PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Is vaginal breech delivery associated with higher risk for perinatal death and cerebral palsy compared with vaginal cephalic birth? Registry-based cohort study in Norway.
AUTHORS	Bjellmo, Solveig; Andersen, Guro; Martinussen, Marit; Romundstad, Pål; Hjelle, Sissel; Moster, Dag; Vik, Torstein

VERSION 1 - REVIEW

REVIEWER	Mary Jane Platt Norwich Medical School, University of East Anglia, Norwich, UK
REVIEW RETURNED	11-Nov-2016

GENERAL COMMENTS	A well executed study, clearly described, and a useful addition to the literature on this topic. With any observation study, using routinely collected data, there are limitations, but these are clearly and fairly discussed.

REVIEWER	Dr Susan Reid Murdoch Childrens Research Institute, Australia
REVIEW RETURNED	23-Nov-2016

GENERAL COMMENTS	Thank you for the opportunity to review this interesting manuscript. The topic is of great importance and has the potential to impact on obstetric practice and on the lives of families. The aim was to investigate whether Norwegian term singletons (without congenital malformations) presenting in breech had increased risks of stillbirth, neonatal mortality and cerebral palsy compared with term singletons with cephalic presentation. My comments are all general in nature. As the authors point out, it is a complex area. If I have understood the situation correctly, the main area of complexity appears to be that the associations between mode of delivery and outcome of breech presentation are confounded by decision-making around mode of delivery, where those at higher risk are more likely to have an operative delivery. Another complexity is that, in some cases, mode of delivery is affected by the knowledge that the birth will be a stillbirth; the authors state that vaginal birth is the delivery mode of choice in this situation. The authors have used a careful step-wise approach to data analysis and to understanding of the data. However, it seems to me that, after all that work, the main messages remained somewhat elusive. While acknowledging my more limited understanding of the data, I

	would like to make some suggestions that may or may not be useful. 1. Knowing that reverse causality might be a factor in using stillbirths as an outcome, I would probably omit this. 2. Neonatal deaths and cerebral palsy are an either/or and may be separate outcomes of similar causal pathways, i.e. a newborn will not be given a label of CP if they have died. Consequently, I would lump these together as one outcome. 3. I would then compare the prevalence/risk of NNM or CP between planned vaginal cephalic births and planned breech cephalic births. This would help answer the question as to whether the risk of choosing vaginal delivery when the baby is in breech exceeds the risk of vaginal delivery if the baby were to be delivered with cephalic presentation. 4. Repeating the process using actual mode of delivery might provide additional information about the cephalic and breech groups that proceed to operative delivery, despite the fact that we already know that the chance of this happening is greater in the breech group. I had some concerns about the suggestion by the authors that their data show that fetuses in breech have an antenatally acquired inherent risk of adverse outcome. Even if one compares the risk of adverse outcome between breech and cephalic groups who had planned caesarean delivery, it is difficult to interpret the results because the reasons for the planned operative delivery are unclear. The reason may be purely elective (choice) or for maternal or fetal indications (such as breech) that are not acute/emergent. Having said that, it is probably likely that antenatal factors are on the causal pathway, I'm just unsure that the data support this conclusion. Due to my own limited knowledge in this area, I would have liked more discussion around the factors from the collective literature that might increase the risk of breech presentation in the first place and how they may be associated with adverse outcome. This is an important paper, and well thought out, but I think it could be a bit more focussed so that the interpretation is clearer and more useful in the clinical context.

REVIEWER	Edward M Jados, Diane Haggerty, Nigel Paneth Michigan State University, United States
REVIEW RETURNED	06-Dec-2016

