Reviewer's report

**Title:** Efficacy and safety of thrice weekly DOTS in tuberculosis patients with and without HIV co-infection: an observational study

**Version:** 2 **Date:** 27 May 2013

**Reviewer:** Onn Min Kon

**Reviewer's report:**

This is a well written study and they indicate that the treatment failure was identical to that of HIV negative cases. They also infer that the rates of treatment failure are identical to that of historic daily therapy in the HIV positive group. However as stated by the authors there are several reasons for not being able to interpret this data completely. The major weakness of the study is the lack of a control arm of HIV infected cases having daily therapy and having just the comparator of HIV negative subjects as it then does not allow for a fair comparison of an appropriate 'control' arm.

The cohort characteristics are significantly different at baseline and with disparate disease presentations and severity. In addition the drop-out rates are significantly higher in the HIV group. These factors may therefore introduce bias into the studied co-infected group. It would be important to know what the causes of drop-outs were and for instance were these due either to adverse effects or death as an early detrimental effect of the thrice weekly approach?

Despite the similar relapse rates, in the completed study arm there were more treatment extensions in the co-infected arm and hence again we cannot be certain of the effect of this on their study cohort. In addition 'seriously unwell' cases are exclusion factors.

The authors also accept that lack of DST make complete interpretation of the data difficult and by definition as the cases with HIV had less mycobacterial load, it is difficult to interpret sputum and culture conversion rates as being representative of a real comparison.

Finally the definition of treatment success and failure are in themselves difficult to interpret as these incorporate extrapulmonary disease and despite the subset analysis of only the smear positive pulmonary disease - the inability to directly compare the 'success' microbiologically makes interpretation suboptimal.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

I declare that I have no competing interests