Author’s response to reviews

Title: Does implementation of the PECARN rules for minor head trauma improve patient-centered outcomes in a lower resource emergency department: A retrospective cohort study

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Author’s response to reviews:

The authors of this manuscript thank the reviewers for their feedback and the opportunity to revise this manuscript. We believe this revised version is much improved and addresses the reviewer’s comments.

Reviewer 1:

When you talked about "lower resource setting" initially, I was thinking that you meant it was more difficult to get a CT, in which case the use of the PECARN rules would be ideal. But, were you talking about QI and administrative resources?

We thank the reviewer for this comment. The reviewer is correct, and we understand we may have created some confusion by using “lower resource setting”, which was modified into “limited resource setting” throughout the manuscript. In our study’s setting, CTs were readily available, yet expensive for 15% of our patient population who are self-payers. It is correct that, by low resource setting, we specifically meant lack of administrative and educational resources in order to translate knowledge, implement guidelines and change practice. As opposed to previous studies on the impact of the utilization of the PECARN rules (1-9), the implementation
of these in our study took place in a setting with no Pediatric Emergency Medicine trained physicians, and no administrative resources to assist in quality improvement (QI) initiatives. Therefore, what we set out to study was whether a simpler implementation (not electronically based, no feedback…) could still help reduce the use of CTs. We were able to show that even with limited QI and administrative resources, the PECARN head CT rules are easy to use and efficient guides for ED physicians in their clinical decision-making regarding imaging of children with minor head trauma, with undeniable potential in reducing the rate of CT scanning. This was further clarified in the manuscript as follows:

The following sentence was added to the Background section on pages 4 and 5:
As opposed to previous studies on the impact of the utilization of the PECARN rules (1-9), the implementation of these in our study took place in a setting that lacked Quality Improvement (QI) and administrative support, which we considered for the purpose of this study as a limited resource setting.

The following sentence was added to the Methods section on page 7:
As opposed to previous studies (1-9), the implementation of the PECARN rules in our study took place in a limited resource setting that lacked administrative and educational resources to assist in QI initiatives.

The following sentence was added to the Discussion section on page 12:
The main findings of a significant decrease in CT scanning rates among low risk patients less than two years of age without any adverse effect on patient outcomes, suggest that the PECARN rules reliably identify patients at low risk for ciTBI and that their implementation can safely reduce the burden of CT imaging on children with head trauma, even in settings with limited administrative and educational resources and limited implementation efforts and QI initiatives, in order to translate knowledge, implement guidelines and change practice.

When making the point of talking about lack of QI and administrative resources, the concept is brought up without much explanation. It might be worth it to describe what you mean prior to make the conclusion that such resources would have been beneficial.

We thank the reviewer for this comment. Most published studies showing a positive impact from the implementation of the PECARN rules were conducted in developed countries (1, 3, 4, 7-10), with adequate administrative resources, or conducted specifically as QI projects (5, 6). Specifically, Nigrovic et al. decreased CT scanning rates through individual provider feedback (6). They had assembled a team, composed of a nurse educator and research expert, a QI expert, and an administrator, to review the literature on implementation, increase awareness about the PECARN rules and develop strategies to encourage their adoption. A head trauma electronic order set that included a link to the guideline and supporting text was also created for support. In our setting, we did not have this support to improve awareness and adherence to guideline recommendations. In fact, we did not have enough staff (administrative or medical) to implement a true QI project which would include PDSA cycles and a multidisciplinary team available to track results and provide feedback. We also did not have Information Technology (IT) support to develop an electronic tool to ease the use of the PECARN rule as other places have done (5-7).
nor to help generate regular reports that would be used for PDSA cycles and feedback to physicians.

We clarified this point as recommended in the Discussion section of the manuscript on page 15.

What were rates of CTs on "trivial" injury mechanisms? Did this rate fall also after implementation of the rules?

We thank the reviewer for this comment. We unfortunately do not have any data on trivial injury mechanisms since, for the purpose of our study, we excluded patients with trivial injury mechanisms which were defined as ground-level falls or running into stationary objects, and those with no signs or symptoms of head trauma other than lacerations or abrasions. Trivial injuries were excluded from our study, since they did not fit the PECARN rules criteria (11).

