

# **The significance of a systematic approach in intensive care pain treatment and sedation**

**A descriptive and explorative study of nurses' and physicians' practice in the assessment of mechanically ventilated intensive care patients' analgesic and sedative needs**

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”Bare når virkeligheten belærer oss, kan vi forandre den”  
Bertolt Brecht



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## **Abbreviations**

ICU	Intensive care unit
MV	Mechanical ventilation
NRS	Numeric rating scale. This abbreviation designates the quantification of pain levels in this dissertation.
RASS	Richmond Agitation and Sedation Scale
ATICE	Adaptation to the Intensive Care Environment
CAM-ICU	Confusion Assessment Method for the Intensive Care Unit (ICU)

## List of original papers

### Paper 1

Wøien H, Stubhaug A, Bjørk IT. Analgesia and sedation of mechanically ventilated patients - a national survey of clinical practice. *Acta Anaesthesiologica Scandinavica* 2012; 56, 23-29.

### Paper 2

Wøien H, Balsliemke S, Stubhaug A. The incidence of delirium in Norwegian intensive care units; deep sedation makes assessment difficult. *Acta Anaesthesiologica Scandinavica* 2012; doi: 10.1111/j.1399-6576.2012.02793

### Paper 3

Wøien H, Værøy H, Aamodt G, Bjørk IT. Improving the systematic approach to pain and sedation management in the ICU by using assessment tools. *Journal of Clinical Nursing* 2012; doi: 10.1111/j.1365-2702.2012.04309

### Paper 4

Wøien H, Bjørk IT. Intensive care pain treatment and sedation: Nurses' experiences of the conflict between clinical judgment and standardized care: An explorative study. *Intensive and Critical Care Nursing*. Accepted November 10th 2012; In press; <http://dx.doi.org/10.1016/j.iccn.2012.11.003>

## Summary

The importance of high quality pain treatment and sedation in the intensive care unit (ICU) is well documented. Stressful and uncomfortable daily medical and nursing interventions constitute an important part of ICU treatment. Critically ill patients treated on mechanical ventilation therefore generally need both pain treatment and sedation. A shift from deep to light sedation has been introduced into ICU treatment, allowing the ICU patient to be awake and breathe spontaneously. The major advantages of this approach are decreased ventilator time and that the patient is able to communicate pain and discomfort, to describe treatment effects, and to mobilize. Despite the proven benefits of this strategy, a substantial incidence of suboptimal analgesia and sedation is documented, and ICU professionals struggle to implement feasible methods that support this approach. The application of pain treatment and sedation guidelines, assessment tools, and daily sedation interruption is strongly recommended, but is still not routine in the ICU. In 2007, there was a lack of knowledge about pain treatment and sedation practice in Norwegian ICUs, and there were no indications that Norwegian practice was better organized than in other countries. The aim of this dissertation was to study the processes of analgesia and sedation in intensive care. This was accomplished by a national survey and the implementation of a systematic approach in two Norwegian ICUs. The purpose was to achieve an accurate balance between adequate pain treatment and sedation in critically ill mechanically ventilated patients, and to recognize delirium at an early stage.

The first empirical study was a national survey that aimed to describe Norwegian ICU nurses' and physicians' perceptions of practice, cooperation, and problems in the daily use of procedures for analgesia and sedation in ICU (study I). One nurse and one physician representing each of the 54 Norwegian ICUs were included. In the second empirical study, a prospective descriptive two-site study was developed to explore the effect of introducing a systematic approach to pain, sedation and delirium management in the ICU by the implementation of four assessment tools (study IIa and IIb). Frequency of pain and sedation documentation, the number of days when a sedation level was prescribed, patients' levels of pain and sedation, and the amount of analgesics and sedatives used were documented for 39 patients corresponding to 281 ICU days before implementation of the tools versus 139 patients corresponding to 958 ICU days after implementation (study IIa). This substudy also included data from a questionnaire completed by 55 ICU nurses before and after implementation on their perceived benefit

of the assessment tools. In substudy IIb, we also tested the usefulness of the Confusion Assessment Method for Intensive Care (CAM-ICU) in the ICU population and described the incidence of delirium in the same cohort. Finally, through the use of focus group interviews we explored how 14 ICU nurses at the two study sites experienced their ability to perform clinical judgments of patient pain, sedation and confusion levels 1 month and 3 months after implementation of assessment tools, and how the tools influenced these judgments (study III).

## Introduction

The empirical foundation of this dissertation is built upon qualitative and quantitative published research findings between 1990 and 2008. In the early phase of this literature review, we discovered a lack of information about Norwegian intensive care unit (ICU) analgesia and sedation practice. Simultaneously with the theoretical work, we therefore conducted a national survey in autumn 2007. Based on up-to-date research and relevant information from the national survey on Norwegian ICUs' need for improvement, an implementation study focusing on a systematic approach in the field of ICU pain treatment and sedation began in January 2009. At that time, pain had been identified as a stressor for many intensive care unit (ICU) patients, and unrelieved pain was shown to disrupt and interfere with the ICU patients' circulation and respiration and thereby contribute to prolonged mechanical ventilation and immobilization (Desbiens et al., 1996; Epstein & Breslow, 1999). The intensity of pain was described as moderate to severe by more than 50% of critically ill patients (Puntillo et al., 2001; Stanik-Hutt et al., 2001; Gelinas, 2007). Published research reported a poor frequency and quality of pain assessments in the ICU population (Chanques et al., 2006; Payen et al., 2007; Ouimet et al., 2007a), and that pain remained under-treated (Gelinas et al., 2004; Gelinas, 2007). Furthermore, potential for improvement in ICU sedation was reflected in the significant incidence of oversedation reported (Martin et al., 2005; Payen et al., 2007; Weinert et al., 2007). Studies showed that optimized sedation management improved patient outcomes, and that oversedation prolonged patients' time to recovery (Kollef et al., 1998; Fraser & Riker, 2007). Oversedation could be avoided in cases where nurses and physicians had defined common goals and titrated and evaluated patients' analgesics and sedative needs individually (Brattebø et al., 2002). It had also been suggested that excessive sedation could be avoided by daily interruption of sedation and by the use of valid assessment tools (Kress et al., 2000; Jacobi et al., 2002; Payen et al., 2007).

The ICU nurse's role in the processes of pain treatment and sedation is to complete independent assessments and evaluate observed effects of analgesics and sedatives intended to achieve pain relief, an appropriate level of consciousness and tolerance for each patient, and early detection of delirium. The use of pharmacological and non-pharmacological interventions is essential for patient safety and comfort, and therefore constitutes a major part of the ICU nurse's work. Since analgesics and sedatives

in ICU are drugs with potentially serious side effects, nurses bear a large responsibility in maintaining and developing the quality of pain treatment and sedation.

Research among long-term sedated critically ill patients on mechanical ventilation (MV) has revealed negative experiences such as memory delusions, anxiety, delirium, and post traumatic stress syndrome. This has been partly explained by inadequate pain treatment and oversedation (Jones et al., 2001; Ely et al., 2003; Samuelson et al., 2007; Girard et al., 2008a). The importance of a systematic approach to the detection of delirium in the ICU at an early stage is evident, and it has been strongly recommended that delirium should be assessed and treated as a part of the analgesia and sedation regime (Jacobi et al., 2002; Ely et al., 2004a; Ely et al., 2004b). Delirium in critically ill patients has proved to be a marker of mortality (Ely et al., 2004a; Lin et al., 2004), increased hospital stay (Quimet et al., 2007a), and long-term cognitive impairment (Jackson et al., 2004). Clinicians often fail to detect delirium in ICU patients because systematic assessment is not performed (Ely et al., 2004b).

Results from studies stress the importance of high quality pain treatment and sedation in ICU (Kress et al., 2003; Payen et al., 2007; Sessler & Varney, 2008). Systematic evaluation and documentation of pain, sedation and level of confusion have been emphasized as important steps in providing adequate pain relief and comfort (Sessler & Varney, 2008), and have been associated with positive outcomes (Ely et al., 2004b; Chanques et al., 2006; Payen et al., 2007). Optimizing pain and sedation practice is a recognized quality marker for ICU treatment (Jacobi et al., 2002; Jones et al., 2001b). This includes the use of assessment tools that help nurses and physicians to adjust and evaluate pain treatment and sedation in ICU, and to detect delirium at an early stage.

The existing results from the approach of light sedation studies including frequent monitoring of pain, sedation and confusion have indicated a positive effect on a wide set of clinical outcomes (Brook et al., 1999; Kress et al., 2000; Kress et al., 2003; Schweickert et al., 2004). Promising results from a study in 2004 (Brattebø et al., 2002) demonstrated that relatively simple changes in sedation practice in a Norwegian ICU were both effective and achievable. However, the evidence regarding analgesia and sedation in ICU indicates that the integration of the routine use of written protocols and subjective scoring systems is difficult to incorporate into daily routines (Tallgren et al., 2006).

Information about the collaboration between physicians and nurses in Norwegian ICU's when using pain and sedation assessment scales and protocols was incomplete in 2007 when the development of this doctoral study started. At that time, European studies supporting the need for balanced pain treatment and sedation in ICUs showed that treatment regimes and choice of medication differed widely and required improvement (Soliman et al., 2001; Samuelson et al., 2003; Martin et al., 2005; Egerod et al., 2006). The application of pain treatment and sedation guidelines and assessment tools was not routine, and daily sedation interruption was rarely in use. Previous pain treatment and sedation surveys have focused on the use of various medications and regimes. What had not been fully explored was the process of clinical judgment used by nurses and physicians to assess patient needs and how they work together in achieving a defined level of pain and sedation for the ICU patient (Egerod, 2002; Egerod et al., 2006). The present dissertation focuses on the lack of consensus in ICU pain treatment and sedation, the effect of a systematic approach, and how this influences nurses' clinical judgment. The overall aim was to assess, intervene in and support the processes of analgesia and sedation used by nurses and physicians in the clinical ICU field, in order to achieve an accurate balance between adequate pain treatment and sedation in mechanically ventilated patients, and to recognize delirium at an early stage.

A combination of quantitative and qualitative methodological approaches was used. From a professional point of view, the assumptions of this dissertation have been related to general features of the unforeseen situation of the acute critical illness in the ICU patient and the high technology environment. Hence, for me as a researcher, the quantification of the patients' levels of pain, sedation and confusion is one approach to study this field. Structured observation and documentation by nurses and physicians are significant means of acquiring knowledge, and strongly associated with their clinical judgment. Treatment decisions based on multidisciplinary communication and collaboration are important factors in correcting interventions and achieving a systematic approach. The intention of this dissertation has been to describe pain treatment and sedation practice, and to indicate associations between the documentation of defined treatment goals and actual practice. By adding a focus group interview study, we aimed to expand knowledge in the field of assessing ICU patients' analgesic and sedative needs.

## **Organization of the dissertation**

In chapter 1, I described the background for this dissertation. An overview of study aims and research questions, and a table reviewing the empirical studies included is outlined in chapter 2. Chapter 3 presents a more in depth description of ICU pain treatment and sedation in mechanically ventilated patients. This includes a description of clinical judgment, and a review of the literature up to the study onset, illustrated by a model showing the linkages between research and practice. To get an overview of the field of ICU pain treatment and sedation, and to prepare the implementation of a systematic approach, I have chosen to describe central concepts and main relationships illustrated in the model thoroughly. In chapters 4 and 5, the methodology of the empirical studies is presented, followed by a summary of the results. Based on the results from the empirical studies included in the dissertation, a discussion is presented in chapter 6. This includes a section with an updated review of the literature up to 2012 that supports the main relationships illustrated in the model in chapter 3. Chapter 7 presents conclusions, implications for clinical practice, and future perspectives.



## Aims of the study

The specific aims and research questions (RQ) were as follows:

1. To describe practices and cooperation among Norwegian ICU nurses and physicians in the everyday use of procedures for analgesia and sedation in mechanically ventilated patients.

RQ1: What characterizes Norwegian nurses' and physicians' knowledge, practices and attitudes related to pain treatment and sedation in intensive care?

2 a) To describe the effects of introducing a systematic approach to pain and sedation management into the ICU

2 b) To register the nurses' opinions regarding the importance of the selected tools for the quality and safety of the routines before and after the implementation

2 c) To study the incidence of delirium by the use of a confusion assessment tool in two Norwegian ICUs

RQ2: In what way will the implementation of pain and sedation assessment tools influence how physicians prescribe and nurses document patient pain and sedation levels?

RQ3: What is the incidence of delirium among ICU patients in two Norwegian ICUs?

RQ4: How useful is the confusion assessment tool in an ICU population?

3. To examine how nurses' experienced their ability to perform clinical judgments of patient pain and sedative needs after the implementation of four assessment tools, and how the tools influenced these judgments.

RQ5: What is the nurses' perceived usefulness of instruments implemented to assess patient analgesic and sedative needs?

## Overview of the studies in the dissertation

In the early phase of the work for this dissertation, I discovered a lack of information about Norwegian ICU analgesia and sedation practice. I therefore conducted a national survey in Autumn 2007. Based on a literature review and results from the national survey on the need to improve this in Norwegian ICUs, a two-site implementation study focusing on a systematic approach in the field of ICU pain treatment and sedation was developed and began in 2009. This included a study of the incidence of delirium by the use of a confusion assessment tool. During the implementation phase, nurses at both study sites were interviewed twice in focus groups (table 1).

Table 1 Overview of the aims and design of the study and of the source of data

	<b>Aim</b>	<b>Design</b>	<b>Source</b>
<b>Study I</b>	To study Norwegian ICU nurses' and physicians' perceptions of practice, cooperation, and problems in the daily use of procedures for analgesia and sedation in ICU.	National survey with descriptive and comparative design	Nurses and anesthesiologists representing Norwegian ICUs treating mechanically ventilated patients for >24 hours
<b>Study IIa</b>	To study the effect of introducing a systematic approach to pain, sedation and delirium management into the ICU by the implementation of four assessment tools.	1. Prospective descriptive two-site study 2. Questionnaire	1) Documented pain treatment and sedation data in ICU patients before and after implementation 2) Nurses from both ICUs responding to a questionnaire before and after the implementation of tools
<b>Study IIb</b>	To test the usefulness of a confusion assessment tool in our ICU population and to describe the incidence of delirium	Prospective descriptive two-site study	Confusion assessment scores from ICU patients included in study IIa
<b>Study III</b>	To examine how ICU nurses experienced their ability to perform clinical judgments of patient pain, sedation and confusion levels after the implementation of assessment tools, and how the tools influenced these judgments	Qualitative: explorative and descriptive study	Experienced ICU nurses representing each study site

## **Pain management and sedation in the ICU**

The history of mechanical ventilation (MV) started with the use of prolonged manual positive pressure ventilation in Copenhagen, at the time when the polio epidemic was raging through Europe and the United States. Danish physicians made a breakthrough in the treatment of patients dying from respiratory paralysis. In 1952, Bjørn Ibsen and his team accomplished manual ventilation through a tube placed in the trachea of polio patients (Lassen, 1953). These patients were awake but required intensive nursing care while treated with their respiratory and circulatory failure. Later on, ICU treatment of complicated illnesses has increased and the need for opioids and sedatives to make the patients tolerate treatment and MV has been essential. For many years the approach of deep sedation was well accepted among ICU nurses and physicians and they thought that unconsciousness and no memories from the ICU stay benefited the patients' outcome. Advances in medical treatment and technology have resulted in synchronized MV adjusting for patients' individual respiratory drive which is important in recovery from critical illness. Heavy sedation and immobilization in mechanically ventilated patients are now related to both short-term and long-term complications. The shift from heavy to light sedation in ICU patients has been a major challenge in ICU treatment the last decades (Riker & Fraser, 2009).

Important goals in ICUs are to assist patients to endure all types of treatments and interventions with minimum impact on appropriate level of consciousness and tolerance (Nelson et al., 2004; Pun & Dunn, 2007). Most critically ill patients need MV and are continuously under stress. Pain treatment and sedation in ICU is therefore widely used and is often classified together in the literature (Egerod, 2002), yet they ought to be kept separate, as pain treatment and sedation often require different interventions. Analgesic therapy seems to have one common understanding, but for many ICU physicians and nurses the concept of sedation seems to be unclear, thus indications, interventions and outcomes become unclear (Egerod, 2002). So, in this chapter, the central concept encompassing the field of ICU pain management and sedation is clarified, with the intention of building a systematic approach to achieving the goal of an awake and cooperative patient. Furthermore, a model will illustrate the landscape of the extensive literature in the field as described in published research up to 2008, at the time of the study onset. The strength of the relationships between the elements in the model will be discussed, and give directions for the empirical studies in this dissertation.

To build an empirical foundation of the processes of pain management and sedation in mechanically ventilated ICU patients, I conducted a review of the literature before starting the study. The search strategy included searches in MEDLINE, CINAHL and Cochrane, using MeSH headings (respiration, mechanical ventilation, pain measurement, analgesic, sedative, pain, sedation, clinical protocol, nursing assessment, algorithms and practice guidelines) and textwords. In addition, the reference lists of identified studies were examined. Studies published between 1990 and 2008 were included. The search was not limited to randomized controlled trials because many descriptive and observational studies have been published in this area, and provide important information in the field of ICU pain treatment and sedation.

## **Central concepts**

### **Pain and pain management**

In critically ill patients, pain is expressed both verbally and non-verbally and can be defined as any patient report or sign described as intense discomfort. This is consistent with the International Association for the Study of Pain that defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (Merskey & Bogduk, 1994). The intention of ICU pain management is to minimize and relieve patients' pain, and to keep it at an acceptable level allowing the patient to rest and to mobilize if possible. This implies a multidisciplinary approach including routine discussions of choices of analgesics, analgesic adjuvants and non-pharmacologic interventions and the effects achieved. Pain intensity in adult ICU patients can be measured and scored on a Visual Analogue Scale (VAS), a horizontal 100mm line with anchors representing sensory extremes or a categorical Numeric Rating Scale (NRS), a horizontal 100mm line with anchors representing sensory extremes but with visual numbering from 0 to 100 (Jensen et al., 1986; Jensen & Justic, 1995). Behavioral categories such as face relaxation and muscle tonus have been used as variables in pain measurement tools when patients are not able to communicate verbally. At the onset of our empirical studies in 2009, existing behavioral pain scales had not been fully tested with regard to reliability and validity (Ahlers et al., 2008).

## Sedation and sedation management

The term 'to sedate' has its origin in Middle English, Old French and Latin, and means to calm (Oxford Reference Online 2008). Sedation can be thought of as either a process or a state. The process of sedation is sedation management that aims to reduce anxiety, stress, irritability, or excitement by the administration of a sedative agent, drug or non-pharmacological adjuvant. Sedation leads to alteration of sleep and wakefulness (Oxford Reference Online 2008). A state of sedation is the result of the process that should be in accordance with the sedation goal, and is completely dependent on the process of sedation.

The management of sedation has two primary intentions. First, sedation is recommended to allow patients the ability to tolerate unpleasant diagnostic, surgical procedures or nursing interventions, and to relieve anxiety and discomfort. Second, sedation for uncooperative patients may expedite and simplify special procedures that require little or no patient movement (Oxford Reference Online 2008). Examples of sedation processes include the titration of an amount of sedative to attain the level where the patient is able to tolerate the treatment (sedation goal). ICU patients' need for sedation and their actual levels of sedation can be measured by using valid sedation assessment tools.

The literature describes different types of sedation states (Marino, 2007, chapter 50). Only conscious and unconscious sedation are described in this dissertation. Patients receiving conscious sedation are capable of rational responses, and they are able to maintain their airway for ventilation. The hallmarks of conscious sedation are minimal effects on the respiratory, cardiac and nervous system reflexes (Riker & Fraser, 2009). Patients receiving conscious sedation are cooperative, have stable vital signs (pulse, respiratory rate, and temperature), shorter recovery room convalescence, and a lower risk of developing drug-induced complications (ibid). Unconscious sedation is a controlled state of anesthesia, characterized by partial or complete loss of protective nerve reflexes, including the ability to independently breathe and respond to commands. The patient is unable to cooperate, has fluctuating vital signs, prolonged recovery room convalescence, and a higher risk of anesthetic complications.

In the empirical studies in this dissertation, sedation assessment is adequate when it is based on the Society of Critical Care Medicine (SCCM) clinical practice guidelines for the sustained use of sedatives and analgesics in critically ill adults (Jacobi et al., 2002). An adequate level of sedation is defined as the level of sedation where the medical

condition is satisfactory and where the patient is able to tolerate intensive care without feeling discomfort. This means that an adequate level of sedation is individual, and differs between patients according to their clinical circumstances (Jacobi et al., 2002). Undersedation and oversedation cause several problems. Undersedation usually produces changes in the level of consciousness as a consequence of stress and lack of sedation. These changes have adverse consequences for the outcome of ICU patients, and may result in inadequate ventilation, hypertension, tachycardia and discomfort. Oversedation often occurs as a result of accumulation of sedative and analgesic agents, and can be associated with prolongation of mechanical ventilation and weaning (Kollef et al., 1998).

In order to avoid potential complications of both under- and oversedation, regular assessment of the patient's need for sedation is necessary by using a valid and reliable sedation assessment scale, objective tools, or biomarkers.

### Treatment options and intervention

The treatment options of analgesic and sedative needs can be divided into three groups: Analgesics and sedatives: 1) Morphine-like compounds for treating pain in critically ill patients. 2) Drugs that depress the central nervous system (CNS) causing calmness, relaxation, reduction of anxiety, sleepiness, slowed breathing, slurred speech, staggering gait, poor judgment, and slow, uncertain reflexes. At high doses or when analgesics and sedatives are abused, many of these drugs can cause unconsciousness and adverse side effects (Oxford Reference Online 2008).

Pharmacological adjuvant: Analgesics and sedatives given to achieve greater effects as a supplement or potent combination medication.

Non-pharmacological adjuvant: Complementary nursing therapies e.g. relaxation, comfortable rest in bed, removal of noise, repeated information in short form, the presence of significant others, light, music and mobilization.

### Symptoms of side effects

Side effects are defined as any effects of a drug, chemical or other medicine that may occur in addition to its intended effect, especially an effect that is harmful or unpleasant (Oxford Reference Online 2008). The occurrence of side effects in ICU patients constitutes an important component in the planning of an appropriate pain and sedation treatment strategy.

## Level of consciousness and tolerance

Consciousness is a quality of the mind generally regarded to comprise qualities such as subjectivity, self-awareness, sentience, sapience, and the ability to perceive the relationship between oneself and one's environment (Oxford Reference Online 2008). In the ICU, the patients' level of consciousness varies on a continuum between deep unconsciousness, and awake and co-operative. The patients' consciousness decreases and fluctuates because of critical illness and intensive care treatment, but may also improve towards the level of cognition (De Jonghe et al., 2003). Consciousness is most frequently measured by the Glasgow Coma Scale (GSC) in the ICU. The Reaction Level Scale is another instrument with a similar endpoint, and may also be used with intubated patients and patients with ocular swelling (De Jong et al., 2005). Additionally, for patients in the ICU, the level of consciousness may be scored on a valid tool that includes grades of awakeness and, in some cases, the level of comprehension (De Jonghe et al., 2003). The scores are defined as responses to instructions such as eye opening, handgrip, and nodding and are important features in the assessment of the sedation level. GCS scores should be documented separately from scores assessed by sedation assessment tools, because the scores give different information.

In the ICU setting, tolerance can be defined as the patient's ability and capacity to endure pain or hardship, to relax and cooperate while receiving MV and undergoing intensive care treatment. Tolerance can be measured using a valid sedation assessment tool based on levels of calmness, ventilator synchrony and face relaxation (De Jonghe et al., 2003).

## Symptoms of delirium

Delirium as a concept has been described in more than twenty different terms, and a common nomenclature has been initiated (Morandi et al., 2008). The Diagnostic and Statistical Manual of Mental Disorders (DSM IV) (American Psychiatric Association 2000) defines delirium as "a disturbance of consciousness with inattention accompanied by a change in cognition or perceptual disturbance that develops over a short period of time (hours to days) and fluctuates over time." Delirium subgroups are based on possible motor or psychomotor subtypes (Meagher & Trzepacz, 2000). Hyperactive delirium is characterized by increased psychomotor activity and agitation versus the hypoactive delirium described as reduced psychomotor activity and lethargy (Meagher et al., 2008; Peterson et al., 2006). A third variant of delirium, subsyndromal delirium, is described in

the literature as a state where the patient fluctuates unpredictably between hyper- and hypoactive delirium (Ouimet et al., 2007b). Delirium has an acute onset and in ICU patients the ability to handle information may vary, making the assessment of the state of consciousness and cognition difficult. Delirium is diagnosed based on etiology: delirium due to a general medical condition, substance-induced delirium, delirium due to multiple etiologies, and delirium not otherwise specified when the etiology is undetermined (Pandharipande et al., 2005). Different assessment tools have been developed to identify delirium in ICU patients.

It is important for ICU clinicians to recognize delirium at an early stage, and to reduce the duration of delirium and the impact of risk factors for delirium in ICU, when possible (Ely et al., 2001a). This means an aggressive approach in treating infections, to avoid under- and over sedation, to keep the patient awake and alert and able to mobilize as far as possible, and to support qualitative sleep patterns (ibid).

## **The processes of pain management and sedation in ICU**

The treatment of ICU patients is complex and therefore demonstrating that one intervention leads to a certain effect may be confounded by different sources of error. Outcomes of analgesia and sedation may be related to outcomes of treatment in general. Examples are tachycardia or increased blood pressure that may be interpreted as symptoms of stress and anxiety, but could in fact be side effects of drug treatment, medical interventions and the consequences of critical illness in general. Research on pain treatment and sedation in ICU also poses methodological challenges due to heterogeneity, small sample sizes and lack of blinding. An awake and cooperative patient able to communicate improves the likelihood of treating pain and evaluating sedation adequately.

In 2008, the use of pain and sedation protocols with or without daily sedative interruption, and the use of assessment scales were the key recommendations that supported the right balance in ICU pain and sedation treatment (Kress et al., 2000; Jacobi et al., 2002; De Jonghe et al., 2005; Payen et al., 2007; Sessler & Varney, 2008). Early in my work with this dissertation I made a model to illustrate this extensive field of pain management and sedation in ICU. The model aimed to show the relationships suggested in the literature, between the assessment of the need for analgesia and sedation while on MV in intensive care, nursing interventions related to analgesia and sedation, treatment options and patient outcomes (figure 1).



