Reviewer's report

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

Version: 2 Date: 5 April 2011

Reviewer: John Norrie

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Major Compulsory Revisions

The authors provide a clearly written and comprehensive protocol of a complex intervention cluster trial including community mobilisation and health management committee strengthening to influence the rate of birth attendance by skilled health workers. There are several issues arising from a statistical and trial methods angle, as follows:

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?

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?

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?

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.

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.

Minor revisions
6. Page numbers would be helpful

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.
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?
9. The authors mention also a ‘pyramid’ for Nepal’s health system – useful to maybe provide a graphic illustrating this for the reader?
10. ‘VDC’s may also provide an incentive at their discretion’ – explain what these incentives are, and to whom?
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.
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?
13. Interim analysis – it would be useful to include more details on the role and remit of the independent DMC.

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests:
I declare that I have no competing interests