Understanding and optimising electronic audit and feedback to improve quality of care

Gude, W.T.

Citation for published version (APA):
Chapter 8

Effect of audit and feedback with action implementation toolbox on pain management in intensive care

A cluster randomised trial

Wouter T. Gude*
Marie-José Roos-Blom*
Evert de Jonge
Jan Jaap Spijkstra
Sabine N. van der Veer
Niels Peek
Dave A. Dongelmans
Nicolette F. de Keizer

* Equal contributors

Submitted.
Abstract

**Objective**  To assess the effect of audit and feedback (A&F) with action implementation toolbox on pain management in intensive care units (ICUs).

**Design**  Two-armed cluster randomised controlled trial comparing electronic A&F with a blank structured action plan (*feedback only* group) to the same intervention extended with an action implementation toolbox (*feedback with toolbox* group) containing suggested improvement actions.

**Setting**  Twenty-one ICUs in the Netherlands.

**Main outcome measures**  Proportion of patient-shift observations with adequate pain management, composed by two process indicators (measuring pain at least once per patient in each shift; remeasuring unacceptable pain scores within 1 h) and two outcome indicators (acceptable pain scores; unacceptable pain scores normalised within 1 h).

**Results**  Adequate pain management improved by 14.8% (95% confidence interval (CI), 14.0% to 15.5%) in the *feedback with toolbox* group and by 4.8% (95% CI, 4.2% to 5.5%) in the *feedback only* group. The effect was limited to the two process indicators. The *feedback with toolbox* group achieved larger improvement than the *feedback only* group (*p*=0.049).

**Conclusion**  Our A&F intervention improved pain management processes but not outcomes. The toolbox amplified the effects. Future research should focus on the effectiveness of a toolbox with actions mainly targeting improvement of patient outcomes.

**Trial registration**  ClinicalTrials.gov, NCT02922101.
Effect of audit and feedback with toolbox on pain management in intensive care

Introduction

Patients admitted to intensive care units (ICUs) receive complex and high-tech treatment which make them high healthcare cost consumers and susceptible to harm. Therefore, ICUs continuously strive to improve the quality of care they deliver [268]. One area of focus concerns management of pain. More than 30% of the ICU patients experience moderate to severe pain at rest and this increases to 50% during common care procedures such as chest tube and wound drain removal, and arterial line insertion [84,269]. Pain is associated with discomfort, sleep deprivation, and an increased morbidity, mortality and length of stay [85–87]. Validated pain assessment tools exist such as the visual analogue score (VAS) or numerical rating score (NRS) in patients able to self-report [270], and the critical care pain observational tool (CPOT) or behavioural pain score (BPS) in patients not able to self-report [271,272]. The severity of pain is often underestimated by ICU professionals, and as a consequence pain is treated inadequately [94,95]. Providing ICUs with performance data about their pain management practice such as audit and feedback (A&F), can be an effective strategy to improve the quality of ICU pain management [233].

A&F is commonly used for improving the quality of care in the ICU [233,243,273,274]. A&F provides a summary of clinical performance over a specified period of time [117], and is an effective strategy to improve quality of care, but its effects are variable and often marginal [21,108]. A&F seems most effective when baseline performance is low, and feedback is provided repeatedly, by a supervisor or senior colleague, in verbal and written formats, and includes specific targets and action plans on how to change behaviour [21,45]. Information on how these factors should be operationalised in order to deliver effective A&F interventions is still unclear [27]. Head-to-head trials comparing different variations A&F are necessary to increase the understanding and effect sizes of A&F [235].

Control Theory [100] predicts that health professionals confronted with feedback indicating a discrepancy between current and desirable practice will be prompted to take action to improve practice, until the discrepancy is eliminated. In practice, however, health professionals often lack the skills, time, capacity or knowledge to interpret feedback and formulate what improvement action is necessary [21,26,160,244]. Similarly, they may not be aware of barriers that could hamper the implementation of their intended actions [120]. Augmenting A&F with an action implementation toolbox, containing lists of potential barriers in the care process and suggested improvement actions with supporting materials, could facilitate health professionals to plan improvement actions, and increase the likelihood that actions are completed [121].

In this study we aimed to assess the effect of adding an action implementation toolbox to an electronic A&F intervention on the quality of pain management in ICUs. We hypothesised that ICUs in both study groups achieve improvement, but that ICUs that used the toolbox improve more than those that did not.

Methods

Study design

This study was a pragmatic, two-armed cluster randomised controlled trial (cRCT) using block randomisation, with randomly permuted blocks of two or four, each consisting of an equal number of ICUs allocated to each study arm. A researcher unaffiliated with the study and
blinded to the identity of the units performed the randomisation. ICUs in both groups received access to an online dashboard that provided A&F on pain management performance and a blank structured action plan, but were randomly allocated to receive the intervention with (feedback with toolbox group) or without (feedback only group) the action implementation toolbox. Investigators were, due to the nature of the intervention, not blinded to the group allocation of an ICU. ICUs were aware that there were two variations of the intervention being evaluated, but they were not told which aspect (i.e. the toolbox) was randomised. The study took place from January 2017 to June 2018. Further details can be found in the study protocol [121]. The trial was registered with ClinicalTrials.gov (NCT02922101). The study results are reported according to the CONSORT statement for cluster randomised controlled trial [275].

Setting

Currently all 82 Dutch ICUs collect data on demographics, physiology, and clinical diagnoses of all patients admitted to their ICU and deliver these data monthly to the Dutch National Intensive Care Evaluation (NICE) registry [77]. The NICE registry supports participating ICUs to quantify and improve their quality of care by offering them benchmark feedback about patient outcomes such as mortality and length of stay for more than 20 years. Each participating ICU receives biannual reports and has access to an online tool that enables them to perform additional analyses on their data at any time.

Four recently developed quality indicators for assessing ICU pain management that were introduced by NICE in 2016 were used for this study. The development of indicator set followed a modified RAND procedure and was performed in collaboration with pain management experts from the field [276]. The resulting indicator set consisted of two process and two outcome indicators, all using a patient-shift as unit of observation, that is, pain management should be adequate for each patient during each shift:

1. Proportion of patient-shifts during which pain was measured at least once (process);
2. Proportion of patient-shifts during which an unacceptable pain score (defined as VAS≥4, NRS≥4, CPOT≥3, or BPS≥6 was measured, and pain was remeasured within 1 h (process);
3. Proportion of patient-shifts during which pain was measured and no unacceptable pain scores were observed (outcome);
4. Proportion of patient-shifts during which an unacceptable pain score was remeasured within 1 h, and the pain score was normalised (outcome).

Participants

ICUs were eligible for participation if they were willing and able to submit the data items needed to calculate the pain management indicators monthly in addition to their regular data upload [77,277]. Furthermore, they had to allocate a multidisciplinary quality improvement team (consisting of at least an intensivist and nurse) with one person identified as the key contact person during the trial. We invited all 82 ICUs that participated in the NICE registration by telephone and e-mail. ICUs were recruited from January 2016 to November 2017. The medical managers of the participating ICUs signed a consent form to formalise the ICUs’ commitment.
Effect of audit and feedback with toolbox on pain management in intensive care

**Intervention**

The A&F intervention was informed by Control Theory [100] and guided by evidence and the latest recommendations for designing A&F [121, 122]. The central component was an online dashboard that provided two key functionalities: (1) gaining detailed insight into performance on the four pain management indicators, and (2) developing and managing action plans. Figure 8.1 depicts the dashboard and describes how the action planning functionalities differed for study groups. The feedback only group received a blank, structured action plan where ICUs could list, for each indicator, potential barriers in the care process and actions to overcome these barriers. Actions could be assigned to one or more people in the ICUs’ quality improvement team, a deadline, and given additional details in free text. The toolbox, for ICUs in the feedback with toolbox group only, was integrated in the action plan (Figure 8.1); providing a prefilled list of potential barriers in the care process and associated suggested actions for improvement. Some actions included supporting materials (e.g. a slide show presentation discussing the importance and relevance of measuring pain every shift). The toolbox was the same for all ICUs in the feedback with toolbox group. ICUs could select potential barriers and actions they considered relevant and suitable for their local practice into their action plans.

**Figure 8.1:** The NICE dashboard displayed an overview of pain management performance (upper part) and four types of pages specific to the selected indicator (lower part). The difference between study groups was only in the action plan page. The feedback only group received a blank structured action plan and could record and update potential barriers and intended actions. The action plan for the feedback with toolbox group was supplemented with a pre-filled list of potential barriers and suggested actions (indicated by the NICE icon). Some actions included supporting materials (indicated by a wrench icon) available for download. Users could add suggested actions to their action plan and specify their description (plus sign) or hide them if they were not relevant (minus sign).
We developed the action implementation toolbox (i.e. potential barriers to adequate pain management, suggested improvement actions, and supporting materials) simultaneously with the indicators, combining evidence from literature and guidelines and knowledge from ICU experts [278], and informed by Flottorp et al.’s integrated checklist for determinants of practice [279] and Systems Engineering Initiative for Patient Safety (SEIPS) model [241]. It started with identifying barriers that could potentially lead to poor performance on any of the four pain management indicators. Then, for each barrier, goal-oriented actions were formulated that could overcome the barrier and attain higher performance. For each action we collected supporting materials to facilitate its implementation.

Each ICU received an educational outreach visit at the study start to explain the dashboard, the action plan, and the toolbox (if applicable). After this visit one NICE researcher held telephone calls every 4-6 weeks with ICUs to monitor their progress and to verify whether action plans were complete and up-to-date, and encouraged ICUs to update their plan if this was not the case. The ICUs were followed-up for six months.

Outcome measures

The primary outcome measure was the proportion of patient-shift observations where pain management was adequately delivered, which we defined as a composite of the four indicators. Hence, pain management was considered adequate if, for a specific patient during a specific shift (i.e. night, day, or evening shift), pain was measured at least once, and no unacceptable pain scores were observed or unacceptable pain scores were followed up with repeated measurement and normalisation of pain scores within 1 h. Secondary outcome measures were the four indicators individually. Pain was measured with VAS or NRS in patients able to self-report, or with BPS or CPOT in ventilated or sedated patients and defined acceptable or normalised when VAS<4, NRS<4, CPOT<3, or BPS<6; and unacceptable when VAS≥4, NRS≥4, CPOT≥3, or BPS≥6 [94,271,280].

Sample size

Based on the 2012 Cochrane review of A&F, we expected the feedback only group to achieve a median absolute improvement of the performance of 4.3% (interquartile range (IQR): 0.5%-16%) [21]. We calculated that we would need 24 ICUs with an average cluster size of 600 patient-shift observations in six months to have 80% power to detect a significant difference in the performance between the feedback only and feedback with toolbox group of 10% (with a two-sided unpaired t-test with α=0.05).

Statistical analysis

We estimated odds ratios (ORs) and 95% confidence intervals (CIs) using mixed-effect logistic regression analysis. We included ‘study group’, ‘time’ (in months) and the interaction term ‘study group × time’ as covariates. With the interaction term we determined the difference in change during the 6 months follow-up period between the two study groups i.e. the effect of the toolbox. We added a random effect for ‘ICU’ to adjust for variation in performance between the ICUs before the study started, and for ‘patient admission’ to adjust for clustering within patients.

We performed a regression analysis for the primary and each of the four secondary outcomes, including data from up to three months before the pre-intervention to six months
post-intervention. We followed this approach to adjust for any differences between the *feedback only* and *feedback with toolbox* group prior to the intervention start [261, 281]. We censored the first month of the intervention period to allow ICUs time to start using the intervention.

