Author's response to reviews

Title: Community mobilisation and health management committee strengthening to increase birth attendance by trained health workers in rural Makwanpur, Nepal: a cluster randomised controlled trial

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Author's response to reviews: see over
Community mobilisation and health management committee strengthening to increase birth attendance by trained health workers in rural Makwanpur, Nepal: a cluster randomised controlled trial

Thank you very much for considering our trial for publication, and thanks to the reviewer for his helpful comments. We have responded to them point by point, with alterations to the manuscript where appropriate.

Major Compulsory Revisions

1. The authors describe substantial improvements in Nepal, including the rural setting of the proposed trial, in the attendance of trained (skilled) health workers over the preceding decade (e.g. an increase from less than 5% to 17%, say), with successful national level programmes implemented. The authors need then to discuss in more detail how feasible it is going to be to recruit to, and retain, the skilled birth workers and the participants in the control clusters, given these strong trends external to the study?

   We’re not sure we quite understand this point. Trained birth attendants are supposed to be present in all village development committees in Nepal. The training programme and retention have been such that this is not necessarily the case. Our intervention will not directly recruit birth attendants. It is possible that activities by women’s groups and health management committees could lead to local recruitment, or training of local individuals. Indeed, this would be a good outcome.

   We don’t understand the point about participants in the control clusters. The intervention clusters will have women’s groups and health management committees strengthening, with a focus on the problems of birth attendance; the control clusters will not. In both arms of the study there will be the existing birth attendants in place, and mothers and their families will freely choose where they wish to have their delivery and whether to seek a skilled attendant or not. If the reviewer is concerned about recruiting control arm women to the data collection exercise, we have been running a surveillance system for almost a decade now, and we do not envisage problems in getting consent for data collection.

   The issue of the national trend to increased skilled birth attendance is that most people think it has been too slow. The intervention aims to accelerate the adoption of trained birth attendance on a background of this slow increase. The secular change will be manifest in the control areas, and any difference between intervention and control groups will be attributable to the intervention.

2. The authors need to discuss in more detail the potential for contamination across the intervention and control arms – there is a good description of the interactive randomisation
process, but it seems for example that there was no control of the randomisation to ensure some physical or geographical separation of the 43 village development clusters – so two clusters assigned to the two different groups may be adjacent?

This is true. There is a possibility of contamination, although the topography will limit it, mobility within the district – especially of women – is also limited, and we did not see much diffusion of change in the previous trial. We wanted to involve all the village development committees in the district and to have district officials be a part of the process of allocation. Contamination will tend to reduce the perceived effect of the intervention, and we were willing to accept the compromise. We have added the following paragraph to the Design section.

“We considered the issue of contamination. Within each rural VDC, houses tend to be clustered in scattered settlements. Each VDC has one health institution: a health post or primary health centre. Not all of these offer institutional delivery. It is therefore possible that a woman might cross into another VDC for her delivery (historically, since institutional delivery was rare, the crossover tended to be either to the district hospital in the municipality of Hetauda or to a large hospital in another district entirely). The intervention was not designed to increase trained birth attendance through institutional delivery at a specific health facility. We seek only to increase such deliveries at any appropriate institution. One means to do this will be the activities of women’s groups, which are specific to individually allocated VDCs. Health Management Committees will operate around the institutions specific to their VDCs, but may not in all cases aim to increase deliveries at their own institutions. Where institutional delivery is not possible, the blanket aim is to put processes in place to ensure that local residents make the right choice of site so that they have a safe delivery. For contamination to occur, either the influence of women’s group activities must disseminate beyond the VDC (push factor), or the influence of HMC activities must encourage attendance at their institutions (pull factor). On the basis of our experience during the previous trial of women’s groups, we do not think that the former is likely to be a strong effect. The latter is a possibility which would tend to reduce the difference between intervention and control arms of the trial.”

3. Figure 1 gives the complicated stratification of the clusters – based on ‘previous project activities’ and not say cluster characteristics – the authors need to justify why this stratification is necessary, and describe it in more detail in the text – it is a bit isolated and disjointed at present?

We have added some information on stratification to the Design section:

“We have already worked in 30 VDCs in Makwanpur district to evaluate the effectiveness of women’s group interventions, and we felt it was important to stratify sampling on the basis of previous exposure of clusters to programme activities. The success of these activities had led to measurable differences between VDCs. We stratified clusters into four groups. Group 1 included control clusters from 2002-2005, and intervention clusters from 2005 to 2008. Group 2 included intervention clusters from 2001-2008. In group 3 we monitored birth outcomes from 2005-2008. In group 4, we had not previously conducted any intervention or monitoring activities. We randomly allocated equal numbers of clusters from each group to intervention and control clusters using the methods detailed below.”

4. Statistical Analysis Plan – ‘We hope to be able to analyse at the level of the individual’ – ‘hope’ sounds a bit non-committal for such a fundamental aspect of the analysis – what would be the perceived barriers to stopping this? And if it wasn’t possible to analyse at the individual level, what would be the nature of the analysis at cluster level.
This was an unnecessarily self-deprecating statement. Because of our previous experience of collecting individual data, we know that we will be able to analyse at the individual level. We have rewritten the paragraph:

“We will compare the primary outcome in intervention and control arms, using data for two years of intervention. We will conduct the analysis at the level of the individual, and the procedure of choice will be random effects logistic regression models grouped on cluster. If quadrature checks suggest that this is inappropriate, we will use generalised estimating equations.”

5. In addition, the authors state that ‘we will adjust the models for covariates if the baseline comparison of arms suggests imbalance’ – such ‘conditional’ adjustment only adjusting for covariates that seem out of balance in the dataset at hand is not good statistical practice – the better approach is to adjust for a pre-specified set of covariates known to be strongly associated with outcome, regardless of their significance in the data set at hand.

We apologise to the reviewer for putting him through this in two different protocols! Because of the stratification of the sample at design and allocation stage, we do not envisage substantial baseline differences between intervention and control arms. Because of the clustered nature of the sample, it is possible that there may be some imbalance between arms. We are therefore prespecifying adjustment for socioeconomic status and religion. Experience suggests that these will also account for differences in from caste, education and parity. The amended section follows:

“We will compare the primary outcome in intervention and control arms, using data for two years of intervention. We will conduct the analysis at the level of the individual, and the procedure of choice will be random effects logistic regression models grouped on cluster. If quadrature checks suggest that this is inappropriate, we will use generalised estimating equations. Analyses will be adjusted for socioeconomic status and religion.”

Minor revisions

6. Page numbers would be helpful

Apologies: we have added them.

Discretionary changes

7. There are a number of theory-based constructs in the design and delivery of the trial e.g. ‘action research cycle’, ‘appreciative enquiry methods’, ‘conditional cash transfers’, ‘plausibility analysis’, ‘human development index’, ‘the four ‘D’ cycle – discovery, dream, design, and destiny’ – and so on, that are not consistently given methodological references, and in any case could do with a paragraph on each briefly explaining the concept and specifically how it applies to this complex intervention trial.

We have added references and some explanation of the theory-based constructs.

“Participatory action cycle approaches are often used in community mobilisation. The approach is problem focussed, and the process begins by individuals coming together to develop an understanding of the problem and its causes. This group continues to work together with other stakeholders to address the problem and initiate social change. The actions taken are then critically examined and the cycle continues through iteration. {Hart, 1995 #36}{Rifkin, 2001
8. The description of the interventions is good, and in particular the narratives about the ‘formative work’ that led to their development – but in the specification of the improvement in ‘health management committee strengthening’, it would be useful to have more insight into how these committees are structured, and how variable they will be across the 20-odd intervention clusters?

We have added information on this on p5 and on p10

“It is recommended that one of these representatives be from a minority (Janajhati), ethnic group and another from a lower caste (Dalit) group. Social, or community workers (such as school teachers, or community members involved in development activities) are also recommended, and a Female Community Health Volunteer is usually a member of the HMC.”

“HMC members, community representatives, and health facility employees participated. Our formative research found 18 out of 43 HMCs scored well on indicators of resource mobilisation, staff management, service monitoring, management of health volunteers, and regularity of meetings. 10 were in control areas, and eight in intervention areas.”

9. The authors mention also a ‘pyramid’ for Nepal’s health system – useful to maybe provide a graphic illustrating this for the reader?

We have added a diagram, Figure 1.

10. 'VDC’s may also provide an incentive at their discretion’ – explain what these incentives are, and to whom?

We have added this information.

“VDCs may also provide a financial or non financial incentive at their discretion. These may include the provision of a uniform, umbrella or bicycle {Family Health Division, 2067 #498}”

11. The list of primary and secondary outcomes could do with more description – why are these the most important outcomes, and what specifically decided the split between primary and secondary.

We wanted to run a trial with a clear outcome that accorded with both international and national priorities: skilled birth attendance. For clarity of analysis, this is the primary outcome (of which institutional delivery is a subset. We have added a short paragraph to the section on outcomes:

“Skilled birth attendance is an internationally accepted indicator of the success of interventions to improve maternal health. {Campbell, 2006 #165} {UN, #80} This is mainly because it is thought to be on the causal pathway, and because maternal mortality is a sufficiently rare outcome to prevent its use in trials of this nature. Institutional deliveries are a subset of deliveries conducted by a skilled attendance. Our intervention targets health systems and communities. The causal pathway to improved outcomes includes uptake of antenatal and postnatal care services and improved management of maternal morbidities. Previously, our intervention sought to improve neonatal survival, and it will be interesting to examine if further neonatal gains can be made with increased utilization of services.”

12. The sample size calculation was clear enough – could possibly be better presented as a small table – and why include indicative powers of 70% - this would generally be considered
underpowered and hence not of interest?

We have removed the estimates for 70% power. We have made a table:

**Table x. Sample size for different powers and intercluster variation coefficients**

<table>
<thead>
<tr>
<th>Births per cluster</th>
<th>Intercluster coefficient of variation</th>
<th>Skilled birth attendance proportion in control group (%)</th>
<th>Skilled birth attendance proportion in intervention group</th>
<th>Power (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>200</td>
<td>0.35</td>
<td>20</td>
<td>30</td>
<td>90</td>
</tr>
<tr>
<td>200</td>
<td>0.35</td>
<td>20</td>
<td>27</td>
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<tr>
<td>200</td>
<td>0.25</td>
<td>20</td>
<td>26</td>
<td>80</td>
</tr>
</tbody>
</table>

On balance, we think that the table does not add much, in view of the straightforwardness of the following amended paragraph:

“For two years of intervention (200 births per cluster), if $k = 0.35$, 42 clusters would detect an increase in trained attendance from 20% to 30% at 90% power, and from 20% to 28% at 80% power. If $k = 0.30$, 42 clusters would detect an increase in trained attendance from 20% to 28% at 90% power, and from 20% to 27% at 80% power. If $k = 0.25$, 42 clusters would detect an increase in trained attendance from 20% to 27% at 90% power, and from 20% to 26% at 80% power. Overall, a conservative level of powers, births and values of $k$ suggests that the sample size will be able to detect an increase in birth attendance by trained health workers of around 10% over two years.”

We are happy to add the table if the editors would like us to.

13. Interim analysis – it would be useful to include more details on the role and remit of the independent DMC.

We have added this:

“The role of the data monitoring committee will be to decide whether the study protocol been followed adequately, whether enrolment has been adequate, and whether randomization has resulted in comparable groups so that, in the absence of interventions, it would be reasonable to expect similar health outcomes over time. The committee will review interim data for completeness, quality and adherence to ethical requirements, and will make recommendations on the continuation of the trial or its modification.”

We look forward to hearing from you.

Yours sincerely

Joanna Morrison