NHS

West and South Yorkshire and Bassetlaw
Commissioning Support Unit

NHS Leeds West Clinical Commissioning Group
Annual Research Report 2013-14

Contents

Foreword

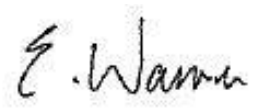
This last year (2013/14) has seen the formation of new Clinical Commissioning Groups (CCGs) and Commissioning Support Groups. For CCGs this has meant understanding the whole range of statutory duties for which they are now responsible and commissioning excellent quality commission support to enable them to discharge such duties.

In 2012 the Health and Social Care Act placed a statutory duty to promote research on the NHS including NHS England and the emerging CCGs. Over the last year the Research Service of West and South Yorkshire and Bassetlaw Commissioning Support Unit (WSYB CSU) has been supporting NHS Leeds West Clinical Commissioning Group (CCG) to fulfil all of its responsibilities in relation to research and this annual report sets out the achievements of the service.

The annual report highlights that, despite a newly formed CCG and supporting Research Service, not only are we achieving all of the national research governance metrics in relation to research, but they are being exceeded in Leeds West. It is also encouraging that over 70% of practices within Leeds West CCG are actively engaging participants to take part in research by recruiting them to studies; again this exceeds national requirements.

Making research real for commissioners is also a key goal of the service and in listening to the needs of commissioners, the research team, working in collaboration with our Academic Health Science Network (AHSN) and University partners, have established a pioneering new way to bring academia and the NHS together, via our ARC forums (Applying Research in Commissioning Decisions), to support evidence-based commissioning. The forum is proving to be extremely successful and demonstrates that there is great potential for nationwide rollout.

This annual report reflects the commitment of the Research Service to provide excellent quality support to NHS Leeds West CCG, working in collaboration with the CCG to promote and conduct research for the health and wellbeing of patients and the public.



Erica Warren
Principal Associate for Research
West and South Yorkshire and Bassetlaw Commissioning Support Unit

Executive Summary

In England, the NHS constitution confirms research as a core function of the NHS which re-affirms the commitment of the NHS, throughout the UK, to promote and conduct research to improve health & social wellbeing and to improve NHS patient care services. The Health and Social Care Act 2012 also reaffirms this through the powers and duty it places on the Secretary of State and others to support and promote research.

The revised NHS constitution published in March 2013 outlines that the NHS aspires to the highest standards of excellence and professionalism as a key standard. This standard makes reference to a commitment to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population.

This April the NHS entered its second year as reimagined in the Health and Social Care Act 2012. For the first time NHS England will include research in the 2014/15 "standard contact" they provide NHS organisations for use when commissioning services. Research has also been included in planning guidance issued by NHS England to Providers and Commissioners to ensure they understand the importance of research to delivering high quality care. These are two great steps that should really help embed research as a core priority for the NHS.

This report provides a description of the work that the West and South Yorkshire and Bassetlaw Commissioning Support Unit (WSYB CSU) has undertaken in delivering a comprehensive research service on behalf of and in collaboration with NHS Leeds West Clinical Commissioning Group (CCG) to ensure that the CCG has met its statutory obligations with regards to research.

Purpose of this report

The purpose of this paper is to provide an update on the research service provided by the WSYB CSU to the NHS Leeds West CCG. This report summarises the last 12 months from 1st April 2013 to 31st March 2014.

Power to conduct, commission or assist the conduct of research into specified matters	Power	**Section 5 NHS Act 2006** **Schedule 1 (paragraph 13)** A CCG has the power to conduct, commission or assist the conduct of research into – (a) any matters relating to the causation, prevention, diagnosis or treatment of illness; and (b) any such other matters connected with any service provided under the 2006 Act as the CCG considers appropriate. CCGs also have related functions under section 5, including the ability to obtain and analyse data.	Health and Social Care Act 2012 Section 6 http://www.legislation.gov.uk/ukpga/2012/7/section/6/enacted

Duty in respect of research	Duty	**Section 14Y NHS Act 2006** Each CCG has a duty, when exercising its functions, to promote research and the use of evidence obtained from research.	Health and Social Care Act 2012 Section 26 http://www.legislation.gov.uk/ukpga/2012/7/section/26/enacted

The team at the WSYB CSU ensures all the research activity which is led or hosted within West Yorkshire is undertaken in accordance with current governance and regulatory requirements, ultimately ensuring the safety and quality of care of our patients. (Please refer to Appendix 1 for team biographies). This service operates in 4 core areas;

Research Governance

The WSYBCSU will act as a signatory for permission for research activity and will provide;

- A letter of permission to the researcher outlining that they can now engage with individual General practices to carry out research activity
- Process the Research Passport (if required) by the members of the research team
- Issue a Letter of Access (if required) to the members of the research team

However in following circumstances;

- Where there is an Excess treatment Cost Associated with the Research
- Where the Principle Investigator is a member of staff within the CCG
- Where the participants are members of staff within the CCG

The WSYB CSU will not provide permissions until authorisation has been given in writing by the CCG.

Whilst acting on behalf of the General practices within a CCG the WSYB CSU will as part of its core offer

- Work with researchers/potential applicants for research governance approval to support them through the local/site specific elements of the applications process
- Process applications for research governance permission/permission in line with current CSP/RDMIS requirements
- Ensure all necessary documentation is available to facilitate the permission/permission process
- Ensure comprehensive risk assessment is undertaken on all applications for approval, which consider:
    - Science
    - Information
    - Finance
    - Ethics
    - Health and Safety
- Ensure all permission/permission activity complies with the Research Support Services (RSS) framework as advocated by the Department of Health (DoH) and the National Institute for Health Research (NIHR)
- Ensure all applications are processed within the required timescales and local Yorkshire and Humber Clinical Research Network (YH CRN) metrics are achieved throughout
- Act as ‘first point of contact’ for all Excess treatment cost funding requests

Research Management and Development

- The team provides support and involvement in a number of externally funded research grants, acting as the lead NHS organisation
- We provide regular reports to the Department of Health (as required) regarding progress with projects
- We work closely with the Chief Investigators and project management teams to ensure timely completion of the project, within budget
- We act as ‘first point of contact’ for all external research partners/stakeholders
- We work closely with the Primary Care Research Network (PCRN)

- We ensure each of the services/functions outlined above are managed in accordance with NHS standing financial instructions and the relevant governance and regulatory frameworks
- We manage and administer the Research Capability Fund process on behalf of the CCGs in West Yorkshire
- We work closely with the CCGs on research grant applications, especially where the CCG will act as the NHS host organisation

Research Engagement

- We maintain regular contact with the CCGs
- We make CCGs aware of all relevant obligations regarding research activity
- We work with CCGs to ensure research is promoted throughout its region
- We hold regular research network meetings with the GPs
- We attend where necessary clinical governance meetings to report on research permissions/permission activity
- We provide at least an annual report detailing NIHR and non NIHR activity, consistent with reports provided from research networks, both comprehensive and topic specific
- We ensure appropriate representation at strategic and operational meetings for each of the functions/service outlined above

e.g. YH CRN Board/Executive (as required)
Bradford Institute for Health Research (BIHR)
Collaborations for Leadership in Applied Health Research (CLAHRC)
Academic Health Science Network (AHSN)
West Yorkshire R&D Managers Group
R&D Forum

(This is not an exhaustive list as new vehicles for dissemination / promotion are evolving, e.g. the use of social media)

Knowledge Transfer

- We facilitate dissemination through research network meetings
- We provide evidence and expert support to the projects and programmes transformation team
- We share live learning, acting as a conduit for evidence learned between projects throughout the WSYB CSU
- We contribute to evidence briefings and reports
- We provide CCGs with quarterly updates on recent research activity

Research Governance

Research Permissions

Following agreement to the WSYB CSU RM&G protocol recommendation to the Leeds West CCG Board in August 2013, WSYB CSU is now acting as a signatory for NHS permission. WSYB CSU ensures compliance with the statutory obligations of the CCG in relation to the provision of research management and governance as outlined by the Research Governance Framework (2005) and the Research Support Services (RSS) framework as advocated by the Department of Health (DoH) and the National Institute for Health Research (NIHR).

In total, throughout 2013/14 WSYB CSU has provided NHS permission for 30 studies to commence activity with NHS Leeds West CCG. Figure 1 and table 1 below show the number of studies assured each month.

Figure 1: Shows the number of research permissions 2013-14 by month provided by WSYB CSU on behalf of NHS Leeds West CCG

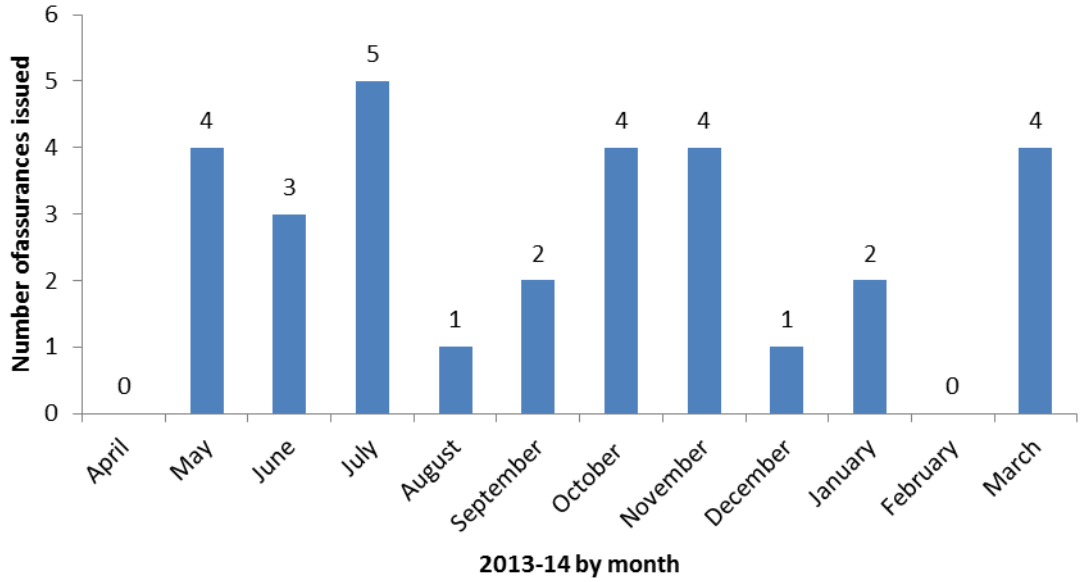


Table 1: List of studies given permission 2013-14 by WSYB CSU on behalf of NHS Leeds West CCG

