Reviewer's report

Title: Extending an evidence hierarchy to include topics other than treatment: revising the Australian 'levels of evidence'

Version: 1 Date: 13 February 2009

Reviewer: Mike Clarke

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General

This is an interesting, well written account of the development of the new “levels of evidence” or hierarchy for use by the NHMRC and others. I am pleased to see the move away from a single hierarchy to a variety that are more in tune with the fact that the randomised trial is likely to be inappropriate as a study design for resolving uncertainty in many aspects of health and health care.

I find it difficult to review manuscripts in which the main material is something (in this case the new hierarchy) into which so much work and though has gone and which is probably not open for revision at this stage. I have, therefore, tried to keep separate my comments on the description of the process for developing the new hierarchy and the presentation of the instrument in this manuscript, from my comments on the hierarchy itself (by putting the latter after the “Discretionary revisions” section).

Another general comment is that your reference 10, the review of existing frameworks used by HTA agencies and other guidelines sounds like an extremely important piece of work. Has it been published more widely than in an internal document? If so, please add the relevant citation. If not, could you add something to the manuscript (either in the reference or as a note) to let readers how they might be able to get a copy of that report?

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Major Compulsory Revisions

1. Background: in the penultimate paragraph of the Background, you mention that there was a second stage to your development and adaptation of a system to grade the entire body of evidence and that this will be reported elsewhere. It felt a little late in the manuscript to be mentioned that there and I think it would be better to mention it earlier. I wonder if you had done so in an earlier version of the manuscript given the broken sequence in the reference call outs (see note 6 below, also).
2. Methods: where you mention the searches done by HTanalysts for the NHMRC, you should state when they did this search for comprehensive evidence frameworks. Would it also be possible to include their search strategies, either as an Appendix or make them “available from authors”?

3. Discussion: where you mention the work being done within The Cochrane Collaboration on the synthesis of qualitative research evidence, you should cite the chapter in the recently revised Cochrane Handbook for Systematic Reviews of Interventions (version 5), by Jane Noyes and others.

4. Discussion: you include special considerations about studies of diagnostic test accuracy and it might be helpful to have a paragraph or two about any special challenges (or the lack thereof) for the other study designs that you have added to the hierarchy.

5. Would it be possible to say a little bit more about the impact that the piloting had on changes to the hierarchy. I would be particularly interested to read about the usefulness of the website as a means for obtaining feedback.

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Minor Essential Revisions

6. References: the call outs to references 2 and 3 seem to be out of position (see note 1 above also).

7. Competing interest: I don’t understand the term “sitting fees” and I expect other international readers might not know what it means either. Could you add something to explain it briefly?

8. Table 2: the call outs to notes that are on items in the Intervention column that would also be relevant to the same items in the Screening intervention column, should be added to those items.

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Discretionary Revisions

9. Background: where you list three reasons for why it was necessary to revise the hierarchy, do you think that the first, “it has become increasingly clear that it is not ideal for the assessment of evidence about questions other than treatment effectiveness”, is something that was not clear from the time that the hierarchy was developed? Was there an expectation when it was originally developed that it would or could be used for other questions? If so, I suggest that you are explicit about this expectation in the Background. If not, I suggest that you change this
list of three reasons into one reason known from the start and two reasons that became “increasingly clear”.

10. As I read the manuscript, I wondered if it might benefit from more discussion of the differences between assessing “quality” and “risk of bias”. For example, the assessment of quality might include issues about how a study was done other than the strategies to minimise bias. Such issues might include things like sample size but also things such as: were appropriate diagnostic techniques used to identify “cases” in a case-control study; was an intervention or diagnostic test used in the correct way in a randomised trial or diagnostic test accuracy study, respectively; were outcomes measured accurately in a prognosis study? You pick up on this towards the end of the manuscript, in the “Assessments of study quality” section, but I wonder if that discussion should be noted in the Background as well, and, perhaps, expanded.

Comments relevant to the revised hierarchy

11. For intervention studies, you have continued with a separation of randomised and pseudorandomised trials that appears to be based on the generation of the allocation sequence rather than its concealment. Did you consider adding anything that would allow a trial that used alternate allocation where the underlying sequence was random and foreknowledge of the next assignment was not possible before a participant entered the trial, to be ranked higher than a trial using a random sequence which was known in advance (eg a random number list pinned to a noticeboard?)

12. Why was it necessary to separate screening interventions from other interventions?

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

Declaration of competing interests:

I am employed by the Oxford Radcliffe Hospitals Trust on behalf of the National Institute for Health Research in England, as Director of the UK Cochrane Centre. This is a fixed term contract, the renewal of which is dependent upon the value placed upon my work, that of the UK Cochrane Centre, and of The Cochrane Collaboration more widely by the Department of Health. I am also employed by Cancer Research UK at the Clinical Trial Service Unit and Epidemiological Studies Unit, University of Oxford, working primarily on systematic reviews of treatments for early breast cancer. These jobs involve the conduct of systematic reviews and work - such as this manuscript - relating to systematic reviews may
have an impact on my employment.