Perhaps describing how orders are placed in your ED would be helpful, as well as what is available from the standpoint of follow-up. You bring up electronic order sets; this was surprising to me as the whole time, I was assuming that you had electronic orders. However, looking at Figure 1, I wonder if you are on paper for all documents? Or just for your orders?

We thank the reviewer for this comment. All documents in our ED, including charts and orders, were on paper, and not electronic. Documents were scanned and could only be reviewed on the Electronic Health Records (EHR) at AUBMC. Typically, an order was written and signed by a physician and executed by nurses. When a CT imaging order is placed, nurses would then call the radiology department to inform them of the CT order. We described how orders are placed in our ED, as mentioned above, in the Methods section on pages 5 and 6.

P4, line10: add comma after "variable"

We thank the reviewer for this comment. We modified the text on page 4 accordingly.

P6, line 1: can delete "hereafter referred to at the PECARN rules." This was already stated earlier.

We thank the reviewer for this comment. We modified the text on page 7 accordingly.

P6, line9-10: When you talk about education for the providers, was this just an email? Lecture?

We thank the reviewer for this comment. Education was done as follows: Attending physicians were educated about the PECARN rules through a PowerPoint presentation during the general ED department meeting in December 2013. This presentation was then circulated by email. Residents and rotating trainees were also educated about the rules every year, via lectures. Posters of the PECARN rules were also placed in the ED for reference. This was further clarified in the Methods section on page 7.

P6, line14-15: You make a point of talking about lack of QI teams and less experience in specialized QI intervention efforts. Why are you specifically bringing this up? It seems like you are implying something about this, but don't say what in detail.

We thank the reviewer for this comment. We addressed this point in previous comments and clarified it in the manuscript text as mentioned above.
P7, line 14: maybe mention the number of those that were excluded for the listed exclusion criteria and then refer to Figure 1.
We thank the reviewer for this comment. We modified the text accordingly on page 9.

P8, line 1: could there have been a change in presentations/verbiage used due to the education done about the rules? How were these cases pulled? By chief complaint? By billing diagnosis?
We thank the reviewer for this comment. For this study’s sample collection, in order to minimize selection bias, we pulled the charts by discharge diagnoses rather than presenting complaints. This also avoided bias from change in terminology for the chief complaint and presentation (history/physical exam). In order to identify the largest number of patients and be as inclusive as possible, we screened all patients, 0 to 18 years of age, who presented to the ED between the 1st of December 2012 and 30th of December 2016, and we reviewed the charts of all patients with the following characteristics to screen them for inclusion:
- Any patient with an ED discharge diagnosis or hospital admission diagnosis of any head related injury, any head injury related complication, any mechanism of injury that raises suspicion of head injury, and other complaints that may involve concomitant head trauma.
- Any patient who had a head CT, orbital CT, facial CT or skull X-rays done in the ED.
- Any patient who was seen in the ED and required any ICU admission.

We added these details to the Additional File on pages 2 and 3. We also added an abbreviated version in the Methods section on page 6.

P8, line 6: how were these pts diagnosed with ciTBI?
We thank the reviewer for this comment. The patients included in this study were diagnosed with ciTBI based on the PECARN definition of ciTBI (11). Clinically important TBI consisted of any of the following descriptions:
• Death from TBI
• Neurosurgical intervention for TBI (intracranial pressure monitoring, elevation of depressed skull fracture, ventriculostomy, hematoma evacuation, lobectomy, tissue debridement, dura repair, other intervention)
• Intubation for more than 24 hours for TBI
• Hospital admission for 2 nights or more for the TBI in association with TBI on CT scan.
• Hospital admission for TBI defined by admission for persistent neurological symptoms or signs such as persistent alteration in mental status, recurrent emesis due to head injury, persistent severe, headache, or ongoing seizure management.

For the purpose of our study, any of the above variables was part of the ciTBI variable. This is found in the Additional File on page 1. However, we added an abbreviated version as a footnote to Table 2 on page 30. We also mentioned that the collected variables are defined in the Additional File in the Methods section on page 8.

P8, line 8: do patients not routinely go home with discharge instructions? Or were you referring to a specific handout on head injuries?
We thank the reviewer for this comment. By discharge instructions, we were referring to written discharge instructions specifically related to head trauma. Based on our experience in the PED
setting, many patients are not given written discharge instructions upon discharge. Aiming to study the rates of these specific written instructions given pre and post-PECARN, we created the “discharge instructions” variable, which consisted of written discharge instructions specifically related to head trauma. This was adjusted in the manuscript on page 10. This was also added as a footnote to Table 2 on page 30.