We also analysed ICUs’ action plans to compare the number of actions ICUs had planned and completed for each indicator between study groups. We summarised these using medians and IQRs. All analyses were performed using R version 3.4.3 (R Foundation for Statistical Computing; Vienna, Austria).

**Results**

From the 82 ICUs that submitted data to the national database, 21 (25.6%) were able to submit the pain management data and provided consent in the time frame of the study. Eleven ICUs were randomised to the *feedback only* group and ten to the *feedback with toolbox* group (Figure 8.2). A total number of 25,141 admissions and 253,530 patient-shift observations were included in the analyses. Table 8.1 shows the characteristics of the participating ICUs and patients.

**Table 8.2** reports the effects of the intervention. We observed an absolute increase in the proportion of patient-shifts with adequate pain management of 14.8% (95% CI, 14.0% to 15.5%) in the *feedback with toolbox* group and 4.8% (95% CI, 4.2% to 5.5%) in the *feedback only* group. This was associated with an OR of 1.13 (95% CI, 1.06 to 1.22) in the *feedback with toolbox* group and 1.04 (95% CI, 1.00 to 1.09) in the *feedback only* group. Improvement in the *feedback with toolbox* group was significantly larger than in the *feedback only* group (p=0.049).
ICUs in both study groups improved on the two process indicators: measuring pain each shift and remeasuring unacceptable pain within 1 h (Table 8.2). In the feedback with toolbox group the six-month absolute improvement was 15.6% (95% CI, 14.9% to 16.3%) and 10.4% (95% CI, 8.4% to 12.5%), respectively. In the feedback only group this was 3.4% (95% CI, 2.8% to 3.9%) and 5.1% (95% CI, 3.3% to 6.9%). Improvement on the two outcome indicators (acceptable pain scores, and normalised pain scores within 1 h) was not statistically significant.

The feedback with toolbox group achieved larger improvements on all four indicators compared to the feedback only group, but this was statistically significant only for the indicator ‘measuring pain each shift’ (p<0.001).

Throughout the study period, participating ICUs included a total of 234 actions into their action plans (Table 8.3). The feedback only group planned a median of 6 (IQR, 5 to 8.5) actions compared to 9 (IQR, 7 to 18.5) in the feedback with toolbox group (p=0.112); and completed 3 (IQR, 2.5 to 5.5) actions compared to 4 (IQR, 2.5 to 12.5) in the feedback with toolbox group (p=0.414). In the feedback only group 80.2% of ICUs’ actions targeted the process indicators; in the feedback with toolbox group this was 71.2%. Example actions included ‘Organise training sessions on the application of pain assessment tools’ or ‘Build a reminder system into the local electronic health record (EHR) that alerts when pain should be (re)measured’. The other 19.8% (feedback only) and 28.8% of actions (feedback with toolbox) targeted pain management outcomes such as ‘Make standard pain medication prescriptions available’ or ‘Increase autonomy or responsibility of nurses to administer pain medication’.

Discussion

We found improvements in pain management practice when ICUs were provided with electronic A&F, regardless of whether they had access to the action implementation toolbox. ICUs
Table 8.2: Effect of the intervention on pain management performance after six months. Bold font indicates significant difference between groups of p<0.05.

<table>
<thead>
<tr>
<th>Pain management indicator</th>
<th>Feedback only</th>
<th>Feedback with toolbox</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate pain management composite</td>
<td>69.3% (25436/36713)</td>
<td>74.1% (27128/36617)</td>
</tr>
<tr>
<td></td>
<td>1.04 (1.00–1.09)</td>
<td>1.13 (1.06–1.22)</td>
</tr>
<tr>
<td>Measuring pain each shift</td>
<td>79.3% (29115/36713)</td>
<td>82.7% (30269/36617)</td>
</tr>
<tr>
<td></td>
<td>1.04 (1.00–1.09)</td>
<td>1.24 (1.15–1.34)</td>
</tr>
<tr>
<td>Acceptable pain scores</td>
<td>85.2% (24797/29115)</td>
<td>87.4% (26458/30269)</td>
</tr>
<tr>
<td></td>
<td>0.99 (0.93–1.05)</td>
<td>0.97 (0.93–1.05)</td>
</tr>
<tr>
<td>Remeasuring unacceptable pain within 1 h</td>
<td>79.5% (639/804)</td>
<td>74.2% (670/903)</td>
</tr>
<tr>
<td></td>
<td>0.71 (0.55–0.92)</td>
<td>1.44 (0.79–2.56)</td>
</tr>
<tr>
<td>Normalised pain scores within 1 h</td>
<td>79.6% (804/4318)</td>
<td>74.2% (903/3811)</td>
</tr>
<tr>
<td></td>
<td>0.99 (0.93–1.05)</td>
<td>0.97 (0.93–1.05)</td>
</tr>
</tbody>
</table>

Baseline performance was measured over the three months preceding the intervention start.

Table 8.3: Planned and completed actions to improve pain management indicators.

<table>
<thead>
<tr>
<th>Pain management indicator</th>
<th>Number (%) of actions planned</th>
<th>Number (%) of actions completed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Feedback only (n=81)</td>
<td>Feedback with toolbox (n=153)</td>
</tr>
<tr>
<td></td>
<td>Feedback only (n=51)</td>
<td>Feedback with toolbox (n=96)</td>
</tr>
<tr>
<td>Measuring pain each shift</td>
<td>30 (37.0%)</td>
<td>51 (33.3%)</td>
</tr>
<tr>
<td></td>
<td>19 (37.3%)</td>
<td>37 (38.5%)</td>
</tr>
<tr>
<td>Acceptable pain scores</td>
<td>8 (9.9%)</td>
<td>20 (13.1%)</td>
</tr>
<tr>
<td></td>
<td>5 (9.8%)</td>
<td>12 (12.5%)</td>
</tr>
<tr>
<td>Remeasuring unacceptable pain within 1 h</td>
<td>35 (42.2%)</td>
<td>58 (37.9%)</td>
</tr>
<tr>
<td></td>
<td>22 (43.1%)</td>
<td>31 (32.3%)</td>
</tr>
<tr>
<td>Normalised pain score within 1 h</td>
<td>8 (9.9%)</td>
<td>24 (15.7%)</td>
</tr>
<tr>
<td></td>
<td>5 (9.8%)</td>
<td>16 (16.7%)</td>
</tr>
</tbody>
</table>

Abbreviations: IQR interquartile range. Performance pre-intervention includes three months before implementation of the intervention.
with the toolbox achieved larger improvements than those without toolbox. Improvement in both groups was mostly due to an increase in measuring pain each shift, and on repeating pain measurements within 1 h after an unacceptable pain score was observed. We found no change in the proportion of acceptable pain scores, or unacceptable pain scores that were normalised within 1 h. ICUs that received the toolbox achieved larger improvements on all four indicators compared to the other ICUs, but this was statistically significant only for measuring pain each shift.

Improvement on ICU pain management was particularly centred around its processes (i.e. measuring pain each shift and remeasuring unacceptable pain within 1 h), and less around its outcomes (i.e. achieving acceptable and/or timely normalised pain scores). This corresponded with the action plans that ICUs developed during the trial, where by far most (>70%) of actions in both study groups targeted the process indicators. Although the toolbox included actions that were designed to improve both on processes and outcomes of pain management, these findings suggest that the toolbox insufficiently supported ICUs to improve pain outcomes. ICUs with toolbox did plan and complete more actions than ICUs without, but these differences were not significant. Instead, ICUs may needed support beyond the toolbox, such as financial or human resources, or more time to achieve changes in their pain management outcomes.

Despite the significant improvement on both process indicators there remained ample room for improvement. For instance, about 75% of patient-shifts where unacceptable pain was observed, pain was not remeasured within 1 h. Sensitivity analyses showed that this percentage was similar when taking a two or three-hour threshold [282], which eliminates the hypothesis that the 1 h may be an unrealistic time frame in practice. One potential explanation suggested by some of the participating ICUs was that nurses may not have recorded the normalised pain score into the EHR because they considered this administrative task irrelevant or time-consuming. This might have also resulted in an underestimation of the process indicator scores.

The lack of improvement in the proportion of shifts with acceptable pain scores may also be explained in part by the fact that pain scores measured in the first shift of patients’ ICU admission are not influenced by pain management in the ICU. Patients from the operating room or from the emergency room may arrive at the ICU with high pain scores. Obviously, this will not be influenced by the quality of pain management provided by the ICU. Another explanation could be that the increase in the number of pain measurements has led to the identification of more shifts in which patients experienced unacceptable pain.

The proportion of shifts with unacceptable pain scores that normalised within 1 h remained constant at around 80%, but this number should be interpreted with caution as it is only based on 20% of shifts in which the pain measurement was actually repeated. We don’t know if the rate of normalisation of unacceptable pain scores was comparable in the 80% in which no repeated measurement was performed within 1 h.

Previous A&F interventions that aimed to improve pain assessment and treatment found similar or larger effects than our study. The feedback only group improved on adequate pain management with 4.8% which is in line with the 4.3% absolute improvement found in the Cochrane review on the effectiveness of A&F on health outcomes in general [21]. Chanques et al. [280] found an improvement on measuring pain twice a day of 16.4%, and Erdek and Pronovost [283] found an increase in the amount of 4 h nursing intervals in which pain was assessed of 29% and of 38% in which pain was treated. Their somewhat larger effect can be explained by their larger room for improvement.
A strength of this study is that the toolbox provides suggestions for improvement strategies derived from expert opinion, guidelines and scientific literature. We designed our intervention driven by theory [121] and in accordance with the latest recommendations [122]. Our head-to-head cRCT, comparing two variations of feedback, contributes to the research field of A&F as traditional intervention versus control trials no longer advance the science and effectiveness of A&F [26, 28]. However, some limitations warrant discussion. First, baseline pain management performance was lower in the feedback with toolbox group — despite randomisation. Hence, our finding that ICUs with toolbox improved more than those without toolbox might have been overestimated due to a difference in room for improvement between the two study groups. Due to the limited number of participating ICUs we were unable to use stratified randomisation based on ICUs’ baseline performance. However, because there remained substantial room for improvement at the study end for both groups, as judged by our clinician co-authors, we argue that the baseline difference has not substantially influenced our estimate of the toolbox’s effect size. Second, our power analysis was based on the composite outcome measure and not on the individual indicators. Especially the indicator on normalising unacceptable pain within 1 h was a relevant and important indicator when focusing on improving patient care, but with a much lower denominator compared to the other indicators probably underpowered to detect significant effects. Third, we did not find a significant difference in the number of actions between the groups, which can also be attributed to the low number of included ICUs. Finally, measuring pain in patients not able to self-report pain is difficult and might have resulted in underestimated pain scores. However, for these patients validated tools such as the BPS and CPOT were used.

Unanswered questions and future research

To explore whether and how A&F interventions in combination with an action implementation toolbox can be applied in routine ICU practice and other clinical settings, we will perform a process evaluation exploring the difference in action planning processes between study groups. Future research should investigate how toolboxes may better facilitate improvement on patient outcomes rather than care processes. It may also explore ways to optimise the design and contents of toolboxes to increase the uptake and usefulness. A starting point could be the creation of a dynamic toolbox where participants may share and use each other’s best practices and experiences, rather than our static list of suggested improvement actions.

Conclusion

Our electronic A&F intervention both with and without action implementation toolbox led to improvements in ICU pain management; the toolbox amplified these effects. Improvements focused on enhancing the measurement of pain rather than on avoiding or addressing unacceptable pain scores. The toolbox seems to be a valuable addition to future A&F interventions.