Author’s response to reviews

Title: Deferred and referred deliveries contribute to stillbirths in the Indian state of Bihar: results from a population-based survey of all births

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Dear Dr. Recchioni,

Thank you very much for inviting revision of our manuscript “Deferred and referred deliveries contribute to stillbirths in the Indian state of Bihar: results from a population-based survey of all births” for the BMC Medicine. We thank the reviewers for constructive comments, and we have detailed below how these comments are addressed in the revised manuscript. Please note that the line numbers below correspond to the manuscript version without the track changes.

Reviewer #1

This is an important and well written study. The introduction provides a clear description of the background and justification for this study.
Thank you.

Minor comments:

1. As this was a survey recording gestational age in weeks, please ensure that the definition is specified as $\geq 7$ months (as a proxy for late fetal deaths at $\geq 28$ weeks) throughout e.g. abstract, p7 line 13 etc…

Thank you for this suggestion. We have replaced $\geq 28$ weeks with $\geq 7$ months in lines 32 and 136.

2. Abstract
   a. 'Primi births' is not frequently used as an abbreviation of births to primigravidae.

   We have replaced “primi” with “first born” throughout the manuscript and in the Tables.

   b. The term 'deferred deliveries' is not clear in the abstract - description given in paper, but as not a commonly used term needs some explanation if you use it in the abstract.

   We have added description in lines 43-44.

   c. What is 'push/pull' during the delivery?

   Push refers to the application of manual fundal pressure by the health provider, and pull refers to forceful pulling the baby out during delivery which is typically done in breech presentations. We have added this description in lines 45 and 208.

   d. Why are 'births in private facilities and home' linked together in the abstract results with one OR?
These ORs which were in the same direction were combined to reduce the abstract word count. We have now presented these two separately (lines 49-50).

3. Background - p4 line 10 - this is the ESTIMATED not reported number of stillbirths.

Thank you, this correction is made (line 65).

4. Methods - I think that this could be made more clear for the reader e.g. p5 lines 5 - 21. P5 Lines 5 - 13 if this study was not designed to impact on stillbirth rates please can the authors state clearly for the reader why these interventions may impact on stillbirth rates. Methods, Lines 13 - 21 seem to relate to the sample size calculation for the parent study and not clear of the relevance to this study. p5 Lines 23 - 57 - detailed description of the multistage sampling procedure but was this specifically for this stillbirth study or for the main intervention study outcomes?

The stillbirth assessment was carried out as part of the survey that was designed to evaluate the impact on neonatal mortality in the state of Bihar. The sampling method described is for the neonatal survey which was done to obtain a representative sample of women who gave birth between January and December 2016. This is now stated clearly in lines 89-91 to avoid confusion.

5. Methods - Data collection - p6. I found this a bit hard to follow. Maybe it would be clear to present:

• a section on enumeration including dates (lin1 states March to October 2016) line 8 - January to December 2016 - how do these differ?

• A section on the interviews including dates - were all enumerated interviewed?

Data were collected from March to October 2017 (2016 was an oversight). We have moved this statement to line 125 to avoid confusion.
6. Methods - Analysis p7 lines 16 - 18 - how were the stillbirth interviews verified? Using signs of life questions and gestational age? Or other method?

We used both, the signs of life questions and gestational age, to verify the stillbirths. This is already stated at a few places. We have now stated it explicitly in the analysis section in lines 137-139.

7. Methods - P7 lines 42 - how were rates adjusted for Bihar's population.

We have now added this in lines 147-148.

8. Methods - P7 line 47 - 'fresh stillbirth' term is usually used rather than 'fresh death'

We have replaced the term as suggested (line 150).

9. Methods - p8 lines 21 - 23 - was gestational age in months available for livebirths or only stillbirths? Did you consider including this in the logistic regression?

We could not find this mention in lines 21-23. However, the gestational age was available for all births. Gestational age is used in all the logistic regression models.

10. Methods - Details of how 'deferred delivery' is defined could be provided in the methods alongside the definition of 'referral'.

This was an oversight. We have now added the definition of deferred delivery in lines 156-159.
11. Results- the SBR is still relatively low compared to the NMR in the study. Do the authors have any comment on the potential reasons for this? At this level of mortality, a ratio of around 1:1 may be expected. Is it possible that the method of enumeration missed stillbirths?

The estimated neonatal mortality rate in this population was 24.7 per 1,000 livebirths (not presented in the manuscript). The relationship of 1:1 between neonatal mortality and stillbirth is not necessarily expected as documented in some previously reported studies, which have reported a wide heterogeneity in stillbirth and neonatal mortality decline for different levels of neonatal mortality.


12. Results - P9 lines 54 - end. It would be important to note limitations of 'perceived size at birth' and no data on its accuracy/ validity for stillbirths.

We have commented in discussion that the size of the baby in this study did not necessarily corroborate with the birthweight in discussion, lines 327-329.

13. Results - P10 line 13 - gestational age ≤8 months - it may be clearer to state that this is used as a proxy for preterm birth (noting again the limitations of recalled GA in months in survey data).

In lines 287-289, while discussing the gestation age as a risk factor for stillbirth we have stated that “as the pregnancy length was captured in months in our study, it is not possible for us to comment on whether the babies with gestation period of <8 months were very or moderately preterm”.
14. Results - P10 line 18 - 'deferred deliveries' - what is the validity of this indicator? Presumably it is subject to potential substantial recall bias.

All the data presented in this manuscript are based on the recall of the respondent including deferred delivery. We have added recall bias as a limitation in the discussion (lines 410-411).

15. Results - P11 line 58 - p12 line 23. The overall antepartum and intrapartum SBR rates calculated together=10.1 / 1000 - why is this lower than the overall SBR?

This addition is lower than the overall SBR as 6.2% of the stillbirths could not be classified as stated in line 252.

16. It may be worth noting the large difference between the potential conclusions from the unadjusted and the adjusted analyses.

While we appreciate the point that the Reviewer has made, the adjusted analysis results are generally considered for interpreting the relation of variables with the outcome. We think that it is not necessary to discuss this generally accepted approach.

17. Discussion - The discussion overall is very long the authors may consider condensing and clarifying the arguments presented- maybe consider a table/ panel summarising the key recommendations for INAP from this study.

Thank you for this suggestion. We have added a panel summarising the key recommendations for INAP from this study (line 454 and Panel).

18. Discussion - Further discussion could be given to what the authors can conclude about the most appropriate ways to ask about intrapartum stillbirths in surveys. Both skin appearance and maternal recall of fetal movements are potentially subject to substantial biases.
Thank you for this comment. It is not possible for us to comment fully on appropriate ways to document intrapartum stillbirths in surveys from these data. We are currently planning qualitative work around this aspect in this population.

19. Discussion - Further attention could be given to the potential impact of recall bias on the study findings and the limitations of survey information from maternal recall in general. The recommendations could be clearer.

We have added recall bias is a limitation in lines 410-411. We have also attempted to make the recommendations clearer wherever possible. Addition of the panel has improved the clarity of recommendations.

20. Discussion - P13 lines 44 - 57 - did you collect any data on neonatal deaths and GA in months on livebirths in your study, as this could allow a potential comparison.

We collected similar data on all births. Only comparing gestational age for neonatal deaths and stillbirths and not any other risk factors does not seem appropriate. Such a complete comparison is beyond the scope of this manuscript.

21. P14 line 2 ref 24 - 26 - not sure that these are the most appropriate references - most recent estimates of IPSB rates globally are in Lawn et al Lancet 2016 Stillbirths: rates, risk factors, and acceleration towards 2030. Or alternatively you could reference other single site studies from LMICs on intrapartum stillbirth rates.

Thank you, this was an oversight. We have now cited Lawn et al and our previous publication.

22. P14 lines 21 - 34 - these are all high income references. Are there any data from LMICS? What is known about effectiveness of foetal movement monitoring, esp in LMIC settings? Reference to the Cochrane review could be included.
Not much is available about foetal movement monitoring in LMIC settings. We have now cited the Cochrane review (reference 32).

23. P14 - lines 44 - 52 - very disparate recommendations given. Most of the paragraph above focuses on fetal movements and little on the effectiveness of improving intrapartum monitoring.

Now lines 304-319 – This section deals with foetal movements and the recommendations relate to improving documentation of foetal movements by targeting the pregnant women and health providers, including foetal heart rate monitoring at health facilities which is part of intrapartum monitoring.

24. P15 - lines 1-2. This finding is not surprising and may reflect the poor monitoring of fetal growth in ANC, which is challenging even in HIC settings.

Thank you, noted.

25. P15 line 10 - 16 - this also may not be surprising as you can be SGA term and 2kg.

That is correct. Here, we have discussed it in a similar vein highlighting that these two do not necessarily corroborate.

26. P16 lines 20 - 29 - this is not necessarily due to suboptimal quality of care, as these groups of babies may be expected to have a worse outcome than uncomplicated singleton cephalic babies.

