

## PEER REVIEW HISTORY

BMJ Paediatrics Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Pain management in children and young adults with minor injury in Emergency Departments in the UK and Ireland: a PERUKI service evaluation
<b>AUTHORS</b>	Hartshorn, Stuart Durnin, Sheena Lyttle, Mark Barrett, Michael

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Reviewer name: Dr. Susy Joseph Institution and Country: Government Medical College Thiruvananthapuram, Pediatrics, India Competing interests: none
<b>REVIEW RETURNED</b>	22-Sep-2021

<b>GENERAL COMMENTS</b>	<p>Let me congratulate the authors for taking up this topic of pediatric pain evaluation, assessment and management strategies given and carried out at different health care facilities in order to know about the importance given to pediatric pain assessment and management in the present health care setting. I would like to get clarifications regarding the following points:</p> <ol style="list-style-type: none"> <li>1. What do you mean by structures and processes in relation to pediatric pain? Did you incorporate all as addressed in Table 1?</li> <li>2. What is a Donabedian framework? Did you take into account all the factors mentioned in it?</li> <li>3. "Health care pain outcomes could not be understood in isolation, as they are an outcome of health system related structures and processes". What do you mean by this?</li> <li>4. What is the operational definition of 'minor injuries'?</li> <li>5. What is the reliability of recorded findings (Pain scale evaluation) from the case records since it is a retrospective study?</li> <li>6. Ethical approval and informed consent were not taken. Justify.</li> <li>7. What is the time frame of doing the first pain score and repeat pain score percentage? Was it uniformly carried out in all centres?</li> <li>8. What are the variables included in the assessment proforma for pain score?</li> <li>9. Was it a qualitative study? Justify.</li> <li>10. Did the initial first pain score percentage affected the mode of transport?</li> <li>11. Since the eligibility criteria for inclusion in the study included newborns from birth to children aged 15 years, what was the pain score system incorporated to assess neonatal pain. Please elaborate. Moreover, the title does not mention about neonates.</li> <li>12. What types of procedures/ pain were included as inclusion criteria in neonates?</li> <li>13. What was the rationale for taking children who presented with minor injuries for seven consecutive days?</li> <li>14. This study was done in the period from 2016 to 2017. Are there any changes in the approach to pediatric pain in the present period? Any studies available?</li> <li>15. Are there any comparison studies of pain assessment and</li> </ol>
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	<p>management in adult population? If so, please quote them as references.</p> <p>16. The population included a mix of tertiary and district general hospitals. Was there any statistical difference in assessing and managing pediatric pain at these two centres?</p> <p>17. Was there any statistical difference between trauma centered unit Vs non trauma centered units in terms of perception, assessment and management of pain?</p> <p>18. Why "trauma team activation" is taken as an exclusion criteria?</p> <p>19. Elaborate on the calculation of pain score percentage. What was the tool used?</p> <p>20. What was the dosage of analgesics given according to body weight/age? Please clarify.</p>
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<b>REVIEWER</b>	<p>Reviewer name: Dr. Sajith Kesavan</p> <p>Institution and Country: United Kingdom of Great Britain and Northern Ireland</p> <p>Competing interests: None</p>
<b>REVIEW RETURNED</b>	08-Oct-2021

<b>GENERAL COMMENTS</b>	<p>This paper in my opinion does not add more to the available knowledge about what are the gaps in pain management processes in ER. It can be best described as an audit into documentation of the process rather than evaluation of a service. Even if we assume that documentation is a key quality improving step in the process, the outcome should be assessed in term of how satisfied patients/caregivers/parents are about the pain management service in ER.</p>
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<b>REVIEWER</b>	<p>Reviewer name: Dr. Conrad Kabali</p> <p>Institution and Country: 2264 Spence Lane, Burlington, Ontario, Canada</p> <p>Competing interests: None</p>
<b>REVIEW RETURNED</b>	12-Sep-2021

<b>GENERAL COMMENTS</b>	<p>Page 4, line 26: It will be helpful if you can mention how many sites had good outcomes and whether this was associated with structures and processes put in place in those sites</p> <p>Page 10, line 56: Doesn't sound right to call it "parametric and non-parametric variables". Did you mean to say that you performed parametric and non-parametric tests? If so, please explain the situations that led you to resort to non-parametric tests. Also where are the non-parametric tests? I don't see them in the manuscript</p> <p>Page 11, line 5: Please replace the word "T test" with "independent t-test" as it is conventionally presented in statistics literature. Also report the point estimates and 95% CI along with your p-values throughout the manuscript. The sentence "statistical significance was defined as..." should either read "type I error was set at" or "alpha level was set at".</p> <p>Table 4: Please note, mixing row percentages with column percentages can confuse readers. I would advise that you remove the column percentages in the column "The total number of patients".</p> <p>Page 16, line 10: Greater in comparison to what kind of patients? Please report the difference in proportions and 95% CI. Also note that reporting the chi-square without its degrees of freedom is not helpful. You may also want to keep your p-values but remove the chi-square value because the two convey the same message. In addition, the unknowns add more uncertainty in your comparisons. Can you perform a sensitivity analysis to see how the unknowns may have impacted true results?</p>
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	Table 7: In the p-value column, did you mean that you compared the top vs the bottom quartile? Please clarify. In the footnote, it seems like you used the t-test to compare medians. The t-test is for the comparison of means not medians. Please use the appropriate test for comparing medians. Why only comparing the top vs bottom quartile? You can see the consequences where the p-value is sometimes 1 but the middle quartile is different from the other two (reflecting a non-linear pattern). It is more informative to compare all three columns.
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## VERSION 1 – AUTHOR RESPONSE

