Author's response to reviews

Title: Barriers and enablers in the management of tuberculosis treatment in Addis Ababa, Ethiopia: A qualitative study.

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Author's response to reviews:

Dear editor,

We are very grateful for the helpful feedback on the manuscript "Barriers and enablers in the management of tuberculosis treatment in Addis Abeba, Ethiopia: A qualitative study." (Reference number 7086054501421678)

We hereby submit a revised manuscript where we have addressed the commentaries made by the three reviewers. The manuscript has been copy edited and a title page is included in the manuscript file. Table 2 is now divided into table 2 and table 3 and all tables are in the manuscript files. Our response to the comments and the changes we have made in the manuscript are listed below:

Reviewer one (Alison Grant).

Minor Essential Revisions:
1. We used pseudonyms but did not inform about this in the text. We agree that it is not necessary to use fictive names to present the cases and have thus removed all names.

Discretionary Revisions:
1. Study design: We have added clarifying sentences in the beginning of the methodology chapter (also based on comments from reviewer 3), and hope that the design of the study is spelled out with more clarity.

2. We have added sentences summarizing key points from the tables. Instead of adding it in the result section we have added it in the part of the methodology section that already contains some information on the different participants (participants and data collection).

3. We do not have an exact number of defaulters that we attempted to contact. Some patients who had disappeared from treatment had no address and no one knew where they were to be found. So even if they were identified as potential
participants, no one physically ever tried to locate them. Some patients we made an effort trying to find had given incorrect addresses or were no longer at the premises. Some patients had no address but were known to live within a certain area, and some where found and some where not. Other potential participants were dead by the time we managed to trace them. We have chosen not to elaborate on this in the manuscript.

4. ¿Daily labourer¿ is a person who is not hired somewhere on a permanent basis but who may meet at a regular point every day to compete with others to be hired for the day (e.g. construction work). We have explained this under ¿loss of income¿, one paragraph earlier in the text.

5. The term ¿poor healing conditions¿ is first of all related to what the patients themselves considered to be poor healing conditions. Poverty (lack of food) is considered to reduce the chance of being healed of tuberculosis, because tuberculosis is seen as a disease that to large extent is caused by poverty. Since most patients consider regular access to food (first of all protein rich food) as extremely important to healing, certain symptoms (as pain in the stomach due to hunger or gastritis) serve as reminders of what patients see as poor healing conditions. We have tried to make this clearer in the manuscript by reformulating the sentence and emphasising that the term ¿poor healing condition¿ indicates how it is seen from the patients¿ point of view.

6. ¿Incurable condition¿ is first of all synonymous with HIV/AIDS (from the community¿s perspective). Some of the respondents also mentioned that patients could have an incurable type of TB due to reasons that are not elaborated in this manuscript. We have tried to make this point clearer by reformulating the sentence and adding the explicit meaning in a parenthesis.

7. We have followed the advice of the reviewer on how to organize the discussion. We start the discussion part by describing ¿what does this study add to previous knowledge?¿ followed by the paragraphs on validity and generalizability.

8. The manuscript has now been examined by an authorized proof reader.

Reviewer two (Jean Macq).

Discretionary revisions:
The review did not list specific points to be revised, but had some general comments under the heading ¿general¿. Below we comment on some of these issues.

We believe that the value of our paper is that it demonstrates how variables may interplay at time-specific points in treatment. The study also demonstrates how certain identifiable course of events or support structures may be enablers or barriers in relation to management of treatment. We argue that to understand patients¿ temporal perception of costs and benefits, we must accommodate costs that have accrued in the past. By exploring and mapping different
time-specific scenarios, we may prevent treatment interruption due to a broader understanding of patients' total but also continuously changing situation.

We agree that health personnel often seem to be aware of many of the aspects we investigate, but that these factors might not necessarily be accepted by TB program managers. We have not discussed this in general, but mention that TB program managers may be more reluctant to accept the findings because we do not use the TB control program's strict definition of a defaulter (under validity and transferability).

Reviewer three (Sally Theobald).

Minor Essential Revisions:

1. We have checked the manuscript and ensured all statements are referenced, e.g. the first sentence.

2. We have added information about the methodological basis of the studies outlined in the introduction. On the basis of this information we argue that there is a need for a qualitative study to explore barriers and enablers related to treatment adherence in Ethiopia. The basis of this justification is that several quantitative studies already have been performed in Ethiopia, establishing the fact that non-adherence to TB treatment is a problem. These studies suggest different single variables as causes to non-adherence. The weakness of these studies is that the variables pointed to have not been explored within a broad contextual frame. They have not been assessed in relation to how different variables may interact and how the impact of these variables may change over time (accrued costs) or due to unpredictable changes in someone's situation.

