Author's response to reviews

Title: Adverse outcomes in maternity care for women with a low risk profile in The Netherlands: a case series analysis

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Author's response to reviews: see over
I would like to express my appreciation to the authors for having taken the time to address the reviewers’ comments and suggestions; this reflects their determination and their will to share their results with the professional and scientific communities. As mentioned by the authors, such analysis of unintended or unexpected care related events - which they qualified as a “standardized” one, “can provide additional information” (p.15)

Thank you for the appreciation of our efforts to address the reviewers’ comment and for the improvements and remarks in the manuscript. We have included resulting changes in the pdf file of the manuscript.

Nevertheless, I unfortunately still think that their methods lack the scientific rigor to provide results that can be exploited efficiently. The authors themselves are contradictory on the basis of their approach. In fact, while they mention early in their justification that:

Such insight can be provided by a case-by case analysis of care for pregnant women with adverse outcomes. The database of the Dutch Health Care Inspectorate (DHI) contains these cases with unexpected untoward outcomes and is therefore a valuable source for analysis of critical incidents. (p.5)

In the section entitled “limitations” of the study, they recognise that:

“Our current analysis and the description of the incidents in this article were thus restricted to the reports and data that were available in the database. It is difficult to draw firm conclusions from a case by case analysis but we were able to
What can the reader conclude from this incoherence? What is the level of rigor of the methods applied by the authors in order to attain their objectives?

We agree with the reviewer that an exploration from the results of the analysis of the incidents in the database of the DHI has some limitations which have been described in the ‘Limitation Section’. In particular, we think that there is a risk of selection bias in the cases. Nevertheless, we still think that this national database is unique and contains valuable information on determinants of risk because all cases have a care related component.

This contradiction which impacts the rigor of the methods is confirmed also by the authors in their conclusion where they wrote:

“We used a standardized instrument and aimed for the detection of potential causalities and consequences of high risk” (p.15)

It is well known in the research methodology that the best way to address the causality is attributed to the experimental approach (experimental design and randomised trial) which is not the case in the present study! In fact a case series is a medical research descriptive study which limits statements on the causality of observed correlations.

Thank you for your critical remarks on the methodological approach and our conclusions. We agree with your comments on causality.

We changed the text in the Limitation and Conclusion section that referred to a possible causality and emphasized the importance of performing further rigorous research for the identification of safety determinants.

We added text in the Limitation Section to explain that we were restricted to the reports and data that were available in the database because the cases were closed and we were not authorized to ask for additional information.

Finally, the authors conclude that by applying the “standardised analysis” they obtained “additional information” (p.15); additional related to what kind of information?

We think that a standardized analysis provides additional and more valid information compared to the non-systematic evaluation that is currently performed by involved care providers or by the DHI.

We still doubt that this additional information contributes rigorously to the development of knowledge in the field of the study. It would have been important that the authors get through their study to the conclusion that their “standardized analysis” be generalised, and to the recommendation which provide the conditions for applying the standardized analysis. By the contrary, the authors mention that:

In most cases the DHI imposed the improvement of written protocols followed by improving the organization of urgent care and better communication between care providers. (p.12)
These recommendations are already provided by the DHI. What can be provided through the standardized analysis... some insights which don’t reflect the expected causality?

We adjusted text in the Conclusion Section; we were able to identify safety determinants and contributed to the knowledge that the occurrence of several determinants can lead to adverse outcomes. We no longer describe causality as a result of our study but emphasize the importance of a structural analysis to improve the awareness of care providers on the adverse effects of certain ‘highlight’ determinants. A structural approach and analysis of adverse outcomes enhances learning for all care providers, regardless their involvement in the adverse outcomes.

Table 1
As the total is superior to 100%, it means that cases can be related to one or more determinants. Is it possible to analyse the correlation...?

It is correct to say that cases can be related to one or more determinants. Because of the study sample of 71 cases we think it is not possible to describe a valid correlation.

Table 2
It would have been interesting to understand which measure-s have been recommended to control which determinant-s????

We agree with your comment but for the same reason as described above by table 2 we prefer not to describe a relation between recommended measures and determinants of risk.

I am sorry for not being able to give a high appreciation of the paper.

We improved the text with your advices and remarks and we think that this manuscript contains important lessons on the safety of midwifery care.

Reviewers Comment J. Sandall
We updated reference 1 in our revised manuscript.