

PC-CRTU *in Contact*

Issue 19 – Spring 2009

Editorial

Welcome to the PC-CRTU in Contact Newsletter for Spring 2009. Thank you for your support so far this year. Our work goes from strength to strength.

In the nine months to January, practices in the West Midlands have recruited over 18,000 patients to trials and other well designed studies supported by the UK Clinical Research Network. MidReC, working with the Primary Care Research Network and colleagues in Warwick and Keele has been responsible for a significant proportion of this activity. To put this into context, the West Midlands has been responsible for more than 25% of all primary care recruitment in the UK as a whole and over 10% of all recruitment to clinical research of any kind. This can only be done with your ongoing support so thank you.

Your success in recruiting patients to clinical research makes it possible for us to maintain the very high standards that have made Birmingham a leading member of the National School for Primary Care Research. We are pleased to be able to report that our previous 5* success in the National Research Assessment Exercise has been repeated and improved on in the 2008 results. Taking into account quality and volume of research, Birmingham is now the top performing centre for Primary Care Research in the UK. In this issue of PC-CRTU in Contact you will find an

article from Professor Richard Hobbs outlining this success. Again, this achievement is underpinned by your efforts.

An important development in 2009 is increased investment in research nurse time in a group of the highest recruiting practices. We hope, if this is successful, to be able to expand the scheme to encompass additional practices. If you think that your practice has the capacity to recruit to additional studies then please let us know. Our funding (and therefore that available for practices) is driven more than ever by the numbers of patients we are able to recruit.

The PC-CRTU staff form an important backbone to the work of the network and I am very pleased to introduce Sarah Bathers as a new member of the PC-CRTU management team. As you will see from her article in the Newsletter, she has joined us from the Cancer Clinical Trials Unit at Birmingham and brings with her more than 25 years of experience in Clinical Studies. We are already seeing the fruits of her efforts in helping us to develop and hers is a name (and face) that will surely become familiar to you over the next few years.

Studies currently open to recruitment include:

- ☐ Aerobic exercise and vasomotor systems in menopausal women
- ☐ PAST BP (BP targets for people who have had a stroke or TIA)
- ☐ Preventing weight gain after stopping smoking
- ☐ Stop smoking rapid reduction trial

As ever, we are keen to hear from you if you are interested in taking on new studies. Primary Care Research in West Midlands continues to go from strength to strength with new opportunities for practice involvement. Thank you for your continued support.

Further information about all these studies is included within the newsletter.

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Professor Sue Wilson
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Current studies

ECHOES X

The Echocardiographic Heart of England Screening Study Extension

Between 1995–1999 one of the largest community based studies of heart failure prevalence in the world took place in 16 General Practices within the West Midlands – The Echocardiographic Heart of England Screening Study (ECHOES).

The results provided important new prevalence figures on heart failure and left-ventricular function in primary care patients.

The new follow-up study (ECHOES-X) intends to provide the incidence and progression of heart failure, left ventricular and borderline systolic dysfunction and a cost-effective screening strategy for heart failure in patients at high risk of heart failure. We are therefore re-screening all the surviving original patients from the original 16 participating practices.

As with the original study – all participants will have a physical examination, ECG, Echocardiogram, a Natriuretic Peptide screen and complete two quality of life questionnaires.

Chief Investigator:
Professor Richard Hobbs

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DESCARTE

Evaluating management decisions in acute red throat

The purpose of this study is to find out which people with a sore throat get better without problems, and also the few people who get worse or suffer complications. Finding the answer to this question will be the first step to better target 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.

In the last 18 months, 10,236 patients have been recruited into the study, bringing us closer to our target of 18,000. The West Midlands region has recruited 2,555 patients, accounting for over a quarter of the total recruitment figure, so very well done to all practices. Recruitment is ongoing until the end of April 2009, so there is still time to enter patients and help us reach the 18,000 target.

We are recruiting 16 year olds and over with sore throat as their main symptom. This is

a very simple study, with all data captured on a one page proforma via the website. Most GPs have been very impressed with this system, as once the proforma has been completed a summary of the consultation is provided which can be copied into the patient's medical records. We also have paper versions if preferred.

Unusually this study can be done by any individual GP or all GPs in the practice. The study will continue through to the end of April 2009.

