Reviewer's report

Title: A Systematic Review of the Reporting of Data Monitoring Committees Roles, Interim Analysis and Early Termination in Pediatric Clinical Trials

Version: 1 Date: 1 September 2009

Reviewer: Helen Sammons

Reviewer's report:

Thank you for asking me to review this interesting paper on the reporting of DMC's in paediatrics. It is an important part of the developing methodology in clinical trials in this area and this review adds to the data that is know about DMC's use.

I found the article easy to read and the box of recommendations for reporting extremely useful, and agree that it should be added to the CONSORT statement. DMC's are a good tool for increasing safety and ethical monitoring but there conduct needs to be robust and reproducible.

Minor essential revisions

1) The article is a good overview but i would not consider this a systematic review as it only examined 4 general and paediatric journals. I therefore feel the use of the term systematic review is inappropriate for the methods.
2) It was unclear if the full text of all of the 648 article from the Medline search were read and by whom.
3) Figure 1 is a little confusing as the inclusiveness of each search strategy. It would have been interesting to know how many article were identified by both arms or solely by one arm.
4) Were all 648 citation in arm B of the search RCT's when read?
5) I was a little confused by the 110 article identified and the numbers that had DMC, interim analysis or both, this could be represented clearer.
6) Where were the categories for the risk of bias assessment taken from?

Discretionary revisions

1) Table 2a contained alto of data about the methodology of the trials which was interesting (but this is a sub group of a subgroup so i am unsure of its overall relevance).
2) I did find the breakdown of the data in table 3a-d being broken down into paediatric and general journal distracting and feel the data at this point could have been pooled.
3) the recommendation for DMC for all paediatric trials may need to be tempered to include randomised controlled trials that are carried out over a reasonable time period that allows the review process.
The authors do acknowledge their limitations— the small numbers of journals, their quality and the impact this would have. It is also likely because of the journals selected that these trials would probably have taken place in Europe or North America.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

I declare no competing interests