



PC-CRTU *in Contact*

Issue 20 – Autumn 2009

Editorial

Welcome to the autumn edition of the PC-CRTU in Contact Newsletter.

Thank you for your continued support in a year which has seen considerable expansion within MidReC. We have been successful in securing various key posts which will be based in both the PC-CRTU and the GP Practices to facilitate the research work which is being co-ordinated through MidReC and the local Primary Care Research Network (PCRN-CE). We are pleased to report that the PCRN-CE local network has yet again excelled in national recruitment targets to Primary Care research studies, being second highest recruiter in the country, with over 25,000 patients recruited in the past 12 months.

Congratulations are also to be given to all staff in the PC-CRTU who contributed to the successful GCP Inspection from the MHRA. Our standard operating procedures were reviewed and Paul Aveyard's Rapid Reduction Study was chosen as one of the trials to undergo detailed scrutiny. We are pleased to report that we met their standards and they found no critical findings.

There are 5 new studies on the portfolio and we hope for your continued support in recruitment to the Stroke and TIA (CLAHRC), OTCH, CAM and PAMPERS trials. Further information on these studies can be found inside this issue.

Professor Richard Hobbs has recently been appointed as the Head of the NIHR National School for Primary Care Research, giving us the unique opportunity to link into their national agenda and an opportunity to synchronise the strategic vision of primary care research locally and nationally.

We hope you enjoy this edition of the newsletter and THANK YOU for your continued support!

Sarah Bathers
PC-CRTU and MidReC Manager

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Current studies

Polypill

The National Institute of Health Research (NIHR) and the National School for Primary Care Research (NSPCR) has funded a series of studies to gather data which will be used to inform the design of a pilot randomised controlled trial (RCT) that will test the effectiveness and cost-effectiveness of a polypill strategy against treatment to target for levels of cholesterol and blood pressure.

Ten practices in the West Midlands are currently participating in the study. Computerised searches of GP clinical systems have been carried out. Patients not coded as having a cardiovascular (CV) risk but who have risk factors recorded in their notes have been invited to a CV screening appointment. Screening clinics are currently underway in all practices, and approximately 1800 patients have so far attended an appointment. A number of patients and health care professionals taking part will be invited for an interview to discuss their views on the best way to manage CV risk.

A further 10 practices have agreed to be involved in this project, and have provided us with information from computerised searches. Practice recruitment to this project is now closed, but if you would like any further information about Polypill, please contact:

Kathleen Waldron
Tel: 0121 414 8582
Email: k.waldron@bham.ac.uk

Chief Investigator:
Professor Jonathan Mant

UNIVERSITY OF BIRMINGHAM



HPV Core Messages

Development and evaluation of a set of human papillomavirus (HPV) core messages.

A Human Papilloma Virus (HPV) vaccination programme has recently been introduced in the UK, which will invite girls in school year eight (aged 12–13) to be vaccinated against HPV. Annually, this will amount to over 300,000 girls in the main cohort being eligible for vaccination, with similar numbers in the catch-up cohort of 17–18 year olds. For the programme to be effective, uptake rates need to be high, so vaccination must be acceptable to the target groups of girls and their parents or guardians. As the vaccination programme has only recently been introduced, little is known about attitudes towards, or knowledge about, HPV vaccination. This multi-centre study, funded by Cancer Research UK (in collaboration with Oxford and Cardiff Universities), aims to investigate current levels of knowledge and understanding about HPV in the context of the vaccination programme. The study aims to develop a series of evidence based information messages that will support informed choice, minimise anxiety about HPV vaccination, and improve disease control in primary care.

The initial research phase, in which the views of vaccinated girls and their parents were investigated through a series of individual interviews, has been completed. The findings from these interviews, along with the results from a review of the literature about HPV vaccination and testing, have been used to develop a survey. The survey will focus on determining the views of primary care patients about the core messages that should accompany patient information materials

relating to HPV vaccination. The success of the vaccination programme will also be influenced by the attitudes and opinions of staff involved in its delivery within primary care (GPs and practice nurses), and within the education system (teachers and school nurses). These professionals are the most common contact points for girls and their parents/guardians to obtain information about HPV and vaccination, so, the survey will also investigate the attitudes of healthcare and education professionals towards the HPV vaccination programme.

The findings will be important for all girls aged 12–13 years in the UK, and their parents or guardians. They will also be relevant to those healthcare professionals and teaching staff involved in the delivery of, or education about, the HPV vaccination programme.

We will be recruiting practices in the Wolverhampton and Birmingham East and North PCT areas to take part in the survey phase of the study.

The Chief Study Investigator at Birmingham is Professor Sue Wilson.

If your practice would like to take part in the study, or if you would like further details about the research, please contact:

Dr Sarah Damery, Research Fellow
Tel: 0121 414 3343
Email: s.l.damery@bham.ac.uk

SCOOP Study

SCOOP is an MRC and ARC funded study which aims to assess whether a community based screening programme for osteoporosis reduces the incidence of fractures in older women in a manner that is cost-effective, and acceptable to women and GPs.

We reached our recruitment target of 1,654 randomised participants at the

end of April. This was two months ahead of our recruitment deadline and by the time recruitment closed at the end of June 1,691 ladies had agreed to participate. All our participants are now in the follow-up phase of the study which will continue with annual postal questionnaires until 2014.

We would like to thank everyone involved in the study for their help and contributions to date and for their continued support during the follow-up period.

For further information about SCOOP please contact:

Katie Jarand
Tel: 0121 414 6510
Email: k.e.jarand@bham.ac.uk.



PRISM

Primary Care Streptococcal Management Study

This study provides the opportunity to develop and confirm a clinical rule to predict bacterial infection by comparing baseline clinical features to the results of a throat swab and complements the DESCARTE study which will tell us about 'at risk' groups of patients.

Phase II is a randomised controlled trial (RCT) looking at whether using a rapid near patient throat swab to detect bacterial infections is a good way of targeting antibiotics, as compared with the centor criteria and delayed antibiotic prescription.

We are currently in the phase II recruitment stage. The study will continue into the winter, ending early 2010. So far, from the required 303 patients required, a total of 132 patients have been recruited from 15 practices around Birmingham.

We are currently looking for more practices to participate in this study. If you or your practice is interested and would like further information, please contact:

- **Razia Meer-Baloch**
Tel: 0121 414 3351
Email: r.meerbaloch@bham.ac.uk
- **Beth Hinks (Study Administrator)**
Tel: 0121 414 8545



E-Echoes

A huge thank you to all practices (listed below) for helping us recruit 5,309 subjects – well above our target and ahead of end date!

We are in the process of checking data/analysis and will be in touch with each practice soon. We would like to thank all the staff at the following practices for their enthusiastic help. Rotton Park Medical Centre, City Road Medical Practice, Cavendish Medical Practice, Ann Jones Family Health Centre, Shanklin House Surgery, Burbury Street Surgery, Heathford Group Practice, Broadway Health Centre, Victoria Road Medical Centre, Churchill Medical Centre, St Clements Surgery, Handsworth Medical Centre, Soho Health Centre, Church Road Surgery, Bloomsbury Health Centre, Al-Shafa Medical Practice, Enki Medical Practice, Aston Pride Health Centre, Newtown Health Centre, Hockley Medical Centre

For further details please contact:

Dr Paramjit Gill
Tel: 0121 414 3758
Email: p.s.gill@bham.ac.uk



DESCARTE

Evaluating management decisions in acute red throat

The aim of this study is to find out which people with a sore throat get better without problems, the few who get worse or suffer complications and those who will benefit from antibiotics. Finding the answer to this question will be the first step to better targeting antibiotics in the future to those who will benefit, help avoid side effects when antibiotics are not needed and reduce antibiotic 'resistance' in the community.

This study has now finished recruiting. With the commitment of 104 practices throughout the West Midlands, we have

exceeded our recruitment target and all patient notes reviews have been successfully completed. Data entry is also near to completion. We would like to take this opportunity to say thank you to everyone who has contributed to the study.

We hope that analysing the data will show differences in the presenting signs and symptoms of those patients who go on to develop a complication of worsening symptoms versus those who recovered quickly. If we find a difference we can create a 'Decision Rule', which, after being

prospectively tested, GPs and nurses could use in the future to identify patients likely to get complications or extended symptoms. This could help with targeting antibiotics to those most likely to benefit and help reduce antibiotic prescribing for sore throats.

Contacts:

- **Razia Meer-Baloch**
Tel: 0121 414 3351
Email: r.meerbaloch@bham.ac.uk
- **Beth Hinks (study administrator)**
Tel: 0121 414 8545

**UNIVERSITY OF
BIRMINGHAM**

The University of Birmingham is looking for Practices in Birmingham who are interested in assisting their patients in giving up smoking.



