Author’s response to reviews

Title: Comparative satisfaction of receiving medical abortion service from nurses and auxiliary nurse-midwives or doctors in Nepal: Results of a randomized trial

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Responses to Reviewers’ Comments

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Comparative acceptability of medical abortion among women receiving care from nurses and auxiliary nurse-midwives or doctors in Nepal: Results of a randomized trial

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Reproductive Health
Reviewer #1 Comments

1: 1- The title: the concept of acceptability do not reflect exactly the content of this manuscript.
Response: We agree with the reviewer and have changed the title to reflect the content of the manuscript more accurately. The new title is: Comparative satisfaction of receiving medical abortion service from nurses and auxiliary nurse-midwives or doctors in Nepal: Results of a randomized trial

2- The abstract: Remove reference from the abstract (second line in methods paragraph of the abstract)
Response: The reference has been deleted

3- The background: The subject is contextually relevant, and this paper can make important contribution to policy against unsafe abortion in the specified context and beyond.
Response: We thank the reviewer for the important observation.

4- Methods:

4-1) This manuscript needs a conceptual framework and operational definition of acceptability in the methods. Researchers address briefly this issue in the discussion, and they did well to acknowledge the complexity of this concept of acceptability and the psychological dimension related to it. In the current state of this manuscript, this limitation is insufficiently addressed. Researchers can describe in the methods, conceptual clarification and choices they made to guide the understanding of the whole manuscript.
Response: We have replaced the term “acceptability” by “satisfaction” and accordingly. We have also added the conceptual framework for the analysis of satisfaction and its related dimensions. We thank the reviewer for the suggestions.

4-2) Researchers used the concept of acceptability interchangeably with the one of satisfaction.

The MeSH provides the following definition for patient Satisfaction: The degree to which the individual regards the health care service or product or the manner in which it is delivered by the provider as useful, effective, or beneficial. Is this concept identical to acceptability?
Response: We have not used the MeSH definition of patient satisfaction, but have measured it directly from the women’s responses to the question on satisfaction with the service they received.

4-2) Can the research team describe the tool used to measure "acceptability"? Is it a single question on acceptability or a composite score that takes into account the acceptability of different dimensions of the service provision in both groups? Moreover, health providers have administrated the acceptability form to patient within the facility. How do researchers appraise the effect this arrangement can have on the capacity of patient to express dissatisfaction or negative feedbacks?

Response: The Acceptability Form (ACP 1/3) was completed by the female research assistants (not by the provider) by interviewing the women (MA acceptors) at the time of their follow-up visits (10-14 days after the administration of mifepristone). The ACP form had one direct question on ‘satisfaction’ (how satisfied are you with the method?) that was used to create ordinal scale data. Logistic regression was applied to identify the factors associated with being “highly satisfied” or “satisfied” with MA use.

In addition, the ACP form solicited women’s experience/perceptions regarding pain, amount of bleeding, duration of abortion process, side effects and privacy. For each of these five conditions, women were asked to respond either ‘less than expected’, ‘same as expected’ , ‘more than expected’ or ‘no comment’. We have added these detailed in the revised version of the manuscript.

4-2) Researchers reported in the manuscript that they established separate waiting areas for the two groups to ensure independency: is this enough to ensure independency?

Indeed, patients are aware that the procedure has been performed within a research project that is supervised overall by medical experts. How do this affect the independency of the two groups? Can we reject the possibility that women in the ANM group felt in a safe condition within this research and globally supervised setting and thus reported a high proportion of satisfaction?

Response: The waiting space and examination room arrangements at each site for two groups provided enough independency to reduce interactions between the groups. We believe that a higher proportion of women stating satisfaction served by ANM group was unrelated to the ‘safe condition’ within this research project. In general, women did not express that being part of research group provided them with additional quality of care. In addition, the nurse and auxiliary nurse-midwife group provided the service independent of the group of doctors, except in few referral cases.
4-3) what are the mean ages of providers in both groups?

