



Core Outcome Measures in Effectiveness Trials

www.comet-initiative.org

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Outline

- Background
 - What is the problem?
 - Core outcome sets (COS)
 - The COMET Initiative
- COMET Update
- What next?

What is the problem?

- Several tens of thousands of research studies are underway and 500+ are published every week
- Working through them is overwhelming and made worse by studies of the same topic describing findings in different ways
 - Problems with outcomes in Cochrane reviews
 - 5 most accessed, and most cited in 2009

*Tovey D. Impact of Cochrane Reviews [editorial]. The Cochrane Library 2010 (7 July)

Outcome reporting bias

- the selection of a subset of the original recorded outcomes in a study, selected on the basis of the results, for inclusion in publication.

- Outcomes that are statistically significant are more likely to be fully reported, OR 2.2 to 4.7 (Dwan et al, PLoS ONE 2008)
- ORB suspected in at least one trial in 34% of 283 reviews (Kirkham et al, BMJ 2010)
- 42 significant meta-analyses
 - 8 (19%) would not have remained significant
 - 11 (26%) would have overestimated treatment effect by > 20%

Core outcome sets

– *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*

- Disease/condition specific
- All treatment types or a particular intervention
- Should consider both benefits and harms
- The minimum – expect others to be collected
- Relevant within routine clinical practice
- What, how, when

Advantages of COS

- Increases consistency across trials
- Maximise potential for trials to contribute to systematic reviews of these key outcomes
- Major reduction in selective reporting
- Much more likely to measure appropriate outcomes

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative

- Facilitate and promote development and application of core outcome sets
- Liverpool, 2010; Bristol, 2011
 - Trialists, systematic reviewers, health service users, clinical teams, journal editors, trial funders, policy makers, regulators
- Guidance



- ‘What’ to measure
 - Guidance on methods for developing core outcome sets, including patient involvement
 - Reporting standards
 - Funding applications
- ‘How’ to measure (validity, reliability, feasibility)
 - PROMIS
 - COSMIN
 - TREAT-NMD
 - Musculoskeletal
 - Paediatrics

COMET website and database

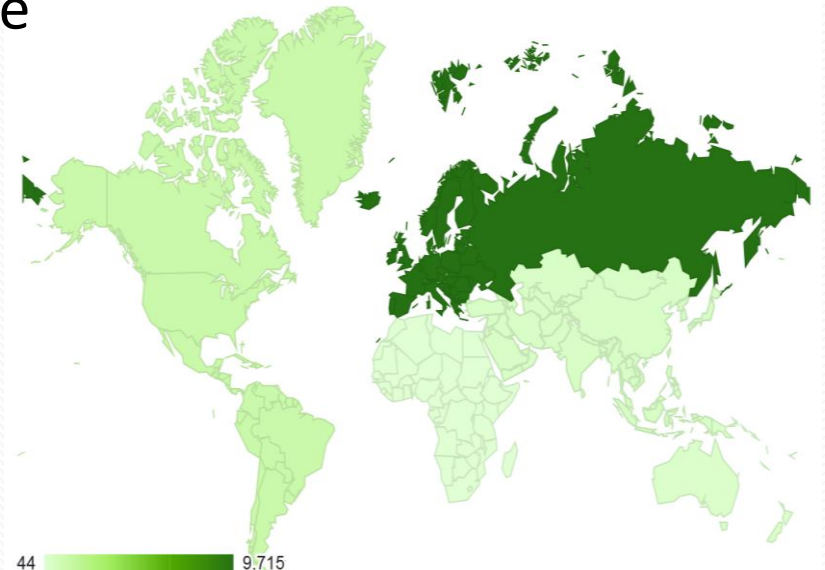
- Work is ongoing to identify, collate and maintain relevant resources in an online searchable database
- 156 completed projects in various areas of health have so far been identified (49 consensus)
- COS development is planned or ongoing in 33 clinical areas, with a further 45 in discussion

www.comet-initiative.org/studies/search



Impact

- Since the launch of the COMET website and database (August 2011), there have been
 - 2243 searches have been undertaken
 - 7001 individuals visited (12143 visits, 52001 page views)
 - 100 countries visiting the site





Commentary

Highly accessed

Open Access

Developing core outcome sets for clinical trials: issues to consider

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Altmetric score
from Altmetric.com

Accesses

Last 30 days: 321 accesses

Last 365 days: 2870 accesses

All time: 2870 accesses

Scope

Identifying existing knowledge

Stakeholder involvement

Consensus methods

Achieving global consensus

Regular review, feedback, updating

Implementation

Clear presentation

Stakeholder buy-in: UK NIHR HTA

- **Funding application form:** Measurement of costs and outcomes
- Details should include justification of the use of outcome measures where a legitimate choice exists between alternatives.
- 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.'



What next?

- Japan - workshop
- PPI meeting
- JLA and UK Duets
- FP7 work packages (ongoing)
 - Engagement with Cochrane Collaboration
 - Provide methodological advice to groups developing core outcome sets, and raise awareness among clinical trialists
 - provide support to COS developers on how the included outcomes in COS should be defined and measured
- COMET III

Save the date

- Thursday 20th and Friday 21st June 2013
- The Midland Hotel, Manchester



In conclusion

- The current lack of consistency is shocking
 - Unacceptable waste
 - There is a clear need to make things better
- It is vital to collect important outcomes in all trials
 - Especially outcomes important to patients
 - There should be a more scientific approach to outcomes
- Growing activity in development of core outcomes and support for COMET
- Improving the quality of evidence to support clinical decisions



www.comet-initiative.org

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