THE EFFECT OF AN ALGORITHM BASED SEDATION GUIDELINE ON THE DURATION OF MECHANICAL VENTILATION FOR INTENSIVE CARE PATIENTS IN AN AUSTRALIAN INTENSIVE CARE UNIT

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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 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 itself 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 who are cared for in intensive care units (ICUs) have life threatening illnesses and require intrusive interventions and monitoring, which may cause discomfort. They often require analgesic medications to relieve pain and sedative medications to reduce anxiety. Agitation and accidental self-harm may result from providing too little medication and the administration of too much may lead to the prolongation of mechanical ventilation. Sedation guidelines offer the potential to reduce these problems.

The aim of this study was to examine the effect of an algorithm based sedation guideline on the duration of mechanical ventilation of patients in an Australian ICU. Secondary aims included the effect of the guideline on the: patients' perspective of their recovery; length of stay in ICU; number of tracheostomies; number of self-extubations and reintubations; and the cost of intravenous sedative medications. The rate of adoption of the guideline and sedation scale was examined.

The intervention was tested in a quasi-experimental preintervention and postintervention study (n= 322). The sample comprised 58% men and the median age was 61.1 years (range 19.7 to 91.8 years). Mean Acute Physiology and Chronic Health Evaluation II score was 21.8 points (range 3 to 45 points). Nineteen percent of patients were admitted post operatively and 81% were admitted for non-operative medical diagnoses. Mechanical ventilation was instigated for 225 (70%) patients prior to admission to the study ICU. There was a 22% mortality rate. The groups were equivalent at baseline.

The mean duration of mechanical ventilation was 4.33 days for the preintervention group and 5.64 days for the postintervention group (p=0.02). There was no difference in the patients' perspective of their recovery. There was no difference in length of stay in ICU and the number of tracheostomies. The number of self-extubations and reintubations were similar. The overall cost of intravenous sedative medications increased slightly in the postintervention phase. Sedation scale adoption was poor in the preintervention phase but increased in the postintervention phase. The sedation

guideline was gradually adopted in the postintervention phase. Adoption data suggests that patients were more deeply sedated during the postintervention phase.

In conclusion, the sedation scale and sedation guideline were well adopted by the nurses. Patients were more deeply sedated when the guideline was used and there was a mean increase in duration of ventilation of 1.31 days. Other secondary patient outcomes were not affected. The successful implementation of a clinical guideline was demonstrated but was not associated with improvements in patient outcomes in this setting.

Chapter One - Introduction

1.1 Background to the study

Introduction

Patients are treated in intensive care for life threatening illnesses. They often require technology to keep them alive such as mechanical ventilators to assist breathing, medications to support blood pressure and invasive catheters to provide nourishment, fluids and monitoring.

Despite the best efforts of clinicians to provide comfort, intensive care patients frequently require analgesic and sedative medications to enable them to tolerate the intensive care environment and the intrusive therapy necessary to treat them. If insufficient analgesic medications are provided, patients may experience discomfort and insufficient amounts of sedative medications may result in anxiety and agitation. Extreme agitation may lead the patient to remove life sustaining devices such as artificial airways. However high doses of these medications may lead to the avoidable prolongation of mechanical ventilation and concomitant adverse effects such as ventilator associated pneumonia. Therefore clinicians are required to administer sufficient medications to provide comfort and simultaneously avoid giving too much medication. However a major difficulty of achieving this ideal situation is the subjective nature of assessing sedation level and sedation requirements of intensive care patients.

An objective assessment of sedation level is required to enable clinicians to titrate sedative and analgesic medications safely and effectively. Generally there are two methods of assessing sedation level: sedation scales and electroencephalography (EEG) derived methods, for example Bispectral Index. Sedation scales are generally used in preference because there are insurmountable technological difficulties associated with EEG derived methods.

The explicit statement of the desired sedation level incorporated in sedation guidelines is understood to be responsible for the significant improvement in patient outcomes associated with their use. Sedation guidelines have been demonstrated to reduce the duration of ventilation, length of intensive care unit (ICU) stay, number of tracheostomies and number of unscheduled self-extubations. The algorithm based sedation guideline used in this investigation was previously found to improve intensive

care patient outcomes, such as duration of ventilation, in a North American ICU (Brook et al., 1999). To date no study, conducted to investigate the effect of a sedation guideline in an Australian ICU, has been published.

Addressing the discomfort associated with intensive care

Intensive care patients are frequently unprepared for the experience of being admitted to and treated in the ICU. Intensive care units have high activity levels reflective of the severity of illness of the patients who are cared for there. Intensive care patients require invasive monitoring using intravascular catheters and they may have to contend with intrusive treatments delivered via artificial airways and intravascular catheters. Verbal communication is impossible for patients who have artificial airways. Sleep may be interrupted in the busy environment. These factors together with the associated symptoms of their illness and the stressful environment present intensive care patients with many sources of discomfort (McKinley, Nagy, Stein-Parbury & Hudson, 2002; Turner, Briggs, Springhorn & Pogieter, 1990; van de Leur, van der Schans, Loef & Deelman, 2004).

Discomfort is unpleasant if it is not relieved and the resulting stress may cause detrimental physiological effects such as increased oxygen consumption and compromised immunity. Severe agitation may result in the removal of life sustaining devices such as artificial airways and may even lead to death (Woods, et al., 2004). Former ICU patients have commented on their inability to sleep (van de Leur, et al., 2004; Turner, et al., 1990) and some have long-term adverse effects from the memories of being distressed in ICU (Jones, Griffiths, Humphris & Skirrow, 2001).

Health care professionals use many interventions to ameliorate the discomfort associated with severe illness and treatment in intensive care, such as reassurance, encouraging sleep wake cycles and the anticipation of physical needs. However these interventions alone are not always effective enough to achieve comfort. Therefore analgesic medication is administered to relieve pain and sedative medication to treat anxiety (Park, 1997). However excessive administration of analgesic and sedative medications may prolong the time for the patient to wake up and breathe unassisted without mechanical ventilation and be discharged from intensive care (Kress, Pohlman, O'Connor & Hall, 2000). Other complications of immobility, such as chest infection,

deep vein thrombosis and pressure sores, are also possible. Assessment of sedation level offers a method of assisting clinicians to provide appropriate amounts of these medications and therefore reduces the probability of administering excessive or inadequate amounts of medication. A target level of sedation is frequently stipulated in sedation guidelines. Sedation guidelines offer a method of standardising the use of sedative medications.

Assessing sedation level

Arguably the same principles of carefully monitoring physiological states when administering vasoactive medications intravenously should be applied when administering sedative medications. However the results of surveys performed in several countries indicate that systematic methods of assessing sedation level are used infrequently (Guldbrand, et al., 2004; Magarey, 1997; Murdoch & Cohen, 2000; Samuelson, Larsson, Lundberg & Fridlund, 2003). The assessment of sedation level is problematic and does not lend itself well to the application of a simple metric value, which is the case when monitoring blood pressure. There are currently two main methods of assessing sedation level: sedation scales and electroencephalography (EEG) derived methods (Riker & Fraser, 2002). To date EEG derived methods have been shown to have technological difficulties, related to electromyographic interference and cortical activity, which is not necessarily associated with wakefulness, causing erroneous results (Sleigh, 2004; Turner, 2004). Sedation scales are the alternative to unsystematic assessment of sedation level and EEG derived methods, although scales also have difficulties associated with subjectivity and reliability (Hill, Bertaccini, Barr & Geller, 1998). Most sedation scales contain numerical values associated with a list of descriptors and clinical judgement is used to assign the patient an appropriate score (De Jonghe, Appere-De-Vecchi, Guyatt, Meade & Outer, 2000). The Ramsay scale is an example of a sedation scale used in ICU patients (Ramsay, Savege, Simpson & Goodwin, 1974). This scale has six descriptors ranging from level one, which denotes agitation to level six, which describes an unrousable patient.

The ideal sedation level for a patient receiving mechanical ventilation is a level at which the patient is calm, co-operative, able to respond to verbal stimulation and understand simple instructions. A target sedation level is stipulated in most sedation guidelines.

Sedation guidelines

Clinical guidelines have been used to improve patient outcomes in a variety of settings (Cook & Giacomini, 1999). Guidelines are understood to standardise care and provide direction for less experienced members of the healthcare team. Sedation guidelines are intended to enable clinicians to maximise the comfort of intensive care patients and reduce the potential for giving too much sedative and analgesic medications. The beneficial effects of sedation guidelines used in ICU include a reduction in the duration of mechanical ventilation, length of ICU stay, number of tracheostomies and number of unscheduled self extubations (Brattebø, et al., 2002; Brook, et al., 1999; De Jonghe, et al., 2005; Mascia, Koch, & Medicis, 2000; Greiner & Greiner, 2004). However to date the effect of a sedation guideline in an Australian intensive care patient population has not been published. In addition investigations which have utilised a practice improvement approach (preintervention and postintervention quasi-experimental design) to evaluating sedation guidelines have not examined the extent of guideline adoption.

Practice improvement and the adoption of clinical practice guidelines

Patient outcomes are often measured to demonstrate the effect of clinical practice guidelines. The preintervention and postintervention quasi-experimental design study is a solution to investigating clinical practice guidelines when contamination of the control group is likely if a randomised control trial (RCT) is used. In fact the preintervention and postintervention designed study underpins many approaches to practice improvement. When research methods other than the RCT are used, adoption data must be simultaneously collected to enable interpretations to be made about the effect of the guideline. Adoption data may also be used to provide feedback to clinicians. It is uncommon for investigators to simultaneously explore the rate of guideline adoption by clinicians.

The Iowa Model of Research Based Practice to Promote Quality Care (Titler, et al., 2001) emphasises the importance of the clinician's involvement in practice improvement, although there is no explicit suggestion to collect adoption data. It is one example of a logical framework on which to base a practice improvement project (Titler, et al., 2001). The Model includes triggers for the project, implications for

stakeholders and suggests a critique of all levels of evidence. The Iowa Model was the theoretical framework for the study described in this thesis and the 'Diffusion of Innovations' (Rogers, 1995) also informed the development of the implementation strategy described in this thesis.

The theory 'Diffusion of Innovations' (Rogers, 1995) has informed the implementation process for clinical practice guidelines. The rate of guideline adoption and the existence of different adoption characteristics have lead to the use of a combination of implementation strategies. The combination of feedback of clinically relevant data, individual information sessions and reminders is understood to be the most effective method of implementing clinical practice guidelines. These implementation strategies were used to encourage the adoption of the sedation guideline used in the study described in this thesis.

1.2 The aim of the thesis

In summary there are several potential problems associated with the delivery of sedative and analgesic medications to mechanically ventilated intensive care patients. There are risks associated with administering inadequate amounts, such as acute agitation which may result in the removal of life sustaining devices and risks associated with administering excessive amounts which may result in the prolongation of mechanical ventilation and associated complications of immobility. Sedation guidelines have been demonstrated to improve patient outcomes by standardising this aspect of care. Most sedation guidelines incorporate a target sedation level which requires the use of a sedation scale.

The purpose of this thesis is to report the investigation of the effect of an algorithm based sedation guideline, previously found to be beneficial by Brook, et al. (1999), on the duration of mechanical ventilation for mechanically ventilated patients in an Australian ICU. An additional aim is to report the extent of the adoption of a sedation scale and a sedation guideline by clinicians.

1.3 Outline of the thesis

The potential problem of discomfort for the intensive care patient has been briefly described in this chapter. The interventions used to provide comfort have also

been outlined. The importance of avoiding excessive and inadequate administration of sedative and analgesic medications has been established. In the second chapter these issues are explored in more detail. The literature is reviewed to identify sedation guidelines which have been shown to be beneficial for intensive care patients. The strengths and limitations of studies, which have investigated the effect of using sedation guidelines, are discussed. Chapter two also includes an outline of adoption theory. The theoretical framework for the study described in this thesis is explained with reference to the process of conducting a practice improvement project. The chapter ends with a description of the aims and the hypothesis of the study.

In chapter three the research methods are outlined, including a description of the intervention, instruments, and data collection methods. The results regarding sample characteristics and patient outcomes are described in chapter four. The adoption of the sedation scale and guideline by the clinicians is described in chapter five. The interpretation of the results, the effect of the intervention and the extent of the adoption of the sedation scale and guideline are discussed in chapter six. The strengths and limitations of the study are explored and recommendations for future research and practice arising from the study are suggested. Finally chapter seven, the conclusion, provides a summary of the research study, results, and the contribution this thesis makes to nursing research and knowledge.

Chapter Two - Literature Review

2.1 Introduction

Conditions which require treatment in an intensive care unit (ICU) are often life threatening. Patients depend on clinical experts and technology to sustain them. Clinicians provide and adjust mechanical ventilation to support the patients' breathing and use intravenous vasoactive medications and fluids to treat the patients' blood pressure. The presence of many seriously ill patients leads to high activity levels. The intensive care environment is characterised by obtrusive noise and high levels of technology. Patients are exposed to intrusive stimuli, invasive procedures and unfamiliar routines. These circumstances, along with the inability to communicate verbally, often lead mechanically ventilated patients to experience high levels of discomfort and anxiety (McKinley, et al., 2002; McKinley, Stein-Parbury, Chehelnabi & Lovas, 2004). Seriously ill patients rely on health care professionals for all their physical and psychological needs. Although the priority of care may often be to support a failing organ, healthcare professionals must simultaneously anticipate other patient needs and provide comfort by reducing pain and distress.

Sedative and analgesic medications are administered to allay anxiety and promote comfort for intensive care patients because, despite the best efforts of health care professionals, other interventions may be insufficient to achieve this. However there is a risk of administering excessive amounts of sedative medication to the patient in an attempt to provide comfort. Excessive administration of sedative medications may lead to the avoidable prolongation of the need for mechanical ventilation (Kress, et al., 2000; Kollef, et al., 1998). However the inadequate administration of sedative medication may lead to unrelieved anxiety and distress. Similarly, the over cautious administration of analgesics may not effectively relieve pain. The psychological effects of inadequate levels of sedation can lead to extreme agitation, which is frequently associated with the accidental removal of artificial airways and intravascular catheters, jeopardising the safety of the patient (Woods, et al., 2004). The potential complications associated with the excessive and inadequate administration of sedative and analgesic medications may lead to adverse effects on patient outcomes, patient experiences and costs. Therefore health care professionals are required to simultaneously administer sufficient medication to provide comfort while ensuring that sedation is not given in

excess. The problem presented to health care professionals is related to the difficulty in assessing sedation level and the clinical judgement of the patient's requirements (Hill, et al., 1998).

Clinical practice guidelines (CPGs) are one method of addressing the need for consistency, providing clear goals for treatment and reducing delay in treatment. Several studies have investigated the effect of protocols and treatment guidelines on improving the delivery of sedation (Brattebø, et al., 2002; Brook, et al., 1999; Devlin, Holbrook, & Fuller, 1997; De Jonghe, et al., 2000; Greiner & Greiner, 2004; Mascia, et al., 2000). Benefits reported include reductions in the duration of ventilation, numbers of tracheostomies, length of ICU stay and costs.

The patient outcomes associated with CPGs can only be measured if the CPG is actually used by clinicians. When the effects of CPGs are investigated using the randomised control trial (RCT) patients assigned to the intervention group receive care stipulated in the CPG. Arguably the use of the CPG is more easily monitored when the RCT design is used. However investigators are increasingly concerned about the potential contamination of the control group when this design is used. Therefore the quasi-experimental preintervention and postintervention design is being increasingly used to 'test' CPGs and is also evident in the practice improvement literature. Baseline data is collected before the implementation of the CPG under investigation and after a period of CPG implementation the same categories of data are again collected. This approach necessitates the collection of adoption data to ensure the CPG was actually used in the postintervention phase and to reduce the likelihood that some factor other than the CPG contributed to any change in outcomes.

The preintervention and postintervention design underpins many approaches to introducing improvements in patient care and research utilisation. Models such as the Iowa Model of Research-Based Practice to Promote Quality Care (Titler, et al., 2001), which incorporate this approach have been shown to improve patient outcomes and lead to sustained change.

The theory, 'Diffusion of Innovations' (Rogers, 1995) has strongly influenced the implementation of CPGs and practice improvement processes. In particular the most

effective CPG implementation strategy and method of introducing research evidence into practice is understood to be a combination of a rigorous systematic review and pilot of the suggested guideline, along with intense educational programs incorporating feedback and reminders. This approach embraces all the specifications of the different 'adopter categories' described by Rogers (1995).

This chapter provides an overview of the background to the study described in this thesis. The rationale for the administration of analgesic and sedative medications to ICU patients is given together with the potential complications. The chapter also contains a critical review of the two main methods of assessing sedation level in ICU. Studies which have investigated the effect of protocols and guidelines on improving the delivery of sedation are described along with their strengths and weaknesses. A detailed discussion of implementation strategies for clinical practice guidelines and the measurement of adoption rates is also provided. The theoretical framework of the project is outlined in the context of improving practice. The benefits of this rigorous approach are also highlighted. The chapter concludes with statements of the study aims.

2.2 The intensive care experience – the need for sedation

The patient's experience of serious illness, the ICU environment and the resulting potential sequelae together with the need for analgesic and sedative medications are explored in detail in this section. The intensive care environment is characterised by high levels of noise and technology. Patients who are admitted to intensive care often require intrusive monitoring, invasive procedures, mechanical ventilation and a large number of therapeutic interventions reflective of their physiological dependence. These intrusive stressful stimuli present an enormous challenge to the patient who is too ill to interpret the environment, communicate or make use of their usual coping strategies. Therefore several factors contribute to the need for sedative and analgesic medications, including:

- the inability to communicate
- thirst
- the presence of invasive monitoring devices
- the cognitive response to stress
- the amnesiac effects of some medications

- pain
- sleep deprivation
- non-elective admission to ICU
- the complex nature of the metabolic derangements characteristic of critical illness
- the ICU environment

Anxiety and long-term unpleasant psychological sequelae may result if discomfort and distress are not alleviated.

Communication difficulties

Patients are faced with communication difficulties. Many require artificial airways in order to breathe and oral endotracheal (ET) tubes, in particular, are a source of great discomfort and frustration (Bergbom-Engberg & Haljamae, 1989; Hupcey & Zimmerman, 2000; Stein-Parbury & McKinley, 2000). Lip reading is notoriously difficult when artificial airways impede the ability to form words with the lips. Alphabet boards and pen and paper are possible solutions but are tiring and require good vision at the very least. The frustration associated with the inability to articulate needs is well documented as a cause of distress (Stein-Parbury & McKinley, 2000; McKinley, et al., 2002; Pochard, et al., 1995; van de Leur, et al., 2004). The associated discomfort of the ET tube may cause patients to attempt to reposition their own tube or actually self-extubate. Either action often results in the caregivers providing (extra) sedation or physical restraint, which arguably may exacerbate existing frustrations. Thirst together with the inability to drink adds to the frustration and it is a commonly cited source of distress for many patients who are orally intubated (Capuzzo, et al., 2001; van de Leur, et al., 2004). Thirst may also be a symptom of an underlying condition.

Invasive devices

Invasive monitoring devices such as intravenous and intra-arterial lines and urinary catheters, together with electrocardiogram cables, contribute to the obtrusive nature of the ICU experience (Stein-Parbury & McKinley, 2000). Patients may misinterpret the reason for the presence of the devices as methods to restrain them, especially since many ICU patients are too weak to reposition their own limbs.

Cognitive effect of stress

Cerebral function is inextricably linked to systemic function. Therefore there are additional potential confounding problems including the pathophysiological effect of critical illness. Detrimental effects include: elevated serum nitrogenous waste, the systemic stress response and fever and hormonal imbalances, which may result in patients having difficulties perceiving and interpreting experiences and information (Crippen, 1999; Ely, et al., 2001; Michelson, Gold, & Sternberg, 1994). There are some deleterious effects (particularly over prolonged periods of time) of the stress response. Adrenaline is known to precipitate feelings of apprehension and fear. The stressed ICU patient has a reduced ability to attend to or process information, which may contribute to disorientation and lead to psychological distress (Crippen, 1999). In addition fluctuating conscious levels as a result of systemic disease processes, stress or sedative medication may cause patients to miss vital pieces of orientating information leading to disorientation and even agitation.

Amnesiac effects of medications

Many medications designed to aid the treatment or ameliorate the effects of critical illness often have cerebral effects, which can lead to perceptual difficulties and disorientation. For example most medications used to sedate and reduce anxiety have amnesiac properties (Crippen, 1999). In the short term amnesia can cause anxiety when patients are unable to remember their whereabouts or circumstances. This may lead to acute agitation and accidental self-harm. Amnesia is associated with distress during recovery because patients discover gaps in their memories and they have difficulty understanding their experience (Jones, et al., 2001).

Sleep deprivation

Sleep deprivation is a common experience for ICU patients (Fontaine, 1989). Sleep is a complex phenomenon essential for normal cell functioning. The mechanisms which result in the beneficial effects are not completely understood, however the effects of deprivation are often observed. The stages of sleep are well established as non rapid eye movement (NREM) stages 1 to 4, followed by a rapid eye movement (REM) stage. Sleep cycles contain all the stages of sleep and each stage is reached sequentially. A sleep cycle generally lasts 90 to 100 minutes. Four to five sleep cycles per sleep session are considered necessary for optimal restoration and renewal. The frequent interventions

ICU patients require interrupt their sleep and prevent them reaching the REM sleep stage, which is considered essential for brain restoration. Four to five nights of disturbed sleep is likely to precipitate sleep deprivation (Fontaine, 1989). In the mildest form, sleep deprivation is characterised by disordered thinking and poor memory, but in the severe form disorientation, paranoia and delusions are evident. Noise reductions, 'clustering' care at night and dimming lights are potential preventative interventions, although studies to evaluate them have not been reported.

Pain

Pain is cited as a frequent cause of distress (Turner, et al., 1990; Pochard, et al., 1995; van de Leur, et al., 2000; Granja, et al., 2005). It is an unpleasant sensory or emotional experience related to the activation of nocioreceptors or neuropathic pathways and usually associated with tissue damage. Pain can lead to agitation in the short-term, difficulties with longer-term psychological recovery and fear and anxiety during subsequent hospital admissions (Hamill, 1994). Potential causes of pain in the ICU patient are vast. Aside from obvious traumatic causes such as burn injuries, fractures and wounds, there are other equally distressing but less well recognised hidden sources of pain including muscle atrophy, immobile joints and neurological pathology. The incidence of pain is difficult to estimate since usual assessment techniques rely on the ability to verbally communicate and self-reports from discharged patients may be unreliable since many people are unable to recall large parts of their intensive care experience (van de Leur, et al., 2004; Granja, et al., 2005). Untreated pain leads to the stress response. The associated increased levels of catecholamines which lead to problems of a blunted immune response and increased oxygen consumption may have serious health consequences such as increased recovery time (Hamill, 1994).

Pain has been reported as a frequent cause of distress by former ICU patients (Turner, et al., 1990; Granja, et al., 2005). It has been reported as a severe problem with more than one third of patients retrospectively reporting intolerable pain and a mean intensity of pain being 3.5 on a scale of 10 (Pochard, et al., 1995). In addition 12% of patients in the van de Leur, et al. (2004) study reported clear recollections of pain. Pain was ranked as the fourth most bothersome stressor by patients in another study of former ICU patients recollections (Granja, et al., 2005). Despite these international reports of pain severity, pain is less frequently reported as a problem for patients in

Australian ICUs (Daffurn, Bishop, Hillman & Bouman, 1994; McKinley, et al., 2002). There may be organisational reasons for this, such as the ratio of registered nurses per patient which is usually 1:1 in Australia. Arguably pain is recognised and treated more rapidly and the patient is reassured by the nurse's constant presence when the nurse to patient ratio is high (McKinley, et al., 2002).

Non-elective admission to ICU

Admission to general ICUs is rarely elective (83% of the patients admitted to the ICU at the Royal North Shore Hospital in 2002 were non-elective) so the patient is either completely unprepared for the experience or inappropriately prepared by media representations. Patients admitted to ICU in an emergency must contend with the realisation of their acute illness, the implications for their future and the noisy unfamiliar environment. They must also contend with the array of procedures and therapies their condition requires.

Analgesic and sedative medications are therefore commonly used to supplement the efforts of staff to reassure patients, allay their fears and provide comfort. However despite the best efforts of intensive care nurses and other health care professionals, ICU patients continue to experience high levels of anxiety and also report unpleasant long-term psychological sequelae.

The incidence of anxiety

Anxiety is a person's response to real or perceived fear leading to a 'persistent feeling of dread, apprehension and impending disaster' (PubMed, 2002). Research indicates that intensive care patients experience high levels of anxiety although this is not extensively recognised at the time of the experience (McKinley, et al., 2004; van de Leur, et al., 2004). The causes of discomfort and anxiety for ICU patients have been outlined in the previous section. However the manifestation of anxiety is dependent on many factors including the previous health of the individual (Crippen, 1999). Signs and symptoms are often similar to a generalised stress response and may include tachycardia, hypertension and feelings of distress. These signs may be masked in the critically ill. Alternatively the behavioural response may be extreme and lead to agitation, in the patient who is unable to cognitively appraise his/her situation.

The participants in the study by Pochard, Lanore et al. (1995) indicated that they experienced a diffuse anxiety disorder during their ICU stay. Sixteen of the 33 participants described an intense fear of dying. Anxiety related to their discharge from ICU was also a source of distress. Similarly other former patients recollect feeling afraid during their stay in ICU (van de Leur, et al., 2004).

Australian research indicates that the ICU population frequently experiences high levels of anxiety (McKinley, et al., 2004). During an investigation to explore the validity of a Faces Anxiety Scale, 85% of 106 ICU patients (90% were mechanically ventilated) reported some anxiety. The mean level of anxiety was 2.9 $\pm$ 1.2 (on a scale of 1 to 5 where 5 is the greatest). Moderate to severe anxiety was reported by 60 % of the patients. Anxiety was not correlated with blood pressure or heart rate in this study. The investigation confirmed that the traditional use of physiological and behavioural signs was an unreliable method for the assessment of anxiety (McKinley, et al., 2004; Frazier, et al., 2002).

There are short and long term adverse effects associated with unrelieved anxiety. In the short term high anxiety levels may predispose the patient to disorientation and agitation. Agitation has potentially serious effects, including accidental self-harm such as removal of artificial airways, violent behaviour and even death (Woods, et al., 2004). Follow-up services for discharged patients and research about the ICU experience have revealed long term effects of unrelieved anxiety. These adverse effects include unpleasant memories of, and associations with ICU, persistent distressing memories and long term psychological sequelae including symptoms of post traumatic stress disorder (PTSD) (Jones, et al., 2001). Unpleasant associations with ICU may adversely affect future experiences of hospitalisation and cause delay in seeking medical help. Clinicians have developed follow-up services in an effort to alleviate some of the physical and psychological effects of the ICU experience. Discussions with discharged patients reveal the nature of unpleasant memories and possible solutions such as the use of alternative sedative drugs, providing conditions conducive to sleep at night and providing regular orientational information (Fontaine, 1989; Jones, et al., 2000; Wagner, O'Hara, & Hammond, 1997).

The long-term effects of being seriously ill in intensive care

Investigations involving former ICU patients indicate that discharged patients are not only left with the physical effects of their critical illness but many have poorer perceived health and are more anxious than the general population (Brooks, Kerridge, Hillman, Bauman & Daffurn, 1997). Intensive care patients' recollections provide essential information about the impact of intensive care treatment. For instance a study investigating memory and symptoms of PTSD after treatment in intensive care reveals a proportion of patients who remember nothing (6%), some who have factual and delusional memories (56%), others who have factual memories (18%) and a few who have only delusional memories (20%) (Jones, et al., 2001). Several studies report higher proportions of patients who remember nothing (30 to 40%) although they report similar numbers of patients who describe unpleasant long-term effects connected to their intensive care experience (20 to 35%) (Daffurn, et al., 1994; Maddox, Dunn, & Pretty, 2001; Russell, 1999). Nurses often believe that amnesia of the ICU experience is a necessary requirement for patients to cope in the long-term (Slomka, et al., 2000). Evidence from an investigation into the long-term psychological outcomes associated with the daily interruption of sedatives suggests that memory of being awake in ICU does not necessarily result in adverse psychological outcomes (Kress, et al., 2003).

A randomised controlled trial was performed to investigate the effect of a daily interruption of sedative medication infusion on duration of ventilation (Kress, et al., 2000). Subsequently a follow-up study was conducted to compare long-term psychological outcomes of intensive care patients who had received a daily temporary discontinuation of sedative medication infusion and those who did not receive this intervention (Kress, et al., 2003). The following assessments were performed: the Revised Impact of Events Scale (IES) (range 0-60, high scores indicate presence of psychological distress); the Medical Outcomes Study 36 item short form health survey; the State-Trait Anxiety Inventory; the Beck Depression Inventory-2; and the Psychological Adjustment to Illness score. Each participant was interviewed to detect PTSD symptoms using the Diagnostic and Statistical Manual of Mental Disorders 4th edition (APA, 1994) criteria. The group to which the patient was assigned was concealed from the investigators who performed these assessments. Despite the fact that the groups had the same proportion of patients who could recall ICU, the intervention group had a better Impact of Events score (11.2 versus 27.3, p=0.02), a lower incidence

of PTSD and a better total Psychological Adjustment to Illness score (46.8 versus 54.3, p=0.08). There were no differences in SF-36 scores between groups. Unfortunately the published report provides an ambiguous description of the groups patients were assigned to. There were two groups of patients. The first group comprised the patients included in the original study and the second may have included patients who had been cared for at the same time and were not enrolled in the original study and patients who were subsequently cared for in that ICU. This is important since it is unclear if some patients received care (over and above the intervention) which was different. Despite this weakness, the study adds to the knowledge of the effects of the ICU experience and provides insight for potential interventions which may prevent long-term psychological distress. The results indicate that lighter levels of sedation are potentially psychologically beneficial for ICU patients in the long-term.

