Clinical Research Network
West Midlands

NHS
National Institute for
Health Research

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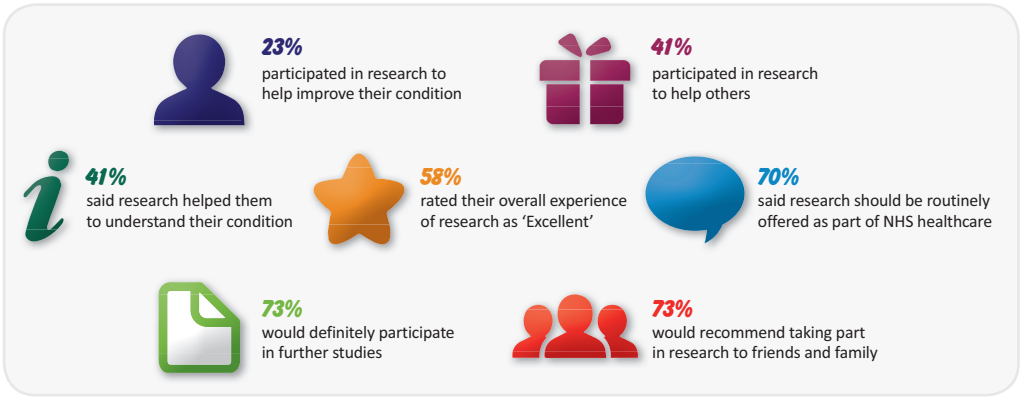
# PARTICIPATE

## Patients' Experience of Research: what can research do for you?

Patient and Public Involvement and Engagement (PPIE) is key to achieving ethically sound research that is relevant to those most likely to benefit from it. It is practical commonsense to involve the public not only in the design of research, as this increases its viability and promotes willingness to participate in studies, but also in the interpretation of data and the dissemination of findings.

Early stage PPIE input into research enables smoother running of projects by ensuring that contact methods and times are appropriate and sensitive to any specific cultural community requirements. It also helps to ensure appropriate wording for research materials, such as consent forms, and questionnaires. For PPIE to achieve its full potential, it is important that it is inclusive and allows a diverse range of individuals to contribute. This may mean using a range of methods – for example, meetings in different localities or with faith communities, online surveys, contact with voluntary groups etc.

Within the West Midlands, the PPIE team of the CRN is looking for volunteers who might be interested in becoming Patient Research Ambassadors (PRAs) to promote health research from a patient point of view. If you are interested, or know of someone who might be, please contact Moe Shaikh, CRN WM PPIE Cross Cutting Theme Lead on 024 76430165 or email mohammed.shaikh@nihr.ac.uk




The Patient Research Experience Survey 2016-17 was carried out nationally across England, following a pilot in 2015 and showed a high level of satisfaction among those who participated in research. The results show how much patients valued research and the benefits that are gained.

**In this edition we feature articles on:**

- I-WOTCH: a multicomponent self-management intervention targeting withdrawal of strong opioids for people living with persistent pain (page 2)
- ARCHIE: a double-blind randomised placebo-controlled trial which aims to determine the effectiveness of giving antibiotic co-amoxiclav to 'at risk' children within five days of them becoming ill with flu or influenza-like illness (page 3)

If you would like to contribute to Participate or for further information, please contact Jenny Oskiera, email: j.oskiera@warwick.ac.uk or jenny.oskiera@nihr.ac.uk

- Study – CHESS
- CRN – update from Pauline Boyle, Chief Operating Officer
- PPIE – Patient Research Ambassadors Needed
- Events – RCGP Midland Faculty Symposium 2018

## Contents

# i-WOTCH

## Improving the Wellbeing of People with Opioid Treated CHronic Pain

### Seeking GP practices to host i-WOTCH study on opioid withdrawal for chronic pain

We are currently recruiting GP practices across the whole Midlands region to take part in the I-WOTCH study. We are a multi-centre, randomised controlled trial aiming to test the effectiveness and cost effectiveness of a multicomponent self-management intervention targeting withdrawal of strong opioids for people living with persistent pain in comparison to best usual care. The chief investigator for the study is Dr Harbinder Sandhu at the Clinical Trials Unit, University of Warwick.

We plan to recruit 468 participants from around 100 general practices, community pain/musculoskeletal services and pharmacies across three locations: the Midlands, North East England and Greater London.

The I-WOTCH intervention is targeting patients using Buprenorphine, Dipipanone, Morphine, Diamorphine, Fentanyl, Methadone, Oxycodone, Papavertum, Pentazocine, Pethidine, Tapentadol, or Tramadol for the treatment of persistent non-cancer pain. These drugs account for 95% of UK strong opioid prescribing in primary care.

### What will it involve for participants?

All participants will be asked to:

- Provide written consent and complete postal questionnaires at baseline, four, eight and twelve months
- Complete a weekly diary booklet recording symptoms and quality of life for four months from baseline

### Participants will be randomised to either:

- **Usual GP care plus a self-learning manual**
  Participants will receive a manual with advice about chronic pain management and potential implications and adverse effects of using opioids, and a relaxation CD plus usual GP care.
- **Usual GP care plus a support programme**
  Participants will attend a three day self-management course led by an I-WOTCH nurse and a lay facilitator held at a venue close to their practice. There will be an average of 12 people in a group. Participants will have two one to one meetings and two telephone calls with the nurse. The nurse will create an opioid tapering plan for the participant at the first meeting and then monitor and discuss their progress over the calls and final one to one meeting. Participants will receive the self-learning manual, relaxation CD, educational DVD and mindfulness CD plus their usual GP care.