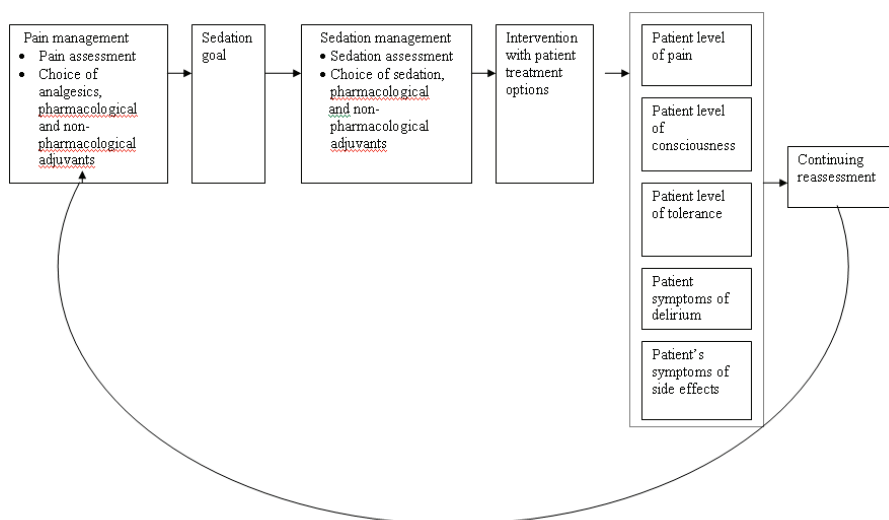


Figure 1 Pain treatment and sedation in mechanically ventilated patients

In 2008, the literature supported that higher patient functionality could be obtained by finding the right balance between analgesia, sedation and side effects. If this were achieved, critically ill patients would be able to tolerate the treatment given, to mobilize, cooperate and feel comfortable. Some researchers also suggested that this could lead to earlier discharge, fewer readmissions, increased satisfaction with care and enhanced cost benefit ratios for the institution (Brook et al., 1999; Kress et al., 2000; Kress et al., 2003; Dasta et al., 2005). Based on the literature review, figure 1 displays essential elements and relationships between pain and sedation management in mechanically ventilated patients, interventions, treatment options and patient outcomes. This model illustrates as described in the literature up to 2008 the complexity of decision-making and assessment strategies in ICU pain treatment and sedation, and how nurses and physicians are challenged in defining adequate treatment and achieving stated goals in mechanically ventilated patients (Carson et al., 2006; Payen et al., 2007; Weinert & Calvin, 2007).

Sedation treatment in ICU is related to pain treatment. Pain must be assessed and treated in critically ill patients before giving sedatives as a substitute for adequate analgesia (Chanques et al., 2006; Fraser & Riker, 2007). Both pain management and the decision of a sedation goal represent important components of nurses' and physicians' assessments of the level of consciousness and degree of adequate sedation. In terms of this, the assessment of pain and sedation influences the choice of analgesia and sedation,

and leads to the choice of appropriate interventions with patient treatment options. The treatment seeks to achieve the following patient outcomes as described in the model:

1. Achievement of an acceptable level of patient pain
2. Achievement of a prescribed level of patient consciousness (awakeness, comprehension, calmness)
3. Achievement of a prescribed level of patient tolerance (ventilator synchrony, face relaxation)
4. An early detection of the development of delirium
5. Decreased side effects of medications – related to patients' report, patient sedation level and physical symptoms

The final step in the model is to continue reassessment of pain and sedation in accordance with the ICU patients' needs. The elements and relationships remain significant in 2012.

In the following, a summary of relevant literature available at the time of the development of the intervention will be presented, which justify the design of the empirical studies in this dissertation. The model remains significant in 2012. In the discussion chapter of this dissertation our results from the empirical studies and research up to 2012 will be presented, based on essential elements and relationships illustrated in the model (figure 1).

## **Evidence supporting the processes of pain management and sedation**

Initially, patient participation in pain management and the need for sedation is preferable, but is often limited because of their severe condition and decreased ability to communicate their needs. A systematic approach including a strategy of multimodal therapy and attentive care aims to put the ICU patient in a situation where the treatment can be tolerated with satisfying pain relief and few or no sedative side effects. In a French controlled study in a medical-surgical ICU, systematic evaluation of analgesic and sedative needs indicated a decreased incidence of pain and agitation, duration of mechanical ventilation and nosocomial infections (Chanques et al., 2006). Several studies have reported improved ICU outcomes after standardized assessment of patient's needs (Brook et al., 1999; Brattebø et al., 2002; De Jonghe et al., 2005; Payen et al., 2007). Nurses play a key role in assessing sedation, as well as determining the dosage and frequency in titrating analgesia and sedatives within prescribed limits (Walker & Gillen,

2006). However, studies have indicated that nurses underestimate pain and the level of sedation (Weinert & Calvin, 2007) and they do not assess pain and sedation levels in ICU patient by routine methods. In 2007, the patients needs for analgesics and sedatives were mainly based on known and well established local practice and individual experience and were not assessed and documented systematically (ibid).

The four main relationships among the elements illustrated in the model include pain and sedation management in ICU patients, interventions, treatment options and patient outcomes (figure 1, page 25), and can be presented as follows:

- Pain management, defined as pain assessment and the choice of analgesics, pharmacological and non-pharmacological adjuvants, influences the prescription of the patients' daily sedation goal
- The pain management and sedation goal directs nurses and physicians in performing sedation management, defined as sedation assessment and choice of sedatives, and pharmacological and non-pharmacological adjuvants
- Pain management, sedation goal and sedation management influence how nurses intervene with different options for the patient.
- The treatment options lead to adequate pain relief, an accurate level of patient consciousness and tolerance, early detection of development of delirium, and decreased side effects of medications

### **Pain management influences the achievement of the patients' prescribed sedation goal**

Many results from research studies support the emphasis on initial provision of analgesia to achieve sedation goals and to maintain comfort in critically ill patients (Richman et al., 2006; Devlin, 2008; Sessler & Varney, 2008). Pain is a common experience for most ICU patients (Puntillo et al., 2001; Stanik-Hutt et al., 2001; Puntillo et al., 2002; Gelinas, 2007; Li et al., 2008) and an aggressive approach to managing pain has been strongly recommended. Pain in ICU patients is reported as under-treated and underestimated by nurses and physicians (Hamill-Ruth & Marohn, 1999; Gelinas, 2007). Pain management includes pain assessment and choices of analgesics, and pharmacological and non-pharmacological adjuvants. The first step in providing adequate pain management is correct assessment. Patients self-reporting are the most valid pain measure, but many ICU

patients are unable to communicate their level of pain. In these cases, nurses have to grade the pain level based on validated and reliable pain scales (Ahlers et al., 2008). In unconscious patients where muscle relaxants are not used, muscle tone and facial grimacing are good indicators for pain level and comfort (Ambuel et al., 1992; De Jonghe et al., 2003; van Dijk et al., 2005). However, it is recommended to combine the assessment of pain behavior variables with NRS score by nurses to ensure that contextual factors which may influence the patient are taken into account (van Dijk et al., 2005). Blood pressure and pulse may be affected by secondary interventions and high levels of metabolic stress due to critical illness, and are no longer valid pain measures in the ICU (Ambuel et al., 1992; De Jonghe et al., 2003; van Dijk et al., 2005). The validity, reliability and feasibility of pain behavior assessment tools were still controversial when the implementation study was started (Li & Puntillo, 2004; Ahlers et al., 2008).

Distinct criteria for pain management in the ICU population are essential so that sedatives are not used as a substitute for analgesia (Jacobi et al., 2002). Adequate analgesia can reduce the need for sedatives in critically ill patients (Devlin et al., 2001; Kress et al., 2002; Puntillo et al., 2002; Bateman & Grap, 2003; Akinci et al., 2005). An ICU patient who has adequate pain relief may not be in need of sedatives. Therefore, by prescribing an individual sedation goal and systematically working towards an awake and alert patient, the patient will be able to cooperate and to evaluate the effect of his or her pain treatment.

In general, assessment and documentation of pain in the ICU is incomplete. The levels of pain are shown to be less frequently assessed than the type and quantity of drugs administered (Payen et al., 2007). Systematic pain evaluation by nurses in ICU patients should be routinely performed, and is related to a decreased incidence of pain and further associated with a shorter duration of MV and a lower rate of nosocomial infections (Chanques et al., 2006).

Pain management and sedation goals are appropriately defined by using valid and reliable tools and guidelines for sedation in intensive care. Clear sedation goals and mutual understanding of realistic individual pain treatment and sedation goals contribute to achieving a desired level of sedation for each patient (Jacobi et al., 2002; Schweickert & Kress, 2008). The overall goal is an awake and alert patient who is able to cooperate and mobilize, but a short-term goal where sedation is unavoidable because of critical illness is a part of ICU treatment. It is easier to assess and evaluate the patients' needs for

sedation on a continual basis if pain and sedation are routinely assessed and a daily sedation goal is set (Schweickert & Kress, 2008).

European studies investigating the use of analgesics showed that anesthesiologists mainly administered fentanyl as an analgesic (Soliman et al., 2001; Guldbrand et al., 2004). The route of administration was mainly reported as continuous infusions supplemented by bolus doses as needed. The use of pharmacological and non-pharmacological adjuvants were not reported in these studies, but these strategies are highly recommended in the SCCM' clinical practical guidelines (Jacobi et al., 2002). Based on the findings above there seems to be growing evidence for an association between pain management and sedation goals.

### **Pain management and defined sedation goals direct nurses and physicians in performing sedation management**

Pain management and sedation goals support the adequate assessment of sedation needs, and systematic evaluation has been reported to result in more precise dosing and reduced use of analgesics and sedatives (Muellejans et al., 2004; Akinci et al., 2005; Schweickert & Kress, 2008). In this way, it might be easier to make an appropriate choice of sedation, and pharmacological and non-pharmacological adjuvants. A scholarly and well designed nursing assessment of sedation needs can ensure enhanced patient outcomes, by guiding therapy to a targeted sedation level and maximizing benefit and minimizing harm related to the patients' experience of being sedated and critically ill (Brook et al., 1999; De Jonghe et al., 2005).

European studies investigating the use of sedatives showed that midazolam was mostly the preferred sedative among anesthesiologists, closely followed by propofol (Soliman et al., 2001; Guldbrand et al., 2004), and mainly administered as continuous infusions supplemented by bolus doses as needed. In 2008, the use of adjuvants was not focused on in studies reporting the use and the effect of analgesics and sedatives in mechanically ventilated patients in the ICU. The use of non-pharmacological adjuvants that may be helpful to comfort a confused or agitated patient is poorly described in studies, including in mechanically ventilated ICU patients.

## **Pain and sedation management influence how nurses intervene with patient treatment options.**

When adequate sedation is performed, the patient will receive the most appropriate interventions. Nursing and medical intervention is defined as immediate action based upon the need for sedation, reassessment when the peak effect is expected, and re-intervention if the sedation level is still unacceptable. The patients' ability to communicate and mobilize may be limited by extended sedation, and the clinicians' ability to interpret physical examinations, especially for neurological injured patients, may also be affected (Jacobi et al., 2002). The mental state in neuroimpaired patients may be due to the patients' physiological state or to sedation therapy causing unconsciousness, and it is important to be able to differentiate between these. Structured sedation approaches have been demonstrated to decrease unnecessary testing of ICU patients (Kress et al., 2000). These approaches have focused on the use of assessment tools, protocol-directed sedation, and daily interruption of analgesics and sedatives (DIS). The practice of DIS, which involves withholding all sedative medications once a day until patients are awake, can limit oversedation (Kress et al., 2000; Girard et al., 2008a). Girard et al (2008a) combined the use of DIS and daily spontaneous breathing trials with a wake up and breathing protocol. Patients in the intervention group spent more days without breathing assistance than the control group, fewer days in ICU and fewer in hospital, and had a lower mortality. Until 2008, the use of assessment tools was reported in published surveys more often than the use of protocols, and the reported use of daily interruption of analgesics and sedatives was low (Rhoney & Murry, 2003; Guldbrand et al., 2004; Martin et al., 2005; Egerod et al., 2006; Mehta et al., 2006).

## **Interventions by nurses and physicians lead to adequate pain relief, an accurate level of patient consciousness and tolerance, early detection of development of delirium and decreased side effects of medications**

Pain release in the ICU patient is achieved by continuous titration of individual and appropriate doses of analgesics, analgesic adjuvants, and by the use of non-pharmacological interventions. There is a close connection between this treatment and the

prescribed sedation level and the systematic assessment of patients' pain (Chanques et al., 2006).

Due to advanced medical treatment, mechanically ventilated patients lack control of their personal state of awakesness and comprehension. Nursing and medical interventions are those that facilitate the level of awakesness and comprehension and reduce patients' level of stress, based upon response measures throughout a continuum of consciousness. The purpose is to achieve a level of consciousness that makes neurological examination possible and the patient able to communicate. This includes the capacity to tolerate intensive care treatment without pain (Jacobi et al., 2002; De Jonghe et al., 2003).

Furthermore, in critically ill patients, nursing and medical interventions are those that contribute to achieving a state of calmness, ventilator synchrony and face relaxation (De Jonghe et al., 2003). Ventilator settings are adjusted so the patient is comfortable and when oxygenation and ventilation are complicated, analgesia and sedation are titrated. Facial grimacing and muscle tone is observed to assess and treat stress and discomfort (ibid).

Delirium measures can be implemented by systematic observation and assessment by nurses of changes in mental state or behavior in the patient, and checking, if possible, to see whether the patient is oriented to person, time, and place. Further treatment efforts should focus on assessing for the presence of known risk factors: "Both prevention and treatment should focus on the reduction and/or elimination of predisposing and precipitating factors. The theoretical goals of management are "to improve the patient's cognitive status and reduce the risk of adverse outcomes such as aspiration, prolonged immobility, increased length of acute care, institutionalization, and death" (ICU Delirium and Cognitive Impairment Study Group, 2008). Factors associated with delirium can be divided into host factors, factors of critical illness and iatrogenic factors (Girard et al., 2008b). Effective treatment of delirium is based on treatment of the patient's basic diagnosis. Severe illness processes, the need for O<sub>2</sub> supply and increased O<sub>2</sub> demand may lead to inadequate oxidative metabolism. This cascade leads to the development of delirium, explained by the inability to maintain ionic gradients causing cortical spreading depression (Maldonado, 2008a; Maldonado, 2008b).

The goal of treating delirium with medications is increased tranquilization and decreased sedation (Shinn & Maldonado, 2000), proving the important association between sedation and delirium. Repeated reorientation of patients, a non-pharmacological

sleep protocol, early mobilization activities, timely removal of catheters, use of spectacles, hearing aids, early correction of dehydration, and minimization of unnecessary noise/stimuli are all factors that contribute to preventing development of delirium (Girard et al., 2008b). In ICU patients, intravenous haloperidol is the preferred drug for the treatment of delirium (Jacobi et al., 2002; Maldonado, 2008a), but also atypical neuroleptics have been used (Schwartz & Masand, 2002; Pae et al., 2004). An association between the use of Haloperidol and lower mortality was documented in a retrospective study (Milbrandt et al., 2005). Randomized controlled trials have still not shown that haloperidol or any other antipsychotic medications are effective in treating delirium (Girard et al., 2008b).

An intervention based on the patients' level of pain, consciousness and tolerance and with a focus on prevention and treatment of delirium contributes to avoiding excessive or inadequate sedation and thereby minimizing pharmacological side effects. Pain and sedative interventions based on continuous assessment ensure that side effects that still might appear are detected early and are treated properly. Continuous reassessment of pain and sedation management, choices of treatment and interventions contribute to achieving the goal of an awake and cooperative pain relieved patient with minimum pharmacological side effects. However, in ICU, many patients will experience phases where communication is not easy because of critical illness and intensive care treatment. In these cases nurses and physicians are challenged in the clinical judgment of patients' analgesic and sedative needs. Making decisions about pain and sedation management in ICU constitutes an important aspect of this field, more than just the choice between the analgesic and sedative categories.

## **Clinical judgment**

Decision making and assessment strategies in ICU pain treatment and sedation are highly complex (Aitken, 2008). An interdisciplinary approach is recommended to achieve effective pain and sedation management (Sessler & Varney, 2008). Clinical judgment is an essential skill for practicing ICU nurses and physicians, and a requirement for making important qualitative distinctions. In ICU, a broad understanding and knowledge is needed to grasp and interpret the characteristics of the clinical situation rapidly, and to respond appropriately to patient symptoms. Nurses' and physicians' clinical judgment is an iterative process including multiple aspects of assessments, such as physiology, treatment options and impact of the treatment. In collaboration with pharmacists,



physicians prescribe adequate pain and sedation treatment dependent on relevant information from nurses and the patients' clinical signs.

Within nursing research, Tanner (2006) has developed a model that describes clinical judgment of experienced nurses (figure 2, page 34). The model was the result of a review of 191 studies describing "clinical judgment" and "clinical decision-making" in nursing. Tanner's Clinical Judgment Model (CJM) may provide guidance for more than expert nurses, e.g. others that focus attention on the field of ICU pain treatment and sedation. In the CJM, clinical judgment is defined as "an interpretation or conclusion about a patient's needs, concerns, or health problems, and/or the decision to take action (or not), use or modify standard approaches, or improvise new ones as deemed appropriate by the patient's response" (Tanner, 2006; p.204). Ideally, clinical judgment in ICU pain and sedation management includes frequent, routine assessments with reliable, valid instruments, assessment-based interventions, reassessment soon after an intervention, and further intervention if necessary (Jacobi et al., 2002; Schweickert & Kress, 2008).

In the following, the four aspects that direct the clinical judgment process among nurses in Tanner's model are exemplified in relation to experienced nurses' clinical judgment in the ICU. *Noticing* is the nurses' initial grasp of the critical setting – a function of their expectations of the patient's acute severe illness. What nurses notice is constituted by their knowledge of specific details related to the complexity of the ICU patients' situation and patterns of responses, and their experiences and value perspectives. Knowing the patient and his or her family is described as central in a nurse's capacity for clinical judgment (Tanner et al., 1993). The *interpretation* of clinical situations is founded on different reasoning patterns and leads to an appropriate *response*. In our case, the recognition of the ICU patient's pattern of response to pain and pain treatment and the need for sedation shapes the nurse's interpretations. Assessment tools may support nurses in describing their judgment. To be able to recognize the patient's need for relief and offer adequate treatment at all times, intensive care nurses build multifaceted systems by linking a broad range of cues and by applying different reasoning patterns (Ebright et al., 2003). Discriminating between levels of pain, consciousness and discomfort in general and finding the right balance with analgesic and sedative treatment is difficult in patients with a reduced ability to communicate. The nurses' previous experiences of care partly direct their assessment and interventions, defined by Tanner (2006, p. 204) as "What the nurses bring to the situation". For example, nurses' attitudes toward pain and values for

providing comfort are shown to influence their decisions about pain treatment and their use of clinical practice guidelines for administration of sedation (Greipp, 1992; McCaffery et al., 2000; Slomka et al., 2000).

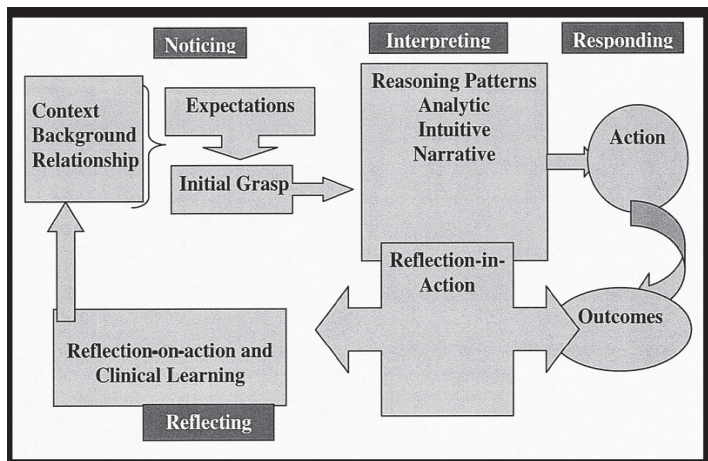


Figure 2 Clinical Judgment Model (Tanner 2006)  
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Systematic assessment can, however, help to clarify the patient’s symptoms, and to help the nurse to differentiate between side effects of potent medications and psychological reactions to being seriously ill. Analytical processes such as hypothetical-deductive reasoning patterns may support different hypotheses, or the nurse may respond intuitively to a given situation. In an ICU situation, this may be to administer an analgesic instead of sedative based on interpretation of previous evaluations and pain level and sedation scores. A significant component in the CJM is *reflection*. *Reflection-in-action* refers to a nurse’s ability to read the patient’s response to medical treatment and nursing interventions. *Reflection-on-action* refers to viewing the situation afterwards as an opportunity for clinical development and learning (Schön, 1983; Tanner, 2006). Confirmation by assessment measures that this intuitive response was correct consolidates the nurse’s position when it comes to the reflection-in-action component of CJM. Such reflection requires the skill to combine complex relationships, and is needed to read the patients’ responses to nursing and medical intervention in the ICU. Viewing the situation afterwards during reflection-on-action closes the CJM circle and causes the nurses critically evaluate their actions. Tanner’s explanation of “reflection” is in

agreement with the description of the act of reflecting-in-action and on-action by Schön'. His illustration of these two concepts can be viewed as the ICU nurses ability to describe how they think when they are dealing with a situation, and how they make use of a repertoire of personal knowledge and experiences and spend time exploring why they acted as they did (Schön, 1983).

Based on the evidence supporting the model (figure 1, page 25), we decided to intervene in and support the processes of analgesia and sedation that nurses and physicians use in the clinical ICU field in order to achieve a balance between adequate pain treatment and sedation in mechanically ventilated patients, and to recognize delirium at an early stage. The methods, data collection and data collected will be presented in chapter 4. The instruments implemented, implementation strategy and the educational session will be described, followed by a description of the data analysis. Validity and reliability is discussed, and the chapter closes with ethical and methodological considerations.

## **Methods**

The empirical part of the dissertation includes two quantitative studies (study I and II), and one qualitative study (study III).

### **Study I**

#### **Design, sample and data collection**

A cross-sectional national survey with a descriptive and comparative design, using postal self-administered questionnaires was conducted in Autumn 2007. Two previous surveys in Denmark formed the basis for the questionnaire (Christensen & Thunedborg, 1999; Egerod et al., 2006). Additional questions were developed to establish which factors determined the clinician's assessment and intervention when deciding on sedation and analgesia. The survey included 8 sections: 1) demographic data; 2) formal sedation practice; 3) questions about where, and by whom, decisions were made regarding the patient sedation level; and 4) indications for sedation and procedures for the sedation and analgesia of patients with different categories of disease. Section 5, 6 and 7 covered perception of effects and types of medication and administration, and frequencies of side effects. Finally, the use of sedation assessment tools was surveyed.

Our intention was to attain a thorough picture of Norwegian pain treatment and sedation in clinical practice. Our targets were therefore nurses and physicians working at the bedside who dealt with pain and sedation in ICU patients on a daily basis and represented ICUs treating mechanically ventilated patients for more than 24 hours. Nurse leaders representing the Norwegian ICUs included were asked to recruit one intensivist/anesthesiologist and one intensive care nurse with a minimum of 2 years experience from the ICU on one specific day. All 54 Norwegian ICUs were represented with 53 nurses and 47 physicians, giving a response rate of 93%.

### **Study II**

After having mapped and identified clinical assessment practices among ICU clinicians, the next logical step was to intervene by implementing pain, sedation, and confusion assessment tools.

## **Implementation strategy**

In 2008, adequate evidence was available to demonstrate that pain and sedation protocols and assessment scales could help nurses and physicians with decision-making (Brook et al., 1999; De Jonghe et al., 2000a; Jacobi et al., 2002b; Girard et al., 2008a) and availability of consistent goals and terminology to describe the level of sedation in ICU patients had been narrowed down (Egerod, 2002). Despite being strongly recommended, pain and sedation protocols and scales were still being scarcely used in ICUs (Soliman et al., 2001; Guldbrand et al., 2004; Martin et al., 2005; Mehta et al., 2006). Low adherence might be explained by lack of education on analgesics and sedatives, poor symptom management, and an absence of multidisciplinary discussion of clinicians' attitudes toward sedation of mechanically ventilated patients (Gelinis et al., 2011). In general, implementation strategies often fail when introducing clinical guidelines into routine daily practice, and no single strategy has proven to be superior (Grol & Grimshaw, 2003). Steps that enhance the process of bringing knowledge into action are illustrated by Graham et al (2006). They point to the need for attention to knowledge creation combined with useful tools that facilitate implementation of tailored knowledge (Graham et al., 2006). Also the dynamic processes illustrated in their "Knowledge to action model" with all phases that influence each other had consequences for study II and III in this dissertation. Tailored knowledge about valid and useful assessment and treatment of pain and sedative needs was adapted to fit the local context in both of the ICUs. The evidence of the effect of systematic assessment of pain and sedative needs was convincing, and easy to communicate to the nurses and physicians at both sites.

Several valid pain, sedation and confusion instruments were available, and a selection was performed by the principal researcher. Probable barriers to implementation were discussed and identified by a group representing both ICUs. We started by gaining the leaders' agreement to the significance of guidelines and use of tools, and we agreed upon general terms for the educational sessions. According to the "Knowledge to action process" described by Graham et al. (2006), the implementation process lasted beyond the period of data collection. After the data collection period we continued to monitor the knowledge use, evaluate outcomes, and sustain knowledge use – which is connected back to the first step in the knowledge translation cycle. However, the last steps including the need to monitor and sustain knowledge use and to evaluate outcomes were only in an early phase when we finalized the implementation of the tools. The time needed for these "follow-up" steps is underestimated, and is of vital importance (Graham et al., 2006).

## **Instruments implemented**

One pain assessment tool, two sedation assessment tools and one delirium assessment tool were implemented in study II. Pain assessment is necessary to complement the assessment of sedation and confusion. The decision regarding what pain assessment tool to use was difficult. Neither of the units documented pain on a routine basis. However, staff in both ICUs was reluctant to use a complicated pain assessment tool in addition to the sedation assessment tools implemented. Also the validity, reliability and feasibility of pain behavior assessment tools were still controversial at study onset in January 2009 (Ahlers et al., 2008; Li et al., 2008). The NRS for pain assessment is not the best tool for a sedated ICU population, but after some consideration, it was chosen as the most suitable for the purpose when designing the current study. Both hospitals implemented the Richmond Agitation and Sedation Scale (RASS). Among validated sedation assessment tools, the RASS is used worldwide. The instrument is easy to use and demonstrates acceptable validity and reliability (Sessler et al., 2002). Hospital 1 also implemented the Adaptation of the Intensive Care Environment (ATICE), as they wanted to test both instruments before taking a final decision on the sedation assessment tool. The ATICE was designed for the purpose of administration of sedation and analgesic to facilitate mechanical ventilation, and to guide titration accurately when trying to gain an individual level of tolerance and consciousness (De Jonghe et al., 2003). ATICE shows acceptable validity and reliability, but more variables are requested to prescribe, assess and document than for the RASS.

The Confusion Assessment Method in the ICU (CAM-ICU) was chosen as the delirium monitoring instrument in study II. This assessment tool is an adaption of the delirium tool Confusion Assessment Method (Inouye et al., 1990), extended to the population of MV patients. CAM-ICU is thoroughly validated in several languages and tested for reliability in different ICU settings (Ely et al., 2001b), and was one of two validated delirium tools available in 2008. It also integrates RASS in the procedure of scoring the patient, making it easier to use in the clinical field.

A questionnaire was developed to characterize the units' assessment and documentation routines related to pain treatment and sedation before and after the implementation of the tools. The questionnaire consisted of seven statements; five based on key variables from the RASS and the ATICE, one statement about pain, and one about confusion. The statements had four answer options: never, seldom, often and always.

Four respondents pilot tested the questionnaire and their comments or recommended changes were implemented in the final version.