Response: The mean age of doctors was 42.4 years (SD= 11.0) while that of the nurses or auxiliary nurse- midwives was 41.7 years (SD = 7.1). This information has now been added in the revised manuscript.

4-4) Why do some patients were not considered for the acceptability form?

Response: Acceptability form was administered at the time of follow-up visited (10-14 days after mifepristone administration). During the course of the study, three (3) women from nurses group did not participate as they were in a hurry. This information has now been provided in the revised manuscript.

Reviewer #2: General Comment

This paper on 'Comparative acceptability of medical abortion among women receiving care from nurses and auxiliary nurse-midwives or doctors in Nepal: Results of a randomized trial' aims to assess whether Medical Abortion (MA) services provided by specifically trained and certified nurses and auxiliary nurse-midwives independently from doctors' supervision, is as acceptable to women as those provided by doctors. The article addresses an important issue in current SRH and MCH discussions, namely the relative lack of availability of legally safe abortion services in many low-income settings as well as the limited number of personnel to provide needed services. While the article's findings could be important, the paper in its current form suffers a number of major methodological, stylistic and content deficiencies that the results and conclusions are hard to believe. This is particularly so because the authors say the paper came from a randomised trial. Before this paper becomes suitable for publication in Reproductive Health, I believe these major deficiencies need to be seriously addressed. Below are my specific comments:

1. Topic, aims and measurement.

The key topic of this paper is the comparability of the ACCEPTABILITY of MA services provided by nurses/auxiliary midwives on the one hand and doctors on the other hand. One of the fundamental problems of the manuscript in its current form is how the authors operationalise acceptability and then proceed to measure it. Throughout the paper, it is not exactly clear what the elements of acceptability comprise. Rather, the authors appear to use and indeed measure
Satisfaction and then mistakenly approximate satisfaction for acceptability. This is a very big flaw because the two are not the same. Clearly, the data presented in table 3 (Level of satisfaction) and table 4 (quality of service indicators) do not really measure acceptability. Indeed, the authors acknowledge the limitation of their measurement of acceptability and satisfaction on page 11, lines 29-40. The authors however appear to discount this measurement problem and suggest that ‘Nevertheless, our study clearly indicates that acceptability and satisfaction with the provision of MA by nurse and auxiliary nurse-midwives is as high as services provided by doctors. Therefore, medical abortion services provided by nurses or auxiliary nurse-midwives providers with appropriate training should be made available to all women wanting early first trimester abortion’.

Response: The authors are grateful to the reviewers for this important comment and have replaced “acceptability” by “satisfaction”. This change reflects more accurately the information collected from women in the study and the content of the manuscript.

In my opinion, the entire paper is built around the concept and measurement of ACCEPTABILITY. Therefore, if the concept or rather the acceptability outcome variables are poorly defined, then the measure itself will be a problem. The authors clearly make no serious attempt to define what acceptability is and what the acceptability outcome variables are. The outcome variables used such as pain, amount of bleeding, level of satisfaction and quality indicators are all very subjective. For example, how much pain or bleeding is considered ok or not? These are clearly measures left to the individual subjectivities of the research participants, and therefore very hard to do any serious objective comparison. In order to measure acceptability, authors will need to ask questions related to:

1. Were the respondent to do MA again, will she come to the same facility or the same caregiver (whether nurse or doctor)?
2. Will the respondent be willing to recommend the present caregiver to another person seeking MA services?
3. If the respondent knew that there were groups of doctors and groups of nurses providing MA services in the same health facility, which group will she prefer? In relation to this question, the authors need to explain whether women were made aware that there were two different groups of MA providers at the health facility. The randomisation procedures described in the manuscript are silent on whether women knew they were being allocated to a group of nurses or doctors.
Response: We agree that the proposed questions by the reviewer would have provided a more valid measure of acceptability. However, the time constraint did not allow us to include these questions. With the information we were able to collect, we feel confident about measuring “satisfaction” and have, therefore, dropped the use of the term “acceptability”.

