Guidance for trialists on implementing a COS

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At the planning stage of a trial, the research team needs to decide which outcomes to measure. They should search the COMET database, and if a relevant high quality core outcome set (COS) exists, this should be integrated into the trial design and detailed in the protocol.

The relevance of a COS depends on its scope, defined in terms of the health condition, target population and whether this is for any intervention or specific types of intervention. These cover the first three elements of a PICO (Population, Intervention, Comparator, Outcomes) structured question for a clinical trial.

The development of a quality assessment tool for a COS is the subject of ongoing work. In the interim, trialists should consider the set of issues previously identified, namely existing knowledge, stakeholder involvement, the consensus methods used, the level of consensus achieved, and whether there has been regular review, feedback and updating of the COS (Williamson et al, Trials 2012;13:132). They should look at the content of the COS and consider whether it is relevant to the research question.

The primary outcome for the trial does not necessarily need to be within the COS however for many effectiveness trials it is likely to be. A COS is a minimum set, and it is fully expected that trialists will measure additional outcomes.

Guidance for the choice of outcomes in trials for specific health conditions has been written by various organisations including regulatory authorities. The inclusion of a COS does not contradict this guidance about collecting additional specific outcomes.

A COS may recommend both which outcomes to measure and how to measure them, for example in terms of the definition or the measurement instrument to be used. Many of the published COS relate only to what to measure, however. In this instance, the trial team will still need to decide what outcome definitions and measurement instruments to use in their trial. It is recommended that before making these decisions, they contact the authors of the COS to establish whether any further work on how to measure outcomes in the COS is ongoing or planned. If not, or the timing of the work means that no results will emerge before the trial is due to begin, it is recommended that the trial team follow guidance on selecting an instrument for measuring core outcomes (deliverable 4.3) and finding an instrument (deliverable 4.1) and search the COSMIN database of systematic reviews of measurement instruments (deliverable 4.2).

If there is no directly relevant COS but a COS exists in a related area, the trial team is recommended to consult relevant stakeholder groups, including both patients and healthcare professionals, to assess whether the COS may be generalisable.

In the absence of a relevant COS, or one of high quality, the trial team should review existing evidence and consult relevant stakeholder groups, including patients and healthcare professionals, as widely as possible within time and resource constraints.

Examples of guidance given to trialists about core outcome sets and the use of the COMET database as a resource for trial design

COMET has a strategy for engaging with relevant stakeholder groups to disseminate and implement its main recommendations (deliverable 1.10). There have been some notable successes to date and some examples are given below.

(1) Trial funders

In the UK, the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme include the following text in their 'Guidance Notes for Completing Full Proposals':

Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established.

(2) Protocol developers

The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidance (Chan et al, BMJ 2013;346:e7586) recommends the following:

Where possible, the development and adoption of a common set of key trial outcomes within a specialty can help to deter selective reporting of outcomes and to facilitate comparisons and pooling of results across trials in a meta-analysis. The COMET (Core Outcome Measures in Effectiveness Trials) Initiative aims to facilitate the development and application of such standardised sets of core outcomes for clinical trials of specific conditions (www.comet-initiative.org). Trial investigators are encouraged to ascertain whether there is a core outcome set relevant to their trial and, if so, to include those outcomes in their trial. Existence of a common set of outcomes does not preclude inclusion of additional relevant outcomes for a given trial.

(3) Journal editors

The CROWN (Core Outcomes in Women's Health) Initiative, www.crowninitiative.org, is a consortium of over 50 gynaecology-obstetrics and related journal editors. CROWN will:

Strongly encourage the reporting of results for core outcome sets. Facilitate embedding of core outcome sets in research practice, working closely with researchers, reviewers, funders and guideline makers.