



Health Services Research Unit

Newsletter

Autumn 2014

Quality and Safety in the NHS: lessons from research



The findings of a large multi-method research programme, funded by the Department of Health's Policy Research Programme, investigating culture and behaviour across the English NHS relating to quality and safety, have been published. The research was carried out by researchers from the Universities of Aberdeen, Aston, Birmingham, Lancaster, Leicester and Sheffield.

Our research reported that many NHS staff in England routinely demonstrate the values of safety, civility, and compassion, providing the highest quality of care to patients even in challenging circumstances. If staff are to provide consistent care, however, they must be well supported. Staff engagement is a key predictor of a variety of the most important outcomes in NHS organisations, including care quality, financial performance, staff absenteeism and even patient mortality.

People in the NHS also describe a regulatory environment crowded with external agencies and serving different but overlapping functions. NHS organisations have to meet multiple expectations, standards, and targets that are sometimes ill-coordinated or conflicting. The result is unnecessary confusion and distraction, dissipation of energy, and distortion of focus, such that organisations are hindered in the development of clear, internally coherent strategies linked to local priorities. Reducing confusion requires streamlining targets, standards, incentives, measures and priorities at every level.

Boards of NHS organisations are also often unclear about their objectives as a team. Moreover, the priorities they identify often inappropriately emphasise productivity, targets and efficiencies above quality and safety. What some Boards claim to value is inconsistent with the reality in their organisations.

Effective senior teams recognise and reward both efforts at innovation and successes at all levels, and ensure they are empowering staff to implement changes that deliver better quality patient care. Staff could be consulted and involved in the co-design and co-implementation of changes to improve quality and safety.

Boards must be problem-sensing to ensure their organisations are constantly learning how to improve quality and safety. This means seeking out and responding to problems, and eliciting the rich views of patients and staff – not relying solely on mandated data collection.

Our research suggests there is considerable variation in quality of care between and within NHS organisations. It also suggests ways of ensuring that all patients receive high-quality, safe, compassionate care across the NHS.

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Decision Aids for Randomised Trials

The use of decision aids in the context of decisions about trial participation is an emergent field. There is a lack of evidence about what information is deemed important to support informed decisions about trial participation, whether different stakeholder groups agree on the relevance and importance of different types of information and whether such tools are useful and acceptable for use in this context.

Informed by the wider trials and decision aid literature, a list of possible items which could be included in a trial decision aid was developed and a Delphi study of multiple stakeholder groups conducted. There was consensus in the Delphi study across all stakeholder groups for the inclusion of many factors (including information about trial participation and standard care; information on the likelihood of receiving different interventions; information to help participants determine what matters most to them; ensuring

information balance; guidance on how to make a decision; conflicts of interest; using plain language and guidance on the development process). However, some areas of divergence of opinion between stakeholder groups emerged (particularly around inclusion of patient narratives). The prototype decision aids were found to be generally well received by stakeholders, with most agreeing they were an improvement on existing patient information leaflets for trials.

Further research is currently being planned to further explore the potential role of patient narratives in the context of decision about trial participation.

For further information, please contact Katie Gillies, email k.gillies@abdn.ac.uk, telephone 01224 438159.



New trial for the treatment of heavy menstrual bleeding commences

Heavy menstrual bleeding (HMB) is a very common and distressing condition which affects over 1.5 million women in the UK. It is responsible for one in 20 women consulting their general practitioner and accounts for 20% of hospital referrals in gynaecology. Initial treatment usually involves the use of drugs, including the combined oral contraceptive pill, as well as a hormone impregnated intrauterine contraceptive device. However, these may be unsuitable or unsuccessful in some women, who will then need surgical treatment. The NICE guideline on HMB recommends endometrial ablation (which destroys the lining of the cavity of the uterus) as well as hysterectomy as options for women resistant to medical treatment.

A minimally invasive form of hysterectomy has recently been developed. Laparoscopic supra-cervical hysterectomy aims to use minimal access techniques via the abdominal route to remove the body of the uterus which is responsible for menstrual bleeding. It is

quick, relatively easy to learn and associated with low morbidity, short hospital stay (under 24 hours) and rapid recovery time. It could therefore potentially offer women the benefit of a total hysterectomy with the minimal invasiveness of endometrial ablation. Before this technique is incorporated into routine clinical practice, it is important that it is subjected to robust evaluation.

