Reviewer’s report

Title: Developing core outcome sets for clinical trials: issues to consider

Version: 1 Date: 20 April 2012

Reviewer: Hywel Williams

Reviewer’s report:

General comment:
This submission from an all star cast who have been instrumental in promoting the concept and use of core outcome sets (COS), is very timely as it sets out the importance of registering disparate efforts in a one-stop-shop (COMET) which will minimize duplication, encourage collaboration, improve methods for developing COS and dissemination and awareness of their existence.

Major comment
1. On page 12, you mention that COS will always require updating (“forever preliminary” if I remember an old OMERACT phrase correctly). But if indeed the COS change every five years on the basis of new and better outcomes of continual modification of existing instruments and domains, is it not possible that such constant changing will defeat the very purpose of COS ie comparability of trial outcome measure over time?

Please add a sentence to demonstrate awareness of this point, and how OMERACT with its 20 year history has overcome such a concern. Maybe the threshold for changing a domain should be very high for instance.

Minor comments
2. The abstract is nicely written, but it is a bit empty. There are no juicy bits in there. “Here we identify key issues” is like saying “results will be presented”. Now I realize that this is not a formal IMRD type paper, but please add a sentence at the end of the abstract that is a little more declarative eg “Key issues to consider include a, b, c etc”

3. Page 6. When you talk about trials always presenting COS as a minimum, you don’t talk about the relationship between COS and choice of primary outcomes in a trial. I realize that a primary outcome does not necessarily need to be a COS in every case, but it is likely to be in most cases? – please add a sentence on your stance on the relationship between primary outcomes and COS.

4. Page 7, middle para “As COS are developed, it will be important to agree a definition” – please consider changing “a definition” to “appropriate instrument” and in the sentence “Examples of lack of standardized definitions..” – please consider changing standardized definitions to “validated instrument”

5. Page 8 – examples are useful here - thank you
6. Page 8 – please explain more about how ORBIT can help COS. Just one sentence will do.

7. Page 8/9 You went straight on from identifying knowledge to deciding what knowledge to tell stakeholders and then you talk about stakeholders. The order of events here does not seem quite right, at least in the chronology of developing COS. I think it is more likely to be (i) scoping the literature (ii) identifying relevant stakeholders and (iii) engaging them with whatever information is appropriate at that particular stage. Please consider re-jigging the order of these sections slightly.

8. page 10 – whatever happened to the OMERCT filter of “truth, discrimination and feasibility”? It surely needs a mention here somewhere.


10. Page 11 consider mentioning the importance of anonymous voting when making final decision – either by email or key pads at meetings, in order to ensure that everyone’s views are included

11. Page 11 – you have a [ref] that needs completing for GRADE

12. Page 13 – you mention conflicts of interest, but you could unpack it a little more with a sentence or two. For example, should an evangelical scale developer be allowed to lead a COS meeting in order to ensure that his/her instrument is voted in as they have built their career on it. Or what about a drug company that has developed an instrument that suits the evaluation of their new drug?

13. Page 14 – the type of data recorded on COMET is useful, but it would be nice if you hinted on whether or not COMET is a site of anything and everything related to COS, or whether there is a minimum standard of scope and methods that should have been done to be included. For example, I see scores of nonsensus consensus statements that purport to be consensus statements, but which in reality are produced by a handful of great and good exchanging a few emails and a meeting. Is the COMET door open for these type of proposed COS?

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Declaration of competing interests:**

None - I am enthusiastic supporter of the ocncpet of core outcoem sets to minimise cheating and increase relevance of clinical trials