Reviewer's report

Title: An effectiveness study of an integrated, community-based package for maternal, newborn, child and HIV care in South Africa

Version: 2 Date: 22 September 2011

Reviewer: John Norrie

Reviewer's report:

The authors present a very well written protocol addressing an important issue. The cluster design appears robust and well specified, with appropriate statistical analyses specified. There follow some minor points which might enhance the clarity of the paper if addressed:

1. Page 2: It would be useful to give more detail on how the authors ‘identified three key implementation gaps affecting progress’ – the three identified look plausible and important, but where there a fourth, fifth and sixth implementation gaps sitting perhaps just behind these that might also have been of importance?

2. The primary outcome – ‘HIV free survival at 12 weeks’ – given the breadth and complexity of the package of interventions, is 12 weeks long enough for all the benefit to have a chance to accrue? Did the authors think of including a longer term follow up e.g. at 6 or 12 months to see if any benefit observed at 12 weeks was sustained over a longer period?

3. Page 3 – ‘adapting and testing Asian community based studies in various African contexts’- useful if the authors could be more expansive and insightful in why the findings in Asia can’t reliably map straight on to the African contexts?

4. Page 5 ‘MTCT may occur during breastfeeding but the greatest risk is with mixed feeding’ – this needs some more explaining / evidencing, since naively you might have thought that exclusive breastfeeding with an HIV mother would confer the highest risk, and exclusive bottle feeding the lowest, and mixed feeding somewhere between these two?

5. Page 8 ‘The question is not merely to develop an efficacious package but also to identify and test delivery strategies that enable scaling up’ – the scaling up part is the most difficult to get to grips with in this Protocol, and probably understandably the least well articulated (given the complexity). It would be good to expand on this aspect. For example, in the Economic Evaluation (page 15) the authors state that ‘costing is a critical component of an effectiveness trial to inform scale up’ – but aren’t many costs of a scale up one-off costs pertaining to infrastructure and capacity building?

6. Page 9 – ‘levels of exclusive and appropriate infant feeding at 12 weeks’ – what is ‘appropriate’ defined as here?

7. Page 9 ‘to assess post intervention levels of maternal depression’ – at what time point – 12 weeks?
8. Page 10 ‘... a baseline survey of all clusters was conducted in order to check on the homogeneity of clusters ... neither stratification nor matching was performed’ – what measures were involved in establishing this homogeneity?

9. Page 10 – given the nature of the intervention and the short follow up time (12 weeks) is an attrition rate of 20% really acceptable – couldn’t this be reduced a fair bit?

10. Page 11 – the authors discuss the key issue of contamination, but the explanation ‘all effort have been made to avoid contamination ...’ could be more comprehensive and hence hopefully convincing? Specifically there is only 1 CBHW per cluster, and most of the deliveries (98%) are in 1 hospital – naively that would seem to make it quite easy for contamination to seep in?

11. Page 12 ‘In each intervention cluster there is one CBHW who covers all households in the cluster’ – how many separate contributions might be made from a single household e.g. sisters, daughters, multiple families within household, and then twin or multiple births? As well as adjusting for cluster are the authors adjusting for clustering within a household?

12. Panel 2 – not really clear what the process measures are as distinct from the outcome measures?

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'