P8, line 9: there's a decimal point missing in the p value
We thank the reviewer for this comment. We modified the text on page 10 accordingly.

P8, line 11: add in a comma before "nor"
We thank the reviewer for this comment. We modified the text on page 10 accordingly.

P9, line 7: add a semicolon before "and"
We thank the reviewer for this comment. We modified the text on page 11 accordingly.

P9, line 20: add "that" before "their"
We thank the reviewer for this comment. We modified the text on page 12 accordingly.

P9, line 8: of those that were admitted on bounce back, what happened? What were their diagnoses?
We thank the reviewer for this question. There were 5 patients who were admitted on bounce back in our study. Of the bounce backs, 5 children were subsequently admitted to the hospital for observation. One had a subdural hematoma, 2 had concussions and 2 presented with vomiting that was later diagnosed as acute gastroenteritis. None of them had any further complications, required surgery or died.

P10, line 9: break this sentence into 2 sentences. Everything after the semicolon is a sentence fragment.
We thank the reviewer for this comment. We modified the text on page 12 accordingly.

P10, line 14: overall CT scanning rates for all ages? Just pediatric? For all diagnoses?
We thank the reviewer for this comment. By baseline overall CT scanning rates, we were referring to CT scanning rates of all included patients, 0 to 18 years of age, before the implementation of PECARN rules. This was further clarified in the manuscript text on page 12.

P11, line 3: add a comma before "compared"
We thank the reviewer for this comment. We modified the text on page 13 accordingly.

P12, line 18-19: change to "a surgical, emergency, or family medicine, rather than a pediatric or pediatric emergency, background"
We thank the reviewer for this comment. We modified the text on page 15 accordingly.
P12, line 20: maybe add "individual" before "provider" to stress that it is the individual provider factors that weaken the impacts of the rules, rather than class of provider factors. We thank the reviewer for this comment. We modified the text on page 16 accordingly.

P13, line 16: change "study" to "study's" We thank the reviewer for this comment. We modified the text on page 16 accordingly.

P14, line 8: delete the first "be" We thank the reviewer for this comment. We modified the text on page 17 accordingly.

P25, line12: for the age variable, is this measurement in months or years? We thank the reviewer for this comment. The age variable was divided into less than 2 years of age and equal or more than 2 years of age. We added the years unit to the “age” variables in Table 1 on page 28.

P25, line 17: perhaps delineate what the "severe mechanism of injury" variable was? I'm assuming you're using what was described in the PECARN paper. If so, you would just need to specifically say that. We thank the reviewer for this comment. Severe mechanism of injury was defined as per the PECARN paper (11) and consisted of a motor vehicle crash with patient ejection, death of another passenger, or rollover; a pedestrian or bicyclist without helmet struck by a motorized vehicle; falls of more than 0.9m (if <2 years of age) or more than 1.5m (if more than 2 years of age); or a head struck by a high-impact object. The ‘severe mechanism of injury’ variable was defined as a footnote to Table 1 on page 29.

P26, line23-26: You list essentially negative CTs and "positive findings," but they don't add up to the total number of CTs obtained. What were the remainders diagnosed with? We thank the reviewer for this comment. We admit this was an oversight. We adjusted the numbers and modified Table 2 on page 30 as follows:

<table>
<thead>
<tr>
<th>Variables, n (%)</th>
<th>Pre-PECARN (N=425)</th>
<th>Post-PECARN (N=937)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT imaging</td>
<td>92 (21.6)</td>
<td>174 (18.6)</td>
<td>0.18</td>
</tr>
<tr>
<td>No acute post traumatic change</td>
<td>84 (91.3)</td>
<td>161 (92.5)</td>
<td>0.73</td>
</tr>
<tr>
<td>Positive findings2</td>
<td>8 (8.7)</td>
<td>13 (7.5)</td>
<td>0.73</td>
</tr>
</tbody>
</table>

2 Positive findings consisted of intracranial hemorrhage/contusion, cerebral edema, traumatic infarction, diffuse axonal/shearing injury, sigmoid sinus thrombosis, midline shift, skull diastasis, pneumocephalus, or depressed skull fracture.

Reviewer 2:

1. Abstract: In the results section, I recommend the authors list the absolute number of patients who had CT scans in &lt;2year and &gt;2year age groups as this enhances the interpretation of the results. We thank the reviewer for this comment. We added the absolute numbers in the Abstract on page 2 as recommended.
In the conclusion section, I recommend the conclusion be altered to reflect the results accurately i.e. PECARN rules did not significantly change the overall CT scan rate but reduced the CT scan rate in patients aged <2 years at low risk of cTBI.

Thank you for the comment. We modified the conclusion of the Abstract on page 2 accordingly.

2. Methods:
   a. The reason for the different durations of pre and post PECARN-implementation is not described. I recommend the authors describe the rationale for this.
   We thank the reviewer for this comment. We collected data over 3 years post intervention as we had aimed to see if there was a change in the CT rates over time. We did the analysis over 6-month intervals; however, we did not find any trend or pattern. Therefore, we decided to group the patients into 1 post-intervention group for ease of description as the 6-month intervals did not add to our results. We justified the choice of our study period in the Methods section of the manuscript on page 5.

   b. The methods section of data collection is insufficiently described. I recommend the authors describe this process in detail. I suggest the authors refer to 'Gilbert et al 1996 Emergency Chart Reviews in Emergency Medicine research. Where are the methods? Ann Emerg Med 1996 MAR;27(3):305-8' or something similar to guide their revision of this section.
   We thank the reviewer for this comment and reference. The data collection team was composed of research assistants (RA) and medical graduates, all with CITI certification and familiar with our medical charts, who were not blinded to the study hypothesis. The principal investigator (PI) and lead RA developed a data collection manual corresponding to the data collection sheet for this study. This manual had the definitions of all the required variables (including all their potential corresponding terminology in the charts) and their corresponding locations on the EHR of the study participants. The data collection team then performed a pilot data collection on a small number of charts and discussed thereafter any concerns regarding the data collection process to evaluate the need to modify the data collection manual accordingly. After training, the data collection team proceeded with the data collection process. The team met regularly thereafter to discuss any potential questions or doubts they may have; consensus was reached with the PI. Finally, multiple quality checks of 15% of the charts were performed in parallel by a second reviewer, to assess the quality of the data. The data collection methods were described as above, in the Methods section of the manuscript on page 8.

   c. Was a sample size calculation performed? Please justify your answer.
   We thank the reviewer for this comment. We did not do sampling for the purpose of this study. The selection of the period was imposed by the implementation of the rule in December 2013 and we selected 1 year before implementation to include all seasons (1st December 2012 to 31st December 2013) and 3 years after implementation to see if there was any change in CT imaging rates over time (1st January 2014 to 30th December 2016). There was no statistical reason for the sample. All pediatric patients presenting to the PED during those periods were included. This was further clarified, as mentioned above, in the Methods section on page 5.
3. Results: under 'Primary Outcomes - CT scanning rates', please list the absolute number of CT scans in the &lt;2years and &gt;2 years cohorts in all risk groups (in addition to the percentages). We thank the reviewer for this comment. We added the absolute numbers, with their corresponding percentages, in all risk groups as recommended, in the Results section on pages 10 and 11.

4. Discussion: The limitations need to be discussed in further detail. Particularly, the reliance on previously documented data might have led to misclassification of patients. The 37 patients whose medical records could not be accessed should also be mentioned as a limitation. We thank the reviewer for this comment. This was adjusted as follows in the limitations section on page 17:
Moreover, we had no access to the medical records of 37 patients among those who were screened for inclusion, which amount to 2% of the excluded patients. Although we kept the data collection simple, following the PECARN predictors, the reliance on previously documented data might have led to misclassification of patients.

5. Conclusions: The conclusion needs to be altered to reflect the results accurately i.e. PECARN rules did not significantly change the overall CT scan rate but reduced the CT scan rate in patients aged &lt;2years at low risk of ciTBI. We thank the reviewer for this comment. We modified the conclusion accordingly on page 18.

Figure 1: Please replace the word 'Scanned' at the top of the flowchart with 'Screened' as this is confusing given the context of CT scanning. We thank the reviewer for this comment. We modified figure 1 accordingly.

References