Background

Missions to bring outcomes together with information and management of standardized true outcomes.

Objectives:
- to collate relevant resources (both applied and methodological) in a publicly available searchable database
- to facilitate exchange of ideas and information
- provide guidance on methods for developing core outcome sets
- develop reporting standards for such studies
- advise on funding applications

Patient involvement

A notable initiative, established to identify appropriate outcomes for clinical trials in rheumatologic conditions in adults, is the OMERACT collaboration (4). It organizes global consensus conferences in a 2-year cycle, where data-driven recommendations are prepared and updated by expert working groups, including recommendations for core sets of measures for most of the major rheumatologic conditions.

It is important to involve patients in the process of identifying appropriate outcomes to measure in clinical trials.

References

Examples of ongoing work to develop cancer core outcome sets

Oesophageal cancer surgery
AGK McNair, J Powell, S Whelan-Johnson, N Blencowe, D Tictomb, R Huxtable, JM Blazey; University of Bristol

- A systematic review identified 77 papers reporting short-term outcomes of oesophagectomy for cancer with or without neoadjuvant chemotherapy. 2D (26.0%) reported numbers of patients not progressing to surgery. Numbers of planned and completed operations were reported in 32 articles (28.1%). All papers reported postoperative mortality but many different definitions for this term were used.
- Of 99 articles reporting morbidity, no single complication was reported in all studies. The most commonly reported complication was anastomotic leakage, reported in 76(79.7%).
- Outcome reporting relating to oesophageal cancer surgery is inconsistent and lacks methodological rigour.

Head and neck cancer
Supervisors: Dr Terry Jones, Dr Catrin Tudur Smith. Research fellow: Ashle Waters, University of Liverpool

- Issues of biological heterogeneity, incidence of post-treatment functional deficits and relatively small numbers provide challenges when deciding on outcomes for RCTs in patients with SCCN

Colorectal cancer surgery
Supervisors: Prof JM Blazey, Dr ST Brookes, Dr K Avery, Mr A McNair. Research fellow: Robert N Whistance, University of Bristol

- This project aims to develop a set of core outcomes for use in colorectal cancer RCTs, and to establish whether this is similar to the information required for core disclosure for informed consent for colorectal cancer surgery.

Breast cancer
L Kilburn, J Barner & J Bliss on behalf of the NCRI Breast Clinical Studies Group

- A long term follow-up CRF and guidance notes have been developed to standardise the way long term follow-up data are collected in academic-led breast cancer trials. The aim is for these to be adopted by CTUs running breast cancer trials and then assess usage and feedback in 6-12 months.

Breast reconstruction surgery

- This systematic review shows that at present, the breast reconstruction literature is of insufficient quality to aid decision-making and well-conducted and designed studies are urgently needed. The rigorous development of ‘core outcome sets’ would dramatically improve study design and comparability and the potential value of research to patients and surgeons.