

Improving core outcome set development: qualitative interviews with developers provided pointers to inform guidance

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Abstract

Objectives: The objective of the study was to explore core outcome set (COS) developers' experiences of their work to inform methodological guidance on COS development and identify areas for future methodological research.

Study Design and Setting: Semistructured, audio-recorded interviews with a purposive sample of 32 COS developers. Analysis of transcribed interviews was informed by the constant comparative method and framework analysis.

Results: Developers found COS development to be challenging, particularly in relation to patient participation and accessing funding. Their accounts raised fundamental questions about the status of COS development and whether it is consultation or research. Developers emphasized how the absence of guidance had affected their work and identified areas where guidance or evidence about COS development would be useful including, patient participation, ethics, international development, and implementation. They particularly wanted guidance on systematic reviews, Delphi, and consensus meetings.

Conclusion: The findings raise important questions about the funding, status, and process of COS development and indicate ways that it could be strengthened. Guidance could help developers to strengthen their work, but over specification could threaten quality in COS development. Guidance should therefore highlight common issues to consider and encourage tailoring of COS development to the context and circumstances of particular COS. © 2017 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

Keywords: Consensus; Core outcome sets; Delphi; Interview; Outcomes; Qualitative research; Research methodology

1. Introduction

There are serious problems with selection and measurement of outcomes in clinical trials and health research. The outcomes used are not necessarily relevant to patients [1] or helpful in making decisions about health care. Inconsistency in which outcomes are measured is a major barrier to evidence synthesis and therefore to improving health care. The magnitude of inconsistency is striking. For example, over 25,000 of the outcomes in cancer trials have only been used once or twice [2]. Moreover, even when trials do measure the same outcomes, these are measured in such different ways that synthesis is often impossible. The extent of this problem is also striking: over 2,000

different measurement instruments have been used across 10,000 trials in schizophrenia, equating to a new instrument being introduced for every fifth trial [3]. A further problem is the incomplete publication of trial results, and particularly outcome reporting bias—the selective publication of a subset of the original recorded outcomes on the basis of the results [4,5]. These problems lead to the use of ineffective, perhaps even harmful interventions, and to widespread waste of scarce health care resources [6].

A concerted effort is needed to address these problems. One solution is to develop agreed standardized sets of outcomes, known as core outcome sets (COSs). A COS is a list of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care [7]. If all trials in a particular clinical area used COS, the findings could be synthesized, and the resultant knowledge could be properly harnessed to benefit patients.

A systematic review of the 198 COSs published between 1981–2013 [8] indicated that a wide range of methods have been used to develop COS. Moreover, where similar

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What is new?**Key findings**

- Against a backdrop of limited funding, participants described core outcome set (COS) development as often driven by practicalities rather than principles, and raised fundamental questions about whether COS development is consultation or research.
- Developers problematized the participation of patient stakeholders, particularly their ability to understand COS and prioritize outcomes.
- They did not similarly problematize the participation of professional stakeholders, although they did describe general difficulties in selecting, accessing, and retaining stakeholders.
- Developers also raised questions about whether COS should be developed internationally and aim for generalizability across different countries.
- Finally, developers wanted support on methods of COS development and stakeholder engagement.

What this adds to what was known?

- COS development is an emergent area, and little was previously known about developers' experiences and methodological choices.
- As the first inductive study in this area, the findings provide insights about the challenges in developing COS, the areas where developers would benefit from methodological guidance and priorities for future methodological research on COS development.

What is the implication and what should change now?

- Limited funding and fundamental uncertainties about whether COS development is consultation or research have wide-ranging implications for COS, and these issues warrant further attention.
- Developers' problematization of patient participation indicates that they found this particularly challenging and points to the need to identify ways to support meaningful patient participation.
- The development of COS ideally needs to encompass the perspectives of stakeholders from countries in which COS are to be used.
- Methodological guidance that addresses the specific challenges developers encountered is a priority.
- Guidance on the application of methods to inform COS, such as systematic reviews, Delphis, and

consensus meetings, was high priorities for developers, but the findings indicate that guidance on patient participation is important too.

methods have been used, these have been applied in different ways. While methods of development will likely need to be adapted to the context of a COS, variation in the methods used can influence which outcomes are ultimately included in a COS. COS development work by three different groups in the same clinical area (pediatric asthma [9–11]) that used different methodological approaches and involved different stakeholder groups resulted in some inconsistent outcomes being rated as important, although there was also some overlap in the outcomes prioritized across the three projects.

Most published COS have been developed in the absence of guidance about how to conduct COS studies. Indeed, the concept of a COS is still being established, and little is known about what should inform developers' methodological choices. As an emergent area of research, understanding developers' perspectives and rationales for their methodological choices will help to enhance future COS development. We therefore conducted qualitative interviews with COS developers about their experiences of COS development to understand the challenges involved, to inform methodological guidance, and to identify areas for future methodological research on COS development.

2. Study design and setting

Reflecting the aims of our study to inform practice, our approach was broadly pragmatic [12] yet interpretive, and we considered how participants constructed their experiences of COS development and what was latent in their accounts as well as the manifest content. The study received ethical approval from the University of Liverpool (reference: RETH000624).

It is important to outline the authors' interests in COS development, as these will inevitably have shaped the study and its findings. E.G. and P.R.W. helped to found the Core Outcome Measures in Effectiveness Trials (COMET) Initiative [7] in 2010. COMET promotes the development and application of COS and fosters methodological research to enhance COS. As members of the COMET Management Group, EG as Co-ordinator and PW as Chair, they have frequent contact with developers. They have also authored multiple COS publications, organized and participated in COMET conferences, and raised awareness about COMET worldwide. B.Y. also has interests in COMET, particularly stakeholder input to the development of COS and since 2015 has cochaired the COMET People and Patient Participation Involvement and Engagement Working Group.

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