Help us help your patients quit smoking

We are looking for GP practices interested in setting up free Stop Smoking Clinics where we can recruit people into the Rapid Reduction Study. More information below:

Rapid Reduction Trial

Comparing success rates between those who quit smoking abruptly and those who reduce smoking prior to quitting: a randomised non-inferiority trial.

Current wisdom tells us the best way to quit is to cease smoking abruptly on a pre-determined quit day and cutting down is not advised. This is because of the belief and evidence that with reduction each remaining cigarette will become more rewarding and harder to give up and in the meantime the smoker will suffer a loss of motivation before reaching the point where total abstinence is attained. However, many smokers feel that reduction is natural and if reduction programmes were offered, many more would take up the treatment.

Cessation success rates are low, particularly in the NHS primary care support where only 7% of smokers achieve one year prolonged abstinence. This means many smokers are going through the treatment services many times, and each time they are offered the same treatment. Patients often choose different pharmacotherapies, but in other respects the treatment is the same every time. A common sense view is that offering repeated courses of identical treatment that failed previously might be less effective than trying different treatment. Rapid Reduction might offer a new way to quit to those who have failed previously.

The Rapid Reduction Trial has two arms: abrupt cessation and rapid reduction: and in both of these arms, the treatment programmes are new and not currently used in the NHS. Those in the abrupt quit arm wear a nicotine patch in the two weeks leading up to their quit attempt and then use a patch, in combination with an acute product, such as inhalator or gum, when they come to quit. Using a patch before you quit increases the chance of success by 50 – 100% and does not lead smokers to overdose on nicotine. Those in the reduction arm are asked to use a nicotine patch two weeks before quitting but also use nicotine gum or something similar to help them cut down during this time. After stopping smoking completely, patients will continue to use a nicotine patch and gum to help them stay off cigarettes. In addition to the NRT, participants receive standard smoking cessation behavioural support.

The trial started in June and we are already collecting data, and at the same time, helping patients of participating practices to quit smoking. Already ten practices are actively involved but we will need many more to progress and complete the trial over the next eighteen months.

What we are looking for are practices prepared to write out to their patients who smoke and encourage them to join the trial. We will cover your labour and post costs in doing this. You also need to provide us with use of a room in the surgery where we can see your patients. This needs to be a regular day or half day each week. We will provide a trained smoking cessation nurse to run free clinics for your patients who want to

give up smoking and we will provide the medication that they use.

We are approaching the time of year, Christmas and particularly New Year, when many smokers become more highly motivated to quit. This then is an ideal time to consider offering such patients even more quit smoking support. The Rapid Reduction Trial offers practices and their patients just such a route to stop smoking success.

Practices who want to take part would be required to write to their list of registered smokers to invite them to the trial and provide a room for use by our Research Nurses one day (morning/afternoon) a week. Your costs would be reimbursed.

To discuss this please contact:

■ **Dr Paul Aveyard**

Tel: 0121 414 8529

■ **Mike Healy, Trial Manager**

Tel: 0121 414 6422



DeMiST

Dietary Management in Smokers Trial: an update on the trial to prevent weight gain when smokers quit

We have come a long way in planning this trial and are almost ready to begin!

As a reminder we are running a trial which compares usual healthy eating advice during smoking cessation with individually tailored dietary advice and a very low calorie liquid diet. We are particularly interested in how hunger and dietary induced ketosis affects cravings for cigarettes. This will pave the way for dealing with post cessation weight gain in primary care, without decreasing and possibly increasing the chances of a successful quit attempt.

We are currently launching this within BEN PCT and Worcestershire PCT and are offering to run this intervention at your practice. Your patients will benefit from

expert smoking cessation and weight management advice. This will be delivered by our trained research nurses (or we can train your own practice nurse to deliver this). They will work under the supervision of a registered dietitian and GP. In return we will be asking your practice to identify and invite overweight smokers to take part; we have funds available to cover this cost. We would also ask that the practice process the prescriptions for NRT and blood tests in the usual way.

For further information or if you would like to take part please contact:

Deborah Lycett, Research Dietitian
Tel: 0121 414 43765
Email: d.lycett@bham.ac.uk

Aerobic Exercise and Vasomotor Symptoms

We have now recruited 1567 patients to the exercise and menopause questionnaire study (phase 1). This is an excellent response from patients who were asked to complete the questionnaire. Many thanks to those practices who helped us with this study. We will start the trial phase of this programme of menopause research in 2010. The trial is focused on assessing the feasibility and acceptability of exercise as a treatment for vasomotor menopausal symptoms. Symptomatic women will be randomised to usual care or one of two exercise interventions for six months. We will be contacting practices about the trial in the new year.

