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

MRC Medical Research Council

European Commission

SEVENTH FRAMEWORK PROGRAMME

NHS National Institute for Health Research

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PLOS ONE

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.

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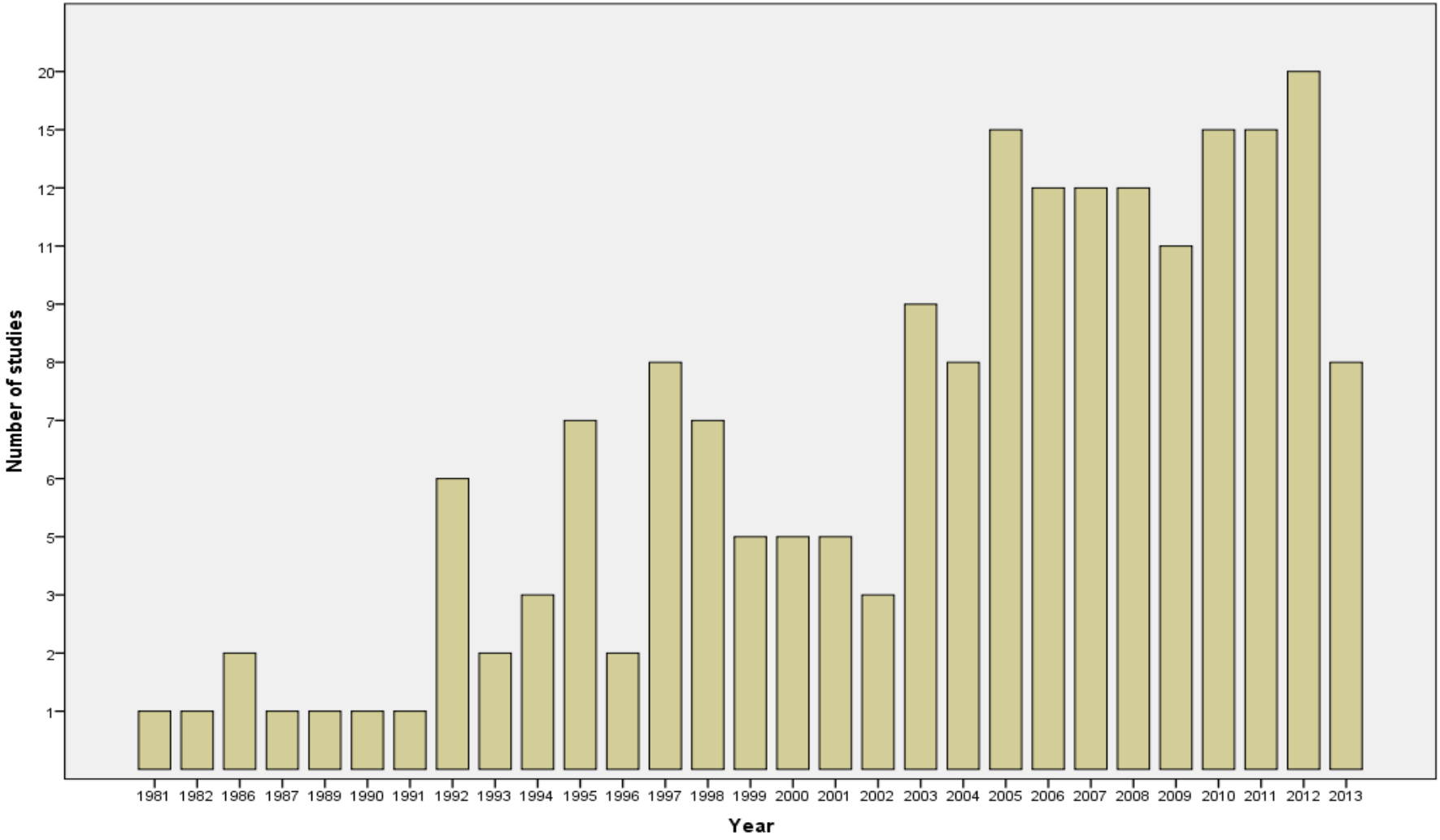
Year of publication



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COMET IV Meeting
Core Outcome Measures in Effectiveness Trials
REGISTRATION FOR THE COMET IV MEETING IS NOW OPEN
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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
Search
The keyword used for the search will be compared with study title, 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 28 October, 2014 - Relevant funding opportunity for a UK-based clinician
The British Medical Association (BMA) awards research grants each year (totalling approximately £500,000) to encourage and further medical research in a variety of areas. One of these grants, the Strutt & Harper, funds 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
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MRC Medical Research Council
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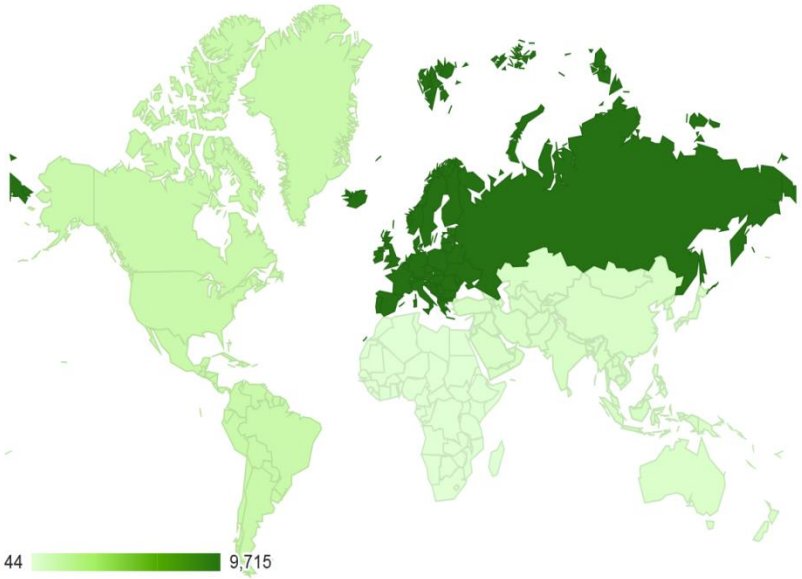
International interest

