observing five PSG patient set-ups in the Sleep Investigation Unit (SIU) in the Hospital in which the study took place and consulting with sleep technologists during PSG patient set-ups in ICU during pilot data collection.

Careful consideration was given to the instructions and advice received from the SIU. Instructions regarding skin preparation and the 10/20 international system (Jasper, 1958) for EEG electrode placement were thoroughly followed to increase the probability of good signal quality. Standard techniques advised by an expert sleep technologist were adopted, for example for each EEG channel the electrodes were aligned to ensure they were opposite each other, the negative EEG electrodes, that is M1 and M2, were placed on the most prominent part of the mastoid bone behind the ears and all electrodes were positioned at least 5cm from one another. In addition, during pilot data collection it was found that there was insufficient amplitude in the EMG detected from electrodes placed over the mentalis muscles so the masseter muscles were used instead.

The rationale for the number and type of PSG channels and sampling rates was based on American Academy of Sleep Medicine (Iber et al., 2007) recommendations, advice from sleep medicine experts and the practicalities of collecting sleep data in ICU.

Illuminance and sound level meters

The international health care literature was consulted to ascertain the most suitable ILM and SLM capable of continuous sampling and recording. In addition the opinion of relevant experts was also sought. At the time there were few ILMs capable of continuous sampling and recording. The most suitable ILM was sourced and trialled in the presence of the company representative. It was later purchased and used during pilot data collection. Unfortunately despite consistent reliability during pilot work, later in the main study problems arose with interruptions in communication between the laptop computer via the USB serial port connector and the ILM software was prone to 'freezing'. Attempts were made to rectify these problems with the company but they reoccurred throughout the main study.

Sound experts from the National Acoustic Laboratory in Sydney and the Faculty of Engineering and Information Technology (FEIT), University of Technology Sydney (UTS) were contacted about the most suitable SLM. An unused SLM was available in the FEIT UTS and was loaned free of charge for the duration of the study. The investigator undertook a self-directed programme in the basics of sound physics and the SLM. This involved reading a text provided by the FEIT UTS and the SLM company resources, brief tutorials with a sound engineer (D. Eager) and performing several manual recordings in the ICU. The investigator mastered the operation of the SLM before it was trialled during pilot data collection.

Questionnaire selection

Appropriate instruments to measure psychological well-being and sleep were found by searching the international health care literature and consulting with experts. Instruments were selected if they were likely to contribute to the aims of the current study and they had been published previously. The validity and reliability had been established for the selected instruments or in the case of the Sleep in intensive care questionnaire (Freedman et al., 1999) extensively tested on ICU patients. Most of the instruments had been used in published investigations conducted in ICU. Sleep experts were contacted about the most suitable questionnaire for self assessment of sleep at home. The instruments are described in Chapter three (Methods).

Human Research Ethics Committee (HREC) clearance

The National Ethics Application Form (NEAF) and Site Specific Assessment (SSA), as required for all health care research in the state of New South Wales, Australia, were completed and submitted to the Human Research Ethics Committees (HREC) of the Hospital and University. Few queries were received from either HREC and they were addressed without difficulty. An example of a HREC concern was the potential discriminatory nature of the exclusion criterion 'a history or evidence of psychiatric illness requiring medication'. (The rationale for this was the unwanted effect of medication on the EEG waveform, rendering interpretation of the amount and quality of sleep impossible.)

Pilot data collection

Pilot work was principally intended to test the feasibility of conducting sleep, illuminance and environmental sound level data collection simultaneously over a 24 hour period in ICU. A number of difficulties were addressed as a consequence which included: low EMG amplitude as described previously; excessive patient sweating jeopardising electrode attachment; practicalities of equipment placement at the bedside, for example the SLM microphone and the ILM head sensor, and enrolment of immobile patients unable to use the visual analogue scales (VAS) for one of the sleep self assessment instruments. Data collection involved 20 ICU patients (seven sleep studies were analysed and viewed) and resulted in a publication of the procedures for environmental sound level measurement in ICU and sound level data for ten sound recordings (Elliott et al., 2010).

In practice it was not possible to ameliorate excessive sweating (ambient temperature was not adjustable). However strategies to enhance electrode attachment in general were set out during pilot work. These included strict adherence to the advice for skin preparation provided by the SIU, checking and replacing electrodes when the patient was to be disturbed by the clinician for care or interventions and investigator presence during times when the patient was mobilised or repositioned.

SLM microphone and ILM head sensor positioning was decided by experimenting with a number of different locations and consulting with bedside nurses. As a result there was only one occasion when the SLM microphone was accidently knocked during data collection in the main study. On advice from an eminent sleep psychologist the ILM head sensor was relocated from the bedside trolley on which the study laptop was situated to being taped to the patients' pillows (this occurred from patient 16 in the preintervention phase and throughout the postintervention phase). The pillow position was considered

more accurate to assess 24-hour illuminance exposure to the patient's retina. In practice recordings did not vary between the two positions.

The Richards Campbell Sleep Questionnaire (RCSQ) (Richards et al., 2000) contains five VASs. Responders are required to mark the scales. A method was developed in which patients who were unable to write could respond to the RCSQ appropriately. During 'testing' patients expressed their satisfaction with the method. The Nurses Observation Checklist (NOC) (Edwards and Schuring, 1993) was tested throughout pilot work. Bedside nurses reported that completing the NOC was straight forward, did not distract them from patient care and added little to their workload.

Twenty patients underwent data collection and ten sleep studies were analysed. Table 1 contains a summary of the types of data collected from 20 patients enrolled in the pilot study.

Table 1: Number of patients undergoing data collection and number of recordings analysed

	Polysomnograph	**Illuminance level**	**Sound level**	**RCSQ[*] (ICU)**	**NOC[†] (ICU)**
Number of patients	20	11	20	8	20
Number analysed	10	10	10	8	20

[*]RCSQ=Richards Campbell Sleep Questionnaire, †NOC=Nurses Observation Checklist

A summary of demographic data is presented in Table 2. Sleep data collected in this series of ICU patients revealed variable total sleep times, prolonged light sleep (stage 1 and 2), reduced slow wave (stage 3 and 4) and REM sleep and fragmented sleep (the longest sleep period without waking was short) (Table 3).

Table 2: Pilot demographics (aggregated data)

	mean±SD*	median	range
Age	63±17	65	27-87
APACHE† II	18.4±8.1	20	5-28
BMI‡ (kg/m²)	27.8±6.2	28	19.5-44.5
ICU length of stay (days)	23.3±31.5	5	2-102
Duration of ventilation (days)	17.1±29.2	2	0-96
Diagnosis (surgical: medical/other)	11:9		
Gender (M:F)	10:10		

*SD = standard deviation, †APACHE = Acute Physiology and Chronic Health evaluation, ‡BMI = Body Mass Index

Table 3: Summary of pilot sleep data

	mean±SD*	median	range
recording time in minutes	1037±362	1044	616-1492.5
S1†%	8.3±6.7	7.7	1.3-20
S2‡%	85.6±10.5	88.1	67-98
S3§%	2.7±4.7	0.75	0-15.5
S4‖%	0	0	0
REM¶%	3.4±4.7	-	0-11
TSTin minutes**	328±131.5	278	141-602
Awakenings	17±10	17	0-33
Longest sleep period†† in minutes	107.6±98	69	25-360
RCSQ‡‡ in mm	65±26	75.4	27.4-94.2
NOC§§in hrs	5.7±2	6.25	0.75-9

*SD = standard deviation, †S1 = stage 1, ‡S2 = stage 2, §S3 = stage 3, ‖S4 = stage 4, ¶REM = rapid eye movement sleep, **TST = total sleep time, ††Longest sleep period = longest time asleep without waking, ‡‡RCSQ = Richards Campbell Sleep Questionnaire, §§NOC = Nurses' Observation Checklist

Illuminance levels collected in the environs of 12 patients indicated that illuminance was appropriate for the time of day. It was found that the main room lights

were turned off consistently before 2300 hours and illuminance was low enough at night (30 lux) to avoid suppressing melatonin secretion (Table 4).

Ten continuous environmental sound recordings were analysed (Table 4). The data indicated that there was little variability in environmental sound levels over 24 hours. Environmental data in these recordings consistently exceeded international standards for sound levels in hospital. Spectral analysis was not performed during pilot work but sound modelling (to determine the sources of some sounds) was performed during the development of the intervention. It was noted that background sound levels in an unused patient room exceeded recommendations for sound levels in hospitals. Background sound level recording in the unused patient room included the room ventilation, pressure relieving mattress and mechanical ventilator without patient care activities and talking. Peak sounds above 80 dB(C) were easily reached by simply placing metal scissors on a metal dressing trolley or raising the bedrails.

Table 4: Summary of pilot illuminance and sound level data

		mean±SD*	median	range
Illuminance recording time		1137±284	1140	786-1470
Illuminance level (lux)				
	Day†	112±252	67	0.6-7440
	Night‡	24± 85	1.5	0.3-533
Sound level recording time		17.5±4.5		13.5-24
LA_{eq}§(dB||)		56.2±4.5		
LC_{Peak}¶(dB)		107.8±7.2		
LAF_{90}(dB)**		46.8±2.5		

*SD= standard deviation, †Day=0600-2100hrs, ‡Night=2100-0600hrs, §LA_{eq}=continuous equivalent sound level, ||dB = decibel, ¶LC_{peak} =Peak sound level, **LAF_{90}=Background sound level

Summary

Considerable time and effort was invested in pilot work which resulted in the selection, mastery and testing of technical equipment and selection of questionnaires to potentially meet the study aims. The procedures and techniques selected enabled the simultaneous collection of sleep and environmental illuminance and sound levels for 24

hours in ICU. The data revealed that there was likely to be scope to improve ICU patients' sleep and environmental noise levels.

APPENDIX C: The Vancouver Interaction and Calmness Scale

The Vancouver Interaction and Calmness Scale

Instructions for use:

Add scores from the Likert scale from each construct of the scale, calmness and interaction. Two scores will be obtained which can be used to describe the patient's level of sedation.

Interaction score /30	Strongly agree	Agree	Mildly agree	Mildly disagree	Disagree	Strongly disagree
Patient interacts	6	5	4	3	2	1
Patient communicates	6	5	4	3	2	1
Information communicated by patient is reliable	6	5	4	3	2	1
Patient cooperates	6	5	4	3	2	1
Patient needs encouragement to respond to questions	1	2	3	4	5	6
Calmness Score /30	Strongly agree	Agree	Mildly agree	Mildly disagree	Disagree	Strongly disagree
Patient appears calm	6	5	4	3	2	1
Patient appears restless	1	2	3	4	5	6
Patient appears distressed	1	2	3	4	5	6
Patient is moving around uneasily in bed	1	2	3	4	5	6
Patient is pulling at lines/tubes	1	2	3	4	5	6

APPENDIX D: Participant information statement and consent form

University of Technology, Sydney and the Royal North Shore Hospital

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Clinical trial (research student project)

Improving the quantity and quality of sleep for the intensive care patient

Invitation

You are invited to participate in a research study. The aim of this study is to minimise the occurrence of sleep disruptions and improve the quantity and quality of sleep experienced by patients while in the Intensive Care Unit (ICU). Several nursing interventions will be put in place and their effect on patients' sleep quantity and quality will be measured using a portable polysomnograph. Sixty patients will undergo a single 24 hour period of sleep monitoring. A simultaneous record will be made of interruptions to the patients' sleep. Using a quality improvement approach, patients will be studied in two groups of 20-30. After each group of patients has been studied, the results will be discussed with the ICU health care personnel who will decide on practices they might implement to improve patient sleep. These might include, e.g. the use of eye shades, earplugs, and variable lighting. Several behavioural and organisational changes such as having blocks of time for uninterrupted sleep, reduction in noise (limiting conversations, sound from television and radio), and limiting the number of nursing procedures at certain times will be considered.

The study is being conducted by:

- Sharon McKinley (supervisor to R. Elliott and S. Ladanyi), Professor of Critical Care Nursing, Northern Sydney Central Coast Area Health Service and the University of Technology, Sydney (telephone: 02 9926 8281)
- Rosalind Elliott, student PhD nursing candidate, the University of Technology, Sydney
- Peter Cistulli (supervisor to R. Elliott), Director and Professor of Respiratory Medicine, The Centre for Sleep Health and Research, Royal North Shore Hospital and the Faculty of Medicine, University of Sydney
- Rachel Foley / Mary Fien, Research Officers, Northern Sydney Central Coast Area Health Service and the University of Technology, Sydney
- Suzy Ladanyi, student Masters in Nursing candidate, Lecturer, Faculty of Nursing, Midwifery and Health, University of Technology, Sydney
- Thomas Buckley (supervisor to S. Ladanyi), Lecturer, Faculty of Nursing, Midwifery and Health, University of Technology, Sydney

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'
The purpose is to investigate if certain nursing practices can minimise the occurrence of sleep disruptions and increase the quantity and quality of sleep for patients in the intensive care unit. Studies on sleep in intensive care patients show that some patients do not get enough sleep and that they are at risk of becoming sleep deprived.

2. 'Why have I been invited to participate in this study?'
You are eligible to participate in this study because you have been in the intensive care unit for more than one night and are likely to be in intensive care unit for two more days.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. 'What does this study involve?'
If you agree to participate in this study, you will be asked to sign the Participant Consent Form. The study will involve sleep monitoring, using a portable device called a polysomnograph for one 24 hour period. The procedure will involve having several small electrodes (dots which pick up and transmit electrical signals) attached to the scalp and face. A gel containing abrasive particles will be used to roughen your skin lightly to improve the electrode contact and quality of data (this is usual practice when conducting a sleep study with a polysomnograph). The electrodes are very similar to those on your chest used to monitor your heart rate. These will transmit electrical signals from the brain, eyes and chin to a computer so that your sleep can be analysed later on. Three further small sensors will be placed on your legs and chest to detect movement. The electrodes and sensors will be removed as soon as the 24 hour monitoring period is completed. The nurse caring for you will also record relevant information about any interruptions to your sleep and rest that happen during this time.

If you agree to participate in this study, you will then be asked to tell us how you felt you slept using a short questionnaire at the end of the sleep monitoring period. An investigator will also contact you after transfer from ICU to the ward to invite you to complete a questionnaire designed to gain an overview of your sleep during the whole time you were in ICU. We would also like to invite you to complete several questionnaires at home by telephone to ask you about your sleep and how you are feeling during your recovery. In addition, the researchers would like to have access to your medical record and charts to obtain information relevant to the study.

6. 'How is this study being paid for?'
One of the main investigators, R. Elliott received a scholarship to conduct the study. The other costs of the study have been covered by a generous donation

from a philanthropic charity (Northcare Foundation) which supports research and education in the Royal North Shore Hospital intensive care unit and the Australian College of Critical Care Nurses. All of the money being paid by this charity will be deposited into an account managed by the University of Technology, Sydney. None of this money is paid directly to individual researchers.

7. 'Are there risks to me in taking part in this study?'
No adverse effects or risks are foreseen as a result of this project. You may have some awareness of the electrodes and in the case that this bothers you can ask for them to be removed. There may also be risks associated with this trial that are presently unknown or unforeseeable however we have not read any reports in the international healthcare literature or witnessed any problems during feasibility studies associated with the use of polysomnography on ICU patients.

8. 'Will participating in this study affect my plans to start a family?'
No

9. 'What happens if I suffer injury or complications as a result of the study?'
It is extremely unlikely that you will suffer any injuries or complications as a result of this study, however if you believe that the study has affected your health in any way you should contact your doctor as soon as possible, who will assist you in arranging appropriate medical treatment. In addition you may call the Hospital Patient Representative on telephone 02 9926 7612.

10. 'Will I benefit from the study?'
This study aims to further knowledge and may improve the future care and treatment of patients in the ICU. However, the results obtained from the study may or may not be of direct benefit to your care and management.

11. 'Will taking part in this study cost me anything, and will I be paid?
Participation in this study will not cost you anything. There is no payment for participating in this study.

12. 'How will my confidentiality be protected?'
Only the investigators named above, health care personnel and your relative will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at the Royal North Shore Hospital.

It is possible that your personal health records and information may be disclosed to other agencies such as Human Research Ethics Committees. This will only occur when necessary and the provisions of Australian privacy law will be complied with.

13. 'What happens with the results?'
If you give us your permission by signing the Consent Form, we plan to discuss/publish the results in health care journals, university thesis and at national and international conferences. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to

you, if you wish. In addition from time to time the Human Research Ethics Committees may audit our research practices and request access to the data to ensure that we comply with their stringent policies.

14. 'What happens to my treatment when the study is finished?'
If a sleep disorder e.g. obstructive sleep apnoea is suspected as a result of this study you and the intensive care specialist will be notified. If a disorder is identified after you have been transferred from the ICU or discharged from hospital the results will be discussed with you and sent to your GP if you agree. Other than identifying a potential sleep disorder your treatment will be unaffected by involvement in this study.

15. 'What should I do if I want to discuss this study further before I decide?'
When you have read this information, one of the researchers listed on page 1 will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him/her on 02 9926 8281

16. 'Who should I contact if I have concerns about the conduct of this study?'
This study has been approved by the Harbour HREC of Northern Sydney Central Coast Health (NSCCH) and the HREC of the University of Technology, Sydney. Any person with concerns or complaints about the ethical conduct of this study should contact the Hospital Research Office (you may contact them on 02 9926 8106 and quote [HREC project number: 0809-201M]) or the University Ethics Officer (you may contact them on 02 9514 9615) who are nominated to receive complaints from research participants.

Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form. This information statement is for you to keep. A copy of the signed Consent Form will also be provided.

University of Technology, Sydney and the Royal North Shore Hospital

PARTICIPANT CONSENT FORM

To be used in conjunction with a Participant Information Statement

Improving the quantity and quality of sleep for the intensive care patient

1. I,..... of..... agree to participate as a subject in the study described in the participant information statement **(attached to this form).**

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity to ask any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the **University of Technology, Sydney and the Royal North Shore Hospital or the health care personnel involved in my care and treatment**.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact R. Elliott/ M. Fien/ R. Foley on telephone 02 9926 8281, who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

8. Complaints may be directed to the Hospital Research Office (telephone: 02 9926 8106) or the University Ethics Officer (telephone: 02 9514 9615)

Signature of participant ***(or person responsible):***	**Please PRINT name**	**Date** __/__/____
Signature of investigator:	**Please PRINT name**	**Date** __/__/____
Signature of witness: ***(bedside nurse)***	**Please PRINT name**	**Date** __/__/____

University of Technology, Sydney and the Royal North Shore Hospital

Improving the quantity and quality of sleep for the intensive care patient

REVOKING CONSENT

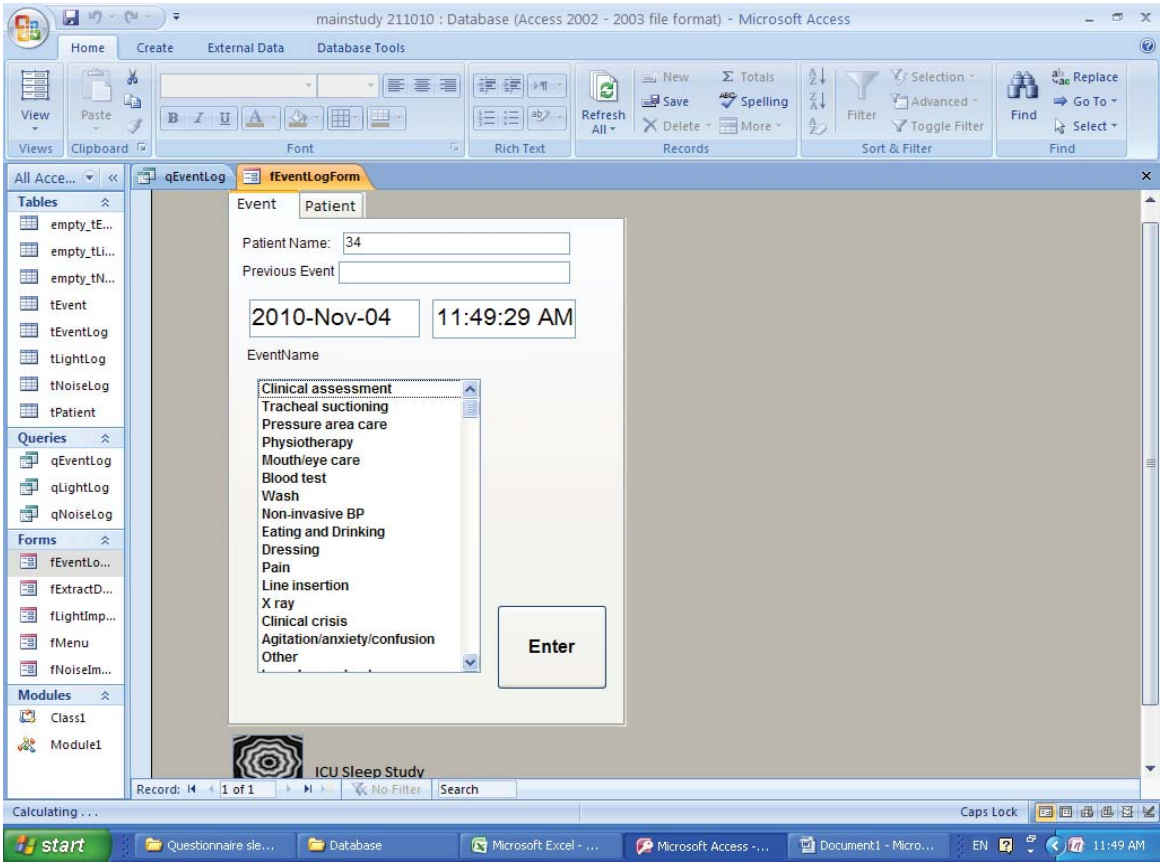
I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the **University of Technology, Sydney, The Royal North Shore Hospital or the health care personnel involved in my care and treatment.**

Signature of participant (***or person responsible):***	**Please PRINT name**	**Date**
		__/__/____

The section for Revoking Consent should be forwarded to:

Professor Sharon McKinley
Critical Care Professorial Office
Level 6, Main building
Royal North Shore Hospital
St Leonards
NSW 2065
Australia

APPENDIX E: The event log



A 'screen dump' containing the Access™ database form used by bedside nurses to record care and treatment (events) during sleep recording

APPENDIX F: Patient information and data collection forms

ICU Sleep study: Data Record Form (to be stored apart from the data collection form)

Study ID No. sequential numbering – check enrolment log
Patient label

Phone no.s	Mobile		Home	Work
Person closest to patient	Name		Relationship	Contact no.
G.P.	Name		Location	Contact no.
Follow-up on the ward	Date		By whom	
Follow-up at home	Date due		Preferred days	Preferred times
Other information				

Date followed up		**By whom**	
Comments			

Instruments completed

Instrument	**Date**
Insomnia Severity Index (on enrolment)	
Richards-Campbell Sleep Questionnaire (RCSQ) (ICU)	
Richards-Campbell Sleep Questionnaire (RCSQ) (ward)	
Sleep in Intensive care Questionnaire (SICQ) (ward)	
Pittsburgh Sleep Quality Index (PSQI) (home)	
Intensive Care Experience (ICE) (home)	
Post-traumatic Stress Disorder –specific event (PCL-S) (home)	
Depression, Anxiety, Stress and Symptoms –short version (DASS-21) (home)	

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ICU Sleep study: Data Collection Form (Study I.D. _____)

Section 1. Patient details on enrolment

DOB	--/--/----	**Age (years)**		**Sex**	M / F
Wgt (kg)		**Height (cms)**		**BMI (wt/ht^2)**	kg/m^2

APACHE III diagnostic code on ICU admission	
APACHE II severity of illness score (1st 24 hours ICU)	
APACHE III severity of illness score (1st 24 hours ICU)	

Past medical history	Include; smoking, alcohol consumption, diagnoses of diabetes mellitus and hypertension, previous surgery
Regular medications (pre admission)	Name and approximate dose
Ongoing clinical problems	Active and inactive problems e.g. weaning from ventilation, sepsis

Visual acuity (circle one)	Excellent	**Hearing (circle one)**	Excellent
	Glasses: reading/distance		Speak loudly
	Other:		Needs assistance/ hearing device

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Section 2. Baseline sedation level, pain intensity, anxiety level, neurological status and quality of sleep at home at enrolment

VICS	Interaction score:			
	Calmness score:			
Pain intensity	1-10			
	Site(s)			
Anxiety level	1-5			
GCS	E	V	M	--/15
Insomnia Severity Index score at enrolment	Total score _____ Note whether: • symptoms of insomnia have been present for > 1 month • frequency of symptoms > 3 times per week • daytime dysfunction present/reported Yes/No • dissatisfaction with sleep quality reported Yes/ no			

SICQ 1st Q	**Rate the overall quality of your sleep at home.** Use a scale of 1 to 10 (1 is poor, 10 is excellent)									
	1	2	3	4	5	6	7	8	9	10
SOFA Score at enrolment i.e. prior to sleep monitoring										

Section 3. Physiological and laboratory parameters during sleep monitoring

Ventilation (during sleep monitoring)	**self**	**PSV**	**SIMV**	**PCV**	**ACV**	**BiPAP**
Approximate duration (hrs: mins)	__:__	__:__	__:__	__:__	__:__	__:__
Time of day on mode (nearest hour using 24 hour clock)	__:__ – __:__	__:__ – __:__	__:__ – __:__	__:__ – __:__	__:__ – __:__	__:__ – __:__
	__:__ – __:__	__:__ – __:__	__:__ – __:__	__:__ – __:__	__:__ – __:__	__:__ – __:__

Highest body temperature (24 hours prior to enrolment)		**Circle one**		**Criteria**
SIRS criteria	**Y/ N**	**Y**	**N**	1. Core temperature >38 °C or <36 °C
		Y	**N**	2. Heart rate >90 beats/min
		Y	**N**	3. Respiratory rate >20/min
		Y	**N**	4. WCC >12 or <4 x 10^9/L or >10% immature neutrophils
Site/focus of infection		**Date identified**		__/__/____

Highest ambient temperature (last 24 hours)		**Lowest ambient temperature (last 24 hours)**	

Nursing Activities Score (total score during sleep monitoring) ☐

Mobility/activity (Highest level of activity achieved during sleep monitoring –circle one)

	Time and date
Stood/ walked	__:__ __/__/____
Chair	__:__ __/__/____
Sat up in bed (>45°)	__:__ __/__/____
Unable to be repositioned/moved	__:__ __/__/____
Unable to sit out	__:__ __/__/____

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 ICU Sleep study: Data Collection Form (Study I.D. _____)

Section 4. Medications during sleep monitoring

Class and type	√	Route	Total dose during sleep monitoring (record dose during sleep monitoring)	Bolus doses and times (continue below table if required)
Anxiolytics				
Diazepam				
Midazolam				
Other sedatives				
Propofol				
Haloperidol				
Temazepam				
Opioids				
Morphine				
Pethidine				
Fentanyl				
Bupivicaine				
Codeine				
Oxycodone hydrochloride (Endone)				
Oxycodone hydro SR (OxyContin)				
Tramadol				
Other analgesics				
Paracetamol				
Indomethacin				
Ketorolac trometamol				
Diclofenac				
Adrenergic stimulators				
Noradrenaline				
Dopamine				
Dobutamine				
Adrenaline				
Salbutamol (infusion)				
Beta Blockers				
Atenolol				
Metoprolol				
Other				
Corticosteroids (state type)				
Clonidine				
Lignocaine				

N.B. 1 Panadeine = 500mg paracetamol plus 8mg codeine, Panadeine forte = 500mg paracetamol plus 30mg codeine

ICU Sleep study: Data Collection Form (Study I.D. _____)

Section 5. Patient's perceived quality of sleep while sleep monitored in ICU

RCSQ (mm)	1.VAS measurement	2. VAS measurement	3. VAS measurement	4. VAS measurement	5. VAS measurement
Comments					
Total score	Sum of Vas 1 to 5 divided by 5				

Section 6. Details on discharge/death

Hospital length of stay (days)		Date of hospital admission: __/__/____ Date of hospital discharge: __/__/____
ICU length of stay (days)		Date of ICU admission: __/__/____ Date of ICU discharge: __/__/____
Duration of mechanical ventilation (days)		
Status on ICU discharge	Dead	Alive

Treatment limitations during ICU stay	Yes	No
	Comments	

Section 7. Data entry

Date entered	--/--/----		Phase 1	Phase 2
Initials (completed)				

Comments

ICU Sleep Study: Sequential Organ Failure Assessment (SOFA) scoring sheet (Study I.D. _____)

Organ system	0	1	2	3	4	9	Organ scores
Respiration PaO_2/FiO_2 **(in mmHg)**	>400	301-400	201-300	101-200 (with respiratory support)	≤100 (with respiratory support)	Variable not measured	
Coagulation **Platelets (x 10^3 /mm^3)**	>150	101-150	51-100	21-50	≤20	Variable not measured	
Liver **Bilirubin (µmol/L)**	<20	20-32	33-101	102-204	>204	Variable not measured	
Cardiovascular **Hypotension**	No hypotension	MAP <70mmHg	dopamine≤ 5.0[H]	dopamine >5.0[H]	dopamine >15.0[H]	Variable not measured	
			or any dose of dobutamine	or adrenaline ≤0.1[H]	or adrenaline >0.1[H]		
			or any dose of milrinone or any dose of levosimendan	or noradrenaline ≤0.1[H] or any dose vasopressin or any dose metaraminol or any dose phenylephrine	or noradrenaline >0.1[H]		
Renal **Creatinine (µmol/L)**	<110	110-170	171-299	300-440	>440	Variable not measured	
OR urine output				or <500ml/day	or <200ml/day		
							Total score

[H] doses in µg/kg/min i.e. mcg / (kg x 60)

Write actual value in relevant box (enables score to be checked later).

ICU Sleep Study: APACHE II Severity of Disease Classification (Study I.D. _____)

A. ACUTE PHYSIOLOGICAL SCORE (APS)											
PHYSIOLOGIC VARIABLE	**High abnormal range**					**Low abnormal range**				APS score
	+4	**+3**	**+2**	**+1**	**0**	**+1**	**+2**	**+3**	**+4**	
Temperature – rectal (ºC)	≥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	≥160	130-159	110-129		70-109		50-69		≤49	
Heart rate (ventricular response)	≥180	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 (mmHg)										
a. if FIO2≥ 0.5 record A- aDO_2	>500	350-499	200-349		<200					
b. if FIO2 ≤ 0.5 record only PaO_2					PO_2>70	PO_2 61-71		PO_2 55-60	PO_2< 55	
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)	≥180	160-179	155-159	150-154	130-149		120-129	111-119	≤110	
Serum potassium (mMol/L)	≥7	6-6.9		5.5-5.9	3.5-5.4	3-3.4	2.5-2.9		≤2.5	
Serum creatinine (uMol/L) (double point score for acute renal failure)	≥300	171-299	121-170		50-120		<50			
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 (GSC) (Score = 15 minus last non-sedated GCS or 0)										
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	

B. AGE POINTS

Assign points to age as follows:

Age (yrs)	pts
≤ 44	**0**
45-54	**2**
55-64	**3**
65-74	**5**
≥75	**6**

C. CHRONIC HEALTH POINTS

If patient has history of severe organ system insufficiency or is immuno-compromised, assign points as follows:

- 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
RENAL	Receiving chronic dialysis
CARDIOVASCULAR	New York Heart Association Class IV
RESPIRATORY	Chronic restrictive, obstructive or vascular disease resulting in sever exercise restriction (i.e. unable to climb stairs, perform household duties); or documented chronic hypoxia, hypercapnia, 2 polycythaemia, severe pulmonary hypertension (>40mmHg) or respiratory dependency
IMMUNOCOMPROMISED	Patient has received therapy that suppresses resistance to infection, e.g. immuno-suppression, chemotherapy, radiotherapy, long-term or recent high dose steroids, or has a disease sufficiently advanced to suppress resistance to infection (e.g. leukaemia, lymphoma, AIDS)

APACHE II SCORE : Sum of A + B + C = (0 to 71)

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ICU Sleep Study: APACHE III Severity of Disease Classification scoring (Study I.D. _____)

A. Physiologic variable	Range and score (circle)									B. Age	Score
Pulse	**8** ≤39	**5** 40-49	**0** 50-99	**1** 100-109	**5** 110-119	**7** 120-139	**13** 140-154	**17** ≥155		**0** ≤44	
Mean BP	**23** ≤39	**15** 40-59	**7** 60-69	**6** 70-79	**0** 80-99	**4** 100-119	**7** 120-129	**9** 130-139	**10** ≥140	**5** 45-59	
Temperature	**20** ≤32.9	**16** 33-33.4	**13** 33.5-33.9	**8** 34-34.9	**2** 35-35.9	**0** 36-39.9	**4** ≥40			**11** 60-64	
Respiratory Rate	**17** ≤5	**8** 6-11	**7** 12-13	**0** 14-24	**6** 25-34	**9** 35-39	**11** 40-49	**18** ≥50		**13** 65-69	
PaO_2 [H]	**15** ≤49	**5** 50-69	**2** 70-79	**0** ≥80						**16** 70-74	
$AaDO_2$ [HH] **Use ICU calculator on intranet**	**0** <100	**7** 100-249	**9** 250-349	**11** 350-499	**14** ≥500					**17** 75-84	
Haematocrit **% (expressed 0.X at RNSH)**	**3** ≤40.9	**0** 41-49	**3** ≥50							**24** ≥85	
WBC count **10^9/ L x 1000**	**19** <1.0	**5** 1.0-2.9	**0** 3.0-19.9	**1** 20-24.9	**5** ≥25					**C. Comorbid condition**	
Serum creatinine without ARF [=] **µmol/L**	**3** ≤43	**0** 44-132	**4** 133-171	**7** ≥172						**23** AIDS	
Serum creatinine with ARF **µmol/L**			**0** 0-132	**10** ≥133						**16** Hepatic Failure	
Urine output **ml/24 hrs**	**15** ≤399	**8** 400-599	**7** 600-899	**5** 900-1499	**4** 1500-1999	**0** 2000-3999	**1** ≥4000			**13** Lymphoma	
Serum BUN (urea) **mmol/L**	**0** ≤6.1	**2** 6.2-7.1	**7** 7.2-11.3	**11** 14.4-28.5	**12** ≥28.5					**11** Metastatic cancer	
Serum Na+ **mmol/L**	**3** 119	**2** 120-134	**0** 135-154	**4** ≥155						**10** Leukaemia/multim[^]	
Serum Albumin **g/L**	**11** ≤19	**6** 20-24	**0** 25-44	**4** ≥45						**10** Immunocompromised	
Serum Bilirubin **µmol/L**	**0** ≤34	**5** 35-51	**6** 52-85	**8** 86-135	**16** ≥136					**4** Cirrhosis	
Serum Glucose **mmol/L**	**8** ≤2.1	**9** 2.2-3.3	**0** 3.4-11.1	**3** 11.2-19.3	**5** ≥19.4						
Total for A:										**Total for C:**	

Select the worst physiological or most abnormal value on ICU admission

[H] If FiO_2 is ≥0.5 record $AaDO_2$; if FiO_2 is <0.5 record PaO_2 ; [=] Acute renal failure is defined as creatinine ≥131 µmol/L and urine output <410ml/day and no chronic dialysis, [HH] Alveolar gas exchange calculated as (FiO_2 x (713) – ($PaCO_2$/0.8)) – PaO_2; [^] Multiple myeloma

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ICU Sleep Study: APACHE III Severity of Disease Classification scoring (Study I.D. _____)

D. APACHE III acute physiology scoring for neurologic abnormalities

Eyes open spontaneously or to painful/verbal stimulation				
	Verbal response			
Motor response	Orientated, converses	Confused conversation	Inappropriate words & incomprehensible sounds	No response
Obeys verbal command	**0**	**3**	**10**	**15**
Localizes pain	**3**	**8**	**13**	**15**
Flexion withdrawal/decorticate rigidity	**3**	**13**	**24**	**24**
Decerebrate rigidity/no response	**3**	**13**	**29**	**29**

Eyes do not open spontaneously or to painful/verbal stimulation				
	Verbal response			
Motor response	Orientated, converses	Confused conversation	Inappropriate words & incomprehensible sounds	No response
Obeys verbal command				**16**
Localizes pain				**16**
Flexion withdrawal/decorticate rigidity			**24**	**33**
Decerebrate rigidity/no response			**29**	**48**
Total score for D: (Score 0 if sedated prior to GCS or uncertain/unknown)				

E. APACHE III acute physiology for acid-base disturbances

	pCO_2								
pH	<25	25 to <30	30 to <35	35 to <40	40 to <45	45 to <50	50 to <55	55 to <60	≥60
<7.15				**12**				**4**	
7.15 to <7.2									
7.2 to <7.25		**9**		**6**		**3**		**2**	
7.25 to <7.3									
7.3 to <7.35					**0**			**1**	
7.35 to <7.4		**5**							
7.4 to <7.45									
7.45 to <7.5			**0**	**2**					
7.5 to <7.55			**3**						
7.55 to <7.6								**12**	
7.6 to <7.65	**0**								
≥7.65									
Total score:									
Total APACHE III score: A + B + C + D + E =									

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ICU Sleep study: Nursing Activities Score (Study I.D. _____)

		Basic activities	Score Circle
1		Monitoring and titration	
	1a	Hourly vital signs, regular registration and calculation of fluid balance	4.5
	1b	Present at bedside and continuous observation or active for 2 hrs or more in any shift, for reasons of safety, severity, or therapy such as non-invasive mechanical ventilation, weaning procedures, restlessness, mental disorientation, prone position, donation procedures, preparation and administration of fluids or medication, assisting specific procedures	12.1
	1c	Present at bedside and active for 4 hrs or more in any shift for reasons of safety, severity or therapy such as those examples above (1b)	19.6
2		Laboratory, biochemical and microbiological investigations	4.3
3		Medication, vasoactive drugs excluded	5.6
4		Hygiene procedures	
	4a	Performing hygiene procedures such as dressing of wounds and intravascular catheters, changing linen, washing patient, incontinence, vomiting, burns, leaking wounds, complex surgical dressing with irrigation, and special procedures (e.g. barrier nursing, cross-infection related, room cleaning following infections, staff hygiene)	4.1
	4b	The performance of hygiene procedures took >2 hours in any shift	16.5
	4c	The performance of hygiene procedures took >4 hours in any shift	20.0
5		Care of drains, all (except gastric tube)	1.8
6		Mobilisation and positioning, including procedures such as: turning the patient; mobilisation of the patient; moving from bed to chair; team lifting (e.g. immobile patient, traction, prone position)	
	6a	Performing procedure(s) up to three times per 24 hours	5.5
	6b	Performing procedure(s) more frequently then 3 times per 24 hours, or with two nurses, any frequency	12.4
	6c	Performing procedure(s) with three or more nurses, any frequency	17.0
7		Support and care of relatives and patient, including procedures such as telephone calls, interviews, counselling; often, the support and care of either relatives or patient allow staff to continue with other nursing activities (e.g. communication with patients during hygiene procedures, communication with relatives while present at bedside, and observing patient)	
	7a	Support and care of either relatives or patient requiring full dedication for about 1 hr in any shift such as to explain clinical condition, dealing with pain and distress, difficult family circumstances	4.0
	7b	Support and care of either relatives or patient requiring full dedication for 3 hrs or more in any shift such as death, demanding circumstances (e.g., large number of relatives, language problems, hostile relatives)	32.0
8		Administrative and managerial tasks	
	8a	Performing routine tasks such as processing of clinical data, ordering examinations, professional exchange of information (e.g., ward rounds)	4.2
	8b	Performing administrative and managerial tasks requiring full dedication for about 2 hrs in any shift such as research activities, protocols in use, admission and discharge procedures	23.2
	8c	Performing administrative and managerial tasks requiring full dedication for about 4 hrs or more of the time in any shift such as death and organ donation procedures, coordination with other disciplines	30.0
Ventilatory support			
9		Respiratory support: any form of mechanical ventilation/assisted ventilation with or without positive end-expiratory pressure, with or without muscle relaxants, spontaneous breathing with or without positive end-expiratory pressure with or without endotracheal tube supplementary oxygen by any method	1.4
10		Care of artificial airways: endotracheal tube or tracheostomy cannula	1.8
11		Treatment for improving lung function: thorax physiotherapy, incentive spirometry, inhalation therapy, intratracheal suctioning	4.4
Cardiovascular support			
12		Vasoactive medication, disregard type and dose	1.2
13		Intravenous replacement of large fluid losses. Fluid administration >3L/m^2/day, irrespective of type of fluid	2.5
14		Left atrium monitoring: pulmonary artery catheter with or without cardiac output measurement	1.7
15		Cardiopulmonary resuscitation after arrest, in the past period of 24 hrs (single precordial thump not included)	7.1
Renal support			
16		Hemofiltration techniques, dialysis techniques	7.7
17		Quantitative urine output measurement (e.g., by indwelling urinary catheter)	7.0
Neurologic support			
18		Measurement of intracranial pressure	1.6
Metabolic support			
19		Treatment of complicated metabolic acidosis/alkalosis	1.3
20		Intravenous hyperalimentation	2.8
21		Enteral feeding through gastric tube or other gastrointestinal route (e.g., jejunostomy)	1.3
Specific interventions			
22		Specific intervention(s) in the intensive care unit: endotracheal intubation, insertion of pacemaker, cardioversion, endoscopies, emergency surgery in the previous 24 hrs, gastric lavage; routine interventions without direct consequences to the clinical condition of the patient, such as: radiographs, echography, electrocardiogram, dressings, or insertion of venous or arterial catheters, are not included	2.8
23		Specific interventions outside the intensive care unit: surgery or diagnostic procedures	1.9
Total:		Add up all numbers that apply (refer to instructions) ------/171%	

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APPENDIX G: Permission to use NAS

From: "D. Reis Miranda" <drm@skynet.be>
To: "'Rosalind Elliott'" <rmelliot@nsccahs.health.nsw.gov.au>
Date: 9/24/08 6:59pm
Subject: RE: the Nursing Activities Scoring system

Dear Mrs. Elliott,
Thank you for your letter and for your interest in NAS.
NAS is an instrument free to be used in clinical and research settings, needing only the classical quotation in any published work making use of it. Therefore, you do not need any particular authorization. I would certainly be interested in knowing the results of your research.
Please note that we published also a manual for use of the instrument. This will help you with the application of the instrument in your studies. For your convenience, I attach a copy of the manual, which was published in the electronic version of the Journal, as "article plus" to the NAS original article. I would also be pleased to helping further in case you would so require.
With kind regards

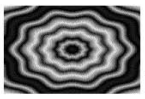
prof.dr. D. Reis Miranda
Oude Gentweg 14
8000 - Bruges
Belgium
Phone/Fax: +32 50 342456

-----Oorspronkelijk bericht-----
Van: Rosalind Elliott [mailto:rmelliot@nsccahs.health.nsw.gov.au]
Verzonden: woensdag 24 september 2008 9:54
Aan: Drm@skynet.be
Onderwerp: the Nursing Activities Scoring system

Dear Dr Reis Miranda
I am writing for permission to use the NAS in a research study. I plan to use the NAS in my study regarding sleep in ICU to quantify the dependency of each patient participant and the interventional/procedural activity they are exposed to during the sleep monitoring period.
Please could you inform me about any necessary procedures required to gain permission to use the NAS?
Many thanks

Rosalind Elliott
Nurse Researcher
Critical Care Nursing Professorial Office
Intensive Care Unit
Level 6, Main Building
The Royal North Shore Hospital
St Leonards NSW 2065 Australia
E mail: rmelliot@nsccahs.health.nsw.gov.au

APPENDIX H: Insomnia Severity Index (ISI)



During enrolment

ICU sleep study: Insomnia Severity Index Study ID. …….

Please take the time to recall the details of your friend's or relative's sleep at home and answer the following questions.

1. Please rate the current (i.e last 2 weeks at home) **SEVERITY** of this person's insomnia problem(s)

	None	Mild	Moderate	Severe	Very Severe
Difficulty falling asleep	0	1	2	3	4
Difficulty staying asleep	0	1	2	3	4
Problem waking too early	0	1	2	3	4

2. How **SATISFIED/dissatisfied** is this person with their current sleep pattern at home?

Very Satisfied				Very Dissatisfied
0	1	2	3	4

3. To what extent does this person consider their sleep problem to **INTERFERE** with their daily functioning at home (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc)

Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

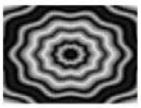
4. How **NOTICEABLE** to others do you think this person's sleeping problems are in terms of impairing the quality of their life at home?

Not at all Noticeable	Barely	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

5. How **WORRIED/distressed** is this person about their current sleep problem at home?

Not at all	Barely	Somewhat	Much	Very Much
0	1	2	3	4

1



During enrolment

ICU sleep study: Insomnia Severity Index Study ID. …….

Guidelines for Scoring Insomnia Severity Scale

Add scores for all 7 items (1a + 1b + 1c + 2 + 3 + 4 + 5) = _____

Total score ranges from 0-28

0-7 = no significant insomnia

8-14 = sub-threshold insomnia

15-21 = clinical insomnia (moderate severity)

22-28 = clinical insomnia (severe)

Insomnia severity index (copyright Charles M Morin, 1993)

Then note whether:

- symptoms of insomnia have been present for > 1 month
- frequency of symptoms > 3 times per week
- daytime dysfunction present/reported Yes No
- dissatisfaction with sleep quality reported Yes No

APPENDIX I: Permission for proxy use of ISI

From: "Charles M. Morin" <cmorin@psy.ulaval.ca>
To: "Rosalind Elliott" <rmelliot@nsccahs.health.nsw.gov.au>
Date: 18/12/2008 12:00:46 am
Subject: RE: Permission to use the Insomnia Severity Index

Dear Rosalind - Permission is granted to use the ISI in your research program; feel free to adapt the ISI as needed and I also think it is a good idea to use a significant other to obtain complementary ratings (you may just need to alter the wording for this version). Good luck!

Charles M. Morin, Ph.D.
Professeur titulaire
Université Laval
École de Psychologie, Pavillon FAS
2325, rue des Bibliothèques
Québec (Québec) Canada G1V 0A6
(418) 656-3275 (tel)
(418) 656-5152 (fax)

_____

De : Rosalind Elliott [mailto:rmelliot@nsccahs.health.nsw.gov.au]
Envoyé : 16 décembre 2008 18:18
À : Charles M. Morin; Charles M. Morin
Objet : Permission to use the Insomnia Severity Index

Dear Dr Morin,
I am currently setting up a study with the aim of improving the quantity and quality of sleep for the adult intensive care patient. In order to obtain an estimate of the patient's usual sleep at home we would like to use the ISI. Please can you grant permission to use it for this purpose? If you agree I would also like to add two words 'at home' to the end of each question (I have attached the adapted document). Would this be OK with you?

In addition I would like to ask your opinion on using a proxy/ significant other to provide responses as I plan to ask the patient's proxy to respond to the ISI on behalf of the patient. I have read your paper published in Sleep Medicine 2001 'Validation of the Insomnia Severity Index as an outcome measure for insomnia research' and note that the correlations of the responses between the patient and the significant other were moderate although statistically significant.
Regards

Rosalind Elliott
Nurse Researcher
Critical Care Nursing Professorial Office
Intensive Care Unit, Level 6, Main Building
The Royal North Shore Hospital St Leonards NSW 2065 Australia
E mail: rmelliot@nsccahs.health.nsw.gov.au

APPENDIX J: Richards Campbell Sleep Questionnaire (RCSQ)

ICU sleep study: Richards-Campbell Sleep Questionnaire
Study patient no. .....Date: __/__/_____

Each of these questions is answered by placing an "X" on the answer line. Place your "X" anywhere on the line that you feel best describes your sleep last night.

1. My sleep last night was:

Deep Sleep — Light Sleep

2. Last night, the first time I got to sleep, I:

Fell asleep almost immediately — Just never could fall asleep

3. Last night, I was:

Awake very little — Awake all night long

4. Last night, when I woke up or was awakened, I:

Got back to sleep immediately — Couldn't get back to sleep

5. I would describe my sleep last night as:

A good night's sleep — A bad night's sleep

Thank you for your assistance.

Critical Care Nursing Professorial Unit, R. Elliott, 02 9926 8281

APPENDIX K: Intensive care nurses' observation checklist (NOC)

ICU sleep study

Intensive care nurses' patients sleep observation tool (adapted from Edwards and Schuring 1993)

Please check on the patient you are looking after every 15 minutes and tick the box in the table below which best describes the patient's status.

Study no.:			**Date:** --/--/----				**Nurse initials:**		
Date of Birth:--/--/----			**ICU admission day:**						
Time	**Awake**	**Asleep**	**Could not tell**	**No time to observe**	**Time**	**Awake**	**Asleep**	**Could not tell**	**No time to observe**
2000					**0200**				
2015					0215				
2030					0230				
2045					0245				
2100					**0300**				
2115					0315				
2130					0330				
2145					0345				
2200					**0400**				
2215					0415				
2230					0430				
2245					0445				
2300					**0500**				
2315					0515				
2330					0530				
2345					0545				
2400					**0600**				
0015					0615				
0030					0630				
0045					0645				
0100					**0700**				
0115					0715				
0130					0730				
0145					0745				
					0800				
Comments regarding the patient's sleep:									

Thank you for completing this chart. Your assistance is greatly appreciated.

Critical Care Nursing Professorial Unit 02 9926 8281

APPENDIX L: Sleep in Intensive Care Questionnaire (SICQ)

ICU sleep study: Sleep in the Intensive Care Unit (ICU) Questionnaire

Please answer the following questions about your sleep while in the intensive care unit.

1. Rate the overall quality of your sleep at <u>home.</u>
Use a scale of 1 to 10 (1 is poor, 10 is excellent)

1 2 3 4 5 6 7 8 9 10

2. Rate the overall quality of your sleep in the <u>ICU</u>
Use a scale of 1 to 10 (1 is poor, 10 is excellent)

1 2 3 4 5 6 7 8 9 10

3. Rate the overall quality of your sleep in ICU on the following days
(1 is no sleep, 10 is excellent)

- **On the first night in the ICU**
  1 2 3 4 5 6 7 8 9 10
- **During the middle of your ICU stay**
  1 2 3 4 5 6 7 8 9 10
- **At the end of your ICU stay**
  1 2 3 4 5 6 7 8 9 10

4. **Rate the overall degree of daytime sleepiness during your ICU stay** (1 is unable to stay awake, 10 is fully alert and awake)

1 2 3 4 5 6 7 8 9 10

5. **Rate the overall degree of daytime sleepiness during your ICU stay on the following days**
(1 is unable to stay awake, 10 is fully alert and awake)

- **On first day in the ICU**
  1 2 3 4 5 6 7 8 9 10
- **During the middle of your ICU stay**
  1 2 3 4 5 6 7 8 9 10
- **At the end of your ICU stay**
  1 2 3 4 5 6 7 8 9 10

Please turn page

6. **Rate how disruptive the following activities were to your sleep during your ICU stay** (Use a scale of 1 to 10, 1 is no disruption, 10 is significant disruption)

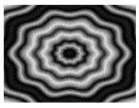
- **Noise**
  1 2 3 4 5 6 7 8 9 10
- **Light**
  1 2 3 4 5 6 7 8 9 10
- **Nursing interventions (i.e. baths)**
  1 2 3 4 5 6 7 8 9 10
- **Diagnostic testing (i.e. chest x-rays)**
  1 2 3 4 5 6 7 8 9 10
- **Vital signs (blood pressure, pulse, temperature)**
  1 2 3 4 5 6 7 8 9 10
- **Blood samples**
  1 2 3 4 5 6 7 8 9 10
- **Administration of medications**
  1 2 3 4 5 6 7 8 9 10

7. **Rate how disruptive the following noises were to your sleep during your ICU stay** (Use a scale of 1 to 10, 1 is no disruption, 10 is significant disruption)

- **Heart rate monitor alarm**
  1 2 3 4 5 6 7 8 9 10
- **Ventilator alarm**
  1 2 3 4 5 6 7 8 9 10
- **Oxygen finger probe**
  1 2 3 4 5 6 7 8 9 10
- **Talking**
  1 2 3 4 5 6 7 8 9 10
- **IV pump alarm**
  1 2 3 4 5 6 7 8 9 10
- **Suctioning**
  1 2 3 4 5 6 7 8 9 10
- **Nebulizer**
  1 2 3 4 5 6 7 8 9 10
- **Doctor's pagers**
  1 2 3 4 5 6 7 8 9 10
- **Television**
  1 2 3 4 5 6 7 8 9 10
- **Telephone**
  1 2 3 4 5 6 7 8 9 10

Thank you for completing this form

APPENDIX M: Modified Sleep in Intensive Care Questionnaire



Ward after night 1

ICU sleep study: Sleep in the Intensive Care Unit (ICU) Questionnaire
Study ID. .....Date: __/__/_____

Please answer the following questions about your sleep while in the intensive care unit.

1. Rate the overall quality of your sleep at <u>home.</u>
Use a scale of 1 to 10 (1 is poor, 10 is excellent)

1 2 3 4 5 6 7 8 9 10

2. Rate the overall quality of your sleep in the <u>ICU</u>
Use a scale of 1 to 10 (1 is poor, 10 is excellent)

1 2 3 4 5 6 7 8 9 10

3. Rate the overall quality of your sleep in ICU on the following days
(1 is no sleep, 10 is excellent)

- **On the first night in the ICU**
  1 2 3 4 5 6 7 8 9 10
- **During the middle of your ICU stay**
  1 2 3 4 5 6 7 8 9 10
- **At the end of your ICU stay**
  1 2 3 4 5 6 7 8 9 10

4. Rate the overall degree of daytime sleepiness during your ICU stay (1 is unable to stay awake, 10 is fully alert and awake)

1 2 3 4 5 6 7 8 9 10

5. Rate the overall degree of daytime sleepiness during your ICU stay on the following days (1 is unable to stay awake, 10 is fully alert and awake)

- **On first day in the ICU**
  1 2 3 4 5 6 7 8 9 10
- **During the middle of your ICU stay**
  1 2 3 4 5 6 7 8 9 10
- **At the end of your ICU stay**
  1 2 3 4 5 6 7 8 9 10

6. What factors or activities were disruptive to your sleep in ICU?

---

7. If you found noise to be disruptive to your sleep in ICU, please list or describe which noises you found disruptive.

Please turn page

ICU sleep study: Sleep in the Intensive Care Unit (ICU) Questionnaire

Study ID. .....Date: __/__/_____

8. Rate how disruptive the following activities were to your sleep during your ICU stay (Use a scale of 1 to 10, 1 is no disruption, 10 is significant disruption)

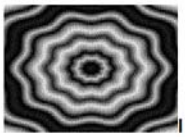
- **Noise**
  1 2 3 4 5 6 7 8 9 10
- **Light**
  1 2 3 4 5 6 7 8 9 10
- **Nursing interventions (e.g. baths)**
  1 2 3 4 5 6 7 8 9 10
- **Diagnostic testing (e.g. chest x-rays)**
  1 2 3 4 5 6 7 8 9 10
- **Vital signs (blood pressure, pulse, temperature)**
  1 2 3 4 5 6 7 8 9 10
- **Blood samples**
  1 2 3 4 5 6 7 8 9 10
- **Administration of medications**
  1 2 3 4 5 6 7 8 9 10

9. Rate how disruptive the following noises were to your sleep during your ICU stay (Use a scale of 1 to 10, 1 is no disruption, 10 is significant disruption)

- **Heart rate monitor alarm**
  1 2 3 4 5 6 7 8 9 10
- **Ventilator alarm**
  1 2 3 4 5 6 7 8 9 10
- **Oxygen finger probe**
  1 2 3 4 5 6 7 8 9 10
- **Talking**
  1 2 3 4 5 6 7 8 9 10
- **IV pump alarm**
  1 2 3 4 5 6 7 8 9 10
- **Suctioning**
  1 2 3 4 5 6 7 8 9 10
- **Nebulizer**
  1 2 3 4 5 6 7 8 9 10
- **Doctor's pagers**
  1 2 3 4 5 6 7 8 9 10
- **Television**
  1 2 3 4 5 6 7 8 9 10
- **Telephone**
  1 2 3 4 5 6 7 8 9 10

Thank you for completing this form

APPENDIX N: Pittsburgh Sleep Quality Index (PSQI)

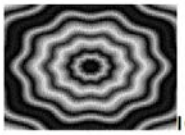
 ICU Sleep study

Pittsburgh sleep quality index (PSQI)

Instructions
The following questions relate to your usual sleep habits during the past month ONLY. Your answers should indicate the most accurate reply for the majority of days and nights in the past month.
Please answer all questions.

1. **During the past month, when have you usually gone to bed at night?**
   USUAL BED TIME _____
2. **During the past month, how long (in minutes) has it usually taken you to fall asleep each night?**
   NUMBER OF MINUTES_____
3. **During the past month, when have you usually rise out of bed in the morning?**
   USUAL GETTING UP TIME _____
4. **During the past month, how many hours of *actual sleep* did you get at night? (This may be different to the number of hours you spend in bed)**
   HOURS OF SLEEP PER NIGHT_____

Critical Care Nursing Professorial Unit 02 9926 8281



ICU Sleep study

For each of the remaining questions, mark the one best response with a cross. Please answer *all* questions.

5. **During the past month, how often have you had trouble sleeping because you.....**

a) Cannot get to sleep within 30 minutes

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

b) Wake up in the middle of the night or early morning

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

c) Have to get up to use the bathroom

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

d) Cannot breathe comfortably

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

e) Cough or snore loudly

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

f) Feel too cold

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

g) Feel too hot

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

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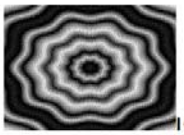

Question 5 continued. During the past month, how often have you had trouble sleeping because you.....

h) **Had bad dreams**

Not during the past month	☐	Less than once a week	☐	Once or twice a week	☐	Three or more times a week	☐

i) **Have pain.**

Not during the past month	☐	Less than once a week	☐	Once or twice a week	☐	Three or more times a week	☐

j) **Other reason(s), please describe**

_____

_____

_____

How often during the past month have you had trouble sleeping because of this?

Not during the past month	☐	Less than once a week	☐	Once or twice a week	☐	Three or more times a week	☐

6. **During the past month, how would you rate your sleep quality overall?**

Very good _____

Fairly good _____

Fairly bad _____

Very bad _____

7. **During the past month, how often have you taken medicine (prescribed or 'over the counter') to help you sleep?**

Not during the past month	☐	Less than once a week	☐	Once or twice a week	☐	Three or more times a week	☐

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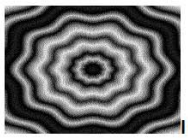


8. **During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?**

Not during the past month	☐	Less than once a week	☐	Once or twice a week	☐	Three or more times a week	☐

9. **During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?**

No problem at all

Only a very slight problem _____

Somewhat of a problem _____

A very big problem _____

_____

10. **Do you have a bed partner or share a room?**

No bed partner or do not share a room

Partner/flatmate in other room _____

Partner in same room, but not same bed _____

Partner in same bed _____

_____

If you have a bed partner or share a room, ask him/her how often in the past month you have had…

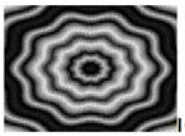
a) Loud snoring.

Not during the past month	☐	Less than once a week	☐	Once or twice a week	☐	Three or more times a week	☐

b) Long pauses between breaths while asleep.

Not during the past month	☐	Less than once a week	☐	Once or twice a week	☐	Three or more times a week	☐

Critical Care Nursing Professorial Unit 02 9926 8281



ICU Sleep study

c) Legs twitching or jerking while you sleep.

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

d) Episodes of disorientation or confusion during sleep.

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

e) Other restlessness while you sleep. Please describe

_____

_____

_____

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

Thank you for completing this questionnaire.

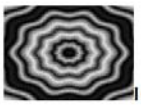
(Buysee, D. J., Reynolds, C. F., Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. Psychiatry Research, 28, 193-213.)

Critical Care Nursing Professorial Unit 02 9926 8281

APPENDIX O: Instruments used to assess psychological well-being during recovery at home

- **Intensive care experience (ICE) questionnaire**
- **Posttraumatic Stress Disorder Checklist for a specific event (PCL-S)**
- **Depression, Anxiety and Stress Scales -21 (DASS-21)**

Intensive care experience questionnaire (ICEQ)



ICU Sleep study

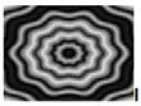
Intensive care experience (ICE) questionnaire

This questionnaire is designed to find out what you felt and remember about your intensive care experience. Please tick the box that best describes what you think about each of the statements below:

How much do you agree:

		Strongly agree	Agree	Neither agree/ disagree	Disagree	Strongly disagree
1.	Most of my memories of intensive care are blurred:					
2.	I never knew whether it was day or night:					
3.	I wish I remembered more about it:					
4.	My care could have been better:					
5.	I wish I had known more about what was happening to me:					
6.	I thought I would die:					
7.	It was always too noisy:					
8.	I have no recollection of being in intensive care:					
9.	I seemed to sleep too much:					
10	I was constantly disturbed:					
11	I thought my care was as good as it could have been:					
12	I was able to let people know what I wanted.					

Critical Care Nursing Professorial Unit 02 9926 8281



ICU Sleep study

Please tick the box that best describes how often these happened:

		All of the time	Most of the time	Some of the time	Rarely	Never
13.	I was aware of someone near to me:					
14.	I knew what was happening to me:					
15.	I felt I was in control:					
16.	I knew where I was:					
17.	I remember my relatives being with me:					
18.	I saw strange things:					
19.	I felt helpless:					
20.	I seemed to be in pain:					
21.	I felt scared:					
22.	I recognised my relatives:					
23.	I felt safe:					
24.	I seemed to have bad dreams					

Open questions

What was best about intensive care?

What was worst about intensive care?

Is there anything else you'd like to tell me about intensive care?

Thank you for completing this questionnaire.

Critical Care Nursing Professorial Unit 02 9926 8281

Posttraumatic Stress Disorder Checklist for a specific event (PCL-S)

ICU Sleep study

PTSD checklist (PCL-S)

The event you experienced recently was a severe illness which lead to your admission to intensive care. Instructions: Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully, then circle one of the numbers to the right to indicate how much you have been bothered by that problem in the past month. Please answer all questions.

		Not at all	A little bit	Moderately	Quite a bit	Extremely
1	Repeated, disturbing *memories, thoughts*, or *images* of the stressful experience?	1	2	3	4	5
2	Repeated, disturbing *dreams* of the stressful experience?	1	2	3	4	5
3	Suddenly *acting* or *feeling* as if the stressful experience *were happening again* (as if you were reliving it)?	1	2	3	4	5
4	Feeling *very upset* when *something reminded you* of the stressful experience?	1	2	3	4	5
5	Having *physical reactions* (e.g., heart pounding, trouble breathing, sweating) when something reminded you of the stressful experience?	1	2	3	4	5
6	Avoid *thinking about* or *talking about* the stressful experience or avoiding *having feelings* related to it?	1	2	3	4	5
7	Avoiding *activities* or *situations* because *they reminded you* of the stressful experience?	1	2	3	4	5
8	Trouble *remembering important parts* of the stressful experience?	1	2	3	4	5
9	*Loss of interest* in activities that you used to enjoy?	1	2	3	4	5
10	Feeling *distant* or *cut off* from other people?	1	2	3	4	5
11	Feeling *emotionally numb* or being unable to have loving feelings for those close to you?	1	2	3	4	5
12	Feeling as if your *future* will somehow be *cut short*?	1	2	3	4	5
13	Trouble *falling* or *staying* asleep?	1	2	3	4	5
14	Feeling *irritable* or having *angry outbursts*?	1	2	3	4	5
15	Having *difficulty concentrating*?	1	2	3	4	5
16	Being *"super-alert"* or watchful or on guard?	1	2	3	4	5
17	Feeling *jumpy* or easily startled?	1	2	3	4	5

Thank you for completing this questionnaire.

Weathers, Litz, Huska & Keane 1993

Critical Care Nursing Professorial Unit 02 9926 8281

Depression, Anxiety and Stress Scales -21 (DASS-21)


ICU Sleep study

DASS-21 questionnaire

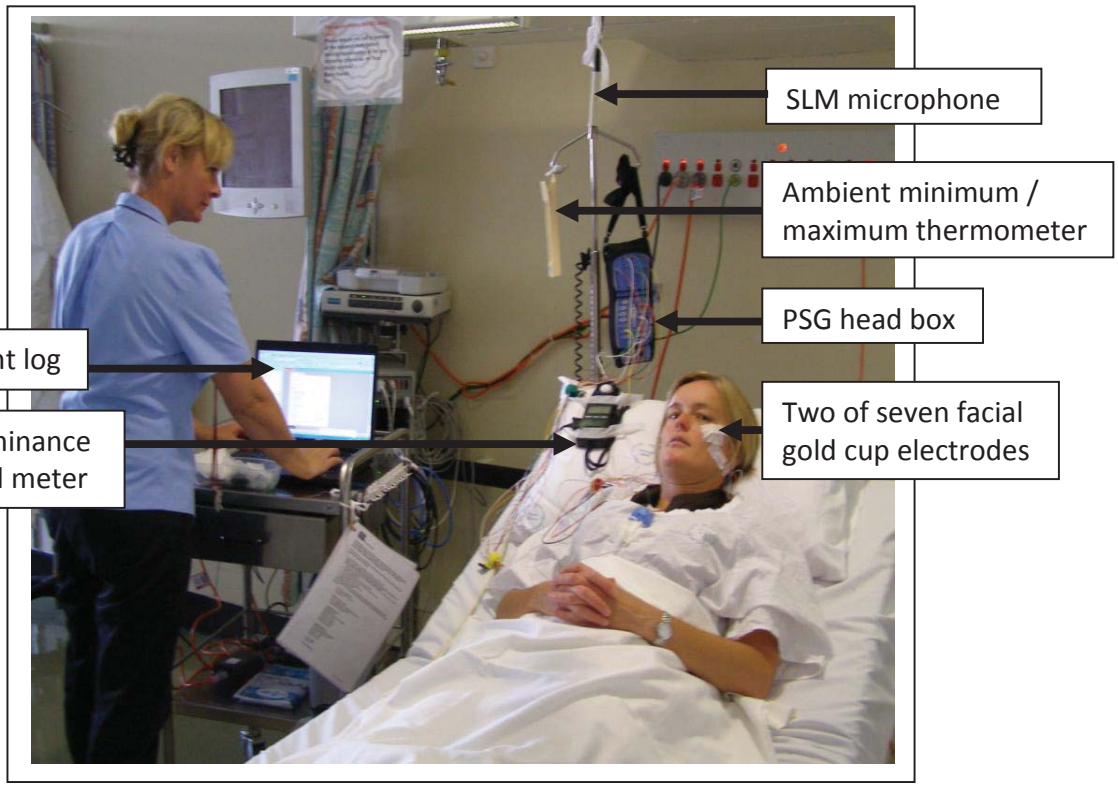
Instructions
Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement. The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of the time
3 Applied to me very much, or most if the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

Thank you for completing this questionnaire

APPENDIX P: Set up for ICU sleep, sound pressure and illuminance level recording



A photograph in which the investigator and bedside nurse demonstrate the set up for ICU sleep monitoring

The photograph shows the SLM microphone hanging one to 1.5 metre above the investigator. The ambient minimum and maximum thermometer and PSG head box hang from an intravenous fluid pole. The illuminance meter is taped to the pillow (the white dome is the head sensor). The bedside nurse is administering the event log on the Access™ database form (laptop computer. PSG electrode placement is not yet complete (the ground electrode has yet to be placed).

APPENDIX Q: Cover letter to accompany questionnaires completed at home

NORTHERN SYDNEY CENTRAL COAST NSW HEALTH

Date

Address

Dear xxxxxx,

Re: ICU Sleep study

Thank you very much for participating in the ICU sleep study. The aim of the ICU sleep study is to improve the quantity and quality of sleep for the intensive care patient.

Please find enclosed questionnaires which I would be most grateful if you could complete. I have enclosed an addressed envelope for you to return them when you have completed them. Feel free to telephone me or the critical care nursing research officer Mary Fien on 02 9926 6051 if you require clarification on any of the questions or have any other queries.

Yours sincerely,

Rosalind Elliott, RN, MN, PhD candidate,
University of Technology Sydney
Royal North Shore Hospital

Royal North Shore Hospital
Critical Care Nursing Professorial Unit
St Leonards NSW 2065
Telephone 02 9926 7111
Facsimile 02 9439 8418
Direct telephone 02 9926 8281
Northern Sydney Central Coast Area Health Service
ABN 48 344 669 728

APPENDIX R: Conversion factors for morphine equivalent doses of opioids and midazolam equivalent doses of benzodiazepines

Equivalent doses of opioids for morphine 1mg (Ballantyne et al., 2009)

Opioid	Dose
Codeine	13mg
Fentanyl	10mcg
Hydromorphone	0.15mg
Methadone	1mg
Oxycodone (endone) *	1.5mg
Tramadol	10mg

* This conversion factor was also used for oxycontin (extended release oxycodone) as there are no data available.

Equivalent doses of benzodiazepines for midazolam 1mg (Ashton, 1994)

Benzodiazepine	Dose
Diazepam	5mg
Temazepam	10 mg

APPENDIX S: Human Research Ethics Committee approval

Northern Sydney Health Human Research Ethics Committee (Harbour)

NORTHERN SYDNEY CENTRAL COAST NSW HEALTH

18 September 2008

Professor S McKinley
Critical Care Nursing Professorial Unit, Level 6
Royal North Shore Hospital
St Leonards NSW 2065

Dear **Professor McKinley,**

Re: ***SITE SPECIFIC ASSESSMENT (SSA)***

Protocol 0809-201M(SP) **- S McKinley, R Elliott, P Cistulli, R Foley, S Ladanyi, T Buckley**
Improving the quality and quantity of sleep for the intensive care patient AU RED Ref: 08/HARBR/158/159

I am pleased to inform you that on the **18 September 2008**, the delegate of the Chief Executive authorised the Site Specific Assessment for the above study on behalf of Northern Sydney Central Coast Health (NSCCH).

It is noted that the approval covers the following sites:

- Adult Intensive Care Unit Royal North Shore Hospital

The documentation included in the approval is as follows:

- Participant Information Statement and Consent Form Version 2, dated 9 September 2008
- Revocation of Consent Version 1, dated 18 August 2008
- ICU Sleep Study Richards-Campbell Sleep Questionnaire Version 1, dated 19 August 2008
- ICU Sleep Study Sleep in the ICU Questionnaire Version 1 dated 19 August 2008
- ICU Sleep Study Pittsburgh Sleep Quality Index Version 1 dated 19 August 2008
- ICU Sleep Study DASS-21 Questionnaire Version 1 dated 21 August 2008
- ICU Sleep Study PTSD Checklist Version 1 dated 19 August 2008
- ICU Sleep Study Intensive Care Experience Questionnaire Version 1 dated 19 August 2008

It is noted that Ethics & Scientific Approval for this project was granted by the HARBOUR Human Research Ethics Committee (HREC) of Northern Sydney Central Coast Area Health or EXTERNAL.

It is further noted that this committee is a LEAD HREC under the NSW Health model for single ethical review of multi-centre research.

The HREC recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purpose of conducting this clinical trial.

At this time, we also remind you that, in order to comply with the *Guidelines for Good Clinical Research Practice (GCRP) in Australia*, and in line with NSH HREC policy, the Chief Investigator is responsible to ensure that:

1. You notify the HREC at the completion of the study at this site and submit a final report (including final results) when available.
2. The HREC is notified as soon as possible of any changes to the protocol. All changes must be approved by the HREC before continuation of the research project. This includes notifying the HREC of any changes to the staff involved with the protocol.
3. All serious and unexpected adverse events are reported to the HREC within 15 working days.

The Research Office
Level 4 Vindin House, Royal North Shore Hospital
St Leonards NSW 2065 * PH: (02) 9926 8106 * Fax: (02) 9926 6179

NORTHERN SYDNEY
CENTRAL COAST
NSW HEALTH

4. The HREC is notified of the outcome of all submissions of this protocol to other Ethics Committees.

As at 18 May 2004, HREC approval is now valid for four (4) years from the date of the approval letter. **Your approval will therefore expire on 18 September 2012.** Investigators are requested to submit a progress report annually on 31 October. **Your first progress report is due on 31 October 2008.** The forms for progress/final reports can be down loaded from the Research Office web page.

Yours sincerely,

Mrs Judy Wells
Research Governance Officer
HARBOUR HREC
NORTHERN SYDNEY
CENTRAL COAST HEALTH

The Research Office
Level 4 Vindin House, Royal North Shore Hospital
St Leonards NSW 2065 * PH: (02) 9926 8106 * Fax: (02) 9926 6179

NORTHERN SYDNEY CENTRAL COAST
NSW HEALTH

18 September 2008

Professor S McKinley
Critical Care Nursing Professorial Unit, Level 6
Royal North Shore Hospital
St Leonards NSW 2065

Dear Professor McKinley,

Re: NATIONAL ETHICS APPLICATION FORM (NEAF) APPROVAL
LOCAL REFERENCE: Protocol 0809-201M(SP) **- S McKinley, R Elliott, P Cistulli, R Foley, S Ladanyi, T Buckley**
Improving the quality and quantity of sleep for the intensive care patient AU RED Ref: 08/HARBR/158/159 Also Medical Records Research Request

Thank you for providing additional information as requested by the Expedited Reviewers of the **HARBOUR** Human Research Ethics Committee (HREC) of Northern Sydney Central Coast Health (NSCCH). Please be advised that your study has now been approved. The documentation included in the approval is as follows:

- Participant Information Statement and Consent Form Version 2, dated 9 September 2008
- Revocation of Consent Version 1, dated 18 August 2008
- ICU Sleep Study Richards-Campbell Sleep Questionnaire Version 1, dated 19 August 2008
- ICU Sleep Study Sleep in the ICU Questionnaire Version 1 dated 19 August 2008
- ICU Sleep Study Pittsburgh Sleep Quality Index Version 1 dated 19 August 2008
- ICU Sleep Study DASS-21 Questionnaire Version 1 dated 21 August 2008
- ICU Sleep Study PTSD Checklist Version 1 dated 19 August 2008
- ICU Sleep Study Intensive Care Experience Questionnaire Version 1 dated 19 August 2008

It is noted that the approval covers the following NSCCH sites:

- Adult Intensive Care Unit Royal North Shore Hospital

It is noted that the study has been assessed by the HREC for *ethical* and *scientific review* ONLY and that clearance on the Site Specific aspects of the trial (local sign-off's, legal documentation etc) MUST be obtained from the above listed sites prior to commencement of research. Each site has different requirements, NSW Area Health Service sites require submission and approval of a Site Specific Assessment (SSA), which can be completed at: **www.ethicsform.org/au**. Please contact the local site for advice on what will be required.

*If you wish to add an additional site to the project within the area you will be required to complete a *'Site Specific Assessment Form'*, downloadable from the Research Office Web Page.

The HREC recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purpose of conducting this clinical trial.

At this time, we also remind you that, in order to comply with the *Guidelines for Good Clinical Research Practice (GCRP) in Australia*, and in line with NSH HREC policy, the Chief Investigator is responsible to ensure that:

1. You notify the HREC at the completion of the study at this site and submit a final report (including final results) when available.
2. The HREC is notified as soon as possible of any changes to the protocol. All changes must be approved by the HREC before continuation of the research project. This includes notifying the HREC of any changes to the staff involved with the protocol.
3. All serious and unexpected adverse events are reported to the HREC within 15 working days.

NORTHERN SYDNEY
CENTRAL COAST
NSW HEALTH

4. The HREC is notified of the outcome of all submissions of this protocol to other Ethics Committees.

As at 18 May 2004, HREC approval is now valid for four (4) years from the date of the approval letter. **Your approval will therefore expire on 18 September 2012.** Investigators are requested to submit a progress report annually on 31 October. **Your first progress report is due on 31st October 2008.** The forms for progress/final reports can be down loaded from the Research Office web page.

Yours sincerely,

Dr Liz Newton
Chairperson
HARBOUR HREC
NORTHERN SYDNEY
CENTRAL COAST HEALTH

The Research Office
Level 4 Vindin House, Royal North Shore Hospital
St Leonards NSW 2065 * PH: (02) 9926 8106 * Fax: (02) 9926 6179

University of Technology Sydney Human Research Ethics Committee

25 November 2008

Professor Sharon McKinley
CB10.07.207
Faculty of Nursing, Midwifery & Health
UNIVERSITY OF TECHNOLOGY, SYDNEY

Dear Sharon,

UTS HREC 2008-292 – MCKINLEY, Professor Sharon, CISTULLI, Professor Peter, FOLEY, Ms Rachel, BUCKLEY, Mr Thomas (for ELLIOT, Ms Rosalind PhD student and LADANYI, Ms Suzy Honours student) – "Improving the amount and quality of sleep for the intensive care patient (Ratification)"
[*External Ratification: Northern Sydney Health Human Research Ethics Committee (Harbour) (EC00333) HREC approval – 0809-201M 18/09/08 to 18/09/12].*

At its meeting held on 11/11/2008, the UTS Human Research Ethics Committee considered the above application, and I am pleased to inform you that your external ethics clearance has been ratified.

Your UTS clearance number is UTS HREC REF NO. 2008-292R

Please note that the ethical conduct of research is an on-going process. The *National Statement on Ethical Conduct in Research Involving Humans* requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year). The Ethics Secretariat will contact you when it is time to complete your first report.

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

If you have any queries about your ethics clearance, or require any amendments to your research in the future, please do not hesitate to contact the Ethics Secretariat at the Research and Innovation Office, on 02 9514 9615.

Yours sincerely,

Professor Jane Stein-Parbury
Chairperson
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APPENDIX T: Rest and sleep guideline

Rest and sleep for the intensive care patient

1.0 Document Authorisation

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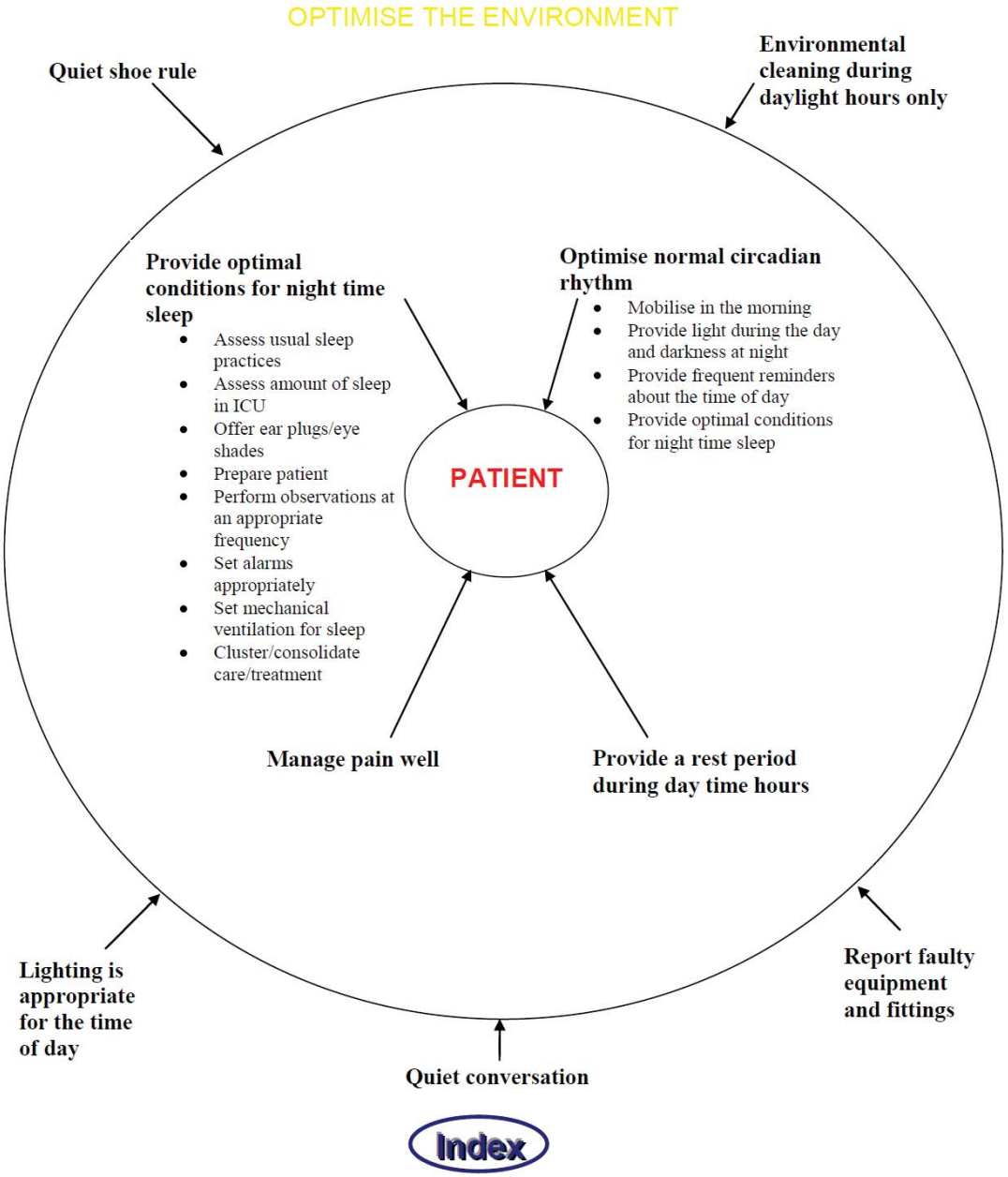

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3.0 Bedside rest and sleep checklist

1. Optimise the environment	○ Report faulty equipment and fittings ○ Wear 'quiet' shoes ○ Environmental cleaning during daylight hours only ○ Talk quietly ○ Ensure lighting is appropriate for the time of day	
2. Rest and sleep interventions	○ Manage pain well	
	○ Optimise normal circadian rhythm	• Mobilize in the morning • Provide light during daytime and darkness at night • Provide reminders about the time of day • Provide mental stimulation during daylight hours
	○ Provide a rest period during daylight hours	• 1330 to 1500hrs
	○ Provide optimal conditions for night-time sleep	• Assess usual sleep practices • Assess sleep in ICU • Offer ear plugs and eye shades • Prepare for night-time sleep • Perform observations at an appropriate frequency • Set alarms appropriately • Set mechanical ventilation to encourage night-time sleep • Cluster care • Deliver hygiene at appropriate times • Explain unavoidable night-time disturbances
3. Consider sleep promoting medication	○ Benzodiazepines/propofol ○ Non-benzodiazepine hypnotics ○ Antipsychotics ○ Antidepressants	• Always consider non-pharmaceutical strategies first • Only use sleep promoting medication in the short term

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4.0 Scope

This guideline applies to all patients who are treated in ICU however there may be circumstances in which the interventions described are not safe or appropriate. Health care professionals should assess each patient for suitability. All personnel who work in ICU are responsible for implementing the interventions when appropriate.

5.0 Background

5.1 Sleep disruption in ICU patients

Sleep disruption is known to adversely affect health. International health care literature (Cooper et al. 2000, Edéll-Gustafsson et al. 1999, Freedman et al. 2001, Friese et al. 2007, Gabor et al. 2003) and research conducted in the ICU at the Royal North Shore Hospital indicate that ICU patients' sleep is significantly disrupted. Noise levels are intrusive and disturbances for procedures and interventions are frequent.

5.2 Guideline development

An extensive consultation was performed during June 2010 with personnel working in the ICU regarding the data from the research. Many useful suggestions were provided. The interventions in this guideline are based on those suggestions, patient feedback during our research and evidence from the international health care literature. There is little doubt that the interventions contained herein may lead to conditions which are more conducive to rest and sleep.

6.0 Aim

- To ensure that the patient is given adequate opportunity to rest and sleep while treated in the intensive care unit

7.0 Standards

- Sound level (continuous equivalent) will not exceed 45(A)dB during night time hours (2300 to 0700hrs) in patient treatment areas (reference values for sound levels are provided in Appendix C)
- Mean light levels will not exceed 9 lux during night time hours (2300 to 0700hours) (reference values for light levels are provided in Appendix C)
- A snap shot audit will be performed for one 24 hour period each month for all patients treated in ICU on that day
    - 80% of patients will have a Rest and Sleep Summative Index of ≥ 8 at a 'good' level of care

      The audit document (section 12) contains the details of the Rest and Sleep Summative Index.

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8.0 Optimise the environment

8.1 Report faulty equipment and fittings

Follow the Hospital guidelines for reporting faulty equipment (trolley wheels etc) and fittings (squeaking door hinges). This will contribute dramatically to noise reduction and a more therapeutic environment.

8.2 Quiet shoe rule

Personnel who work in ICU should wear suitable shoes. Occupational health and safety and infection control policy suggests that shoes must cover the foot and have adequate gripping soles. In addition styles of shoes which are known to generate noise should not be worn e.g. high heels, shoes with soles that make a squeaky sound.

8.3 Environmental cleaning during daylight hours only

Environmental cleaners are requested to mop and polish floors between 0700 to 1800hrs in order to reduce the associated disruption to patients. In addition rubbish containers should be emptied no later than 2200hrs. Wherever rubbish containers are not heavy they should be removed to the corridor in order to replace the rubbish bin liner (if this does not contravene occupational health and safety and infection control policy).

8.4 Quiet conversation

All personnel working in ICU are requested to talk quietly at all times, especially at night, whether at the bedside or on the phone or in conversation with a colleague. Personnel working in ICU should remind each other to be cognizant of the need for a quiet environment when talking.

8.5 Lighting is appropriate for the time of day

Blinds should be opened and lights switched on between 0700hrs and 1800hrs with the exception of day time rest times. As a general rule the main room lights should be turned off before 2300 hours and during the daytime rest time. Use the examination lamps and dimmer lights above the bed for procedures which do not require bright light, e.g. during pressure area care. Reference values for light levels are provided in Appendix C.

9.0 Rest and sleep interventions

Together with optimising environmental conditions for rest and sleep, careful care planning throughout the 24 hours can improve the opportunity for restful sleep. The following interventions provide the basis of conditions conducive to rest and sleep.

9.1 Manage pain well

Adequate pain relief is essential to ensure rest and sleep. Pain assessment and management should be provided according to the ICU pain and sedation management guideline (located on the ICU intranet).

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9.2 Optimise normal circadian (day/night) rhythm

There are a number of interventions which can maintain or encourage a normal circadian rhythm (night/day cycle).

9.2.1 Mobilise in the morning

If the patient is able to get out of bed it is better if this is achieved in the morning (before midday), facing natural light if possible.

9.2.2 Provide light during the day and darkness during the night

Sunlight which has a higher proportion of short wave light (or blue light) is preferable to artificial light for providing a daytime cue. However artificial light of sufficient intensity (50-300 lux) will provide a strong enough cue. It is particularly important to minimize patient exposure to high intensity light between 0200 and 0400 hours as this is the time of natural melatonin (a sleep promoting and maintaining hormone) secretion (Claustrat et al. 2005). High light levels at this time have the potential to suppress melatonin secretion. In addition, light exposure at this time, repeated over many nights, may shift secretion to daytime causing a shift in the circadian rhythm.

9.2.3 Provide frequent reminders about the time of day

Patients should be regularly reminded of the time of day. Wherever possible, alert patients should be provided with a watch or clock.

9.2.4 Provide mental stimulation during daylight hours

Mental stimulation (e.g. TV, radio, encourage visitors to read/talk to the patient about matters external to ICU) is encouraged during daylight hours (even in sedated/unconscious patients). Head phones (for music and TVs) should be used in open plan areas of the ICU to minimize disruption to other patients. Nurses, physiotherapists, social workers and speech pathologists are encouraged to provide relatives and friends of the patients with guidance on how they may provide mental stimulation during daylight hours. Social workers can provide access to DVD players and a DVD library.

9.2.5 Provide optimal conditions for night time sleep (see section 9.4)

9.3 Rest period during daytime hours

An hour and half rest time during daylight hours is encouraged (from 1330 to 1500hours). During this time, light should be reduced and the patients' visitors encouraged to take a break away from the ICU or to sit quietly beside the patient.

9.4 Provide optimal conditions for night-time sleep

There are many simple interventions which will positively contribute to good night-time sleep.

9.4.1 Assess usual sleep practices during health

Wherever possible an assessment of usual sleep practices during health should be performed. A brief summary should be added to the multidisciplinary ICU care plan (page 2: nationality, language, cultural requirements and personal preferences). The family/friends may be consulted if the patient is unable to provide information. If possible follow the patient's usual sleep practices. If the patient has a history of poor/disordered sleep other interventions may be attempted to increase the likelihood of sleep. Medical officers should consider referring patients

who are suspected of having sleep disorders to the respiratory/sleep medicine team for further investigation.

9.4.2 Assess the quality and amount of night-time sleep while in ICU

The patient should be asked about how they slept and any related concerns during ward rounds each morning. If there is concern about the amount of night time sleep the patient is experiencing in ICU an assessment may be performed over a number of nights. The recommended instrument for patient self-report is the Richards Campbell Sleep Questionnaire (RCSQ) (Richards et al. 2000) and for nurse assessment is the Nurses Observation Checklist (NOC) (Edwards and Schuring 1993). These instruments can be found in Appendix A. They may provide useful information regarding the time of day the patient is sleeping and sleep duration.

Arguably the patient is best placed to judge the quantity and quality of their sleep so the RCSQ should be completed in preference to the NOC but not all patients will have the cognitive ability to complete it. The RCSQ is administered by requesting the patient to mark the line of each item (if the patient is unable to write the nurse should ask the patient to indicate either by pointing or nodding at the correct position on each line while the nurse slowly runs a pen over the line). Responses are scored by measuring the distance from the low end of the scale to the mark made by the patient in mms. The total score for the RCSQ is calculated by adding the score for each VAS and dividing by five. High scores indicate good quality sleep. No reference values are available for guidance on when to implement sleep improvement intervention. However when there is concern that a patient is not sleeping the RCSQ can be used as a measure of whether attempts to improve sleep have been successful. The RCSQ also gives an indication of the nature of sleep difficulties e.g. frequent disturbances or inability to get to sleep.

For patients who are unable to self report their sleep, nurse assessment using the NOC may provide an estimation of their total sleep time. The NOC is administered by the nurse overnight by observing the patient's behaviour every 15 minutes. The estimated total sleep time is derived by adding all the ticks in the 'Asleep' column and multiplying by 15 minutes. Total sleep time for healthy adults ranges from 390 to 450 minutes.

9.4.3 Offer ear plugs and eye shades as appropriate

Ear plugs and eye shades are available for patient use where appropriate however caution must be exercised in using them:

- Patients should be sufficiently orientated to time and place (eye shades and ear plugs may worsen disorientation)
- Ear plugs should not be used if there is a history of ear infection, excessive ear wax or recent damage to the ear canal/ear drum
- An ear canal examination with an aurosope is recommended for patients who have a history of excessive ear wax production or other ear condition
- Ear plugs are single use only
- Follow the instructions for insertion carefully (see Appendix B)
- Take the following action for patients who are unable to remove the eye shade/ear plugs themselves:

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- Rest the eye shade over the eyes without pulling the elastic over the back of the head (the patient can shake his/her head to remove it). If the eye shades fall off place a small piece of white dressing tape to hold it lightly to the skin on the forehead.
- Attach some string or tape to the ear plug and lightly pin it to the patient's pillow after inserting the ear plug (before inserting instruct the patient to turn their head from side to side to remove the ear plugs at any time if they wish)

9.4.4 Prepare patient for night-time sleep

A 'settling' procedure is advisable for all patients. This should follow the patient's usual night-time practices if possible. When the patient's usual bed time is not known the recommended time for settling is between 2100 and 2200hours. Patients who are disorientated should be reminded of the time of day and provided with verbal cues such as, 'It is night-time now and time to sleep'.

Sleep promoting medication should be considered if appropriate. Many sleep promoting medications have a short time to onset (30 minutes to 1 hour) of effect so it must be prescribed so administration is at the most appropriate time for the patient. This will require care planning so that the medication is given after the last major intervention for the night (e.g. pressure area care at 2300hours). See also section 10.

A warm drink should be offered if appropriate (although coffee should be avoided for obvious reasons).

9.4.5 Perform neurological observations and vital signs at an appropriate frequency

Staff specialists and senior registrars should guide nurses regarding the appropriate frequency of performing neurological observations and vital signs. Neurologically and cardiovascularly stable patients may require less intensive and frequent assessment. In these cases the frequency of overnight recordings should be prescribed on the patient's flowchart. Minimum requirements for all patients include four hourly neurological and cardiovascular observations (please see relevant document on the ICU intranet). Whenever possible observations should be performed with other care/treatment to reduce the number of interruptions (see also section 9.4.8).

9.4.6 Set monitor and equipment alarms appropriately

Immediate action should be taken to investigate and remedy any alarm. However the following guidelines may further reduce noise associated with inappropriately set alarms. Alarms must be audible and sufficiently loud to alert ICU health care professionals at all times.

- **Monitor settings**

Alarms must always be set to maintain safety. Monitor alarms should be set 10% either side of the prescribed parameters. Consider reducing the alarm sound volume over-night. Alarm sound volumes must be increased again during daytime hours (i.e. from 0800 to 2200 hours). It should be stressed that monitor alarms should be audible (above background noise) at all times for safety reasons.

- **Mechanical ventilator alarms**

Mechanical ventilator alarms should be set according to ICU policy. Apnoea alarms must never be disabled unless end of life care is in place. In the case that the patient is repeatedly apnoeaic while receiving pressure support ventilation an alternative mode or setting should be discussed with the ICU staff specialist or senior registrar. Mandatory settings/modes should be considered

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for patients on long-term ventilator weaning regimens during night-time hours if this appears to be a problem.

Peak inspiratory pressure alarms must be set 10cmH_2O above the patient's own peak inspiratory pressure but never above 40cmH_2O. The staff specialist or senior registrar should be called if the inspiratory pressure repeatedly sounds the alarm to discuss alternative ventilator modes and settings.

Less 'critical' alarms including minute volume and tidal volume alarms should be set to reflect the patient's condition. They may not be required. Bedside nurses should discuss this with the ICU staff specialist or senior registrar.

- **Intravenous fluid/medication pumps**

Wherever possible intravenous fluids and medications should be prepared when there is less than one hour remaining in the syringe/bag/bottles (except in the case of bags/syringes containing S4 and S8 medications which must be removed from the locked cupboard just before use and cannot be left unattended) in order to reduce the frequency that intravenous fluid pumps alarm.

9.4.7 Set mechanical ventilation to encourage night-time sleep

Evidence suggests that hypocapnia associated with mechanical ventilator settings (e.g. inspiratory pressures which lead to high minute volumes) may lead to frequent awakenings (Parthasarathy and Tobin 2002, Toublanc et al. 2007). Medical officers should consider prescribing mandatory settings or a mode which allows for restful night time sleep.

9.4.8 Cluster/consolidate care/treatment

Wherever possible care/treatment should be consolidated (e.g. perform mouth care just prior to or after pressure area care or attend to clinical assessment during pressure area care) so that the patient is uninterrupted for several 1.5 to 2 hour periods during the night. Clinical assessments should be performed before 2300 hours and after 0630 hours if possible. The bedside nurse should co-ordinate clustered care and allocate appropriate times for other members of the multidisciplinary team to attend to the patient.

9.4.9 Deliver hygiene needs at appropriate times

There should be no requirement to perform extensive hygiene procedures after 2300 hours and before 0630 hours. The only exception to this is if the patient is lying in a grossly soiled bed or requests a full wash. As a general rule a full body wash should be performed during the afternoon/early evening or according to the patient's preferences.

9.4.10 Explain unavoidable night-time disturbances

In the case that there is a medical emergency or a new patient is admitted to the room patients should be informed of the reason for the disturbance. If the patients are awake or the next time they are disturbed for an intervention explain the reason for the disturbance (e.g. clinical crisis or a new patient admitted). This will greatly allay anxiety and may enable the patients to return to sleep sooner.

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10.0 Medications used to promote sleep

The effectiveness of any medication used to promote sleep will be greatly enhanced by using the interventions described previously. However if non-pharmacological interventions have been attempted and causes of sleep disruption addressed, medication may be offered. Patient centred strategies avoiding 'multipharmacy' is advised when selecting suitable medication (this is particularly important during delirium). Prescribing and administration guidelines must be checked prior to prescribing. Further advice may also be sought from the ICU pharmacist. **Table 1** (next page) provides brief information and typical doses on sleep promoting medications. Further information and supporting evidence follows the table.

Ideally sleep should be allowed to occur naturally for the intensive care patient. It should be highlighted that many medications used to promote sleep tend to extend sleep time without increasing REM sleep (and even mildly suppressing it) or slow wave (stages 3 and 4) sleep. However there is no doubt that some sleep is better than none so sleep 'promoting' medication should be considered for patients who are unable to sleep at night (at least in the short term) after non-pharmacological strategies have been attempted (Weinhouse and Watson 2009).

It should be noted that the information contained in this section is not based on the effects of these medications on the sleep of ICU patients. Few investigations using polysomnography (which allows quantification of sleep stages) have been conducted in ICU and studies used to evaluate the effectiveness of medication on sleep have used nurse observation (Ibrahim et al. 2006, Shilo et al. 2000) or actigraphy (Bourne et al. 2008). Therefore some 'experimentation' may be required before the most effective medication is found for an individual patient.

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Table 1: Typical medications and doses of medication used to promote sleep in ICU patients at the Royal North Shore Hospital*

Medication	Medication class	Administration Typical hypnotic dose range (adult)	Cautions
Temazepam	Benzodiazepine	Oral/enteral: 10-20mg once per night (30 minutes before settling)	Reduce dose in liver failure. Check liver function
Propofol	Intravenous sedative/anaesthetic agent	Intravenous: Mechanical ventilation: 1.0 to 3.0 mg/kg/hour Self-ventilating: no greater than 0.5mg/kg/hour	Short-term use only Continuous respiratory monitoring. Check liver function
Zolpidem	Nonbenzodiazepine hypnotic	Oral/enteral: 5-10mg once per night (immediately before settling) N.B. Not available on the Royal North Shore Hospital formulary	Short-term use only (2 to 4 weeks). Associated with hallucinations. Extended half life in liver impairment.
Zopiclone	Nonbenzodiazepine hypnotic	Oral/enteral: 3.75-7.5mg once per night (immediately before settling). N.B. Not available on the Royal North Shore Hospital formulary.	Short-term use only (2 to 4 weeks). Associated with hallucinations. Extended half life in liver impairment.
Haloperidol	Typical antipsychotic	Provide maintenance doses used for treatment of delirium for night-time settling Intravenous (slow): 2-10mg which can be repeated Oral/enteral: 5-15mg per day	Monitor QT interval and liver function. Observe for extrapyramidal symptoms. No more than 100mg/day.
Olanzapine	Atypical antipsychotic	Oral/enteral: 2.5-20mg^ once per night several hours before settling	Short term use only. May cause hypotension.
Quetiapine	Atypical antipsychotic	Oral/enteral: 25-200mg^ once per night an hour before settling	Short term use only. May cause hypotension. Monitor QT interval.
Amitriptyline	Tricyclic antidepressant	Oral/enteral: 25-150mg^ once per night one to two hours before settling	Monitor QT interval and for anticholinergic effects. Increased seizure risk.
Doxepin	Tricyclic antidepressant	Oral/enteral: 25-150mg^ once per night one to two hours before settling	Monitor QT interval and for anticholinergic effects. Increased seizure risk.
Mirtazapine	Noradrenergic and specific serotonergic antidepressant	Oral/enteral: 15-60mg^ once per night one to two hours before settling	Higher doses may have a stimulatory effect.
Dexmedetomidine	Alpha agonist	Intravenous: Loading dose 1 microgram/kg over 10 to 20 minutes followed by maintenance infusion 0.2 to 1 mcg/kg/hr titrated to effect.	Not to be used as a continuous infusion for more than 24 hours. Continuous respiratory monitoring.

*Clinicians must check relevant guidelines before prescribing and administration. ^No formal hypnotic dose-ranges have been published. Suggested doses are taken from research studies into primary and secondary insomnia and cited in a respected sleep medicine text (Kryger et al. 2005). It is recommended that lower doses are given to the elderly and patients with a low BMI. If it proves to be ineffective the dose may be increased on subsequent nights.

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10.1 Benzodiazepines/propofol

Benzodiazepines and propofol are gamma-aminobutyric acid (GABA) agonists with sedative and anxiolytic effects. Shorter acting benzodiazepines are preferred for the purposes of sleep promotion as they have a shorter half life and may produce less severe daytime sleepiness (Kryger et al. 2005). As with any medication with the potential for physiological and psychological tolerance and dependence, benzodiazepines should be used for the shortest possible time. In addition rebound insomnia is a known effect and may manifest after only short periods of use, potentially impairing the patient's recovery after treatment in ICU. Benzodiazepines should be used cautiously in patients with severe hepatic insufficiency and doses adjusted for patients with renal failure. Liver function tests are recommended during prolonged use.

10.1.1 Short/intermediate acting benzodiazepines

Temazepam is a short acting benzodiazepine. Onset of effect is within 50 minutes and peak effect is within two hours so it is best if the patient is left undisturbed for several hours after administration. Oxazepam is used to treat anxiety and has sleep promoting effects. It has similar pharmacokinetics to temazepam.

10.1.2 Long acting benzodiazepines

Diazepam is a nonhypnotic medication which may be used for sleep promotion. It is used to treat alcohol withdrawal and anxiety. It has a very rapid onset of effect with a sustained action over many hours. Clonazepam is occasionally used to aid sleep but is predominately used as an anticonvulsant.

10.1.3 Propofol

Propofol is an intravenous anaesthetic widely used in ICU at low doses to produce light sedation. A slightly higher dose at night may enable sleep. Its use is mostly limited to patients who are intubated/tracheostomised as respiratory depression occurs at relatively low doses. However in some circumstances where other medications are not suitable (e.g. agitation in head injured patients) very low doses may be administered with extreme caution to patients breathing spontaneously without an artificial airway (one to one supervision and respiratory status monitoring provided) to promote sleep. Evidence suggests that propofol may extend sleep time and promote slow wave sleep (Rabelo et al. 2010).

10.2 Nonbenzodiazepine hypnotics

Better alpha1 subunit receptor selectivity is associated with the newer GABA agonists such as zolpidem, zaleplon and zopiclone (Drover 2004). This translates into important hypnotic effects but fewer side effects than associated with the benzodiazepines. Less tolerance and rebound insomnia are observed after treatment with these newer GABA agonists compared to benzodiazepines. All have mild anxiolytic effects and zopiclone and zolpidem produce negligible amnesia at low doses. All three medications have been found to preserve stages 3 and 4 (slow wave) sleep. Evidence suggests that zopiclone mildly suppresses rapid eye movement sleep. Zaleplon and zolipem are said to produce more 'natural' sleep than many nocturnal hypnotics. Clearance of the 'Z' sleep medications is significantly prolonged in patients who have liver failure; doses should be adjusted accordingly. Zaleplon is not available in Australia

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however some patients may bring their own medications into hospital therefore some information about zaleplon is provided in this section.

10.2.1 Zaleplon

Has a rapid elimination so it has fewer residual side effects (after a single nocturnal dose). Zaleplon is ideally suited for insomnia related to prolonged time to sleep onset. It has amnesic effects so it is recommended that it is given at least four hours before 'morning' (Drover 2004).

10.2.2 Zolpidem and zopiclone

Have a more delayed elimination and therefore result in residual sedation and may be more effective for insomnia in which sleep maintenance is problematic rather than for prolonged time to sleep onset. Zolpidem should not be re-administered for night-time awakening as its relatively long effects will carry over into the daytime (Kryger et al. 2005).

Long-term use of all the nonbenzodiazepine hypnotics described in this section is not recommended and should not exceed two to four weeks. They have been associated with severe sleep related disorders such as sleep walking, sleep eating and sleep talking. Psychiatric symptoms including hallucinations and even self harm have been noted (Hoque and Chesson 2009). Flumazenil is the antidote for zolpidem and zopiclone.

10.3 Antipsychotics

The GABA agonists may exacerbate delirium so their administration for sleep promotion during delirium is not recommended. In addition the administration of multiple medications should be avoided during delirium. Therefore additional nocturnal doses of antipsychotics may assist in sleep promotion for patients who are delirious.

10.3.1 Typical

The typical antipsychotic haloperidol may be a useful hypnotic.

10.3.2 Atypical

The atypical antipsychotics may be considered for patients treated in ICU who have preexisting psychiatric illness (e.g. schizophrenia, bipolar depression)*, dementia or delirium. They have fewer extrapyramidal side effects than the typical antipsychotics but may cause cognitive impairment and hypotension at high doses.

- Olanzapine has antipsychotic, antimanic and mood stabilizing effects. Evidence suggests that it prolongs sleep time and non-rapid eye movement sleep stages 2 to 4 but suppresses rapid eye movement sleep (Gimenez et al. 2007). Sedative effects occur four to six hours after administration.
- Quetiapine has similar effects to olanzapine. Onset of sedative effects occur one to two hours after administration. A number of cases of QT interval prolongation have been reported, especially at higher doses.
- Risperidone is used in the treatment of several psychiatric illnesses and to ameliorate the symptoms of dementia. In patients with these preexisting illnesses administration of a once daily dose at night may assist in sleep promotion while reducing daytime somnolence (a known effect of risperidone).

The majority of antipsychotic medications have been associated with QT interval prolongation and extrapyramidal side effects.

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*N. B. It is recommended that the advice of the patient's mental health team is sought before changing medication regimen.

10.4 Antidepressants

Antidepressants may be used to lift the spirits and promote sleep in longer term ICU patients. They also have other side effects which may be helpful to longer term patients e.g. appetite stimulant.

10.4.1 Tricyclics (TCAs)

TCAs have useful sedative effects and several medications in this class e.g. amitriptyline and doxepin have been used exclusively for their sleep promoting properties. The effect of TCAs on sleep architecture varies between medications (Mayers and Baldwin 2005). Increased slow wave sleep (stages 3 and 4) has been reported for amitriptyline and doxepin (Mayers and Baldwin 2005). In fact doses of doxepin as low as 3mg have been shown to be effective hypnotics in the treatment of primary insomnia (Roth et al. 2007). The onset of effect for amitriptyline and doxepin is between two and six hours so administration earlier in the evening is advised.