Dear Dr. Manu Raj and Prof. Imti Choonara,

Thank you for giving us the opportunity to submit a revised draft of our manuscript titled "The processes and outcomes of pain management in children and young adults with minor injury in Emergency Departments in the UK and Ireland: a PERUKI service evaluation" for consideration for publication in the BMJ Paediatrics Open (Manuscript ID bmjpo-2021-001273). We appreciate the time and effort that you and the reviewers have dedicated to providing your valuable feedback on our manuscript. We are grateful to the reviewers for their insightful comments on our paper. We have been able to incorporate changes to reflect all the suggestions provided by the reviewers. We have highlighted the changes by tracking changes in the marked document as requested. Here is a point-by point response to the reviewers' comments and concerns:

Formatting Amendments (where applicable):

Editor in Chief Comments to Author :

You MUST respond in full to the comments of the reviewers.

Title add "in Emergency Departments in the UK and Ireland" after "injury"

Response: Title updated.

Your study was a retrospective case note review, so please avoid use of the word prospective

Response: Updated abstract and methods to remove prospective and detail as retrospective review.

Conclusions delete the 1st sentence "Our study has utilised an adapted Donabedian framework to detail suboptimal acute clinical pain management for paediatric patients in the ED".

Response: Sentence deleted.

Please also use the term "an adapted Donabedian framework" once only in the methods. You repeat it many times in the paper.

Response: Updated methods to use term only once.

Do you need new recommendations or implementation of existing guidelines?

Response: We have added in details about the latest RCEM QIP and potential routes to help ameliorate paediatric pain control: "RCEM has introduced a national quality improvement project for 2021/2022 on "Pain in Children" with data entry commencing October 2021 with the project anticipated to last for a year. The results of this project including any initial benefits and if they are long-lasting are awaited. One recommendation we advocate is the introduction of national measures for pain assessment and management similar to the previous national improvements implemented in sepsis management. This would allow comparison between sites and could support improvements in the quality of services. Another avenue which we feel warrants further exploration involves giving ownership of pain reporting and control to families."

Reviewer: 1

Dr. Conrad Kabali

### Comments to the Author

Page 4, line 26: It will be helpful if you can mention how many sites had good outcomes and whether

this was associated with structures and processes put in place in those sites

Response: Owing to the limitation on the number of tables/figures, we have elected to look at the sites which had local guidelines/policies covering all aspects of pain assessment compared to the sites with no local guidance to see if this showed a difference. In the five sites which have local policy/guidelines on all aspects of pain assessment and management as described previously, the mean percent of patients with pain scores recorded was 42.9% (CI: 39.1-46.7%). This compared to the six sites where there were no local guideline documents where the mean rate of patients with pain scores recorded was 47.3% (CI: 43.9-50.6%). This has been added to the manuscript. This lack of difference shows that it is more complex than the presence of local guidance. We have added additional statistics looking at the different types of hospital or the presence of trauma centre mentioned below which were also not significant.

Page 10, line 56: Doesn't sound right to call it "parametric and non-parametric variables". Did you mean to say that you performed parametric and non-parametric tests? If so, please explain the situations that led you to resort to non-parametric tests. Also where are the non-parametric tests? I don't see them in the manuscript

Response: Updated to remove the term parametric and non-parametric variables and replaced with continuous and categorical variables. No non-parametric tests are used.

Page 11, line 5: Please replace the word "T test" with "independent t-test" as it is conventionally presented in statistics literature. Also report the point estimates and 95% CI along with your p-values throughout the manuscript. The sentence "statistical significance was defined as..." should either read "type I error was set at" or "alpha level was set at".

Response: Updated wording to independent t-test and alpha level was set at 0.05. The point estimates and 95% CI have been included with each p-value throughout the manuscript.

Table 4: Please note, mixing row percentages with column percentages can confuse readers. I would advise that you remove the column percentages in the column "The total number of patients".

Response: Column percentages removed to improve clarity as suggested.

Page 16, line 10: Greater in comparison to what kind of patients? Please report the difference in proportions and 95% CI. Also note that reporting the chi-square without its degrees of freedom is not helpful. You may also want to keep your p-values but remove the chi-square value because the two convey the same message. In addition, the unknowns add more uncertainty in your comparisons. Can you perform a sensitivity analysis to see how the unknowns may have impacted true results?

Response: We have added in the p-value of comparing all 5 groups and I have then grouped the variables and clarified that greater "than patients who presented by all other methods". Proportions and 95% CI for both groups added for comparison. Chi square value removed.

On performing a basis sensitivity analysis to show how the unknowns may have impacted true results by removing them from the dataset, the relationship was still significant relationship as p value <0.00001 ( $\chi^2 = 83.9$ ). Likewise, if we split the unknown pre arrival analgesia evenly (50/50) and add half of them into 'yes' and half into 'no' the relationship was still significant relationship as p value <0.00001 ( $\chi^2 = 49.1$ ). There is a risk of introducing bias by removing the unknown data from the dataset as it only looks at 2649 patients compared to the full dataset of 3888.

Table 7: In the p-value column, did you mean that you compared the top vs the bottom quartile? Please clarify. In the footnote, it seems like you used the t-test to compare medians. The t-test is for the comparison of means not medians. Please use the appropriate test for comparing medians. Why only comparing the top vs bottom quartile? You can see the consequences where the p-value is sometimes 1 but the middle quartile is different from the other two (reflecting a non-linear pattern). It is more informative to compare all three columns.

Response: I have updated the test used to compare the medians to Mood's Median test and I have included the IQR for all the median values. For the other values, I have compared all three groups using the Pearson Chi Square test. I have updated the p value column heading to remove the reference to comparing the top and bottom quartile and I have added in the 95% confidence intervals.

Reviewer: 2

Dr. Susy Joseph, Government Medical College Thiruvananthapuram

### Comments to the Author

Let me congratulate the authors for taking up this topic of pediatric pain evaluation, assessment and management strategies given and carried out at different health care facilities in order to know about the importance given to pediatric pain assessment and management in the present health care setting. I would like to get clarifications regarding the following points:

1. What do you mean by structures and processes in relation to pediatric pain? Did you incorporate all as addressed in Table 1?

Response: Clarification added of how structures and processes relate to pediatric pain –“ The structures related to paediatric pain are the physical and organisational characteristics where healthcare occurs and the processes are the actual steps involved in optimal analgesic practices (recognition of pain, assessment, intervention, reassessment, and maintenance of pain relief).”

Elements that were not evaluated included certain elements of the adapted Donabedian framework including the patient/parent satisfaction, the level of staff involved in pain assessment/prescribing or the information systems/alerts/reminders used in each department. The data collected did not include the assessment of maintenance of pain control due to the universal lack of reassessment demonstrated across the network. These are detailed as limitations in our study.

2. What is a Donabedian framework? Did you take into account all the factors mentioned in it?

Response: The introduction has been updated to clarify what a Donabedian framework is. “Donabedian created a conceptual model that provides a framework for examining health services and evaluating quality of health care which has been used in several domains of healthcare to drive improvement.” We did not evaluate all elements of the adapted Donabedian framework including the patient/parent satisfaction, the level of staff involved in pain assessment/prescribing or the information systems/alerts/reminders used in each department. The data collected did not include the assessment of maintenance of pain control due to the universal lack of reassessment demonstrated across the network. These are detailed as limitations in our study.

3. “Health care pain outcomes could not be understood in isolation, as they are an outcome of health system related structures and processes”. What do you mean by this?

Response: Each emergency department’s pain outcomes could not be viewed in isolation, but understood as outcomes that are a result of the local processes and structures which include prehospital care, resources (guidelines, staffing, tools, medicines etc) and processes at each department from reception to discharge. This has been clarified in the manuscript.

4. What is the operational definition of ‘minor injuries’?

Response: As different coding systems are used across the network, the identification of eligible children at each site was delegated to the site lead. The exclusion of major trauma which is defined as an injury severity score of >15 has been included in the manuscript. The remaining trauma that is not major trauma is minor trauma. The breakdown of injuries included is listed in the results.

5. What is the reliability of recorded findings (Pain scale evaluation) from the case records since it is a retrospective study?

Response: The pain scale evaluations were drawn from recorded data and not based on descriptive text in medical recorded. We have acknowledged the retrospective nature as a limitation in our study.

6. Ethical approval and informed consent were not taken. Justify.

Response: In the UK & Ireland, at the time the study was done, the process to determine whether ethics approval and consent were required involved the study proposal being reviewed by Birmingham Children’s Hospital Research and Innovation department. It was deemed to be service evaluation based on assessment against the Health Research Authority framework and ethical approval and consent were not deemed necessary. Routinely collected patient data was retrospectively collected and then irrevocably anonymised, and transmitted securely to the central study team and consent was not deemed necessary for this.

7. What is the time frame of doing the first pain score and repeat pain score percentage? Was it uniformly carried out in all centres?

Response: The time frame for performing repeat pain assessments was not uniform in all centres. The median time interval between pain assessment in 122 episodes of pain reassessment was 68.5 minutes (IQR 37.25-110.75 minutes) with a range from 4 minutes to 254 minutes. In 29 instances where the pain was reassessed the interval was unknown as the time of one of the pain assessments was not documented. This detail has been added to the results.

8. What are the variables included in the assessment proforma for pain score?

Response: We included pain score/rating and time of assessment. The method section has been updated to include this information.

9. Was it a qualitative study? Justify.

Response: The approach of this study was quantitative. The design was mainly focused on quantitative analysis to show the network practices of pain assessment and management across a network and compliance to standards. The inadequate performance of the sites led the analysis to try delve deeper to use qualitative methods of combining the data from our previous study looking at the structures in each site to gain more insight into why practice are recurrently suboptimal and the authors then combined the site data with the previous collected data on the actual structures in these sites to see if explanatory data could be found to help explain and illustrate the poor performance and see if any insights could be elicited.

10. Did the initial first pain score percentage affected the mode of transport?

Response: The first initial pain score was based on an assessment by either the ambulance service or the ED triage nurse after the mode of transport has been decided. We did not include parental assessment of pain in the study so the mode of transport was determined by the parent and not the first pain score. The children who were seen a healthcare provider before arrival (GP/ED/ambulance) had an average pain score of 3 and a median pain score of 2 (n=132) compared to children who self-presented who had an average pain score of 2 and a median pain score of 2 (n=2008) on their first pain assessment.

