<table>
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<tr>
<th>PF / N-PF</th>
<th>Research Type</th>
<th>Study Title</th>
<th>Status</th>
<th>Summary of Study</th>
<th>Chief Investigator</th>
<th>Site or PIC</th>
<th>Site or PIC Name</th>
<th>Type of Research</th>
<th>Funder</th>
<th>Expected Study End Date</th>
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<tbody>
<tr>
<td>PF</td>
<td>Other</td>
<td>ALDOES - Targeted Screening for Alcohol-related Liver Disease in Primary Care: Feasibility Pilot and Men Study</td>
<td>Approved</td>
<td>The research involves: 1. Questionnaires 2. Qualitative research methods 3. Collection of data 4. Laboratory tests and analysis. The long term aim is to improve the earlier detection and treatment of alcohol induced liver disease, and thus to reduce liver related mortality. This study is being undertaken by the study team at Nicholstown Surgery.</td>
<td>Dr Nick Sheron</td>
<td>Site Nicholstown Surgery</td>
<td>Study Administrating Questionnaires / Interviews for Quantitative or Mixed</td>
<td>UHS</td>
<td></td>
<td>31/03/12</td>
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<tr>
<td>PF</td>
<td>Immunology &amp; Immune</td>
<td>Investigation of the Regulation of Immune Responses in Humans. V.2.</td>
<td>Approved</td>
<td>The main aims of this research are: 1) to understand how the immune system reacts to foreign chemicals (drugs and contact sensitizers) and how the responses differ between people who develop allergies compared with people able to tolerate a given chemical. 2) to understand how the immune system interacts with the skin in allergic and non-allergic responses to environmental chemicals. 3) to understand the effects of immunomodulatory compounds on the magnitude of the immune response.</td>
<td>Dr Michael Arden-Jones</td>
<td>Site Nicholstown Surgery</td>
<td>Study limited to working with human tissue samples, other human biological samples, other human biological samples and/or data</td>
<td>Action Medical Research</td>
<td></td>
<td>31/03/12</td>
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<tr>
<td>PF</td>
<td>Musculoskeletal</td>
<td>Men as Carers in Multiple Sclerosis In Follow Up End of Study Declaration Due</td>
<td>Approved</td>
<td>The aims of this research are to identify the supports needs and preferences for support of male carers caring for women with MS with palliative and end of life care needs. The project will be conducted in three stages; ethical approval is only being sought for Stage One at this time. Stage One involves in-depth interviews of 20 men caring for women with severe MS. The aim is to understand how they are living and coping with caring for a female relative with MS, to learn from them what support would be useful and how they would prefer to receive such support.</td>
<td>Professor Julia Addington-Hall</td>
<td>PIC Western Community Hospital, Turner Centre, St James' Hospital</td>
<td>Study Administrating Questionnaires / Interviews for Quantitative or Mixed</td>
<td>The MS Society of Great Britain &amp; Northern Ireland</td>
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<td>01/09/11</td>
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<tr>
<td>PF</td>
<td>Stroke</td>
<td>OTCH: RCT of an OT Intervention for Residents with Stroke in UK Care Homes</td>
<td>Approved</td>
<td>The aim of this research is to identify the supports needs and preferences for support of male carers caring for women with MS with palliative and end of life care needs. The project will be conducted in three stages; ethical approval is only being sought for Stage One at this time. Stage One involves in-depth interviews of 20 men caring for women with severe MS. The aim is to understand how they are living and coping with caring for a female relative with MS, to learn from them what support would be useful and how they would prefer to receive such support.</td>
<td>Professor Catherine Backley</td>
<td>Subsidised Site Care Homes</td>
<td>Other Clinical Trial or Clinical Investigation</td>
<td>NIHR - HTA</td>
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<td>31/07/12</td>
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<tr>
<td>N-PF</td>
<td>Other</td>
<td>A Heideggerian Hermeneutic Exploration of the Meaning of Leading a Clinical Nurse Leaders of Hospital and Community Nursing Teams Caring for an Older 'Unpopular Patient' In Follow Up End of Study Declaration Due</td>
<td>Approved</td>
<td>A meta data analysis of qualitative research has already been undertaken by the researcher. The researcher has revealed that the clinical leader's role in leading a nursing team caring for an 'unpopular patient' has not been directly investigated. There is evidence that the creation of the 'unpopular patient' within nursing results in less than optimal care of the patient but no evidence related to the role of the clinical leader. Clinical nurse leaders have a responsibility to ensure the quality of the service provided by the team they lead. This research embraces a qualitative methodology, Heideggerian Phenomenology, to illuminate the experience of clinical nurse leaders leading nursing teams caring for an 'unpopular patient'. The sample will be purposive and will include nurse leaders in community hospitals and nurse leaders who lead community nursing teams. Informed verbal and written consent will be obtained. The researcher will use in-depth interviews to collect narrative data. The interviews will be audio-recorded and transcribed by the researcher. The data analysis will be undertaken using hermeneutics. The researcher will maintain a reflective diary to record and understand any bias held and its potential influence on the data. The final product of the research is acknowledged</td>
<td>Ms Jacqueline MacCallum</td>
<td>Site Community Hospitals</td>
<td>Study Involving Qualitative Methods Only</td>
<td>No External Funding</td>
<td></td>
<td>31/10/12</td>
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<tr>
<td>N-PF</td>
<td>Disease</td>
<td>Study Title</td>
<td>Status</td>
<td>Principal Investigator</td>
<td>Site</td>
<td>Study Involvement</td>
<td>Funding</td>
<td>Date Approved</td>
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<tr>
<td>N-PF</td>
<td>Stroke</td>
<td>Cortical Activity Changes Among Stroke Patients</td>
<td>Approved</td>
<td>Mr Sebastien Pullett</td>
<td>Western Community Hospital</td>
<td>Clinical Trial or Clinical Investigation</td>
<td>No External Funding</td>
<td>31/10/12</td>
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<tr>
<td>PF</td>
<td>Diabetes</td>
<td>Stroke Survivor and Carer Perceptions of the Role of a Work Rehabilitation Service</td>
<td>Approved</td>
<td>Ms Liz Cullen</td>
<td>Work Rehabilitation Service, Rose Road</td>
<td>Study Involving Qualitative Methods Only</td>
<td>No External Funding</td>
<td>30/09/11</td>
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<td>PF</td>
<td>Cancer</td>
<td>A Trial of Devices for Intractable Urinary Incontinence Following Prostate Cancer Surgery</td>
<td>Approved</td>
<td>Dr Mandy Fader</td>
<td>Continence Service</td>
<td>Clinical Investigation or Other Study of a Medical Device</td>
<td>Prostate Cancer Charity</td>
<td>31/03/12</td>
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<tr>
<td>N-PF</td>
<td>Diabetes</td>
<td>A Qualitative Study to Investigate the Psychological Consequences of Self-monitoring Blood Glucose (SMBG) in People Newly Diagnosed with Type 2 Diabetes After Attending DESMOND (Diabetes Education &amp; Self Management for the Ongoing &amp; Newly Diagnosed)</td>
<td>Approved</td>
<td>Professor Sue Latter</td>
<td>Diabetes Centre - St James’ Hospital</td>
<td>Study Involving Qualitative Methods Only</td>
<td>No External Funding</td>
<td>20/12/10</td>
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| PF | Renal & Urogential | The PADPROM Project: Quality of Life of Pad Users Questionnaire | Approved | The aim of this project is to develop a valid and reliable questionnaire to measure the Quality of Life of people who use pads to manage incontinence. This questionnaire will form part of the ICIQ project.  
Sampling Frame: Participants will be identified from databases held by Continence Advisory Services (CAS) in Southampton, Hampshire, The Isle of Wight and London. The CAS will act as intermediaries between the research team and potential participants. They will be asked to identify men and women, over 18 years who experience light and moderate to heavy urinary or urinary and faecal incontinence and wear pads.  
Methodology:  
Plan:  
Phase 1: Identification of QoL issues through semi-structured interviews (months 19)  
Phase 2: Questionnaire Reduction and Refinement (months 916)  
Phase 3: Phase 3a Test of the PROM and Phase 3b Retest of the PROM (months 1624)  
Phase 4: Sensitivity to change (months 2436)  
Phase 1 up to 20 participants will be interviewed in their homes, to identify key themes to help formulate questions. Experts (including members of the CAS) will also be asked to take part in a mini modified Delphi Technique to consider validity of the identified themes.  
Phase 2 125 participants will be recruited to self complete the questionnaire and then provide feedback in a face to face interview in their homes. Evaluating the questionnaire for appropriateness, clarity and relevance of the questions.  
Phase 3 is divided into two events:  
Phase 3a An initial test of the postal questionnaire by 350 pad users, completed in their homes.  
Phase 3b A second copy of the questionnaire will be sent to all participants of 3a, to retest the reliability of the instrument. At this stage Dr Mandy Fader | PIC | CAS Clinics - Soton | Study Administering Questionnaires / Interviews for Quantitative or Mixed Qualitative / Quantitative Studies | SCA Hygiene Products AB | 31/03/13 |
| PF | Oral and Gastrointestinal | STOPAH Approved | Approved | Alcohol related liver disease accounts for the majority of alcohol related deaths in the United Kingdom. Alcoholic hepatitis, where the liver is very inflamed, is a serious form of the disease. The death rate from alcoholic hepatitis is particularly high amongst those patients who have severe Professor Mark Thursz | Site | GP Practices | NOT SET | NIHR | 01/02/14 |
| PF | Respiratory | An Investigation of the Mechanism of Action of Sere tide in COPD Approved | Approved | This study is investigating the possible mechanisms of action of an inhaled treatment (Sere tide), currently used worldwide in millions of patients with COPD (Chronic Obstructive Pulmonary Disease) and how it improves the symptoms of these patients. Previous research has failed to identify the mechanisms at play other than dilation of the airways. The research community has long thought the mechanism to be immune based or anti-inflammatory but despite intensive research this has not yet been identified. Dr Simon Bourne | PIC | Quitters | GSK | 01/02/12 |
| N/PF | Infection | Feasibility Study of Hypnosis in Patients with Venous Leg Ulcers | Approved | Leg ulceration remains a significant health care problem and drain on NHS resources. Not all patients respond to recognised treatments regimes (compression bandaging) and living with chronic ulceration can severely affect quality of life and mental wellbeing (Nilsson, Bergqvist & Lindhagen, 1997). The aim of this project is to test the feasibility and potential effectiveness of hypnosis on anxiety, depression and pain in a group of patients with chronic venous leg ulcers. | Ms Cheryl Dunford | Site | The Adelaide Health Centre | Study Administering Questionnaires / Interviews for Quantitative or Mix Qualitative / Quantitative Studies | University of Southampton | 27/01/11 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PF | Generic Health Relevance | Screening for Malnutrition by Nurses: Barriers and Facilitators | Approved | Screening for malnutrition by community nurses: Barriers and facilitators: Study involving qualitative methods only. | Dr Sue Green | Site | Community Nurses Workplace | Study Involving Qualitative Methods Only | Nutricia Ltd | 31/03/11 |
| N/PF | Generic Health Relevance | Offender Health Needs and Access to Healthcare Services | Approved | Offender health needs and access to healthcare services. Recent studies concerning offender health needs have largely focused on the health of prisoners, yet there has been limited research exploring the health needs and access to healthcare services of community based offenders on probation and the process of offender healthcare commissioning for this group. The current study seeks to address this gap in research and explore probation and health trainer staff and offender healthcare commissioner’s knowledge, perceptions and attitudes to offender health needs and access to healthcare whilst on community based probation orders. The study will use qualitative focus groups/interviews conducted in the South Central Strategic Health Authority and a national survey of the aforementioned key stakeholders across England and Wales. The study period will last 9 months. | Dr Julie Parkes | Site | Local Delivery Units - Offender Health | Study Administering Questionnaires / Interviews for Quantitative or Mix Qualitative / Quantitative Studies | University of Southampton | 29/10/10 |
| PF | Generic Health Relevance | Support Matters v.1 | Approved | Support Matters: Use of assistant staff in the delivery of community nursing services in England | Dr Karen Spilsbury | Site | Community Nursing Service Managers | Study Administering Questionnaires / Interviews for Quantitative or Mix Qualitative Studies | NIHR - Service Delivery and Organisation (SDO) | 30/12/11 |
Following stroke, damage to the central nervous system can leave individuals with a diversity of impairments that impact on ability to function during day to day life. Physiotherapy focuses on promoting recovery from such impairments and optimising function; learning is central to this. There are two subdivisions of learning: implicit and explicit. Implicit learning refers to the acquisition of a skill without knowledge or conscious awareness that learning is taking place. Learning to ride a bike is typically implicit – it is broken down into component steps and the learner will be able to verbally describe what those steps are. It has been shown that during treatment sessions, physiotherapists give patients almost constant instructions and feedback relating to how they are moving. In these circumstances, the patient is learning explicitly. Yet, evidence within healthy people has shown that skills learnt in this way are not always robust and may not be retained over time. There are very few studies that specifically consider implicit and explicit learning post.