### What will it involve for GP practices?

- Identification of potential participants from computer record search
- Checking of list before mail-out
- Mail out of study invitation letters (via Docmail)
- Access to patient records at a later date for data collection of consultations, health service activity, prescriptions and NHS number

**Funding Acknowledgement:** This project is funded by the National Institute for Health Research, Health Technology Assessment (project number 14/224/04). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA, NIHR, NHS or the Department of Health.

If your GP practice is interested in the study or for more information, please contact your local facilitator, please see back page.

# Chronic Headache Education and Self-management Study (CHESS)

CHESS Chronic Headache Education and Self-management Study

A multi-centre, randomised controlled trial evaluating an education and self-management support programme for people living with chronic headaches (headache ≥ 15 days/month for ≥ 3 months). The trial is led by Professor Martin Underwood at the Clinical Trials Unit, University of Warwick.

**We are currently recruiting people aged ≥18 years living with chronic headaches from the Midlands and North-east London.**

### What will it involve for participants?

**All participants will be asked to:**

- Complete an electronic diary of headache frequency, duration and severity weekly for 6 months and monthly for a further 6 months
- Complete a telephone interview with a research nurse to classify their headache type
- Complete postal questionnaires at baseline, 4, 8 and 12 months

**Participants will be randomised to either:**

a. *A group headache education and self-management support programme.* Participants will attend a two day education and self-management course held at a venue close to their practice; followed by a one-to-one consultation and up to eight weeks of telephone support with a nurse

b. *Usual GP care plus relaxation CD.* Participants will receive standard treatment and sent a relaxation CD

### What will it involve for GP practices?

- Identification of potential participants from computer record search
- Screening of list before mail-out
- Mail-out of study invitation letters (via Docmail)
- Access to patient records for data collection of consultations, health service activity, and medication use related to headaches at 12 months

If your practice is interested in taking part in the study or you would like any further information regarding CHESS please contact your local research facilitator, details on the back page.

# ARCHIE - The early use of Anti-biotics for 'at-risk' Children with Influenza

## Study summary

Children with underlying medical conditions such as asthma, diabetes and cerebral palsy are 'at risk' of becoming more unwell from bacterial infections if they get flu. ARCHIE is a double-blind randomised placebo-controlled trial which aims to determine whether giving the antibiotic co-amoxiclav to 'at risk' children within five days of them becoming ill with flu or influenza-like illness might:

1. Help stop them from developing bacterial infections and becoming more unwell
2. Help them get better more quickly
3. Affect how well antibiotics work against similar infections in future

**Practice involvement**: We are looking for practices to

- Identify and flag potentially eligible patients via a database screen prompt
- On presentation of an eligible patient during the winter season to call the ARCHIE recruitment hotline to inform central trial office if family happy to be contacted (approx. 5-10 min call)

A CRN nurse will then attend the patient at home for consent, baseline, randomization and study medication dispensing. The CRN nurse will carry out follow up including medical notes review. The practice may be asked to give additional information if their participant has an SAE.

**Patient involvement:** In addition to the child completing a five day course of study medication a nose and throat swab will be taken. Family will be asked to complete weekly diary for a month after study entry.

**Recruitment status:** Seasonal from October to April.

**Funder:** NIHR's Programme Grants for Applied Research Programme.

For further information, please contact your local research facilitator, details on the back page.

# PACT - Testing the Delivery of the Best Asthma Treatment Based on Genetics

A study by researchers from across the UK, funded by Action Medical Research, is aiming to discover whether treating asthmatic children according to their genetic status can improve their quality of life and asthma control.

One in every 11 children in the UK has asthma. When asthma is well managed, children can lead full and active lives. Unfortunately, not all asthma is well controlled. There is evidence that the routinely used controller medication salmeterol is ineffective in 1 of 7 cases. Previous work by Professor Somnath Mukhopadhyay from Brighton and Sussex Medical School suggests that certain gene variations are linked to poor asthma control in children.

As a result, working with general practitioners, PACT is designed to assess the effectiveness of prescribing children, whose asthma is inadequately controlled, either salmeterol or montelukast according to their beta2 receptor genetic status compared to standard asthma management regimes. Participants' genotype status is established from self-administered saliva tests.

PACT is novel as no hospital visits are required with all outcome data being completed by participants online at three monthly intervals for one year. This design allows participants to complete their quality of life and asthma control questionnaires at their convenience, with associated costs reduction.

At the end of the study, all participants and GPs will receive gene test and study results.

Healthcare professionals can find out more about the study at www.pactstudy.org.uk or by calling the Tayside Clinical Trials Unit on 01382 383932.

If your practice would like to take part, or would like further information, please get in contact with your local research facilitator, details on the back page.

# QUAlity of life, Sleep and rheumatoid ARthritis: QUASAR

The quality of life, sleep and rheumatoid arthritis, or QUASAR, has been designed by Dr John McBeth to investigate the relationships between sleep and quality of life and asks participants to wear a sleep monitor 24 hours a day for 30 days, while using a smartphone app to record daily symptoms.

Talking about the importance of the study, Dr McBeth explains:
*"There's evidence that people with rheumatoid arthritis (RA) report high levels of sleep disturbance and we don't yet know why that is. What we do know is that research suggests that disturbed sleep is linked to poor health related quality of life. By focusing on the interaction between how people sleep and factors that affect our everyday lives, for example levels of pain and fatigue and our mood, it is hoped that the results of the QUASAR study will enable us to develop new, or better target existing, sleep interventions to ultimately improve the quality of life of those with rheumatoid arthritis who experience sleep disturbance."*

## Who is eligible?

- ≥18 years
- Diagnosis of RA and use of DMARDs
- Access to an Apple/Android smartphone/tablet
- No shift work

## Primary care support

QUASAR is open to new PIC sites who will be responsible for displaying posters. We would also like to chat to practices with the ability to screen GP databases to assist in the mailout of GP letters.