3. At the beginning of the methods section we have added sentences that argue why we used in-depth interviews and focus groups in particular: We found that in-depth interviews conducted during different stages of treatment to be the most appropriate method for exploring how context-specific enablers and barriers interact over time. Focus group discussions were conducted for further exploration and validation of the information from the in-depth interviews.

4. We have added two sentences in the methodology section to justify why we chose the research sites we did: The research sites were chosen based on discussions and advices from local researchers at Armauer Hansen's Research Institute (AHRI) as well as from WHO's TB/Leprosy advisor at the Ministry of Health in Ethiopia. The three sites were considered to be typical DOT clinics, but they were also chosen because they represented diversity in the sense that they were located in three different areas of town.

5. We have added a few sentences in the discussion part (validity and transferability) on the implications of our research participants not fulfilling the formal criteria of a defaulter. We believe that the implications of not strictly following the definition of a defaulter are few. One implication may be that TB program managers will be more reluctant to accept the findings from this study.
Another implication may be increasing awareness of the many patients that may default from treatment due to poverty related barriers early in treatment (< 4 weeks), but that are not registered as defaulters.

6. We have addressed issues related to validity in the discussion part (validity and transferability) and have decided to describe in further detail (in this section) how the different mechanisms deployed in the study increase the trustworthiness of the research project as a whole. We argue that the study is strengthened by the fact that different groups of participants are interviewed (TB patients on treatment, TB patients that had interrupted treatment, patients on re-treatment, relatives, health personnel), the same subject are studied from a prospective as well as a retrospective view (time triangulation), and different methods are deployed (retrospective and prospective in-depth interviews and focus groups). Trough method and data triangulation we are convinced that the findings are internally valid. The analysis has been thorough and systematically performed. As already mentioned, the first author and the research assistant thoroughly discussed and clarified the content of each tape recorded interview. Clarifying notes were added and main themes and issues to be explored in subsequent interviews or focus groups were systematically written down. We have added a few points in the paragraph analysis: A memo (notes on each participant, including main contents of the interview) was made enabling the second and third author to read about each of the participants that were interviewed and quoted in the manuscript.

Generalized descriptions of findings were summarized in an analysis document that all authors commented on.

7. The quotes are now put in italics.

8. We appreciate the suggestion to make a diagram demonstrating the interplay of factors. We find it hard though, to truly demonstrate the complexity and dynamics in a diagram. We found it particularly difficult to integrate the issues related to time and to give a complete illustration of the time-specific scenarios. We have decided not to include such a diagram.

9. The four points under crisis precipitated due to completion of the intensive phase (result section) is based on a synthesis of the various sources of data. We have now made this explicit in the text.

10. We have made some changes in the section implications of practise, trying to strengthen some of the main points in this heading. We argue that TB programs should address nutrition, and that providing incentives as one glass of milk or a small meal could have a positive influence on both case detection rates and treatment completion. We also elaborate on issues related to decentralization of DOT/community based DOT, adding more international references, including a recent review of randomized controlled trials, comparing DOT with self-administration of therapy. This review provides no evidence that the routine use of DOT in low- and middle income countries improves cure or treatment completion in people with tuberculosis, and strengthens the arguments of those advocating for decentralization of DOT to family or community members.
11. We have phoned a representative of the Federal Ministry of Health in Ethiopia, (working with TB related issues) regarding potential changes in how DOT is administered in Ethiopia today. They confirmed what we held to be our knowledge: There have been no major changes in the way the services are organized, as for example regarding length of treatment or the type/level of decentralization of the services. However, there has been established a formal collaboration between health programs focusing on patients with TB and health programs focusing on patients with HIV/AIDS. This is mentioned in the discussion part under implications for practice.

12. The whole article has been proof read.

Discretionary revisions:

1. We appreciate the suggestion made on restructuring the result section by moving interplay of factors to the beginning of the result section as case stories in boxes. We do believe though that these case stories are strong pedagogical tools in demonstrating how different variables are interrelated, and how single variables alone seldom serve as causes for interruption of treatment. In addition, the case stories draw attention to some of the typical time related scenarios, which is an emphasised perspective in this manuscript. By moving the case stories into boxes they will be less focused upon, and maybe not even read by all readers. We have therefore chosen to leave the structure as it is.

2. We have added attitudes of health staff in the heading previously called rigid routines.

END