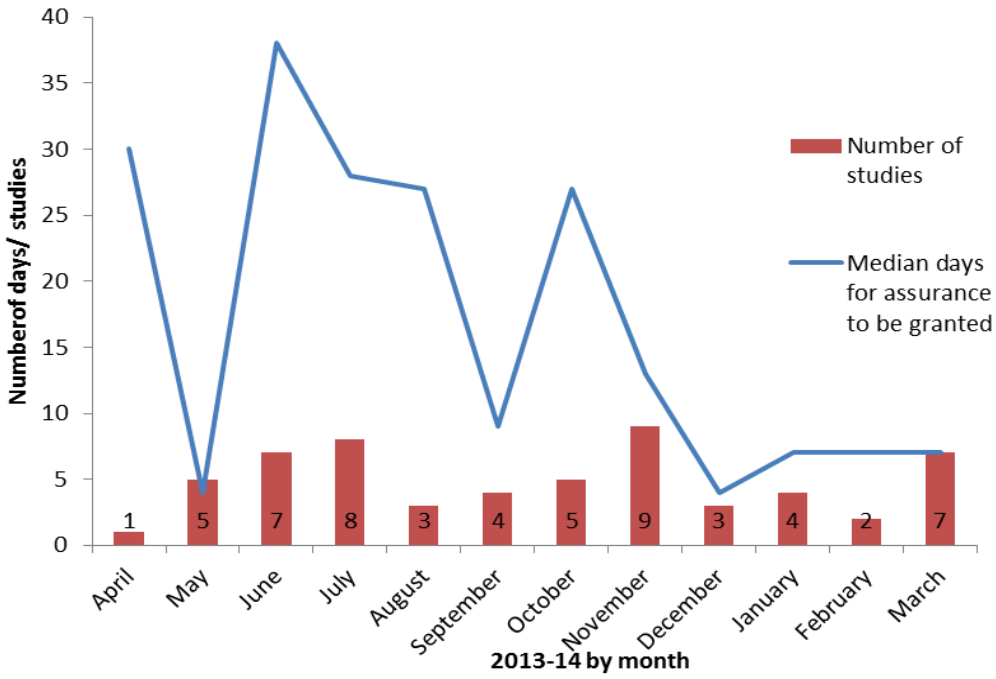
May	
1.	Research Project into Triage
2.	Mechanisms and Reversibility of Heart Failure associated with Diabetes
3.	Reviewing Provision of Medical Abortion Services
4.	Patient Perspective of QOF Related Opportunistic Health Promotion
June	
5.	National Guidance for Measuring Assistive Technology
6.	Routine Assessment and Monitoring of Pain in Advanced Cancer
7.	SASS - Symptoms Awareness Study
July	

8. CANDID - CANcer DIagnosis Decision rules
9. Txt4Flu -Text Messaging Reminders for Influenza Vaccine in Primary Care (v1)
10. BAFTA - Birmingham Atrial Fibrillation Treatment of the Aged Follow up Study
11. IMPACCT - Improving management of pain from advanced cancer in the community
12. Stool Sampling in Primary Care: A Feasibility Study
August
13. The PMR Study - An inception cohort of primary care patients diagnosed with Polymyalgia Rheumatica
September
14. EVRA - Early Venous Reflux Ablasion Ulcer Trail v1.0
15. MALT Study - Overcoming Barriers to Mainstreaming Assisted Living Technologies - Phase 2
October
16. OA treatments- patient adherence, QoL and healthcare resource use
17. Promoting self-management of pain from advanced cancer (IMPACCT 1.3)
18. The PROMOTE Study - Pain Reduction with Oral Methotrexate in knee Osteoarthritis, a pragmatic phase III trial of Treatment Effectiveness
19. Vitamin D and Longevity (VIDAL) Trial
November
20. The RESTART Study - REstart or STop Antithrombotics Randomised Trial
21. An exploration into prescribing for the older patient with reduced kidney function
22. The ROSE Study - Rivaroxaban Observational Safety Evaluation
23. A randomised, multi-centre, open-label, active-comparator, pragmatic clinical trial of low-dose colchicines versus naproxen in patients with acute gout (CONTACT)
December
24. Developing Alternative Methods to Detect Influenza Antibodies
January
25. TIRCON - A randomized, double blind, placebo controlled trial of deferiprone in patients with pantothenate kinase-associated neurodegeneration (PKAN)
26. The influence of ‘significant others’ on sickness absence due to back pain
March
27. A Longitudinal study of cognition in people over 50
28. Making case for exceptionality
29. ADDRESS-PMR - The Diagnostic Accuracy of Ultrasound in Suspected PMR
30. Patterns of Engagement With Homeless Persons

The Department of Health and the NIHR want to make research start up faster and its delivery easier for Chief Investigators in the NHS. The NIHR approach is to make NHS providers’ performance in starting and delivering research transparent and accountable, through changes to new NIHR contracts, which include the introduction of a 70 day benchmark from submission of valid application to initiation of research.

