



PC-CRTU *in Contact*

Issue 13 – Summer 2005

Welcome to the summer 2005 edition of the In-Contact newsletter. Since our last edition and following their review, the Department of Health have confirmed another five years funding for the Research Support Facility, albeit with a different configuration. At present the new contract has yet to be finalised but we will give you more information when we have it.

MidReC is at somewhat of a watershed with a number of our major studies now at the follow up stage having completed recruitment and a new set about to start over the next six months or so. BAFTA, BETS and CUBE have all completed recruitment and are in follow up – thank you to all of you involved – and the good news is that practice workload for follow up is in general minimal.

Several studies are either in the process of starting recruitment or looking for practices to participate over the next six months. The Rotavirus incidence study concerns children aged from birth to five years presenting in primary care with diarrhoea and aims to assess which of them have rotavirus. This is in order to judge the potential impact of new therapies. The CP450 study – variability in response to warfarin – aims to recruit 400 patients from 100 practices (ie. only four or five per practice) prior to commencement of warfarin (for example for atrial fibrillation). This will allow evaluation of differences in warfarin metabolism that might be important in targeting treatment in the future. The TASMINH2 study is an RCT of self management in hypertension which will test whether increasing patient involvement

in their management leads to better control of blood pressure. We will need 30–35 patients with treated but poorly controlled hypertension from 14–16 practices. E-ECHOES (screening for heart failure in ethnic minorities) will be recruiting practices with high asian or afro-caribbean populations in order to perform echocardiographic screening on this important but understudied group. I would urge you to consider whether you are interested in any/all of them and look for more detail at the individual articles. Finally, two ongoing studies the Self-testing study aims to determine the prevalence of self-testing by sending a postal questionnaire to adults on practice lists, and the MMP9 study, evaluating the accuracy of a potential serum marker for colorectal cancer, continues to recruit practices in the catchment area of the Queen Elizabeth.

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PRACTICE NURSES RESEARCH GROUP

We will be arranging a meeting in the Autumn to feed back results of the nurses questionnaire and will be sending out a copy of the results to all nurses in the near future.

PRACTICE MANAGERS GROUP

Date for your diary

The next meeting of the Practice Managers Group will be held on **Tuesday 25 October 2005** at Hornton Grange, University Conference Park.

The afternoon will begin at 1300 hours with lunch served in the restaurant followed by a meeting in the Evesham Room. If you would like to come along, please contact Ros Salter on 0121 414 6505 or email: r.a.salter@bham.ac.uk

SW SAPC 2006

The South West meeting of the Society for Academic Primary Care will be held in Birmingham next Spring – final date to be decided (possibly end of February).

This will be a great opportunity for local practices to see research happening in the Midlands and South West. Further details in the next edition of this newsletter.

Training

Research Training

For details of training throughout the Summer/early Autumn, please contact Ben Cullen at South Birmingham PCT either via email: benjammin.cullen@sbpct.nhs.uk or tel: 0121 442 3497, or Maggie Hope from the Birmingham Research Training Collaboration (BRTC) via email: m.hope@bham.ac.uk or Tel: 0121 414 5346.

RSF Training Programme 2006

A Needs Assessment Exercise is being conducted to inform the development of the 2006 Training Programme.

If there are any courses that you would like to see the Research Support Facility organise or if you would like your name to be placed on our mailing list, please contact Sheila Bailey either via email: s.m.bailey.20@bham.ac.uk or Tel: 0121 414 2845.

New Studies

Rotavirus Surveillance Study

We will be conducting a surveillance study to estimate the disease burden of rotavirus gastroenteritis in children under the age of 5. This will include the assessment of incidence rates, age distribution, severity and seasonal variations, as well as sibling transmission and GP practice costs.

The study will run for 12 months and we hope to start recruiting patients early Autumn 2005.

We have already invited 20 of our research active practices but if your practice would like to take part, please contact Jo-Anne Lacey on 0121 414 3323 or email: laceyj@adf.bham.ac.uk

News from the Mental Health team

Mental health research network and primary care

The Mental Health Team is delighted to report that the Mental Health Research Network (MHRN) has decided to appoint a series of Primary Care Leads in each of the eight hubs across England. Dr Helen Lester, a reader in Primary Care in the Department in Birmingham has been appointed the West Midlands Regional Primary Care Mental Health lead. Primary care is we hope going to play a key role in the Heart of England MHRN hub.

