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: 16 August 2013

Reviewer: Petros Isaakidis

Reviewer’s report:

I have read this study with great interest: the authors address an extremely important and relevant topic, especially in LIC & MIC. MDR-TB patients go through unacceptable challenges both due to the disease and the current treatment regimens and any effort to alleviate their suffering and to control the epidemic should be encouraged and supported. The authors report on an interesting programme and they looked at different support interventions and their potential associations with treatment outcomes. Interestingly they have used mixed methods which make the study more interesting and "rich". However the quantitative part has some major weaknesses that the authors do not address in their report neither do they discuss the limitations of their study.

Even though the mixed methods design seems promising, I tend to propose to the authors to downsize the quantitative part and focus on the qualitative findings.

Major Compulsory Revisions

The authors should explain how the randomization of DOTS centers was done and whether the cluster randomization was accounted for the sample size calculations and the analyses. Design effect and intra-cluster coefficient (ICC) may be discussed.

The use of Mantel-Haenszel method seems an appropriate choice. However it is better used to calculate risk ratios rather than ORs in RCTs and cohort studies. Logistic regression is better reserved for case -control studies. The fact that the differences with ORs in this particular study are small doesn't change the fact that the authors may seek statistical advise (cluster data) and chose one measure of association rather than several. Then the chosen analysis method should be presented first in the Methods. For example, the M-H method is now only mentioned first time in the Table.

The authors haven't collected additional data from patients not receiving support and they justify it "to avoid dilution effects". Please elaborate.

How the readers will assess whether the 3 arms are comparable?

Similarly Table 2 is "crying" for the inclusion of the control group

The authors should explain how the increased numbers on the control
(no-support) arm partially compensates for not reaching the desired sample size in the intervention arms.

Again it is not clear how cluster randomization was accounted for

The Discussion does not discuss at all the existing evidence or the lack of it. This is is major issue; references are all used in the introduction, they are mostly from Nepal and authored by the study authors. No single citation was included in the discussion section.

The authors do not discuss the study limitations nor the strengths.

The suggestions to the NTP to incorporate support interventions therefore are therefore not supported neither by the study-produced evidence, nor any existing evidence. The only argument being "it will take time to run RCTs".

Minor Essential Revisions

The qualitative methodology (formative and explanatory part) should be elaborated more. The authors should describe the theory their approach was based on, the details of data collection, whether saturation was reached or not, how emerging themes were iterated.

Discretionary Revisions

**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