If you or your practice is interested, please contact:

- **Razia Meer-Baloch**
Tel: 0121 414 3351
Email: r.meerbaloch@bham.ac.uk
- **Kirandeep Jheeta**
Tel: 0121 414 3140
- **Beth Hinks** (study administrator)
Tel: 0121 414 8545



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.

Over the last year we have recruited over 1,000 women from 17 practices across the Midlands. We are now in the final phase of patient recruitment and hope to meet our target of 1,654 women in the study before recruitment closes at the end of June.

Follow-up commenced in December 08 and will continue for the next 5 years for those recruited at the beginning of the study. We would like to take this opportunity to thank all of you who have been helping us with the study.

For further information about SCOOP please contact:

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Ethnic Echocardiographic Heart of England Screening Study

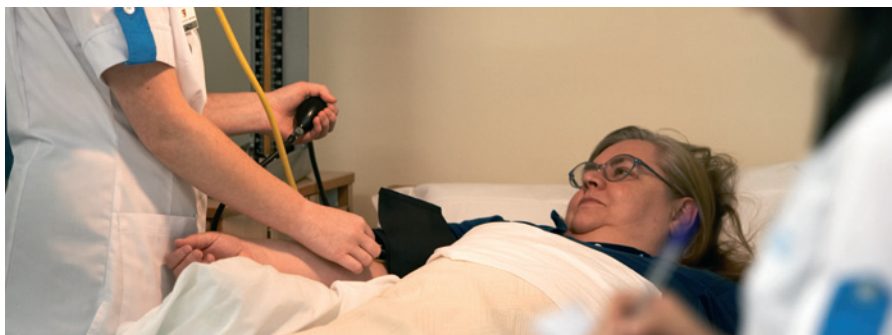
E-Echoes

We have now recruited 4,288 subjects to this study. This is an excellent response from the South Asian and African-Caribbean communities.

Many thanks to all the practices for their help in achieving this and their continuing support. We continue to screen in more practices within Heart of Birmingham teaching PCT and look forward to completing this within the next few months.

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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.

The study has come to the end of Phase I and due to the commitment of the 11 practices that recruited for the study, the region has exceeded its recruitment target.

Phase II, which commenced recruitment in December 2008, is a randomised controlled trial (RCT) looking at whether throat swabs, used to detect bacterial infections, are a good way of targeting antibiotics, as compared with the centor criteria and delayed antibiotic prescription.

If you or your practice is interested in hosting this study, please contact:

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- **Kirandeep Jheeta**
Tel: 0121 414 3140
- **Beth Hinks (Study Administrator)**
Tel: 0121 414 8545

Polypill

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

Eleven practices in the West Midlands are currently participating in the study. Computerised searches of GP clinical systems have been carried out and patients with an unknown cardiovascular (CV) risk on the basis of the information gathered from the computer searches have been invited to a CV screening appointment. Screening clinics are currently underway in two practices, and

approximately 55 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.

We are not currently looking for more practices to participate in this study, although it is likely that we will need a further 10 practices in the future to be involved in this project.

If you may be interested and would like further information, please contact:

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Chief Investigator:
Professor Jonathan Mant

Self Monitoring of Blood Pressure in Hypertension and Diabetes: A Postal Survey

This RCGP (Heart Research UK) funded survey has successfully recruited four practices with surveys sent to 2172 patients. So far data has been received from 967 patients giving a return rate of 56%, and complete analysable data from 873 patients. Data has yet to be entered from the most recent recruited practice but overall we have so far found 227/771 (29%) of the pre-identified hypertensive population are currently self monitoring blood pressure (SMBP). When patients have concurrent diabetes (Type 1 or 2) then this figure rises to 54/171 (32%). For both groups just under 90% are monitoring BP using an electric monitor device 203/227 (89%) and 47/54 (89%) respectively. 57/271 (21%) are monitoring blood pressure on a monthly basis, however, the majority of those with concurrent diabetes are not monitoring blood pressure on a regular basis 23/69 (33%).

Additional data is being collected on the demographic characteristics, methods and frequency of SMBP of these participants. MRC funding has been granted for the next stage of the study where we will be undertaking interviews with individuals recruited from this survey to explore the practice of self monitoring more in-depth.

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

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GPs please note...

If any practice is undertaking research outside of MidReC, please be aware that you need to check that all relevant R&D and ethical approvals have been obtained for the study.

New studies

Preventing weight gain after stopping smoking. A Cochrane review and an opportunity to help us with a new trial.

Weight gain after smoking cessation is a common concern of smokers, and often puts people off quitting or leads to people going back to smoking once they have stopped.

About 80% of people who quit gain weight and on average gain around 5kg during their first year of abstinence and a further 2kg over the next few years. It's not really clear why people gain weight when they stop. We know one factor is that their metabolic rate drops, so even to stay at the same weight, people need to eat less or exercise more, or both. Also, many people become more hungry, there being a close connection between hunger and 'nicotine hunger'. Whatever the cause though, weight gain is important. In a cohort of middle aged smokers followed over eight years, we have found that in those who continued smoking, more than half remained in the ideal body weight category. In those who stopped and stayed stopped, more than half were overweight, one quarter were obese and only one quarter was an ideal weight. Stopping smoking increased the incidence of type II diabetes by 50% in the MRFIT study. But

smokers are caught between a rock and a hard place because smoking itself induces insulin resistance and increases the incidence of diabetes by about 50%. The ideal, then, would be to stop smoking and not put on weight. How can we achieve this?

In a Cochrane review published in Issue 1 2009 of the Cochrane library, we reviewed the effects of (1) interventions specifically designed to aid quitting whilst limiting weight gain and (2) first line pharmacotherapies (bupropion, nicotine replacement therapy and varenicline) for smoking cessation for their ability to limit post cessation weight gain whilst supporting a quit attempt. Limiting weight gain is an important health goal in itself but may also help more people quit successfully.

In the first part of the review, we found trials that had examined drug treatments to limit

weight gain and also trials of interventions that had used behavioural approaches. Some of the drug treatments clearly worked, but some of these weight loss drugs had rare but serious side-effects so they are no longer available to use. Of the drugs that were safe to use, studies did not look at whether the drugs suppressed weight after treatment ended and so it was not possible to find out their long-term effects. No weight limiting pharmacotherapies can be recommended for clinical use based on the available data.

Several different types of behavioural methods have been tried. The findings of the review run counter to the common clinical opinion in the field of smoking cessation that treating both smoking and weight at the same time can be detrimental to the quit attempt. Although we did find evidence that joint treatment can be detrimental, this was only the case for interventions where participants were given advice only. A range of other behavioural treatments have also been tested, in conjunction with smoking cessation interventions, that show signs of promise although there was not enough evidence to form any firm recommendations. Specifically, individually tailored diet and exercise interventions resulted in a significant reduction in weight gain at 12 months and did not seem to either increase or decrease quit rates. A very low calorie diet (like the Cambridge diet) and cognitive

Trial to prevent weight gain when smoker's quit

The Cochrane review highlighted the possibility that a very low calorie diet (VLCD) can significantly improve smoking abstinence as well as promote short term weight loss. In the single trial of VLCD, we found that the VLCD appeared to work by alleviating hunger and at the same time reduce cravings for cigarettes. This sounds very odd – a diet that makes you less hungry. The probable reason for this is that these extreme diets quickly exhaust glycogen stores and the person burns fat and consequently is in ketosis. Ketosis suppresses hunger – hence the magic effect. The problem is that unless a person learns new dietary patterns, they will quickly put on all the weight that they have lost. However, when stopping smoking, if reducing hunger reduces urges to smoke, this diet might have a particular usefulness in preventing weight gain and enhancing cessation success.

The Cochrane review also showed that long term weight loss was achieved best in those who received individualised modestly calorie restricted diet rather than general dietary advice and that this did not reduce abstinence. This is at odds with the hunger produces nicotine hunger hypothesis, and needs to be confirmed.

We are therefore planning a trial to compare these different dietary approaches head to head. We will compare the effects of a VLCD followed by individualised dietary planning to individualised dietary planning alone, to usual care when stopping smoking. Our primary outcomes will measure hunger, urges to smoke, 4 week abstinence and weight. Participants will be followed up at 6 and 12 months.