HEALTH is a multi-centre randomised controlled trial comparing the clinical and cost-effectiveness of laparoscopic supra-cervical hysterectomy with second generation endometrial ablation. The trial, which is funded by the National Institute for Health Research, and jointly sponsored by NHS Grampian and the University of Aberdeen, will recruit 648 women across the UK. Recruitment commenced in April 2014.

For further information, please email health@abdn.ac.uk.

The POPPY Trial reports its findings

Pelvic organ prolapse in women is mostly treated by surgery, ring pessary or by exercises. However, there is currently little evidence to show whether or not exercises can improve the symptoms of prolapse. This study aimed to determine the clinical and cost-effectiveness of individualised pelvic floor muscle training (PFMT) in the management of women with pelvic organ prolapse.

The POPPY trial was a multi-centre randomised controlled trial in 23 UK and two international gynaecology centres. Women with newly-diagnosed prolapse were randomised to either the intervention group, who received an individualised PFMT programme from a physiotherapist during five appointments over 16 weeks, or the control group, who received an advice leaflet, giving general lifestyle advice, by post.

447 women were randomised (225 intervention; 222 control). When compared to the control group, benefits to the intervention group were observed in terms of significantly fewer prolapse symptoms at 6 and 12 months, and greater perceived improvement in prolapse at 6 and 12 months. Uptake of further prolapse treatment by 12 months was

greater in the control group (50%) compared to the intervention group (24%). Prolapse severity was improved more in the intervention group compared to the control group (27% versus 20%), although this finding was not statistically significant. There were additional benefits to the intervention group at 6 months of better prolapse-related quality of life, and fewer urinary and bowel problems.

The net cost of the intervention, allowing for further treatment received/avoided, was £132 per woman.

We concluded that pelvic floor muscle training is effective and potentially cost-effective and should be recommended for the conservative management of prolapse. A 24-month follow-up of the women is ongoing, to evaluate longer-term outcomes. It is important that we implement and continue to evaluate this treatment so that women can benefit from evidence-based management.

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

The SIMS Trial: Adjustable Anchored Single-Incision Mini-Slings Versus Standard Tension-Free Mid-Urethral Slings in the Surgical Management Of Female Stress Urinary Incontinence

Urinary incontinence (UI) is a common and distressing condition for women, particularly over the age of 40 years, affecting approximately 6 million women in the UK. UI has a negative impact on a woman's social, physical and psychological wellbeing, leading to embarrassment, low self-esteem and social isolation. UI is associated with negative effects on the productivity of working women, with some avoiding employment because of fear of embarrassing situations.

Stress urinary incontinence (SUI) is the most common type of UI in premenopausal women, accounting for almost half of cases. It is defined as involuntary leakage of urine on effort, exertion, or on sneezing or coughing. Should conservative therapy fail (which occurs in about one third of cases) then surgery is the next option.

Of the surgical treatments available, standard tension-free mid urethral slings (SMUS) are the most commonly performed procedures for SUI and are usually performed under general anaesthetic. Single-incision mini slings (SIMS), the third generation of the mid urethral slings, can be performed under a

local anaesthetic and are associated with reduced morbidity and earlier recovery.

The aim of this pragmatic UK-wide multicentre RCT is to determine the clinical and cost-effectiveness of SIMS compared to tension-free SMUS. In this collaborative trial, funded by the NIHR Health Technology Assessment programme, the SIMS trial will randomise 650 participants to either of the two treatment arms; compare the patient-reported success rates and cost-effectiveness at 12 months. In addition, we will compare various secondary outcomes such as objective success rate (24 hour pad test/ home cough stress test), postoperative pain scores, recovery period and impact on women's quality of life and sexual function. Patients will be followed up for 3 years and will be compensated for their time and inconvenience with a voucher. The study started in December 2013 and will run for a total of 66 months.

