

Project Title: Development of a quality assessment tool for core outcome set development

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Specific grant objectives and what has been achieved:

1. Development of a quality assessment instrument for core outcome sets

Project deviations: The original plan as highlighted in the above objective was for the investigators to develop a quality assessment tool, with the aim to hold a consensus meeting at the end of the process to approve a minimal set of standards for use in core outcome set development. Funds were requested from the Network to host the consensus meeting only.

Early on in the development process, it was recognised that there was a considerable amount of overlap between the final reporting of a core outcome set and quality, with the agreement that quality items might be a subset of the reporting items. Quality also needed to be better defined in accordance to core outcome set (COS) development strategies. The decision was therefore taken forward to firstly develop the reporting guideline and then reconsider the quality aspect. As originally requested, the Network funds were still used for consensus meeting purposes.

Project outputs:

COS-STAR (Core Outcome Set-STAndards for Reporting) Guideline

The development of the COS-STAR reporting guideline consisted of an initial reporting item generation stage, a two-round Delphi survey involving nearly 200 participants representing key stakeholder groups, followed by a consensus meeting and testing. The consensus meeting took place in London and contained 17 international participants representing COS developers, COS users, journal editors and patient representatives. The final output from the meeting was a checklist of 18 items considered essential for transparent and complete reporting in all COS studies. The checklist was accompanied by an explanation and elaboration document which described with examples, the importance and rationale of each reporting item. The protocol and final guideline for the study was published and is available. In 2 years since publication, the guideline has already been cited 76 times (Google Scholar)

Study protocol:

Kirkham JJ, Gorst S, Altman DG, Blazeby J, Clarke M, Devane D, Gargon E, Williamson PR. COS-STAR a reporting guideline for studies developing core outcome sets (protocol). *Trials* 2015; **16**:373

<https://www.ncbi.nlm.nih.gov/pubmed/26297658>

Final guideline:

Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Devane D, Gargon E, Moher D, Schmitt J, Tugwell P, Tunis S, Williamson PR. Core Outcome Set – Standards for Reporting: The COS-STAR Statement. *PLoS Medicine* 2016; **13**(10):e1002148

<https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002148>

COS-STAD (Core Outcome Set-STAndards for Development)

Following the completion of the reporting guideline, the study team developed a set of minimum standards for COS development studies which addressed the quality assessment issue as described in the original application. The methods for developing the minimal standards (as a measure of minimum quality) followed a similar format to the reporting guideline, this time with over 250 participants included in the consensus exercise. The minimum standards consists of 11 minimum recommendations for COS development which covers three key domains; scope, stakeholder representation and the consensus process. As COS-STAD contained fewer items, it was decided not to bring together experts for a formal consensus meeting to discuss only a small number of items, particularly considering that the expertise of the Management Group covered the majority of stakeholder groups.

The COS-STAD statement is now published in PLoS Medicine

Kirkham JJ, Davis K, Altman DG, Blazeby JM, Clarke M, Tunis S, Williamson PR. Core Outcome Set STAnDards for Development: The COS-STAD Recommendations. *PLoS Medicine* 2017; 14(11): e1002447

<http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002447>

This reference is included in the guidance that the COMET Initiative sends out to COS developers registering a new COS study in the COMET database.

Next steps:

- 1) Following the development of COS-STAD and COS-STAR, the study team were invited by BioMed Central to develop a protocol guideline to aid the editorial/peer review process of COS protocols submitted to journals. This work was also completed and has recently been submitted to *Trials* (Core Outcome Set-STANDARDISED Protocol Items: The COS-STAP Statement).
- 2) Work is ongoing to obtain a baseline assessment of studies that adhered to the COS-STAD recommendations for certain clinical conditions. It is anticipated that a prospective evaluation of COS-STAD will be undertaken when the guideline has been published for a sufficient amount of time.