Reviewer's report

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

Version: 1 Date: 28 August 2009

Reviewer: Jonathan Emberson

Reviewer's report:

I enjoyed reading this clear and comprehensive review article of the principles of good questionnaire design in clinical trials. I have just a few suggestions/comments which I hope the author might find helpful:

Minor Essential Revisions:

1. Page 5. It should be made clear that the coding of text responses to open-ended questions (eg, using MEDRA terms) should be done by study personnel who are blinded to the treatment allocation.

Discretionary Revisions:

1. Page 10 (mode of administration). Methods used to administer questionnaires presumably have an impact on the representativeness of the subsequent sample (eg, a questionnaire that can only be completed online will effectively exclude some eligible people from taking part). Therefore, depending on what the population of interest is, different modes of administration may be preferable.

2. There didn't seem to be any mention of the possible advantages of being able to answer questionnaires anonymously (though this may not, admittedly, be directly applicable to RCTs)

3. Page 12, last line of 2nd paragraph. Suggest replacing “data are valid” with “data are internally valid”.

4. While data completeness is of course desirable, in some circumstances there may be arguments in favour of allowing participants to ‘bypass’ certain sections of questions. For example, some previous studies have allowed participants to bypass questions on sexual history or on sexual experiences in childhood. The advantage of doing this is that the results from the remainder of the questionnaire can still be collected (and can even be used to predict which factors are associated with the likelihood of responding to these other ‘more sensitive’ questions)

5. Number of questions asked versus detail of answers received. In some situations, asking too many questions may have a detrimental effect on the recruitment of large numbers of people. However, if too few questions are asked then it might not be possible to properly characterise the relationship between these factors and, say, the risk of some subsequent outcome. One method of
resolving this could be to ask detailed questions only in a random subsample of participants and to use the answers to these questions to better characterise (calibrate) the answers to the shorter questions obtained in the whole sample. For example, detailed questions on physical activity in a random subsample of participants in a cohort study could be used to help understand what the relationships between answers to a crude question on physical activity and risk of heart disease observed in the whole sample actually mean.

6. In certain circumstances, it might be highly desirable to obtain repeated questionnaires from at least a subsample of participants, because these follow-up questionnaires may be the only way to actually understand subsequent associations (eg, the association between baseline current smoking and the subsequent 10-year risk of cancer can only be meaningfully interpreted if you also know how many of the current smokers continued to smoke during that period)

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests