Reviewer's report

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

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Reviewer: Violet N Chihota

Reviewer's report:

The authors set to investigate if use of culture had an impact on patient outcomes/management of TB in Tanzania a resource limited setting. They conducted a randomised trial in Northern Tanzania. They found that

Major comments:

The authors mention that they enrolled adults defined as equal or more than 6 years of age. Is this correct? I would imagine that getting consent for some of these (less than 18) and the those defined herein as children (less than 6 years) would not be possible but rather get consent from parents/guardians? How was consenting done for children? This raised major ethical concerns.

Minor Comments

In abstract under results the authors mention that at eight weeks 100% of participants in follow up period were receiving appropriate care. This sentence needs to be rephrased to make clear the denominators. Also they should avoid just putting a percentage without clearly showing the numbers and denominators.

Introduction

Need to include data on TB prevalence/incidence in Tanzania to ensure the extent of the problem is well defined.

Methods

Need to make clear in methods what study design was used and perhaps make clear that this was individually randomised and not cluster randomised.

The authors mention that one sputum was taken at enrolment and subsequent specimens the following two mornings. How many subsequent specimens were taken?

Why was TST done?

Participants were referred for treatment to two different centres. Was the management the same at these two referral centres? This needs to be made clear otherwise it will be difficult to generalise the findings on outcomes.

Under laboratory procedures, unless authors make clear that further to assessing unconcentrated sputum in the intensified diagnostic group, concentrated sputum
was assessed and that culture was performed, the distinction between the two groups will not be very clear in this section.

Results

In the methods section, the authors mention that the study was implemented in both hospitalised and outpatients. However, it is not clear from the results what proportion were hospitalised vs outpatients. It may be very difficult to generalise the results from hospitalised patients as they are more likely to be sicker. Is suppose this is why there was high early mortality.

If more than one specimen was collected, surely the results will be different across the specimens in some cases. How were discrepant results handled. What TB case definitions were used? This is not very clear.

The authors mention that 358/3249 patients met the criteria for TB? Do they mean were TB suspects? In the inclusion criteria it is clear that they were targeting TB suspects for enrolment. There was a lot of screening failures for the study and wonder why this many participants were screened ie 3249. Seems some definitions should be included in the methods to make clear who met the criteria to be included in study.

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

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests.