The use of core outcome sets to inform guideline development

Key facilitators:

Paula Williamson, University of Liverpool

Elizabeth Gargon, University of Liverpool

Nichole Taske, National Institute for Health and Care Excellence (NICE)

Background

A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in a specific condition. They are also suitable for use in clinical audit or research other than randomised trials that report on health-related outcomes. This allows research to be compared and combined as appropriate and ensures that all studies provide usable information. An increasing number of COS developers also intend their COS for use in routine health care practice. The COMET Initiative provides and maintains a database of COS, as well as carrying out methodological research and producing guidelines for COS development. Many organisations now actively endorse the use of COS and the COMET database, including the National Institute for Health and Care Excellence (NICE) who recommend the use of COS where appropriate in their methods manual for developing guidelines https://www.niceorg.uk/process/pmg20/chapter/developing-review-questions-and-planning-theevidence-review).

It is important that relevant stakeholders are involved in the development of COS to ensure that COS appropriately reflect outcomes that are important to those groups, particularly patients and health care professionals. Guideline developers are now involved in the development of some COS. If COS also appropriately reflect outcomes that are important to guideline developers, this will result in more effective and efficient use of published research. Finally, research recommendations emerging from guidelines, particularly where evidence is sparse or low quality, can likewise flag important gaps in COS development and so continue the evidence life cycle.

The use of COS in guidelines will ensure that outcomes important to patients and health care professionals are considered. High quality COS can aid guideline developers in prioritising outcomes for inclusion in their guidelines, and COMET makes it easier for guideline developers to identify and use COS.

Objectives

i. To describe the rationale for using COS in clinical guidelines and demonstrate how the COMET database helps to facilitate this.

ii. To describe the issues to consider when deciding whether a COS is applicable to a guideline in development.

Target audience

Guideline developers, patients, clinicians, academia, students, HTA agencies, policy makers, review authors, review editors, consumers, statisticians, methodologists, trialists, researchers.

Approximate timing

Introduction to course - 5 minutes

COS, The COMET Initiative, and the relevance to guideline developers - 20 minutes

Demonstration of the COMET database - 10 minutes

Discussion - 15 minutes

Introduction to group work - 10 minutes

GROUP WORK 1
Work through examples of COS. Consider assessing whether an existing COS is relevant to your guideline – what might you need to think about? Scope, how, where, and who? What challenges might you encounter? - 30 minutes
Bring discussions together, go through issues to consider COS min standards - 30 minutes

GROUP WORK 2
Applying minimum standards criteria to their COS - 30 minutes
Discussion - 20 minutes

Summary and take-home points - 10 minutes

Facilitator Bio's

Paula Williamson, University of Liverpool

Paula Williamson is Professor of Biostatistics. She is Director of the MRC North West Hub for Trials Methodology Research (HTMR), Director of the Clinical Trials Research Centre (CTRC), and Head of the Department of Biostatistics at the University of Liverpool. Paula chairs the University of Liverpool's Health and Biomedical Informatics Group and is a member of the Farr Institute through HeRC North. Paula co-founded and has led the COMET (Core Outcome Measures in Effectiveness Trials) Initiative since 2010. She was appointed as an NIHR Senior Investigator in 2014, gave the Bradford Hill Lecture in 2017, and is current Chair of the MRC HTMR Network.

Elizabeth Gargon, University of Liverpool

Elizabeth Gargon obtained a PhD in the Institute of Translational Medicine (Biostatistics) at the University of Liverpool in 2016. She joined the University of Liverpool as a research assistant for a research programme funded by the National Institute of Health Research (NIHR) and worked in collaboration with Alder Hey Children's NHS Foundation Trust. She is now a member of the COMET (Core Outcome Measures in Effectiveness Trials) Initiative Management Group and the Project Coordinator.

Nichole Taske, National Institute for Health and Care Excellence (NICE)

Dr Nichole Taske is an Associate Director (Methods and Economics) in the Centre for Guidelines at the National Institute for Health and Care Excellence (NICE). She graduated with a PhD in clinical genetics from the Australian National University in 1997. She has worked as a postdoctoral research fellow both in Australia and the UK specialising in inherited chanelopathies. In the UK, she undertook further studies in health policy, planning and financing at the University College London (UCL) and the London School of Economics (LSE). In 2003 she joined Bazian Ltd (now an Economist Intelligence Unit within the Economist Group), a private company that provides evidence-based health reports for governments, insurers, publishers and research organisations. Nichole joined NICE in 2004 and is currently responsible for overseeing the technical quality assurance of guidelines in development in addition to leading on the development, evaluation and implementation of guideline development methodologies across the programme.