

1st COMET Network meeting

Date and venue

20 June 2013 (15.30-17.00 BST), Midland Hotel Manchester UK during COMET III meeting.

Background

This meeting was organised as part of Work Package 3 for COMET's European Union funded project (FP7-HEALTH-2012-INNOVATION-1), principally to bring together people who have been involved in the development of core outcome sets (COS) in UK and Ireland to discuss how the COMET Initiative might facilitate the development of new COS. The meeting was the first opportunity to bring together people who have worked on a wide range of COS to discuss how a system of support might be put in place and managed. The intention was that the experience of the participants would help to highlight areas in which assistance might have been particularly beneficial as they developed their COS, identify ways in which support might be provided to new developers, and explore the possibilities for providing this support. It was organised by Liz Gargon and Mike Clarke, and facilitated by Mike from the COMET Management Team. The agenda is shown below.

Agenda

1. Welcome and introductions
2. Brief description by each participant of their experience with COS development
3. Group discussion to
 - a. reflect on experiences and lessons learned
 - b. consider whether they might have benefited from guidance when developing a COS:
 - i. If so, what guidance and when?
 - ii. If not, why?
 - c. suggest ways in which they might be able to help others
 - d. outline ways in which they might be able to to get involved in COMET and supporting people who are developing COS
 - e. decide what should happen next
4. Conclusions

Attendees

Bronagh Blackwood, Belfast, Northern Ireland (Mechanical ventilation COS)
Maarten Boers, Amsterdam, The Netherlands (OMERACT and WP3 lead)
Mike Clarke, Belfast, Northern Ireland (WP2 lead)
Declan Devane, Galway, Ireland (Maternity care COS)
Angus McNair, Bristol, England (Oesophageal cancer COS)
Jochen Schmitt, Dresden, Germany (HOME COS)
Ian Sinha, Liverpool, England (Asthma COS)
Peter Tugwell, Ottawa, Canada (OMERACT)
John Zajicek, Plymouth, England (Alzheimer's disease COS)

Discussion at the meeting, and subsequent notes from COMET

The attendees highlighted some of the challenges they had faced in developing their COS and what they expect future developers might need help with. Issues they highlighted are:

- Choosing between narrow and broad topic areas for the COS (for example, intensive care generally, or mechanical ventilation in intensive care units) [Note: the systematic review of COS has found that this varies across existing COS, with about 40% being for particular interventions (e.g. drugs, surgery, etc)]
- Deciding on whether the primary outcome measure for a trial should be in the COS [Note: this is likely to be a decision taken on a trial by trial basis, and depends on the specifics for each trial]
- Getting the balance right in the development of a COS between researchers, practitioners, patients and carers (e.g. parents), and how to manage the decision making process [Note: this is the subject of ongoing research]
- Finding ways to get patients or healthcare consumers to lead the process of COS development [Note: the systematic review of COS has found only one COS that was led by patients]
- Ensuring that the involvement of the pharmaceutical industry is managed well [Note: this is being explored in ongoing research]
- What interests should be disclosed by those involved in the COS development [Note: comments to date have identified that the development of a specific outcome measurement instrument should be declared]
- Need for reporting guidelines for COS [Note: in light of this and other feedback, it has been agreed that an explicit aim of the COMET Initiative should be to prepare guidance on the reporting of COS. The systematic review of COS will include a description of the quality of the reports of COS]

Next steps agreed at the meeting, and subsequent notes from COMET

The attendees suggested the following actions, which might help support future developers of COS:

- Involvement of regulators in both understanding the concepts for COS and the development of specific COS, to help with implementation [Note: COMET is working on this, and has provided input to a European Medicines Agency consultation, had discussions with the FDA and will explore interaction with regulators in Japan]
- Provide human resources to help with the administrative and organisational aspects of COS development, with an emphasis on methodological expertise rather than content expertise [Note: COMET continues to provide advice on several grant applications, and the support role is being included in the funding requested for some of these projects]
- Provide help without human presence in the COS development process, for example through documentation, internet resources and peer review of plans [Note: as above, COMET continues to provide advice on several grant applications, and the support role included in the funding requested for some of these projects]
- Provide examples of invitation letters, questionnaires, meeting agenda, slideshows, consensus building methods, e-Delphi tools [Note: the COMET website is likely to include a repository of this type of material]

- Help with funding (if COMET had access to a central pot of money and was able to make financial awards) [Note: it is not clear whether COMET would be in a position to have access to resources that could be allocated in this way]
- “Train the trainers”: provide training to people who might facilitate the development of COS, perhaps using the “Issues to Consider” paper as the framework for this [Note: a methods workshop at COMET III meeting was the start of this process, and future network meetings will seek to identify people who will volunteer as trainers and then determine appropriate ways to train them]
- Develop a training pack for COS developers, containing materials to help with
 - raising awareness of the need for COS
 - planning the process to use to develop a COS
 - determining the existing use of outcomes (for example, with the ORBIT matrix)
 - deciding on the scope of the COS
 - “borrowing from” an existing COS, rather than having to develop a new one
 - choosing the primary outcomes
 [Note: the COMET website is likely to include a repository of this type of material]
- Develop reporting guidelines for articles that describe the development of a COS [Note: as above, following this and other feedback, it has been agreed that an explicit aim of the COMET Initiative should be to prepare guidance on the reporting of COS]