The RASS, ATICE and the CAM-ICU were translated into Norwegian using a forward-back translation procedure (Wild et al., 2005). The phases of translation for the instruments according to Wild (2005) were as follows:

1. First, written permission was gained from all of the tool owners.
2. The forward translation was performed by a group of three experienced ICU nurses and one anesthesiologist who translated the tools from English to Norwegian.
3. The group met and compared and merged the forward translations.
4. The back translation was performed by a professional translator, who retranslated the final Norwegian version into English, without seeing the original version.
5. The group who prepared the Norwegian version compared the retranslation with the original version, and decided on a back translation version.
6. The retranslated Norwegian version was sent to the owner of the tools for approval and was accepted in December 2008.
7. Cognitive debriefing was finally conducted by the group involving critical identification of words, concepts and clarifying unclear aspects.
8. Proofreading was conducted by the whole group who performed a final review of the translation.

Two electronic dictionaries were used, - “Clue” and “Wordnet” and for definitions we used one medical reference work (Wyller & Sveen, 2002).

### **The educational session**

All intensive care nurses and physicians at both sites were invited to a 3-hour pain, sedation, and delirium assessment day-time course that was provided by the principal investigator (HW). Background information about the assessment tools and the Norwegian versions of the NRS for pain measurement, the RASS, the ATICE, and the CAM-ICU were distributed to all the nurses and physicians at both sites. We performed 5 educational sessions at Hospital 1 and 3 at Hospital 2. The protocol instructing how to perform the assessment and documentation was explained in detail (figure 3).

1. Nurses document patient's pain level at least every 8 hours in all patients receiving analgesics or sedatives.
2. Physicians prescribe each patient's level of sedation for the next 24 hours during their morning rounds.
3. Nurses document each patient's level of sedation within 2 hours after the beginning of the shift and then at least every 8 hours. Delirium scores are documented once every 8-hours shift.
4. An observed mismatch between prescribed and observed level of sedation triggers nurse intervention, which is recorded in the individual charts either as a dose adjustments or other actions.
5. Procedures known to increase pain and discomfort are preceded by dose adjustments of analgesics and sedatives.
6. After every intervention, the nurses evaluate and document pain and sedation

Figure 3 Protocol for pain, sedation and delirium assessment

In the educational sessions, all of the tools were presented and discussed, and their use was explained using different patient cases as examples. The six sequences in the protocol were explained, and the order of assessment was emphasized. The participants were trained in the assessment process, starting with pain scoring followed by sedation scoring. If the patient responded to verbal stimuli, the CAM-ICU was rated at the bedside by the nurse using the Harvard CAM-ICU flowsheet. The scores were documented on the patient's chart as digits for the pain and sedation assessment tools, and as "CAM-ICU-positive", "CAM-ICU-negative" or "unable to be assessed" (UTA) for the confusion assessment tool. An NRS score  $<3$  was defined as no pain. According to the protocol, procedures known to increase patient pain and discomfort should be preceded by dose adjustments of analgesics. After every intervention, the nurses were expected to evaluate and document pain and sedation levels. When the expected peak effect of analgesics or sedatives or other pain and sedation interventions has been attained, reassessment should be performed, followed by re-intervention if the reference or required level is not achieved. Because pain, sedation level and, especially, delirium symptoms fluctuate, regular scoring with all instruments was performed by the nurse at the bedside. Because of lack of time, most physicians attended a 1-hour course in addition to individual counseling at the morning round on how to prescribe the level of sedation for the next day. The tools were implemented immediately after the educational sessions. During the study period, three ICU nurses at Hospital 1 and two ICU nurses at Hospital 2



were available in the ICUs, with repeated the use of the instruments in short sessions and daily follow-up of the clinicians. The level of sedation was prescribed daily by the physicians and documented by the nurses according to the protocol. Individual counseling was given on how to prescribe during the morning rounds, based on the RASS and ATICE scores documented in the previous 24 hours.

### **Design, sample and data collection**

In intensive care, a clear description of phenomena is needed before causality can be examined. The purpose of the descriptive design in study II was to describe pain treatment, sedation and the identification of delirium as they naturally happen, and in that way identify possible problems with, and give explanations for, current pain treatment and sedation practice (Polit & Beck, 2004). In December 2008, baseline variables of prescription and documentation practice were prospectively collected from the ICU working sheets of mechanically ventilated patients aged 18–80 years, intubated or mask-ventilated on admission, and with an ICU stay > 48 hours at two sites, Hospital 1 (H1) and Hospital 2 (H2). The variables were 1) Rate of sedation prescriptions; 2) Registration of pain and sedation levels; and 3) Quantities of analgesics and sedatives administered to 39 patients on 281 ICU days. After an educational session in January and February 2009, we conducted an implementation study at the same two sites between April and August 2009 introducing four assessment tools. Prospective collection of pain, sedation and delirium data were collected from ICU working sheets of 139 mechanically ventilated patients who had 958 patient days at H1 and H2, aged 18–80 years, intubated or mask-ventilated on admission, and with an ICU stay > 48 hours. For each patient, data were collected from day 1 until ICU discharge or death. Scores generated from the use of the assessment tools implemented were included. Chart audits were regarded as an effective method of measuring adaption of the tools (Elliott et al., 2006).

The 145 ICU staff in the educational sessions received a 7-item questionnaire at the start and the end of study II. The questionnaires were anonymised, but coded with the intention to pool the answers before and after the implementation of the tools. They were administered 15 minutes before and collected in at the start of each educational session. 12 weeks after implementation of the tools, the nurses and physicians received the same questionnaire at the afternoon shift or in their mail box. Research assistants at both sites gathered the answers. Only verbal reminders were used to collect these data.

## **Study III**

### **Design, sample and data collection**

The aim of study III was to evaluate the perceived usefulness of the tools implemented. To collect data we used an exploratory and descriptive qualitative approach, conducting focus group interviews (Krueger & Casey, 2009). Focus group interviews allow participants to express ideas, emotions and contradictions in their own words (Krueger & Casey, 2009). Even though both nurses and physicians were educated about the tools, bedside nurses were those who assessed the patients and documented the scores by the use of the tools many times a day. We therefore assumed that experienced ICU nurses would contribute to a detailed discussion and we also expected that their clinical judgment based on years of experience would help differentiate between aspects of the influence of using tools in the assessment of pain, sedation and confusion. Focus group interviews also facilitate interactivity and dialogue among participants and stimulate more spontaneous expressive and emotional views than individual interviews (ibid). A total of 14 ICU nurses each with more than 5 years ICU experience were recruited by the head nurse at both sites. The participants were assigned to two focus groups, one per ICU. Their experiences were studied over time, first at the beginning of April and then the same groups were interviewed 12 weeks later, to capture all nuances in their use of the tools.

Table 2 Overview of inclusion criteria, sample and tools implemented in the studies

	<b>Inclusion criteria</b>	<b>Sample</b>	<b>Tools implemented</b>
<b>Study I</b>	One ICU nurse and one anesthesiologist representing each of the 54 Norwegian ICUs treating mechanically ventilated patients for >24 hours	53 ICU nurses and 47 anesthesiologists represented all of the 54 Norwegian ICUs	
<b>Study IIa</b>	<p>1. Documented data before and after implementation from ICU working sheets from patients aged 18–80 years, intubated or mask-ventilated on admission and with an ICU stay &gt; 48 hours, were included.</p> <p>2. Nurses from both ICUs responding to a questionnaire before and after the implementation of tools</p>	<p>Documented data on prescription and documentation practice</p> <p>1) Rate of sedation prescriptions</p> <p>2) Registration of pain and sedation levels</p> <p>3) Quantities of analgesics and sedatives administered to a sample of 39 patients corresponding to 281 ICU days before, and 139 patients corresponding to 958 ICU days after implementation.</p> <p>55 nurses responded to the questionnaire before and after the implementation of tools</p>	<p><u>For measuring pain:</u> The Numeric Rating Scale (NRS)</p> <p><u>For sedation assessment:</u> The Richmond Agitation and Sedation Scale (RASS) and the Adaptation of the Intensive Care Environment (ATICE) instrument</p>
<b>Study IIb</b>	Confusion assessment scores from at least 120 ICU patients included in study IIa	139 patients were scored with the confusion assessment tool	The Confusion Assessment Method in the ICU (CAM-ICU)
<b>Study III</b>	Experienced ICU nurses working at both study sites during the implementation period	14 ICU nurses in two groups from each study site	

## **Data analysis**

### **Study I and II**

The assumptions required for the methods of statistical analysis were checked and verified in studies I and II (Altman, 1991; Polit & Beck, 2004). Data were analyzed using the SPSS version 16.0. One challenge in our analysis in study II was that the duration of the patients' stays in hospital varied. To conduct a descriptive analysis of the pain and sedation scores for each patient, we had to aggregate data based on a daily mean score. In a next step, we calculated frequencies and dispersions. By the use of aggregation of data, the pain and sedation scores were not presented chronologically as they appeared in the clinical situations. In the delirium study (study IIb) patients were categorized as positive if scored as CAM-ICU-positive at least once; as negative if scored as CAM-ICU-negative at least once and never scored as CAM-ICU-positive; and as UTA (unable to be assessed) if no valid CAM-ICU status (positive or negative) could be scored at any time. These data were also aggregated when preparing descriptive statistics, based on a daily minimum score (CAM-ICU-positive). For categorical data (studies I and II), group comparisons were performed using Chi-square tests for independent groups and McNemar's test for dependent groups. Differences between continuous variables were tested with the t-test. The association between delirium and independent variables (ICULOS, age, sex, subspecialty, and medication use) was analyzed using forward logistic regression.

### **Study III**

In study III the recorded and transcribed data from the four interviews were interpreted using a systematic classification process of coding and identifying themes or patterns. The transcribed text consisted of a total of 101 pages. The text was first read through to gain an overall impression, and then the text was read analytically several times. Three levels of coding were selected as appropriate, starting with the examination of the data line by line at Level 1. Text was broken down to meaning units, and at Level 2 compared and conceptualized into categories. We defined cluster categories for coded data to condense the information from Level 1. On Level 3, we further condensed the information into higher level interpretations to form central themes emerging from the categories (Graneheim & Lundman, 2004; Kvale & Brinkmann, 2009). Themes were

defined as elements that recurred regularly in the data that provided meaning and identity to an abstract entity (Polit & Beck, 2004). The themes were analyzed for interpretation of meaning by being more critical, going beyond the manifest meaning, and to search for the underlying meaning of the text. This method of analysis complies with Graneheim and Lundman (2004) who consider categories as the text's manifest content, and themes as the expression of the latent content.

## **Validity and reliability**

### **Study I**

The survey questionnaire was tested. The pilot testers reported that the questions were easy to answer and relevant. One additional question on following the prescribed level of sedation during day and night was requested. Reliability was also ensured because of all of the participations had long experience with ICU patients and daily clinical work at the bedside. We expected that these nurses were the most credible informants in the study. Their experiences were at the level of being able to assess complex situations without being disturbed by high technology challenges. In addition, their daily bedside functions with ICU patients ensured a correct picture of their unit's current practice of pain and sedation management.

### **Study II**

To ensure validity and reliability in study II we implemented validated tools and made sure that all nurses and physicians received sufficient information about the tools. Expert nurses were available to answer questions during the whole study period. The staff was obliged to participate in thoroughly prepared educational sessions carried out during daytime working hours. Different methods were used combining PowerPoint presentations and oral plenum discussions, including two pauses during the 3-hour session. After each session, the principal investigator and the research assistants evaluated the educational sessions with the intention of improving the participants' understanding of the connections between pain treatment, sedation and delirium.

### **Study III**

To enhance rigor in study III, the analysis process was described in great detail. In the analysis, reliability was enhanced by discussing the similarities within and the differences between attributes and concepts related to the assessment of pain, need for sedation, and

confusion, so that agreement was achieved on which categories were built. Consensus among the researchers was attained by discussion of the development of condensed meaning units and codes. The reliability of coding was strengthened in this way (Barbour, 2005; Elliott et al., 2006). A combination of skills held by the observer and the moderator contributed to the reliability of the information gained in the interviews and the analysis. The researchers discussed and compared the interpretations and conclusions during the analysis process to strengthen the trustworthiness of the research findings.

## **Ethical considerations**

Approval by the Regional Ethics Committee was waived for the national survey (study I) because data were not related to individual patients. Participation in the study was voluntary, and informed consent was implied by the return of a completed questionnaire. Studies II and III were approved by each hospital's institutional review board and The Regional Committee for Medical Research Ethics [Approval No. 6.2009.414]. Participation in the survey of nursing staff before and after implementation was voluntary, and informed consent was given by returning the completed identity-numbered questionnaires. The focus group interview (study III) was approved by the Norwegian Social Science Data Services. All of the studies were conducted in accordance with the Declaration of Helsinki (World Medical Association, 2009).

## Results from the empirical studies

The results from the empirical studies involving the four papers are summarized in this chapter. Table 3 presents an overview of the research questions, aims, and papers:

Table 3 Overview of the research questions, aims, and papers included in the dissertation

Research question (RQ)	Empirical study	Aim	Paper
RQ2: What characterizes Norwegian nurses' and physicians' knowledge, practices and attitudes related to pain treatment and sedation in intensive care?	Study I	To describe the practice and cooperation among Norwegian ICU nurses and physicians in the daily use of procedures for analgesia and sedation in mechanically ventilated patients.	<b>Paper 1:</b> Analgesia and sedation of mechanically ventilated patients - a national survey of clinical practice
RQ3: In what way will the implementation of pain and sedation assessment tools influence how physicians' prescriptions and nurses' documentation of patients' pain and sedation levels are registered?  RQ4: What is the incidence of delirium among ICU patients in two Norwegian ICUs?  RQ5: How useful is the CAM-ICU in our ICU population?	Study II	1) To describe the effects of introducing a systematic approach to pain and sedation management in the ICU  2) To register nurses' opinions regarding the importance of the selected tools for the quality and safety of the routines after the implementation  3) To study the incidence of delirium by the use of a confusion assessment method for the ICU	<b>Paper 2:</b> Improving the systematic approach to pain and sedation management in the ICU by using assessment tools  <b>Paper 3:</b> The incidence of delirium in Norwegian intensive care units; deep sedation makes assessment difficult
RQ6: What is the nurses' perceived usefulness of instruments that were implemented to assess patients' analgesic and sedative needs?	Study III	To examine how nurses experienced their ability to perform clinical judgments of patient pain and sedative needs after the implementation of the four assessment tools and how the tools influenced these judgments.	<b>Paper 4:</b> Intensive care pain treatment and sedation: Nurses' experiences of the conflict between clinical judgment and standardized care: An explorative study

## **Study I**

The national survey reached a response rate of 93%. Only one third of the nurses and physicians in the national survey reported routine pain monitoring. Half of the departments titrated sedation according to a scoring system, but written pain treatment and sedation protocols were not routinely used in Norwegian ICUs. Fentanyl and morphine were reported as the most used analgesics, while the most commonly used sedatives were propofol and midazolam. The majority of respondents was concerned about side effects of analgesics and sedation leading to gastrointestinal problems, and circulatory instability and delayed awakening. In general, side effects were reported to occur more often during the use of sedatives than during the use of analgesics while patients were on MV. Nurses and physicians agreed upon the same top three indications for sedation: patient tolerance of ventilation, tolerance of medical and nursing interventions, and patient symptoms such as dyspnea, anxiety or pain.



## Study II

Patient demographics and treatment data from study IIa (Paper II) and IIb (Paper III) are shown in Table 4.

Table 4 Demographic variables (139 patients from both hospitals)

Variables		Hospital 1 N=101	Hospital 2 N=38	Both hospitals N=139	p- value*
Age in years, mean (SD)		54.0(14.0)	56.7 (2.7)	54.8 (15.0)	0.144
	<65, n (%)	74 (73.3)	24 (63.2)	98 (70.5)	
Gender	Female, n (%)	40	12	52 (37.4)	0.168
Mechanically ventilated from day 1, n (%)		95 (94)	38 (100)	138 (99.3)	0.547
SAPS II score, mean (SD)		42.2 (16)	42.1 (16.3)	42.3 (15.92)	0.325
ICU LOS	Median (range)	4 (1-35)	6 (1-54)	5.0 (1-53)	
	Mean (SD)	6.15 (6.2)	8.84 (9.5)	6.9 (7.4)	0.036
In-ICU mortality, n (%)		14 (13.9)	11 (28.9)	25 (18.0)	0.006
Subspecialty:	Heart and lung medicine, n (%)	34 (33.7)	14 (36.8)	48 (34.6)	
	Other medicine, n (%)	20 (19.8)	7 (18.4)	27 (19.4)	
	Neurosurgery, n (%)	26 (25.7)	1 (2.7)	27 (19.4)	
	Other surgery, n (%)	21 (20.8)	16 (42.1)	37 (26.6)	0.022
Airway device:	Tracheotomy, n (%)	53 (52.5)	17 (44.7)	70 (50.4)	
	Oral intubated, n (%)	39 (38.6)	15 (39.5)	54 (38.8)	
	Mask ventilated, n (%)	3 (3)	6 (15.8)	9 (6.4)	
	Extubated, n (%)	6 (5.9)	0	6 (4.4)	

\*Pearson's chi-square test

SAPS, Simplified Acute Physiology Score

In study II a, before the implementation of the tools, pain was usually documented using descriptive text in the nursing documentation, and was registered on only 6/281 ICU working sheets (2.1%). Data describing the relationship between prescribed and documented sedation levels was unavailable for 97 % of the days at H1 and 45% at H2. This might be explained either by the lack of a written prescriptions or missing documentation of sedation levels during the day. In general, the prescribed doses of medications covered wide ranges. Fentanyl was the most frequently prescribed analgesic and propofol and midazolam the most commonly used sedatives.

After implementation, the NRS pain scores were documented with a mean of 2.5 times per day for the patients in whom pain was assessed. A defined sedation level was prescribed for 70% of the total number of patient days. For patients in whom sedation levels were scored, the mean frequency of documentation was 3 times per day. Written prescriptions or documentation of sedation levels were missing for 58.5% of the 958 patient days. This resulted in events of both prescription and documentation of sedation levels for only 41.5% of the patient days. A match between physicians' prescriptions of sedation levels and documented sedation scores occurred on 27.2% of the days. Pain and sedation scores after adjustments made in response to procedural pain or discomfort were not documented.

The median NRS pain score was 0.8 (range 0–5). The patients had a documented pain level higher than 5 on the NRS in 18/824 registrations. 49% of the patients self-reported pain at least once during their stay at the ICU. When the patients were unable to communicate their pain, the nurses made the assessments on their behalf. Almost no patients had a pain level scored higher than 5 on the NRS. An absence of documented pain levels were reported for 19.7% of the days. Patients whose pain levels were not documented were statistically significantly less likely to have a documented RASS value ( $p < 0.001$ ). For 108 patients, all NRS scores were less than 3. The mean RASS level for the patients included was  $-2.27$  ( $SD = 1.57$ ), ranging from  $-5$  to  $0$ . No differences in sedation levels occurred between patients in the two ICUs ( $p = 0.12$ ). The most common pharmacological treatment was a combination of continuous and bolus doses of analgesia and sedation, mainly fentanyl and propofol respectively. After the implementation of the tools the nurses were still allowed to titrate continuous and bolus doses within wide ranges.

In study IIb the incidence of delirium was 23%. Forty-one patients were scored as UTA at all timepoints. On 394/858 (45.9 %) of the study days patients were scored as CAM-ICU-negative. The median number of coma- and delirium-free days among 137 patients was 1 day (IQR 0-3 days). The distribution of CAM-ICU status during the patients ICU stay showed that the patients who tested positive on the CAM-ICU, were scored as CAM-ICU-positive mainly for 2 days or less. The ICU length of stay was the only significant predictor for a positive CAM-ICU score ( $p < .016$ ). The subtype of delirium based on concomitant RASS-score showed that 81.2% of the CAM-ICU-positive patients were classified as having hypoactive delirium, 9.4 % hyperactive delirium, and 9.4 % mixed delirium.

In study II, a completed questionnaire from the evaluation of the unit's assessment routine of patients' need for analgesics and sedatives were supplied by 55/145 nurses, both before the training session and at the end of the implementation period. After implementation of the NRS, RASS, ATICE and CAM-ICU, significant improvements were seen for all 7 variables scored by the nurses. The greatest improvements were seen in the assessment of confusion, ventilator synchrony and face relaxation (table 5).

Table 5 Mean difference between nurse assessments of 7 patient variables before and after implementation of the assessment tools (55 nurses)

Variables <sup>a</sup>	Mean difference	95% Confidence interval	p-value <sup>b</sup>
Awakeness and comprehension	0.52	0.30–0.74	<0.001
Calmness and agitation	0.69	0.49–0.89	<0.001
Ventilator synchrony	0.88	0.63–1.12	<0.001
Face relaxation	0.80	0.56–1.05	<0.001
Overall sedative needs	0.39	0.18–0.61	<0.001
Pain	0.64	0.43–0.86	<0.001
Confusion	0.93	0.71–1.15	<0.001

<sup>a</sup> Four answer categories; never=1 and always=4, <sup>b</sup> Paired T-test.

### Study III

Four themes evolved as central for the ICU nurses participating in the focus groups:

1) Balancing clinical judgment and the use of tools; 2) Improvement of collaboration, documentation and goal achievement; 3) Enhanced evaluation of the patient's response; and 4) Emphasis on the ICU patient's characteristics.

The ICU nurses in our study agreed upon the main benefits of using measurement tools for the assessment of pain, sedation and confusion. The use of the tools also supported common goals of achieving continuity and consistency in treatment, and was described as especially helpful in the early identification and interpretation of symptoms. This influenced the nurses' choice of type and time of intervention. The clinicians in our study reported that the tools contributed to more nuanced assessments and to distinguishing better between patients conditions. By scoring the patient's condition, the nurses were encouraged to determine exact levels and to respond to a current score, compared to without using tools.

Despite their recognition of the usefulness of the tools in the interviews, greater importance was almost always still attached to personal knowledge and experience. The

nurses' experience guided their assessments and interventions to a great extent. During the second interviews, the nurses reported no negative influence of the tools on their judgment, despite initial concerns that they would be too restrictive. They were less skeptical and did not feel limited by the tools, but still relied heavily on personal judgment when deciding on analgesic and sedative treatment, viewing the tools as a contributory factor in decision-making.

The theoretical perspective that guided the focus group study was Tanner's Clinical Judgment Model (CJM) (Tanner, 2006). After implementation of the tools, *reflection-on-action* – defined as viewing the situation afterwards as an opportunity for clinical development and learning (Tanner, 2006) – was perceived as easier. Documented scores were discussed when deciding on both short-term and long-term patient goals, and the nurses felt that sharing thoughts on evaluation of patients was a dynamic way of working. Both pain and confusion were considered easier to identify and treat when assessed systematically. The feeling of having underestimated pain earlier and that pain assessment now had gained more focus was stated by two nurses. The benefit of distinguishing between pain and other symptoms was emphasized as well, and the use of the tools provided an opportunity for clinical development and learning.

Assessment by the use of tools is not straightforward, and this may explain why our nurses were still cautious in their attitude towards the assessment tools. In both our groups and across interviews, the improvement in collaboration perceived to be due to the tools applied mainly to the nursing group. The participants stressed the importance of including both nurses and physicians in the implementation of the tools.

## **Discussion**

In this section methodological considerations will be described and the findings from study I, II and III will be discussed in the light of the research questions.

### **Methodological considerations**

#### **Study I**

By using questionnaires as a single source of information in study I, we may not have received sufficient information about the use of protocols and medications for analgesia and sedation in Norwegian ICUs and the degree of cooperation between nurses and physicians in using them. The respondents interpreted questions individually, and there may have been categories that were absent, thus preventing respondents from reporting their actual practice. Free text items were not included, and this may have hindered the respondents in clarifying answers. However, we achieved a high response rate of 93%, and all of the Norwegian ICUs were represented by either an ICU nurse and/or a physician. This may have strengthened the attained data.

#### **Study II**

In the very early planning phase of this dissertation we outlined a randomized controlled trial (RCT) aimed to study the effect of two different pain and sedation regimes. RCTs represent the strongest design to measure effects of interventions (Polit & Beck, 2004). Because of the lack of use of systematic assessment tools at both study sites, we were not able to collect documentation of patients' level of pain, sedation or confusion. Consequently these constraints made an experimental approach impossible at that moment, and a descriptive design was chosen.

Focusing only on written documentation in study II provided a limited description of pain and sedation practice. Important nuances in clinical judgment may not have been covered. First, the documented scores may not have agreed with what the patients were actually experiencing. Second, the decision processes were influenced by the context and the culture surrounding the patients. The use of direct observation methods might have added important information about both interdisciplinary and multidisciplinary pain and sedation management processes. How did they decide the pain level of the non-communicating patient? Did they capture the patients' alterations in both pain and

confusion throughout the whole day? A collection of data from the patients after critical illness may also have strengthened our data. We did not study such phenomena. However, the overall intention in this study was that the use of assessment tools in patients who were able to be awake and alert would enable them to express their needs by themselves. For patients unable to communicate, we registered their analgesic and sedative needs and incorporated the documented scores in both the short-term and long-term treatment strategy. By focusing on a systematic approach and to achieve the goal of an awake and alert patient, we intended to avoid excessive use of sedation.

In studies I and II, we used a descriptive design aimed to identify current practice before and after implementation of the tools. By using this descriptive design, the outcomes observed may have been biased by factors other than the tools implemented. Protection against bias was achieved through:

1) Linkages between conceptual and operational definitions of variables.

The main concepts and operational definitions in our study are outlined in chapter 3. In study I, we sought to achieve a real picture of Norwegian pain treatment and sedation in the ICU. However, the meaning of sedation was not outlined, and there was a risk of classifying pain and sedation as one concept and in this way introducing bias into some of the questions in the survey. In study II, we focused on the differentiation between the concepts of pain, sedation and confusion in the educational sessions. We discussed the meaning of the concepts but did not test the participants' knowledge afterwards. In addition we were not able to include the physicians in all these discussions, and the lack of multidisciplinary cooperation before implementation may have weakened the clinical processes of pain and sedation treatment.

2) An appropriate sample and adequate sample size.

The sample in both study I and II seems appropriate. Highly experienced bedside ICU nurses and physicians are the most able to give a correct picture of the ICU clinical practice. The sample size in study II covered adequate documentation from patients and an adequate number of treatment days, but as an implementation study, we would have gained an even more complete answer about the effect of introducing a systematic approach into ICU by following up the documented use of the tools for a longer time. The intention of the questionnaire before and after the educational session was to include both nurses and physicians. Because of the low physician attendance at the 3-hours sessions, and because the nurses were the main group using the tools in daily assessments and documentation, we assumed that we achieved sufficient information by concentrating on

this group. In retrospect we came to a different conclusion, and acknowledge that the physicians may have contributed with important data by participating in the questionnaire study.