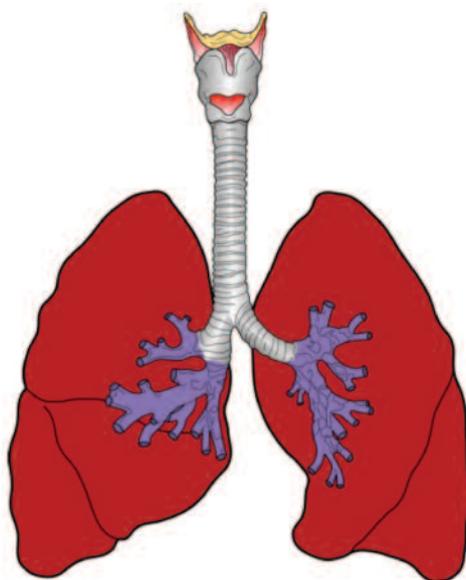
For further information, please contact Tracey Davidson, email t.davidson@abdn.ac.uk, telephone 01224 438180.

The TWICS trial:

Theophylline with Inhaled Corticosteroids

Chronic Obstructive Pulmonary Disease (COPD) is a progressive lung disease characterised by progressive airflow limitation. It affects approximately 1 million people in the UK, is the sixth leading cause of death in the UK and costs the NHS approximately £1 billion annually. One of the features of COPD is exacerbations characterised by worsening breathlessness. These episodes are associated with increased mortality, accelerated rate of lung function decline, reduced physical activity and reduced quality of life.

The majority of COPD treatment guidelines recommend inhaled corticosteroids, usually in combination with other inhaled medication to reduce exacerbation rates and to improve lung function. However, the airway inflammation underlying COPD is relatively insensitive to the anti-inflammatory effects of inhaled corticosteroids and even high doses fail to prevent exacerbations. Pre-clinical and pilot clinical trials indicate that theophylline, at low dose, increases the sensitivity of COPD airway inflammation to the anti-inflammatory effects of inhaled corticosteroids. Theophylline is a cheap (5p/day) drug that has been used to treat COPD and asthma for 70 years, but, at high doses, has a narrow therapeutic index with a relatively high incidence of side effects and the requirement for



blood monitoring. It is anticipated that, at low dose, side effects will be minimal and blood monitoring will not be necessary.

The TWICS trial has been funded by the NIHR HTA Programme to investigate whether the addition of low dose oral theophylline to inhaled corticosteroid therapy in patients with COPD at high risk of exacerbation reduces the risk of exacerbation. Other outcomes include cost-per-QALY gained, quality of life, lung function and mortality.

The study aims to recruit 1424 participants in at least seven geographical areas of the UK. A key feature of this study is the recruitment and follow-up of participants in primary care settings as well as in secondary care. Participants will be randomised to receive theophylline or placebo for a period of 12 months and will be followed-up at 6 and 12 months. Recruitment to the trial started in February 2014.

The trial is led by Professors Graham Devereux and David Price of the University of Aberdeen, and the trial office is based in the Centre for Healthcare Randomised Trials (CHaRT).

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



Staff profile: Gladys McPherson

Gladys McPherson joined the Unit as a programmer in February 1999. She graduated in Maths from the University of Aberdeen in 1993 followed by an

MSc in Information Systems at Robert Gordon University in 1995. She had previously completed a BA in Biology with the Open University followed by a PGCE in Secondary Education with a view to teaching Biology and general Science at Secondary school level.

Gladys was initially employed to work on the RECORD trial, HSRU's first large multi-centre trial. Her remit was to build programming solutions not only for RECORD, but for trials that the Unit would undertake in the future. She also further developed and marketed the Aberdeen Randomisation Service, offering automated randomisation solutions to other researchers and institutes throughout the UK.

CHaRT was formed in 2005 and Gladys was promoted to Senior IT Manager. The programming solutions evolved to embrace newer technologies and data collection moved on to the Web. The programming team currently has eight team members in total supporting 17 trials with a further six in development. Support is also provided for non-trials work and several Delphi studies have been supported over recent years. In 2011, Gladys completed a PhD exploring 'The Role of Minimisation in Treatment Allocation for Clinical Trials' and, following on from this work, a new generic algorithm was incorporated into the randomisation service.

