Reviewer's report

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

Version: 1 Date: 14 October 2007

Reviewer: David Moher

Reviewer's report:

General
The author reports a case study in which he (a group of students provide data for the 2nd summary approach) examined the quality of a single trial published in 1991, in three different ways: two summary approaches; and one very detailed approach. The author concludes that there are differences in the assessment of quality across these different approaches: the two summary approaches provide strikingly different estimates of quality (although similar to one another) compared with the author’s very detailed approach. The author suggests that short summary approaches, such as using components in a checklist like manner and a scale are not only insufficient but may underestimate serious flaws in the quality of a trial report. The author suggests that a very thorough review of each trial included in a systematic review is warranted.

There is no doubt that issues of quality, both methodological and reported, should be considered in the conduct of any systematic review for the reasons, and others, mentioned by the author. The quality of the studies included in a systematic review may well impact upon its results and interpretation. Similarly, there is at least one study (reference 11 in this manuscript) showing the limitations of using a summary (scales) approach to quality assessment (more data will help confirm the reliability of this initial finding). While there is evidence to support the author’s perspective, this case study might itself be problematic. I have some major concerns and several less serious ones.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

The use of certain components in the first summary assessment (e.g., randomization) is based on a substantial evidence base (e.g., Pildal, J., Hrobjartsson, A., Jorgensen, K., Hilden, J., Altman, D. & Gotzsche, P. Impact of allocation concealment on conclusions drawn from meta-analyses of randomized trials. Int J Epidemiol. 2007;36:847-857). Focusing on items that might introduce bias is likely of greatest interest to systematic reviewers – they are likely more interested in knowing whether quality is introducing bias into the results of their review more than anything else. While scales may not be appropriate (more data, similar to reference 11 in this manuscript, will help confirm initial concerns) there is general agreement to support the use of individual components for which there
is evidence to support their use as a quality assessment method (reference 7 in this manuscript). However, the evidence base for the 30 ‘flaws’ reported by the author are not provided in the article (nor are any references provided beside any of them). And it is questionable whether all of them are important (e.g., item 1, item 29). While I am appreciative of the author’s perspective he provides little by way of convincing data to support the use of a highly detailed approach to quality assessment.

The first summary approach used by the author suggests that the trial in question was of at least acceptable quality; similarly for the second summary approach. While the reader knows the elements included in the first approach (e.g., inclusion criteria) we know nothing about the components of the second summary approach. This is important because both approaches may have used overlapping elements to quality assessments and so having similar assessments of quality might be expected.

My second major concern is that the detailed approach was completed by the author alone. No data is provided on inter-rater reliability. Nor is it clear that a second reader would have the same concerns (and quality results) as the author. The author indicates (page 3) that the data were checked – by whom. There is no indication in the acknowledgement section of the manuscript.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Minor concerns
Throughout the manuscript the author continually refers to “we”. Given this is a single authored manuscript the author should change all occurrences of “we” to “I”.

The author provides no definition of internal validity (last line of page 3). Such a definition should be provided.

On the last line of the 3rd complete paragraph (page 2) the author notes that reference 24 was not included in reference 23. Perhaps this is because reference 24 was published in September 1991 and it looks like reference 23 was published in the early part of 1992, and likely in press several months before than.

There is no traditional approach to quality assessment (Moher D, Jadad AR, Nichol G, Penman M, Tugwell P, Walsh S. Assessing the quality of randomized controlled trials: an annotated bibliography of scales and checklists. Control Clin Trials 1995;16 (1):62-73). The approach used by Balk (reference 25) is quite different than what the author mentions in the opening paragraph (page 2). And the results of the Balk study are substantially different from other studies examining quality.

Table 1 goes well beyond the ‘simple’ three elements described by the author in
the text of the manuscript.

The author needs to provide more details regarding the scale used in the second summary approach.

Discretionary Revisions (which the author can choose to ignore)

**What next?:** Reject as not of sufficient priority to merit publishing in this journal

**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.