Reviewer’s report

Title: Abstracts in high profile journals often fail to report harm.

Version: 2 Date: 13 December 2007

Reviewer: Sally Hopewell

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12 December 2007

Thank you for asking me to review this manuscript which sets out to determine how frequently harms are reported in abstracts of randomized trials in high profile medical journals.

I think the manuscript is clear and well written, addressing an area of importance to readers and users of randomized trials published in medical journals.

I have some comments and considerations which I will outline below:

Major

Page 3, para 2: The authors refer to the “latest CONSORT Statement”. This is actually one of several extensions to the CONSORT Statement which cover different types of data, designs and interventions. The wording should be clarified here to refer to the CONSORT extension for reporting harms in randomized trials (http://www.consort-statement.org/?o=1044).

Page 3, para 3: There are studies which have been conducted looking at the extent to which abstracts report harms, it would be good to acknowledge this additional research here thus placing this current study in context. Similarly the findings of this current study are not discussed with those of previous studies in the discussion section.

Page 3, para 4: It is not clear how these high profile journals were identified, how reports of RCTs were identified from within these journals, and how the sample was selected. More details in the methods section clarifying these points would improve the study’s transparency and reproducibility.

Page 5, para 3: It would be very worthwhile to know what sort of information trialists reported in the abstracts when they reported information on harms. For example did they provide numerical data or more generic statements such as “no significant difference in harms was noted between groups”. My feeling is that a number of abstracts report the later which is not useful and helpful to the reader. If abstracts did report generic statements such as these, how did you clarify these within your study?

Page 8, para 4: It is not clear whether the authors are referring to the CONSORT Statement or the CONSORT extension for reporting harms here. Both guidelines
provide recommendations for reporting both efficacy and harms when reporting a RCT. The challenge is how to get journals to endorse these guidelines and for authors to comply.

Minor

Page 3, para: You should clarify that you are assessing abstracts of RCTs.

Page 4, para 1: How was the main endpoint defined. It is not entirely clear if this refers to the main endpoint of the trial (i.e. the primary outcome) or the main endpoint in relation to harms. This should be clarified.

Page 5, para 1: A random sample of 363 articles was selected. Was this based on some pre-specified sample size calculation or something else.

Page 5, para 1: It would be better to refer to â##arm## of a trial rather than â##branch##.

Page 5, para 2, line 3: Delete â##percent##.

Page 5, para 2: â##The plurality of articles favoured the intervention##, which intervention do you mean, do you mean the experimental intervention.

Page 5, para 3: Did any studies report information about harms in the abstract but not in the full text of the publication?

Page 7, para 2, line 2: Insert â##the## before intervention group.

Page 7, para 2, line 5: Replace â##longer## with â##larger##.

Page 8, para 2: It is not strictly true that electronic abstracts can easily be obtained from electronic databases. This is certainly the case for databases which are freely available such as PubMed but not for those which require a subscription such as EMBASE. You should clarify this.

Page 8, para 3: The CONSORT extension relates to harms and not safety.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.