| N-PF | Stroke | How Do Different Styles of Information Provision Affect Learning During Early Gait Training Post Stroke? A Feasibility Study | Approved | Following stroke, damage to the central nervous system can leave individuals with a diversity of impairments that impact on ability to function during day to day life. Physiotherapy focuses on promoting recovery from such impairments and optimising function; learning is central to this. There are two subdivisions of learning: implicit and explicit. Implicit learning refers to the acquisition of a skill without knowledge or conscious awareness that learning is taking place. Learning to ride a bike is typically implicit – it is broken down into component steps and the learner will be able to verbally describe what those steps are. It has been shown that during treatment sessions, physiotherapists give patients almost constant instructions and feedback relating to how they are moving. In these circumstances, the patient is learning explicitly. Yet, evidence within healthy people has shown that skills learnt in this way are not always robust and may not be retained over time. There are very few studies that specifically consider implicit and explicit learning post. | Ms Louise Johnson | Site | Western Community Hospital | Other Clinical Trial or Clinical Investigation | No External Funding | 04/11/11 |

| N-PF | Diabetes | BBR-012 Diabetic Foot Ulcer Study | Approved | This study aims to look at the effect of oral isoniazid (BBR012) versus placebo on rate of healing of diabetic foot ulcers (DFUs). The design of this study follows research indicating that this antituberculosis treatment may also have an effect on wound healing. The primary issues which may require consideration prior to commencing this study include justification of the research, its design, the use of placebo, number of subjects, justification of recruitment and inclusion/exclusion criteria. | Professor Andrew Boultin | PIC | Royal South Hants Hospital | CTRMP | Bridge BioResearch Rights (Jersey) Ltd | 20/06/12 |

| N-PF | Diabetes | Illness Representations in Diabetes and Depression: Validation of a New Measure - v1.1 | Approved | Diabetes and depression is common with approximately 20% of people with diabetes also suffering from depression. People with both diabetes and depression can have difficulties integrating the self-care demands of their diabetes with their management of depression. Difficulties can also arise from taking multiple medications at the same time. Previous research has highlighted the particular challenges faced by these patients as depression with chronic physical illness results in worse health when compared with depression alone, chronic physical/illness alone, or with any combination of physical illnesses without depression. Illness representations are also amenable to change with a recent systematic review concluding that patients participating in an intervention to change negative illness perceptions showed improvements in HbA1c level and psychological well-being. People’s beliefs about having both diabetes and depression and the relationship between the two conditions may be associated with health outcome. However, the existing literature and validated measures of illness representations have focused on beliefs about each condition. | Ms Jenny McSharry | PIC | GP Databases | Study Administering Questionnaires / Interviews for Quantitative or Mixed Qualitative / Quantitative Studies | University of Southampton | 01/09/12 |

| N-PF | Diabetes Cardiacal | TECOS - A Randomised, Placebo Controlled Clinical Trial to Evaluate Cardiovascular Outcomes after Treatment with Sitagliptin in Patients with Type 2 Diabetes Mellitus and Inadequate Glycaemic Control on Mono or Dual Combination Trial Antihyperglycemic Therapy | Approved | People with type 2 diabetes mellitus have high levels of glucose (sugar) in their blood that can cause damage to eyes, kidneys, nerves, and blood vessels and have a high risk of heart attacks and strokes (cardiovascular disease). Although lowering blood sugars has been shown to decrease rates of other diabetes related complications, it is not clear whether or not blood sugar control will reduce the likelihood of cardiovascular disease. This study is going to look at the effect of Sitagliptin (a prescription drug used to lower blood sugar in adult patients with diabetes) on cardiovascular outcome and safety. This will be a multinational, double-blind, placebo-controlled trial where either Sitagliptin or a placebo will be added to a patient’s usual treatment. | Professor Rury Holman | Site | GP Databases | CTRMP | Merck & Co. Inc | 01/12/14 |
Measuring the level of insulin in an individual can help to predict their response to treatments for Type 2 diabetes. However, testing insulin production has been difficult and is therefore rarely done. The researchers have developed a practical and inexpensive urine test as an alternative measure of insulin production.

It is believed that individuals with very low insulin production will not respond well to new treatments that rely on the body making its own insulin. These treatments are incretin-based agents, which are a large financial burden on the NHS (these agents are more expensive than older alternatives such as insulin treatment). Studies have shown that a patient’s own insulin secretion is a strong predictor of response to older diabetes treatments but this has not been examined for incretin-based agents. To investigate this, insulin production will be measured using this new urine test in 900 people who are about to start these new medications. Their response to the new treatments will be assessed by measuring change in the HbA1c over a 6-month period. The team will then examine how the results of the urine test can predict treatment response.

Professor Andrew Hattersley

**N-PF**

Generic Health Relevance

MCQ - The Motivation and Cognition Questionnaire

Approved

This study will design and develop a questionnaire tool which will identify the presence of potentially rare or difficult to detect cognitive or motivational adverse events in individuals with ADHD who are being treated with MPH drugs eg Ritalin etc. A semi-structured interview question route will focus on both the positive and negative effects of MPH drugs on cognition and motivation. Examples and experiences will be collected from the four groups of participants – clinicians, teachers, parents and patients (adults and children) in order to create the motivation and cognition questionnaire (MCQ).

Dr Hanna Kovshoff

Site CAMHS

Study Involving Qualitative Methods Only

The European Commission

31/12/12

**N-PF**

Mental Health

The Talking Sense Communication Programme for Dementia Family Carers

Approved

This study will be investigating if family carers of people with dementia benefit from communication therapy and training.

This study will only involve carers of people with dementia. Dementia sufferers experience difficulties communicating and family carers have described communication and associated behaviour difficulties as being one of the hardest to cope with.

Mr Colin Barnes

Site Speech & Language Therapy

Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

St Halley Stewart Trust

02/03/15

**PF**

Diabetes

ASCEND: A Randomised 2x2 Factorial Study of Aspirin versus Placebo, and of Omega-3 Fatty Acid Supplementation versus Placebo, for Primary Prevention of Cardiovascular Events in People with Diabetes

In Follow Up - End of Study Declaration Due

ASCEND aims to demonstrate whether aspirin reduces the risk of cardiovascular events in individuals with diabetes who do not already have diagnosed occlusive arterial disease, and whether such benefits outweigh any potential hazards from bleeding. In order to do this reliably, at least 15,000 patients with diabetes and no clinical evidence of occlusive arterial disease will be randomly allocated to receive 100mg aspirin daily or matching placebo tablets for at least 7 years. A study of this size should have excellent power to detect a 12-15% proportional reduction in the cardiovascular event rate among such patients.

Dr Jane Armitage

Site Nicholstown Surgery

CTIMP

British Heart Foundation

01/10/12

**PF**

Respiratory

PRIMIT: A PRimary care trial of a website-based infection control intervention to Modify Influenza-like illness and respiratory Transmission

In Follow Up - End of Study Declaration Due

Influenza and other respiratory viruses result in overstretched primary care services, and also hospital bed shortages due to the cardiovascular and respiratory complications, especially when viruses causing influenza-like illness (ILI) circulate in the community. Minimising the spread of respiratory infections could have considerable benefit for both patients and the health service.

Professor Paul Little

Site Nicholstown Surgery

Study Administering Questionnaires / Interviews for Quantitative or Mixed Qualitative / Quantitative Studies

MRC

31/12/13
The majority of cancers (>75%) are diagnosed in people aged 70 years and over, and ageing of the population is considered a major determinant of the future cancer burden. Research into the needs of older people with cancer, and those of older family caregivers, friends or lay carers who care for them is, however, limited. Very little is known, for example, about the experiences of older caregivers caring for people at home towards the end of life.

This study aims to describe the experience and support needs of older family caregivers (or other lay carers) caring for older partners, relatives, or close friends aged 65 and over with advanced cancer at home. It will investigate the role of formal health and social care services in supporting them and explore how older people and their lay carers manage their own care at home.

A longitudinal mixed methods design will be utilized. Qualitative, semi-structured interviews will form a major part of the study, with participants engaging in up to 3 in-depth interviews during up to a six month period.

Observation of a nominated care activity will complement data collection, providing a picture of aspects of caregiving difficult to capture in interviews alone. Finally a measure of service use will be used to collect quantitative data on utilization of service use.

Interviews will take place in people’s homes or care setting if preferred and recruitment will be via hospice–based home and day care teams.

Chronic obstructive pulmonary disease (COPD) is a long term lung condition which gradually causes a reduction in patient’s exercise capacity, ability to perform day to day activities, and breathlessness. As part of the management of this condition, patients are often offered a pulmonary rehabilitation programme, an evidence based intervention, to improve their quality of life and disease management. Adherence to such programmes can be very low and it is not currently known why this is or how to improve adherence. This research is designed to explore the views of patients with chronic lung disease about the management of their condition and about pulmonary rehabilitation. The researcher will interview patients individually, asking questions relating to their perceptions of their lung disease and pulmonary rehabilitation, before and after they attend a pulmonary rehabilitation programme. Interviews will be audio-taped and transcribed verbatim. The researcher will read the transcripts repeatedly to identify any common themes that relate to the research question. This will help us understand the relationship between patient perceptions of their disease, their behavioural intentions, and their behaviour. The information will be used to improve pulmonary rehabilitation services, with the ultimate goal of improving adherence and hence increasing patient benefit.

The fast-changing climate of the NHS has resulted in many changes for how Psychologists present themselves to other clinical staff. For example, the issue of Psychologists integration in teams is one which attracts much attention in current health policy literature. Stakeholders showed an overwhelming preference for the integration of psychologists within teams but only if psychologists retained their unique identity and contribution (e.g. offering a counter-balance to the ‘medical model’) (Department of Health, 2007). Clinical Psychologists are also expected to assume more leadership roles and provide consultancy to organisations (Department of Health, 2007). Moreover, implementation of the new Improving Access for Psychological Therapies (IAPT) programme has further implications for the roles psychologists will undertake in the future. The impact of these changes for Psychologists is unknown, but could potentially affect the way they are treated by other staff.

Workplace bullying has recently been placed high on the national agenda of the NHS (Health Service Journal: Feb, 2009). One study of workplace bullying prevalence in a community NHS trust found 1 in 3 staff members reported being bullied in a twelve-month period (Quine, 1999). Whilst negative workplace acts have been investigated in doctor and nursing professions in the UK (Quine, 2001; Quine 2003.), it has not yet been studied within the NHS Psychologist workforce.
More than 4300 adults of working age die from accidents in England and Wales each year. More than half a million people are admitted to hospital and 5.8 million attend A&E departments every year. Research shows that the majority of injured people admitted to hospital and nearly half of those treated in Emergency Departments are not fully recovered one year later. Many people suffer bouts of depression or anxiety after accidents, which can make it harder for them to recover. Recent research in the UK has identified substantial areas of unmet need in obtaining appropriate care for injured people. We are undertaking a 4 year programme of research measuring how accidents affect people's lives, how much they cost patients and the NHS and exploring people's use of services with the aim of quantifying the impact of injuries and determining how best to meet the needs of injured people.

To achieve this, the research will comprise two linked studies carried out at research sites in Nottingham, Loughborough, Bristol, and Surrey.

**Study A:** we will recruit 680 participants between 16-70 years who have been admitted to hospital following an unintentional injury. Participants will complete a series of questionnaires over a 12 month period asking about their health, work and social life before and after the accident, as well as the injury related costs they incurred and the services they used.

**Professor Denise Kendrick**

**Site Provider Staff**

**Study Administering Questionnaires / Interviews for Quantitative or Mixed Qualitative / Quantitative Studies**

**Department of Health**

**30/09/13**

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There is justification in the literature for promoting optimal child language development through advising and supporting parents. Theory and research evidence suggest that this approach may prevent some language delay, and the negative effects that delay has on a child's educational, social and emotional development. Services of this nature are being developed in the UK, however, there is very little reported evidence of effectiveness of these services. This study aims to develop a language promotion service in accordance with theory and to investigate its effectiveness. A randomised controlled trial is planned with two experimental groups; a control group and a group which receives the language promotion service. The service will be given to families when the baby is approximately 1;6 years of age. Measures of parent talk to children and child language levels will be taken for each family before the intervention (baseline measure) and after the intervention at intervals until the child is aged 2;0 years. Mean scores for each experimental group (observed measures, and mean differences from the baseline measure) will be compared using independent t-tests. It is expected that parents who receive a language promotion service will increase the quantity and quality of their talk to their children, and that their children will also develop more language skills than parents from the control group.

**Mrs Clare Smith**

**Site**

**Battenburg Clinic**

**Other Clinical Trial or Clinical Investigation**

**NHS - ESC**

**31/07/13**

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The aim of the study is to provide clinical evidence to predict which patients are at high risk of developing pneumonia within 30 days of seeing their GP with a cough and suspected chest infection. Antibiotics are commonly prescribed to patients suspected of having chest infections but only a small proportion are likely to develop complications such as pneumonia who would then actually benefit from taking the antibiotics. This results in over-prescribing antibiotics which encourages the development of antibiotic resistance and the inherent risk of the side effects of taking these drugs.

Costs of the research at this site will be covered by NHS Service Support Costs.

**Professor David Mant**

**Site**

**Nicholstown Surgery**

**Other Clinical Trial or Clinical Investigation**

**No External Funding**

**01/07/13**
This is a study aiming to explore the clinical reasoning processes that extended scope physiotherapists. These practitioners are physiotherapists who work outside their normal scope of practice and therefore are able to utilise investigations such as MRI/Xray to help diagnosis/management of patients in the management of low back pain. The research will use focus groups which will involve physiotherapists and senior physiotherapists who do not do work outside their scope. Focus groups with both sets of physiotherapists will be completed to compare and explore how they make decisions in terms of diagnosis and management plans for patients. The groups will be facilitated by the chief investigator, and observed by a second researcher who is likely to be a University study supervisor who will be making some notes on the interactions. The role of the second researcher/observer is to make notes on what was said, and this will be helpful when providing further data. The participants will have consented to being audio-taped and observed. Data will be analysed for theoretical concepts relating to decisions for the diagnosis and management of low back pain. There will be an initial pilot study and 2 separate groups, 1 in primary care and 1 in secondary care. The session will be run for approximately one hour. In addition, there will be some time at the start of the session needed to explain the group and answer questions, therefore total time is likely to be approximately up to 1.5 hours, per focus group.

Mr Neil Langridge Site Stoneham Centre Moorgreen Hospital Study Involving Qualitative Methods Only No External Funding 01/09/11

It has been recognised by successive governments and the professional body for pharmacy that pharmacists, especially in the community, are an under-utilised resource. Recent contractual changes (2005) to the community pharmacy contract has started to reward pharmacists for clinical services rather than merely a medicine supply function. The Pharmacy White Paper of 2008 cited these changes but went much further, highlighting what future services could be provided from community pharmacy. The concept of healthy living pharmacies was proposed and this research is to determine if this concept can be translated into practice under the name of ‘Healthy Living Pharmacies’. As part of the research it is important to canvass healthcare professionals’ opinion on this role expansion for community pharmacy.

Dr Jane Portlock Site Citizens Panel Database Study Administering Questionnaires / Interviews for Quantitative or Mix Qualitative / Quantitative Studies Department of Health 31/07/10

This study will aim to investigate what processes naturally occur during the implementation of accessible information within specialist clinical sessions. The study will specifically focus on the clinical sessions carried out by specialist learning disability community nurses, within Portsmouth City area and will aim to achieve the following objectives:

1. To identify what verbal and non-verbal processes occur during the implementation of accessible information for adults with learning disabilities at a specialist clinical level.
2. To explore the community nurses’ evaluation of the session in terms of what happened during the implementation and to add to the description of the processes observed.
3. To explore the associations of the identified processes across each observation.

Ms Clare Mander Site The Kestrel Centre Study Involving Qualitative Methods Only No External Funding 31/12/10

Heart failure is a major and increasingly prevalent condition affecting >700,000 people in the UK, with an estimated 68,000 new cases annually. In spite of improvements in outcomes over the last 20 years, morbidity and mortality remain high and there is a need for better treatments in order to improve outcomes. Drugs of the angiotensin converting enzyme inhibitor (ACEI) class, such as enalapril, form one of the mainstays of the treatment of heart failure. The aim of this study is to evaluate whether a new drug, LCZ696 is safe and effective in preventing cardiovascular death or heart failure hospitalisation compared to enalapril.

Professor Iain Squire PIC Heart Failure Nurses CTIMP No External Funding 31/10/15
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<th>PF</th>
<th>Generic Health Relevance</th>
<th>Title</th>
<th>Status</th>
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<tbody>
<tr>
<td>PF</td>
<td>POWER - Positive Online Weight Reduction Study</td>
<td>Approved</td>
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**Obesity is a major and rapidly rising public health threat. NICE provide recommendations to implement lifestyle changes through diet and exercise. An average practice will have more than 1000 patients with obesity and most practice staff have neither the training nor the time to implement intensive obesity management programmes. By providing an intervention which requires fewer resources for training and for intervention this study will allow a much greater group of patients to benefit both locally and nationally.**

The study has developed written behavioural manuals for both patient and practitioner, this will create a less resource intensive intervention to support behavioural change by converting these materials into a web format. Once converted into a web format, the study will then explore the impact of different levels of nurse support required to achieve effective weight change.

- **Phase 1 part 1**
  - In depth interview with patients
- **Phase 1 part 2**
  - Up to 5 focus groups held for health professionals
- **Phase 2**
  - Pilot RCT. After website has been developed a trial will be piloted where participants will take part in delivering 1 of 4 arms
  - A Web only
  - B minimal face to face support
  - C intensive face to face visits
  - D normal care

**Professor Paul Little**  
**Site** The Adelaide Health Centre

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<tr>
<th>PF</th>
<th>Generic Health Relevance</th>
<th>Title</th>
<th>Status</th>
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<tbody>
<tr>
<td>PF</td>
<td>An Investigation into Embryonic Human Development</td>
<td>Approved</td>
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**Women who attend the Princess Anne hospital for termination of pregnancy will be invited to help with the study and their human embryonic and fetal materials from pregnancies terminated in the first trimester will be collected after counselling and consent processes. The research will be investigating embryonic genetics to further understand the expression and function of developmental genes in humans.**

**Professor David Wilson**  
**PIC STC Treatment Centre in the RSH Laboratory**

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<th>PF</th>
<th>Generic Health Relevance</th>
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<tbody>
<tr>
<td>PF</td>
<td>Clinicians? Treatment Beliefs in Back Pain</td>
<td>Completed - End of Study Report Outstanding</td>
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**Persistent nonspecific low back pain (PNSLBP) is a common problem in UK primary care. The recent NICE guidelines (May 2009) present a number of options for the management of PNSLBP including conventional, complementary/alternative, and combined physical and psychological treatments. There has been no research to date documenting primary health care practitioners’ (HCPs) responses to the NICE guidelines. This current project will explore HCPs’ attitudes towards, experiences of, and beliefs about recommended treatments for PNSLBP, in the context of the NICE guidelines. Individual facetoface interviews will be carried out with approximately 20 primary care clinicians. Inductive qualitative analysis will be used to summarise clinicians' perspectives and to identify factors that facilitate and act as barriers to adherence to NICE guidelines.**

**Dr Felicity Bishop**  
**PIC Health Care Professionals**

**Professor Paul Little**  
**Site The Adelaide Health Centre**

**Other study**  
**NIHR - Research for Patient Benefit**

28/02/13
Diabetes is one of the commonest of all chronic medical conditions in the UK, affecting approximately 1.9 million adults, over 90% of whom have Type 2 diabetes. Type 2 diabetes can cause severe complications, including cardiovascular disease, blindness, renal disease and neurological complications and can reduce life expectancy by 8 to 10 years. Structured patient education programmes reduce the risk of developing complications fourfold, but in 2007 only 11% of people with Type 2 diabetes reported that they had been offered structured education. Internet based self management programmes have the potential to be a cost-effective way of increasing patient access to self management training and improving abilities to manage diabetes and lead to better outcomes. However, most internet based interventions have a very high dropout rate which limits their effectiveness. This is a 3 part study that is the foundation of an NIHR programme grant for a 5 year programme of work to develop and evaluate a new computer based diabetes self management intervention for adults with type 2 diabetes. It will determine 1) features that adult patients with type 2 diabetes want from an internet based intervention to improve self management and the factors that would make them likely to continue using such a programme 2) features that health professionals would like to see in such an intervention and would encourage their involvement 3) "participatory design" where a group of people with type 2 diabetes and health professionals are actively involved in the design process and provide iterative feedback as the intervention is developed. Dr Elizabeth Murray PIC GP Practices Study Involving Qualitative Methods Only NIHR 30/09/13

This pilot study aims to test the credibility, feasibility and acceptability of a promising theory-based psychological intervention for patients with marked beliefs that pain should be avoided, accompanied with a range of avoidance behaviours. The pilot has been designed to optimise the training, content, and delivery of contextual cognitive-behavioural therapy (CCBT), and to test it against current practice (i.e. a physiotherapist-led intervention). Patients referred to the musculoskeletal services for physiotherapy-led treatment of chronic lower back pain not requiring referral elsewhere will be eligible for recruitment to this study. 92 patients (46 in each arm) will be recruited over a period of 9 months. Patients will be individually randomised on a 1:1 basis, to receive either the CCBT or the physiotherapy-led intervention. Measures of pain, disability, quality of life, mood and beliefs will be assessed at baseline, post treatment and at 6 months post randomisation. Primary outcomes will consist of credibility, feasibility and acceptability of treatment to patients. Secondary outcomes will include change on the measures described above. Dr Tamar Pincus Site The Adelaide Health Centre Other Clinical Trial or Clinical Investigation Arthritis Care UK 30/04/12