Similarly Scragg, Jones, & Fauvel (2001) aimed to identify psychological distress in former ICU patients and the effect of duration of ICU stay, age, gender and time since discharge on distress associated with the ICU experience. This descriptive study used several instruments including the Experience after Treatment in Intensive Care 7 Item Scale (ETIC-7) developed by Scragg, et al. (2001) (Appendix A) to ascertain if any post traumatic stress disorder symptoms were related to the ICU experience. The ETIC-7 contains 7 items based on the criteria for post traumatic stress disorder (PTSD) specified by the Diagnostic and Statistical Manual of Mental Disorders 4th edition (APA, 1994). Possible scores range from zero (no signs of PTSD) to 21(high likelihood of PTSD). This questionnaire consists of seven questions designed to screen for post traumatic stress disorder symptoms associated with the patient's experience of intensive care for example 'When reminded of your stay in the Intensive Care Unit, does it make you feel anxious or unwell (for example, heart racing or thumping, nausea, sweating)?'. There are four possible responses to each question on a scale from 'Not at all' which was given a score of zero to 'Often' which is recorded as three. An open-ended question at the end of the Scale 'Do you have any comments that **you** would like to add?' is included. The ETIC-7 correlated with other scales such as the Hospital Anxiety and Depression (HADS) and IES and it was shown to be reliable. The internal consistency for the ETIC-7 was high with a reported Cronbach's alpha of 0.84 (Scragg, et al., 2001). The ETIC-7 correlated with the Impact of Events Scale (IES) (Horowitz, Wilner, & Alvarez, 1979) (Pearson correlation r = 0.5, $p \geq 0.0001$) and the Trauma

Symptom Checklist (TSC-33) (Briere & Runtz, 1989) (Pearson correlation r = 0.56, $p \geq 0.0001$) (Scragg, et al., 2001).

In the ETIC-7 validation study described above 80 patients out of 142 (56% of the total sample) returned the postal questionnaires which contained four measures of psychological distress. There were high rates of anxiety, depression and PTSD symptoms in this group of former ICU patients (Scragg, et al., 2001). Forty seven percent scored more than 12 on the HADS, which is generally considered to indicate a clinical disorder. The IES is widely used to identify PTSD symptoms. Scores of 20 or higher indicate a high number of symptoms and scores higher than 30 indicate severe symptoms and a high likelihood of PTSD. Fifteen percent of respondents scored more than 30 on this scale. There was a weak, although statistically significant, negative correlation between the ETIC-7 score and age ($r^2 = 0.048$, $p = 0.05$), that is the younger respondents had higher scores. There was also a weak correlation between the ETIC-7 score and time since discharge ($r^2 = 0.053$, $p = 0.04$) which was statistically significant. Respondents who had been discharged the longest had higher scores. There was no significant correlation between ETIC-7 and duration of stay in ICU. However regression analysis showed that higher ETIC-7 scores were associated with lower age and longer time since discharge. There was no effect for gender or duration of stay in ICU.

The report does not describe the content of the responses to the open ended question at the end of the ETIC-7; 'Do you have any comments that you would like to add?'. Scragg, et al. (2001) acknowledged the limitations of this self administered survey investigation. They identified several other limitations including small sample size and lack of specificity in self reports. Furthermore, despite similar demographics between those who returned questionnaires and those who did not, there may still have been subtle differences in psychological make up between the groups. The overall results contribute to the greater understanding of the experience of treatment after ICU. For example the results indicate that former ICU patients rarely experience full PTSD symptoms but many experience significant psychological distress and younger patients may be slightly more at risk. The ETIC-7 may be useful for identifying patients who remain troubled or distressed by their ICU experience.

Nursing interventions ameliorate many of the stressors presented to critically ill patients. However there are many difficulties associated with relieving distress in the ICU patient. Analgesic and sedative medications are administered when nursing interventions are insufficient to achieve comfort.

2.3 Interventions to provide comfort: the use of analgesic and sedative medications

The primary interventions necessary to ameliorate and relieve discomfort in the critically ill include effective communication, reassurance and the promotion of day and night cycles. The mainstay of preventing and relieving pain in ICU includes specific nursing interventions together with the administration of analgesic medications. Frequent repositioning and passive limb exercises prevent contractures and joint stiffness. Reassurance and information giving, together with the presence of the nurse, increases confidence and reduces feelings of vulnerability (McKinley, et al., 2002). These interventions are powerful nursing tools in the attainment of patient comfort. However on occasions these interventions may be inadequate to sufficiently provide analgesia and reduce anxiety, thus analgesic and sedative medications are frequently considered. These medications are usually administered intravenously to mechanically ventilated patients. The relatively short half life of many intravenous analgesic and sedative medications allows the nurse to adjust the dose to the patient's requirements using a continuous infusion. The medications morphine and fentanyl are the most frequent intravenous analgesics to be administered to patients cared for in Australian ICUs. Midazolam and propofol are the most frequently administered sedative medications.

Analgesic medications

The most commonly administered type of analgesia in ICU is an opioid such as morphine sulphate or fentanyl. Opioids produce their effects by attaching to specific receptors in the brain, spinal cord and peripheral tissue, reducing pain perception. The mu (μ-1) receptor is the primary receptor responsible for analgesia. There are potential problems associated with the administration of opioids. The side effects include reduced gastrointestinal motility leading to constipation and even paralytic ileus. Shorter-term effects include hypotension resulting from histamine release and respiratory depression related to μ-2 receptor effect in the respiratory centre. Nausea and vomiting are symptoms related to stimulation of the chemoreceptor trigger zone in the brain. Most

opioids are metabolised in the liver and eliminated by the kidneys. The duration of their action (one to four hours) is related to several factors: lipid solubility and percentage body fat, liver function and renal function (Gehlbach & Kress, 2002).

Morphine sulphate is a readily available cost effective opioid commonly used in ICU. It has a high affinity for μ receptors and its mild anxiolytic effects associated with euphoria are often useful for critically ill patients. However morphine sulphate may precipitate histamine release and cause associated haemodynamic instability in some patients. Anecdotally some patients report (often distressing) visual and auditory hallucinations. Other patients describe a disturbing dysphoria which is most likely associated with the active metabolites produced during elimination.

Fentanyl is a synthetic opioid which is twice as costly as morphine sulphate. It has lipophilic properties which may result in a rise in half-life (9-16 hrs when given as an infusion). Intermittent administration results in a shorter duration of action. Fentanyl has no anxiolytic effects. It is associated with reduced histamine release and therefore less haemodynamic instability and less bronchospasm than morphine.

Despite the potential for providing excellent analgesia for musculoskeletal pain, non-steroidal anti-inflammatory drugs are no longer administered to critically ill patients. The potential risks associated with their administration in some patients, that is gastrointestinal bleeding and renal failure, outweigh the potential benefit.

Dexmedetomidine, a novel α_2-agonist medication which offers 'awake' sedation and analgesia, shows promise. However to date insufficient data exist to support its use for non-operative critically ill patients. Small trials have established the safety of dexmedetomidine in post-operative patients (Triltsch, et al., 2002). However the aim of these trials appears to be the reduction of other sedative and analgesic medication requirements and to study its cardiovascular effects rather than to establish the effectiveness of dexmedetomidine as a sole agent to relieve discomfort in critically ill patients. Dexmedetomidine is not currently available for use for non-operative patients in Australia.

Sedative medications

Most sedatives have an anxiolytic and calming effect. Their effect is not confined to the cerebral cortex and reticular activating centre because most have a depressive effect on other major body systems, causing respiratory depression and reduced cardiac output.

Many sedative medications are said to have large volumes of distribution, that is, they are widely distributed in the tissues (in fat deposits). This usually poses no difficulty when they are given as intermittent doses, however if the drugs are administered via continuous infusion the peripheral fat tissues can become saturated. Once the infusion is terminated the sedative is released back into the circulation leading to prolonged sedative effects. Anecdotal reports from patients indicate that they often experience a disturbing dysphoria associated with the metabolites of many sedative medications.

Benzodiazepines are the most commonly used sedative agents for ICU patients (Murdoch & Cohen, 2000; Soliman, Melot, & Vincent, 2001). They have anxiolytic effects and inhibit central nervous system activity. Benzodiazepines are lipophilic and cross the blood brain barrier rapidly. The anxiolytic effects and corresponding attenuation of the stress response can predispose the patient to hypotension, especially if intravascular depletion exists. Lorazepam, midazolam and diazepam are the most commonly administered benzodiazepines in ICU. Lorazepam is a relatively short acting sedative which has less lipophilic effects than midazolam and diazepam. Lorazepam is only available in oral preparation in Australia. Midazolam is the most commonly used sedative for ICU patients in Australia and Europe (Magarey, 1997; Soliman, et al., 2000; Samuelson, et al., 2003). It has a rapid onset of action and patient recovery is swift when administered intermittently and therefore may be tritrated to effect more easily than other benzodiazepines. Care must be exercised when it is administered as a continuous infusion to prevent accumulation in the peripheral tissues and prolonged action.

Propofol is a fast acting sedative that has similar pharmacological effects to benzodiazepines. It is commonly used for short-term continuous sedation of mechanically ventilated patients. Propofol is highly lipophilic and rapidly crosses the

blood brain barrier (Gehlbach & Kress, 2002). Patients must not be intravascularly depleted prior to administration as this can increase the likelihood of hypotension. The cardiovascular side effects of bradycrdia, hypotension and reduced cardiac contractility are more profound for patients with existing cardiac disease. Propofol contains high levels of triglycerides therefore prolonged administration can produce complications associated with hyperlipidaemia and increased energy intake. Controversy persists about the relative benefits of propofol over midazolam (Chamorro, et al., 1996; Barrientos-Vega, et al., 1997; Magarey, 2000).

All medications should be given with caution and within strict therapeutic guidelines. Aside from the potential for hypersensitivity reactions that some individuals may have, there are potential side effects which must be considered when administering any medication. The main unwanted side effects have been outlined above. The consequences of the inadequate or excessive administration of analgesic and sedative medications may have serious consequences for ICU patients.

2.4 The complications associated with the inadequate and excessive administration of analgesic and sedative medications

Inadequate administration of medications

The unpleasant effects of untreated anxiety and distress are associated with complications such as agitation which may lead to accidental self-harm including unscheduled self-extubation (Vassal, et al., 1993; Woods, et al., 2004). In addition patients may experience, hypertension, increased oxygen consumption and an inability to tolerate mechanical ventilation (Hill, et al., 1998) which can prolong ICU or hospital stay (Kollef, et al., 1998; Woods, et al., 2004). Untreated severe agitation may even lead to premature death. Longer-term complications associated with severe agitation include PTSD (Nelson, Weinert, Bury, Marinelli &Gross, 2000).

Excessive administration of medications

Whilst inadequate sedation levels cause potential problems, the administration of excessive amounts of sedation has different but equally serious potential complications. The prolonged time to waking associated with excessive sedation increases the duration of ventilation and leads to additional risks such as ventilator associated pneumonia (Devlin, et al., 1997; Nelson, et al., 2000). The prolonged need

for ventilation increases ICU stay and exposes the patient to unnecessary risks associated with reduced mobility and a stressful unfamiliar environment. The excessive use of sedation also has financial and ethical implications. The unnecessary prolongation of ICU stay for individual patients impacts on the availability of ICU beds for others.

Although the consequences of the inadequate administration of analgesic and sedative medications is more remarkable and memorable in the clinician's mind, it may be argued that excessive administration of these medications is more common as the effects are not immediately obvious and therefore go unrecognised day to day. Although the true incidence of the excessive administration of sedation is unknown, the antecedents of it are operationalised as the unnecessary prolongation of ventilation and length of stay in ICU. Many studies investigating the effect of interventions to reduce the complications of sedation delivery use duration of ventilation and length of ICU stay as outcome measures. The incidence of excessive administration of sedation is also substantiated by some recent reviews of sedation practices. For example 32% of Clinical Nurse Consultants (CNCs) in a country wide survey of Australian ICU sedation delivery practices reported the excessive administration of sedative medication as the most frequent complication (Magarey, 1997). Although this is a survey of sedation practices and therefore did not provide data about actual incidence of the excessive use of sedative medication the results may be viewed as an estimate of the likely prevalence. The survey was anonymous and used clinical nursing leaders (CNCs) whose role in most States included quality activities which impact on patients outcomes such as duration of mechanical ventilation and length of ICU stay.

The unwanted effects of the inadequate or excessive administration of analgesic and sedative medications are well established. However the long-term effects of specific regimens and strategies are currently unknown.

The long-term effects of sedative medication

The potential long-term psychological effects of ICU are established. However the long-term effect of different sedation regimens and sedation levels on quality of life and psychological well being after intensive care treatment is open to debate. Few studies have been performed, probably because many factors interplay to affect these

outcomes. Nelson, et al. (2000) examined the relationship between the use of sedative medication and neuromuscular blocking agents and health related quality of life. The records of 24 patients with acute lung injury were reviewed and data concerning the duration, daily dose and route of sedative and neuromuscular blocking agents were recorded. The patients completed a post-discharge questionnaire containing the Centre for Epidemiology Studies-Depression (CES-D) instrument for assessment of depressive symptoms and seven items relating to the occurrence of PTSD symptoms. Both CES-D and PTSD scores correlated positively with number of days of sedation (r^2=0.30; p< 0.01, and r^2=0.32; p< 0.01, respectively), and with length of ICU stay and length of ventilatory support. PTSD scores also correlated with days of neuromuscular blockade. A higher incidence of depressive and PTSD symptoms was evident for patients who received higher doses of sedative medications and had a longer ICU stay. The investigators were unable to make separate outcome comparisons for the many different sedative medications because most patients received multiple medications during their ICU stay. Therefore the relative benefit of one sedative medication over another in the long-term could not be judged. Indications from the results of the Kress, et al. (2003) study, which was described previously, are that lighter levels of sedation, or at least periods of wakefulness, may be psychologically protective.

Evidence is accumulating to indicate that predetermined explicit goals for the administration of analgesic and sedative medications improves patient outcomes. Furthermore carefully titrating analgesic and sedative medications according to the patient's requirements reduces the likelihood of providing inadequate or excessive amounts of medications and avoids the associated complications. The goal of administering these medications for ICU patients is to provide comfort by relieving pain and reducing anxiety. Patients who are comfortable tolerate monitoring and treatments and experience fewer complications.

2.5 The goals of administering analgesic and sedative medications

The aims of administering analgesic and sedative medications are primarily to reduce anxiety and promote comfort, which also avoids excess oxygen consumption. Effective analgesia is the first priority closely followed by anxiolysis. Dyspnoea associated with metabolic disorders and difficulty tolerating endotracheal intubation and positive pressure ventilation, especially during lung-protective strategies such as

permissive hypercapnia, can be effectively relieved by the judicious administration of sedative medications (Gehlbach & Kress, 2002; Hill, et al., 1998). Sedation may also be given to facilitate care such as dressing changes, and to promote synchrony with mechanical ventilation.

Complete amnesia is no longer recommended as a goal of sedation as it may result in serious psychological sequelae such as PTSD symptoms (Jones, et al., 2001). There are reports of adverse psychological effects when patients are unable to recall factual events about their illness. It is becoming evident that partial amnesia may also cause problems for some patients. Partial amnesia, in the presence of delusional ICU memories, may increase the likelihood of PTSD symptoms during recovery (Griffiths & Jones, 2000). PTSD is rare but it is understood that patients who persistently believe their delusional memories about ICU are real, have a higher incidence of reporting PTSD symptoms (Jones, et al., 2001). Evidence is accumulating to suggest that better awareness may help the patient contextualise their ICU experiences and normalise usual memory storage processes (Kress, et al., 2003; Jones, et al., 2001).

Nevertheless it is well recognised that deep sedation is an absolute necessity during the administration of neuromuscular blocking agents. The absence of motor activity should not be the sole goal of sedation, as a lack of motor activity is not indicative of a quiet state of mind. Many patients appear to be calm but on closer examination may be experiencing ‘quiet’ delirium. The administration of sedative medications does not negate the need for human presence and reassurance. It is generally accepted that an ideal sedation level is one in which the patient can obey simple commands, is able to tolerate therapy, is not unduly anxious and can understand explanations. This state corresponds to a sedation score of two or three on the Ramsay Scale. The use of a sedation scale to record and assess sedation level is a requirement of sedation guidelines. The use of a sedation scale to monitor sedation level together with an agreed target sedation level, which is often stipulated in sedation guidelines, standardises sedation delivery practices.

2.6 Monitoring sedation level

Arguably the same principles of carefully monitoring blood pressure when administering vasoactive medications intravenously should be applied when

administering sedative medications. However the assessment of sedation level can be subjective and therefore more complex to monitor than other patient parameters during therapy. Consequently there are few reliable objective sedation assessment tools available for clinicians to use. Despite difficulties with the reliability of sedation assessment tools, the use of guidelines and routine interruptions in sedative medication infusions have suggested improved outcomes, highlighting the potential benefit of titrating sedation agents to achieve a target sedation level (Brattebø, et al., 2002; Brook, al., 1999; Kollef, et al., 1998; Kress, et al., 2000). The two main methods of assessing sedation level are processed electroencephalography (Bispectral Index Score or Patient State Index) and clinical scoring scales. Both methods have limitations when used to monitor sedation levels for the mechanically ventilated intensive care patient.

Sedation scales

Clinical sedation scales are the predominant method of assessing sedation level. The difficulties associated with their use are similar to any other patient scoring system which relies on the interpretation and subjective judgement of patient signs and behaviour, for example the Glasgow Coma Scale. The clinical value of a sedation scoring system is dependent on its reliability, validity and complexity during routine use (Carrasco, 2000; Hansen-Flaschen, 1994; Hill, et al., 1998). Reliability refers to the ability of the scoring system to produce accurate measurements under different conditions, whereas validity is the degree of confidence that the scale is measuring the characteristic or behaviour that it was intended to measure (Streiner & Norman, 1995). The complexity and length of time needed to use a scoring system for assessments will have a direct effect on the willingness of clinicians to adopt the system for every day use (Carrasco, 2000; De Jonghe, et al., 2000)

Most sedation scoring systems require an observation of the patient's response to a physical and verbal stimulus. The patient is given a discrete score which best corresponds to the descriptors on the scoring system. The majority of scoring systems are continuous scales, however a few require the clinician to add scores from different domains in the scoring system.

Many sedation scoring systems are based on the Ramsay sedation scale (Appendix B) which was developed in the 1970's to assess sedation level at the bedside

during an investigation into the efficacy of a sedation agent, in 30 ICU patients (Ramsay, et al., 1974). There is no report of a validation process in the published paper. The Ramsay scale comprises three assessment constructs: conscious level, signs of agitation and presence of anxiety. After observing the patient's response to an auditory stimulus and a light physical stimulus if there is no response to the auditory stimulus, the clinician assigns the patient a score of one to six, where one denotes agitation and six, heavy sedation.

The Ramsay scale is reported to have good inter-rater reliability in one study (De Jonghe, et al., 2000). The inter-rater correlation was high (r^2=0.76, p< 0.001) in this validation study for the Sedation Agitation Scale (SAS) (Riker, Picard, & Fraser, 1999; De Jonghe, et al., 2000). Furthermore the criterion validity of the Ramsay Scale was demonstrated by a high degree of correlation with the SAS (r^2=0.83, p<0.001). One hundred and thirty eight observations of 45 patients were performed by pairs of evaluators using three sedation scoring systems, the SAS, the Ramsay Scale and the Harris scale. Observers were nurses with an average of 5.9 years ICU experience and were trained in the use of all three sedation scales. The nurses were not caring for the patient at the time that observations were performed which reduced the likelihood of familiarity bias. However the results from this study must be interpreted with caution because the design and statistical methods described in the paper may not have been the most appropriate to test the hypothesis. The assumptions for the Pearson's product moment correlation coefficient were not met, for example fourteen patients were evaluated more than once (indicating repeated measures of the variable 'sedation level') and both of the evaluators where present during the assessment (which presents the possibility that observations were not obtained independently). An extensive search of the literature revealed one further study which reports validation of the Ramsay scale but unfortunately this study cannot be properly evaluated because it is only published in the form of a conference abstract (Carrasco, Molina, Costa, Soler & Cabré, 1992).

Until recently the Ramsay scale was the sedation scale used almost exclusively in both research and clinical practice. However despite its popularity many experts question the clinical usefulness of the scale (De Jonghe, et al., 2000; Hansen-Flaschen, 1994). For example the scale does not allow for the occasional ICU patient who displays two extremes of behaviour in a short period of time; agitation and stupor. The

clinician is forced to choose between two descriptors which are represented by a score of one for agitation and four for stupor, on the Ramsay scale. If a target sedation level has been predetermined the clinician may find it difficult to select the appropriate treatment for the patient. It is also possible for patients to be agitated and only respond to a loud auditory stimulus. The patient displaying this behaviour would not fit any descriptor on the Ramsay scale. Despite these limitations the Ramsay scale remains popular. The continued widespread use of the scale is probably explained by the fact that it was the only existing scale for several years, it is relatively simple to use and it is short.

The varied results of several country wide postal surveys about sedation practices in ICU indicates a lack of consensus amongst clinicians about the most appropriate method of assessing sedation level. In a postal survey of 255 British ICUs, 142 (67%) units used a sedation scoring system (Murdoch & Cohen, 2000). Most used the Ramsay scale and the remaining units used the Addenbroke's, the Glasgow Coma Scale modified by Cook (GCSC), the Sheffield or other systems. Previously a postal survey in Denmark, revealed that only 16% of the units surveyed used a sedation scoring system, which was exclusively the Ramsay scale (Christensen & Thunedborg, 1999). An electronic mail survey of 647 intensive care units across Europe revealed a wide variation in assessment practices, the use of sedation scoring system ranging from 18% (Austria) to 72% (UK and Ireland). The majority used the Ramsay scale (74%) (Soliman, et al., 2001), but extensive methodological problems related to the reliability of electronic mail and the low response rate, particularly from non-English speakers, reduces the validity of these results.

More recently a study performed in Sweden revealed similar results (Samuelson, et al., 2003). Sixteen percent of the ICUs surveyed used sedation scoring systems including the Ramsay scale. Only 27% used sedation guidelines. There was a 98% response rate to this postal survey which included most of the adult intensive care units in Sweden. Conversely an overall increase in the use of sedation scales was revealed during a survey conducted about sedation delivery practices in Nordic (Sweden, Denmark, Finland, Iceland and Norway) ICUs. Fifty-two percent of ICUs used a sedation scale (Guldbrand, et al., 2004). The most commonly used scale was the Motor Activity Assessment Scale (MAAS) followed by the Ramsay Scale.

The results of a postal survey of ICUs with more than 5 beds performed in Australia in the mid nineties revealed low use of sedation scales (Magarey, 1997). The Clinical Nurse Consultants from 65 ICUs (90%) responded to the sedation practices questionnaire. Very few ICUs used a scoring system (17%) and 63% reported that light levels of sedation were used in their unit. Reporting bias and varying participant interpretation are recognised limitations of the survey designed study, but the studies described give a reflection of sedation delivery practices.

Monitoring sedation level using processed electroencephalograph

No units in the sedation practice surveys described above reported using the processed form of electroencephalograph to monitor sedation level for mechanically ventilated ICU patients. The Bispectral Index (BIS) (Aspect Medical Systems, Newton, US) and Patient State Index (PSI) (Physiometrix, North Billerica, US) are processed forms of electroencephalograph (EEG) recording (Cheng, 1996). Bispectral Index and PSI provide continuous analysis of sedation level and an alternative method to using scales. The EEG provides a recording of the aggregated postsynaptic electrical action potentials of the large pyramidal neurons in the cortical layer of the brain (Cheng, 1996). The electroencephalograph is routinely used to assess the presence of abnormal electrical brain activity and frequently to detect subclinical seizure activity. Bispectral Index monitoring is less cumbersome (3 or 4 electrodes are applied to the forehead) and therefore is preferable to the traditional EEG for continuous use in ICU and the operating room. Bispectral Index and PSI monitoring offer a single relative value or index, which represents an integrated measure of cerebral electrical activity (Schneider, Heglmeier, Schneider, Tempel & Kocks, 2004). These methods of monitoring have been used to guide the administration and measure the effects of anaesthetics and sedatives in the operating room, where they have been proven to be effective (Nasraway, Wu, Kelleher, Yasuda & Donnelly, 2002; Schneider, et al., 2004; Turner, 2004; Sleigh, 2004).

Despite recent interest in the use of BIS or PSI as objective methods of monitoring the depth and effect of sedation in ICU patients, numerous methodological difficulties remain unresolved and affect the clinical usefulness of this method of assessing sedation level. These include technological issues related to the version of BIS

or PSI machine, skin impedance, filtering, signal quality index and electromyographic (EMG) activity (Riker & Fraser, 2002). Cerebral cortical activity which is not necessarily associated with conscious level and EMG activity during spontaneous movement often result in spuriously high scores (Sleigh, 2004). Therefore there is no conclusive evidence to support the general utility of BIS or PSI to assess or monitor the depth of sedation in ICU patients. The goal of sedation for most patients is a level at which they are calm but are able to move spontaneously and BIS is unreliable for this sedation level. Consequently, in the ICU environment, sedation scoring scales remain the most common approach to assessment of sedation level and to providing a consistent target sedation level while current technological difficulties and inconclusive reliability persist with BIS and PSI.

2.7 Clinical practice guidelines for sedation delivery in intensive care

The judicious and appropriate use of sedative medications is an essential goal of providing safe effective sedation for ICU patients. One method of achieving this goal is the use of evidence based clinical practice guidelines which incorporate sedation scales for the maintenance of analgesia and sedation in ICU patients. Several investigators have published sedation guidelines developed for the intensive care setting and described improvements in patient outcomes.

The challenging and controversial nature of the subjective assessment of sedation level and requirements has probably contributed to uncertainty in developing clinical practice sedation guidelines for ICU patients. Therefore only a few guidelines exist to guide the clinician in administering sedation to ICU patients. Nevertheless the use of simple guidelines based on a target sedation level has lead to some impressive improvements in outcomes (Devlin, et al., 1997; Kollef, et al., 1998; Brook, et al., 1999; Mascia, et al., 2000; Brattebø, et al., 2002; Greiner & Greiner, 2004; De Jonghe, et al., 2005). Benefits reported include reduced duration of ventilation, reduced length of stay in ICU and reduced costs. The improvements in patient outcomes, including duration of ventilation for each of the studies, are summarised in Table 1, page 31.

A sedation guideline used by Brook, et al. (1999) which was shown to be particularly beneficial was formatted as a clinical algorithm. The clinical algorithm is a network of possible decisions and consequences arranged in a rational sequence,

incorporating clinical practice guidelines (Cook, Greengold, Gray Ellrodt &Weingarten, 1997). Algorithms are useful for busy clinicians because they are easily interpreted and do not require the user to read large amounts of text to make a clinical decision.

The sedation guideline described by Brook et al.

The algorithm based sedation guideline used in the study which is the basis of this thesis was an adaptation of the sedation guideline, previously shown to be beneficial in the study by Brook, et al. (1999) (Appendix C). That study was conducted in a North American medical ICU. The treatment for each patient was directed by a critical care fellow and overseen by a board-certified critical care medicine physician. The registered nurses provided direct care to the patients and the ratio of registered nurses to mechanically ventilated patients was 1:2 (Ahrens, T, personal communication 2003). Mechanically ventilated patients with acute respiratory failure (n=321) were randomised to two groups: either the usual ad hoc sedation practices (n=159) or a nurse initiated algorithm based protocol (n=162) during a 12 month period. Patients were randomised at the time of the initiation of mechanical ventilation. Block randomisation was performed using opaque envelopes which were opened during the initiation of ventilation after informed consent was obtained.

The algorithm was specifically developed for patients with acute respiratory failure by a critical care nurse, a pharmacist and the medical director of the intensive care unit in which the study was performed (Ahrens, T, personal communication 2004). The exact process and the research used to develop the guideline is not provided in the published paper. The first prompts on the algorithm required a decision about the cause of discomfort, possible reversible causes of discomfort and the need for analgesia or sedation (Appendix C).

Table 1

Summary of the results obtained from published investigations of the effect of sedation guidelines in intensive care

Study	Population (n)	Study design	Duration of ventilation (No. of days)	Length of stay in ICU (No. of days)	Comments
Brattebø, et al. (2002)	Surgical. 147 in each group	Preintervention and postintervention	Pre 7.4 versus post 5.3 (mean)	Pre 9.3 versus post 8.3 (mean)	Primary outcome duration of ventilation. Conventional statistical analyses not reported.
Brook, et al. (1999)	Medical. 159 and 162	Randomised controlled trial	Control 5.2 versus intervention 3.7 (mean) (p = 0.003)	Control 7.5 versus intervention 5.7 (mean) (p= 0.013)	Primary outcome duration of ventilation.
De Jonghe, et al. (2005)	Medical. Pre 54 and post 48	Preintervention and postintervention	Pre 10.3 versus post 4.4 (median) (p=0.014)	Pre 15 versus post 8 (median) (p=0.043).	Primary outcome duration of ventilation. Quality improvement project with a sample size.
Devlin, et al. (1997)	Medical and surgical. 50 in each group	Preintervention and postintervention	Pre 2.5 versus post 2.0 (p= NS*)	Pre 4.3 versus post 3.75 (p=NS*)	Primary outcome was cost and amount of sedative medications used. Sample size calculation not reported.
Greiner & Greiner (2004)	Medical. Number of patients not stated	Preintervention and postintervention	Pre 10.3 versus post 8.1 (mean)	Pre 11.4 versus post 9.1 (mean)	Primary outcome duration of ventilation. Few details regarding method and analysis in published report.
Kress, et al. (2000)	Medical. 75 in each group	Randomised controlled trial	Control 7.3 versus intervention 4.9 (median) (p = 0.004)	Control 9.9 versus intervention 6.4 (median) (p = 0.02)	Primary outcome duration of ventilation. Intervention was a daily ‘wake up’ not a sedation guideline.
Mascia, et al. (2000)	Medical and surgical. Pre 72 and post 84	Preintervention and postintervention	Pre 13.2 versus post 6.95 (mean)	Pre 19.1 versus post 9.9 (mean)	Primary outcome cost and amount of sedative medications used. Quality improvement project. Sample size not reported.

