Author's response to reviews

Title: No Short-Cut in Assessing Trial Quality: A Case Study.

Authors:

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Version: 3 Date: 14 May 2008

Author's response to reviews: see over
Cover Letter to the Editors

Dear Editors of Trials:

My paper has been further revised in accordance with the helpful comments and suggestions from Referee 2, Referee 3 and the Editorial Board. A point by point explanation of how their suggestions were implemented in the present version is given below.

Response to Referee 2: Dr. David Moher

1. "Adequate concealment of randomized allocation” changed to ”Adequate allocation concealment.” Similar examples, where detected, were also changed.

2. A citation for not using scores as weights in meta-analysis (Greenland 1994) has been added.

3. The conclusions of the paper has been edited in many parts. The issue of the amount of time required to perform a comprehensive review is discussed explicitly, and specific suggestions for systematic reviews are provided.

4. Paragraph starting with ”Consider an analogy ...” has been deleted. Sentence ending with ”I believe, are worthy of attention.” has been deleted. However, the sentences relating the limitations three and four have been retained, as I think they need to be there.

5. Peer review process: It has been noted that Burke at al. was reviewed more than 15 years ago, and since then many improvements have taken place. But I also point to recent lapses in the process (Krumholtz et al. 2007) and the need for continued concern.

Response to Referee 3: Dr. Paul Glasziou

The main point in Dr. Glasziou’s comments relates to the need to separate minor flaws from major bias generating flaws, an issue also noted by the Editorial Board.

The In-Depth Dissection section in the present version accordingly focuses on the major deficiencies in implementation and analysis that generated bias in this trial. I also note that all these flaws in trial conduct, protocol deviation, and analysis contributed to yield findings favoring antibiotic treatment. Most minor details have been removed from the main paper. The details of all major and minor flaws are provided in Additional File 2.
Response to the Editorial Board

1. Length of the main paper: The In-Depth Dissection section, where the bulk of the findings of my study are presented, has been reduced by a third. Minor flaws and related details have been weeded out.

2. Major bias generating flaws are now explicitly noted and the different types of flaws (design, implementation, analysis and reporting) are clearly separated.

3. I agree that the tone in parts of the paper was unnecessarily harsh. Now, without sacrificing accuracy, I have tried my best to express myself in a moderate tone.

4. In line with your excellent suggestion, three practical recommendations for systematic reviews are now given in the Conclusion. This, however, has added to the length of the paper, partly negating the reduction in length noted above.

5. The truncation of author initials was due to a formatting error on my part. This has been rectified.

6. Two references have been added (Greenland 1994 & Krumholtz et al. 2007). Both relate to the comments by Dr. Moher.

I thank you and all the three referees for reviewing my paper. The thoughtful comments and suggestions given have helped me considerably in improving it, and I sincerely hope that the revised version will meet your approval.

Sincerely,

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