Reviewer's report

Title: Neonatal Near-Misses in Ghana: A Prospective, Observational, Multi-Center Study

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Reviewer: Pauline Kale

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This is a relevant study on neonatal Near Miss in developing countries. Since an instrument for neonatal near miss tracking is proposed, it is very important to assess its validity. Some questions about the composition of the study population and the calculation of indicators of severe morbidity and neonatal mortality should be reviewed.

A) About the study population

The first step of the study was the revision of the admission ledgers at each site to identify newborns with complications by trained research assistants (Line 31 up to 33 of page 5). A total of 725 newborns were identified across the three sites as having experienced some type of complication at birth that might categorize them as a neonatal near miss.

A.1) 725 children were born at the three sites? If yes, the prevalence of "live births with complications" were about 8.6% (considering the number of live births of the three sites from April up to July 2015 (n = 8433). Or, this frequency included babies that were born at other hospital, but admitted to the neonatal units at KATH, CCTH, and KBTH? Did these babies have the same complications to be included in the study?

A.2) Which complications were considered at the first step of the study?

A.2) If babies admitted to the neonatal units at KATH, CCTH, and KBTH, regardless of where they were born, were recruited for participation (Lines 20 to 24 of page 5), but they don’t belong to the live birth cohort of each hospital. In general, neonatal near miss studies recruit children from the maternity where the birth occurred. How many children were in this situation? What kind of implication could the interpretation of the results considering that children born in other health facilities and transferred to hospitals were included in the study population?

B) About the definition of neonatal near miss proposal using the NNMAT tool

Second step: the screening of "neonatal near-miss" (Classified as met any of the four NNMAT criteria), but, at that moment, they are being classified as life-threatening using the NNMAT criteria - 578 live births with complications). So, the prevalence of life-threatening was 79.7%. As expected, the prevalence at the second step increased. The next step is the survival up to 28 days of the delivery to classify babies as cases of neonatal near miss. I suggest that children classified as life-threatening by the NNMAT tool but not yet known about the occurrence of
neonatal death, should be called as "life-threatening children" (not neonatal near miss cases). The text about these results is confusing (Linhas 25 a 37 da página 7).

B.1) The major question is: Why the validity (sensitivity and specificity) of the definition of neonatal near miss using the NNMAT tool wasn’t assessed? Although it is not the objective of the study assess the validity of the definition of neonatal near miss proposed, the justification of the study directs the reader to this question. There is a subgroup of children (456) with individual data of death (gold standard to neonatal near miss) that allows to do this analysis. I suggest the authors to assess the validity of neonatal near miss using the NNMAT tool.

C) About the indicators of neonatal sever morbidity and mortality (third objective of the study)

Data from table 2:

725 children with complications were recruited for the study.

578 live births with complications were classified as "life-threatening children" using the NNMAT criteria.

456 babies for whom neonatal death data were available and it was possible to classify them according to neonatal near miss. 310 of them were classified as neonatal near miss case (table 3).

Data from table 3:

The neonatal near miss rate (not ratio) considered 578 children with life-threatening conditions according to NNMAT criteria (without complete individual death information) as near miss cases. The neonatal near miss rate per 1000 live births was 68.5. It's important to consider that there aren't individual near miss (according to NNMAT criteria) and death data for all 8433 live births. The study population recruited for the study is 725 children with complications (not all live births of the three sites).

C.1) Considering only children classified as "life-threatening children" using the NNMAT criteria who had individual follow-up data for neonatal death classification, the real number of neonatal near miss cases is 310 (table 2). The sample consists of 725 children with complications (not all live births) and only 456 children have individual neonatal death data available).

D) Other remarks:

D.1) Methods

* Line 13 up to 35 of page 4 (just to check the numbers): KATH and KBTH have approximately the same frequency of deliveries annually (11,000)?
Line 49 of page 5: Key variables: The category "don't know" was accounted as "no" or the record was excluded from the analyses? If these categories were added, what kind of implication would result? Differentiated misclassification bias?

D.2) Results

Tables

* The * at number 725 does not have the corresponding explanation in the footer of table 2.

* Lines 32 and 33 of table 4: Birthweight < 1800g ou &lt;1.750g (methods)?

D.3) Discussion

* The lines 48 of page 8 up to 12 of page 9 should be rewritten. The authors mentioned a study that compare cut off points of the pragmatic criteria of different definitions of neonatal near miss. They must consider that in this paper (reference 3), the authors said "Periodic studies could apply a more complete definition, based on the literature on the subject and considering the availability of more technology in the care. When qualified information can be obtained on criteria other than the pragmatic ones, we recommend the incorporation of clinical, laboratory, and management criteria".

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
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