This study is focused on identifying the factors which facilitate and hinder the use of contractual processes to manage and strategically develop General Dental Services. We have identified the nature of the relationship between the commissioner and supplier to be of central importance. The model below summarises some of the major themes identified as relevant to the investigation. The two parties (commissioner and GDP) each bring a different perspective to the relationship (seen as the line drawn between the two opposing forces). A number of factors are hypothesised to determine the success (or failure) of the contracting relationship: here the issue of 'Trust' and 'The extent of flexibility within contract terms used to guard against perverse incentives' are two which have been identified. Further aspects will be identified in the literature review preceding the study. Using activity theory we will map differences in perspectives of commissioners and GDPs, and using interviews as well as non-participant observation we will explore how each party perceives the other, as well the relative success (or failure) of different types of negotiation styles observed in the various PCTs studied. Dr Rebecca Harris Site Dental Practices Study Administering Questionnaires / Interviews for Quantitative or Mixed Qualitative / Quantitative Studies NIHR 30/09/15
<table>
<thead>
<tr>
<th>N-PF</th>
<th>Other</th>
<th>The Changing Healthcare Paradigm and User Involvement in Assistive Technology Decision Making. What Aspects of Wheelchair Selection Do Wheelchair Users Want To Be Involved In?</th>
<th>Approved</th>
<th>Ms Alejandra Cano</th>
<th>PIC Southampton Wheelchair Services</th>
<th>Questionnaire, Interview or Observation Study</th>
<th>King's College London</th>
<th>01/09/11</th>
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**Difficulties with mobility is the most common problem for disabled older people. Wheelchairs are the most visible pieces of Assistive Technology (AT) to keep independence. AT is not always used to its full potential and items are often abandoned. There is little user involvement when the final decision is made regarding AT. Choosing a wheelchair that the user is not happy with and might not use is a waste of money and may have a negative impact on the user's health and quality of life and independence. Involving patients in the selection encourages patients to take control and manage their long-term condition. It is not known whether or to what extent this approach is occurring when choosing a wheelchair.**

**Ms Alejandra Cano PIC Southampton Wheelchair Services**

**Questionnaire, Interview or Observation Study**

**King's College London**

**01/09/11**

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**pp Musculoskeletal**

| RM Pain Trial | Approved | Distal arm pain is pain in the elbow, forearm, wrist or hand and comprises of a number of specific and non-specific musculoskeletal conditions. The condition is both important and costly however the best approach to managing symptoms is unclear. This study aims to investigate which types of advice result in a long-term reduction in arm pain and disability. Also to investigate whether immediate (fast-track) physiotherapy results in long-term reduction in arm pain compared with physiotherapy delivered at the usual time which is usually after a 7 week waiting list period. | Dr Gareth Jones | Site Stoneham Centre | Other Clinical Trial or Clinical Investigation | Activity Care UK | 31/01/14 |

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**Dr Gareth Jones**

**Site Stoneham Centre**

**Other Clinical Trial or Clinical Investigation**

**Activity Care UK**

**31/01/14**

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**pp Musculoskeletal**

| ASPEN - Alexander Technique and Supervised Physiotherapy Exercises in back pain | Approved | The Alexander technique (AT) involves a teacher using verbal instruction and hand contact to help patients become aware of and to avoid harmful habits of muscle which may cause pain. It is applied to everyday tasks such as standing and sitting at a desk etc. This study will compare AT with an optimal set of conventional exercises to assess if AT has benefits to exercise. This application is for a feasibility study prior to the main trial to assess recruitment methods. | Professor Paul Little | Site GP Practices | Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice | NIHR - Efficacy and Mechanism Evaluation Programme | 01/06/14 |

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**Professor Paul Little**

**Site GP Practices**

**Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice**

**NIHR - Efficacy and Mechanism Evaluation Programme**

**01/06/14**

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**PF Stroke**

| LvlCIT - Development & Pilot Evaluation of LvlCIT v1 | Approved | When someone has a stroke they can lose motor function in one arm and hand as a result. It has been shown that intensive exercise assists recovery of movement, but people can be discouraged by slow progress and so stop using their weak limb. Constraint Induced Therapy (CIT) has been shown to reduce this habitual non-use. The use of the unaffected arm is impaired with the use of a mit and thus forces use of the weakened arm. This has been hindered by the lack of time therapists are able to provide and also patients lack of confidence to do the task alone at home. This study aims to use a web-based program of support (including online therapist support) alongside a mit that provides restriction of fine hand movement of the unaffected arm without affecting performance of everyday tasks (e.g. the mit has a high friction palm to allow grip on a walking aid and the internal material is designed to prevent heat build up). Stage 1: To develop a web-based therapy program (LvlCIT) to support patients carrying out Constraint Induced Therapy (CIT) at home. This will be developed working closely with at least 12 patients, 6 carers and 6 therapists to identify and resolve any problems. Stage 2: Carry out a pilot trial on 60 patients who have just been discharged from hospital and who have loss of arm and hand function post-stroke. Participants will be randomly assigned to either usual care or LvlCIT. Motor function, related problems, and effect on quality of life | Professor Jane Burridge | Site Western Community Hospital | Other Clinical Trial or Clinical Investigation | NIHR | 30/11/13 |

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**Professor Jane Burridge**

**Site Western Community Hospital**

**Other Clinical Trial or Clinical Investigation**

**NIHR**

**30/11/13**

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**N-PF Musculoskeletal**

| Manipulations SOM | Approved | The aim of the study is to determine how Physicians in Dorset and Hampshire use Musculoskeletal (MSK) manipulations in their current MSK Physiotherapy Practice. Questions will be posted to addresses in the region that employ MSK Physio in both NHS and private sectors. A cover letter and questionnaire along with a prepaid envelope will be sent. A follow-up letter will be sent to non-respondents at 2 & 4 weeks. | Dr Kay Caldwell | Site Queen Alexandra Hospital (Physio) | Study Administering Questionnaires / Interviews for Quantative or Mix Qualitative / Quantitive Studies | Na | 02/02/12 |

**The aim of the study is to determine how Physicians in Dorset and Hampshire use Musculoskeletal (MSK) manipulations in their current MSK Physiotherapy Practice. Questions will be posted to addresses in the region that employ MSK Physio in both NHS and private sectors. A cover letter and questionnaire along with a prepaid envelope will be sent. A follow-up letter will be sent to non-respondents at 2 & 4 weeks.**

**Dr Kay Caldwell**

**Site Queen Alexandra Hospital (Physio)**

**Study Administering Questionnaires / Interviews for Quantative or Mix Qualitative / Quantitive Studies**

**Na**

**02/02/12**
| NJ-PF | Cardiovascular | Patient-Instructor Relationships and Adherence to Exercise | Approved | Cardiac rehabilitation is offered as a secondary treatment for patients post cardiac event. There are four main phases: 1: Medical intervention. 2: Exercise training and psychological support. 3: Structured exercise programme for 6-12 weeks. 4: Voluntary continuation of long term maintenance of behaviour change undertaken within the local community. It has been reported that patients are less likely to continue to phase 4. This study will focus on why this is so. The study will last for 6 months with patients requested to complete a personal information sheet, emotional ability test and one hour semi-structured interviews. Exercise instructors will be required to complete a personal information sheet, emotional ability test and a leadership inventory. | Dr Chris Wagstaff | Site | The Adelaide Health Centre | Study Administering Questionnaires / Interviews for Quantitative or Mix Qualitative / Quantitive Studies | No External Funding | 26/03/12 |
| NJ-PF | Stroke | CSR - Community Stroke Reviews V.1 - A 6-week and 6-month multidisciplinary review of a patient’s needs following a stroke using the Community Stroke Review (CSR) tool reduces the incidence of unplanned admissions within 12-months post discharge compared to a 6-week review only | Approved | Post stroke patients report feeling unsupported. The National Stroke Strategy recommends each person receives a multidisciplinary person-centred review of their health including physical, psychological and emotional, social care status and secondary prevention needs after 6 weeks, 6 months and annually following hospital discharge. Most areas offer the 6 week review but less than a quarter offers a 6 month review. This study aims to measure the effectiveness of the 6 month review and whether this then reduces unplanned hospital admissions using the CSR (Community Stroke Review) tool which provides a standardised format and facilitates a multidisciplinary review. The outcome will provide evidence to inform future investment decisions. In short: does a 6 week and 6 month multidisciplinary review of a patient’s needs following a stroke using the CSR tool reduce the incidence of unplanned admissions within 12 months post discharge compared to a 6 week review only? | Ms Lesley Collier | Site | Western Community Hospital | Study Limited to Working with Data (Specific Project Only) | South Central Cardiovascular Network | 30/12/12 |
| PF | Respiratory | BUPA Study - Analysis of the Upper Respiratory Microbial Community - V1 | Approved | To undertake a pilot study in order to gain an insight into the carriage of respiratory microbes within the general population to enable future improvements in clinical care by informing vaccine and antibiotic development and policy. | Dr Stuart Clarke | Site | Nicholstown Surgery | Basic Science Study involving procedures with human participants | BUPA Foundation | 01/10/12 |
| PF | Neurologic al | PRoBaND - Parkinson's Repository of Biosamples and Network Datasets | Approved | This study involves people with Parkinson’s disease and their relatives and is being conducted across a network of clinics in the United Kingdom. The clinical features of the Parkinson condition will be recorded carefully and repeated over time. Blood samples will be taken for gene tests and for longer term storage to support future research. | Dr Donald Grosset | Site | Biteme Park Surgery | Other Clinical Trial or Clinical Investigation | Parkinson’s UK | 08/01/17 |
| NJ-PF | Stroke | Non-invasive Brain Stimulation for People with Stroke - Combining transcranial Direct Current Stimulation (tDCS) with Robot Therapy for the Impaired Upper Limb in Early Stroke Rehabilitation | Approved | The Trust is acting as a PIC for this study with the main site being the University (approval has already been gained for the main site). Participants will have a diagnosis of sub-acute stroke with significant impairment of motor function in an upper limb. Participants will be randomised to either Transcranial Direct Current Stimulation (tDCS) or sham (DCS) whilst playing computer games controlled by the impaired limb supported by a robotic arm. They will participate for 18 sessions plus one follow-up session. Consent will be taken at the University. | Professor Jane Burridge | PIC | Western Community Hospital | Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice | Wessex Medical Research | 03/10/13 |
| PF | Cardiovascular | HEAT - Helicobacter Eradication Aspirin Trial | In Process | Aspirin is a valuable drug, often prescribed at low doses to reduce the chance of heart attacks and strokes. However, aspirin can sometimes cause internal bleeding from ulcers. We are trying to find out whether this occurs more in patients who carry the bacteria Helicobacter (H.) pylori. This bacteria is present in the stomach of more than half the world’s population who usually do not know they have it because it seldom causes symptoms. We are conducting a study to find out whether getting rid of the bacteria with antibiotics reduces the chance of ulcer bleeding. | Professor Christopher Hawkey | Site | GP Practices | CTIMP | NHSR | 06/02/16 |
The study involved longitudinal research as it collects data at two or more points in time and is therefore better equipped than cross-sectional research to determine the effect of change within participants as it is possible to observe changes at an individual level throughout the study when comparing previously submitted data (Ruane, 2005). The study used the same participants throughout using a fixed sample panel design as again this is a superior research method to determine change in specific individuals as the effects of the intervention can be monitored on the same participants (Ruane, 2005).