GENERAL COMMENTS	The authors of this review are Nigel Paneth, Professor of Epidemiology & Biostatistics and Pediatrics & Human Development at Michigan State University, and Diana Haggerty and Edward Jados, both of whom are graduate students in the Department of Epidemiology and Biostatistics who are writing theses and/or dissertations on cerebral palsy General comment: This paper gives important and interesting information about a practice that is rapidly disappearing in the US, namely vaginal breech delivery. Randomized trials have shown that neonatal mortality and morbidity are higher in vaginal breech than in c-section breech delivery, although it has not been shown that later outcomes, such as cerebral palsy, are higher. These trials have led to a policy of delivering most US breech babies by c-section. But as the authors note, trials have been performed in countries with higher neonatal mortality than Norway and it is possible that under conditions of lower mortality, the disadvantage of vaginal breech

	delivery compared to cesarean breech delivery would not be present. This paper makes a major contribution in showing, apparently, that a low rate of NNM and CP can be achieved in vaginal breech deliveries, and is innovative in that CP is rarely available for analysis in studies addressing this question. But the paper is not as strong as it could be, in our view, because the authors also seek to demonstrate again that breech delivery, no matter how accomplished, is higher risk than cephalic delivery. This conclusion is well known and does not need reiterating, and obscures the key message of the paper. We see several issues that the authors might wish to address 1. The introduction to this paper indicates that the paper will help shed light on the question of whether vaginal breech delivery is safe, a question that depends upon a comparison of breech deliveries delivered in the two different ways. But unfortunately, the paper becomes sidetracked because it frames the analysis in terms of a comparison of breech vaginal deliveries to cephalic vaginal deliveries (page 4, lines 50-55). That comparison is not very interesting, both because it is well established that breech births are higher risk than cephalic births for a variety of reasons, and because it does not help the practitioner decide how to deliver a breech birth. One wonders why cephalic deliveries belong in the paper at all, except perhaps to be mentioned briefly as a frame of reference for the frequency of NNM and CP. The abstract is especially puzzling, because none of the numerical data relate to the key question, but rather focus on comparing breech to cephalic deliveries. The final abstract conclusion that vaginal delivery for breech is safe, seems an afterthought not supported by any numerical data cited in the abstract. 2. Another element of the analysis that distracts from the main theme is the inclusion of stillbirths in the analysis. 90% of stillbirths in most samples, including this one, occur prior to delivery and thus cannot be influenced by the mode of delivery. Moreover, it would seem unlikely that a known antepartum stillbirth would be delivered by c-section, producing, as the authors note, reverse causation, i.e. that stillbirth leads to vaginal delivery, not the other way around. But the authors do have data (page 9) on intrapartum stillbirths, and, sparse though those data are, one can calculate a substantially higher intrapartum SB rate in breech than cephalic births. But data are not provided on intrapartum SB in relation to mode of delivery among breeches, which is the main question. Doubtless numbers would be very small, so we do not see how the stillbirth data contribute to resolving the clinical question of importance. 3. A limitation of this paper is the restriction to rare and major outcomes such as mortality and CP. The authors acknowledge that this means that power is limited, and, indeed, many of the key comparisons do not achieve significance in this large database even with elevated OR's. But the authors do not discuss the concern about higher levels of short term neonatal morbidity with vaginal breech delivery (more ICU admissions, longer length of stay, etc), an outcome in many studies of breech delivery, and which are not assessed here. The authors have Apgar scores, but do not compare them in the key contrast, vaginal breech and c-section breech. This comparison might be interesting, as well as comparisons of other information the authors might have on neonatal morbidity. If interventions related to CP (magnesium in labor; head or body cooling post-natally) are available, it would be valuable to see the

	frequencies in the two types of breech deliveries 4. It is difficult to understand the issue of planned deliveries. Much of the information is missing, but we are not told the critical part, namely how much is missing in breech deliveries, which should be the focus of attention. Reference is made to a "similarly named variable". This is obscure. The authors also include under planned vaginal delivery, instances where initiation of delivery was listed as "elective". But it might be that elective refers to waiting until the onset of labor, but still intending to deliver by c-section. The section on intention needs better explanation of the variables, and how they operate within the world of breech deliveries. 5. Surprisingly often the language is vague and uncertain, and one is not sure whether the authors are describing breech deliveries or all deliveries. Page 13, paragraph beginning on line 27, is an example. 6. The authors show only multivariate odds ratios, not univariate. But the change, or lack of change in the OR resulting from adjustment should always be shown. Other concerns: 1. ABSTRACT: a. For some of the results (e.g. the 30% and 70% excess of CP) it is not clear from the abstract who is the comparison group. b. One also wonders why these two odds ratios, one of which is not close to significant and the other of which is borderline, are worth placing in the abstract. c. The odds ratio for CP in line 30 is not significant and the claim of an increase is not justified d. Line 29: OR for still birth lies outside the confidence limits provided. 2. Page 5. If stillbirth is to be retained in the analysis, it should be defined (deferral to a WHO definition is insufficient). 3. Page 9, lines 53 and 55: Same confusion as in abstract as to who is the comparison group. This should always be specified and not assumed to be known to the reader. 4. The text describing results is not as clear as the tables. Explaining the results better would be helpful, but this reflects the lack of certainty as to the true focus of the paper. 5. The discussion emulates the abstract in assigning inference to an OR not close to significance (page 17, lines 28-31) 6. Figure 1 should also show the number of breech deliveries remaining for analysis, because that population is the key population in this paper. 7. Table 1 shows neither measures of association nor p values/confidence limits. Yet knowing how potential confounders are distributed is important information 8. Table 2 footnote should say that NNM and SB are removed from the denominator

