COMET INITIATIVE

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

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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 e.g. pain. Outcome domains are constructs which can be used to classify broad aspects of the effects of interventions e.g. functional status. The careful selection of appropriate outcome domains and outcomes is therefore crucial to the design of randomised controlled trials (RCTs), and these need to be relevant to health service users and other people making decisions about health care, if the findings of pragmatic RCTs are to influence health-care decision-making. There is a growing recognition among clinical researchers that insufficient attention has been paid to outcomes to be measured in clinical trials. Likewise, the process of clinical audit needs to be strengthened to maximise its benefits for health care. One key part of clinical audit is the monitoring and reporting of outcomes, with data being collected to allow comparisons between centres and over time. Therefore, it is important that outcomes selected and reported in audit and studies other than randomised trials can also be synthesised or compared. Using core outcome sets (COS) in these settings will improve the standards of reporting and data synthesis.

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative brings together people interested in COS. COMET aims to provide guidance on developing COS, methods to promote user involvement, and preparing reporting standards for such projects. Work is ongoing to identify, collate and maintain relevant resources in an online searchable database [http://www.comet-initiative.org/studies/search].

What is a core outcome set (COS)?

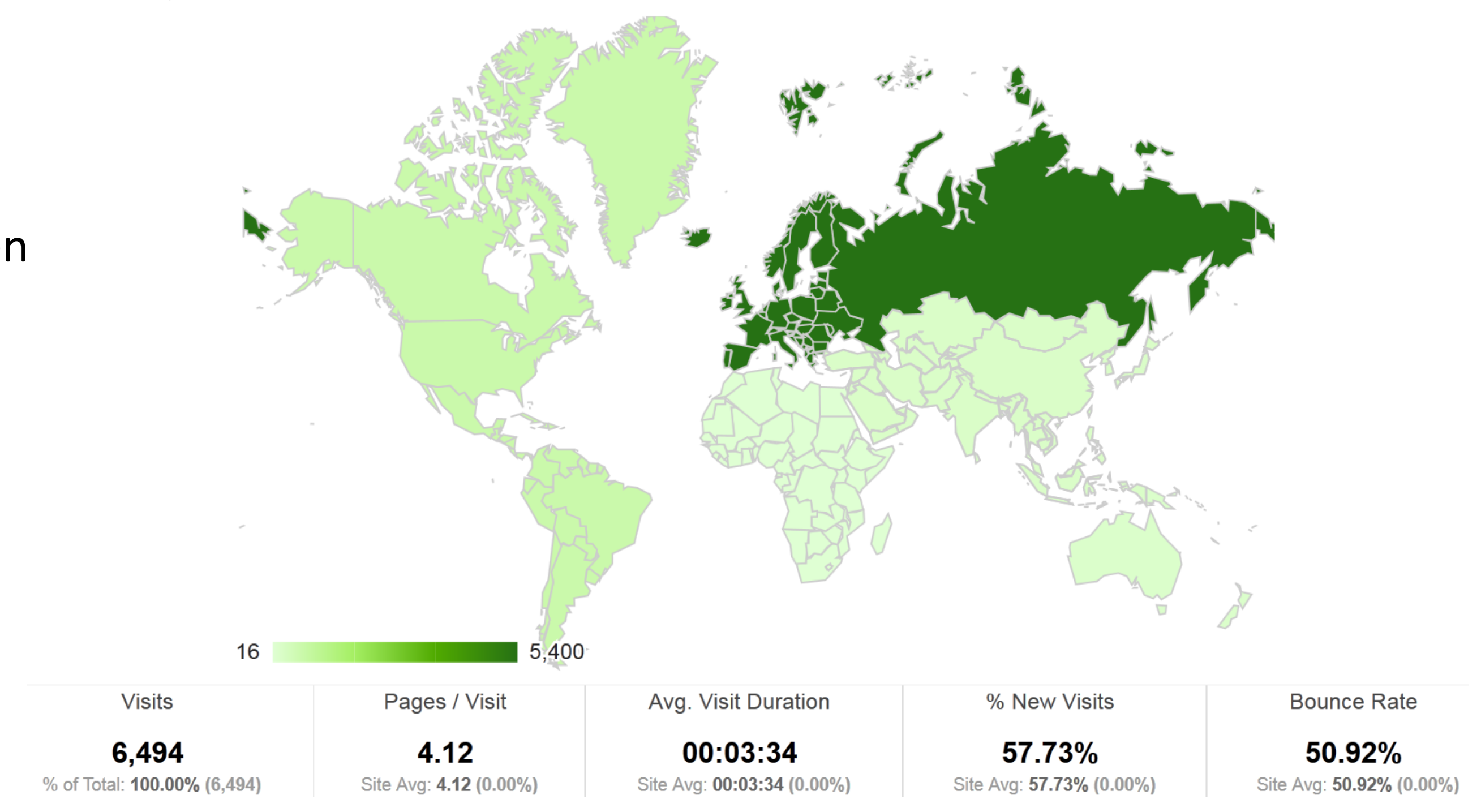
It is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health/health care.

Scope of a COS:

- Disease/condition specific
- Focuses on all treatment types or a particular intervention
- Should consider both benefits and harms
- The minimum - expect other outcomes to be collected
- Focus of effectiveness trials
- Relevant within routine clinical practice

Results

162 relevant projects in various areas of health have been identified to date, and there is a systematic review underway. Examples exist where the involvement of patients in COS development has identified an outcome that might not have been considered by practitioners alone. Despite increasing recognition of the importance of incorporating patients' opinions, their involvement has been limited. COS development is planned or ongoing in 26 clinical areas, with a further 34 in discussion; 5 of these are cancer projects including head and neck cancer, colorectal cancer, oesophageal cancer, breast cancer and prostate cancer (see below). In the months since the launch of the COMET website and database (August 2011), 1248 searches have been undertaken, with 3763 individuals (6494 visits) from 90 countries visiting the site. Eighty-seven of the 1248 searches undertaken have been in cancer, making it the most searched for disease category.



Visits	Pages / Visit	Avg. Visit Duration	% New Visits	Bounce Rate
6,494	4.12	00:03:34	57.73%	50.92%
% of Total: 100.00% (6,494)	Site Avg: 4.12 (0.00%)	Site Avg: 00:03:34 (0.00%)	Site Avg: 57.73% (0.00%)	Site Avg: 50.92% (0.00%)

Development of core outcomes for surgical management of localised prostate cancer

Mr Thomas Lam (PI), University of Aberdeen
Co-Applicants: Professor James N'Dow, Dr Sara MacLennan, Dr Craig Ramsay, Professor Marion Campbell and Professor Vikki Entwistle

The project aims to develop a standardised set of outcomes for surgery for localised prostate cancer which are important to all stakeholders in order to optimise decision making. The project will utilise a mixed methods approach consisting of qualitative and quantitative studies, including systematic reviews of the literature and focus group interviews with patients; a consensus meeting attended by representatives from each key stakeholder group (i.e. patients, surgeons and NHS Urology heads of service); a series of Delphi studies on patients, surgical experts and NHS heads of service; and a final consensus meeting.

www.comet-initiative.org/studies/details/153

COS for curative treatment of oesophageal cancer

Jane M Blazeby (PI), Natalie S Blencowe, Rhiannon Macefield, Sara T Brookes, Kerry Avery, Fiona Mackichan, Sean Strong, Chris Metcalfe. ROMIO team

This work will generate core sets for oesophageal cancer surgery and definitive chemoradiotherapy. Core sets for each treatment modality will be categorised as:

- Core outcomes for reporting in trials
- Core disclosure for information for informed consent for patients undergoing treatment.

www.comet-initiative.org/studies/details/144

Development of a COS for Reconstructive breast surgery: The BRAVO (Breast Reconstruction and Valid Outcomes) Study

Jane M Blazeby (PI), Jane Barker, Sara T Brookes, Simon J Cawthorn, Diana Harcourt, Christopher Holcombe, Caroline Oates, Shelley Potter, Joseph A Ward, Robert P Warr, Sherif Wilson, Eva Weiler-Mithoff, Zoe Winters

Breast cancer affects 44,000 women every year, of whom 40% will require a mastectomy. Loss of a breast can have a dramatic impact on QoL and reconstructive breast surgery is offered to improve outcomes. Decision-making about reconstructive surgery is challenging and women and surgeons require high quality outcome information to allow them to decide what types of procedure best suit their needs and values. Well-designed studies offer the best outcome data, but a series of systematic reviews critically appraising the quality of outcome reporting in breast reconstruction have shown this to be inconsistent and lack standardisation. A COS for reconstructive breast surgery is therefore needed.

www.comet-initiative.org/studies/details/152

Development of COS for informed consent & clinical trials of colorectal cancer surgery

Supervisors: Professor JM Blazeby, Dr ST Brookes, Dr K Avery, Mr AGK McNair
Research Fellow: Mr RN Whistance, University of Bristol

Objectives:

1. To perform systematic literature reviews to produce a comprehensive long-list of all outcomes reported in RCTs of colorectal cancer surgery
2. To supplement the long-list with additional issues identified through semi-structured interviews with colorectal cancer patients and surgeons
3. To use Delphi consensus methods to refine the outcome long-list into a COS agreed by key stakeholders
4. To host consensus meetings with key stakeholders to discuss disagreements, ratify the COS and aid dissemination and uptake of the findings.

www.comet-initiative.org/studies/details/122

The CONSENSUS Study (Squamous Cell CarcinOma of the OropharyNx: Late PhaSE CliNical TrialS; Core OUtcomeS)

Supervisors: Dr Terry Jones, Dr Catrin Tudor-Smith, Professor Bridget Young
Research fellow: Aoife Waters, University of Liverpool

Issues of biological heterogeneity, incidence of post-treatment functional deficits & relatively small numbers provide challenges when deciding on outcomes for trials for patients with SCCHN. Currently, core outcome measures, whether surrogate, functional, QoL or survival related, do not exist, making it difficult to identify optimal treatment regimens when comparing data from competing trials. This project aims to include all relevant stakeholders to define such measures.

www.comet-initiative.org/studies/details/121

Implications

COS will increase the efficiency and value of the research process. Design of new trials will be simplified, risk of measuring inappropriate outcomes reduced, and selective reporting of outcomes less likely. By improving the evidence base, COMET will make it easier for people to make well-informed decisions about healthcare.

MRC Hubs for Trials Methodology Research
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