Reviewer's report

Title: Single dose of gentamicin in combination with metronidazole versus multiple doses for prevention of post-caesarean infection at Bugando Medical Centre in Mwanza, Tanzania: A Randomized, equivalence, controlled trial

Version: 2 Date: 18 February 2013

Reviewer: Alexander M Aiken

Reviewer's report:

I congratulate the authors on conducting a well-executed equivalence trial in an important and little-studied field. The manuscript covered many of the issues that have previously been poorly conducted in other studies in this field and the study gives an important addition to scientific knowledge.

I have only the following minor and discretionary revisions:

Minor:

- I suggest the authors read some additional papers - I'm afraid two of these are papers that I have written - Allegranzi B et al Lancet 2011; Aiken AM et al, Internation J Surg, 2012 and Aiken AM et al, J Hosp Infection 2013. The first two papers are systematic reviews that summarise previous work in this area in sub-Saharan Africa, and the third looks at epidemiological methods for SSI surveillance in some comparable work done in Kenya. These are all be freely available on the web, but please contact me on alexander.aiken@lshtm.ac.uk if any difficulties getting hold of these. It is up to the authors whether or not they feel it worthwhile to reference these papers.

- In the sample size calculation, the authors should indicate what rate of SSI they were expecting to see, though this may be in the reference which I haven't examined. It appears that their sample size was probably too small as the spread of the effect estimate was quite broad and crossed over their pre-defined limits - they should also discuss what sample size might have been more suitable later on - I would guess about 1500-2000 patients in total might have been ideal?

- the practicalities of telephone-based follow up are not covered in enough details: for example, were all patients able to provide a phone number or were some people excluded because they didn't have this ? Were any evaluations done to see if information over the phone was accurate - how reliable did the authors feel that phone calls were ?

- The authors actually conducted this trial as a single-blinded trial as the outcome assessors did not know the intervention status of the patients (double blind =both patients and assessors unaware). If it is possible to fit "single-blind" into the title and abstract, that would help make the reader aware of this additional strength of the study earlier on.
- there is no mention of adverse effects with gentamicin. There is known to be a (theoretical) risk of interactions between gentamicin and long acting neuromuscular junction blockers often used as part of surgical anaesthesia in this region - for this reason, some centres do not use gentamicin pre-operatively. Was this considered when gentamicin was selected for use in the trial? Did any patients experience post-operative respiratory depression? What anaesthetic agents were typically used for these patients?

Discretionary revisions:

I don’t think the section in the introduction on the microbiology of wound infections is particularly helpful, as no further microbiology is reported as part of this study.

There are a few parts of the text where the authors could make the language a bit more typically scientific - for example, it sounds slightly odd to say that "prophylactic antibiotics ... tremendously reduce post-caesarean infection" : perhaps "substantially" ? In the paragraph on sample size, it would be better to say "Briefly, we used...." rather than "We briefly used..." - the sense is quite different. When describing Mwanza Hospital, you could start by saying "In 2010, there were...." rather than having the year at the end of the sentence.

**Level of interest:** An article of outstanding merit and interest in its field

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

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

**Declaration of competing interests:**

I have a non-financial competing interest: I have recommended that the authors read three additional papers, two of which I have been first author on. The authors are in no way obliged to reference any of these papers.