

POSTER PRESENTATION

Open Access

Core outcomes for randomized trials and core information for clinical decision-making: implications for outcome selection

Angus McNair^{1*}, Robert Whistance¹, Rachel Forsythe¹, Rhiannon Macefield¹, Sara Brookes¹, Jane Blazeby^{1,2}, CONSENSUS-CRC working group¹

From 3rd International Clinical Trials Methodology Conference
Glasgow, UK. 16-17 November 2015

Introduction

Core outcomes sets (COS) are an agreed minimum group of outcomes to measure in trials. Core information sets (CIS) are defined as the agreed minimum information required for clinical decision-making. Theoretically, these concepts should be closely aligned, however, there is no evidence that COSs adequately inform CISs. This study compared COS and CIS for colorectal cancer (CRC) surgery.

Methods

All potential outcomes/information of importance were identified through systematic literature reviews, reviews of hospital information leaflets and patient interviews. This informed Delphi questionnaires which asked stakeholders (patients, surgeons and nurses) from a sample of UK CRC centres to rate the importance of 1) outcomes and 2) information on a five-point Likert scale. Respondents were resurveyed following feedback from stakeholder groups. Outcomes/information rated as less important were discarded according to pre-defined criteria. The final COS and CIS was agreed at separate international consensus meetings with professionals and patients. Comparisons were made between core set items.

Results

Data sources identified 1216 outcome/information of CRC surgery that informed a 116 item questionnaire. Centre response rates were 79% (64/81), including 93 surgeons and 11 clinical nurse specialists, and 97 of 267 patients. Stakeholders prioritized 51 and 23 items in the

first and second surveys, and consensus meetings reduced this to a 9 item COS and 10 item COS. The sets were identical apart from additional length of hospital stay information.

Conclusion

Stakeholders largely agreed on the content of COS and CIS in CRC, but further research is needed to demonstrate this in other settings.

Authors' details

¹University of Bristol, Bristol, UK. ²University Hospitals Bristol NHS Foundation Trust, Bristol, UK.

Published: 16 November 2015

doi:10.1186/1745-6215-16-S2-P65

Cite this article as: McNair et al.: Core outcomes for randomized trials and core information for clinical decision-making: implications for outcome selection. *Trials* 2015 **16**(Suppl 2):P65.

Submit your next manuscript to BioMed Central
and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at
www.biomedcentral.com/submit



¹University of Bristol, Bristol, UK

Full list of author information is available at the end of the article