*NS = Not Significant

Nurses were able to determine the type and dose of sedative and the need for continuous infusion based on the algorithm and an assessment of sedation level using the Ramsay scale. The nurses were able to initiate the medication without a prescription from the medical officer.

Implementation and compliance with the algorithm was achieved through personal communication between the guideline developers and the bedside nurses. The exact methods used to introduce this research project are not described. A dedicated researcher was assigned to check patients daily to ensure that all patients randomised to receive sedation via the nurse initiated algorithm based protocol were receiving the correct medication and were sedated to Ramsay sedation score of three (Ahrens, T, personal communication 2002). However adherence data were not collected. The authors acknowledge this limitation and are unable to comment about the results in relation to adherence level.

Benefits that were both clinically and statistically significant were revealed in the group that received sedation via the nurse initiated algorithm. The median duration of ventilation was 55.9 hours (95% CI: 41.0 to 90.0 hours) as opposed to 117.0 hours (95% CI: 96.0 to 155.6 hours) in the control group. Mean duration of ventilation was significantly shorter for patients in the algorithm directed group, 89.1 hours (3.7 days) (SD 133.6 hours) versus 124.0 hours (5.2 days) (SD 153.6 hours) in the control group ($p = 0.003$). Patients in the algorithm group had a shorter mean length of stay in ICU (5.7 days versus 7.5 days) ($p= 0.013$) and in hospital (14.0 days versus 19.9 days) ($p<0.001$), had fewer tracheostomies and received less sedative medication than the control group. Other studies reporting the use of sedation guidelines describe similar improvements in outcomes.

Other studies reporting the use of sedation guidelines

Brattebø, et al. (2002) performed a study using a quality improvement design in a mixed general ICU in Norway. A group of nurses and doctors developed a one-page sedation guideline incorporating the Motor Activity Assessment Scale (MAAS) (Devlin, et al., 1997). The guideline was disseminated after considerable contributions from clinicians and several modifications. The guideline was placed in strategic positions around the ICU and at the patients' bedsides. Several methods of publicising

the new guideline and instructions on its use were used such as e-mail, posters and personal letter. The guideline required that the doctors prescribe a daily sedation score target and the nurse was then able to titrate the medications morphine and midazolam according to the sedation guideline.

Baseline data for 147 patients (severity of illness, ventilator time, length of ICU stay and mortality) were taken from the existing ICU clinical database. Data were collected from a further 138 patients after the sedation guideline was implemented. There were reductions in mean ventilator time from 7.4 days (117.6 hours) to 5.3 days (127.2 hours) and mean length of stay in ICU from 9.3 days (223.2 hours) to 8.3 days (199.2 hours) after the implementation of the guideline (Brattebø, et al., 2002). Unfortunately the published research report is lacking detail about the methods including a sample size calculation, and a conventional statistical analysis of the results was not reported. Control charts were used to display the data and p values were not provided. There was no difference between the preintervention and postintervention groups for the characteristics of age and severity of illness score (other characteristics such as gender and diagnosis were not given). Fewer critical incidents, related to sedation delivery practices, occurred in the postintervention phase. The authors identified several factors that contributed to the success of their project. The simplicity of the guideline, the multidisciplinary collaborative approach to guideline development and implementation, and the continuous feedback mechanism designed to promote clinician ownership and involvement in the project were acknowledged as contributing to the successful outcome.

Another quality improvement study performed in France also reported an impressive reduction in the duration of ventilation and length of ICU stay (De Jonghe, et al., 2005). This prospective quasi-experimental preintervention and postintervention study included a sample size calculation and was powered at 80% to detect a 50% reduction in the duration of ventilation (mean 10 days and standard deviation 8 days). Fifty-four patients were included in the preintervention phase for baseline data collection and data from a further 48 patients was collected after the instigation of a new sedation guideline. The patient groups were equivalent in clinical characteristics at baseline. Again a multidisciplinary inclusive approach was used for the development of the guideline and included the Adaptation to Intensive Care Environment Scale (De

Jonghe, et al., 2003) for assessment of sedation level. Strategies used for dissemination were not outlined and adoption was not measured. However patient outcomes were impressive. The median duration of ventilation for patients in the intervention group was 4.4 days compared to 10.3 days in the control group (p=0.014). Median length of ICU stay was also shorter in the intervention group, 8 days as opposed to 15 days in the control group (p=0.043). The incidence of pressure sores was also investigated and again the difference was statistically significant in favour of the intervention group (9 sores versus 20 in the control group, p=0.04). Considerably less sedative medications were used in the intervention group. Although there was no change in other clinical practice during the period of the study, the lack of comment about the rate and extent of adoption of the guideline is a limitation of this study. Without this information it is difficult to be certain that the intervention was solely responsible for the improvement in patient outcomes.

The preintervention and postintervention studies performed by Devlin, et al. (1997) and Mascia, et al. (2000) were pharmoeconomical investigations. The interventions used in both studies were locally developed sedation guidelines and guidelines for the delivery of neuromuscular blocking medications were also implemented in the Mascia, et al. (2000) study. There was a reduction in the duration of ventilation and length of stay for patients receiving sedation using the sedation guidelines in both studies, however the results did not reach statistical significance in the Devlin, et al. (1997) study. The large reduction in the mean duration of mechanical ventilation (13.2 days preintervention versus 6.95 days postintervention) and mean length of ICU stay (19.1 days preintervention versus postintervention 9.9 days in the Mascia, et al. (2000) study, may be attributed not only to the significant reduction in the administration of sedative medications but also a reduction in the use of neuromuscular blocking medications. Devlin, et al. (1997) reported sedative medication cost savings of US$3363 ($p$= 0.081) during the period of the study and reductions in all medication costs were reported by Mascia, et al. (2000).

The details presented in the published report for the Greiner & Greiner (2004) preintervention and postintervention study are insufficient to be able to properly evaluate the results. The intervention used in the randomised controlled trial performed by Kress, et al. (2000) was a daily interruption of continuous infusions of sedative

medications. This single intervention resulted in a statistically significant reduction in the median duration of mechanical ventilation (7.3 versus 4.9 days in the intervention group, $p = 0.004$) and in the median length of stay in ICU (9.9 versus 6.4 days in the intervention group, $p = 0.02$).

Implementation strategies used in the study performed by Brattebø, et al. (2002) were successful in encouraging clinicians to use guidelines and in achieving demonstrable improvements in patient outcomes. Furthermore Mascia, et al. (2000) and Devlin, et al. (1997) included clinicians to develop sedation guidelines which resulted in clinically significant improvements in patient outcomes. Individual and group information reminder sessions were provided during the implementation phase in these studies (Devlin, et al., 1997; Brattebø, et al., 2002; Mascia, et al., 2000). An inclusive approach to clinician involvement during guideline development and the use of several methods of communicating messages about the use of a new guideline are recommended for successful guideline implementation or adoption.

2.8 Implementing and measuring the adoption of clinical practice guidelines

Clinical practice guidelines

'Clinical practice guidelines (CPGs) are systematically developed statements designed to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances' pg. 410, (Davis & Taylor-Vaisey, 1997). Unlike protocols, policies, clinical pathways and standards of care, CPGs are designed to assist decision making rather than prescribe, mandate or give authority for an aspect of care or procedure.

Clinical practice guidelines are widely advocated in the evidence based practice health care literature, particularly by the medical profession, as a method of improving patient care and research utilisation (Cook, et al., 1997; Hammond, 2001). Evidence based practice has evolved from Evidence Based Medicine (EBM) where testable evidence takes precedence over opinion and anecdote. Levels of evidence are assigned to different research methodologies, for example the randomised controlled trial is considered to reveal the strongest evidence and is assigned the highest category on a scale which ranks evidence gained from the research methodologies (Hammond, 2001). Correctly developed CPGs operationalise the implementation of evidence based

practice. In order to adhere to these principles the Institute of Medicine in the USA has suggested that the use of the term 'guideline' should be restricted to systematically developed advisory statements which have been created according to validated methodologies (Hammond, 2001).

Clinical practice guidelines are considered to be an explicit statement of the shared common goals for patient care. They assist clinicians in the day to day care of their patients, improve the outcomes of health care and optimise resource allocation (Cook, et al., 1997). It is suggested that CPGs reduce variability and provide clarity for less experienced members of the health care team. Other proponents maintain that the standardisation of care accelerates clinical decision making by bedside clinicians which increases patient safety and therefore positively affects patient outcomes (Brook, et al., 1999). These positive views are not shared by all. In fact controversy exists concerning the usefulness and validity of many CPGs. For example some health care professionals consider the evidence based movement and CPGs a form of 'cook book medicine' which reduces the opportunity for professional autonomy and creativity. Similarly others are concerned that the standardisation that CPGs are purported to promote does nothing to encourage problem solving and may 'deskill' health care professionals (Mead, 2000). Furthermore there is the ever present obvious problem of reporting bias where only CPGs which have resulted in positive outcomes are published (Weingarten, 2000).

The lack of evidence on which many guidelines are based, their unsystematic development and the number which require updating have been highlighted as problems (Hayward, 1993; Shaneyfelt, Mayo-Smith, & Rothwangl, 1999; Grilli & Lomas, 1994). Grilli & Lomas (1994) suggest that greater attention must be paid to the process used to develop CPGs if they are to be widely adopted by health professionals as a quality improvement strategy.

The implementation or adoption of CPGs

Despite evidence that not all CPGs are rigorously developed there are many examples of improved patient outcomes after the implementation of guidelines (Cook, et al., 1997; Brattebø, et al., 2002; Brook, et al., 1999; Devlin, et al., 1997; Kollef, Levy et al., 1998; Kress, et al., 2000; Marciniak, et al., 1998; Mascia, et al., 2000;

Weingarten, Riedinger, Conner, Johnson & Gray Ellrodt, 1994; De Jonghe, et al., 2005). Furthermore many advocates of CPGs highlight the need for professional decision making even when CPGs are available because CPGs are 'just guidelines' not a blanket statement about patient care in all circumstances (Gray Ellrodt, et al., 1995; Hayward, 1997; Davis & Taylor-Vaisey, 1997). Gray Ellrodt, et al. (1995) highlight the fact that 100% compliance should never be the aim of any implementation strategy since a CPG cannot guarantee 100% specificity and validity in all patient circumstances. The aim of any implementation strategy should be to communicate the fundamental principles of the guideline. Multifaceted approaches to implementation which use several communication methods and maximise clinician involvement have been shown to be effective for encouraging the adoption of sedation guidelines.

The development of CPGs should always involve consideration of the most effective dissemination and implementation strategies because the development of CPGs does not necessarily guarantee their adoption. A multifaceted inclusive approach is advised. This involves systematically developing the CPG in a multidisciplinary team with the people who will be using it, using the implementation strategies they suggest (Davis & Taylor-Vaisey, 1997). An inclusive approach to implementation was identified by the social behaviour theorist Rogers (1995) as particularly successful. Moreover the influence of Rogers (1995) 'Diffusion of Innovations' model is evident when exploring the literature concerning the implementation and adoption of CPGs.

Factors which increase guideline adoption. Rogers (1995) uses diffusion to mean the special communication of an idea and subsequent social change. Unlike other authors who consider dissemination a planned form of change and diffusion as spontaneous and unorganised, Rogers (1995) makes no differentiation. He describes the innovation as an idea, practice or object which is perceived by the individual as new. It matters little if the innovation is actually new, it just has to be perceived by the individual as new to qualify as an innovation (Rogers, 1995). According to Rogers (1995) the rate and extent of adoption of an innovation is influenced by the nature of the innovation (attributes of the CPG) and the manner in which it is communicated (dissemination strategies) to members of a social system (health care professionals).

Applying Rogers (1995) theory of the 'Diffusion of Innovations' to the adoption of CPGs, it is evident that there are certain characteristics of CPGs perceived by individuals which increase their likelihood of being adopted. The characteristics are described below.

- The perceived relative advantage of the guideline or the degree to which it is perceived to improve on previous practices: Rogers (1995) highlights the fact that the guideline does not have to have a great deal of objective advantage but the perceived relative advantage of the innovation is of great importance. Relative advantage can be measured in financial terms, social prestige, satisfaction and convenience.
- Perceived compatibility with existing values and previous experience is another factor which increases the rate of adoption: For example, guidelines which propose the use of alcohol and chlorhexidine hand rub as an alternative to hand washing for hand decontamination are often difficult for nurses, who have been indoctrinated for years to wash their hands with soap and water, to accept. Hand washing is entrenched in nursing culture despite evidence which is readily available that nurses do not decontaminate their hands adequately using soap and water.
- The lack of perceived complexity for the user is another characteristic which increases the rate of adoption: The quality and simplicity of guidelines has a significant effect on their adoption (Davis & Taylor-Vaisey, 1997).
- The ease with which the innovation can be tried before full adoption reduces uncertainty and increases confidence: In other words the potential adopters who are able to learn as they do are more likely to adopt.
- The observability describes the visibility of the results or outcomes of a new CPG to other potential adopters: Clinical practice guidelines which make immediate observable positive differences to patient outcomes or comfort are highly likely to be adopted (Grilli & Lomas, 1994).

Given that perceived compatibility increases the likelihood of adoption, it is perhaps not surprising that successfully implemented CPGs have an explicit measurable goal at the outset. Successfully implemented CPGs also stipulate goals which are congruent with organisational objectives and do not deviate excessively from the existing goals and values of the people working in the context (Hayward, 1993;

Humphris, 1997). Clinicians are more heavily influenced by explicit goals which contain statements about improved patient comfort and outcomes rather than cost containment (Ockene & Zapka, 2000). Externally generated guidelines, for example guidelines developed by professional organisations without intensive educational support and local adaptation, are notoriously difficult to implement (Lomas, et al., 1989). This is probably because the people who are expected to use them do not share the same vision as the organisation which developed the guidelines. However guidelines are more likely to be considered if the organisation that published the guideline is credible and well known.

Implementation strategies. To date the most prevalent strategies for implementing guidelines appear to be locally developed intensive educational programs, which incorporate reminders and systems which feedback compliance rates and patient outcomes relevant to the bedside clinician (Davis & Taylor-Vaisey, 1997; Ockene & Zapka, 2000). The use of patient feedback, that is the subjective experience of being a patient, is known to be a meaningful indicator for bedside clinicians when making judgements about the effectiveness of clinical practice guidelines (Titler, et al., 2001; Davis & Taylor-Vaisey, 1997). Furthermore audit feedback underpins many quality improvement projects using the 'plan, act, do' cycle. However the effectiveness of CPG related performance feedback is inconclusive. It has also been suggested that practice may return to baseline levels if the feedback is withdrawn (Anderson, 1993). The use of CPG related performance feedback during implementation is just one of many strategies available to improve overall awareness and familiarity with the CPG. This strategy may be particularly powerful if it leads to the practice becoming routine early on in the adoption process.

An intensive education program incorporating didactic presentations, personal discussions and continuous feedback was used by Brattebø, et al. (2002) successfully to implement a sedation guideline in a surgical intensive care unit. Likewise Brook, et al. (1999) used a multifaceted approach to ensure the intervention group received the algorithm based sedation guideline which has been described previously in this chapter. Information gained from one of the principal investigators suggests that apart from intense information sessions and poster reminders, there was also a person allocated from the research team to do daily bedside rounds (Ahrens, T, personal communication

2002). Informal adherence checks were made and clinician's queries were answered. The authors of both publications describe implementing sedation CPGs using multifaceted educational programs where a form of academic detailing comprised a major aspect of the program. Academic detailing is a form of intense one to one information giving which has been used successfully by pharmaceutical representatives and pharmacists to improve awareness of products, increase sales and improve prescribing practices by physicians for many years (Rogers, 1995). Information giving is tailored to the needs of the clinician and time is dedicated to answering queries and discussing options. Academic detailing is probably the most powerful method of affecting the uptake of a CPG. However it is arguably the most labour intensive and most difficult to measure. A possible explanation for the effectiveness of academic detailing is that the process is dependent on the information giver's responsiveness to the individual members of the social group.

An examination of the literature to date reveals that CPGs which have been widely adopted have been implemented using education programs which are responsive to the needs of the social group they are aimed at. Therefore to appreciate the multifaceted approach which is necessary to implement CPGs the characteristics of the potential adopters also deserves consideration.

Adopter characteristics. Rogers (1995) not only described characteristics of successfully adopted innovations, he also described the categories of people in terms of their likelihood of adopting the innovation and their role during adoption. His descriptions were based on observation and designed to facilitate studies about the process of adoption. He described five types of adopter categories: innovators, early adopters, early majority, late majority and laggards.

Rogers (1995) reserved the term 'change agent' for highly informed individuals who are external to the social group and are invited to affect change or lead the adoption of innovation. According to Rogers (1995) change agents are often expert professionals with an elevated social status. Their elevated status can make communication of the innovation to potential adopters problematic. However opinion leaders are noted to offer a solution to this problem. The definition of a change agent has become less rigid over the years and now includes the recognition that change agents may be part of the same

social group and can possess interpersonal skills that transcend the potential difficulties associated with an elevated social status. Moreover the change agent is noted to possess qualities which include perseverance and stamina. The term ‘change champion’ is used interchangeably with ‘change agent’. Arguably the role is better described by the term ‘change champion’.

The innovators are the first to adopt new ideas and comprise approximately 2.5% of the social group. However unlike early adopters they are not usually well integrated with peers in local networks and typically they have a limited role persuading others to adopt the change. Early adopters (13.5%) and the early majority’ (34%) are similar in characteristics however early adopters tend to be viewed as making judicious choices in adopting new ideas; they are highly respected by their peers and are perceived as highly credible. Often these informal leaders make effective opinion leaders. Opinion leadership is earned and maintained by the individual’s level of competence, adherence to group norms and approachability. The effectiveness of employing so-called ‘opinion leaders’ has been demonstrated during practice guideline implementation projects involving physicians (Hayward, 1993). Early adopters are ideally targeted at the beginning of the development and implementation phase. However care must be taken not to exhaust individuals in this group, as they are highly enthusiastic. Another problem associated with over working the opinion leader is that their social group may come to perceive them as synonymous with the change agent and this may reduce their effectiveness.

The late majority (34% of the social group) tend to be very sceptical of new ideas and do not adopt the new idea until most of their peer group have adopted it. This cautious group is better targeted when the opinion leaders have been identified. Suggestions and non-threatening information sessions can be provided to gently introduce the subject. Peer pressure is often necessary to persuade the laggards (16%) to adopt new ideas even though they are often socially isolated from their network. An aspect of social prestige associated with the innovation is a powerful method of persuasion for this group. Rogers (1995) warns change agents not to neglect the consideration of the adopter characteristics when planning implementation strategies. Information giving alone is notoriously unsuccessful at achieving the sustained adoption of innovations and this has been confirmed more recently when implementing CPGs

produced by professional organisations (Hagemeister, et al., 2001; Hesdorffer, Ghajar, & Iacono, 2002).

Attractive advertising appears to increase awareness of CPGs for a short period. For example the awareness of general practitioners, interns and cardiologists of antihypertension guidelines disseminated in Germany was tested using a ten-item questionnaire (Hagemeister, et al., 2001). The antihypertension guidelines were distributed by specialist societies in Germany in the form of journal articles. Only 23.7% of the participants showed adequate guideline awareness or sufficient knowledge of the guideline (Hagemeister, et al., 2001). Similar results were revealed in a postal survey of the compliance rates for traumatic head injury care in 433 trauma centres with neurosurgical expertise in North America (Hesdorffer, et al., 2002). Participants were asked questions related to adherence to the CPGs which were disseminated by the American Association of Neurologic Surgeons in 1995. Aside from recognised difficulties associated with self reporting bias, this survey provided useful insight into the practices of neurosurgical centres in North America. Use of CPGs for the care of patients with traumatic head injuries varied from 69% in more highly specialised centres (level II) to 43% in level I trauma centres. The results suggest that information alone is an insufficient way of ensuring guidelines are implemented. However the powerful effect of a neurosurgical trainee program suggests that educational strategies, which incorporate the opportunity to 'test' the procedure or CPG, are very effective. Trainees may also act as opinion leaders and offer incidental academic detailing.

Ideally the development of the CPG should be achieved through collaboration. Similarly implementation programs should be aimed at all members of the health care team and incorporate tutorials, didactic presentations and reminder cards. Patient related outcome data should be incorporated in ongoing awareness campaigns. Clinicians should be given the opportunity to acquire and maintain the skills necessary to use the CPG and be able to engage in safe problem solving activities. The combined effect of these approaches is known to be the most effective strategy for the sustained adoption of CPGs (Ockene & Zapka, 2000).

The most effective strategy for guideline adoption has been described above. However few authors discuss methods of measuring the rate of adoption. The usual

method to establish the extent of guideline use is to measure changes in patient outcome. The context and circumstances may not support the use of a randomised control trial to 'test' a CPG. For example there may be concerns about contamination between the control group and intervention group. In this case other experimental methods may be used such as, preintervention and postintervention designs. These methods require the collection of data in addition to patient outcomes to assess the extent that the intervention was used. If outcomes alone are measured, any change cannot be confidently attributed to the innovation because factors other than the CPG may be responsible (Larson, 2003).

Measuring the rate of guideline adoption. Questionnaires and survey design investigations are frequently used to elucidate adoption of CPGs (Pathman, Konrad, Freed, Freeman & Koch, 1996; Hesdorffer, et al., 2002) but actual adoption data are rarely collected. Often when authors claim to report CPG adoption, it is evident that in fact the data are the participants' self reported use of the guideline or practice. The assumptions made when using these methods are that respondents practice as they say they do and that the mere knowledge of the CPG translates into guideline adoption. There is also the well recognised limitation of questionnaire designed studies; the reliability of self reports is variable.

Other research methods used to investigate adoption include ethnographic approaches and collection of data which reflect the CPG use (Angus, Hodnett, & O'Brien-Pallas, 2003). Although ethnographic approaches are able to identify difficulties with CPG use there are limitations to these methodologies. There is a lack of reportable adoption data and the potential influence of the presence of the investigator on practice cannot be ignored.

Arguably these difficulties with measuring adoption can all be related to the difficulty operationalising 'adoption'. To truly examine the uptake of a CPG an accurate operational definition of 'adoption' is required. To date many authors have reported adoption data on the basis of operational definitions which describe clinicians' knowledge of the existence of the CPG and their perceived knowledge of the CPG. A combination of measurement strategies, incorporating the collection of patient

outcomes, field notes and audits using unambiguous operational definitions, may be the most effective method to gauge the adoption of CPGs.

The Iowa model of Research-Based Practice to Promote Quality Care (Titler, et al., 2001), which is the theoretical framework for the study described in this thesis, incorporates many aspects of the accepted ideal implementation and evaluation strategy for CPGs. The influence of the principles of Rogers (1995) theory is evident in the Iowa Model. The following aspects of the Model reflect the principles of Rogers (1995) theory: the triggers which reflect the perceived advantage of changing practice, congruence between the goal of the CPG and the organisation, feedback mechanisms for audit data to clinicians and the necessity to trial a CPG before full adoption.

2.9 The theoretical framework of this study

The Iowa Model of Research-Based Practice to Promote Quality Care

The theoretical basis of the study described in this thesis is the Iowa Model of Research-Based Practice to Promote Quality Care (Titler, et al., 2001) (Figure 1, page 46). The Iowa Model provides a systematic framework on which to base a quality improvement project and to transfer research knowledge into nursing practice. This model has been adapted from the original model developed in 1994 in response to feedback from many nursing researchers who have successfully used it to improve patient care practices in many settings (Titler, et al., 1994).

The Iowa Model has the appearance of a clinical algorithm; options are given for each decision, and feedback loops are incorporated to encourage a continuous quality improvement process (Figure 1, page 46). The first boxes represented on the model are labelled ‘triggers’. Triggers are factors which give rise to the idea for practice improvement or cause the rationale for aspects of nursing care to be questioned (Titler, et al., 1994). They are the impulse for change or may contribute to the perception that other practices may be advantageous. Quality improvement data such as increased patient falls in a department may be the problem-focused trigger. However perceived or anecdotal problem focused triggers can also be the impetus for change. For example, frequent bowel problems for critical care patients may drive a group of clinicians to investigate the incidence of bowel problems and interventions in this population. Knowledge focused triggers originate from new evidence or information which has

come to light. Arguably clinical practice guidelines may be powerful sources of information because the onerous task of critiquing the analysis has been performed and this reduces the workload for busy clinicians. Newly published research, meta-analyses and systematic reviews are often distributed to individuals via professional organisations. Regular journal club sessions led by nurses who are skilled in the interpretation of research findings are also sources of knowledge triggers.

The prompt ‘Is this topic a priority for the organisation?’ is designed to encourage the investment of time and energy in topics which are relevant to the organisation. The probability of obtaining funding and resources is increased, and individual commitment is likely to be stronger if the topic is congruent with the aims and philosophy of the organisation (Titler, et al., 1994). The feedback loop brings the decision maker back to explore other triggers if the topic is not a priority.

Where the topic is a priority for the organisation the next instruction is to form a team. The relevant research and literature is assembled and critiqued. If the research base is deemed sufficient then a pilot project is designed and conducted. This process enables the assessment of the new practice in a small group of patients and the feasibility of the widespread use of the new practice can be explored. If the research base is insufficient, then other forms of evidence are considered. If these are inadequate the decision is made to conduct a research investigation using an adequate sample size.

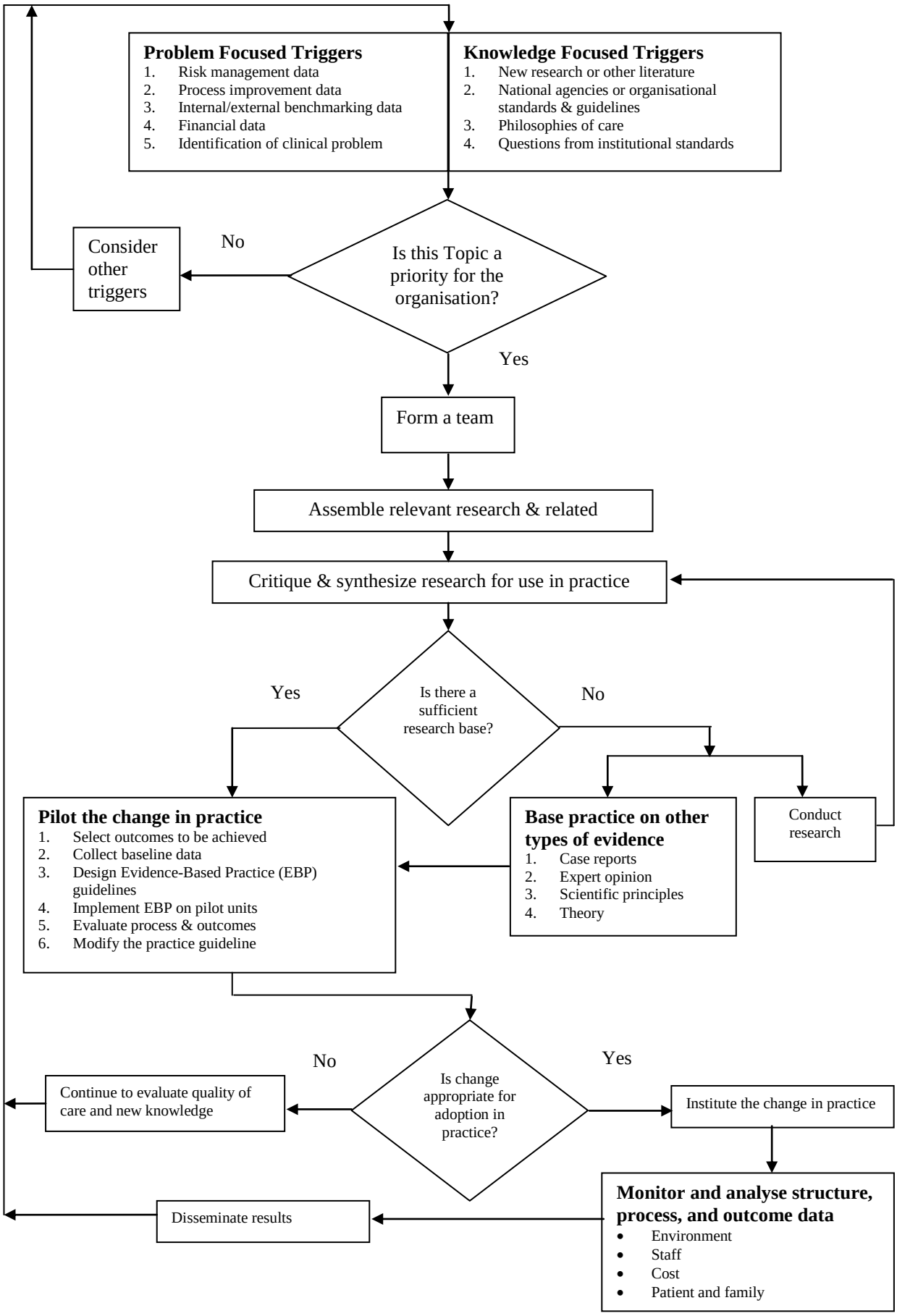

Figure 1. ***The Iowa Model of Research-Based Practice to Promote Quality Care***

Once the pilot project is complete a decision must be made about the appropriateness of adopting the change in practice across the organisation. If the change is not adopted the feedback loop brings the decision-maker back to the triggers to continue to evaluate quality of care and new knowledge. If the change is adopted all important aspects of health care outcome data are evaluated and monitored. This includes outcomes for the patient, family, workers, environment and costs. Finally the results are disseminated and the feedback loop brings the decision-maker back to the triggers.

