

Title: Development of a core outcome set for the evaluation of shared decision-making interventions in healthcare

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Background:

Despite decades of shared decision-making (SDM) research, the impact of implementing SDM interventions within health care remains uncertain. High-quality health technology assessment (HTA) requires an understanding of how SDM interventions impact clinical and health service outcomes. However, synthesis of the existing literature is hindered by substantial heterogeneity in the evaluation of interventions to facilitate SDM. A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported in all effectiveness studies.

The aim is to develop a generic COS for evaluating the impact of a variety of SDM interventions, tailored to and interacting with a range of patient populations, healthcare settings and contexts. Outcomes for consideration may include assessments of the behaviours and experiences of patients and health professionals, the dynamics within patient-professional interactions, health outcomes for individuals and for the wider population, and the cost-effectiveness of care. We will define this new, comprehensive COS as the COS-SDMi.

Methods:

Through engagement with key interest-holders (including patients and members of the public, clinicians and academics), we have agreed on the scope of the COS. We adhere to the Core Outcome Measures in Effectiveness Trials (COMET) handbook and Core Outcome Set-STAndards for Development (COS-STAD) guidelines. This has involved the production of a 'long' (extensive) list of candidate outcome domains using evidence synthesis, a COS developed in the context of Rheumatology, and qualitative interviews with interest holders internationally. The immediate next step is the prioritisation of a 'short' (refined) list of core outcome domains, utilising a sequential two-round international online Delphi survey. We will reach consensus on the final outcome set through international meetings, applying modified nominal group techniques. The project has been registered in the COMET database (www.comet-initiative.org/Studies/Details/3586).

Results:

The results of the evidence synthesis, qualitative interviews, and work to develop the Delphi survey with key interest-holders will be synthesised and presented for consideration at ISDM 2026. We anticipate attendance by patient and professional interest holders from diverse backgrounds. This work will result in the publication of the final COS-SDMi.

Discussion:

The broad scope of the COS will ensure its applicability and utility within diverse healthcare contexts and enable the synthesis of evidence to draw clear conclusions about the impact of SDM interventions, to influence healthcare policy.

Dissemination, to publicise the COS to patients, funders, journal editors, international regulatory bodies and HTA boards, will be through our patient/public advisory group, professional networks, and executive group channels.