Author’s response to reviews

Title: The power of peers: an effectiveness evaluation of a cluster-controlled trial of group antenatal care in rural Nepal

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Version: 1 Date: 02 Aug 2019
Author’s response to reviews:

August 1, 2019

Reproductive Health
c/o BioMed Central

Dear Reproductive Health Editors,

Thank you for processing our manuscript and to the reviewers for taking the time to provide such a detailed and thoughtful review. We have revised the manuscript accordingly, and here we provide our responses to the reviewers’ insightful comments. Our responses follow the arrows and are indented.

Reviewer #1: A well written article of relevance to the field especially in view of additional research needed on Group ANC. Methodological and other limitations well acknowledged by the authors and may affect grade of evidence

- Thank you so much for your review and feedback.

Reviewer #2: Abstract:

Please mention the results of knowledge of key pregnancy danger signs under the Results section, not only in the Conclusion.

- Thank you. We have added this important point to the Results section of the Abstract beginning on line 106.
Method:

Please add a paragraph on the study setting in the beginning of the Method section.

-> Thank you and we have added a paragraph at the beginning of the Methods section beginning on line 197.

I think it would be more intuitive for the reader if the paragraph "Study design" comes before the paragraph on "Group ANC Intervention"

-> Thank you. Because this study evaluates an intervention, we felt the study design would be easier to understand once we have described what that intervention was. For example, we can describe the primary outcomes and the outcomes for the nested cohort in the context of what the intervention is trying to achieve. As such, we’ve left the order as is.

Please describe the intervention in detail, only referring to a paper not yet published does not allow the reader to assess the scientific value of the study.

-> Thank you. We also submitted to Reproductive Health a complementary paper ‘Measuring fidelity, feasibility, costs: an implementation evaluation of a cluster-controlled trial of group antenatal care in rural Nepal’ which separately focuses on evaluating the implementation process and describes the intervention in greater detail. We requested the journal to consider these two papers simultaneously and to publish both simultaneously if they are both accepted. Thus, we are deferring this edit to the decision on the other manuscript. If they can both be published together, the reader will be able to see a very detailed description of the intervention alongside the outcomes. If not, then we will add more to the description in this manuscript.
Please motivate why a non-randomised design was used instead of a randomised.

-> Thank you and we added a sentence describing this in the Methods, under Study Design on lines 231-232.

Please motivate why you have only chosen perinatal mortality outcomes and no outcomes related to maternal morbidity or mortality (for example eclampsia, severe haemorrhage etc.)

-> Thank you and we added a sentence describing this to the Methods, under Study Design on lines 236-237.

Please explain why only women who had given birth previously were included in the study and no pregnant nulliparas. Potentially one could argue that the impact of the intervention would be greater among nulliparas. Obviously it would not allow for analyses on whether the proportion of institutional births increased before and after the intervention, but it would still be possible to compare the intervention and control group in terms of percentage of institutional birth.

-> Thank you for this important consideration and piece of feedback. We conducted a difference in difference analysis, so we needed to compare the institutional birth rate at baseline and at endline, between control and intervention groups. Women who were nulliparas during the intervention were included in the endline analysis, as they had one delivery during the study period.

Results

Table 1: Please include parity and education under maternal characteristics.
Thank you but we don’t have data on total parity, as we only collected a 2 or 3 year birth history. We also don’t have data on maternal education, although we agree that this is an important indicator and have included it in the data collection for future studies.

Discussion

Please comment on reasons to why there was increased institutional birth and ANC coverage in both groups after intervention (and even more in the control group).

Thank you. Please see the last 2 sentences in the first paragraph of the discussion beginning on lines 553-555: “We hypothesize that the CHW home visit care component has likely driven the improvement in these outcomes, though it is possible that there are other unmeasured reasons for this change over time. Given the short time-period and the relatively stable environment, it is likely that the CHW home visit care component is responsible for the changes observed”.

Please comment on reasons to why there was improved knowledge about danger signs during pregnancy and not in the other variables (labour, post partum etc).

Thank you. We added a sentence to the second paragraph in the Discussion on lines 559-562 describing that this was likely related to the relatively high frequency with which this topic was discussed during group ANC.