Over the next few months, we plan to work closely with existing practice networks across the West Midlands and also network with research practices in Coventry and Leicester about greater involvement in mental health research. We want to foster a culture of 'bottom-up' as well as 'top-down' research and see part of that role as encouraging individual GPs and Primary Care teams with good ideas in mental health to work these up to a protocol stage. We also plan to develop a series of short training courses covering key mental health topics for primary care practitioners.

We hope this will lead to a greater understanding of the importance and relevance of mental health and encourage practices to participate in allied research projects. We plan to appoint a research and teaching co-ordinator to the mental health team to facilitate this process in the early autumn.

The effects of exercise in women with postnatal depression

The Departments of General Practice and Public Health at the University of Birmingham are about to start a randomised controlled trial to investigate the effects of exercise, centred on pram pushing, in women with postnatal depression.

The findings from general population based research have indicated a strong relationship between exercise participation and depressive symptomatology, but there is no real evidence as to whether this might also be true for postnatal depression.

The reluctance by some postpartum women to take drug interventions and the limited availability of psychological therapies highlights the need for further research that investigates the merits of alternative interventions that might reduce postnatal depression. This study aims to evaluate the feasibility and acceptability of an exercise intervention in postpartum women reporting depressive symptomatology. Walking in the form of 'pram pushing' will be particularly encouraged. This study will recruit women who have given birth in the previous 12 months and who are experiencing depressive symptomatology. The intervention will involve

offering women two individualised exercise consultations and support phone calls promoting exercise over the course of the 12-week intervention period. Participants will be asked to complete a series of questionnaires assessing their physical activity and levels of postnatal depression at various times throughout the trial.

We will be approaching general practices in the near future to ask you to take part in this study. Involvement will mean that we will write to women in your practice who have been diagnosed with postnatal depression in the previous 12 months. All other work will be undertaken by researchers.

If you are interested in helping us with this study please contact:

Amanda Daley
email: a.daley@bham.ac.uk
Tel: 0121 414 3762

Research Development Awards

We are delighted to announce recent successes in securing prestigious Researcher Development Awards from the Department of Health. These very competitive awards were made to only 15 people in the UK this year, and three of the successful applications came from Birmingham.

Elizabeth England (Mental Health Team), Angela Ryan and Helen Stokes-Lampard (both from the Cancer and Screening Team) have secured funding to undertake their PhDs and to continue to develop their research careers. Congratulations to all three of them!

What are these Awards?

To quote from the Department of Health website: '[The personal award scheme] aims to develop the research capacity of the NHS workforce, underpinning the development of the NHS evidence base. To achieve this vision, fellowship funding will be provided for researchers working in the field of health and/or health care delivery, undertaking research for the benefit of the NHS.'

Applications are invited from individuals working in any scientific discipline or sector that can demonstrate a role in, or contribution to, improving health, health care delivery or services.

The Researcher Development Award (RDA) – offers 3 years full-time funding (or 4 years funding at 75% pro rata) to undertake a PhD and is aimed at individuals of outstanding potential early in their research careers. It aims to fast track them through a customised research training programme in an environment reflecting their individual talents and training needs.'

www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchCapacity

News from the Screening and Clinical Decision Making Team

BETS – Birmingham Elderly Thyroid Study: First results are in!



The aims of the study were to determine the prevalence of sub-clinical thyroid dysfunction (out of range serum TSH levels combined with a normal free T4) and investigate the association between sub-clinical dysfunction and cognition, depression and atrial fibrillation. The final analysis of the AF data is still in progress but analysis of the thyroid function and cognition data is now complete and it is one of the largest thyroid function studies undertaken to date. Findings of this study have already been presented at national conferences and we are due to spread our wings in the autumn when our abstracts have been accepted for presentation both within Europe and North America.