The Iowa Model of Research-Based Practice to Promote Quality Care (Titler, et al., 2001) has been used successfully to improve or introduce several patient care practices in varied settings, for example tracheal suctioning in an intensive care unit, post cardiac catherisation care in an acute cardiology ward and the appropriate use of physical restraints across a health care organisation (Taylor-Piliae, 1999; Lundin, Sargent, & Burke, 1998; Cruz, Abdul-Hamid, & Heater, 1997). The Model is also a logical framework on which to increase the use of evidence based practice and increase research awareness (Van Mullem, et al., 1999).

Examples where the Iowa Model has been utilised to introduce evidence based health care. Taylor-Piliae (1999) used the Iowa Model to conduct a quality improvement project in an eight-bed intensive care unit at a hospital in Hong Kong. The aim of the project was to improve the procedure for tracheal suctioning of ventilated patients. The improved outcomes, for example fewer complications associated with suctioning and reduced costs associated with using fewer suction catheters, were attributed to the widespread adoption of changes in practice. The Iowa Model provided a logical framework to introduce several research findings about suctioning practices. These changes were initiated and suggested by the nurses themselves and were not imposed on the nurses.

The Iowa Model was also used by Lundin, et al. (1998) to improve outcomes for patients receiving cardiac catheterisation in a Wisconsin hospital, North America. As a result the length of bed rest after the procedure was reduced, patients were discharged two hours earlier and costs were reduced. There was no increase in adverse events related to earlier mobilisation.

Cruz, et al. (1997) described the use of the Iowa Model to design a project to reduce the inappropriate use of physical restraints in an acute care setting. Phase I of the project was reported. The trigger for this project was evidence of frequent use of restraints for elderly patients in their own organisation and evidence in nursing research of widespread inappropriate restraint use. Cruz, et al. (1997) formulated a strategy to increase utilisation of research related to this aspect of practice. Knowledge of the appropriate use of restraints for the elderly increased after the implementation of an education program.

Van Mullem, et al. (1999) described the integration of the Iowa Model in a project designed to assess and develop a culture which was supportive of nursing research utilisation in a group of hospitals in Wisconsin, North America. The aim of the study was to assess existing research knowledge and develop a strategy for increased research utilisation. The authors concluded that the Iowa Model provided a framework not only for the assessment process but also to increase research activity in the following month. The projects described above would have been strengthened by reporting a research design and data collection methods which enabled interpretative statistical testing. A more rigorous approach would improve the generalisability of the results. The design of the study described in this thesis was developed following an appraisal of the Iowa Model and was consequently selected as the theoretical framework. In contrast to the studies described above, the research design and data collection methods enabled interpretative statistical testing to be performed. The use of the Iowa Model is represented diagrammatically in Figure 2, page 49.

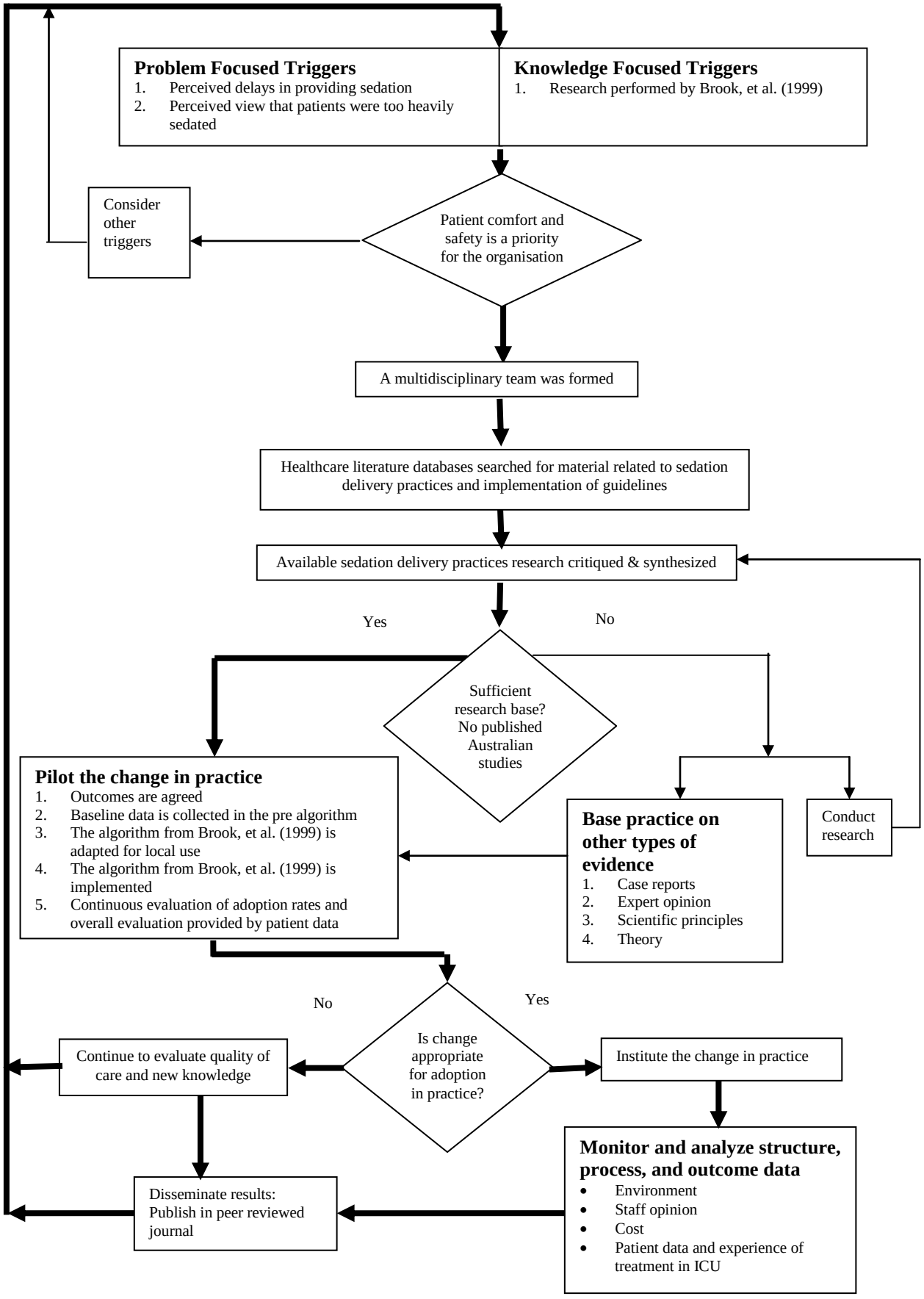

Figure 2. ***The application of the theoretical framework (Iowa Model of Research-Based Practice to Promote Quality Care) to the sedation study (Bold lines indicate application to the study)***

The application of the theoretical framework to the study design

The problem focused triggers which influenced the initiation of this project were the nurses' dissatisfaction about delays in providing sedation and the inconsistencies in sedation practices and anecdotal reports from the intensivists who felt that on occasions the patients were too heavily sedated. Given the priority afforded to any trigger related to patient comfort in the study ICU, the Brook, et al. (1999) study was presented in journal club in the intensive care unit at the Royal North Shore Hospital and the implementation of a sedation guideline was explored. A team was formed to investigate this issue. The team consisted of a Professor of Critical Care Nursing, a research Project Manager, three research assistants, an intensivist, a Clinical Nurse Educator, two clinical nurses, a Nurse Unit Manager and a clinical epidemiologist. The knowledge focused triggers available included the evidence emerging from studies performed in North America and Europe about the advantages of using standardised sedation protocols (Devlin, et al., 1997; Brook, et al., 1999; Mascia, et al., 2000; Kress, et al., 2000).

The level of evidence supporting the implementation of the sedation guideline presented in the randomised controlled trial performed by Brook, et al. (1999) was high. Despite an extensive search of several healthcare databases, published studies investigating the effect of sedation clinical practice guidelines in Australia were not located. While critiquing the available research, the quality of the study by Brook, et al. (1999) was recognised. The cultural differences between intensive care practices in North America and Australia were acknowledged. This was a major component of the decision to measure the effect of the guideline before making the decision to adopt it. Therefore a preintervention and postintervention study was planned to trial the sedation protocol shown to be beneficial in the Brook, et al., (1999) study (denoted by the box labelled 'Pilot the change in Practice' in the Iowa Model).

The study aims were agreed as being, primarily, to investigate the effect of the algorithm based sedation guideline on the duration of ventilation in ICU patients. Baseline data were collected before the implementation of the sedation algorithm in the preintervention phase. The algorithm based guideline shown to be beneficial in the Brook, et al. (1999) study was adapted very slightly. Lorazepam, which is unavailable as an intravenous preparation in Australia, was replaced with midazolam. The study

design and detailed methods used to encourage the adoption of the sedation guideline are fully described in chapter three. Since actual patient data were not available until the completion of the study, guideline adoption data were collected in the postintervention phase and formed the basis of the feedback provided to clinicians, which is suggested in the Iowa Model.

2.10 The differences between the North American and Australian health care contexts

No published studies investigating the effect of sedation clinical practice guidelines in Australia were located in an extensive search of the health care literature. The study by Brook, et al. (1999) was performed in North America. There are major cultural differences between intensive care practices in North America and Australia, for example legal requirements for the prescription of medications, the model of care and postgraduate education of nurses are all different. The lack of published studies performed in Australian intensive care units and the differences in intensive care practices between countries contributed to the decision to perform the study described in this thesis.

The legal requirements for the prescription of medications

The medications in the algorithm based guideline in the study by Brook, et al. (1999) were nurse initiated, meaning that the nurses did not require a medical prescription to be able to administer each individual medication. The medical officer was only required to prescribe the guideline. An investigation of the legal requirements for prescribing the guideline in Australia revealed that nurses would be required to demonstrate competence in administering each of the medications if the medical officer was not required to prescribe each individual medication. Therefore only nurses who had participated in a predetermined accreditation process would be able to administer the medications. This process would have involved prior approval from the New South Wales Department of Health had this approach been followed. The frequent turn over of staff which is common in tertiary referral centres would have added a financial burden and complexity to the study. It was decided the best alternative would be to ask the medical officers to prescribe all the guideline medications. The workload was reduced by pre-printing the prescriptions for the continuous infusions on the patient flow chart

with space for the medical officers' signature. Prescribing instructions were included in the electronic document placed on the intranet for the medications.

The model of care

In the American study unit there was a ratio of one registered nurse to two ventilated patients (Ahrens, T, personal communication 2003), whereas Australian intensive care units operate on a registered nurse to patient ratio of one to one. Most North American ICUs are described as 'open' units meaning that management of the unit or the patient is not co-ordinated by one medical specialist. However like many Australian ICUs, the unit in which the Brook, et al. (1999) study was performed was a 'closed unit'. The so-called 'closed unit' is commonly co-ordinated by an intensivist, a qualified intensive care medical specialist who has the overall responsibility for patient management and patient admissions. This model of organising ICU treatment minimises variability in patient management and is said to be one of the main contributors to the better outcomes reported from Australian ICUs (Fisher & Herkes, 1997).

Postgraduate critical care nursing education

Postgraduate critical care nursing education is commonly a joint venture between the tertiary education and health care sectors in Australia. Education is specific to the particular speciality and includes development and assessment of clinical competence. In contrast, postgraduate education in North America is primarily provided by the tertiary education sector and concentrates on generic nursing knowledge. There is more responsibility on the individual registered nurse to pursue learning opportunities and demonstrate critical care nursing expertise. Clinical competence is developed through continuing education programs provided by a variety of agencies such as the health care sector, professional bodies and commercial education providers.

2.11 Summary of findings located in the literature

Intensive care patients require analgesic and sedative medications to be comfortable and tolerate treatment in the intensive care unit. Patients who receive inadequate amounts of these medications may experience more pain and anxiety, as well as increased stress and oxygen consumption. Patients who become agitated may remove life sustaining airway devices. Conversely excessive amounts of analgesic and

sedative medications may lead to a prolonged duration of ventilation, length of ICU stay and the complications of immobility.

Sedation assessment scales provide clinicians with an objective measure of sedation level and allow them to titrate sedative medications to a predetermined level. Therefore sedation scales are an integral part of most sedation guidelines. Sedation guidelines have been demonstrated to improve intensive care patient outcomes, such as a reduction in the duration of ventilation, length of ICU stay, and number of tracheostomies and unscheduled self-extubations.

Furthermore patients in health care contexts other than ICU have benefited from the implementation of CPGs. Clinical practice guidelines are understood to standardise care and provide direction for less experienced members of the health care team. The implementation of CPGs has been strongly influenced by Rogers (1995). Strategies to encourage clinicians to adopt CPGs are reflective of different people's levels of receptiveness to innovative ideas; adopter characteristics.

An example of a practice improvement model, the Iowa Model of Research-Based Practice to Promote Quality Care (Titler, et al., 2001) also incorporates many aspects of Rogers (1995) theory. The Iowa Model has been used by several nurse investigators to introduce research evidence into health care practice in several different contexts.

2.12 Study hypothesis and aims

The broad aim of the study described in this thesis was to investigate the effect of an algorithm based sedation guideline, developed for the Brook, et al. (1999) study, in an Australian ICU, which was shown to be beneficial in a North American intensive care context.

Hypotheses

The hypotheses of the study described in this thesis were that mechanically ventilated patients exposed to the new sedation algorithm based guideline would have a shorter duration of ventilation, improved experience of recovery after ICU (reflected as lower scores on the ETIC-7 scale), a shorter length of ICU stay and fewer

tracheostomies, reintubations and unscheduled self-extubations than those who receive usual sedation practices.

Primary aim

The primary aim of the study reported in this thesis was to determine whether an algorithm based sedation guideline reduced duration of mechanical ventilation for ICU patients.

Secondary aims

One of the secondary aims of this study was to determine whether the use of a sedation guideline improved the experience of recovery after ICU for mechanically ventilated patients, reflected by lower ETIC-7 scores. Other secondary aims were to determine whether the use of a sedation guideline reduced the length of ICU stay, the incidence of unscheduled self-extubations, the rate of reintubation and the number of tracheostomies. The effect of the study intervention on the costs of intravenous analgesic and sedative medications was also examined. In addition the rate of adoption of the new practices of sedation scoring and use of a sedation guideline by bedside clinicians was explored.

Chapter Three - Methods

3.1 Introduction

This chapter outlines the methodological approaches of the study. A description of the research design, participants and setting, instruments and procedure is provided. A methodological defense is incorporated in the chapter and provides justification for the design, participant selection, choice of instruments, sample size, statistical power, and data collection methods.

3.2 Research design

The Iowa Model of Research-Based Practice to Promote Quality Care (Titler, et al., 2001), which has been described previously in chapter two, guided the project design. The Iowa Model outlines a rigorous approach to quality improvement incorporating steps to thoroughly examine the literature, implement guidelines and conduct research where evidence is not available. The quasi-experimental preintervention and postintervention independent samples design is incorporated in the Iowa Model. Therefore this project was performed using the design suggested in the Iowa Model to compare the duration of ventilation before and after the implementation of an algorithm based sedation guideline. The project was conducted in two phases, a ten-month preintervention data collection phase (November 2002 to October 2003) was followed by a twelve-month postintervention phase (November 2003 to December 2004.

Randomisation of patients to an intervention or control group would have been impractical for this quality improvement project which was directed at a whole unit where geographical and staffing issues increase the probability of contamination. In the study unit patients are cared for in close proximity in two six-bedded rooms in addition to three separate isolation rooms. ‘Patient allocation’ is the model of care practised in this unit. Since continuity is not the primary objective of patient allocation and the aim is to allocate the nurses according to their skill and patient acuity, each patient may be cared for by a different nurse each day. The model of care and the impossibility of blinding the clinicians to a guideline intervention could contribute to confusion amongst bedside clinicians and lead to contamination of a control group. It is understood that the ‘before and after’ study design or the quasi-experimental preintervention and postintervention prospective design, used for many investigative quality improvement

projects, is a highly effective method of facilitating the adoption of a clinical practice guidelines (Titler, et al., 2001). Long-term change is more easily sustained when this design is used in combination with effective educational programs (Brattebø, et al., 2002; Cook, et al., 1997; Kitson, Harvey, & McCormack, 1998). The Iowa Model, which incorporates these approaches, has been used successfully by nurses to improve patient outcomes in several countries (Titler, et al., 2001).

3.3 Study outcomes

The study was designed to measure the effect of an algorithm based sedation protocol on duration of mechanical ventilation in general intensive care patients. Data were collected on the duration of ventilation in addition to the following secondary outcome measures: the influence on the intensive care patient of the implementation of the sedation guideline using the Experience after Treatment in Intensive Care-7 questionnaire (ETIC-7) (Scragg, et al., 2001); the length of ICU stay; the number of tracheostomies and the number of self-extubations and reintubations. In order to monitor the rate at which clinicians adopted or incorporated the Ramsay Scale and sedation guideline into their practice, chart audits were performed on random days for nine months of both of the phases. The costs of intravenous sedative and analgesic medications were examined retrospectively using the hospital's pharmacy database.

3.4 Setting

The project was performed in a 15-bed general adult intensive care unit at a metropolitan 600-bed hospital in Sydney, Australia. The hospital is a tertiary referral centre for several health conditions, including burn injury, spinal injury, renal disease and cardiology. The intensive care unit is classified as 'a closed unit'. That is the admission and subsequent care of patients is directed by the intensive care specialist medical officer. Each of the eight intensive care specialist medical officers (two are part-time) are allocated to the unit in rotation for seven days at a time. In addition the patients in the unit are cared for by an intensive care fellow (registrar) along with two resident medical officers. The intensive care specialist and intensive care fellow are on site for 12 hours of the day and are easily accessible by pager or telephone at any other time. The resident medical officers are in attendance for 24 hours and undertake 12 hour shifts each.

There are two daily ward rounds conducted, in the morning and afternoon, when a thorough patient assessment and plan of care is discussed with the nurse and medical officers. The intensive care specialist handover is a multidisciplinary meeting which occurs on a Monday morning in a tutorial room away from the main unit for reasons of patient privacy, and the large number of healthcare professionals who participate. Other teaching orientated patient discussions are also facilitated in the tutorial room on Tuesday mornings, Thursday afternoons and Friday lunchtime.

Nurses undertake a variety of shifts, that is eight, 10 or 12 hours. Self rostering is practised which allows nurses to determine the most convenient roster according to their needs, whenever possible. The average vacancy rate while the project was conducted was nine Full Time Equivalents (FTEs) or 12% of the required 70 FTE for this 15 bed unit. However at the study completion vacancies had dropped to zero (Spiers, B, personal communication 2004). The percentage of nurses working less than 75% of the Full Time Equivalent is 19% (12 FTEs of the 61 FTE) (Spiers, B, personal communication 2004).

Registered nurses perform all the nursing care for ICU patients. Nurses are allocated to care for patients by the nursing team leader of the previous shift. The allocation is performed on the basis of the nurse's level of experience and the patient needs. Some effort is made to ensure that nurses are not allocated to care for patients in single isolation rooms for more than one shift in succession. The registered nurse to patient ratio is 1:1 for mechanically ventilated patients with the additional clinical support of a Clinical Nurse Educator, Nurse Unit Manager and Clinical Nurse Consultant during the day Monday to Friday. At any other time an after hours Nurse Unit Manager responsible for the nursing workforce throughout three ICUs is available for consultation and clinical assistance. There are two Patient Services Assistants who provide help with repositioning patients, along with their additional 'house keeping' responsibilities during the day. The physiotherapist performs rounds twice a day when the patients' lungs are auscultated, sputum clearing treatments are provided and limb exercises are performed and prescribed. A physiotherapist is available on-call at night. There is a Senior Social Worker and Chaplain available predominately for assistance with relatives' concerns during the day, and an on-call service exists at night.

All new nurses undertake a three month orientation program, which includes an initial two week supernumerary introduction followed by suggested learning goals such as the completion of competencies and work books. There is a daily education session for all registered nurses at 1430 hrs Monday to Friday where a variety of nursing issues are discussed. A monthly journal club conducted by the Professor of Critical Care Nursing and a multidisciplinary team case presentation lead by a nurse caring for one of the current ICU patients are examples of regular sessions. The daily education session time was used to provide information about this study and the use of the new sedation guidelines.

Over 31% of the nurses have a postgraduate critical care nursing qualification (Spiers, B, personal communication 2004). Most of the nurses enrol in critical care courses at local tertiary education centres. The successful completion of several locally developed clinical competencies is a requirement of the Graduate Certificate in Critical Care nursing at the University of Technology, Sydney. Few extensive nursing protocols are used on the unit but the locally developed competencies are based on research evidence and have policy and guideline content. All competencies and existing clinical practice guidelines are located on the local intranet, which is accessible to all bedside clinicians.

A follow-up service is provided for all general intensive care patients who can be contacted by telephone. The hospital database containing records of patient admissions and discharges is consulted to locate patients and to reduce the likelihood of telephoning deceased patients. (A separate service provided by the Social Work department follows up bereaved ICU patients' relatives.) The follow-up telephone call comprises of a semistructured interview designed to stimulate discussion and identify any difficulties. Questions include reference to sleep patterns, mobility, finances and relationships. The entire format for the telephone prompts is located in Appendix D. Occasionally patients express a desire to return to ICU to be better able to piece together their experiences of ICU. The return visit is facilitated by the nurse who co-ordinates the service or the ICU chaplain. The telephone service was used in this project to facilitate the collection of data related to the patient's experience of treatment in ICU, after hospital discharge, that is the Experience of Treatment after Intensive Care-7 questionnaire (ETIC-7) (Scragg, et al., 2001).

3.5 Methods

Sample

The unit research assistants systematically checked intensive care patients for study eligibility each day. Research participants were selected on the basis of whether they were mechanically ventilated while they were in intensive care. Participants were eligible for inclusion if they were adults older than 17 years. Patients were excluded if they:

i) had a primary diagnosis of head injury or other neurological insult and where the aim of sedation was to reduce or minimise intracranial pressure and/or cerebral artery spasm.

ii) were not expected to live for more than 24 hours after admission, e.g. patients who had a diagnosis of brain stem death or who were likely to require brain stem death tests.

iii) had an explicit ventilation weaning goal on admission e.g. post operative coronary artery bypass graft patients recovering from general anaesthetic.

iv) were likely to be ventilated for more than 21 days, e.g. patients with neurological conditions such as Guillain-Barré Syndrome and myasthenia gravis, and patients who had sustained a recent complete spinal cord lesion above cervical spine vertebra number five.

v) had previously been enrolled in the study and were readmitted to the intensive care unit more than 72 hours after they were discharged. However for the purposes of this project patients who were readmitted within 72 hours were regarded as being in the same ICU admission.

vi) had sustained a burn injury covering more than 15% of their body surface area.

Measurement of primary outcome and secondary outcome data

Patients were selected consecutively until the required sample size of 163 patients per group (see section 3.8 for sample size) was achieved in each phase. Primary outcome data concerning the duration of mechanical ventilation were collected while the eligible patients were cared for in ICU. The Experience after Treatment in ICU (ETIC-7) data were collected from the surviving patients who were eligible for the guideline had returned home. Other secondary outcome and demographic data were collected for all eligible mechanically ventilated patients while they were in ICU. These

were length of ICU stay, number of tracheostomies, number of reintubations and unscheduled extubations, age, gender, diagnosis, Acute Physiology and Chronic Health Evaluation II score (APACHE II) (Knaus, Draper, Wagner & Zimmerman, 1985). Adoption data for the sedation scale and guideline were collected for all patients cared for in ICU once a month on a random day for the duration of the study. Costs for intravenous sedative and analgesic medications were examined using the Hospital's pharmacy database at the conclusion of the study.

Instruments. The Acute Physiology and Chronic Health Evaluation score II (APACHE II) (Knaus, et al., 1985) (Appendix E) and APACHE III modified ANZICS diagnostic codes (ANZICS, 2004) (Appendix F) were used for data collection on admission to ICU. The ETIC-7 (Scragg, et al., 2001) (Appendix A) was recorded after the completion of the routine follow-up phone call. Duration of ventilation, length of ICU stay, number of tracheostomies, number of unscheduled self extubations and reintubations, APACHE III ANZICS modified diagnostic codes (ANZICS, 2004) and total APACHE II score were documented on an additional data sheet specifically designed for the project (Appendix G).

The Acute Physiology and Chronic Health Evaluation II (APACHE II) (Appendix E) (Knaus, et al., 1985) scoring system is a refinement and simplification of the original APACHE (Knaus, Zimmerman, Wagner, Draper & Lawrence, 1981) severity of disease classification system. This classification system is designed to predict risk of death in-hospital for severely ill ICU patients. Scores are assigned to a series of 12 physiological variables, which have been shown to predict outcome. Existing chronic illness, age group and neurological status on admission are also assigned scores. Higher APACHE II scores indicate greater severity of illness. The highest possible score is 71. The lowest possible score is zero, which is an indication of good health and an age below 44 years. The system is used in many countries for research comparing treatment regimens in intensive care, as well as for monitoring quality of care, by classifying patients into prognostic groups. The APACHE II scoring system was chosen to classify patients in this project as the researchers were already familiar and highly trained in its use because APACHE II scores are routinely collected in Australian ICUs for the Australian and New Zealand Intensive Care Society (ANZICS) database. In addition the APACHE II scoring system has been validated and

found to be reliable in investigations comparing severity of illness scores and prognostic value (Gunning & Rowan, 1999).

The Acute Physiology and Chronic Health Evaluation III ANZICS modified diagnostic codes (APACHE III) (Appendix F) are widely used to assign patients to diagnostic groups for ICU research (ANZICS, 2004). 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). All categories were assigned to non-operative and postoperative groups. This classification system was modified by the Australian and New Zealand Intensive Care Society and is used during routine data collection in Australian ICUs (ANZICS, 2004) (Appendix F). The modifications include assignment of category numbers and inclusion of ten other categories including burns, head trauma, sepsis with shock, coronary artery bypass grafts and spinal injury.

The ETIC-7 (Appendix A) consists of seven questions designed to screen for post-traumatic stress symptoms associated with the patient's experience of intensive care. For example 'When reminded of your stay in the Intensive Care Unit, does it make you feel anxious or unwell (for example, heart racing or thumping, nausea, sweating)?' Patients rated their response to each question on a four-point scale 'Not at all' which was given a score of zero to 'Often' which was recorded as three. An open-ended question at the end of the Scale 'Do you have any comments that **you** would like to add?' was posed to all patients who agreed to complete the Scale. The total score was calculated for each patient and the responses to the open-ended question were entered verbatim to the database. The lowest total score possible is zero and the highest twenty-one. Reliability and validity of the ETIC-7 has been established in previous research (Scragg, et al., 2001). An extensive description of the study performed by Scragg, et al. (2001) is provided in chapter two.

The ETIC-7 was chosen for this project as a method of capturing the patients' perspective of their experience after ICU. The aim of using this tool was to detect if there was any difference after the implementation of the sedation guideline. The other factors influencing the choice of this scale were the reliability and validity demonstrated in the Scragg, et al. (2001) study, the brevity of the scale and the low probability of burdening patients.

Definitions

The following operational definitions were used to ensure consistency in the study process:

- The duration of ventilation was defined as the days between the start and finish of mechanical ventilation. The start of mechanical ventilation was taken as the time of intubation or for patients who were admitted after mechanical ventilation had already been instigated, the time of admission to the study ICU. Mechanical ventilation was considered to be successfully discontinued when the patient had been able to breathe without an invasive mechanical ventilator for 24 hours, and was recorded at the actual time mechanical ventilation was ceased.
- The length of ICU stay was defined as the days between the start and end of ICU the stay. The start of the ICU stay was time and date of admission to the study ICU. The ICU stay was considered complete when the patient was discharged from the study ICU to another ward or facility or the time and date of death. For the purposes of this study patients who were readmitted to the study ICU within 24 hours were not considered to have been discharged.
- Unscheduled self-extubation was defined as the extubation or decannulation of a tracheostomy which was unplanned and facilitated by the patient.
- Reintubation. This term was applied to patients who required intubation early after extubation (within 24 hours) for an acute deterioration in respiratory status related to the original condition for which they were mechanically ventilated.

Procedure

Preintervention: The introduction of the Ramsay Sedation Scale. There was no sedation scoring system in use in the ICU before the start of this project and therefore clinicians relied on their individual judgement to assess the patient's sedation level. Consequently target sedation levels were rarely discussed. Eighteen months prior to the introduction of the intervention and ten months before data collection began, the Ramsay Sedation Scale (Ramsay, et al., 1974) (Appendix B) was introduced. The Ramsay Scale was introduced in the preintervention stage to enable a comparison to be made of patient sedation levels before the implementation of the sedation guideline. The Ramsay Scale is a sedation scoring system designed to assess and monitor the patient's

sedation level. Discrete descriptors of behavioural responses to stimuli are used to assign a score. A minimum score of 1 is assigned to patients displaying signs of agitation and a maximum score of 6 indicates a heavily sedated state where physical stimuli does not elicit a physical response (see chapter two for a fuller explanation, page 26). The Ramsay Scale was introduced in preference to other sedation scoring systems because it was integral to the sedation algorithm developed by Brook, et al. (1999) (Appendix C). Use of an alternative scoring system would have changed the algorithm, which we intended to use without substantial alteration, and therefore would have resulted in difficulties interpreting the results in relation to those found by Brook, et al. (1999). The nurses were requested to record the patient's Ramsay Score at least every four hours and ideally hourly when documenting other patient parameters.

In an effort to reduce the likelihood of bedside clinicians changing their sedation delivery practices, and to enable a comparison of data to be made before and after the implementation of the sedation guideline, the full reason for using the new scale was not explained. Bedside clinicians were informed that the introduction of the scale was one method of reducing the subjectivity in assessing patients' sedation needs and was part of a larger future change in the delivery of sedation. Information sessions were provided which included information about how to use the scale, in particular the term 'Glabellar tap'. I did not stipulate a target score and asked my colleagues to continue with their existing practices. These sessions often led to lively debate about the limitations of using sedation scales but all conceded that increased objectivity would be useful. The patient observation charts were reproduced with the words 'sedation score' printed in a space at the top of the chart. Laminated Ramsay Sedation Scale cards were attached to the bedside tables with the charts used by the nurses to document the patients' progress (Appendix B). Frequent personal reminders were also provided and new nurses and medical officers were orientated to the scale.

On a random day in each month, for nine months, (unknown to the bedside clinicians) an audit was conducted of the charts of all ICU patients currently admitted to ICU to track bedside nurses' adoption of the Ramsay score (Appendix H). The previous 24 hours of each patient's chart was reviewed for Ramsay scores. The following questions were used to track the documentation of Ramsay score:

1) Was the Ramsay score recorded?

2) What were the last 6 Ramsay scores?

A category from the list below was marked according to the responses to the previous questions and the patient's condition:

- **Perfect adoption** describes complete adoption with no deviation from documenting the Ramsay score at least every four hours during daylight hours.
- **Non-adoption - clinical judgement** describes deviation from documenting Ramsay score when the clinicians used their clinical judgement about the patient's condition. For example after neuromuscular relaxing agents are administered it is potentially distressing for the patient to be asked to respond when they cannot move, so any scale which requires a behavioural response cannot be used.
- **Non-adoption - not for guideline** describes deviation when it is not appropriate to assess sedation level. For example, the patient who is waiting for transfer to the ward generally does not require assessment of sedation level.
- **Non-adoption - no reason** describes deviation from documenting the Ramsay score when there is no obvious rationale.

This information was not relayed to clinicians during the preintervention phase to avoid the potential effect of excessively increasing awareness of sedation delivery practices and thus causing clinicians to change their practices before the implementation of the sedation guideline. Instead the data were used to direct the intensity and frequency of information sessions about the Ramsay Scale implementation and strategies to encourage the adoption of this method of assessing sedation level.

Postintervention: The implementation of the sedation guideline. Prior to the introduction of the sedation guideline in this study, sedation delivery practices in the study unit involved the prescription of the medication by the medical officer and administration by the nurse of the amount he/she considered appropriate for the individual patient's requirements, according to the prescription. The most commonly administered medications were morphine for pain and midazolam for anxiety and sedation. The medical officer prescribed a dose range. The rationale and conditions under which sedative medications were administered was ad hoc and reliant on the bedside clinicians' knowledge, experience and personal judgement.

Patients, in the postintervention phase of the project, received sedation delivered using an algorithm based clinical practice guideline. The algorithm based sedation guideline used in this study was intended to be a replication of a sedation guideline which was previously shown to be beneficial (Brook, et al., 1999). However due to the lack of availability of intravenous lorazepam in Australia, a similar sedative medication, midazolam, was used (Appendix I). The protocol involves an initial assessment of the need for sedation on the basis of a target Ramsay Score of 3, and there is a prompt to assess the need for analgesia. Alternative regimens for sedation and/or analgesia follow. The intervention described is a standardised version of the sedation practices which were used for mechanically ventilated patients before the algorithm was implemented. The use of an intravenous opioid for analgesia and an intravenous benzodiazepine medication for reducing the effect of stressors and sources of discomfort such as the presence of the endotracheal tube, was usual practice before the algorithm was implemented. In accordance with Australian legal requirements the medical officer prescribed all medications in the algorithm based sedation guideline before administration by the Registered Nurse. The route and equipment used for administering the medications was the same for both phases.

The sedation guideline was introduced using several strategies to reach as many bedside clinicians as possible as quickly as possible (the aim was to reach 90% of bedside clinicians in one month). For example group presentations and individual bedside teaching were performed and the full explanation of the guideline was placed on the ICU intranet site and in the orientation book given to all new nurses. Laminated copies of the guideline were placed in easily accessible positions around the unit. They were placed on the bedside tables used by the nurses to document the patient's progress and near the cupboards containing the sedative and analgesic drugs. In addition humorous cartoon reminders were placed on the doors of the drug cupboards. The cartoons were changed every two months. Several group presentations were provided where the general topic of sedation was discussed along with the complications of providing too little and too much sedation. Pharmacology was covered, including the clearance of drugs and their volume of distribution. The rationale for using the guideline was discussed, including the impressive reduction in duration of ventilation in the Brook, et al. (1999) study.

I performed daily (Monday to Friday) rounds to check use of the guideline and answer questions. Temporary casual nurses were considered a priority and individual bedside information sessions were provided. Occasionally the permanent nurses required reminders. Individual and group reminder sessions were provided in the form of informal bedside tutorials and in-service education presentations. Bedside nurses were approached to check their understanding of the algorithm and they were encouraged to highlight any difficulties. Problems were acknowledged and strategies were discussed to deal with them. For example bedside nurses were concerned about the potential additional workload associated with administering intermittent doses of drugs which require two nurses to witness their removal from a locked drug cupboard (Schedule 4 and 8 drugs in Australia). The strategy to address this potential additional workload was to encourage nurses to prepare drug infusions when they deemed it highly likely that a patient would progress to continuous infusions. Nurses were instructed to administer the intermittent doses of medication from the infusion syringe and progress to administering the continuous infusion as directed by the guideline.

After the guideline was implemented on a random day of each month, for nine months, (unknown to the bedside clinicians), I conducted an audit of the charts of all ICU patients currently cared for in ICU to track adoption rates for the guideline and Ramsay Scale. The previous 24 hours of each patient's chart was reviewed for Ramsay Scores and sedation delivery. The following questions were included in the audit of each chart:

1) Was the Ramsay Score documented?
2) Were fentanyl and midazolam used?
3) What were the last 6 Ramsay Scores

An adoption category was selected from the list below according to the responses to the previous questions and the patient's condition:

- **Perfect adherence** describes complete adoption of the guideline with no deviation from either drug regimen or the Ramsay target score of three.
- **Non-adherence - clinical judgement** describes deviation from the guideline when the clinicians used their clinical judgement about the patients sedation needs. For example if the patient showed signs of alcohol withdrawal or renal impairment.
- **Non-adoption - not for guideline** describes deviation when it is not appropriate to use the guideline. For example the cardiothoracic patients who are cared for using a

clinical pathway or the patients with burns greater than 15% of their body surface area.

- **Non-adoption - no reason** describes deviation from the guideline when there is no obvious rationale.

The results of these audits were placed on a dedicated area of the education notice board and in the unit newsletter (Appendix J). Graphs were also presented which allowed comparisons to be made between audit data collected month by month. This method of recording and presenting adoption data was chosen to provide information in an easily accessible way for busy clinicians. The language was chosen carefully to be informative and non-threatening and thus encourage clinicians to use the algorithm and document the Ramsay Scale. Additional information pertaining to the guideline and sedation delivery practices in general, such as the pharmacological differences between fentanyl and morphine and the benefits of using sedation scoring systems, was provided at the same time. Cartoons and humorous reminders were attached to the information with the aim of attracting clinicians to the topic of sedation (Appendix K).

Bedside clinicians were encouraged to be autonomous and consider and act in accordance with the needs of the individual patient rather than adhering rigidly to the guideline. I, the principal investigator, acted as an advocate for some of the less experienced nurses in approaching the medical officers about any prescribed sedative medication which was not part of the guideline.

To encourage adherence to the legal requirements for the administration of the medication contained in the sedation guideline the patient observation chart was preprinted with the infusion medications and their doses with space for the date and the medical officer's signature. An example of the correct prescription of the bolus medications was presented as a scanned medication chart and added to the full explanation of the guideline which was placed on the intranet (and accessible to all bedside clinicians).

3.6 Data collection

Data were collected while the patient was in ICU, as described previously (3.5 methods, instruments) in the same manner for all eligible patients admitted to the ICU in both phases of the project. Data collection was conducted over a nine-month period

in the preintervention phase (November 2002 to September 2003) and a nine-month period in the postintervention phase (November 2003 to September 2004). At two to three months following discharge all eligible patients who were able to be contacted by telephone were invited, at the conclusion of their routine follow-up telephone call (explained in section 3.4, setting), to give responses to questions in the ETIC-7 (Scragg, et al., 2001). Approximately 35% of the patients in both groups responded to the ETCI-7. The ETIC-7 took approximately 30 seconds to complete. Adoption data were collected on a random day each month.

I collected the ETIC-7 data, in my capacity as co-ordinator of the telephone follow-up service. This along with the project design precluded blinding to group membership. The telephone follow-up service was conducted with limited resources. In order to reach the maximum number of patients in the two to three month discharge period three attempts were made to contact the patient. Consequently not all eligible surviving patients completed the ETIC-7. Many patients moved house when they recovered and some did not supply a correct contact telephone number. On rare occasions if the patient was tired or burdened, for example they were very preoccupied by financial hardship or were extremely breathless, their participation was not requested.

3.7 Data entry

Data were entered into the computer database from the data collection sheets on a weekly basis and responses to ETIC-7 were entered immediately after each telephone call by the researcher. A password protected Access® (Microsoft, California, 1997) database was used for storage of data and the management of multiple data entries. Data was transferred to Excel® (Microsoft, California, 1997) for analysis. Monthly visual checks of the database for data entry inaccuracies were made. Examples of errors were birth dates in 2003 and discharge dates before admission dates. These errors were corrected by systematically filtering the data in Excel® format before data analysis by searching each column for data which was outside of a predetermined range.

3.8 Sample size

Sample size estimates for this project were based on the findings of previously published research (Brook, et al., 1999). A significant mean difference of 35 hours (1.45 days, p=0.003) between groups was detected in duration of ventilation, in the Brook, et al. (1999) study. Given that the Royal North Shore Hospital ICU is a general adult ICU similar to the ICU used in the Brook, et al. (1999) study a similar magnitude of benefit in decreased duration of ventilation, that is 1.4 days and a standard deviation of 4.5 days, could be expected. The sample size calculation of 163 patients in each group was based on 80% power to detect a difference in the duration of mechanical ventilation between groups of 1.4 days. Statistical significance was defined as a two-tailed p value less than 0.05.

3.9 Data Analysis

Baseline characteristics

Sample characteristics were identified to describe the sample. Equivalence of the two groups (preintervention phase and postintervention phase) baseline characteristics was tested using t test for interval data that is, age and APACHE II, and Chi-square tests for categorical data, that is APACHE III ANZICS modified diagnostic code and gender.

Primary aim

The primary aim of the project was to investigate the effect of a sedation guideline on the duration of ventilation in ICU patients. The aim was tested by comparing the duration of ventilation of the preintervention group with the postintervention group. The distribution of duration of ventilation was assessed for normality using frequency plots. The data were found to be non-normally distributed with a positive skew. Therefore the data was logarithmically transformed in base 10. A student's t test was performed for unrelated groups on the normally distributed transformed data.

Secondary aims

The secondary aim of the project was to investigate if there was any difference in the intensive care experience reflected by the ETIC-7 scores between the preintervention group and the postintervention groups. The distribution of ETIC-7 scores was assessed for normality using frequency plots. The data were non-normally

distributed with many extreme low values and unsuitable for transformation. Therefore the non-parametric test, Mann Whitney U, was employed. Content analysis was performed for the responses to the open ended question at the end of the ETIC-7,'Would you like to add any comments?'.

Further aims of the project were to investigate the effect of the introduction of an algorithm based sedation guideline on length of ICU stay, number of tracheostomies, number of unscheduled self-extubations and number of reintubations. A comparison of the length of stay between the preintervention group and the postintervention group was performed. The frequency plot for length of ICU stay was non-normally distributed with a positive skew and therefore data were logarithmically transformed in base 10. A student's *t* test for unrelated data was performed. The Chi square test was used to compare the number of tracheostomies between the two groups. The cost of sedative and analgesic medications were examined retrospectively but not subjected to inferential statistics. Adoption data were summarised and described but not subjected to data analysis. Prevalence data violates many of the assumptions required for formal inferential statistics and therefore was interpreted as the trends of adoption.

3.10 Ethical considerations

Ethics approval was granted by the Human Research Ethics Committees (HREC) of the Royal North Shore Hospital and the University of Technology, Sydney. The main ethical considerations were privacy and confidentiality, access to information and potential distress from answering questions contained in the ETIC-7.

The HRECs waived the requirement for written informed consent because the patients were receiving a standardised version of the usual sedation practices, and more specifically there was no change in the usual medication regimen, that is an opioid medication for pain relief and a benzodiazepine type drug for reducing anxiety. Verbal informed consent was obtained before collecting the ETIC-7.

The follow-up interview was conducted at the conclusion of the usual follow-up telephone call in a quiet private office away from other patients and members of the public. Confidentiality was maintained for all of the patients' data. The data collection

sheets were coded and stored in a locked filing cabinet in an office only accessible to healthcare professionals. The main project database was password protected.

The ETIC-7 was collected at the conclusion of the follow-up telephone call. Patients were invited to participate and given the option to decline again when the ETIC-7 was complete. No patients became distressed during the collection of the ETIC-7, however existing strategies to support any patient who became distressed during the follow-up call would have been used should this have occurred.

Chapter Four - Results-Clinical Outcomes

4.1 Introduction

This chapter describes the characteristics of the sample. The two groups are compared at admission for gender, age, diagnosis and the instigation of mechanical ventilation prior to admission to the study intensive care unit (ICU). Differences between groups for mortality are also explored. The results of a two sample t-test for unrelated data on the primary study outcome, duration of mechanical ventilation are presented. The results of a Mann Whitney U test for the secondary outcome, the Experience after Treatment in ICU-7 (ETIC-7) data are described. Content analysis was used to explore the comments provided by patients on completion of the ETIC-7. The themes, which emerged from these comments, are described. The results of a two sample t-test for unrelated data on the secondary outcome, length of stay in ICU are presented. Differences between the groups are compared for number of tracheostomies using Chi square tests. Raw data for the number of reintubations and self-extubations in each group are presented. Finally the average monthly costs for intravenous sedative and analgesic medications used for the two phases of the study are compared.

4.2 Sample characteristics

There were more men (58%) than women in the sample (42%) and the mean age of the patients was 61.1 years (range 19.7 to 91.8 years). The mean Acute Physiology and Chronic Health Evaluation score II (APACHE II) score was 21.8 points (range 3 to 45 points). Nineteen percent of patients were admitted post operatively and 81% were admitted for other non operative medical diagnoses. Mechanical ventilation was instigated for 225 (70%) patients prior to admission to the study ICU. There was a 22% mortality rate.

4.3 Comparison of groups

A total of 322 patients who required mechanical ventilation were included in the analysis. The preintervention group contained 159 and the postintervention group 163. The groups were equivalent on all characteristics (Tables 2 and 3).

Table 2

Group characteristics

Characteristic	Preintervention (n=159)	Postintervention (n=163)	*p*
Number of males (%)	93 (58.5)	94 (57.5)	0.88*
Age in years			
mean	60.2	62.0	0.35†
standard deviation	18.3	16.9	
range	21.2 - 91.7	19.7 - 91.8	
Diagnosis, number of patients (%)			
operative	29 (18.2)	32 (19.6)	0.76*
non-operative	130 (81.8)	131 (80.4)	
Instigation of mechanical ventilation prior to admission to study ICU (%)	114 (71.7)	111 (68.1)	0.48*
APACHE II score			
mean	21.6	21.9	0.67†
standard deviation	7.9	7.7	
range	3 - 45	4 - 42	
Number of deaths (%)	30 (18.9)	40 (24.5)	0.22*

* Chi-square, † t-test

Table 3

APACHE III diagnostic code group comparisons

Characteristic	Preintervention (n=159)	Postintervention (n=163)	*p*
APACHE III diagnostic code			0.06*
Respiratory (%)	33 (21)	45 (28)	
Cardiac (%)	35 (22)	42 (26)	
Gastrointestinal (%)	21 (13)	21 (13)	
Neurological (%)	9 (6)	0 (0)	
Sepsis (%)	34 (21)	31 (19)	
Trauma (%)	14 (9)	15 (9)	
Other (%)	13 (8)	9 (5)	

*Chi-square

4.4 The effect of the intervention on the duration of mechanical ventilation

Duration of ventilation data was logarithmically transformed in base 10 as the distribution was positively skewed and was representative of a normal logarithmic distribution. The logarithmic transformed data represented a normal distribution. Therefore a t test for unrelated data was performed. Duration of ventilation was longer in the postintervention group and this was statistically significant (Table 4).

Table 4

The effect of the intervention on duration of mechanical ventilation (days)

	Preintervention (n=159)	Postintervention (n=163)	Difference (days)	*p*
median	4.80	5.64	0.84	
interquartile range	1.85 - 7.02	2.69 - 7.71		
range	0.1 - 180.7	0.2 - 57.1		
mean (±SD), antilogarithm	4.33 (± 2.97)	5.64 (±2.61)	1.31	0.02*
95% confidence intervals (antilogarithm)	3.66 - 5.14	4.86 - 6.54		

* t-test

4.5 The effect of the intervention on the Experience after Treatment in ICU-7 (ETIC-7) score

Three attempts were made to reach the former ICU patients by telephone when they returned home and this resulted in 60 of 159 patients in the preintervention group and 58 of 163 patients in the postintervention group (approximately 35% of the sample) completing the ETIC-7 tool. Refusals were rare (two per group); the primary reason for not obtaining patient response to the ETIC-7 was failure to make contact during the three telephone calls.

There are four possible responses to each ETIC-7 item on a likert scale from 'Not at all' (score of zero) to 'Often' (score of three). An open-ended question at the end of the scale 'Do you have any comments that you would like to add?' is included. Internal reliability of the seven ETIC-7 items was tested using Cronbach's alpha. The internal reliability was high and revealed a Cronbach's alpha of 0.81

The distribution for the raw ETIC-7 scores was non-normal and the high frequency of extreme low values did not allow logarithmic transformation. Therefore the non-parametric Mann Whitney U test was used to analyse the effect of the intervention on ETIC-7 score. There was no significant difference between groups in ETIC-7 scores (Table 5).

Table 5

The effect of the intervention on the Experience after Treatment in ICU-7 (ETIC-7) score

	Preintervention (n=60)	Postintervention (n=58)	*z* score	*p*
median	0	0	-0.65	0.52*
interquartile range	0 - 3.5	0 - 3.5		
range	0 - 16	0 - 18		
mode	0	0		

* Mann-Whitney U

Twenty-five out of 60 patients in the preintervention group and 14 patients out of 58 patients in postintervention group responded specifically to the open ended question on the ETIC-7 tool ‘Would you like to add any other comments?’. Data were examined using content analysis and the main points are summarised in Table 6. In summary, many spontaneously commented on their inability to remember ICU and several patients who had unreal memories commented with bemused acceptance. Some patients who had higher ETIC-7 scores recounted more bothersome memories than patients who did not comment.

Table 6

Content analysis for the open ended question, 'Would you like to add any comments?'(ETIC-7)

Content	Preintervention (n=25)	Postintervention (n=14)
Bad images and blamed medication*	3 (pt 6 = 0, pt 104 = 0, pt 151 = 0)†	0
Cannot remember ICU	5	4
Deluded and bemused	7	2
Bad images and bothered*	4 (pt 85 = 5, pt 89 = 16, pt 101 = 2, pt 116 = 6)†	5 (pt 291= 0, pt 257 = 18, pt 243 = 3, pt 239 = 7, pt 227 = 1)†
Reassuring images	3	1
Religious memories	0	1
Feel lonely at home now	2	0
Guilt for what the family went through	0	1
Distressed by hospital	1	0

*Included paranoid thoughts and perceptions of persecution
†Patient ETIC-7 scores provided

4.6 The effect of the intervention on length of ICU stay

The distribution for length of stay data was positively skewed and represented a normal logarithmic distribution. Therefore a logarithmic transformation in base 10 was performed on all data and a t test for unrelated data was performed. There was no statistically significant difference in length of stay between the groups (Table 7).

Table 7

The effect of the intervention on length of ICU stay (days)

	Preintervention (n=159)	Postintervention (n=163)	Difference	p
median	7.2	7.2	0	
interquartile range	4.14 - 11.49	4.15 - 13.78		
range	0.33 - 189.88	1.22 - 70.69		
mean (antilogarithm)	6.80 (±2.44)	7.96 (±2.35)	1.16	0.11*
95% confidence intervals (antilogarithm)	5.91 - 7.82	6.98 - 9.09		

* t-test

4.7 The effect of the intervention on the number of tracheostomies

Chi square test was performed to analyse the effect of the intervention on the number of tracheostomies performed while the patients were cared for in the study ICU. Although there was a trend of an increase (5.2%) in the number of tracheostomies in the postintervention phase, this was not statistically significant (Table 8).

4.8 The effect of the intervention on the number of reintubations and unscheduled self-extubations

Raw data for the number of reintubations and self-extubations in each group are also presented (Table 8). As numbers in each group were small, a statistical test was not performed to compare groups.

Table 8

The effect of the intervention on the number of tracheostomies, reintubations and unscheduled self-extubations in each group

	Preintervention (n=159)	Postintervention (n=163)	χ^2 statistic	*p*
Number of patients with a tracheostomy (%)	21 (13.2)	30 (18.4)	1.63	0.20
Number of reintubations (%)	7 (4.4)	6 (3.6)		
Number of self-extubations (%)	2 (1.3)	2 (1.2)		

4.9 The incidental effect of the intervention on the cost of intravenous sedative and analgesic medications

The hospital pharmacy routinely records costs for all medications in a specific database. The database was inspected retrospectively to examine the incidental effect of the intervention on costs of the most commonly administered intravenous sedative and analgesic medications including, propofol, midazolam, fentanyl and morphine. The data includes information for all medications administered to all patients regardless of whether they were eligible for the sedation guideline. The medication costs presented here include medications which were given for sedation and to facilitate anaesthesia for procedures in the study ICU. Overall costs for intravenous sedative and analgesic medications slightly increased in the postintervention (Table 9).

Table 9

The costs for intravenous sedative and analgesic medications during the preintervention and postintervention phases of the study (Australian dollars)

	Preintervention (A$)	Postintervention (A$)
Propofol	82,822	58,965
Fentanyl	30,644	50,786
Midazolam	80,626	97,967
Morphine	31,477	36,729
Total cost	225,569	244,447
Cost per month	17,351	18,803

4.10 Summary of main findings

The preintervention and postintervention groups in this study were similar in all characteristics. The intervention used in this study resulted in a significant increase in the duration of mechanical ventilation. There was no significant difference in ETIC-7 scores between the groups. Length of ICU stay between groups was not different. There was no difference in the number of tracheostomies between groups and the number of reintubations in the groups was similar. Overall cost for intravenous analgesic and sedative medications increased slightly in the postintervention phase.

Chapter Five - Results-Guideline Adoption

5.1 Introduction

Data on the adoption of the use of the Ramsay Sedation Scale were collected throughout the study. Data on the adoption of the sedation guideline were collected in the postintervention phase, that is, after its introduction. On a random day each month unknown to the clinicians a chart review of all patients admitted to the intensive care unit was performed. The adoption data reported in this chapter pertains to a chart review of 71 patients in the preintervention phase of the study during a nine-month (November 2002 to September 2003) period and a chart review of 95 patients in the postintervention phase during a nine-month (November 2003 to September 2004).

5.2 The adoption of the Ramsay Sedation Scale in the preintervention phase

The Ramsay Scale was introduced to assess the level of sedation. It was introduced prior to the preintervention phase with three aims, the first of which was to allow clinicians to become familiar with using it. The second aim was to obtain rates of adoption that might be contrasted to rates of adoption after the introduction of the sedation guideline. The third aim was to enable a comparison to be made between the patients' sedation level prior to the implementation of the sedation guideline and the patients' sedation level after the implementation of the sedation guideline. The Ramsay Score was rarely documented in the early stages of the preintervention phase. There were a total of 114 recordings of Ramsay Score out of a possible 426 (six scores each on 71 patients' charts). The percentage of patients' charts with at least one score recorded remained low through the preintervention phase (Figure 3). During month three, 70% of charts had one or more Ramsay Scores recorded. Month four was the lowest recorded month, with only 30% of charts containing one or more Ramsay Scores. The adoption data categories reflect these trends. The most frequent category from the chart review during the preintervention phase was 'Non-adoption – no reason' (NANR) (Figure 4). The median Ramsay Score during this phase was three and the mode was two (Figure 5).

5.3 The adoption of the Ramsay Sedation Scale in the postintervention phase

In the postintervention phase the Ramsay Score appeared to be recorded more consistently. There were 335 recordings out of a possible 570 opportunities to record the Ramsay Score (six scores each for 95 patients' charts). The percentage of charts

with at least one Ramsay Score recorded remained high through the postintervention phase (Figure 3). One hundred percent of the charts had one or more Ramsay Scores recorded in month three whereas in month one only 50% of charts had one or more Ramsay Scores recorded. The adoption categories recorded during this phase support this data. The majority of charts reviewed suggest that there was a high rate (50%) of 'Perfect adoption' (PA) (Figure 4). The median Ramsay Score during this phase was three and the mode was three (Figure 5).

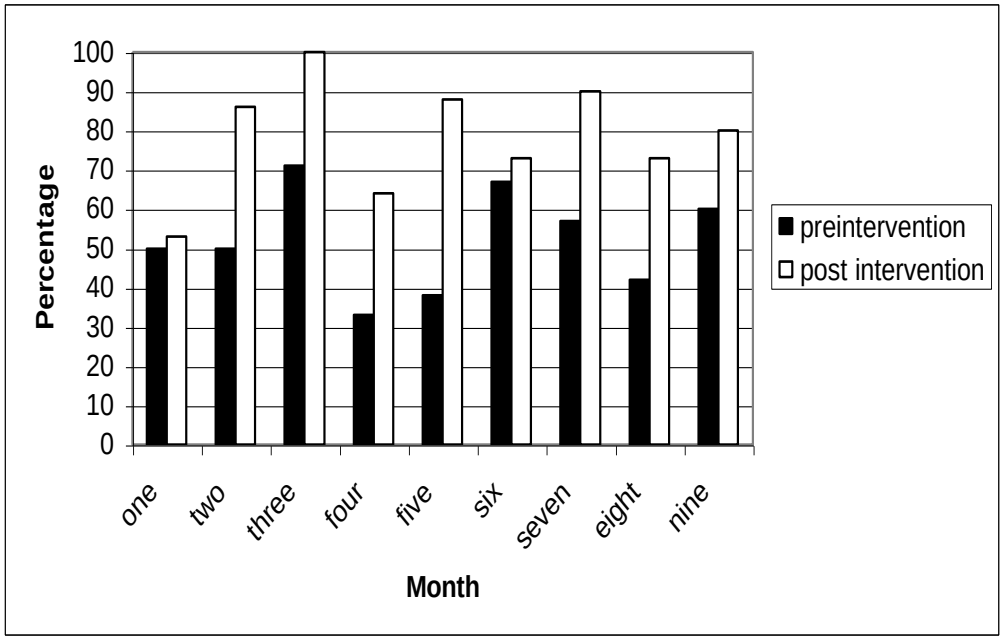

Figure 3. ***The percentage of charts with one or more Ramsay Score recordings in the previous 24 hours***

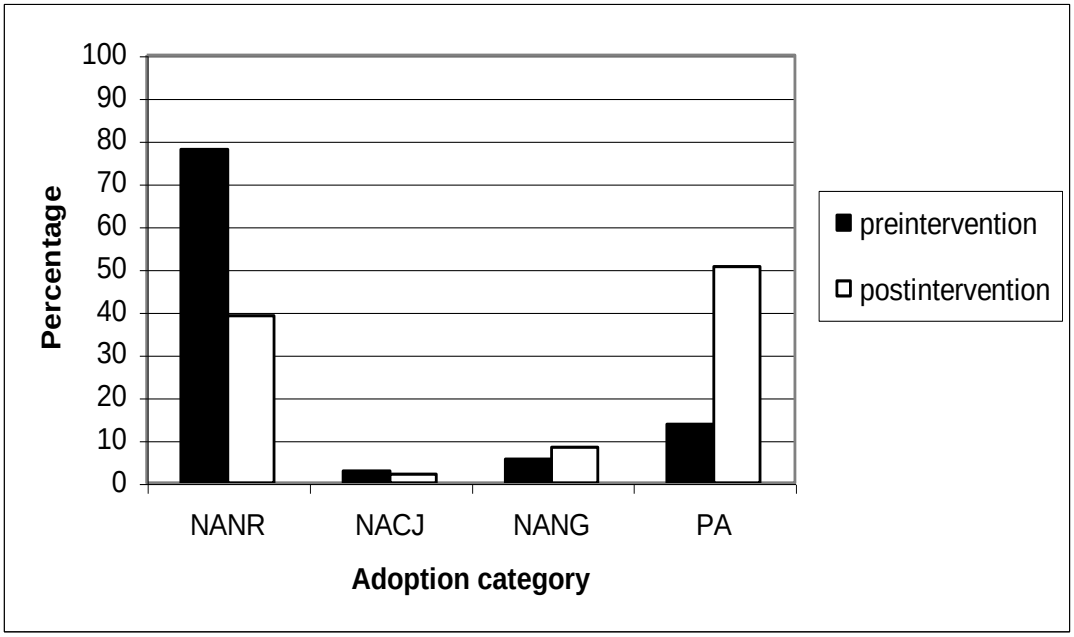

Figure 4. ***The percentage of patients' charts by adoption category for Ramsay scale*** (Key: NANR: non-adoption – no reason; NACJ: non-adoption – clinical judgement; NANG: non-adoption – not for guideline; PA: perfect adoption)

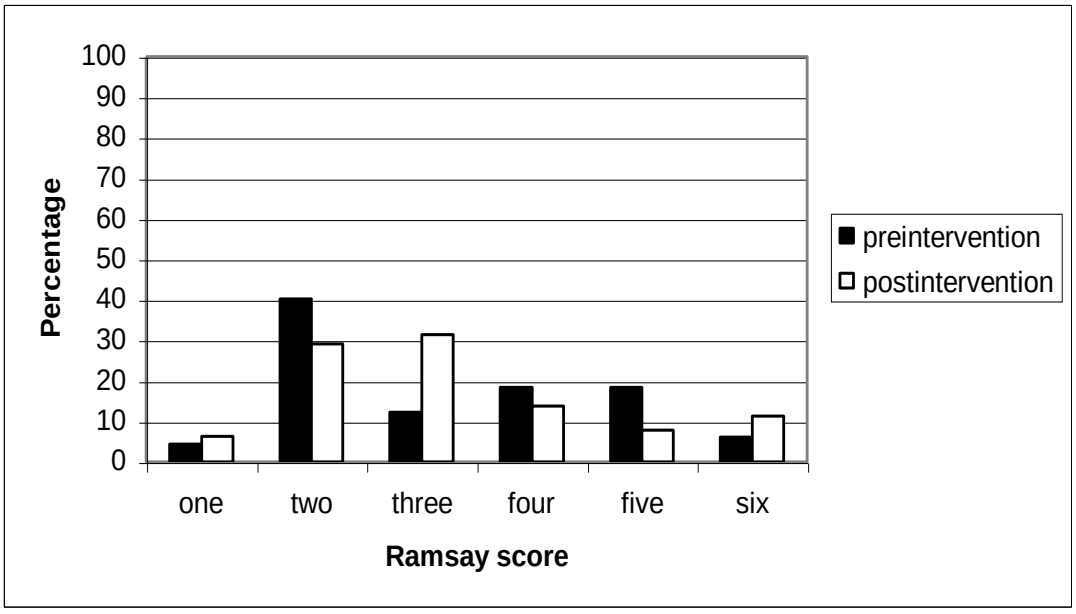

Figure 5. ***The percentage of patients' charts by Ramsay Score***

5.4 The adoption of the sedation guideline

Ninety-five patients' charts were reviewed for adoption of the sedation guideline in the post intervention phase. The review revealed two main adoption categories, 'Non-adoption - not for guideline' and 'Perfect adoption' (Figure 6). The percentage of patients' charts placed in the 'Non-adoption - no reason' fluctuated through the study period (Figure 7). The highest percentage was detected in month nine.