Added to the above is the issue of outcome. The authors suggest on page 10, lines 12-29 that they have already presented data on the safety and effectiveness of MA services provided by doctors and nurses. In my opinion, the outcome of the MA services provided by these two group of caregivers should be an important determinant of both satisfaction and ACCEPTABILITY. Strangely, the authors ignored this important dimension.

Response: We have added the information on the comparative outcomes (effectiveness) of MA services provided by doctors and nurses [complete abortion rates were 97.3% for nurses or auxiliary nurse-midwives and 96.1% for doctors. The risk difference (95% CI) for complete abortion was 1.24% (-0.53%, 3.02%), which falls within the pre-defined equivalence range (-5%, 5%). There were 5 cases (1%) of failed abortion in the doctor arm and 0 in the nurse and auxiliary nurse-midwife group; the remaining cases were incomplete abortions. There were no serious complications and no difference in side effects by type of provider. Nurses or auxiliary nurse-midwives reported discussing less than 2% of cases with other providers and referred 1% of cases to other providers, a pattern similar to that of doctors] Additional information is also available in reference [1] cited in the manuscript.

Even on the factors associated with high satisfaction of MA, the authors do not examine type of outcomes. This is really baffling given that the main outcome that most, if not all, the women who sought MA were looking for was completeness or complete termination of the pregnancy. The issue of outcome is very important because if the women were to equally accept MA services provided by both doctors and nurses, yet the outcomes (completeness) for one group of caregivers (e.g. doctors) is better than the other group (e.g. nurses), it would be hard to accept the authors' conclusion that 'The findings provide support for extending safe and accessible medical abortion services by government-trained nurses and auxiliary nurse midwives to women seeking early first trimester pregnancy termination'. Therefore, it will be important to examine whether the type of MA outcome affected level of acceptability.

Response: The authors have performed preliminary Fisher’s exact test (F-test) to measure the associations between types of outcome and level of satisfaction by types of MA providers (p value =0.000) . We found inconsistent results by type of provider group and, therefore, did not include in the manuscript.
In addition to the above problems, the manuscript suffers other deficiencies. For example, in tables 2 and 3, authors report only percentages without indicating frequencies. Similarly, since authors are interested in comparing acceptability across the two groups, they could have performed further statistical analysis such as comparison of means to see if the differences they found were statistically significant or not. At the moment the results, discussion and conclusion appear forced as the data does not seem very credible.

Response: The frequencies have been included in the revised version in both Table 2 and 3.

2. Discussion

On page 11, lines 24-27; authors write that 'There is also some further indication that the gender of the provider played a role in women's discomfort with the procedure; the study found that more women in the doctors' group reported discomfort with the vaginal examination which may be attributed to a large number of men in that group'. I think this point is potentially interesting but the authors' attribution of the discomfort that more women in the doctors' group felt to the large number of men in the doctors' group is inadequate. What exactly is it about male doctors that will make women undergoing MA uncomfortable? Is it just the large number of males? I think it has got something to do with simply being the opposite sex so that even if you had one male doctor examining women, this discomfort would still be reported. Authors might need to draw on contextual understanding of gender roles to explain this.

Response: We agree with the reviewer and have revised the sentence

3. Conclusion

As I have suggested, the conclusion drawn in this paper appears very forced. I think the authors are making too much claim here. It may be useful, given all the limitation issues raised, to call for further trials before making claims about rolling MA services by nurses and ANMs.

Response: The safety and efficacy results of the randomized trial have been published and referred in the manuscript. This paper addresses the issue of satisfaction of the provision of MA by provider type, another critical element in making recommendations, from the perspectives of women. Together, these results provide a sound and valid evidence for rolling MA services by nurses and ANMs in settings like rural Nepal where doctors are in short supply. We, therefore, maintain that our conclusions are fully supported by the findings from the study.
Reviewer #3: September 20, 2016

Thank you for the opportunity to review your paper. I think it is an excellent paper on a rigorous study and will be a great contribution to our field. The intention to treat analysis, the best fit model and the low level of lost-to-follow-up are all strong indicators of the strength of this paper. I have only a few suggestions that I think will help clarify things for your readers.

