Reviewer's report

**Title:** Questionnaires in clinical trials: guidelines for optimal design and administration

**Version:** 1  **Date:** 11 August 2009

**Reviewer:** David J Torgerson

**Reviewer's report:**

I am a big fan of Edwards’ work in this area, which is why I accepted the invitation to review this paper. Whilst well written I found it a little disappointing as I do think an overview of the work in this area is warranted. I felt the start of paper didn’t get to the important reason for the need of this paper quickly enough. The author diverted into the CRASH study and various regulatory bodies when the key issue of maximising data collection in a reliable way could have been made more succinctly. In quite a bit of the paper it wasn’t clear what was deemed to be ‘good practice’ based on opinion or no evidence compared with what was based on good evidence. It wasn’t until page 15, where the author started to discuss the evidence to support various aspects of data collection based mainly on his systematic reviews that it was possible to be sure that there was evidence to underpin the recommendations. I feel the paper has a role but would be better restructured and just focus on those aspects of data collection design that is underpinned by the evidence.

I feel a major compulsory revision should be to restructure the paper and focus on aspects underpinned by the evidence.

David Torgerson

**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 have no competing interests