For further information, please contact your local research facilitator, details on the back page.

# The West Midlands Primary Care Team

## Supporting the delivery of research in the primary care setting

*by Pauline Boyle, Chief Operating Officer, Clinical Research Network West Midlands.*

*Over one million people have taken part in Primary Care research nationally in the past 10 years, and 175,000 of these were recruited in GP practices in the West Midlands. The contribution of these practices is significantly helping the NHS to gather evidence about new treatments and services in order to improve patient care.*

### What did we do well as a Clinical Research Network and as a Primary Care Speciality last year?

As one of 15 Local Clinical Research Networks (CRNs) in England, the CRN West Midlands has been recognised for innovation and improvements in a number of key areas. For example, our leadership and support of the Patient and Public Involvement and Engagement induction programme, our continuous improvement initiatives and success in exceeding our participant recruitment target. Primary Care is one of our 30 specialities and the primary care delivery support team contributes significantly to these areas of success. Their engagement with the GP practices and community pharmacies, and their support for the delivery of National Institute for health Research (NIHR) Portfolio studies in both the Primary and Secondary Care settings is pivotal to the increasing the opportunities for patients to take part in research across all of our specialties. Primary Care in the West Midlands recruited just short of 10,000 patients into NIHR portfolio studies last year, which was a significant contribution to both our recruitment target and future funding. Interestingly, an increasing amount of the work that they undertake supports the wider Network endeavour rather than just Primary Care and can often go unrecognised. For example, their support of practices to act as Patient Identification Centres (PICs) and their support to study delivery in hospices and care homes. It is a misconception that research in the Primary Care setting is easy to do, but Primary Care studies can often be complex, sensitive and very difficult to recruit to, leaving the GP practice requiring a lot of support to deliver them. Without the support and dedication of our Primary Care delivery support team, many GP practices simply would not take part in research and the Network would not achieve the high levels of recruitment that we currently enjoy. It is for these and many more reasons that the CRN recognises the significant contribution that our Primary Care team provide.

### What does your vision for the future of the Network look like and how do you see primary care contributing to the continued success?

I am excited about the many opportunities for research. The development of digital technology to support clinical trials will transform the way we deliver trials, making us more efficient and meeting the needs of our population.

As you know, the way we deliver health and social care is changing. More services will be delivered in Primary Care as well as non-NHS organisations. We need to be flexible and adaptable in order to take advantage of the new opportunities for patients to have the opportunity to participate in a clinical trial.

If we get this right, clinical trials will be part of everyone's business, no matter where health and social care is delivered.

Patients will actively seek out opportunities to participate and we will continue to develop our workforce to meet these new demands. The expansion of the delivery of studies within Primary Care is an exciting opportunity and I am confident that we can work together to continue to provide a first class service for our population.

We also need to recognise the contribution Primary Care makes in all aspects of clinical research in their contribution to PIC activity and recruitment in community pharmacies and hospices.

### How do you see the Primary Care role contributing to the future success of the Network?

The future success of the Network is largely dependent on the dedication and commitment of our staff to support the timely and effective delivery of studies brought to us by our research community. I am well aware of the co-operation and collaboration that our Primary Care team have demonstrated. This has resulted in huge progress in streamlining and standardising their structure and many of their processes to improve the researcher experience, and has encouraged researchers to bring their repeated business to the West Midlands because of our excellent reputation. I am keen to support the team to build on this progress and really get them working as one team across the whole of the West Midlands, operating seamlessly together across the three localities. A Primary Care delivery support team which is dedicated, resilient, and which can quickly and positively respond to support the delivery of research in a changing Primary Care landscape, will enable them to quickly engage and support the new GP configurations and new models of healthcare providers. This will certainly add value and contribute to the wider CRN WM success.

Finally I would like to take this opportunity to sincerely thank the Primary Care team for their continued dedication and professionalism which has undoubtedly resulted in better outcomes for our population. I am looking forward to exciting opportunities ahead of us in which Primary Care will take the lead.

# Centre of Precision Rehabilitation for Spinal Pain (CPR Spine)

The assessment and management of spinal pain disorders are an international challenge and come at great individual and societal costs. Appropriate identification of patient-specific interventions are a major priority and comprehensive assessments, taking into consideration the multidimensional nature of spinal pain, are warranted to inform safe and precise rehabilitation.

CPR Spine was established at the University of Birmingham in 2016, bringing together cutting edge technologies with multi-disciplinary expertise (physiotherapy, osteopathy, anatomy, neurophysiology, and bioengineering) to develop our understanding of personalised rehabilitation for individuals with spinal pain. Effective precision rehabilitation enables improved effectiveness (clinical and cost) as it identifies which patients to target with rehabilitation, when and how to target them; and therefore enables more effective use of rehabilitation resources.

CPR Spine includes a research facility with state of the art facilities including systems for human movement analysis, quantitative sensory testing, electromyography, elastography, ultrasonography and electroencephalography.

Our new **Masters degree in Spinal Pain** provides students with research and project management skills focused to spinal pain. The combination of flexible learning, taught modules and the research thesis makes this a stimulating programme which gives students skills, awareness and the intellectual discipline required to carry out rigorous, effective, patient centered research into spinal pain and rehabilitation.

UNIVERSITY OF BIRMINGHAM | CENTRE OF PRECISION REHABILITATION FOR SPINAL PAIN

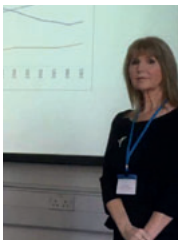
For more information on our research and educational opportunities in CPR Spine see http://www.birmingham.ac.uk/research/activity/cpr-spine/index.aspx

As well as being a leading research and education centre, CPR Spine actively engages with those individuals who are affected by a spinal complaint. This involvement extends from active participation in the process of conducting research with our CPR Spine Patient and Public Involvement Group to the CPR Spinal Register; a database of individuals with spinal pain complaints (neck, mid-spine and low back) who are interested in participating in research projects within the centre or receiving news of new findings and research projects.

If you wish to join the CPR Spine Spinal Register please contact cprspine-ppi@contacts.bham.ac.uk

# Study Reveals Treatment gap in Patients Suffering from an Irregular Heartbeat Leaving them at an Increased Risk of Stroke

**http://www.birmingham.ac.uk/university/colleges/mds/news/2017/06/irregular-heartbeat-stroke.aspx**



A study carried out by a team of researchers from the University of Birmingham's Institute of Applied Health Research and published in Heart, has discovered that patients with paroxysmal atrial fibrillation (PAF) are significantly less likely to receive anticoagulants for stroke prevention than patients with persistent or permanent AF.

Author Andrea Isaew, research nurse, inspired by a close relative's management of PAF, said that although the gap is narrowing, we need to remind ourselves that all patients with AF are at increased risk of stroke. Paroxysmal AF patients should be given the same priority for stroke prevention as other AF patients. While the anticoagulant treatment gap has narrowed over the years, from 15% in 2000 to 13% in 2015, over the same period a diagnosis of paroxysmal AF became three times more common. This means that the number of paroxysmal AF patients missing out on anticoagulants is greater now than 16 years ago.

**Full paper can be accessed at:**

**http://heart.bmj.com/cgi/content/full/heartjnl-2016-310927**

**http://heart.bmj.com/cgi/rapidpdf/heartjnl-2016-310927?ijkey=hz82OiSmqWTEgP6&keytype=ref**

# Rococo study: a real-world evaluation of an over-the-counter medicine in acute cough (a multicentre, randomised, controlled study)

This was the first study to recruit participants presenting to pharmacies, therefore the study population was more likely to resemble the broader population seeking cough medicines.

Four general practitioner (GP) surgeries and 14 pharmacies took part in the UK. 163 Participants were randomised to the study.

**Participants:** aged ≥18 years who self-referred to a GP or pharmacist with acute cough of <7 days' duration with a cough severity ≥60 mm on a 0–100 mm visual analogue scale (VAS).


Lucy Parsons, Lead Pharmacist, Jhoots, Cradley Heath receiving her plaque from Sheila Bailey, Research Facilitator CRN:WM

**Interventions:** Participants were randomised to CS1002 (Unicough) or simple linctus (SL), a widely used cough treatment, and treatment duration was seven days or until resolution of cough.

**Methods of evaluation:** Participants completed their assessments and compliance with medication in a daily diary. Each participant received a tamper-evident unidentifiable patient pack.

Seven Jhoots pharmacies within West Midlands Central took part in this study. We are arranging for those pharmacies to receive an NIHR 'Research Active' plaque for display in the pharmacy as recognition for taking part in the study.

Full article: **http://bmjopen.bmj.com/content/7/1/e014112**

## Ulipristal acetate versus CONventional management of heavy menstrual bleeding (HMB; including uterine fibroids): a randomised controlled trial and exploration of mechanism of action (UCON)

Previous research has shown that a hormone releasing coil, which is fitted inside the womb, is effective in reducing the impact and symptoms of heavy menstrual bleeding. Other medical treatments, including the contraceptive pill and non-hormonal treatments also reduce bleeding, but not as well as the coil. Ulipristal has been found to quickly reduce bleeding in women with large, non-cancerous growths in the womb, known as fibroids. It is not known whether this drug is effective in reducing the impact of heavy menstrual bleeding in women who do not have fibroids, or have small insignificant fibroids. It is also unclear how ulipristal stops menstrual bleeding and its effect on the womb lining.

The aim of the study is to test the hypothesis that ulipristal acetate (UPA; Esmya®), is more effective than the levonorgestrel releasing intrauterine system (LNGIUS, Mirena®) for the long term treatment of HMB. Furthermore, we aim to understand the mechanism of action UPA on the endometrium and its effects upon the vasculature and structure of the uterus. The study will be looking to recruit females aged 18 years or over who perceive their bleeding to be heavy or troublesome.

### What is involved for practices?

- Search GP database in accordance with inclusion/exclusion criteria as defined in the study protocol
- GP to check the list
- Mail out to potentially eligible patients using DOCMAIL

### Practice remuneration

- Service support costs: **£56.97** (database search and list checking)
- Research costs: **£12.44** per patient mailing using DOCMAIL

The above costs are pro-rata based on a mailing of 41 patients.

**This is PIC activity and recruitment and consent will be undertaken by the study team located at Birmingham Women's hospital.** We are looking to recruit ten practices within this locality.

UCON is funded by Medical Research Council (MRC) and National Institute for Health Research (NIHR) – Efficacy and Mechanism Evaluation (EME) programme (Ref 12/206/52)

For more information, please contact your local research facilitator, or Anu Krishna, contact details on the back page.

## Birmingham Scientists Awarded RCGP Research Paper of the Year 2016 for the TargetCOPD Trial

Dr Rachel Jordan and Professor Peymane Adab, representing the multidisciplinary team from the University of Birmingham's Institute of Applied Health Research, won the prize for category two, which included papers from ophthalmology, respiratory health and renal research areas.

The annual awards, presented by the Royal College of General Practitioners (RCGP), give recognition to an individual or group of researchers who have undertaken and published an exceptional piece of research relating to general practice or primary care.

