Health Services Research Unit

Newsletter **Winter 2013**

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HSRU celebrates its 25th anniversary

2013 marked the 25th anniversary of the opening of the Health Services Research Unit. The Unit was formally opened on the 5th of July 1988 by Sir Andrew Watt Kay. At that time, the stated goal for the Unit was to "improve the effectiveness and efficiency of health services in Scotland by undertaking research and working for the implementation of proven change" with the identified priorities of: a) the efficient use of medical technologies; and b) studies of the "balance of care", directed towards the transfer of clinical activities away from specialist hospitals. Given the current policy focus on moving care from hospital to community settings and maximising time patients spend at home, it is clear that the Unit was ahead of its time in identifying these areas as prime for research.

Over the last 25 years, the Unit has continued to lead in many domains of health services research. For example the National Institute of Health Research recently published the "top ten" studies from its portfolio – three of these were led from the Unit, with the seminal study on effective guideline dissemination strategies led by Jeremy Grimshaw (former programme director, now in Ottawa), together with many colleagues who are still in the Unit, rated number one. We look forward to the next 25 years with great expectation!

Trial Forge:

a systematic approach to making trials more efficient

What's the connection between randomised controlled trials and Sir Chris Hoy? Okay, you might think not much but that might change with HSRU's Trial Forge initiative for trial methodology research.

Despite trials being a cornerstone of evidence-based healthcare, much of the trial process is an evidence-free zone. For example, all trials have to recruit participants but, so far, methodological research has produced high quality evidence for only a handful of recruitment interventions. More generally, research questions may not reflect what patients are most interested in; outcomes may burden trials with collecting data that are never published, and trial design decisions may guarantee irrelevance to those expected to use the trial results. Trials are in desperate need of efficiency improvements.

This is where Sir Chris Hoy fits in, or rather British Cycling. Performance director Dave Brailsford put Team GB's dominance at the 2012 Olympics down to marginal gains - the idea that if you break down everything you could think of that goes into riding a bike, and then improved each element by 1%, you will get a big gain when you put them all together. Trial Forge aims to do the same for trials.

Trial Forge aims to look for marginal gains across all trial processes, from research question to implementation into routine care. It will encourage everyone connected with trials to be more sceptical of what we do by asking for the evidence behind all of our trial decisions. Where no evidence exists (as will often be the case), Trial Forge will provide a platform to highlight this gap and bring researchers and others (including funders) together so that they can fill the gap. Insights from disciplines not normally associated with trials, such as business and organisational change management, will be part of this efficiency drive. Indeed, increased collaboration is at the heart of Trial Forge.

Things are just getting off the ground, with discussions underway with the MRC Methodology Hubs and others about workshops and funding.

For further information, please contact Shaun Treweek, email streweek@mac.com, telephone 01224 438145.

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Unit members receive prestigious awards

Two members of the Unit have recently been recognised for their outstanding contributions to their respective fields. Unit Director, Professor Marion Campbell is among 47 new UK and International Fellows elected to the Fellowship of the Royal Society of Edinburgh (RSE). Fellows are elected following a rigorous examination of their achievements in their relevant fields. The RSE's mission is the advancement of learning and useful knowledge. It is unique in Britain and distinctive internationally in the breadth of its Fellowship, ranging across the sciences, medicine, engineering, the social sciences, arts, humanities, business and public service.

In addition, Professor Lorna McKee has been conferred with the Award of Academician of the Academy of Social Sciences, in recognition of her contribution to the field of social sciences. Lorna is one of only 35 social scientists welcomed as Academicians this year, with only two of these from Scotland.

Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery: the MASTER trial

Around one in five men that undergo prostate surgery for cancer or benign disease end up leaking urine as they walk around, cough or do physical activity. This ruins the quality of these men's lives, lowers their self-esteem, can stop them working and damages their personal relationships. Traditionally, these men undergo major surgery to have a plastic artificial urinary sphincter device inserted to control their incontinence. A newer surgery which is less invasive, the male sling, is also available. The number of men needing surgery for this type of incontinence is set to rise due to the improvements in detecting early prostate cancer. Therefore, the effectiveness and definitive costs of the treatment must be assessed to inform the NHS on the best treatment strategy.

MASTER
Male synthetic sling versus
Artificial urinary Sphincter Trial

MASTER will compare the advantages and disadvantages of these two incontinence operations. This will be done by considering two primary outcomes: 1) the clinical effectiveness of implanting the male sling versus the artificial urinary sphincter in terms of patient reported incontinence at 12 months; 2) the cost-effectiveness measured in quality adjusted life years at 24 months.

MASTER will randomise 360 participants to the two treatment arms as well as following-up a further 360 participants that are not eligible for randomisation. This is a collaborative UK wide randomised trial funded by the NIHR Health Technology Assessment programme and sponsored by North Bristol Trust. The trial commenced in September 2013 and will be open for recruitment in January 2014.

