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## The importance of the proper procedures in the process of implementing new guidelines

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### ABSTRACT

This is a report of research giving no direct outcome with respect to the aims of the study. However the value of the paper is to highlight the reasons for the failure; the lessons to be learnt from this failed exercise are to be found in the body of the paper.

**Objective:** The purpose of this study was to develop, implement and evaluate clinical guidelines on pain and sedation in a mixed medical and surgical Danish intensive care unit (ICU).

**Method:** A retrospective before-and-after analysis of protocol implementation.

**Main outcome measure:** The effect of the clinical guidelines was to be evaluated in number of hours for which the patients needed mechanical ventilation, hours spent in the ICU, days admitted to the hospital, and use of opioids and sedatives per patient day.

**Results:** As the project was unsuccessful, data can neither confirm nor disprove that guidelines can reduce duration of mechanical ventilation, length of stay in an ICU or in the hospital.

**Conclusion:** The study gives no outcome with respect to the original aims; however the lesson to be learnt from this failed exercise is that encouragement of the staff to use implemented protocols and guidelines is more important than the actual construction of the protocol algorithm or scale itself.

### KEYWORDS

Clinical pharmacy, critical illness, guidelines, implementation, intensive care unit

### INTRODUCTION

Patients in intensive care units (ICUs) frequently require analgesia and sedation in order to minimise pain, agitation and anxiety, and to facilitate mechanical ventilation. Pain and sedation regimens in ICUs may be suboptimal. As untreated pain is one of the largest factors contributing to stress and because stress is on its own associated with increased morbidity, it seems sensible to focus on optimising pain and sedation strategies [1-3].

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It has been shown that caregivers often underestimate pain intensity [4, 5]. One explanation might be that caregivers in the ICU have to rely on subjective assessment rather than a standardised method of assessment. The use of subjective assessments, however, hinders continuity in care by compromising documentation and communication between caregivers, and limits accurate titration of analgesic and sedative drugs, which may place the patients at risk of both under and overdosing, both potentially prolonging the stay in the ICU. Several sedation assessments tools have been developed and validated over the years, the Richmond Agitation-Sedation Scale, the Motor Activity Assessment Scale (MAAS), the Ramsay Scale, etc. None of these, however seem to cover every aspect of pain or sedation assessment in a satisfactory way. Prescription practice of sedatives and analgesics varies considerably among physicians [6-8]. The use of clinical guidelines employing systematic sedation assessment tools in ICUs has been shown to reduce patient time on mechanical ventilator by 21–32%, ICU length of stay by 11–24% and overall hospital stay by 11–30% [9-12].

Daily interruptions in the continuous sedation (wake up calls) can prevent over-sedation and reduce time on ventilator significantly without the patient having any recollection of the interruptions [13]. Additionally, these patients seem

to have a lower incidence of psychological complications than critically ill patients treated with continuous sedation. Finally, no difference in the number of unintentional events regarding treatment approach was observed between the intervention and the control group. The importance of having written protocols for sedation and described procedures for 'wake up calls' is underlined by the fact that these items are both incorporated in a Danish model aiming at reducing the incidence of ventilator-associated pneumonia.

## Aim

The purpose of this study was to develop, implement and evaluate clinical guidelines on pain and sedation in a mixed medical and surgical Danish ICU. The effect of the clinical guidelines was to be evaluated by the number of hours in which the patient needed mechanical ventilation, hours spent at the ICU, days spent in hospital, and use of opioids and sedatives per patient day.

## METHOD

### Development of the protocol and guidelines

A group consisting of a pharmacist, two ICU consultants and a Critical Care Nurse Specialist, all of whom were part of the regular staff, developed an evidence-based analgesia and sedation protocol specifically for the 8-bed medical-surgical ICU. The protocol and the associated guidelines were based on guidelines from the Task force of the American College of Critical Care Medicine of The Society of Critical Care Medicine, in collaboration with The American Society of Health-system Pharmacists and in alliance with the American College of Chest Physicians [14].

In this protocol, pain intensity was to be evaluated and rated every hour to guarantee consistency in the assessment. If the patient was awake a self-reporting system (i.e. where the patient him/herself reports the intensity of pain by using a visual analogue scale) was used. If the patient was not awake pain intensity was judged by the nurse using a numeric rating scale. Pain intensity was to be printed on the patient's medical chart along with other vital signs and parameters and hence optimise communication between caregivers (both nurses and physicians) by improving documentation.

To assess the sedation level, the MAAS was chosen. MAAS was translated into Danish from English and Swedish by a group of nurses working in the ICU with a good knowledge of English or Swedish. Consensus was achieved during a semi-structured group interview with the nurses participating in the translation process. A pharmacist, an attending ICU consultant, and the clinical

development nurse approved the final version. Other ICU consultants subsequently evaluated this version.

The nurses were given the right to initiate analgesic and sedative treatment according to an algorithm without prior physician consultation. Paracetamol was to be given as background analgesia to all patients having pain. Alfentanil and morphine were the preferred opioid analgesics, with fentanyl as an alternative to patients with manifest renal failure. Propofol was the drug of choice for sedation due to its relatively short half-life and absence of clinical significant metabolites. All attending ICU consultants approved the protocol before implementation.

### Study design

The study was designed as a retrospective before-and-after analysis of protocol implementation. Data representing empiric therapy were to be collected retrospectively for a whole year, while data representing protocol-based therapy were to be collected prospectively for the following whole year.

Patients admitted to the ICU were eligible for inclusion if they required continuous sedation for at least 72 hours. Those not requiring sedatives or needing analgesics only, were excluded. Patient consent was waived, as the protocol did not include any interventions.