We need at least 300 smokers with a BMI of at least 25 to participate in this trial. Each

participant will receive both standard smoking cessation treatment and dietary counselling from a registered dietician. We have found that the most effective way to recruit trial participants is for you to write to your patients who smoke. We will cover your costs in this. If you think we could run the clinics in your practice, please also get in touch with us. This trial will help your patients and you will not be out of pocket.

If your practice is based in and around the Birmingham area and you have patients who would be interested in being involved please contact:

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Nutrition Consultant

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behavioural therapy (CBT) to accept modest weight gain were separately tested in two trials. Both interventions resulted in a significantly increased quit rate at 12 months compared to control conditions and both limited weight gain at 12 months although this was only statistically significant for CBT.

In the second part of our review we summarised the effect of first line smoking cessation drug treatments on preventing weight gain. In the short term, bupropion, also known as Zyban, was the best at reducing weight gain and users gained 1kg less than those who did not use it. People who used varenicline (Champix) and nicotine replacement (such as patches and gum) prevented about half a kilogram increase in weight. Lots of trials have tested these medicines, but too few of them have weighed people in the long-term to know whether these effects last or not. Three trials of nicotine nasal spray where long-term use was allowed suggested long term use of the spray reduced weight gain by 1.5kg after 12 months.

Overall, our review showed that reducing weight gain in people stopping smoking is difficult but not impossible. This is fertile ground for further research to clarify the reasons why people put on weight and to develop effective interventions to help people prevent it.

Aerobic exercise and vasomotor symptoms

Many women are choosing not to use HRT. Therefore, it is increasingly important to identify alternative evidence-based interventions that have the potential to reduce the prevalence of vasomotor symptoms.

One option might be exercise, particularly given that there is already good evidence that regular exercise participation has positive effects upon other symptoms and health concerns that are associated with the menopause, such as depression, fatigue and bone and cardiovascular health risk.

Following our previous pilot work and systematic review we are now planning to conduct a randomised controlled trial of the effects of exercise on vasomotor and other menopausal symptoms. Before we start the trial we plan to ascertain women's (aged 46–55 years) preferences for different methods of promoting exercise (ie. by consultations, telephone support, email prompts etc) and their views about the role of exercise as a potential treatment for vasomotor symptoms.

We will structure the exercise interventions in the trial around these preferences and views.

Participating practices will send a brief questionnaire that asks eligible women about their vasomotor symptoms, exercise participation, menstrual status and HRT use. We hope to obtain at least 1400 completed questionnaires. This programme of work is funded by the National Institute for Health Research. The preference survey should be completed by October 2009 and we plan to start the trial in February 2010.

If you would like more information about this study please contact:

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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 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 in order

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 are already in the process of recruiting and training practices within Birmingham and 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:

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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.

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

Current wisdom tells us that 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 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 will have 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 will 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 will be asked to use a nicotine patch for two weeks before quitting but will 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 will receive standard smoking cessation behavioural support.

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 also looking for nurses who would be willing to run research clinics for us within their practices. If nurses provide this, we will train and supervise them in the techniques and we will cover the costs of their time in providing these clinics.

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

To discuss this please contact:

- ☐ **Dr Paul Aveyard**
Tel: 0121 414 8529
- ☐ **Jackie Ingram**
Nurse
Tel: 0121 414 3105

Under analysis

MMP9 Wolverhampton

Study to establish the added benefit of measuring MMP9 after positive FOBt as part of the NHS Bowel Cancer Screening Programme

This study has recruited 200 patients who had a positive Faecal Occult Blood test and who were referred for colonoscopy to Wolverhampton Bowel Cancer Screening Unit as part of the National Bowel Cancer Screening Programme.

Our aim is to establish whether MMP9 estimation will enable the accurate identification of people who do not have bowel pathology (cancer or high risk polyp) and could therefore avoid the need for colonoscopy.

Analysis of this dataset is currently underway.

This study has been funded by NIHR School of Primary Care.

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FamilyTalk

Parents¹ and children's communication about genetic risk information

Funding: Department of Health, 2006–09

The aim of this multidisciplinary project has been to explore how genetic information is shared between family members to ascertain the implications for children, young people and their parents to inform future service developments and provision. The focus upon children, young people and their parents draws directly on the experiences of two groups, those children and young people directly affected by genetic conditions and those unaffected but with experience within their family.

The following research questions have been explored:

- What is the understanding and perception of genetics and genetic risk across different ages, cognitive development, sexes and genetic conditions?
- What is the understanding and perception of genetics and genetic risk in different cross-cultural groups of the community including Black and Minority Ethnic groups (BMEG)?
- What are the experiences of barriers (real or perceived) in communicating and sharing genetic risk information, in families

affected by an inherited genetic condition?

- What effect does genetic risk information have in terms of health beliefs, decision-making and choice?
- What role should healthcare services take in supporting the sharing of genetic risk information in families?

Outcomes

The study recruited from across England, a total of 35 families affected by 6 different types of genetic condition. The 6 genetic conditions reflected different patterns of inheritance and variation in the levels of associated morbidity and mortality. The final stage of data analysis is now underway with the project due to finally complete at the end of May 2009. Interviews of all family members usually took place in the family home.

The project will highlight the implications for children and young people in understanding and coping with the knowledge of their own and any future family's risk to a particular genetic disease. The findings will provide insight for parents about sharing genetic information within their families, including



framing of discussions and eliciting children's and young people's need for information at different stages of development. The evidence generated will assist and inform the future development and integration of genetics into children and family healthcare services including primary care, and raise awareness of the advice and support required from health professionals for children, young people and their parents, about sharing genetic information.

If you require any further information about this study please contact:

- **Dr Alison Metcalfe**
Chief Investigator
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Footnote¹: All types of parents, biological, step, adoptive or foster parents and same sex parents were included in the recruitment.

Healthcare Workers' Attitudes Towards Working During Pandemic Influenza

Pandemic influenza will put healthcare services in the UK under severe strain, and if the response to a pandemic is to be effective, it is important that the NHS continues to be able to provide critical care to those who need it. This relies on healthcare workers (HCWs) of all types continuing to come to work. This study, funded by the NIHR Research for Patient Benefit (RfPB) Programme, is a two-phase multi method investigation to look at the factors that might encourage or discourage HCWs to work during an outbreak of pandemic influenza.

The first phase of the research was based on a series of focus groups, carried out with different types of healthcare workers. The focus groups aimed to explore the opinions of group participants about working during a pandemic and the changes to working conditions that might make them more likely to remain at work. The findings from this research phase were used to develop a questionnaire survey which was sent to 3,000 HCWs across the West Midlands to see how widely these opinions were held, and to gauge potential levels of absenteeism amongst key HCWs during a pandemic.

It is anticipated that when complete, the results of this project will help UK contingency planning, at both national and local levels, should an influenza pandemic occur. If the factors (positive and negative) associated with attitudes towards working during a

pandemic can be identified, it may be possible to predict how HCWs will respond during a pandemic and the ways that patient care can be improved if appropriate contingency measures are implemented to address barriers to working. These contingency measures may help to change the attitudes of those HCWs who might be identified as reluctant to work, and ensure that HCW absenteeism during a pandemic is kept to a minimum. The research on the project is led by Dr Heather Draper of the University of Birmingham Centre for Biomedical Ethics.

For further information about the study, please contact:

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Completed studies

UNIVERSITY OF
BIRMINGHAM



UNDERSTANDING THE EXPERIENCE OF COLPOSCOPY: A step towards service improvement

Every year over 120,000 patients are referred for a colposcopy appointment as a result of the national cervical screening programme.

It is well documented that this referral is associated with considerable anxiety for patients, and that default rates for these appointments may be high. The aim of this study was to better understand this experience from the patients' viewpoint and to identify potential service improvements together with patients' relative preferences for changes to their appointments.

This investigation into women's experience of colposcopy has now been completed. The study employed a two-phase multi-method approach to explore the experience that women have of referral to, and attendance at, colposcopy clinics. Qualitative interviews with patients in two West Midlands clinics identified that this is often a very emotional time for women, and

there is limited understanding of the purpose of the cervical smear test and the meaning of abnormal results. Patients were able to suggest potential improvements for the colposcopy service, which were further investigated in the subsequent phase of this project.

This stage applied a patient preferences questionnaire (called a best-worst discrete choice experiment) to find out the strength of preference that patients had for various aspects of their colposcopy appointments. The findings emphasised the value of a positive and supportive staff attitude, with the feeling of 'not being rushed' during the appointment also significant. Having information in advance, and their choices consulted mattered to women, although surprisingly, the least important



preference was for additional information provision in the form of an appointment with their GP or practice nurse.

The cervical screening programme has seen numerous developments over the past 20 years including the introduction of nurse colposcopists, changes in techniques and improvements in patient information material. It is envisaged that these results will update our current knowledge on women's feelings and preferences as they go through the cervical screening programme.

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BETS II:

Birmingham Elderly Thyroid Study Follow-up: Are current reference ranges appropriate for identification of thyroid dysfunction in the elderly?

The follow-up and screening phase of the BETS II study has been successfully completed and we would like to again thank all the practices who participated. Overall 74% (4378/5881) of the original cohort were contactable, deemed well enough to participate and invited to attend a practice based screening clinic. Ninety eight patients who had been treated as a result of their participation in BETS 1 (either due to identification of overt thyroid dysfunction or via participation in our trial of therapy for subclinical hypothyroidism) were not eligible for screening. Seventy-four percent agreed to participate (n=3233) and 2945

(67%) were successfully screened for thyroid function. Only four new cases of overt disease were identified (2 hypothyroid, 2 hyperthyroid) and 158 individuals had subclinical results (129 hypothyroid) – we have yet to determine if these represent new cases or cases of persisting subclinical dysfunction.

Due to changes in the assay our laboratory uses for thyroid function testing and associated changes in the reference ranges we have had to add a few additional steps in the action plan to correct our data prior to analysis. Standardisation for changes to assays and reference ranges are therefore being

undertaken and proportions changing disease status and predictors of status change are being explored. Whilst the low numbers of new cases of overt disease suggest repeated testing of thyroid function in older age may not be required unless clinically indicated, final analysis will identify groups for whom repeated testing may be worthwhile and will be able to advise on screening in this age group.

Contact details:
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Department of Primary Care Clinical Sciences and MidReC: Top centre for primary care research in the UK: it's official!

Primary Care Clinical Sciences (PCCS) was one of the top returning units for the University of Birmingham in the recently published RAE 2008, second only to Music in terms of highest proportion of 'world leading' (4*) designated papers (50% to our 35%).

The HEFCE Research Assessment Exercise (RAE) is one of the world's largest and most rigorous external reviews of research quality conducted at all higher education institutions in the UK. It involves expert peer review of around 70 discrete areas of research across universities, assessing their main publications, together with research grant income, research training activities, and research environment. 2008 was the first national review since 2001.

In terms of national ranking in primary care (against other universities), PCCS ranked a close 3rd most successful primary care centre in the UK purely on proportion of our work designated world class research. However, with substantially the largest quality return (first and second ranked only 55% and 75% as many papers respectively, and fourth and fifth ranked only 30% of our volume), on quality-adjusted research volume for primary care, we were top!

Overall, PCCS at Birmingham delivered 13% of the total UK volume of research in primary care, 35% of which was rated 'world leading' and a further 30% 'internationally excellent,' cementing our status as top UK centre. Our research was also rated 5* (top category denoting international excellence) in RAE 2001 and we are a founding member of the NIHR School for Primary Care Research (Hobbs, Deputy Director). Furthermore, we are also the only RAE 2001 5* primary care research centre that substantially increased our volume return in 2008 (doubled from the second highest volume in 2001). PCCS at Birmingham has now been RAE assessed as world class for primary care research for 12 years continuously.

We remain one of the largest centres for academic primary care in Europe – focusing on applied and translational research under 3 main clinical programmes: cardiovascular disease; cancer and chronic disease; and clinical

decision making; with additional expertise in behavioural medicine (smoking cessation, exercise), ethnicity health, and longitudinal cohort studies. The programmes are supported by cross-cutting methodology expertise and major investments in research infrastructure, particularly the Primary Care Clinical Research and Trials Unit (PCCRTU) and large Primary Care Research Networks (MidReC and PCRN-CE). The department currently has five clinical and four non-clinical Chairs, two Readers (one non-clinical), eight senior lecturers (five non-clinical) and a strong early career track for clinical and non-clinical scientists. Since 2000, external research income within the groups exceeded £25 million, around a third each from the MRC and NIHR, and 25% from medical charities.

Professor Richard Hobbs
Head of Primary Care Clinical Sciences

MSc in Clinical Primary and Community Care – clinical placements

The Department of Primary Care Clinical Sciences is running a number of MSc accredited modules centred around cardiovascular disease management.

As part of the course the students are expected to spend time in primary care based heart failure, hypertension and cardiovascular disease management clinics to gain specific related competencies.

The student complement is mostly made up of GPs, practice nurses and pharmacists. Students would come to the clinic on one occasion to observe and then be assessed (in one visit) within their own practice undertaking competencies in patient diagnoses and classification, treatment suggestions based on national guidelines and have knowledge of cardiovascular risk factors.

There will be a remuneration of £50 per student visit to your clinic and £100 if you visit them in their practice.

If you would be interested in undertaking supervision and assessment of 1 or more students from the courses I would be very pleased to hear from you.

Please contact:

Ellen Murray

Tel: 0121 4143761

Email: e.t.murray@bham.ac.uk.

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

1. MSC Clinical Primary and Community Care

This is a new programme of learning aimed at health care professionals working within primary care. The aim of the programme is to provide skills at a higher level that will produce leaders within clinical specialism who are able to practice autonomously and deal with complex clinical problems. It can be taken either full time over 1 year, part time over 2 years or flexitime over 5 years. Each clinical module can also be undertaken as a stand alone module accruing 20 MSc credits.

The programme contains two core modules in epidemiology and statistics and qualitative research methods and then a number of optional modules in clinical and non clinical areas, eg. Anticoagulation, Hypertension, Heart Failure, Cardiovascular Disease Management and Ethics and Law. The aim of the clinical modules is to enable professionals to be competent to run a primary care clinic in that specialty. They comprise pre-course learning material, face to face teaching covering theory and practice and clinical supervision in practice which has proved an invaluable aspect of

New staff



Sarah Bathers joined the department of Primary Care Clinical Sciences to manage the PC-CRTU in October 2008. The PC-CRTU is a dedicated and expert primary care Clinical Research and Trials Unit which comprises research practices (MidReC) the research support facility (RSF) and the Clinical Trials Unit.

Sarah has over 25 years clinical trials experience and has co-ordinated many cancer clinical trials in this time including the NEAT1 study which examined the efficacy of anthracyclines in the adjuvant treatment of early breast cancer. She became Breast Team Leader in 1999 overseeing a portfolio of multi-centre clinical trials in breast cancer and supportive care. In 2004 she took on the additional role of Assistant Director of Operations role within the Cancer Research UK Clinical Trials Unit (CRCTU).

Sarah has a particular interest in further developing departmental governance robust systems which will be implemented across the department to ensure compliance with required regulatory standards. She will also set, maintain and communicate policy, quality standards and trial management frameworks

Refs:

Epirubicin and cyclophosphamide, methotrexate, and fluorouracil as adjuvant therapy for early breast cancer.

Poole CJ, Earl HM, Hiller L, Dunn JA, **Bathers S**, Grieve RJ, Spooner DA, Agrawal RK, Fernando IN, Brunt AM, O'Reilly SM, Crawford SM, Rea DW, Simmonds P, Mansi JL, Stanley A, Harvey P, McAdam K, Foster L, Leonard RC, Twelves CJ; NEAT Investigators and the SCTBG.

N Engl J Med. 2006 Nov 2;

355(18):1851–62.

PMID: 17079759

[PubMed – indexed for MEDLINE]

NEAT: National Epirubicin Adjuvant Trial-toxicity, delivered dose intensity and quality of life.

Earl HM, Hiller L, Dunn JA, **Bathers S**, Harvey P, Stanley A, Grieve RJ, Agrawal RK, Fernando IN, Brunt AM, McAdam K, O'Reilly S, Rea DW, Spooner D, Poole CJ; NEAT Investigators.