For further details please contact:

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

Past BP

The National Institute of Health Research (NIHR) has funded this study which will explore whether more intensive blood pressure (BP) targets for people who have had a stroke or transient ischaemic attack (TIA) can be achieved in a Primary Care setting, and whether more intensive therapy is associated with adverse effects on quality of life.

Computerised searches of GP clinical systems will be used to identify patients with a validated history of stroke/TIA who are not already on 3 or more anti-hypertensive agents. Patients will be excluded from the study if their systolic BP is <125mmHg or if they are being treated for diabetes mellitus with microalbuminuria or other condition for which a lower BP target is specified.

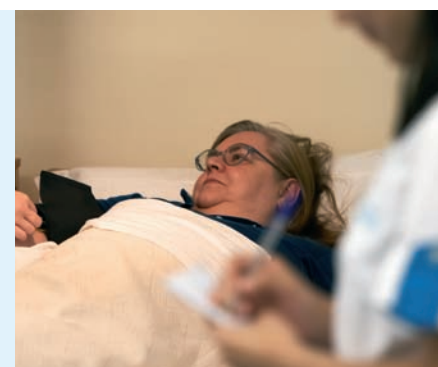
The intervention will be a systolic BP target of 130mmHg (or a 10mmHg reduction, whichever is lower) versus a systolic BP target of 140mmHg (as recommended by current national guidelines).

The primary outcome will be change in systolic BP over 6 months; however patients will be monitored for 12 months. Secondary

outcomes will include quality of life, adverse events and clinical outcomes such as stroke and other vascular events.

Researchers will follow up patients over the course of a year and they will be seen by practice nurses and GPs every one to three months. In order to maintain patients' BP within their target, GPs will use a study algorithm to titrate their BP medication accordingly. Researchers will also be measuring 24 hour BP in all study participants at the beginning and end of the study.

We have received a lot of interest in this study and have already recruited and trained 14 practices across Birmingham and Solihull, Warwickshire and Worcestershire. The feedback from patients taking part in the study



has been very positive so far and they feel it is a 'good thing' to have their BP monitored regularly and maintained within a specific target. We would be very interested to hear from practices across Birmingham and Solihull, Warwickshire and Worcestershire, who would be interested in taking part.

Principal Investigator:
Professor Jonathan Mant

If your practice would like to take part or would like further information, please contact:

Kathleen Waldron,
Stroke Prevention Research Administrator
Tel: 0121 414 8582
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New studies

Optimisation of the Management of Stroke and Transient Ischaemic Attack (TIA)

Part of the NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) for Birmingham and Black Country.

It is now well recognised that people who suffer from a Transient Ischaemic Attack (TIA) or Stroke benefit from early intensive treatment in terms of early medical management and thrombolysis and stroke unit care respectively. Therefore, it is relevant for health services to consider how best to provide services for patients who have had a TIA or Stroke so as to ensure that they receive speedy diagnosis and prompt treatment to provide the best possible outcomes. This study will aim to identify current barriers to timely and effective treatment so that

people in Birmingham who develop a TIA or Stroke are optimally treated. This will be achieved by gathering information about symptoms and management including timing from people who have had a TIA or Stroke attending two Birmingham Hospitals (UHB and Heartlands). Data will be collected from a variety of sources including the hospital wards, outpatient clinics, A&E services, West Midlands Ambulance service and local GP practices. These findings will be compared with published optimum care standards. Previously developed simulation models for TIA management and acute stroke care will be used to allow consideration of the likely effects of policy and service changes on outcome and cost effectiveness. The results of these will be fed back to local care commissioners, GPs, specialists and patients in order to plan service improvements. Once interventions have been

placed we will perform repeat cycles of the investigative process to assess the impact on service improvement and patient care.

We are looking to recruit practices within South Birmingham and BEN PCTs that refer patients with stroke or TIA to Heartlands and/or UHB Hospitals, and would be very interested to hear from you if you would like to take part in this study.

Principal Investigator:
Professor Richard McManus

If you are interested to know more about this study, please contact:

Mrs Sheila Bailey, Project Officer
Tel: 0121 414 7956
Email: s.m.bailey.20@bham.ac.uk

Acupuncture, osteopathy, yoga, herbal medicine, mindfulness?

The University of Birmingham is setting up a cross-disciplinary research network with an interest in complementary and alternative medicine (CAM) and other mind-body practices.

Some of these therapies are being delivered by qualified medical or nursing staff with additional qualifications, while others are being delivered by professionally-trained specialist practitioners (acupuncturists, homeopaths, osteopaths, reflexologists, sports massage) or teachers (yoga, mindfulness, tai chi, Alexander Technique).

Increasingly patients and healthcare professionals are looking for novel ways to manage chronic conditions, support palliative care or promote wellbeing. Some CAM approaches have been incorporated into NICE and DH guidance. Most research, to date, has been in the areas of musculoskeletal disorders, anxiety and depression, and cancer; looking at

how these types of therapies or practices can support conventional care (www.library.nhs.uk/CAM). Other areas remain under-researched to date, but a recent House of Lords report highlighted that this is likely to change if higher quality research bids are prepared, which is precisely what this network will focus on.

The network will consist of health care professionals and managers, as well as academics across the sciences, social sciences and humanities. This will provide a forum for sharing of best practice and enabling the development of research bids that are genuinely interdisciplinary and involve patients and clinical professionals, which

is essential when looking at complex interventions to comply with MRC guidance.

If you are interested in being part of this network, or are already involved in any groups or networks that might like to connect with the University of Birmingham, then please contact:

□ **Dr Nicola Gale, Research Fellow**
Tel: 0121 414 9089
Email: n.gale@bham.ac.uk

□ **Dr Eliot Marston, BUPA Translational Research Manager**
Tel: 0121 414 9020
Email: e.d.marston@bham.ac.uk



A cluster randomised controlled trial of an occupational therapy intervention for residents with stroke living in UK care-homes

OTCH is the acronym for a cluster randomised controlled trial of an occupational therapy intervention for residents with stroke living in UK care-homes. The trial has been funded by the National Institute for Health Research and will run for four years. The trial is supported by the Stroke Research Network, and the Primary Care Research Network.

The purpose of the trial is to conduct a Phase III RCT to evaluate the effects of a targeted course of occupational therapy (with provision of adaptive equipment, minor environmental adaptations and staff education) for people with stroke living in a care home. In particular we will examine

the effects on independence in self care activities of daily living and mobility.

We hope to recruit around 6 care homes (private, charitable, not for profit and local authority) for older people in each of the trial areas including South and East Birmingham, Bangor, Oxford, Portsmouth, Nottingham, Devon and Preston. The care homes will be recruited and randomised in blocks to allow the therapists' workload to be spread across the period of the study. With the co-operation of the Primary Care Research Network, participating homes will be identified. We will then ask GPs/Practice Nurses to check the notes of those identified for evidence

of stroke and TIA, and identify those who are receiving end of life care. All eligible patients will be invited to participate in the study by either a senior member of the care home staff, a research network nurse or therapist, or a GP or Geriatrician.

It is anticipated that care home recruitment will begin in January 2010.

For further information please contact:

Professor Cath Sackley

Tel. 0121 414 4198

Email to c.m.sackley@bham.ac.uk.

The effectiveness of exercise as a treatment for postnatal depression



The National Institute for Health Research (NIHR) has funded a three year study which will investigate whether exercise is an effective adjunctive treatment for postnatal depression. This is a collaborative study between the Universities of Birmingham, Bristol and Cardiff, the Mother and Baby Unit at Birmingham and Solihull Mental Health Foundation Trust and the Children and Families Division at SBPCT.

Evidence has shown exercise to be useful in managing depression, but few studies have focussed specifically on postnatal depression. Previous studies of exercise and postnatal depression have used small samples and had methodological flaws. Exercise may also have additional benefits to postnatal women, including regaining fitness levels and losing the weight gained during pregnancy.

The primary aim of this study is to determine whether an exercise intervention in addition to usual care, is superior to usual care only,

in reducing symptoms of postnatal depression. All women who have recently given birth in Birmingham (SB PCT and BEN PCT) will be identified using the computerised Child Health System (CHS) and invited by their GP or Health Visitor to participate in the study. The study has been designed to involve minimal workload for practices and we will only ask practices to confirm that patients are suitable for the trial. We will screen women for postnatal depression 6–8 weeks after giving birth and those who fulfil the trial criteria will be invited to participate in the study. We hope to recruit 208 women with postnatal depression over 18 months.

Patients randomised to the exercise intervention will be offered two one-to-one home exercise consultations with a female physical activity facilitator and further supportive phone calls over the course of the six month intervention. Participants will also be mailed information on local

opportunities to exercise at regular intervals throughout the intervention.

This study is due to start recruiting in November and your practice will soon be receiving further details about this study.

