Reviewer's report

**Title:** A Randomized Controlled Trial of Standard versus Intensified Tuberculosis Diagnostics on Treatment Decisions by Physicians in Northern Tanzania

**Version:** 3 **Date:** 12 November 2013

**Reviewer:** Violet N Chihota

**Reviewer's report:**

The authors set out to determine the impact of providing intensified diagnostic strategy (concentrated smear and culture) vs traditional method (smear only) on patient outcomes. The were therefore two arms (intensified diagnostic arm and standard of care arm) to which patients would be individually assigned. The randomised trial was powered at 80% and they need to enrol 120 participants (at least 60 per arm). However due to end of project funding the anticipated sample size was not achieved. In total 70 participants were enrolled, 37 in the standard arm and 33 in the standard arm.

**Major comments**

1. The study was therefore under powered to measure the primary endpoint of appropriate treatment.

2. It seems plausible to me that the authors have a very important finding of early high mortality among TB suspects regardless of HIV status. They also refer to high mortality in the conclusions section in the abstract, the results and conclusions. It appears that death occurred 7.8-26 days after enrolment to the study and would most likely have been the time people were being investigated for TB. To this end the study highlights an issue that is key to the TB programme. This to me is more interesting and can be stratified by arm without requiring the same sample size as was required for the impact evaluation. The title of the paper would also need to change in this case.

**Minor comments**

1. In the methods the authors mention that parent provided informed consent for participants <18 years of age. Because these are minors parents give assent for the minors to take part in the study.

2. Under inclusion criteria - Adults are defined as anyone 6 years and above for the purposes of the analysis. What is the justification of using this cutoff?

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being
published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests