Author’s response to reviews

Title: Tuberculosis recurrence in cured smear-positive tuberculosis patients in southern Ethiopia: retrospective cohort study

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Author’s response to reviews: see over
The reviewer’s comment: Major Compulsory Revision

1. Major drawback in this study is the choice of the cohort to study the recurrence rate and mortality rate for TB patients. The cohort of cured and treatment completed TB patients is not the ideal one either for recurrence rate or for mortality rate. The ideal cohort for recurrence is smear positive cured patients. But this study has included in the cohort smear positive completed, smear negative completed and EPTB completed to study the recurrence rate where the recurrence status cannot be certain. This cohort will not give the true recurrence rate among the cured smear positive cases. Therefore I suggest that recurrence rate should be restricted to smear positive cured patients only.

I respond to the reviewer’s comment as follows:

We have removed treatment completed smear-positive, smear-negative and EPTB cases and restricted our report of recurrence to cured smear-positive TB cases only.

The revised part of the findings section of abstract on page 2 paragraph 3 now reads:

368 cured smear-positive TB patients which were followed for 1463 person-years. Of these, 187 patients (50.8 %) were men, 277 patients (75.5 %) were married, 157 (44.2 %) were illiterate, and 152 patients (41.3 %) were farmers. 15 of 368 smear-positive patients had recurrence. The rate of recurrence was 1 per 100 PYO (0.01 per annum). Relapse was not associated with age, sex, occupation, marital status and level of education.

The revised part of the results section on page 7 paragraph 1 now reads: 397 smear-positive TB patients were registered. Valid data was obtained for 368 (92.7 %) cases.
Complete information was not obtained for 29 (7.3 %) of which 8 (2.0%) have moved to other districts. However, no difference was observed by age, sex, and TB category was found compared to the patients we enrolled.

Of the 368 smear-positive TB patients which were followed. 187 patients (50.8 %) were men, 277 patients (75.5 %) were married, 157 (44.2 %) were illiterate, and 152 patients (41.3 %) were farmers (Table 1). 368 cured smear-positive TB patients were followed for 1463 person-years. 15 of 368 smear-positive patients had recurrence. The rate of recurrence was 1 per 100 PYO (0.01 per annum). Relapse was not associated with age, sex, occupation, marital status and level of education.

**The reviewer’s comment: Major Compulsory Revision**

2. The ideal cohort for mortality rate is all the cases registered in the programme. Mortality are more among defaulters and failures. Exclusion of these cases from the cohort will result in underestimation of mortality rate among TB patients. Moreover, cured and completed cases have the least mortality among the treatment outcomes. Therefore reporting a low mortality rate from such a cohort will not be of any help to the programme because most of the deaths occur among defaulters and failures. Since the study cohort is not the ideal cohort to report TB mortality I suggest that the mortality component may be removed from the study objective.

**I respond to the reviewer’s comment as follows:**
We have removed the mortality component from the manuscript.

**The reviewer’s comment: Major Compulsory Revision**

3. Since there were nine annual cohorts within the total cohort, different annual cohorts were followed up for different periods. The percentage of cases either recurred or died among the total cases cannot be reported as the outcome. The authors have concluded that 11% of cases either died or recurred. This statement has no meaning without the period of follow up. What is the period of follow up in this study? The only way to report the recurrence rate in this cohort study is by person time rate because different cases are followed up for different periods. That is, the number of cases recurred per sum of person years of follow up I suggest wherever mere percentages are used for recurrence rate in the manuscript have to be reported as person time rate only.

**I respond to the reviewer’s comment as follows:**

We have changed the values expressed in percent and expressed it per person time of observation. *The revised part of the results section on page 2 paragraph 3 line 3 now reads: 368 cured smear-positive TB patients were followed for 1463 person-years. 15 of 368 smear-positive patients had recurrence. The rate of recurrence was 1 per 100 PYO (0.01 per annum).*