Title
Pediatric postoperative pain management in surgical wards – an intervention study

Background
Pain is underestimated and undertreated despite a lot of research on the field (1, 2). Under-treated pain after surgery may cause increased risk of complications, increased risk of morbidity and mortality, developing chronic postsurgical pain, as well as potentially longer hospital stays (3-5).

Possible causes for the undertreatment of pain in children may be healthcare providers’ misconceptions and their lack of knowledge about pediatric pain management (6, 7), inconsistent use of pain assessment tools (8, 9), and lack of available guidelines for pediatric pain management (9). Healthcare providers working in surgical wards have an important role and responsibility to provide postoperative pain management.

Some studies have explored the effect of educational interventions on pediatric postoperative pain management by using questionnaires (10, 11) or combining questionnaires and chart reviews (12-14), combining questionnaires, chart reviews and focus group interviews with healthcare providers (15), and one study by combining use of questionnaire, observational study and interviews with children on recovery units (9). These studies revealed increased knowledge about pediatric pain management (10-13), and increased documented use of nonpharmacological pain management (12, 13) after intervention.

None of these studies have explored if an educational intervention improve pediatric postoperative pain management on surgical wards by combining use of questionnaires and observational study, focus-group interviews with healthcare providers and interviews with children. Therefore, we will carry out a pre-post educational intervention study where we explore healthcare providers’ knowledge and attitude regarding pediatric postoperative pain management, their clinical practice and their experience of barrier and facilitators for effective pain management, and children’s’ experiences of pain and postoperative pain management.

Aims
The overall aim is to improve pediatric postoperative pain management on surgical wards. The aim of this study is to explore healthcare providers’ knowledge and clinical practice in pediatric postoperative pain management in surgical wards, and to evaluate whether an educational intervention would improve postoperative pain management.

Methods
Design
This study has a pre-post intervention design, with four measurement points: baseline (T1), and one month (T2), six months (T3) and 12 months (T4) after intervention.

Procedure
This study will be conducted on four surgical wards in one university hospital in Norway. There will be used different methodological approaches for data collections (interviews, questionnaire, observational study) with four measurement points; baseline (T1), and one month (T2), six months (T3) and 12 months (T4) after intervention.
To get a broader view of barriers and facilitators for effective pediatric postoperative pain management, there will be carried out focus group interviews with healthcare providers. Further, data about healthcare providers’ knowledge and attitudes regarding pediatric pain will be collected using a questionnaire. Data about nurses’ pediatric postoperative pain management will be collected using non-participant observational study and data about children’s experience about pain and pain management will be collected using face-to-face interviews with children.

**Tailored educational intervention**

The intervention will be based on previous research and results from baseline (T1). The intervention will be a one-day educational day and includes lectures and workshops with main focus on the lowest competence in pediatric postoperative pain management. Healthcare providers at the included surgical wards will be invited to participate on this educational day. As a supplement, there will be provided clinical supervision in pediatric postoperative pain management and reminders (such as lectures and posters) over a period of six months after educational day.

This study will have different phases (see table 1).

**Table 1 Overview of the different phases in the study**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Activity</th>
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<tbody>
<tr>
<td>Preparations</td>
<td>Explore nurses’ barriers and facilitators for effective pediatric postoperative pain management on surgical wards Data collection using (pre project)</td>
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<td></td>
<td>• Questionnaire regarding barriers and facilitators for nurses</td>
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<td>Phase 1</td>
<td>Explore healthcare providers’ knowledge, clinical practice children’s experiences of pain and pain management, and healthcare providers’ experiences of barriers and facilitators for effective pain management Data collection using (baseline – T1)</td>
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<tr>
<td></td>
<td>• Questionnaire PNKAS-N</td>
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<td></td>
<td>• Observation of clinical practice</td>
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<td>• Face-to-face interviews with children</td>
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<td></td>
<td>• Focus group interviews with healthcare providers (barriers and facilitators)</td>
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<td>Phase 2</td>
<td>Develop and implement a tailored educational intervention</td>
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<td></td>
<td>Develop tailored educational intervention based on:</td>
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<td></td>
<td>• Available research</td>
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<td></td>
<td>• Results from baseline</td>
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<td>• Feedback from head of the relevant units</td>
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<td></td>
<td>• Staff views about the facilitators and barriers to optimized pediatric pain management</td>
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<td></td>
<td>Implementation of the intervention</td>
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<tr>
<td></td>
<td>• Seminar (lecture and workshop)</td>
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<td>• Clinical supervision</td>
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</table>
**Interviews with children**