11. Since the eligibility criteria for inclusion in the study included newborns from birth to children aged 15 years, what was the pain score system incorporated to assess neonatal pain. Please elaborate. Moreover, the title does not mention about neonates.

Response: The study did not assess the pain score system used for each pain evaluation. The pain score systems used in different sites in the PERUKI network is detailed in a previous study we published (The structures of paediatric pain management: a PERUKI service evaluation study. *BMJ Paediatric Open* 2021;5:e001159). The title uses the term children and of the 3888 presentations, two were neonates as minor injury are infrequent in this age group. Children and young people is the accepted universal term of the RCPCH.

12. What types of procedures/ pain were included as inclusion criteria in neonates?

Response: This study did not look at procedural pain, it was an evaluation of all children and young people (including neonates) who presented with a minor injury/injuries sustained prior to attendance at hospital.

13. What was the rationale for taking children who presented with minor injuries for seven consecutive days?

Response: The rationale allowed us to get a continuous sample of injuries that present to the ED including the evenings and weekends when presentations and resources available in the ED can differ. The sites included across the entire research network have a total annual paediatric ED census of 1,225,000 (sites range from 11,500-65,000) so getting a snapshot across the various departments over 1 week period to give an insight into how pain is managed.

14. This study was done in the period from 2016 to 2017. Are there any changes in the approach to pediatric pain in the present period? Any studies available?

Response: The latest RCEM audit from 2018 which is referenced in the paper has not demonstrated any improvement in the management of pain and this is described in the paper. There have been no structural modifications to drive change despite 7 national audits. (Royal College of Emergency Medicine. Pain in children: clinical audit 2017/18 - national report 2018).



15. Are there any comparison studies of pain assessment and management in adult population? If so, please quote them as references.

Response: We have included the details of the outcomes of Sampson work on pain management in UK ED's from 2020 – "How can pain management in the emergency department be improved? Findings from multiple case study analysis of pain management in three UK emergency departments" and her previous work on Interventions to improve the management of pain in emergency departments: systematic review and narrative synthesis based on adult ED's. This paper may not be directly comparable given differences in design but it highlights many similar issues.

16. The population included a mix of tertiary and district general hospitals. Was there any statistical difference in assessing and managing pediatric pain at these two centres?

Response: There was no statistical difference between the assessment of pain between the tertiary and DGH's ( $p = 0.516$ ) or the management of pain ( $p = 0.384$ ). Details added to the manuscript.

17. Was there any statistical difference between trauma centered unit Vs non trauma centered units in terms of perception, assessment and management of pain?

Response: There was no statistical difference between the assessment of pain between the trauma centres and the non-trauma centres ( $p = 0.159$ ) or the management of pain ( $p = 0.059$ ). Details added to the manuscript.

18. Why "trauma team activation" is taken as an exclusion criteria?

Response: This study looked to evaluate routine pain assessment and management in stable paediatric patients with minor injuries. It did not want to include unstable patients/severely injured patients who were being managed by a dedicated trauma team where assessment, resources and priorities can differ. Major trauma patients may not be able to report their pain due to the severity of their injuries. Trauma team activation is an indication of major trauma and reflects a different process to the typical processes involved in pain management.

19. Elaborate on the calculation of pain score percentage. What was the tool used?

Response: This was the percentage of patients who had a pain score recorded during their ED presentation. This has been clarified as part of the methods. Based on the data collected in our previous study - The structures of paediatric pain management: a PERUKI service evaluation study. BMJ Paediatric Open 2021;5:e001159 - the pain score tools were validated pain score assessment tools and included the numerical rating scale (82% of sites), Wong Baker Faces Pain scale (63% sites), FLACC scale (34% sites), Visual analogue scale (24% sites), verbal pain intensity scale (21% sites), revised facial pain scale (16%) and other scales (13%).

20. What was the dosage of analgesics given according to body weight/age? Please clarify.

Response: This varied based on the medication and the local sites policy. There was no documented weight in 46% of patients ( $N = 1798$ ) and 22% of these received analgesia ( $n = 398$ ). Certain medications for example Ametop and Entonox are not weight based. Certain medications for example LAT gel or paracetamol can be age or weight based.

Reviewer: 3

Dr. Sajith Kesavan

### Comments to the Author

This paper in my opinion does not add more to the available knowledge about what are the gaps in pain management processes in ER. It can be best described as an audit into documentation of the process rather than evaluation of a service. Even if we assume that documentation is a key quality improving step in the process, the outcome should be assessed in term of how satisfied patients/caregivers/parents are about the pain management service in ER.

Response: We have listed in our limitations that we did not elicit patient/parents/caregivers satisfaction in relation to pain management as this is an area which warrants further research. It is not yet understood whether families and clinicians have the same goals in pain management, and a similar level of understanding of assessment or interventions so further research is needed in this area. We have added this in as an area we would recommend to be explored in the future.

## VERSION 2 – REVIEW

<b>REVIEWER</b>	Reviewer name: Dr. Susy Joseph Institution and Country: Government Medical College Thiruvananthapuram, Pediatrics, India Competing interests: none
<b>REVIEW RETURNED</b>	06-Dec-2021

<b>GENERAL COMMENTS</b>	Authors have responded to my questions with the needed references. Main drawback is the retrospective nature of study. Also, the authors have not taken patient /parent level of satisfaction and the level of health worker assessing and managing pain. All the limitations of study have to be strictly mentioned one by one.
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<b>REVIEWER</b>	Reviewer name: Dr. Simon Craig Institution and Country: Murdoch Childrens Res Inst Competing interests: None
<b>REVIEW RETURNED</b>	14-Dec-2021

<b>GENERAL COMMENTS</b>	<p>Thank you for the opportunity to review this paper examining the processes and outcomes of pain management in patients &lt;16 years of age with minor injuries in UK and Ireland emergency departments. I understand that this is a revised paper, but was not involved in the original review. I therefore apologise if any of my comments / suggestions have previously been raised, or are in disagreement with previous reviews.</p> <p>Overall, it is clearly written, however, I am not sure that the choice of subjects (children with minor injuries, a significant proportion of which had no pain on arrival, and who may not spend long enough in the ED to require a single (or repeated) pain assessment) was ideal.</p> <p>In the "key messages" section the authors highlight important concepts of oligoanalgesia and failure to reassess pain scores, and then note that pain was assessed in &lt;60% of children, that structures, processes and outcomes are variable across sites, and suggest a new body of recommendations is required.</p> <p>I agree that pain is often poorly documented and treated, however, I am unsure that going into detail in a population of patients with minor injuries is particularly helpful. A number of children with a pain score of 0 received analgesia. A significant confounder with this study is that many children with minor injuries do not need to spend a long time in the ED, and may not be there long enough to require repeated pain assessments. Was ED length of stay measured? What is the justification for concentrating on children with minor injuries?</p> <p>The conclusion in the abstract includes "pain management and the associated outcomes have not been adequately addressed and prioritised within existing network structures and processes" – I do not understand how this paper demonstrates this.</p> <p>The introduction is clearly written. The stated aims are to describe the network's processes and resultant 'real world' pain outcomes</p> <p>The methods section starts with presentation of a comprehensive table of structures, processes and outcomes. It is unclear what bearing this has on the rest of the methods section, as many processes and outcomes listed are not included.</p> <p>With regards to data collection, it would be helpful to see more detail on how charts were abstracted (single abstractor vs two</p>
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	<p>independent abstractors, whether they were blinded to the study hypothesis, any interrater agreement testing). Please provide the coding criteria in a supplementary appendix.</p> <p>There are a large number of tables, some of which are probably unnecessary.</p> <p>Table 2 – it is unclear whether “repeat pain score” is a percentage of all patients, or a percentage of patients who had at least one pain score documented.</p> <p>Table 3 – is it necessary to have 6 age groups? Consider combining the first three into a &lt;2 years group.</p> <p>RCEM guidelines are mentioned regarding opiate administration (17 received an opiate as per RCEM guidelines) – which guidelines are referred to (they are not referenced)?</p> <p>Table 7 – I am not sure how helpful this is. It may be worth considering multiple linear regression to identify factors which predict higher completion rates of pain scores, or multiple logistic regression to identify predictors of “good” pain score completion rates (i.e. &gt;75% of patients or whatever the authors feel is adequate).</p> <p>Supplementary table 1 – provides data on medications given. No details are available regarding slings, splints, ice packs, injected local anaesthetic, nerve blocks or haematoma blocks.</p> <p>In summary, the paper has studied a group of children with minor injuries who may not be in sufficient pain (or stay in the ED long enough) to require any documentation (or reassessment) of pain. Due to the large number of “minor” cases in most EDs, notes are often quite brief, and this may also impact on the study findings. Documentation of analgesia and documentation of pain assessment is recorded, however, there does not appear to be an attempt to examine non-pharmacological pain relief (which is important in many minor injuries - e.g. ice pack, sling, splint, etc) or patient / parent satisfaction with pain relief (which the authors acknowledge is an important outcome)</p> <p>The conclusions that “a new body of recommendations is required” is not supported by the study findings.</p>
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<b>REVIEWER</b>	<p>Reviewer name: Dr. Samina Ali</p> <p>Institution and Country: University of Alberta Faculty of Medicine &amp; Dentistry, Pediatrics, Canada</p> <p>Competing interests: None</p>
<b>REVIEW RETURNED</b>	20-Dec-2021