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Mary Jane Platt
Institution and Country: Norwich Medical School, University of East Anglia, Norwich, UK
Please state any competing interests: None declared

Please leave your comments for the authors be low

A well-executed study, clearly described, and a useful addition to the literature on this topic. With any observation study, using routinely collected data, there are limitations, but these are clearly and fairly discussed.

***Reply**: We are very grateful and appreciate the reviewer's overall assessment of our manuscript.*

Reviewer: 2
Reviewer Name: Dr Susan Reid
Institution and Country: Murdoch Children's Research Institute, Australia
Please state any competing interests: None declared

Comment 1. Knowing that reverse causality might be a factor in using stillbirths as an outcome, I would probably omit this.

***Reply:** We understand the comment and this possibility was also discussed within the author group before the first submission. In line with the suggestion by the reviewer, we have now removed the results related to stillbirths from the major part of the results section and from the tables 3 through 5. However, we have kept stillbirths the aim of the study and as a predefined outcome measure (as this was our original aim) and in table 2, as we think that it is relevant to show the significantly higher prevalence of stillborn in breech compared with cephalic. This finding may also be consistent with our speculation that fetuses presenting in breech may have an antenatal injury responsible for their excess risk for neonatal mortality. (see our response to the same reviewer's comment 5)*

Comment 2. Neonatal deaths and cerebral palsy are an either/or and may be separate outcomes of similar causal pathways, i.e. a newborn will not be given a label of CP if they have died. Consequently, I would lump these together as one outcome.

***Reply:** Thank you again for this proposal. Again, we considered this possibility ourselves, as we –in line with the reviewer - considered the causal pathways leading to neonatal death and CP are similar. We have now calculated and included a new variable; a composite adverse outcome variable comprising intrapartum death + neonatal death + cerebral palsy in tables 2 to 5. However, the risk for this composite outcome associated with the breech position was attenuated compared with the risk for neonatal death. We therefore now interpret this as further support of our speculation in the original manuscript, that CP and neonatal death may for the most have different causal pathways. We have in the revised version added this new information in the methods section and in the results section, and our interpretation of this finding has been included in the discussion section*

Comment 3. I would then compare the prevalence/risk of NNM or CP between planned vaginal cephalic births and planned breech cephalic births. This would help answer the question as to whether the risk of choosing vaginal delivery when the baby is in breech exceeds the risk of vaginal delivery if the baby were to be delivered with cephalic presentation.

***Reply**: See our response to comment 2. As shown in the revised tables, the risks for the composite adverse outcome associated with breech were lower than for the outcome NNM, but higher than the risk for CP.*

Comment 4. Repeating the process using actual mode of delivery might provide additional information about the cephalic and breech groups that proceed to operative delivery, despite the fact that we already know that the chance of this happening is greater in the breech group.

***Reply**: We agree.*

Comment 5. I had some concerns about the suggestion by the authors that their data show that fetuses in breech have an antenatally acquired inherent risk of adverse outcome. Even if one compares the risk of adverse outcome between breech and cephalic groups who had planned caesarean delivery, it is difficult to interpret the results because the reasons for the planned operative delivery are unclear. The reason may be purely elective (choice) or for maternal or fetal indications (such as breech) that are not acute/emergent. Having said that, it is probably likely that antenatal factors are on the causal pathway, I'm just unsure that the data support this conclusion. Due to my own limited knowledge in this area, I would have liked more discussion around the factors from the collective literature that might increase the risk of breech presentation in the first place and how they may be associated with adverse outcome.

Reply: *We realize, and agree with the reviewer that we may have overemphasized this interpretation in the original paper. We have revised the arguments underlying this interpretation slightly in the revised version: We still consider that the higher overall prevalence of stillborn in breech compared with cephalic position may support this interpretation, but in addition we now emphasize that the higher proportion of infants born SGA in the breech than in the cephalic group also support the speculation. However, we have in the revised version tried to be more careful regarding this speculation.*

This is an important paper, and well thought out, but I think it could be a bit more focused so that the interpretation is clearer and more useful in the clinical context.

Reply: *We appreciate the reviewer's overall assessment of the manuscript, and hope that the revised version is now clearer. In addition to emphasizing the importance of the comparison group being vaginal cephalic delivery (see below), we have revised the first paragraph of the discussion section in order to improve the focus of our findings.*

Reviewer: 3

Reviewer Name: Edward M Jados, Diane Haggerty, Nigel Paneth
Institution and Country: Michigan State University, United States
Please state any competing interests: None declared

Please leave your comments for the authors below

We see several issues that the authors might wish to address

1. The introduction to this paper indicates that the paper will help shed light on the question of whether vaginal breech delivery is safe, a question that depends upon a comparison of breech deliveries delivered in the two different ways. But unfortunately, the paper becomes sidetracked because it frames the analysis in terms of a comparison of breech vaginal deliveries to cephalic vaginal deliveries (page 4, lines 50-55). That comparison is not very interesting, both because it is well established that breech births are higher risk than cephalic births for a variety of reasons, and because it does not help the practitioner decide how to deliver a breech birth. One wonders why cephalic deliveries belong in the paper at all, except perhaps to be mentioned briefly as a frame of reference for the frequency of NNM and CP. The abstract is especially puzzling, because none of the numerical data relate to the key question, but rather focus on comparing breech to cephalic deliveries. The final abstract conclusion that vaginal delivery for breech is safe, seems an afterthought not supported by any numerical data cited in the abstract.

Reply: *We have divided the response to this comment in two parts: a) the choice of the comparison group, and b) the "puzzling" abstract.*

Regarding a), we consider vaginal cephalic birth to be the appropriate comparison group as this should be considered the "natural way" of delivery (i.e. the normal birth). The question of whether breech vaginal delivery as practiced in Norway with an overall very low perinatal mortality, is safe, or not, should be related to the outcome of a normal birth, and not primarily by comparison with caesarean breech delivery. The latter comparison only explores the relative risk for adverse outcome within the breech group, whereby the caesarean delivery group is heterogeneous, comprising both low and high risk deliveries. High risk deliveries will increase the risk for adverse outcome, as shown in the cephalic caesarean delivery group, while the inclusion of a high proportion of low risk deliveries will reduce the risk. Although we do not know the relative proportions of high and low risk births in the caesarean breech delivery group, we, as clinicians (three of the authors are obstetricians) assume it is most likely that the proportion of low risk pregnancies in caesarean breech delivery will be much larger than high risk. Thus, comparing the outcomes of mode of delivery of two low risk groups, will most likely favor the caesarean delivery group. Moreover, there are a number of papers suggesting that caesarean delivery may have long-term adverse consequences for the child itself and for the mother and child in later births. For example a study in the Netherlands found that elective caesarean delivery for term breech doubled the risk of neonatal mortality in subsequent pregnancies as compared with planned vaginal breech delivery[1].

A further important argument is that a comparison of adverse outcomes within the group of breech births does not take into account the perinatal mortality in the background population. We may in this regard remind reviewer(s) 3 that the perinatal mortality in the planned caesarean group in breech in the TBT was significantly higher than the perinatal mortality in children delivered vaginal in breech in Norway and in a number of other developed countries. Also, in a systematic review of the risk for adverse outcome of planned breech vaginal with planned breech caesarean delivery, the authors state that "…the 0.3% perinatal deaths from 75 193 vaginal breech deliveries was even lower than the perinatal mortality in a cephalic vaginal delivery group reported by a WHO team"[2].