If you would like further information about the study please contact:

Ruth Blamey (Research Associate)

Tel: 0121 414 6891

Email: r.v.blamey@bham.ac.uk.

**Principal Investigator
Dr Amanda Daley**



Completed studies

Public attitudes toward colorectal cancer screening

MMP9

ABSTRACT

Background: Colorectal cancer (CRC) is a major cause of death in the United Kingdom. Regular screening could significantly reduce CRC-related morbidity and mortality. However, screening programmes in the United Kingdom have to date seen uptake rates of less than 60%. Attitudes towards screening are one of the primary factors determining patient uptake.

Methods: A questionnaire was sent to people aged 50–69 years who were registered with general practices in the West Midlands. A total of 11 355 people (53%) completed the questionnaire. Multivariable logistic regression analyses were performed to identify those factors (gender, age, ethnicity, deprivation,

number of symptoms, and their duration) that most strongly contributed to negative/positive attitudes in the primary care population.

Results: Fourteen percent of respondents had a negative attitude towards screening. Men, older people, and those with Indian ethnic backgrounds were more likely to have negative attitudes toward screening, whereas people with Black-Caribbean ethnic background, people with multiple symptoms and those reporting abdominal pain, bleeding, and tiredness were more likely to have a positive attitude.

Conclusion: Culturally relevant screening strategies should aim to increase knowledge of the symptoms and signs related to bowel

cancer among South Asian ethnic groups in the United Kingdom. It is also important to find ways to increase the acceptability of screening among asymptomatic patients.

Acknowledgment: We are grateful to the general practices and their patients who participated in the study and to Cancer Research UK for funding the study.

Full manuscript available at: Taskila T, Wilson S, Damery S, Roalfe A, Redman V, Ismail T, Hobbs R. Factors affecting attitudes toward colorectal cancer screening in the primary care population. *Br J Cancer*. 2009 Jul 21;101(2):250–5.

Integrating genetic risk assessment for multi-factorial conditions into primary care

Authors: Alison Metcalfe, Sue Wilson, Debbie McCahon, Vicki Sleightholme, Paramjit Gill and Trevor Cole

Published in Primary Care Research and Development 2009; 10: 200–209

Abstract

The genetic basis of many common, multi-factorial conditions is increasingly being understood but use of the knowledge created, raises major dilemmas for primary care. Identification of individuals that may be genetically predisposed to serious medical conditions provides the opportunity to offer screening or prophylactic treatment, for early detection or prevention and delay in disease onset in many complex conditions. We describe a new pilot service development to introduce genetic risk assessment for a wide range of conditions to primary care, and discuss the findings from its evaluation. The evaluation highlighted the issues about the incorporation of genetic risk assessment in primary care. The results of the evaluation along with findings from other studies, juxtaposed with the implications of developments in genetics suggest that changes are required to accommodate the integration of genetic risk assessment into primary care clinical practice. We discussed what these changes are, the benefits and

drawbacks, and whether primary care can and is ready to make the changes required, further shifting the focus from disease treatment to disease prevention.

Overview of article

The journal article published in July 2009 described the difficulties of incorporating genetic risk assessment and screening into the primary care setting based on findings from an evaluation study. In the article we discuss the benefits and drawbacks of introducing genetic risk assessment for common multi-factorial conditions into primary care, including raising the question; why is

cancer treated differently from other commonly occurring conditions? The study is part of a series of studies carried out in the Primary Care department to investigate GPs and other health professionals' views of genetics and its incorporation into mainstream services for diagnosis, treatment options and preventative measures.

If you require any further information please do not hesitate to contact me

Alison Metcalfe
Email: a.m.metcalfe@bham.ac.uk



Wilson, S., Draper, H., Ives, J (2008) 'Ethical issues regarding recruitment to research studies within the primary care consultation' *Family Practice* 25: 456–461.

Draper, H., Wilson, S., Flanagan, S., Ives, J. (2009) Offering payments, reimbursement and incentives to patients and family doctors to encourage participation in research. *Family Practice* 26(3):231–238

Ives, J., Draper, H., Damery, S., Wilson, S. (in press) 'Do Family Doctors have an obligation to participate in research'. *Family Practice*

This series of three articles examines some key ethical issues that arise when family doctors and academic researchers collaborate in research.

The first article examines the potential ethical conflicts that arise when family doctors are asked to recruit their patients into a study during the patient consultation. This practice, though relatively common, has the potential to undermine informed consent, as it places restrictions on the amount of time the patient has to consider the request. However, the article concludes that the requirements for properly informed consent may vary from study to study, and we should be careful not to impose too strict a set of rules on recruitment and the on the time needed to give informed consent. Patients, after all, may sometimes be happy to make a quick decision.

The second article considers the problem of using financial incentives and reimbursements to encourage both family doctors and patients to participate in research. It is argued that whilst payment can be problematic in some instances, reimbursement is an ethical requirement, but that the distinction between the two is not always clear. The paper also discusses the difference between inducement, coercion and payment. It concludes by

suggesting that, given the potential for conflict of interest when family doctors are paid or reimbursed for their participation, this process should always be made transparent.

The third and final article asks whether family doctors have an obligation to participate in research, and whether they can be expected to facilitate recruitment into Primary Care studies. Three arguments are offered in support of the claim that family doctors do have such an obligation – the argument from fairness, the argument from reason and the argument from utility. It is, however, argued that researchers have reciprocal obligations towards family doctors, which include financial remuneration, reciprocal consideration of role, expertise and credit, and provision of training where necessary. The article concludes by suggesting that only when researchers fulfill their obligations, do the obligations of family doctors become morally binding.

Taken together, these three papers offer an introduction to some of the key ethical issues arising from research in Primary Care and the surrounding literature, and present arguments in defence of a particular ethical position on those issues – aiming both to educate and to generate debate and discussion.



WELCOME TO RESEARCH NURSES

We would like to extend a very warm welcome to our MidReC Practice based nurses.

The first nurse came into post on 22 June 2009 and since then we have been making steady progress and are pleased to report 9 surgeries are now at various stages of the process and study recruitment has been commenced by those first in post.

Our existing nurses are:

- ❑ Susan Read at Greenridge Surgery
- ❑ Julie Timmins at Riverbrook Medical Centre
- ❑ Debra Easlea at Bellevue Medical Centre
- ❑ Somi Spannuth at The Wand Medical Centre
- ❑ Jackie Sherrington at Kingsfield Medical Practice
- ❑ Andrea Thompson at Tudor Practice
- ❑ Maki Chermahini at Ridgacre House Surgery
- ❑ Sue Maiden at Grange Hill Surgery

Laurie Pike Health Centre will be appointing soon.

Monthly support meetings have been commenced and we look forward to working with this new team to enhance the success of research activity out in the Primary Care setting.

Jackie Ingram

Nurse Lead, PC-CRTU

Email: ingramjt@adf.bham.ac.uk



West Midlands Research Design Service



What is the RDS?

The RDS exists to provide help to people preparing research proposals for submission to peer-reviewed funding competitions for applied health or social care research. The RDS essentially consists of a team of methodologists based in universities and the NHS across the West Midlands, able to advise and provide practical support when you are developing your grant application. As the RDS is funded by the NIHR for this purpose, such help is provided free of charge.

Who can use the RDS?

The RDS will provide advice to NHS researchers, and others working in partnership with the NHS, who are developing research proposals for submission to national, peer-reviewed funding competitions.

For more information on West Midlands RDS please contact Marie Crook on 0121 414 6270 or rdscentre@contacts.bham.ac.uk
www.wm-rds.bham.ac.uk

How can the RDS help me?

The RDS can advise on all aspects of preparing grant applications,

- ❑ Formulating research questions
- ❑ Building an appropriate research team
- ❑ Involving patients and carers
- ❑ Designing a study
- ❑ Appropriate methodologies for quantitative research, eg. statistical issues, health economics
- ❑ Appropriate methodologies for qualitative research, eg. sampling, analytical strategies
- ❑ Identifying suitable funding sources
- ❑ Regulatory issues
- ❑ Writing lay summaries
- ❑ Identifying the resources required for a successful project.

Advice and support is best provided face-to-face. RDS staff will be happy to meet with you at a convenient time and place to discuss your research. It is preferable to contact us at an early stage to discuss your ideas.

Courses

CPD courses available within the Department of Primary Care Clinical Sciences

The CPD team exists to try and meet the educational needs of health care professionals involved in all aspects of primary care chronic disease management. The current palate of courses has been driven by demand from our students. Details of all developments are available on www.medicine.bham.ac.uk/cpd and some information on a selection of the courses is given below



MSc accredited courses

❑ Cardiovascular disease prevention and management in the community 7–11 December 2009

Comprising self directed learning, contact days involving lectures, seminars, group discussion and practical placements. This course is aimed at health professionals working in the community who are required to develop their competencies to an advanced level. Programme includes: anatomy, physiology, normal structure and function of the cardiovascular system, risk factors, treatment, interventions and effectiveness.