<b>GENERAL COMMENTS</b>	<p>Thank you for this opportunity to review this manuscript. Performing a network-wide assessment of pain practices is not an easy task, and I comment the authors for prioritizing this topic and doing so. I recognize that this is the first time that I am reviewing this manuscript, and that it is a revision, so I will try to limit my comments to core thoughts, as I am cognizant of the fact that the authors have already receive feedback from another group of reviewers, to which they have responded in this version.</p> <p>Some general comments, in reviewing the tracked changes version, to facilitate my understanding of what was already changes:</p> <p>1. The Donabedian framework's use and success in other settings should be further expanded upon, as it is the premise upon which this entire paper is built. If it is not valid, rigorous and appropriate, the premise for this paper falls short. can you describe where and</p>
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	<p>how it was used with success, rather than alluding to its use?</p> <p>2. Since the Donabedian framework was adapted to the peds pain/emergency setting by the authors (for the purposes of this study), this should be acknowledged as a limitation, as it was not rigorously tested or used an external panel of experts.</p> <p>3. Study setting: please describe the PERUKI network of hospitals better: annual range of volumes of peds patients in the ED, distribution of urban vs rural sites, cities/countries that are a part of PERUKI. after reading this section, i was still not sure of the setting and if it was similar to where i practice. I see that some of this is provided in results, but perhaps a brief review of at least geographic area, here, would be helpful to a non UK reader. 1-2 tightly written sentences could cover this very well, and allow for better understanding of setting.</p> <p>4. The time frame of data collection overlaps with high respiratory season, which may influence the ability to capture pain scores. Lack of capturing of seasonality should be addressed in limitations.</p> <p>5. Can you include the full definition of minor trauma? What ICD codes/diagnoses did you employ?</p> <p>6. Can you please include the Case Report Form as an appendix?</p> <p>Overall, I appreciate the framing of these findings as an opportunity to improve quality and policy, rather than looking to individual practitioner changes. I think this is an important lens to apply to the issue of oligoanalgesia in children.</p>
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## VERSION 2 – AUTHOR RESPONSE

Editor in Chief Comments to Author:

1. Your paper needs to be focussed on pain. Some of the information presented is irrelevant (eg Mode of transport "The rate of ambulance arrivals ranged from 0 - 45.5% (median 3.7%, IQR 2.3% - 5.5%)").  
Sentence deleted

Title

2. Shorten by deleting "The processes and outcomes of"  
Done

3. What this study adds delete the last sentence  
Done

Abstract

4. Conclusion delete the last sentence  
Done

Methods

5. 1st sentence delete "by the authorship who are subject matter clinical and academic experts in paediatric pain"  
Done

6. Delete Table 1 -it is not necessary  
Done and provided as an online supplementary table

Results

7. Table 2 simplify by listing all DGHs and then all tertiary centres  
Done

8. Table 3 list totals only. If you want to mention the ages in detail do so in a supplementary table  
Done

9. Mode of transport, Table 4 and pre-hospital analgesia section . Condense to two-three sentences describing analgesia more likely to be administered for ambulance cases (this is as expected and not a main point). Delete Table 4  
Done

10. Pain assessment section Delete "There were no statistical differences in the assessment of pain in tertiary centres compared to district general hospital's ( $p = 0.516$ ) or in the management of pain ( $p = 0.384$ ). There were no statistical differences in the assessment of pain in hospitals classified as trauma centres compared to non-trauma centres ( $p = 0.159$ ) or in the management of pain ( $p = 0.059$ )" and Table 7.  
Done

11. Table 6 should be deleted or made into a supplementary table  
Done

12. Supplementary Table 1 is important and needs to be in the main paper  
Added as table 4

13. Delete table 7 and the accompanying text  
Done (as per point 10)

#### Discussion

14. Delete the 1st sentence which repeats Methods  
Done

15. Shorten by focussing on your finding not your opinion on pain management, which may be better stated in an editorial following publication of your paper  
Done

Reviewer: 1 Dr. Susy Joseph, Government Medical College Thiruvananthapuram

1. Main drawback is the retrospective nature of study.

We agree, and this is highlighted first within our limitations section

2. Also, the authors have not taken patient /parent level of satisfaction and the level of health worker assessing and managing pain. All the limitations of study have to be strictly mentioned one by one. We had previously mentioned the lack of assessment of patient/parent level of satisfaction, and have added lack of healthcare worker satisfaction.

Reviewer: 2 Dr. Simon Craig, Murdoch Childrens Res Inst

1. I am not sure that the choice of subjects (children with minor injuries, a significant proportion of which had no pain on arrival, and who may not spend long enough in the ED to require a single (or repeated) pain assessment) was ideal. I agree that pain is often poorly documented and treated, however, I am unsure that going into detail in a population of patients with minor injuries is particularly helpful. A number of children with a pain score of 0 received analgesia. A significant confounder with this study is that many children with minor injuries do not need to spend a long time in the ED, and may not be there long enough to require repeated pain assessments. Was ED length of stay measured? What is the justification for concentrating on children with minor injuries?

The ED length of stay was measured and we have values for 3648 presentations. The median length in the department for the minor injury management was 113 minutes (IQR 72-167 minutes). This data was not recorded in 240 patients. We have added this detail to the manuscript. We recognise that a number of children had a pain score of 0 and received analgesia. This may in certain cases be due to mandating pain scores in some sites so a value is given to allow the triage to be completed although it may not be accurate but the data we collected does not allow us to draw conclusions on this. Pain may relate to procedures performed in the ED for example burn dressings. Children with minor injuries are a large proportion of patients presenting to the department who deserve to be managed appropriately.

2. The conclusion in the abstract includes "pain management and the associated outcomes have not been adequately addressed and prioritised within existing network structures and processes" – I do not understand how this paper demonstrates this.

This statement is based on the repeated performance of 7 National Audits by RCEM on Paediatric Pain management and is stated in greater detail in the previous article (Structures of paediatric pain management: a PERUKI service evaluation study) which we have updated as a reference to help strengthen this point "Seven successive national audits of ED childhood pain management since 2003 have demonstrated some improvement in prehospital analgesia (29% in 2017/2018 audit), and in recording of pain score on arrival (national median of 12% in 2003 to 55% in 2017/2018). However, continued deficiencies persist in timely management of pain in patients with moderate and severe pain, and most notably a near complete absence of pain re-evaluation after administering analgesia."

