Author’s response to reviews

Title: Comparison of neonatal red cell transfusion reporting in neonatal intensive care units with blood product issue data: a validation study

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Author’s response to reviews:

Dear Dr Boodhun,

Thank you for allowing us the opportunity to revise our manuscript “Comparison of neonatal red cell transfusion reporting in neonatal intensive care units with blood product issue data: a validation study” publication in BMC Pediatrics. We also thank the reviewers for their helpful comments.

We have addressed the Reviewers’ comments in the following pages (comment in italics, with our responses following).

The authors approve this final ‘to be published’ version for submission.

Yours sincerely

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Reviewer 1

Perhaps it would be worth considering using this validation data as a smaller part of a study utilising the clinical data it examined.
This paper provides the background necessary for the data referenced to be used in a more in-depth study. In order to fully examine the changes in reporting over time and by patient severity while keeping a concise message, we have not included a clinical component to this study.

Background

This section could be strengthened to show the reader why it is important that this study is undertaken.

A paragraph explaining the role of validation studies has been added to the background.

Methods

Why was 2007-2010 selected? Is one of the databases examined not collecting neonatal transfusion data anymore?

Linked data from the Blood Watch Program was available for this period of time, but this is not a routinely collected and linked database. The 2007-2010 period was chosen to make opportunistic use of these data.

Discussion

As a validation study, I would have expected the discussion to start with overall findings of the study in direct relation to its aims. A more focused discussion on the importance of the study's findings and why they matter would assist the reader.

The first paragraphs of the discussion have been reworked to relate more directly to the aims of the study. A paragraph on the role of validation studies has been added to the background section to assist the reader understand the importance of the results.

Where does this study sit with what is already known in the literature? Are there any other similar studies available?

The results of this study are similar to other studies in different populations (p10). We were unable to find comparable studies within the neonatal literature.

Overall suggestions

As discussed previously, if the authors presented a stronger argument for why it is important to undertake validation studies and why this particular one is important, it would strengthen the manuscript significantly. Certainly from my point of view (clinical), I have struggled to gain a clear understanding of why it was important to undertake this study.
We have included extra information (P1) and reworked the discussion to address this.

Reviewer 2

1. In the abstract methods and results, it is confusing which group comparisons are being described: there are three: NICUS, the Blood Watch data, and the Admitted Patient Data Collection "hospital data", but the methods section refers to "the two datasets", but then goes on to refer to the third group "hospital data" in the results. I think this needs to be a bit more explicitly defined.

The datasets referred to have been clarified.

2. The quantitative agreement between measures is assessed with a weighted Kappa, with the table implying this was computed for the number of transfusions grouped into 1-2, 3-4, 5-9, 10+.

   - Why were these groups chosen?
   
   - Could this have been analysed as a continuous scale of units transfused?
   
   - If there is some significance to these groupings, why then in table 4 are number of transfusions grouped as 1, 2, 3-9, 10+ (splitting the 1-2 group and grouping the 3-9)?
   
   - Regardless, the reason for analysing like this should be specified in the methods section.

Groups were selected based on clinical relevance and to provide adequate sample for analysis. Due to the discrete nature of the data and the small range of number of transfusions, we felt it was more appropriate to analyse the data as categorical rather than continuous. Detail has been added to the methods (P7). We have changed table 4 to reflect the grouping used in table 3.

3. Tests of change over time are given p-values in the results section (for changing transfusion rates). I could not find the type of test mentioned anywhere in the text - this should be described in the methods section.

This has been added.

I wonder whether a measure of quantitative agreement would be helpful, and if this was considered not to be the best approach, I think this should be explained in greater detail in the methods section.

As above, due to the nature of the data, we felt it was more appropriate to analyse the data as categorical rather than continuous. Detail has been added to the methods (P7).