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Measuring expectations of quality of life: how to improve health related quality of life assessment (CIQOL)

Health-related quality of life (HRQL) and other self-reported outcomes are frequently used in clinical trials. Phrasing of questions are, however, often non-specific and the extent to which patients' replies are affected by their personal frames of reference is unknown.

We investigated people's responses to supplementary quality of life questions as part of a wider randomised controlled trial which compared different treatment regimens for Paget's disease. Analysis of these replies showed that many participants contrasted their current health with how they had felt previously, or against some self-defined reference group. The chosen frame of reference was found to be important since it could impact on HRQL measures to an extent considered to be clinically important.

Following on from this, we carried out a qualitative study to investigate the reference frames used by an elderly population living with a chronic metabolic bone disorder.Twenty-one participants (11 male, 10 female) with ages ranging from 59-91 years, were interviewed retrospectively about their responses to supplementary HRQL questions, using cognitive interviewing techniques and semi-structured topic guides.

Participants discussed undergoing a process of goal setting in achieving a desired level of quality of life. Participants did this by developing reduced goals using their self in the past as a reference point from which to adjust their current expectations for their quality of life. Participants also used other unhealthy people as a reference frame from which upward comparisons were made, thus reinforcing the hypothesis that comparison with others is often used in shaping one's own expectations.

These findings suggest the inclusion of supplementary questions in HRQL questionnaires could be useful to identify biased or obscured results in clinical trials.

CIQOL has been funded by the Chief Scientist Office.

For further information, contact Clare Robertson (E-mail: c.robertson@abdn.ac.uk Telephone: 01224 551100)

Staff News

We welcome (from left to right) Lara Kemp (Receptionist), Susan Campbell (Research Fellow) and Virginia Paul-Ebhohimhem (Research Assistant) to the Unit. Allan Walker, Christiane Pflanz-Sinclair, Alex Gordon and Susie Wong have recently left and we wish them well in their new appointments.

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Editorial team: Cynthia Fraser and Kathleen McIntosh.
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Health Services Research Unit

Newsletter **Summer 2007**

Message from the new Director…

In January 2007, I took over the reins of the Unit, following Adrian Grant's decision to step down from the post. The success of the 2006 CSO review provided a strong platform for me to plan for the Unit's future with optimism and confidence. The Unit's contract has now been extended to 2013, with the next review planned for 2011.

Following my appointment to Director, I was delighted that Craig Ramsay agreed to take up the post of Programme Director for the Health Care Assessment Programme, which I vacated. Craig was previously the Unit's Senior Statistician. He will build on his extensive evaluative and methodological expertise to develop a strong portfolio of methodological research to underpin the ongoing programme of trials, systematic reviews, and economic modelling.

Over the next five years, we expect continued growth and evolution of the two major programmes of research within the Unit – the Health Care Assessment Programme and the Delivery of Care Programme. More emphasis will, however, be placed on methodological development and on more active engagement with policymakers and our partners in the NHS.

With regard to methodological development, a Unit such as HSRU is well placed to lead on the "science" of health services research as well as the application of such research. Whilst methodological development has been a feature of the Unit's work in the past, a key objective for the next five years is to further promote this type of research, working in collaboration with other international experts in the field. This will capitalise on the theoretical and methodological perspectives that the newer disciplines, now represented within HSRU (e.g. health psychology, applied anthropology, healthcare management), will add to our research.

Similarly, active engagement with policy-makers and our NHS partners is a key objective for both HSRU and the wider research community. I have recently expanded the membership of the Unit's advisory group to include representatives of both policy-makers and NHS management to ensure the Unit's research continues to address the needs of the wider NHS.

I am delighted to be leading such a successful Unit into its next phase and look forward to sharing developments with you through the newsletter over the coming months and years.

Marion Campbell

Staff profile: Craig Ramsay

Craig Ramsay is the new Programme Director for the Health Care Assessment (HCA) programme. The underlying philosophy of the HCA programme is the iteration between systematic reviews and primary research, underpinned by robust methodology. The programme is one of the most successful in the UK and Craig plans, in particular, to develop the methodology of health services research.