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<table>
<thead>
<tr>
<th>N-PF</th>
<th>Evaluation of a Patient Held Record for Patients with MRSA</th>
<th>In Process</th>
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<td>The research approach is appropriate for the proposed study and it was given careful consideration. An applied qualitative research approach is proposed. Semi-structured interviews will be carried out with approximately 2500 vascular surgery patients who are MRSA positive and holding a patient held record (PHR) for MRSA. Qualitative studies are widely used and valued in evaluation studies. However, an alternative design approach was also discussed. It was originally proposed that interviews with a smaller number of patients (n=10) would be carried out, with the purpose of using the data to develop and test a questionnaire survey tool aimed at measuring patient satisfaction. It was subsequently agreed that a questionnaire survey tool should not be designed until a more meaningful and in-depth qualitative study of patients’ perceptions had been undertaken. This decision was reached by senior members of the research team Dr J. A. Prieto &amp; Prof. M Fader. One exclusion criterion concerns patients who are unable to speak English sufficiently fluently to participate in a semi-structured interview. Whilst the research team agree it is unfair to exclude people from the study, this was purely for the practical issue of being able to understand, transcribe and analyse interview data. Another ethical concern is that participants may be upset about having MRSA. An experienced researcher will handle this situation sensitively. Dr Jacqui Prieto</td>
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<td>Research Involving Qualitative Methods Only</td>
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<td>Southern Health NHS Foundation Trust</td>
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<th>N-PF</th>
<th>Investigating the Job Demands and Support Available to IAPT Workers</th>
<th>In Process</th>
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<td>The Job Demands-Resources Model of Burnout (JD-RM; Demerouti, Bakker, Nachreiner &amp; Schaufeli, 2001) posits that burnout develops, irrespective of the type of occupation, when job demands are high and job resources are low (Appendix A). This model has been chosen for the theoretical basis of the study as it allows for specific recommendations to be made in the context of the particular occupation by reducing or redesigning job demands and increasing job resources to reduce work-related stress (Demerouti et al., 2001). No research has been conducted investigating whether burnout affects IAPT workers. The government has made a commitment to funding the programme which includes training thousands of therapists. Given the impact that burnout can have on mental health workers’ performance, absenteeism and turnover, it is essential that this is investigated in IAPT workers to ensure that the IAPT investment is secure. Research Question - Are PWPs, HI therapists and Counsellors in IAPT services experiencing emotional strain, disengagement or burnout and what, if any, external factors might be related to this and their ways of coping? Miss Sophie Westwood Site Psychologists Study Administering Questionnaires / Interviews for Quantitative or Mix Qualitative / Quantitive Studies No External Funding 30/06/13</td>
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<td>Rational - Improving Access to Psychological Therapies (IAPT) services deliver evidence-based treatment approved by the National Institute for Clinical Health and Excellence (NICE) primarily for depression and anxiety disorders. The workforce comprises Psychological Wellbeing Practitioners (PWPs) who are trained to deliver low intensity interventions in line with Step 2 (mild to moderate disorders) of the model of stepped care, ‘High Intensity’ (HI) therapists who are trained to deliver treatment in accordance with Step 3 (moderate to severe disorders) of the model of stepped care (Department of Health, 2011) and Counsellors. Work-related stress has been defined as ‘the adverse reaction people have to excessive pressures or other types of demand placed on them at work’ by the Health and Safety Executive (2007). Demerouti, Bakker, Nachreiner and Elzinga (2002) stated that this can develop into ‘burnout’ which is a chronic, long-term (mental) health impairment. Burnout can be costly for individuals and organisations due to increases in turnover, absenteeism and reduced productivity (Conides &amp; Dougherty, 1993; Jackson &amp; Maelach, 1982; Leier &amp; Maelach, 1988; Shirom, 1989). The Job Demands-Resources Model of Burnout (JD-RM; Demerouti, Bakker, Nachreiner &amp; Schaufeli, 2001) proposes that burnout develops, irrespective of the type of occupation, when job demands are high and job resources are low (Appendix A). This model has been chosen for the theoretical basis of the study as it allows for specific recommendations to be made in the context of the particular occupation by reducing or redesigning job demands and increasing job resources to reduce work-related stress (Demerouti et al., 2001). No research has been conducted investigating whether burnout affects IAPT workers. The government has made a commitment to funding the programme which includes training thousands of therapists. Given the impact that burnout can have on mental health workers’ performance, absenteeism and turnover, it is essential that this is investigated in IAPT workers to ensure that the IAPT investment is secure. Research Question - Are PWPs, HI therapists and Counsellors in IAPT services experiencing emotional strain, disengagement or burnout and what, if any, external factors might be related to this and their ways of coping? Miss Sophie Westwood Site Psychologists Study Administering Questionnaires / Interviews for Quantitative or Mix Qualitative / Quantitive Studies No External Funding 30/06/13</td>
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COPD is a lung disease characterized by persistent air flow limitation that is usually progressive and associated with enhanced chronic inflammatory response in airways and the lungs. Not only does it affect the respiratory system, it has an impact on others including the musculoskeletal system through tissue depletion, weight loss and muscle wasting.

It is also known to be associated with poor nutritional status through both reduced oral intake and increased energy expenditure thus leading to a negative energy balance.

Pulmonary rehabilitation is an evidence-based programme of intervention often prescribed for COPD patients. One of the main elements of pulmonary rehabilitation is a prescribed exercise programme. Exercise is known to be associated with altered nutritional status but at present we do not fully know how pulmonary rehabilitation affects nutritional status because it is a complex intervention which includes not only exercise but also dietary advice. It is possible that people with COPD who undertake pulmonary rehabilitation might benefit from some form of nutritional supplementation. However, before trialling such an intervention it is important first to establish the baseline nutritional status.
### Evaluation of the Personal Health Budgets Pilots

**Status:** Approved

**Summary of Study:**
An important new theme in health care policy is about giving more control to patients regarding how they receive their care. One way to achieve this goal is to allocate a budget to individual patients and give them (more) choice about how this money is spent on their care. Personal health budget (PHB) holders can choose how they would like their resource to be managed. There are three options:

1. Notional budget: Patients find out how much money is available to them and will talk to their GP or care manager about different ways to allocate the money.
2. Real budget held by a third party: An organisation or trust holds the money for the patient and helps him/her to decide what he/she needs and buys the services they have chosen.
3. Direct payment: The patient receives a cash payment to buy services they and their doctor/care manager has decided they need.

In 2009, the Department of Health invited Primary Care Trusts to become pilot sites in implementing personal health budgets. The commissioned evaluation will determine whether these budgets do improve choice and improve outcomes. Of the 70 PCTs involved in the pilot programme, 20 will be selected to participate in the full evaluation, whilst process information will be collected from the further 50 sites. A controlled design (without randomisation) will be used to compare the experiences of people receiving these budgets and people continuing under the usual care regime. The evaluation will specifically look at what services people used and how much this cost. It will also ask people the degree to which their health and quality of life changed (improved) as a result of the care they received.

**Chief Investigator:** Professor Julien Forder

**Funder:** Department of Health

**Expected Study End Date:** 01/04/12

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### Knowledge Exchange in Public Private Collaborations in Healthcare: PCTs and FESC Providers

**Status:** Approved

**Summary of Study:**
We want to learn what helps the knowledge exchange process between management consultants and NHS commissioners, what hinders it and how management consultants and NHS commissioners work together. We have designed a three phase study.

**Phase I:** We will carry out interviews with 810 professionals from leading management consultancies and key NHS staff supporting public private partnerships from SHAs and the Department of Health. We will then carry out about 6 focus groups with management consultants.

**Phase II:** We will shadow 12 management consultants for a maximum of 5 days each as they go about their day to day routines. In addition, we will interview NHS commissioners to find out how they use and embed research and knowledge, as a result of working in these public-private collaborations. In Phase III, we will test if the findings from this study can be applied more widely through a survey of other commissioners working with management consultants across the UK.

**Chief Investigator:** Dr Lesley Wye

**Funder:** NIHR

**Expected Study End Date:** 20/12/13

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### Liberating the NHS - To Assess NHS Employees Perception of Change to the NHS Following the White Paper “Equity and Excellence - Liberating the NHS”

**Status:** Approved

**Summary of Study:**
This is a student MBA dissertation study. The student wants to survey staff across the NHS in the UK about their reactions to the White paper. It would involve an anonymous online questionnaire being sent from our comms team to all staff. It would be up to staff whether or not they completed it. It should take about 15-20 mins to complete.

**Chief Investigator:** Dr Kirk Chang

**Funder:** No External Funding

**Expected Study End Date:** 31/12/11
We seek to study organisational and behavioural change in the NHS following the publication in 2008 of High Quality Care for all (HQCfA, also known as the Darzi review and the Next Stage Review). HQCfA called for an NHS where quality is the organising principle. We aim to build a cumulative picture of the current NHS, including insights into how staff throughout NHS organisations – from those at the top, such as executives and boards, those in the middle, such as managers and senior clinicians, and those at the “sharp end” of services are trying to implement high quality care and at the same time as dealing with the increasing pressure on NHS resources. We include a special focus on the experiences and views of patient and carer organisations. Because this is a very complex area to study, we have designed a multimethod, multilevel project involving collection of varied types of data, and use of different levels of analysis across many organisations in the NHS. The project will comprise a series of integrated studies as follows:

1. Pan-NHS studies of:
   1a. The views and experiences of patient and carer organisations
   1b. Views of ~150 staff stakeholders at every level across a wide range of organisations and involved with the NHS
   1c. Staff satisfaction and opinion (assessed by the National Staff Survey)
   1d. Analysis of publicly available/routinely collected information about NHS organisations across the NHS in England

2. Teamworking and organisational studies in focused sample of up to 70 NHS organisations
   2a. Top Management Team values and innovation
   2b. Effective team and interteam working
   2c. Publicly available and routinely collected information about participating organisations

3. Detailed case studies of around 12 NHS organisations of different kinds
   3a. Ethnography (i.e. observations), interviews and documentary analysis to characterise culture and behaviour to support quality and quality improvement
   3b. Publicly available and routinely collected information about participating organisations