Their paper, published in July 2016 by the Lancet, assessed the effectiveness and cost-effectiveness of two alternative approaches to targeted case finding for chronic obstructive pulmonary disease (COPD) compared with routine practice.


Professor Peymayne Adab, Professor Helen Stokes-Lampard (Chair of RCGP) and Dr Rachel Jordan

The research, funded by the National Institute for Health Research, found that active case finding was more cost-effective than opportunistic case finding, at a saving of over £40 (£333 vs £376 per case detected, respectively).

Commenting on the award Dr Jordan said:

*"A large number of people with COPD are not diagnosed until their disease is quite advanced. GPs could identify people at risk from their practice lists and invite them for further tests. By doing so, many people with early COPD who could potentially benefit from effective treatments could be identified earlier. The next challenge is to identify therapies which can genuinely improve outcomes in those detected earlier".*

The TargetCOPD trial is currently in the process of analysing the longer-term data, and we are also seeking further funding to update our economic analysis. We thank all of the Birmingham General Practices and their patients for being involved in the study, which has clearly been well received by the research and clinical community and will feed into national practice guidelines.

# EXVITD

Does Vitamin D improve response to resistance and exercise training (RET) and improve muscle and bone health? EXVITD is a placebo controlled randomised trial of the effects of RET combined with vitamin D supplementation on muscle and bone health in men and women aged 65 years or over who are ambulatory (with or without walking aids)

Muscle and bone loss are inevitable consequences of ageing, even if our health is good. The purpose of this study is to find out whether a period of strength training combined with a vitamin D3 supplement is any more effective at improving muscle and bone function than strength training alone. Although physical activity (particularly strength training) is crucial for good muscle and bone health and physical performance, there is evidence to suggest that older people do not respond well to strength training compared with younger people. Approaches to optimising this 'blunted' responsiveness using exercise training and nutritional supplements such as vitamin D, may have additive effects on physical performance and therefore represent a good strategy to reduce falls and fractures as well as maintain physical independence. Although we know that resistance exercise training (RET) may be beneficial to frail older adults, there are very few studies investigating its effect in combination with vitamin D3 supplementation.

### Benefit to patients

- Two DXA scans to assess body composition and hip and spine bone mineral density at the QE hospital
- BP monitoring
- Venepuncture for markers of inflammation/stress and bone turnover
- Monitoring of serum vitamin D3
- Calcium status
- Free exercise sessions (two times per week) for six months. Sessions will be based at The Morris Centre, QE hospital site, Mendelsohn Way, Birmingham B15 2TH
- Opportunity to socialise, make new friends and improve fitness levels.
- Travel expenses included (to and from the venue)

### Practice involvement

- Conduct a search to identify potentially eligible patients
- GP to check the patient list
- Conduct one mailshot inviting potentially eligible patients

### Practice re-imbursement

Practices will be paid £593.51 (pro rata based on the identification of 875 patients) with the potential to recruit 31 patients per practice.

**This is PIC activity and patients will be consented by the study team. Your involvement ends with the patient mailing. The Clinical Research Network can support your practice with the search and mailings.**

We are looking to recruit practices within the vicinity of the Queen Elizabeth hospital (although we would consider practices slightly further afield).

**Funded by:** National Osteoporosis Society Sponsor: University of Birmingham

**Chief Investigator:** Dr Carolyn Greig, Reader in Musculoskeletal Ageing and Health, University of Birmingham

For further information, please contact your local research facilitator, Sheila Bailey, details on page xx.

# Long-term Registry of Patients with Atrial Fibrillation UK Extension: AF-GEN-UK

This study will compare how patients with atrial fibrillation are managed by heart specialists (cardiologists) and other doctors (non-heart specialists), including general practitioners.

The registry will establish a 'snapshot' survey of the contemporary diagnosis and management of patients with AF among non-cardiologists and cardiologists in the UK at the time of enrolment, and to provide important information on outcome events (stroke, AF-related hospital admissions, death etc.) and any management changes over the first 12 months since AF diagnosis.

Arthritis Research UK

### Practice involvement

- Opportunistically identify potentially eligible patients during consultation or from the AF disease register, searching of the computerised GP records, or use of the GRASP-AF software (which interrogates GP electronic records for AF patients)
- GP or nurse will record demographic (age, sex, ethnicity, etc.) and clinical information (medical history, current medication, AF symptoms, current treatment etc.) in the electronic Case Record Form (eCRF)
- The patient will be followed up once, 12 months later. Follow-up will be by patient visit or telephone and review of the medical records
- Complete a short (five item) quality of life questionnaire at baseline and again at 12 month follow up

If your practice would like to take part in this study, please contact Marie Crook, contact details on the back page.

# Latest Publications

## The future role of receptionists in primary care

Litchfield I, Burrows M, Gale N, Greenfield S. Br J Gen Pract *In press*

The growing complexity of the primary care environment and the increasing expectations of patients and policymakers are placing huge demands on the primary care workforce. Recent reports on the challenges and opportunities facing primary care in the UK acknowledge that, to meet these demands, the potential of all members of the primary care team, including both clinical and non-clinical staff must be realised.

Arguably the most visible among the primary care workforce are receptionists, required to work under unprecedented levels of pressure and scrutiny yet without any concurrent change in their training or support. The breadth and importance of the role of receptionists is now being recognised in the UK. After decades of underestimating their contribution, it may be that the single most important step is educating patients, policymakers, and GPs as to the potential of receptionists to become an integral part of the primary care service that previously they have been employed to defend.

## Adaption, Implementation and Evaluation of Collaborative Service Improvements in the Testing and Result Communication Process in Primary Care From Patient and Staff Perspectives: A Qualitative Study

Litchfield I, Greenfield S et al. BMC Health Serv Res 17 (1), 615. 2017 Aug 30.