Craig graduated in Mathematics and Statistics at Edinburgh University in 1993. After receiving a post graduate diploma in Information Systems from Napier University, he joined the Information and Statistics Division of the Common Services Agency, Edinburgh. Craig joined the Unit in January 1995 as a statistician. Since 2004, he has led the statistical team within the Unit. He has developed expertise in various methodological issues related to health services research with a particular interest in the effect of the learning curve in health technology assessment and non-randomised evaluations.

MRC Training Fellowship awarded to Jonathan Cook

A MRC Special Training Fellowship in Health Services and Health of the Public was recently awarded to Jonathan Cook and will focus on statistical methods for randomised surgical trials. An extensive training programme, consisting of short-courses, masters modules and personal mentoring, will be an integral part of the fellowship. While primarily based in the Unit, Jonathan will be working at the Ottawa Health Research Institute, Canada for 12 months.

The work will focus on key issues which impact upon the design, conduct and analysis of surgical randomised trials. The specific aims are to:

- assess methods for quantifying expertise;
- create a database on intracluster correlation coefficients;
- build a predictive model for recruitment;
- investigate the impact of learning upon the treatment comparison; and
- test the usefulness of efficacy estimators.

The fellowship runs from August 2007 - July 2011 and will be conducted in collaboration with researchers in the UK, Germany and Canada. Jonathan is keen to speak to anyone with similar research interests who would be interested in collaborating in this work.

For further information, contact Jonathan Cook
(E-mail: j.a.cook@abdn.ac.uk Telephone: 01224 559580)

A new outcome measure developed for the REFLUX Trial: the Reflux questionnaire

The REFLUX Trial is a large UK multicentre randomised trial comparing a policy of relatively early laparoscopic surgery with continued best medical management for people with gastro-oesophageal reflux disease (GORD). The results of this trial will be available later this year.

The trial required a valid measurement of treatment outcome, and whilst there are a number of quality of life tools available, none were sufficiently specific to assess the spectrum of gastro-intestinal symptoms associated with the treatment of GORD. A new condition-specific outcome measure was, therefore, developed for use within this trial.

Potential items were identified via a series of interviews and focus groups with GORD patients. The final measure, which consists of 31 items covering seven categories (heartburn; acid reflux; wind; eating and swallowing; bowel movements; sleep; work, physical and social activities), has two outputs: a quality of life score and five Reflux symptom scores.

Initial findings suggest that this measure is valid, reliable, acceptable to respondents and simple to administer in both a clinical and research context. Although the principal aim was to develop an outcome measure for use in the REFLUX trial, it is hoped that the questionnaire will prove more widely applicable.

This is a UK collaborative study that has been funded by the NHS R&D HTA Programme and is co-ordinated from the Health Services Research Unit.

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

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Contamination effects in trials of educational interventions

Contamination in controlled trials occurs when people who were not intended to receive an intervention inadvertently do so: for example, in a trial of a new diet, someone in the experimental group discusses the intervention with a family member who is a control participant. Contamination tends to bias estimates of effectiveness towards no effect, and to reduce trials' power to detect significant differences in outcomes. The common approach to avoiding contamination is to use a cluster randomised trial (e.g. randomise the entire family, not each individual member).

HSRU were part of a national research group, funded by the NHS HTA Research Methodology Programme, tasked with assessing methodological issues related to contamination effects. The research had three main components:

- analysis of results of trials in previous literature reviews to see whether studies that avoided contamination resulted in bigger effect sizes;
- statistical simulation of biases between cluster and patient randomised trials; and
- investigation of biases associated with using a novel statistical technique (Complier Average Causal Effect models).

The results showed that few studies empirically quantified contamination and that cluster randomised trials might produce greater biases to individually randomised trials. Complier Average Causal Effect analyses produced results that were less biased than intention to treat or per protocol analyses, when contamination was present. They showed that individually randomised trials would in most situations be more powerful than cluster randomised trials, despite contamination.

The probability, nature and process of contamination should be considered when designing and analysing controlled trials of educational interventions in health. Cluster randomisation may or may not be appropriate and should not be uncritically assumed always to be a solution.

