Author’s response to reviews

Title: Influence of weight gain, according to Institute of Medicine 2009 recommendation, on spontaneous preterm delivery in twin pregnancies

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To

Editor-in-Chief

BMC Pregnancy and Childbirth

RE: Ms. No. PRCH-D-16-00410 - Influence of weight gain, according to Institute of Medicine 2009 recommendation, on spontaneous preterm labor in twin pregnancies

We thank the Editor and the Reviewers for their helpful comments that enabled us to improve our manuscript.

Listed below is a detailed response to the comments, and attached are the files of the revised version of the manuscript. We hope you find the revised version of our manuscript suitable for publication in BMC Pregnancy and Childbirth
With warm regards,

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Editor's comments

Comment #1: Within the ethics and consent to participate section- please state why this is not applicable. If this is because the study is a secondary analysis of existing public data, please state this. If you did not need formal ethics approval please confirm that this complies with national guidelines and provide a reference which supports this. "

Response to Comment #1: We thank the Editor for his comment. Our Institution does not require a board approval for retrospective studies. The statement on page #8 has been modified accordingly and now reads "The present work was exempt from IRB approval as per Institutional policy on retrospective studies".

In addition, as suggested by the Editor, we provided a reference related to the national guidelines and protocols for management of twin pregnancies that were followed at our Institution, on page #8 that now reads "All twin gestations were followed according to national guidelines for management of twin pregnancy. The protocol included maternal clinical assessment and ultrasound monitoring every two weeks, from 16 weeks, for monochorionic diamniotic pregnancies and every four weeks, starting from 20 weeks, for dichorionic diamniotic gestations".

Comment #2: Please also state if any administrative permission required/granted for access to data, please provide details in the Ethics and Consent to Participate section.
Response to Comment #2: At our medical center, women provide upon admission a written consent to the use of their clinical anonymized and de-identified data. It was stated within the Materials section, on page #8 of the revised version of the manuscript.

Comment #3: As you likely noted from the reviewer comments, your manuscript needs to be copyedited. We recommend that you ask a native English speaking colleague to help you copyedit the paper. If this is not possible, you may need to use a professional language editing service. For authors who wish to have the language in their manuscript edited by a native-English speaker with scientific expertise, BioMed Central has a new in house editing service. The new editing tool can provide both scientific and language editing: http://authorservices.springernature.com/

Response to Comment #3: We agree with the Editor about the need to copyedit the manuscript in order to improve its readability. Therefore, we asked a colleague who is a native English speaking, to perform proof reading editing and added him as an author of the revised version of the manuscript.

Comment #4: Thank you for providing an availability of data and materials section. Currently the statement is a bit unclear. For all journals, BioMed Central strongly encourages that all datasets on which the conclusions of the paper rely should be available to readers (except for files containing identifying patient information). We encourage authors to ensure that their datasets are either deposited in publicly available repositories (where available and appropriate) or presented in the main manuscript or additional supporting files, in machine-readable format (such as spreadsheets rather than PDFs) whenever possible.

Response to Comment #4: We understand the preference of the journal to provide access to the dataset for the readers. Moreover, our institutional policy about data sharing only allows us to provide de-identified and anonymized data on specific and justified request from another Institution, without allowing public availability of the data.

Therefore, the following statement was included within the information regarding availability of data and materials: "The datasets generated during and/or analyzed during the current study are not publicly available due to institutional policy but are available from the corresponding author on reasonable request".
Reviewer #1:

Comment #1: The authors present a retrospective cohort study of diamniotic twin pregnancies comparing those delivered preterm with spontaneous labor using maternal weight gain as a major variable. Questions for the authors:

Please use the term 'spontaneous preterm delivery' instead of 'preterm labor' in the title of the paper

Response to Comment #1: We thank the Reviewer for his comment and modified the title of the paper according to his suggestion. It now reads "Influence of weight gain, according to Institute of Medicine 2009 recommendation, on spontaneous preterm delivery in twin pregnancies”

Comment #2: How was the sample size chosen?

Response to Comment #2: The Reviewer has a point in his comment. Moreover, as we acknowledged in the paragraph on strengths and limitations of the study, sample size is one of the potential limitations of retrospective studies. In our analysis we included all available data on pregnancies matching the inclusion criteria, within the study period, although power calculations were not performed.

Comment #3: Why were deliveries prior to 28 weeks excluded?

Response to Comment #3: The reason for exclusion of women with a gestational age <28 weeks was added to the Materials section that now reads "We decided to set a gestational age < 28 weeks at delivery as an exclusion criteria in order to have a better definition of the weight gain trend for each patient. A shorter pregnancy duration could be a confounding factor in defining the maternal weight gain”.