In your background section, it would be nice to know a little more about the differences in training/skills/education between nurses and auxiliary nurse midwives. You have this information in procedures but I found myself wondering about this distinction earlier.

Response: The authors have added the training/education levels differentiating staff nurse and ANMs [To be a staff nurse, one need to complete a three years’ Proficiency Certificate Level (PCL) nursing course after completing 10th grade. Whereas, auxiliary nurse-midwif follows a 18 month course after completing 10th grade]. The revised manuscript includes this information.

P. 6 - it seemed odd to me that women are monitored for 3 hours after misoprostol insertion. Was this a part of the study or national protocol? I'm not sure it is evidence-based practice.

Response: This was part of the study protocol

p.6 - I'm wondering if you monitored or controlled waiting time on the days of mife, miso and follow-up visits? Could this have impacted satisfaction in any way?

Response: No we did not monitor or controlled waiting time and hence cannot suggest any potential effect of this on satisfaction analysis. In the context of Nepal, waiting time for service is generally not a significant factor for women seeking health care.

I think it would be better to be clearer earlier the definition of "complications" or adverse events resulting from the procedure and your definition of side effects. You have a nice description of side effects just before the Discussion section but it might be better defined earlier.

Response: We are grateful to the reviewer for the suggestion and have added the suggested information.
p. 9, just under the placeholder for Table 3, it is not clear if your measurement of appropriate counseling was to include the signs of complications or the expected symptoms of the medication, or both. It would be nice to hear more in the text about the components of satisfactory counseling since this is a point of debate in our field. I wonder if this might be better described as the quality and content of the provider-client interaction (counseling) rather than "quality of services"? Related to this point, I don't believe that the first or last variables in Table 4 are truly quality/provider interaction measures. I think that the first variable (and the extraordinarily high level of acceptance) on availability could merely be described in the text. The last variable is quite important but I don't think it belongs with these other "quality" variables.

Response: We appreciate the reviewer’s comments. However, many studies consider quality and content of provider interaction as an important component of quality of service. We recognize the debate on what constitute the quality of service. However, we feel the integrated set of indicators are well placed together in Table 4 to provide insights from women’s perspectives on the quality of service they received.

p. 9 - could it be that the correlation between higher gestation and higher satisfaction could be related to relief at the termination of the unwanted pregnancy rather than actual satisfaction with the procedure?

Response: This can be a possibility, but we did not examine it.

Discussion - I think it is worth mentioning that a part of your measurement is really about how well providers counseling meets a woman's expectations of what she believes her abortion process will be like. This shows comprehension by women themselves and is a key part of the interaction.

p. 10 - I think that the first line of your second paragraph of your Discussion should be cited. I'm not sure this paragraph is even important. There is a big difference between an "acceptable level of privacy", which is important and privacy being "less than expected".

Response: We have modified the sentence as “privacy and confidentiality can be valued features for women seeking abortion”

p.11 - I'm not sure the term "emergency procedure" is correct. Abortion is certainly highly stigmatized and is a personal decision but it is not necessarily for an emergency. Difficult?
Personal? I can't think of a great term but I found this odd. Earlier in this paragraph, it would be good to mention that these are "elective" abortion services.

Response: We thank the reviewer for the important observation. We have omitted “emergency procedure” and have added “elective”, as suggested.

I also had a question about Table 1. Is it true that you did not ask about previous experience with MA? Was this, by chance, exclusion criteria? The number of women who had a previous abortion was not small. These women may know more about what to expect and their previous experiences may have affected their levels of satisfaction. Depending on how you dealt with this, I think this could be a limitation.

Response: We have inserted these sentences as foot notes under Table 1. ‘Medical abortion (MA) was introduced in Nepal in 2009 just few months ahead of the study and only 18 women participating in this study had previously used MA. It is was not asked where they obtained the MA and the abortion outcome with MA use, hence these conditions were excluded’.

Table 5 - I found the label "Management of symptoms by women" to be unclear.

Response: We have replaced by ‘Factors associated with “high satisfaction” of medical abortion’ for this Table 5.

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