Core Outcome Measures in Effectiveness Trials

www.comet-initiative.org
Core outcome set

• An agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care
COMET Initiative

• To raise awareness of current problems with outcomes in clinical trials
• To encourage COS development and uptake
• To provide resources to facilitate this - COMET database, guidance, software, workshops, annual international meetings
• To encourage evidence-based COS development
COMET - looking back

- Liverpool 2010
- Bristol 2011
- Manchester 2013
- Rome 2014
Choosing Important Health Outcomes for Comparative Effectiveness Research: A Systematic Review

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Abstract

Background: A core outcome set (COS) is a standardised set of outcomes which should be measured and reported, as a minimum, in all effectiveness trials for a specific health area. This will allow results of studies to be compared, contrasted and combined as appropriate, as well as ensuring that all trials contribute usable information. The COMET (Core Outcome Measures for Effectiveness Trials) Initiative aims to support the development, reporting and adoption of COS. Central to this is a publically accessible online resource, populated with all available COS. The aim of the review we report here was to identify studies that sought to determine which outcomes or domains to measure in all clinical trials in a specific condition and to describe the methodological techniques used in these studies.

Methods: We developed a multi-faceted search strategy for electronic databases (MEDLINE, SCOPUS, and Cochrane Methodology Register). We included studies that sought to determine which outcomes/domains to measure in all clinical trials in a specific condition.

Results: A total of 250 reports relating to 198 studies were judged eligible for inclusion in the review. Studies covered various areas of health, most commonly cancer, rheumatology, neurology, heart and circulation, and dentistry and oral health. A variety of methods have been used to develop COS, including semi-structured discussion, unstructured group discussion, the Delphi Technique, Consensus Development Conference, surveys and Nominal Group Technique. The most common groups involved were clinical experts and non-clinical research experts. Thirty-one (16%) studies reported that the public had been involved in the process. The geographic locations of participants were predominantly North America (n = 164; 83%) and Europe (n = 150; 76%).

Conclusions: This systematic review identified many health areas where a COS has been developed, but also highlights important gaps. It is a further step towards a comprehensive, up-to-date database of COS. In addition, it shows the need for methodological guidance, including how to engage key stakeholder groups, particularly members of the public.

Year of publication

![Bar chart showing the number of studies by year from 1981 to 2013. The x-axis represents the year, and the y-axis represents the number of studies. The chart shows a significant increase in the number of studies from 2006 onwards.](image-url)
Website

REGISTRATION FOR THE COMET IV MEETING IS NOW OPEN
Click here for further details and registration

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative brings together people interested in the development and application of agreed standardised sets of outcomes, known as 'core outcome sets'. These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition, and are also suitable for use in clinical audit or research other than randomised trials. The existence or use of a core outcome set does not imply that outcomes in a particular trial should be restricted to those in the relevant core outcome set. Rather, there is an expectation that the core outcomes will be collected and reported, making it easier for the results of trials to be compared, contrasted and combined as appropriate; while researchers continue to explore other outcomes as well. COMET aims to collate and stimulate relevant resources; both applied and methodological; to facilitate exchange of ideas and information, and to foster methodological research in this area.

When searching the COMET database, please note that a systematic review is currently underway to identify eligible material, and we are continually updating the database as we identify eligible studies. Therefore, the records retrieved by any search might increase on a daily basis.

Search COMET database

The COMET database currently contains 552 references of planned, ongoing and completed work.

Enter Keyword

The keyword used for the search will be compared with study titles, abstract and author’s surname.

View full search options

Core resource pack

Useful references for core outcome set developers.

This includes an overview of the problems with outcomes in trials; key issues to consider in the development of a core outcome set; examples of core outcome set development, and things to think about once a COS is agreed. To read more, click here.

Latest News

Tuesday 29 October, 2014 - Relevant funding opportunity for a UK-based clinician

The British Medical Association (BMA) awards research grants each year (totaling approximately £500,000) to encourage and further medical research in a variety of areas. One of these grants, the Barrett Harper Fund, supports research into improving the development or implementation of clinical outcome measures, including qualitative measures. Applications are invited from BMA members and can be for either research in progress or prospective research. For any further information on the BMA Research Grants please see www.bma.org.uk/researchgrants

Tuesday 02 September, 2014 - Nature Medicine News

Group seeks standardization for what clinical trials must measure - read the full news
International interest

- Since launch of database on website in August 2011:
  21491 visitors, 6137 searches, 141 countries

- COMET IV: Austria, Canada, Denmark, France, Germany, Ireland, Italy, Netherlands, Poland, Portugal, Romania, Switzerland, UK, US
Developing core outcome sets for clinical trials: issues to consider

Paula R Williamson *, Douglas G Altman, Jane M Blazeby, Mike Clarke, Declan Devane, Elizabeth Gargon and Peter Tugwell

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Scope
- Identifying existing knowledge
- Stakeholder involvement
- Consensus methods
- Achieving global consensus
- Regular review, feedback, updating
- Implementation
- Clear presentation
PPI in COS

• Published COS (n=198)
  - 16% involved either patients, carers, patient support group representatives, service users
  - Represented 4% to 100% of all participants

• Ongoing COS (n=49)
  - 90% involve either patients, carers, patient support group representatives, service users

• Patient and Public Involvement Working Group
## Frequency of methods

<table>
<thead>
<tr>
<th>Main methods</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semi-structured group discussion</td>
<td>106</td>
</tr>
<tr>
<td>- <strong>Meeting</strong> <em>(descriptions include meeting, colloquium, conference where not</em></td>
<td>60</td>
</tr>
<tr>
<td><em>described as consensus development conference)</em></td>
<td></td>
</tr>
<tr>
<td>- <strong>Workshop</strong></td>
<td>41</td>
</tr>
<tr>
<td>- <strong>Round table discussion</strong></td>
<td>5</td>
</tr>
<tr>
<td>Literature/systematic review</td>
<td>63</td>
</tr>
<tr>
<td>Delphi</td>
<td>29</td>
</tr>
<tr>
<td>Consensus development conference</td>
<td>18</td>
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<tr>
<td>Survey</td>
<td>17</td>
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<tr>
<td>NGT</td>
<td>15</td>
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<tr>
<td>Focus group</td>
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<tr>
<td>Interviews</td>
<td>1</td>
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<tr>
<td>No methods described</td>
<td>20</td>
</tr>
<tr>
<td>Unstructured group discussion</td>
<td>19</td>
</tr>
</tbody>
</table>

*Descriptions include task force, work group, working group/party, committee, board, panel*
Results – improvements over time

Studies reporting full RA COS (%)

Mean number of clinical outcomes

- Drug studies
- Non-drug studies

- WHO/ILAR RA COS guideline
- EMA guideline
- FDA guideline

- 1985
- 1990
- 1995
- 2000
- 2005
- 2010

- 100
- 80
- 60
- 40
- 20
- 0

- 7.0
- 6.5
- 6.0
- 5.5
- 0.0

Mean number of clinical outcomes
SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials

An-Wen Chan,1 Jennifer M Tetzlaff,2 Peter C Götzsche,3 Douglas G Altman,4 Howard Mann,5 Jesse A Berlin,6 Kay Dickersin,7 Asbjørn Hróbjartsson,3 Kenneth F Schulz,8 Wendy R Parulekar,9 Karmela Krleža-Jeric,10 Andreas Laupacis,11 David Moher10

High quality protocols facilitate proper conduct, reporting, and external review of clinical trials. However, the completeness of trial protocols is often inadequate. To help improve the content and quality of protocols, an international group of stakeholders developed the SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Interventional Trials). The SPIRIT Statement provides guidance in the form of a checklist of recommended items to include in a clinical trial protocol.
Endorsement and uptake

• Trial funders: NIHR HTA, ARUK, AMRC, HRB (Ireland)

• ‘Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established.’

• Review sent in Sep to 245 funders in 31 countries - to be followed up
Promotion

• US meeting, Baltimore, April 2014

• Nature Medicine, August 2014

• New projects started since COMET III:
  - 37 ongoing, 1 in planning stage (database)
  - 16 where people have registered interest, submitted funding applications, etc
COMET - going forwards

- Maintain and keep the database up to date
- Reporting guideline
- Quality assessment tool
- COMET Strategic Plan – consultation
- Implementation plans
- Methods to monitor uptake
COMET IV Programme

- Survey of COS developers
- Survey of outcomes used in Cochrane reviews
- Network meetings to develop capacity to support activity
- Guidance on how to select a measurement tool

- Recently developed core outcome sets
- **Contributed posters**
- Patient engagement
- Stakeholder perspectives

- Methods workshops
Wednesday 20th and Thursday 21st May 2015

We are pleased to announce the 5th Meeting of the COMET Initiative

University of Calgary,
Alberta, Canada