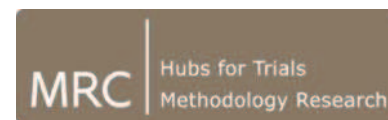


MRC HTMR Network Update



Theme 1: Prioritisation and trial design for cost-effectiveness analysis

Trials that assess the cost-effectiveness of health technologies often rely on patient recall to measure healthcare use. However, the existing measures are characterised by inconsistency and a lack of validation. Theme 1, in collaboration with the MRC HTMR hubs in Oxford and the North West, have begun to develop a standardised resource-use measure (ISRUM) that could increase data quality, improve generalisability and reduce research burden in trials. We have used Delphi surveys to identify and reach agreement on a minimum set of core resource-use items that should be included in a standardised instrument for UK health economic evaluation (Thorn et al. in press). Initial findings demonstrate that it is feasible to develop a short, standardised resource-use instrument for use in RCTs. We are extending this work to develop and validate the ISRUM questionnaire through an MRC funded PhD studentship.

Theme 1 also has a work-package on Value of Information (VoI) methods to help identify whether a new trial is a good investment of research resources. VoI calculations are computationally demanding. Theme 1 members Howard Thom, Wei Fang, Jhenru Wang, and Nicky Welton are working in collaboration with Mike Giles (Oxford) on exploring the application of efficient methods from the field of financial mathematics to VoI calculations.

Following the success of the hub-network funded short course on Value of Information Methods held at UCL in London in June 2016, the course materials were integrated into a 5-day short course on “Bayesian Methods for Health Economics” held in Florence in June 2017, a collaboration between Nicky Welton (ConDuCT-II, Theme 1), Gianluca Baio and Anna Heath (UCL), Chris Jackson (Cambridge Biostatistics Unit), Mark Strong (Sheffield). The course received very positive feedback, and will run again in June 2018. This dissemination activity is key to the adoption of VoI methods in practise. The theme also contributed to the development of a new short course “Introduction to Bayesian Data Analysis in WinBUGS”.

Theme 2: Integrative and dynamic research methods to optimise recruitment to RCTs



The QuinteT Recruitment intervention (QRI), pioneered by theme members in ConDuCT-I has been going through a process of

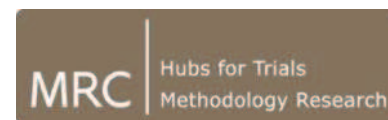
extended and iterative development, considering how it may be tailored to particular contexts, from integration at the outset of an RCT, to involvement partway through RCTs encountering recruitment difficulties. In ConDuCT-II, theme 2 members have been involved in a number of studies where the QRI has been embedded in the RCT to understand and optimise recruitment. These include 12 ongoing studies, four completed studies, three studies in the early stage of set up and a further four studies with embedded QRIs under review. An evaluation of the effectiveness of the QRI, which considers the components of a QRI and its implementation, is underway (Rooshenas et al, in progress).

Theme 2 members have continued to undertake qualitative synthesis across a range of RCTs with integrated QRIs, to understand the intricacies of the process of recruitment. Current areas of exploration include how surgeons present keyhole and open operations in the context of surgical trials (Paramasivan et al), the impact of recruiter's treatment biases on recruitment (Mills et al) and how recruiters describe the process (Jepson et al) and rationale (Conefrey et al) for randomisation. Research findings from this synthesis work have been translated into practical teaching material for recruiters, with team members running two very well received events this year to medical students (Granule) and surgical trainees (Bostic).

The team have also been active in developing and refining innovative research methods aimed at improving trial recruitment processes, with publications on a measure of informed consent (Wade et al, 2017) and a framework for screening and approaching patients for recruitment (The SEAR framework, Wilson et al).

Follow the QuinteT team on Twitter: @QuinteTBristol

MRC HTMR Network Update continued...



Theme 3: Improving feasibility study designs and conduct to enhance trial quality and results

In Autumn 2016, the FACT theme was successful in obtaining a HTMR small grant to conduct the ReSurgEnT (Research on Surgeons and Engagement in Trials) study. The aims of the study are: 1) To identify the key strategies leading to successful trial conduct within surgical trainee collaboratives; and 2) To use this to develop methods/recommendations to enhance clinician engagement in trials across clinical specialities and to inform the medical curriculum in training future clinicians to engage with research. Methods include non-participant observation of key trainee and trial meetings, and semi-structured interviews with key stakeholders. The study is now underway with Clare Clement being appointed as the study researcher. Thus far, three network meetings have been observed, and six interviews have been carried out. Further meeting observations and interviews are planned with trainee collaboratives across the country. If anyone is aware of any ongoing trials involving surgical trainees, please get in touch with Clare: c.clement@bristol.ac.uk

Follow the study on twitter: [@ResurgentStudy](https://twitter.com/ResurgentStudy)

In other news, the first paper from the QuANTOC study (An ethnographic study of group decision-making and member roles to understand and improve how Trial Steering Committees and Trial Management Groups contribute to trial conduct) was published in 2016 in *Trials*.

The article can be viewed on the [NCBI website](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4930562/pdf/13063_2016_Article_1425.pdf) [www.ncbi.nlm.nih.gov/pmc/articles/PMC4930562/pdf/13063_2016_Article_1425.pdf]

Theme 4: Outcomes in RCTs – assessment, reporting and integration in decision-making

In collaboration with the COMET initiative, Theme 4 members have been involved in producing the COMET Handbook. The Handbook provides guidance on the development, implementation, evaluation and updating of core outcome sets and is based on an accumulation of the continued methodological work that has been



going on in Theme 4 and other Hubs in recent years.

Read the article here, and follow COMET on Twitter: [@COMETinitiative](https://twitter.com/COMETinitiative)

In other work, members of Theme 4 have developed a new outcome measure for assessing wounds after surgery for use in RCTs. One of the key features of the outcome measure is its design as a ‘dual-completion’ questionnaire – intended for completion by patients and/or observers (healthcare professionals). They have taken a novel approach to item construction and used plain language with medical terminology alongside. The rationale behind this method is that when there is a need to collect information from patients and professionals on the same outcome, the use of separate questionnaires with different items and wording may run the risk of measuring different issues. A ‘dual-completion’ questionnaire ensures that the same construct is being measured regardless of who is completing the questionnaire, making data amalgamation easier and outcome measurement more streamline for trials. Work so far has shown that combining plain language and medical terminology in items has advantages for content validity in the development of the questionnaire and ensures that items are interpreted as intended. Plans are underway to use dual-completion questionnaires in other studies and settings where the views of patients and professionals are needed on the same issue (e.g. Delphi surveys for core outcome set development) and further validate the method.

As part of her NIHR Doctoral Research Fellowship project, Theme 4 affiliate Amber Young has started work on the development of a core outcome set for burns for use in RCTs. The project will include the views of patients including children and parents of children who have suffered from burns injuries. This is an area where there is much heterogeneity in outcome measurement and reporting and a core outcome set is much needed. Amber’s study protocol was published in *BMJ Open* in July.

The article can be viewed on the [BMJ Open website](http://bmjopen.bmj.com/content/7/6/e017267.long) [<http://bmjopen.bmj.com/content/7/6/e017267.long>]

NIHR Fellowship Update

The NIHR Trainees Coordinating Centre (TCC) launched Round 11 of the NIHR Fellowship Programme in the week commencing 2 October 2017. The fellowships programme offers opportunities at all levels; from PhD through to Senior Research Fellowships, and is aimed at anyone looking to further their career in applied health research and funds research from across the breadth of the NIHR's remit.

We've undertaken a series of initiatives in the last year to promote careers in clinical trials. Last October we launched the second edition of the [Clinical Trials Guide for Trainees](http://www.nihr.ac.uk/funding-and-support/documents/Clinical-Trials-Guide.pdf) (www.nihr.ac.uk/funding-and-support/documents/Clinical-Trials-Guide.pdf) which includes; case studies from trainees and Clinical Trials Units (CTU), additional guidance on how you can structure a fellowship based around a clinical trial and/or clinical trials training, and further guidance for how you can utilise NIHR Fellowships to start or further your career in clinical trials. The guidance also includes a useful link to a database for searching CTUs interested in supporting fellowships.

To encourage this aim, the NIHR Transitional Research Fellowship can be used to embark on a clinical trials career. This award can provide an intense period of clinical trials training for those new or relatively new to trials and who wish to transition to become a future health research leader competent in clinical trials. Any applicant interested in applying for



National Institute for Health Research

a Transitional Research Fellowship is advised to contact Nicola Melody via tccawards@nihr.ac.uk to discuss their proposal.

As part of its commitment to continuous improvement, the NIHR is launching a streamlined application process for researchers applying for funding. In response to wide user feedback we are making applying to NIHR for funding as simple as possible whilst retaining our commitment to research excellence. The streamlined, two-stage form is being rolled out across NIHR research and training programmes from summer 2017. NIHR Trainees Coordinating Centre will use an adapted version of the NIHR Standard Application Form (SAF) for training awards. The main differences are the inclusion of an extended CV and an updated training and development section. Round 11 of the NIHR Fellowship Programme will also be using the new shorter application form and further information can be found on the NIHR website or by clicking [here](#).



Nicola Melody
Senior Programme Manager
NIHR TCC

For more information on the NIHR fellowships and to apply for round 11, please go to www.nihr.ac.uk/fellow

NEW GUIDANCE: Using personal information in health research



Using information about people in health research is the newest edition to the MRC Ethics Series, replacing Personal information in medical research.

This practical guidance reflects the current relevant legal framework when using information about people in health research. It will be revised to reflect the new General Data Protection Regulation (GDPR), which is expected to come into force on 25 May 2018. However, if you follow the advice in this guide you will

be well placed to meet the requirements of GDPR. This guide is part of the MRC Ethics Series and replaces the 2003 publication Personal Information in Medical Research.

For more please visit Supporting research using health data from Policy & Guidance on the MRC Regulatory Support Centre website: www.mrc.ac.uk/regulatorysupportcentre.

Events, Training & Conferences

NETWORK EVENTS

Save the date!

14 November 2017

UKCRC Registered CTUs Directors' Meeting - London

24 November 2017

UKCRC Registered CTUs QA Operational Group National Meeting - venue tbc

7 December 2017

Patient and Public Involvement & Engagement Task & Finish Group Workshop - London

16 May 2018

UKCRC Registered CTUs Directors' Meeting - London

OTHER EVENTS

Registration is now open for the following courses.

Please note that places are limited

Workshop on economic evaluation alongside surgical trials—University of Bristol

21st November 2017

For more information please email joanna.thorn@bristol.ac.uk

Current Development in Cluster Randomised

Trials and Stepped Wedge Designs —Queen Mary University of London

30th November 2017

For more information and to book please visit the [QMUL website](#).

Statistics for Clinical Trials —University of Oxford

4th—8th December 2017

For more information and to book please visit the University of Oxford [Continuing Education website](#).

Independent Data Monitoring Committees—University College London

14th December 2017

For more information visit www.ucl.ac.uk/ictm/education/short-courses/IDMC

Fundamental of Clinical Trials—University of Nottingham

19th—23rd March 2018

For more information please visit www.nottingham.ac.uk/nctu

Introduction to Cancer Clinical Trials for Statisticians Course—University College London

21st and 22nd March 2018

To register please visit the UCL on-line store at <http://onlinestore.ucl.ac.uk/>. Questions should be directed to ctc.training@ucl.ac.uk.

Contact us



Please use these details if you would like to contact the Network Secretariat, provide feedback or contribute to a future edition of The Exchange.

Saeeda Bashir

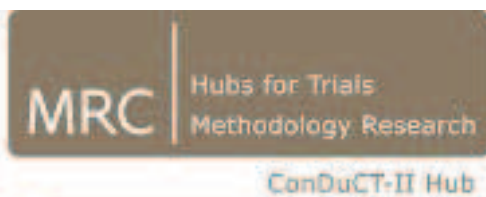
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Economic evaluation alongside surgical trials Workshop

Health economists working on surgical RCTs, CIs of surgical RCTs, trialists and those interested in economic evaluations of surgical interventions are invited to attend this event.

Tuesday 21 November 2017

St James Priory, Whitson Street, Bristol, BS1 3NZ
Chairs: Professor Jane Blazeby and Professor Will Hollingworth

The meeting will provide an opportunity to hear about experiences of economic evaluations conducted alongside RCTs in surgery and promote discussion about the methodological issues that make the design, conduct and analysis of economic evaluation alongside surgical trials unique.

Session themes:

Micro-costing; extrapolation beyond the trial; placebo surgery; using routine data

Confirmed speakers:

Professor Alastair Gray (University of Oxford); Professor Claire Hulme (University of Leeds); Dr Graham Scotland (University of Aberdeen)

Attendance is free with lunch and refreshments provided

For a detailed agenda and registration, please email htmr-conduct@bristol.ac.uk