



*National Institute for  
Health Research*

Promoting  
**excellence**  
and **impact**

Showcasing the  
**School for Primary  
Care Research**

**ABSTRACT BOOK**

26 September 2014  
Mathematics Institute  
University of Oxford



Cover and page footer 'Penrose Paving' by John Cairns, [www.johncairns.co.uk](http://www.johncairns.co.uk)

### **PENROSE PAVING**

The paving in front of the Andrew Wiles Building is constructed from just two different diamond-shaped granite tiles, each adorned identically with stainless steel circular arcs. There are various ways of covering the infinite plane with them, matching the arcs. Every such pattern is non-repetitive and contains infinitely many exact copies of what you see before you. The non-repeating pattern was discovered by Roger Penrose in 1974. The version you see here, with the circular adornments, was designed by him in 2012.



# Welcome

Welcome to the second National Institute for Health Research School for Primary Care Research (NIHR SPCR) scientific meeting with the current eight member departments. We are pleased to be holding the showcase in the recently completed, superb facilities of the Mathematical Institute at the University of Oxford.

The showcase aims to highlight excellence and impact across the full range of primary care research funded by the School. Our intention is to foster enthusiasm and collaboration amongst researchers, and inspire future primary care leaders.

Since expanding its membership in 2009, the School has had a prolific period with an emergence of ground-breaking research and publications which continue to have an impact on policy and practice. Our research not only illustrates the School's diversity in areas of expertise and multidisciplinary skills sets, it shows an increasing commitment to evidence based research and capacity building.

We hope you are inspired by this day of research, education and discussion.



Professor Richard Hobbs,  
Director of the NIHR School  
for Primary Care Research.



Professor Tony Avery,  
Senior Scientific Committee  
Chair.



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# Programme

9.30	Registration and coffee	Mezzanine Lower Ground
10.30	Welcome, Professor Richard Hobbs, NIHR SPCR Director	Lecture Theatre 1
10.40	Keynote address, Professor Trish Greenhalgh	Lecture Theatre 1
11.15	Parallel sessions	Lecture Theatre 3 and 6, Seminar C3, 4, 5 and 6
12.15	Lunch and posters	Mezzanine Lower Ground
13.15	Parallel sessions	Lecture Theatre 3 and 6, Seminar C3, 4, 5 and 6
14.15	Plenary lectures, Associate Professor Carol Coupland and Dr Clare Taylor	Lecture Theatre 1
15.15	Tea	Mezzanine Lower Ground
15.45	Summing up and poster prize	Lecture Theatre 1
16.00	Panel Discussion: ‘How to achieve impact in PC research’ with Professors Roger Jones, Paul Little, Debbie Sharp, David Mant and Richard Hobbs	Lecture Theatre 1



# Parallel Sessions

Venue	Time	Session	Presenter
Lecture 3		<b>CARDIOVASCULAR</b>	<b>CHAIR:</b>
	11.15	Receptionist rECognition and rEferral of Patients with Stroke (RECEPTS): a prospective cross-sectional observational study.	Elizabeth Bates
	11.30	The prognostic utility of tests of platelet function for the detection of "aspirin resistance" in patients with established cardiovascular or cerebrovascular disease: A systematic review and economic evaluation.	Janine Dretzke
	11.45	The Role of Reception Staff in the Triage of Patients Presenting to General Practice with Acute Stroke: Insights of Receptionists and Primary Care Staff.	Elizabeth Bates
	12.00	Gout and risk of subsequent vascular event: a multilevel discrete time event history analysis in the Clinical Practice Research Datalink (CPRD).	Lorna Clarson
Lecture 6		<b>MENTAL HEALTH</b>	<b>CHAIR:</b>
	11.15	Women's Experiences of Psychosis: What do General Practitioners Need to Know? A Qualitative Analysis of the Influence of Gender on Day-to-Day Experiences of Psychosis and Related Healthcare Needs.	Anna Lavis
	11.30	Distinguishing between emotional distress and psychological disorder in primary care attenders	Adam Geraghty
	11.45	Characteristics of effective collaborative care for treatment of depression: A Systematic Review and Meta-regression of 74 Randomised Controlled Trials.	Peter Coventry
	12.00	A pragmatic randomised controlled trial to evaluate the effectiveness of a facilitated exercise intervention as a treatment for postnatal depression: the PAM-PeRS trial	Amanda Daley
C3		<b>MULTIMORBIDITY/ LONG TERM CONDITIONS I</b>	<b>CHAIR:</b>
	11.15	Multimorbidity and patient safety incidents in primary care: A systematic review.	Peter Bower
	11.30	A Cochrane Systematic Review of computer-based diabetes self-management interventions for adults with type 2 diabetes.	Elizabeth Murray
	11.45	Glucose, blood pressure and cholesterol levels and their relationships to clinical outcomes in type 2 diabetes: a retrospective cohort study.	Evan Kontopantelis
	12.00	Development of a new intervention for patients with severe Chronic Fatigue Syndrome/ ME; a collaborative approach based on patient and public involvement.	Clare McDermott
C4		<b>METHODOLOGY I</b>	<b>CHAIR:</b>
	11.15	Evaluation of the patient-reported outcome (PRO) content of clinical trial protocols.	Derek Kyte
	11.30	Disconnects between clinical guidelines and real world practices: a qualitative exploration of the role of NICE guidelines in primary care management of low back pain.	George Lewith
	11.45	The Oral Steroids for Acute Cough (OSAC) trial: RCT design and recruitment methods.	Harriet Downing
	12.00	Developing the science of recruitment to clinical trials: from ideas to practice with Systematic Techniques for Assisting Recruitment to Trials (START).	Jo Rick
C5		<b>LIFE I</b>	<b>CHAIR:</b>
	11.15	Measuring sexual wellbeing - the Sexunzipped online survey.	Julia Bailey
	11.30	Exploring the acceptability and feasibility of using an interactive digital intervention for sexual problems: A qualitative interview study.	Lorna Hobbs
	11.45	"Even 'daily' is not enough": How well do we measure domestic violence and abuse? A thinkaloud study of a commonly used self-report scale: implications for questionnaire design.	Maggie Evans
	12.00	Cortisol Evaluation in Abuse Survivors (CEASE study): feasibility and acceptability of salivary cortisol specimen collection in a community-based study on domestic violence and abuse and mental health.	Natalia Lokhmatkina
C6		<b>MEDICAL EDUCATION</b>	<b>CHAIR:</b>
	11.15	A randomised controlled trial of the effect of using simulated patients on the acquisition by medical students of musculoskeletal examination skills.	Jim Parle
	11.30	Feasibility of an RCT of a brief communication intervention for GPs to enhance the elicitation of patient concerns during primary care consultations.	Rachael Summers
	11.45	Systematic review of undergraduate medical education in the UK general practice setting.	Sophie Park
	12.00	Meta-ethnography of student and patient perspectives of undergraduate medical education in the UK general practice setting.	Sophie Park

Venue	Time	Session	Presenter
Lecture 3		<b>MULTIMORBIDITY/ LONG TERM CONDITIONS II</b>	<b>CHAIR:</b>
	13.15	Self-help interventions for weight loss in overweight and obese adults: systematic review and meta-analysis.	Jamie Hartmann-Boyce
	13.30	A nurse-led telephone supported self-management intervention for people with mildly symptomatic chronic obstructive pulmonary disease (COPD): a randomised controlled trial (PSM-COPD).	Kate Jolly
	13.45	Candidates for care in primary care: Experiences of patients with Multiple Sclerosis and primary care professionals.	Abigail Methley
	14.00	What 'hassles' do patients with multimorbidity report, and which patients report the most 'hassles'?	Peter Bower
Lecture 6		<b>METHODLOGY II</b>	<b>CHAIR:</b>
	13.15	Consent for research in primary care.	Gemma Lasseter
	13.30	Development of a measure of Patient Reported Experiences and Outcomes of Patient Safety in Primary Care: the PREOS-PC instrument.	Ignacio Ricci Cabello
	13.45	Identifying Moderators of Treatment Outcome in Musculoskeletal Shoulder Disorders.	Cliona McRobert
	14.00	Symptom Interpretation and Decision-making Processes in Patients with Lung or Colorectal Cancer (sub-study of CANDID (CANcer Diagnosis Decision study)).	Gemma Mansell
C3		<b>THE CONSULTATION</b>	<b>CHAIR:</b>
	13.15	Barriers to and Facilitators of Implementation of Research Evidence and Complex Interventions in Primary Care: a Systematic Review of Reviews.	Rosa Lau
	13.30	Safe general practice: a qualitative study of patients' perspectives.	Caroline Sanders
	13.45	Effectiveness of Strategies to Optimise Implementation of Complex Interventions in Primary Care: a Systematic Review of Reviews.	Rosa Lau
	14.00	Diagnosis and monitoring of chronic kidney disease in primary care - systematic review and meta-analysis of bias of glomerular filtration rate estimating equations.	Daniel Lasserson
C4		<b>THE YOUNG</b>	<b>CHAIR:</b>
	13.15	Pressures on parents sending unwell children to nursery: a qualitative study from the Parents' Choices About Daycare (PiCarD) project.	Fran Carroll
	13.30	Supporting self-care for families of children with Eczema with a web-based intervention plus health care professional support: Pilot randomised controlled trial	Miriam Santer
	13.45	Psychological Impact of childhood Eczema: birth cohort study.	Matthew Ridd
	14.00	Whooping cough in school aged children presenting with persistent cough in UK primary care after the introduction of the pre-school pertussis booster vaccination: a prospective cohort study.	Kay Wang
C5		<b>DATA</b>	<b>CHAIR:</b>
	13.15	Inconsistencies in quality of life data collection in clinical trials: a potential source of bias? Interviews with research nurses and trialists.	Derek Kyte
	13.30	Use of Primary Care databases to evaluate drug benefits and harms: Do different databases give the same results?	David Reeves
	13.45	Withdrawing Performance Indicators: Retrospective Analysis of General Practice Performance Under the UKs Quality and Outcomes Framework	Evan Kontopantelis
	14.00	Hacking into health research: Supporting rapid Patient & Public Involvement (PPI) through Patient Hack Days.	Sarah Knowles
C6		<b>LIFE II</b>	<b>CHAIR:</b>
	13.15	ProAct65+ trial of exercise promotion for older adults in primary care.	Steve Iliffe
	13.30	Predicting five-year dementia risk using routinely collected primary care data: the development and internal validation of a new dementia risk algorithm.	Kate Walters
	13.45	Experiences of loneliness in later life: typologies, self-management, and interventions.	Kalpa Kharicha
	14.00	"It really was a roller-coaster": the impact of domestic violence on the adult friends and relatives of survivors	Alison Gregory



# Keynote address

## Professor Trish Greenhalgh

*Professor of Primary Health Care and Dean for Research Impact  
Barts and the London School of Medicine and Dentistry*

### Research impact: defining it, measuring it, maximising it, questioning it

The UK higher education sector is under pressure from government to demonstrate that it makes a difference. That aside, few of us want to be the kind of academic that sits in an ivory tower thinking clever thoughts while Rome burns below. As Karl Marx said, many academics only interpret the world, but the true purpose of scholarship is to change it. The 'impact agenda' thus contains two goals that may occasionally be in tension with one another. The first is to demonstrate impact as defined by a relatively narrow set of government-driven criteria and metrics (most notably in UK, the 'Impact' section of the Research Excellence Framework). There is much emphasis in policy circles, for example, on the need for medical schools to build links with industry with a view to generating 'health and wealth' (that is, improving survival or quality of life while also saving money and boosting business for our national industries). The second goal, more in line with the vision of engaged scholarship articulated by Marx, is to align the research agenda with such things as community-campus partnerships and a commitment to social justice.

Whilst it is easy to be cynical about the colonisation of academia by commercial interests, many universities now boast fruitful industry collaborations that have not only supported the development of new drugs, devices and technologies (and, in a few cases, led to measurable economic benefit for the university) but which have also accelerated the uptake and use of innovations for societal benefit. Nevertheless, much of the impact from biomedical research to date has been through a wide range of non-commercial partnerships with clinical provider organisations, national policymakers, councils, schools, faith groups, third-sector organisations and citizens. In short, 'impact' is much more than commercial spin-offs.

As the first Dean for Research Impact appointed by a UK higher education institution, Prof Greenhalgh will summarise prevailing national and international debates about what research impact is; how it should be measured; how to balance the potentially conflicting agendas of 'economic' and 'societal' impact; and how to build capacity at all levels for delivering on both these agendas.





# Plenaries

## Associate Professor Carol Coupland

*Reader in Medical Statistics, Faculty of Medicine & Health Sciences, University of Nottingham*

### Antidepressant use and the risk of cardiovascular outcomes: a cohort study using a primary care database

Carol Coupland, Trevor Hill, Richard Morriss, Michael Moore, Antony Arthur, Julia Hippisley-Cox

*University of Nottingham, Nottingham, University of Southampton, Southampton, University of East Anglia, Norwich, UK*

#### Objectives

Antidepressants are one of the most commonly prescribed medications in primary care. There is concern that selective serotonin reuptake inhibitor (SSRI) antidepressants may increase the risk of cardiovascular outcomes but evidence is inconclusive.

We carried out a study to assess the associations between antidepressants and risk of cardiovascular outcomes.

#### Method

A cohort of patients aged 20 to 64 with a diagnosis of depression was identified using the QResearch primary care database. Cox models were used to estimate hazard ratios for the associations between antidepressant treatment and myocardial infarction, stroke/transient ischaemic attack (TIA) and arrhythmia adjusting for confounders.

#### Results

During five years of follow-up 772 patients had a myocardial infarction, 1106 had a stroke/TIA and 1452 were diagnosed with arrhythmia.

There were no significant associations between antidepressant class and myocardial infarction over five years follow-up, although in the first year patients prescribed SSRIs had a significantly reduced risk of myocardial infarction compared with no antidepressant use (adjusted hazard ratio 0.58, 95% CI 0.42 to 0.79).

There were no significant associations between antidepressant class and stroke/TIA. There was some evidence of a reduced risk of arrhythmia with SSRIs (adjusted hazard ratio 0.84, 95% CI 0.73 to 0.97).

#### Conclusions

This study has found no evidence that SSRIs are associated with an increased risk of myocardial infarction, stroke/TIA or arrhythmia, but some evidence that they are associated with a reduced risk of myocardial infarction and arrhythmia. This is reassuring in light of recent safety concerns.

## Dr Clare Taylor

*General Practitioner and NIHR Doctoral Research Fellow, Primary Care Clinical Sciences, University of Birmingham*

### Incidence and survival of patients with a first diagnostic label of heart failure in general practice

Clare Taylor, Linda Nichols, Ronan Ryan, Richard Hobbs, Tom Marshall

*University of Birmingham, Birmingham, University of Oxford, Oxford, UK*

#### Objectives

The epidemiology of heart failure (HF) has been described by screening studies which represent well-phenotyped and distinct cohorts of patients who voluntarily took part in research. NHS general practice records provide a valuable source of data directly from the UK population.

#### Methods

An open retrospective cohort study was carried out using data from The Health Improvement Network (THIN) database containing anonymised patient records from 570 GP practices in the UK. Records of patients over the age of 45 with a Read code of HF were extracted from 1st January 1990 to 31st May 2012. Index date was the first recorded HF diagnosis and outcome was death. Participants were followed until they left the practice (censored) or died. Data were analysed to establish incidence and survival rates of patients with HF.

#### Results

A total of 55,255 patients had a Read code of HF. The incidence of first recording of HF was 0.29, 1.03, 3.28, 8.86, 16.53 and 18.60 per 1000 person-years at risk respectively in patients' aged 45-54, 55-64, 65-74, 75-84, 85-94 and  $\geq 95$  years. Overall survival rates were 81.5% at one year from date of diagnosis, 51.6% at five years and 29.5% at ten years. Survival rate comparisons by year of diagnosis, confirmed vs unconfirmed case and deprivation index will also be presented.

#### Discussion

HF is increasingly recorded in patients over the age of 45 years in general practice. Survival rates are poor at ten years. These findings represent real-life general practice and complement other epidemiological studies in HF.

# Abstracts - parallel sessions

## Measuring sexual wellbeing - the Sexunzipped online survey

Julia Bailey, Ona McCarthy, Ken Carswell, Menelaos Pavlou, Andrew Copas, Greta Rait, Graham Hart, Angela Nicholas, Elizabeth Murray

University College London, London School of Hygiene and Tropical Medicine, London.

### Introduction

Research often focuses on problems such as HIV and STI, ignoring dimensions of sexual health such as sexual pleasure and satisfaction. We describe the development of the Sexunzipped online questionnaire which measures different dimensions of sexual wellbeing.

### Methods

There were several steps in questionnaire development:

- Selection of existing outcome measures, development of new items
- Interviews with young people regarding meanings and wording (n=12)
- Long questionnaire, piloted online (up to 173 questions)
- Factor analysis to decide which outcomes to drop
- Shorter questionnaire deployed in the Sexunzipped online trial (up to 111 questions)
- Interviews after the Sexunzipped online trial (n=22)

### Results

The Sexunzipped online questionnaire covered knowledge, self-efficacy (confidence), safer sex intentions, sexual behavior (condom and contraception use, use of services, partner numbers), sexually transmitted infections, pregnancy, sexual problems, partner abuse, regretted sex, sexual pleasure, relationship satisfaction and sexual satisfaction. Although the questionnaire was long, 92% completed it in full in the Sexunzipped online RCT.

Young people enjoyed filling in the questionnaire, appreciating the convenience and privacy of an online format, the relevance of questions, the non-judgmental tone and range of response options.

### Discussion

It is a challenge measuring sexual wellbeing since it has different meanings for individuals, and for different religious, social and cultural groups. Whilst we can never know the precise meanings of participants' answers, well-designed surveys with a large range of response options and free-text comment boxes can help to ensure that people can give the responses that they wish to.

## Receptionist rECognition and rEferral of Patients with Stroke (RECEPTS): a prospective cross-sectional observational study

Ruth Mellor, James Sheppard, Elizabeth Bates, Janet Jones, Satinder Singh, George Bouliotis, Connie Wiskin, Richard Macmanus

University Of Birmingham, Birmingham, University of Oxford

### Objectives

Key to acute stroke care is prompt access by emergency ambulance to a specialist department offering thrombolysis. However 20% of acute stroke patients contact primary care, experiencing significant delay and reducing access to optimal care. Reception Staff are the first point of contact with Primary Care and are instrumental in directing patients toward appropriate care. This study uses a novel approach to describe their recognition of acute stroke and behaviour when encountering it.

### Methods

520 unannounced simulated patient telephone calls (USPTs) were made to 52 West Midlands primary care practices by medical role players enacting acute stroke vignettes based on FAST (Face, Arm, Speech) and posterior stroke symptoms. Descriptive statistics summarise the proportion of calls referred for immediate clinical care by reception staff. Logistic regression analyses examine the likelihood of immediate referral by ease of recognition (defined by a lay and expert panel), by number and type of symptom.

### Results

69% (360/520) of calls were referred for immediate care, with 61% (317/520) of callers told to call 999. Difficult vignettes were 85% less likely to be immediately referred than easy to recognise vignettes (OR 0.15, 95% CI 0.08 to 0.26,  $p < 0.001$ ). Likelihood of immediate care fell as the number of FAST symptoms declined from three to none (posterior stroke) (OR 0.03 95% CI 0.01-0.08,  $p < 0.001$ ).

### Conclusions

Reception staff's responses during medical emergencies can profoundly impact clinical outcomes. The value of training for this neglected group, with particular focus on presentations with lesser known or fewer symptoms, is clear.

## The role of reception staff in the triage of patients presenting to general practice with acute stroke: Insights of receptionists and primary care staff

Elizabeth Bates, Janet Jones, Ruth Mellor  
University of Birmingham

### Objectives

One in five patients with acute stroke contact their GP first. Accessing specialist care inside a tight timeframe is crucial and many experience significant delay as a result. Little is known about the experience of reception staff handling these calls and the task is complex. In the qualitative branch of the RECEPts study of 52 practices in the West Midlands we aim to:

- Describe the experience and confidence of reception staff in identifying clinical urgency for patients presenting with acute stroke.
- Identify both barriers to / opportunities for improving access to thrombolysis.

### Methods

Seven focus groups were carried out at West Midlands GP practices and results analysed using a framework approach.

### Results

Results demonstrate a depth of experience in handling contact with acutely unwell patients which lends itself to unique insights into this process.

- Experienced staff feel confident in their ability to detect cues and respond to triggers associated with medical emergencies, including acute stroke.
- Confident staff differentiated routine negotiation around appointment making from emergency situations.
- Less experienced staff lack clarity on the boundaries of their responsibility and the acceptability of information seeking in emergencies.
- Absence of clear policy on handling of acute stroke compounds this.
- Discomfort with expectations of responsibility beyond the current mutually accepted limitations of their role is evident.

### Conclusions

This study highlights the importance of defining and developing receptionists' role in patient access during medical emergencies. Findings have the potential to improve patient safety and allocation of resources.

## What 'hassles' do patients with multimorbidity report, and which patients report the most 'hassles'?

Olumide Adeniji, Peter Bower, Cassandra Kenning  
University of Manchester.

### Objectives

A major problem in current primary care is that services are set up for single long-term conditions, whereas many older patients have more than one. Qualitative research suggests that patients experience 'hassles' in their care, including multiple appointments, poor co-ordination, and conflicting recommendations. However, there is limited quantitative evidence on the hassles that patients experience, or factors predicting hassles.

### Methods

The OPTIMUM study surveyed 1460 patients with multimorbidity from 4 large practices in Greater Manchester. Patients completed measures including demography, multimorbidity and 'hassles' using the Parchman (2005) scale.

### Results

Overall, 33% of patients completed the measures (n=486). The most frequently reported hassles related to lack of information and poor communication, as well as poor access to specialist care. In multivariate analysis, self-reported numbers of long-term conditions, current employment, and symptoms of depression predicted high levels of hassles. Reports of a discussion with the GP about their conditions in the last 12 months and increasing age were associated with lower reported hassles.

### Conclusion

As expected, increasing numbers of long-term conditions were associated with greater reports of hassles. It is not clear whether the associations with depression and age represent reporting issues, or more clinically important effects. The study did suggest that frequent discussions with the GP may be important in reducing perceptions of hassles. New models of service delivery need to be tested to improve the experience of patients with multimorbidity.



## Disconnects between clinical guidelines and real world practices: a qualitative exploration of the role of NICE guidelines in primary care management of low back pain

Felicity Bishop, Alex Dima, Jason Ngui, Paul Little, Rona Moss-Morris, Nadine Foster, George Lewith

University of Southampton, Southampton, Kings College London, London, Keele University

### Introduction

Our aim was to examine the role and relevance of national guidelines in clinical practice within the context low back pain (LBP) in primary care.

### Methods

We conducted a qualitative study using semi-structured interviews and inductive thematic analysis. A purposive sample of 53 primary care clinicians were interviewed (20 from NHS, 21 the private sector, 12 both; 16 GPs, 10 chiropractors, 8 acupuncturists, 8 physiotherapists, 7 osteopaths, 4 nurses).

### Results

Clinicians discussed a complex process of matching individual patients (perceived in terms of medical history, clinical presentation, personal preferences, concerns, and psychosocial context) to familiar treatments (viewed primarily in terms of likely effectiveness). National clinical guidelines comprised one of many possible inputs to this process, which was embedded in personal experience and inter-professional networks and constrained by organisational factors. Some clinicians found the term used in the NICE guideline - "non-specific LBP" - unfamiliar and of limited relevance to practice. Clinicians were frustrated by disparities between the idealised care pathway described in the guideline and the real-world situation of short consultation times, difficult-to-access specialist services and failure to commission guideline-recommended treatments.

### Conclusions

Our findings suggest specific actions that address key elements of decision-making and could increase the relevance of guidelines for clinical practice. These actions involve: ensuring terminology used in guidelines reflects that used in clinical practice; dispelling the image of guidelines as rigid and prohibiting patient-centred care; providing opportunities for clinicians to engage in experiential learning about guideline-recommended CAM therapies; and commissioning guideline-recommended treatments for NHS patients.

## Pressures on parents sending unwell children to nursery: a qualitative study from the Parents' Choices About Daycare (PiCaRD) project

Fran Carroll, Leila Rooshenas, Amanda Owen-Smith, Hareth Al-Janabi, Sandra Hollinghurst, Alastair Hay

University of Bristol, Bristol, University of Birmingham

### Introduction

Nursery or other childcare options are central to many parents' lives. Working pressures can lead to continued daycare use, even when children are unwell, thus perhaps encouraging the transmission of a range of childhood infections. This study investigated factors affecting parents' daycare decision-making when children are unwell.

### Methods

31 semi structured interviews were conducted with parents of children attending eight nurseries in Bristol. Interviews explored parents' priorities for sending their child to nursery, how they decide when their child is marginally unwell, and any factors that would facilitate or alter the decisions they currently make.

### Results

Parents often found the decision about sending their marginally unwell child to nursery difficult. Respiratory symptoms were viewed differently to other symptoms of common childhood infections (e.g. sickness and diarrhoea) and generally did not warrant children staying at home. Financial and work-related pressures, and the availability of alternative child care options, were frequently mentioned as factors that affect decision-making in this context. Parents identified the ability to swap or be reimbursed for unused daycare sessions as key factors that could influence their decision-making.

### Discussion

Some of the factors affecting decision-making are modifiable, thus having the potential to reduce the spread of infectious illnesses within these settings. Further research will explore: (1) how parents trade-off such factors, (2) the impact of these factors on the probability of children being sent to nursery when unwell and (3) a nursery-based intervention aimed at making these decisions easier for parents in a bid to encourage keeping children home when unwell.



## Gout and risk of subsequent vascular event: a multilevel discrete time event history analysis in the Clinical Practice Research Datalink (CPRD)

Lorna Clarson, Samantha Hider, John Belcher, Ed Roddy, Carl Heneghan, Christian Mallen

Arthritis Research UK Primary Care Centre, Primary Care Sciences, Keele University, Keele, Department of Primary Care Sciences, Oxford University

### Objectives

Current evidence suggests that gout is an independent risk factor for excess cardiovascular morbidity and mortality, and yet suboptimal care for patients with gout in primary care persists. We aimed to identify risk factors specific to these gout patients which may contribute to their increased risk of vascular disease.

### Methods

Multilevel discrete-time survival analysis was used to analyse the effect of changing vascular risk factors on risk of vascular event (cardiovascular, cerebrovascular or peripheral vascular) in each year following diagnosis of gout for 8386 primary care gout patients with no prior vascular event.

### Results

Increasing age, Charlson co-morbidity score, incident prescription of aspirin or statins, and measurement of BP or BMI (whether normal or high), and mean daily dose of 300mg of allopurinol or less were associated with increased risk of vascular event. Female gender, incident diagnosis of hyperlipidaemia or CKD, a mean daily dose of allopurinol of >300mg, increasing persistence with allopurinol, and each successive year following diagnosis of gout all reduced risk of vascular event.

### Conclusion

The effect of some risk factors differed from those previously reported using continuous survival analysis, with increased risk of vascular event associated with measuring BP and BMI even when recorded as normal, and hyperlipidaemia and CKD appearing protective, perhaps demonstrating that those most at risk are those not under surveillance for alternative reasons. This would support the introduction of a routine vascular surveillance from diagnosis of gout.

## Characteristics of effective collaborative care for treatment of depression: A systematic review and meta-regression of 74 randomised controlled trials

Peter Coventry, Joanna Hudson, Evangelos Kontopantelis, Janine Archer, David Richards, Simon Gilbody, Karina Lovell, Chris Dickens, Linda Gask, Waquas Waheed, Peter Bower

University of Manchester, Manchester, University of York, York, University of Exeter, Lancashire Care NHS Foundation Trust, Preston, King's College, London

### Objectives

Collaborative care is a complex intervention based on chronic disease management models and is effective in the management of depression, but there is still uncertainty about which components are effective. We aimed to identify factors associated with improvement in depression and use of anti-depressant medication in adults with depression receiving collaborative care.

### Methods

The CC-DAN trials registers were searched from inception to 9th February 2012 and updated on 29th December 2013. Inclusion criteria were: randomised controlled trials of collaborative care for adults  $\geq 18$  years with a primary diagnosis of depression or mixed anxiety and depressive disorder. Random effects meta-regression was used to estimate regression coefficients with 95% confidence intervals (CIs) between study level covariates and depressive symptoms and relative risk (RR 95% CI) and anti-depressant use.