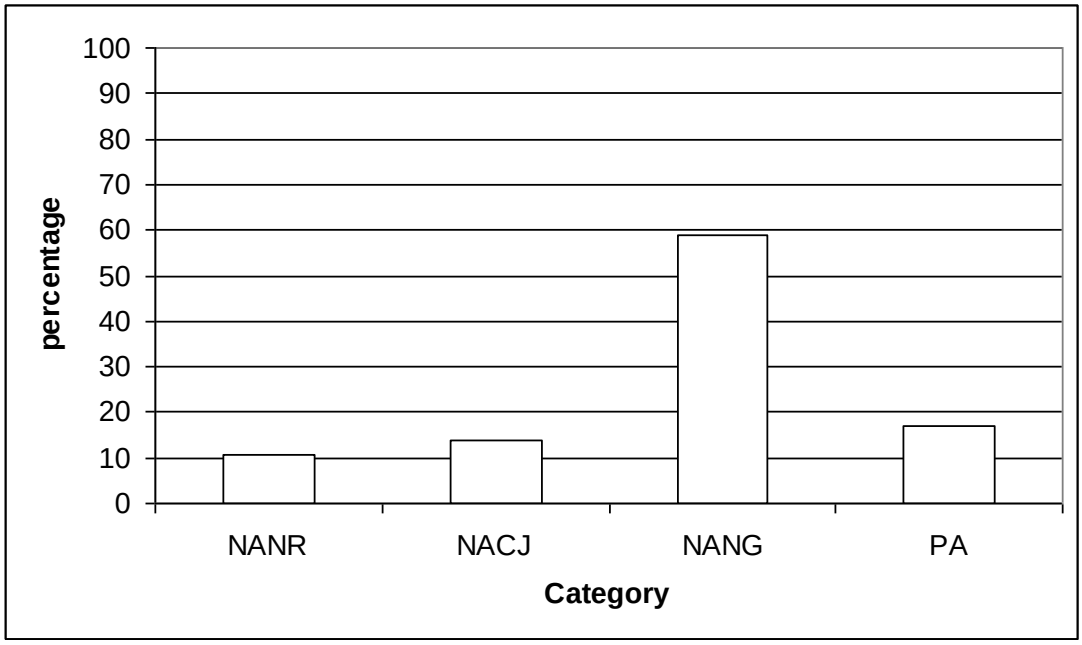

Figure 6. ***The postintervention phase percentage of adoption category for sedation guideline***
(Key: NANR: non-adoption – no reason; NACJ: non-adoption – clinical judgement; NANG: non-adoption – not for guideline; PA: perfect adoption)

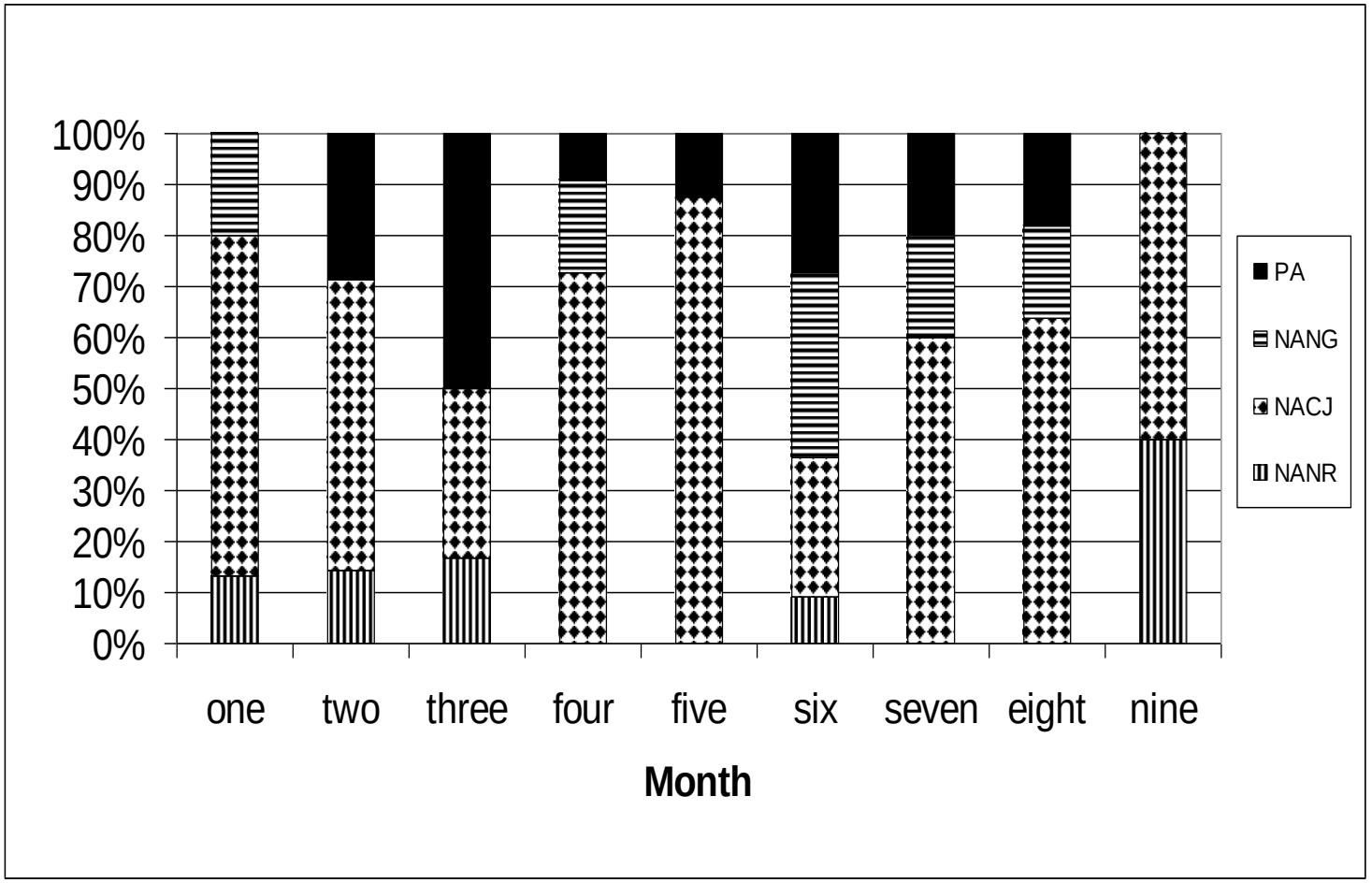

Figure 7. ***The percentage adoption category for the sedation guideline by month***
(Key: NANR: non-adoption – no reason; NACJ: non-adoption – clinical judgement; NANG: non-adoption – not for guideline; PA: perfect adoption)

5.5 Summary of main findings

Adoption rates for the Ramsay Sedation Scale were low in the early stages of the preintervention phase. The median Ramsay Sedation Score was two and the mode was three during the preintervention phase. The Ramsay Sedation Score was recorded more frequently in the postintervention phase. High rates of adoption reflected by frequent recordings were evident throughout this phase. The median Ramsay Score was three and the mode was three during the postintervention phase. Adoption of the sedation guideline fluctuated during the postintervention phase. The main adoption categories were ‘Non-adoption - not for guideline’ and ‘Perfect adoption’.

Chapter Six - Discussion

6.1 Summary of major findings

This study investigated the effect of an intervention, the algorithm based sedation guideline previously shown to be beneficial in the Brook, et al. (1999) study, on duration of mechanical ventilation in intensive care patients in an Australian intensive care unit (ICU). The intervention was expected to reduce the mean duration of ventilation in the group that received the sedation guideline. The sample size was calculated at 80% power to detect a mean difference in mechanical ventilation between groups of 1.4 days. The primary outcome data for duration of ventilation and data for the secondary outcomes including length of ICU stay, number of tracheostomies, reintubations and self-extubations were collected while the patients were in the study ICU. The Experience after Treatment in Intensive Care-7 (ETIC-7) was collected from 35% of the patients in each group approximately two months after the patients had returned home during a follow-up telephone conversation. Costs related to the use of intravenous sedative and analgesic medications during the study were also examined retrospectively using the hospital's pharmacy department database. Data concerning the adoption of the Ramsay sedation scale and the sedation guideline were collected from patient charts on random days during the study, together with the recorded sedation level.

The intervention resulted in a statistically significant increase in the duration of mechanical ventilation. The median difference between groups was 0.82 days (i.e. 19 hours, 41 minutes) and the mean difference was 1.31 days (i.e. 31 hours 26 minutes) (p= 0.02). The clinical significance of this result must be carefully considered, as there was no significant effect on the secondary outcomes including ETIC-7 and number of tracheostomies and self-extubations. While there was a trend towards a longer mean length of ICU stay of more than a day this was not statistically significant and the median lengths of ICU stay were identical. The costs of intravenous sedative and analgesic medications increased slightly in the postintervention phase.

Adoption of the Ramsay sedation scale was apparently low in the preintervention phase but increased in the postintervention phase. The median level of sedation in the preintervention phase was three and the mode was two. In the postintervention phase the most frequently recorded Ramsay score was higher, with

both the median and the mode being three. It appears that patients were more heavily sedated when the guideline was being used in the postintervention phase (which was the instruction included in the guideline). Guideline adoption increased through the postintervention phase and audit data reflected that clinicians were routinely using it.

This study highlights the importance of critically appraising and adapting guidelines before local use. The uncritical adoption of guidelines and clinical practices, which have been found to be beneficial in single centre studies, particularly in other countries with different intensive care structures and practices, may not result in better patient outcomes in other settings and may be inappropriate.

6.2 Clinical outcomes

The duration of mechanical ventilation

There was a statistically significant increase in duration of mechanical ventilation in the postintervention group. Despite this the clinical significance of the increase in duration ventilation is questionable. Other outcomes were unchanged and there were no increases in adverse events which may have been attributable to the change in sedation delivery practices, for example unscheduled self-extubations and mortality.

The characteristics of the preintervention and postintervention group were equivalent and there were no obvious changes in clinical practice other than the sedation guideline during the study. Although recruitment took two months longer in the postintervention phase the season in which data collection took place for each phase was similar. The preintervention data collection phase was conducted between November 2002 to September 2003 and the postintervention phase was conducted between November 2003 to September 2004. There was a positive change in the study ICU nurse staffing levels, from up to 12 vacant Full Time Equivalents in the preintervention phase to zero vacancies in the postintervention phase. The presence of permanently employed nurses reduces variability and increases the likelihood of the guideline being used. These factors suggest that the intervention was most likely to be responsible for the increase in duration of mechanical ventilation. Further confirmation that the intervention was likely to be responsible for the change in duration of ventilation was that the mode of the Ramsay score was higher in the postintervention

group. This indicates that patients were kept at a slightly deeper level of sedation, according to the guideline, in the postintervention phase and may account for the slight increase in duration of ventilation.

The median increase of 0.84 days (19 hours 19 minutes) and mean increase of 1.31 days (31 hours 26 minutes) in duration of ventilation revealed in this study contrasts with the results reported in studies from countries other than Australia. Significant decreases in the duration of ventilation have been reported previously as a result of the use of sedation guidelines (Brook, et al., 1999; Mascia, et al., 2000; De Jonghe, et al., 2005). In the randomised controlled trial performed by Brook, et al. (1999) there was a reported median reduction of 2.5 days (61 hours) in the intervention group. Similarly, the quality improvement study performed by Brattebø, et al. (2002) found a mean reduction in duration of ventilation of 2.1 days (50 hours). De Jonghe, et al. (2005) reported a remarkable reduction in median duration of ventilation of 5.9 days (141.6 hours). Likewise two quality improvement projects revealed a reduction in mean duration of ventilation of 6.25 days (150 hours) and 2.2 days (52.8 hours), although these studies were not powered to detect a statistically significant change in ventilation (Mascia, et al., 2000; Greiner & Greiner, 2004). An earlier quality improvement project was not powered to detect a change in ventilation and revealed no change in duration of ventilation (Devlin, et al., 1997). Recently a group from Melbourne, Australia investigated the effect of protocol directed sedation delivery on patient outcomes using the guideline previously found to be beneficial by Brook, et al. (1999) (Bucknall, Manias, Presneill, McEwen & Rose, 2004). The results of this RCT have yet to be published but they support the results of the study reported in this thesis. There was a trend towards an increase in duration of mechanical ventilation in the intervention group, although this was not statistically significant, that is 3.64 days (88 hours) in the intervention group versus 2.6 days (64 hours) in the control group (Bucknall, T, personal communication, 2005) (the comparatively short duration of ventilation was achieved because all ventilated patients were included). There were no differences for other clinical outcomes for example length of ICU stay, number of tracheostomies inserted and number of unscheduled extubations (Bucknall, T, personal communication, 2005).

There are a number of factors that may account for the increase in duration of ventilation in this study in contrast to others. A fundamental difference that must be highlighted is the difference in baseline values of duration of mechanical ventilation between this study and others. The duration of ventilation (median 4.80 days) for eligible patients in the preintervention phase in this study was shorter than the baseline duration of ventilation reported in other published studies referred to previously. The baseline median duration of ventilation ranged from 5.1days (124 hours) in the Brook, et al. (1999) study to a lengthy 13.2 days (317 hours) in the Mascia, et al. (2000) study. However it is unclear if Mascia, et al. (2000) studied a subgroup of ICU patients specifically with tracheostomy and a need for prolonged ventilation. Devlin, et al. (1997) reported a low baseline median value of 2.54 days (61 hours), but at least one third of the patients were admitted postoperatively. Similarly, the inclusion of postoperative patients was probably responsible for the low median value of 2.6 days (64 hours) for the control group in the Melbourne study (Bucknall, T, personal communication 2005). In summary it appears that the ICU in this study may have been achieving the standards desired from the guideline at the outset; improvements were difficult to achieve using a guideline developed for a context with different baseline practices and outcomes.

Another apparent difference in baseline sedative delivery practice that requires exploration is the baseline sedation level. Chart audits were performed during both phases and the documented Ramsay Scores were recorded for each patient cared for in the ICU on the random day of the month that the audit was conducted. These audits did not include all the patients in the study, nevertheless they provide an indication of practice at the time. The most frequently documented baseline (preintervention) Ramsay Score was two, which is indicative of a calm co-operative patient who is easily roused by voice. Usual sedation delivery practices in ICUs in other studies did not involve using a target sedation level or sedation scales, therefore sedation level was not recorded for the control groups (Brook, et al., 1999; Mascia, et al., 2000; Brattebø, et al., 2002; De Jonghe, et al., 2005; Devlin, et al., 1997). Therefore reported improvements in duration of mechanical ventilation in those studies may be partly attributable to lighter target levels of sedation, in the intervention groups compared to usual practice. However in the study described in this thesis the most frequently documented Ramsay Score in the postintervention phase was Ramsay Score three, which is indicative of a

patient who is slightly more deeply sedated than a patient who is sedated to a Ramsay Score of two, the preintervention sedation level.

Seasonal differences between the phases are potential confounders for a preintervention and postintervention ICU study. It is generally accepted that more severely ill patients are cared for in the ICU in winter and some times of the year are associated with increased presentation of certain traumatic injuries, such as spinal injuries in summer. This potential difference between groups would be identified using severity of illness scoring systems and diagnostic codes would identify differences between groups for the presenting illness or injury. However other seasonal factors such as increases in sick time for health care professionals during winter months could negatively impact on a preintervention and postintervention study by increasing the numbers of temporarily employed professionals who are often less familiar with specific local guidelines. There were no obvious seasonal differences in the times that data collection occurred between the phases in this study. Low numbers of permanently employed health care professionals could also adversely affect a preintervention and postintervention study. This was not a difficulty in the study, on the contrary, the number of vacancies for nurses decreased steadily to zero during the study.

The increased use of fentanyl in the postintervention phase, recorded in the hospital pharmacy database, is another potential factor, which could affect duration of ventilation and warrants consideration. Fentanyl is known to have a larger volume of distribution than morphine. When fentanyl is given continuously it accumulates in the body fat and is slowly released back into the circulation when the infusion is discontinued. This effectively results in the medication being available in the body for slightly longer than other opioid medications and may prolong the time for the patient to wake (Gehlbach & Kress, 2002). The doses of medication administered and time to wake up for each patient, for whom data were collected for this study, was not recorded. Therefore it is impossible to be certain if patients who received sedation in the postintervention phase took longer to wake or received more continuous infusions than patients in the preintervention phase. However registered nurses working in the study unit comply with the legal requirements of administering opioid medications and administer medication according to the medical officer's prescription, which was the sedation guideline in the postintervention phase. The first steps on the guideline require

non pharmaceutical interventions and thereafter bolus medications are suggested. In conclusion the most likely explanation for the increase in duration of ventilation was the deeper level of sedation stipulated in the guideline and not the use of fentanyl.

An objective of this study was to specifically investigate the effect of a sedation guideline, which was previously found to be beneficial in a North American ICU, in an Australian ICU. This study, along with a randomised controlled study recently conducted in Melbourne, Australia, further adds to the notion that patient outcomes in Australian tertiary centres appear to be comparable or better than in similar centres world wide (Fisher & Herkes, 1997). Guideline directed care may add little or no benefit in units which have high nurse to patient ratios, continuous intensive care medical specialist directed care, 24 hour onsite medical coverage and consensus about clinical practice amongst clinical leaders.

Secondary clinical outcomes

The Experience after Treatment in Intensive Care-7 (ETIC-7) score. The ETIC-7 was collected with the aim of obtaining a patient perspective of the use of the sedation guideline. Data for the ETIC-7 were obtained from 60 patients in the preintervention phase and from 58 in the postintervention phase. There was no difference in ETIC-7 scores between groups. The scores obtained from patients who responded to the questionnaire in this study are similar to those obtained during the development of the ETIC-7 (Scragg, et al., 2001). The scores ranged from zero to 18, the median score was two and the mode was zero (Scragg, et al., 2001). The interquartile ranges were not reported but the 75% quartile was approximately 4 (71% of patients scored 4 or less). More than 20% of patients scored more than eight. However the patients in the Scragg, et al. (2001) study were different to the patients in the study reported in this thesis. The patient group in the Scragg, et al. (2001) study was younger, not all the patients were ventilated and the numbers of ventilated patients were not reported. Younger patients were more likely to experience symptoms of post traumatic stress disorder (PTSD) (Scragg, et al., 2001) and it is rare for patients to receive sedative medication when they are not ventilated.

The lack of difference in ETIC-7 scores between groups in this study contrasts with the results of other studies, which examined the effect of sedation on psychological

outcomes. Pochard, et al. (1995) found that the presence of psychological distress was higher in former ICU patients who had been mechanically ventilated for longer and received sedative medication for longer. In addition Nelson, et al. (2000) reported a positive correlation between days of sedation and the occurrence of depressive and PTSD symptoms. However there was no difference between groups of patients who received low doses and high doses of sedative medications. Furthermore Kress, et al. (2003) reported that patients exposed to a daily wake up, when sedative medications were temporarily terminated, had better psychological adjustment to life after the ICU experience than patients who had not been subjected to this intervention while they were cared for in ICU. Despite the apparent difference between results obtained in this study and the studies described above, content analysis of open ended question included in the ETIC-7 reveals that patients who reported bothersome unpleasant memories scored the highest ETIC-7 scores, and patients who reported memories with bemused acceptance had lower scores. Few patients responded to the open ended question and responses in this study were predominately connected to memories of ICU. The small number of patients and wide variation in responses does not allow firm conclusions to be made about the significance of these results, however there appeared to be a trend towards psychological distress in patients whose ETIC-7 scores were highest. Scragg, et al. (2001) did not report the responses of the open ended question in the ETIC-7 'Would you like to add any comments?'.

The ETIC-7 has had limited reported use. It may not be sufficiently sensitive to detect differences in PTSD symptoms when there are only small increases in duration of ventilation and length of ICU stay. A larger sample size may be necessary to identify differences between groups. In the current study 60 patients responded to the ETIC-7 in the preintervention phase and 58 responded to it in the postintervention phase, about one third of all the study participants.

The length of stay in intensive care (ICU). The trend to a small increase in the length of stay was not statistically significant at the 5% level using a two-sided test. The mean difference between groups was 0.84 days and there was no difference in median length of stay between the groups. It therefore must be interpreted as random variation. Other studies have reported significantly shorter lengths of ICU stay (Brook, et al., 1999; Kress, et al., 2000; Mascia, et al., 2000; De Jonghe, et al., 2005). Brattebø, et al.

(2002) and Devlin, et al. (1997) also reported trends to shorter lengths of stay. However ICU length of stay is a problematic outcome to compare between ICUs, hospitals and countries where provision for high acuity patients and ICU discharge policies vary considerably. Some hospitals may be more conservative than others about the level of acuity of patients cared for in wards which provide less intense nursing and medical care. Patients may remain in ICU for longer in hospitals which have more conservative policies and procedures. In addition, some patients may remain in ICU longer if there are no beds available on the wards. As a result comparisons between organisations is problematic without prior knowledge of the particular organisation's ICU discharge policies and the demand for ICU beds. However comparisons made within the same organisation after the instigation of a change in practice are valid, supposing policies and patient activity levels remain the same throughout the duration of the study. Therefore as discharge and admission policies were unchanged during the study, the trend towards an increase in ICU stay in the study can be attributed to the intervention, the sedation guideline.

The number of tracheostomies. No statistical difference was found in the number of tracheostomies between the preintervention (13.2%) and postintervention (18.4%) groups. However the trend for 5% more tracheostomies in the postintervention group is of interest and may be explained by the longer duration of ventilation in that group. The difference in the rate of tracheostomies (13.2% versus 6.2 %) in the Brook, et al. (1999) study was statistically significant. Similarly De Jonghe, et al. (2005) showed a trend toward lower rates although this was not statistically significant. Brattebø, et al. (2002) and Devlin, et al. (1997) did not report tracheostomy rates.

The number of reintubations and unscheduled self-extubations. The number of reintubations and unscheduled self-extubations was similar in the preintervention and postintervention groups. Brook, et al. (1999) reported no difference between the intervention and control groups for reintubation; unscheduled self-extubation rates were not reported in that study. Brattebø, et al. (2002) used an existing anonymous incident reporting system database to examine adverse events during their quality improvement project. There were no increases in the number of critical incidents during the project. Rates of unscheduled self-extubations were similar in the intervention and postintervention groups in the De Jonghe, et al. (2005) study. Devlin, et al., (1997) and

Mascia, et al. (2000) did not report rates of reintubation or unscheduled self-extubations.

The baseline or control group rates of reintubation and unscheduled self-extubation compare favourably with the rates reported from other studies. The reintubation rate for the control group in the Brook, et al. (1999) study was 13.2%, which is much higher than the preintervention rate in this study (4.4%). The rate of unscheduled self-extubations in the preintervention group of the De Jonghe, et al. (2005) study was 7.4% which is considerably higher than the preintervention group rate of 1.3% in the study described in this thesis. Furthermore a European study reported a 10.8% rate of unscheduled self extubation (Boulain, 1998). The study was specifically designed to identify the rate and predisposing factors for unscheduled extubations. It was found that poor endotracheal tube fixation and lack of intravenous sedation were the major predictors for unscheduled extubations. The contrast in outcomes further reinforce the observation that the baseline outcome measures in the study described in this thesis appear to be better than those of ICUs in other health care systems. There may be limited room for improvement in the study setting by using sedation guidelines shown to make a difference to outcomes in those other systems.

Cost of intravenous sedative and analgesic medications. The medication costs, presented in chapter four, include the costs for medications administered to all patients cared for in the ICU irrespective of eligibility for the sedation guideline. The costs include medications used for sedation and to facilitate anaesthesia for procedures conducted in the ICU. No firm conclusions can be made about the effect of the sedation guideline on costs. However even though cost containment was not a primary aim of this study, it would have been neglectful not to examine changes in medication costs for the study ICU.

The total costs related to the administration of intravenous sedative and analgesic medications were not examined in this study. However the routes and equipment for administering medications were the same for both phases, so differences in the medication usage costs are reflective of overall medication costs related to the introduction of the sedation guideline. The overall cost of medications in the postintervention phase was slightly higher than in the preintervention phase. Since, the

most likely reason for the increase in duration of ventilation in the postintervention phase was the deeper sedation level, arguably the cost could be reduced by simply using a lighter target level of sedation.

The small differences in costs between phases in this study contrasts with other studies where significant cost savings were reported. Devlin, et al. (1997) reported a 60% reduction and Mascia, et al. (2000) reported a 75% reduction in medication costs. Other investigations reported reductions in the dose of medications or continuous infusions (De Jonghe, et al., 2005; Brook, et al., 1999). Brook, et al. (1999) translated the reduced length of ICU stay into cost savings which were considerable for the group of patients who received the sedation guideline (n=162). There was an estimated total cost saving of US$349,920 for the hospitalisation of patients in the intervention group.

The intervention used in the study described in this thesis directed clinicians to use the more expensive synthetic opioid, fentanyl, in the place of morphine but the relatively expensive short acting anaesthetic propofol was not included in the guideline. The total costs of propofol decreased indicating that the use of propofol reduced in the postintervention phase. Devlin, et al. (1997) attributed their cost savings to the fact that no patients in their postintervention group received propofol.

The intervention, the sedation guideline, resulted in an increase in the duration of ventilation but there was little difference in secondary outcomes. The existing baseline practices and outcomes in the study ICU were closer to those achieved using ‘best’ practice than achieved in the intervention groups and preintervention phases in other studies and therefore it was less likely that improvements could be achieved.

6.4 The adoption of the Ramsay sedation scale and the sedation guideline

Prior to the introduction of the sedation guideline, adoption of the Ramsay sedation scoring system was poor and the most common adoption category was ‘Non-adoption - no reason’ (NANR). After the introduction of the sedation guideline the most common category for the sedation scale was ‘Perfect adoption’ (PA). However the most common adoption categories for the sedation guideline were ‘Non-adoption - not for guideline’ (NANG) and PA.

The difference in numbers of patients' charts reviewed between the phases in the study is due to chance. There were a higher number of patients present in the ICU on the random days that data collection was performed in the postintervention phase. The charts of all patients in the unit on the relevant day were reviewed.

The audit of charts was selected as a relatively accurate method to measure adoption and to be able to provide clinicians with information about the progress of the adoption of the guideline. This labour intensive method was chosen in preference to a questionnaire survey to enable records to be made about actual use of the guideline, to avoid self-report of respondents' guideline use and to record actual sedation level in both phases. We planned to report rates of adoption from the outset because feedback loops are acknowledged as particularly powerful methods to positively influence clinicians (Davis & Taylor-Vaisey, 1997; Ockene & Zapka, 2000). Titler & Everett (2001), with much experience in practice improvement, are strong advocates of using feedback to not only influence clinicians but also to make minor adjustments to the implementation process. Adjustments were made to the frequency and extent of information sessions about the Ramsay sedation scoring scale and the guideline throughout the investigation on the basis of the adoption data collected in this study.