3. The methods section starts with presentation of a comprehensive table of structures, processes and outcomes. It is unclear what bearing this has on the rest of the methods section, as many processes and outcomes listed are not included.

This table has now been removed and the methods have been updated.

4. With regards to data collection, it would be helpful to see more detail on how charts were abstracted (single abstractor vs two independent abstractors, whether they were blinded to the study hypothesis, any interrater agreement testing). Please provide the coding criteria in a supplementary appendix. The details are now included in a supplementary appendix 1 including inclusion and exclusion criteria. The data is entered using a single extractor and there is no interrater agreement testing. The extractors were not blinded. As different coding systems are used across the network, the identification of eligible children at each site was delegated to the site lead. The exclusion of major trauma which is defined as an injury severity score of >15 has been included in the manuscript. The remaining trauma that is not major trauma is minor trauma. The breakdown of injuries included is listed in the results. We did not define minor trauma based on ICD codes.

5. There are a large number of tables, some of which are probably unnecessary.

This has been addressed, in response to the recommendations of the Editor in Chief

6. Table 2 – it is unclear whether "repeat pain score" is a percentage of all patients, or a percentage of patients who had at least one pain score documented.

We have edited the column heading to make clear that this is the percentage of all patients.

7. Table 3 – is it necessary to have 6 age groups? Consider combining the first three into a <2 years group.

Age breakdown has been removed from this table (but provided as a supplementary table)

8. RCEM guidelines are mentioned regarding opiate administration (17 received an opiate as per RCEM guidelines) – which guidelines are referred to (they are not referenced)?

We have added this reference (The Royal College of Emergency Medicine: Management of pain in children. Best Practice Guideline 2017; 1-1)1.

9. Table 7 – I am not sure how helpful this is. It may be worth considering multiple linear regression to identify factors which predict higher completion rates of pain scores, or multiple logistic regression to identify predictors of "good" pain score completion rates (i.e. >75% of patients or whatever the authors feel is adequate).

Table 7 has now been removed, as per recommendations from the Editor in Chief

10. Supplementary table 1 – provides data on medications given. No details are available regarding slings, splints, ice packs, injected local anaesthetic, nerve blocks or haematoma blocks.

In the limitations section, we have made note of the fact that, due to our reliance on retrospectively reviewing analgesic prescriptions, we have not been able to provide data on non-pharmacological analgesia practices.

11. The conclusions that "a new body of recommendations is required" is not supported by the study findings.

This has been reworded to more research is required.

Reviewer: 3 Dr. Samina Ali, University of Alberta

1. The Donabedian framework's use and success in other settings should be further expanded upon, as it is the premise upon which this entire paper is built. If it is not valid, rigorous and appropriate, the premise for this paper falls short. can you describe where and how it was used with success, rather than alluding to its use?

As per the editors comments, we have removed this from the main body and have added in a limitation to the need for further validation.

2. Since the Donabedian framework was adapted to the peds pain/emergency setting by the authors (for the purposes of this study), this should be acknowledged as a limitation, as it was not rigorously tested or used an external panel of experts.

Done

3. Study setting: please describe the PERUKI network of hospitals better: annual range of volumes of peds patients in the ED, distribution of urban vs rural sites, cities/countries that are a part of PERUKI. after reading this section, i was still not sure of the setting and if it was similar to where i practice. I see that some of this is provided in results, but perhaps a brief review of at least geographic area, here, would be helpful to a non UK reader. 1-2 tightly written sentences could cover this very well, and allow for better understanding of setting.

Done

4. The time frame of data collection overlaps with high respiratory season, which may influence the ability to capture pain scores. Lack of capturing of seasonality should be addressed in limitations. We have made reference to this in the limitations section.

5. Can you include the full definition of minor trauma? What ICD codes/diagnoses did you employ? As different coding systems are used across the network, the identification of eligible children at each site was delegated to the site lead. The exclusion of major trauma which is defined as an injury severity score of >15 has been included in the manuscript. The remaining trauma that is not major trauma is minor trauma. The breakdown of injuries included is listed in the results. We did not define minor trauma based on ICD codes.

6. Can you please include the Case Report Form as an appendix?

This has been included as supplementary appendix 1.

### VERSION 3 – REVIEW

<b>REVIEWER</b>	Reviewer name: Dr. Simon Craig Institution and Country: Murdoch Childrens Res Inst Competing interests: None
<b>REVIEW RETURNED</b>	02-Feb-2022

<b>GENERAL COMMENTS</b>	<p>Thank you for the opportunity to review this revised manuscript.</p> <p>The authors have made some changes, but do not appear to have addressed some concerns raised in my previous review</p> <p>This is a large study of many children with minor injuries (selected by the site lead, but not according to a specific diagnostic coding system), many of whom were documented as having no pain whatsoever (40% no pain and another 30% mild pain), and spent a relatively brief time in the emergency department (although I had trouble identifying where in the manuscript ED length of stay is</p>
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	<p>described). The authors then draw conclusions regarding provision of analgesia (which may not be necessary if there is no pain or mild pain which improves rapidly) and reassessment of pain scores (which may not be possible if the patient has already been discharged home). Further, it is impossible (using retrospective methodology) to determine whether or not pain relief was offered, but declined. These limitations are not addressed.</p> <p>The "key messages" section states that structures, processes and outcomes of paediatric pain are highly variable across sites. However structures and processes are not presented in this paper.</p> <p>The adapted framework (supplementary appendix 2) does not appear to relevant to the rest of the paper (which is a structured chart review). It could be removed.</p>
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<b>REVIEWER</b>	<p>Reviewer name: Dr. Samina Ali Institution and Country: University of Alberta Faculty of Medicine &amp; Dentistry, Pediatrics, Canada Competing interests: None</p>
<b>REVIEW RETURNED</b>	15-Feb-2022