As part of the NIHR Research Support Services (RSS) framework for local health research management we are measured against a local metric of 30 days to grant NHS permission. Figure 2 below shows the progress we have made over the last 12 months in achieving this across the West Yorkshire CCGs in order to ensure that we meet the NIHR RSS framework for local health research management. This framework of good practice is designed to enable front line staff to collaborate in offering consistent professional streamlined services to support clinical research in the NHS in England; this includes a 30 day median as a metric for achieving NHS permission.

Figure 2: Shows the median number of days for research permissions to be granted against number of studies assured by month



The median days for NHS permission provided by the WSYB CSU across West Yorkshire for 2013 to 2014 is 18 days. The median for NHS Leeds West CCG is 20 days; thus the service is achieving and exceeding the national metric of 30 days.

Research Monitoring

Monitoring is the act of overseeing the progress of a research study, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

The purpose of monitoring is to verify that;

- The rights and well-being of human subjects are protected;
- The reported trial data are accurate, complete, and verifiable from the original document where clinical observations are recorded and;
- The conduct of the study is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

WSYB CSU completes a risk assessment for every study and a monitoring plan is put in place accordingly to the level of risk the study poses. Study oversight and issue resolution is a constant for all studies. To date there are no issues to report.

Research Amendments

All amendments to former PCT and recently approved primary care studies across West Yorkshire are notified to the WSYB CSU. WSYB CSU processes all amendments according to the agreed research permission protocol with Leeds West CCG and National Guidance to ensure the appropriate approvals for the amendment types.

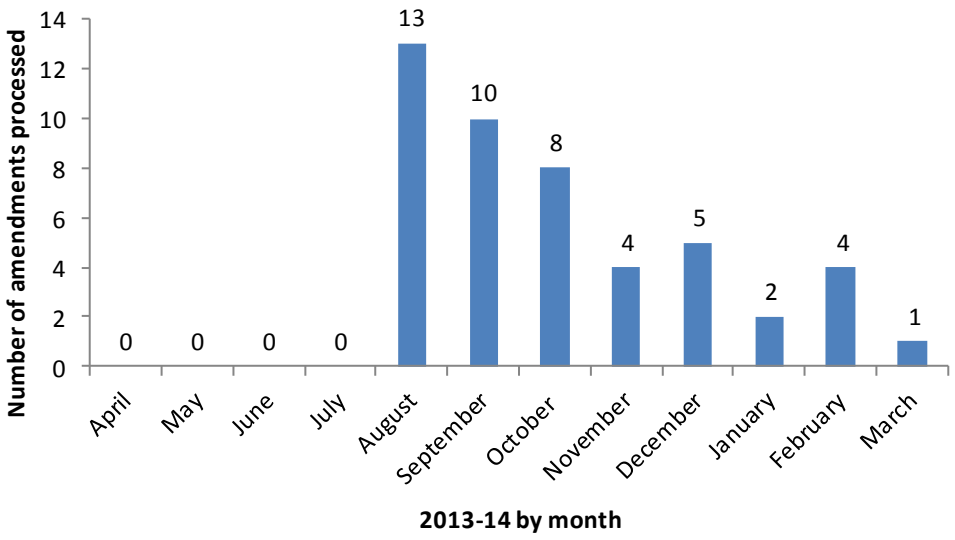
The NIHR Coordinated System for gaining NHS Permission (CSP) Amendments Process was implemented in 2011. In recognition of the large number of amendments that have no impact on NHS Organisations, the process has been updated introducing the concept of 'notifiable' and 'non-notifiable' amendments.

Notifiable	An amendment that impacts on participating NHS Organisations and therefore needs to be considered and may need change control actions
Non-notifiable	An amendment that does not have an impact on NHS Organisations.

These are then considered to be 'substantial' or 'non-substantial'.

Substantial	For example; changes to the procedures undertaken by participants; any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study.
Non-Substantial	For example; minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications.

Figure 3: Shows the number of amendments processed by WSYB CSU on behalf of NHS Leeds West CCG, from 1st April 2013 to 31st March 2014.



Letters of Access for research and Honorary Research Contracts

Alongside the permission/permission process, Letters of Access (LoAs) and Honorary Research Contracts (HRCs) are needed to engage and allow researchers to commence their research study.

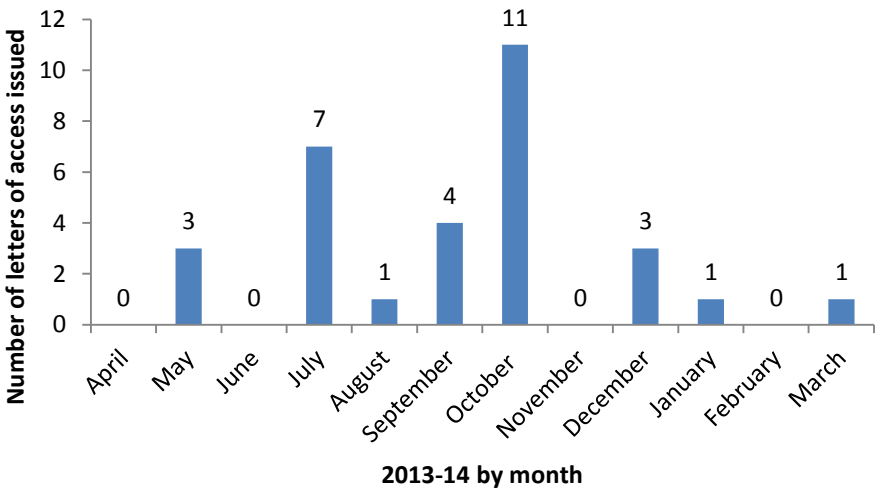
As a result of the partnership arrangements that characterise research, this activity raises a number of HR management issues for NHS organisations. Research within the NHS is often undertaken by NHS staff not directly employed by the host NHS organisation, or by non-NHS staff, particularly researchers employed by universities. This raises issues about responsibility, accountability, patient safety and duty of care. Research is also frequently undertaken across a number of NHS organisations and requires arrangements for both NHS and non-NHS staff to work across those organisations. The Research Governance Framework requires all parties undertaking research within the NHS to be clear about responsibilities and liabilities.

The UK Health Departments have coordinated the development of a good practice resource pack to help the NHS and other research employers take a consistent approach to handling HR arrangements for those undertaking research in the NHS. The WSYB CSU uses this pack to facilitate;

- Research Passports for Higher Education Institute researchers who need to undertake their research within NHS organisations; and
- Honorary Research Contracts or Letters of Access, in line with the nature of the researchers' activity, and the NHS and/or employers responsibility for that activity.

This allows us to ensure that the risks associated with research activity are suitably managed only allowing appropriately screened personnel to undertake research activity. Figure 4 below shows the number of Letters of Access processed.

Figure 4: Shows the number of letters of access for research activity processed in 2013-14 by month by WSYB CSU on behalf of NHS Leeds West CCG


Number of letters of access issued
12
10
8
6
4
2
0
0
3
0
7
1
4
11
0
3
1
0
1
April
May
June
July
August
September
October
November
December
January
February
March
2013-14 by month

Research Management and Development

Research Development Portfolio

Below are summaries of a selection of the current research projects supported by the WSYB CSU research team. We have also provided extract which relate to research grants which are in development. The summaries include the rationale for each project, the benefits of the research for the CCG and its local population and the work done by the WSYB CSU to support the research teams involved.

Current Research Projects

1. OK-Diabetes

OK-Diabetes is a NIHR Health Technology Assessment funded three year project based at the University of Leeds, Institute of Health Sciences.

It is a vital piece of research addressing an urgent health inequality. On average men with a learning disability (LD) die 13 years earlier than the general population and women with a learning disability die on average 20 years earlier. Studies of general practice data (NHS MiQuest system) in the UK have shown higher prevalence of diabetes in people with LD (Glover et al, 2012) and lower retinal screening rates.

People with learning disabilities are also more likely than the general population to be admitted to hospital as an emergency with complications of diabetes, these complications are usually avoidable through enhanced care in Primary Care (Turner and Emerson, 2013). This is a very vulnerable patient group who need additional support to manage their long term conditions. The aim of OK-Diabetes is to begin the process of establishing how best to support diabetes management in people with a learning disability.

OK-Diabetes project has two phases; the aim of the first phase of the project is to identify adults who have mild or moderate learning disability, and type 2 diabetes, and who are not taking insulin. The study team at the University of Leeds wants to talk to these individuals and maybe a supporter, to find out how they are managing their diabetes.

In the second phase the results of the project will be used to develop a programme to support self-management, for people who may find it difficult to look after their diabetes. This programme will be trialed with a representative sample of the Phase 1 participants in a Randomised Controlled Trial. It is hoped that the self-management tool created from this project will assist healthcare users with mild to moderate learning disabilities to better manage their condition. Wider implementation of this tool will not only help this cohort of patients to manage their Hb1Ac but also increase awareness of the condition thus reducing the potential frequency and severity of complications.

The better management of Type 2 Diabetes in this group could potentially reduce the spend of the treatment of complications within this cohort of patients.

WSYB CSU has been involved in the development and rollout of this research across the Bradford, Leeds and Wakefield CCGs through consistent engagement with the project team, holding an advisory position on the Project Management Group. They have supported recruitment by linking this cutting edge research into training and meetings for GPs, Nurses and Practice Managers. They have also supported practices who wish to take part by helping them run the searches to identify eligible patients.

This is the largest trial of its type in the UK and the CCGs of Bradford, Leeds and Wakefield are at the forefront of research for this vulnerable patient group. With only 1 or 2 patients eligible per practice, to be successful the project requires over 50% of practices to participate, making it one of the most ambitious studies for the area but also one of the most unifying; recruiting many practices that don't often take part in research. So far 43% of practices across the three areas have taken part and the number increases every day. It is vital that the health inequalities facing this patient group and the huge burden of avoidable complication costs are addressed; and this research with the participation of the CCGs brings us one step closer to this goal.

