Reviewer's report

Title: Strengthening Health Human Resources and Improving Clinical Outcomes Through an Integrated Guideline and Educational Outreach in Resource-Poor Settings: A Cluster-Randomized Trial

Version: 2 Date: 9 June 2010

Reviewer: Graeme MacLennan

Reviewer's report:

Major Compulsory Revisions

Analysis plan
   - It would be useful to have the analysis plan to consider the primary outcome first, so that the most important analysis strategy is outlines first, then the subsequent analyses can be assessed in relation to this
   - Kaplan Meier is to be used to assess the time to event (event being HCW leaving the HC). As you are using Stata for analysis why not using Cox regression which allow for adjustment for clustering and HCW baseline covariates?
   - Worker satisfaction, I am not familiar with the tool, so excuse me if this is a daft question: How are you calculating the HC worker satisfaction based on multiple HCW in each HC, will it be an average of some sort? If so, why not use the HCW scores on the tool and adjust for clustering. Also, what will you do for scores of HCW that leave, or join, after baseline? (I suppose this is covered in the sensitivity sentence at the end of the paragraph).

Potential confounders
   - I am assuming that these confounders are measured at baseline? A couple of them are clearly not going to change from baseline, but some may (for example the number of patients seen per day, this is also an outcome), and some a post randomisation measurement that are related to the intervention (number of PALM plus training sessions, exposure to other MoH training). These last two I suppose are analogous to in a therapeutic trial say number of therapy sessions attended or number of number of non trial therapy sessions and as such are not baseline covariates but more measures of the fidelity of the intervention? This would then suggest that these were being used in a secondary analysis to the ITT, an adjusted treatment received analysis to account for ‘non-compliance’ with intervention by not attending the PALM PLUS training?
   - There are rather a lot of confounders at cluster level given the sample size of 30 clusters clearly the effects of these can only be explored individually, can we have more details on the strategy?
Would be useful to see a CONSORT flow diagram of the trial mapped out (in addition to the randomisation figure, which I thought was useful).

Minor Essential Revisions

Abstract:
- The guidelines for authors state not to use abbreviations in the abstract.

Analysis Plan
- I suggest you add something along the lines that you will present effect sizes and 95% confidence intervals for outcomes.

Sample size
- I can closely replicate the sample size calculation (not getting exactly same is not uncommon due to rounding and software using). As a personal preference I like to see the unadjusted sample size, the ICC and the inflation factor reported, then the adjusted sample size. Also, what does the (m) indicate next to the average cluster size, mean or median (assuming mean)? Slight confusion of loss to follow-up of HCW, surely if someone is lost to follow-up then they don’t work in the HC anymore and that’s the primary outcome? Minor point.

Discretionary Revisions
- Health Centre analysis of appropriate treatment initiation. This is going to be a proportion of total treatment initiation within each Health Centre, however, if you have access to the characteristics of each patient, perhaps this could be analysed at the patient level (this is just a suggestion)

**Level of interest:** An article whose findings are important to those with closely related research interests

**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