Author's response to reviews

Title: Pre-referral rectal artesunate in severe malaria: a fundamentally flawed trial

Authors:

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Author's response to reviews:

Dear Editors-in-Chief of Trials:

We are submitting the second revised version of the paper "Pre-referral rectal artesunate in severe malaria: a fundamentally flawed trial" by Karim F Hirji and Zulfiqarali G Premji for continued consideration for publication in your journal.

We extend our sincere thanks to the two reviewers for their helpful comments on the previous version of our paper. We particularly appreciate the effort taken by Dr. Janet Wittes to provide us detailed stylistic and linguistic corrections and suggestions.

In the second revised version, we have implemented 7 of the 8 major suggestions given by Dr. Wittes, and 3 of the 4 minor essential revisions and both of the discretionary suggestions of Dr. Cook. The details are given in our point-by-point response to the reviewers. The corresponding changes in the manuscript are marked in red.

This version draws attention to a new paper on the cost-effectiveness of pre-referral rectal artesunate (reference no. 10). Also, the last sentence of the paper is better explained with two added references (references 81 and 82). These changes are marked in blue. No other changes of substance have been made.

The stylistic/linguistic changes suggested by Dr. Wittes, and other similar minor changes independently made by us are not marked.

We thank you, your editorial team, Dr. Cook and Dr. Wittes for continued kind assistance,

Sincerely,

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Authors' Responses to Review Reports

Response to Reviewer I
Reviewer: Jonathan Alistair Cook

Minor Essential revisions:
1. The one and only reason given by Gomes et al. for excluding cases from data analysis is the FDA filing. This is what they state in the first paragraph of the Statistical Methods section; there is no speculation on our part involved here. Therefore we have not made any changes to the statements in question.
2. The sentence has been modified along suggested lines.
3. The sentence in question has been rephrased.
4. The sentence in question has been rephrased.

Discretionary Revisions:
1. We have modified the text to reflect the concern expressed. We did not feel that any additional data analysis was needed.
2. Implemented as suggested.

Response to Reviewer II
Reviewer: Janet Wittes

1. Changed as suggested.
2. Sentence softened as suggested.
3. Medium term defined.
4. Age: The terms "assessed age" and "apparent age" are never defined. Assessed by whom? The "overall mean age" for children in the artesunate group is given but that is not done for the placebo group. Why not? Why are the age distributions by group for children not given?

When our students do research in rural areas, the age of the child or date of birth is always requested. Most parents can recall the month and year of birth of a young child accurately, even in Africa.

We have rewritten the relevant sentences to clarify our points.
5. Changed as suggested.
6. Sentence deleted as suggested.
7. Sentence deleted as suggested.
8. Digits of precision reduced as suggested.