The discussion on the qualitative results is mainly a repetition of the results, please discuss the results in more depth and in the light of other evidence.
Thank you and we added a more in-depth discussion and new citations for other evidence throughout the Discussion section.

Please comment on why the study was conducted although obviously underpowered (as you describe).

Thank you. The sample size calculation is an estimate. During the course of the study we recognized that we had overestimated the sample size and the effect size. We needed to complete the study in the pre-specified time period due to funding and programmatic considerations. We also were bound by the constraints of government programmatic decisions in where the intervention could be delivered and tested (to your point about the limitation of non-randomized design as we mention) and were unable to expand the program to additional village clusters/expand the study setting to overcome this limitation.

Overall a well written and interesting manuscript, although it struggles with the limitation of being underpowered.

Thank you once again for your helpful feedback and review.

Reviewer #3: Thank you for giving me the opportunity to review the manuscript entitled "The power of peers: an effectiveness evaluation of a cluster-controlled trial of group antenatal care in rural Nepal". The manuscript is clear and well written. I have however a few comments and questions that may further improve the quality of the manuscript.
Comments

Why was the outcome "institutional birth selected"? It is not an outcome that is directly related to ANC as such, other than birth preparedness being discussed.

-> Thank you. This paragraph from our accompanying paper (which we describe in greater detail our rationale for pursuing a separate paper studying the implementation process on lines 212-213; see also response to Reviewer 2’s comment #4) explains our concept model and why we thought our intervention would improve institutional birth:

“In 2012, Bayalpata Hospital implemented comprehensive emergency obstetric care services and found that the institutional birth rate in the catchment area population significantly increased from 30 to 77% [7]. Qualitative data showed that targeting social support, birth planning, and resources may be important for reaching the remaining group of women not accessing services [7, 8]. The success of CenteringPregnancy in high-resource settings [9, 10], and participatory action women’s groups in low-resource settings [11, 12], suggested that these group care models may promote women’s empowerment and social support network development to address resource and sociocultural barriers to care. In addition, we hypothesized that the increased amount of face time with practitioners offered by the group model and decentralized high-risk pregnancy detection through prenatal labs and ultrasound, may increase birth planning success.”

In the introduction content of ANC is being mentioned as critical to decreasing maternal mortality. However, there is nothing in the project design that mentions that content of ANC care is being evaluated. I would suggest to remove it in the introduction.
Thank you. We mention both the content of ANC and the effect of institutional birth services (in brief in section beginning on line 208). Both of these are important to our intervention. We evaluate the content in our accompanying paper (which also describes the intervention components in greater detail), and the effect on institutional birth in this paper.

Why was not timely completion of ANC included? This would be a quality component of accessing ANC timely to be able complete the 4 recommended visits.

Thank you. We included completion of 4 ANC visits, as is recommended by national guidelines. However we did not collect data on the dates of those visits, as this was challenging using our data collection methodology. CHWs were asking women to report on their ANC visits after their delivery. Women would likely have a hard time remembering their ANC visit dates in the postnatal period.

Although one of the primary outcome variables were 4 completed ANC visits, the manuscript does not mention the number of group ANC visits that were offered, nor does the manuscript mentioned the number of visits recommended in the national ANC program. Please add this to increase understanding of the national context the project was implemented in but also the design of the intervention.

Thank you. We have added this to the Methods section, under Group ANC intervention beginning on line 206.

Wad the decentralized labs and ultrasound examination part of the national program or only specific to the project? This is not clear in the manuscript. It may explain the increased in
attendance in both groups, and not only the community health worker (CHW) intervention. Please clarify this.

-> Thank you. The decentralized labs and ultrasound examination is specific to this group ANC intervention, and not part of the national program. This is described in detail in our accompanying paper, submitted at the same time as this paper.

Is the CHW program implemented nationwide or was it just in the project? This is important to clarify. It is not clear for now in the manuscript. If there was a general increase in both groups due to CHW implication, then this would be major if translated to a national level implemented program. Please clarify this in the manuscript.