Reassuringly we identified very few cases of previously undiagnosed overt thyroid disease during this study (0.4% were biochemically hyperthyroid and an identical proportion hypothyroid) suggesting current practices and symptomatic screening are effective in identifying thyroid disease in the elderly. The prevalence of subclinical dysfunction was somewhat lower than predicted with 2.9% meeting biochemical criteria for subclinical hypothyroidism and 2.2% for subclinical hyperthyroidism.

So subclinical disease is less prevalent than we initially believed, but what are its implications? Well in terms of cognition and depression the results suggest very few.

There were no differences between groups (euthyroid, sub-clinical or clinical disease) for cognition (MEAMS and MMSE scores), anxiety or depression (HADS scores). Looking at serum TSH and free T4 as continuous variables we did identify significant associations, between TSH and cognition and free T4 and depression – but in reality these statistically significant associations are artefacts of the large sample size and have no clinical relevance. You would need to increase TSH by 10 units to increase MMSE score by 0.1 and the association between free T4 and depression speaks a similar story with a 10 unit shift in free T4 needed to change the depression score by 0.3 – not something we'd recommend!

So in summary, unidentified overt thyroid disease in elderly patients is rare (less than 1%) although a significant number of patients (around 5%) have results indicating sub-clinical disease. Sub-clinical disease, however, is not related to increased levels of depression or cognitive dysfunction. Next edition we'll be able to report on whether there is increased likelihood of AF in these patients ... so watch this space!

With very best wishes Lesley Roberts
Email: l.m.roberts@bham.ac.uk

Use of medical self-tests by members of the public



A study about 'self-testing' is being coordinated from the Department of Primary Care and General Practice at the University of Birmingham. The study is funded by Cancer Research UK and is a collaboration between researchers from the University of Birmingham, Aston University and Birmingham Women's Hospital. The study is funded by Cancer Research UK.

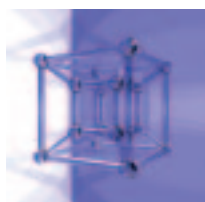
Self-testing is where a member of the public buys a test from a chemist, supermarket or over the internet to see if they may have a condition without involving a doctor or nurse. Examples include tests for cholesterol, chlamydia, prostate specific antigen and faecal occult blood.

The range and accessibility of self-tests has increased dramatically over the last few years, but there have been very few studies looking at who is using self-tests and how or why they are being used. This study aims to describe the prevalence of the use of self-tests and determine factors that are associated with using them.

The study has two stages. The first stage involves sending a short questionnaire about the use of self-tests to people selected from general practice lists. A small number of people will then be invited to attend focus groups to discuss self-tests. This will inform the design of a second in-depth questionnaire about factors that may be associated with using self-tests. This in-depth questionnaire will be sent to people who have used a self-test; people who have not used a self-test but would use one in the future; and people who have not used and would not use a self-test. The responses will be compared to establish those factors that are associated with using self-tests.

It is hoped that the outcomes from this study will include recommendations about how to improve the appropriate use of self-tests and also health services, as well as information to prepare health professionals for patients who are using self-tests.

We have recruited several general practices for the first mailing, and we are sending out the first questionnaire to people selected from these practices. We may recruit further general practices to extend this mailing in the future. If you are interested in collaborating with this research, please contact **Sue Clifford (s.clifford@bham.ac.uk) on 0121 414 8038 or Angela Ryan (a.v.ryan@bham.ac.uk) 0121 414 8015.**



CUBE (C13 Urea Breath Test and Eradication) MRC-CUBE Study

CUBE is a MRC-funded national randomised controlled trial to determine the cost-effectiveness of *H. pylori* 'test and treat' compared with empirical acid suppression for dyspepsia in primary care. The trial is co-ordinated by the CUBE Trial Office at the University of Birmingham.

The study completed patient recruitment in February, with 699 patients recruited.

Follow-up on these patients is ongoing and a novel method of data collection will soon be starting. The Practice Nurse has been asked to do this, using an online database similar to that used when randomising patients to the study.

