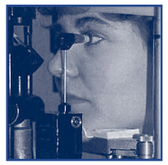
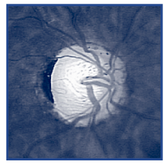
The clinical and cost effectiveness of screening for open angle glaucoma

A group led by HSRU, including collaborators in Aberdeen, Birmingham, London and Oxford, has been funded by the NHS Health Technology Assessment Programme to undertake evaluation of the clinical and cost effectiveness of screening for open angle glaucoma in the UK. The project group is funded for 14 months from February 2005 and includes clinical research fellows, systematic reviewers, medical statisticians and health economists.



Intraocular pressure measurement by applanation tonometry

Glaucoma is a major cause of blindness in the UK of which open angle glaucoma is the most common form. Open angle glaucoma is characterised by progressive reduction in the field of vision and optic nerve damage, and it can lead to blindness if untreated. During the early stages of glaucoma, most people have no symptoms. The risk of Glaucoma increases with age, and as the population in the UK is aging, the number of people affected by glaucoma will increase. Glaucoma can be diagnosed by measuring intraocular pressure, examination of optic disc and visual field, or any combination of these tests. Various tests are available to assess these modalities, although, accuracy, acceptability and cost varies considerably among the tests.



Glaucomatous optic nerve damage

The project will assess the extent to which screening for open angle glaucoma would meet the UK National Screening Committee criteria for a screening programme. The research involves systematic reviews of the diagnostic accuracy and impact of screening tests for glaucoma, with decision analysis and Markov modeling to evaluate the clinical and cost effectiveness of alternative screening strategies compared to current case finding.

For more information contact Jennifer Burr (email j.m.burr@abdn.ac.uk or telephone 01224 559715).

Selected Unit publications

Avenell A, Grant AM, McGee M, McPherson G, Campbell MK, McGee MA, for the RECORD Trial Management Group. The effects of an open design on trial participant recruitment, compliance and retention - a randomised controlled trial comparison with a blinded, placebo-controlled design. *Clin Trials* 2004;**1**:490-498.

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Glazener CM, Herbison GP, MacArthur C, Grant AM, Wilson PD. Randomised controlled trial of conservative management of postnatal urinary and faecal incontinence: six year follow-up. *BMJ* 2005;**330**:337-339.

Grant AM, Scott NW, O'Dwyer P, for the MRC Laparoscopic Groin Hernia Trial Group. Five-year follow-up of a randomized trial to assess pain and numbness after laparoscopic or open repair of groin hernia. *Br J Surg* 2004;**91**:1570-1574.

Langston A, McCallum M, Campbell MK, Robertson C, Ralston SH. An integrated approach to consumer representation and involvement in a multicentre randomised controlled trial. *Clin Trials* 2005;**2**:1-8.

Maher C, Baessler K, Glazener CM, Hagen S, Adams L. Surgical management of pelvic organ prolapse in women. *The Cochrane Database of Systematic Reviews* 2004, Issue 4 Art. No.: CD004014. DOI: 10.1002/14651858.CD004014.pub2.

Norris SL, Zhang X, Avenell A, Gregg E, Bowman B, Serdula M, Brown TJ, Schmid CH, Lau J. The long-term effectiveness of lifestyle and behavioural weight loss interventions in adults with type 2 diabetes: a meta-analysis. *Am J Med* 2004;**117**:762-774.

Staff news

We welcome Silvia Anton, Bronwyn Davidson, Kirsty Gordon and Tania Lourenco to the Unit.

Miriam Brazzelli, June Younes and Donna Paterson have recently left the Unit and we wish them well in the future.

UNIVERSITY OF ABERDEEN

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

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Health Services Research Unit

Newsletter
Spring 2005

Evidence that supplements of calcium and/or vitamin D3 do not prevent osteoporotic fractures - The RECORD trial

The RECORD trial (funded by the Medical Research Council, Shire Pharmaceuticals and Nycomed) investigated the effect of calcium and/or vitamin D3 supplements on the incidence of further fractures in men and women aged over 70 years with a previous low-trauma fracture. Fractures resulting from osteoporosis occur after minor trauma and are an important cause of ill-health. After the age of 50 years, one in three women and one in twelve men will have an osteoporotic fracture, such as those of the hip, wrist or spine. Those people who have already had one osteoporotic fracture are at increased risk of a further fracture. It is not clear if supplements of calcium and/or vitamin D3 are effective in the secondary prevention of fractures.

The trial office in HSRU coordinated the recruitment of 5292 participants from 21 centres in the UK, who were randomised to 1000mg calcium, 20mcg vitamin D3, both, or placebo. Most participants were able to walk out of doors unaccompanied and less than 1% came from nursing homes. The trial mainly examined the prevention of low-trauma fractures, but other outcomes including health status, mortality, falls and adverse events were also sought. Participants were followed up for between 24 and 62 months. Six hundred and ninety-eight (13%) had a further low-trauma fracture, including 183 people with hip fractures. Results have been recently published in The Lancet[1]. There were no statistically significant differences between those allocated calcium and those not; those allocated vitamin D3 and those not; and those allocated both calcium and vitamin D3 versus placebo. No significant differences were detected for hip fractures, mortality, falls or quality of life. Potentially serious adverse events were rare and did not differ between the groups.

The findings do not support the use of routine calcium and/or vitamin D3 supplements for the prevention of further fractures in older people with a recent low-trauma fracture.

Reference

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For more information contact Alison Avenell (email a.avenell@abdn.ac.uk or telephone 01224 554336).

Staff profile: Lorna McKee

Lorna McKee joined the Health Services Research Unit in June 2004 on secondment. Lorna is Professor of Management at the University of Aberdeen Business School and has previously held research posts at the universities of York, Aston and Warwick prior to moving to Aberdeen. Working with colleagues in the Institute of Applied Health Sciences, her remit is to explore opportunities for collaboration on the organisation and delivery of health care. Lorna is vice-chair of the NHS Service and Delivery and Organisation (SDO) Programme board.

Contents

Outcome after transposed intestinal segment surgery (OTIS)

The Unit works closely with the University of Aberdeen's Academic Department of Urology. Funds have recently been received to assess the longer-term implications of surgery to augment or replace the bladder. Each year in the UK around 3000 people have major surgery because their bladders are seriously diseased or must be removed. The most common reason is cancer in the bladder.

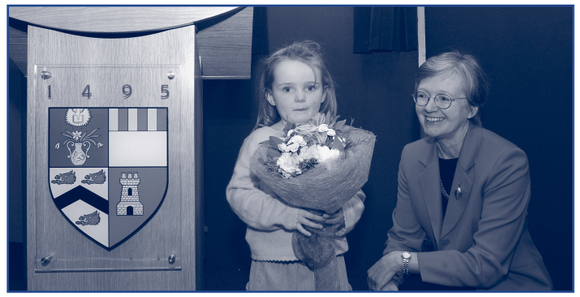
Some surgical procedures are more complicated than others but all involve using bowel segments to provide a system for storage and voiding of urine. The technically easiest way is to divert the urine either by using a segment of bowel to bring urine to a bag on the front of the abdomen, or by connecting the ureters (which normally carry urine from the kidneys to the bladder) to the large bowel. More complex ways are to use pieces of bowel to patch into the bladder or replace it altogether. There is no ideal procedure. Problems such as urine leakage, bowel disturbance, and sexual dysfunction are common and these often have a profound effect on people's lives. Increasingly, surgeons are tending to recommend the more complex operations in the hope that these will provide a higher quality of life. But it is not clear which operation is best for different types of patients.

The OTIS study (**O**utcome after **T**ransposed **I**ntestinal **S**egment **S**urgery) is aimed at establishing which is the best type of surgery for individuals or groups of patients. Funding was received from the BUPA Foundation. The wider implications for both the patients and the NHS will be studied in a formal economic evaluation to identify cost-effective care. In total 640 patients will be recruited from 10 UK centres over an 18 month period with a minimum of one year follow up of all patients.

For more information contact James N'Dow
(email j.ndow@abdn.ac.uk or telephone 01224 553858).

CHaRT Launch 1-2 November 2004

The establishment of the Centre for Healthcare Randomised Trials (CHaRT) was described in our last newsletter. The centre has since enjoyed a very successful formal launch during the first week of November 2004. Formal opening of the Centre took place on the Monday morning. The Principal of Aberdeen University, Prof C Duncan Rice introduced the Centre, explaining how strategically important it was for Aberdeen to continue to lead high quality randomised controlled trials. Apart from the University, the other joint funder of CHaRT is the Chief Scientist Office (CSO) of the Scottish Executive Health Department; Dr Alison Spaull confirmed CSO's commitment to the need for formal trials units such as CHaRT to position Scotland to lead such trials, particularly with the emergence of the UK Clinical Research Networks. Professor Janet Darbyshire from the Medical Research Council's Clinical Trials Unit in London then spoke about the regulatory, ethical and scientific challenges facing triallists, and how the concentration of the core competencies needed to support trials under one roof in a formal trials unit was undoubtedly the way forward to meet these challenges. Finally, John Norrie, CHaRT's Director, gave a brief description of CHaRT's remit and staff, and the seven trials currently supported. He finished by launching the STOPPIT website (a trial of prevention of pre-term labour in twin pregnancies), and showcased the web based data capture system. The launch of CHaRT received good coverage in the Scotsman, the Press and Journal, and a short report on BBC radio.