Thus we consider it highly appropriate to use "normal birth" (i.e. cephalic vaginal delivery) as the reference. Our choice of comparison group is also in line with the already mentioned systematic review and meta-analysis published in BJOG in 2015 (documenting the higher relative risk for adverse neonatal outcomes of breech vaginal compared with breech caesarean deliveries) where the authors conclude that "A comparative study on vaginal breech and vaginal cephalic delivery is recommended"[2]. It is also in line with one of our own previous studies on the risk for CP associated with breech birth, published in Dev Med Child Neurol in 2009[3], and finally, the two other reviewers have accepted this approach (reviewer 2 underscores this comparison group).

None the less we have in the revised version made this choice clearer by changing the title of the paper, and by including some of the arguments above in the introduction, referring more often to the comparison group in the results section, as well as emphasizing this in the revised discussion.

Regarding 1b), we understand that the conclusion of the abstract was difficult to understand without reading the whole manuscript. We have in the revised version of the results section of the abstract included some of the essential information leading to the conclusion.

2. Another element of the analysis that distracts from the main theme is the inclusion of stillbirths in the analysis. 90% of stillbirths in most samples, including this one, occur prior to delivery and thus cannot be influenced by the mode of delivery. Moreover, it would seem unlikely that a known antepartum stillbirth would be delivered by c-section, producing, as the authors note, reverse causation, i.e. that stillbirth leads to vaginal delivery, not the other way around. But the authors do have data (page 9) on intrapartum stillbirths, and, sparse though those data are, one can calculate a substantially higher intrapartum SB rate in breech than cephalic births. But data are not provided on intrapartum SB in relation to mode of delivery among breeches, which is the main question. Doubtless numbers would be very small, so we do not see how the stillbirth data contribute to resolving the clinical question of importance.

Reply: *This concern was also raised by reviewer 2, and we refer to the responses to her.*

3. A limitation of this paper is the restriction to rare and major outcomes such as mortality and CP. The authors acknowledge that this means that power is limited, and, indeed, many of the key comparisons do not achieve significance in this large database even with elevated OR's. But the authors do not discuss the concern about higher levels of short term neonatal morbidity with vaginal breech delivery (more ICU admissions, longer length of stay, etc), an outcome in many studies of breech delivery, and which are not assessed here. The authors have Apgar scores, but do not compare them in the key contrast, vaginal breech and c-section breech. This comparison might be interesting, as well as comparisons of other information the authors might have on neonatal morbidity. If interventions related to CP (magnesium in labor; head or body cooling post-natally) are available, it would be valuable to see the frequencies in the two types of breech deliveries

Reply: *The limited statistical power is mainly related to the comparisons within the breech group, while in the comparison with cephalic births, the excess risk for NNM is significantly increased. As the main focus of the study is NNM and CP, we would like to stick to these robust outcomes, compared with for example transfer to NICU that depends very much of the attending physician, and local practice and the subjective assessment of the Apgar scores. We have rephrased slightly this paragraph (limitations) in the revised version, emphasizing that in particular the results of the analyses restricted to the breech delivery group should be interpreted with caution.*

4. It is difficult to understand the issue of planned deliveries. Much of the information is missing, but we are not told the critical part, namely how much is missing in breech deliveries, which should be the focus of attention. Reference is made to a "similarly named variable". This is obscure. The authors also include under planned vaginal delivery, instances where initiation of delivery was listed as "elective". But it might be that elective refers to waiting until the onset of labor, but still intending to deliver by c-section. The section on intention needs better explanation of the variables, and how they operate within the world of breech deliveries.

Reply: *We realize that our attempt to explain how we classified births into planned vaginal and planned caesarean delivery may have been confusing. Unfortunately, the MBRN does not record planned mode of delivery before birth, which would have been ideal. Instead this information (like all other information) is completed at birth, immediately after the child has been delivered. Having discussed how to categorize planned mode of delivery with the MBRN, we ended up with the following approach by using the following available variables (A-C):*

A) FSTART ("Start/initiation of birth"): This variable has the following codes 1: Spontaneous; 2: Induced; 3: Caesarean delivery, and the rest is missing.

