

ConDuCT Hub News: Winter 2010/2011



We are pleased to announce the second meeting of the COMET (Core Outcomes Measures in Effectiveness Trials) Initiative which will take place 11 - 12th July, 2011 in Bristol. This will bring together individuals interested in the development and application of “core outcome sets” in many different areas of health care.

Confirmed speakers include Professor Doug Altman, Professor Holger Schönemann and Sir Iain Chalmers.

For registration information and abstract submission see

<http://www.cometmeeting2011.org/>

PhD studentships are available!

Further information is available at:

<http://www.findaphd.com/custadverts/4year/bristolsocmed/conduct.asp>

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Grant Awards

The Health Economics theme has been awarded grants to fund two cross-hub collaborations:

Development of a central repository of resource-use data collection instruments for trial-based economic evaluations. A collaboration with the North-West and Midland hubs, led by Professor Dyfrig Hughes of the University of Bangor.

A workshop on applied issues in using ICECAP (generic ‘capability’ or quality of life) measures in clinical trials and economic evaluations. A collaboration with the Midland hub, led by Professor Joanna Coast of the University of Birmingham.

For more information on the ConDuCT hub, please visit our website http://www.methodologyhubs.mrc.ac.uk/about_us/hubs/conduct_hub.aspx

Meet Jane Blazeby, Professor of Surgery and Director of MRC ConDuCT Hub for trials methodology research



Jane is an academic surgeon who enjoys combining clinical practice with health service research with the overall aim of improving standards of care in the NHS. Jane grew up in Salcombe, South Devon and was educated in local schools before studying Medicine at Bristol University. During undergraduate years, she was Captain of the University Ladies Sailing Club, completed an intercalated BSc in Medical Microbiology and met her future partner when leading a youth group. She decided to follow a career in surgery and thoroughly enjoyed her time as a junior doctor in Bristol. It was undertaking a higher degree, funded by an NHS Research Training Fellowship, based at the Department of Social Medicine (1993 to 1995), however, which changed the course of her career and fuelled her enthusiasm for health services research.

Jane's MD thesis investigated quality of life outcomes after surgery for oesophageal cancer. It included the development of a questionnaire module to supplement the widely used European Organisation for Research and Treatment of Cancer (EORTC) core questionnaire, the EORTC QLQ-C30, and a longitudinal study evaluating patient reported outcomes after surgery for oesophageal cancer. This work showed that surgery for oesophageal cancer that does not lead to survival of at least two years has a major detrimental impact on quality of life – influencing how surgeons and patients make informed treatment decisions. She went on to chair the EORTC Quality of Life Group and to lead the international development and validation of a portfolio of patient reported outcome measures to assess quality of life in gastro-intestinal cancers that are nowadays very widely used in clinical trials in oncology.

Jane gained an MRC patient orientated Clinician Scientist award in 2000 and was appointed as an honorary consultant surgeon at University Hospitals Bristol NHS Trust. This enabled her to further establish principles and practices of integrating patient reported outcomes in trials in surgical oncology and gave her the opportunity to undertake a distance learning MSc in Epidemiology and Public Health (at the London School of Hygiene and Tropical Medicine). Jane describes this as the best course she has ever done and she recommends it to all clinical health services researchers. More recently she has really focused upon methodology in trials, within ConDuCT aiming to overcome some of the challenges in difficult trials, including surgical trials. Outside of work Jane is interested in reading, family life and she attends a local church. She has three children and is married to the artist, Nicholas Jones.

A Guide to the ConDuCT Hub

The aim of the ConDuCT hub is to provide an environment for collaborative research on methods to improve the design and completion of randomised controlled trials (RCTs). The hub is based in the School of Social and Community Medicine at the University of Bristol, and draws on the existing expertise of the school in six research programmes or ‘themes’:

- **Qualitative Research Methods** (Lead: Jenny Donovan, Ali Heawood)
Aim: Encourage and develop the integration of standard and innovative qualitative research methods throughout challenging-to-conduct RCTs
- **Statistical Methods** (Lead: Chris Metcalfe)
Aim: Establish the best way of applying novel statistical methods, where such methods have the potential to improve the design and analysis of challenging RCTs
- **Economic Evaluation in RCTs** (Lead: Sian Noble)
Aim: Develop methods to overcome challenges in conducting economic analyses alongside RCTs
- **Evidence Synthesis and Value of Information (VOI)** (Leads: Tony Ades, Nicky Welton)
Aim: Develop and apply EVI methods to improve RCT design and assist research funders to prioritise trials
- **Improving Trial Conduct** (Lead: Athene Lane)
Aim: Develop methods to improve data quality assurance, participant retention and study cohesion
- **Embedding PROs into RCTs** (Lead: Jane Blazeby)
Aim: Support the increased inclusion of robust PROs in RCTs, and investigate barriers to, and the potential added value of, PROs incorporated alongside clinical outcomes in RCTs

Further information about our research can be obtained from the MRC HTMR website

http://www.methodologyhubs.mrc.ac.uk/about_us/hubs/conduct_hub.aspx

or the School of Social and Community Medicine’s own website <http://www.bristol.ac.uk/fmd/>

Our Recent Activities

New Starters

We are pleased to welcome Robert Whistance to the ConDuCT hub! Rob has been awarded an NIHR PhD fellowship award (2011-2014) to work on developing core outcome sets for informed consent and clinical trials of colorectal cancer surgery. He will be working under the supervision of Jane Blazeby, Sara Brookes and Angus McNair.

Workshops

The Value of Information theme, in collaboration with Arthritis Research UK and supported by the MRC HTMR, organised a one-day workshop on 'Biologic therapies for inflammatory joint disease: Models for decision making' in London, September 2010. This workshop was attended by rheumatologist clinicians, statisticians, health economists, representatives from NICE, and Hub members.

The aim of the workshop was to explore the role of indirect comparisons and new methodologies such as Value of Information analysis in the prioritisation and design of further research on biologic therapies (in particular, the need for head-to-head trials of these therapies). Presentations and discussions focused on the health economic models used to evaluate treatment of inflammatory joint diseases with biologics.

A need was identified for consensus on model assumptions, structure or outcomes chosen, and it was decided to form a Clinical Studies Group that could work towards finding consensus on the model inputs and methodology. This will be a collaborative exercise involving modellers and clinicians, with the involvement of NICE.

Introducing ... the PRIME monitoring process:

Peer Review Intervention for Monitoring & Evaluating sites

The Trial Conduct theme has developed a new process of site monitoring that successfully increased study performance and consistency for the multi-centre RCT in which it was established (doi: 1016/j.jclinepi.2010.10.003). The process uniquely emphasises peer review and support, and focuses on observation of trial procedures as well as the more common features of monitoring to ensure GCP. Benefits were seen through training and development, sharing best practice and from early solutions to problems.

We now plan to assess the effectiveness of the monitoring method in other studies – if you are involved in a multi-centre trial and would be interested in discussing this further, contact Athene.Lane@bristol.ac.uk

Publications

Mills N, Donovan JL, Wade J, Hamdy FC, Neal DE, Lane JA. *Exploring treatment preferences facilitated recruitment to randomised controlled trials*. J Clin Epidemiol 2011; In press

Metcalf C. *The analysis of cross-over trials with baseline measurements*. Statistics in Medicine 2010; **29**: 3211-3218

Lane JA, Wade J, Down L, Bonnington S, Holding P, Lennon T, Jones A, Salter CE, Neal DE, Hamdy JL, Donovan JL. *Peer review intervention for monitoring and evaluating sites (PRIME) that improved randomised trial conduct and performance*. J Clinical Epidemiology 2011 doi: 10.1016/j.jclinepi.2010.10.003

Noble S, Hollingworth W, Tilling K. *Missing data in trial based cost-effectiveness analysis: The current state of play*. Health Economics (In Press). Published online Dec 2010
doi:10.1002/hec.1693

Potter S, Brigid A, Whiting PF, Cawthorn SJ, Avery KN, Donovan JL, Blazeby JM. *Reporting clinical outcomes of breast reconstruction: a systematic review*. J Natl Cancer Inst. 2011; **103**: 31-46.

Presentations

Jane Blazeby: 'Core outcomes sets to improve trial conduct' at NCRI consumer liaison group meeting, a national meeting for service users linked to clinical studies groups in cancer, Leeds, September 2010.

Jason Madan: 'Using Bayesian methods to synthesise evidence on the efficacy of electronic aids to smoking cessation ' at Society of Medical Decision Making annual meeting, Toronto, October 2010.

Jenny Donovan: 'The contribution of qualitative research methods to RCTs' at National School of Primary Care, Manchester, November 2010.

Lisa Hampson: 'Comparison of causal estimators for survival data' at RSS Primary Care Study Group Meeting, London, November 2010.