Francesca Norrie presenting Janet Darbyshire with a posy

From left to right: *Alison Spaull (CSO Director), John Norrie (CHaRT Director), Janet Darbyshire (Director, Medical Research Council's Clinical Trials Unit, Duncan Rice (Principal, University of Aberdeen) Adrian Grant (Director, HSRU)*

In the afternoon, the first meeting of CHaRT's Scientific Advisory Board took place. On Tuesday, CHaRT led an Institute of Applied Health Sciences Study Day on Randomised Trials, which was very well attended by approximately 100 delegates. During the morning the external speakers gave expert talks on issues in clinical trials, and in the afternoon the local speakers continued the theme.

For more information contact John Norrie
(email j.norrie@abdn.ac.uk or telephone 01224 558988).

Consumer involvement in research: the activities of research funding organisations

The unit has recently reported the findings of a project on the activities of research funding organisations to encourage consumer involvement in research.[1-3] A postal questionnaire and key informant interviews were used to investigate whether, why and how the major public and voluntary sector funders of health-related research in the UK, seek to encourage and facilitate consumer involvement in the identification and prioritisation of research topics, the design of projects, the assessment of proposals, and the conduct of funded studies.

The organisations that fund health-related research have varied constitutions and remits, and use a range of structures and processes to identify and prioritise research topics and decide which research proposals to fund. About two thirds of respondents reported involving consumers in each of these activities. Informants described a variety of approaches, which seemed likely to permit different types and degrees of influence to different types of consumer.

About two thirds of respondents said their organisations encouraged researchers to involve consumers in their projects. Our interviews uncovered a range of rationales and approaches for doing this. Several organisations now make consumer involvement either a condition of funding or one of the criteria against which research proposals are assessed. However, they noted the difficulty of assessing the quality of consumer involvement, and recognised that the appropriateness of particular forms of involvement might vary according to the type and context of research.

Most informants suggested there was a trend towards increasing consumer involvement in all aspects of the research enterprise, although several had concerns about the appropriateness of this. They noted the lack of research evidence about the effects of consumer involvement, and also the costs of promoting and supporting it. We suggest that the effects and appropriateness of consumer involvement in different aspects of the research enterprise should be investigated further, but in the broader context of the structures, processes and values that currently shape research activity.

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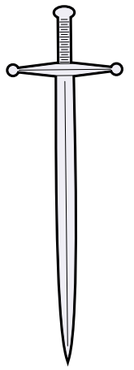
2. O'Donnell M, Entwistle VA. Consumer involvement in research projects: the activities of research funders. *Health Policy,* 2004; **69**: 229-238.
3. O'Donnell M, Entwistle VA. Consumer involvement in decisions about what health related research is funded. *Health Policy,* 2004; **70**: 281-290.

For more information contact Vikki Entwistle
(email v.a.entwistle@abdn.ac.uk or telephone 01224 554337).

A proposed charter for data monitoring committees

Formal monitoring of accumulating data in randomised controlled trials (RCTs) is now common. There is wide variation in the structure and organisation of data monitoring committees (DMCs), however, with little published guidance on how they should operate. The NHS Health Technology Assessment (HTA) Programme commissioned the DAMOCLES (**DA**ta **MO**nitoring **C**ommittees: **L**essons, **E**thics, **S**tatistics) Group to examine the processes of monitoring accumulating trial data and to identify ways to maximise the likelihood that DMCs make 'right' decisions.



Several commentators had previously suggested that any DMC would benefit from the development of a 'standard operating procedure' or 'charter' outlining its mode of operation and the responsibilities of different parties. One product of the DAMOCLES study was the development of a template for such a charter. The DAMOCLES study used a combination of research strategies (which considered the behavioural, procedural and organisational aspects of data monitoring) to inform this.

The proposed charter addresses nine key elements of the workings of a DMC: the roles and responsibilities of the DMC; the role of the DMC before or early in the trial; the composition of the DMC; relationships with other trial committees; organisation of DMC meetings; documentation and communication; decision making; reporting procedures; and the role of the DMC after the trial.

As the proposed charter aims to promote a systematic and transparent approach to the structure and operation of DMCs, we recommend that a detailed charter be prepared for every DMC before the start of the trial. Full details of the DAMOCLES charter have recently been published in the Lancet[1]. The full report of the study is also available as part of the HTA Monograph series[2].

For more information contact Marion Campbell
(email m.k.campbell@abdn.ac.uk or telephone 01224 554480).

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1. The DAMOCLES study group. A proposed charter for clinical trial data monitoring committees: helping them to do their job well. *Lancet* 2005; **365**: 711-722.
2. Grant AM, Sydes M, McLeer S, Clemens F, Altman DG, Babiker A, Campbell MK, Darbyshire J, Elbourne DR, Parmar M, Pocock S, Spiegelhalter D, Walker A, Wallace S. Issues in data monitoring and interim analysis of trials (the DAMOCLES study). *Health Technology Assessment* 2005; **9** (7).