The process of testing and result communication is complex and reliant on the coordinated actions of care providers, external groups in laboratory and hospital settings, and patients. This fragmentation leaves it vulnerable to error and the need to improve an apparently fallible system is apparent. However, primary care is complex and does not necessarily adopt change in a linear and prescribed manner influenced by a range of factors relating to practice staff, patients and organisational factors. To account for these competing perspectives, we worked in conjunction with both staff and patients to develop and implement strategies intended to improve patient satisfaction and increase efficiency of existing processes. Here we describe the factors influencing the implementation of service amendments and the evaluation of their impact.

Join dementia research

Join Dementia Research (JDR) was launched approximately two years ago and as of 31 August 2017 has 30,449 volunteers enrolled on the site. Of the people enrolled 5,514 have a diagnosis of dementia.

Prior to 31 August 2017 people who have enrolled on the JDR site from information received at pharmacies equal 45 of the 29,190 enrolled from information at that time. Jhoots pharmacy kindly agreed to actively promote JDR in 14 pharmacies in the West Midlands: Central (7) North (3) and South (4), and promoted dementia research to patients who receive dementia medication or who express an interest from the banners located in their stores. The promotion of JDR in pharmacies has now closed and the results are not yet known. The JDR team continue to find new ways to promote and engage with people in the community and the manager of the Irish Association in Birmingham is considering becoming a professional JDR champion and actively promote JDR to their three dementia groups that take place weekly with approximately 50 people with a dementia diagnosis.

It is hoped that actively promoting JDR in the community will increase upon the 5,514 and also to enrol more patients who have a dementia diagnosis.

If you would like any further information or would like to promote JDR please contact CRN-WM@contacts.bham.ac.uk or visit www.joindementiaresearch.nihr.ac.uk/

# Brain Blood Vessels Health Study

### What is the influence of atrial fibrillation, high blood pressure and age?

Atrial fibrillation is one of the most common forms of abnormal heart rhythm and is associated with increased risk of stroke, cognitive decline and dementia. This British Heart Foundation funded research project seeks to better understand the precise mechanisms for this. We at the University of Birmingham Institute of Cardiovascular Sciences believe an important potential contributing factor is that the ability of brain blood vessels to tightly control their blood flow is impaired as a result of atrial fibrillation.

### Patient/volunteer involvement

The single study visit lasting one morning will be performed in the Institute of Cardiovascular Sciences, City Hospital Birmingham. The study includes a small blood sample, completion of some questionnaires/quizzes, and monitoring of your brain blood flow, breathing, and blood pressure. Travel to the hospital and parking charges will be reimbursed.

### Enrolment period

Recruitment is ongoing until early December 2017. Study will finish in January 2018.

### Practice Involvement

We are currently looking for practices to identify and invite three groups of **men and women** aged over 50 years to participate, with a particular focus on the first and third group.

1. **Patients with atrial fibrillation**
2. Patients with normal heart rhythm but high blood pressure
3. **Individuals with normal heart rhythm and normal blood pressure**

If your practice would be interested in helping us with this important study, please contact your local research facilitator. Practices will be reimbursed for their time.

# Summary Results: Patient Research Experience Survey 2016/17

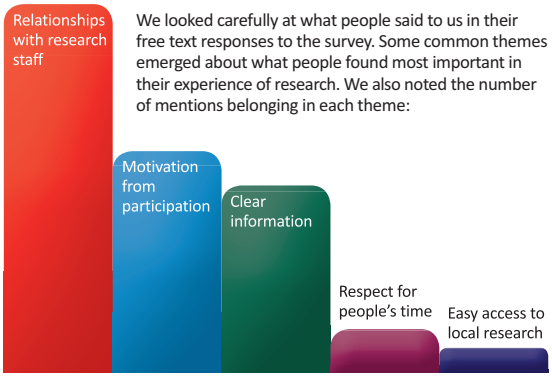
These are summary results of a patient survey about experience of participating in clinical research. The survey was carried out by Local Clinical Research Networks across England and the results were collated and analysed nationally. The local surveys included the same or very similar core questions and a free text box. The survey followed a pilot in 2015/16.

The number of respondents to the survey (3,320) was much higher than the original pilot (597) which means the data is very reliable and confirms the findings from the pilot.

**The feedback showed that:**

**90%** of patients had a good experience of particiating in clinical research

**86%** of patients would be happy to take part in another research study




We looked carefully at what people said to us in their free text responses to the survey. Some common themes emerged about what people found most important in their experience of research. We also noted the number of mentions belonging in each theme:

## What the themes mean in order of emphasis

### Research Staff

The feedback from research participants emphasized the friendliness, professionalism, knowledge, approachability, helpfulness, and respectfulness of staff being most important. This strong appreciation of staff was also expressed frequently in comments of those who had indicated that they were unlikely to take part in another research study.

LEARNING: Good working relations with staff are clearly key to good patient experience of a research study.

### Motivation

Responses revealed much about the importance of motivation to patients for participating in research. In particular:

- altruism and improving medical knowledge
- possibility of improving own health condition
- better medical monitoring
- learning about a medical condition

LEARNING: It is important to acknowledge and appreciate the patient's motivation for participating in a research study.

### Information

Feedback showed that good and timely information is very important to the patient's journey through a research study. This included information about the:

- research study itself
- practical arrangements for participating such as reminders etc. for visits
- progress of the research study (particularly a long one) and any interim findings
- results at the end of the research study

LEARNING: Having the right information at the right time is important to feeling fully engaged.

### Time

This was mentioned in a good number of comments in the feedback, particularly about timing of research appointments and waiting time whilst on a visit.

LEARNING: It is important to respect the patient's time given to participate in a research study.

### Access

There were also a range of comments generally about access and these tended to be about:

- flexibility of timing
- location
- travel
- parking
- disability access

LEARNING: There are a number of practical factors that can affect experience in attending a research study and can significantly contribute to the burden of doing so.

For more details about the background, the questions and full results of the Patient Research Experience Survey please read the full report which is available at https://www.nihr.ac.uk/why-research-matters or on request from Mana Golsorkhi on 020 3328 6707 or email: crnppie@nihr.ac.uk.

# Patient Research Ambassadors needed to Support Primary Care Research

The Clinical Research Network West Midlands Primary Care PPIE team are supporting the roll out of the NIHR Patient Research Ambassador Initiative.

Patient Research Ambassadors (PRAs) promote health research from a patient point of view. They could be a patient, service user, carer or lay person who is enthusiastic about health research and willing to communicate that to other patients and public as well as healthcare professionals.

There are a number of PRAs who help to raise the profile of research in an acute setting. We are keen to establish PRAs to help local practices and health centres, promote research and work with existing groups such as Patient Participation Groups in the region.

If you would like to find out more information about the patient experience in primary care research survey or are keen to establish patient research ambassador at your organisation then please contact your local research facilitator.

You can also contact Moe Shaikh, CRN WM Patient and Public Involvement and Engagement Cross Cutting Theme Lead on 024 76430165 or email mohammed.shaikh@nihr.ac.uk or contact Mary-Anne Darby, CRN WM Head of Patient and Public Involvement and Engagement in Research on 01902 447193 or email mary-anne.darby@nihr.ac.uk.

# Research Codes for Primary Care

Dr Mark Porcheret

Clinical coding of patient consultations is standard practice in primary care; however the use of codes for research purposes in general practice has to date been variable. Research is part of core business within the NHS, so it is essential that NHS staff have the tools they need to code research activity in general practice computer systems in a clear and consistent way with generic research codes (which could be specific to an individual study via a study ID) for recording research activities.

## Benefits of generic research codes to:

**Primary care sites**

- Patient identification: easy identification of patients approached about or entered into studies. Codes ensure a record of research participation remains in the patient's lifelong electronic record, making patient follow-up easier
- Preventing multiple approaches: ensuring patients aren't sent multiple requests to take part in the same study, or in different studies. Sometimes, multiple approaches may be appropriate and practices will be able to monitor this activity
- Safety: enabling swift identification of patients who need to be contacted about a specific study
- Administration: reduces paperwork, saves time, ensures easier monitoring and searching in patient records, reduces the need for free text. National research codes allow future proofing of coding, as systems develop and change and data is migrated across systems.
- Other: helpful in audit, making it an easier process and improving data quality

## NIHR CRN

- Aid mapping of activity: to ensure practices can better track activity and provide more accurate information to the network
- Patient Identification Centre (PIC) work/screening: using codes will allow practices to capture PIC activity and to identify patients participating in specific studies, e.g. if participation in one study is an exclusion criterion for another
- Recruitment: pop-ups during consultations can alert clinicians about studies a patient may be eligible for, potentially enhancing recruitment


A manual has now been launched, incorporating the work of the former Primary Care Research Network (PCRN) working group and, in particular, Dr Mark Porcheret, to whom we extend our grateful thanks for his sterling work in steering the process through to completion.

If you would like more information about research codes for primary care, or would like to receive a copy of the full manual, please contact your local research facilitator, details on the back page.

# The Role of GP Receptionists: A Research Study

*Michael Burrows, Ian Litchfield, Nicola Gale and Sheila Greenfield*

The roles of the GP receptionist are varied and essential to the smooth running of the practice. As well as undertaking administrative and clerical duties such as filing, maintaining medical records and making appointments, they also undertake functions more directly related to patient health, such as booking appointments, communicating test results and managing repeat prescriptions. However the complexities of primary care are increasing and these responsibilities are placed on staff without formal training. This has clinical consequences for patients and medico-legal concerns for practices. Funded by the Health Foundation, we aim to explore in greater detail the parameters of the GP receptionist's role in modern healthcare, exploring the scope of their current activities and ultimately identifying areas that might benefit from targeted support. Further details can be found in our published protocol.

**Getting involved**

We are currently recruiting participants and would like to encourage receptionists across the West Midlands to complete our questionnaire. This will take only a few minutes and includes questions about the nature of current responsibilities, and their interactions with colleagues and patients. It can be accessed via: https://bham.onlinesurveys.ac.uk/gp_receptionist-survey_v1. The second phase involves speaking with patients and a broader cross-section of staff to gather a range of perspectives on the role.

If your practice is interested in being involved in either phase or if you would like any further information about our work please contact Michael Burrows; Mjb538@bham.ac.uk or on 07528 528868.

# The Diagnostic and Prognostic Value of the Symptom of Shortness of Breath in Primary Care: A Cohort Study

## Background

When a patient consults their GP, the GP may record a symptom (e.g. shortness of breath) rather than a diagnosis (e.g. asthma) in the patient's computerised record. This may happen if the GP regards a symptom as representing a self-limiting illness, or the diagnosis is not clear at the time of an initial consultation.

Complaints of breathlessness and wheeze are common reasons why patients consult their GP, and may simply be a short-term and minor problem, or could be an early sign of chronic obstructive pulmonary disease (COPD), asthma, or ischaemic heart disease (IHD). The similarity of symptoms related to these conditions may make their diagnosis at initial presentation difficult, and often requires a number of tests.

## The study

This was a study of adults aged ≥18 years, performed within the Clinical Practice Research Datalink (CPRD) – a database drawing on GP records in England.