10.4.2 Mirtazapine

Mirtazapine is similar to the TCAs. It has not yet been extensively evaluated as a hypnotic. There have been mixed results of its effects on sleep architecture however it consistently prolongs sleep time, reduces time to sleep onset and improves the subjective quality of sleep (Mayers and Baldwin 2005). Its onset of effect occurs within three hours. Clinical observations suggest that higher doses (>30mg/day) are associated with less sedative effects (Kryger et al. 2005).

There are a number of unwanted drug interactions with medications commonly administered in ICU and TCAs. For example the risk of seizure is greatly increased when TCAs are used concomitantly with the analgesic tramadol.

10.5 Alpha agonists

Alpha agonists have a role in the management of agitation and have sedative effects. The alpha-2 agonist dexmedetomidine has sedative and analgesic qualities and may be particularly useful if agitation leads to sleep disruption.

10.5.1 Dexmedetomidine

Dexmedetomidine is approved as a procedural anaesthetic and post-operative short term (24 hours) sedative and analgesic. It reduces noradrenaline release in the brain producing a sedative state representative of natural sleep. Patients are easily roused during sedation with dexmedetomidine. There is a dose dependent slowing of the EEG so that slow wave sleep (stages 3 and 4) is maintained but rapid eye movement sleep is suppressed. It has yet to be properly evaluated as a medication to promote sleep. Dexmedetomidine has an immediate onset of effect and sedation is maintained by infusion.

10.5.2 Clonidine

Clonidine has alpha as well as beta effects. It is an effective antihypertensive often used for hypertensive crisis. It has useful sedative effects and is also used during opioid withdrawal to

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ameliorate some of the sympathetic nervous system symptoms. It may have a limited application for sleep promotion in the ICU setting, if dosing is timed for nocturnal sleep.

10.6 Exogenous melatonin

Melatonin is used for the short-term alleviation of insomnia. This naturally occurring hormone is both sleep promoting and maintaining. Despite its popularity in the treatment of primary insomnia e.g. jet lag and shift work the effectiveness of exogenous melatonin as a sleep medication is yet to be clearly elucidated (Buscemi et al. 2005, Buscemi et al. 2007). Investigations performed in ICU did not use polysomnography and were largely inconclusive (Bourne et al. 2008, Ibrahim et al. 2006, Shilo et al. 2000). Difficulties occur in emulating the typical endogenous pulsatile secretion of the hormone together with its short half life probably explain why many study results are inconclusive. The high doses required to achieve an adequate plasma level overnight when administered once at the beginning of the night likely persist in the body and may upset normal circadian rhythm. Some studies investigating the effect of melatonin on insomnia suggest that it may be more effective when administered to adults older than 55 years as there is an age related decrease in endogenous melatonin (Brzezinski et al. 2005).

The typical dose is 2 mg once a day (1-2 hours before settling).

The current advice of the authors of this guideline is that it is better to provide conditions which encourage the normal circadian secretion of endogenous melatonin (see section 9.2) than to administer exogenous melatonin.

11.0 Patient exceptions from the Rest and Sleep guideline

Patient safety and comfort are paramount at all times. Vigilance and careful consideration of the individual needs of each patient treated in ICU will ensure that essential aspects of care and treatment are not overlooked. 'An exception list' can never be exhaustive however a couple examples of when the interventions in this guideline may not be appropriate or safe are provided below:

- Clinical crisis/acute medical deterioration

Regardless of the time of day the main light above the patient's bed should be turned on. Interventions may not be able to be clustered/consolidated until the patient is sufficiently stable. Treatment and care should be continued according to the clinical priorities even if this means disturbing others.

- Palliation/end of life care

Relatives and friends of the patient should not be encouraged to leave during the afternoon rest time if death is imminent. Alarms and monitoring may be removed. Lighting can be adjusted as befits the situation.

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12.0 Audit document: Rest and Sleep Summative Index

Instructions: Check that the descriptors are evident. Higher scores require incremental addition of descriptors from previous level(s) i.e. 'excellent' rating is achieved when descriptors from 'minimal' and 'good' levels are evident together with 'excellent' descriptors.

Intervention	Levels of care (all descriptors present)			Score
	Minimal (1)	Good (2)	Excellent (3)	
1. Provide optimal conditions for night time sleep	Patient settled before 2200hrs Alarms: Set as described in guideline Patient did not receive a full body wash between 2300 and 0630 hours unless requested	Ear plugs and eye shades offered Evidence of orders for frequency of neurological and vital sign observations Evidence that care/treatment were consolidated so that patient was uninterrupted for two 1.5 to 2 hour periods	Usual sleep practices noted in multidisciplinary care plan Evidence that ICU staff specialist/senior registrar has considered mechanical ventilatory requirements	
2. Optimize normal circadian rhythm	Mean light level is <9 lux between 2300 and 0700hours	Patients who are required to mobilize are assisted before midday	Mental stimulation is provided during daylight hours	
3. Manage pain well	Assessment of pain intensity/location recorded ≤ 4 hours Analgesia administered if pain is suspected (e.g. recent traumatic/burn injury)	Effectiveness of pain control interventions recorded	Patient states that pain is controlled to a level in which mobility is possible (or pain free).	
4. Provide a rest period during day light hours	Blinds are drawn and lights are dimmed between 1330 and 1500hours	Visitors who wish to be present are requested to sit quietly by the bed	Evidence of reduced activity between 1330 and 1500hours	
			Summative score	

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Appendix A: Richards Campbell Sleep Questionnaire

Each of these questions is answered by placing an "X" on the answer line. Place your "X" anywhere on the line that you feel best describes your sleep last night.

1. My sleep last night was:

Deep Sleep — Light Sleep

2. Last night, the first time I got to sleep, I:

Fell asleep almost immediately — Just never could fal asleep

3. Last night, I was:

Awake very little — Awake all night long

4. Last night, when I woke up or was awakened, I:

Got back to sleep immediately — Couldn't get back to sleep

5. I would describe my sleep last night as:

A good night's sleep — A bad night's sleep

Richards et al. 2000

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Appendix A: Intensive care nurses' patients sleep observation tool

Please check on the patient you are looking after every 15 minutes and tick the box in the table below which best describes the patient's status.

Study no.:			**Date:** —/—/——				**Nurse initials:**		
Date of Birth:—/—/——			**ICU admission day:**						
Time	**Awake**	**Asleep**	**Could not tell**	**No time to observe**	**Time**	**Awake**	**Asleep**	**Could not tell**	**No time to observe**
2000					**0200**				
2015					0215				
2030					0230				
2045					0245				
2100					**0300**				
2115					0315				
2130					0330				
2145					0345				
2200					**0400**				
2215					0415				
2230					0430				
2245					0445				
2300					**0500**				
2315					0515				
2330					0530				
2345					0545				
2400					**0600**				
0015					0615				
0030					0630				
0045					0645				
0100					**0700**				
0115					0715				
0130					0730				
0145					0745				
					0800				
Comments regarding the patient's sleep:									

Edwards and Schuring 1993

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Appendix B: Instructions for the safe insertion and use of ear plugs

1. Do not insert if ear damage or excessive ear wax is suspected
2. Obtain a new pair of ear plugs (do not use if the packaging is open)*
3. Wash hands don gloves and apron
4. Roll rather than squeeze the ear plug between the fingers to make a small cylinder
5. Pull the pinna (outer ear) outwards and upwards
6. Gently insert the ear plug quickly into the ear canal before it can re-expand
7. Gently push the ear plug with the tip of your gloved finger while it expands in the ear (approximately one minute)
8. Repeat for the other ear

*NB to avoid ear infections earplugs are one use only (do not reuse even for the same patient)

Appendix C: Reference values for sound and light levels

Sound levels

The threshold for human hearing is 0(A)dB. Sound levels in a quiet library are approximately 20-30 (A)dB. A busy meeting room may have sound levels at 50-60 (A)dB. Sounds levels near a busy road such as the Pacific Highway are around 80 (A)dB. Rock concerts may be louder than 100 (A)dB and the threshold for pain (analogous to standing near a space rocket taking off) is 130(A)dB. Since the decibel scale is logarithmic each increase of 10dB is perceived as a doubling in sound level. Sound level standards for hospitals are provided below:

- **EPA, New South Wales 2000**

Max 45 dB

- **Australian Standard AS/NZS 2107/2000**

Max 45 dB

- **Environmental Protection Agency, US 1974**

Day 45 dB
Night-time 35 dB

Light levels

Light (i.e. illuminance) levels are measured in lux. Complete darkness is zero. An overcast day is around 100 lux and a bright sunny day is 1000 lux. The main room lights in the ICU emit between 50-300 lux depending on the dimmer setting and depending on the area of the room. Typical light levels during data collection in the preintervention phase of the ICU Sleep Study, at night, were 1 lux. The main room lights were turned off and small lights near the nurses' station were used.

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13.0 Acknowledgments

Thank you to all of the personnel working in ICU at the Royal North Shore Hospital for their useful suggestions and enthusiasm. Special thanks to all of the nurses who assisted in data collection during the preintervention phase of the ICU Sleep Study.

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APPENDIX U: Presentation of results to ICU health care personnel

Improving the amount and quality of sleep for intensive care patients.

Baseline data and discussion: solving the puzzle

Rosalind Elliott, Professors Sharon McKinley and Peter Cistulli and Mary Fien

NORTHERN SYDNEY CENTRAL COAST NSW HEALTH

UNIVERSITY OF TECHNOLOGY SYDNEY

Outline

- Background
- Design
- Demographic data
- Sleep data
- Sound data
- Light data
- The puzzles that need to be solved
- Questions for discussion

Background

- Sleep disruption is bad for health leading to stress related illness
- International healthcare research indicates that ICU patients do not sleep well
  - Prolonged light sleep (Stages 1 and 2)
  - Reduced deep/slow wave sleep (Stages 3 and 4)
  - Reduced rapid eye movement (REM) sleep
  - Significant sleep disruption and sleep fragmentation
- No published objective sleep data from ICU's in Australia
- Research indicates that noise levels are excessive in ICU

Design

- Aim
  - To improve sleep for ICU patients
- Preintervention and post intervention
  - Comparison of sleep before and after the implementation of an intervention
- Development and implementation of an intervention suggested by clinicians and personnel working within the ICU

Design continued

- Preintervention phase
  - Baseline data collection
    - 24 hour sleep recording using polysomnography
    - 24 light and sound levels
    - Nurse administered event log (thank you)
    - Nurses' assessment of the patients' sleep overnight (thank you)
    - Patients' self assessment of sleep in ICU and the ward afterwards
    - Patients' sleep and psychological status during recovery at home after discharge from hospital

Design continued

- Intervention phase
  - Purpose of today's discussions
    - To discuss the baseline data
    - To suggest interventions which may improve sleep for ICU patients – to solve the puzzle

Design continued

- Post intervention phase
  - Collect data to compare with the preintervention phase
    - 24 hour sleep recording using polysomnography
    - 24 light and sound levels
    - Nurse administered event log
    - Nurses' assessment of the patients' sleep overnight
    - Patients' self assessment of sleep in ICU and the ward afterwards
    - Patients' sleep and psychological status during recovery at home afterwards

Demographic data

n =30	Mean ± SD	Median (Range)
Age	59 ± 20	65.5 (22-85)
Gender M/F (% male)	20/10 (66)	
Intubated/trache during sleep monitoring, n (%)	17 (56)	
Duration of mechanical ventilation, days	13.25 ± 13.31	8.5 (0-40)
Length of ICU stay, days	17.13 ± 14.58	12 (3-45)
Length of hospital stay, days	45.16 ± 41.39	36.5 (7-186)
Status on discharge from ICU	1 died	

Demographic data

n=30		
	Mean ± SD	Range
APACHE II score (severity of illness)	15.3 ± 6.35	7-31
APACHE III score (severity of illness)	57.3 ± 25.2	18-104
Diagnosis (ANZICS modified APACHE III)	n (%)	
Operative, 11 (36%)		
Cardiothoracic /Respiratory	6 (20)	
Musculoskeletal	1 (4)	
Abdominal/G.I.	2 (6)	
Other	2 (6)	
Non-operative, 19 (64%)		
Respiratory	3 (10)	
Cardiac	7 (24)	
Sepsis	3 (10)	
Trauma	6 (20)	

Sleep data: Polysomnography (PSG)

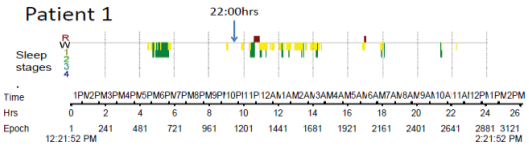
Parameter	Results (n=22) Mean ± SD (range)	Normal values Mean ± SD (range)
Total sleep time (hours)	5:06 ± 4:05 (6 mins-17:20)	7:30 ±1 (6 -8 hours)
Daytime sleep (0600-2100) (%)	53 ± 26 (0-100)	0 %
Stage 1 (%)	34.87 ± 28.88 (3.8-100)	2-5 %
Stage 2 (%)	60.75 ± 27.97 (0-92)	45-55 %
Stage 3 (%)	0.98 ± 2.59 (0- 9.5)	3-8 %
Stage 4 (%)	0.41 ± 1.92 (0-8.8)	10-15 %
Rapid Eye Movement (%)	2.49 ± 4.4 (0- 17.3)	20-25 %
Arousal index (no. per hour of sleep)	116.71 ± 161.03 (2-642)	15-30/hr
Sleep efficiency index (%)	21.9 ± 17.05 (0.5-73.2)	28 %

Sleep data: sleep fragmentation

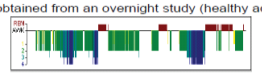
Parameter	Mean ± SD	Median (Range)
Duration of sleep episodes, hh:mm:ss	00:05:47 ± 00:09:52	00:02:30 (00:00:30-01:44:30)
No. of sleep episodes	55 ± 45	47 (5-164)
No. of sleep stage changes	164 ± 139	138 (10-522)

Sleep fragmentation

Patient 1

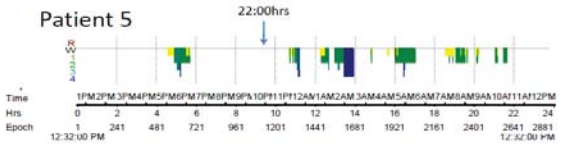


Normal hypnogram obtained from an overnight study (healthy adult)

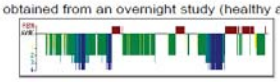


Sleep fragmentation

Patient 5



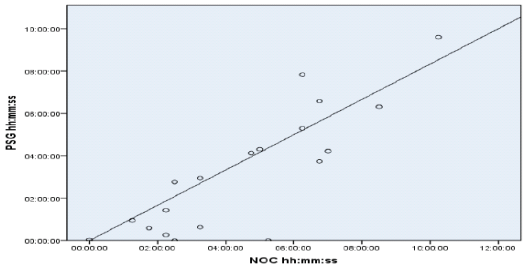
Normal hypnogram obtained from an overnight study (healthy adult)



Sleep time at night (2000-0800hrs): PSG, Nurse & Patient

Instrument	Mean ± SD	Median	Range
Polysomnography (hours:mins)	3:14 ± 2:54	2:57	0-9:36
Nurses' observation (hours:mins)	4:30 ± 2:42	4:45	0-10:15
Patient - Richards Campbell Sleep Questionnaire (mm) (0 is poor and 100 is excellent)	48.9 ± 28.4	59	0-84

Night time sleep: Comparison of nurses' observation with PSG



r = 0.85, p=<0.000

Reference values for 'A' weighted decibels

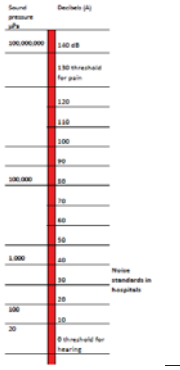
EPA, New South Wales 2000
Max 45 dB

Australian Standard AS/NZS 2107:2000
Max 45 dB

Environmental Protection Agency, US 1974
Day 45 dB
Night 35 dB

Sound data

n=27	Mean ±SD	Range
Average (Continuous equivalent) sound level, L(A)dB	56.4 ± 1.68	52.7-59.5
Peak (highest) sound level, L(C)dB	103.5 ± 24.3	1-138
Background sound level (sound exceeded 90% of the time, LAF_{90})	46.85 ± 2.9	42-53
Number of peak sound levels above >80(C)dB	6242 ± 2501	690-11319
Number of peak sound levels above >90(C)dB	357 ± 163	40-702
Number of peak sound levels above >100(C)dB	14 ± 8	1-38



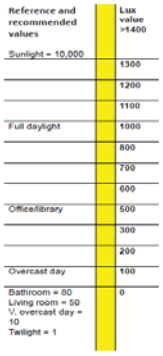
Sound data: sources of noise

- Background noise comprises
  - Air conditioning
  - Ventilators, bed mattresses etc
- Other sources
  - Conversation contributes to sound level
    - On average 8dB (i.e. almost a doubling in sound level)
  - Alarms
    - 'stop' on IV medication syringe driver =71dB
    - Switching Drager ventilator on and alarm = 70dB
    - Monitor 'crisis' alarm = 56dB
- Apparently innocuous activities e.g. placing scissors on a metal trolley =71dB

Light levels

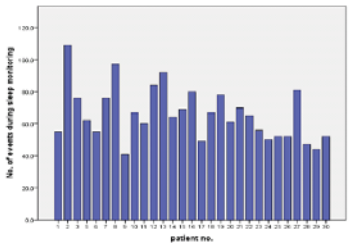
Light data

Illuminance level (Lux)	Mean ± SD	Range	Median	Mode
24 hours	70.27 ± 103	0.01-977	34.9	1.06
Night (2100-0600hrs)	9.36 ± 24.37	0.01-515	2.03	1.06
Day (0600-2100hrs)	107.7 ± 114.75	0.06-977	73.9	54.6

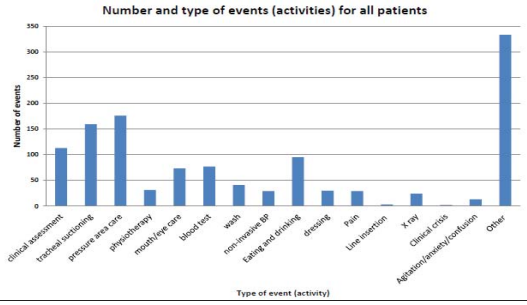


Event log: total no. of events during sleep monitoring

N=29	
Mean ± SD	65.8 ± 15.5
Median	64
Range	41-109



Event log



Other variables

- Medications
  - Most patients did receive one medication or more known to affect sleep
    - Low doses of benzodiazepines (n=14)
    - Atypical antipsychotics (n=3) e.g. quetiapine
    - Antidepressants (n=3) e.g. duloxetine
- Mechanical ventilation
  - Pressure Support (n=15)
  - Pressure Control (n=4)
  - Non-invasive (n=2)

The puzzles that need to be solved

- Intrusive sound levels
- Significant sleep fragmentation
- Reduced slow wave/deep and REM sleep
- Poor quality of sleep reported by patients

Question 1 for discussion

- How best can we give ICU patients the opportunity to rest and experience restorative sleep while in ICU?