<b>GENERAL COMMENTS</b>	The authors have adequately addressed previously voiced concerns and suggestions.
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### VERSION 3 – AUTHOR RESPONSE

Dear Dr. Manu Raj and Prof. Imti Choonara,

Thank you for giving us the opportunity to submit minor revisions on our manuscript titled "Pain management in children and young adults with minor injury in Emergency Departments in the UK and Ireland: a PERUKI service evaluation" for consideration for publication in the BMJ Paediatrics Open (Manuscript ID bmjpo-2021-001273.R3). We appreciate the time and effort that you and the reviewers have dedicated to providing your valuable feedback on our manuscript. We are grateful to the reviewers for their insightful comments on our paper. We have been able to incorporate changes to reflect all the suggestions provided by the reviewers. We have highlighted the changes by tracking changes in the marked document as requested. Here is a point-by point response to the reviewers' comments and concerns:

Editor in Chief Comments to Author :  
Your paper is much better. A few minor points to address

Associate Editor  
Comments to the Author:  
(There are no comments.)

Reviewer: 1  
Dr. Simon Craig, Murdoch Childrens Res Inst  
Comments to the Author  
Thank you for the opportunity to review this revised manuscript.

The authors have made some changes, but do not appear to have addressed some concerns raised in my previous review

1. This is a large study of many children with minor injuries (selected by the site lead, but not according to a specific diagnostic coding system), many of whom were documented as having no pain whatsoever (40% no pain and another 30% mild pain), and spent a relatively brief time in the emergency department (although I had trouble identifying where in the manuscript ED length of stay is described). The authors then draw conclusions regarding provision of analgesia (which may not be necessary if



there is no pain or mild pain which improves rapidly) and reassessment of pain scores (which may not be possible if the patient has already been discharged home).  
Further, it is impossible (using retrospective methodology) to determine whether or not pain relief was offered, but declined.  
These limitations are not addressed.

Response:

The ED length of stay is now detailed in the "Pain Assessments" section of the results. The limitations has been updated to note the omission of the offered but declined due to the retrospective nature of this study. The limitations has been further expanded to include the suggestion of "A future prospective study is needed to gain more granular detail into structures, processes and outcomes relating to pain management across the PERUKI network".

2. The "key messages" section states that structures, processes and outcomes of paediatric pain are highly variable across sites. However structures and processes are not presented in this paper.

Response: Wording updated to reflect the outcomes which are presented in the paper – "Outcomes related to paediatric pain are highly variable across sites. More research is required to determine the core structures and processes to overcome the suboptimal outcomes for paediatric pain management."

3. The adapted framework (supplementary appendix 2) does not appear to relevant to the rest of the paper (which is a structured chart review). It could be removed.

Response:

We have chosen to keep to framework in our manuscript. We agree however that not all elements of the framework were addressed in the retrospective data collection of this study. This has been mentioned in the limitations section. The outcome elements that have been addressed include the percentage of children with minor injury that had a recorded pain assessment ( this is a standard of care and reflect the quality of pain management across the network), the reassessment of pain post analgesia intervention is a process measure relating to the Continuity of care which is inclusive of reassessment. The time interval between pain assessments is a measure of process. We agree that in order to fully reflect all elements of the structures/ Process/ outcomes framework approach a future study will need to include this framework in the study design.

Reviewer: 2

Dr. Samina Ali, University of Alberta Faculty of Medicine & Dentistry

Comments to the Author

The authors have adequately addressed previously voiced concerns and suggestions.

#### VERSION 4 – REVIEW

<b>REVIEWER</b>	Reviewer name: Dr. Simon Craig Institution and Country: Murdoch Childrens Res Inst Competing interests: None
<b>REVIEW RETURNED</b>	26-Feb-2022
<b>GENERAL COMMENTS</b>	<p>I still have a few queries which (in my view) have not been fully addressed. However, I think this is probably now at the point that ongoing discussions should be between the editor and the study authors. I am unsure whether an additional round of reviews would be particularly helpful.</p> <p>I agree that a prospective observational study would provide a better idea of where the barriers are,...</p> <p>I still think that a major problem is that the study authors are advocating for more assertive pain assessment / reassessment based on a study where 40% of children had no pain, and 30% only had mild pain. I am not convinced that a repeat pain score is important for children with minor injuries who have no pain on the</p>

	<p>initial assessment, and who have a relatively brief ED length of stay.</p> <p>Also, selection bias (selected by the site lead, but not according to a specific diagnostic coding system) is an issue which I do not think has been addressed.</p> <p>Finally, I disagree with the inclusion of the framework in this paper. The framework, although likely to be quite valuable, is of limited relevance to the study design / findings of this particular paper. It is currently placed in an appendix, which is not likely to be accessed by most readers.</p>
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