The importance of core outcome sets for practitioners, patients and researchers

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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 for systematic reviews and COMET for core outcome sets

What is a “core outcome set”?

- An agreed standardised set of the most important (“core”) outcomes
- Disease/condition specific (might cover all treatment types or a particular intervention)
- Both benefits and harms
- Measured and reported as the minimum (other outcomes will usually be collected)
- Relevant to routine clinical practice

Why have core outcome sets?

- Several tens of thousands of research studies are underway
- 500+ clinical trials are published every week
- Working through this evidence is overwhelming
- It is made worse by studies of the same topic describing their findings in different ways
- Systematic reviews might help but the authors of each review need to bring together and make sense of a variety of studies, using a variety of outcomes, measured in a variety of ways
- And, the reviewers need to choose outcomes that the readers want to see
- **We need to be able to compare, contrast and combine research to improve health care and improve health**

Cancer trials

- 1977: World Health Organisation convened a meeting to discuss “Standardization of Reporting Results of Cancer Treatment”, Turin
- 1979: meeting of 30 representatives from international cooperative groups working on trials in cancer, Brussels
- 1979: WHO Handbook for Reporting Results of Cancer Treatment

Reporting Results of Cancer Treatment

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On the initiative of the World Health Organization, two meetings on the Standardization of Reporting Results of Cancer Treatment have been held with representatives and members of several organizations. Recommendations have been developed for standardized approaches to the recording of baseline data relating to the patient, the tumor, laboratory and radiologic data, the reporting of treatment, grading of acute and subacute toxicity, reporting of response, recurrence and disease-free interval, and reporting results of therapy. These recommendations, already endorsed by a number of organizations, are proposed for international acceptance and use to make it possible for investigators to compare validly their results with those of others.

Cancer **47:207–214, 1981.**

ADVANCES IN CANCER THERAPY are made by continual investigation and evaluation of treatment results and their incorporation in the practice of oncology. This requires comparisons between results and necessitates the availability of appropriate data in a suitable form. Thus, standardization of assessment and of reporting of results is an important step that aims at increasing the amount of usable therapeutic information at the disposal of the physician. It has, therefore, become necessary to develop a "common language" to describe the results of cancer treatment and to agree upon internationally acceptable general principles for reporting and assessing data.

On the initiative of the World Health Organization, two meetings on the Standardization of Reporting Results of Cancer Treatment have been held in Turin, 1977 and in Brussels, 1979 with representatives of the European Organization for Research on Treatment of Cancer, the National Cancer Institute USA, the International Union Against Cancer, the Council for Mutual Economic Aid (COMECON), as well as members of several other organizations (ECOG, MRC, SAKC, SWOG, VA). This report is a summary of the conclusions and recommendations resulting from these combined efforts. A WHO technical report has been published in handbook form by the World Health

* Writing Committee Representing the Participants at the Meetings on Standardization of Reporting of Results of Cancer Treatment, Turin 1977 and Brussels 1979.

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Items

- Acute toxicity
- Chronic or late toxicity
- Partial response (>50% decrease in tumour load)
- Complete response (100% disappearance)
- Date of first recurrence
- Date of death

Miller et al (1981) “These recommendations, already endorsed by a number of organizations, are proposed for international acceptance and use to make it possible for investigators to compare validly their results with those of others.”

More recent examples

- OMERACT (rheumatoid arthritis)
- IMMPACT (pain)
- Paediatric asthma
- Maternity care

- Why do we need initiatives such as these?
- What’s the problem?

"The studies … varied greatly in intervention design, outcome measurements and methodological quality." *(Preventing childhood obesity)*

"Appropriate short- and long-term outcomes need to be defined for children and youth at various weight levels, rather than using conventional or adult-oriented outcomes." *(Treating childhood obesity)*

"The studies were heterogeneous in terms of study design, quality, target population, theoretical underpinning, and outcome measures, making it impossible to combine study findings using statistical methods.."

(Promoting activity in children)

"No study reported relevant data on diabetes and cardiovascular related morbidity, mortality and quality of life.." *(Preventing Type 2 DM)*

"We sought data for rate of falls, number of people falling, and number of people sustaining a fracture. However, few studies provided fracture data."

(Preventing falls in the elderly)

"Definitions of abstinence varied considerably ... In five studies it was unclear exactly how abstinence was defined." *(Nicotine replacement therapy)*

Crohn's disease

“It might therefore be useful to standardise the outcome measures that need to be reported in future randomised trials and reviews.”

HIV/AIDS

“Using outcome measures that are common across clinical trials may permit fair comparison of various interventions in different populations, and future studies should consider using outcomes based on a common set of standardized outcome measures.”

Dementia

“Given the heterogeneity of study designs, inclusion criteria, and the variety of outcome measures employed in studies of interventions for agitation and psychosis in dementia, utilization of standardized outcome measures and inclusion criteria would facilitate comparisons of outcomes across studies and future meta-analyses.”

Schizophrenia trials

- In the 1990s, Thornley and Adams identified 2000 trials in schizophrenia
- Assessing more than 600 different interventions
- Using 640 rating scales
- In a review of chlorpromazine, they concluded “if rating scales are to be employed, a concerted effort should be made to agree on which measures are the most useful. Studies within this review reported on so many scales that, even if results had not been poorly reported, they would have been difficult to synthesise in a clinically meaningful way.”

Psychiatric symptoms (194 scales in 1250 trials)

- Brief psychiatric rating scale (800 trials)
- Scale for assessment of negative symptoms (113)
- Inpatient multidimensional psychiatric rating scale (68)
- Positive and negative syndrome scale (67)

Cognitive functioning (97 scales in 141 trials)

- Wechsler adult intelligence scale (24 trials)
- Digit symbol test (18)
- Continuous performance task (14)
- Wechsler memory scale (13)

Behaviour (80 scales in 367 trials)

Side effects (67 scales in 431 trials)

Social functioning (66 scales in 127 trials)

Neurological and psychomotor functioning (41 scales in 92 trials)

Global measures (20 scales in 392 trials)

Thornley B, Adams C. BMJ 1998.

Example from outside health

Choosing a route to the train station

1: “2 miles” 2: “25 minutes” 3: “very pretty”	1: “2 miles” 2: “4 kilometres” 3: “not too far”	1: Walking 2: In a taxi 3: On a Vespa

What would you prefer to have been measured?

Distance, time or beauty?

Systematic review of evidence on selective outcome reporting

- Studies reporting positive or significant results are more likely to be published
- Outcomes that are statistically significant are more likely to be fully reported
- 40–62% of publications had at least one primary outcome changed, newly introduced or omitted compared to the protocol

Dwan et al. PLoS ONE 2008.

Advantages of core outcome sets

- Increase consistency across trials
- Maximise potential for a trial to contribute to a systematic review of these key outcomes
- Appropriate outcomes more likely to be measured
- Reduction in selective reporting

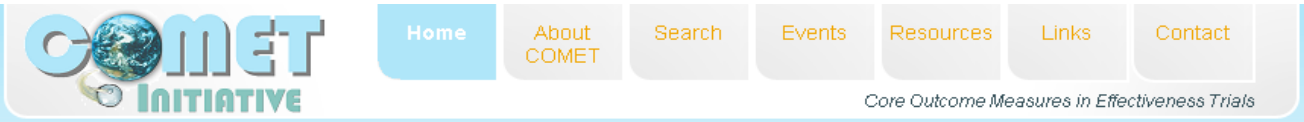
Core Outcome Measures in Effectiveness Trials

http://www.comet-initiative.org/home/

COMET Initiative

- Facilitate and promote development and application of core outcome sets. Has already identified work on core outcome sets in over 70 health-related areas
- Liverpool, UK, January 2010
- Bristol, UK, July 2011
- Trialists, systematic reviewers, health service users, clinical teams, journal editors, trial funders, policy makers, regulators
- International initiative

Website



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 stimulate 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 title, 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
Natalie Blencowe and Jane Blazeby
1 June, 2011

View all COMET BMJ blogs

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 end points 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]

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 Marriott City Centre, Bristol, UK

  Visit conference website

- 19th Cochrane Colloquium, 19-22 October, 2011 - Palacio de Congresos de Madrid, Madrid, Spain

  Visit workshop website

Search results

COMET Initiative

Home | About COMET | Search | Events | Resources | Links | Contact

Core Outcome Measures in Effectiveness Trials

Search results

Found **4** matching studies

Submit search results enquiry

	Study Title	Year	Disease Category	Disease Name	View
☑	Developing a core outcome set for childhood asthma *Supervisors: Professors Paula Williamson...*	Unpublished	Child health Lungs & airways	Asthma	
☑	Outcomes in clinical trials of inhaled corticosteroids for children with asthma are narrowly focussed on short term disease activity *Sinha, I. P. Williamson, P. R. Smyth, R....*	2009	Child health Lungs & airways	Asthma	
☑	An official American Thoracic Society/European Respiratory Society statement: asthma control and exacerbations: standardizing endpoints for clinical asthma trials and clinical practice *Reddel, Helen K. Taylor, D. Robin Batema...*	2009	Child health Lungs & airways	Asthma	
☑	The asthma health outcome indicators study *Smith, M. A. Leeder, S. R. Jalaludin, B....*	1996	Lungs & airways	Asthma	

Download Selected Results as CSV

Need to store or share a link to these results, please use the url below:

http://www.comet-initiative.org/studies/searchresults?guid=ce9d58f9-422c-41bc-ae99-b3

Current search criteria

Shown below is a summary of the search criteria used in your most recent search.

Click the "x" icon to remove a search criteria.

- Target Population - Age (17 matches)
  - Minimum age of population: 0 (17 matches)
  - Maximum age of population: 18 (17 matches)
- Health Area - Disease Name (4 matches)
  - Asthma (4 matches)

4 matching studies found

Modify criteria

W3C XHTML 1.0

Next steps

- ‘What’ to measure
- Guidance on methods for developing core outcome sets, including patient involvement
- Reporting standards

- ‘How’ to measure (validity, reliability, feasibility)
  - PROMIS
  - COSMIN
  - TREAT-NMD
  - Musculoskeletal
  - Paediatrics

Development of core outcome sets: Issues to consider

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

Core outcome sets can help …

- Identify the primary outcome for sample size calculation in a trial
- Describe power for other core outcomes, if they achieve this sample size
- Standardization within multicenter trials
- Comparisons between trials
- Meta-analyses of similar studies
- Reduce the possibility of biased reporting
- Users of the results of trials would be cautious of any trials that do not report the core outcomes
- **Compare, contrast and combine research to improve health care and improve health**

Conclusions

- Core sets of outcomes should be used routinely by researchers
- But, they should not stifle the development and use of other outcomes
- Researchers wishing to use additional outcome measures should continue to do so
- But, selective reporting should be avoided by presenting the findings for the core set and all additional outcome measures collected

- Core sets should not be restricted to research studies. They are also relevant within routine practice

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 for systematic reviews and COMET for core outcome sets

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