For further information, please contact the Trial Administrator, Vivienne Tsimbili on 0121 414 3765 or Email: e.v.tsimbili@bham.ac.uk

News from the Screening and Clinical Decision Making Team continued

MMP9 Study

Increased levels of MMP9 have been found in the blood of people with colorectal cancer and polyps. Two complementary studies aim to establish the accuracy of MMP9 and determine whether it will be of value in increasing the proportion of colorectal cancers diagnosed at an early stage of disease. These studies are the result of collaboration between the University Hospital Birmingham NHS Foundation Trust (Mr Tariq Ismail), the Department of Primary Care and General Practice and the Institute for Cancer Studies at the University of Birmingham, and the Wellcome Trust Clinical Research Facility at the Queen Elizabeth Hospital.

Study to see if measuring MMP9 could improve referrals to colorectal clinics

A study to assess the value of a new blood test in improving the appropriateness of urgent referrals to colorectal clinics has been underway since February. The study will compare the MMP9 level of people who have been referred to a colorectal clinic with the results of examinations and investigations done at, or shortly after their clinic visit. If a high MMP9 level does identify people with colorectal cancer or polyps, the test could assist general practitioners in deciding which patients should be referred urgently. Our aim is to recruit around 1060 patients, and we are about one third of the way to this target. Recruitment is taking place at the colorectal clinics at the Queen Elizabeth and Selly Oak Hospitals. We write to people who have been sent appointments at these clinics to tell them about the study, and we also put up a poster at the clinics to inform people who had appointments made at very short notice.

People who think that they may want to take part are asked to complete short questionnaires about their symptoms and general health. A blood sample is then taken from those people who provide informed consent. The diagnosis is collected from their hospital records at a later date, and relevant information is also collected from the NHS Central Register.

Your patients may be asked to take part in this study, but we envisage that there will be no additional work for practice staff because recruitment is taking place in secondary care.

For further information contact Angela Ryan (a.v.ryan@bham.ac.uk) or Sally Warmington (s.a.warmington@bham.ac.uk) on 0121 414 8589.

Study to evaluate the suitability and acceptability of measuring MMP9 as a screening test for colorectal cancer

Cancer Research UK has recently funded this study following successful feasibility work in 2004. The aim is to assess the accuracy and acceptability of MMP9 as a potential screening test for colorectal cancer. All participating patients will provide a blood sample for MMP9 estimation and have a colonoscopy (gold standard). Comparison of MMP9 levels and colonoscopy results will establish the accuracy of this test.

Practices agreeing to participate have been asked to provide lists of patients aged 50-69 years, excluding people already under investigation or treatment for colorectal cancer or unable to give informed consent.

Patients are sent a short symptom questionnaire by post. Responders who report one or more lower gastrointestinal symptoms and who may be interested in taking part in the evaluation of MMP9 will be asked to attend a research clinic (staffed by departmental research nurses) at the practice. Patients who provide informed consent will have a blood sample and colonoscopy at the Wellcome Clinical Research Facility (QE Hospital).

Our first general practices research clinics have just commenced with colonoscopies booked to take place from mid July onwards. The first phase of practice recruitment is now almost complete. We aim to recruit a total of 29 practices within travelling distance of the QE.

Any other practices interested in participating should contact either Dr Sue Wilson, (s.wilson@bham.ac.uk) or Val Redman (v.d.redman@bham.ac.uk) on 0121 414 2688.

DIAGNOSIS & EXPERTISE IN GENERAL PRACTICE

Study Title: Clinical Reasoning in General Practice – the Development of Diagnostic Expertise

We are trying to understand how diagnostic expertise develops with years in General Practice and aim to propose recommendations to improve this process. We are recruiting GPs at different stages in their career (years in practice) from small and large practices. You will work through a number of scenarios of hypothetical patients to give your diagnosis and management plan.

We estimate that we will need around two hours of your time and you will be recompensed at the usual hourly MidReC rate. We will also provide you with feedback (how your case management compares with best practice) and a copy of the final project report. We believe that you will find the study very interesting and that you will learn from it, as we will also learn from you.

We are currently busy constructing the scenarios and collating the best available evidence from the literature. We will contact you early September in order to arrange appointments for data collection in November. GP registrars will be contacted separately in August. If you are already interested in participating, please contact us using the details below.