❑ Management of Heart Failure in Primary Care 1–4 February 2010

This course focuses on the validation of competencies for all primary care clinicians involved in heart failure care in the community. Programme includes: anatomy, physiology and function of the heart, echocardiogram, epidemiology and definition of heart failure, investigations, managing related clinical events and the role of the specialist nurse.

❑ Hypertension Management in Primary Care 1–4 March 2010

This course was developed to assist clinicians in the management of hypertension in the community, examining aetiology, patho physiology and presentation of hypertension. Some of the areas this course will cover are the history of hypertension, measurement of blood pressure, primary and secondary hypertension, end organ damage and evidence based treatment. Other topics discussed will be policies, costs, protocol and audit development.

❑ Anticoagulation in Practice Conference – 22 and 23 April 2010

Anticoagulation in Practice Conference 2010 is the fourth joint meeting of major anticoagulation interest groups, covering Primary care, Specialist and also patient groups. General Practitioners, Practice Nurses, Biomedical Scientists, Pharmacists and Patients are all invited to attend Anticoagulation in Practice 2010 at the Wolfson Centre, a state of the art conference facility within the Medical School of University of Birmingham. If you would like to register for this course please go to www.medicine.bham.ac.uk/cpdcourses

We are receiving registrations daily and places are filling up fast. Details of all NCAT courses and events are available at www.anticoagulation.org.uk or from Amy Partleton – 0121 414 2677 Email – a.partleton@bham.ac.uk

CPD courses available

Gastroenterology update day for primary care – Wednesday 4 November 2009 – £95

This course aims to provide theoretical and practical knowledge of common disorders of the digestive system and how to manage them in primary care and the interface with secondary care.

- ❑ An understanding of when to refer bowel disorders to secondary care
- ❑ Update on common GI conditions including bowel cancer treatment and screening, iron deficiency, IBS, IBD, C difficile infection and abnormal liver function tests

Oral Anticoagulation Management for Health Care Assistants and Assistant Practitioners – 2010 dates – 27 January, 10 March, 14 July, 29 September, 17 November – £150

The course is aimed at health care assistants and assistant practitioners working within anticoagulation clinics. This course aims to provide a basic knowledge of point of care (POC) devices including blood testing technique and quality control for oral anticoagulation management in primary care. Learning objectives:

- ❑ A basic knowledge of the principles of anticoagulation therapy, indications for its use, side effects and interactions
- ❑ An understanding of the principles of point of care testing, finger prick technique and quality control
- ❑ A knowledge of health and safety issues of blood sampling in practice and liaison with laboratory services
- ❑ An understanding of the important components of a protocol for management of oral anticoagulation in primary care

Details of all CPD courses and events are available at www.medicine.bham.ac.uk/cpdcourses or from Jo Leggat – 0121 414 3354 Email – j.leggat@bham.ac.uk

Further courses later in 2010 will include:

- ❑ Introduction to biomedical ethics – February/March
- ❑ Battling the bulge: Fighting obesity in the 21st century – March
- ❑ Religion and spirituality – March/April
- ❑ Stroke prevention in primary care – June
- ❑ Chronic Kidney Disease update 2010 – June
- ❑ Atrial Fibrillation – detection and treatment – June
- ❑ An update on travel health – October



THE UNIVERSITY OF
WARWICK

NHS
**National Institute for
Health Research**

Do you want to take part in research co-ordinated by Birmingham, Keele or Warwick Universities? If you did not reply to our letter earlier this year, here is another chance.

Reply slip

Birmingham, Keele and Warwick Primary Care Research networks are now working in conjunction with the Primary Care Research Network for Central England (PCRN-CE). If you or your practice is interested in taking part in supported, remunerated, relevant research in Primary Care, please complete and return the form below. PCRN-CE is working with the following Topic Specific Networks. Please tick if you have a particular research interest in any of the following:

- ☐ Cancer
☐ Stroke
☐ Medicines for Children
☐ Mental Health
☐ Primary Care
☐ All of the above
☐ Other

Please let us know if you have a particular research interest not listed above.

Name: Practice code:

Practice address:

Postcode:

Please note: You will always be able to choose the level of involvement your practice would like to undertake. Only studies which have been independently peer reviewed and funded through national competition and commercial research asking relevant questions will be adopted by the PCRN-UK.

Please fax back to: 0121 414 2282

or post to: Tina Sexty (PCRN-CE Administrator)
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