The importance of having core outcome sets in a clinical trial

Dear Editor,

Core outcome sets (COS) are predefined, standardized lists of outcomes that should be expected to be measured and reported in all clinical trials about a specific health condition or intervention. COS should be carefully selected systematically and involve input from patients, health-care professionals, and researchers. The ultimate goal of having COS is to establish a uniform set of outcomes that are relevant, meaningful, and essential to assess the effectiveness of a particular intervention.[1]

Having predefined COS makes it easy for clinicians to compare trials investigating similar interventions in different studies. However, the use of COS was found to be quite low in major clinical journals.[2] If COS are utilized for all research, the researchers will not only report positive but also negative outcomes, which usually get excluded in the write-up at the time of drafting the manuscript. This will reduce reporting bias. Once COS are defined, the upcoming research is more streamlined and focused as there is clarity about the outcomes that need to be investigated for that trial. It is expected that the patients themselves should actively participate in the development of COS, ensuring that the results reflect their priorities and experiences. The relevance of clinical trial results to the patients is increased by this patient-centered approach. Meta-analysis of randomized controlled trials becomes more robust and the ultimate results available are more reliable when based on a standardized set of outcomes like COS. This facilitates a comprehensive synthesis of evidence, thus offering the clinicians a more comprehensive understanding of the overall effectiveness of the intervention under investigation.

Using COS allows researchers to allocate resources more effectively. The uniformity of measured outcomes among trials facilitates a more precise evaluation of the clinical impact and cost-effectiveness of different interventions. Several reasons make COS implementation by all researchers a daunting task. The important reasons are the time taken to develop COS, costs involved in developing and implementing COS, challenges in managing stakeholders (patients, researchers, sponsors, practitioners, industry members), which lead to issues with arriving at a consensus, ignorance about COS, and not accepting implementation of COS.[3]

To encourage researchers and trialists to implement COS in their trials, the "Core Outcome Measures in Effectiveness Trials" (COMET) initiative was launched in 2010.[4] In addition to bringing together individuals interested in the creation and implementation of agreed-upon COS, the COMET initiative seeks to gather and promote relevant applied and methodological resources, promote methodological research, and enable the sharing of ideas and knowledge.

Hill *et al.*[5] published a systematic review and Delphi study to investigate heterogeneity among various outcomes in research related to regional anaesthesia. From the 206 papers identified, 224 unique outcomes were generated. After three Delphi rounds, the authors selected 10 core outcomes and 13 outcome parameters and reached a consensus after a final Delphi survey and video conference. The outcome parameter categories were sensory testing, any additional intervention, intraoperative opioid consumption and at various time points, block duration, adverse events, length of stay, and quality of recovery.

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Conflicts of interest

There are no conflicts of interest.

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