For further information, contact Craig Ramsay (E-mail: c.r.ramsay@abdn.ac.uk Telephone 01224 558994)

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The CATHETER Trial:
urethral catheters for reducing urinary tract infections

Approximately 25% of patients admitted to hospital will require urethral catheterisation at some stage during their stay, and the risk of developing bacteriuria in catheterised patients is approximately 5% per day. Catheter-associated symptomatic urinary tract infections are the leading cause of hospital acquired infections, accounting for between 23% and 40% of all cases. Such infections result in additional morbidity and mortality and represent a considerable economic burden to the health care sector, patients and their carers.

A recent Cochrane review of randomised controlled trials reported that some types of urinary catheters may reduce urinary tract infections in hospitalised patients. However, it was concluded that more research is needed to fully assess the impact of antibiotic and antiseptic coated catheters on urinary tract infections.

The CATHETER Trial is a multicentre UK trial which aims to establish the clinical benefits and cost-effectiveness of using antibiotic (nitrofurazone) or antiseptic (silver) impregnated urethral catheters over standard urethral catheters in hospitalised adults requiring short term (≤ 14 days) catheterisation.

The trial aims to identify at risk sub-groups of patients, such as those vulnerable to severe infection; the elderly and those in intensive care, where use of more expensive catheters might be particularly beneficial.

We aim to recruit 5700 participants, from eight UK centres, who will be randomly allocated to have either a standard or treated catheter as part of their routine care. They will then be asked to fill in questionnaires in hospital, and after they go home, to find out whether a urine infection occurred, and if this affected their health, treatment, or hospital stay.

The trial results will have implications for the management of patients requiring short-term urethral catheterisation in hospital and rationalise catheter purchasing policies for large organisations like the NHS.

This trial has been funded by the NHS R&D HTA Programme for a period of 33 months and will finish in October 2009.

For further information, contact Professsor James N'Dow
(E-mail: j.ndow@abdn.ac.uk Telephone: 01224 553858)
Trial website:
https://www.charttrials.abdn.ac.uk/catheter/index.php

Foam sclerotherapy for varicose veins: a systematic review of safety and efficacy

Varicose veins in the legs affect 20–30% of adults. Ultrasound-guided foam sclerotherapy is a new treatment option in which sclerosant foam is injected into affected veins, guided by ultrasound monitoring. The foam causes inflammation of the vein wall which leads to blockage and destruction of the vein. As a result of concerns about the safety of this procedure, the UK Interventional Procedures Programme of the National Institute for Health and Clinical Excellence (NICE) commissioned our group to undertake a systematic review of the evidence.

The main conclusions, derived from 69 studies involving over 9000 patients, were that:

- complete blockage of treated veins was achieved, on average, in 87.0% of cases.
- recurrence/development of new veins rate was 8.1% (at follow-up ranging from six weeks to six years after surgery).
- foam sclerotherapy was associated with a lower rate of complete blockage compared with surgery. However, there was substantial variation between the studies.
- serious complications, including pulmonary embolism and deep vein thrombosis, were infrequently reported (a median of less than 1.5%).
- other adverse events were more common. The main ones are listed in the table.

Adverse events	Median, %	Range, %
Pain at the site of injection	25.6	0.6 - 41.0
Matting/skin staining/ pigmentation	17.8	0 - 66.7
Thrombophlebitis	4.7	0 - 25.0
Headache	4.2	0.7 - 23.0
Visual disturbance	1.4	0 - 5.9
'Minor' vein thrombosis	0.7	0 - 17.6
Chest tightness/vasovagal symptoms	0.5	0 - 2.8
Transient confusion	0.5	0 - 1.2
Local neurological injury	0	0 - 0.7

In May 2007, NICE issued guidance on this procedure and concluded that ultrasound-guided foam sclerotherapy is efficacious in the short-term. However, due to the occurrence of transient side effects in a small proportion of patients, the procedure should only be used with special arrangements for consent.

For further information, contact Xueli Jia
(E-mail: x.jia@abdn.ac.uk Telephone: 01224 559801)

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