Demographics recorded were age, gender, and SAPS II-score, a system for classifying severity of disease. Data collected for comparative evaluation were duration of mechanical ventilation in hours, length of stay in ICU in hours, length of stay in hospital in days, duration and dosages of sedatives and opioids.

### Protocol implementation

Implementation of the protocol was attempted twice. First during the autumn 2003 by a clinical pharmacist, who was not present for daily patient-care management rounds and only intervened on an irregular basis. Information and reminders were given at the morning assembly (with physicians only) and at the mid-day conference (with all caregivers), where questions regarding the protocol and the algorithms could be asked and discussed.

Over time, it became clear to the authors that only very few of the caregivers were acting according to the instructions in the protocol. As a consequence, minor modifications were made to the protocol and implementation was attempted again. During the second attempt (autumn 2005), two soon-to-become pharmacists were present for daily patient rounds for two months and interventions were made daily on a regular basis.

## RESULTS AND DISCUSSION

As a result of the first implementation failing, data was only collected for a short period (October and November) for each of three years. In total data from 55 patients was used to obtain the following results, 19 from 2002, 20 from 2004, and 16 from 2005. There was no significant difference in the distribution of gender, age or SAPS II-score. Unfortunately, this number proved to be too small a sample to draw any conclusions on the effect of the clinical guidelines on hours the patients needed mechanical ventilation, hours spent in the ICU, days in hospital or use of opioids and sedatives per patient day.

The subsequent discussion will deal with the implementation, the barriers met and what went wrong.

Two months' bedside teaching and pharmacist intervention showed that the care staff did not comply with the protocol and the algorithms.

According to the protocol that was introduced in 2003 the patients' pain intensity had to be rated at least once every hour. In 2004 pain intensity rating was recorded in only 55% of the cases, and never by the patient him/herself. In 2005, after two months' bedside teaching and pharmacist interventions, the pain intensity rating was recorded in 84% of the cases, an increase of 53%. The pain intensity rating had dropped to 79% two months after the bedside teaching had ended.

The nurses reported difficulties in evaluating the patients' level of activity by using the MAAS as they thought it contained descriptions of activity that could not be translated to patients admitted to the ICU. The pharmacists perceived that the protocol and the algorithms were rarely used, when pain treatment or sedation was initiated, pain intensity or sedation level monitored or when medication was tapered. Daily interruptions of propofol infusions were made in 25 of 35 possible situations and always after an intervention by the pharmacists. The nurses mostly administered sedation according to their personal clinical experience, or they consulted the physicians.

Fentanyl was the most frequently used opioid, regardless of kidney function. When challenged by the pharmacist, the nurses often expressed irritation, as they knew by experience that the patient at some point would develop acute tubulointerstitial nephritis and thereafter would have to be treated with fentanyl. However, the pharmacist also sometimes had to intervene in cases where morphine was used for patients with reduced renal function.

The major problems in this study were a possibly unsuitable protocol, irregular interventions by the pharmacist, and caregiver barriers towards following the guidelines given in the protocol. In order to ensure consistency in use it is important that the users of the protocol and algorithms understand the background and purpose and feel secure and confident in the use of the guidelines. This can be achieved by continuing education in combination with daily encouragement and intervention, so that everyone, including new staff, understands the rationale behind protocol and the importance of following it. The choice, wording and layout of the protocol and algorithms are secondary if the caregivers do not follow it.

In this protocol the nurses were given the right to initiate treatment with analgesics and sedatives according to the algorithms on their own without prior physician consent. This was done in order to optimise the pain and sedation treatment, to give the nurses more direct involvement in the decisions related to patient care and improve communication between caregivers. The authors found it surprising that the nurses were reserved about the protocol and the possibility of greater autonomy and responsibility and kept on doing things as they had before. However, recent research on caregiver barriers has shown that some nurses experience information overload when presented with research findings and many feel unable to evaluate the quality of the research [15]. It has also been found that nurses who undertake research themselves are more likely to adhere to guidelines than research-inactive nurses.

However, not only the nurses failed to adhere to the protocol. The doctors also seemed unconcerned and did not prescribe an individual level of MAAS for each patient evidenced by chart review. If the physicians had shown more interest in the levels of pain intensity, the sedation level and wake-up sessions, the nurses might have felt a greater responsibility and enthusiasm in complying with the protocol and the instructions.

It is well known that caregivers are – to some extent – conservative in adapting new procedures/therapies. Sometimes this may be a prudent attitude, but in some cases this strategy is not acceptable. Successful implementation requires full commitment of all members of the health-care team. Continuing information and encouragement may give the staff a feeling of ownership of the process and increase their commitment and willingness to change work routines. However, teaching and information can only do that much. An approach advocated today is the planting of 'experts' who know, understand and are willing to comply with the protocol among the caregivers (both nurses and physicians). These experts should act

as good examples to the rest of the caregivers. Having the caregivers participating in the compilation of protocols and guidelines gives them a greater feeling of ownership, which may facilitate implementation. Finally, the approval, interest, support and demand from the management are crucial.

## CONCLUSION

The results from this study can neither confirm nor disprove that clinical guidelines on pain and sedation bring about changes in duration of mechanical ventilation, length of stay in an ICU or in the hospital, the use of propofol and opioids. Thus it is a study with no direct outcome regarding the original aims.

However, recent published literature still suggests that protocols and guidelines can help reduce mechanical ventilation time, length of stay in the ICU, and thus improve recovery. Hence, the lesson to be learnt from this failed exercise is that encouragement of the staff to use protocols and guidelines is more important than the construction of the protocol algorithm or scale itself.

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