### Results

74 trials were identified (85 comparisons, across 21,345 participants). Collaborative care that included psychological interventions predicted improvement in depression ( $\beta$  coefficient -0.11, 95% CI -0.20 to -0.01). Systematic identification of patients (RR 1.43, 95% CI 1.12 to 1.81) and the presence of a chronic physical condition (RR 1.32, 95% CI 1.05 to 1.65) predicted use of anti-depressant medication.

### Conclusion

Collaborative care that included psychological treatment, with or without antidepressant medication, improved depression more than those without psychological treatment. Trials that systematically identified patients with depression and included patients with a chronic physical condition improved use of anti-depressant medication. Using individual rather than study-level data will increase opportunities to detect differential treatment effects across individuals in randomised trials of collaborative care.

## A pragmatic randomised controlled trial to evaluate the effectiveness of a facilitated exercise intervention as a treatment for postnatal depression: the PAM-PeRS trial

Amanda Daley, Ruth Blamey, Kate Jolly, Andrea Roalfe, Katrina Turner, Mary McGuinness, Ian Jones, Debbie Sharp, Christine MacArthur

*University of Birmingham, Bristol University, Cardiff University, Birmingham and Solihull Mental Health Foundation Trust, Birmingham*

### Introduction

Postnatal depression affects about 10-15% of women in the year after birth. The purpose of the study was to investigate the effectiveness of exercise as an adjunctive treatment for postnatal depression.

### Methods

94 women who fulfilled ICD-10 criteria for major depression (clinical interview assessment) in the first six postnatal months were recruited and randomised to usual care plus an exercise intervention or usual care only. The primary outcome was symptoms of depression using the Edinburgh Postnatal Depression Scale (EPDS) at six month post-randomisation. Secondary outcomes included EPDS score as a binary variable (recovered and improved), social support and physical activity at six and 12 month post-randomisation.

### Results

146 women were eligible and 94 were randomised. 34% reported thoughts of self harm at baseline. After adjusting for baseline EPDS, analyses revealed a -2.04 mean difference in EPDS score, favouring the exercise group (95% CI: -4.11 to 0.03,  $p=0.05$ ). When also adjusting for pre-specified demographics the effect was larger and statistically significant (mean difference= -2.26, 95% CI: -4.36 to -0.16,  $p=0.03$ ). Based on EPDS score a larger proportion of the intervention group were recovered (46.5% versus 23.8%,  $p=0.03$ ) compared with usual care at six months follow up.

### Discussion

This trial contributes evidence to indicate that a facilitated exercise intervention may be an effective treatment for women experiencing postnatal depression, including those at risk of self harm.

## The Oral Steroids for Acute Cough (OSAC) trial: RCT design and recruitment methods

Harriet Downing, Sara Brookes, Elizabeth Orton, David Timmins, Anthony Harnden, Sandra Hollinghurst, Denise Kendrick, Paul Little, Michael Moore, Matthew Thompson, Kay Wang, Alastair Hay

*University of Bristol, University of Oxford, University of Nottingham, University of Southampton*

### Introduction

Acute lower respiratory tract infection (LRTI) is one of the most common conditions managed in primary care. Antibiotics are known to be largely ineffective, but are still prescribed for most adult patients. Many LRTI symptoms are mediated by inflammation and similar to those of asthma, for which systemic and inhaled corticosteroids are highly effective. This study examines the effectiveness of oral corticosteroids for acute LRTI, compared to placebo.

### Methods

OSAC is an individually randomised, superiority trial requiring between 326 and 436 patients to detect a 20% reduction in (i) duration of 'moderately bad' (or worse) cough, and (ii) severity of symptoms on days 2-4 (reported through a symptom diary), with between 80% and 90% power and a two-sided alpha of 5% (assuming 20% attrition). Since 01 July 2013, GP practices from SPCR centres in Bristol, Nottingham, Oxford and Southampton have been randomising patients to receive oral prednisolone (40mg/day for 5 days) or placebo.

### Results

At the time of abstract submission (31 March 2014), 194 patients had been recruited, with primary outcome data available for duration of bad to worse cough, and symptom severity, for 91% and 95% respectively. Recruitment is expected to close by July 2014 with definitive results available after September 2014. Recruitment results and methods will be presented at the conference.

### Discussion

Results from this trial will increase knowledge regarding the clinical and cost-effectiveness of corticosteroids for LRTI. The 'efficacy dose' used will establish the value of further research into lower dose and/ or inhaled corticosteroids.



## The prognostic utility of tests of platelet function for the detection of “aspirin resistance” in patients with established cardiovascular or cerebrovascular disease: A systematic review and economic evaluation

Janine Dretzke, David Moore, Marie Lordkipanidzé, James Hodgkinson, Sue Bayliss, David Fitzmaurice  
University of Birmingham, Université de Montréal,  
Montréal, Quebec, Canada

### Background

Aspirin is well-established for secondary-prevention of cardiovascular disease, however some patients suffer repeat cardiovascular events. Whether this is due to an inability of aspirin to sufficiently modify platelet activity is uncertain.

### Objective

Systematic review of the association between platelet function test (PFT) defined “aspirin-resistance” and risk of adverse clinical outcome(s), and an exploratory model-based cost-effectiveness analysis.

### Methods

Standard systematic review methods (PROSPERO: 2012:CRD42012002151; searches: 4/2012) and development of a speculative economic model. Analyses were confined to studies on patients prescribed aspirin as sole anti-platelet therapy. Results 101 relevant studies were identified. Methodological/clinical heterogeneity of studies created inconsistency in results, however some PFTs may have some prognostic utility (trend for more events in groups classified as “aspirin-resistant”). Absolute outcome risk was not substantially different between “aspirin-resistant” and “aspirin-sensitive” designations.

If PFTs can accurately identify patients at high risk of clinical events and such patients benefit from treatment modification, the speculative economic model found a test-treat strategy likely to be cost-effective. However, neither assumption is currently evidence based.

### Conclusions

Protocol-driven and adequately powered primary studies are needed to evaluate the prognostic ability of each PFT in the same population(s). For any PFT to inform individual risk prediction, it will need to be considered in combination with other prognostic factors, within a prognostic model.

This project was funded by the NIHR HTA Programme (10/36/02). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR, NHS or the Department of Health.

## “Even ‘daily’ is not enough”: How well do we measure domestic violence and abuse? A thinkaloud study of a commonly used self-report scale: implications for questionnaire design

Maggie Evans, Emma Howarth, Alison Gregory, Gene Feder  
University of Bristol

### Introduction

Domestic violence and abuse (DVA) is widespread with repercussions for the physical and mental health of individuals and populations. Accurate measurement is essential to estimate prevalence and to assess the impact of interventions. The self-report Composite Abuse Scale (CAS) is a well-validated tool and is widely used, but mis-matches were observed in a recent trial, between women’s CAS scores and their verbal accounts of abuse, casting doubt on its effectiveness as a stand-alone tool.

### Methods

Cognitive thinkaloud interviewing was used with a sample of 27 women recruited from DVA agencies, to investigate how participants interpret and respond to CAS items, following Tourangeau’s model of cognitive processes. Framework analysis was conducted to explore difficulties arising and other emergent issues.

### Results

Difficulties were identified in all four cognitive processes: comprehension, recall, judgment and response. Items were misunderstood or interpreted differently by different people; some items did not map well onto underlying concepts nor did they match women’s experience; the six point response scale was problematic; women were reluctant to disclose some types of abuse for fear of repercussions and also found painful memories hard to recall accurately. Under-reporting was widespread.

### Discussion

Mixed methods research, including cognitive interviewing, and user involvement should be hard-wired into future questionnaire design, particularly for sensitive topics. The study forms a useful platform for the further amendment or development of measurement tools. Within DVA research, respondents’ concerns about personal safety and need for emotional support when completing questionnaires must be taken seriously.

## The prognostic utility of tests of platelet function for the detection of “aspirin resistance” in patients with established cardiovascular or cerebrovascular disease: A systematic review and economic evaluation

Janine Dretzke, Richard Riley, Marie Lordkipanidzé, Sue Jowett, Jennifer O'Donnell, Joie Ensor, Eoin Moloney, Malcolm Price, Smriti Raichand, James Hodgkinson, Sue Bayliss, David Fitzmaurice, David Moore

University of Birmingham, Université de Montréal, Montreal, Quebec, Canada

### Background

Aspirin is well-established for secondary-prevention of cardiovascular disease, however some patients suffer repeat cardiovascular events. Whether this is due to an inability of aspirin to sufficiently modify platelet activity is uncertain.

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### Results

101 relevant studies were identified. Methodological/clinical heterogeneity of studies created inconsistency in results, however some PFTs may have some prognostic utility (trend for more events in groups classified as “aspirin-resistant”). Absolute outcome risk was not substantially different between “aspirin-resistant” and “aspirin-sensitive” designations.

If PFTs can accurately identify patients at high risk of clinical events and such patients benefit from treatment modification, the speculative economic model found a test-treat strategy likely to be cost-effective. However, neither assumption is currently evidence based.

### Conclusions

Protocol-driven and adequately powered primary studies are needed to evaluate the prognostic ability of each PFT in the same population(s). For any PFT to inform individual risk prediction, it will need to be considered in combination with other prognostic factors, within a prognostic model.

This project was funded by the NIHR HTA Programme (10/36/02). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR, NHS or the Department of Health.

## Distinguishing between emotional distress and psychological disorder in Primary Care attenders

Adam Geraghty, Beth Stuart, Paul Little, Tony Kendrick, Berend Terluin, Michael Moore

University of Southampton, University Medical Centre, Amsterdam, the Netherlands

### Introduction

Distinguishing between emotional distress and psychological disorder is complex. Psychometric measures can help, however, with only one dimension (such as depression), patients' general emotional distress may result in scores that erroneously suggest psychological disorder. The aim of this study was to use the Four Dimensional Symptom Questionnaire (4DSQ) to explore the psychological symptoms of primary care attenders using four dimensions: distress, depression, anxiety and somatisation.

### Method

This was a cross sectional survey study. Three hundred and eighty patients attending general clinics in Hampshire completed questionnaire packs containing the 4DSQ, PHQ-9 and the GHQ-12 whilst in the waiting room.

### Results

The 4DSQ classified 22% (83/380) as having heightened distress levels; 9% (32/367) as cases of depression, and 6% (23/380) as cases of anxiety. The GHQ-12 classified 25% (90/354) as cases of emotional disorder. The PHQ-9 classified 16% (60/375) as cases of depression using score of 10 as a cut point. If a score 5 (mild depression) was used as a cut point, the PHQ-9 classified 36% (134/375) as cases. Of those deemed cases by the GHQ-12, the 4DSQ classified 64% (58/90) of those as having heightened distress; 32% (25/60) were classified as cases of depression. Of those deemed cases by the PHQ-9 ( $\geq 10$ ), the 4DSQ classified 88% (53/60) as having heightened distress and 50% (28/56) as cases of depression.

### Discussion

Psychometrically distinguishing between distress and depression reduced the number of patients classed as cases. Conceptualising psychological symptoms in this way may help to reduce overdiagnosis and overtreatment of depression.

## **“It really was a roller-coaster”: the impact of domestic violence on the adult friends and relatives of survivors**

*Alison Gregory, Gene Feder, Emma Williamson  
University of Bristol*

### **Introduction**

Domestic violence (DV) is experienced by 25% of women in the UK during their lifetime and has far-reaching health consequences for survivors. Research indicates that most survivors will discuss their situation with relatives or friends, and that social support has potential to buffer against negative implications for survivors, and to protect against future abuse. There is, however, an absence in the literature about the knock-on consequences for the health and wellbeing of this supportive network.

### **Methods**

Adults in a variety of close relationships with a DV survivor were recruited for qualitative interviews. Recruitment involved a range of strategies including: social media, advertising resulting from a radio interview, and flyers in community settings. Interviews were carried out face-to-face, over the telephone or using Skype, and the resulting transcripts coded using NVivo software. A thematic analysis is on-going.

### **Results**

Twenty three participants were recruited and interviewed. The relationship participants had with a survivor were: friend, current partner, mother, father, sister and work colleague. Emerging themes point towards variations in the impact on the social network that are dependent on: when and what is disclosed by the survivor, the closeness of the survivor-supporter relationship, the survivor having children, and prior experience of DV by the supporter. The toll described was multifaceted and potentially onerous.

### **Discussion**

Findings from the analysis of the qualitative interviews will be presented alongside discussion regarding the challenges faced in recruitment of participants, and in conducting interviews in this sensitive topic area.

## **Self-help interventions for weight loss in overweight and obese adults: systematic review and meta-analysis**

*Jamie Hartmann-Boyce, Ben Fletcher, Susan Jebb, Paul Aveyard  
University of Oxford*

### **Objectives**

To review the effectiveness of self-help interventions for weight loss in overweight and obese adults, examine which strategies these interventions recommend, and investigate relationships between intervention characteristics and weight change.

### **Method**

We included randomized controlled trials with follow-up of six months or longer comparing self-help interventions with other self-help interventions or controls. Systematic searches were run. Two reviewers extracted data and coded interventions against a taxonomy of self-management strategies for weight loss. Meta-analyses were conducted for weight change at six months using baseline observation carried forward.

### **Results**

Searches returned 24 included studies, representing 40 interventions. Pooled results detected a significant effect of fixed programmes (static websites/print) compared with minimal controls (mean difference -2.2kg, 95% CI -3.5 to -0.8, 2 studies) and of tailored/interactive programmes compared with minimal controls (mean difference -1.8kg, 95% CI -3.5 to -0.1, 6 studies), though statistical heterogeneity was high in the latter group ( $I^2 = 84\%$ ). Pooled data from direct comparisons detected a small but significant effect in favour of tailored/interactive versus fixed programmes (mean difference -0.9kg, 95% CI -1.5 to -0.4, 7 studies). Most interventions recommended goal setting and self-monitoring, and half promoted some form of support from others (non-professionals). There were insufficient data to statistically evaluate associations between recommended strategies and weight change.

### **Conclusions**

Self-help interventions can lead to significant weight change at six months. Evidence from direct comparisons suggests tailored and interactive programmes may be more effective than fixed interventions, but reasons for variation in their results remain largely unknown.



## Exploring the acceptability and feasibility of using an interactive digital intervention for sexual problems: A qualitative interview study

Lorna Hobbs, Julia Bailey, Elizabeth Murray  
University College London

### Introduction

There is a high prevalence of people with sexual problems (e.g., erectile problems, lack/loss of sexual desire etc.) within general practice and sexual health services, and many more people experience sexual problems but do not seek help for them. Barriers to help-seeking include stigma, embarrassment and geographic inconsistencies in service provision. A way to overcome some of these barriers might be to offer help and support via the internet. Interactive digital interventions (IDIs) for sexual problems have the potential to provide a convenient, anonymous, wide-reaching, and potentially cost-effective alternative to face-to-face treatment. However, little is currently known about their acceptability and feasibility.

### Methods

Thirty semi-structured, qualitative interviews were conducted with people experiencing sexual problems, before and after using a web-based sex therapy program (sextherapy.london.nhs.uk). The study used purposive sampling and iterative thematic analysis to identify themes within the data.

### Results

Attitudes towards using sextherapy.london.nhs.uk were positive, with privacy, anonymity, convenience, and ease of use cited as key reasons. Facilitators and barriers to the use of IDIs were identified. Changes reported by participants included less embarrassment, increased acceptance of the problem, realisation there was not a problem, improved partner communication, and increased sexual function. Despite high acceptability, a lack of continued engagement and a desire for more tailoring/interactive features were reported by some participants.

### Discussion

The current study established the acceptability and feasibility of sextherapy.london.nhs.uk, and identified factors that may increase the appeal, uptake and use of IDIs for sexual problems. However, further research is needed to identify effective engagement strategies.

## ProAct65+ trial of exercise promotion for older adults in primary care

Steve Iliffe, Denise Kendrick, Tash Masud, Dawn Skelton, Heather Gage

UCL, University of Nottingham, Glasgow Caledonian University, University of Surrey

### Objective

To increase physical activity in older adults

### Methods

A pragmatic three arm parallel design cluster RCT of class-based exercise (FaME), home-based exercise (OEP) and usual care amongst people aged 65 years and over in primary care. The primary outcome was the proportion reporting 150 minutes of moderate to vigorous physical activity (MVPA) per week, 12 months after cessation of the intervention. Secondary outcomes included balance, falls risk, falls, fear of falling, quality of life, social networks and self-efficacy. An economic evaluation was embedded.

Results: 1256 people from 43 general practices joined the trial. A significantly higher proportion in the FaME arm reported at least 150 minutes of MVPA per week compared to usual care (AOR 1.78, 95% CI 1.11-2.87,  $p=0.02$ ). There was no significant difference between OEP and usual care (AOR 1.17, 95% CI 0.72-1.92,  $p=0.52$ ). Participants in the FaME arm added around 15 minutes of MVPA per day to their baseline physical activity level. There was a reduction in falls rate in the FaME arm compared with usual care (IRR=0.66, 95% CI 0.49, 0.90:  $p=0.009$ ). Perceptions of benefit from exercise and balance confidence were significantly improved in both arms, compared to usual care. There were no statistically significant differences between intervention and usual care in other secondary outcomes.

The cost per extra person exercising at or above target was £1,919.64 in London, £1,560.21 in Nottingham (mean £1,739.93).

### Conclusions

The FaME intervention increased self-reported physical activity levels amongst community-dwelling older adults 12 months after the intervention, and significantly reduced falls.

## Experiences of loneliness in later life: typologies, self-management, and interventions

Kalpa Kharicha, Kate Walters, Steve Iliffe, Mima Cattan, Jill Manthorpe, Carolyn Chew-Graham, Claire Goodman, Maggie Kirby-Barr, Janet Whitehouse

*University College London, Northumbria University, King's College London, Keele University, University of Hertfordshire, Public contributor, London, University of the Third Age (U3A)*

### Objectives

To describe typologies of loneliness from older people's accounts of their experiences.

To understand how older people may manage their loneliness.

To explore older people's attitudes towards interventions to reduce loneliness, including the role of primary care professionals.

### Methods

Thirty community-dwelling people aged 65+, identified as feeling lonely from questionnaire responses to 1) 'Do you feel lonely much of the time?' or 2) the de Jong-Gierveld 6-item loneliness scale, were interviewed face-to-face.

Interviews were recorded and transcribed. Thematic analysis is being undertaken by a multi-disciplinary team, including older people.

### Results

Emerging findings suggest that loneliness in later life is associated with a broad range of experiences and circumstances, many life-long. Social and emotional types of loneliness were less evident than life-long/transient types. Loneliness is characterised in terms of context, severity and frequency, including loneliness described as more painful in earlier life. Interventions aimed specifically at lonely older people were not popular with this sample; barriers include stigma of attending such services, assumed to be for those severely disabled and isolated. Reported strategies for self-management included getting outdoors, comparing oneself to people worse off, planning, and cultivating mental resilience. Primary care interventions were considered inappropriate, except by those with co-existing depression/anxiety being treated by medication.

### Discussion

Loneliness in later life is complex and often inseparable from life events and circumstances. Investment in interventions to reduce loneliness may need to be focussed on supporting individuals at risk at times of particular vulnerability as well as maintaining community supports more generally.

## Hacking into health research: Supporting rapid Patient & Public Involvement (PPI) through Patient Hack Days

Sarah Knowles, Claire Planner, Ailsa Donnelly, Suzy Bourke, Bella Starling, John Baker

*University of Manchester, PRIMER PPI Group*

### Introduction

Health research funders increasingly emphasise the need to involve patients in prioritising research questions and designing studies. However, opportunities for such collaboration can be limited. 'NHS Hack Days' are one-off events bringing together technological experts with clinicians to generate innovative solutions to healthcare problems. We received an ESRC Transformative Research grant to explore whether 'Patient Hack Days', bringing together experts-by-experience with researchers to design new research projects, could support rapid PPI collaborations.

### Method

Six PPI members from groups across Greater Manchester are pitching research ideas to a mixed audience of PPI groups and researchers. Teams will work together during the day to coproduce study proposals.

### Results

The event will be independently evaluated by INVOLVE using the Generic Learning Outcomes Framework to determine the potential for generating new research proposals and the perceived value of the format to both researchers and PPI partners. We will present:

- The project proposals created on the day.
- The evaluation comparing the Hack Day method to other PPI formats to determine its potential to foster innovation and relative costs and advantages over traditional approaches.

### Discussion

The event will be held in April 2014. The 60 available places were filled within three weeks of registration opening, with PPI places filled within two weeks, and researchers attending from Nottingham, London, Leeds and Sheffield. We will outline our findings and discuss the potential of Patient Hack Days as a model of PPI that could be used across the School to enhance involvement and foster unique collaborations.

## Withdrawing performance indicators: retrospective analysis of general practice performance under the UKs Quality and Outcomes Framework

Evangelos Kontopantelis, David Springate, David Reeves, Darren Ashcroft, Jose Valderas, Tim Doran

University of Manchester, University of Exeter University of York

### Objectives

To investigate the effect of withdrawing incentives on recorded quality of care, in the context of the UK Quality and Outcomes Framework pay-for-performance scheme.

### Design

Retrospective longitudinal study, from 2004/5 to 2011/12, using data for 644 general practices and a total of 13,772,992 patients, extracted from the Clinical Practice Research Datalink.

### Intervention

The removal of financial incentives for aspects of care for patients with asthma, coronary heart disease, diabetes, stroke and psychosis.

### Main outcome measures

Performance on eight clinical quality indicators withdrawn from a national incentive scheme: influenza immunisation (asthma) and lithium therapy monitoring (psychosis), removed in April 2006; blood pressure monitoring (coronary heart disease, diabetes, stroke), cholesterol level monitoring (coronary heart disease, diabetes) and blood glucose monitoring (diabetes), removed in April 2011. Multilevel mixed effects multiple linear regression models were used.

### Results

Mean levels of performance were generally stable after the removal of the incentives, both short- and long-term. For the two indicators removed in April 2006, levels in 2011/12 were very close to 2005/6 levels, although a small but statistically significant drop was estimated for influenza immunisation. For five of the six indicators withdrawn from April 2011, there was no significant impact on performance following removal and differences between predicted and observed scores were small.

### Conclusions

Following the removal of incentives, levels of performance across a range of clinical activities generally remained stable. This indicates that health benefits from incentive schemes can potentially be increased by periodically replacing existing indicators with new indicators relating to alternative aspects of care.

## Glucose, blood pressure and cholesterol levels and their relationships to clinical outcomes in type 2 diabetes: a retrospective cohort study

Evangelos Kontopantelis, David Springate, David Reeves, Darren Ashcroft, Martin Rutter, Iain Buchan, Tim Doran  
University of Manchester, University of York

### Background

Observational data have been used to inform target levels for modifiable risk factors in type 2 diabetes but these data are limited by confounding. We aimed to describe the shape of observed relationships between risk factor levels and clinically important outcomes in type 2 diabetes after adjusting for multiple confounders.

### Methods

We used retrospective longitudinal data on 246,544 adults with type 2 diabetes from 600 practices contributing to the Clinical Practice Research Datalink between 2006 and 2012. Proportional hazards regression models quantified the risks of mortality, microvascular or macrovascular events associated with four modifiable risk factors: HbA1c, systolic/diastolic blood pressure and total cholesterol, while controlling for numerous patient and practice covariates.

### Findings

U-shaped relationships were observed between all-cause mortality and levels of the four risk factors. The lowest risks were associated with HbA1c 7.25-7.75%; total cholesterol 3.5-4.5 mmol/L; systolic blood pressure 135-145 mmHg; and diastolic blood pressure 82.5-87.5 mmHg. Coronary and stroke mortality related to the four risk factors in a positive, curvilinear way, with the exception of blood pressure which related to coronary deaths in a U-shape. Relationships for macrovascular and microvascular events varied from U-shaped to positive and negative curvilinear.

### Interpretation

We identified several relationships which, when considered in the light of relevant trial data, support a call for major changes to clinical practice. Most importantly, our results support trial data indicating that normalisation of glucose and blood pressure can lead to poorer outcomes, which makes a strong case for target ranges for these risk factors rather than target levels.





## Evaluation of the patient-reported outcome (PRO) content of clinical trial protocols

Derek Kyte, Helen Duffy, Benjamin Fletcher, Adrian Gheorghe, Rebecca Mercieca-Bebber, Madeleine King, Heather Draper, Jonathan Ives, Michael Brundage, Jane Blazeby, Melanie Calvert

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### Objective

Qualitative evidence suggests patient-reported outcome (PRO) information is frequently omitted from trial protocols, which may lead to inconsistent PRO data collection and risks bias. Empirical evidence of PRO protocol content is lacking, therefore, we performed a review of the completeness of such content in UK clinical trial protocols.

### Method

Two independent investigators searched the NIHR Health Technology Assessment programme database (inception to August 2013) for trial protocols including a primary or secondary PRO. A third reviewer was involved in the event of disagreement. Two investigators independently extracted data and evaluated the content of each protocol using a specially developed PRO-specific protocol checklist, alongside the 'Standard Protocol Items: Recommendations for Interventional Trials' (SPIRIT) Checklist. Disagreements were resolved through discussion and the intervention of a third investigator if required.

### Results

The 75 most recent HTA trial protocols containing a PRO primary or secondary outcome were evaluated. Protocols included a mean of 10/33 (33%) PRO-specific checklist items, however, over half (61%) of the included items were incomplete. A greater proportion of recommended SPIRIT items (63%) were present in the protocols, indicating that general methodological information was more comprehensively reported.

### Conclusions

The PRO components of HTA clinical trial protocols are suboptimal. Detailed instructions on PRO data collection, training and management were often missing, and even where such information appeared, it was frequently incomplete. There is emerging evidence that these findings may be indicative of PRO protocol content generally. Consensus guidelines are required, which are aimed at improving PRO content in clinical trial protocols.

## Inconsistencies in quality of life data collection in clinical trials: a potential source of bias? Interviews with research nurses and trialists

Derek Kyte, Jonathan Ives, Heather Draper, Thomas Keeley, Melanie Calvert

University of Birmingham

### Objectives

To explore reported inconsistencies in health related quality of life (HRQL) data collection in clinical trials.

### Methods

We undertook a qualitative study, conducting 26 semi-structured interviews with research nurses, data managers, trial coordinators and research facilitators involved in the collection and entry of HRQL data in clinical trials, across one primary care NHS trust, two secondary care NHS trusts and two clinical trials units in the UK. We used conventional content analysis to analyze and interpret our data.

### Results

Interviewees reported (1) inconsistent standards of HRQL measurement in trials, which appeared to risk the introduction of bias; (2), difficulties in dealing with HRQL data that raised concern for the well-being of the trial participant, which in some instances led to the delivery of non-protocol driven co-interventions, (3), a frequent lack of HRQL protocol content, training and education for trial staff, and (4) that HRQL data collection could be associated with emotional and/or ethical burden.

### Conclusions

Our findings suggest there are inconsistencies in the standards of HRQL data collection in some trials resulting from a general lack of HRQL-specific protocol content, training and education. These inconsistencies could lead to biased HRQL trial results. Future research should aim to develop guidelines and training programmes which aid the optimal collection of both standard and 'concerning' HRQL data, whilst minimising the risk of bias.

## Diagnosis and monitoring of chronic kidney disease in primary care - systematic review and meta-analysis of bias of glomerular filtration rate estimating equations

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University of Oxford, NIHR Oxford Biomedical Research Centre, University of Birmingham

### Introduction

Estimated glomerular filtration rate (eGFR) underpins the detection, staging and monitoring of chronic kidney disease (CKD) in primary care. NICE is considering changing from the current MDRD equation for eGFR reporting to the newer CKD-EPI equation. We undertook a systematic review and meta-analysis to address this question.

### Methods

We searched MEDLINE, EMBASE and the Cochrane library for diagnostic accuracy studies comparing eGFRs calculated with the MDRD or CKD-EPI equation to gold standard measured GFR. We used measured GFR in each study to allow comparison to a typical primary care population. Random effects meta-analysis of the observed bias (estimated - measured GFR) and meta-regression of bias against study group characteristics were undertaken using R (version 3.0.2).

### Results

Of 155 studies (61,574 patients) examining the MDRD equation, 84 studies (35,801 patients) reported data for meta-analysis and of 64 studies (35,801 patients) examining the CKD-EPI equation, 38 studies (8,280 patients) reported data for meta-analysis. MDRD had a greater weighted mean bias of -7.0 ml/min/1.73m<sup>2</sup> (95% CI -9.7 to -4.3) compared with CKD-EPI mean bias of -4.7 ml/min/1.73m<sup>2</sup> (95% CI -8.1 to -1.3). Meta-regression of bias against measured GFR demonstrated that MDRD bias worsens at higher levels of renal function (beta coefficient = -0.15, 95%CI -0.26 to -0.05), but CKD-EPI bias is unaffected.

### Discussion

CKD-EPI and MDRD both under-estimate renal function, but CKD-EPI bias is smaller and does not worsen at typical levels of renal function found in primary care. CKD-EPI will therefore be more accurate than MDRD in primary care.

## Consent for research in primary care

Gemma Lasseter, Richard Huxtable, Lesley Wye, Chris Salisbury

University of Bristol

### Objectives

Involvement in primary care research is often hindered by concerns about the confidentiality of patient records. Consequently there is no universal patient consent system in the UK for primary care identifiable medical records research. This study investigated what patients think about such a consent system and how they prefer to be invited to consent.

### Methods

Phase 1 used cognitive interviews to assess patients' attitudes about researchers accessing medical records for different research purposes and the impact of recruitment documentation on the opportunity to give or decline consent. Phase 2 examined the feasibility inviting patients to provide prior informed consent for researchers to access identifiable medical records for different research purposes.

### Results

Preliminary results from Phase 1 show that interviewees were generally in favour of medical records research, but were concerned about the use of their identifiable information, especially if this information might be physically removed from their general practice. Recommendations for improving research recruitment documentation focused on shortening information sheets and simplification of text. Phase 2 is currently ongoing.

### Discussion

Research recruitment documentation influences patients' willingness to provide informed consent for researchers to access their identifiable medical records. Therefore we recommend that patients are closely involved in evaluating these documents prior to use. In terms of medical records research, overall patients have little understanding of the information held in their records or how it is used for research, nevertheless many are willing to opt-in and provide their informed consent.

## Effectiveness of strategies to optimise implementation of complex interventions in primary care: a systematic review of reviews

Rosa Lau, Fiona Stevenson, Bie Nio Ong, Krysia Dziedzic, Sandra Eldridge, Hazel Everitt, Anne Kennedy, Evangelos Kontopantelis, Paul Little, Andrew Morden, Nadeem Qureshi, Anne Rogers, Shaun Treweek, Richard Peacock, Elizabeth Murray

University College London, Keele University, Queen Mary University of London, University of Southampton, University of Manchester, University of Nottingham, University of Aberdeen, Archway Healthcare Library, London

### Background

Getting evidence or complex interventions implemented into routine practice is often a challenge in primary care. Complex interventions are defined as interventions with several interacting components, e.g. guideline, technology based intervention. It is important to evaluate the effectiveness of different strategies to optimise implementation. Implementation strategies are classified using the EPOC taxonomy [professional, organisation, structural, financial and regulatory interventions].

### Aim

To assess the impact of different strategies to facilitate implementation of complex interventions.

Method: Five electronic bibliographic databases were searched until November 2012. Citations and full-text papers were independently screened by two reviewers, against pre-defined selection criteria [population: general practice/primary care teams in developed countries; intervention: implementation of complex interventions, by using single/multifaceted implementation strategies; comparison(s): usual care, no strategy, another strategy (single/multifaceted); outcomes: degree of implementation, e.g. process, professionals' behaviour or performance; study design: reviews]. Data were extracted using standardised data abstraction forms. Findings were summarised, described narratively and synthesised using a framework approach.

### Results

A total of 100 relevant reviews were included. There were more reviews on professional interventions compared to other EPOC interventions. Many strategies were associated with small-moderate effects - some more variable than others. Multifaceted implementation strategies were not necessarily better than single strategies. A number of potential active components that may contribute towards the effectiveness of an intervention were identified.

### Conclusions

"One size fits all" interventions do not work in healthcare organisations. The effectiveness of complex intervention is likely to vary depending on its compatibility with context.

## Barriers to and facilitators of implementation of research evidence and complex interventions in primary care: a systematic review of reviews

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### Background

Getting evidence or complex interventions implemented into routine practice is often a challenge in primary care. Complex interventions are defined as interventions with several interacting components, e.g. guideline, technology based intervention. To bridge this evidence to practice gap, it is important to understand the causes, usually described as factors that impede/facilitate implementation.

### Aim

To explore barriers and facilitators of implementing research evidence/complex interventions in primary care.

### Method

Five electronic bibliographic databases were searched until November 2012. Citations/full-text papers were independently screened by two reviewers. Eligible reviews had to explore barriers and/or facilitators to implementation of research evidence/complex interventions in general practice/primary care teams. Standardised data abstraction forms were developed to capture contextual information, barriers/facilitators identified from results/discussion. Data were synthesised applying an iterative approach and using meta-synthesis techniques, which involved identification and refinement of themes/ concepts, formation of a conceptual framework, identification of common and refutational relationships, and construction of lines of argument.

### Results

60 relevant reviews were included. 21 main themes emerged: 1) outer context: policy, infrastructure, incentives, role of stakeholders, type/growth of technology, dominant paradigms/ influential organisations, economic climate/ governmental financing, public awareness; 2) organisational: relationship, resources, skill mix, involvement, culture, processes and systems; 3) professional: role, attitudes to change, competency, philosophy; 4) intervention: nature, implementation issues and privacy/safety. They were further divided into 42 sub-themes.

### Conclusion

This is a comprehensive overview that is not restricted to any types of interventions. The review findings will inform a wide audience including healthcare professionals, researchers, managers and policy makers.



## Women's experiences of Psychosis: What do General Practitioners need to know? A qualitative analysis of the influence of gender on day-to-day experiences of psychosis and related healthcare needs

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### Introduction

There are recognised gender differences in the clinical presentation of psychotic disorders, both in illness onset and course. Women often develop a first episode of psychosis (FEP) later than men, leading their illness experiences to be embedded in different social contexts. Yet, little research has assessed whether women experience a FEP and its effects on their lives, identity and wider health in ways that differ from men.

There is also a lack of knowledge regarding how women, during and following a FEP, engage with healthcare services and what their particular support needs might be. Because women often have better functioning following a FEP than men, they are more likely to be discharged from specialist services solely to primary care.

### Aims and Methods

By analysing women's accounts of their daily lives during and following a FEP, this study aims to offer clinically-relevant answers to these existing gaps in both the current literature and healthcare structures. It does this by employing anthropologically-underpinned qualitative analysis, undertaking semi-structured interviews with 30 women and ten men.

### Results

This paper reports key emerging findings from the ongoing data analysis. Specifically, it offers insights into the healthcare needs of women in primary care by engaging with narratives of their reproductive and physical health; medication management; social, childcare and financial needs.

### Discussion

Exploring the intersections between all these facets of women's lives, both during a FEP and in its aftermath, seeks to ensure that ways in which women with psychosis are supported in primary care are gender-appropriate.

## Cortisol Evaluation in Abuse Survivors (CEASE study): feasibility and acceptability of salivary cortisol specimen collection in a community-based study on domestic violence and abuse and mental health

Natalia Lokhmatkina, Stafford Lightman, Sarah Blake, Richard Morris, Victoria Powers, Gene Feder

University of Bristol, University College London

### Introduction

Domestic violence and abuse (DVA) is a common and hidden problem for women attending general practice. Abused women are more likely to develop depression, anxiety, and post-traumatic stress disorder. One potential mechanism through which DVA causes these problems is the hypothalamic-pituitary-adrenocortical axis, which produces cortisol, biomarker of stress. The current study aims at determining (1) the feasibility of home-based biomarker specimen collection embedded into a study on mental health and DVA and (2) the acceptability of this assessment to women accessing specialist DVA services.

### Methods

Methodological analysis of an on-going home-based study examining the relationship between DVA, mental health, and salivary cortisol. Participants complete three saliva samples at home alongside with questionnaire survey and return these via regular mail. Women who have experienced DVA are recruited through specialist DVA agencies. Non-abused controls are recruited through local communities.

### Results

210 (72%) of eligible women were recruited by 28.02.14. Of these 210 women, 173 (82%) returned their saliva samples. Return rates from service users and community controls were 71% and 90%, respectively (Pearson chi2 test = 13.40;  $p = 0.000$ ). One set of samples was lost in post. Three sets of samples arrived outside of required 14 days.

### Discussion

Recruitment of women accessing DVA services and community controls into a biomarker study on mental health was possible. Home-based salivary cortisol specimen collection was acceptable to DVA service users and non-abused controls. Mailing source of error was rare. This study informs future research on mental health in primary care and DVA in primary care.

## Symptom interpretation and decision-making processes in patients with lung or colorectal Cancer (sub-study of CANDID (CANCer Diagnosis Decision study))

Sarah McLachlan, Gemma Mansell, Tom Sanders, Sarah Yardley, Danielle van der Windt, Carolyn Chew-Graham, Lucy Brindle, Paul Little

*Arthritis Research UK Primary Care Centre, Primary Care Sciences, Keele University, Staffordshire, Primary Care and Population Sciences Division, University of Southampton, Southampton, UK*

### Objective

To investigate patients' interpretations of potential symptoms of lung or colorectal cancer and their decision making following symptom recognition.

### Method

Semi-structured qualitative interviews were conducted with nine patients with lung cancer and 20 with colorectal cancer, who had been diagnosed in the previous 12 months. Patients were asked about the period of time from the development of symptom(s) through to diagnosis, and to describe their thought processes and decision-making.

### Results

Patients described a pathway from pre-symptom perception through to hindsight following diagnosis. Patients appeared to make rational, logical decisions about their symptoms in a similar way to how a GP would assess the symptom when a patient first presents (offering benign explanations, watching to see if the symptom persists or progresses, or linking the symptom with co-morbidities or ageing). Many patients sought help when their alternative explanations were no longer viable. Some symptoms, such as pain or bleeding, were seen as key triggers for patients and often they delayed help-seeking if these symptoms were not present.

### Conclusion

The findings suggest that prompting patients for more detail on their symptoms during the consultation may provide crucial contextual information to help aid decision-making for referral. The model of symptom interpretation and help-seeking developed in this study could be used by primary care practitioners to help facilitate this process. The results could also have implications for public health campaigns to help educate patients as to what is not key, as well as what are key symptoms of lung or colorectal cancers.

## Development of a new intervention for patients with severe Chronic Fatigue Syndrome/ME; a collaborative approach based on patient and public involvement

Clare McDermott, Sarah Frossell

*University of Southampton, Hampshire, UK, Dorset Bespoke Project*

### Introduction

Severe Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME) can result in patients becoming housebound, wheelchair or bedbound. There is currently little treatment available for this severely disabled patient group.

This study set out to answer the research question, 'How can the experiences of patients who have recovered or substantially improved from CFS/ME be used as a resource to help current CFS/ME patients?'

### Method

We conducted 5 learning cycles over two and a half years (2009-2012) using Patient and Public Involvement from over 40 current and recovered patients, carers, local patient support groups and specialist CFS/ME clinicians.

A series of development groups met in half day workshops with the goal of understanding and modelling the key elements and skills required for recovery from CFS/ME, drawing on the lived experience of patients.

Group sessions were facilitated using the conceptual model of 'modelling success' from Neuro-Linguistic Programming. Within the groups, all members acted as equal peers, contributing individual insights and experience to the process.

### Results

Group members identified key recovery skills, and how best to communicate these in ways which are meaningful to those with CFS/ME. Barriers to effective communication were discussed and group members suggested and explored creative ways of addressing these issues.

### Discussion

Insights generated by this development group have been used to devise and refine a community based intervention for patients with severe CFS/ME. This intervention is the subject of an National Institute of Health Research funded feasibility study which is currently recruiting patients in Dorset and Oxford.

## Identifying moderators of treatment outcome in musculoskeletal shoulder disorders

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### Introduction

Musculoskeletal shoulder pain is common and is associated with reduced function, quality of life and work capacity. Half of all patients presenting with shoulder disorders in primary care report persistent pain six months after consultation. Prognostic factors have been identified however do not directly assist with treatment decision-making. Moderators of shoulder treatment outcome (prognostic factors associated with specific treatment outcomes) and profiles of ideal responders to three commonly used treatments (physiotherapy, injection and education, advice and pain relief) are unknown.

### Methods

A systematic review was conducted to identify potential moderators of outcome in patients with shoulder disorders. Clinical consensus workshops employing focus groups with nominal group technique identified potential moderators and possible profiles of responders to the three commonly used treatments.

### Results

The review identified 'presence of painful arc at baseline' as the only moderator of treatment effect with confirmatory evidence. Additional potential moderators were suggested, however, due to methodological and statistical issues these lack confirmatory evidence.

Clinical consensus workshops identified additional potential moderators of treatment effect. 15 dichotomous clinical questions were deemed relevant to shoulder treatment decision-making. Profiles of likely best and worst responders to each treatment were also proposed.

### Conclusion

Few studies have explored moderators of treatment response using a priori hypotheses, adequate statistical power and appropriate statistical methods. Clinical consensus data supplements systematic review findings to underpin a future clinical decision analysis study using conjoint analysis. This will aim to identify international clinical perception of likely best responders to commonly used treatments for shoulder pain.

## Candidates for care in primary care: Experiences of patients with Multiple Sclerosis and primary care professionals

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*University of Manchester, Keele University*

### Introduction

Multiple Sclerosis (MS) is a chronic degenerative condition; people with MS may require repeated contact with primary, secondary and social care. The aim of this qualitative study was to investigate the role of primary care from the perspectives of people with MS and primary care professionals.

### Method

26 people with MS were purposively sampled from community and primary care settings. Thirteen General Practitioners (GPs) and 15 Practice Nurses (PNs) were purposively sampled from practices in NW England. Semi-structured interviews explored experiences of receiving or providing care. Transcripts formed data which were analysed using constant comparative analysis, using the concept of candidacy as a theoretical framework (Dixon Woods et al., 2006).

### Results

How patients and professionals interpreted symptoms as leading to candidacy for care dictated their help-seeking. Patients were often unsure as to whether symptoms were MS related, or treatable, and often did not know which services to access for care. PNs did not have much contact with people with MS and lacked confidence and knowledge about the condition and local services. GPs reported greater involvement with patients with MS where they reported difficulties accessing local specialist and community health services.

### Conclusions

Candidacy is an appropriate model to explain help-seeking and access to health care for MS: use of health services is based on both patient and professionals' interpretation of symptoms, perceptions of services and previous experiences. To improve perceptions of candidacy there is a need for greater education for patients and professionals on symptoms of MS and information on availability of local services.



## A Cochrane Systematic Review of computer-based diabetes self-management interventions for adults with type 2 diabetes

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### Introduction

Diabetes education programmes can reduce the risk of diabetes-related complications four-fold. However, people appear to have difficulties attending, with uptake in the UK often as low as 11%. Computer-based self-management programmes have the potential to improve access, but evidence about their effectiveness and active components is lacking.

The aim of the study was to assess the effects of computer-based diabetes self-management interventions on health status, cardiovascular risk factors and quality of life of adults with type2 diabetes and to define the active ingredients of successful interventions.

### Methods

We retrieved 8715 abstracts from a systematic search of six electronic bibliographic databases. Standard Cochrane methodology was used with double screening of abstracts and independent data extraction. Studies that met the inclusion criteria were analysed and a taxonomy of behaviour change techniques was used to define the ingredients of the intervention.

### Results

Sixteen randomised controlled trials with 3578 participants met the inclusion criteria. Computer-based diabetes self-management interventions appear to have small benefits on glycaemic control: the pooled effect on HbA1c was -0.2%. A sub-group analysis on mobile phone-based interventions showed a larger effect: the pooled effect on HbA1c from 3 studies was -0.50%. Prompting self-monitoring of behavioural outcome and providing feedback on performance were 2 techniques commonly used in the more effective interventions.

### Discussion

Computer-based diabetes self-management interventions to manage type2 diabetes appear to have a small beneficial effect on blood glucose control and this effect was larger in the mobile phone sub-group. There was no evidence of benefit for other biological, cognitive, behavioural or emotional outcomes.

## Multimorbidity and patient safety incidents in primary care: A systematic review

Maria Panagioti, Jonathan Stokes, Sudeh Cheraghi-Sohi, Peter Bower

*University of Manchester*

### Objectives

Multimorbidity is increasingly prevalent and represents a major part of the workload in primary care. Patients with multimorbidity are potentially more likely to experience safety incidents due to the complexity of their needs and their frequent interactions with health services. Despite this, there is no clear evidence about the association between multimorbidity and patient safety in primary care. This is the first systematic review to examine whether any particular types of safety incidents are more prevalent in patients with multimorbidity and whether there are any specific groups of patients with multimorbidity who are more susceptible to safety incidents in primary care.

### Methods

Three electronic bibliographic databases (Medline, Embase and CINAHL) were searched. We included quantitative studies which reported an outcome of the association between multimorbidity and patient safety.

### Results

After screening 7,210 titles/abstracts and 351 full-texts, 80 studies were included in the review. A descriptive synthesis of the studies is performed due to high between-study heterogeneity. Clear evidence was obtained about the impact of multimorbidity on certain types of safety incidents (adverse drug events; medication adherence) whereas for other types of incidents the results were mixed (appropriateness of treatment; screening error). The risk for safety incidents was stronger for patients reporting multiple conditions (multimorbidity) compared to those reporting two conditions (comorbidity).

### Conclusions

The findings of this review will enhance the understanding of the safety incidents experienced by patients with multimorbidity and will guide the design of interventions to facilitate effective service delivery and ameliorate threats to safety in patients with multimorbidity.

## Meta-ethnography of student and patient perspectives of undergraduate medical education in the UK general practice setting

Sophie Park, [Nada Khan](#), Alice Malpass  
UCL, University of Bristol

### Objectives

10-15% of undergraduate medical education in the UK is conducted in a general practice setting. We are using meta-ethnography as part of a systematic review to synthesise empirical qualitative evidence of student and patient perspectives in this field.

### Method

We systematically searched databases, and from 169 included empirical studies, 74 qualitative studies were identified. We used Noblit and Hare's 7 stage process to map and translate concepts across included papers. This process allows researchers to develop new insights and knowledge by making connections across included papers.

### Results

We identified 10 key papers within two main thematic groups describing the student and patient perspective of undergraduate teaching in general practice. Group 1 papers highlighted the GP as a broker influencing the interactions between patients and students. The papers emphasise that participatory learning is beneficial for the student and patient. Group 2 papers represent the socio-cultural spaces of learning that shape the interpersonal interactions within the teaching consultation. Students act as mediators between the polarised environments of hospital and general practice and integrate these competing cultures. Students feel a tension between the 'real world' training offered in general practice versus the 'textbook medicine' in the hospital setting and which students felt dominated their exams and assessments.

### Conclusions

GPs need to be aware of their role as a broker of interactions between patients and students. This has implications for effective training of GP tutors. Students are managing competing cultures, and need support to address their expectations and learning within GP placements.

## Systematic review of undergraduate medical education in the UK general practice setting

Sophie Park, [Nada Khan](#)  
University College London

### Background

UK medical schools deliver 10-15% of their undergraduate curriculum in general practice at a cost of £100 million per year. This study aims to systematically identify, summarise and synthesise empirical research evidence about delivering undergraduate medical education in the UK general practice setting.

### Methods

We searched databases using terms relating to general practice and medical education. Studies about undergraduate medical education in UK general practice were included. We produced a descriptive synthesis summarising all papers as well as in-depth syntheses of quantitative papers using objective outcome measures and qualitative papers using meta-ethnography.

### Results

Database searches retrieved 12477 records for title and abstract screening. Of these, 169 papers were included in the review. A wide range of learning activities across different specialties are taught in general practice placements. Medical students learned clinical skills as well or better in general practice as in hospital settings, and received more teaching and feedback from general practice tutors compared to hospital tutors. Patient satisfaction and enablement is not affected, but patients experience lower relational empathy with their GPs when a student is present in their consultation. GPs have a powerful role as a broker of the interactions between patients and students, and as transient members of the learning community, the role and involvement of patients requires careful facilitation.

### Conclusions

We will discuss the findings of this systematic review and potential implications for general practice learning. We hope this review will inform future practice, policy and research through highlighting existing findings and potential future perspectives.



## A randomised controlled trial of the effect of using simulated patients on the acquisition by medical students of musculoskeletal examination skills

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### Background

Acquisition of the skills to perform musculoskeletal examinations is core to doctors' training but health service pressures and the (morally correct) desire not to inflict unnecessary pain on patients may be reducing competence of newly qualified doctors. We hypothesised that structured, scenario based training (SSBT) using simulated patients (SPs) would result in better acquisition of musculoskeletal examination skills than 'usual learning' i.e. clinical experience and teaching on wards and in outpatients.

### Methods

We performed an RCT in two separate year cohorts in one medical school, randomising students to SSBT with SPs or usual learning; musculoskeletal module is in year 4 of the 5 year course. Students' examination skills were assessed in a single OSCE station; for cohort 1 (n = 208) the OSCE was in 5th year; for cohort 2 (n = 379) in 4th year. Delay between module and OSCE was ~8/12 (IQR 4-12) for intervention group and ~7/12 (4-10) for control group. OSCE examiners and statistician were blind to allocations.

### Results

There was a difference in mean musculoskeletal OSCE station scores of 3 percentage points ( $t=2.50$ ,  $p=0.013$ ) between intervention and control arm. There was no attenuation of difference in OSCE scores with time between module and OSCE.

### Discussion

Scenario-based structured musculoskeletal skills training with SPs produces significant improvement in medical students' musculoskeletal OSCE scores which does not appear to reduce over time.

In conclusion, SPs are effective in training medical students in musculoskeletal examination skills and more effective than traditional learning in clinic.

## Use of Primary Care databases to evaluate drug benefits and harms: Do different databases give the same results?

David Reeves, David A Springate, Darren Ashcroft, Ronan Ryan, Tim Doran, Richard Morris, Ivan Olier, Eavn Kontopantelis

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### Introduction

Primary care databases (PCDs) are increasingly used as a resource for research, but issues around the validity of studies based on PCDs remain. We conducted the first fully independent replications of published PCD studies in a different PCD covering the same target population.

### Methods

We replicated two previous PCD drug effectiveness studies through the Clinical Practice Research Datalink (CPRD). The first was an investigation of the effects of Statins on mortality of patients with ischaemic heart disease using QRESEARCH. The second was a cohort study of the effect of Beta-blocker therapy on survival in cancer patients using the Doctors' Independent Network (DIN-LINK).

### Results

We successfully replicated the methods of the two original studies in CPRD, but only by obtaining additional detail from the authors. Although notionally covering the same patient population, we found some notable demographic and health differences between our cohorts of CPRD patient and the cohorts from QResearch and DIN-LINK.

Despite these differences key results using CPRD were remarkably similar to those previously obtained using QResearch. Results from our replication of the DIN-LINK study were more complex: taken individually, the two databases produced a different picture of the risks of beta-blockers, even adjusting for demographic and other differences, but when directly compared in all important aspects the findings did not differ statistically.

### Conclusions

Our results are largely reassuring regarding the validity of results obtained using three different PCDs, but also provide a caution about relying too heavily on the findings from a single database.



## Safe general practice: a qualitative study of patients' perspectives

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 Primary Care Patient Safety Translational Research Centre*

### Introduction

Safety research has tended to emphasise practitioner errors, with little attention to patient perspectives. In this study, we explore patients' own understandings of safety.

### Methods

Interviews were conducted with patients recruited from general practices in northern England. Participants were asked basic socio-demographic information; thereafter, topics were largely introduced by interviewees themselves. Transcripts were coded and analysed using NVivo10 (qualitative data software), following a process of constant comparison.

### Results

Thirty eight people (14 men, 24 women) from 19 practices in rural, small town and city locations were interviewed. Many of their concerns (about access, length of consultation, relationship continuity) have been discussed in terms of quality, but, in the interviews, were raised as matters of safety. Three broad themes were identified: (i) trust and psycho-social aspects of professional-patient relationships; (ii) choice, continuity, access and the temporal underpinnings for safety; (iii) organisational and systems-level tensions constraining safety. For patients, achieving safe care involved balancing priorities, weighing up costs and benefits of different options, and flexible interpretation of "rules".

### Discussion

Conceptualisations of safety included common reliance on the apparatus of accreditation, accountability, procedural rules and regulation that formed a taken-for-granted framework to safe care, but were also individual and context-dependent. Safe care was realised in the interaction between doctor and patient. According to this view, safety is not just a property of systems, but personal and contingent. However, the systems approach has dominated safety thinking, and patients' individualistic and relational conceptualisations are poorly accommodated within current service organisation.

## Development of a measure of Patient Reported Experiences and Outcomes of Patient Safety in Primary Care: the PREOS-PC instrument

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### Objectives

To develop a patient reported instrument to measure patient safety experiences and outcomes in primary care in England.

### Method

The instrument was developed in three stages. First, we developed a conceptual framework and compiled the information for item generation through a process that included a systematic literature review of instruments, a meta-synthesis of qualitative studies and four focus groups with patients. Second, we developed the first version of the instrument by selecting and modifying pre-existent items and creating new items when necessary. Third, we developed the final version of the instrument through an iterative process that involved an Expert Panel and cognitive interviews with patients.

### Results

The systematic review identified 23 instruments. Most of them were restricted to adverse drug reactions and did not show evidence for adequate psychometric properties. The meta-synthesis included 55 articles. Main themes identified were patients' concerns/experiences about 1) adverse drugs events, 2) patient-provider communication, and 3) diagnosis error. Twelve themes emerged from the focus groups, most of them related to factors contributing to the occurrence of adverse events. As a result of multiple iterations we developed the "Patient Reported Experiences and Outcomes of Safety in Primary Care" (PREOS-PC), which contains 70 items and covers 12 patient safety domains.

### Conclusions

PREOS-PC is the first patient reported instrument to measure patient safety experiences and outcomes in primary care in England. Feasibility of administration methods and psychometric properties of the instrument are currently being analysed through a two-stage pilot-test involving 10,000 patients from 50 practices across England.



## Developing the science of recruitment to clinical trials: from ideas to practice with Systematic Techniques for Assisting Recruitment to Trials (START)

Jo Rick, Peter Bower, David Collier, Sandra Eldridge, Jonathan Graffy, Anne Kennedy, Peter Knapp, Chris Salisbury, Nicola Small, David Torgerson, Shaun Treweek, Paul Wallace

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### Introduction

Published data show that a minority of RCTs recruit successfully, but there are few evidence-based methods which are known to impact on recruitment. The most robust test of the effectiveness of a recruitment method is an RCT comparing one method with an alternative, 'nested' in an ongoing 'host' trial. Such studies are rare, largely delivered in an ad hoc way, and almost always tested in the context of a single host trial, limiting their utility.

In 2006, the NIHR School funded pilot work which resulted in a MRC Methodology grant (Systematic Techniques for Assisting Recruitment to Trials - START) designed to develop the conceptual, methodological and logistical framework for nested trials.

### Methods

START involves three interrelated work packages:

- (I) Methodology - to develop methods for design, analysis and reporting of nested recruitment studies;
- (II) Interventions - to develop effective and useful recruitment interventions;
- (III) Implementation - to recruit host RCTs and test interventions through nested studies.

### Results

Recruitment has been challenging, with resources and complexity deterring some potential hosts. To date START has developed two recruitment interventions and recruited 10 host trials covering c.18,000 participants.

The presentation will focus on recruitment outcomes for the completed nested RCTs, the findings of the feasibility study and the implications for future research in this area.

### Discussion

START has demonstrated that Nested RCT methodology is achievable, but the complexity and added burden mean the approach is unlikely to find widespread acceptance without other drivers such as funding requirements.

## Psychological Impact of childhood Eczema: birth cohort study

Chris Penfold, Sarah Sullivan, Liam Mahedy, Richard Morris, Miriam Santer, Parker Magin, Giles Dunnill, Sarah Purdy, Matthew Ridd

*University of Bristol, Cardiff University, University College London, University of Southampton, University of Newcastle, Australia, University Hospital Bristol NHS Trust, Bristol*

### Introduction

Childhood eczema is common, yet there is limited research on its impact on children's long-term mental health. We sought to examine the psychological impact of childhood eczema using a prospective birth cohort.

### Method

We used data from the Avon Longitudinal Study of Parents and Children (ALSPAC). Mothers completed questionnaires, sent at 11 time points between birth and 12 years of age, asking whether their child had an eczematous rash. Adolescent mental health was measured using the Strengths and Difficulties Questionnaire (SDQ) completed by the parent when the study child was 16 years old. Longitudinal latent class analysis was used to derive phenotypes of childhood eczema experience. This classification of childhood eczema was used as an independent variable in linear regression models of adolescent SDQ subscales at 140 and 198 months of age.

### Results

3257 children (22.8% of initial cohort) had complete eczema and SDQ data. Four phenotypes of childhood eczema were generated using latent class analysis – no eczema (n=1954, 60.0%), early onset/clearing (n=557, 17.1%), late onset (n=317, 9.7%) and persistent (n=429, 13.2%). Compared with those who had no childhood eczema, at 140 months, early onset/clearing and persistent eczema were associated with the hyperactivity subscale of the SDQ (b=0.09, p=0.02 and b=0.10, p=0.02 respectively). At 198 months, persistent eczema was weakly positively associated with the conduct disorder subscale (b=0.17, p=0.02).

### Discussion

There is weak evidence of associations between sub-groups of children with eczema and hyperactivity/conduct disorder in adolescence. Whilst these findings are supported by previous research which has shown similar associations (Schmitt 2010 & 2011; Genuneit 2014), loss-to-follow up means our need to be interpreted with caution. Similarly, the mechanism by which these effects occur is unclear and may be due to the effect of having a long-term condition rather than eczema per se (Pinquart & Shen 2011).

## Supporting Self-Care for Families of Children With Eczema With a Web-Based Intervention Plus Health Care Professional Support: Pilot Randomized Controlled Trial

Miriam Santer, Ingrid Muller, Lucy Yardely, Hana Burgess, Paul Little

*University of Southampton*

### Introduction

Childhood eczema causes significant distress through sleep disturbance and itch. The main cause of treatment failure is non-use of prescribed treatments. We tested a web-based intervention to support families of children with eczema and sought to explore whether health care professional (HCP) support is necessary to engage participants with this.

### Methods

Carers of children with eczema were invited through primary care mail-out and randomised to three groups: website only; website plus HCP support; usual care. Patient Oriented Eczema Measure (POEM) was measured at baseline and 12 weeks. 26 qualitative interviews were carried out to explore participants' experiences.

### Results

143 carers were recruited through 31 practices. We found a decrease of 2 or more in follow-up compared with baseline POEM score in: 23/42 (55%) of participants in 'website only' group; 18/47 (38%) in 'website+HCP' group; and 16/49 (33%) of 'usual care' group. 75/93 (81%) of participants allocated to website groups completed core modules and there were no consistent differences in website use data between 'website only' or 'website+HCP' groups.

Qualitative interviews suggested that HCP support was valued highly only by a minority, generally carers who were less confident managing eczema or less confident using the internet.

### Discussion

This pilot RCT showed greater improvement in eczema in website groups compared with usual care. If effective in a full-scale trial, the intervention could be promoted to all families of children with eczema. HCP support was not strongly valued by participants and did not lead to better website use than web-based intervention alone.

## A nurse-led telephone supported self-management intervention for people with mildly symptomatic chronic obstructive pulmonary disease (COPD): a randomised controlled trial (PSM-COPD)

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### Objectives

To determine the effectiveness of a nurse-led telephone supported self-management intervention for people with mildly symptomatic COPD.

### Methods

Feasibility study with focus group, followed by multi-site randomised controlled trial with embedded qualitative study. We plan to recruit 556 participants to the RCT.

Eligible patients are identified from primary care COPD registers; score 1 or 2 on the MRC breathlessness scale; COPD is confirmed by post-bronchodilator spirometry.

Intervention: components include encouragement to attend a smoking cessation service, physical activity, correct use of inhalers, confidence with action plan for an exacerbation. Four telephone consultations with 2 standard postal prompts over 24 weeks, physical activity booklet, pedometer and self-monitoring diaries. Underpinned by social cognitive theory.

Control group receive standard leaflet on COPD.

Outcomes at 6 and 12 months: Primary- St Georges Respiratory Questionnaire. Secondary - smoking and physical activity (IPAQ-short), self-management activities, Hospital Anxiety and Depression Scale, self-efficacy for managing their COPD and undertaking physical activity, MRC dyspnoea scale, health care utilisation (primary care consultations for COPD; prescriptions for antibiotics; hospital admissions; attendance at smoking cessation service), EuroQoL EQ-5D-5L. Accelerometry to measure physical activity(12 months).

### Results

90 people were invited to the feasibility study; 35 (39%) responded (15 positively) and 12 were recruited (13%). Posting the accelerometers to participants and asking them to start the accelerometer identified problems ; a different approach will be used in the main trial.

Recruitment has commenced for the main RCT.

### Conclusions

The feasibility study provided useful information about intervention acceptability and trial processes.



## Feasibility of an RCT of a brief communication intervention for GPs to enhance the elicitation of patient concerns during primary care consultations

Rachael Summers, Michael Moore, Beth Stuart, Paul Little, Stuart Ekberg, John Heritage, Paul Drew, Fiona Stevenson, Jane Ogden, Carolyn Chew-Graham, Stewart Mercer, Lucy Brindle, Paul Roderick, Geraldine Leydon

*University of Southampton, Queensland University of Technology, Australia, University of California in Los Angeles (UCLA), Los Angeles, USA, Loughborough University, University College London, University of Surrey, Keele University, University of Glasgow*

### Objectives

Assess the feasibility of an RCT involving an intervention based on North American research suggesting a simple change to GP questions is likely to elicit patient concerns more successfully. Chiefly to determine:

1. Whether UK GPs can be trained to successfully deploy the intervention questions of 'any' and 'some' issues/concerns.
2. The extent to which patients consult GPs with multiple concerns in mind.
3. The extent to which patients' multiple concerns actually get voiced within GP consultations.
4. Whether soliciting possible multiple concerns increases consultation length.

### Methods

GPs were recruited via the PCRN. All eligible patients on a participating GP's list were invited to participate either on the day of their appointment or in advance (telephone/written invitation). Patients completed pre and post-consultation questionnaires (including demographics, HADS, EQ-5D, number of concerns intended, number of concerns raised, MISS-21). Consultations were video-recorded. GPs were randomised into either 'control', 'any' or 'some' groups. After recording 3 consultations, GPs in an intervention group watched a training video and were provided with written reminders of the intervention wording before undertaking subsequent consultations. The minimum sample required 294 patients, and GPs were asked to recruit between 14-20 patients.

### Results

21 GPs recruited 320 patients (ANY=102, SOME=108, CONTROL=110). There were no significant differences between the groups for key variables (age, sex, and ethnicity). Data analysis is ongoing.

### Conclusions

It is feasible to recruit GPs and patients to the videoed communication RCT. Further analysis is needed to enable further conclusions to be drawn.

## Predicting five-year dementia risk using routinely collected primary care data: the development and internal validation of a new dementia risk algorithm

Kate Walters, Sarah Hardoon, Irene Petersen, Steve Iliffe, Rumana Omar, Irwin Nazareth, Greta Rait

*University College London*

### Background

Routinely collected data has potential uses to assess dementia risk in primary care, informing case finding of dementia.

### Objective

To develop and internally validate a 5-year dementia risk algorithm.

### Design

Cohort risk score development study.

Setting: 472 UK general practices participating in The Health Improvement Network database.

### Participants

1,194,619 patients aged 60-95 years without evidence of dementia at baseline. We randomly selected 80% of practices for a development cohort and 20% for validation. We developed risk algorithm models for two age groups (60-79 years, 80+years).

### Main outcomes/measures

Five year risk of recorded dementia. Potential predictors included socio-demographic, CVD risk factors, lifestyle and mental health variables.

### Results

Dementia incidence was 0.19/1000PYAR (95%CI 0.18-0.19) for those 60-79years (N=6017 cases) and 1.65/1000PYAR (95%CI 1.62-1.69) for those 80-95years (N=7104 cases). Predictor variables included age, gender, year, deprivation, smoking, BMI, heavy alcohol use, anti-hypertensive drugs, diabetes, stroke/TIA, atrial fibrillation, aspirin, depression/antidepressants. The 80-95years model also included systolic blood pressure, total cholesterol/HDL ratio, anxiety/anxiolytics and NSAIDs. The discrimination and calibration were good for 60-79years model, but not 80-95years model. For the 60-79years model, D statistic=2.03 (95%CI 1.95-2.11), C statistic=0.84 (95%CI 0.81-0.87), calibration slope=0.98 (95%CI 0.93-1.02). For the 80-95years model D statistic=0.86 (95%CI 0.76-0.95), C statistic=0.56 (95%CI 0.55-0.58), calibration slope=1.04 (95%CI 0.89-1.18). We will discuss sensitivity, specificity, positive/negative predictive values.

### Conclusion

It is possible to predict 5 year risk of dementia diagnoses using routinely collected data for those aged 60-79 years, but not those 80+ years. This model should be externally validated.

## Whooping cough in school aged children presenting with persistent cough in UK primary care after the introduction of the pre-school pertussis booster vaccination: a prospective cohort study

Kay Wang, Norman Fry, Helen Campbell, Gayatri Amirthalingam, Timothy Harrison, David Mant, Anthony Harnden

*University of Oxford, Public Health England, London*

### Objectives

To estimate the prevalence and clinical severity of whooping cough (pertussis) in school aged children with persistent cough since the introduction and implementation of the pre-school pertussis booster vaccination (PSB).

### Methods

Between November 2010 and December 2012, we prospectively recruited children aged 5 to 15 years who presented with a persistent cough of two to eight weeks' duration from 22 general practices in Thames Valley. Exclusion criteria included: underlying medical condition likely to be causing cough, known immunodeficiency, and PSB received less than one year previously. Recent pertussis infection was detected based on an oral fluid anti-pertussis toxin IgG titre of  $\geq 70$  arbitrary units. Cough frequency was measured in six children with laboratory-confirmed pertussis.

### Results

56/279 children (20.1%, 95% confidence interval [CI] 15.4%-24.8%) had evidence of recent pertussis infection. 261 children (93.5%) received complete primary pertussis vaccinations and 224 (80.3%) received the PSB. The risk of pertussis increased sharply in children who received the PSB  $\geq 7$  years ago, more than tripling from 11.7% (95% CI 6.9%-16.5%) to 39.6% (95% CI 26.5%-52.8%). 24-hour cough frequency varied ten-fold among six fully vaccinated pertussis-positive children (151-1587 coughs).

### Conclusions

Pertussis can still be found in one-fifth of school aged children presenting in primary care with persistent cough and can cause clinically significant cough in fully vaccinated children. The risk of pertussis increases significantly in children who received the PSB seven years ago or longer. These findings will help inform current consideration of the need for an adolescent pertussis booster vaccination in the UK.



# Abstracts - Poster presentations

## 1. A prospective cohort observational study to determine the incidence of VTE among care home residents: study design and progress to date

Patricia Apenteng, Ellen Murray, Peter Bradburn, Marie-Lucie Gibbons, Carl Heneghan, Richard Hobbs, David Fitzmaurice.

*University of Birmingham, University of Oxford*

### Introduction

Around 60,000 deaths a year in the UK are due to venous thromboembolism (VTE) with around 50% of these acquired in hospital. Whilst the clinical benefit of prophylactic treatment for VTE in hospitals is established, in the care home setting we have little understanding of VTE incidence, or prevention and treatment strategies. This on-going study aims to determine for the first time the incidence of VTE among care home residents in UK.

### Methods

The study aims to recruit 1000 care home residents from Care Homes in Birmingham and Oxford and follow them up for one year. Participants will undergo two case note reviews of their Care Homes and GP records, comprising of a baseline assessment and a follow up assessment one year after enrolment. The baseline assessment will include data on levels of VTE risk, demographics, mobility index and VTE prevention strategies. Year one follow up assessment will comprise the index events: hospital admission, non-hospital intervention for suspected VTE, and diagnosed VTE. Participants who die prior to the year one follow up will have end of study status and have a notes review following their death.

### Results

The main outcome of interest is the rate of VTE events per 100 person years. Key secondary outcomes include associated non-hospital interventions, hospital admissions and deaths. Recruitment is ongoing and 60% of the target sample size has been recruited from 38 care homes.

### Discussion

Achievements to date will be discussed.

## 2. Psycho-behavioural Factors Associated with Optimal Influenza Vaccine Response in Older Adults

Kieran Ayling, Thomas Bowden, Lucy Fairclough, Paddy Tighe, Ian Todd, Heather Buchanan, Ian Macdonald, Paul Greenhaff, Kavita Vedhara

*University of Nottingham*

### Objectives

Effective vaccination relies on an individual's immune system responding robustly to antigens present in the vaccine. Therefore, those with reduced immune functionality (e.g., the elderly), frequently achieve suboptimal vaccine outcomes. Psycho-behavioural factors (including diet, mood and physical activity) have been shown to impact both directly and indirectly on immune responses to vaccination. Thus, interventions targeting these factors have the potential to act as an effective, non-pharmacological vaccine adjuvant. As the first step in developing a psycho-behavioural vaccine adjuvant, this novel study aims to establish which psycho-behavioural factor(s) exerts the greatest influence on vaccine outcomes and at what time (pre- or post-vaccination) this influence occurs.

### Method

As part of an on-going cohort observational study, 200 older adults (65-85 years) will be recruited from primary care. Behavioural (Diet, Physical Activity Sleep) and psychological factors (Positive and Negative Affect, Depression, Perceived Stress) will be assessed at frequent intervals during the two weeks before, and four weeks following influenza vaccination. Multiple antibody, T-cell and cytokine responses to the vaccine will be assessed via serum samples taken pre-vaccination, at 4 weeks and 3 months post-vaccination.

### Results

The independent and combined contribution of psycho-behavioural factors to vaccine outcomes will be determined by advanced clustering approaches. The factor(s) most strongly associated with optimal vaccine response will become the focus for developing a brief psycho-behavioural intervention deliverable in primary care.

### Conclusions

Understanding the factors associated with optimal vaccine response among the elderly is vital for developing an effective psycho-behavioural adjuvant to enhance vaccine efficacy in older adults.



### 3. The role of social participation in older adults with musculoskeletal pain

Shula Baker  
Keele University

#### Objectives

Musculoskeletal pain is a common reason for primary care consultation and is associated with poor physical (e.g. cardiovascular disease (CVD)) and mental health (e.g. depression) in later life. Restricted social participation (RSP) (e.g. problems socialising) is greater in older adults with pain but its role on pain-related outcomes is unclear. The aim of this work is to evaluate the role of RSP as a mediator or moderator of pain-related outcomes (focusing on CVD and depression) in older adults.

#### Method

Data collected in the English Longitudinal Study of Aging will be used in a structured series of mini analysis. Path analysis will examine whether RSP explains the relationship between pain and depression/CVD (i.e. mediates the association). Secondary mediators (e.g. comorbidity) will also be included to identify additional mechanisms. To determine whether the associations between pain and CVD/depression are moderated by RSP, interaction terms will be examined.

#### Results/ Conclusions

If found to be a mediator RSP would be a suitable target for interventions in primary care. If found to be a moderator, older adults could be stratified by levels of RSP and appropriate interventions targeted.

### 4. The Bristol Archive: Study #1 Identifying effective techniques and practices that GPs use to facilitate patient adherence to recommended treatments

Rebecca Barnes, Chris Salisbury, Matt Ridd, Chris Metcalfe  
University of Bristol

#### Introduction

Notwithstanding strong links between communication and health care outcomes, consultations studies in primary care research are relatively uncommon. Our aim is to create an electronic archive of video-recorded consultations plus linked data to facilitate re-use. An initial mixed methods study will use the archive to explore associations between individual patient socioeconomic status (SES), the nature of GP recommendations for medical and nonmedical treatments, and subsequent patient-reported adherence.

#### Methods

We aim to recruit 240 patients and 24 GPs from 12 GP practices sampled across Bristol CCG. Consultations will be video-recorded with 10 unselected consenting adult patients for each GP. Practice, GP and patient surveys, plus patient record data will also be collected. The primary outcome measure for our study will be patient-reported adherence to medical and/or non-medical treatment advice 10 days post-visit using an adapted version of the Brief Medication Questionnaire. A communication measure will be developed to capture GP-initiated treatment recommendation practices.

#### Results

Conversation analytic methods will be used to develop a new measure for the systematic and comparative investigation of treatment recommendations from an interactional point of view. In our planned statistical analysis, associations with different treatment recommendation practices and patient-reported adherence will be estimated as the coefficients for a binary covariate (high/low patient SES) in a series of regression models.

#### Discussion

The economic and health costs of patient non-adherence to treatment recommendations are considerable. Consultation studies may help to identify effective techniques and practices that GPs use to facilitate outcomes such as behaviour change and adherence.

## 5. Design, validity and clinical utility of Smartphone App to assess short-term pain trajectories

John Bedson, Kelvin Jordan, Kate Dunn, David White, Stephen Dent, Danielle van der Windt.

Keele University

### Objective

Short-term changes in symptoms can be important for accurate diagnosis, predicting long-term outcome (prognosis), and assessing short-term response to treatment. The aim of this project is to design and test a Smartphone application (PainApp) for assessing short-term changes in pain intensity in people with musculoskeletal conditions.

### Methods

The project is carried out in four phases: (I) discussion of objectives, acceptability, and content of the PainApp with Keele's Research User Group (RUG); (II) design of the PainApp; (III) discussion of face validity and utility with the RUG and clinical advisory group; (IV) testing of acceptability and validity in a prospective cohort study. Primary care consultants (adults,  $n \geq 150$ ) with musculoskeletal pain receiving a new prescription for stronger classes of analgesics (opioid combinations, NSAIDs) will be invited to use the PainApp during 4 weeks to enter daily scores for pain intensity, impact of pain on sleep and activities, well-being, analgesics use, and perceived side effects. After 4 weeks, participants will be invited to discuss PainApp recordings with their GP and make further decisions regarding pain management. Questionnaires will be completed at baseline and 1 month follow-up to assess validity of pain recordings and symptom trajectories, and invite participants' opinions regarding acceptability and usefulness of the App. Medical record review will be used to assess changes in analgesics prescribing over 3 months, compared to a random sample of similar consultants not using the PainApp.

### Results

Phase I has been completed, and by the time of the Showcase, Phase IV will be underway.

## 6. An exploration of the psychological impact and adaptation post-myocardial infarction in UK South Asians

Mimi Bhattacharyya, Fiona Stevenson, Kate Walters

University College London

### Introduction

Past research has suggested both between and within-ethnicity variation in cardio-vascular risk and depression. The interaction of these factors with adaption and quality of life after an acute cardiac event in different ethnic groups is not well understood.

### Methods

Study sample: We purposively sampled from those who have had a myocardial infarction (MI) in the preceding year by ethnic group.

### Interviews

28 semi-structured interviews were conducted exploring illness perception, beliefs and health behaviours, psychological symptoms, experiences and adaptation following an MI amongst South Asian (Indian and Bangladeshi) in comparison to Caucasian people.

### Analysis

Interviews were interpreted where required, audio-recorded, transcribed and analysed using the 'framework' approach, identifying key themes and their meaning.

### Results

Emerging findings show heterogeneity of feelings after the cardiac event which included anger, shock, resentment, depression, anxiety, frustration and fatalism, as well as acceptance with a tendency for Indian men to 'normalise' the event. All groups highlighted the need for an individualised long term rehabilitation programme however not all participants liked a group rehabilitation approach. Greater differences were apparent in psychological adaptation by socio-economic circumstances, including prior work status than by ethnic group, with returning to work presenting a particular challenge for some.

### Conclusions

There were few differences in the psychological adaptation experienced after the cardiac event between the ethnic groups. The heterogeneity in views and experiences related more to the socio economic background, age and work status of the participants. Rehabilitation programmes should be tailored for individuals and include specific support for returning to work.

## 7. Developing a Taxonomy of Techniques to Harness the Placebo Effect in UK Primary Care

Felicity Bishop, Beverly Coghlan, Adam Geraghty, Hazel Everitt, Paul Little, [George Lewith](#)  
University of Southampton

### Introduction

Harnessing placebo effects in clinical practice is contentious and requires robust scientific study. We aimed to develop a taxonomy of methods of generating placebo effects.

### Method

We conducted a systematic review of 125 clinical trials/ placebo studies, identifying all procedures used on placebo recipients. Procedures that we evaluated as plausible contributors to placebo analgesia were added to the taxonomy; we surveyed 21 placebo experts to ensure comprehensiveness. We then used nominal group technique to obtain 20 patients' and 22 clinicians' views on primary care applications of these procedures.

### Results

The taxonomy comprises 29 techniques grouped under 5 domains: patient (n=7 techniques); practitioner (n=3); healthcare setting (n=4); treatment (n=9); and patient-practitioner relationship (n=6). GPs and patients expressed diverse views; analysis suggested that techniques based on changing how GPs interact with patients were more acceptable than techniques involving deception or placebo treatments.

### Conclusions

This taxonomy can guide further research on translating scientific understandings of placebo effects into clinical practice, to benefit patients. Some methods for harnessing placebo effects in primary care appear to be acceptable to GPs and patients and could be prioritised in future research.

## 8. Effect of primary care consultation for knee problem on pain and function - application of propensity scores

[Milisa Blagojevic-Bucknall](#), Kelvin Jordan, George Peat  
Keele University

### Background/Objectives

Estimating treatment effects using observational data may lead to biased and imprecise estimates due to confounding by indication (decision on treatment is related to risk of outcome). An approach based on propensity scores (PS- the likelihood of receiving treatment given patient characteristics) may help overcome this. The aim was to use PS to investigate the effect of consulting primary care for knee problems on long term outcome of pain.

### Method

600 participants were surveyed at baseline and four follow-up points spanning 6 years, with linked medical record data. Therefore repeated measures were available for exposure (consultation), outcomes (pain, function) and covariates. PS for consultation was estimated at each time point and via multilevel model. Consulters and non-consulters were matched on PS in order to adjust for the likelihood to consult in the final models estimating association of consultation with pain and function. Traditional multivariable regression was also applied for comparison. Sensitivity analyses assessed impact of omitting influential variables from the analyses.

### Results

Unadjusted models revealed that those who consulted had significantly worse pain and function. This remained true for function but not pain following PS (regardless of estimation process) and multivariable adjustment. Estimates following PS adjustment were closer to the null with smaller standard errors compared to multivariable adjustment. PS adjusted effect of consultation was more robust to omission of influential variables than multivariable regression.

### Conclusion

Propensity scores should be considered whenever plausible when estimating treatment effects using observational data, including repeated measures study designs.





## 9. Why do parents of preschool children attend A&E departments with minor illness? A qualitative synthesis

Leah Bowen, Alison Heawood, Sarah Purdy  
University of Bristol

### Objectives

To understand the reasons that parents of preschool children present directly to the Emergency Department for minor illnesses.

### Method

A systematic search of qualitative literature was undertaken. Synthesis of identified work was analysed using a thematic approach.

### Results

Parents visited A&E departments because of a perceived clinical need. Parents are not able to confidently assess the severity of their child's condition and/or have a low threshold for consulting.

Symptoms were the primary worry for parents. Commonly breathing difficulty and fever. The persistence of symptoms and failure of the illness to respond to home treatments typically triggered a request for care.

The decision about attending A&E depended on parents' knowledge and confidence in care providers. Many found primary care too difficult to access (long appointment times, short-opening hours, unable to see a particular doctor etc.) while others felt that A&E provided superior care and allowed their child to have all the tests and procedures that they believed were necessary.

Rather than navigating the primary care system that many found too frustrating, and compounded by the belief that the GP could well refer families to hospital anyway, parents felt that primary care providers represented an unnecessary intermediary and preferred to directly attend A&E.

### Discussion

There appears to be some misunderstandings among parents regarding appropriate service use and knowledge of expertise available in primary care. There also appears to be a genuine service issue surrounding access in primary care which if addressed could reduce A&E attendances for minor illnesses in young children.

## 10. CANCER Diagnosis Decision Rules Study (CANDID)- An overview by the Study Manager

Susan Broomfield, Paul Little  
University of Southampton

### Objectives

To identify the best combination of symptoms and examinations for GPs to use to predict which patients may go on to develop lung or colorectal cancer.

Prospective diagnostic cohorts are being recruited to develop and validate Clinical Prediction Rules for each cohort. The incremental utility of incorporating additional measures (e.g. genetic, inflammatory and lifestyle information including smoking and alcohol status) in the prediction models will be explored.

### Method

Two prospective cohorts of patients presenting in primary care with lung and colonic symptoms are being recruited. We have developed simple web-based clinical proformas and will follow up patients in National Cancer Registries and GP records to ascertain cancer cases.

Eligible patients enter the study period on the date they present to their general practitioner with lung or lower bowel symptoms consistent with those identified for inclusion in the appropriate cohort. Patients are invited to provide additional measures (e.g. genetic, smoking, dietary, and alcohol history) - but these are optional to ensure no effect on recruitment and the most generalisable sample possible.

### Results

To date recruitment has only been opportunistic and has 228 in the lung and 263 in the colorectal cohort. To enable additional recruitment based on mailed invitations the study has developed MIQUEST search capability which is currently being implemented.

Conclusion: Recruitment is going well in some of the 8 academic centres, and the protocol is feasible.

## 11. Urinary bacterial resistance to antibiotics in children: NIHR-SPCR doctoral fellowship 2013 to 2016

Ashley Bryce, Alastair Hay, Ceire Costelloe, Mandy Wootton  
University of Bristol, Queen Mary University of London,  
Public Health Wales

### Objectives

My doctoral fellowship aim is to examine urinary bacterial resistance to antibiotics in children. We will conduct two systematic reviews exploring:

1. Prevalence and risk factors for antimicrobial resistance (AMR) in paediatric urinary bacteria.
2. Faecal carriage of bacterial AMR in children.

These reviews will inform the analysis of an observational study which is an investigation of urinary AMR in children (<5 years) presenting to primary care with acute undifferentiated illness using data previously collected from the NIHR funded Diagnosis of Urinary Tract Infection in Young children (DUTY) study. This study, known as DUTY-PCAR (Primary Care Antibiotics and Antibiotic Resistance) will build on previous successful NSPCR funding in this area to investigate prevalence of, and risk factors for, AMR.

### Methods

Systematic Reviews will be conducted according to PRISMA guidelines and will explore:

1. Epidemiology of, and risk factors for, AMR in urinary isolates from children.
2. Epidemiology of AMR in the faecal flora of healthy children.
3. The relationship between antibiotic prescribing and AMR in faecal bacteria.

DUTY-PCAR will conduct sensitivity testing on all DUTY urine isolates, in addition to bacterial typing and AMR genotypic testing. Risk factor information will be obtained from DUTY original case report forms complemented by data on antibiotic exposure from children's primary care medical notes.

### Results/Conclusions

The results from this study will provide new knowledge in an under-researched population; will inform clinicians regarding the impact of routine antimicrobial use; and help them make better informed decisions regarding the appropriate use of antibiotics for children.

## 12. Understanding the causes of miscommunication in Primary care consultations for children with Acute Cough: early findings from the Unpac study

Christie Cabral, Rebecca Barnes, Jenny Ingram, Patricia Lucas, Niamh Redmond, Joe Kai, Alastair Hay, Jeremy Horwood  
University of Bristol, University of Nottingham

### Background

Acute respiratory tract infections (RTI) in children are the most common reason parents consult primary care in the UK. There is clinical uncertainty around identifying those cases for which antibiotics are appropriate which contributes to over-prescription. Parents report being confused by RTI information and advice received during consultations and feel their concerns are not always addressed. Misunderstandings in the consultation can contribute to unnecessary antibiotic prescription and future consultations. This study is examining videos of primary care consultations for children with RTI in order to understand how shared understanding or misunderstandings came about.

### Methods

Data were drawn from 60 videos of primary care consultations for children aged 3 months to 12 years collected in 6 primary care practices selected from socio-economically contrasting localities. A framework for analysis is being developed using the parent satisfaction and enablement scores (collected at the time of videoing) and the diagnosis and treatment decisions. The nature and distribution of communication behaviours will be examined using conversation analytic methods in order to understand whether these differ between consultations with high and low parent satisfaction, or high and low parent enablement, or consultations with different diagnoses or treatment decisions.

### Results

Analysis is ongoing.

### Discussion

Findings will be discussed in relation to previous work on communication within these consultations and implications for clinician communication training will be identified.

### 13. Birmingham Atrial Fibrillation Treatment of the Aged- Follow-Up Study

Hollie Caulfield, Kate Fletcher, Jonathan Mant  
University Of Birmingham, University Of Cambridge

#### Background

BAFTA was a Randomised Controlled Trial of warfarin versus aspirin for stroke prevention in people aged 75 and over with a diagnosis of atrial fibrillation (AF). 249 practices in the UK randomised 973 patients, with a further 467 non-randomised patients being followed up through medical record review only (total 1440 patients). Follow-up was for an average of 2.7 years. BAFTA found that there were fewer primary events in patients assigned to warfarin than in those assigned to Aspirin.

#### Aim

This study will follow up the original 1440 patients to increase the average follow up to 9 years. Aims are to show: longer-term effects of anticoagulation treatment and incidence of haemorrhage (as compared to antiplatelet/ no therapy) in terms of mortality and risk of cardiovascular events; long-term adherence to anticoagulation therapy; and long term survival.

#### Methods

Miquet searches of patient electronic medical records for major vascular events; haemorrhages and drug history will be carried out. Mortality data will be obtained from MRIS. Patients no longer registered with original practices will be traced via NHS numbers. 'Intention to treat' and 'on treatment' analyses will be performed for the randomised and non-randomised cohorts. Analyses will compare all-cause mortality, stroke and vascular event rates, and haemorrhage rates.

#### Results/Conclusions

Data collection is ongoing. To date 143 practices covering 783 patients have begun their searches; 52 have returned data. Data collection will be completed by September 2014 and the results will be available at the end of the year.

### 14. Application of causal inference methods (MSMs) to electronic health records

Edmore Chamapiwa  
University of Manchester

The fundamental problem of causal inference in both experimental and observational studies is that it is impossible to simultaneously expose a subject to both treatment and control conditions, since only one of the two possible conditions can be observed at a given time. Randomised controlled trials address this through randomisation, but not all research questions can be addressed using RCT designs. Routinely collected observational data (such as the primary care databases) is being increasingly used for research purposes. To infer on causality using observational data, structural causal models have been developed. One such class of structural causal models, Marginal Structural Models (MSMs), has an appealing attribute of being able to give unbiased estimates of the causal effect of a time varying treatment in the presence of time varying covariates which are both mediators and confounders (Robins, 1998). MSMs would appear to offer a number of advantages over more traditional methods for analysing complex longitudinal data, including many topics in primary care. However, MSMs are useful models for causal inference provided their assumptions are not violated, namely: no unmeasured confounding, positivity, consistency and correctly specified models. This PhD research work is evaluating statistical methods for validating these assumptions and for mitigating violations of these assumptions. This presentation reports on applications of these methods to simulated and real primary care data (e.g. diabetes control study data from CPRD). The overall objective of this PhD is to develop methods and strategies for the optimal application of MSMs to clinical topics in primary care.



## 15. Health Related Quality Of Life in gout: cross-sectional analysis from a prospective cohort study

Priyanka Chandatre, Chrisian Mallen, Sara Muller, Jane Richardson, Samantha Hider, Keith Rome, Ed Roddy  
Keele University, Keele, Health and Rehabilitation Research Institute, Auckland University of Technology, New Zealand

### Objectives

To investigate the cross-sectional associations between socio-demographic, comorbid and gout characteristics and HRQOL using the Gout Impact Scale (GIS) and generic questionnaires.

### Methods

1805 patients with gout consultations or prescriptions for colchicine or allopurinol were mailed a questionnaire to ascertain self-reported gout characteristics, comorbidities and HRQOL. Associations between HRQOL and independent variables were assessed in linear regression models (adjusted for age, gender, socio-economic status and comorbidities).

### Results

1184 completed questionnaires were received (adjusted response 65.5%). Worse generic and gout-specific HRQOL was seen in females, current or polyarticular gout, increasing attack frequency, comorbidities (stroke and renal failure), anxiety, depression, body pain, obesity, no further education, and highest neighbourhood deprivation ( $p < 0.05$ ). Those taking allopurinol had greater Health Assessment Questionnaire Disability Index (HAQ-DI) disability but lower GIS unmet treatment need. Using the GIS, poor HRQOL was seen with hyperuricaemia, non-Caucasian ethnicity and being unmarried/living alone.

On multivariable analysis attack frequency, polyarticular gout, allopurinol use, current gout attack and anxiety remained significantly associated ( $p < 0.05$ ) with GIS. Body pain and depression remained associated with GIS ( $p < 0.01$ ), Physical Function 10 (PF10,  $p < 0.01$ ) and HAQ-DI ( $p < 0.01$ ), whilst alcohol frequency was associated with PF10 ( $p < 0.01$ ) and HAQ-DI ( $p < 0.01$ ).

### Conclusions

Gout characteristics were associated only with gout-specific HRQOL and frequency of alcohol intake only with generic HRQOL measures. Pain and depression were associated with both types of measure. Use of the GIS and generic questionnaires together may provide the optimal chance of detecting gout-specific and other characteristics affecting HRQOL.

## 16. Gout - 'not something you brag about'. A qualitative study of Health Related Quality of Life in gout

Priyanka Chandatre, Christian Mallen, Sara Muller, Jane Richardson, Samantha Hider, Keith Rom, Ed Roddy  
Keele University, Auckland University of Technology, New Zealand

### Background

Gout is the commonest inflammatory arthritis affecting 1.4% of the population in the UK. We conducted focus group interviews to gain an in-depth understanding of how gout and its treatments affect HRQOL from the patients' perspective.

### Objectives

To explore the influence of gout and its treatment on HRQOL.

### Methods

A sub-sample of 17 participants (16 males; range 51-85 years) was selected from a primary care gout cohort according to attack frequency and treatment with allopurinol. All interviews were conducted by a single moderator, tape recorded and transcribed verbatim. Thematic analysis was conducted independently by three reviewers until no new themes were detected.

### Results

Physical health was affected due to pain, swelling, tiredness and lack of sleep. Fear of pain worsening on activity caused reduced mobility and dependence on others. Lack of empathy and understanding of the severity of symptoms by physicians, family and friends caused feelings of loneliness. The unpredictable nature of attacks made it difficult to make commitments or plan for the future. Although participants recognised that treatments can improve HRQOL by reducing pain and swelling, treatments were thought to cause embarrassment (diarrhoea due to colchicine), additional health problems (kidney problems due to non-steroidal anti-inflammatory drugs) and inconvenience (lifelong 'pill-popping' associated with allopurinol). Too many dietary restrictions curbed enjoyment of life.

### Conclusions

Our study highlights the major burden of gout on psychological HRQOL in addition to physical HRQOL found in quantitative studies. Clinicians should recognise and address the impact of gout on psychological well being.

## 17. The mediation of social influences on smoking cessation and awareness of the early signs of lung cancer

John Chatwin, Caroline Sanders, Andrew Povey, Adam Firth, Tim Frank, Anne Kennedy, Richard Booton, Phil Barber  
University of Manchester, Lancashire, University of Southampton, Dorset, Wythenshawe Hospital

### Introduction

Whilst there has been no clear consensus on the potential for earlier diagnosis of lung cancer, recent research has suggested that the time between symptom onset and consultation can be long enough to plausibly affect prognosis. We present findings from a qualitative study involving in-depth interviews with patients who had been diagnosed with lung cancer (n=11), and people who were at heightened risk of developing the disease (n=14).

### Methods

A grounded theory methodology was drawn upon to conduct thematic and narrative based analysis.

### Results

We focus on three main themes which emerged from the study: i) fatalism in pathways to help seeking and the process of diagnosis; ii) Awareness of smoking risk and response to cessation information and advice. iii) The role of social and other networks on help seeking. Key findings included: poor awareness among participants of the symptoms of lung cancer; the perception of lung cancer as part of a homogenisation of multiple illnesses; ambivalence about the dangers of smoking; close social networks as a key trigger in help-seeking.

### Discussion

We suggest that future smoking cessation and lung cancer awareness campaigns could usefully capitalise on the influence of close social networks, and would benefit from taking a 'softer' approach.

## 18. Patient factors which predict prescription of allopurinol in primary care: a cross-sectional study in the Clinical Practice Research Datalink (CPRD)

Lorna Clarkson, Samantha Hider, John Belcher, Carl Heneghan, Christian Mallen  
Keele University, University of Oxford

### Objectives

Current evidence suggests that with persistent adequate suppression of serum urate, gout can be considered a "curable" disease, unlike other inflammatory arthritides but that only a minority of gout patients receive urate lowering therapy (ULT). We aimed to determine which patient-related factors predicted prescription of allopurinol (the most commonly used ULT) in primary care.

### Methods

The electronic patient records from the CPRD for 8105 patients with gout managed in primary care were examined, and logistic regression used, to calculate the odds ratio of prescription of ULT according to age, gender, comorbidities and consulting behaviours.

### Results

Only 3246 (40%) patients were prescribed allopurinol at any point following diagnosis of gout. History of kidney disease, BMI >25 and increasing number of consultations for gout, number of other prescription items, and age at diagnosis of gout all predicted increased OR of prescription of allopurinol. Male gender, and increasing Charlson co-morbidity index, number of all prior consultations and age at time of prescription of allopurinol all predicted reduced OR of prescription of allopurinol.

### Conclusions

These results refute previous suggestions that low rate of prescription for allopurinol is related to GP's anxieties about renal function, since history of CKD predicts increased odds of receiving allopurinol. Further research is required to establish why those with increasing co-morbidity and age, potentially at greatest risk of negative health outcomes, and men, the majority of gout patients, have reduced odds of receiving ULT and how prescription of ULT in primary care can be targeted at those likely to benefit most.

## 19. The feasibility and acceptability of regular weighing of pregnant women by community midwives to prevent excessive weight gain: RCT

Amanda Daley, Kate Jolly, Amanda Lewis, Sue Clifford, Sara Kenyon, Andrea Roalfe, Susan Jebb, Paul Aveyard  
*University of Birmingham, University of Oxford*

### Introduction

Pregnancy is a critical period for the development of later obesity. Regular weighing of pregnant women is not currently recommended in the UK. This study aimed to demonstrate the feasibility of regular weighing by community midwives (CMWs) as a potential intervention to prevent excessive gestational weight gain.

### Method

Low risk healthy and overweight pregnant women cared for by eight CMWs were randomised to usual care or usual care plus the intervention at 10-14 weeks of pregnancy. The intervention involved CMWs weighing and charting weight gain on an IOM weight gain chart, setting a weight target and giving brief feedback at antenatal appointments. The focus of the study was on process evaluation outcomes. Data on other outcomes were also collected including gestational weight gain. We interviewed women and CMWs about their views of the intervention.

### Results

CMWs referred 123 women, 95 agreed to participate and 76 were randomised. Over 90% of women were weighed at 38 weeks of pregnancy demonstrating high follow up. There was no evidence the intervention caused anxiety. In the interviews most women commented they had found the intervention useful in encouraging them to think about their weight and believed it should be part of routine antenatal care. CMW's felt the intervention could be implemented within routine care without adding substantially to consultation length.

### Discussion

Pregnant women were keen to participate in the study and the intervention was feasible and acceptable to both pregnant women and CMWs. An effectiveness trial is now planned.

## 20. Trends of substance misuse and treatment recorded in England and Wales General Practice (1994-2012)

Hilary Davies, Irene Petersen, Irwin Nazareth  
*University College London*

### Background

Illicit drug use is a multifaceted public-health problem. The United Kingdom has one of the highest prevalence of illicit drug use in Europe. There has been an overall reduction of overall illicit and problem drug use and in the UK over the past 10 years. People who use illicit drugs often seek help from their GP. The aim of the study was to investigate the recording rate of illicit drug use and pharmaceutical treatment in primary care settings.

### Methods

A cohort (16-64 years) was extracted from The Health Improvement Network (THIN). First recording rate of illicit drug use and pharmaceutical treatment was estimated for each calendar year (1994-2012). Poisson regression was fitted to calculate Incidence Rate Ratios (IRR).

### Results

We identified 35,508 people with a record of illicit drug use and 10,869 individuals with prescriptions for pharmaceutical treatments. Males (IRR 2.02, 95%CI:1.97–2.07), people aged 16-24 (16-24 versus 45-64: IRR 6.68, 95%CI:6.39–6.99) and the most deprived (IRR 4.17, 95%CI:3.98–4.37) were more likely to have a record of illicit drug use. Males (IRR 1.23 95%CI:1.18-1.28), in the age-group; 25-34 (25-34 versus 45-64: IRR 2.17 95%CI:2.03–2.33) and the most deprived (3.92 95%CI:3.58–4.30) were the groups more likely to receive pharmaceutical treatment.

### Conclusion

GPs in UK record illicit drug use and some individuals receive pharmaceutical treatment. The demographics agree with national surveys. However, more individuals are being treated in community drug clinics than in primary care. GPs could enhance their role in identification and possible treatment of illicit drug users.



## 21. Liver Disease Early Detection Study (LDEDS)

Magdy El-Gohary, Michael Moore, Sophia Haynes, Nick Sheron

*University of Southampton*

### Introduction

Mortality from liver disease has seen a five fold increase from 1970 to 2010. The management of most cases of developing liver disease involves lifestyle intervention and behavioural change. Recently developed biomarkers for the detection of liver fibrosis have been shown to have good prognostic accuracy in over 1000 patients, categorising patients into red, amber and green; depicting high risk, possible risk and low risk of liver fibrosis/cirrhosis respectively. A recent study ALDDeS involved testing patients in a primary care setting at risk of liver disease using these biomarkers. Subsequent reduction in alcohol intake was seen in over half of patients with the greatest reduction seen in the red group. An independent technique to assess for liver fibrosis is now available, liver elastography, which is a non-invasive assessment of liver elasticity.

### Methods

Patients who were found to have an amber or red test from the ALDDeS study are invited back to have a repeat blood test in addition to being offered liver elastography using a portable FibroScan machine. A selection of patients who had a green test are also invited. An AUDIT-C questionnaire is carried out. Results of the investigations are fed back to the patients' GPs.

### Results

Seven patients have so far been recruited into the study. All have been found to have a median elastography result of <7.5kPa suggesting no evidence of fibrosis. Blood test results are awaited.

### Conclusions

This study is very early on at the present time.

## 22. Antidepressants for Insomnia: Cochrane Review to assess the effects, safety and tolerability of antidepressants for insomnia in adults

Hazel Everitt, David Baldwin, Andrew Mayers, Andrea Malizia, Sue Wilson

*University of Southampton, Bournemouth University, University of Bristol*

### Background

Insomnia is common, 10-38% of the general population report sleep problems in the last year. It can cause daytime fatigue, distress, impairment of daytime functioning and reduced quality of life and is associated with increased mental health problems, drug and alcohol abuse and increased healthcare utilisation. Management depends on the duration and nature of the sleep problem. It may involve: treating co-existing medical problems; advice on sleep habits and lifestyle (sleep hygiene); medications and psychological therapies such as cognitive behavioural therapy.

Hypnotics (benzodiazepines and 'Z' drugs) are commonly prescribed for insomnia and are effective but the potential of addiction and dependence limits their use and NICE guidelines recommend only short term use (2 to 4 weeks). However, long-term hypnotic use remains widespread. Antidepressants are widely prescribed for insomnia despite being unlicensed for this use, and limited evidence for their effectiveness in insomnia. A significant factor is likely to be concern regarding the use of hypnotics and clinicians seeking alternative treatments for insomnia that can be used longer term. There is poor availability of psychological treatments, thus alternative medications are tried.

### Method

Cochrane Systematic Review (protocol published). We will use the rigorous Cochrane processes to assess the current evidence (or lack of it) behind the use of antidepressants for insomnia, including their efficacy, safety and tolerability.

### Results

The results will inform decisions on the use of antidepressants for insomnia and highlight areas for further research.

## 23. How does home monitoring reduce blood pressure: a systematic review

Ben Fletcher, Jamie Hartmann-Boyce, Lisa Hinton, Richard McManus

*University of Oxford*

### Introduction

Evidence from randomised controlled trials demonstrates the positive effect of home blood pressure monitoring (HBPM) on blood pressure (BP) control in hypertensives. However, the mediators through which HBPM improves BP are yet to be fully established; including the impact of HBPM on medication adherence and lifestyle factors in patients, and the prescribing behaviour of general practitioners.

### Method

A systematic review of randomised controlled trials where HBPM, either alone or as part of a complex intervention, is compared to control or usual care. Outcome measures of interest are medication adherence, medication persistence, and lifestyle factors including diet, physical activity and smoking, and where available, their links to BP change.

### Results

A narrative synthesis of available data will first be carried out, stating whether statistically significant differences in outcomes were seen between experimental groups. Meta-analysis and/or meta-regression will be conducted depending on levels of clinical and statistical heterogeneity. Meta-analysis will be carried out, if appropriate, comparing studies where HBPM alone was compared to no intervention; or where HBPM as part of a complex intervention was compared to no intervention; and where the same outcome measures were used across studies (i.e. pill count or self-reported measure for adherence).

### Discussion

The review will further explore the mechanisms through which HBPM leads to better BP control in hypertensives. The results will help clarify targets for future investigations of HBPM, particularly those mediating factors that are shown to be positively affected.

## 24. Exploring patients' understanding of emotional distress and reasons for consulting primary care

Adam Geraghty, Miriam Santer, Jenny McSharry, Lucy Yardley, Paul Little, Ricardo Muñoz, Michael Moore

*University of Southampton, Palo Alto University, USA, University of Manchester*

### Introduction

Patients frequently present to primary care experiencing emotional distress that does not meet the criteria for psychological disorder. Despite being distinct from major depression or anxiety, emotional distress still causes significant suffering, functional impairment, is associated with frequent attendance, and can lead to psychological disorder. This research project explores patient's conceptualisations of their distress experience and their expectations of their GP.

### Methods

Twenty-three semi-structured face-to-face interviews were conducted with patients who had presented to primary care experiencing distress, and their GPs had not diagnosed disorder or prescribed antidepressants. Interviews were transcribed verbatim and analysed using inductive thematic analysis.

### Results

Data analysis is on going at present. Preliminary findings indicate that patients distinguish between emotional distress and emotional disorders such as depression and were wary of the prescription of antidepressants. Patients appeared to be aware of specific stressors causing their distress and narratives around coping and a failure to cope were common.

### Discussion

Understanding distressed patients' experiences and their expectations of primary care may help GPs distinguish emotional distress from psychological disorder. This, in turn, may improve the targeting of appropriate care options for patients presenting with psychological symptoms.

## 25. Assessing the needs of stroke survivors in the UK: GPs perspectives

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*University of Oxford*

### Introduction

Of the one million stroke survivors in the 100,000 are resident in care homes. A regular structured assessment of care needs for all stroke survivors is recommended in guidelines (Royal College of Physicians and NICE) and is particularly important for residents in care homes given their multiple dimensions of need. After hospital discharge, medical care to patients with stroke is provided by primary care, yet there is little data reported on how well care complies with guidelines, and particularly in the care home setting, who carries out reviews. We set out to establish the current primary care practice concerning 6 and 12 month reviews after acute stroke, for patients who are community dwelling or in care homes.

### Method

Cross sectional online survey of general practitioners (GPs) and care home managers (both residential and nursing homes). The survey has been developed based on the awareness-to-adherence model of clinical guideline compliance and it will be distributed to 800 respondents (600 GPs and 200 care home managers) after being piloted.

### Results

The results of this survey will provide information about the adherence and its determinants to guidance for needs assessment in stroke survivors, as well as the main reasons for professional adherence or lack of it, identifying key evidence gaps.

### Discussion

We will discuss the results in relation to research priorities that address the quality of care provided or coordinated by GPs for stroke survivors, whether they are community dwelling or due to greater complexity, frailty and dependency, are resident in care homes.

## 26. Defining latent phenotypes of patients with hand Osteoarthritis; a fresh approach to understanding musculoskeletal conditions

Elaine Thomas, Joanne Protheroe, Danielle van der Windt, Daniel Green  
*Keele University*

### Objectives

Hand problems in older people are due to a range of conditions, with osteoarthritis (OA) being the most frequent cause of pain and disability. The aim of this fellowship is to define functional classifications of hand OA that could be meaningful in a primary care setting.

### Method

Data from a large, population-based prospective cohort study collected information on hand pain and problems at baseline and 3 years. Hand OA phenotypes were identified using Latent Transition Analysis, a longitudinal technique employed to both define sub-groups based on cross-sectional data and incorporate change over time. Variable selection was driven by previous research and advice from our Research Users Group.

### Results

From an initial set of 15 variables, the derived model included 9 variables: 3 pain, 5 function and 1 stiffness measure. The optimal model separated the population into 5 potential phenotypes at baseline: 'least affected', 'poor gross function', 'high pain during activities', 'high pain and poor gross function' and 'severely affected'. Phenotype definitions showed only slight variations over the 3 year period, mostly indicating progression in severity of problems.

### Conclusion

Phenotypes of patients with hand OA, based on brief self-report items of pain, function and stiffness have been defined. It provides evidence that there is movement between some classes, but little movement into less severe phenotypes from those in the highly affected group. Further work will include examining both phenotype definition stability and prediction of movement over time, and the content and outcome of primary care for hand OA phenotypes.



## 27. OxWATCH: Oxfordshire Women and Their Children's Health - A feasibility study

Sian Harrison, Carl Heneghan, Christopher Redman, Paul Leeson, Mary Selwood, Ingrid Granne

*Oxford University*

### Introduction

Some specific pregnancy disorders are known to be associated with increased incidence of long-term maternal ill health (e.g. late onset type 2 diabetes with gestational diabetes; arterial disease with pre-eclampsia). To what degree these later health conditions are a consequence of the woman's constitution prior to pregnancy or whether pregnancy itself triggers changes in a woman's health is unknown. This study aims to investigate which pre-pregnancy factors affect a woman's pregnancy and how pregnancy itself affects a woman's long-term health.

### Methods

The study will recruit a cohort of 12,000 nulliparous women aged 18-40 years. Baseline biophysical, genetic, socioeconomic, behavioural and psychological assessments will be conducted and samples of blood, urine, saliva and DNA will be collected. Women who become pregnant will be recalled for pregnancy and post-pregnancy assessments.

### Results

The cohort study will evaluate pregnancy and maternal health outcomes. Statistical analysis will identify pre-pregnancy and pregnancy-specific predictors of adverse pregnancy and health conditions. We are currently conducting a pilot study to assess the feasibility of undertaking the pre-pregnancy cohort. To date 80 women have been recruited; preliminary data will be available for the showcase.

### Discussion

The study will provide a comprehensive and unique health profile of women of this age and help us understand which women are likely to develop particular conditions both in pregnancy and in later life. The results will enable health care services to target those women at risk of adverse outcomes and to provide optimal care to women before, during and after pregnancy.

## 28. How do GPs manage Giant Cell Arteritis(GCA): A primary care survey

Toby Helliwell, Sara Muller, Samantha Hider, Jane Richardson, Christian Mallen

*Keele University*

### Background

Giant Cell Arteritis (GCA) is the commonest large vessel vasculitis yet a full time UK general practitioner (GP) can expect to see just 1 case every 1-2 years. However, given the potentially serious complications of GCA including visual loss, GPs need to recognise GCA early and instigate appropriate management. GCA may be difficult to identify, particularly in atypical cases. For example, headache has been shown to be absent in just under a quarter of GCA patients which may falsely reassure clinicians resulting in delayed diagnosis and potential visual loss.

### Objectives

To investigate how GPs identify GCA.

### Methods

A postal questionnaire survey of 5000 randomly selected UK GPs was undertaken. Questions included experience of diagnosing and managing patients with GCA.

Results: 1249 questionnaires were returned. The mean age of responders was 43 years and they had been qualified as a GP for a mean of 14 years (SD 9.03). 879 responders (70.4%) indicated that they had diagnosed a patient with GCA. Headache was the predominant feature (n=1071 (86%)) used to identify GCA. Other commonly reported features were visual disturbances (n=671 (53.9%)), jaw symptoms (n=420 (33.7%)) and temporal artery/scalp tenderness (n=468 (37.6%)). 21.86% (n=273) indicated that they only use headache as a symptom for identifying GCA.

### Conclusions

GPs in the UK rely overly on headache when diagnosing GCA. Educating clinicians about other presenting symptoms and atypical presentations is essential to optimise diagnosis, reduce the potential for visual loss for this patient group and to reduce potentially serious long term complications.



## 29. Validation of home blood pressure monitors in patients with atrial fibrillation

James Hodgkinson, Una Martin, Louise Beesley, Richard McManus, David Fitzmaurice

*University of Birmingham, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital, Queen Elizabeth Medical Centre, Birmingham, University of Oxford*

### Introduction

Hypertension is the most common cardiovascular disorder and atrial fibrillation (AF) is the most common clinically significant arrhythmia. Both frequently coexist and reliable and valid measurements are necessary to ensure treatment of both AF and hypertension is effective. However, blood pressure (BP) measurement in patients with AF is difficult and uncertain because of substantial BP fluctuation, and no BP monitor is currently validated for use in AF patients. Home BP monitoring offers the potential to improve BP measurement in AF as more readings can be taken, improving accuracy. The primary aim of this study is to ascertain if home BP monitoring equipment is reliable and accurate in AF, with a secondary aim to consider if a more complex self-monitoring regime involving additional measurements is necessary in this population to ensure accuracy.

### Methods

Validation studies of four home BP monitors - selected as the best performing home monitors in the general population - will be conducted in subjects with AF following both the European Society of Hypertension International Protocol (ESH-IP) protocol and the British Hypertension Society (BHS) protocol. Further to the validation studies, additional readings will be taken - a total of ten with each device - to assess variation in BP in AF, and to what extent taking extra readings can improve the accuracy of BP measurement in this population.

### Discussion

We will establish if the best performing current home BP monitors, validated and known to be accurate in the general population, can be validated and recommended in AF.

## 30. Serum uric acid and the risk of respiratory disease: a population-based cohort study

Laura Horsfall, Irwin Nazareth, Irene Petersen  
*University College London*

### Introduction

Uric acid is the most abundant molecule with antioxidant properties found in human blood serum. We examined the relationship between serum uric acid and the incidence of respiratory disease including any effect modification by smoking status.

### Methods

A cohort with serum uric acid measured between January 1st 2000 and December 31st 2012 was extracted from The Health Improvement Network primary care research database. New diagnoses of chronic obstructive pulmonary disease (COPD) and lung cancer were ascertained based on diagnostic codes entered into the medical records.

### Results

During 1,002,496 person years (PYs) of follow-up, there were 3,901 COPD diagnoses and 1,015 cases of lung cancer. After multivariable adjustment, strong interactions with smoking status were detected with significant negative relationships between serum uric acid and respiratory disease for current smokers but no strong relationships for never or ex-smokers. The relationships were strongest for lung cancer in heavy smokers ( $\geq 20$  cigarettes per day) with predicted incidence rates 97 per 10,000 PYs (95%CI; 68 to 126) in the lowest serum uric acid quintile (100 to 250  $\mu\text{mol/L}$ ) compared with a predicted 28 per 10,000 PYs (95%CI; 14 to 41) in the highest quintile (438 to 700  $\mu\text{mol/L}$ ).

### Conclusions

Low levels of serum uric acid are associated with higher rates of COPD and lung cancer in current smokers after accounting for conventional risk factors.

### 31. Experiences of kidney monitoring for early stage chronic kidney disease in primary care: findings from the ESKIMO study

Jeremy Horwood, Kristina Bennert, Julie Evans, Rosemary Simmonds, Tom Blakeman, Louise Locock, Elizabeth Murray, Gene Feder

*University of Bristol, University of Oxford, University of Manchester, University College London*

#### Introduction

Early stage Chronic Kidney Disease (CKD stages 1 to 3) is a contestable medical condition; it can be an indication of risk of poor renal function rather than a medical condition per se. Relatively few people identified with the early signs of renal impairment will progress to the later stages of kidney disease, so patients with no symptoms of an illness may be being unduly medicalised. However, there is awareness that poor renal function is a risk factor for other problems such as heart disease and is under-reported in primary care. Early stage CKD is now a condition that is included on the Quality and Outcomes Framework register so primary care professionals have to find ways to identify and manage this new group of patients. There is little current guidance for how best to tell people they have the early stages of kidney disease with its associated risks.

#### Methods

Interviews are being conducted to investigate health care professionals' experience of identification, disclosure and management of patients with early stage CKD in primary care and patients' experiences of diagnosis and understanding of risks.

#### Results

Data collection and analysis is presently ongoing.

#### Discussion

Based on findings from the interviews, we will summarise and synthesise the differing perspectives to develop guidance for GPs and produce a Healthtalkonline module on 'kidney health'. This will incorporate patients' views of being given a diagnosis of CKD and address the issues of concern to health care professionals of disclosing and managing this condition in primary care.

### 32. Features of primary care and their effect on unscheduled secondary care: a systematic review

Alyson Huntley, Dan Lasserson, Lesley Wye, Richard Morris, Kath Checkland, Helen England, Chris Salisbury, Sarah Purdy

*University of Bristol, University of Oxford, University College London, University of Manchester*

#### Background

Reducing unscheduled care use in the secondary care sector (USC) is a priority for the NHS. Our objective was to conduct a systematic review to identify studies that describe influencing factors at primary care organisation level that impact on levels of USC.

#### Methods

A search strategy was developed and run in five databases in October 2012. The review included observational studies, randomised and other controlled trials describing both in hours and out of hours services. Studies included people of any age, of either sex living in OECD countries with any health condition.

#### Results

42 studies were identified describing influencing features on emergency department (ED) visits (n=26) and emergency hospital admissions (EHA) (n=22). Patient factors associated with increased USC were increased age, reduced socioeconomic status, lower education, chronic disease and multimorbidity. Generally, better access to primary care was associated with reduced USC in the USA. However, the relationship in Europe is less clear where out of hours primary health care has existed for longer. Proximity of patients to health care strongly influences their use. The limited evidence about continuity of care suggests it reduces USC. Evidence relating to quality care markers is limited and mixed, but generally the availability of tests and specialist services reduces USC.

#### Discussion

The majority of research found was observational and from different healthcare systems. Therefore we need to be cautious as to whether modification of some of the factors identified would result in reduced use of USC.



### 33. Mistletoe in early Breast Cancer (MBC): The trials and tribulations of developing a placebo for a randomised controlled trial

Alyson Huntley, Gene Feder, MBC Research team  
University of Bristol

#### Background

A Cochrane review suggests mistletoe therapy, the most widely used complementary therapy in European cancer care may be useful in enhancing quality of life and mitigating adverse effects of cancer treatments; but placebo-controlled trials are required. We plan to conduct a pilot randomised placebo-controlled trial in the UK. Sub-cutaneous injections of mistletoe cause a local skin reaction. We sought a placebo to replicate this reaction.

#### Methods

We planned to use a widely used aluminium hydroxide (AL (OH) 3) vaccine adjuvant known to produce a local skin reaction.

#### Problems & solutions

##### Safety

Aluminium is potentially neurotoxic and ingestion has been associated with neurodegenerative conditions

Public perception of aluminium's potential toxicity is poor and could undermine trial recruitment, despite expert advice on Al (OH) 3 safety when used as a vaccine adjuvant.

Continued debate and investigations have revealed a calcium phosphate adjuvant as an alternative. This adjuvant will produce less of a skin reaction but has a much better safety profile, and will be more acceptable to trial participants.

##### Production

Vaccine adjuvants are suspensions and this requires specialised production methods and product stability needs to be established. The placebo needs to be encapsulated in glass ampoules to copy the mistletoe product.

We have identified a NHS clinical trial pharmacy support unit which is able to produce the placebo.

#### Conclusion

We are commissioning the production of the calcium phosphate adjuvant placebo and once we have the product and the stability data we can start to recruit to the pilot trial.

### 34. The REFER (REfer for Echocardiogram) Study: A Prospective Validation of a Clinical Decision Rule, NT-proBNP, or their combination, in the Diagnosis of Heart Failure in Primary Care

Rachel Iles, Clare Taylor, Andrea Roalfe, Martin Cowie,  
Richard Hobbs

University of Birmingham, University of Oxford, Imperial  
College

#### Objectives

Heart failure has a major impact on patients reducing quality and length of life, and treatment costs are high. Diagnosis is often difficult because individual symptoms and signs are generally weak predictors of heart failure (HF). This prospective, observational, diagnostic study aimed to validate the performance of a simple previously validated clinical decision rule (CDR), a natriuretic peptide assay, or their combination, for diagnosing HF in primary care. We aimed to determine if the CDR can be used in routine clinical practice to establish referral for echocardiography in patients presenting with symptoms suggestive of HF, to quantify the most reliable cut-off levels of the natriuretic peptide assay in a group of symptomatic presenting patients, and to model the cost-effectiveness of using the CDR in primary care

#### Methods

Thirty General Practices in Birmingham participated from 1st May 2011 - 31st August 2013 and enrolled 353 patients presenting with new and recent onset symptoms suggestive of HF (breathlessness, lethargy or ankle oedema of over 48 hours duration with no obvious recurrent, acute or self-limiting cause). The patients underwent clinical assessment, ECG, natriuretic peptide testing and echocardiography. An Expert Consensus panel then used a three step process to determine if the patient had HF, and patient notes were reviewed at six months and twelve months to assess data on medications, hospital and nursing home admissions, A&E attendance, referrals, presentation with new symptoms, and death.

#### Results and conclusion

The final analysis is underway and will be completed end August 2014 (final follow-up).

### 35. The cumulative incidence of Chronic Kidney Disease (CKD) in young adults (aged 18 to 40 years) with Impaired Glucose Tolerance (IGT)

Feroz Jadhakhan, Paramjit Gill, Tom Marshall  
University of Birmingham

#### Background

It is known that risk of chronic kidney disease (CKD) is elevated in patients with diabetes mellitus but it is not clear whether the risk of developing CKD is elevated in people with impaired glucose tolerance (IGT) and if so whether the increased risk is confined to people with IGT who progresses to type 2 diabetes (T2DM).

#### Objective

To systematically review literature to determine the incidence of CKD in young adults (aged 18 to 40 years) with IGT.

#### Methods

CINAHL, EMBASE, MEDLINE, PubMed, Cochrane libraries and grey literature will be systematically searched from inception to February 2014. Two independent reviewers will undertake screening search results, extraction of data, study selection and quality assessment. Studies including young adults aged (18 to 40 years) with IGT containing any of the following CKD markers will be included: Estimated Glomerular Filtration Rate (eGFR), albumin creatinine ratio (ACR), protein creatinine ratio (PCR), serum creatinine (SCr) and creatinine clearance (CrCl) levels. Studies at any time period after diagnosis of IGT and with any length of follow-up will be included.

#### Results

Relative Risks (RR) and Odd Ratios (OR) will be extracted or calculated from raw data. If possible, study results will be combined in a meta-analysis.

#### Conclusion

Results of this review will establish the evidence for the association between IGT and risk of developing CKD in young adults.

### 36. Can we understand costs and consequences of patient and public involvement in Primary Care Research?

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Keele University, University of Manchester, University of Birmingham, University College London

#### Objectives

Patient and Public Involvement (PPI) in research is seen as good practice and is a requirement of NIHR funding. However, there is variability in PPI practice and a true understanding of the costs (financial and non-financial) and consequences (impact) of PPI is lacking. This study aims to investigate the costs and consequences of PPI within primary care research and make recommendations to the School for Primary Care Research on PPI practice. The study also aims to apply new methods of investigation, particularly the concept of 'willingness to pay' for PPI in health research.

#### Method

This mixed methods study comprises: (1) a documentary analysis, (2) electronic survey to principal investigators of SPCR funded projects (n=197), (3) self-completed mailed survey to PPI representatives involved in SPCR projects, (4) observations of SPCR project meetings with PPI involvement, (5) an exploratory 'willingness to pay' survey to NIHR funding panel members. Patients initially advised on the research question and funding application, themes for inclusion in the questionnaires, and the content and format of the patient questionnaire. Patients advised on recruitment and consent procedures also.

#### Results

The results of the documentary analysis and two surveys will be presented, together with an update on the observation and 'willingness to pay' studies.

#### Conclusion

This study will describe costs and consequences of PPI in research projects funded by the SPCR and make recommendations for good practice. We will also test out novel approaches to investigating the financial costs associated with PPI.



### 37. COPD Screener Study

Rachel Jordan, Nicola Adderley, Peymane Adab, Brendan Cooper, Alexandra Enocson, David Fitzmaurice, Martin Miller, Richard Riley

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#### Objectives

A COPD diagnosis requires confirmation with quality diagnostic spirometry, which is known to be difficult to perform repeatedly and accurately in primary care. Simple screening tests (e.g. PiKo-6, copd6) are available but not fully evaluated. A simple test with sufficient sensitivity and specificity, which could be easily undertaken in primary care, could reduce the numbers of people requiring referral to expensive spirometry services.

We aim to evaluate the performance of a simple COPD screener (Vitalograph lung monitor) as an initial screening test for COPD in primary care, administered to people reporting respiratory symptoms, compared to GOLD standard quality diagnostic spirometry.

#### Methods

We will carry out a case-control study embedded within the existing Birmingham COPD Cohort Study. A total of 496 patients, 298 patients with a COPD diagnosis (cases) and 298 patients reporting respiratory symptoms but with no COPD diagnosis (controls), will perform pre- and post-bronchodilator COPD screener tests followed by quality diagnostic spirometry by a trained researcher. Patient assessments will begin in April 2014.

We will compute test accuracy statistics and estimate the sensitivity, specificity, positive and negative predictive values for the COPD screener test, and compare these to post-bronchodilator quality diagnostic spirometry. In secondary analyses, we will: use a range of alternative thresholds to define a 'positive' screener test result, and the test accuracy at each threshold will be summarised; compare test performance using pre- vs post-bronchodilator COPD screener; and evaluate the effect of a combination of specific questions on test performance with COPD screener.

### 38. Understanding variations in outcome in COPD: use of routine primary and secondary care clinical data for over one million patients held in an electronic database: the Hampshire Health Record (HHR)

Lynn Josephs, Matt Johnson, Paul Roderick, Mike Thomas  
*University of Southampton*

#### Objectives

Can routine data be used to characterise patients with COPD, to highlight variations in healthcare provision and outcome?

#### Methods

Retrospective observational study, using patient-anonymised data held in the HHR. Prevalent cohort with COPD as at 31/12/2010 defined and described, with 2 year follow-up of processes of care and outcomes (hospital admissions, attendances, mortality).

#### Results

21,243 patients identified with COPD, mean age (SD) 71.5 (11.7) years, 55.0% male. FEV1 values available in 19085 patients (89.8%) and % Predicted FEV1 in 10236 (48.2%); median (IQR) %predicted FEV1 was 58 (43 – 72)%. FEV1/FVC ratios available in 17536 (82.5%); median (IQR) FEV1/FVC was 58.1 (47.0 – 69.0)%. Smoking status recorded in 21068 (99.2%): 37.8% 'current smokers', 51.0% 'ex-smokers', 10.4% 'never-smokers'. Over the two years, 2777 patients (13.1%) had one or more respiratory hospital admission; additionally, 1285 (6.0%) attended A+E with a respiratory complaint. 2446 (11.5%) patients died (12.2% of men, 10.7% of women,  $p < 0.001$ ). Comparing those who died with those who survived, mean (SD) age was greater (79.2 (9.8) versus 70.5 (11.6) years,  $p < 0.001$ ) and mean (SD) FEV1 was lower (1.13, (0.45) versus 1.47 (0.65) litres,  $p < 0.001$ ). Death occurred in 856 of 2777 who were hospitalized (30.8%), compared to 1590 of 18466 (8.6%) of those who were not ( $p < 0.001$ ).

#### Conclusions

Routine observational data are useful for studying variation in COPD outcomes. We highlight the high percentage still smoking and the poor prognosis of COPD, with more than 1 in 10 patients dying over 2 years (almost 1 in 3 of those hospitalised).



### 39. Does the experience of managing multimorbidity predict outcomes in patients in primary care?

Cassandra Kenning, Peter Bower, Chris Gibbons, Peter Coventry, Louise Fisher, Penny Bee, Christine Bundy  
*University of Manchester*

#### Objectives

Multimorbidity is common in primary care, but there is less clarity about the mechanisms which lead to poor outcomes in patients with multimorbidity, especially those mechanisms that might be amenable to intervention. We explored links between patient experience of managing multimorbidity, their ability to self-manage and their health outcomes.

#### Method

A prospective study design was used. We surveyed patients with multimorbidity from 4 large practices in Greater Manchester, using a range of self-report measures including measures of their clinical conditions, measures of their experience of multimorbidity and service delivery (including the MULTIPLES scale), and outcomes (measures of self-management behaviour, and self-reported health). We then assessed patients 4 months later with the same measures.

#### Results

Four hundred and eighty six patients were included (33% response rate). Measures of self-management at 4 month follow up were predicted by a range of patient characteristics, including beliefs about their conditions and experience of 'hassles' in health services. Health status at 4 months was predicted by age, and patient experience of managing their multimorbidity (as measured by the MULTIPLES scale).

#### Conclusions

The study is the one of the first quantitative demonstrations that patient experience of managing multimorbidity (including 'emotional representations', 'treatment burden', 'prioritising conditions', 'causal links' and 'activity limitations') is associated with health status in the short term. The findings can help to identify and develop interventions that might improve outcomes in patients with multimorbidity.

### 40. Health on the web: a randomised controlled trial of work-based online screening and brief intervention for reducing alcohol intake

Zarnie Khadjesari, Elizabeth Murray, Stuart Linke, Rachael Hunter, Nick Freemantle  
*UCL, Camden and Islington NHS Foundation Trust, London*

#### Introduction

An estimated 11-17 million work days are lost annually in Britain due to alcohol-related sickness, with total costs to the workplace of £6.4bn. The workplace provides an ideal setting for online screening and brief intervention, with access to a potentially large sample of adults from varying socioeconomic groups. The aim of this study was to determine the effectiveness of online screening and brief intervention for alcohol misuse within a workplace setting.

#### Methods

Employees of a large company were invited to take part in an online health check, including questions on smoking, diet, physical activity and alcohol consumption. Employees drinking above recommended limits ( $\geq 5$  AUDIT-C) were entered into the trial. The intervention group received feedback on all behaviours. The control group received feedback on all behaviours except alcohol intake. The primary outcome was past week alcohol consumption. Secondary outcomes included AUDIT, EQ-5D, days off work, number and duration of hospital admissions.

#### Results

3,375 employees took part in the health check, of which 1,330 (39%) scored  $\geq 5$  AUDIT-C. Follow-up data were collected for 80% of participants at 3 months. Participants were mostly male (75%), married (77%) with relatively healthy lifestyles. There was no significant difference between groups for any outcome. Both groups reduced their median AUDIT-C score by 1.

#### Discussion

In the context of an online health check, this pragmatic trial did not find brief advice to reduce alcohol intake when compared with no feedback. Completion of the AUDIT-C alone may have led both groups to reduce their drinking slightly.

## 41. Identifying the needs of migrant women exposed to domestic violence and the role of primary care: a systematic literature review and qualitative synthesis

Nadia Khelaifat, Ali Heawood, Gene Feder  
University of Bristol

### Introduction

Domestic violence is widespread yet remains under-researched and concealed in healthcare settings. The needs of migrant women exposed to domestic violence are particularly poorly understood and recognised. To address this, we are conducting a systematic review and synthesis of the qualitative evidence to examine the support needs of these women, including barriers and facilitators encountered within (primary) healthcare.

### Methods

The following databases were searched from inception: MEDLINE, CINAHL, PsycINFO, EMBASE, PubMed, and Web of Science. The systematic search strategy had three main concepts: domestic violence, migrant women and health care (see PROSPERO protocol: [http://www.crd.york.ac.uk/PROSPERO/display\\_record.asp?ID=CRD42014008718#.UzVxUPI\\_t5E](http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014008718#.UzVxUPI_t5E)).

Relevant qualitative papers are being synthesised using the methods of meta-ethnography.

### Results

The database search yielded a total of 5527 findings. After deduplication, 3822 findings are currently screened. Two reviewers are independently assessing titles and abstracts of identified records to determine eligibility using inclusion and exclusion criteria adopted from a previous meta-analysis. First and second order constructs will be extracted from eligible qualitative papers to develop a synthesis of migrant women's needs.

### Discussion

This systematic review and qualitative synthesis will be used to refine existing domestic violence interventions to identify and address migrant women's support needs in primary care.

### Conclusion

While there is a large body of literature on domestic violence against women, to date no synthesis of the qualitative evidence on the support needs of migrant women regarding domestic violence has been conducted. Without such a synthesis, individual studies risk being lost and may fail to inform tailored interventions.

## 42. 'I spent a week worrying about it and wondering whether to go ahead and take it' Deciding to take, or continue with antidepressants

Susan Kirkpatrick, Claire Anderson, Sue Ziebland, Tony Avery  
University of Oxford, University of Nottingham

### Introduction

Antidepressant prescribing in the UK has more than doubled in the last decade. This research explored patient narratives about depression and its treatment, in order to improve health professional understanding of what it is like to use antidepressants.

### Methods

Narrative interviews with a maximum variation sample of people taking antidepressants. Recruitment was through GPs, pharmacists, support groups, social networking sites, community groups and local advertising across the UK. Interviews were video recorded and analysed systematically using qualitative thematic methods, supported by computer software.

### Results

For some, finding the right medication was like 'waving a magic wand'. Others struggled with intolerable side effects. It could take several years to find an antidepressant that worked, and some people never had. Concerns about antidepressant use included; worries about dependency; fear of stigma; feelings of failure about needing antidepressants to enhance mood, and uncertainties about the future. A full analysis with video and audio extracts from the interviews can be seen on [www.healthtalkonline.org](http://www.healthtalkonline.org)

### Discussion

A diagnosis of depression can have an emotional impact. Taking an antidepressant can change people's view of themselves. They may struggle with the idea of needing medication to help them manage their lives. GP's and practice staff can help support patients by understanding their concerns in the context of their daily lives. Patients value time to talk with their GP, continuity of care, regular review appointments and the offer of a range of options relating to overcoming depression, as well as a prescription.

### 43. 'I'd always seen myself as invincible but suddenly I'd got this condition that wasn't going to go away': The emotional impact of a diagnosis of asthma in adulthood

Susan Kirkpatrick, Louise Locock, Helen Salisbury, Sue Ziebland  
University of Oxford

#### Introduction

In the UK, 5.4 million people currently receive treatment for asthma. While awareness of childhood asthma is high, fewer are unaware it can start in adulthood. Few research studies have explored the emotional impact of diagnosis in adulthood; how people understand the condition, and the effect on daily life.

#### Methods

Narrative interviews with a maximum variation sample of 38 people with asthma, recruited through health professionals, support groups, and local advertising. Interviews were audio or video recorded and analysed systematically using qualitative thematic methods, supported by computer software. Findings will be published on [www.heatlthalkonline.org](http://www.heatlthalkonline.org) in late 2014. This paper focuses on the subset of 18 people diagnosed in adulthood.

#### Results

Being diagnosed with asthma in adulthood can come as a shock. Commonly asthma is thought of as a childhood condition that improves over time. People find it difficult to come to terms with having a potentially life threatening condition and managing new medication. It can take people a while to accept the emotional impact of diagnosis and its implications for their daily lives.

#### Discussion

Adults diagnosed with asthma have no past personal disease experience to help them manage the condition. The process of finding the right level of medication, and learning self-management techniques can be a lengthy one. Newly diagnosed adults may need to adjust their personal sense of identity, and reassess their lifestyle and capabilities. It is important that health professionals acknowledge the emotional impact on individuals, and offer appropriate support and information.

### 44. Connect & Collaborate: Improving engagement with computerised therapies through qualitative synthesis

Sarah Knowles, Stefan Rennick-Egglestone, Gill Toms, Penny Bee, Karina Lovell, Peter Bower  
University of Manchester, University of Nottingham

#### Introduction

Computerised therapies play an integral role in efforts to improve access to psychological treatment for patients with depression and anxiety. However, although the recent HTA REACT trial identified substantial problems with uptake, there has been a lack of detailed investigation into barriers and facilitators of engagement. We aimed to review the literature on patient experience of computerised therapy, to inform future development and design.

#### Method

Systematic review and meta-synthesis of qualitative studies of user experiences of computer delivered therapy for depression and/or anxiety.

#### Results

8 studies were included. All except one were of desktop based cognitive behavioural treatments. Black and minority ethnic and older participants were underrepresented, and only one study addressed users with co-morbid physical health problems. We identified two overarching concepts - the need for treatments to be sensitive to the individual, and the dialectal nature of user experience around apparent 'common factors', with different degrees of support and anonymity experienced as both positive and negative. Fostering a sense of connection and collaboration may enable computerised therapies to be more responsive to individual users and resolve the dialectal tensions of experience.

#### Discussion

Computerised therapies can be understood to have 'common' factors, analogous to but distinct from the common factors of traditional face-to-face therapies. We aim to exploit these common factors to improve uptake and support engagement, through enhancing perceived connection and collaboration in mental health technologies. We will present our plans for further research drawing on user-led design to develop innovative and engaging mental health technologies.



## 45. Patient-Reported Outcome Assessment in Clinical Trials: A Systematic Review of Guidance for Trial Protocol Writers

Melanie Calvert, Derek Kyte, Helen Duffy, Adrian Gheorghe, Rebecca Mercieca-Bebber, Jonathan Ives, Heather Draper, Michael Brundage, Jane Blazeby, Madeleine King  
*University of Birmingham, London School of Hygiene & Tropical Medicine, London, University of Sydney, Australia, Queens University, Canada, University of Bristol*

### Objective

Evidence shows that the quality of patient-reported outcome (PRO) trial data can be undermined by inconsistencies in trial conduct. To help ensure optimal PRO data collection, PRO components should be clearly documented in the study protocol; it remains unclear, however, exactly what PRO information should be routinely included. The aim of this systematic review was to review and summarize current PRO-specific guidance for clinical trial protocol developers.

### Method

Two independent investigators searched the MEDLINE, EMBASE, CINAHL and Cochrane Library databases (inception to February 2013) for PRO-specific guidance regarding trial protocol development. Further guidance was identified via Google, Google scholar and requests to UK-registered clinical trials units and experts in the field. Two investigators independently extracted all PRO-specific recommendations from the included documents.

### Results

21,175 citations were screened, 54 of which met our inclusion criteria.

163 unique PRO-specific protocol recommendations were extracted from the included guidance documents. A further 10 recommendations were related to other supporting trial documentation. Only 2% of recommendations appeared in more than half of the documents included in the study, highlighting a lack of consensus present in the PRO guidance literature reviewed.

### Conclusions

PRO-specific protocol guidance was difficult to access, lacked consensus and therefore may be challenging to implement in practice. It is unlikely that protocol developers could effectively internalise the sheer number of different recommendations in existence. There is a need for consolidated, easily accessible, consensus-driven PRO guidance for trial protocol writers, aimed at minimising inconsistencies in PRO data collection.

## 46. Chinese herbal medicine and polycystic ovary syndrome: A randomised feasibility and pilot study in the United Kingdom (ORCHID)

Lily Lai, Andrew Flower, Michael Moore, Philip Prescott, George Lewith  
*University of Southampton*

### Introduction

Polycystic ovary syndrome (PCOS) affects 6-18% of women of reproductive age and oligomenorrhoea and amenorrhoea are cardinal symptoms. Conventional management is associated with side-effects and increased cardiovascular risk and although anecdotal evidence supports the use of Chinese herbal medicine (CHM), this requires further rigorous investigation. This study aims to explore the feasibility of conducting a randomised clinical study using CHM for regulating menses in PCOS.

### Methods

This prospective, pragmatic, practitioner and patient-blinded study randomised 40 PCOS patients with oligomenorrhoea and/or amenorrhoea into 2 parallel groups - standardised or individualised CHM granules, prescribed at 16g per day for 6 months.

Our primary outcome measure was menstrual regularity; Secondary measures were body mass index, waist hip ratio, hirsutism and quality of life. Other data included liver and kidney function, compliance and practitioner-blinding. Feasibility outcomes included suitability of primary outcome measure for main study and recruitment rate. Procedures were piloted such as pharmacy randomisation and practitioner-blinding.

### Results

30 patients (75%) completed the study, 3 were lost-to-follow-up (7.5%) and 7 withdrew (17.5%). Reasons for withdrawal were pregnancy (n=2), taste (n=3) and adverse events (n=2). Liver and kidney function at Week 4 was normal (n=35), abnormal and subsequently withdrawn (n=1) and unable to attend appointment (n=4); and at final visit was normal (n=30), abnormal (n=0) and unable to attend appointment (n=10). As the last participant visit is due March 2014, unblinded data will be available for presentation.

### Conclusions

This study will evaluate the feasibility of conducting a CHM RCT for PCOS and determine whether further research is warranted.

## 47. Modifying effects of widespread pain on treatment of index musculoskeletal conditions in primary care: a multi-trial subgroup evaluation

Martyn Lewis, Nadine Foster, Umesh Kadam, Elaine Hay  
Keele University

### Introduction

Patients in primary care often present with more than one medical complaint; it is hypothesised that treatment response in intervention studies of musculoskeletal pain at an index site may be influenced by the presence of co-morbid factors. The aim of this study was to conduct a trials subgroup evaluation to explore this hypothesis.

### Methods

A secondary analysis of five primary care trials of musculoskeletal pain disorders with a total sample of 1632 participants (back pain (Hay et al., 2005), neck pain (Dziedzic et al., 2005), shoulder pain (Hay et al., 2003), knee pain (Hay et al., 2006; Foster et al., 2007)). Participants in each trial were stratified into two groups (presence/absence of 'widespread pain' (WP or non-WP)) according to the ACR classification. Differences in treatment effect between the two groups were evaluated in respect of short (1 to 3 months) and long-term pain and disability outcomes (6 to 12 months). Longitudinal linear regression modelling including an interaction term for treatment and study group was used to estimate differences in treatment response across WP and non-WP subgroups.

### Results

Interaction effects were recorded between WP and non-WP subgroups – notably for physiotherapy versus injection (shoulder trial) over long-term outcome: the WP subgroup performing relatively worse in respect of injection treatment.

### Conclusion

Evidence is provided that a targeted approach to treatment on the basis of patient subgroups stratified according to widespread pain may yield more favourable clinical outcomes than a standard treatment across all patients. The clinical implication is that we might need to move the traditional focus away from site-specific pain treatment to a broader approach that encompasses multisite pain.

## 48. Meeting the healthcare needs of recently arrived migrants to the UK - the perspectives of primary care providers

Antje Lindenmeyer, Sabi Redwood  
University of Birmingham

### Objectives

While the complexity of providing primary care services to recently arrived migrants is well understood, little is known about the experiences of providers. Our study aims to

- Scope and map local provision of healthcare and health advice
- Identify providers' understandings of migrants' entitlements to healthcare
- Identify barriers and enablers for migrants' access to healthcare
- Identify barriers and enablers to patient-provider communication

### Method

Ongoing study using qualitative methods; funding from SPCR has been confirmed. We will interview primary care professionals and other stakeholders (Third Sector Organisations; NHS diversity leads) individually or as part of a focus group. Professionals will be purposively sampled from 3 CCG areas in Birmingham. Data will be analysed thematically, using the Framework Method.

### Results

Preliminary results will be available by the time of the conference. We will focus on barriers and enablers to access to primary care and successful communication with providers. Three expected thematic areas of 1) access, 2) communication and 3) understandings of health and illness will be further developed; we also aim to explore the role of primary care as a site of cross-cultural dialogue. Any emerging themes will be included.

### Conclusions

We anticipate that this research will add to the NSPCR theme of patient-provider interaction by focusing on health care professionals' perspectives on engaging with migrant patients and mapping factors that may contribute to good communication. Findings will shed light both on challenges faced by primary care practitioners and opportunities to improve access and care provision for migrants.

## 49. Reduced dietary salt intake in heart failure patients

Kamal R. Mahtani, Carl Heneghan, David Nunan, Nia Roberts, Igbo Onakpoya, Richard Hobbs

*University of Oxford*

### Background

Current national and international guidelines for the management of heart failure include advice to reduce salt intake. However they consistently make reference to a lack of evidence underpinning this advice. A recent systematic review and meta-analysis of randomised controlled trials concluded that low salt diets were harmful for patients with heart failure. However the review was later withdrawn and there currently exists no systematic review on this topic.

### Aim

To conduct a Cochrane systematic review of randomized controlled trials that evaluate the impact of low salt diets on patients with heart failure

### Methods

We will search the Cochrane Database of Systematic Reviews (CDSR), the Database of Abstracts of Reviews of Effects (DARE), MEDLINE (OvidSP), EMBASE (OvidSP), CINAHL (EBSCOhost); Science Citation Index Expanded (SCI-EXPANDED) and Conference Proceedings Citation Index- Science (CPCI-S) on ISI Web of Science, current trials registries and consider all randomised controlled trials (RCTs) which include a low salt diet compared to a standard diet. Primary outcomes will be cardiovascular related mortality and all-cause mortality. Secondary outcomes will include hospitalizations, change in NYHA functional class and adverse events.

### Conclusions

There currently exists no systematic review for the role of reduced dietary salt intake in heart failure patients despite it widely being advocated. We anticipate the results of our review to therefore be of high relevance to both national global policies in this field.

## 50. Behavioural Change Intervention in Improving Weaning Food for Children in rural Gambia: Phase one Formative Research

Buba Manjang, Semira Manaseki Holland, Karla Hemming, Chris Bradley, Tim Stokes, Jeroen Ensink

*University of Birmingham*

### Background

Formative research helps researchers obtained first-hand information on community's structure, knowledge and behaviour of people for the design and formulation of an intervention.

### Objectives

To identify messages for behaviour change intervention for mothers weaning food preparation and handling practices in rural Gambia.

### Methods

We applied mixed method study design using adapted tools for collection of data from mothers, grandmothers and community elders in rural Gambia.

### Results

Only 4(13%) of mothers washed their hands with soap and water before preparation of food and 2(7%) washed hands when contaminated during cooking. Mothers have knowledge regarding hygiene practices but evidence from our observation checklist shows these were not practiced.

We observed 25(83%) of mothers washed utensils in the mornings before food preparation while 28(97%) washed cooking pots before food preparation. Only 3(10%) of mothers practiced re-heating of left over or stored food before feeding child and there was an increased level of contamination for such stored food.

### Conclusion

We found four key messages for the intervention formulation, but the details along with a discussion of some of its achievements and limitations are outlined in the document.



## 51. Patient Safety Toolkit project: Piloting a patient safety toolkit in General Practices in England

Kate Marsden, Kathy Perryman, Rachel Spencer, Umesh Kadam, Lucy Doos, Sarah P Slight, Brian Bell, Anthony Chuter, Aneez Esmail, Paramjit Gill, Sheila Greenfield, Michael Moore, Ignacio Ricci Cabello, Manny Samra, Jose Valderas Martinez, Aziz Sheikh, Sarah Purdy, Stephen Campbell, David Reeves, Tony Avery

*University of Nottingham, University of Manchester, Keele University, University of Durham, Patient Partnership Group, RCGP, University of Birmingham, University of Southampton, University of Oxford, University of Exeter, University of Edinburgh, University of Bristol*

### Objectives

The development of a patient safety toolkit for use in general practices could play a major role in preventing patients from being harmed. This study involves 3 stages, each with its specific aim:

Stage 1: To identify a group of patient safety tools that represent the key attributes of safe general practice.

Stage 2: To pilot the identified tools in a sample of general practices across the West Midlands, Greater Manchester and the East Midlands, with the aim of selecting tools based on their performance, perceived effectiveness and coverage of key safety issues.

Stage 3: To implement the final version of the toolkit.

The preliminary findings from stage 2 are presented here.

### Method

The toolkit was piloted in 27 general practices. Each practice was asked to focus on a small number of tools so that detailed feedback could be obtained. A combination of qualitative and quantitative techniques was used to explore the particular attributes of the different tools.

### Results

Several core tools were identified for inclusion in the final patient safety toolkit, based on their performance, coverage of key safety issues and qualitative feedback. The core tools for stage 3 include a safety culture tool, an instrument for the identification of patients at risk of harm, a set of prescribing safety indicators and a patient safety questionnaire.

### Conclusions

The pilot demonstrated that a combination of different feedback mechanisms was a valuable and effective process for identifying tools that are acceptable and feasible for inclusion in the toolkit.

## 52. Prescribing of antipsychotics in United Kingdom primary care

Louise Marston, Irwin Nazareth, Irene Petersen, Kate Walters, David Osborn

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### Objectives

To determine the frequency of: 1) antipsychotic prescribing to people with psychosis/bipolar disorder, 2) other diagnoses including depression, anxiety and dementia 3) no record of these diagnoses. To describe prescribing patterns in these three groups.

### Method

Prescribing rates for first and second generation agents were calculated overall and by age group, sex and deprivation. Summary statistics for dose and duration were determined for the three most commonly prescribed first and second generation agents.

### Results

In total, 47,724 individuals were prescribed antipsychotics; 13,941 solely received first generation agents, 27,966 solely received second generation agents. Prescribing rates were higher in females, older people and in those from the most deprived areas. More than half those receiving first generation antipsychotics had no psychosis/bipolar record in their notes.

Thirty six percent of those prescribed quetiapine had psychosis/bipolar disorder; risperidone 46%, olanzapine 63%. In individuals without such records, common diagnoses included anxiety, depression and dementia. Median daily doses and duration of treatment were greater in those with schizophrenia (eg risperidone median daily dose 4mg; IQR 2-6: median duration 1.2 years), compared to those depression or anxiety (risperidone 1mg; IQR 1-2: 0.6 years). Between 6% and 17% of patients receiving antipsychotics had no record of any diagnoses we explored.

### Discussion

In primary care, approximately half of people prescribed antipsychotics have no record of psychotic/bipolar disorder. They are often older people, with conditions including dementia, non-psychotic depression, anxiety and sleep disorders, some have none of these.

### 53. Experience of an online self-report registry for patients self-managing/monitoring their oral anticoagulation therapy

Deborah McCahon, Jennifer Baker, Ellen Murray, David Fitzmaurice

University of Birmingham

#### Background

Whilst trial evidence demonstrates that patient self-management (PSM) of warfarin therapy is a safe and effective model of care, little is known about safety and effectiveness outside trial conditions. An online self-report registry for PSM patients could provide the opportunity to collect real world data related to utilization and patient outcomes. The usefulness of such a registry, however, depends upon the quality of the data recorded. This paper examines the feasibility of an online self-report registry and explores patient outcome data.

#### Methods

An online PSM self-report registry was developed. Participants recorded INR test dates, results and warfarin dosages using the registry over 12 months. Participants provided feedback via a survey and reported demographic data, disease characteristics and adverse events. Data accuracy was assessed through comparison of INR results recorded online with results stored on 19 INR testing devices. Percentage time spent within therapeutic range (TTR) and adverse events were examined.

#### Results

39/45 (87%) completed the study. Age ranged from 26-83 years, 44% had undertaken PSM for >5 years. 42/45 contributed 1669 INR results. 66% (25/38) reported that the registry was easy to navigate and use. Agreement between self-reported INR results and source INR data was high (99%). 83% had >60% TTR (ranged 22%-100%).

#### Conclusion

This study demonstrates that our online PSM registry is feasible, accurate and acceptable to patients. This registry could provide a valuable resource for gathering evidence of clinical effectiveness and safety of this developing model of care and be further developed to provide feedback for patients.

### 54. What is the current NHS service provision for patients severely affected by Chronic Fatigue Syndrome/ME? A national scoping exercise

Clare McDermott, Atheer al Haddabi, Hiroko Akagi, Michelle Selby, Diane Cox, George Lewith

University of Southampton, Leeds and West Yorkshire CFS/ME Service, Leeds, West Yorkshire, Dorset CFS/ME Service, Wareham, Dorset, University of Cumbria

#### Introduction

Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME) in its most severe clinical presentation can result in patients becoming housebound, wheelchair or bedbound, and unable to access outpatient services. Severe CFS/ME presents particular treatment and support needs and clinical risks. The National Institute for Health and Clinical Excellence (NICE) guidelines advise referral of patients with severe CFS/ME for specialist medical care. There has been minimal research to date on what NHS specialist provision is currently available in England for severely affected CFS/ME patients.

#### Methods

All 49 NHS specialist CFS/ME adult services in England were asked to complete a questionnaire on service provision for severe CFS/ME.

#### Results

All 49 services replied. In total, 33% of specialist CFS/ME services were unable to provide a service for housebound patients due to lack of funding. For the 55% of specialist CFS/ME services that did treat patients with severe CFS/ME, treatment provided followed the NICE Guidelines. Remaining services (12%) offered occasional or minimal support where funding allowed. There is one NHS inpatient specialist CFS/ME unit in England.

#### Discussion

Study findings highlight major inequities in access to specialist care for patients with severe presentation of CFS/ME. Where treatment was provided, this appeared to comply with NICE recommendations for this patient group.

## 55. Feasibility study for a community based intervention for individuals with severe CFS/ME

Clare McDermott, Selwyn Richards, Sarah Frossell, Diane Cox, Caroline Eyles, Geraldine Leydon, Paul Little, George Lewith

*University of Southampton, Dorset CFS/ME Service, Dorset Bespoke Project, Dorset, University of Cumbria*

### Introduction

Chronic Fatigue Syndrome/ME (CFS/ME) is characterised by debilitating fatigue, pain and other symptoms. Severe CFS/ME can lead to patients becoming housebound, wheelchair or bedbound.

Study Aims are to:

1. Establish whether the intervention can be successfully delivered as planned and how it could be improved.
2. Collect quantitative outcome data to document likely effect sizes and variability, rates of recruitment and retention to guide the design of a future RCT.
3. Explore, through qualitative interviews, the experience of patients, carers and clinicians in participation.

### Method

Design: Feasibility and acceptability study of a community based intervention for adults with severe CFS/ME, with qualitative and quantitative evaluation.

Setting: Domiciliary care delivered by multi-disciplinary teams based at specialist NHS CFS/ME services.

Participants: 20 patients diagnosed with severe CFS/ME according to Centers for Disease Control (1994) criteria.

Intervention: includes audio-recordings on recovery skills, therapist contact and social contact via peer recovery support group. Based on the concept of 'modelling success' (derived from Neuro-Linguistic Programming), adapted for use in severe CFS/ME through Patient and Public Involvement development work.

One year active intervention + one year support and follow-up.

Primary measure: Clinical Global Impression of Change

Secondary outcome measures include:

- Electronic activity and sleep measurement
- Patient reported outcome measures on fatigue, pain, physical function, anxiety, depression, self-efficacy and quality of life.
- Therapist completed outcome measures.

### Results

This study is recruiting patients in Dorset and Oxford. Results will be available in 2016.

## 56. Assessing the impact of the Patient-Doctor Depth of Relationship on general practice consultations

Samuel Merriel, Christopher Salisbury, Christopher Metcalfe, Matthew Ridd

*University of Bristol*

### Introduction

Seeing the same general practitioner (GP) is thought to be important in ensuring quality of patient care. Studies have quantified the numbers and types of problems that are raised in GP consultations, but there is little evidence about the effect of increasing depth of patient-doctor relationships on the content of consultations.

### Methods

229 consultations of 30 GPs from 22 practices were video recorded. Participants also completed Patient-Doctor Depth of Relationship (PDDR) scale (range 0-32) and the communication scale of the General Practice Assessment Questionnaire (GPAQc). Associations between PDDR and consultation length, and the numbers and types of issues and problems were analysed using regression modelling.

### Results

190 of 229 participants (83.0%) completed the PDDR and GPAQc surveys. 56.8% of these participants were female, with a mean age of 56 years. 58 participants (30.1%) had a deep relationship with their GP (PDDR = 32). Multiple regression analysis, accounting for age, gender and deprivation, showed non-significant increases in consultation length and number of problems for patients with a deep relationship with their GP, and these patients raised significantly more issues to address (mean difference 0.7 95% CI 0.1, 1.3).

### Discussion

There was some evidence that patients had longer consultations, and raised more problems and issues with GPs that they felt they had a deep relationship with. This could be due to patients feeling more comfortable raising additional issues with a GP they know well, or that more issues are addressed as the GP knows the patient's medical history.



## 57. What do patients and health practitioners think of diabetes prevention efforts offered in primary care? Findings from a qualitative systematic review on diabetes prevention in primary care

Josie Messina, Caroline Sanders, Stephen Campbell, Rebecca Morris  
University of Manchester

### Background

Type 2 diabetes is on the rise; however, many future cases can be prevented through lifestyle interventions. Primary care is an important setting for diabetes prevention because it is a patient's primary point of contact with the health care system and lifestyle advice could be integrated into care.

### Aim

To explore patient and practitioner views of diabetes prevention interventions in primary care for patients at risk of developing type 2 diabetes.

### Methods

This systematic review took on an iterative approach which included using several databases (Medline, CINAL, ASSIA) and a stacking of terms approach. Narrative and thematic analysis were utilised to identify emerging themes.

### Results

A database of 6646 records was screened, and 24 papers (qualitative and quantitative) were included in this synthesis.

Findings suggest that diabetes prevention interventions in primary care are well received by patients and practitioners; however the primary care environment and a patient's understanding and motivation for change can impact on delivery and uptake. In addition, the evidence suggests that patients do not easily understand or follow advice. The data also points to targeted and tailored advice with appropriate follow up. While primary care can be an ideal setting for prevention messages practitioner can face several challenges in providing prevention advice such as knowledge barriers, lack of time and resources for example.

### Discussion

Providing a rich account of patient and practitioner experiences in this area has the potential to highlight what is working well, as well as suggested areas for improvement in diabetes prevention efforts in primary care.

## 58. More than a 'mini'-stroke: a systematic review of fatigue, cognitive and psychological impairment following transient ischaemic attack

Grace Moran, Benjamin Fletcher, Melanie Calvert, Max Feltham, Cath Sackley, Tom Marshall  
University of Birmingham, University of Oxford, University of East Anglia

### Introduction

TIA (transient ischaemic attack) and minor stroke are characterised by short-lasting symptoms which are assumed to resolve completely. However, anecdotal evidence suggests these patients may experience ongoing residual impairments. This review aimed to: (1) investigate the prevalence and time course of fatigue, anxiety, depression, PTSD and cognitive impairment following TIA/minor stroke; (2) explore the impact on QoL, change in emotions and return to work; (3) inform future research.

### Methods

A systematic review searched electronic databases and grey literature between January 1993 and April 2013. Two authors screened studies, extracted data and assessed risk of bias. Included studies were adult TIA/minor stroke participants containing any of the outcomes: fatigue, anxiety, depression, PTSD, cognitive impairment and QoL. Random-effects meta-analysis pooled outcomes by measurement tool.

### Results

Searches identified 5,976 records, 289 remained after screening, 31 were eligible. Only 6 included studies had controls. Results suggest high levels of cognitive impairment and depression post-TIA/minor stroke which decreased over time. However, frequencies were variable between studies. Limited information was available on anxiety, PTSD and fatigue. Meta-analysis revealed measurement tool administered influenced prevalence of cognitive impairment: Mini-Mental State Examination- 17%(95% CI 7,26); neuropsychological test battery- 39%(95% CI 28,50); Montreal Cognitive Assessment- 54%(95% CI 43,66).

### Discussion

Primary care is where cognitive and psychological problems would present. Treating these impairments is important because they affect QoL and may impact stroke prevention. Biological effects (e.g. high blood pressure) and behavioural change (e.g. reduced medication adherence) may counteract preventative treatment. Findings will inform subsequent research to enhance understanding of TIA/minor stroke patients treatment needs.

## 59. Missed opportunities for the prevention of stroke and transient ischemic attack (TIA) in primary care

Grace Moran, Max Feltham, Melanie Calvert, Tom Marshall  
*University of Birmingham*

### Introduction

Primary prevention of stroke is essential, first stroke can result in severe disability/death. Primary care offers the best opportunity to implement preventative action and stroke prevention guidelines exist. However, there may be missed opportunities for prevention in primary care, where patients may not receive optimal stroke/TIA prevention despite indications for treatment. This study will investigate: the proportion of stroke/TIAs with prior missed opportunities for prevention in primary care; the relationship to patient characteristics; how proportion of missed opportunities has changed over time.

### Methods

A retrospective case review of data from The Health Improvement Network (THIN), a large anonymised database of UK primary care records. Cases are adult first-ever stroke/TIA patients with a minimum of one year data prior to the event. Four categories of missed opportunities for stroke/TIA prevention will be defined: (1) untreated high blood pressure (BP) ( $\geq 160/100$ mmHg), (2) untreated moderately high BP and high risk ( $\geq 140/90$ mmHg), (3) atrial fibrillation with high stroke risk but no anticoagulants, (4) familial hypercholesterolaemia/high risk and no lipid-modifying drug therapy. High risk is defined as a history of cardiovascular disease (CVD) or an estimated CVD risk of  $\geq 20\%$  over 10 years.

### Results

The proportion of patients with missed opportunities for prevention will be presented for the four risk factors. A logistic regression model will investigate the relationship between patient characteristics and probability of missed opportunities.

### Discussion

This study is important as it will quantify the main frequency of different types of missed opportunities and offer insight into which patient characteristics are predictive of missed prevention opportunities.

## 60. The prevention of Acute Kidney Injury in primary care: A qualitative study exploring 'sick day rules' for individuals with chronic kidney disease

Rebecca Morris, Peter Bower, Donal O'Donoghue, Andrew Lewington, Sarah Harding, Paul Roderick, Tom Blakeman  
*University of Manchester, University of Southampton, Salford Royal Foundation Trust, Salford, St James' University Hospital, Leeds*

### Introduction

Improving acute illness management, particularly for patients at increased Acute Kidney Injury (AKI) risk, has the potential to improve health outcomes and reduce healthcare expenditure. AKI is preventable through the implementation of recommendations (such as temporary cessation of certain medications) during acute illness yet this does not occur in routine practice. There is a need to explore current use of, and planning for, urgent care for people at risk of AKI.

### Method

Semi-structured interviews will be conducted with patients, GPs, practice nurses and community pharmacists within the North West of England. Using Normalisation Process Theory as a framework for data generation and analysis, interviews will explore planning for urgent care for people with early stage Chronic Kidney Disease (CKD) and the work implications of implementing an action plan for the temporary cessation of medications during acute illness.

### Results

Analysis will highlight factors influencing the planning of urgent care and the consideration of AKI prevention in everyday clinical practice. Factors that enable and constrain the implementation of recommended best practice including the temporary cessation of medicines such as ACE Inhibitors will be examined. This will include logistical issues that may arise between health care professionals, patients and carers.

### Discussion

Planning for urgent care use is necessary to address the translational gap between policy priorities and everyday clinical care. The implementation of an action plan into routine delivery of care to prevent AKI by temporarily stopping medications for people with early stage CKD with acute illnesses requires a whole systems approach.

## 61. Measuring the outcome of primary care from the patient's perspective

Mairead Murphy, Chris Salisbury, Sandra Hollinghurst  
*University of Bristol*

### Introduction

Existing patient-reported outcome measures (PROMs) fail to capture the outcomes that patients seek through consulting in primary care, which makes it difficult to assess interventions intended to improve primary care. This abstract describes phase 1 of a PhD designed to address this by developing a generic PROM for primary care. This phase describes the outcomes influenced by primary care.

### Method

The outcomes were derived from a thematic analysis. A maximum variation sample of 30 patients and eight clinicians across five Bristol health-centres were interviewed to establish the outcomes they wanted from primary care. Outcome themes emerged inductively through coding these interviews.

### Results

10 outcomes were identified. These occupy 3 domains, to be later explored through factor analysis:

1. Health Empowerment: This includes understanding, self-care, adherence to a shared plan, confidence in seeking healthcare and access to health-related support.
2. Health Status: This includes symptoms, the impact of symptoms and side-effects of medication.
3. Health Perceptions: This includes health satisfaction, health concerns, and confidence in future health.

### Discussion

Health Status is the main reason for providing healthcare, but one which primary care cannot always influence. Its continuous, co-ordinating and comprehensive nature puts primary care in a unique position to also impact domains 1 and 3.

No existing PROM covers the all outcomes described above. The PROM in development will therefore enhance the value of research into primary care, and have a resultant effect on policy, as the recommendations arising from trials and service evaluations depend on the outcome measure used.

## 62. Association of smoking cessation with diabetes control

Linda Nichols, Ronan Ryan, Amanda Farley, Andrea Roalfe, Mohammed Mohammed, Lisa Szatkowski, Tim Coleman, Richard Morris, Andrew Farmer, Paul Aveyard, Deborah Lycett

*University of Birmingham, University of Bradford, University of Nottingham, University College London, University of Oxford, Coventry University*

### Introduction

Preliminary evidence suggests control of diabetes deteriorates initially after stopping smoking. Our objective was to examine whether smoking cessation was associated with deterioration in diabetes control.

### Methods

A retrospective cohort study (01/01/05-31/12/10) was conducted using The Health Improvement Network (THIN) database, which is representative of the UK population. Inclusion criteria were: patients aged over 18, registered with their practice for at least one year on 01/01/05, diagnosed with type 2 diabetes mellitus (T2DM) and whose last recorded smoking status before 2005 was current smoker. An adjusted multilevel regression model was developed to investigate the association between change in HbA1c and stopping smoking.

### Results

10,692 adults with T2DM were current smokers at 1st January 2005. Of these, 3,131 (29%) quit smoking and remained abstinent for one year or longer. After adjustment for potential confounders, patients who quit smoking had a mean post-quit increase in HbA1c of 2.3mmol/l (95% CI 1.91 to 2.77,  $p < 0.001$ ) that persisted for three years. The deterioration was not mediated by weight gain.

### Discussion

Smoking cessation is associated with deterioration in glycaemic control in people with type 2 diabetes that persists for three years and appears not to be caused by weight gain. The rise in HbA1c is minor for each patient and clinician but will substantially increase microvascular complications in the whole population, which could be prevented by prompt action to improve glycaemic control on cessation.



## 63. Blood CEA levels for detecting recurrent colorectal cancer in primary care: a Cochrane Diagnostic Test Accuracy Review

Brian Nicholson, Beth Shinkins, Indika Pathiraja, Rafael Perera, David Mant  
University of Oxford

### Introduction

30-50% of patients will develop recurrence following curative surgery for primary colorectal cancer. To detect recurrence international guidelines recommend that blood Carcino-embryonic Antigen (CEA) is measured as part of an intensive follow-up regime, and recent RCT evidence suggests that CEA alone could be performed in primary care. However, there is no consensus on the optimal CEA threshold, with substantial variability in clinical practice. The most recent meta-regression of 20 studies suggests that a cut-off of 2.2µg/L provides the ideal balance between sensitivity and specificity, but this level generates a high level of false-alarms and is implemented by few clinicians.

### Methods

We have conducted a Cochrane Diagnostic Test Accuracy (DTA) review to determine the optimal single-measurement blood CEA threshold for use as a triage test to prompt further investigation for CRC recurrence after curative resection. Sensitivity analysis will investigate the influence of laboratory technique, the reference standard used, and the methodological quality of each study using QUADAS-2.

### Results

Systematic searches returned 6827 records for assessment. After the exclusion of duplicates, 3811 abstracts were screened, from which 268 full text articles were selected for detailed assessment. At the time of writing, 201 of these had been excluded, 9 were outstanding, and data from 58 included studies were extracted awaiting QUADAS-2 assessment and statistical analysis.

### Discussion

We intend to present the final results of this DTA review at the SPCR showcase.

## 64. Physical activity for the prevention and treatment of major chronic disease: an overview of systematic reviews

David Nunan, Kamal R Mahtani, Nia Roberts  
University of Oxford

### Objectives

To conduct the first overview of Cochrane systematic reviews of physical activity interventions and to contrast which are the most effective in preventing and/or treating major chronic disease.

### Methods

We will search the Cochrane Database of Systematic Reviews for systematic reviews of randomised controlled trials that have a primary focus on disease related outcome. We will restrict reviews to those in selected major chronic diseases. Two authors will independently screen search outputs, select studies, extract data and assess quality of included reviews using the assessment of multiple systematic reviews tool; resolving all discrepancies by discussion and consensus with a third author. The data extraction form will summarize key information from each review, including details of the population(s) (e.g. disease condition), the context (e.g. prevention, treatment or management), the participants, the intervention(s), the comparison(s) and the outcomes.

### Results

The primary outcomes of interest are prevention of chronic disease and/or improved outcome, treatment or management of chronic disease. These outcomes will be summarised and presented for individual chronic diseases (e.g., the change in blood pressure in hypertension or glucose control in diabetes). Secondary outcomes of interest are to describe the structure and delivery physical activity interventions across chronic disease conditions and adverse events associated with physical activity.

### Conclusion

We anticipate that our results will provide the most up-to-date data on the efficacy of physical activity for preventing and treating chronic disease and will be used to underpin worldwide guidelines, policy-makers and clinical implementation of physical activity interventions.

Additional author: Professor Carl Heneghan, University of Oxford.

## 65. The effectiveness, safety and costs of orphan drugs: an evidence-based review

Igho Onakpoya, Elizabeth Spencer, Matthew Thompson, Carl Heneghan

University of Oxford, University of Washington, Seattle, USA

### Introduction

Current evidence suggests that a greater number of orphan drugs are being approved for use in the management of orphan diseases. The objective of this review is to evaluate the effectiveness and safety of orphan drugs which have been granted marketing licenses in Europe, determine the annual costs of each drug, compare the costs of branded orphan drugs against their generic equivalents, and explore any relationships between orphan disease prevalence and annual costs.

### Methods

The EMA database will be searched to identify orphan drugs granted marketing authorizations. For each approved drug, we will examine the level of available evidence regarding effectiveness using a checklist adapted from the OCEBM Levels of Evidence. The quality and strength of the available body of evidence for each orphan drug will then be evaluated using a checklist adapted from the GRADE criteria. Two reviewers will independently evaluate the level, quality and strength of the evidence, and extract data. Disagreements will be resolved through consensus.

### Results

Results of effectiveness, safety, quality and level of evidence and annual costs will be presented in tables, and summary statistics of these will be described narratively. Scatter plots will be used to display the relationship between variables and annual costs. Where generic versions of any orphan drugs were available, bar charts will be used to compare the relative prices of generics with their generics.

### Discussion

This will summarize the main findings of the analysis, as well as focus on the implications of the results for research, practice and policy.

## 66. Can high quality General Practice reduce suicide rates? A feasibility study

Jim Parle, Lorraine McFarland, Ronan Ryan, Linda Nicols, Nick Freemantle

University of Birmingham, University College London

### Objectives

To examine general practice data to establish the extent to which unknown, non random, practice-specific risk factors contribute to the variation in suicide rates between UK general practices.

To inform a strand of health services research for the development of preventative approaches to reduce 'successful' suicide.

**Method** Data from 562 general practices in The Health Improvement Network (THIN) database will be included. THIN data will be extracted to examine variables known to be associated with risk of suicide for each case identified. This will include; year of birth; gender; socioeconomic status; lifestyle data; smoking and alcohol status; diagnosis of a mental disorder; dates of the last 3 consultations; number of consultations within 12 months prior to death; history of attempted suicide. Suicide rates will be analysed using crude and adjusted Statistical Process Control (SPC) charts.

**Results** The study will identify the frequency of known patient related risk factors for suicide and general practices characteristics. Read codes for suicide and intentional self harm will be used to identify potential cases of completed suicide. Free text fields will be searched to verify deaths not coded as suicide but which may have been due to suicide. Suicide rates will be calculated for each practice based upon the number of completed suicides and number of attempted suicides.

### Conclusions

The identification of non-random variation in suicide rates in general practice which is not explained by known patient risk factors for suicide will contribute to the development of proactive preventative approaches to reduce 'successful' suicide.

## 67. Primary Care Simulation for GP Speciality Trainees

Sandeep Singh Randhawa

*University of Birmingham, Birmingham West Midlands,  
Hollier Simulation Centre, West Midlands*

### Introduction

High fidelity simulation centre use is increasing across healthcare settings. Benefits include improved clinical care, practical competencies, safety and team-work. Emergency Primary Care is an area for future development. Thus a Work Place Based simulation training was designed for GP speciality trainees by a pilot collaboration.

### Method

1 day training course designed to include a range of urgent Out of Hour cases in simulated settings. Speciality Trainees were contacted via e-mail for recruitment.

Simulation training utilised small groups - maximum 8 trainees per session. Video recording observation and scenario debrief was used. Participants completed Pre & Post Course semi-structured questionnaire with subsequent qualitative & quantitative analysis.

### Results

- 5 simulation dates - January 2013 - March 2013
- 30 simulation scenarios
- 23 participants

Trainees felt the course was interesting and relevant to the RCGP curriculum and matched learning needs. Video feedback was also well received. Furthermore there were significant improvements ( $p < 0.05$ ) in specialist trainees self-ratings on diagnosing emergencies, out of hours consultations, telephone consultations, home visits as well as fitness to practice.

### Conclusions

Trainees significantly improve confidence and skills in emergency simulation scenarios from this training. Thus simulation can help standardise trainee experiences in Primary care and plug gaps in education/training. The use of video debrief also encourages reflection in/on-action.

Wider use of simulation in Primary Care Out of Hours training for the MRCGP curriculum as well as the CSA is advocated. Longer term follow up data would also be insightful.

## 68. Diagnosis and treatment of Gout in Primary Care: A qualitative study of patient experience

Jane Richardson, Jennifer Liddle, Samantha Hider,  
Christian Mallen, Ed Roddy

*Keele University*

### Background

Gout is the most common form of inflammatory arthritis, affecting around 1-2% of the population, and is frequently managed in primary care in the UK. Objectives: The aim of our research was to explore people's experiences of the diagnosis and treatment of gout in primary care and to investigate their priorities when consulting health care professionals.

### Methods

We carried out 43 semi-structured video-recorded interviews with a diverse sample of people with gout in the UK. Interviews were transcribed and analysed thematically. Informed consent was obtained from all participants.

### Results

Severe pain was a frequent reason for consultation and the primary concern for most patients was how best to reduce their pain. Many patients felt that their GP understood how painful the condition was although some felt GPs did not acknowledge the significance of their pain. There was a desire for more information provision at diagnosis. Patient experience of treatment varied widely, from those who were happy to take prophylaxis, through to those who wished to manage the condition through diet and lifestyle. Patients wanted more information about the long-term impacts of treatment.

### Conclusions

Understanding the broad range of patient experience of diagnosis and treatment can be helpful to both patients and practitioners. For patients, knowing more about other people's experience of various treatments can help them to make decisions about their own care. For practitioners, knowing more about patients' views and experiences may help them in supporting patient choices and adherence to prescribed treatment.





## 69. Treating acute gout in primary care. A randomised head-to-head comparison of naproxen and low-dose colchicine

Ed Roddy, Christian Mallen, Paul Little<sup>4</sup> Miriam Santer, Carl Heneghan, Tony Avery, Kamal Mahtani, Milisa Blagojevich-Bucknall, Rajnikant Mehta, Sue Jowett, Elaine Hay

Keele University, University of Nottingham, University of Oxford, University of Southampton

### Objectives

Acute gout is a common excruciatingly painful condition that is largely managed in primary care. It is most commonly treated with non-steroidal anti-inflammatory drugs (NSAIDs) which are effective but have frequent side-effects, particularly in the elderly. Low-dose colchicine is thought to be effective and well-tolerated and is recommended by the British National Formulary as an alternative to NSAIDs. GPs may be wary of low-dose colchicine because of their experience that higher doses cause intolerable side-effects. This randomised trial will directly compare the effectiveness of low-dose colchicine and naproxen for reducing pain in patients consulting their GP with acute gout.

### Methods

Participants will be recruited from up to 100 general practices. The primary outcome measure is change in pain intensity from baseline over days 0-7. Secondary outcome measures include time to complete resolution, patient global assessment of response, side-effects, use of other analgesics, and cost. Outcome measures are collected via self-complete questionnaires at 1 week and 4 weeks, and daily pain diary (days 1-7). A sample size of 200 patients per arm is required (power 90%, small between-group effect size 0.3). Repeated measures analysis will be undertaken, taking the dependent variable as the mean change in pain intensity between baseline and each of the 7 follow-up time-points. A cost-utility analysis will determine the most cost-effective treatment for acute gout.

### Results

86 practices have agreed to take part. Recruitment commenced in January 2014. In the first 4 weeks of recruitment, six participants have been recruited from the first ten participating practices.

## 70. Patient Safety Toolkit project: piloting a set of prescribing safety indicators in general practices in England

Sarah Rodgers, Tony Avery, James Barrett, Tim Morrell  
University of Nottingham

### Objectives

The aim of this study is to pilot the acceptability, technical feasibility, reliability, and validity of 23 NIHR/RCGP prescribing safety indicators to determine whether they should be included in a patient safety toolkit for use in general practices.

### Method

Practices download the prescribing safety indicators from PRIMIS Hub using CHART (Care and Health Analysis in Real Time) software, run the computer queries on their GP clinical system to identify patients at risk of medication error and upload the anonymised results to CHART online to allow for comparative analysis of at-risk patients at CCG level. Reliability and validity of the results will be established through analysis of anonymised patient level data and feedback from CCG Primary Care Pharmacists. Acceptability and feasibility will be explored using semi-structured interviews and focus groups with practice staff.

### Results

All general practices in one Nottinghamshire clinical commissioning group (CCG) have been recruited into the study (n=15) and data collection is ongoing. By the time of the conference, we will be able to present the number of at-risk patients identified for each of the prescribing safety indicators and provide details on the reliability and validity of these findings.

### Conclusions

Use of the prescribing safety indicators will make it easier for GPs to avoid some of the common medication errors made in primary care and will demonstrate a practice's commitment to patient safety. It is possible that comparative analysis at CCG level could be used to target medicines management resource to those practices with greatest need.

## 71. Understanding the delayed prescribing of antibiotics for respiratory tract infection in primary care: A qualitative analysis

Rachel Ryves, Caroline Eyles, Michael Moore, Lisa McDermott, Paul Little, Claire Ballinger, Geraldine Leydon  
*University of Southampton*

### Objectives

Respiratory tract infections (RTI) are usually brief and self-limiting, with antibiotics having little clinical benefit in most cases. Unnecessary prescriptions drain NHS resources, have serious consequences to patient health and can lead to increased antibiotic resistance. NICE guidelines recommend delayed antibiotic prescribing to help reduce prescriptions. However, this strategy is not consistently used by GPs with limited research on when, why and how delayed prescribing is used, including barriers to its use. The aims of this qualitative study were to elicit GPs experiences and views on the barriers and enablers to delayed prescribing in RTI.

### Methods

National UK prescription data were used to identify practices with high and low prescribing rates. A purposive sample of 30 GPs is planned. The full dataset and findings will be available by June 2014. So far 14 telephone interviews have been conducted. Thematic analysis was used to identify key themes.

### Results

Initial findings suggest GPs have a good understanding of delayed antibiotic prescribing; but certain barriers hinder their ability to implement this in practice, such as patient expectations and GP concerns. GPs reported that delaying prescriptions were facilitated by a strong patient-practitioner relationship. Some GPs suggested techniques such as telephone re-consultation and stamping prescriptions were useful ways to delay prescribing. Many desired training and provision of a standardised guideline from a credible source to facilitate delayed prescribing.

### Discussion

These findings are important as they indicate areas that could be addressed to support GPs on occasions when delayed antibiotic prescribing is the optimal approach.

## 72. The 3D Study: Improving the management of patients with multimorbidity in general practice

Chris Salisbury, Mei-See Man, Peter Bower, Sara Brookes, Ali Heawood, Sanrda Hollinghurst, Bruce Guthrie, Cindy Mann, Imran Rafi, Stewart Mercer  
*University of Bristol, University of Manchester, University of Dundee, Royal College of General Practitioners, University of Glasgow*

### Introduction

Despite an increasing prevalence of patients with multimorbidity, current management practices follow treatment guidelines for separate long term conditions (LTC). This can lead to issues of repetitive multiple clinic appointments, polypharmacy and adherence problems, depression and patients complain that no-one treats them as a whole person.

This NIHR-HS&DR funded study builds on previous SPRC funded projects around multimorbidity (project numbers 24,25,43,47,61,62,66) to develop, optimise and evaluate a new approach to improve the management of multimorbidity in general practice.

### Methods

This pragmatic cluster randomised controlled trial will target 1383 multimorbidity patients (defined as having 3 or more QOF registered LTCs) recruited from 32 practices around Bristol, Manchester and Glasgow. Practices cluster randomised to the intervention will implement strategies to maximise continuity of care and offer longer appointments with named GPs, '3D' reviews focussing on the 'Dimensions of Health' (patients' priorities, quality of life, and disease control), 'Depression' (assessment and treatment) and 'Drugs' (pharmacist recommendations, strategies to simplify drug regimes and improve adherence). Each practice will have a linked general physician in hospital for telephone advice. Participants will be followed up for 12 months with the primary outcome being health related quality of life (EQ-5D) at 12 months.

### Results

The study is currently in set-up phase and about to recruit pilot practices.

### Discussion

There is widespread interest in how to improve care for patients with multimorbidity. If successful, this intervention could improve the quality of life of patients, their experience of care and reduce NHS and patient costs.

## 73. An ethnographic study of unplanned admissions in heart failure

Helen Cramer, Margaret Glogowska, Rachel Johnson, Umesh Kadam, Daniel Lasserson, Sarah McLachlan, Sarah Purdy, Tom Sanders, Rosemary Simmonds  
*University of Bristol, University of Oxford, Keele University*

### Objectives

To gain a greater understanding of factors underlying unplanned hospital admissions for heart failure, and to identify opportunities to avoid or reduce such admissions.

### Method

A multi-site longitudinal approach was taken, employing ethnographic methods. Qualitative data were collected through non-participant observation in clinical settings, patient, carer and health care professional interviews, patient/carers diaries, and analysis of documents. The overall sample comprised 31 patients, nine carers, and 24 health care professionals. Patients were followed for periods of up to 11 months to provide rich insight into their journeys with heart failure.

### Results

Unplanned admissions resulted from complex interplay between multiple factors. At the patient level, knowledge and self-management were important, particularly where patients were managing comorbidities such as chronic kidney disease. Specialist heart failure nurses played a significant role in supporting patients with self-management, although some did not have access to this service. Patients and carers expressed the need for more information, especially on discharge from hospital. Health care professionals reported difficulties in communicating with patients about diagnosis and prognosis, and in managing comorbidities with conflicting medication regimens. The challenges involved with implementing patient education were also highlighted. There was considerable variability in the organisation of services for heart failure across the three study sites.

### Conclusion

Factors leading to unplanned admissions in heart failure are manifold and complex. Findings suggest that patient and health care professional education, the adoption of a holistic approach to patients' care, and increased access to specialist services may provide promising avenues for reducing unplanned admissions.

## 74. Self-Management Strategies of UK Cancer Survivors

Catherine Shneerson, Nicola Gale, Taina Taskila, Sheila Greenfield, Inigo Tolosa, Roger Holder  
*University of Birmingham, The Work Foundation, London, University Hospitals Birmingham, West Midlands*

### Introduction

The study purpose was to map patterns of self-management (SM) from pre-diagnosis into survivorship, and explore any associations between SM uptake and quality of life (QoL), health beliefs and ability to work.

### Methods

A cross-sectional survey was sent to 957 UK cancer survivors identified from a UK teaching hospital. Ethical approval was obtained. The questionnaire gathered information on their use of SM practices (diet, exercise, complementary therapies, psychological therapies, spirituality/religion, support groups) and whether these had changed from pre-diagnosis, during treatment and into survivorship. Their health beliefs (health locus of control), QoL (EQ-VAS & EQ-5D), and their ability to work (ability to work scale) were also measured.

### Results

Across all categories of SM uptake was highest in the survivorship phase. Sub-group analyses revealed differences relating to the categories of SM, income, age, gender, ethnicity, cancer type and treatment type. A significant positive association between SM uptake and the EQ-VAS ( $p=0.004$ ), and SM uptake and internal health locus of control ( $p=0.043$ ) was found. However no significant association was found between SM uptake and the EQ-5D ( $p=0.109$ ) or SM uptake and ability to work ( $p=0.550$ ).

### Discussion

The positive correlation between SM uptake and EQ-VAS suggests that cancer survivors using SM generally have a more positive health outlook. Likewise, those with a high internal locus of control may be more willing to make health decisions involving SM practices on a day-to-day basis. Differing levels of work ability may affect the utilisation of certain SM practices, potentially affecting occupational satisfaction.



## 75. The Prevalence and Causes of Prescribing and Monitoring Errors in UK Primary Care

Sarah Slight, Rachel Howard, Maisoon Ghaleb, Nick Barber, Bryony Dean Franklin, Anthony Avery

*Durham University, University of Hertfordshire, UCL, Imperial College Healthcare NHS Trust, University of Nottingham, University of Reading*

### Objectives

To examine the causes of prescribing and monitoring errors in general practice.

### Methods

As part of a GMC funded study, pharmacists reviewed a 2% random sample of medical records in 15 purposively selected general practices, and identified a selection of prescribing and monitoring errors to be discussed with individual prescribers. Thirty-two semi-structured interviews and six focus groups were audio-recorded, and recurring themes and concepts identified and mapped to the categories outlined in Reason's Accident Causation Model<sup>1</sup> with the aid of the computerised software QSR N-Vivo 8.0.

### Results

Seven high-level categories of error-producing conditions were identified: the prescriber, the patient, the team, the task, the work environment, the computer system and the primary/secondary care interface. The occurrence of prescribing errors appeared to be related to the prescriber's therapeutic training, drug knowledge and experience, knowledge of the patient, perception of risk, and physical and emotional health. GPs perceived some patients as difficult and demanding. The importance of feeling comfortable within the practice team was also highlighted. GPs reported regular periods of high workload and time pressures; this inherently stressful environment "rather than ignorance" was felt by some to contribute to errors being made. Patients often visited their GPs before hospital correspondence was received, thus resulting in many GPs trying to piece together what changes had been made with little or no information.

### Discussion

Many of the errors identified in this study could have been prevented. We believe pharmacists could provide an important role in helping GPs and practice staff prescribe safely.

## 76. ClinicalCodes: An online Clinical codes repository to improve the validity and reproducibility of research using electronic medical records

David Springate, Evangelos Kontopantelis, Darren Ashcroft, Ivan Olier, Rosa Parisi, Edmore Chamapiwa, David Reeves  
*University of Manchester*

Lists of clinical codes are the essential 'building blocks' for research undertaken using electronic medical records (EMRs) and are used to identify symptoms, diagnoses, hospital referrals, immunisations, prescribed medications and diagnostic tests. Despite accurate definitions of such medical entities being a prerequisite for valid EMR studies, the publication of clinical code lists is rarely, if ever, a requirement for obtaining grants, validating protocols or publishing research.

We evaluated the levels of transparency in clinical code list reporting in a representative sample of UK primary care database studies. Of 392 studies examined, only 35 (9%) published the entire set of clinical codes lists needed to reproduce or validate the study.

There are four main consequences of lack of transparency in clinical code use: definitions are not available for peer review; comparisons between studies of the same clinical conditions are potentially invalidated; one cannot tell if differences between studies of the same clinical topic are simply due to artifactual differences in code lists; effort is wasted by researchers in reinventing existing code lists.

To address these problems, we have built a centralised online repository ([www.ClinicalCodes.org](http://www.ClinicalCodes.org)) where EMR researchers can share and download clinical code lists, link them to different studies and annotate them with descriptive metadata. The repository will better enable researchers to build on previous code lists and compare disease definitions across studies. It will also reduce duplication, increase efficiency and facilitate tracking changes in disease definitions or clinical coding practice through time and the sharing of clinical definitions.

## 77. Self-reported somatic symptom explanations and attributions: cross-sectional findings from the screening phase of an on-going longitudinal cohort study on unexplained physical symptoms in primary care

Kethakie Sumathipala, Marta Buszewicz, Kate Walters, Louise Marston, Irwin Nazareth  
University College London

### Introduction

Up to a third of patients attending primary care experience unexplained physical symptoms (UPS). These can be distressing for patients, difficult for doctors to manage and costly. We know little about patients' beliefs on the cause of their symptoms.

### Objectives

To explore patients' symptom severity and association with self-reported explanations and attributions.

### Methods

This study was conducted as part of a screening phase for a longitudinal cohort study of outcomes of UPS. Consecutive adult attendees (aged 18 and over) at nine general practices in socio-economically diverse urban and suburban locations were approached to participate during January-December 2013. Participants completed a questionnaire that included the Patient Health Questionnaire, somatic symptom module (PHQ-15), which was used to identify general practice attendees scoring  $\geq 5$  with UPS for the cohort study. Other questions included in the screening questionnaire were for self-reported causes for the symptoms, whether the patient was consulting about these on that day, age and sex.

### Expected output

2813 (69% Female and 31% Male) patients from nine general practices in north and central London completed the screening questionnaire. 1904 had PHQ-15 scores of  $\geq 5$  (74% Female and 26% Male). The distribution of symptom scores will be presented and the explanations given by participants for their symptoms will be discussed.

### Impact

Self-reported symptom explanations and attributions can provide important insight for the management of patients with UPS in primary care.

## 78. Eliciting patient concerns (EPaC) project: GP views of trial participation and the acceptability of a brief communication intervention

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University of Southampton, Loughborough University, University College London, University of Surrey, Keele University, University of Glasgow, University of California in Los Angeles (UCLA), USA, Queensland University of Technology, Brisbane, Australia

### Objectives

Investigate GP views of participating in a study evaluating the feasibility of conducting an RCT of a brief communication intervention for GPs, designed to enhance the elicitation of additional patient concerns (APCs) within general practice. Exploring participant perspectives on:

- Eliciting APCs in general practice.
- The intervention utility.
- The intervention deliverability within the study and in general practice.
- The trial processes.

### Methods

21 GPs recruited to the feasibility trial, via the PCRN were invited to participate in an audio-recorded semi-structured interview (face-to-face or telephone). Fieldnotes collected during the intervention phase informed the interviews and the analysis. Transcripts were analysed using Nvivo 10 and Framework Approach.

### Results

17 GPs have been interviewed to date. The preliminary framework is organised into 3 themes: 1. 'perspectives on APCs', 2. 'experiences of trial participation' 3. 'intervention acceptability'

1. The importance of eliciting APCs, including reducing the need for multiple visits and increasing patient and GP satisfaction, was recognised. A number of factors influencing GP willingness to pursue additional concerns were identified.
2. Participants were satisfied with their trial experiences in general. Specific suggestions for improving trial experiences were identified.
3. GPs evaluated the ease of intervention delivery positively. However, some noted similarities with their usual practice and its potential for 'routine' use was not unanimously supported.

### Conclusions

The intervention was acceptable to GPs within a trial context. There was some support for the utility of the intervention as one communication tool, if used selectively rather than for all consultations.

## 79. Public perceptions of non-pharmaceutical interventions for reducing transmission of respiratory infection: systematic review and synthesis of qualitative studies

Emma Teasdale, Miriam Santer, Adam Geraghty, Paul Little, Lucy Yardley

University of Southampton

### Objectives

To review and synthesise the qualitative literature on public perceptions of non-pharmaceutical interventions such as hygiene, mask wearing and isolation that aim to reduce the transmission of acute respiratory infections.

### Methods

Five online databases (MEDLINE, PsycINFO, CINAHL, EMBASE and Web of Science) were systematically searched. Reference lists of articles were also examined. We selected papers that used a qualitative research design to explore perceptions and beliefs about non-pharmaceutical interventions to reduce transmission of acute respiratory infections. We excluded papers that only explored how health professionals or children viewed non-pharmaceutical respiratory infection control. Three authors performed data extraction and assessment of study quality. Thematic analysis and components of meta-ethnography were adopted to synthesise findings.

### Results

Seventeen articles from 16 studies in 9 countries were identified and reviewed. The synthesis showed that some aspects of non-pharmaceutical respiratory infection control (particularly hand and respiratory hygiene) were viewed as familiar and socially responsible actions to take. There was ambivalence about adopting isolation and personal distancing behaviours in some contexts due to their perceived adverse impact and potential to attract social stigma. Common perceived barriers included beliefs about infection transmission, personal vulnerability to respiratory infection and concerns about self-diagnosis in emerging respiratory infections.

### Conclusions

People actively evaluate non-pharmaceutical interventions in terms of their perceived necessity, efficacy, acceptability, and feasibility. To enhance uptake, it will be necessary to address key barriers, such as beliefs about infection transmission, rejection of personal risk of infection and concern about the potential costs and stigma associated with some interventions.

## 80. Self Measurement and management using the Internet for Lowering blood pressure in Everyday practice - The SMILE study

Tammy Thomas, Katherine Bradbury, Marta Glowacka, Lisa Ware, Sarah Williams, Paul Little, Richard McManus, Michael Moore, Lucy Yardley

University of Southampton, Bournemouth University, North-West University, South Africa, University of Oxford

### Objective

Blood pressure is one of the most common measurements taken in clinical practice, with hypertension also being the most common reason to initiate lifelong drug treatment. We wish to create systems that will allow us to identify effective self-management strategies to lower blood pressure by estimating the benefits of home measurement and tele-monitoring alongside a web-based lifestyle intervention. This intervention is intended to be effective in better targeting of treatment to those at risk by empowering patients to make decisions about their own medication and lifestyle.

### Method

This is a feasibility study to develop a preliminary version of the website and; assess the acceptability of the intervention and of randomisation; monitor recruitment rates; identify key logistic problems; and understand the experiences of clinicians and patients through qualitative enquiry. Patients are randomised to one of 3 parallel groups : group 1: usual care and management of medication; group 2: home measurement of blood pressure with an agreed medication titration plan; group 3:, as in group 2 but in addition an internet based lifestyle intervention.

### Results

Study in progress

Preliminary versions of the website have been developed. Currently 49 patients have consented from 8 practices and are being followed up. The qualitative study of patient and clinician experiences is ongoing.

### Conclusion

The study is feasible and the intervention is likely to be acceptable to participants. Based on this pilot/feasibility work, we have been awarded an NIHR PGfAR grant (DIPPS).





## 81. Alternative Treatments of Adult Female Urinary Tract Infection: Quality Control and Antimicrobial Activity of an Herbal Medicinal Product

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University of Southampton, UCL

### Introduction

Urinary tract infections (UTI) are one of the most common female conditions treated by general practitioners, and the majority of patients are prescribed antibiotics. With increased antimicrobial resistance to antibiotics, and what is a self-limiting condition, alternative treatment strategies are being investigated to alleviate the uncomfortable symptoms. The herbal medicinal product (HMP) *Arctostaphylos uva ursi* has a traditional use for treating UTI, but lacks rigorous clinical investigation. Its efficacy is now being tested in a double-blind randomised controlled trial. This study is supporting the trial through quality control analysis and antimicrobial testing of the HMP, investigation of its mode of action, and determination of an effective and safe dosing regime.

### Methods

- High Performance Liquid Chromatography helped analyse the quality of 3 commercial *uva ursi* sample extracts. Nuclear magnetic resonance will facilitate a full chemical profile.
- In-vitro antimicrobial activity of the extracts and constituents were assayed using 96-well microtiter plates, testing the minimum inhibitory concentration (MIC) at different pH against uropathogens.
- The dosing strategy was established through a literature search of the traditional use of *uva ursi*.

### Results

Two of the 3 commercial extracts contained their stated 20% arbutin content. *Uva ursi* and its compounds arbutin and hydroquinone exhibited antimicrobial activity against seven microbes including *Escherichia coli* and methicillin-resistant *Staphylococcus aureus* (MRSA); MICs ranged from 32–512 µg/mL. Hydroquinone demonstrated the greatest activity and its efficacy increased with alkaline pH.

### Discussion

Commercial HMP's are not equivalent. The quality and strength may vary according to the extraction technique.

## 82. Self-monitoring of blood pressure in pregnancy: The BuMP study

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### Objective

Raised blood pressure (BP) affects 10% of pregnancies worldwide, of which a high proportion develop pre-eclampsia. Around 15% of maternal mortality is due to pre-eclampsia so early detection and prevention is paramount. This study aimed to provide preliminary evidence that self-monitoring of blood pressure could improve the detection of gestational hypertensive disorders including pre-eclampsia, whilst involving women in their antenatal care.

### Methods

Prospective un-blinded observational pilot study of self-monitoring BP in pregnancy. Eligible women were those defined by the UK NICE guidelines as at higher risk of pre-eclampsia. Participants attended a study appointment between 12-16 weeks pregnant alongside standard antenatal care. All participants were asked to take two BP readings twice daily three times a week and record these. Participants could submit their BP readings via text message. The primary end points were: the difference in clinic and self-monitored BP readings (systolic and diastolic), and the test performance of self-monitoring in the detection of gestational hypertension and pre-eclampsia compared to standard care.

### Results

201 participants were recruited from April to December 2013 with the expectation that approximately 10-20% will develop gestational hypertension and/or pre-eclampsia. Baseline demographic data, a comparison of home vs clinic BP readings and the test performance in relation to detection of raised blood pressure will be presented.

### Conclusion

Self-monitoring of BP in pregnant women has the potential to improve the detection of gestational hypertensive disorders including pre-eclampsia. If successful, it would be applicable to many hundreds of thousands of women in the UK.

### 83. Primary care patients' views and experiences of being treated for depression: a secondary analysis of qualitative data

Katrina Turner, John Percival, David Kessler, Jenny Donovan

*University of Bristol*

#### Introduction

We aim to undertake a secondary analysis and synthesis of multiple qualitative data sets in order to describe and compare patients' views and experiences of different treatment modalities for depression.

#### Method

The data set to be analysed consists of 184 interview transcripts taken from five separate qualitative studies. These studies were all nested within different primary care-based depression trials and entailed conducting in-depth interviews with patients to explore their views and experiences of treatments for depression.

Treatments assessed within the trials included usual GP care, antidepressants, CBT, facilitated physical activity and listening visits. They were delivered by various individuals - GPs, CBT therapists, Physical Activity Facilitators and Health Visitors - and aimed at different patient groups (women with antenatal depression, women with postnatal depression, patients with a new episode of depression, and patients with treatment resistant depression).

The data will be analysed thematically. Initially we will identify themes evident within the data set as a whole. We will then make comparisons within and across the five data sets in order to highlight the views and experiences of specific patient groups.

#### Results

Preliminary analysis suggests themes previously associated with specific treatments are also apparent in patients' accounts of other treatments, and that patients may use different treatments sequentially or simultaneously in order to manage their depression.

#### Conclusions

Our study will improve understanding of how depression is currently managed within primary care and how patients experience different treatments. Findings could inform future clinical guidelines, the development of treatments and the design of clinical trials.

### 84. Optimising outcome prediction in primary care: the use of longitudinal data in prognosis research

Daniel Lasserson, George Peat, Kelvin Jordan, Kate Dunn, Christian Mallen, Danielle van der Windt, Gemma Mansell

*Keele University, University of Oxford*

#### Objective

In current prognosis research prediction of future outcome is usually based on one (baseline) assessment only. This seems out of touch with clinical practice where information from several visits may be used to estimate prognosis and decide on treatment and referral. Our aim is to investigate the use of longitudinal data to increase predictive performance of prognostic information.

#### Methods

Individual patient data were obtained from existing prospective cohort studies of primary care patients presenting with back (3 cohorts) or shoulder pain (2 cohorts). Outcome measures included pain and function, measured at baseline, short-term (within 4-6 weeks), and long-term follow-up (>6 months). Potential prognostic factors include time-varying factors, including psychological factors (e.g. fear-avoidance beliefs, coping, catastrophising). Logistic regression was used to investigate the added predictive performance of repeated assessments of pain, function and prognostic factors compared to a single assessment in the prediction of long-term outcomes.

#### Results

Preliminary results indicate that short-term changes in pain and function are more strongly associated with long-term outcome than baseline values of these measures, although the results are not consistent across all datasets. Where psychological factors do predict outcome, short-term changes seem to be strongly associated with outcome than baseline values, but associations are generally weak.

#### Conclusion

This is work in progress; preliminary results indicate that monitoring of early changes in pain and function may help to predict long-term outcomes of pain and function. Further analysis will compare predictive performance of repeated (short-term) assessments of pain or function with a multivariable baseline prognostic model.

## 85. PROstate Cancer Support Intervention for ACTIVE Surveillance (PRO-ACTIVE): a feasibility study into the design and evaluation of a psycho-educational support intervention for managing distress in prostate cancer patients undergoing active surveillance

Sam Watts, Geraldine Leydon, Caroline Eyles, Stephanie Hughes, Emily Arden-Close, Brian Birch, George Lewith  
*University of Southampton*

### Introduction

The prevalence of anxiety and depression in prostate cancer patients (PCa) being managed with active surveillance (AS) is estimated to be as high as 22% and 13%. Anxiety is a significant predictor for transference to radical treatment. Men undergoing radical treatment experience various physical side effects and a reduced quality of life. To prevent this transition support interventions are needed to help AS patients better manage their psychological distress.

### Method

We undertook a series of qualitative interviews with 20 AS patients. The interviews were designed to elicit a greater understanding of the psychological and emotional distress in AS, what causes it and how best to manage it with the aim of developing an AS specific support intervention.

### Results

AS patients articulated a need for more detailed information about PCa and AS. The main themes that emerged from these interviews were; 1) problems associated with being managed with AS and 2) how best to manage survivorship. The patients acknowledged a degree of emotional distress and indicated they would like guidance on self-care approaches to alleviate these conditions. The participants were positive about group based support and the development of an AS specific support website. These data have been utilised to develop a support intervention for AS patients (PRO-ACTIVE) which is due to begin piloting in February 2014.

### Discussion

Our results indicate that men being managed with AS would welcome specific additional psycho-educational support to help them better cope and manage with the burden of living with an untreated cancer.

## 86. A Conversation Analytic Examination of Caller Requests for Telephone-Based Cancer Support

Catherine Woods, Paul Drew, Geraldine Leydon  
*University of Southampton, Loughborough University*

### Introduction

It is estimated that one in three people will have cancer by 2050. Despite the growing number of people affected by cancer living in the United Kingdom and the clear demand for telephone based cancer care, little research has been directed towards understanding the process of seeking and delivering cancer related telephone help. The research on face-to-face communication literature has shown that cancer patients have a range of informational and supportive needs which are not always met during consultations.

### Methods

This PhD is based on 350 calls to the largest cancer helpline in the United Kingdom and is using the principles of Conversation Analysis (CA) to gain an empirical understanding of how helpline calls are organised, the concerns callers raise in this context and how call-handlers provide cancer-based support. This presentation will provide findings from an analysis on the interactional practices callers use to present their concerns in the opening moments of the call.

### Results

The analysis found that callers request informational support about treatment, current symptoms and prognosis (including end of life and reoccurrence issues). Callers present their concerns in three main formats (similar to how patients raise medical concerns in doctor-patient interactions).

### Discussion

The analysis provides more of an understanding about the problems callers bring to cancer helplines (rather than just glossing over the request with “information” or “advice”) and the communicative practices for seeking telephone-based support.





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