Reviewer’s report

Title: Care of the Mother-Infant Dyad: a Novel Approach to Conducting and Evaluating Neonatal Resuscitation Simulation Training in Bihar, India

Version: 0 Date: 02 Mar 2017

Reviewer: Riccardo Pfister

Reviewer’s report:

Summary

The global study aim of a partially presented work is to reduce one of the three main causes of early neonatal death (i.e. asphyxia) by a combined maternal and neonatal care approach. The current part of the study assessed in-situ simulation training on nurse competency in India. Competence was evaluated across scenarios of increasing clinical complexity requiring simultaneous management of mother and neonate; it focuses on the evaluation of the key steps of neonatal resuscitation and the time elapsed to reach these key steps.

Roughly 300 video-recordings determine an improvement of interventions and their timing with increasing complexity and hence additional simulation experience. The study speculates that its improved practical mother-newborn simulation has also the potential to reduce real-life early neonatal mortality. However, the study is more of a 'methodology paper' in that it tests the effectiveness of the PRONTO simulation training. In addition, although the study finds consistent trends, results do not show statistical significance.

General comments

The subject is of high importance and general interest. It concerns alternative ways of education in low resource countries and more specifically in the field of early neonatal healthcare.

Overall an interesting concept that is well conceived and merits publication although the speculations of reduced early neonatal mortality remain to be proven. Indeed the paper appears to present one (the first?) out of several planned publications.

The conclusion is in its first part a discussion of limitations and in the following section a very general statement not sufficiently based on the actual results. In my option this conclusion needs to be entirely reformulated.

Main points of interest:

* Interesting education concept in low income setting
Main points of critique:

* No statistically significant results, only trends
* Competing interest of two authors (including last author): PRONTO board
* The larger part of neonatal asphyxia occurs in utero during management of labour that was not addressed in this work.
* Maternal support per-partum as tested in this work may increase maternal survival, but will only marginally improve neonatal care (by freeing time/care for neonatal resuscitation).

Specific comments

Title

As PRONTO has already been published, I am not sure the 'novel approach' is really appropriate. However, I agree that using simulation-based training in low-income settings remains innovative so I can accept the wording.

Abstract

Introduction: Although perinatal asphyxia is a preventable cause of death, NR has the potential to prevent only a fraction of it. In high income-countries the larger part of neonatal asphyxia occurs during labour and delivery and this is probably similar in low-income countries.

Results: None of the presented results were statistically significant. It would have been nice to have not only the reduction time, but also the absolute time in the abstract to understand the clinical relevance. As an example the initiation of positive pressure ventilation (PPV) 20 seconds faster may be clinically less relevant if you know that it came down from 114 to 94 seconds.

Background

End of page 4: I have troubles in making sense out of these numbers. If there are indeed 13 paediatricians for a population of 104 million (and just 40% of the population were paediatric, 1 paediatrician would serve 3.2 million children…
Page 5, 90-93: A large proportion of the improvement hypothesis bases on avoidance of intrapartum maternal complications to reduce asphyxia. However the association of intrapartum complications and neonatal deaths is a retrospective association (Ref 5) without necessarily a cause to effect. Therefore, if intrapartum maternal complications were avoided, this may not necessarily change neonatal mortality or morbidity.

Page 5, 95-97: It is a bit limited to mention only two NR courses as widely used. There are many large-scale NR courses (Canadian, Australian, several European). The argument may be more acceptable in English speaking low-income countries.

Page 6, 125:

The reduction of neonatal mortality in the Mexico study was found at 8 month only and not at 4 and 12. As it stands written, it does not reflect the reality that has to take into account sustainability. I very much believe in simulation based training, but we need to give realistic figures to proof it's efficiency.

Methods

Page 7

A flow-chart of the full research project would have been nice to understand immediately that rounds are more geographically than time determined.

Page 9, 186 &192: The way how the videos were coded needs to be stated more clearly. The latter results tables may report some/all (?) of the evaluation criteria, but more detail is required in methods.

Results

Although there was a trend in improvement in the use of key steps of NR and time elapsed from delivery to the key steps, unfortunately none of the results were statistically positive.

However, the fact that no statistical difference was found does not necessarily mean there was no difference. For this statement it would have been necessary to have a non-inferiority power calculation.

Tables

To the point

Discussion
The first chapter summarizes the findings, but concludes on data that at the very best show a trend that was not statistically significant.

Whilst I would agree that management of the mother and child simultaneously is relevant for resources-limited environments, and that all trends of the PRONTO program tended towards improved patent management, the present study is not convincing in that none of the comparisons are statistically significant.

A discussion of the limitations or auto critique explaining why results were not significant may have been appropriate in this section.

Page 14, line 295

missing 'to'

Conclusion

The first part of the conclusion is more of a discussion of limitations section.

The following section calls the current effect of the PRONTO training program (although no statistically significant improvement was presented!) 'a stride in thinking skill acquisition' on simulated situations whilst criticizing the limited 'real-life' effect from other NR programs. I don't think this is an appropriate statement. A conclusion needs to refer to the actual results of the study: the study was feasible but there was no significant improvement although there was a consistent trend.

I very much believe in simulation training, but I think this conclusion does not reflect the results and needs to be entirely reformulated.

List of abbreviations

To the point

List of abbreviations

26 up-to-date references.

7 web references

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

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

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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