Core Outcome Measures in Effectiveness Trials

www.comet-initiative.org
Acknowledgements

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International Advisory Group

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• Dr Irmgard Eichler (EMA)
• Professor David Flum (PCORI)
• Dr Piero Olliaro (WHO)
• Dr Sean Tunis (CMTP)
• Ms Liz Whamond (Cochrane)
DMARD trials for rheumatoid arthritis

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Health care research is untidy

• It needs to be tidied up if it is to achieve its aim of helping practitioners and patients to improve health care and health

• This needs initiatives such as the Cochrane Collaboration and Green Park Collaborative

• And COMET .....
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
Scope of a COS

• “The specific area of health or healthcare that the COS is to apply to, in terms of health condition, population and types of interventions needs to be determined.”

• All stages or severity of a specific health condition or focussed on a particular disease category
  - e.g. in colorectal cancer, a COS might be developed for all patients or it may focus on patients with metastatic disease

• All treatment types or for a particular intervention
  - e.g. in morbid obesity, a COS may be created to use in trials of all interventions or just bariatric surgery alone
Commentary

OMERACT: An international initiative to improve outcome measurement in rheumatology
Peter Tugwell*1, Maarten Boers2, Peter Brooks3, Lee Simon4, Vibeke Strand5 and Leanne Idzerda6

• www.omeract.org
• Trials 2007 8:38
Improvements over time (Kirkham et al, *Trials* 2013)

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Studies reporting full RA COS (%)

Mean number of clinical outcomes
The COMET Initiative

• To raise awareness of current problems with outcomes in clinical trials
• To encourage COS development and uptake
• To provide resources to allow practitioners to develop COS, e.g. COMET database, guidance

• An international network of trialists, systematic reviewers, health service users, practitioners, editors, funders, policy makers, regulators
COMET Initiative

• ‘What’ to measure

• ‘How’ to measure (validity, reliability, feasibility)
  - COSMIN
  - PROMIS
  - PROQOLID
  - TREAT-NMD ROM
Welcome to the COMET Initiative website

The COMET initiative brings together researchers interested in the development and application of agreed standardised sets of outcomes, known as a 'core outcome set'. These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition. They do not imply that outcomes in a particular trial should be restricted to those in the core outcome set. Rather, there is an expectation that the core outcomes will be collected and reported to allow the results of trials to be compared, contrasted and combined as appropriate, and that researchers will continue to explore other outcomes as well. COMET aims to collate and disseminate relevant resources, both applied and methodological, as well as facilitating exchange of ideas and information, and fostering methodological research in this area.

Search COMET database

The COMET database currently contains 38 references of planned, ongoing and completed work.

Enter Keyword [Search]

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

View full search options

BMJ Blogs

We maintain a BMJ blog about COMET activities and outputs. Our most recent blog is shown below:

Core outcomes for surgical procedures Notable Bancroft and Jane Brassley 1 June, 2011

View at COMET BMJ blog

Help, I want to...

- Search COMET
- Send general feedback/enquiry
- Register a new project/study
- Report a missing study

Upcoming events

- Two day meeting 11-12 July, 2011 Ashton Court Mansion, Bristol, UK
- Visit conference website
- Clinical Trials Methodology Conference, 4-5 October, 2011, Bristol Mammot City Centre, Bristol, UK
- Visit conference website
- 18th Cochrane Colloquium, 19-22 October, 2011 - Palacio de Congresos de Madrid, Madrid, Spain
- Visit workshop website

Latest News

- Thursday 16 June, 2011: COMET website launched

Today we launch our searchable COMET website database, please leave your feedback and suggestions.