Since caesarean delivery is expected to be correctly coded, immediately after delivery, we recoded this variable into a modified variable "mod_FSTART", whereby "missing" are recoded to vaginal delivery (in line with general use of data from the MBRN) using the following syntax:

```
RECODE FSTART (SYSMIS=1) (MISSING=1) (1=1) (2=2) (3=3) INTO mod_FSTART.
```

B) KSNITT ("Caesarean delivery"): *This variable has the following codes: 1: Elective; 2: Emergency; 9: Unspecified; and the rest is missing.*
This variable was recoded into a modified variable, according to the syntax:

```
RECODE KSNITT (1=1) (2=2) (SYSMIS=0) (MISSING=0) (9=9) INTO mod_KSNITT.
```

C) KSNITT_PLANLAGT ("Planned caesarean delivery"): *This variable has the following codes: 1: No; 2: Yes; and the rest is missing. The variable was then recoded using the following syntax:*

```
RECODE KSNITT_PLANLAGT (1=1) (2=2) (SYSMIS=1) (MISSING=1) INTO
mod_KSNITT_PLANLAGT.
```

The tables shows the number of missing values for each of these variables (as can be seen, the variable initiation of birth was complete – Table R1)

Table R1: Initiation of birth (induced birth are included in planned vaginal deliveries)

	«FSTART»			
	Cephalic		Breech	
	N (%)		N (%)	
Spontaneous	417 887	(83)	7793	(47)
Induced	59 622	(12)	74	(5)
Caesarean	25 838	(5)	8033	(48)
Missing	0		0	
Total	503 347	(100)	16700	(100)

.

Table R2 Overview of missing information of the variables used to classify birth in planned vaginal and planned caesarean delivery (CD).

	"KSNITT_PLANLAGT"*		**"KSNITT"***			**Planned mode of delivery****	
	Cephalic	Breech	Cephalic	Breech		Cephalic	Breech
	CD	*CD*	*Elective CD*	*Elective CD*			
	N (%)***	N (%)***	N (%)***	N (%)***		N (%)***	N (%)***
No	139 252 (28)	5145(31)	30 297 (6)	4069 (25)	Vaginal	474 976 (94)	7917 (47)
Yes	19 346 (4)	6423 (39)	21 289 (49)	7070 (42)	CD	28 731 (6)	8783 (53)
Missing	344 749 (68)	5132 (30)	451 761 (90)	5561 (33)	***Missing***	0	0
Total	503 347	16 700	503 347	16 700	Total	503 347	16 700

* Original variables in the MBRN
** as estimated in the paper
*** Per cent of total

*Using the three modified variables, we divided the population into planned vaginal delivery ("*planl_vag*") according to the following syntax (NE means "not equals"):*

```
COMPUTE planl_vag=0.
IF (mod_FSTART NE 3 AND mod_KSNITT NE 1 AND mod_KSNITT_PLANLAGT NE 2) planl_vag=1.
```

*And planned caesarean delivery ("*planl_sectio*") using the syntax (EQ = Equals):*

```
COMPUTE planl_sectio=0.
IF (mod_FSTART EQ 3 OR mod_KSNITT EQ 1 OR mod_KSNITT_PLANLAGT EQ 2) planl_sectio=1.
```

The major potential misclassification of these variables (planned mode of delivery) are related to planned breech caesarean delivery, where a mother whose delivery might have been planned for *caesarean delivery in advance, may go into birth, and if she then needs an emergency caesarean delivery, she may (by mistake) been coded as "no" on the variable "*KSNITT_PLANLAGT" (*planned caesarean delivery). As we excluded the unspecified caesarean delivery from the planned caesarean delivery group, this may also have resulted in some misclassification. There is potential misclassification of planned vaginal cephalic delivery (the reference group) as well, but this misclassification is negligible taking into account the total number of vaginal cephalic deliveries.*

Thus, to understand how we did this classification would require a detailed, technical description of how we used available variables in the MBRN, and it would probably still be difficult for the reader to understand. We therefore propose in the revised version to just state that: "We divided cephalic and breech births into the two categories originally planned vaginal and caesarean deliveries, based upon the initial handling of the birth, using information on how the birth started (spontaneous, induced, or by caesarean delivery) and how caesarean delivery was recorded (as elective, emergency or planned). Births that did not satisfy these criteria were categorized as planned vaginal delivery".

If the reviewers or the editor find it essential, we propose to add the detailed description above as online supplementary material. The last sentence above would then be extended as follows: "Births that did not satisfy these criteria were categorized as planned vaginal delivery (a detailed description is provided as supplementary material online)".

We have in addition expanded the paragraph on the limitations of this variable (the potential misclassification) in the revised version.

5. Surprisingly often the language is vague and uncertain, and one is not sure whether the authors are describing breech deliveries or all deliveries. Page 13, paragraph beginning on line 27, is an example.

Reply*: We apologize for the oversight, this has been corrected in the revised version.*

6. The authors show only multivariate odds ratios, not univariate. But the change, or lack of change in the OR resulting from adjustment should always be shown.

Reply*: This is a misunderstanding probably explained by an imprecise description under statistical methods (methods section), and we have therefore rephrased the sentence on this in the revised version. However, as we stated in the results section of the original manuscript: "Multivariable analyses adjusting for gestational age, parity, maternal age, sex and SGA did not substantially affect any of the associations described above (data not shown)". The tables did not indicate that we presented adjusted ORs. However, to make this even more clear we have in the revised version added this information in the title of the tables. For example in "Table 3: Prevalence and unadjusted odds ratios (OR) with 95% confidence intervals (CI) for various composite outcomes among singletons born at term, without congenital anomalies according to actual mode of delivery."*

Other concerns:
1. ABSTRACT:
a. For some of the results (e.g. the 30% and 70% excess of CP) it is not clear from the abstract who is the comparison group.

Reply: *We have revised the results section of the abstract, and hope that this is now more clear.*

b. One also wonders why these two odds ratios, one of which is not close to significant and the other of which is borderline, are worth placing in the abstract.

Reply: *Again, the results section of the abstract has been completely revised.*

c. The odds ratio for CP in line 30 is not significant and the claim of an increase is not justified

Reply: *Again, we have completely revised this part of the abstract.*

d. Line 29: OR for still birth lies outside the confidence limits provided.

Reply: *We apologize for this mistake, which has been corrected.*

2. Page 5. If stillbirth is to be retained in the analysis, it should be defined (deferral to a WHO definition is insufficient).

Reply*: We have removed stillbirths from the tables 3-5. In table 2 we now present stillbirth in line with the WHO definition as well as for antepartum and intrapartum stillbirth.*

3. Page 9, lines 53 and 55: Same confusion as in abstract as to who is the comparison group. This should always be specified and not assumed to be known to the reader.

Reply: *We of course principally agree with the reviewer, and we have revised the major part of the results section in line with this suggestion.*

4. The text describing results is not as clear as the tables. Explaining the results better would be helpful, but this reflects the lack of certainty as to the true focus of the paper.

Reply: *We believe this comment is mainly related to the misconception of what is the appropriate comparison group, and the misunderstanding of the focus. We wanted to study if the practice of vaginal breech delivery as practiced in a country with low perinatal morality is safe, using vaginal cephalic delivery as the comparison group as clearly stated in the introduction of the originally submitted paper, and obviously understood by the two other reviewers (reviewer 1 "clearly described"). None the less we have slightly revised the results section as well. As already mentioned; to underscore the main focus even further, we have now added the comparison group to the title of the paper, and included the relevance of this choice in the introduction.*

5. The discussion emulates the abstract in assigning inference to an OR not close to significance (page 17, lines 28-31)

Reply: *We have revised this part of the manuscript.*

6. Figure 1 should also show the number of breech deliveries remaining for analysis, because that population is the key population in this paper.