Funding: Department of Health Investigators: Dr Olga Kostopoulou, Professor Brendan Delaney

Research Fellows: Dr Craig Munro, Dr Radhika Nath, Mr Jurriaan Oudhoff
Any enquiries and expression of interest should be addressed to Dr Olga Kostopoulou, Tel: 0121 414 5390, email: o.kostopoulou@bham.ac.uk

News from the Cardiovascular Team

SMART Follow-up Study: What Happens Outside Trial Conditions?



D McCahon, E Murray, D Fitzmaurice,
H Sandhar

Background: SMART (Self-Management of Anticoagulation, a Randomised Trial) compared clinical and cost effectiveness of patient self-management (PSM) with routine oral anticoagulation management. It was the first UK based trial, involving 617 patients, demonstrating that PSM was as clinically effective as routine care in terms of INR control.

Objective of SMART follow-up study:
To evaluate clinical effectiveness of PSM compared to routine care outside trial conditions.

Design: Multi centred retrospective study.
Setting and patients: 63 patients from primary care practices continued with PSM following SMART completion. These patients were matched by age and INR target with control patients identified from the SMART database. INR results were collected for the period 01/07/03–30/06/04.

Intervention: Patients used the CoaguChek S coagulometer (Roche diagnostics) and a simple dosage chart. Guidelines for PSM were agreed and signed by the patient and a clinical supervisor.

Primary outcome measure: INR control.
Secondary outcome measures: Frequency of clinical follow-up, testing and quality control procedures and costs

Results so far: 78 patients were recruited, 38 PSM, 40 control. INR percentage time in range was 71% PSM vs 58% matched control, SMART results 75% PSM vs 64% control. 87% PSM patients were supervised by their GP and 13% by a hospital anticoagulation clinic. Frequency of testing for PSM ranged from 1 to 6 weeks, (mean 19 days). Frequency of review interval ranged from 12 to 24 weeks for 58% of patients and 40% had no clinical review during the 12-month study period. Methods of EQA (quality control), 39% of patients compared INR results from their coagulometer with a venous sample analysed by a local laboratory and 45% compared INR results on their coagulometer with a laboratory or practice coagulometer, 16% had no EQA system in place. Cost analysis is currently being undertaken.

Conclusion: PSM is as clinically effective outside trial conditions. The majority of patients are performing some method of EQA and having a regular clinical review.

Variability in response to warfarin: a prospective analysis of pharmacogenetic and environmental factors (CP450 study)

Rationale for the study: There is a great deal of variability in the dosage requirement of warfarin to maintain the international normalized ratio (INR) within a target range. This is increasingly an issue for primary care. Recently, pharmacogenetic and environmental factors have been shown to affect warfarin metabolism and therapeutic dosing regimes. Warfarin is metabolised by the liver enzyme cytochrome P450 isoform CYP2C9. Individuals with genetic variants of the enzyme require either abnormally low or high doses of warfarin to achieve therapeutic anticoagulation. Research also suggests that other genetic and environmental factors such as age, weight, liver disease, vitamin K intake, interacting medications and alcohol intake affect warfarin dose requirements and susceptibility to bleeding complications.

Aims: The purpose of the study is to define genetic and environmental factors that determine variability in response to warfarin. The proposed outcome of the study would be the development of a clinically useful and practical algorithm (that takes into account the relevant genetic and environmental factors) that will help clinicians individualise anticoagulant therapy. The potential benefits of this would include improved safety of warfarin with reduced morbidity and mortality, improvement in patient quality of life, improvement in the cost effectiveness of warfarin therapy and improved uptake of warfarin, particularly for atrial fibrillation.

Study population: A patient cohort of 400 pre warfarin patients will be recruited from primary care within the West Midlands. This will equate to an average of only four patients from each practice. Many thanks to all who have responded and are interested in participating in this study. We have had a very good response so far and we are still recruiting practices. We aim to recruit 100 practices in Birmingham and hope to start patient recruitment in October this year.

For further information please contact
Debbie McCahon Tel: 0121 414 2954.

UK B-Type Natriuretic Peptide Pilot Study



The UK B-Type Natriuretic Peptide Pilot Study is an MRC funded pilot study in collaboration with University of Oxford. BNP is a blood test that can help in the diagnosis of heart failure. The study that is based in general practice; aims to test BNP guided treatment of elderly patients at risk of heart failure, which in turn will hopefully reduce patient symptoms and hospital admissions.

