Author’s response to reviews

Title: The trend of caesarean birth rate changes in China after ‘universal two-child policy’ era: A population-based study in 2013-2018

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Author’s response to reviews:

Dear editor and reviewers,
Thank you so much for all your comments again. In this revised version, we made some changes according to the reviewers’ comments. We could answer most of the questions from editor and reviewers. Please find the detailed point-by-point responses below.

Editorial comments:
In the Discussion, you say:

"Secondly, NFPCP study mainly targeted participants from rural areas in which the caesarean delivery rate was relatively lower. Thus, we are not reporting the national caesarean delivery rate here due to the sample representation. Nevertheless, the trends of caesarean delivery rate changes in NFPCP study were consistent with the previous published national data. (CITATIONS HERE)"

Please add the relevant citations at the end of this statement.
Response: Thanks for your point. We have added the citations at the end. The published study reported the overall rate of caesarean delivery in China was 34.9% in 2014 and there was a decline in some super cities from 2008 to 2014, and a steadily declined trend of caesarean delivery rate was also found between 2012 and 2016 reported in another study. A study recently reported that caesarean delivery rates plateaued between 2012 and 2016 and the rates increased from 2016 to 2018.


Reviewer reports:

Reviewer #1: The revised manuscript has answered all the questions I came up with in the last review. Based on a smaller scale of sample in 2013-2018, the author reanalyzed the trend of caesarean delivery rate changes in China due to the "universal two-child policy". They added some appropriate statistical methods to solve the problems or to help explain the areas that were not clearly explained in the previous version, and added space in the conclusion section to explain the results in depth, making the full text more scientific and logical.
For the correlations between the covariates and caesarean delivery rate, they added quantitative analysis (e.g. OR value) to prove that these indicators are reasonably considered as covariates. Since the previous version didn't explain how the policy affected the rate of caesarean delivery clearly, the author applied ITS with segmented linear regression to evaluate the effects of the universal two-child policy. This is a major change in the full manuscript, and this improvement makes their results more statistically significant and convinced. As for the comparability of samples in 1% national population sample survey in 2015 and NFPCP, the author also gives a literature-based explanation.
Overall, this study focused on the impact of China's universal two-child policy on caesarean delivery rate, which is relatively novel and realistic, and thus could be considered acceptable.

Response: Thanks for your point. Thank you so much for all your comments and suggestions on the current study. We appreciate all your brilliant ideas to help us to revise the manuscript.
Reviewer #3: I appreciate that the authors have promptly revised the manuscript according to the reviewers' comments. However, some of the comments seem not to be adequately addressed, and some new issues occur in the revised version. Considering the high-standard requirements from BMC Medicine, this manuscript may not reach the scientific criteria for publication. Therefore, my suggestion is "reject". New comments are as follow:

Major comments:

1. Study design
Although the authors dropped the data in 2011 and 2012, the principles of sampling and the quality of data are still not clearly elaborated. As the information of those who did not participate in the NFPCP was not available, it would be necessary to conduct a horizontal comparison with other similar studies in China.

Response: Thanks for your point. Detailed design, organization, and implementation of the NFPCP have described elsewhere (in Chinese). [Zhang S, Wang Q, Shen H. Design of the national free proception health examination project in China. Zhonghua yi xue za zhi. 2015;95(3):162-5.] In order to better understand the study design, we translated the study design in English here. Additionally, NFPCP have covered 3245 counties/districts across 31 provinces in mainland China, the representativeness and NFPCP participants are based on couples planning to conceive. There are no any published studies about planned pregnancies, thus, we could not make a horizontal comparison. A future study comparing data between participants in NFPCP and those who did not participate in NFPCP is needed to address the issue.

Regarding the quality of data, 1) NFPCP collects data with standard operating procedures to control the quality of data, including epidemiological investigation, physical and clinical examination, and follow-up; 2) NFPCP information system also uses the built-in automatic logic checks and instrumental interface to avoid human errors; 3) As a regular work for maternal and child healthcare centers, the local NFPCP operators usually take quality inspection of NFPCP at least once at the county or district level.


2. Statistical methods
It seems that the marginal effect analysis was not appropriate. Would it be more suitable for examining the trends that are in the same direction before and after a specific time point (so-called "marginal effect")? But in this study, the trends are opposite before and after the implementation of the two-child policy.