### 3) The use of valid and reliable tools.

The NRS is not reliable for pain measurement in non-communicating ICU patients. However, the use of the NRS forced the nurses to make decisions on whether the analgesic doses were too high, too low or appropriate, based on a complex assessment. This approach was strengthened by combination with valid sedation assessment scales. Both the RASS and ATICE, and the CAM-ICU have been validated in mixed ICU populations and are regarded as highly reliable (Sessler & Varney, 2008). An instrument is reliable to the extent that it's measures reflect true scores, i.e. the extent that errors of measurement are absent from scores obtained (Polit & Beck, 2004). The nurses felt that the CAM-ICU was complicated to apply, and the number of patients they were unable to assess may have been biased by their uncertainty in the use of the tool. Some patients may have been able to be assessed by the nurses, but we did not have resources to check this during all day and night.

### 4) Data collection procedures ensuring environmental control.

The data were collected every day directly from the ICU working sheet. Obvious errors were double-checked by the bedside nurse and in additional documentation, but bias may have been introduced when documentation errors were not detected.

## **Study III**

The context and most likely additional factors may have influenced the participants of the focus groups in study III. The nurses' versions of their experience of performing clinical judgments with the tools implemented were communicated in an unusual setting. To sit together in a meeting room and discuss a particular theme for 1.5 hours together with colleagues is not usual for ICU nurses working shifts. The information from the participants may not be complete because the atmosphere and discussions may direct topics in certain directions. The acquired information must therefore be cautiously handled. By meeting the participants twice this may have led to a more consistent version of their experiences with clinical judgment and use of assessment tools.

One of the two researchers had participated in developing the educational session and completed the implementation study. The familiarity of the author with the educational session and the implementation of the tools may have strengthened the basis

for the study and may have influenced the responses of the participants of the focus group interviews. However, the familiarity of the author may have weakened the study by the influence of focusing on the positive effect, inducing the participants to communicate only positive attitudes to the use of the tools. There was, however, no evidence of this, as the participants communicated their clinical experiences and were definitely prepared to express criticism.

## **Norwegian pain treatment and sedation practice before implementation of the tools**

In 2007, a representative sample of experienced ICU nurses and intensivists contributed to provide a realistic picture of the Norwegian pain treatment and sedation practice for patients on MV. As reported by nurses and physicians in study I, this practice differed significantly from recommended practice. The impact of international clinical trials and guidelines on Norwegian ICU clinicians' practice seemed minimal with infrequent use of protocols. Pain treatment and sedation were given without the use of pain and sedation assessment scales in many instances, and daily interruption of sedation was rare. Respondents reported that collaborative decision-making between nurses and physicians resulted in a positive association between prescription and documentation of sedation level, indicating a potential to improve treatment through increased collaboration.

The huge variation of systematic pain and sedation assessments, and the lack of use of valid and reliable pain and sedation assessment tools that we found in Norwegian ICUs have been found in other countries (Egerod et al., 2006; Mehta et al., 2006; Mehta et al., 2009). Pain assessment tools are not used regularly in ICUs compared with the regular use of sedation assessment tools (Mehta et al., 2009). Less than 50 % of patients treated with analgesics and sedatives were systematically assessed for pain in a French multi-center study (Payen et al., 2009). This is in contrast to the current knowledge regarding analgo-sedation and ICU patients' pain experience (Gelinass, 2007; Gelinass & Johnston, 2007; Payen et al., 2007). Strøm et al (2010) promoted an approach of 'no sedation' in a randomized controlled study. Despite a respectable publication demonstrating an association between 'no sedation' and increased days without ventilation, pain was not properly documented in this study. If the 'no sedation' approach is introduced for in ICU patients in the future, my opinion is that safe pain management, including control of the patients' level of pain, is absolutely necessary. Only one third of



the Norwegian nurses and physicians reported routine pain monitoring, clearly describing the need for focusing on pain assessment and documentation in Norwegian ICUs.

Concerns about side effects of analgesics and sedation were a central finding in study I. In general, side effects were reported more often under sedatives than under analgesics while patients were on MV, indicating that oversedation in Norwegian ICUs is a problem. In Egerod's study, side effects were associated with the low use of objective and subjective assessments (Egerod et al., 2006), and this may be part of the explanation in Norway too. Our results may be interpreted as an understanding and a motivation among Norwegian nurses and physicians to reduce the side effects. Their agreement upon the indications for sedation was perceived as an ideal basis and supported the interventions in study II, focusing on a systematic approach of both prescriptions and documentation of pain, sedation and confusion levels. The results from study I and the above-mentioned studies provided the basis for the design of the implementation in study II.

### **The significance of physicians' prescriptions and nurses' documentation of patients' pain, sedation and confusion levels**

The implementation of pain, sedation and confusion assessment tools in the two ICUs in study II led to an improved systematic documentation of pain, sedation and confusion. Intensive educational sessions and follow-up were contributory factors in the successful improvement, by stimulating nurses and physicians to focus on the assessment of pain, sedation and confusion. The effect obtained by conducting a study was also a contributory factor. Our findings with regard to the nurses' evaluation before and after implementation of the tools are in agreement with recent studies confirming that the assessment of confusion, ventilator synchrony and face relaxation are essential variables for the assessment of pain and sedation in non-communicating ICU patients (Ely et al., 2001a; Ely et al., 2004a; De Jonghe et al., 2003; Pudas-Tahka et al., 2009; Arbour & Gelinas, 2010). The results from the questionnaire among the nurses also indicated that the implemented tools helped them to focus on significant signs and symptoms.

The tools implemented in study II were useful for the assessment of pain and sedation to adjust and justify treatment. Our results are supported by the number one recommendation in pain and sedation management in the ICU (Payen, 2010); to put forward the use of pain, sedation, and delirium assessment tools that would assist nurses

and physicians in the optimum use of analgesics and sedatives. The patient's long-term outcome may then be improved.

## **Pain management**

The positive relationship between documented levels of pain and sedation reported in study II is in accordance with the findings presented by Payen et al (2009). They demonstrated that patients assessed for pain levels were more likely to be assessed for sedation levels, to receive non-opioids, dedicated analgesia during painful procedures, and fewer sedatives than patients whose pain had not been assessed. The patients in Payen' study (2009) also had a shorter duration of MV and a reduced length of stay in the ICU.

After implementation of the tools, the results still indicated insufficient documentation of pain. Re-evaluation after introduction of pain and sedation interventions were rarely documented using NRS, RASS or ATICE scoring on the ICU working sheets. A relatively low rate of pain level documentation has also been recognized in other ICU populations (Chanques et al., 2006; Gelinis & Johnston, 2007; Payen et al., 2009). A positive trend in pain reassessment was found in a pre-post comparison after implementation of the critical-care pain assessment tool (Gelinis et al., 2011a). The same study also demonstrated continuation of pain reassessments at 3 and 12 months post-implementation. Several studies have shown that systematic pain assessment in ICU patients functions as a marker for good clinical practice (Chanques et al., 2006; Payen et al., 2009; Skrobik et al., 2010). The reasons for not applying systematic pain assessment may be related to the gap between research evidence and its use by professionals in individual patient care. The lack of an appropriate pain assessment tool might also explain the low rate of pain documentation (Wang & Tsai, 2010). The pain behavior assessments are based on expressions on the patient's face, body movements, muscle tension, and respiration, and today the validity, reliability and feasibility of pain behavior assessment tools in ICU have improved (Jackson et al., 2010a; Skrobik et al., 2010; Gelinis et al., 2011b). The Behavioral Pain Scale has been used for many years and has shown acceptable reliability and validity, but does not discriminate well when the pain is more than 5 on the NRS (Ahlers et al., 2008; Pudas-Tahka et al., 2009). This is critical because the 'no sedation' approach presupposes systematic, valid pain assessment to ensure patient safety and comfort. Both the Critical-Care Pain Observation Tool and the adult Nonverbal Pain Scale is shown to capture pain in nonverbal sedated critically ill

patient, but further testing of the tools is necessary (Marmo & Fowler, 2010; Gelinas et al., 2011). The visual NRS is suggested to be the most appropriate tool for ICU patients able to self-report their pain (Chanques et al., 2010), supporting the choice of the pain assessment tool used in our study.

The low pain scores documented on the NRS indicated adequate treatment of patient pain. In view of the patients' relatively deep sedation levels and the high number of patients unable to communicate, another explanation may be that the patients received too high doses of sedatives, thereby masking any measurable analgesic effect. As the rate of pain assessment still was not optimal after the implementation of the tools, this illustrates a serious consequence of the lack of a systematic approach among nurses and physicians. Even uncomplicated monitoring of pain may guide therapeutic medication titration and lower the incidence of pain, as well as decreasing agitation and the duration of MV (Chanques et al., 2006; Haslam et al., 2012). The use of pain, sedation, and delirium assessment tools assists nurses and physicians in the optimum use of analgesics and sedatives, thus improving the patients' long-term outcome.

Analgo-sedation has been an approach to gain more control of patients' sedation level (Rozendaal et al., 2009; Strøm et al., 2010). Both ultra-short acting analgesics and morphine have been administered in combination with propofol and dexmedetomidine to avoid accumulative effects and oversedation. The use of pharmacological and non-pharmacological adjuvants including regional anesthesia is considered an important part of the analgesia strategy (Martin et al., 2010). Some studies have indicated that repositioning and music as adjuvants to analgesia in ICU have positive effects (Cooke et al., 2010; Tracy & Chlan, 2011), but larger studies are needed to demonstrate any relationships between these interventions and changes in pain levels.

## **Sedation goal**

Greater evidence for an association between pain management and sedation goal and the choices of patient sedatives, and pharmacological and non-pharmacological adjuvants has emerged between 2008 and 2012. Routine pain management and prescription of an individual goal of sedation are important factors in avoiding oversedation (Jackson et al., 2009). The overall goal of keeping the patient awake and alert has proved to be beneficial to several patient outcomes, such as length of ICU and hospital stay, duration of MV, mortality, nosocomial infections and costs (Jackson et al., 2010a; Awissi et al., 2012). However, the achievement of prescribed and set goals for sedation is not straight forward.

In a systematic review of the incidence of suboptimal sedation, Jackson et al (2009) found a lack of standardization of methods of assessment and definitions of optimal sedation. The authors call for a more uniform approach to monitoring depth and quality of sedation, and in this way influence the strong association between sedation practice and adverse patient outcomes (Jackson et al., 2009). Despite low quality of some data in their review, they found a substantial incidence of suboptimal sedation, with a greater tendency towards oversedation (ibid). Another study showed that clinicians using sedation assessment scales and protocols perceived greater control over their sedation practice and better communication between nurses and physicians (Guttormson et al., 2010). According to Guttormsens' study (2010), nurses also describe sedation as necessary for patient comfort and characterize mechanical ventilation as uncomfortable and stressful (Guttormson et al., 2010). Their personal attitudes characterizing MV as inherently uncomfortable may influence pain management and sedation practices.

## **Sedation management**

According to international recommendations regarding alert and awake ICU patients (Sessler & Varney, 2008; Devlin et al., 2010; Strom et al., 2010), our results of a mean RASS score of -2.27 indicate that the patients were too heavily sedated. The mismatch between prescribed and documented sedation levels and the high doses of analgesics and sedatives administered reinforce this interpretation.

Sedation protocols promoting the avoidance of excessive sedation have shortened the duration of MV in ICU patients and the ICU length of stay (Girard et al., 2008c; Devlin et al., 2010) and may be a relevant intervention in Norwegian ICUs in addition to the use of assessment tools. The protocol in our study did not have other directions to avoid excessive sedation than the use of the tools. The majority of studies focusing on a systematic approach assume the use of assessment tools and/or daily interruption of sedation (DIS). DIS has in some studies been shown to reduce the complications related to the excessive use of opiates and sedatives and prolonged MV (Dotson, 2010; Roberts et al., 2010; Miller et al., 2012b). In another a randomized trial the use of DIS was combined with protocolized sedation and compared to a control group strategy of only protocolized sedation. DIS showed no benefits in clinical outcomes or in nursing workload (Mehta et al., 2012). The possibility of long-term psychological sequelae due to DIS has been questioned, and further research is needed to indicate patients' long-term

effects of this intervention (Mehta et al., 2008; de Wit M. et al., 2008; Anifantaki et al., 2009). The use of DIS is increasing, but a wide range is still reported, reaching from no routine use at all up to 62% reported use (Patel et al., 2009; O'Connor et al., 2010; Wøien et al., 2012). Barriers to the use of DIS include nurses' concerns regarding removal of invasive devices, patient discomfort, respiratory compromise, and withdrawal syndromes (Dotson, 2010). A lack of shared understanding of why one might perform a daily interruption of sedation has been reported (Miller et al., 2012a; Miller et al., 2012b).

In 2012, the goal of analgesia and sedation is still to relieve pain and help the patient adapt to the ICU environment, but the significance of maintaining the ability to mobilize and to communicate needs has growing interest. The introduction of early mobility programs combined with sedation protocols has been incorporated in the ICU, and results from studies have shown improved outcomes such as more ventilator-free days, reduced ICU and hospital length of stay, decreased duration of delirium and improved physical functioning (Schweickert et al., 2009; Needham et al., 2010; Bassett et al., 2012).