For further information, please contact Kirsty Shearer, email k.d.shearer@abdn.ac.uk, telephone 01224 438096.

Reflux Trial reports results

The initial results from the REFLUX trial published in 2008 showed that laparoscopic fundoplication for people with chronic symptoms of gastro-oesophageal reflux disease (GORD) significantly improved reflux-specific and general health-related quality of life for at least up to 12 months after surgery. These data provided promising evidence that surgical management might well be cost-effective, but there was uncertainty, especially about longer-term costs and benefits, to provide clear guidance for decision makers. For this reason, longer-term follow-up to five years was funded by the NIHR HTA Programme.

The REFLUX trial recruited 810 participants with GORD from across the UK between March 2000 and June 2004. 357 were recruited to the randomised comparison (178 randomised surgery, 179 randomised medical management) and 453 to the preference groups (261 surgical and 192 medical management). For the five year follow-up, participants were asked to complete annual postal questionnaires, including the disease-specific REFLUX instrument, general health-related quality of life measures (SF-36, EQ-5D), medication use, surgical events and health service use.

After five years, people who were in the randomised surgery group continued to have less symptoms of reflux than those who remained on medication. Health-related quality of life scores also favoured the randomised surgical group, but differences attenuated over time and were generally not statistically significant at five years.

Some people in the medical groups did have fundoplication surgery during follow-up. Most people in the randomised medical group (82%) continued to take anti-reflux medication at five years. About one quarter of those in the randomised surgery group were also taking some anti-reflux medication at five years. Following fundoplication, 3% had surgical treatment for a complication and 4% had subsequent reflux-related operations. Dysphagia, flatulence and inability to vomit were similar in the two randomised groups.

Despite being initially more costly, a surgical policy is highly likely to be cost-effective: the incremental cost-effectiveness ratio was £7,028 per additional quality adjusted life year. These findings were robust to changes in approaches and assumptions.

The results from the five year follow-up have been published as part of the journal Health Technology Assessment, the British Medical Journal and the British Journal of Surgery.

For further information, please contact Seonaidh Cotton, email s.c.cotton@abdn.ac.uk, telephone 01224 438178.

Concept SSM:

re-conceptualising support for self-management of long term conditions

Concept:SSM
Conceptualising Support for Self Management

As the prevalence of long term conditions has risen, so have concerns about limited healthcare resources and the quality of patients' experiences. These concerns have all contributed to interest in the idea that health services should work more collaboratively with patients and support them to self manage their conditions; however, policy ideals have not been widely achieved in practice. In part, this is because the summary descriptions that have been used to promote collaborative approaches and support for self-management to clinicians do not adequately reflect why these approaches are important, what they entail, or how they might vary over different situations.

In a previous Health Foundation-funded project, we illustrated some of the practical problems that can arise when concepts such as 'equal partnerships', 'patient activation' and 'patient-led goal-setting' are interpreted narrowly or used without attending to the diverse, complex and dynamic realities of health service work and of the daily lives of people with long term conditions. We also showed that by focusing on what people value being able to be and do (valued capabilities) and recognising that their capabilities are socially shaped (including within and by healthcare relationships), we could, in principle, shed light on what is important about collaborative approaches. We could also better understand the practical and ethical complexities that health professionals face as they try to support people to manage their long term conditions.

Concept SSM is a recently awarded Health Foundation project. It will consider how the potential of a focus on capabilities, and of a clear recognition that capabilities are socially shaped, can be exploited in practice to help improve the ways health and social care services support people with long term conditions. We will use published literature and primary research to inform the development of a so-called "relationally theorised capabilities-based conceptual analysis and model of support for self management" as well as a set of illustrative vignettes of health and social care practice. Drafts of all of these will be tested and refined in discussion with groups of health and social care professionals, people who live with and advocate for others with long term conditions, and quality improvement specialists.

For further information, please contact Vikki Entwistle, email vikki.entwistle@abdn.ac.uk, telephone 01224 438146.

Staff profile: Charis Glazener

Charis Glazener joined the Unit on its first day, in July 1988 and is now the last remaining member of staff from that era. She graduated in Medicine at Dundee University in 1979 and joined the Unit in 1988 as a Health Services Research Training Fellow funded by the Wellcome Trust. Her background was in obstetrics and gynaecology, and she undertook a number of clinical trials in Bristol leading to her MD in unexplained infertility. Returning to Aberdeen, she gained membership of the Royal College of Obstetricians and Gynaecologists in 1986, and became a Fellow in 2003. Her initial research in HSRU was in postnatal care, leading to a PhD. This work sparked her involvement in a number of related randomised trials in neonatology, postnatal support and incontinence. As a result of her interest in postnatal incontinence, she became involved in setting up the Cochrane Incontinence Review Group when Adrian Grant took over as Director in the mid-90s. The Cochrane reviews were used to identify gaps in the evidence base, which she helped to address by running a number of large NIHR-funded RCTs, most recently in prolapse surgery (PROSPECT and VUE). She was promoted to Professor of Health Services Research in 2009 and is now the Co-ordinating Editor of the Cochrane Incontinence Review Group based in Aberdeen. Her research interests include urinary and faecal incontinence, prolapse, enuresis, and postnatal issues such as maternal morbidity, particularly the epidemiology of the long term consequences of childbirth. Her 33-year career in research has led to a large number of international collaborations and friendships, which have provided her with much personal satisfaction, support and fruitful research.