Adoption of the Ramsay Sedation Scale. Ramsay Scores were documented infrequently during the preintervention phase. Nurses were not informed of the reason for recording the score, although they were assured that changes were planned for the future. Although aware that nurses would be reluctant to document the score, I was keen to avoid changing sedation practices before the guideline was implemented. Thus there was no obvious advantage for clinicians to adopt the practice of recording the Ramsay Score in the preintervention phase. A fundamental requirement for successful adoption is for 'would be adopters' to perceive an advantage (or the hope that the innovation will be better than the status quo) in adopting an innovation (Rogers, 1995). This proposition is supported when the findings from the postintervention phase are reviewed. Adoption of the sedation score increased possibly because nurses saw the advantage of an objective measure of sedation level and the benefits of aiming for a predetermined target level of sedation that was agreed on by nursing and medical carers. In this phase, sedation scoring peaked at three months and was maintained throughout. The chart audits indicate that most patients in the postintervention phase were sedated to a

Ramsay Score of three. Audits performed in the preintervention phase indicate that most patients were sedated to a Ramsay Score of two, which is reflective of usual practices before the introduction of the guideline. This difference may account for the difference in the primary outcome, duration of ventilation.

Adoption of the sedation guideline. Interpretation of the sedation guideline adoption data is unsurprisingly difficult since operationalisation was complex. The two main concepts incorporated in the operational definition of the adoption of the guideline were the use of the Ramsay scale and use of the medications proposed in the guideline to achieve the suggested level of sedation. One other study investigating clinician perception of sedation guidelines used four aspects of sedation medication administration to measure actual physician adherence to the guidelines; route, dosage, choice of medication and frequency of administration (Slomka, et al., 2000).

Slomka, et al. (2000) used physician and nurse self-reports of guideline use along with actual physician adherence. The use of more than one measure of adoption may overcome some of the complexity of operationalising adoption. Additional observations made in the process of collecting and disseminating adoption data augment the numerical data in this study. For example the notes I took during the process of conducting the study reveal that the sedation guideline was accepted by medical officers and nurses and that there was a general willingness to adopt the principles underpinning it.

The low occurrence of the PA category may be explained by the presence of many patients who were ineligible for the guideline according to the instructions for use. Another reason for the low occurrence of the PA category is that clinicians were encouraged to individualise care while maintaining the principles of the guideline, that is to use clinical judgement to select the treatment to keep the patient comfortable, at a target Ramsay sedation level of three. The mode for Ramsay Scores in the postintervention phase was three, suggesting that clinicians were aware of these principles. Clinicians' decisions were always respected and clinicians were not coerced into using the guideline. While clinicians were informed of the benefits of the standardisation of care they were simultaneously advised that guidelines cannot guarantee 100% specificity and validity in all patient circumstances (Weingarten, 2000).

One hundred percent adoption was never the aim of the implementation strategy used in this study; the aim was to have patients optimally sedated to a specific level described as a Ramsay score of three.

The major adoption categories for the guideline were NANG and PA. It is particularly evident that during month six there were large numbers of patients who were not eligible for the guideline. This corresponds to a holiday period when the cardiothoracic recovery unit closed and patients who required emergency cardiac surgery were cared for in the general intensive care unit using the usual cardiac surgery clinical pathway. No attempt was made to change the care provided for this group of patients as the existing clinical pathway is considered to contribute to an excellent standard of care. At times in months seven and eight there were many patients in intensive care who were not receiving mechanical ventilation and therefore ineligible for the guideline.

It is conceivable that interpretation of the Ramsay Score changed from the preintervention phase to the postintervention phase. Nurses were fully aware that the target Ramsay Score was three in the postintervention phase. There is a subtle distinction between Ramsay Score of two, which describes a level of comfort where the patient is ‘co-operative, orientated and tranquil’, and a level of three conveying a level of comfort in which the patient is ‘responsive to commands’. The descriptor for the Ramsay Score of two requires observation of the patient’s behaviour, whereas arguably, the descriptor for Ramsay Score of three suggests that a stimulus must be used to elicit a response from the patient. Two explanations are possible; the nurses may have administered more sedation to achieve the sedation level of a Ramsay Score of three or alternatively they may have documented Ramsay Score of three even though the patient was in fact sedated to level two. However the notes I took during the process of conducting the study indicate that it is unlikely that nurses documented the Ramsay Score inaccurately. The most obvious explanation for the increase in duration of ventilation was a deeper sedation level.

An alternative interpretation for the relatively small PA category for Ramsay score in the postintervention phase may have been documentation omissions and nurses

may well have achieved a sedation level of three. Documentation omission constituted 'Non-adoption' in this study.

6.5 Strengths and weaknesses of the study

There are many strengths of this study, which warrant consideration. These include the: study design, sample size calculation, equivalence of groups and measurement of adoption data. Other strengths were the successful strategy used to implement the sedation guideline and retrospective consideration of the cost implications of the intervention.

The quasi-experimental preintervention and postintervention design contributed to the rigour of the study. The inclusion criteria used to select the patients resulted in group equivalence and reinforces the appropriateness of the choice of design for the context and subject of investigation. A randomised controlled trial was not used as contamination between patients was a concern and would have jeopardised the objectives of the study. The possibility of control group contamination has been acknowledged by others conducting sedation guideline trials (Brook, et al., 1999; De Jonghe, et al., 2005).

A sample size calculation was performed to enable a difference of 1.4 days duration of ventilation to be detected at 80% power. In fact a difference in mean duration of ventilation of 1.31 days was detected albeit in the opposite direction of the Brook, et al. (1999) study and the outcome hoped for in this study. Few quality improvement projects incorporate a sample size calculation. In fact inadequate power is a common limitation of many studies. During an investigation into the plastic surgery literature it has been reported that 85% of studies using continuous variables had inadequate power to detect the desired mean difference of one standard deviation (Chung, Kalliainen, Spilson, Walters & Kim, 2002). Chung, et al. (2002) reported that the power of studies using other variable categories was equally weak. The current study was sufficiently powered, strengthening the validity of the results obtained.

Arguably the design utilised in this study may address many of the weaknesses inherent in applying the randomised control trial design to test a multifaceted change in clinical practice. Unlike medication trials, investigations which involve the

implementation of changes in clinical practice including patient assessment and care, are at a higher risk of contamination. This is especially the case when models of nursing care include patient allocation, rather than primary nursing. Nurses are likely to care for different patients each shift when patient allocation is used. Different patients may be in different study groups and this may lead to contamination of the control group. Therefore the design used in this study offers an effective way of measuring practice development. Furthermore, when outcomes are combined with a full description of the study ICU and adoption rates, it enables clinicians to make informed decisions about the applicability of the practice to their own ICU.

This study utilised random prevalence surveys to measure actual use of the sedation scale and guideline. Adoption data which reflect actual CPG use are rarely collected. Most quality improvement investigations emphasise clinical outcomes to measure the entire process. Some investigations have used self reported use or awareness of CPGs to measure adoption (Hagemeister, et al., 2001; Pathman, et al., 1996). Slomka, et al. (2000) used nurse and physician interviews and actual physician adherence to the sedation guideline to assess clinicians perceptions of a sedation guideline. Adherence in Slomka, et al. (2000) study was measured using a chart review of four aspects of the medication administration: choice of medication, route, frequency and dose. There was a large discrepancy between the physician self-reports of adherence (69%) and their actual adherence (20%) (Slomka, et al., 2000). The simultaneous measurement of patient outcomes would have strengthened the Slomka, et al. (2000) study. It is difficult to attribute results entirely to changes in practice if the actual use of the practice is not measured, but equally changes in practice may not actually benefit patients. Therefore collection of adoption data in conjunction with the measurement of clinical outcomes has strengthened the reliability of the results in the study described in this thesis.

The adoption data in this study were used not only to measure sedation scale and guideline usage, they were also used to strengthen the implementation process and target areas for improvement. Feedback of patient outcome data is understood to be particularly influential for clinicians. However the definitive patient outcomes for this study were not expected to be available until nine months after the implementation of the guideline. Therefore adoption data were fed back to clinicians to inform and enhance awareness about the sedation scale and guideline. This, together with respectful

individualised approaches to information giving, resulted in a successful implementation strategy. I provided individual information sessions to over 80% of the nurses working in the study unit over a period of a month at the beginning of each phase of the study. Current clinical practice reveals that the use of the Ramsay Sedation Scale is firmly embedded in practice and suggests that the implementation of the scale was sustainable. Inclusive implementation activities such as these are understood to underpin successful sustainable practice improvement (Kitson, 2000; Kitson, Harvey & McCormack, 1998; Titler & Everett, 2001; Harvey, et al., 2002).

The study had several limitations that must be considered. Throughout the two study phases the limitations of the Ramsay scoring system were openly acknowledged with clinicians. These limitations are well recognised and common to many sedation scoring systems (De Jonghe, et al., 2000). For example the Ramsay scale is a scale which uses behavioural responses and therefore cannot be used to classify patients who are quietly disorientated and distressed. A difficulty of the Ramsay scoring system is that it incorporates three different constructs (conscious level, signs of agitation and suggestions of anxiety) in the same scale. The limitations of the Ramsay scale may have contributed to the poor adoption during the preintervention phase when nurses perceived no advantage in using it. However it was considered important to maintain the integrity of the Brook, et al. (1999) CPG as closely as possible to assess its applicability to a general ICU in Australia.

Other limitations of the study include the effect of my (R. Elliott) presence during the audit. My presence, particularly during the early stages of the postintervention phase, was incentive for bedside nurses to record the patient's Ramsay score. However this was also part of the implementation strategy.

Despite an extensive search of the health care literature few instruments or methods of measurement were located which would specifically address the secondary aim of this study; would the use of a sedation guideline improve the experience of recovery after ICU for mechanically ventilated patients? Other studies investigating recovery after ICU had specific aims such as functional status, quality of life and the detection of PTSD symptoms. For example Mascia, et al. (2000) used functional status at discharge from hospital to assess the patient impact of a change in sedation and

neuromuscular blocking agent delivery practices. Neuromuscular blocking agents have known adverse effects on muscular function. Physical function would not have been an appropriate measure for the current study as patients who received neuromuscular blocking agents did not meet the inclusion criteria. Likewise psychological instruments which are designed to detect depression or measure quality of life would not have specifically addressed the secondary aim.

The ETIC-7 was selected to assess the patient's perspective of the change in sedation delivery practices. The presence of post traumatic stress disorder symptoms has been used previously, as an outcome, to detect differences in psychological outcomes between different sedative and analgesic medication regimens administered in ICU (Nelson, et al., 2000). However the high number of extreme low values obtained from the patients in this study and the brevity of the ETIC-7 are reasons to continue to search for other instruments which might better address the secondary aim of this study. In the absence of more suitable instruments the ETIC-7 was selected for the low likelihood of it being burdensome for patients and the ease with which it could be completed by telephone.

Limited resources precluded collecting the types and doses of analgesic and sedative medications administered to patients who were eligible for the sedation guideline in this study. Not only would this information have provided definitive information about the extent and rate of adoption it would also provide information about the number of patients receiving continuous infusions which is known to prolong the duration of ventilation (Kollef, et al., 1998).

6.6 Implications for clinical practice

The clinical significance of the increase in duration of ventilation in this study was not large, however it warrants consideration. The length of stay and other secondary outcomes in the study unit were unchanged, although there was a trend to longer length of ICU stay. The preintervention (baseline) duration of ventilation and other clinical outcomes at the outset compare favourably with those of other health care systems. Furthermore if the guideline previously shown to be beneficial by Brook, et al. (1999) had been adapted for local use this may have eliminated the undesirable effect of deepening patients' sedation level. Improvements in clinical practice may not be

realised if existing local practices and outcomes are different to those where the guideline was originally developed.

The implementation strategy in this study was successful and supports the notion that approaches which are inclusive, individualised and respectful of clinicians result in high adoption rates for practice improvement activities. This intuitive way of encouraging adoption has an extensive literature using terms such as ‘academic detailing’ and espousing its virtues. It is therefore desirable to disseminate the strategy used in this study in uncomplicated terms to allow others to benefit from the insight gained.

The findings of this study contribute to the understanding of the implementation and adoption of CPGs and may assist others in similar endeavours. The results also reinforce the possibility that baseline practice may already approach the ideals of CPGs in the clinical practice settings in which they are to be applied. The application of CPGs, which have not been adapted or developed for local use may not achieve the same aims.

6.7 Future recommendations

Several areas requiring further investigation related to sedation delivery practices and the implementation of CPGs have emerged from this study. The study used a preintervention and postintervention quasi-experimental design, which utilised specific inclusion criteria, a sample size calculation and the measurement of adoption. The application of this design to other areas of practice may reveal other useful information about developing and measuring CPGs.

Further investigation is required to reveal other more accurate ways of operationalising adoption of complex innovations such as CPGs. The adoption of changes in clinical practice often incorporate subtle changes in the assessment, planning and implementation of patient care, which is complex to measure. A standardised method of measuring adoption might overcome some of these difficulties.

Evidence is gradually emerging about the suitability of some sedative medications over others, for example lorazepam is understood to be more suitable than midazolam for some patients because it does not produce active metabolites (McKenzie,

et al., 2005). However controversy persists about the relative benefits of propofol over midazolam (Magarey, 2000; Barrientos-Vega, et al., 1997; Chamorro, et al., 1996; Whitcomb, Huddleston, & McAndrews, 2003; Sherry, McNamara, Brown & Drummond, 1996; Ronan, Gallagher, George & Hamby, 1995; Cremer, et al., 2001). The suitability of a new α-2-receptor agonist, dexmedetomidine, for sedation and analgesia has shown promise for some selected ICU patient groups, however safety has not been confirmed for its sole use as a continuous longer-term infusion in the general ICU population (Shehabi, Ruettimann, Adamson, Innes & Ickeringill, 2004; Triltsch, et al., 2002). Large trials are required to establish the circumstances under which different patient groups may benefit from the use of alternative sedative agents.

Furthermore all future studies investigating the effect of sedation guidelines should include the collection of data regarding the use of continuous analgesic or sedative medication infusions and the doses and amounts of medications administered to patients. In addition, if there are different medication options included in the guideline, data should be collected to document the type of medication administered. This data would provide valuable information about the extent and rate of guideline adoption and allow further interpretations to be made about the possible reason for changes in outcomes.

In addition, the long-term effects of the depth of sedation and sedative medications requires investigation. A retrospective investigation of the effect of different analgesic and sedative medication regimens, in former ICU patients with acute lung injury, revealed a positive correlation between the length of time patients received sedative medications and the presence of depressive and PTSD symptoms at follow-up (Nelson, et al., 2000). There was no correlation with severity of illness and there were no differences in psychological outcomes between groups of patients who had received lower or higher doses of sedation. The variation in medication regimens that were administered to patients meant that firm conclusions about the relative benefit of one sedative or dose of sedative medication over another for preventing long-term negative psychological effects could not be made. Patients who were exposed to a daily ‘wake up’ intervention, in which the continuous sedative medication infusion was temporarily discontinued, had better psychological outcomes than patients who did not receive this intervention (Kress, et al., 2003). The majority of patients had some memory of their

ICU experience however none of the patients who received the intervention could remember being awake in ICU. Real memories of the ICU experience appear to improve psychological outcomes (Jones & Griffiths, 2000) however the exact level of sedation and sedative agents which reduce the likelihood of poor psychological outcomes is unknown. Further investigations are required, to investigate the most suitable sedative and analgesic medications and depth of sedation, to assist clinicians to make informed decisions about individual patients comfort needs.

The use of former ICU patients' recall of comfort levels while in ICU to inform practice is unwise. Many patients have inaccurate memories of the ICU experience and recall may be unreliable (van de Leur, et al., 2004). Other surrogate measures of the patients' perspective of comfort levels are therefore required to evaluate changes in practice. For example the Faces Anxiety Scale (McKinley, et al., 2004) was developed to assess anxiety levels in ICU patients. This scale is easily administered at the bedside and does not require patients to be able to verbally respond or write. This is preferable to retrospective exploration of comfort levels, as many former patients cannot recall their ICU experience. This subject requires further investigation.

The ETIC-7 was selected to identify any changes between the patients' perspective of their recovery prior to and after the change in sedation delivery practice. The validity of the ETIC-7 to detect psychological distress in Australian former ICU patients has not been investigated and therefore the ETIC-7 requires validation in the Australian ICU patient population. The results obtained from the study described in this thesis and the Scragg, et al., (2001) study could be used to enable a sample size calculation to be performed to enable group comparisons to be made for future investigations.

The problems associated with objectively measuring sedation level have been explored in previous chapters. Sedation scales have problems associated with the interpretation and subjective judgement of the patient's signs and behaviour that are necessary to assign the patient a score. To date electroencephalographic methods such as Bispectral monitoring present difficulties of artificially elevated readings caused by electromyographic interference and cortical activity unrelated to conscious state (Sleigh, 2004). There are also individual variations in the numerical values obtained at different

sedation levels for patients. Interpretation of the numerical value in relation to sedation level and each patient's sedation needs is complex. However the Vancouver Interaction and Calmness Scale (VICS) (de Lemos, Tweeddale, & Chittock, 2000) shows promise as a more valid measure of sedation level. Unlike other scales, which incorporate several constructs in the same scale or scoring system, the VICS incorporates two constructs in two different subscales: calmness and interaction. The VICS was reported to be reliable, valid and responsive during initial testing (de Lemos, et al., 2000). The VICS requires further investigation to confirm its validity in countries other than Canada, for example Australia.

Follow up research is warranted to investigate the effect of a locally developed guideline on the duration of mechanical ventilation in an Australian intensive care unit. A locally developed guideline would be an explicit statement of the goals and standards of the best existing practice in the unit, not of those in another unit. Arguably this would increase the probability of improving the status quo. In addition there would be an opportunity for local clinicians to be involved in the development, adoption and evaluation of the sedation guideline, the method espoused in most practice improvement models.

Although data are not available for the actual sedation level of patients in the Brook, et al. (1999) study it would be reasonable to assume that a Ramsay Score of three was lighter than the sedation level achieved in the control group. The patients in the preintervention phase of the study described in this thesis were more lightly sedated and therefore the most likely explanation for the increase in duration of ventilation was that patients in postintervention phase were more deeply sedated. The reason that a deeper level of sedation is used in the care of patients in the North American ICU may be the lower ratio of nurses to patients compared to Australian ICUs. The usual ratio of registered nurses to patients is 1:2 in many North American ICUs including the ICU in the Brook, et al. (1999) study (Ahrens, T, personal communication 2003). Arguably the improved clinical outcomes achieved by investing time and resources in the development of CPGs may be better used for recruiting and retaining registered nurses who are able to engage constantly with the patient, titrate sedative medications frequently and allow the patient to be kept at lighter levels of sedation. The benefits of employing high numbers of registered nurses has been espoused in the Magnet hospital

literature, however the specific interventions and decision making that registered nurses use to ensure patient safety requires further investigation to support the accepted advantage of the 1:1 ratio in Australian ICUs.

6.8 Summary of the interpretation of the results

This study was the first quasi-experimental preintervention and postintervention investigation of the effect of a sedation guideline on the duration of mechanical ventilation to be performed in an Australian intensive care unit. The design, sample size calculation and collection of adoption data contribute to the validity of the results.

The primary outcome, duration of mechanical ventilation, was longer in the intervention (postintervention) group in this study. This contrasts with results from other studies where large reductions in the duration of mechanical ventilation have been reported as a result of using sedation CPGs. However the duration of mechanical ventilation in the control (preintervention) group compared favourably with the duration of ventilation of control groups in all other studies. The most frequently recorded Ramsay Score during the preintervention phase was two and during the postintervention phase it was three. Since the groups were equivalent at baseline and no other ventilation or sedative delivery practices changed for the duration of the study, the most likely explanation for the longer duration of ventilation detected in the current study was that patients were more deeply sedated in the postintervention phase.

There was no difference in ETIC-7 scores between the groups. This contrasts with the results of other studies, which have used other psychometric instruments. However there was a trend towards higher ETIC-7 scores in both groups for patients who reported bothersome unpleasant memories.

There was a trend towards a longer length of ICU stay for the postintervention group, which contrasts with the results of other studies but reflects the longer duration of ventilation in this group. There was also a slight trend towards more tracheostomies in the postintervention group, which is also explained by the longer duration of ventilation in that group. The number of unscheduled self-extubations and reintubations was similar for the groups. There was a slight increase in the overall cost of intravenous analgesic and sedative medications in the postintervention phase.

The Ramsay sedation scale was not widely adopted in the preintervention phase. The likely explanation is that the bedside nurses did not perceive any advantage for recording the Ramsay Score. When the sedation guideline was introduced in the postintervention phase Ramsay scale adoption increased. The use of the Ramsay scale was an integral part of using the sedation guideline which stipulated a target sedation level of Ramsay Score three.

Chapter Seven-Conclusion

7.1 Introduction

This thesis reports the results of a preintervention and postintervention quasi-experimental study investigating the effect of an algorithm based sedation guideline on the duration of mechanical ventilation for intensive care patients. The intervention was expected to reduce the duration of mechanical ventilation. The patients' perspective of their recovery after the guideline was introduced was investigated using the Experience after Treatment in Intensive Care-7 (ETIC-7) item scale. Additional secondary outcomes included the length of stay in the intensive care unit (ICU), number of tracheostomies, number of unscheduled self-extubations and number of reintubations as these outcomes are known to be related to the quality of sedation delivery practice. The extent of the adoption of the sedation scale and guideline by clinicians was also examined.

As described in chapter two, the interventions and treatment ICU patients receive along with the intensive care environment present many potential sources of discomfort to the patient. The usual strategies used to provide comfort by health care professionals are not always sufficient. Therefore analgesic medications are administered to relieve pain and sedative medications are used to reduce anxiety and discomfort. While patients require sufficient amounts of these medications to provide comfort, judicious administration is required to avoid the complications of excessive use. Sedation scales are used in ICUs to assess and monitor sedation level. They are often incorporated into sedation guidelines. Sedation guidelines standardise sedation delivery practices and have been demonstrated to improve patient outcomes.

The Iowa Model of Research-Based Practice to Promote Quality Care (Titler, et al., 2001) was used as the theoretical framework for this practice improvement investigation. This model provided a logical framework on which to base this investigation. Rogers (1995) theory the 'Diffusion of Innovation' also informed the implementation and evaluation of the project.

The intervention, the algorithm based sedation guideline described in chapter three, was expected to reduce the duration of mechanical ventilation. The guideline was

implemented using various methods including individual information sessions, visual reminders and feedback of adoption rates.

7.2 Summary of findings

A preintervention and postintervention quasi-experimental design was used in this study of two groups of 159 and 163 patients. The sample was selected using inclusion criteria and convenience sampling was used until the required number of patients was achieved in each group. There was group equivalence in baseline characteristics including diagnosis and severity of illness. Patient outcome data such as duration of mechanical ventilation, length of ICU stay, and number of tracheostomies were collected while the patients were cared for in the ICU. The comparison of costs for the intravenous analgesic and sedative medications between the two phases was examined retrospectively using the hospital's pharmacy database. Adoption data were collected on a random day of the month on all patients cared for in the ICU on that day.

The duration of mechanical ventilation

The duration of ventilation was longer in the postintervention (intervention) group. The likely explanation for this was the deeper sedation level achieved for patients in the postintervention phase, as stipulated in the sedation guideline. The most frequent Ramsay sedation score recorded in the postintervention phase corresponded to a deeper level of sedation than the most frequently recorded sedation score recorded in the preintervention phase.

Secondary clinical outcomes

The ETIC-7 was collected at the conclusion of the follow-up telephone call, approximately two months after the patient was discharged from hospital. There were no differences in ETIC-7 scores between the groups. There was a trend towards a longer length of ICU stay and number of tracheostomies for patients in the postintervention group. However there were no differences in the number of unscheduled self-extubations or reintubations. There was a slight increase in overall costs for intravenous sedative and analgesic medications in the postintervention phase.

Adoption of the Ramsay sedation scale and the sedation guideline

Preintervention adoption was poor for the Ramsay sedation scale but this improved in the postintervention phase. The most frequent Ramsay sedation score recorded in the postintervention phase was three which corresponded to a deeper sedation level compared to the most frequently recorded sedation score in the preintervention phase which was two. Adoption of the sedation guideline improved throughout the postintervention phase. The implementation strategy resulted in the sustainable adoption of the Ramsay scale and the sedation guideline.

7.3 The contribution this thesis makes to nursing research and knowledge

In conclusion the material presented in this thesis contributes to the understanding of the effect of a sedation guideline in intensive care patients cared for in an Australian ICU. The results contribute to the understanding that clinical practice guidelines developed and measured in other health care contexts require adaptation for local use otherwise improvements in patient outcomes are unlikely. In addition evidence from this study indicates that guideline directed care may add little or no benefit in units which already achieve exemplary patient outcomes and where there is consensus about clinical practice amongst clinical leaders, which is the case for many Australian ICUs.

The multifaceted implementation strategy used to introduce both the Ramsay sedation scale and the sedation guideline was highly effective and has resulted in their long-term adoption. Individual information sessions comprised the major part of the implementation strategy. It is widely understood that clinicians respond positively to individual information sessions where they have the opportunity to discuss and understand the principles of the clinical practice guideline. Therefore the results of this study reinforce previous knowledge about the effectiveness of this strategy.

Finally the logical design of this study not only increases the validity of the results, it also offers an alternative to the RCT design for others conducting practice improvement projects. The design used in the current study, together with a sample size calculation and collection of adoption data overcomes many of the difficulties associated with investigating a multifaceted change in clinical practice using the RCT design. The adoption data collected in the current study contributed to the interpretation

and the reliability of the results. The approach contributes to the knowledge of conducting effective practice improvement investigations.

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APPENDIX A

Experience after Treatment in Intensive Care 7 Item Scale (ETIC –7) (Scragg, et al., 2001)
Patient study number:
DOB:

Please circle answer closest to the way you feel	Not at all	Rarely	Sometimes	Often
1. Have you had upsetting thoughts or images about your time in the Intensive Care Unit that came into your head when you didn't want them?	0	1	2	3
2. Have you experienced 'flashbacks', which make you feel, as if you are back in the Intensive Care Unit?	0	1	2	3
3. Have you felt upset when you were reminded of your stay in the Intensive Care Unit?	0	1	2	3
4. Have you had bad dreams or nightmares about your time in the Intensive Care Unit?	0	1	2	3
5. When reminded of your stay in the Intensive Care Unit, does it make you feel anxious or unwell (for example, heart racing or thumping, nausea, sweating)?	0	1	2	3
6. Have you tried not to think about, talk about, or have feelings about your time in the Intensive Care Unit?	0	1	2	3
7. Have you tried to avoid activities, people or places that remind you of the Intensive Care Unit (for example, doctors appointments, visiting hospital or television programs about hospitals)?	0	1	2	3

(Score guide: Minimum possible score, indicating no symptoms = 0, maximum score = 21)

Do you have any comments that **you** would like to add?

APPENDIX B

(Information provided at the bedside to enable nurses to assess the patient's sedation level using the Ramsay Sedation Scale)

The Ramsay Sedation Scale

Score	Descriptor
1	Anxious and /or agitated
2	Co-operative, orientated and tranquil
3	Responsive to commands
4	Asleep, responds briskly to light glabellar tap or loud auditory stimuli
5	Sluggish response to light glabellar tap or loud auditory stimuli
6	Unresponsive to stimuli

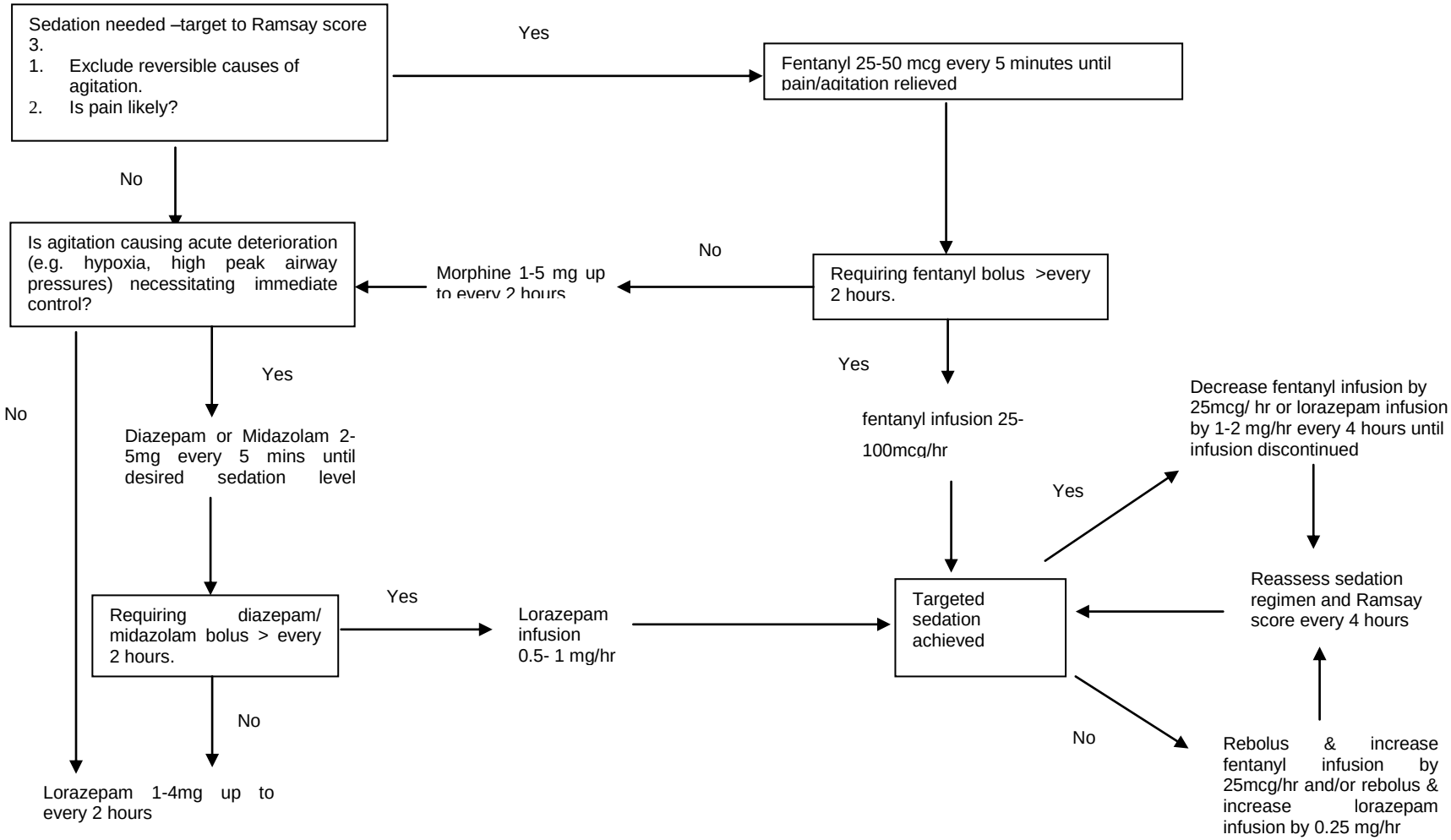
(Ramsay, et al., 1974)

Additional instructions when using the Ramsay Sedation Scale

- Ideally the patient's sedation level should be assessed every 1 –2 hours but once every 4 hours is an absolute minimum.
- At night if the patient appears to be sleeping do not disturb them. The sedation assessment can wait until the patient requires repositioning or some other intervention.
- Descriptors for scores 4 and 5 include the term 'Glabellar tap'. This describes the procedure of tapping the patient in the forehead between the eye brows. Alternative descriptors for these sedation scores are:
- Score of 4 = responds briskly to gentle shoulder shake
- Score of 5 = responds sluggishly to noxious stimuli

APPENDIX C

The sedation algorithm used in the study conducted by Brook, et al. (1999)



APPENDIX D

ICU Follow-up telephone call information (and verbal cues)

Name:
Hospital Number:
Telephone call date:

Introduce yourself. Establish what name to address them by. Explain briefly purpose of the clinic i.e. ' a forum to allow you to express any concerns and have questions answered'.

