Reviewer’s report

Title: Performance and Impact of GeneXpert MTB/RIF® and Loopamp MTBC Detection Kit® Assays on Tuberculosis Case Detection in Madagascar

Version: 0 Date: 25 Apr 2019

Reviewer: Paul Drain

Reviewer’s report:

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Review for BMC ID

Manuscript Number: INFD-D-19-00692

Full Title: Performance and Impact of GeneXpert MTB/RIF® and Loopamp MTBC Detection Kit® Assays on Tuberculosis Case Detection in Madagascar

In this study, the research team evaluated Xpert and LoopAmp testing for tuberculosis among 548 adults with presumed pulmonary TB in Madagascar. They used the results of diagnostic accuracy to determine how implementation of the tests may improve diagnostic algorithms. They reported that the novel sputum based assays provided the most benefit when used as an add-on test for sputum-smear negative testing. In these scenarios, the added value was for additional case detection.

The authors are presented some potential impact data on the introduction of the two sputum tests. However, simply projecting the number of cases from one study to a national level is not accurate. There would need to be more description of the placement of these machines, function of each machine, training of health care workers, etc. In addition, this type of analysis would benefit from a formal cost analysis and cost-effectiveness analyses. For these reasons, I would favor removing the precise number of additional cases diagnosed per year on a national level in both the abstract and the manuscript. The point is already made by indicating that these tests can increase case detection by 24% and 22%. To generate these numbers, the investigators should do a proper analysis with sensitivity estimates, and ideally a cost-effectiveness component.

Study strengths include performed 2 sputum cultures. Please add this to the discussion.
Need to add if HIV testing was performed on participants, and if so the percent positive. And, if not, why it was not performed as this would be an additional study limitation, even if overall country prevalence is low.

The analyses would benefit from presenting the positive and negative likelihood ratios for each algorithm.

Should remove sentence in Discussion on "making such approach cost-effective". As stated, this requires more formal analyses.

Should add a Table 1 that describes the sociodemographic and clinical characteristics of the cohort.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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