Response: Thanks for your comments. As structural difference of participants’ characteristics exists in different survey years, trend of crude or even standardized caesarean delivery rate may not reveal the real trend. Marginal effects analysis used in this study is measure the changes in the probability of caesarean delivery as the survey year changes (taking 2016 as the reference year) while holding all the other explanatory variables constant. Thus, we feel the marginal effect analysis is suitable for the analysis in the current study.
3. Result interpretation
It would be better if the authors could interpret their results on a more objective and insightful basis in the Discussion section, e.g. taking into account the latest research outputs and viewpoints of peers (such as JAMA. 2020 Jan 7;323(1):89-91; Risk Manag Healthc Policy. 2020 Mar 19;13:245-253.), comparing the results in the context of the literature, and discussing the significance and implications of the present study. In addition, result interpretation with a focus on the statistical methods is also needed.

Response: Thanks for your point. We have added the latest research to the discussion and discussed the significance and implication of the present study.

“A study recently reported that caesarean delivery rates plateaued between 2012 and 2016 and the rates increased from 2016 to 2018 [Trends in Cesarean Delivery Rates in China, 2008-2018]. However, the study was limited by the use of crude rates without adjustment for maternal characteristics. Besides, the study did not report the underlying influencing factors. Another study showed that the launch of two-child policy did not alter the caesarean delivery rate based on analysis of data from 2012 to 2016 using segmented logistic regression approach [A Segmented Logistic Regression Approach to Evaluating Change in Caesarean Section Rate with Reform of Birth Planning Policy in Two Regions in China from 2012 to 2016]. Nevertheless, the study assessed caesarean delivery rate in two provinces and the conclusion could not be generalized. Besides, the study ended before the increase captured in the current study.” [page 21, line 358-366].

Minor comments:

1. Line 67 "ITS showed the caesarean delivery rate…": Technically, ITS is a type of data, not the name of the analysis. It should be ITS analysis or segmented linear regression.
Response: Thanks for the comment. We have corrected “ITS” to “ITS analysis” in the text [page 4, line 67].

2. Line 202: It is stated that the reference level for nationality was "Han nationality", but in Supplementary Table 1, the reference level was "Others" instead.
Response: Thanks for the comment. The description of “reference level for covariates” is for marginal effects calculation. And the Supplementary Table 1 is the quantitative analysis measuring the relationship between covariates and caesarean delivery.
“To examine the trend of caesarean delivery rate over time, we used marginal effect of year to measure the expected change of caesarean delivery rate on the conditional mean of covariates, which could minimize, or reduce at least, the negative effect caused by structural differences of annual participants’ characteristics on.” “reference level for covariates: age was ‘25-29 years’, BMI was ‘normal weight’, nationality was ‘Han nationality’, education was ‘no higher education’, household register type was ‘rural’, adverse pregnancy outcome history was ‘without adverse pregnancy outcomes’, parity was ‘primipara’, full-term births was ‘yes’, and number of fetus was ‘singleton’.”

3. Figure 1: The sum of the three numbers (15 948, 960, and 9 398 045) is 9 414 953, not 9 414 963.
Response: Thanks for your comments. This is a typo. We have corrected the number from “9 414 963” to “9 414 953”. [page 12, figure 1]

4. Line 244: Please specify "quantitative analysis".
Response: Thanks for your point. We have specified the “quantitative analysis”. “Then we did a quantitative analysis measuring the association between covariates and caesarean delivery”. [page 13, line 242-243]

5. The mathematical symbol for "greater than or equal to" would be better to change into "≥" and specify what "NA" represents in Table 1.
Response: Thanks for the comment. We have changed the symbol to “≥” and “NA” represents “Not Available” in Table 1. [page 15-16, Table 1].

6. Line 266-267: Please describe what data Figure 2-A2 and Figure 2-A4 show.
Response: Thanks for your point. Actually, we have described data Figure 2-A2 and Figure 2-A4 showed, just after we mentioned it.

7. Line 412-414: Please provide the reference for "the previous published national data".
Response: Thanks for your point. We have added the citations. The published study reported the overall rate of caesarean delivery in China was 34.9% in 2014 and there was a decline in some super cities from 2008 to 2014, and a steadily declined trend of caesarean delivery rate was also found between 2012 and 2016 reported in another study. A study recently reported that caesarean delivery rates plateaued between 2012 and 2016 and the rates increased from 2016 to 2018.


8. Line 417-418: It is not appropriate to use "immediate influence". This should be interpreted without presumed causality.
Response: Thanks for your comment. We avoided the word “influence”, and we have revised the sentence as “The decreasing trend of caesarean delivery rate was reported after immediate release of the universal two-child policy.” [page 22, line 392-393]

9. Some data shown in the figures are not consistent with the corresponding data in tables (such as Figure 2 A2, A4 and the β2 values in Supplementary Table 3).
Response: Thanks for your comment. In the revised version, we have double checked the data and updated values in supplementary table 3.