Research agenda

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In addition to the research needed to generate and implement core outcome sets (COS) in many areas of health care, we have identified a wide range of research that is needed to improve the methods associated with COS. We outline a research agenda in this deliverable, beginning with some background on the need for this research and describing four main areas for study.

The credibility of a COS depends on both the use of sound methodology in its development and transparent reporting of the processes adopted, while its implementation in clinical trials will depend on effective dissemination and its acceptance by the research community including researchers, patients and the public and funders.

1) Methodological quality of COS: Although the issues to be considered in the development of COS have recently been described (1), to date there has been no formal quality assessment of the couple of hundred COS studies that we have already identified and included in the COMET database (2). Defining the quality of a COS is not straightforward. In principle, a “good” COS is one that eventually leads to improved outcomes for patients but this might be far down-stream of the development process. Our systematic review has revealed wide variation in the methods used to develop COS and work is needed to assess the implications of these different methods for both minimising bias and maximising efficiency in the development of COS, and for ensuring uptake. As an example, although benefits have been shown for involving health service users in trial design (3), only 16% of the published COS reported that there was input from patients in their development.

2) Assessment of reports of COS: Even if robust methods are identified for developing COS this might be not easily assessed from a report of that process. Instead, the best that can be realistically expected is the ability to assess whether and how the report by the developers shows that they minimised the biases that can occur in the process. There is a pressing need to assess the published reports of COS using internationally recognised criteria that are valid and reliable. This is particularly important for the research community using COS, in order to allow people to decide whether a COS is good enough to be adopted and, in some cases, to decide between different COS that may be relevant to a particular research study. It is also important for COS developers, to help them to report their methods in a way that will allow users to judge the quality of what they did. This research could underpin the development of an evidence-based reporting guideline for COS.

3) Implementation of COS: Previous research has identified perceived challenges to the widespread implementation of COS (4). These include slow or limited uptake, multiple groups developing differing COS for the same topic, accessibility of relevant COS to all stakeholders, and process for adding new outcomes to the COS over time. Several methods have been suggested to improve the uptake of COS, including improved dissemination and accessibility (such as the COMET databases), pressure from funders as a means of reducing waste in research (5), and advocacy by patients and the public. Future developers

and funders of COS would benefit from evidence on the effectiveness of different strategies and how best to implement these.

4) Measuring the impact of COS: Despite extensive searches, the only study we are aware of that has assessed the impact of individual COS is our recent study of published trials involving rheumatoid arthritis (RA) patients. This found that by 2010 the relevant COS containing seven outcomes (published 1995, FDA-recommended 1999) was reported in over 70%, with 90% of trialists saying they would use the COS if they were to lead a new trial in RA (6). Therefore, given the number of ongoing and planned COS, it is timely to examine the level of uptake of a wider range of existing COS and to understand the reasons why trialists do and do not include these recommended outcomes in their studies. Furthermore, our survey of new Cochrane Reviews from 2007 and 2011 (a deliverable for Work Package 2) found that none of these nearly 800 systematic reviews made explicit reference to a COS in their design or results and research is needed to understand the attitude of researchers to the use of COS in systematic reviews, and to identify barriers and facilitators.

Proposed agenda for methodological research

In summary, to improve the methodology, reporting and implementation of core outcome sets (COS), research is required to address the following objectives:

(i) To compare different methods used to develop COS, with respect to minimising bias and maximising efficiency, and in relation to the degree of uptake;
(ii) To understand better the patient perspective and improve patient and public engagement in studies developing COS;
(iii) To develop and disseminate methodological guidance for COS development;
(iv) To develop and disseminate a quality assessment instrument for studies developing COS;
(v) To develop and disseminate a guideline for reporting studies developing COS;

(vi) To compare different methods for disseminating, improving access to and promoting the use of COS on their uptake in trials and reviews;
(vii) To examine the level of uptake of existing COS and understand the reasons why researchers (including trialists and systematic reviewers) do and do not use them.

The outputs of this research could impact immediately on the quality of ongoing and planned COS studies, and improve the uptake of COS.

References

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