Author’s response to reviews

Title: Gridlock from Diagnosis to Treatment of Multidrug-Resistant Tuberculosis in Tanzania: Low Accessibility of Molecular Diagnostic Services and Lack of Healthcare Worker Empowerment in 28 Districts of 5 high burden TB Regions with Mixed Methods Evaluation

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Author’s response to reviews:

We would like to thank the editor and reviewers for highly relevant and useful comments and suggestions for improving this report. We appreciate the reviewers for seeing this as an interesting and important report. Below, you will find a point-by-point description of how each comment has been addressed in the proposal. Original reviewer’s comments are in bold face, responses in regular typeface.

Editor Comments:

Please respond to each of the reviewer's comments (detailed at the end of this email) in turn with a particular focus on the following:

1. Methods: Clearly describe on mixed method design and qualitative data analysis

2. Results: to re-structure presentation of results according to aim of the study and quantitative results followed by explanation of qualitative results.
We appreciate the summary guidance from the Editor and have more clearly described the mixed methods design and qualitative data analysis (see page 2/line 56-69 and Figure 1) as we as reordering the Results section (see new Figures 5) and response to individual reviewers.

Reviewer reports:

Carl Abelardo Antonio (Reviewer 1): The paper’s results overall are interesting. However, I would like to request for further information on the methodology, and a clarification on the presentation of results.

1. METHODOLOGY: Authors used a mixed methods design, which is appropriate for the evaluation thus undertaken. However, the methods or procedures used for the quantitative and qualitative component were not equally described with sufficient detail to allow for assessment of the appropriateness of the results. In fact, the paper has a more extensive discussion of the quantitative component of the study, to the neglect of the qualitative part. Specific suggestions:

1.1. Study design: Describe the quantitative and qualitative components of the study separately instead of indicating that a "mixed cross-sectional and retrospective cohort design" was utilized as this tends to confuse and confound the reader.

We appreciate the interest and recognition of the importance of our mixed approach to test the hypothesis. We have now rearranged the Methods paragraph to flow more logically and acknowledge both the quantitative and qualitative aspects (line 110 – 116) as follows, “For the retrospective cohort design, TB patients registered as retreatment cases and PLWH that attended those randomly selected districts in the previous year, 2015, were audited. While for the cross-sectional component the selected participants were the district coordinators for TB and leprosy (DTLCS) responsible for the district TB clinics or district AIDS coordinators (DACs) responsible for district HIV clinics, and the laboratory managers or designated head of the laboratories performing molecular diagnostics for MDR-TB diagnosis was interviewed. A qualitative component was used to collect information describing the reasons for the observed findings.”

1.2. Data analysis: It seems that authors used a concurrent mixed methods design, and proceeded to embed the qualitative results within the quantitative data (i.e., used the interview data to explain the findings from the analysis of the TB cohort data). The entire section on data analysis should be reformulated to reflect (a) data analysis for quantitative data (this is already present in the paper), (b) data analysis for interview data (currently lacking in the paper, see below for further comments), and (c) the method for integration of these two.

We appreciate for an observation and comments for (a). We have added the contents (line 149-153) as follows as responses for (b) “For the qualitative part, data analysis was undertaken by S.G.M. The author read interview texts and familiarized with the content. Using an open code,
the author independently identified key issues and the theme from each of the health care workers. Issues were transcribed in excel spreadsheet version 2014 and transferred into SPSS version 20. Results were summarized by number and proportions.”

(c) We have integrated the findings of all sections in a figure 4 (added to integrate the observed findings). Describing the observed bottlenecks and potential determinant factors.

1.3. Qualitative data analysis: Authors to please describe how the interview data were transformed into the results presented in Table 1. Authors to also reconsider reduction of qualitative data to frequencies, as this is an inappropriate method.

Thank you for comments. This is now articulated in the final paragraph of the Methods (as per response to review Section 1.2 as well).

2. RESULTS: I would surmise that the research yielded a rich trove of data, something which is not shown in the paper in its current formulation. An examination of Table 1 shows that a lot of factors affect the delivery of an effective intervention in the selected communities. I would like to offer the following recommendations in the presentation of results:

2.1. Authors to first present the results of the quantitative analysis. Analysis of qualitative data can then be used to explain the phenomenon observed (i.e., are the identified bottlenecks consistent with what the numerical data from teh TB registers show?)

We appreciate for the comments and we have re arranged the Results to fit this recommendation. Now the quantitative analysis starts is followed by the qualitative section, which also now mirrors the presentation of Methods.

2.2. It might also be helpful if the bottlenecks can be converted into a diagrammatic representation of where these occur from the time a patient comes in for the initial consultation all the way to completion of treatment.

Thank you very much for the comment. We have created a diagrammatic representation of the bottlenecks as suggested. The diagram is labeled as Figure 4.

Halima Dawood, MBBCh, MSc (Reviewer 2): This study sought to identify healthcare worker related barriers to implementation of diagnosis of drug resistant tuberculosis. They found under utilization of molecular diagnostics in high risk individuals for the diagnosis of drug resistant TB.

Abstract: The conclusion is a recommendation rather than a finding of the study. The summary in the text better summarizes the findings of the study
Thank you for the comment; we have changed the statement (conclusion section of the abstract) which initially read “Innovative workforce interventions are required before the full potential of molecular diagnostics can be realized.” and now it reads “Underutilization of molecular diagnostics in high-risk groups was a function of front-line healthcare workforce training and lack of equipment access which likely contributed to the observed delay in MDR-TB diagnosis in Tanzania.” The current statement now summarizes the findings.

Method: this mixed method (qualitative and quantitative) study use cross-sectional and retrospective design. It is unclear what random sampling was used for? The study appears to have many components, however, it is difficult to clearly understand the methods as written.

It is unclear why health care worker consent was waived and how patient confidentiality was maintained.

We agree that we combined the cross-sectional and retrospective cohort design. The random sampling was used for selecting 4 districts out of several districts in purposefully selected high burden regions. For example Dar es Salaam – Ilala has 11 districts and 4 districts were selected randomly. We have added a figure to summarize the study design and simplify the description of what was done.

Health care workers consenting were waived because they fulfill the official task of managing patients and participation in this study had no alternative options for the benefit of population they serve.

Results:

The study found that only 39% of districts had laboratory capacity for MDR-Tb diagnostics, with insufficient staff training and functional machines.

In addition healthcare worker knowledge of clinical application and interpretation of the results was not optimal. Opportunities for diagnosis and treatment of MDR-TB were missed. Suggest restructure results to align with each of the study aims so it will be easier to follow.

We appreciate for the observation and we have restructured the Results as also requested by the other Reviewer. The flow of Results now starts with findings from the retrospective cohorts,
follows with the laboratory findings then concludes with the interview of health care workers (line 160-222).

Discussion: Suggest a revision of the structure of the discussion to include possible reasons for study findings, unanswered questions and future recommendations.

We have added a diagram to illuminate the bottlenecks that deserve further interventional study (see new Figure 4). In the Discussion section we have also provided more clear recommendations for how researchers and policymakers should act on these findings (line 230, 254, 265 through 282 and Figure 4).