Comment #4: The use of 'pregestational weight' is subject to recall bias. Would the results be different if the first recorded weight in pregnancy were used? Indeed, what was the mean gestational age at enrollment?

Response to Comment #4: We agree with the Reviewer regarding the risk for recall bias determining by the use employment of pregestational weight. Moreover, IOM recommendations, that we followed in the design of the present study, take into consideration this variable. We attempted to reduce the risk of bias with an early assessment of pregnant women by obstetric booking that is performed, at our medical center, before 8 weeks of gestation. This was incorporated in the Materials section of the revised version of the manuscript on page #7, that
now reads "At our Maternal-Fetal Unit, women undergo their first access at obstetric booking that is usually performed during the first trimester after a positive pregnancy test (<8 weeks of gestation)."

Comment #5: I recommend the authors include the specific methodology for defining inadequate, average and excessive weight gain referred to in their reference 18 for clarity: "We then divided the IOM lower limit of normal weight gain at 37-42 weeks by 37 to determine the IOM recommended weight gain per week. For normal-weight women, this was 1.0 lb per week (37 lbs over 37 weeks); for overweight women, this was 0.84 lb per week (31 lbs over 37 weeks); for obese women, this was 0.68 lb per week (25 lbs over 37 weeks)."

Response to Comment #5: We thank the Reviewer for his comment and agree with him on the need of clarifying the criteria employed for comparison of our data. Therefore, the suggested statement has been incorporated within the second paragraph on page #8 of the revised version of the manuscript, that now reads "We compared this weekly weight gain to a hypothesized weekly IOM cut-off, calculated as IOM cuts-off at term/37 weeks, as previously reported, represented for normal-weight women, this was 1.0 lb per week (37 lbs over 37 weeks); for overweight women, this was 0.84 lb per week (31 lbs over 37 weeks); for obese women, this was 0.68 lb per week (25 lbs over 37 weeks)."

Reviewer #2:

Comment #1: While this study reports on an interesting and important topic (impact of gestational weight gain on birth outcomes for twin births), there are some weaknesses in the presentation that need to be addressed before this should be published. In addition, the unclear presentation makes it difficult to thoroughly review the methods and interpretation.

Response to Comment #1: We thank the Reviewer for his comment and agree with the need of clarifying the presentation of the data, as well as their interpretation in order to improve the level of the manuscript.

Comment #2: There is a concerning inconsistency in how the authors describe how this study fits with the previous literature. Several related studies are described and these citations are used to justify certain methodological decisions. However, the authors also state that this is the first study to do the analyses described (p. 11, lines 13 - 18). If this study differs from those previous studies in an important way, this needs to be clarified. The authors should be clear on what this study adds to the literature - if it is a replication in a different population, that's ok, just be clear about it.
Response to Comment #2: We thank the Reviewer for his comment. We reorganized the Discussion section in order to describe the available literature on the subject and then compare the previous studies to our report, paying attention to the differences brought by our work.

This has been updated on page #12-14 of the revised version of the manuscript.

Comment #3: Although it has been used once before, I would still like to see more justification for assuming that weight gain is linear. (I.e., that it is ok to adjust for weight gain for preterm births by calculating weekly weight gains using term cutoffs/37 weeks.) Given how critical this is to your study, it seems like it deserves more attention.

Response to Comment #3: We understand the Reviewer's concern. We had the same concern in the moment we designed our study. Since there were no data regarding weekly weight gain cutoffs for twin pregnancies in IOM recommendations, we decided to apply linearity to weekly gain cutoffs as performed within IOM recommendations for single pregnancies.

Comment #4: Language: There are numerous grammatical errors through the manuscript. Although I tend to consider this a minor issue, some are substantial enough to impact understanding and therefore need to be addressed before a decision about publication is made. For instance, a test is described as a Fisher test. Does that refer to the Fisher's Exact Test?

Response to Comment #4: We agree with the Reviewer on the need of improving the written English. The manuscript underwent proof reading by a native language speaker.

Comment #5: The tables would benefit from more description. For instance, in Table 2: is there a column missing, for statistical significance for overweight? It would be helpful to add a little more detail describing this table and clarifying what the statistical significance is testing.

Response to Comment #5: We thank the Reviewer for his comment. All tables were implemented with comments giving more explanation regarding the content. Regarding Table 2, our study design included a two by two comparison between women underweight versus normal weight and overweight versus normal weight. For this reason in the previous version of this table another column with related p value was not present. Moreover, Table 2 was modified in order to become clearer to the reader.