Core Outcome Measures in Effectiveness Trials

www.comet-initiative.org

Twitter: @COMETinitiative
Twitter statement

• Speakers will indicate if they do not wish for their talk/photo to be tweeted
• When quoting speakers use their Twitter username
• Please ask poster authors before taking photos of their work and putting on Twitter
• Use the official hashtag #COMETVII
Personal statement

• **Conflict of interest:** I chair the COMET Management Group

• **Funding sources for COMET:** MRC, European Commission, NIHR
COMET Initiative

• To raise awareness of current problems with outcomes in clinical trials
• To encourage COS development and uptake
• To promote patient and public involvement in COS development
• To provide resources to facilitate this
• To avoid unnecessary duplication of effort
• To encourage evidence-based COS development
The COMET Handbook: version 1.0

Paula R. Williamson¹, Douglas G. Altman², Heather Bagley¹, Karen L. Barnes¹, Jane M. Blazey³, Sara T. Brookes³, Mike Clarke⁴, Liz Gargon¹, Sarah Gorst¹, Nicola Harman¹, Jamie J. Kirkham¹, Angus McNair³, Cecilia A. C. Prinsen⁶, Jochen Schmitt⁷, Caroline B. Terwee⁵ and Bridget Young³
How would you decide whether a relevant COS was of sufficient quality COS?
How would you decide whether a relevant COS was of sufficient quality COS?
How would you decide whether a relevant COS was of sufficient quality COS?
“Doctors know about the illness, but patients know about the impact”
## COS outcomes (not involving patients)

<table>
<thead>
<tr>
<th>Domain</th>
<th>n (% of 234)</th>
<th>Domain</th>
<th>n (% of 234)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality/survival</td>
<td>82 (35)</td>
<td>Perceived health status</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Physiological/clinical (≥1)</td>
<td>213 (91)</td>
<td>Delivery of care</td>
<td>43 (18)</td>
</tr>
<tr>
<td>Functioning (≥1)</td>
<td>84 (36)</td>
<td>Personal circumstances</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Physical</td>
<td>70 (30)</td>
<td>Resource use (≥1)</td>
<td>67 (29)</td>
</tr>
<tr>
<td>Social</td>
<td>14 (6)</td>
<td>Economic</td>
<td>33 (14)</td>
</tr>
<tr>
<td>Role</td>
<td>10 (4)</td>
<td>Hospital</td>
<td>16 (7)</td>
</tr>
<tr>
<td>Emotional/wellbeing</td>
<td>19 (8)</td>
<td>Need for intervention</td>
<td>34 (15)</td>
</tr>
<tr>
<td>Cognitive</td>
<td>13 (6)</td>
<td>Societal/carer burden</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Global quality of life</td>
<td>90 (38)</td>
<td>Adverse events/effects</td>
<td>82 (35)</td>
</tr>
<tr>
<td>Life impact</td>
<td>126 (54)</td>
<td></td>
<td></td>
</tr>
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</table>
## COS outcomes (involving patients)

<table>
<thead>
<tr>
<th>Domain</th>
<th>n (% of 65)</th>
<th>Domain</th>
<th>n (% of 65)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality/survival</td>
<td>17 (26)</td>
<td>Perceived health status</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Physiological/clinical (≥1)</td>
<td>61 (94)</td>
<td>Delivery of care</td>
<td>10 (15)</td>
</tr>
<tr>
<td>Functioning (≥1)</td>
<td>44 (68)</td>
<td>Personal circumstances</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Physical</td>
<td>41 (63)</td>
<td>Resource use (≥1)</td>
<td>17 (26)</td>
</tr>
<tr>
<td>Social</td>
<td>11 (17)</td>
<td>Economic</td>
<td>4 (6)</td>
</tr>
<tr>
<td>Role</td>
<td>1 (2)</td>
<td>Hospital</td>
<td>8 (12)</td>
</tr>
<tr>
<td>Emotional/wellbeing</td>
<td>10 (15)</td>
<td>Need for intervention</td>
<td>11 (17)</td>
</tr>
<tr>
<td>Cognitive</td>
<td>8 (12)</td>
<td>Societal/carer burden</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Global quality of life</td>
<td>31 (48)</td>
<td>Adverse events/effects</td>
<td>23 (35)</td>
</tr>
<tr>
<td>Life impact</td>
<td>51 (78)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Developments

• 64% ‘what’, 36% ‘what and how’

• Early phase: devices, pre-clinical

• COS for clinical practice:
  - for research: n=270 studies (88%)
  - for research and practice: n=37 studies (12%)
  - ongoing studies: 46% for research and practice
Improvements over time (Kirkham et al, *BMJ 2017*)

Studies measuring full RA COS (%)

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

Drug studies

Years:
- 1985
- 1990
- 1995
- 2000
- 2005
- 2010
- 2015

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

BMJ 2017;357:j2262
COS Uptake and Endorsement

It is important to assess the uptake and use of COS in clinical trials, and other research, in order to avoid the development of these COS contributing to the research waste which their development aims to reduce. Assessing uptake can also highlight the benefits of measuring and reporting COS in trials while allowing review and feedback to ensure ongoing relevance, and removal of barriers and facilitators to uptake.

The following organisations actively endorse the use of COS and the COMET database.

**Trialists**

- SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials

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**Trial Funders**

- National Institute for Health Research (NIHR), UK: Guidance Notes For Completing Full Proposals
- Horizon2020:
- Deutsche Forschungsgemeinschaft (DFG) German Research Foundation
- Proposal Preparation Instructions: Clinical Trials Programme – Draft Proposals
- Proposal Preparation Instructions: Clinical Trials Programme – Full Proposals
- Arthritis Research UK (ARUK)
- Health Research Board (HRB)

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**Trial Registries**

- ISRCTN

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**Regulatory Authorities**

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Podcasts

This collection of Podcasts highlights the importance of the development and use of COS to people from a range of different backgrounds.

“This whole idea of COS is taking on a new role, a new importance…”

Hans-Georg Eichler (Senior Medical Officer, European Medicines Agency). October 2018.

“I believe that the development and use of core outcome sets is one of the most important advances to date in evidence-based medicine and surgery.”

Hywel Williams (Director of the NIHR Health Technology Assessment Programme, Professor of Dermato-Epidemiology and Co-Director of the Centre of Evidence-Based Dermatology). April 2018.
Implementing core outcomes in kidney disease: report of the Standardized Outcomes in Nephrology (SONG) implementation workshop

Allison Tong¹,², Braden Manns³,⁴, Angela Yee Moon Wang⁵, Brenda Hemmelgarn³,⁴, David C. Wheeler⁶, John Gill⁷, Peter Tugwell⁸, Robert Pecoits-Filho⁹, Sally Crowe¹⁰, Tess Harris¹¹, Wim Van Biesen¹², Wolfgang C. Winkelmayer¹³, Adeera Levin⁷, Aliza Thompson¹⁴, Vlado Perkovic¹⁵, Angela Ju¹,², Talia Gutman¹,², Amelie Bernier-Jean¹,², Andrea K. Viecelli¹⁶,¹⁷, Emma O’Lone¹,², Jenny Shen¹⁸, Michelle A. Josephson¹⁹, Yeoungjee Cho¹⁶,¹⁷, David W. Johnson¹⁶,¹⁷, Bénédicte Sautenet²⁰, Marcello Tonelli³,⁴ and Jonathan C. Craig²¹; for the SONG Implementation Workshop Investigators²¹
COMET VII

- Patient participation and involvement
- How to influence COS uptake
- Global COS initiatives
- Methods - ‘what’, ‘how’, patient inclusion
  - workshops
  - contributed talks
  - posters

Save the date
We are pleased to announce the 7th Meeting of the COMET Initiative
Thursday 15th and Friday 16th November 2018
Rode Hoed, Amsterdam
More details and registration to follow
Drop in sessions

DelphiManager: Q&A drop in session

Registration desk

Day 1: 15.15-15.45 Break time
Day 2: 14.30-15.00 Break time

Including patients in COS development: Q&A drop in session

Zwanenzaal

Day 2: 12.30-13.00 Lunch