Recently Added Studies

- Proposal for standardized definitions for efficacy endpoints in adjuvant breast cancer trials: the STEEP system
- View details

- Development of a common outcome data set for fall injury prevention trials: the Prevention of Falls Network Europe consensus
- View details
A Systematic Review of Studies That Aim to Determine Which Outcomes to Measure in Clinical Trials in Children

Ian Sinha¹, Leanne Jones¹, Rosalind L. Smyth¹, Paula R. Williamson²

1 Institute of Child Health, University of Liverpool, Liverpool, United Kingdom, 2 Centre for Medical Statistics and Health Evaluation, University of Liverpool, Liverpool, United Kingdom

Background

In clinical trials the selection of appropriate outcomes is crucial to the assessment of whether one intervention is better than another. Selection of inappropriate outcomes can compromise the utility of a trial. However, the process of selecting the most suitable outcomes to include can be complex. Our aim was to systematically review studies that address the process of selecting outcomes or outcome domains to measure in clinical trials in children.

Methods and Findings

We searched Cochrane databases (no date restrictions) in December 2006; and MEDLINE (1950 to 2006), CINAHL (1982 to 2006), and SCOPUS (1966 to 2006) in January 2007 for studies of the selection of outcomes for use in clinical trials in children. We also asked a group of experts in paediatric clinical research to refer us to any other relevant studies. From these articles we extracted data on the clinical condition of interest, description of the method used to select outcomes, the people involved in the selection process, the outcomes selected, and limitations of the method as defined by the authors. The literature search identified 8,889 potentially relevant abstracts. Of these, 70 were retrieved, and 25 were included in the review.
COMET Database

- Systematic review - 28,000+ abstracts
- 198 published COS
  - 62 explicitly for a particular intervention type (e.g. drugs, surgery, etc)
  - 35 explicitly involved patients or carers
  - 147 involved US/Canada

- Plus a further 50+ ongoing COS projects
- Other relevant articles
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

* Corresponding author: Paula R Williamson prw@liv.ac.uk


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

**MOMENT -- Management of Otitis Media with Effusion in Cleft Palate: protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey**

Nicola L Harman, Iain A Bruce, Peter Callery, Stephanie Tierney, Mohammad Owaise Sharif, Kevin O’Brien and Paula R Williamson

*Triage 2013, 14:70*  
doi:10.1186/1745-6215-14-70

**Accesses**

- **Last 30 days:** 167 accesses
- **Last 365 days:** 651 accesses
- **All time:** 651 accesses
Stakeholder involvement

• Health care practitioners
• Patients, carers, representatives
• Regulators
• Industry representatives
• Researchers

• Stage of involvement may vary by group
Patient and public involvement

• Impact of involvement
  – Rheumatology (OMERACT): fatigue
  – Chronic pain (IMMPACT): expansion of previously proposed core outcome domains
  – Multiple sclerosis: fatigue, continence
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.
Professor Hywel Williams, Chair of the NIHR HTA Commissioning Board: ‘Patients and professionals making decisions about health care need access to reliable evidence. The new COMET database will help researchers across the NIHR family and beyond when choosing the outcomes to include in the studies that will establish this evidence base’.
## Response to EMA consultation

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NICE clinical guidelines

• Selection of outcomes always been important
• GRADE since 2009 - assesses the quality of the evidence by outcome rather than study
• PICO framework for each clinical question
• Addition to methods within NICE to check the COMET database
• Project underway comparing published COS with outcomes in related NICE clinical guidelines
Journal endorsement

• **Core Outcomes in Women’s Health (CROWN)** - a consortium of 29 O&G journals to implement core outcome sets across the board, including AJOG, BJOG, Cochrane, etc

• Co-ordinating rapid peer-review of manuscripts describing core outcome sets and publishing these simultaneously across participating journals
Future work

• Maintain and keep the database up to date
• Quality assessment tool
• Methods for COS development
• Methods for engaging consumers - initial meeting of UK PPI organisations
• Methods to promote implementation
• Monitoring uptake
COMET and GPC

- GPC identifies priority clinical areas
- COMET searches database and non-database list (50+ ongoing projects)

- Existing COS: GPC appraisal

- Gap identified: GPC and COMET facilitate COS development