## Results

In this study, we found a much higher rate of COPD, asthma and IHD diagnosis in the next six months in patients presenting with an undiagnosed breathlessness/wheeze symptom for the first time compared to patients without a recorded breathlessness or wheeze symptom. This suggests these symptoms are strong markers that helped GPs to make a diagnosis. However, there were still higher rates of COPD, asthma and IHD diagnosed after the first six month period. We think this increased rate may be partly explained by some in diagnosis.

Some patients were initially prescribed drugs relevant to their future diagnosis despite the notes not having a diagnosis label recorded, but two-thirds of patients did not receive potentially appropriate medication in the initial six months after presenting with a breathlessness or wheeze symptom. This may represent a missed opportunity for early management.

Patients who received no relevant management in the first six months still had noticeably increased risks of COPD, asthma, and IHD. Furthermore, it was found that patients with a breathlessness or wheeze symptom had increased death rates.

## Conclusions

These findings suggest that presentation to primary care of breathlessness and wheeze can be an early indicator of later diagnoses of asthma, COPD and IHD, and also an indicator for earlier mortality.

Primary Care clinicians should consider more targeted investigations, monitoring and follow-up when patients initially present with symptoms of wheeze or breathlessness, to ensure accurate diagnosis, appropriate management and health and lifestyle advice are given to patients as early as possible.

## Patient and Public Involvement and Engagement (PPIE)

We held a number of PPIE meetings, members from the local 'Breathe-Easy' group, where the study idea, analysis and results were discussed. The study team is very grateful for the contribution of the PPIE group.

## Outputs

- Two papers are in preparation for submission to academic journals
- Two presentations of the results have been made at academic conferences (Society for Academic Primary Care, 206 and 2017)
- Summary of results sent to local Clinical Commissioning Groups (as suggested by the PPIE group)

# Local Contacts

**For more information about any study, or further information about anything else in Participate, please contact your local research facilitator**


## West Midlands Central

### Birmingham and the Black Country

| | | | |
|---|---|---|---|
| *Clinical Specialty Research Lead* | **David Shukla** | david.shukla@nhs.net | |
| *Research Manager* | **Louise Jones** | louise.jones@nihr.ac.uk | 0121 415 8092 |
| *Research Facilitator* | **Sheila Bailey** | sheila.bailey@nihr.ac.uk | 0121 414 7956 |
| *Research Facilitator* | **Beth Hinks** | elizabeth.hinks@nihr.ac.uk | 0121 414 8545 |
| *Research Facilitator* | **Sarah Hinton** | sarah.hinton@nihr.ac.uk | 0121 414 8593 |
| *Research Facilitator* | **Lucy Hughes** | lucy.hughes@nihr.ac.uk | 0121 415 8740 |
| *Research Facilitator* | **Marie Crook** | marie.crook@nihr.ac.uk | 0121 414 6270 |
| *Research Facilitator* | **Anu Krishna** | anuradha.krishna@nihr.ac.uk | 0121 414 6643 |
| *Research Facilitator* | **Saif Uddin** | saif.uddin@nihr.ac.uk | 0121 414 8614 |
| *Research Facilitator - Finance* | **Hilary Percival** | hilary.percival@nihr.ac.uk | 0121 414 8537 |

## West Midlands North

### Staffordshire, Stoke and Telford

| | | | |
|---|---|---|---|
| *Clinical Research & Specialty Co-Lead* | **Mark Porcheret** | m.porcheret@keele.ac.uk | 01952 255062 |
| *Research Manager* | **Jenny Stevens** | jenny.stevens@nihr.ac.uk | 01952 255062 |
| *Senior Research Facilitator* | **Jessica Graysmark** | jessica.graysmark@nihr.ac.uk | 01952 255062 |
| *Research Facilitator* | **Jenny Titley** | jenny.titley@nihr.ac.uk | 01782 734730 |
| *Research Facilitator* | **Mark Evans** | mark.evans@nihr.ac.uk | 01782 733923 |
| *Research Facilitator* | **Natalie Burgess** | natalie.burgess@nihr.ac.uk | 01782 734964 |
| *Research Facilitator* | **Sam Hunt** | samantha.hunt@nihr.ac.uk | 01782 734892 |
| *Research Facilitator* | **Jenny Simm** | jenny.simm@nihr.ac.uk | 01952 255062 |
| *Research Facilitator* | **Lucy Andrew** | lucy.andrew@nihr.ac.uk | 01952 255062 |
| *Research Facilitator* | **Gerri Mulcahy** | gerri.mulcahy@nihr.ac.uk | 01782 733963 |
| *Research Facilitator* | **Charlotte Thorley** | charlotte.thornley@nihr.ac.uk | 01952 255062 |
| *Research Facilitator Assistant* | **Sophie Hollinshead** | sophie.hollinshead@nihr.ac.uk | 01952 255062 |

## West Midlands South

### Coventry, Herefordshire, Warwickshire and Worcestershire

| | | | |
|---|---|---|---|
| *Clinical Specialty Research Lead* | **Jeremy Dale** | jeremy.dale@warwick.ac.uk | 02476 575919 |
| *Research Manager* | **Sue Elwell** | sue.elwell@nihr.ac.uk | 02476 575854 |
| *Senior Research Facilitator* | **Becky Harrison** | r.l.harrison@warwick.ac.uk | 02476 575853 |
| *Research Facilitator* | **Sue Wright** | s.wright.3@warwick.ac.uk | 02476 575919 |
| *Research Facilitator* | **Aman Johal** | amanpreet.johal@warwick.ac.uk | 02476 574127 |
| *Research Facilitator (projects & Hereford)* | **Jenny Lee** | jennifer.lee@warwick.ac.uk | 07920 531 364 |