-> Thank you. The CHW program was implemented by Nyaya Health Nepal and it is not a national program. This was clarified in the Methods section, under Group ANC intervention beginning on line 2016. It is likely that the CHW program led to the general improvement in outcomes across intervention and control groups. We have included this in the Discussion section of the paper on lines 553-555.

The objective of group ANC was not clearly stated. Since you are measuring facility-based births and completion of 4 ANC visits as primary outcomes, this was the original hypotheses that these two variables would increase in the intervention group. Please explain this in the methods.

-> Thank you and yes, the hypothesis was that the intervention would improve empowerment, social support, and relationships with healthcare providers, all of which would
improve ANC completion and facility-based birth rates. This is explained in more detail in our accompanying paper, which we submitted simultaneously and which we’ve referenced. This is also explained in the Background (lines 180-187).

Was there any possibility of assessing the content of care in both the intervention and control groups? If the content of care is poor, it may be difficult for women to motivate themselves to come (given the financial and geographical barriers relayed to transport). This may explain that there was no difference in terms of the primary outcomes.

- Thank you. The content of care in the group visits was assessed in our accompanying paper, submitted simultaneously to this journal as we note elsewhere in this response letter. We also assessed the knowledge gained from the ANC content in both intervention and control groups—in the nested cohort. This is described in the Methods section (beginning on line 259) and detailed in the Results section (beginning on line 412 and in Table 3).

For those who did not present for all 4 ANC visits, was there any follow-up to understand the reasons and barriers for showing up? This could provide more insights into how group ANC could be improved.

- Thank you. Yes, we conducted KII that included variation in birth outcomes, including home birth. These results are described in the qualitative results section beginning on line 446.
There is no clear definition for stillbirths. The WHO uses from 28 weeks of gestation but given the constraints in pregnancy dating in low resource settings this may be a challenge. The project used however ultrasound for pregnancy dating and the accurate information pregnancy length may have been more prevalent.

-> Thank you. When asking about a birth history we asked women about births (live or still) after 28 weeks of 7 months gestation. Dating of pregnancies in this low-resource setting can be challenging at times. In this study, we used women’s self-report of stillbirths greater than 28 weeks. In the group ANC intervention, ultrasound was used in the third trimester for fetal presentation, and placental location primarily. The goal of the antenatal ultrasound in this study was not for dating.

Why is stillbirth rate higher in the control group after the study period (dramatically higher)? This is not even mentioned in the results or discussion section although it was a secondary outcome.

-> Thank you. As noted earlier, there are significant challenges globally around measurement of stillbirths and in this study we used women’s self-report of stillbirths given the constraints of our study (i.e. not using antenatal ultrasound for dating). Given the primary goals of the program, we chose the stillbirth rate as a secondary outcome (as you correctly note) and only present these outcomes in Table 2. Our study results do not have the explanatory power to determine the reasons behind these higher rates at endline though we hope to study further in the future.
Other comments:

Number of women dying every day differ in the abstract and background (830 vs. 800).

-> Thank you for noting this. We have corrected in the plain language summary and in the background (now consistently at 830).

Line 373: where home visits and CHW home visits in reality the same thing? That is, home visits were done by CHWs in both the control group and the intervention group?

-> Thank you. Yes, these were the same.

Line 496: USG is mentioned for the first time Please spell out abbreviation.

-> Thank you. This has been corrected.

728: "Enrolment" is not correctly spelt. AS for now there are two l's.

-> Thank you but this is the American English spelling of the word.

Line 525: The birth planning tool mentioned is not explained earlier in the next.

-> Thank you and we have added an explanation.

Line 571-572: It is not clear what it means with "qualitative data only collected in the intervention site". It was assumed that qualitative data is collected in the intervention and control groups. Is there another type of qualitative assessment apart from the assessment understanding danger signs etc.?
Thank you. The knowledge assessment (for danger signs, etc) was a survey conducted in both the intervention and control groups. Qualitative data, from key informant interviews and focus group discussions, were collected only in the intervention group. A sentence was added to the Study Design in lines 255-256 to clarify this.

Line 617: You mention no impact in "health outcomes". You are however not really measuring health outcomes. You are measuring completion of services or service packages. Would it make more sense to re-phrase accordingly?

Thank you and we have corrected this language in the Conclusions section in lines 646-648.