Now lines 359-364 – In our previous publication from the same population, we had documented the suboptimal quality of care in the form of poor/no abdomen check-up, poor skills of the health providers to manage a breech presentation or perform C-section. In addition, as highlighted in this manuscript, many referrals are made for C-section or complicated deliveries from the public to private sector as doctors in the former are either poorly skilled or not available to provide optimal quality of care.
27. P16 lines 31 - again may not be surprising as vaginal delivery is usually the preferred mode in otherwise uncomplicated pregnancies with fetal death in utero diagnosed.

Here, we are referring to the possibility of a baby dying in utero because of delay in providing emergency obstetric care. This is in line with the sub-optimal delivery care as highlighted in the point above.

28. P17 lines 5 - 8 - what could account for this finding? Different case mix, poorer quality of care, lack of standards etc…

Now lines 369-382 - We have re-organised this section to improve the readability. The reasons for this could include poor skills of health providers, poor management of complications, and delay in referral. As highlighted in this manuscript, the referrals of complicated deliveries from the public to private sector does result in a case mix that is different from the public sector.

29. P17 - line 41 - were most referrals due to breech presentation? What % of all referrals were due to breech?

Now lines 383-384 – 75.4% of the breech positions among all births were referred in this population. The statement is now modified to reflect the intended message.

30. Table 1 - the footnotes to this table are confusing - maybe consider superscript numbering instead as would be easier then to find reference.

Table 1 footnotes are updated as suggested.

31. Table 1 - Birthweight - consider condensing 'not weighted' and 'don't know if weighted' to a single category.
We have shown these two categories separately on purpose to highlight that parents of stillborn babies are not aware of this aspect. In the stillbirth group, 84.6% of the respondents said “do not know if weighed” as compared with only 8.9% for all births put together.

Reviewer #2

This is a comprehensive study of stillbirths in Bihar, benefitting from data collection which included cases as well as all births as denominator. It is overall well written and delivers some important messages about maternal and pregnancy related risk factors, as well as place of birth and related aspects of maternity care. I have some suggestions which hopefully will help bring these messages out more clearly.

Thank you.

Firstly, in regarding definitions:

1. Deferred and Referred need to be defined in abstract, as results are given there using these terms

We have added definitions for deferred and referred in lines 42-43 and 52-53.

2. I also cannot see an explanation of 'Deferred' in the Methods section.

This definition is now added in lines 156-159.

There is a lot of data presented and while the paper is already long, some of the findings would merit further comment:
3. The lack of routine collection of weight of the stillborn is itself an important finding, as well as a clear weakness of the study, in light of the well published evidence that fetal growth restriction is one of the strongest risk factors. This will remain so unless there is an effort to improve collection of such data. Perhaps this could be emphasised more, and if possible also brought into the abstract.

We have made specific recommendations to improve birthweight documentation in lines 329-335. We have now added a line in abstract (line 51).

4. Discussion, p 14 - re decreased fetal movement: it would be worth adding that in such a survey, the presence of 'decreased' movement could have been = absent fetal movement, already indicating fetal demise.

We agree. We have now stated this in lines 305-306.

5. Page 16, line 31: 'Furthermore, antepartum stillbirth was significantly higher in vaginal deliveries' - is this not surprising? Would merit comment.

Now line 359 – We have re-worded this statement as “Furthermore, antepartum stillbirth were more likely to be delivered vaginally” to avoid misinterpretation. This finding is not surprising as majority of stillbirths were delivered vaginally in this population.

6. Why do the authors think private sector deliveries have a higher rate of SB?

Lines 369-382 - The reasons for this could include poor skills of health providers, poor management of complications, and delay in referral. As highlighted in this manuscript, the referrals of complicated deliveries from the public to private sector does result in a case mix that is different from the public sector.

It would also be worth commenting on some of the negative findings, e.g.
Elaboration on some of these points will make the findings more relevant to all readers, including clinicians, epidemiologists and health service planners.

7. Why was 'No antenatal visit' NOT associated with SB risk? (Table 3)

No antenatal care also had higher odds for stillbirth but of borderline significance (1.32, 0.93-1.88), and was in the last model of the sequential multiple logistic model (Table 2). This drop in statistical significance is most likely related to intrapartum stillbirths wherein no ANC visit had lower odds for stillbirth (Table 3). We have now re-phrased lines 336-337 to highlight that no ANC was of borderline significance for overall stillbirth in addition to being significantly associated with antepartum stillbirths.

8. Why do the authors think primips have a higher rate of ANTEpartum stillbirth? (Table 3)

The finding of higher risk of stillbirth in the first born is documented previously in other populations as well. Unfortunately, the available data in this survey does not allow us to explore the possible reasons for this.

We thank the BMC Medicine for considering our manuscript, and would be pleased to respond to any further queries related to this submission.

Best regards,

Rakhi Dandona