- 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



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Commentary

Highly accessed Open Access

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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Trials 2012, **13**:132 doi:10.1186/1745-6215-13-132

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)

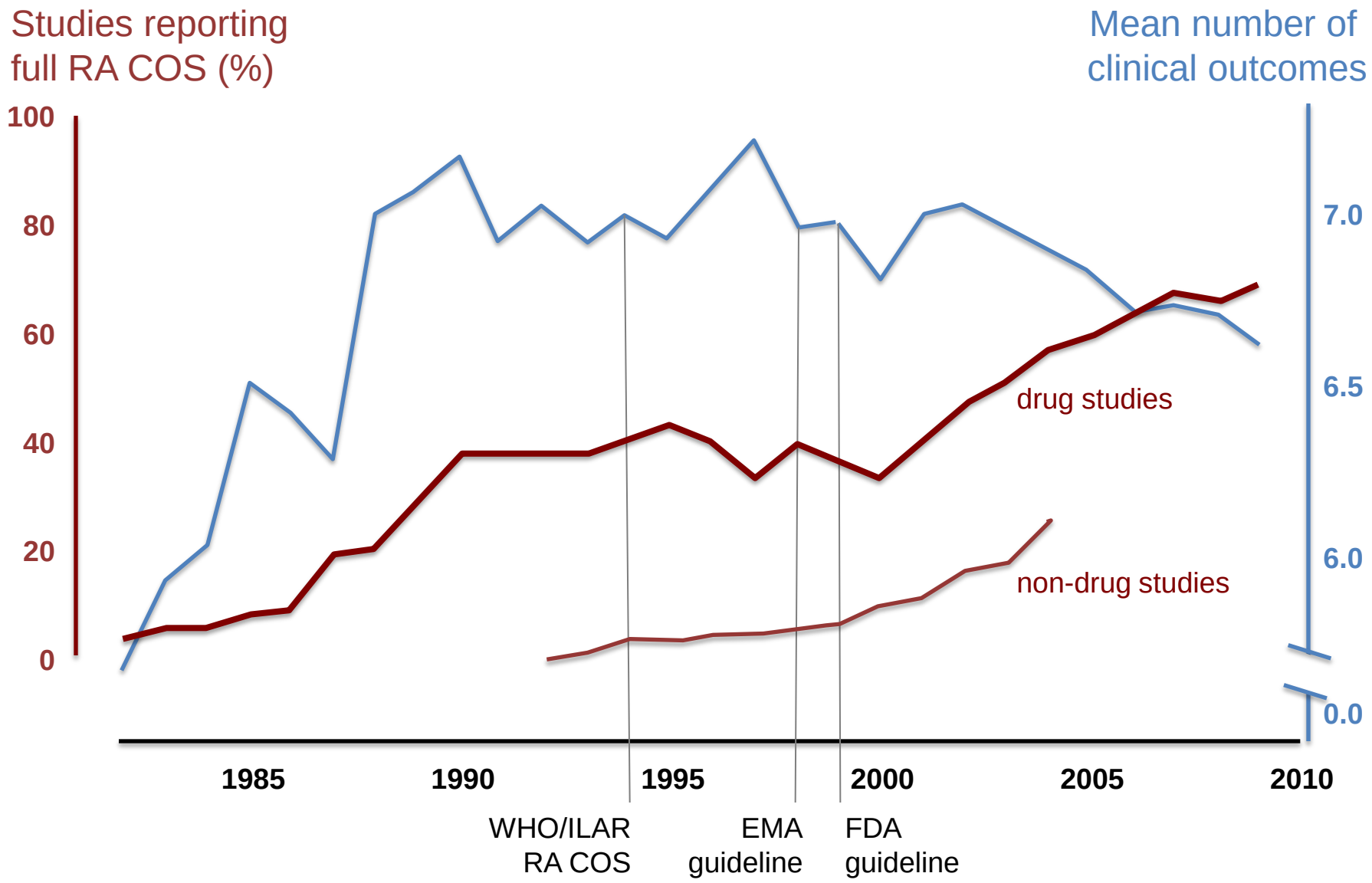
- 90% involve either patients, carers, patient support group representatives, service users

- Patient and Public Involvement Working Group

Frequency of methods

Main methods		n
Semi-structured group discussion		**106**
- *Meeting (descriptions include meeting, colloquium, conference where not described as consensus development conference)*	*60*	
- *Workshop*	*41*	
- *Round table discussion*	*5*	
Literature/systematic review		**63**
Delphi		**29**
Consensus development conference		**18**
Survey		**17**
NGT		**15**
Focus group		**3**
Interviews		**1**
No methods described		**20**
Unstructured group discussion *Descriptions include task force, work group, working group/party, committee, board, panel*		**19**

Results – improvements over time



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

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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

mittees/institutional review boards, regulatory agencies, medical journals, systematic reviewers, and other groups rely on protocols to appraise the conduct and reporting of clinical trials.

To meet the needs of these diverse stakeholders, protocols should adequately address key trial elements. However, protocols often lack information on important concepts relating to study design and dissemination plans.[2-12] Guidelines for writing protocols can help improve their completeness, but existing guidelines vary extensively in their content and have limitations, including non-systematic methods of development, limited stakeholder involvement, and lack of citation of empirical evidence to support their recommendations.[13] As a result, there is also variation in the precise definition and scope of a trial proto-

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

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