Reply: *The study population is the total number of singletons without congenital malformations born in cephalic as well as in breech, but we have added another box to figure 1 showing the number of breech and cephalic births in the final study population.*

7. Table 1 shows neither measures of association nor p values/confidence limits. Yet knowing how potential confounders are distributed is important information

Reply: *Table 1 in fact shows how potential confounders were distributed. It is not essential whether differences in distribution occurred by chance or not. The choice of including the potential confounders in the multivariable analyses were then based upon theoretical knowledge of how these may be related to exposure and outcome.*

8. Table 2 footnote should say that NNM and SB are removed from the denominator

Reply: *Thank you for this comment, this has been corrected in the revised version.*

Reference:

1. Vlemmix F, Kazemier B, Rosman A, et al. 764: Effect of increased caesarean section rate due to term breech presentation on maternal and fetal outcome in subsequent pregnancies. American Journal of Obstetrics & Gynecology 2013;**208**(1):S321.
2. Berhan Y, Haileamlak A. The risks of planned vaginal breech delivery versus planned Caesarean section for term breech birth: a meta-analysis including observational studies. BJOG 2015.
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VERSION 2 – REVIEW

REVIEWER	Sue Reid Murdoch Childrens Research Institute, Australia
REVIEW RETURNED	15-Feb-2017

GENERAL COMMENTS	Thank you for the opportunity to re-review this manuscript. I am happy with the changes made by the authors in what is quite a complex area. I just have one suggested change and a general suggestion about wording, which the authors may choose to ignore. P7 line 12: Should be the comparison be between vaginal or caesarean breech delivery and vaginal cephalic delivery? Because the data are quite complex, I found it difficult to work out the main results associated with each table using the text provided. This is an example of the way I made more sense of the text: Breech position where vaginal delivery was planned (presumably less complicated) had 2-3x increased risk of NNM, no increased risk of CP, and 2x increased risk of either NNM or CP, compared to planned vaginal cephalic delivery. Breech lie where caesarean delivery was planned (presumably more complicated) had 1-2x risk of NNM, no increased risk of CP, and 1-2x risk of either outcome, compared to planned vaginal cephalic delivery. If lie was breech, planned vaginal delivery was associated with increased risk of NNM over planned caesarean delivery (OR 1.5). However, because 10% of planned breech vaginal deliveries

	actually delivery by caesarean because of complications, there was no increased risk of NNM if actual delivery was breech compared to caesarean.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 2 Reviewer Name: Sue Reid Institution and Country: Murdoch Childrens Research Institute, Australia Please state any competing interests: None declared Please leave your comments for the authors below Thank you for the opportunity to re-review this manuscript. I am happy with the changes made by the authors in what is quite a complex area.

I just have one suggested change and a general suggestion about wording, which the authors may choose to ignore. P7 line 12: Should be the comparison be between vaginal or caesarean breech delivery and vaginal cephalic delivery?

Reply: Thank you for pointing out the unclear wording here. We appreciate have re-phrased the paragraph as follows:

“Second, we explored the risks for NNM, CP and the composite outcome according to “actual mode of delivery” by comparing vaginal or caesarean breech delivery with vaginal cephalic delivery.” Because the data are quite complex, I found it difficult to work out the main results associated with each table using the text provided. This is an example of the way I made more sense of the text: Breech position where vaginal delivery was planned (presumably less complicated) had 2-3x increased risk of NNM, no increased risk of CP, and 2x increased risk of either NNM or CP, compared to planned vaginal cephalic delivery. Breech lie where caesarean delivery was planned (presumably more complicated) had 1-2x risk of NNM, no increased risk of CP, and 1-2x risk of either outcome, compared to planned vaginal cephalic delivery.

Reply: We appreciate the suggestion for improved readability. We have amended the text in line with the reviewer’s suggestions. However, in line with the criticism expressed by reviewer number 3 to the first submitted version, we felt it we need to keep the exact OR with the corresponding 95% confidence intervals in the text.

If lie was breech, planned vaginal delivery was associated with increased risk of NNM over planned caesarean delivery (OR 1.5). However, because 10% of planned breech vaginal deliveries actually delivery by caesarean because of complications, there was no increased risk of NNM if actual delivery was breech compared to caesarean.

Reply: We appreciate the suggestion however in this case we prefer to use the original wording.

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

VERSION 3 – REVIEW

REVIEWER	Sue Reid Murdoch Childrens Research Institute, Australia
REVIEW RETURNED	14-Mar-2017

GENERAL COMMENTS	Thanks for addressing these final issues. An interesting paper!