Reviewer's report

Title: Prioritising neonatal medicines research: UK Medicines for Children Research Network scoping survey

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Reviewer: Stephanie Stephanie

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The manuscript deals with a very important topic for improving neonatal drug therapy. However, there are major concerns. The following answers to the questions of the BMC reviewer report form points out the major concerns.

1. Is the question posed by the authors well defined?

Yes, the questions posed by the authors are well defined.

2. Are the methods appropriate and well described?

The methods used to analyse question 1 “Which medicines do you use on your Neonatal Unit?” are not adequate. Although the paper Choonara, I. and S. Conroy, “Unlicensed and off-label drug use in children” provides definitions for the terms “unlicensed” and “off-label” the authors seem to use and analyse only the “not licensed drugs”. “off-label” is not described and defined although it should have a much higher percentage than the “unlicensed” drug use.

Question 2 of the survey “What are the most important therapeutic gaps?” poses an open question to the neonatologists. So the wording of the answers concerning the “therapeutic gap” should be very versatile. In the methods section it is therefore important to describe how these different wording was grouped together to form the final ranking list provided in figure 1. It might have been better to offer an array of therapeutic areas to the neonatologists to have a more standardized answer.

The response rate of 36% is not representative. Surveys should have response rates above 50% minimum, especially when the network has dedicated itself to solve this kind of problem. Maybe it had been worth to send a third or fourth reminder.

The definition of the child classes should be done according to international classification systems (EMEA or FDA): Please clarify the term “term infant” and “preterm infant”. It might be “preterm neonate” and “neonate” i.e. “newborn”.

3. Are the data sound?

No, the data are not sound. The definitions of the terms “licensed”, “prescription for medicines” and “medications” are not appropriately done. The authors write: “6.2% of prescriptions were for medicines that had neither licenses nor doses
specified for term and preterm infants. 63.5% of medications were missing a license or dose for either term or preterm infants.” What is the difference between the “prescriptions for medicines” and the “medications”. The numbers seems to be very different and it is not clear whether there is a difference concerning the drug treatment.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
No, see answer to question 2 and 3.

5. Are the discussion and conclusions well balanced and adequately supported by the data?

6. Are limitations of the work clearly stated?
The most relevant limitation of the word, the low response rate, is clearly stated.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
Yes

8. Do the title and abstract accurately convey what has been found?
Yes

9. Is the writing acceptable?
No, the writing is not acceptable. It is necessary the use and / or define standardized terms for describing the population investigated and the classification systems referring to.

Level of interest: An article of importance in its field

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests