

The SUPPORT Collaboration: SUPporting Policy relevant Reviews and Trials



The SUPPORT Project is an international collaboration that involves a world-class partnership between low and middle income countries (LMICs), European scientists and LMIC policymakers. Its objective is to provide training and support to encourage researchers and policymakers in collaborative policy-relevant research. HSRU is an integral member of SUPPORT, working alongside nine partners from three continents - Europe, South America and Sub-Saharan Africa.

The Unit's main task within SUPPORT is to develop software that aims to help trialists to conduct and manage pragmatic randomised controlled trials (RCTs). RCTs are accepted as the most valid means of evaluating health, social and educational intervention. However for LMICs there is a huge disparity between the burden imposed by the major regional health problems and what is known about the effect of interventions aimed at reducing this burden. More trials are needed but trial management in LMICs is often problematic.

The software, to be known as the Trial Management Tool (TMT), will package the best of existing material together with some new material about the conduct of pragmatic RCTs into a single accessible tool. TMT will be available in both English and Spanish. The Unit previously developed a Trial Protocol Tool, which supports the production of a high quality research protocol, as part of a similar collaboration, PRACTIHC (www.practihc.org). The TMT will be modelled on this highly successful tool.

For further information, see the SUPPORT website at <http://www.support-collaboration.org> or contact Susan Campbell (E-mail: s.e.campbell@abdn.ac.uk Telephone: 01224 559023)

Recent publications

Azuara-Blanco A, Burr J, Thomas RE, MacLennan GS, McPherson S. The accuracy of accredited glaucoma optometrists in the diagnosis and treatment recommendation for glaucoma. *Br J Ophthalmol* 2007;91(12):1639-43.

Burr J, Mowatt G, Siddiqui MAR, Hernandez R, Cook JA, Lourenco T, Ramsay CR, Vale L, Fraser C, Azuara-Blanco A, Deeks J, Cairns J, Wormald R, McPherson S, Wright D, Rabindranath KS, Grant A. The clinical and cost effectiveness of screening for open angle glaucoma: a systematic review and economic evaluation. *Health Technol Assess* 2007;11(41)

Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald A, Knight R, Entwistle VA, Garcia J, Roberts I, Grant A. Recruitment to randomised trials: Strategies for Trial Enrolment and Participation Study (STEPS). *Health Technol Assess* 2007;11(48)

Cuthbertson BH, Amiri AR, Croal BL, Rajagopalan S, Brittenden J, Hillis G. Utility of b-type natriuretic peptide in predicting medium-term mortality in patients undergoing major non-cardiac surgery. *Am J Cardiol* 2007;100(8):1310-3.

de Verteuil R, Hernandez R, Vale L, Aberdeen Technology Assessment Review Group. Economic evaluation of laparoscopic surgery for colorectal cancer. *Int J Technol Assess Health Care* 2007;23(4):464-72.

Fayers P, Langston AL, Robertson C, PRISM Trial Group. Implicit self-comparisons against others could bias quality of life assessments. *J Clin Epidemiol* 2007;60:1034-9.

Jia X, Mowatt G, Burr J, Cassar K, Cook JA, Fraser C. Systematic review of the safety and efficacy of foam sclerotherapy for venous disease of the lower limbs. *Br J Surg* 2007;94(8):925-36.

Mowatt G, Glazener CM, Jarrett M. Sacral nerve stimulation for faecal incontinence and constipation in adults. *The Cochrane Database of Systematic Reviews* 2007, Issue 3. DOI: 10.1002/14651858.CD004464.pub2.

Norrie J. Trials of venous thromboembolism prevention. *Lancet* 2007;370(9591):915-7.

Staff News

There have been several new appointments recently. We welcome to the Unit: (back row from left to right) David Jenkinson (Statistician), Charles Boachie (Statistician), Julien Masse (Secretary), Soji Adeyemi (Programmer), Keith Davidson (Senior Programmer); (front row from left to right) Kathryn Charles (Research Fellow), Suzanne Breeman (Trial Manager), Seonaidh Cotton (Trial Manager); and (not in photo) Mark Crowther (Clinical Research Fellow). Alison Murray and Robyn de Verteuil have recently left and we wish them well in their new appointments.



The CHaRT Team



Editorial team: Cynthia Fraser and Kathleen McIntosh.
The Health Services Research Unit is funded by the Chief Scientist Office of the Scottish Government Health Directorates. However, the views expressed in this publication are those of the authors alone.

This newsletter is produced twice yearly by the Health Services Research Unit, University of Aberdeen, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD. Telephone: 01224 553909. Fax: 01224 554580. Email: c.fraser@abdn.ac.uk. WWW: <http://www.abdn.ac.uk/hsru/>



Health Services Research Unit

Newsletter

Winter 2007/08

CHaRT achieves full registration as a UK Clinical Research Collaboration Trials Unit

The Centre for Healthcare Randomised Trials (CHaRT), HSRU's formal trials unit, has reached a very important milestone by becoming one of 17 clinical trials units in the UK to achieve full registration with the UK Clinical Research Collaboration. This achievement is recognition of how well CHaRT has successfully built on HSRU's record in conducting major healthcare trials. CHaRT's application, which was judged by an international panel of experts, was required to meet a number of key competencies.

Our track record in delivering landmark trials of significant healthcare questions was of fundamental importance, as was evidence of the sustainability of our funding. We are fortunate that the Scottish Funding Council's Scottish Collaboration of Trialists (ScoT) is providing important infrastructure funding for CHaRT between 2005 and 2009 and the Chief Scientist Office also continues to provide support. Our track record means we are confident we can continue to support CHaRT's activities through winning competitive external grant funding from UK public funders such as the NIHR HTA Programme and the MRC, and becoming fully registered will underpin these ambitions.

Demonstrating the high quality of our core processes to design, conduct, analyse and report multicentre randomised controlled trials was likewise important and having a set of simple, but comprehensive, standard operating procedures was essential. The recent appointment of Samantha Wileman as CHaRT/HSRU Quality Assurance Manager gave huge impetus to the completion of this task, and we are one of the few trials units to have a dedicated QA Manager. This strategic appointment followed on from that of our Research Managers (shared between Kirsty McCormack and Ruth Thomas), who help John

Norrie, the Director, in the task of objectively and transparently selecting which trials CHaRT will support - trials that are commensurate with CHaRT's remit. This separation of the 'upstream' activities from the 'downstream' part of CHaRT - the delivery of the portfolio of the adopted trials, superbly run by Alison McDonald (Senior Trials Manager) and Gladys McPherson (Senior IT Manager) - is proving a very effective solution.

Currently CHaRT has a portfolio of 12 ongoing trials, primarily of non-drug technologies, in a variety of specialities including orthopaedics, critical care, urology and ophthalmology.

For further information, see CHaRT website at www.chartrials.abdn.ac.uk/ or contact John Norrie, (E-mail: j.norrie@abdn.ac.uk Telephone: 01224 558988)



HSRU will be 20 years old this year!

To mark this special anniversary, HSRU will be hosting a one-day conference reviewing key developments in health services research over the past 20 years and assessing its impact on health care.

"Making a Difference in Health Care: 20 Years of Health Services Research"

Monday 7th July 2008

King's College Conference Centre, University of Aberdeen.

Please see enclosed leaflet and registration form or go to our conference website

www.abdn.ac.uk/hsru/conference

for further details.

Screening for open angle glaucoma: a systematic review and economic evaluation

Glaucoma is an important cause of blindness. Open angle glaucoma (OAG), the most common form of glaucoma, is without symptoms in the early stages. Early detection and treatment may reduce the burden of sight loss and consequent disability associated with this condition.

This project, funded by the National Institute for Health Research (NIHR), was led by Jennifer Burr and involved research teams from HSRU and the Health Economics Research Unit (HERU) as well as specialists in glaucoma from across the UK. We assessed whether screening for OAG met the UK National Screening Committee (NSC) criteria, and compared different screening strategies with the current practice of detecting glaucoma which relies on opportunistic case finding. We obtained data on costs and effectiveness from systematic reviews of the literature to model two potential screening strategies.

In one model, the 'Technician' strategy, people considered to be at risk of OAG would be invited to receive two tests (a measurement of intraocular pressure and a second test not pre-specified). Those who tested positive for OAG would be referred for specialised optometrist assessment. In the second model, the 'Glaucoma Optometrist' strategy, patients would be invited to see a specialised optometrist for assessment straight away.

Screening was more likely to be cost-effective as glaucoma prevalence increased; for 40 year olds compared with 60 or 75



year olds; when the re-screening interval was greater (10 years); and for the 'Technician' strategy compared with the 'Glaucoma Optometrist' strategy.

Overall, the findings of the research suggest that screening the general population for OAG is unlikely to be cost-effective, and does not meet the NSC criteria for a screening programme. However targeted screening for specific sub-groups at higher risk may be cost-effective although further research on the selection and organisation of optimal screening approaches, and on how best to identify individuals 'at risk' and encourage their attendance for screening is required.

*For further information, contact Jen Burr
(E-mail: j.burr@abdn.ac.uk Telephone: 01224 559715)*

Reference: Burr J, Mowatt G, Siddiqui MAR, Hernandez R, Cook JA, Lourenco T, Ramsay CR, Vale L, Fraser C, Azuara-Blanco A, Deeks J, Cairns J, Wormald R, McPherson S, Wright D, Rabindranath KS, Grant A. The clinical and cost effectiveness of screening for open angle glaucoma: a systematic review and economic evaluation. *Health Technol Assess* 2007;11(41).

Recruitment to randomised trials: Strategies for Trial Enrolment and Participation Study (STEPS)

Randomised controlled trials (RCTs) are widely accepted as the gold standard for evaluating healthcare interventions but it is unclear why many trials recruit well while others do not. Using a number of different perspectives and concentrating on the participation of collaborating researchers, the aim of STEPS was to identify factors associated with good and poor recruitment to multicentre trials.

The study had three distinct components:

- Part A - an epidemiological review of a cohort of trials funded by the MRC and the NHS HTA programme.
- Part B - case studies of four trials recommended by the funders which appeared to have particularly interesting lessons for recruitment.
- Part C - a single in-depth case study of a large multicentre trial - the MRC Corticosteroid Randomisation After Significant Head Injury [CRASH] Trial - to examine the feasibility of applying a business-orientated analytical framework to trial recruitment.

Of the 114 trials reviewed in Part A, less than one-third recruited to their original target and 53% were awarded an extension. Factors observed more often in trials that recruited successfully were having dedicated trial managers, being a cancer or a drug trial and evaluating interventions which were only available inside the trial.

The analyses in Part B suggested that successful trials were those addressing clinically important questions at a timely point. The investigators were held in high esteem by the interviewees and the trials were firmly grounded in existing clinical practices.

The process of the case study in Part C drew attention to a body of research and practice in a different discipline (academic business studies). A reference model was generated which enabled identification of weaker managerial components within the trial and development of initiatives to strengthen them.

STEPS identified that future trials should consider the different needs of trials which occur at the different phases in a trial's lifecycle. Greater emphasis should also be placed on the process of actually doing trials. The complexity of large trials means that unanticipated difficulties are highly likely at some time in every trial; successful trials appear to be those flexible enough and robust enough to adapt to these unexpected issues.

*For further information, contact Alison McDonald
(E-mail: a.mcdonald@abdn.ac.uk Telephone: 01224 554338)*

Reference Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald AM, Knight R, Entwistle V, Garcia J, Roberts I, Grant A; The STEPS group. Recruitment to randomised trials: strategies for trial enrolment and participation study. *The STEPS study. Health Technol Assess.* 2007; 11(48).

Staff profile: Jennifer Burr



Jennifer Burr leads the Health Technology Assessment (HTA) group within HSRU, which is part of the Unit's Health Care Assessment programme. This group comprises systematic reviewers, health economists, statisticians, information science and administrative staff.

Jennifer graduated in medicine from the University of Birmingham and subsequently underwent postgraduate training in ophthalmology. After she obtained an MSc in epidemiology and statistics

from the London School of Hygiene and Tropical Medicine in 2002, Jennifer joined HSRU as the Chief Scientist Office supported clinical research fellow. At the end of the fellowship year, Jennifer was appointed to lead the HTA work in HSRU, supported by Luke Vale, Graham Mowatt and Cynthia Fraser. Within the HTA portfolio, the Unit is undertaking Technology Assessment Reports (TARS) for NICE and other UK policy makers, systematic reviews for NICE's Interventional Procedures Programme, and also undertakes other commissioned reviews for the NIHR HTA programme.

Jennifer's research interests focus on healthcare evaluation in relation to eye disease and more widely across non-drug related interventions. Since joining the Unit, Jennifer has developed ophthalmology as one of the Unit's research themes with an increasing portfolio of work. This includes the FILMS trial (Full thickness macular hole and Internal Limiting Membrane peeling Study) and a programme of work in glaucoma - developing a glaucoma specific utility measure; evaluation of screening for open angle glaucoma; and alternative surgical interventions for angle closure glaucoma - all of which have led to proposals for future primary research.

Quality Assurance at HSRU

During the past five years, there has been a striking change in the environment in which research is conducted and delivered. In order to meet the wide range of legal, ethical, regulatory and governance requirements, and to demonstrate that HSRU is performing at a high standard, the role of Quality Assurance (QA) Manager has been created within HSRU. Samantha Wileman has been appointed to this position.

The key QA objectives for HSRU include:

- Ensuring quality is demonstrated throughout the delivery of all HSRU activities.
- Implementing in-house quality assurance systems.
- Developing, implementing and managing a new Unit-specific Standard Operating Procedures (SOP) system.
- Providing advice and reporting upon compliance within the Research Governance Framework.
- Providing QA representation for HSRU.

In addition to taking responsibility for assuring quality for current activities, Samantha has a strategic role in ensuring HSRU



FOCCUS Trial gets underway

FOCCUS (Fluid Optimisation and Critical Care Utilisation in Surgery) is a multicentre randomised trial of pre-operative fluid loading and post-operative ICU care for patients undergoing major surgery. The place of pre-operative optimisation in major surgery is unclear despite meta-analysis of level 1 evidence suggesting benefit. This may be due to a variety of reasons including lack of equipoise and lack of ICU resources, but this evidence base has failed to change clinical practice. Another reason for failure to implement this strategy relates to the fact that pre-operative optimisation is a complex intervention that includes fluid loading, optimisation of oxygen delivery, ICU care before and after surgery and invasive monitoring in ICU. FOCCUS aims to separate these interventions to identify whether individual components of this intervention may offer benefit.

FOCCUS started recruitment in Aberdeen in September and will also recruit at Glasgow Royal Infirmary and the Royal Alexandra Hospital in Paisley. We aim to recruit 200 patients over a 14 month period and perform 6 month follow-up with the primary outcome being cost-effectiveness. The team, led by Brian Cuthbertson, includes Daniela Rae, Seonaidh Cotton, Marion Campbell, John Norrie, Luke Vale, Rodolfo Hernandez, Alison McDonald and Gladys McPherson from HSRU as well as other local and national investigators.

This study is funded by the Chief Scientist Office of the Scottish Government Health Directorates with a grant of £225,000.

*For further information, contact Seonaidh Cotton
(E-mail: s.c.cotton@abdn.ac.uk Telephone: 01224 551126)*



adapts to changing regulatory and governance environments, and in improving its processes to make quality assurance an easier task. To date, she has assisted with; the successful UKCRC accreditation of CHaRT; project specific R&D monitoring visits; the revision of the Staff Handbook; the drafting of the revised set of SOPs for CHaRT; and the piloting of a Staff Development Manual which is planned to be rolled-out to all staff later this year. Another new

development has been the introduction of a bi-annual QA newsletter in order to keep staff up-dated - not only with HSRU-specific issues - but also with any relevant regulatory changes that may affect the Unit.

*For further information, contact Samantha Wileman
(E-mail: s.wileman@abdn.ac.uk Telephone: 01224 554196)*