Question 2 for discussion

- What do we do now which might help to achieve this?
  - How can we do this more often?

Question 3 for discussion

- Of the things that are not happening now what would we need to do to make them happen?

Questions for discussion continued

- The 'miracle' question
  - a question based on our existing strengths, to help find solutions to this puzzle
    - Imagine this research project is complete. Patients treated in the ICU consistently remark on how well they sleep in ICU. How did we achieve this?

APPENDIX V: Reminder signs

ICU Sleep Study

Sleep architecture

- Consolidated period
  - Total sleep time (TST) is approx. 7.5 hours
  - Wakefulness accounts for <5% of TST
- Comprises two separate states:
  - Non- rapid eye movement (NREM) sleep (stages 1 to 4)
  - Rapid eye movement (REM) sleep
- Sleep onset is through NREM sleep
- Occurs at night and has a recognizable pattern
  - Progresses through stage 1 to 4 then REM (cycle)
  - Each cycle is 90 to 110mins long

For information on how to enhance ICU patients' sleep please use the guideline 'Rest and Sleep for the ICU patient', on the ICU intranet

ICU Sleep Study

Tips on reducing noise levels in ICU

- Set alarms appropriately
- Attend to alarms swiftly
- Report faulty equipment
- Converse quietly at all times
- Move to within 1.5 metre of the person with whom you are conversing
- Wear shoes that do not 'click' or 'squeak'

For more details see the guideline 'Rest and Sleep for the ICU patient' on the ICU intranet

ICU Sleep Study

Sleep and shift work: practical tips to help

- Wear sunglasses on your way home after a night
- Be most active when you get up
- Sound & light proof your sleeping area
- Switch off phones
- Use a 'settling' routine
- 'Educate' family, friends & neighbours about shift wor..
- Eat & drink healthily (not too much caffeine, fat, salt or carbs!)
- Take prophylactic naps during breaks
- Schedule time to catch up on sleep on days off
- Schedule regular holidays (at least every 6 months)
- Avoid demanding schedules e.g. frequent rotations, excessive overtime

ICU Sleep Study

A polite reminder: daytime rest period

- 1330 to 1500hrs each day
- Dim lights (pull blinds and switch off non-essential lights)
- Reduce activity and noise levels
- Essential treatment and care e.g. physiotherapy may need to continue
- Close family/friends may be present but should be requested to sit quietly

Source: Rest and Sleep for the ICU patient, ICU intranet

ICU Sleep Study

Sleep: interesting facts

- Exposure to noise at night can result in immune suppression even if the person does not visibly wake
- The common rabbit and man have the same sleep duration (7-8 hrs/24hrs) however the rabbit is nocturnal and man is diurnal
  Siegel 2005
- Insufficient sleep reduces the effectiveness of a low energy diet
  Nedeltcheva et al. 2010
- 20-25 hrs sleep deprivation equates to the effect of a 0.1% blood-alcohol level on driving performance
  Lamond and Dawson 1999
- Dreams occur in all sleep stages (although they are vivid in REM sleep)
  Siegel 2003

For your ideas on how to increase ICU patients' to rest and sleep see the guideline, 'Rest and Sleep for the ICU patient' on the ICU intranet

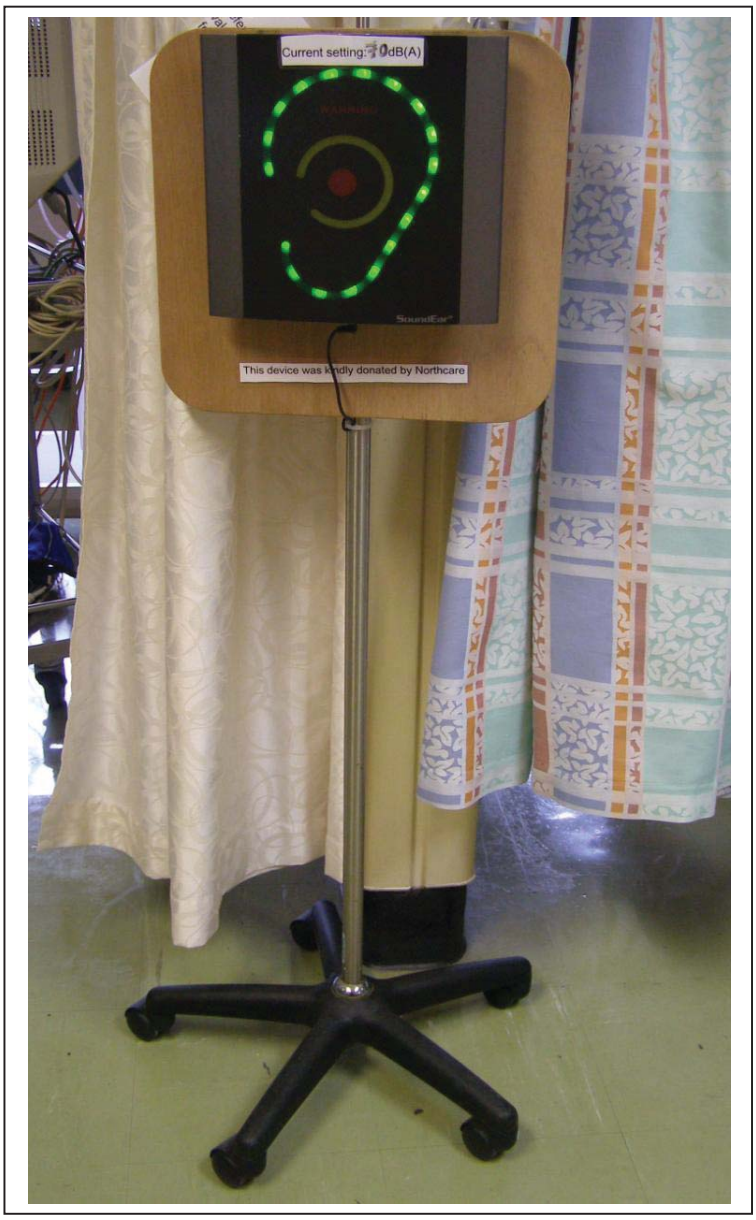
ICU Sleep Study

Sleep wisdom

- 'Sleeping is no mean art: for its sake one must stay awake all day' Friedrich Nietzsche
- 'There is more refreshment and stimulation in a nap, even of the briefest, than in all the alcohol ever distilled' Edward Lucas
- 'People who say they sleep like a baby usually don't have one' Leo J. Burke
- 'Life is something that happens when you can't get to sleep' Fran Lebowitz
- 'Consciousness: that annoying time between naps' Author Unknown
- 'There is no snooze button on a cat who wants breakfast' Author Unknown

For your wisdom read the guideline 'Rest and Sleep for the ICU patient', on the ICU intranet

APPENDIX W: The SoundEar 2000© (visual sound level reminder)



Photograph showing the SoundEar 2000© used as a visual reminder of sound pressure levels

Appendix X: 'Sleep' presentations

Sleep architecture

A brief overview of normal sleep in adults

Rosalind Elliott
Research student

NORTHERN SYDNEY CENTRAL COAST NSW HEALTH
UNIVERSITY OF TECHNOLOGY SYDNEY

Outline

- Definition
- Components of healthy sleep
- Measurement of sleep
- Light sleep: Stage 1 and 2
- Slow wave sleep: Stage 3 and 4
- Rapid eye movement (REM) sleep
- Sleep over the lifetime
- Factors affecting sleep architecture
- Overview of ICU sleep data
- Discussion

Definition

A reversible behavioural state of perceptual disengagement from and unresponsiveness to the environment characterised by postural recumbence, behavioural quietness and closed eyes

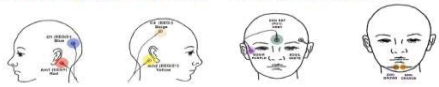
Kryger et al. 2005

Components of healthy sleep

- Consolidated period
  - Total sleep time (TST) is approx. 7.5 hours
  - Wakefulness accounts for <5%
- Comprises two separate states:
  - Non- rapid eye movement (NREM) sleep (stages 1 to 4)
  - Rapid eye movement (REM) sleep
- Sleep onset is through NREM sleep
- Occurs at night and has a recognizable pattern
  - Progresses through stage 1 to 4 then REM (cycle)
  - Each cycle is 90 to 110mins long

Measurement of sleep

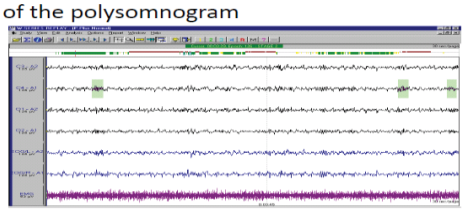
- Polysomnography is the 'gold standard'
  - Electroencephlogram (EEG) – brain wave activity
  - Electrooculogram (EOG) – eye movements
  - Electromyogram (EMG) – muscle movement



  - Enables sleep to be staged

Measurement of sleep

- Sleep is staged by studying the EEG, EMG and EOG activity on each 30 second epoch (period) of the polysomnogram



Light sleep: stages 1 and 2

- Constitute up to 60% of total sleep time (TST)
  - Stage 1 accounts for 2-5% TST
- Polysomnographic features include
  - Reducing activity in the EEG
  - Slow eye movements (EOG)
  - Low level muscle activity (EMG)
- Person is easily woken in stage 1
- Stage 2 becomes the more prevalent NREM sleep component of each cycle as the night progresses

Slow wave sleep: stages 3 and 4

- Constitute up to 20% of total sleep time (TST)
  - Stage 3 accounts for 3-8% TST
- Polysomnographic features include
  - Slow wave activity in the EEG
  - No eye movements (EOG)
  - Very low level muscle activity (EMG)
- Person is difficult to wake while in stage 3 and 4
- The proportion of deep sleep decreases in each sleep cycle towards morning

Rapid eye movement (REM) sleep

- Constitutes up to 25% of total sleep time (TST)
- Polysomnographic features include
  - 'Saw tooth' wave activity in the EEG
  - Rapid eye movements (EOG)
  - No muscle activity (EMG)
- Wakening threshold is variable during REM sleep
- There is a higher proportion of REM in each cycle as the night progresses

Sleep over the lifetime

- Newborns
  - Enter REM sleep (active sleep) before NREM sleep (quiet sleep)
  - Active sleep constitutes 50% of TST
  - Short sleep cycle (approx. 50 mins)
  - Sleep stages emerge in the first year
- At two years sleep stages are clear
- Slow wave sleep (stage 3 and 4) decreases from 40% TST in childhood across adolescence and almost disappears at 60 years (esp. in men)
- The proportion of REM sleep remains constant

Factors affecting sleep

- Age
- Noise
  - 37-40dB results in sleep disturbance (in adults)
- Circadian rhythm
  - Shift work/jet lag
    - Sleep tends to occur as the body temperature falls
  - Melatonin
    - Released during night time hours (midnight to 0300hrs)
    - Sleep promoting and maintaining
  - Zietgebers (time givers)
    - Light levels (melatonin secretion is suppressed by light)
    - Exercise

Factors affecting sleep

- Prior sleep history
  - Previous sleep loss
  - Slow wave sleep predominates during recovery from total sleep loss
  - REM sleep predominates during recovery from REM sleep loss
- Ambient temperature
  - Body is unable to thermoregulate during REM sleep

Factors affecting sleep

- Medications
  - Benzodiazepines suppress deep sleep
  - Many antidepressants suppress REM sleep
  - Beta blockers and opioids reduce SWS and REM sleep
  - Corticosteriods reduce REM sleep
  - Adrenaline reduces total sleep time
- Illness/pathology
  - Sleep disorders, obstructive sleep apnea
  - Sleep fragmentation as a result of
    - pain, neurological disorders, SIRS etc

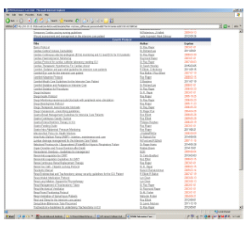
Overview of ICU sleep data

Parameter	Results (n=22) Mean ± SD (range)	Normal values Mean ± SD (range)
Total sleep time (**hours**)	5:06 ± 4:05 (6 mins-17:20)	7:30 ±1 (6 -8 hours)
Daytime sleep (**0600-2100**) (%)	53 ± 26 (0-100)	0 %
Stage 1 (%)	34.87 ± 28.88 (3.8-100)	2-5 %
Stage 2 (%)	60.75 ± 27.97 (0-92)	45-55 %
Stage 3 (%)	0.98 ± 2.59 (0- 9.5)	3-8 %
Stage 4 (%)	0.41 ± 1.92 (0-8.8)	10-15 %
Rapid Eye Movement (%)	2.49 ± 4.4 (0- 17.3)	20-25 %
Arousal index (**no. per hour of sleep**)	116.71 ± 161.03 (2-642)	15-30/hr
Duration of sleep episodes, hh:mm:ss	00:05:47 ± 00:09:52 00:02:30 (00:00:30-01:44:30)	

Rest and Sleep Guidelines for the intensive care patient

- Located on the ICU intranet
- Main components
  - Assessment of sleep during health
  - Noise reduction
  - Clustering care
  - Appropriate ventilation settings at night
  - Rest period during daylight hours
  - Reduced activity at night (e.g. hygiene) if possible

Rest and sleep guideline for intensive care patients



Sleep and shift work: information and practical tips to survive

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Outline

- Introduction
- Components of healthy sleep
- Shift (night) workers' sleep
- Circadian Rhythm
- Factors affecting the ability to cope with shift work
- Circadian Rhythm: practical tips
- Sleep: practical tips
- Type of shift and time frame to change: practical tips
- Overview of ICU patients' sleep

Introduction

- Definition: shift work
  - Work conducted outside the 0700 to 1800hrs time zone
- Shift work is associated with negative health outcomes
  - There is no magic bullet
  - However better self-care can reduce the likelihood and even eliminate negative health outcomes

Components of healthy sleep

- Consolidated period
  - Total sleep time (TST) is approx. 7.5 hours
  - Wakefulness accounts for <5%
- Comprises two separate states:
  - Non- rapid eye movement (NREM) sleep (stages 1 to 4)
  - Rapid eye movement (REM) sleep
- Sleep onset is through NREM sleep
- Occurs at night and has a recognizable pattern
  - Progresses through stage 1 to 4 then REM (cycle)
  - Each cycle is 90 to 110mins long

Shift (night) workers' sleep

- Potential sleep problems associated with all types of shift work
  - Very early shifts and night shifts are the worst
- 10 hours less sleep per week than day workers
- Less stage 2 and REM sleep but a greater proportion of deep sleep than day workers
- Often experience sleep maintenance insomnia and sleep deprivation
  - Neurological effect comparable to a breath ethanol conc. of 0.045%

Circadian Rhythm

- *Homo sapiens* is a diurnal species
  - Biologically hard wired to be active during the day and sleepy at night
  - Takes 1 week for complete circadian realignment (i.e. to change from being awake during the day to night) or 90 minutes per day
  - It is easier to go back to being awake during the day and sleepy during the night
  - Slight variations in individual's circadian rhythms
    - 'Night owls' /late phasers and 'morning larks'/early phasers
    - Advancing age tends towards 'morningness'

Factors affecting the ability to cope with shift work

- Dependent on the following factors
  - Circadian rhythm
  - Sleep
  - Domestic situation
  - Type of shift and time frame to change (rapid or slow change)

Circadian rhythm: practical tips

- Exposure to appropriate light levels
  - Wear dark glasses on the way home from a night shift
  - When you get up expose yourself to bright light (artificial room light is fine)
  - very sleepy on night duty go out into a well light room for a few minutes
- Activity levels
  - Be most active when you get up (not on your way home)
- Less crucial to align circadian rhythm if rapid rotation of shifts

Sleep: practical tips

- Sleep during daytime is never as good however:
  - Sound and light proof your sleeping area
    - Ear plugs
    - Eye shades
  - Switch off phones
  - Use your usual 'settling down' regimen
  - 'Educate' your family, friends and neighbours
- Food and drink
  - Healthy is best
  - Avoid large intakes of caffeine and junk food
  - Eat protein at night and carbohydrate sparingly

Sleep: practical tips

- Very short prophylactic naps are beneficial (taken during official breaks!!)
- Ensure ample opportunity to sleep for longer periods during days off
- Schedule regular holidays (don't accumulate lots of leave and become too sick to use it!)
- If sleep complaints are on-going consider seeing a sleep expert (sleep investigation unit)

Type of shift & time frame to change: practical tips

- Minimise/reduce exposure to:
  - >5 night shifts in a row
  - >four 12 hour shifts in a row
  - <48 hours off between several night shifts
  - Excessive overtime
  - Backward rotating shifts (early to night to late)
  - Long commuting
  - <8 hours off between shifts

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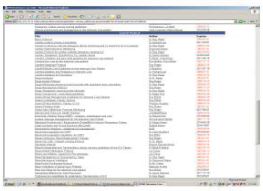

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