**Research questions**
How do children experience pain and postoperative pain management?

**Data collection**
At baseline there will be conducted 8-12 face-to-face semi-structured interviews with children 6-18 years old. Children 6-9 years old will be given opportunity to use write and draw technique to tell their story about how they experienced pain management during the hospital stay. Older children will be offered to participate in an individual interview. A semi-structured interview guide will be developed including questions related to:

- Tell about how you were doing after the surgery
- Did you have pain after surgery
- Were you asked if you had any pain?
- When you were in pain, did someone help you?
- Do you have any suggestions to the nurses on how they could manage children's pain in a better way?
- Do you have any suggestions to the children who are undergoing surgery (on how to manage pain)?

All children will be asked to rate the worst pain experienced postoperatively using a numeric rating scale (NRS) from 0 "no pain" to 10 "worst pain imaginable" or a face scale depending on their cognitive capabilities. These interviews will take place before the child is discharged from hospital, and all interviews will be audio-recorded.

**Data Analysis**
Children's responses to the interview questions will be transcribed verbatim and structured using NVivo (QRS NVivo Pro for Windows, version 11). Content analysis will be used to the transcripts by using a six-step approach (18):

1. Creating and organizing files for the data
2. Reading through the text and forming initial codes
3. Coding the data
4. Describing the social setting, people involved, and events
5. Analyzing data for identifying emerging themes
6. Interpreting and making sense of the findings

**Focus group interviews with healthcare providers**

**Research questions**
How do healthcare providers experience pediatric postoperative pain management? How do healthcare providers experience barriers and facilitators for effective pain management?
Data collection
At baseline there will be conducted two focus group interviews with healthcare providers (two to four nurses, two surgeons, and two anesthesiologists in each group). A semi-structured interview guide will be developed including questions related to:

- How do you experience pediatric postoperative pain management in your department?
- How do you experience pain assessment in your department?
- Is there a need for improvement in pediatric postoperative pain management in your department?
- If so, what is possible to do to improve pediatric postoperative pain management?
- What is difficult to achieve regarding improvement of pediatric postoperative pain management?

The interviews will be audio-recorded.

Data analysis
The interviews will be transcribed verbatim and structured using NVivo (QRS NVivo Pro for Windows, version 11). Content analysis will be used to the transcripts by using a six-step approach (18):

1. Creating and organizing files for the data
2. Reading through the text and forming initial codes
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Questionnaire for healthcare providers (nurses and physicians)

Research questions
What kind of knowledge and attitudes do healthcare providers have about pediatric postoperative pain management?

Data Collection
All nurses at all four wards (160 nurses) and all surgeons (experienced) at the corresponding wards (60 surgeons) will be invited to answer the questionnaire “The Pediatric Nurses’ Knowledge and Attitudes Survey Regarding Pain Questionnaire - Norwegian version” (PNKAS-N). The PNKAS was developed by Manworren (16) and translated into Norwegian, tested and validated according to Norwegian conditions by Hovde el al. (17). The questionnaire is based upon guidelines for acute pain management in infants, children and adolescents, American Pain Society, The World Health Organization and the Joint Commission on Accreditation of Healthcare Organizations. The PNKAS-N consists of questions about general pain management, pain assessment, and use of pharmacological and nonpharmacological treatment of pain in children. In addition, healthcare providers’ age, education and work experience will be recorded. The PNKAS-N will be distributed to the healthcare providers four times, baseline (T1), and one month (T2), six months (T3) and 12 months (T4) after intervention.

Data Analysis
The data will be analyzed with statistical methods using SPSS version 25 (IBM SPSS Statistics for Windows, version 25.0. IBM Corp, Armonk, NY, USA). Descriptive and correlational statistics will be used to describe and summarize data. Means, standard deviations, medians, and interquartile ranges will be calculated for continuous data. Frequency counts and proportions will be
calculated for categorical data. Multiple linear regressions for repetitive measurement will be used for analyzing the effect of the intervention.