Gladys chairs the Scottish Trials Programming Group which was set up to share information and improve efficiency in the delivery of clinical trials in Scotland. She is a member of the faculty on the Edinburgh Clinical Trials Management course, leading the authorship and delivery of the workshop on Data Management. She is also a member of the Scottish Food Frequency Questionnaire Collaborative Group and University of Aberdeen's Clinical Research Operational Group.

For further information, please contact Gladys McPherson, email g.mcpherson@abdn.ac.uk, telephone 01224 438176.

Recent publications

1. Burr JM, Hernandez R, Ramsay CR, Prior M, Campbell SE, Azuara-Blanco A, Campbell MK, Francis JJ, Vale L. Is it worthwhile to conduct a randomised controlled trial of glaucoma screening in the United Kingdom? *J Health Serv Res Policy* 2014;19(1):42-51.
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3. Francis JJ, Duncan EM, Prior ME, MacLennan G, Marshall AP, Wells EC, Todd L, Rose L, Campbell M, Webster F, Eccles MP, Bellingan G, Seppelt I, Grimshaw JM, Cuthbertson BH, SuDDICU study groups. Comparison of four methods for assessing the importance of attitudinal beliefs: an international Delphi study in intensive care settings. *Br J Health Psychol* 2014;19(2):274-91.
4. Glazener C, MacArthur C, Hagen S, Elders A, Lancashire R, Herbison P, Wilson D, ProLong Study Group. Twelve year follow up of conservative management of postnatal urinary and faecal incontinence and prolapse outcomes: randomised controlled trial. *Br J Obstet Gynaecol* 2014;121(1):112-9.
5. Hagen S, Stark D, Glazener C, Dickson S, Barry S, Elders A, Frawley H, Galea MP, Logan J, McDonald A, McPherson G, Moore KH, Norrie J, Walker A, Wilson D. Individualised pelvic floor muscle training in women with pelvic organ prolapse: a multicentre randomised controlled trial. *Lancet* 2014;383(9919):796-806.
6. Marshall AP, Weisbrodt L, Rose L, Duncan EM, Prior M, Todd L, Wells E, Seppelt I, Cuthbertson B, Francis JJ. Implementing Selective Digestive Decontamination in the intensive care unit: A qualitative analysis of considerations identified by critical care nurses. *Heart Lung* 2014;43(1):13-8.
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8. Siddiqi N, Neil C, Bruce M, MacLennan G, Cotton S, Papadopoulou S, NIAMI investigators. Intravenous sodium nitrite in acute ST-elevation myocardial infarction: a randomized controlled trial (NIAMI) *Eur Heart J* 2014 doi:10.1093/eurheartj/ehu096.
9. Sullivan F, Hinds A, Pitkethly M, Treweek S, Wilson P, Wyke S. Primary care research network progress in Scotland. *Eur J Gen Pract* 2014;doi: 10.3109/13814788.2013.879116.
10. Treweek S, Bonetti D, MacLennan G, Barnett K, Eccles MP, Jones C, Pitts NB, Ricketts I, Sullivan F, Weal M, Francis JJ. Paper-based and web-based Intervention Modelling Experiments identified the same predictors of general practitioner antibiotic prescribing behaviour: an evaluation of the Intervention Modelling Experiment methodology. *J Clin Epidemiol* 2014;67(3):296-304.

Staff News

We welcome the following new staff members to the Unit: Data coordinators Fiona Cherry, Georgia Mannion-Krase and Jess Wood; programmers Janet Nixon, Sahista Kauser and Brian Taylor; Becky Brown (Research Fellow); trial managers Gordon Fernie and Karen Innes; Bev Smith (receptionist); Jemma Hudson, Beatrix Goulao and Lorna Henderson (statisticians). Welcome back to Eilidh Duncan who recently returned from maternity leave and to Mags Watson who has joined us on a 12 month secondment.

Natalie Paterson, Lana Mitchell, Yvonne Fernie, Charles Boachie, Andy Elders, Maria Prior, Sharon McCann, Hanne Bruhn and Moira Ritchie have recently left the Unit. We wish them all well.



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