Reviewer's report

Title: The effectiveness of providing counselling and financial support to patients receiving treatment for multi-drug resistant TB: mixed method cohort and qualitative studies

Version: 1 Date: 13 April 2013

Reviewer: Christine Heidebrecht

Reviewer's report:

This is important and timely study. As rates of MDR-TB continue to rise, it is critical that interventions to improve treatment outcomes (such as those described in this paper) are explored alongside efforts to reduce transmission and combat further development of resistant bacterial strains. While the authors acknowledge that larger RCTs are required to verify their findings, this mixed-method study is a valuable initial investigation.

Major Compulsory Revisions:
1. Consider using “intervention study” rather than “cohort study”
2. The paper does not mention the impact that individual DOTS+ treatment centres may have had on treatment outcomes. It would be helpful for the authors to address this in the discussion section, and to include some characteristics of the centres in the results section.
3. The intervention component incorporates a cluster randomized design; did the sample size calculation account for this (i.e. account for the fact that within-cluster variation is going to differ from between-cluster variation)? If not, this should be identified as a limitation.
4. I’m unclear about the order in which recruitment of interview respondents and randomization of intervention sites occurred, given that all interview respondents were from the five centres that were allocated to the intervention arms. Please clarify this.
5. The authors state that age was the only variable that had a significant effect when the model was fitted; it would be helpful for the paper to include the other variables that were considered for inclusion in the model.
6. What were the inclusion criteria for interview respondents and participants in the intervention study? Did all individuals approached to participate in the intervention study consent? If not, please describe the number who refused, and address the possibility of selection bias.
7. The Discussion section should be expanded to include limitations of the study, generalizability of results (this will differ between the qualitative and quantitative components), and the impact of the lower than desired sample size in the intervention arms.
8. Please outline the types of questions that were asked in the formative and explanatory studies.

9. Please expand on the interview coding process, including whether coding reliability between researchers was assessed.

10. Were there seven DOTS+ centres in the Kathmandu Valley at the time of study initiation (i.e. did the study include all DOTS+ centres in the area)? If not, how were the sites chosen?

11. Who conducted the counseling in the two intervention arms – were they members of the research team or centre staff? Please describe the nature of the counseling (including duration). Was the frequency (“every 2-3 weeks”) consistent across sites?

12. Please expand on “dilution effects” (Methods section). Was there a concern that more time spent with patients in the control arm to collect additional characteristics would start to approximate/resemble counseling?

13. Table 3 presents adjusted ORs produced by logistic regression and Mantel-Haenszel tests, but the text does not describe why both tests were used. Please address.

Minor Essential Revisions:

14. “Extremely drug resistant TB” (first paragraph in Introduction section) should be “extensively drug resistant TB”

15. There is an individual listed under Roles of Authors who is not identified as an author (PM). Please address.

16. Tables 1 and 2: identify count (or N), and %

Discretionary Revisions:

17. Consider modifying the title of the article to reflect the outcome.

18. Table 3: consider using N instead of “count”

19. Table 3: consider using sub-headings rather than footnotes.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.