Document diagnosis, the event that led to admission to intensive care and the events in intensive care.

Admission date and brief diagnosis:

Circumstances since returning home: 'Perhaps we can start by briefly summarising how life has been for you since you left the hospital?'

'As I explained earlier the purpose of this follow-up telephone call is to resolve any concerns you may have had about being in intensive care and any concerns you believe may have risen as result of your serious illness. While preparing to operate this service we have made ourselves familiar with various studies. Some studies suggest that people who have been a patient in intensive care have certain concerns. I am going to ask your some questions that may apply to you.'

Mobility
'Do you think this episode of illness has affected your ability to get around? Y N (circle one)
Are there any particular aspects of your mobility that are concerns for you now?' Y N (circle one)
Some people say they have problems balancing after their illness. Has your sense of balance been affected?' Y N (circle)

'Have you had any rehabilitation since returning home?' Y …..N (Circle)

Sleep/ concentration
'Some people say they have problems sleeping when they get home after a spell in intensive care. Have you had any problems relaxing or sleeping? Y N (circle one)
Please can you describe the quality and quantity of your sleep. Is this different to the way you were before your intensive care admission?'. Y N (circle one)

'Similarly some people find difficulty concentrating when they have been seriously ill. Would you say this applies to you? Y N (circle one)
Please elaborate/explain.'

APPENDIX D

ICU Follow-up telephone call information (and verbal cues)

‘ A few studies indicate that some people who have been patients in intensive care have hearing difficulties. Does this apply to you, please elaborate?’ Y N (Circle)

Family/ relationships/ support

‘Some people say that their family circumstances change when they have been seriously unwell. For instance do you believe this has illness affected/changed your responsibilities or role in your home life?

Y N (circle one)

Alternatively do you find that you are more dependent or reliant on others?’ Y N (circle one)

‘Other people report difficulties in relating to their family and friends after being very ill. Would you say this applies you?’ Y N (circle one)

‘Can you identify any support mechanisms available to you in your everyday life? Do you believe these are sufficient to enable you to cope with your circumstances?’ Y N (circle one)

Occupation/work/financial

‘Prior to being admitted to intensive care were you in paid employment?’ Y N Retired (circle one).

‘Do you believe this admission has affected your ability to work? For instance have you been able to return to work?’ Y N (circle one)

‘Again research suggests that some people find their financial situation changed after a serious illness. Does this apply to you? ’ Y N (circle one)

APPENDIX D

ICU Follow-up telephone call information (and verbal cues)

‘If finances are a problem is there any assistance we could offer e.g. referral to social worker?’

Please comment on the level of care you received while in ICU was it:

unsatisfactory	**satisfactory**	**excellent**

‘Are there any other issues that you wish to discuss?’

'If yes would you like to make an appointment to see us here in the outpatients department?'
Y N (Circle)

Referral Record N.B. See referral information folder if applicable.
Referred Y N (Circle)
To whom and why? (**Comment below –important**)

APPENDIX E

Acute physiology and chronic health evaluation II (APACHE II)

BASELINE DATA DAY 1	APACHE II Severity of Disease Classification (refer to manual for notes on completion)	Hospital ID: Patients Initials: Patients Study ID:

A. ACUTE PHSIOLOGY SCORE (APS)	PHYSIOLOGIC VARIABLE	*High Abnormal Range*					*Low Abnormal Range*				APS Scores
		+4	+3	+2	+1	0	+1	+2	+3	+4	
	Temperature – rectal (°C)										
	Mean arterial pressure - mmHg										
	Heart rate (ventricular response)										
	Respiratory rate (non-ventilated or ventilated)										
	Oxygenation: A - aDO_2 or PaO_2 (mmHg) a. if FiO_2 > 0.5 record A –aDO_2										
	b. if FiO_2 < 0.5 record only PaO_2										
	Arterial pH										
	Serum sodium (mMol/L)										
	Serum potassium (mMol/L)										
	Serum creatinine (mg/100ml) (double point score for acute renal failure)										
	Haematocrit (%)										
	White blood count (total/mm^3) (in 1,000s)										
	Glasgow Coma Score (GCS) (Score = 15 minus actual GCS)										
	Serum HCO3 (venous – mMol/L) (Only use this if no ABGs available)										

B. AGE POINTS		
Assign points to age as follows:	Age (yrs)	Points
	< 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:	Points	DEFINITIONS: Organ insufficiency or immuno-compromised state must have been evident prior to this hospital admission and conform to the following criteria:	
		LIVER	Biopsy proven cirrhosis & documented portal hypertension (PH); episodes of upper GI bleeding due to pH or prior episodes of hepatic failure/encephalopathy/coma
a. for non-operative or emergency post-operative patients	5	RENAL	Receiving chronic dialysis
		CARDIOVASCULAR	New York Heart Association Class IV
b. for elective post-operative patients	2	RESPIRATORY	Chronic restrictive, obstructive or vascular disease resulting in severe exercise restriction (i.e. unable to climb stairs, perform household duties); or documented chronic hypoxia, hypercapnia, 2 polycythemia, severe pulmonary hypertension (>40mmHg)or respiratory dependency
		IMMUNOCOMPROMISED	Patient has received therapy that suppresses resistance to infection, e.g. immunosuppression, 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 – a sum of:	A. APS points =	B. Age points =	C. Chronic Health points =	Sum of A + B + C = (0-71)

APPENDIX F

Acute physiology and chronic health evaluation III (APACHE III)

ANZICS adapted APACHE III diagnostic codes (ANZICS, 2004)

Precipitating factors leading to admission to ICU. Mark one primary factor from the list below that precipitated the primary system failure/insufficiency and caused the patient's admission to ICU.

Non-operative admissions

Cardiovascular

101 Cardiogenic shock
102 Cardiac arrest
103 Aortic aneurysm
104 Congestive heart failure
105 Peripheral vascular disease
106 Rhythm disturbance
107 Acute myocardial infarction
108 Hypertension
109 Other cardiovascular disease

Respiratory

201 Aspiration pneumonia
202 Respiratory neoplasm including larynx/trachea
203 Respiratory arrest
204 Pulmonary oedema (non cardiac)
205 Bacterial/viral pneumonia
206 COPD
207 Pulmonary embolism
208 Mechanical airway obstruction
209 Asthma
210 Parasitic pneumonia
211 Other respiratory diseases

Gastrointestinal

301 Hepatic failure
302 GI perforation/obstruction
303 GI bleeding –varices
304 GI inflammatory disease (ulcerative colitis, Crohn's, pancreatitis)
305 GI bleeding – ulcer/laceration
306 GI bleeding - diverticulosis
307 Other GI disease

Neurological

401 Intracerebral haemorrhage
402 Subarachnoid
403 Stroke
404 Neurologic infection
405 Neurologic neoplasm
406 Neuromuscular disease
407 Seizure
408 Other neurologic disease

Sepsis

501 Sepsis (other than urinary)
502 Sepsis of urinary tract origin
503 Sepsis with shock (Other than urinary tract)
504 Sepsis with shock (urinary tract origin)

Trauma

601 Head trauma +/- multi trauma
602 Multiple trauma excluding head
603 Burns
604 Multiple trauma + spinal cord injury
605 Isolated cervical cord injury

Metabolic

701 Metabolic coma
702 Diabetic ketoacidosis
703 Drug overdose
704 Other metabolic diseases

Haematologic

801 Coagulopathy/neuro/thrombo
802 Other haematologic diseases

Others

901 Renal diseases
1001 Other medical diseases

APPENDIX F

ANZICS adapted APACHE III diagnostic codes (ANZICS, 2004)

Post-Operative admissions

Cardiovascular

1201 Dissecting/ruptured aorta
1202 Peripheral vascular disease – no graft
1203 Peripheral artery bypass graft
1204 Elective AAA
1205 Carotid endarterectomy
1206 Valvular heart surgery
1207 CABG
1208 Other cardiovascular diseases

Respiratory

1301 Respiratory infection
1302 Respiratory neoplasm - lung
1303 Respiratory – mouth/larynx/sinus/trachea
1305 Other respiratory diseases

Gastrointestinal

1401 GI perforation/rupture
1402 GI inflammatory disease
1403 GI bleeding
1404 GI obstruction
1405 GI neoplasm
1406 Cholecystitis/cholangitis
1407 Liver transplant
1408 Other GI diseases

Neurological

1501 Intracerebral haemorrhage
1502 Subdural/epidural haematoma
1503 Subarachnoid haemorrhage
1504 Laminectomy/spinal cord surgery
1505 Craniotomy for neoplasm
1506 Other neurologic disease

Trauma

1601 Head trauma +/- multi trauma
1602 Multiple trauma excluding head
1603 Burns
1604 Multiple trauma + spinal cord injury

Renal

1701 Renal neoplasm
1703 Other renal diseases

Gynaecologic

1801 Hysterectomy
1802 Pregnancy related disorder

Orthopaedic

1901 Hip or extremity disorder

APPENDIX G

Data collection sheet

Private and confidential

Admission Date (mm/dd/yyyy eg Mar/18/2002): 2. Admission Time (24:00):	3. Patient status (Circle one): Pre algorithm Post algorithm	4. Study patient no. 5. Patient label

Demographics
6. Diagnosis on admission (APACHE III classification ANZICS modified version):
7. APACHE II score on admission (please see over)
8. Date of Birth (mm/dd/yyyy)
9. Gender (circle one) M / F

10. Invasive ventilation commenced prior to admission? (Circle one) Y / N			
11. Duration of invasive ventilation	Start Date (mm/dd/yyyy) Time (24:00)	Finish Extubation / decannulated Date(mm/dd/yyyy) Time (24:00)	12. Self extubation? (circle one)
Onset of ventilation (day of admission if intubated prior)			Y / N
2nd intubation			Y / N
3rd intubation			Y / N
4th intubation			Y / N

13. Tracheostomy inserted? (Circle one) Y / N	Date (mm/dd/yyyy) Time(24:00)	14. Maintained ventilatory status without invasive ventilation (see explanatory notes for definition) for greater than 24 hours.	Date (mm/dd/yyyy) Time(24:00)

15. Status at discharge (Circle one): Survived Dead	16. Treatment limitation order during ICU admission? (Circle) Y / N
17. Invasively ventilated on discharge/death? (Circle one)	Y / N

18. Time of death/discharge (24:00)	**20. Entered into study database?** (Tick box) ☐
19. Date of death/discharge (mm/dd/yyyy)	

APPENDIX G

Instructions for completing data collection sheet

1. Insert the patient's ICU admission date using the format: month/ day/ year
2. Insert the patients ICU admission time using the 24 hour clock i.e. 3pm is 1500hrs
3. Indicate whether this patient has been enrolled prior to the implementation of the sedation algorithm. All data collected from patients before implementation should be circled pre algorithm and data collected once the algorithm has been implemented should be circled post algorithm.
4. Patients should be assigned a study number and their details will be recorded separately with this study number (1 to 320).
5. Stick the patient's hospital identity sticker here.
6. Use the APACHE III (ANZICS modified version) number to classify the main diagnosis for this patient at the time of their admission.
7. Use the APACHE II scoring sheet which can be found on the back of the data collection sheet to calculate the patients APACHE II score at the time of their ICU admission.
8. Record the patient's date of birth in this space using the format: month/ day/19xx.
9. Record the patient's gender at the time of this ICU admission by circling the appropriate letter.
10. Indicate by circling Y for 'yes' and N for 'no' if the patient was receiving invasive ventilation prior to this ICU admission. Invasive ventilation is defined as any mode of ventilation (Pressure support, Synchronized intermittent mandatory ventilation, pressure control) which required the use of an airway such as a tracheostomy or endotracheal tube.
11. Record the date and time the patient received invasive ventilation. Do not record episodes where the patient is removed from invasive ventilation for less than 24 hours. Do not record episodes of non-invasive ventilation such as BiPAP and CPAP. Also record the time and date of intubation and extubation (in the case of an endotracheal tube) or decannulated (in the case of a tracheostomy tube).
12. Indicate by circling Y for 'yes' and N for 'no' if the patient accidentally or deliberately removed their own endotracheal or tracheostomy tube during this ICU admission.
13. Indicate by circling Y for 'yes' and N for 'no' if the patient has a tracheostomy tube (irrespective of the type of tracheostomy tube) during this ICU admission.
14. Record the date and time when the patient was able to maintain their ventilatory status without invasive ventilatory support (as defined in point 11 above) for a full 24 hour period. Further explanation: patients who have tracheostomies may undergo 'portex or CPAP sprints' in between episodes of invasive ventilation (i.e. pressure support and synchronized intermittent mandatory ventilation), only record the time and date when they are able to maintain their respiratory status without any invasive ventilatory support for a whole 24 hours.
15. Circle the appropriate response for the patient's status at discharge from ICU.
16. Circle Y for 'yes' and N for 'no' if the patient has any type of treatment limitation recorded in their progress notes during this ICU admission (treatment limitation orders may include 'do not resuscitate orders', 'do not escalate treatment to include vasoactive drugs', 'do not increase respiratory support' or 'do not defibrillate'.
17. Indicate by circling Y for 'yes' and N for 'no' if the patient is receiving invasive ventilation on discharge. Invasive ventilation is defined as any mode of ventilation (Pressure support, Synchronized intermittent mandatory ventilation) which requires the use of an airway such as a tracheostomy or endotracheal tube. Do not include non-invasive modes of ventilation such as BiPAP or/and CPAP.
18. Record the time of the patient's discharge using the 24 hour clock i.e. 12 midnight is 2400hrs.
19. Record the patients discharge date using the format month/ day/ year.
20. Tick this box when the data from this data sheet has been collected and the data has been entered into the study database.

APPENDIX G

Inclusion and exclusion criteria

Inclusion criteria

i) Mechanically ventilated patients of both sexes aged 17 years or older.

Exclusion criteria

vii) Patients who are less than 17 years old.

viii) Patients who have a primary diagnosis of head injury or other neurological insult and where the aim of sedation is to reduce or minimise intracranial pressure and/or cerebral artery spasm.

ix) Patients who are not expected to live for more than 24 hours on admission e.g. patients who have a diagnosis of brain stem death or may require brain stem death tests.

x) Patients who have explicit ventilation weaning goals on admission e.g. post operative patients recovering from general anaesthetic.

xi) Patients who are likely to be ventilated for more than 21 days e.g. patients with neurological conditions such as Guillain-Barré Syndrome and myasthenia gravis, and patients who have sustained a complete spinal cord lesion above cervical spine vertebra number 5.

xii) Patients who have previously been enrolled in the study but are readmitted to the intensive care unit more than 72 hours after they were discharged.

xiii) Patients who have sustained a burn injury covering more than 15% of their body surface area.

APPENDIX H

Adoption data collection sheet

Sheet for collecting guideline adoption data

Choose a random day once a month and record the following data:

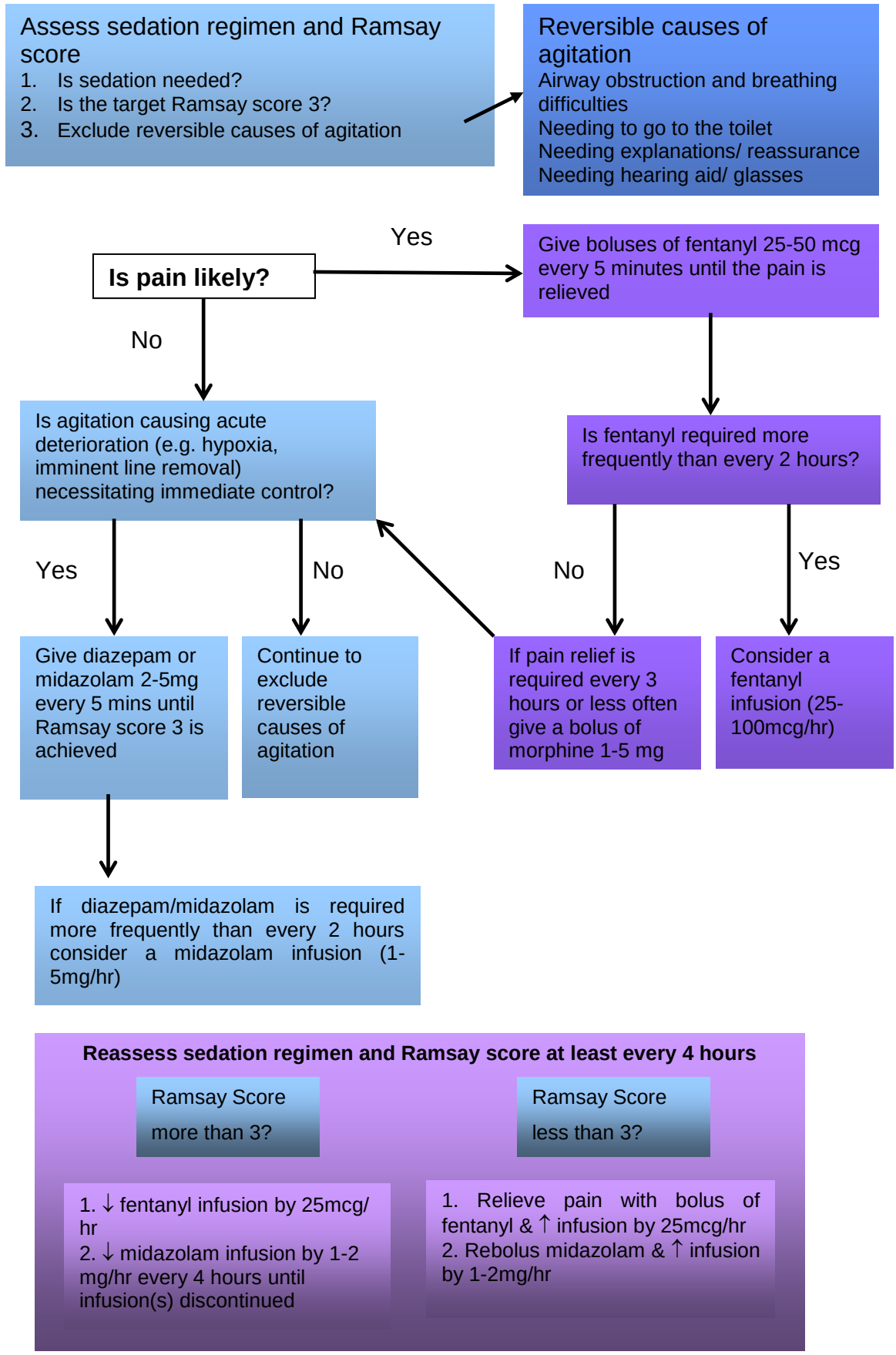
Patient no.:
(this is not the number assigned to patients in the main study, all charts for patients admitted to ICU are checked)
Date:
Time:
Completed by:

For the past 24 hours record the following	Yes	No	Comments			
1. Was the Ramsay Score recorded every 4 hours?						
2. Is the patient eligible for the guideline/ is he/she an exception?						
3. Were the medications fentanyl and midazolam used for analgesia and sedation?						
4. Record the last 6 Ramsay scores (24 hours):						
5. Adoption category : Ramsay scoring (CIRCLE)	PA	NACJ	NANG		NANR	
6. Adoption category: Guideline (CIRCLE)	PA	NACJ	NANG		NANR	

Key
PA Perfection adoption
NACJ Non adoption clinical judgement
NANG Non adoption not for guideline
NANR Non adoption no apparent reason

APPENDIX I

The Royal North Shore Hospital Intensive Care Unit sedation algorithm



APPENDIX J

Example of feedback provided to nurses during the study

The RNSH sedation algorithm for mechanically ventilated patients

Information and audit data
Presented by Roz Elliott (CNC)

APPENDIX J

The RNSH sedation algorithm was introduced in November 2003. In order to monitor adoption of the guideline an audit is performed each month (on a random day). This information is presented on this notice board in the form of graphs and in the '6th Sense' newsletter.

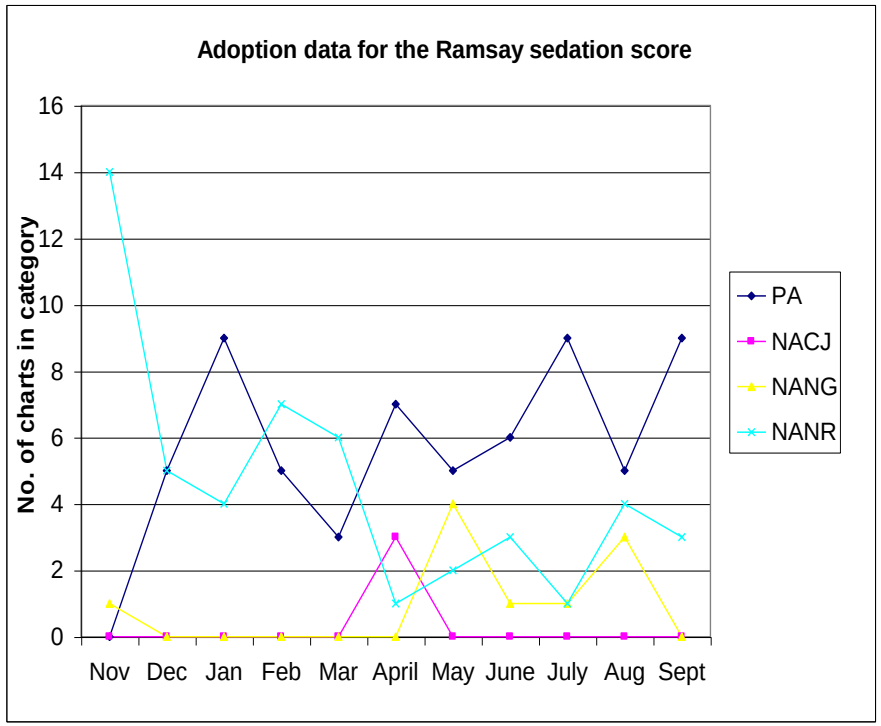
The following categories have been used to classify the degree of adoption:

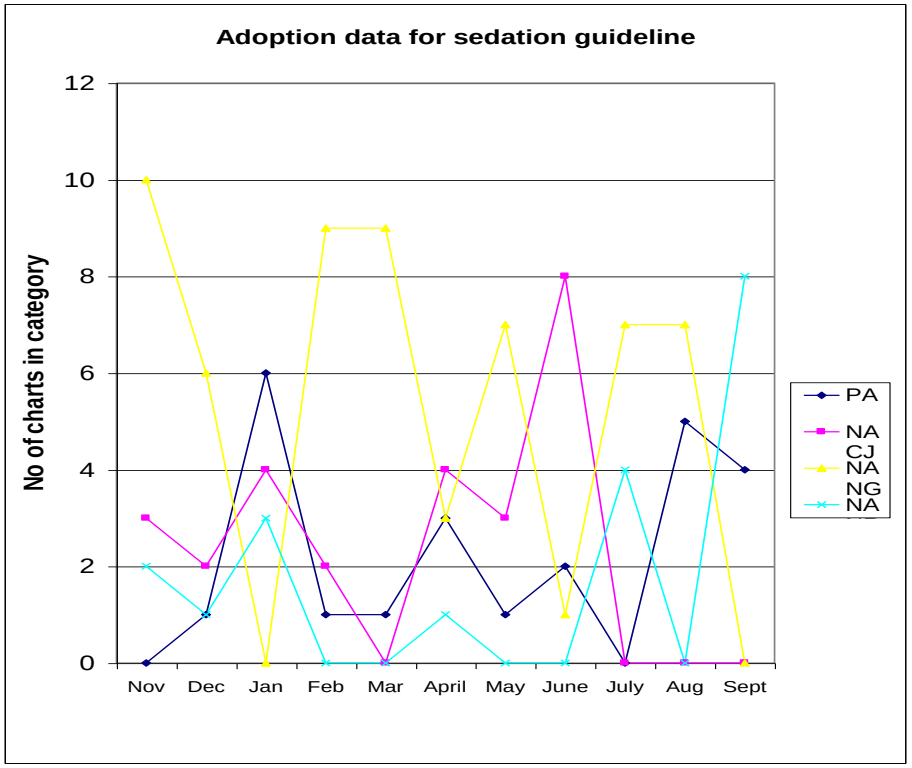
- **Perfect adoption (PA)**. This term indicates that the sedation guideline was followed exactly or that the Ramsay score was documented every four hours.
- **Non-adoption –not for guideline (NANG)** Patients who have had cardiothroacic surgery are cared for using the cardiothoracic pathway and all analgesia and sedation should be given according the guidelines provided in the pathway. The only exception for the assessment of sedation level using the Ramsay score is when the patient is receiving muscle relaxants.
- **Non-adoption clinical judgement (NACJ).** This describes deviations from the guideline which have occurred because other events have occurred which do not allow the algorithm to be used (allergy, ICP, haemodynamically unstable, renal failure etc).
- **Non-adoption no apparent reason (NANR).** This category represents deviation from the guideline or assessment using the Ramsay scale which cannot be explained and has no apparent rationale.

APPENDIX J

The audit performed on random days between November 2003 and September 2004

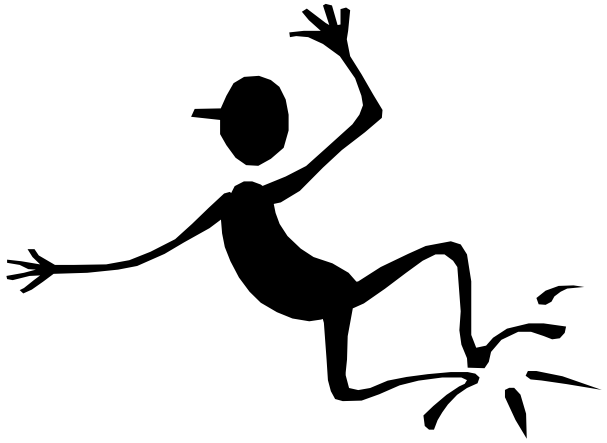
The results of the audit conducted on these days are presented below.





General comments:

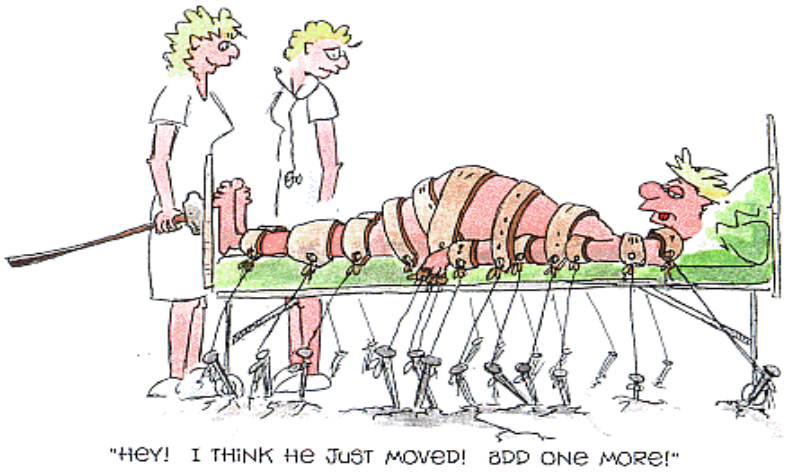
Yet again there were clinical reasons that many patients were not eligible for the sedation guideline (e.g. burns, CABG). A comparison of the months to date are presented. There is a 100% adoption rate for the Ramsay sedation scoring system which is very encouraging. This is not clearly reflected by the graph but is noted when I conduct my daily rounds. The sedation guideline has been widely accepted however there are always areas for improvement. The overall aim is to keep the patient comfortable and this is achieved by targeting to a sedation level of 3 on the Ramsay Scale. The only time that the Ramsay should not be recorded is when the patient is receiving muscle relaxants and cannot respond physically. On occasions patients have been sedated to deeper levels without direct orders. Discussion on each ward round should include an assessment of the patient's sedation needs and deeper sedation levels must be discussed and ordered by the medical officer.



APPENDIX K

Example of some reminders used during the implementation of the sedation guideline

It is easier with the RNSH sedation algorithm!!!!



Ref: website www.nurstoon.com/restraint.html

Accessed 11/08/03 2000hrs

Are you using the RNSH Sedation algorithm? Which medications are you signing out for your patient?