## **The assessment and incidence of delirium among ICU patients**

In study IIb, delirium was assessed among the 139 patients with the CAM-ICU. The incidence of 23% CAM-ICU-positive scored patients was at the lower end of the range given in previous delirium studies. Exclusion of the 41 patients who were "unable to assess" (UTA) at all measurements resulted in a higher percentage of CAM-ICU-positive scored patients. We do not find comparable studies reporting as high a percentage of patients scored as UTA as we registered. This high percentage of UTA patients in relation to the detection of delirium is not discussed in the literature, except as part of the advice to avoid excessive use of sedatives. In our study, the number of patients scored as UTA was explained by a deep sedation level, RASS-values between -3 to -5, and we concluded that oversedation in the ICUs probably was present. The national survey (study 1) clearly described a lack of routine sedative assessment in Norwegian ICUs confirming the high risk of both undersedation and oversedation. The explanation for this low incidence of delirium may, however, be the presence of deep sedation in a large proportion of patients making CAM-ICU testing impossible or difficult. The huge variation in the incidence of delirium in ICU has been related to the patient population, and differences in both use of instruments and time for assessments (ref). Our results indicate that the general level of sedation may also influence the incidence of delirium in a study. The patients' ability to

communicate their needs was decreased due to oversedation. This, in turn, could be a consequence of the lack of systematic assessment and defined and documented treatment goals. The wide ranges of doses prescribed and the use of high doses of continuous analgesics and sedatives strengthened this interpretation. There is emerging evidence that ICU delirium is related to the administration of benzodiazepines; thus, strategies that can avoid this group of drugs may reduce the incidence of delirium and associated sequelae (Devlin et al., 2010). The nurses in both ICUs were allowed to titrate continuous infusions and bolus doses of sedatives within wide ranges according to a prescribed level of sedation. In a mixed ICU population, the routine range of sedation may be influenced by the doses often required by neurosurgical patients. Daily sedation interruption might have reduced the number of deeply sedated patients and subsequently the frequency of patients scored as UTA, but this method was not in use in the hospitals.

Even though the CAM-ICU helped the nurses in the early detection of delirium, the nurses did not find scoring with the tool easy. Assessment of the delirium status in patients with a RASS score of -3 was reported as difficult. Our opinion is that patients at this sedation level may be difficult to score with the CAM-ICU test. Another challenge is that the CAM-ICU allows delirium to be scored in patients on sedatives. This may be interpreted that the threshold for achieving a positive score is reduced by sedation alone. Bergeron et al (2005) clearly support us in that there might be reasons other than cognitive impairment for not being scored as RASS=0, e.g. the influence of a sedative. We propose that some CAM-ICU studies may report an artificially high incidence of delirium because of these challenges. This shows the general difficulties of delirium assessment in intubated patients unable to talk, often with the complication of muscular weakness in ICU patients.

Delirium due to drug use may be just as dangerous as due to sepsis. The low incidence of CAM-ICU-positive patients may give a wrong impression of the status of delirium in ICUs. Due to such considerations, several authors now report the number of delirium and coma-free days, not only the delirium-free days. The patients in our study were either in a coma or scored delirium-positive on 464/858 days (54.1%), while they were scored as delirium and coma-free on 394/858 days (45.9%).

Due to training sessions, both study sites were familiar with non-pharmacological interventions and were aware of how to identify the early signs of delirium. We have focused on the importance of ICU nurses and physicians being able to recognize delirium at an early stage and to try to reduce the duration of delirium and the impact of risk

factors as much as possible. An aggressive approach to treating infections, avoiding undersedation and oversedation, keeping the patient awake and alert and able to mobilize as much as possible, achieving normal sleep rhythms, and the use of valid assessment tools has been strongly recommended. However, the assessment and treatment of delirium seems to be more challenging than the assessment and treatment of pain and sedative needs. One reason may be the lack of evidence of pharmacological treatment, which in turn may lead to inconsistencies in everyday practice (Jackson et al., 2010b). At H1, CAM-ICU-positive patients were treated with haloperidol more often than patients at H2. Some patients were treated with haloperidol even though they were not CAM-ICU-positive. Today, there is no evidence that one class of antipsychotic drugs is more efficient than another, but haloperidol remains the drug of first choice (Zaal & Slooter, 2012). More evidence is needed to deepen our understanding of the pharmacological treatment of delirium. This, in turn, may motivate ICU professionals to try to detect delirium early.

### **Nurses' perceptions of the use of pain and sedation assessment tools in ICU patients**

The ICU nurses participating in the focus group interviews agreed about the main benefits of using measurement tools for the assessment of pain, sedation and confusion. Scores have been described in other studies as useful for communicating target and actual sedation levels between nurses and physicians (Walker & Gillen, 2006; Aitken et al., 2009). The respondents in our study confirmed that the use of the tools was supportive in achieving continuity and consistency in treatment and to distinguish between pain and other symptoms. The respondents considered that both pain and confusion were easier to identify and treat when assessed systematically. However, they reported poor attention to ICU pain management, as described in other studies as a lack of both systematic assessment and documentation of patient pain (Payen et al., 2009; Wøien et al., 2012). A proactive attitude among the experienced ICU nurses was highlighted, similar to other studies that describe the nurses' ability to recognize the ICU patient's pattern of responses, an intuitive grasp of the clinical situation, and a response without obvious forethought (Tanner, 2006; Aitken et al., 2009; Hoffman et al., 2009). Despite the nurses' recognition of the usefulness of the tools, greater importance was almost always still attached to personal knowledge and experience. This is not surprising

and has been seen by other authors who have reported that sedation scores were used in combination with the nurses' own clinical judgment of the patient's level of sedation (Saggs, 1998; Gelsthorpe & Crocker, 2004; Walker & Gillen, 2006; Weir & O'Neill, 2008). According to Saggs (1998), the use of the tools enhanced practice by enabling the nurses to form a clearer clinical picture at the bedside, but the tools did not replace clinical judgment (Saggs, 1998). During the second interviews in our study, the nurses reported less skepticism and did not feel limited by the tools. They still relied heavily on personal judgment when deciding on analgesic and sedative treatment, viewing the tools as a contributory factor in decision-making. Low adherence to systematic assessment may be explained by difficulties in judging non-communicating patients and the absence of multidisciplinary discussion of clinicians' attitudes toward the sedation of ICU patients (Tanios et al., 2009; Gelinias et al., 2011b). The improvement in collaboration perceived to be due to the tools applied mainly to the nursing group. The participants stressed the importance of including both nurses and physicians in the implementation of the tools. This points to a very important issue related to implementation of new knowledge in clinical practice: we believe that by increasing the inclusion of physicians in the use of tools the rate of both assessments and documentation of scores may be strengthened.

### **Factors influencing the effect of the implementation**

In our case, we followed recommendations of implementation strategies, by identifying possible barriers before implementation, and by customizing the interventions (Graham et al., 2006). Low adherence to the use of clinical pain treatment and sedation guidelines has been explained by lack of knowledge of symptom management, analgesics and sedatives, and an absence of multidisciplinary discussion of clinicians' attitudes toward sedation of mechanically ventilated patients (Gelinias et al., 2011b). Time may be the main reason for the improvement potential documented in the ways the two ICUs in our study gave pain treatment and sedation. Results after four months showed only the first signs of changes in this area, and close long-term, follow-up of the protocol is strongly recommended, especially the need to monitor and sustain knowledge use. Low adherence might also be explained by lack of multidisciplinary discussions. Experiences from implementing systematic pain assessment support this explanation (Gelinias et al., 2011a). The mismatch between prescribed and documented sedation level in study II, and the statements from the nurses in the focus groups support the significance of close collaboration between nurses and physicians.



Today, three years after the implementation of the tools, we still have to work on the maintenance of structured assessments and documentation, and to arrange workshops where discussions and practical training in this field can take place. Even though pain treatment and sedation in the ICU is a multidisciplinary project, we clearly see that the nurses are the ones most motivated to adopt a systematic approach. More focus on shared understanding and consensus on the part of nurses and physicians with regard to goals would benefit the effects of the implemented tools in our ICUs. A collaborative approach has been shown to be successful in reducing the adverse consequences of oversedation (Vasilevskis et al., 2011).

The “ABCDE bundle” might be an effective approach to the successful daily management of the needs of ICU patients for analgesics and sedatives. This focuses on five evidence-based steps of care; **A**wakening and **B**reathing, **C**oordination of daily sedation and ventilator-removal trials; **C**hoice of sedative or analgesic exposure; **D**elirium monitoring and management; and **E**arly mobility and **E**xercise (Pandharipande et al., 2010). The experiences of the Vanderbilt University – one of the places where sedation and delirium have been under intense study for years – is that you will not succeed before you change your routines when doing rounds. On rounds, nurses and physicians are urged to talk about the ABCDE. Researchers from the Vanderbilt University stress that the conversation on rounds and the bedside documentation is a key point (Personal discussions with Dr. E. Wesley Ely, Vanderbilt University Medical Center, 2012).

## Conclusions

The main conclusions of the studies in this dissertation are:

1. In 2007, pain treatment and sedation practice in Norwegian ICUs was characterized as disorganized by nurses and physicians. Written protocols and systematic assessments of pain and sedation were not routine, and side effects of sedative and analgesic drugs were perceived as a major problem. There was clearly potential for improvement by using a systematic approach.
2. By implementing pain and sedation assessment tools in two ICUs, nurses and physicians practiced a systematic approach, and the nurses described an improved focus on significant signs and symptoms in the ICU patients. Scoring by the tools was performed partly according to the study plan. The rates of pain and sedation assessments were lower than recommended by recent research reports. A clear potential for improvement in pain and sedation management in the ICU was present, illustrated by the mismatch found between prescribed and documented sedation levels, and the lack of written prescriptions and documentation in general.
3. 23% of patients admitted to two mixed ICUs over 4 months were classed as delirious (CAM-ICU-positive) at least once during their stay. A large proportion of patients were not able to be assessed due to heavy sedation. The CAM-ICU was difficult to use in patients with sedation so deep that they did not give eye contact and responded only weakly to verbal stimulation.
4. As described by the nurses, the use of assessment tools contributed to an improvement in the quality of the assessment of pain treatment and sedation. The use of clinical assessment tools was generally viewed favorably and supported nurses in their decision-making, but a certain reserve on the part of the nurses was evident. Despite the nurses' recognition of the usefulness of the tools in the interviews, greater importance was almost always still attached to personal knowledge and experience. This kind of support should be seen as a complementary data source amongst the complex processes that contribute to the use of clinical judgment by nurses in the ICU.

The results from the empirical studies support the significance of a systematic approach to achieve a balance of pain relief and sedation, in both short-term and long-term treatment in ICU. The assessment tools were well accepted by the nurses and physicians, and the tools applied helped nurses to focus on significant signs and

symptoms in the ICU patients. The use of the tools was perceived to improve the quality of pain control and sedation, and supported nurses in their decision-making. However, great importance was attached to personal knowledge and experience when nurses assessed patients' need for analgesia and sedation. In addition, the rates of pain and sedation assessments were lower than recommended by recent research reports. In general, the study shows that there is still a clear potential for improvement in pain and sedation management in Norwegian ICUs.

So far, no publications disagree with the significant benefits of a thorough systematic clinical assessment, including the use of pain and sedation assessment tools. Early detection of delirium in ICU is still not satisfactory, but there is an increased and widespread use of delirium assessment tools and implementation and validation studies (Patel et al., 2009; Spronk et al., 2009; van Eijk et al., 2011). If our goal is to keep the patient awake and cooperative and able to mobilize, we have to focus on our responsibility to agree upon short-term and long-term goals, and to make systematic observations and documentation of the levels of pain, sedation and cognitive function.

## **Implications for clinical practice**

The implementation study aimed to increase the understanding of a systematic approach and to facilitate further research in the field of ICU pain treatment and sedation. There is still a lack of standardization of assessment methods and a clear definition and understanding of what constitutes optimal sedation in ICU patients (Jackson et al., 2010a). A systematic approach assists ICU nurses and also physicians to manage pain and sedation in critically ill patients, by providing a basis for proper interventions based on sound assessments. The outcomes of analgesia based and light sedation in critically ill patients do not show uniquely long term effects. More studies of the effect of these approaches, including regularly assessing the pain and sedative needs, may contribute to a broader understanding of the knowledge of patients' responses, and encourage further research.

## **Future perspectives**

This dissertation has discussed, in depth, factors influencing pain treatment and sedation in ICU patients. Because the investigations conducted showed that there are methodological and clinical challenges in assessing pain and sedation, further urgent research in this field is proposed.

To achieve a balance between adequate pain treatment and sedation in MV patients and to recognize delirium at an early stage, written protocols, including the use of valid assessment tools, are necessary. We found no studies that document any negative effects of a structured assessment of the ICU patient's need for analgesia and sedation and for the early detection of confusion and delirium. There is, however, still a gap between evidence-based recommendations and actual practice (Flaatten, 2012). Revised guidelines for clinical practice are required. Unfortunately no new international guidelines for pain management and sedation in the ICU have been published since 2002. The barriers to implementation of new knowledge need to be studied further. Daily checklists have proved very effective in the areas of surgery and infection control, for example, and it is likely that they will prove just as useful in achieving analgesia and sedation goals in ICU patients if implemented consistently and effectively (Byrnes et al., 2009).

Because of the trend towards “no-sedation”, pain assessment and control in the ICU is more important than ever. To achieve the goal of an awake and cooperating patient on MV we have to establish fair conditions for the patient. How to achieve this must be demonstrated in multi-center studies focusing on critically ill patients' experienced pain, and for studies that evaluate the processes of pain assessment and documentation in these patients, including studies examining methods of assessment and pharmacological and non-pharmacological interventions.

Direct observational studies on how nurses and physicians work in the clinical field to achieve balanced analgesia and sedation may illuminate new important factors in the field. How do they judge the complexity of the critically ill patient and how do they differentiate between analgesic and sedative needs? What is the effect of a close collaboration combined with a systematic approach?

Detecting delirium in ICU patients is still related to positive outcomes, but more research is needed to study the influence of medication, the identification of pain, and early mobilization on the development of delirium in the ICU.

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## Errata

### Formal errors which have been corrected in the thesis:

**Page 23: Mixed delirium** is described in the literature as a state where the patient fluctuates unpredictably between hyper- and hypoactive delirium. A variant of delirium, subsyndromal delirium, **display some features of delirium but do not meet the full diagnostic criteria** (Ouimet et al., 2007b).

