We completed screening of over 280 patients at 9 East Birmingham practices, resulting in recruiting the eligible patients needed, as part of this piloting stage. These patients are now being seen on a fortnightly basis over the next six months to monitor their BNP levels whilst having their medication titrated.

If you would like more information, please contact: Rachel Hare, Study Coordinator –
r.hare@bham.ac.uk

TASMINH 2 – An RCT of Patient Self Management of Hypertension



This study will compare self management of hypertension (self monitoring plus self titration of medication following plan agreed with GP) with normal care. We will be looking for 14-16 practices to recruit a total of 480 patients (ie 30-35 patients with poorly controlled treated hypertension per practice). This study will start recruiting patients in January 2006 so we will be looking for practices who are interested in the autumn.

Those practices who were involved in the original TASMINH study (RCT of self monitoring in hypertension) may be interested to know that the main paper arising from this work has been accepted by the BMJ and should be appearing in print around October time.

Any queries about the self monitoring/self management of hypertension work to
Dr Richard McManus
r.j.mcmanus@bham.ac.uk

Results from Completed Studies

Vaginal Vaults Smears 'Know More, Do Less'

Background: The vaginal vault smear is a test for cellular atypia in women who have undergone a hysterectomy. In asymptomatic women the test has poor sensitivity and specificity. Current guidelines recommend: vault smears should not be used after hysterectomy for benign pathology; two vault smears (6 and 12 months post-surgery) should be taken when there is evidence of completely excised CIN II/III in the specimen.

Aim: To describe primary healthcare professionals' self-reported knowledge and behaviour relating to the use of vault smears.

Design of Study: Questionnaire.

Setting: South Birmingham.

Methods: Postal questionnaire survey to primary healthcare professionals (general practitioners and practice nurses, n=424).

Results: Response rate 80.0%, completed response rate 68.9%. Mean knowledge score was 7.3 out of possible 12 (SD 1.9); range 0-10. No significant differences were observed between GPs and practice nurses in knowledge scores, although differences were noted in the frequency of performing vault smears. An inverse relationship was observed between frequency of performing vault smears and level of knowledge about the test. There

was a positive association between requesting further information and the 'knowledge score'. Only 11% correctly answered a question based on current guidelines.

Conclusions: Knowledge of current guidelines was poor. Those who undertook fewest vault smears appeared best informed. This suggests that if all primary care professionals practised according to current guidelines, the number of vault smears performed may be reduced. Unnecessary vault smears may cause additional anxiety in women and have financial consequences for the NHS.

Eighth Annual Conference of the UK Federation of Primary Care Research Organisations

Impact and Improvement

28-29 November 2005

Thistle Hotel, Bristol

The UK Federation of Primary Care Research Organisations is the collective body for research and development organisations in the United Kingdom.

This year's conference – **Impact and Improvement** – will be an opportunity to demonstrate the importance of Primary Care Research with examples of the impact on health outcomes, patient care, service developments and capacity building.

Outline Programme

- ☐ Plenary sessions
- ☐ Papers, posters and workshops
- ☐ Research Interest Groups
- ☐ Annual General Meeting of the UK Federation of Primary Care Research Organisations
- ☐ Conference dinner with entertainment

Keynote Speakers will include

- ☐ Ms Noreen Caine, Deputy Director of R&D, Department of Health
- ☐ Professor Sir Denis Pereira Gray
- ☐ Professor David Weller

Information about the programme and speakers will be available on the website as arrangements progress: www.ukf-pcro.org

The conference will be of particular interest to:

- ☐ Researchers at all levels of expertise
- ☐ Research teams
- ☐ Primary Care Trusts and consortia
- ☐ Academic departments involved in primary care research
- ☐ Research networks, research organisations and RDSUs.

Conference Fees:

- ☐ £195 (non residential) for two days attendance. Accommodation at an additional cost is available (please state on booking form).
- ☐ £145 for one day attendance.

Please note there is a discount of £15 on the conference fees provided you quote MidReC member on the booking form.

This newsletter has been printed using re-cycled paper

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