Title: Implementation of the Xpert MTB/RIF assay for tuberculosis in Mongolia: a qualitative exploration of barriers and enablers

Summary: Rapid and improved detection of all types of tuberculosis (TB) are global priorities. WHO approved Xpert MTB/RIF assay from Cepheid, Inc. is a molecular-based rapid test with potential to revolutionize TB diagnosis. GeneXpert implementation required consistent laboratory support with costly logistical interventions. In this interview based study, authors conducted semi-structured interviews with laboratory staff (N=8) and TB physicians (N=16) using an inductive-deductive approach to explore the specific challenges in implementation of the Xpert MTB/RIF test within Mongolia's National Tuberculosis Program. Key barriers to Xpert MTB/RIF implementation identified were: lack of awareness of program guidelines; inadequate staffing arrangements; problems with cartridge supply management; lack of local repair options for the Xpert machines; lack of regular formal training; paper based system; delayed treatment initiation due to consensus meeting and poor sample quality. Enablers to Xpert MTB/RIF implementation included availability of guidelines in the local language; provision of extra laboratory staff, shift working arrangements and additional modules; capacity for troubleshooting internally; access to experts; opportunities for peer learning; common understanding of diagnostic algorithms and decentralised testing. This study data will be useful to facilitate implementation of GeneXpert MTB/RIF assay in other countries.

Recommendation: Accept with minor revisions as described below

Abstract: The abstract has accurately summarized the contents of the manuscript.

Introduction: introduction is well written and very apt to the topic. I would recommend adding Incidence and prevalence rate of MDR-TB and HIV-TB in Mangolia in the second paragraph.

Methods: All the interview questions were relevant. The authors should have asked few more questions on sample collection, distance and travel time for specimens, waste disposal system for cartridges etc.

Results: 1. According to the Mongolian NTP guidelines 2014 the following specimens can be used for Xpert MTB/RIF testing: sputum, urine, stool, pleural fluid, ascites, gastric lavage, and surgical tissue samples. Have Mangolian NTP guidelines mentioned the proper protocols (as recommended by WHO guidelines) for other extra-pulmonary specimens especially urine, stool and gastric lavage? Did authors include extra-pulmonary specimens in total number of specimens tested (table 1 data)?

2. Poor sample quality - line 273, "'Error results' from Xpert MTB/RIF testing (i.e., notification of an error is displayed in the Check Status screen of the GeneXpert machine) were reported to occur occasionally." Authors need to provide detailed analysis i.e. percentage for error results accompanied with their specific error codes.

3. Poor sample quality - line 276, "The quality of the sample (e.g. when patients did not collect sputum correctly) was reported as the most common reason for error" results experienced by participants when using Xpert MTB/RIF testing". Here I would expect more information like how specimens were collected? Did proper instructions were given to patients? Please comment on distance, transport conditions (especially temperature) and travel time for transportation of these specimens.

4. The leading cause of error results observed in the present study was due to poor sample quality and improper equipment maintenance. Both these can be easy to fix with proper precautions. As per my understanding, an 'error' result indicates that the Xpert MTB/RIF assay in a given test was aborted by internal quality control mechanisms including improper filling of the cartridge reaction tube, cartridge reagent probe integrity failure, cartridge internal pressure excess, or equipment malfunction. All 'error' results are accompanied by specific error codes that provide additional information as to the underlying cause of failure. Therefore, it is very important to find out whether the technical staff had enough knowledge & training to differentiate between these different error codes? Improper filling of the cartridge reaction tubes or internal pressure excess could be due to the very viscous sample quality, presence of food particles or air

bubbles etc; and it can be avoided during sample processing step by proper liquefaction of the viscous sample with increased the incubation time, avoiding addition of food particles or air bubbles into the sample chamber. If there is an issue in sample quantity (less quantity) or quality (poor quality) one can expect false negative result rather than error. So authors need to reexamine technical staff with this regards.

Discussion: In this section, authors have properly discussed a range of potential factors that served as a barrier or enabler to the implementation of Xpert MTB/RIF testing and steps needed to improve the integration of GeneXpert MTB/RIF assay within the Mongolian NTP.

Conclusion: the authors accurately summarized the contents of the interview as well as specific lesson learned, in the conclusion.

References: I would recommend including the Mongolian NTP issued 2014 guidelines in the references.