Author’s response to reviews

Title: Adherence to guidelines and suboptimal practice in term breech delivery with perinatal death - a population-based case-control study in Norway

Authors:

Solveig Bjellmo (solveighbjellmo@gmail.com)

Sissel Hjelle (sissel.hjelle@helse-mr.no)

Lone Krebs (lkrb@regionsjaelland.dk)

Elisabeth Magnussen (Elisabeth.Balstad.Magnussen@stolv.no)

Torstein Vik (torstein.vik@ntntu.no)

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Author’s response to reviews:

Dear Kate Kerber

Editor, BMC Pregnancy and Childbirth

Thank you for giving us the opportunity to resubmit a revised version of our manuscript ID PRCH-D-19-00854 entitled “Adherence to guidelines and suboptimal practice in term breech delivery with perinatal death - a population-based case-control study in Norway” by Solveig Bjellmo, Sissel Hjelle, Lone Krebs, Elisabeth Magnussen and Torstein Vik.

We appreciate the remarks and advices given by the editor and reviewers, and we have revised the paper in accordance with the remarks.

Before we respond to the reviewers’ specific comments, we want to emphasize that because of the very few included cases in this study, there is a challenge in how detailed we can present individual cases. According to data protection rules and the requirements of the Ethical committee, results must not be presented in a way that could identify individual cases. We have tried to adhere to these requirements, which limits our possibility to describe some of the cases in too much detail in the manuscript. This applies for a couple of cases with complicated deliveries, or who died of other diagnoses, completely independent of the delivery. Since, as we understand it, this correspondence will also be published online by the BMC, we can not provide this
detailed information in this response letter either. Should more detailed information be required by the editor or the reviewers, we may provide this information in a separate confidential mail with an explicit assurance that it will not be published online. Otherwise, we hope that editor, reviewers and readers can trust the assessments done by the four senior obstetricians in this few cases. We will refer to this general comment in the specific responses as appropriate.

Please find below our point-by-point comments to the remarks and concerns raised by the reviewer.

Editorial Requirements:

-- Please include as supplementary materials a completed STROBE checklist for items that should be included in case control studies and update the manuscript as needed.

Reply: We have provided a completed STROBE checklist as a supplementary file.

Reviewer(s)’ Comments to Author:

Reviewer: 1

Reviewer Name: Ageeth Rosman

Comment: It is a nicely written manuscript of a highly relevant topic. I only ask myself why the audit is done by only obstetricians and no midwives or others involved in perinatal care. Sometimes an audit from another perspective can reveal new information.

Reply: We appreciate the reviewer’s overall assessment of our manuscript.

The point regarding the inclusion of midwives or others involved in perinatal care is well taken. However, this study was designed to study if there were deviations from written guidelines on the obstetric management of fetuses in breech position (i.e. by planned CD, or by vaginal delivery). These guidelines are proposed by obstetricians and they are intended to advice this group of professionals. Nonetheless, we recognize that involving midwives and/or neonatologists might have revealed new and interesting information. However, we think that an audit including other perspectives would have required a somewhat different (broader) design, for example through interviews of the mothers as well as of other professionals on how they experienced the process. The design of our study was strictly directed towards the obstetric management. However, it may also be emphasized that a neonatologist’s perspective was to some extent covered by the senior author, professor Torstein Vik, although he did not have the professional competence to assess the obstetric management of the delivery.
Reviewer: 2

Reviewer Name: Reihaneh Pirjani

Comment 1: In my opinion, the article is well designed and accurately described. I would draw the authors' attention on some minor criticisms:

In the first paragraph of page 10, in which independent deaths are explained, the number of deaths in uncomplicated CD group should be mentioned "two" since although the further death was mainly due to poor antenatal care, ultimately the delivery method was cesarean section.

Reply: We thank the reviewer for the positive comment, and we agree that there are two cesarean deliveries in the “group” of independent deaths. We have therefore tried to alter the text in accordance with this in the first paragraph of page 10.

Comment 2: According to the aim and method of this study, it is better to mention the delivery method on page 11 of line 51 in parenthesis instead of gender.

Reply: Thank you for your comment, we have replaced gender with delivery method in the manuscript page 11 of line 51.

Comment 3: It is suggested that in line 38 of page 12 the word "response to" replace with the word "management of".

Reply: Thank you again for your comment, we have replaced “response to” with “management of” in the manuscript as suggested in line 38 page 12.

Reviewer: 3

Reviewer Name: Janneke T Gitsels - van der Wal, PhD

The paper examines and describes thoughtfully an important subject, namely the use of guidelines and (sub)optimal practice in term breech deliveries with perinatal death. Although the small numbers of perinatal death in term breech deliveries (1999-2015), acknowledged by the authors, the results show insights in underlying causes of potentially avoidable perinatal deaths. The open and blind reviews of the individual cases and controls show the importance of this kind of method as a necessary addition to the national birth registration to understand the perinatal deaths.

Reply: We appreciate the positive comment.
Comment 1:

Abstract - conclusion

- I doubt about the correctness of the sentence 'that current guidelines in Norway are well functioning'. The aim was to examine whether the guidelines have been used or not, and not whether the guidelines have been functioned or not.

Reply: Thank you for this comment. We agree that this conclusion was an overinterpretation and have removed the sentence (page 3 line 2-3).

Comment 2: Methods

1. The study period is 1999-2015; for what reason starts the period in 1999, and why didn't the period start in or after 2000, the year of the publication of Hannah's research?

Reply: We understand the comment. However, the present audit was undertaken as an extension of our previous study (BMJ Open, Year 2017, Volume 7; pages: e014979) where we, using register-based information reported a slightly higher mortality in breech compared to cephalic deliveries. We therefore wanted to include the same study years as in the previous paper, but extended the study period, as we in this study did not include cerebral palsy, a diagnosis requiring at least five years follow-up. We tried to explain this in the introduction of the originally submitted manuscript. We have now changed the wording slightly by including the word extension in the last paragraph of the revised background.

Since the Hannah study had less impact on clinical care in Norway than in many other studies, we consider the inclusion of 1999 and the first years following the TBT to be less problematic, and we have also assessed if the handling of the deliveries were in line with current (updated) and actual (at the time of the delivery) guideline. Due to the very low number of cases (due to the very low perinatal mortality in our country), we considered it to be important to include as many cases as possible and to include the same birthyears as in the previous study.

2. P 6 under Open Review: "A structured questionnaire addressing the main points of the current Norwegian guidelines for breech deliveries". Is it a questionnaire or a topic list?

Reply: We thank the reviewer for raising the issue and making us reconsider our wording. However, as we have written in the methods section, the obstetricians were given a structured questionnaire (and not a list of topics) and were asked to response to the questions addressing each of the recommendations addressed in the guidelines. Consequently, we have therefore not changed this wording in the revised manuscript.
3. Appendix 1: in Norway, during a vaginal breech delivery anesthesia is common sense. Why? We also know the negative side-effects of an epidural, such as a decrease of contractions, a longer duration of dilatation and the risk for fever, including the use of antibiotics for mother and sometimes the neonate. Could you explain the use of anesthesia? In the Netherlands, for example, anesthesia is not a standard use of care during a vaginal breech delivery.

Reply: Thank you for a very interesting and important comment. This is indeed a controversial issue and the diversity in many national guidelines regarding this is interesting. In Norway, and especially in the hospitals with the highest vaginal delivery rate for breech presentation the obstetricians often use both Løvset’s manoeuvre and Piper forceps routinely. Because of these interventions’ epidural is recommended for all women attending vaginal delivery in breech presentation, both to ensure that the women have anesthesia if/or when instrumental delivery is necessary but also to be able to use the same anesthesia if an emergency CD is needed.

However, we are aware that studies from both Finland and Switzerland (published in 2016) report that the use of epidural was associated with higher adverse outcomes for the infant, and increased the risk for emergency CD. On the other hand, a recent systematic review published in 2018 concerning the use of epidural in cephalic births concluded that epidural anesthesia had no impact on the risk of CD. To our knowledge there have been few studies assessing this for breech deliveries and further studies are required to address this topic.

Although this perspective and a comparison of guidelines would indeed be very interesting, such comparison is beyond the scope of the present study, and we are concerned that the manuscript would be too long and overloaded with information. However, since probably some readers will raise the same question as the reviewer, regarding this point, we have added a footnote in the supplementary table describing why epidural anesthesia is included in the Norwegian guidelines.