**Observational study**

*Research questions*

How do healthcare providers practice pediatric postoperative pain management?

*Data Collection*

Non-participant observational studies of clinical practice will be carried out for four-hours periods, one week per ward, at all four surgical wards at all measurement points. The observational study will focus on observing the nurses general pain management practice, pain assessment (use of pain assessment tools), use of pharmacological and nonpharmacological treatment of pain in children. A checklist and field notes will be used based on the PNKAS-N themes and essential areas of pediatric pain management identified in a literature review. Field notes will include descriptions of what is occurring during the period of observation and records of comments made by nurses related to pediatric pain management. The field notes will be recorded partly during the observation and partly after the observation (directly after), depending on the situation at the unit. No data about the child will be recorded except age, gender and type of surgery. The other data that will be recorded is what the situation gives, but no data that can identify the patient will be recorded. Observational studies will be carried out at baseline (T1), and one month (T2), six months (T3) and 12 months (T4) after intervention.

*Data Analysis*

The data will be analyzed with statistical methods using SPSS version 25 (IBM SPSS Statistics for Windows, version 25.0. IBM Corp, Armonk, NY, USA). Descriptive and correlational statistics will be used to describe and summarize data. Means, standard deviations, medians, and interquartile ranges will be calculated for continuous data. Frequency counts and proportions will be calculated for categorical data.

*Ethical considerations*

Approval from the Norwegian Regional Committee for Medical Research Ethics and necessary approval from the hospital will be obtained. This study is based on the experience from the study *Pediatric Pain Management - an Intervention Study* where both the interview guides for interviews with children and the observational study checklist were pilot tested. The information letters to children will be sent to the hospital's youth council to ensure the adolescents feedback before the study start. Further, we would cooperate with the hospital’s youth council throughout the whole study period to ensure feedback.

The participants will receive both verbal and written information about the study explaining that it is voluntary to participate in the study and that it will not affect the treatment if they do not want to participate. Written informed consent will be obtained from all participants who are participating in the survey, the persons (nurses, children and their parents) who are present during the observational studies, and both the children (> 12 years) and the parents that are participating in the interviews. Verbal informed consent will be obtained from children younger then 12 years. The interviews will be transcribed and coded so that no data collected include names or other sensitive information that can identify the participants. Data will be stored securely, and ethical research guidelines will be followed.

*Research Group*

- Morten Carstens Moe, Professor, Surgeon, Division of Head, Neck and Reconstructive Surgery, Oslo University Hospital, Norway
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- Kjersti Langmoen, Intensive Care Nurse, MSc, Children's Surgical Department, Division of Head, Neck and Reconstructive Surgery, Oslo University Hospital, Norway

**Schedule 2019-2026**

<table>
<thead>
<tr>
<th>Preparation</th>
<th>May 2018 – February 2019</th>
<th>Data collection T1 April – May 2019</th>
<th>Intervention September – January 2020</th>
<th>T2 October 2019</th>
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<tr>
<td></td>
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<td>PNKAS-N</td>
<td>Observational study</td>
<td>PNKAS-N</td>
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<td>• Observational study</td>
<td>• Interviews with children</td>
<td>• Observational study</td>
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<td>• Focus group interviews with healthcare providers</td>
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| T3   | February 2020 | - PNKAS-N  
|      |              | - Observational study |
| T4   | September 2020 | - PNKAS-N  
|      |              | - Observational study |

**Data analysis**  
June 2019 – December 2020

**Publications**

<table>
<thead>
<tr>
<th>Paper</th>
<th>September – December 2019</th>
<th>- PNKAS-N (baseline)</th>
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<tbody>
<tr>
<td>Paper 1</td>
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<tr>
<td>Paper 2</td>
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<td>- Observational study (baseline)</td>
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<tr>
<td>Paper 3</td>
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<td>- Interviews with children (baseline)</td>
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<tr>
<td>Paper 4</td>
<td>January – December 2020</td>
<td>- Effect of intervention</td>
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Reference list:


