Core Outcome Measures in Effectiveness Trials

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Acknowledgements

- COMET Management Group:

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- COMET project coordinator:

  Elizabeth Gargon

- International collaborators and ambassadors – too numerous to list but thanks to them all!

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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 definition

Scope of a COS

- Health condition, population and types of intervention
- e.g. in colorectal cancer, a COS might be developed for all patients or it may focus on patients with metastatic disease
- e.g. in morbid obesity, a COS may be created to use in trials of all interventions or just bariatric surgery alone

- Research or practice setting

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

COMET - looking back

- Liverpool 2010
- Bristol 2011
- Manchester 2013
- Rome 2014

COMET Resources

- COMET database
- Advice – design, funding applications, public and patient involvement
- Methodological guidance
- Reporting guidance
- E-Delphi software
- Training and research workshops
- Annual international meetings
- Downloadable slide set

Website

REGISTRATION FOR THE COMET V 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 **578** 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.

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.

COS have been used rarely in Cochrane Reviews, but the introduction of SoF makes the development and application of COS timelier than ever. To explore these issues as part of our work within COMET, we have performed a survey of Cochrane Reviews to identify the variety of outcome measures used in them. Read the full paper here.

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- Report a missing study
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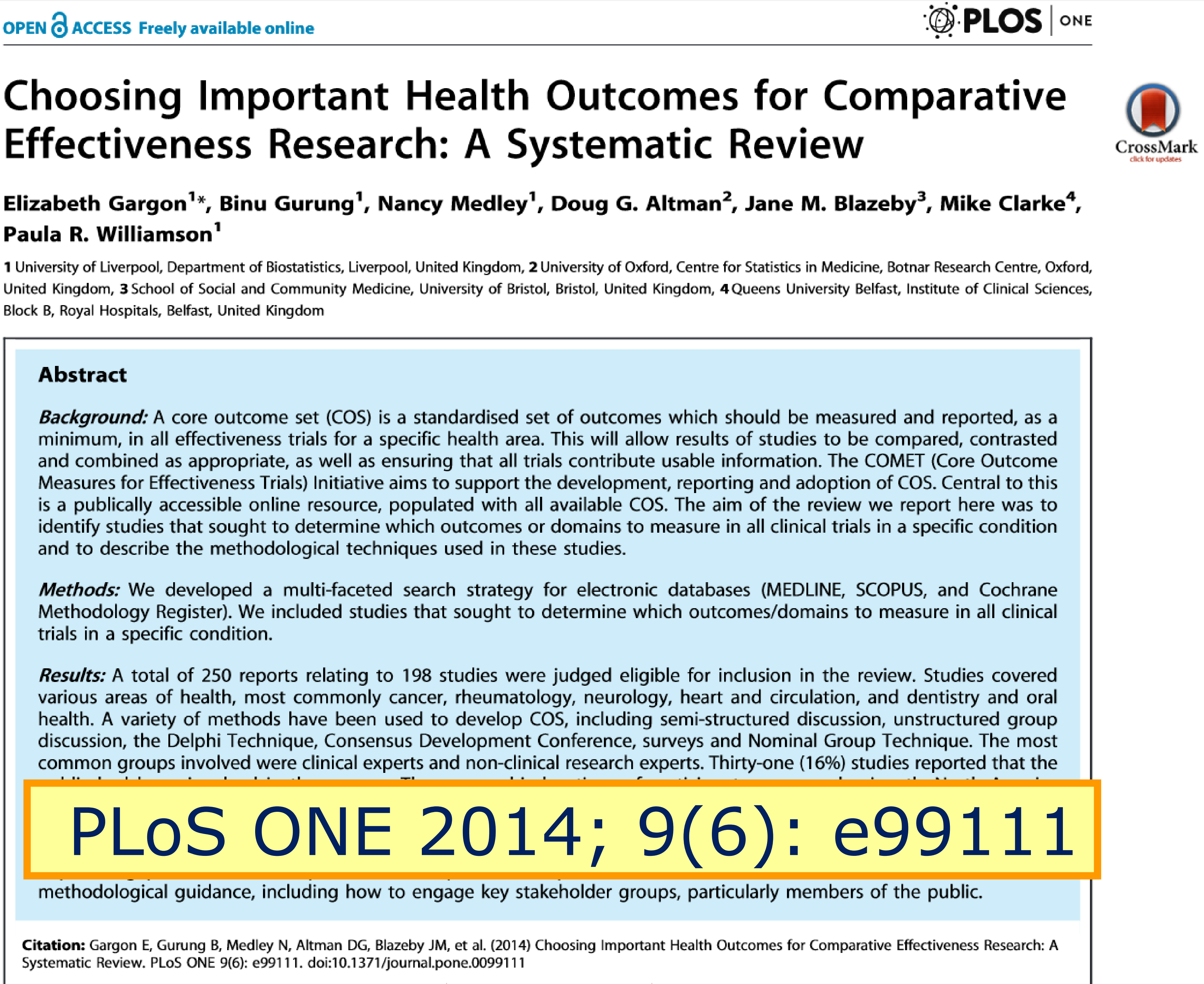

OPEN ACCESS Freely available online

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

methodological guidance, including how to engage key stakeholder groups, particularly members of the public.

PLoS ONE 2014; 9(6): e99111

Citation: Gargon E, Gurung B, Medley N, Altman DG, Blazeby JM, et al. (2014) Choosing Important Health Outcomes for Comparative Effectiveness Research: A Systematic Review. PLoS ONE 9(6): e99111. doi:10.1371/journal.pone.0099111

COMET database

- Includes 357 papers relating to 303 COS
- Of which, 71 are ongoing

- Also, 128 reviews of outcomes in trials
- And, 52 patients’ perspectives

- 2 reviews of COS
    - Sinha 2008
    - Gargon 2014

COMET database

- 84 published COS studies up to end of 2014 involved Canadians in some way

- 14 studies had a corresponding author who was based in Canada
- 52 studies included one or more authors who were based in Canada
- 79 studies involved Canadian participants

COMET website

- >16,500 visits in 2014 (36% more than 2013)

 and 9780 new visitors (43% increase)

- Increased from 66 countries in 2011, to 124 countries in 2014
- Visitors in 2014
  - UK: 49%
  - USA and Canada: 16%
  - Rest of the world: 35%
- 6588 database searches have been run since inception (2383 searches in 2014)

Promotion and collaboration

- Trialists - SPIRIT guidelines
- Trial funders - NIHR (HTA, RfPB, PGfAR), ARUK, AMRC, HRB Ireland
- [Review sent to 245 research funders in 31 countries]
- Industry - EFPIA
- Regulators - EMA, FDA

- Systematic reviewers – Cochrane (Mike Clarke, Day 2)
- Guideline developers – NICE
- Journal editors - CROWN

Prospectively registered COS

- 2011: 12
- 2012: 5
- 2013: 20
- 2014: 19
- 2015: 17

Avoiding unnecessary duplication of effort

- September 2014: Enquiry submitted via website by researcher A to register COS in delirium
- Request from COMET (Liz) for registration information
- Not supplied but project held on COMET private list
- May 2015: Enquiry received from researcher B about the same area
- Liz contacted researchers with request to share details
- Researchers A and B happy to be put in contact
- Working together to bring agreeable structure

Commentary

Developing core outcome sets for clinical trials: issues to consider

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

Article Metrics

13093
Total accesses

12
BioMed Central citations

Altmetric score from Altmetric.com

Article metric FAQ

Accesses

Last 30 days: 835 accesses

Last 365 days: 7593 accesses

All time: 13093 accesses

Scope
Identifying existing knowledge
Stakeholder involvement
Consensus methods
Achieving global consensus
ack, updating
Clear presentation

Trials 2012; 13: 132

Outcome measurement

- ‘What’ to measure
- ‘How’ to measure (validity, reliability, feasibility)
    - COSMIN
    - PROMIS
    - PROQOLID
    - TREAT-NMD ROM

Stakeholder involvement

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

- Stage of involvement may vary by group

COMET PoPPIE Working Group

- People and Public Participation, Involvement and Engagement (PoPPIE)
- Heather Bagley, COMET PPI Coordinator
- Membership

- COMET website presence
- Plain language resources
- EUPATI webinar
- Videos – parent, patient organisation

PoPPIE research agenda – how to?