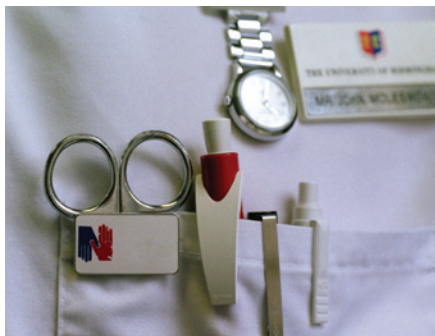
Br J Cancer. 2008 Oct 21;

99(8):1226–31.

Epub 2008 Sep 16.

PMID: 18797468

[PubMed – indexed for MEDLINE]



this course. Experienced professionals are provided locally for the students to provide both support and supervision.

The student has to demonstrate a series of benchmarked competencies in order to receive full accreditation.

**For more information contact
Dr Ellen Murray on 0121 414 3761
or e.t.murray@bham.ac.uk**

2. An update on Chronic Kidney disease management in primary care

The course aims to provide knowledge of guidelines for management of chronic renal failure since the implementation of eGFR. The learning outcomes of the course are an understanding of the epidemiology and physiology of chronic renal problems and the impact of other diseases, in particular diabetes and cardiovascular disease; an understanding of appropriate treatment and management, including QOF and guidelines for referral and an understanding of the relationship between primary and secondary care providers.



This course is being held on Friday 19 June 2009 in the Centre for Professional Development at Birmingham University Medical School.

**For more information please contact
Jo Leggat on 0121 414 3354 or
j.leggat@bham.ac.uk**

3. Stroke prevention in primary care

This course covers how best to reduce stroke risk in people on practice stroke and transient ischaemic attack (TIA) registers, and recent developments in the early management of TIA. The content includes an evidence based approach to the management of blood pressure and cholesterol, use of antiplatelet therapy and the role of carotid endarterectomy.

This course is being held on Monday 8 June 2009 in the Centre for Professional Development at the University of Birmingham Medical School.

**For more information please contact
Jo Leggat on 0121 414 3354 or
j.leggat@bham.ac.uk**

4. Women's health update

The course is aimed at General Practitioners, practice nurses and other primary health care professionals with an interest in women's health.

The aims of the course are to give an update of current options for contraception for women, knowledge of current management of disorders of menstruation,

an update on cervical cancer screening and prevention and the HPV vaccination and potential workload for primary care.

**This course is being held on
Wednesday 29 April 2009 in the
Centre for Professional Development
at the University of Birmingham
Medical School.**

**For more information please contact
Jo Leggat on 0121 414 3354 or
j.leggat@bham.ac.uk**

5. Cancer screening update day

The course is aimed at health care professionals from primary or the acute sector working within an area of the health service involved in screening people for cancer. The learning objectives of the course are an understanding of the current evidence and opinion on screening for cancer, knowledge of current advances in screening for cervical, breast, prostate and colo-rectal cancer and knowledge of future developments in cancer screening.

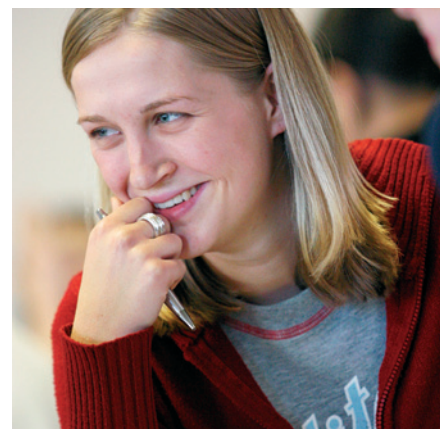
This course is being held on Monday 27 April 2009 in the Centre for Professional Development at the University of Birmingham Medical School.

**For more information please contact
Jo Leggat on 0121 414 3354 or
j.leggat@bham.ac.uk**

Further courses later in 2009 will include:

- ☐ Travel Vaccinations
- ☐ COPD: An update for primary care
- ☐ Oral Anticoagulation Management for Health Care Assistants and Assistant Practitioners
- ☐ Gastroenterology

**For more information please see our
website: www.medicine.bham.ac.uk/cpd**





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: Mrs Sheila Bailey (PCRN-CE Administrator)
Primary Care Clinical Sciences
Primary Care Clinical Sciences Building
University of Birmingham
Edgbaston
Birmingham, B15 2TT

PC-CRTU CONTACTS

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