COMET Initiative

Core Outcome Measures in Effectiveness Trials

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Background:

Clinical trials seek to evaluate whether an intervention is effective and safe. This is determined by comparing the effects of interventions on outcomes chosen to identify the beneficial and harmful effects. The careful selection of appropriate outcome domains and specific outcomes is therefore crucial to the design of randomised trials, and these need to be relevant to health service users and other people making decisions about health care, if the findings are to influence decision-making. There is a growing recognition among researchers that insufficient attention has been paid to the outcomes to measure in clinical trials and that this needs to change. The difficulties caused by heterogeneity in outcome measurement are well known to systematic reviewers, who are hampered by inconsistencies in outcomes assessed and reported in otherwise eligible studies. As such, many meta-analyses cannot include data from key studies because relevant outcomes were not reported.

Why standardise outcomes?

If outcomes were standardised, the design of new trials would be simplified, their risk of measuring inappropriate outcomes would be reduced, and selective reporting of outcomes would be less likely. The choice of outcomes for systematic reviews would be more straightforward and It would be easier to compare, contrast and combine studies. Standardised, core outcome sets (COS) would provide the minimum that should be measured and reported in all clinical trials of a specific condition, but would not restrict outcomes in a particular trial to those in the relevant COS. COS would help review authors to present their findings clearly and succinctly, for example within Summary of Findings tables.

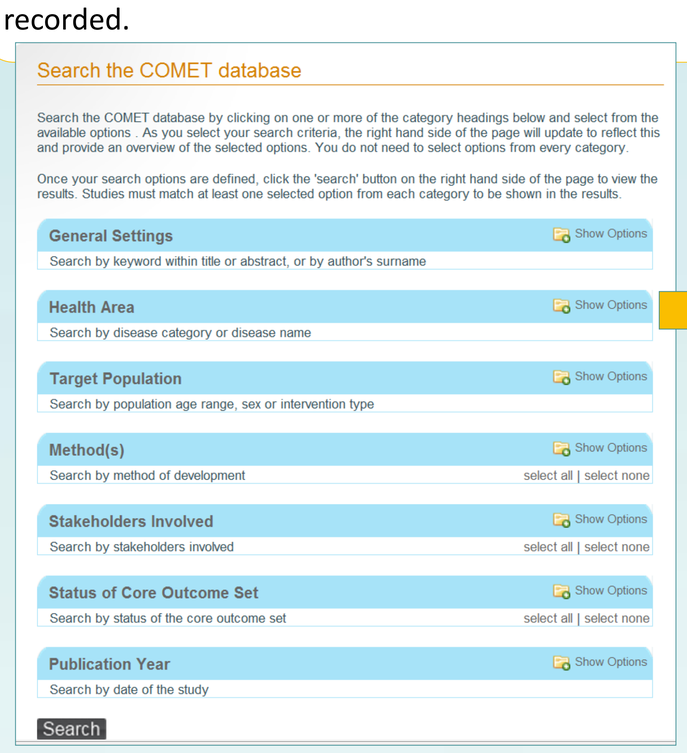
The COMET Initiative database:

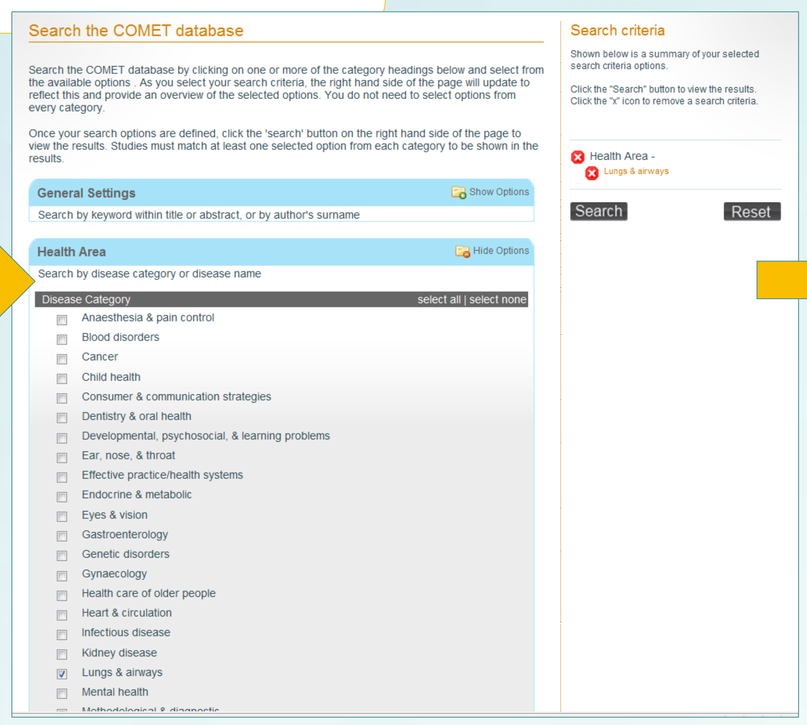
Work is ongoing to identify, collate and maintain relevant resources on the internet. More than 120 potentially relevant studies in various areas of health and health care have been identified. Fifteen planned or ongoing studies have also been recorded.

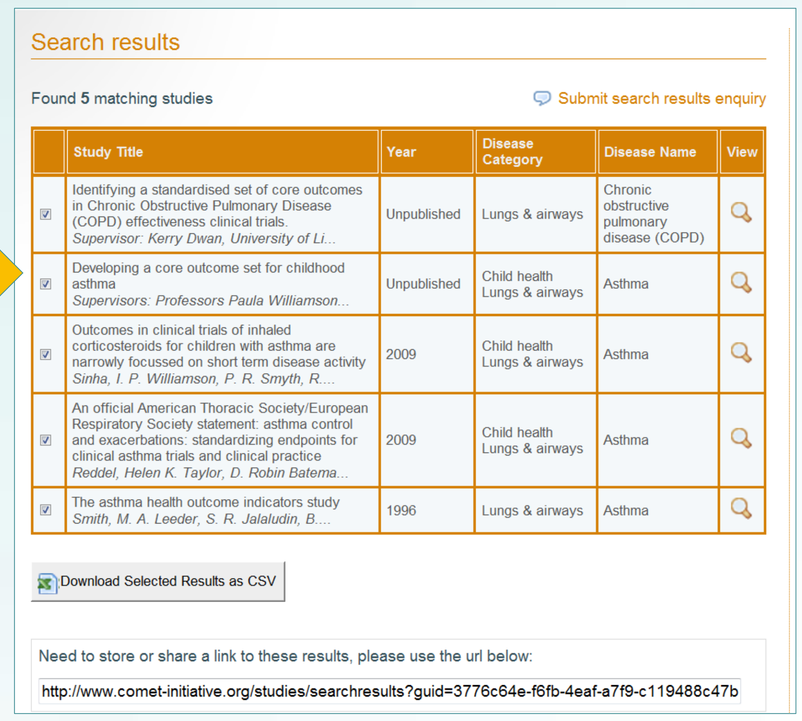
The COMET (Core Outcome Measures in Effectiveness Trials) Initiative:

COMET brings together people interested in COS, with well attended international meetings in 2010 and 2011. COMET aims to collate and stimulate relevant resources, both applied and methodological, to facilitate exchange of ideas and information, and to foster methodological research. This is being achieved through:

- development of a searchable database of completed and ongoing projects in COS development, and a searchable repository for project protocols and other documents
- maintenance of these resources in a publically available searchable database [http://www.comet-initiative.org/studies/search]
- guidance on developing COS
- guidance on integrating patient reported outcomes into COS
- guidance on funding applications to develop COS







Implications for The Cochrane Collaboration and systematic reviews:

COMET will help authors of systematic reviews focus on outcomes of most relevance to people using the reviews. This would include the selection of outcomes for the Summary of Findings tables in Cochrane reviews. COMET will also increase the likelihood that the outcomes were measured in eligible studies, thereby making it easier to include data in the review and any meta-analyse. Through these improvements to the evidence base, COMET will contribute to helping people make well-informed decisions in health care.

MRC Hubs for Trials Methodology Research — North West Hub

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