Dr Sarah Williams  Site  Staff Questionnaire  Study Administering Questionnaires / Interviews for Quantitative or Mixed Qualitative / Quantitative Studies  Department of Health  31/03/12
<table>
<thead>
<tr>
<th>PF / N-PF Research Type</th>
<th>Study Title</th>
<th>Status</th>
<th>Summary of Study</th>
<th>Chief Investigator</th>
<th>Site or PIC</th>
<th>Funder</th>
<th>Expected Study End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-PF Mental Health</td>
<td>N-PF Mental Health</td>
<td>In Follow Up</td>
<td>The goal of the SHARe research is to characterise the clinical, cognitive and neuropsychological character of each consenting individual diagnosed with ADHD together with collecting information about exposure to environmental and genetic risk factors. A minimal set of key indicators selected on the basis of current research knowledge will be collected. These individual characteristics will be related to both etiological factors (genes and environments) and clinical outcomes. The environmental factors of interest will include both social (family and parent factors) and non-social (pre- and perinatal risk) factors hypothesised to be implicated in ADHD.</td>
<td>Dr Margaret Thompson</td>
<td>Site</td>
<td>Battenburg Clinic</td>
<td>Study Administering Questionnaires / Interviews for Qualitative or Quantitative Studies</td>
</tr>
<tr>
<td>N-PF Mental Health</td>
<td>SHARe - South Hampshire ADHD Register</td>
<td>Approved</td>
<td>Currently in the UK, infants receive a vaccine covering diphtheria, tetanus, pertussis (whooping cough), poliovirus types 1, 2 and 3 and Hib at 2, 3 and 4 months of age. They also receive a vaccine for MenC at 3 and 4 months of age, as well as a separate pneumococcal vaccine (PCV) at 2 and 4 months of age. This study will evaluate the feasibility of using a combination vaccine covering diphtheria, tetanus, pertussis, poliovirus types 1, 2 and 3, haemophilus type b (Hib) and meningococcus type C (MenC), when co-administered with a pneumococcal vaccine (PCV). This will be given to healthy infants as a three-dose primary vaccination course at 2, 3 and 4 months of age, with PCV being given at 2 and 4 months. The aim of this study is to determine if the combination vaccine is safe and effective, as this would reduce the total number of injections that infants receive in the primary course of immunisations from 7 to 5. This would potentially improve coverage rates by making immunisation schedules more acceptable to parents. This study will be a randomised-controlled trial, but not blinded as participants will know how many injections they will be receiving. The control group will receive vaccines according to the current UK immunisation schedule (as outlined above). The study group will receive the combination vaccine at 2, 3 and 4 months of age as well as the pneumococcal vaccine at 2 and 4 months of age. The study will also evaluate the safety and efficacy of a combined Hib and MenC vaccine to be used as a booster vaccine at 12 months following the two different primary vaccinations.</td>
<td>Professor Edmund Sonuga-Barke</td>
<td>PIC</td>
<td>Solent NHS Trust</td>
<td>Research Tissue Bank</td>
</tr>
<tr>
<td>PF Medicines for Children</td>
<td>A New Combination Vaccine Against 6 Childhood Diseases</td>
<td>In Follow Up</td>
<td>Currently in the UK, infants receive a vaccine covering diphtheria, tetanus, pertussis (whooping cough), poliovirus types 1, 2 and 3 and Hib at 2, 3 and 4 months of age. They also receive a vaccine for MenC at 3 and 4 months of age, as well as a separate pneumococcal vaccine (PCV) at 2 and 4 months of age. This study will evaluate the feasibility of using a combination vaccine covering diphtheria, tetanus, pertussis, poliovirus types 1, 2 and 3, haemophilus type b (Hib) and meningococcus type C (MenC), when co-administered with a pneumococcal vaccine (PCV). This will be given to healthy infants as a three-dose primary vaccination course at 2, 3 and 4 months of age, with PCV being given at 2 and 4 months. The aim of this study is to determine if the combination vaccine is safe and effective, as this would reduce the total number of injections that infants receive in the primary course of immunisations from 7 to 5. This would potentially improve coverage rates by making immunisation schedules more acceptable to parents. This study will be a randomised-controlled trial, but not blinded as participants will know how many injections they will be receiving. The control group will receive vaccines according to the current UK immunisation schedule (as outlined above). The study group will receive the combination vaccine at 2, 3 and 4 months of age as well as the pneumococcal vaccine at 2 and 4 months of age. The study will also evaluate the safety and efficacy of a combined Hib and MenC vaccine to be used as a booster vaccine at 12 months following the two different primary vaccinations.</td>
<td>Professor Andrew Pollard</td>
<td>PIC</td>
<td>Child Health Database</td>
<td>CITMP</td>
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<tr>
<td>N-PF Mental Health</td>
<td>Emotion Recognition: An ERP Study</td>
<td>Approved</td>
<td>The ability to recognize emotion from non-verbal social signals (i.e. facial and vocal expressions) is a cardinal feature of effective social interaction. This ability develops rapidly during childhood within a family context and is important for children’s emotion regulation and social competence (Saarni, 1999). In fact, children with externalizing symptoms such as attention deficit hyperactivity disorder (ADHD) and conduct problems (CP) have been found to present difficulties in recognizing facial (Shin, Munsch, &amp; Lehmkühler, 2008) and vocal (Cadesky et al. 2000) expressions of emotion. Our recent study (Chronaki et al., 2020) found that emotion recognition deficits are associated with vocal (as opposed to facial) emotional expressions in children with symptoms of attention, hyperactivity and conduct problems. However, it is not clear whether poor auditory attention or an actual emotion processing deficit modulates the above vocal emotion recognition difficulties. The present study aims to extend our previous research by employing a better validated battery of vocal emotional expressions (emotional prosody) and more robust methodologies to disentangle emotion and attention aspects of recognition. The present study will combine behavioural performance measures of emotional recognition with registration of brain activity (e.g. event related potentials, also known as ERP), elicited in the</td>
<td>Miss Georgia Chronaki</td>
<td>PIC</td>
<td>Ashurst Child &amp; Family Centre</td>
<td>Other Study</td>
</tr>
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**Child & Family Sexual Health**

<table>
<thead>
<tr>
<th>N-PF</th>
<th>Mental Health</th>
<th>IMAGE: A Prospective Follow-up Study of the Adolescent and Young Adult Psychiatric and Functional Outcome of Children with ADHD and their Siblings</th>
<th>Approved</th>
<th>Miss Kim Cartwright</th>
<th>Site</th>
<th>Ashurst Child &amp; Family Centre</th>
<th>Study Administering Questionnaires / Interviews for Quantitative or Mixed Qualitative / Quantitative Studies</th>
<th>No External Funding</th>
<th>30/09/11</th>
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The study aims to prospectively follow-up into adolescence and adulthood, a sample of children previously diagnosed with ADHD, their siblings and a group of controls to answer three key research questions: (1) what is the degree of homotypic and heterotypic continuity in previously diagnosed ADHD patients?, (2) do unaffected siblings of ADHD children, who carry familial risk for ADHD, go on to develop problems later in life?, and (3) does expressed emotion (EE) (a measure of the emotional climate of the family) moderate developmental continuities for ADHD children and their siblings?. The three questions will be addressed appropriately by (1) combining rich data on children with ADHD and their siblings collected as part of the International Multicentre ADHD Genetics (IMAGE) project and data collected on these same children/young people as part of the follow-up study to create a longitudinal data set and (2) including measures at baseline in the IMAGE project and at follow-up that tap into a wide range of child/young person behaviours and experiences and robust measures of the family environment.

<table>
<thead>
<tr>
<th>PF</th>
<th>Medicines for Children</th>
<th>Swine Flu (Novel Influenza A H1N1) Vaccine Study</th>
<th>Approved</th>
<th>Professor Andrew Pollard</th>
<th>PIC</th>
<th>Child Health Database</th>
<th>CTIMP</th>
<th>NIHR - HTA</th>
<th>10/09/10</th>
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In the first half of this year a novel Influenza A H1N1 virus has resulted in an influenza pandemic. The United Kingdom has seen a particularly high incidence of disease. The highest rates of disease are being seen in young children. In anticipation of an influenza pandemic two vaccine manufacturers, Baxter and GlaxoSmithKline, have gained marketing authorisation approval from the European Medicines Agency (EMEA) for a pandemic strain vaccine under the "mockup" dossier route based on limited clinical trial data for a candidate H5N1 vaccine. This "mockup" dossier route for pandemic influenza vaccines allows the submission of a core pandemic dossier during the interpandemic period, which results in the approval of a mockup pandemic vaccine. This is followed by a fast track approval of the pandemic vaccine based on the submission of the pandemic variation when the situation arises. The Baxter and GlaxoSmithKline vaccines have now been modified to cover the novel Influenza A H1N1 strain. Given the high rates of swine flu disease in children, this age group is likely to particularly benefit from immunisation against this virus, however there are few data on the use of these vaccines in a paediatric population. The proposed study therefore aims to assess the immunogenicity, safety, and tolerability of these two H1N1 vaccines when administered as two doses three weeks apart to

<table>
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<tr>
<th>N-PF</th>
<th>Paediatrics (Non-Meds)</th>
<th>powdered Infant Formula: Caregiver Perspectives</th>
<th>In Follow Up - End of Study Declaration Due</th>
<th>Professor Chris Griffin</th>
<th>PIC</th>
<th>Milevies / Health Visitors / Nursery Nurses</th>
<th>Study Administering Questionnaires / Interviews for Quantitative or Mixed Qualitative / Quantitative Studies</th>
<th>UK Food Standards Agency</th>
<th>30/04/09</th>
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</table>

Methods used to reconstitute and store powdered milk formula have important microbiological implications for the safety; this is of particular importance given that young infants who consume the reconstituted product may have increased susceptibility to infection. There is a need to reduce the risk and potential for infection that can be caused by implementation of malpractices during reconstitution and storage of powdered infant formula in the home and healthcare settings. This may be achieved by parents and caregivers being equipped with adequate and correct knowledge, positive attitudes and motivation to implement desired behaviours that can minimise microbial risks. Therefore there is a need to determine parent and caregiver behaviours as well as attitudes and perceptions towards current and recommended procedures. Furthermore, there is a need to determine sources of information about powdered infant formula as well as perceptions of sources in terms of trust, content, method and time of delivery of such advice. Cumulatively, this study will help to inform the development of informed, targeted information sources that address microbial risks of preparation and storage of powdered infant formula.
We are interested to know if nighttime postural equipment (NTPE) affects children’s breathing at night. NTPE is used in children with severe motor disorders to provide postural support at night. The equipment comprises customized wedges placed around the child to ensure a stable and supportive sleep position. Usually, but not always, the child lies on their back. There is evidence NTPE reduces hip displacement. However, these children are vulnerable to breathing difficulties and NTPE that fixes children in one position at night may also affect breathing efficiency. Our previous pilot study based in a sleep laboratory found that 9 children with cerebral palsy, 6 had lower average oxygen levels and 3 had improved average oxygen levels when using their NTPE compared to when they were sleeping unsupported. This proposed study will further explore whether the observed difference was related to the use of the NTPE or whether it was simply random night to night variation. 20 children and young people aged 19 years with severe motor disorders (e.g. cerebral palsy) who are regular NTPE users will be studied in their own home at night. Over 14 nights they will alternate one night in their system and one night sleeping unsupported. We will then compare breathing efficiency in the 7 nights of NTPE use compared to the 7 nights sleeping unsupported. This will be achieved by simple home-based monitoring to measure oxygen and carbon dioxide levels.
This application is for a research project that has important public interest as it is researching a condition that causes a burden to families, children and the state. This application to ethics is for project 1 of a programme of research funded by the National Institute of Health Service Research to develop an evidence-based early detection and intervention model (PEDIA) which can be implemented for preschoolers with Attention Deficit Hyperactive Disorder. This will target particularly difficult to treat children and hard to reach families and tailor therapeutic interventions to respond to their particular needs. Further ethics applications will be submitted for other PEDIA projects (P3, 4, 5). In P1 we will conduct a prospective longitudinal analysis of the late adolescent and early adult outcomes (including health economic costs) associated with preschool ADHD in a cohort for which preschool data on ADHD symptoms and other factors was collected between 1989 and 1997. This research will be carried out over a period of 18 months. The planned start date is February 2010 and the project will continue until July 2011. The aim of this research project is (i) to identify children with high ADHD symptoms who are at risk for poor developmental outcome and likely to be of ‘high burden’ to the health service. This will be based on longitudinal data regarding long term psychiatric morbidity, family burden, economic, social and educational outcomes and quality of life (QoL). (ii) to estimate the long term developmental risk associated with Group (laryngotracheobronchitis) is a common cause of upper airway obstruction in children with a peak incidence of 60 per 1000 child years in those aged between one and two years. It is characterised by hoarseness, a barking cough and inspiratory stridor. These symptoms are thought to occur as a result of oedema of the larynx and trachea which have been triggered by a recent viral infection. Para influenza virus type 1 is the agent most commonly identified in cases of croup. It occurs most commonly between the ages of three months to six years and the incidence is highest between one and two years of age. Croup is managed primarily on an outpatient basis with fewer than 5% children being hospitalised. Croup nevertheless, can be a severe condition and prior to the introduction of steroid treatment, intubation was required in 2% of hospitalised children.

Treatment with inhaled or oral steroids is established as an effective treatment in outpatient and hospital settings. Traditional treatment of croup has included the use of humidified air either using warm moist air at home or a cool mist in hospital. Warm moist air has been in use since the 19th century and is continued to be advocated at home as it is readily available either by moving the child to a bathroom and running a hot bath or shower or by boiling a kettle in the room. Cool mists have been used in the hospital setting as the production of an... 

Study: improving the management of childhood coughs with colds and chest infections (workstream 2), application submitted for consideration at the SouthWest 4 REC meeting on 25th August, reference 10/H0102/55. This study is a part of the same programme of research funded by the NRHR. This will be a qualitative investigation with parents and health care professionals. The aim is to understand shared understandings and knowledge of respiratory tract infections, seek information needs. In addition, interviews with parents will explore parental consultation motivations and experiences, and interviews with professionals will explore perceptions of parental views on presenting risk information when children have respiratory tract infections. Interviews with professionals will explore perceptions of parental views on presenting risk information when children have respiratory tract infections. 3C study 09/H0604/67. The TARGET Cohort Study will complement some work currently being conducted as part of another NRHR Applied Research Programme known as ‘PRIME’ (RPPG040710098), led by Professor Paul Little, also an investigator on the TARGET Cohort Study. The PRIME Programme has been funded, in part, to conduct a derivation cohort study (known as the Cough Complications Cohort or 3C), to predict complications of lower respiratory tract infection (RTI), mainly in adults. The TARGET Cohort Study will differ from 3C by (i) recruiting only children with both upper and lower RTI (the clinical distinction can be difficult in young children who do not expectorate sputum and...
**PF Paediatrics**  
Assessing the Impact of Children with ADHD and Well-being of Families, Version 1

**Neural Markers of Reward and Delay Processing in Adolescents with Attention Deficit Hyperactivity Disorder**

**Professor John Brazier** Site  
Ashurst Child & Family Centre

**Study Administering Questionnaires / Interviews for Quantitative or Mixed Qualitative / Quantitative Studies**

**Shire Pharmaceutical**  
31/12/12

**N-PF Mental Health**

ADHD is a common psychiatric disorder affecting between 35% of children, and has a severe impact on a child’s social, emotional and cognitive development. Currently we know that an impulsive drive for immediate gratification is an important symptom of this disorder, and where impulsivity is a core feature it is also thought to be an important neurodevelopmental precursor to comorbid diagnoses of substance use (SUD) and conduct disorders (CD). Although, contemporary models of ADHD propose multiple developmental pathways each leading to different adolescent outcomes of ADHD, one of the most important pathways is underpinned by altered neural activity in brain regions responsible for reward processing. Therefore, the main research aim of this study is to investigate the brain activity of young people with ADHD when their task performance is reinforced by a) receiving a small reward, b) avoiding the loss of a reward or c) a reduction in the amount of time until the end of the task (i.e. they avoid any time delays during the task). Understanding more about the atypical brain response in young people with ADHD when they are processing reward/delay will help us gain further insight into one of the core underlying causes of ADHD, and associated comorbid disorders such as SUD/CD. This may have important consequences for the diagnosis and management of ADHD and associated disorders.

**Dr Samantha Broyd** Site  
Orchard Centre

**Other Clinical Trial or Clinical Investigation**

**University of Southampton**  
31/08/11

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**PF Paediatrics**

**N-PF Mental Health**

ADHD is a common psychiatric disorder affecting between 35% of children, and has a severe impact on a child’s social, emotional and cognitive development. Currently we know that an impulsive drive for immediate gratification is an important symptom of this disorder, and where impulsivity is a core feature it is also thought to be an important neurodevelopmental precursor to comorbid diagnoses of substance use (SUD) and conduct disorders (CD). Although, contemporary models of ADHD propose multiple developmental pathways each leading to different adolescent outcomes of ADHD, one of the most important pathways is underpinned by altered neural activity in brain regions responsible for reward processing. Therefore, the main research aim of this study is to investigate the brain activity of young people with ADHD when their task performance is reinforced by a) receiving a small reward, b) avoiding the loss of a reward or c) a reduction in the amount of time until the end of the task (i.e. they avoid any time delays during the task). Understanding more about the atypical brain response in young people with ADHD when they are processing reward/delay will help us gain further insight into one of the core underlying causes of ADHD, and associated comorbid disorders such as SUD/CD. This may have important consequences for the diagnosis and management of ADHD and associated disorders.

**Dr Samantha Broyd** Site  
Brookvale Adolescent Service

**Other Clinical Trial or Clinical Investigation**

**University of Southampton**  
31/08/11

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**PF Paediatrics**

**N-PF Mental Health**

ADHD is a common psychiatric disorder affecting between 35% of children, and has a severe impact on a child’s social, emotional and cognitive development. Currently we know that an impulsive drive for immediate gratification is an important symptom of this disorder, and where impulsivity is a core feature it is also thought to be an important neurodevelopmental precursor to comorbid diagnoses of substance use (SUD) and conduct disorders (CD). Although, contemporary models of ADHD propose multiple developmental pathways each leading to different adolescent outcomes of ADHD, one of the most important pathways is underpinned by altered neural activity in brain regions responsible for reward processing. Therefore, the main research aim of this study is to investigate the brain activity of young people with ADHD when their task performance is reinforced by a) receiving a small reward, b) avoiding the loss of a reward or c) a reduction in the amount of time until the end of the task (i.e. they avoid any time delays during the task). Understanding more about the atypical brain response in young people with ADHD when they are processing reward/delay will help us gain further insight into one of the core underlying causes of ADHD, and associated comorbid disorders such as SUD/CD. This may have important consequences for the diagnosis and management of ADHD and associated disorders.

**Dr Samantha Broyd** Site  
Brookvale Adolescent Service

**Other Clinical Trial or Clinical Investigation**

**University of Southampton**  
31/08/11
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<th>Study Title</th>
<th>Approval Status</th>
<th>PIC</th>
<th>Site</th>
<th>Other Clinical Trial or Clinical Investigation</th>
<th>NHSR</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td><strong>PF</strong> Generic Health Relevance MALTA - Can We Reduce the Number of Vaccine Injections for Children?</td>
<td>Approved</td>
<td>Professor Andrew Pollard</td>
<td>PDC</td>
<td>Other Clinical Trial or Clinical Investigation</td>
<td>NHR</td>
<td>31/02/11</td>
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<tr>
<td>This is a study to evaluate a reduced dose schedule for Meningococcal serogroup C (MenC) vaccination for infants. Currently in the UK, children receive priming MenC vaccines at 3 and 4 months of age and a combination HibMenC booster at 12 months of age. There is some evidence that fewer doses of priming vaccines may improve antibody responses following the booster dose. Fewer doses will also mean fewer injections for children and reduced costs to the NHS. We would like to compare the current schedule with one group of children who will receive only a single dose of MenC vaccine at 3 months, and another group who will not receive any priming doses of MenC vaccine in infancy. All groups will receive the 12 month HibMenC booster. The antibody responses to each of these schedules will be compared at several time points by doing blood tests (at age 6months, 12months, 12months and 6 days and 13months). The three study groups will receive all other routine infant immunisations according to the current UK schedule. Embedded in this trial will be a pilot study comparing the effect of administering sequential immunisations into consistent limbs or alternating limbs. At present immunisations are administered ad hoc by practitioners into either limb at each time point. Theoretically, administering the same immunisation into the same limb for every dose may improve the immune response. Each of the study groups will be split into 2: one to receive all doses and the other to receive none.</td>
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<tr>
<td><strong>PF</strong> Paediatrics PEDIA 3 - Overcoming Barriers</td>
<td>Approved</td>
<td>Professor Edmund Sonuga-Barke</td>
<td>Speech &amp; Language Therapy, CAMHS, Health Visitors</td>
<td>NOT SET</td>
<td>NHR</td>
<td>30/09/11</td>
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<tr>
<td>The aim of P3 is to conduct interviews with parents and stakeholders in order to identify barriers and solutions to the problems of engagement and treatment of hard-to-reach/high risk families and children. The key objective of P3 is to identify enhancements of the NFPP so as to improve outcomes for subgroups of preschoolers with high levels of ADHD.</td>
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<td><strong>PF</strong> Generic Health Relevance Socioeconomic Inequalities in Chlamydia &amp; Screening in Young People</td>
<td>In Follow Up - End of Study Declaration Due</td>
<td>Professor Rosalind Raine</td>
<td>GUM Clinic - RSH</td>
<td>Study Administering Questionnaires / Interviews for Quantitative / Mixed Qualitative Studies</td>
<td>MRC</td>
<td>11/03/11</td>
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<tr>
<td>People in less favourable socio-economic circumstances (measured by income, occupation, education, living in deprived areas) often have worse health yet lowest use of NHS services. We do not know if this applies to sexual health services for young people, because previous studies in young people have used inconsistent and often inappropriate socio-economic measures. We think education has greater relevance to young people than income or employment. However, we do not know how education is related to sexually transmitted infections or service use or whether young people will provide this information in sexual health settings. In this study, we will use chlamydia screening as a case study to examine social variations in sexual health and service delivery in young people, focusing on chlamydia infection and screening. This study will take place when young people are already screened for chlamydia to make best use of already collected information. We will use two measures of socio-economic circumstances - individual’s educational participation and the socio-economic circumstances of the area in which young people live/are screened - to: find out whether young people in less favourable socio-economic circumstances are more or less at risk of sexual ill health or more or less likely to use services than those in more favourable circumstances - explore what factors</td>
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<tr>
<td><strong>PF</strong> Generic Health Relevance An Investigation into Embryonic Human Development</td>
<td>Approved</td>
<td>Professor David Wilson</td>
<td>STC Treatment Centre in the RSH Laboratory</td>
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<td></td>
<td>31/05/10</td>
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<tr>
<td>Women who attend the Princess Anne hospital for termination of pregnancy will be invited to help with the study and their human embryonic and fetal materials from pregnancies terminated in the first trimester will be collected after counselling and consent processes. The research will be investigating embryonic genetics to further understand the expression and function of developmental genes in humans</td>
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### Does SMS Message Follow Up of Genitourinary Medicine Clinic Non Attendees Improve Subsequent Attendance Rates?

Patients who miss GU appointments waste resources and pose a potential public health risk through onward transmission of STIs.

The aim of this study is to see if the use of text messaging improves subsequent attendance rates in patients who have already missed a clinic appointment.

All patients who have missed an appointment at the GU clinic at the RSH will be randomised and put into 3 groups:

1. Will be sent a text giving details of the clinic walk in service
2. Will be sent a text with the walk in service as well as a health promotional message
3. Will not be sent a text at all

The researcher will then record how many re-book an appointment.

If the results show that either text significantly improves attendance rates, the approach will be incorporated into departmental policy at the RSH.

**Dr Emma Rutland**  
Site: GU Clinic - RSH  
Other study: No External Funding  
Approved: 01/02/11

### Viral Induced Paediatric Asthma Study

Asthma is a disease of the airways. It is amongst the commonest chronic conditions in the UK affecting 1 in 7 children and is responsible each year for many lost school days and some deaths. Most asthma begins in early childhood, up to 80% of asthma attacks in children are caused by the common cold virus (rhinovirus). There are no effective therapies to prevent asthma attacks in children. It has been shown that cells from the airways of asthmatic adult volunteers were less able to produce the antiviral cytokine interferon beta (IFNβ) when exposed to the common cold virus. This explains why asthmatics have attacks with colds. Therapy with inhaled IFNβ might prevent these attacks. Preliminary results show that IFNβ has the same effects in asthmatic cells derived from children. A pilot (Phase 1) clinical trial (completed in 2007) in Southampton in collaboration with Synairgen has shown good tolerance and safety of inhaled IFNβ in adult non allergic, nonasthmatic volunteers. Further trials are now underway in adults with asthma. As part of the development of a pilot (Phase II) clinical study of interferon beta in children, we plan to carry out an observational study to determine the best way of assessing children with attacks of asthma induced by colds. We aim to recruit up to 100 children aged 5 – 11.

**Dr Graham Roberts**  
PIC: Asthma  
Community Nurses  
Infection: NHR  
Approved: 31/03/12

### Feasibility Study of the Adapted New Forest Parenting Programme

To use information from P3, use expert advice and to carry out study to look at feasibility and deliverability of the adapted home-based NFPP. Study will be carried out in two phases: Parenting Prog(1) Apr – July 2011 (8 parents) and Aug – Dec 2011 (8 parents). Analysis will focus on pre and post treatment interviews and mid-treatment telephone interviews.

**Professor Edmund Sonuga-Barke**  
Site: Speech & Language Therapy  
Study Involving Qualitative Methods Only: NHR  
Approved: 31/05/12

### Children with Auditory Attention, Listening and Verbal Comprehension Problems: A Comparison to Two Types of Intervention (v2)

This project aims to investigate two approaches to Speech and Language Therapy intervention. Indirect and direct therapy approaches are regularly used in the treatment of children with language delays and disorders, but the research informing us of their effectiveness is limited. This project hopes to begin to clarify which treatment approach is the most effective for children with attention and listening difficulties and language delays.

**Dr Penny Roy**  
Site: Speech & Language Therapy  
Other Clinical Trial or Clinical Investigation: No External Funding  
Approved: 05/08/11
Chlamydia trachomatis is a highly prevalent sexually transmitted pathogen. It is estimated that 5-12% of sexually active adults in the 16-24 age group in the UK may be infected.1 The potentially serious complications of chlamydia infection are well known and clear links have been found between chlamydia and subsequent pelvic inflammatory disease, ectopic pregnancy and tubal infertility.

Azithromycin 1g single dose or doxycycline 100mg twice daily have been shown in treatment studies to have a >95% microbiological cure. 2 A test-of-cure (TOC), performed at 6 weeks following treatment of chlamydia, is available, however this is not recommended by current BASHH guidelines, unless the patient is pregnant or there are concerns about compliance.

When patients are followed up for longer periods following treatment, it has been found that more than 10% will be chlamydia positive on retesting.2 This is thought to be due to reinfection, from exposure to either an untreated partner or a new sexual partner. However, it has been hypothesised that this may also be the result of re-emergence of a persistent latent infection.2 Thus the microbial cure rate may be lower than first thought. Other reasons for treatment failure may include non-compliance; not taking the required doses for the required length of time, drug interactions or vomiting, this in itself could be reason enough.

Patients Think? Approved

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### Paediatrics

**A New Vaccine for Babies Which Adds Protection Against Hepatitis B**

An open-label randomised study of a new vaccine containing, diphtheria, tetanus, polio, pertussis, Hib and Hepatitis B to examine the immunogenicity and safety of the vaccine when administered concomitantly with one of two types of MenC at 3 and 4 months of age vaccine and followed by a combined Hib/MenC vaccine at 12 months. Participants will be visited at home to receive vaccines and follow-up blood tests at 5 visits over a period of 11 months. The new vaccine is unlicensed but this is a phase III study.

**Professor Adam Finn**

PIC: Child Health Database

CTIMP: No External Funding

Date: 30/11/13

### Mental Health

**The Resting and the Waiting Brain Activities in ADHD**

The main research question regards investigating resting brain activity in adolescent diagnosed with attention–deficit/hyperactivity disorder (ADHD). It specifically aims to investigate the power of very low frequency (VLF) brain oscillation that is found in the resting brain of healthy people using EEG equipment. The major aim is to investigate what happens to this slow brain activity when people are waiting and engaging in goal-directed activities. The research will compare this between patients with ADHD and healthy controls.

**Miss Chia-Fen Hsu**

Site: Solent NHS Trust

Basic Science Study involving procedures with human participants: No External Funding

Date: 01/03/13

### Generic Health Relevance

**Xpert CT/NG - Extended Performance Evaluation of the Xpert CT/NG Assay. Version 1.0**

The study is designed to look at how accurate the Xpert CT/NG assay performs against commercial Nucleic Acid Amplification Tests (NAATs) for rapid detection and differentiation of Chlamydia Trachomatis (CT) and Neisseria Gonorrhoea (NG). The new test is generally able to create a result in under an hour, unlike the current tests that can take 1-2 weeks. This would mean that patients can have a result during the same visit rather than having to wait.

**Dr Rajul Patel**

Site: GUM Clinic - RSH

Clinical Investigation or Other Study of a Medical Device: Cepheid

Date: 31/05/12

### Infection

**APT - Accelerated Partner Therapy - Primary Care Trial**

Sexually Transmitted Infections (STIs) are increasing in young men. Efforts to reduce transmission have failed and the impact of STIs in society is growing. The burden of STI related disease is in women of reproductive age although the prevalence of chlamydia in men & women is similar. The annual NHS costs of untreated chlamydial infection are around £100 million. The White Paper Choosing Health sets out the importance of STIs at national level and led to the National Chlamydia Screening Programme (NCSP). However, chlamydia screening uptake in men is poor. Control of STIs relies on reducing transmission, through reduction in duration of infectivity. Partner notification (PN) aims to reduce duration of infectivity by informing the infected person’s sexual partners of the exposure, offering diagnosis and treatment, and providing advice about prevention. Current PN practice in the UK is outdated and a need for research and development in this field has been recently stated by NICE. New methods of PN need to be applicable to different health care settings and the shift of sexual health care into community services means that new approaches must be particularly relevant to primary care.

We recently completed an MRC funded study “The Accelerated Partner Therapy (APT) Study” in which we developed and undertook an exploratory trial of two new methods of PN in Genitourinary Medicine (GUM) clinics. We termed our new models Accelerated Partner therapy (APT), defined as partner notification strategies which reduce time for sex partners of bacterial STIs to be treated and include assessment by appropriately qualified healthcare professionals.

These included telephone and pharmacist consultations. We have also undertaken work exploring patient views on NHS R&D Form (R&D) Version 3.0 (30231/18944/14/5) diagnosis and treatment, and providing advice about prevention. Current PN practice in the UK is outdated and a need for research and development in this field has been recently stated by NICE. New methods of PN need to be applicable to different health care settings and the shift of sexual
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<tr>
<th>PF / N-PF</th>
<th>Research Type</th>
<th>Study Title</th>
<th>Status</th>
<th>Summary of Study</th>
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<tr>
<td>PF</td>
<td>Mental Health</td>
<td>A Study to Investigate the Prevalence of Mental Illness Among Victims of Homicide and the Demographic, Clinical and Criminological Characteristics of Victims</td>
<td>Approved</td>
<td>To date, homicide research has focused on mentally ill people as the perpetrators of homicide. In contrast, few studies of mentally ill people have investigated the risk of becoming a victim. The few studies which have focused on mentally ill people as victims indicate that mentally ill people are at increased risk of being the victims of crime, particularly violent crime. One recent study conducted by the Centre for Suicide Prevention in Manchester reported that the risk of a mentally ill person becoming a victim of homicide was six times that of the general population. Although research has reported the increased risk faced by mentally ill people, the contribution of mental illness to being a victim has not been researched in detail. Identifying this contribution may help guide management strategies for people with mental illness, particularly in the community to help reduce this risk.</td>
<td>Professor Jenny Shaw</td>
<td>Site</td>
<td>Solent NHS Trust</td>
<td>Study limited to working with human tissue samples, other human biological samples, other human biological samples and/or data</td>
<td>National Patient Safety Agency</td>
<td>31/03/12</td>
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<td>N-PF</td>
<td>Mental Health</td>
<td>Recovering an Ordinary Life: Mental Health Service Users Experiences of Living at Yew House Assessment and Resettlement Service: An Exploratory Qualitative Study</td>
<td>In Follow Up: End of Study Declaration Due</td>
<td>Our research group has recently adapted an established talking therapy - Cognitive Behaviour Therapy (CBT) for psychosis so that it is sensitive to cultural background of ethnic minority patients by exploration and incorporation of service users' and health professionals' views and opinions. The purpose of this study is to test this modified therapy.</td>
<td>Ms Peri Harzouli</td>
<td>Site</td>
<td>Yew House</td>
<td>Study Involving Qualitative Methods Only</td>
<td>No External Funding</td>
<td>31/12/08</td>
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<tr>
<td>PF</td>
<td>Mental Health</td>
<td>Feasibility Study of Culturally Adapted Cognitive Behaviour Therapy</td>
<td>Completed - End of Study Report Outstanding</td>
<td>This study focuses on inpatient mental health rehabilitation services. These services provide care for people with severe mental health problems who have additional problems (such as non-response to medication, substance misuse, and “negative” symptoms which make it difficult for the person to motivate themselves and organise their day to day activities) that mean that they need lengthy hospital admissions which are expensive to the NHS. Anything that can shorten these necessary admissions will therefore be cost-effective. However, little research has been carried out to investigate which aspects of rehabilitation services work best and for which patients. This study attempts to do this. The study consists of four parts. First we will carry out a comprehensive survey of rehabilitation services in England, one part of which will comprise using an assessment measure, developed in another study to rate their quality. In the second part of the study we will develop a training programme for ward staff to help them find ways to assist patients better with their daily activities and to access the community for courses, work and leisure. We plan to evaluate this training programme in the third part of the study through a randomised controlled trial that will include about half the services in Project 1 and the other half that are included in the services that are not.</td>
<td>Dr Shanaya Rathod</td>
<td>Site</td>
<td>Mental Health Outreach Team</td>
<td>Study Administering Questionnaires / Interviews for Quantitative or Mixed Qualitative / Quantitative Studies</td>
<td>Department of Health</td>
<td>30/04/11</td>
</tr>
<tr>
<td>PF</td>
<td>Mental Health</td>
<td>REAL: Rehabilitation Effectiveness &amp; Activities for Life</td>
<td>Approved</td>
<td>This study focuses on inpatient mental health rehabilitation services. These services provide care for people with severe mental health problems who have additional problems (such as non-response to medication, substance misuse, and “negative” symptoms which make it difficult for the person to motivate themselves and organise their day to day activities) that mean that they need lengthy hospital admissions which are expensive to the NHS. Anything that can shorten these necessary admissions will therefore be cost-effective. However, little research has been carried out to investigate which aspects of rehabilitation services work best and for which patients. This study attempts to do this. The study consists of four parts. First we will carry out a comprehensive survey of rehabilitation services in England, one part of which will comprise using an assessment measure, developed in another study to rate their quality. In the second part of the study we will develop a training programme for ward staff to help them find ways to assist patients better with their daily activities and to access the community for courses, work and leisure. We plan to evaluate this training programme in the third part of the study through a randomised controlled trial that will include about half the services in Project 1 and the other half that are included in the services that are not.</td>
<td>Dr Helen Killaspy</td>
<td>Site</td>
<td>Mental Health Outreach Team</td>
<td>Other Clinical Trial or Clinical Investigation</td>
<td>NHRI</td>
<td>01/11/14</td>
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**Adult Mental Health**

| PF Mental Health | Homicide by Patients with Schizophrenia: A Case-control Study | Approved | The number of victims killed by perpetrators with mental illness is increasing. This study will examine socio-demographic, criminological and clinical characteristics and clinical care of people with schizophrenia who commit homicide compared with control cases with schizophrenia who do not commit homicide.

**Case control:**
Data will be obtained from the NCI on criminals who were convicted of homicide.

**Controls:**
Data will be extracted from Hospital Episode Statistics (HES) from patients diagnosed with schizophrenia.

A detailed questionnaire will be sent directly to the consultant psychiatrist responsible for the control patient to complete regarding their care.

**Site:** Western Community Hospital

**Professor Jenny Shaw**

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| N-PF Mental Health | Locus of Control Beliefs and IAPT Psychological Treatment | In Process | A study about people’s beliefs about their health. I would like to find out whether these health beliefs make a difference to people’s talking therapy treatment. If health beliefs do make a difference, we may be able to develop new ways of helping more people to get the best out of their treatment with Talking Change.

**Site:** Talking Change

**Dr Diane Carpenter**

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