Comment 3: Results

1. Table 1: maternal age, it seems weird to skip the age of 17-21 years

Reply: Thank you for pointing this out, we apologize for this mistake. It has been corrected in the manuscript in table 1, page 9.

2. Table 2: assisted vaginal breech delivery: does the small 'g'(breech extraction performed) belong to the 'yes' instead of the 'no'?

Reply: Thank you for your comment, we realize that the variable “assisted vaginal breech delivery” may have led to some confusion. Indeed, all vaginal breech deliveries had some assistance (one or
more manoeuvres were performed). However, the important information is probably how many breech extractions were performed (n=2 in the case and one in the control group). In order to avoid the misunderstanding evident in this comment, we have removed the variable “assisted vaginal breech delivery” from the table, and only kept the variable “breech extraction” in the revised manuscript. In addition, we have added a footnote to the table describing that all the remaining deliveries had some kind of other assisted delivery (i.e. Løvset’s manoeuvre, Veit-Smellie-Mauriceau’s manoeuvre or others).

3. P 12, line 45 'based on several risk factors for adverse outcome'; could you give some examples for those risk factors?

Reply: We understand the comment. However, as stated in the general paragraph at the beginning of this response letter we need to be careful in providing detailed information that could lead to the identification of individual cases.

4. P 12, line 53: when did the other three suboptimal managed deliveries happen? And, why the cut off of 2003, was there a change in guidelines or clinical practice?

Reply: Thank you again for the appropriate comment. The year 2003 was in fact chosen post-hoc by looking at those cases and their birth years, where we discovered that these cases occurred mainly during 1999-2003 (i.e. before or shortly after the Hannah study) and during 2012-2013. From a scientific point of view, we should have pre-defined that we would compare the first 7.5 years with the second 7.5 years period, or the period before and after 2007-2008, when for example ST-analysis (STAN) was introduced in Norway.

However, we have rephrased this information in the results section in the end of the first paragraph on page 12 of the revised manuscript as follows:

“Six of the nine deaths associated with suboptimal care occurred during the first half of the study period (all between 1999 and 2003), while three occurred during the second half (all three during 2012 and 2013).

In the discussion we have replaced the first paragraph on page 16 with the following text:

“Although it was a post-hoc observation that six of nine deaths associated with suboptimal care occurred early in the study period, it may be noteworthy that in the years 2007 and 2008 some new therapeutic and diagnostic measures were introduced in Norway (i.e. therapeutic
hypothermia and ST-analysis (STAN)). It may also be noteworthy that there has been a decrease in the occurrence of cerebral palsy between 1999 and 2010, probably due to overall improvements in antenatal, obstetric and neonatal care”.

Comment 4: Discussion

1. P 16 implication (line 52; a reference is missing (of your previous study).

Reply: Apologize for this mistake. It has been corrected in the manuscript page 16, line 52.

2. A thought: could a vaginal breech delivery in all fours position have a positive influence on the neonatal outcomes? And would it be helpful to train obstetricians and midwives in assisting (breech) deliveries in all fours?

Reply: Thank you again for another very good and interesting comment. In Norway some hospitals deliver breech in “the all four position”/upright position, although this was not the case in any of the deliveries included in this study. We are indeed aware of several articles showing promising results of delivery in this position, and we expect that delivery in upright position will be included in the updated Norwegian guidelines; hopefully published during 2019. We have included this information in the last paragraph on page 17.

3. I miss recommendations for further research, e.g., perinatal deaths in vaginal breech deliveries in the Nordic countries, comparison of guidelines in the Nordic countries, the role of anesthesia in vaginal breech deliveries.

Reply: We appreciate the comment and have added a sentence on this in the last paragraph of the discussion part (page 19).

Comment 5: Conclusion

- The same comment as beforementioned in the abstract-conclusion.

Reply: We have also removed this from the conclusion.

We hope the editor find that we have amended the manuscript appropriately, and that you will find it worth being published.
On behalf of all authors.

Solveig Bjellmo
Department of Obstetrics and Gynecology, More and Romsdal hospital trust, Aalesund
Postbox 1600, 6026 Aalesund, Norway.
Phone (cell): +47 915 79437 // E-mail: solveigbjellmo@gmail.com