Author's response to reviews

Title: Antibiotic prophylaxis for caesarean section at a Ugandan Hospital: a randomised clinical trial evaluating the effect of administration time on the incidence of post-operative infections

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Response to comments by Reviewer Dr Hassan Ba'aqeel

Title: Antibiotic prophylaxis for caesarean section at a Ugandan hospital: a randomised clinical trial evaluating the effect of administration time on the incidence of postoperative infections

Dear Dr Hassan,

Thank you for your continued critical appraisal of our work. It appears we may have misunderstood some of your comments. Hopefully we have addressed them here on.

1. We now understand in hindsight your opinion that even for a setting such as ours, we could have conducted a double blinded study. We shall state this as a serious limitation in our discussion and have done so on page 12, lines 9 -10.

2. For the randomization blocks: we had 4 blocks with 116 each. Each number had either an A or B next to them for allocation to either group (e.g. 431A, 1788B, 9762A, 2012B etc that is what we meant by lettered numbers). Numbers were kept in 4 sealed envelopes and a simple sampling used when picking numbers from envelopes. A patient picked a number say for example 222A which allocated to a specific intervention, another picked say 7787B which allocated them to the other intervention. At generation of the numbers by the computer, we manually added A (pre-incision) and B (post-incision) to equal halves. Therefore each block had half of A and half of B so that at the end of randomising that block, the interventions were evenly distributed. We used such large blocks because we have a high volume unit. In addition we were honestly not aware of the traditional blocking rule. We were however, able to avoid the pitfalls you have warned about. We have edited on manuscript on page 6, line 17 – 20.

3. Regarding Fever morbidity, it was assessed during the 3 days of admission post-operatively and then on the 10th day because this is when mothers return for their first postnatal visit. As with the other postoperative infections on all the observation days as stated in page 7, line 3 -9.

4. About neonatal outcomes we have corrected in the results and Table 3 as noted.

5. We apologise for the discrepancy with the Pan African Trial Registry. We did not update the final protocol as we had other errors too. This has been submitted for corrections. Thank you for pointing this out.

6. We also noticed a few days later that we submitted the when we had not corrected result reporting. We apologise for that. We did correct according to CONSORT as you had correctly pointed this out. Please find attached the correct file with the risk ratio. Table 3 and manuscript revised appropriately.

Addendum:

We are a nascent obstetric outcomes group in Uganda which even as a resource limited setting can be a challenging place to conduct some studies in. We have tried to keep things simple and honest so that we at least produce valid results. In this study we erred on the side of caution calling it a single blinded study. The assessor and the patient were totally blinded.
We have gone back and forth on whether this was single blinded or double blinded. Additionally, we recognise that as a world authority in this subject, you are best placed to advice on this.