For further information, please contact Charis Glazener, email c.glazener@abdn.ac.uk, telephone 01224 438168.

Staff News

The following new staff members are warmly welcomed to the Unit: Rumana Newlands (research assistant), Lindsay Grant (data coordinator), Lana Mitchell (data coordinator), David Cooper (statistician), Louise Cotterell (administrator), Tomas Pohl (programmer), Yvonne Fernie (Secretary/PA), Anna Sierawska (PhD student) and Kirsty Shearer (trial manager).

Augusto Azuara-Blanco, Diane Collins, Shalmini Jayakody, Joanne Coyle, Niina Kolehmainen, Graham Mowatt and Jonathan Cook have recently left the Unit and we wish them all well.

Recent publications

(1) Breeman S, Campbell MK, Dakin H, Fiddian N, Fitzpatrick R, Grant A, Gray A, Johnston L, MacLennan GS, Morris RW, Murray DW, KAT Trial Group. Five year results of a randomised controlled trial comparing mobile and fixed bearing total knee replacement. *Bone Joint Journal* 2013;95-B(4):486-92.

(2) Entwistle VA, Watt IS. Treating patients as persons: a capabilities approach to support delivery of person centered care. *American Journal of Bioethics* 2013;13(8):29-39.

(3) Ford JA, Cummins E, Sharma P, Elders A, Stewart F, Johnston R, Royle P, Jones R, Mulatero C, Todd R, Mowatt G. Systematic review of the clinical effectiveness and cost-effectiveness, and economic evaluation, of denosumab for the treatment of bone metastases from solid tumours. *Health Technol Assess* 2013;17(29):1-385.

(4) Grant AM, Boachie C, Cotton SC, Faria R, Bojke L, Epstein D, Ramsay CR, Corbacho B, Sculpher M, Krukowski ZH, Heading RC, Campbell MK, REFLUX Trial Group. Clinical and economic evaluation of laparoscopic surgery compared with medical management for gastro-oesophageal reflux disease - 5-year follow-up of multicentre randomised trial (The REFLUX Trial). *Health Technol Assess* 2013;17(22):1-166.

(5) Higgins JPT, Ramsay CR, Reeves BC, Shea B, Valentine J, Tugwell P, Wells G. Issues relating to study design and risk of bias when including non-randomized studies in systematic reviews on the effects of interventions. *Res Synth Methods* 2013;4(1):12-25.

(6) Kazimierczak KA, Skea Z, Dixon-Woods M, Entwistle VA, Feldman-Stewart D, N'Dow J, MacLennan S. Provision of cancer information as a "support for navigating the knowledge landscape": findings from a critical interpretive literature synthesis. *Eur J Oncol Nurs* 2013;17(3):360-9.

(7) Kolehmainen N, Duncan EAS, Francis J. Clinicians' actions associated with the successful patient care process: A content analysis of interviews with paediatric occupational therapists. *Disabil Rehabil* 2013;35(5):388-96.

(8) McCann SK, Campbell MK, Entwistle VA. Recruitment to clinical trials: A meta-ethnographic synthesis of studies of reasons for participation. *J Health Serv Res Policy* 2013;doi: 10.1177/1355819613483126.

(9) McKee L, Charles K, Dixon-Woods M, Willars J, Martin G. "New" and distributed leadership in quality and safety in healthcare, or "old" and hierarchical? An interview study with strategic stakeholders. *J Health Serv Res Policy* 2013;18

(10) McPherson G, Campbell MK, Elbourne D. Investigating the relationship between predictability and imbalance in minimisation: a simulation study. *Trials [serial on the Internet]* 2013;14:86. http://www.trialsjournal.com/content/14/1/86/

(11) Mowatt G, Scotland G, Boachie C, Cruickshank M, Ford J, Fraser C, Kurban L, Lam TB, Padhani AR, Royle J, Scheenen TW, Tassie E. The diagnostic accuracy and cost-effectiveness of magnetic resonance spectroscopy and enhanced magnetic resonance imaging techniques in aiding the localisation of prostate abnormalities for biopsy: a systematic review and economic evaluation. *Health Technol Assess* 2013;17(20)

(12) Treweek S, Lockhart P, Pitkethly M, Cook JA, Kjeldstrom M, Johansen M, Taskilla TK, Sullivan F, Wilson S, Jackson C, Jones R, Mitchell E. Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis. *BMJ Open* 2013;3:e002360.

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