- Involve patients as research partners in design of COS studies
- Identify and meet information needs of patients as both research partners and participants
- Identify appropriate consensus methods for patient groups
- Generate appropriate questions for patients taking part in a COS study

PoPPIE research agenda – how to?

- Access and engage patients in COS studies (Facebook? Newsletters?)
- Ensure hard to reach communities are involved
- Bring different stakeholder groups’ views together
- Evaluate the stakeholder experience of taking part

Plain language resources

Involving patients and the public in improving research

How health care treatments are developed

To help doctors and health professionals decide what is the best treatment for patients they need to have evidence about which treatment works best, Treatments are developed and tested by researchers to make sure they work and are safe. To decide which treatments are best for patients, it is important to look at the effect those treatments have on patients. Researchers do this by measuring an 'outcome'. For example, in a study of how well a new asthma treatment works, 'outcomes' might include:

What are the challenges in measuring outcomes?

At the moment, different studies looking at treatments for the same condition often measure different outcomes. For instance, imagine two studies of how to treat migraine.

- Study A -   researchers measure days off sick as an outcome
- Study B – researchers measure symptoms of pain as an outcome

When the two studies are finished, we cannot compare or combine their results because they have used different outcomes. We would not be comparing like with like.

Another problem is when a study team set out to collect information on several outcomes but in the end decide to publish the results on only some of the outcomes. This sometimes happens when the findings for particular outcomes differ from those the team hoped for.

Why is this a problem?

Other researchers could struggle to work out exactly how effective a treatment is because:

- They don't have full results from the study
- The information they do have might be biased

What is the solution?

If all studies in a particular health condition used the same outcomes, they could all be compared and combined. This would make the best use of all the research. When a set of main outcomes has been agreed for a health condition, it is called a 'core outcome set'. If all studies in a particular condition, such as migraine, measured and reported all core outcomes, we could:

- bring together all of the studies to get a better understanding of which treatments are best and
- avoid the problem of some studies only reporting a selection of the outcomes that have been measured.

How are core outcomes agreed upon?

Deciding which outcomes should be core outcomes requires a great deal of discussion. Core outcomes have to be relevant to health professionals, but more importantly, they have to be relevant to patients and carers. Researchers also need to make sure that all these experts – patients, carers and professionals – agree on the core outcomes. To do this they use 'consensus methods'.

What are consensus methods?

These are surveys, meetings and discussions where researchers draw together the opinions of experts. Patients and carers have not always been involved, but now they are being included in recognition of their first-hand experience of living with a condition.

Why is it so important to involve patients in deciding on core outcome sets?

Core outcome sets need to include those outcomes that are most relevant to patients and carers, so it is vital that patients and carers are involved in their development. There are examples of where involving patients in the process identified an outcome that was important to them as a group but which might have been overlooked if the outcome set was developed by practitioners on their own.

How are core outcome sets used when they have been agreed?

When a core outcome set has been agreed for a particular condition, we hope researchers will use it in their studies, whilst adding in other outcomes if they wish. If every

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resources/PlainLanguageSummary

COMET - going forwards

- New COS: from 18/year to 40 by 2018
- Maintain and keep the database up to date
- Reporting guideline
- ‘Self-help’ resources (COMET Handbook)
- Advice from experienced COS developers
- Local network meetings
- COMET ‘PoPPIE’ Working Group
- Quality assessment tool
- Investigation of COS uptake (Karen Barnes)

COMET V Programme

- Recently developed core outcome sets
- COS for trials with children

- Patient engagement
- Links with Cochrane, GRADE, EQUATOR
- Panel discussion

- **Contributed posters**

- Methods workshops

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