2. Action to Support Practices Implementing Research Evidence (ASPIRE)

Action to Support Practices Implementing Research Evidence (ASPIRE) is a major research programme for General practice in West Yorkshire which will produce findings of international interest and significance. ASPIRE is a five year, £2 million programme funded by the NIHR. The aim of ASPIRE is to produce sustainable, feasible, cost-effective interventions that will improve performance and, ultimately, improve patient outcomes. Thus, the results will be of benefit to wider primary care and will ultimately benefit patients within Leeds West.

WSYB CSU has had a valuable input into the original ASPIRE bid, and has maintained a close relationship with the ASPIRE team as the work has progressed. For example, the WSYB CSU team has provided support and assistance in obtaining ethical and R&D approval for the various research components of the programme.

The ASPIRE programme comprises five main work packages. First, the team identified a selection of high-impact recommendations, where a measurable change in clinical practice is likely to lead significant patient benefit. Second, levels of adherence to these recommendations have been measured using analysis of routinely collected data. Third, local health professionals (GPs, nurses, practice managers) have been interviewed about the recommendations, with the purpose of identifying the key factors that help or hinder their delivery. Based upon the results of the interviews, and following a process of discussion with other stakeholders, an intervention package will be developed. This package will aim to support the implementation of the selected evidence-based recommendations into clinical practice. The fourth work package is a full trial of the intervention package, in a random sample of practices across West Yorkshire. The fifth

work package is a 'process evaluation' that runs alongside the trial and examines how the approach works and whether there are any unintended consequences.

The WSYB CSU team has been integral in the delivery of the programme and contributed to the work achieved to date. In particular, the WSYB CSU has extracted the routinely collected data required to demonstrate current levels of adherence to the selected recommendations. The WSYB CSU research team has also provided assistance with the recruitment of health professionals for interviews. This has involved approaching practices directly on behalf of ASPIRE, as well as contacting CCGs and obtaining their support for the programme. This has helped the research team achieve its target number of interviewees as quickly as was feasible, which has ultimately minimised time and costs.

Throughout the programme, the research team strives to engage with relevant bodies and encourage involvement, and the WSYB CSU has played an important role in establishing and maintaining contact with key stakeholders. The WSYB CSU has also contributed to the programme in other ways, including advising on elements of research design, presenting at meetings of the programme's Patient and Public Involvement Panel, and maintaining awareness of other relevant local initiatives.

3. Improving the management of pain in patients with advanced cancer in the community (IMPACCT)

IMPACCT (Improving the management of pain in patients with advanced cancer in the community) is a five-year, £2 million research programme funded by the NIHR. It is an integrated programme consisting of 4 work streams with a collective focus on enabling patients and carers to experience improved cancer pain management within routine care.

The programme began in June 2012 and is led by Mike Bennett, Professor of Palliative Medicine at University of Leeds. It is the largest research grant ever awarded to support palliative care research in the UK and involves 15 research sites across primary and secondary care, incorporating hospices, GP practices, and acute hospitals.

This research programme has been underway for almost 2 years and has recruited 799 research participants. Recruitment challenges and high attrition rates are synonymous with research in advanced cancer and palliative care so these figures are very encouraging and the success is at least in part attributable to the support we have received through WSYB CSU funding. The funding has enabled us to employ clinical staff based at our research sites to support the identification and recruitment of eligible participants. An experienced research nurse (Annie Wing 20% FTE) was appointed at Wheatfields Hospice to help set up patient recruitment and the related research governance processes, Faith Gibson has now taken over Annie's role. Kath Black, a WSYB CSU funded research nurse based at St Gemma's Hospice, supports recruitment to the IMPACCT programme and Adam Hurlow, a palliative care consultant based within Oncology at Leeds Teaching Hospitals Trust, is also funded (one session per week) to support the programme.

As part of the research programme the study team have undertaken an opioid prescribing project which has resulted in the linkage of 14,000 patient records between Western and Yorkshire cancer registry, a hospital oncology management system (PPM) and a primary care regional dataset (SystmOne). This is the first time this linkage has been achieved and will result in a level of detail of prescribing and clinical information not seen before. Again the data searches performed within SystmOne were undertaken by the data quality team at WSYB CSU and the work was part funded by WSYB CSU.

In addition to the financial support the study team has benefitted from the support of Mahendra Patel, Consultant Pharmacist and Pharmacy Academic Lead for the NIHR Comprehensive Local Research Network (NHS) Yorkshire and Humber (CLRN) to identify pharmacy research sites across the region. These research sites will be used to explore ways to optimise the role of pharmacists in cancer pain management.

Research Grants in Development

1. Innovation in the National Health Service (NHS): Clinician entrepreneurship between new rules and old norms in the medium term

WSYB CSU has supported the development of a University of Bradford research grant proposal. This is centred on Innovation in the NHS, the rationale and a summary of the direct CCG benefits are detailed below.

The Health and Social Care Act 2012 constitutes a break with the previous regime in NHS governance. Driven by the coalition government, and thus not a bottom-up change, it supports decision-making being spread throughout the NHS and places clinicians and other health professionals as the main groups responsible for encouraging innovation. However, the kind of change such as that introduced in 2012 creates conditions of uncertainty.

The main aim of the proposed study is to answer the following question: how do new rules introduced by government influence the daily practice of entrepreneurial clinicians, and particularly those working in CCGs whose position has been altered most under the new conditions, and, in turn, impact on their ability to innovate (in the NHS) in the medium-term?

In addressing the overarching aim the study will answer the following research questions:

1. What are the effects of new, government-driven ‘rules’ in shaping the daily practice (viewed here widely to include rules passed by law, those established by professional bodies and practices established within teams) of entrepreneurial clinicians, particularly those working in CCGs?
2. How do clinicians (who are entrepreneurially inclined) respond (e.g. comply, adjust or evade) to government-driven rules: particularly in the process of introducing innovation?

3. What can organisations operating at different levels (i.e. local, regional and national) learn from the processes of entrepreneurial response (Question 2) regarding the development of new rules aimed at facilitating innovation?

This study will i) produce a robust diagnostic toolkit that could be used by NHS organisations in order to analyse their effectiveness in stimulating innovation, ii) produce insights into clinician led innovation in the NHS.

Potential contributions of the project for CCGs are:

- The research will provide an understanding of the response of clinicians to the new NHS landscape with its unfamiliar set of rules and relationships that frame innovation activity in the post-2013 NHS. This understanding, in turn, will provide insights into new ways of thinking about innovation, and how these are implemented in practice, which may be used by other entrepreneurial clinicians who wish to improve the quality, efficiency or effectiveness of healthcare in England.
- Some of these innovations could be in the domain of commissioning itself. In the post-2013 governance regime, clinicians are now involved more directly in the commissioning process through the CCGs and might therefore direct their creativity in the direction of commissioning for their ideas for improvement.
- CCGs will also benefit from access to the diagnostics that will be produced by the study. This will enable them to analyse the efficiency of their structures, processes and culture in stimulating innovation, and identify areas where corrective action can be taken.

2. AlaBAMA - Antimicrobial allergy - its effects on patient outcomes, antimicrobial prescribing and antimicrobial resistance

In response to the NIHR antimicrobial resistance themed call, Dr Jonathan Sandoe from the Leeds Teaching Hospitals Trust has submitted a research proposal (AlaBAMA) to the Programme Grant for Applied Research (PGfAR) funding stream. As the work proposed will initially use electronic health records for research (eHRR) WSYB CSU is supporting Dr Sandoe to gather this data to answer his key questions;

- Whether patients with a recorded allergy to penicillin are more likely to carry resistant bacteria;
- How many people have a penicillin allergy and how this affects antibiotic use;
- In those patients with a recorded allergy to penicillin how this affects patient outcomes (such as admission to hospital, intensive care or death);
- Then, in preparation for conducting a clinical trial of penicillin allergy testing, explore how patients and their doctors would feel about being tested, and potentially taking penicillin again; and,
- Discover if introducing a penicillin allergy testing pathway (in patients with a recorded penicillin allergy and a high risk of infection) can change antibiotic prescribing and reduce the amount of resistant bacteria.

The expected patient benefits from this study arise in those who have their allergy status changed and can resume penicillin treatment which is often the best antibiotic for many types of infection. Societal benefits arise from changes in antibiotic prescribing that reduce resistant bacteria. NHS benefits come from reduced cost from avoiding less good, more costly alternative antibiotics and improved infection management.

Research Engagement

WSYB CSU in collaboration with the NIHR assists NHS Leeds West CCG to deliver on its statutory obligations of research promotion as outlined in the CCG authorisation.

WSYB CSU helps primary care practitioners with the delivery of research through providing technical, financial and practical assistance. The team at WSYB CSU is able to offer advice on the practical implications of undertaking research to ensure that practices delivering research comply with all national and European clinical trial regulatory standards. The quotations included below are from a number of practices within West Yorkshire on their experiences of delivering primary care research.

> *'Holycroft Surgery Keighley have been a RCGP 'research ready' practice for two years now and took the leap to become involved partly due to the interest of a clinician and partly as we consider taking part in research as a component of a forward thinking practice. We were incredibly unsure of how to get involved but were well supported by local research networks and found the training provided comprehensive.*
>
> *Over the last two years we have undertaken 10 studies, some which really just involved data extraction/manipulation, some which were straight forward interviews with researchers and others which had more clinical input. We expressed interest in a few other studies as well but weren't selected. We have allocated one staff member to administer our research work so impact on the practice workload as a whole has been negligible and when properly organised we have found you can really maximise use of any clinician time needed.*
>
> *We've perhaps been surprised by how few patients sometimes qualify for the studies we have undertaken but on the whole we have found willing patient volunteers for most and generally patients seem to reflect positively on being asked to participate. We've been able to develop our interest further by taking part in certain pilot projects during the period as well and despite increasing workload and demands in practice it is encouraging that partners remain committed to continuing research work.*'
>
> 'Caritas Group Practice in Halifax has over the last 3 years successfully integrated our research work in line with our Teaching and learning across three sites within the Practice. We developed a drive team internally comprising of Clinicians and Management support led by a Practice Partner. Regular updates have been provided to all clinical staff during monthly clinical development sessions which have enabled us to engage a mix of Staff and patients in a range of study trials. We are a RCGP Accredited research Practice and recognised as a practice actively involved and supporting research at different locations. Medical students and GP registrars have also engaged in Research studies which has helped to support learning in Practice It is still relatively early days for the practice in research work terms but we hope to establish a Hub and spoke model in Calderdale involving other Practices over the next 2 years'

'Gibson Lane Practice Leeds has been involved in research for the past four years. We were looking at new income streams and decided that research would be both beneficial to the practice and the patients.

We started off slowly with some administrative studies and this gradually increased to more involved clinical studies where the practice consult with the patients and monitor their time on the trial.

The income we gain from research has partly been used to train and employ a research nurse and a practice research administrator. We also have a GP research lead therefore we have a team of staff who can undertake this work without it impacting on the other services we provide as research can be very time consuming.

We are proud to have become a RCGP 'research ready' accredited practice and the staff involved enjoy the versatility of this work. Our patients benefit greatly from being involved in the studies and enjoy the extra care we provide during the study.'

The WSYB CSU presents information on a quarterly basis to the Leeds West CCG board to inform them of all ongoing research activity and to engage with the board in order to further develop research activity and participation across the area.

The revised NHS constitution published in March 2013 outlines that the NHS aspires to the highest standards of excellence and professionalism as a key standard. This standard makes reference to a commitment to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population.

It is this standard which the WSYB CSU drives forward in any activity which it undertakes on behalf of the CCG.

Partnership Working

The WSYB CSU actively works and engages with many partner organisations across the area to ensure that the CCG is fully represented.

The NIHR has restructured and formed a number of local offices which will work with NHS organisation to enhance research activity within the area. The local office is called the Yorkshire and Humber Clinical Research network (YH CRN). Within the newly formed YH CRN, Claire Seymour our Director along with Professor Robbie Foy sit on the partnership board to ensure that primary care research grows and its influence is reflected within the NIHR.

In addition we link in with two major initiatives in the AHSN and the CLARHC. Recently we have worked with the AHSN in assisting with their master class seminar series and their dissemination events, indeed are also represented at the ARC forums. With the CLARHC we are helping the researchers to establish the work that is based in primary care. In West Yorkshire the two largest projects are;

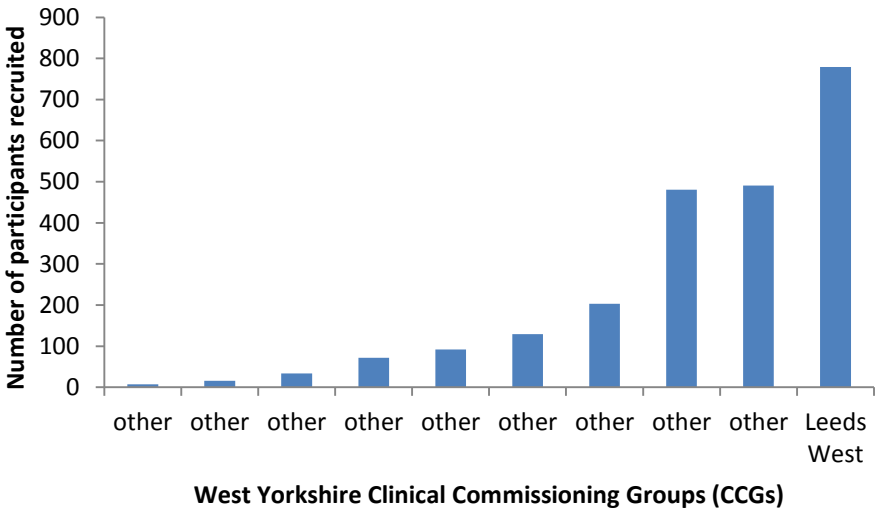
- Technology, led by Professor Mark Hawley, this 5 year project aims to produce a step change in knowledge and practice in the design and use of tele-health and care technologies, within services that are effective, cost-effective and are usable by the broadest possible range of people.
- Elderly Care, led by Professor John Young, this 5 year project is seeking to understand the issue that arise when providing elderly care when the patient is classed as fragile, it will seek to establish a validated electronic fragility index

WSYB CSU works with health professionals throughout the country in the NHS to enable research activity. We actively participate both on a national level at the Research and Development Forum, feeding directly into the work in primary care. This has meant contributing to representations made to the DoH on behalf of research within Primary Care and acting as an Advisor in the recent HRA workshops. Importantly on a local level with the West Yorkshire Research and Development Managers Group, the WSYB CSU represent the CCG's and work with the NHS trusts within West Yorkshire, collaborating with each to make West Yorkshire a place where research can be delivered within the NHS.

Recruitment Data

Throughout 2013/14 member practices of NHS Leeds West CCG have recruited 779 participants into research studies. Figure 5 below shows this in comparison to the other nine West Yorkshire CCGs.

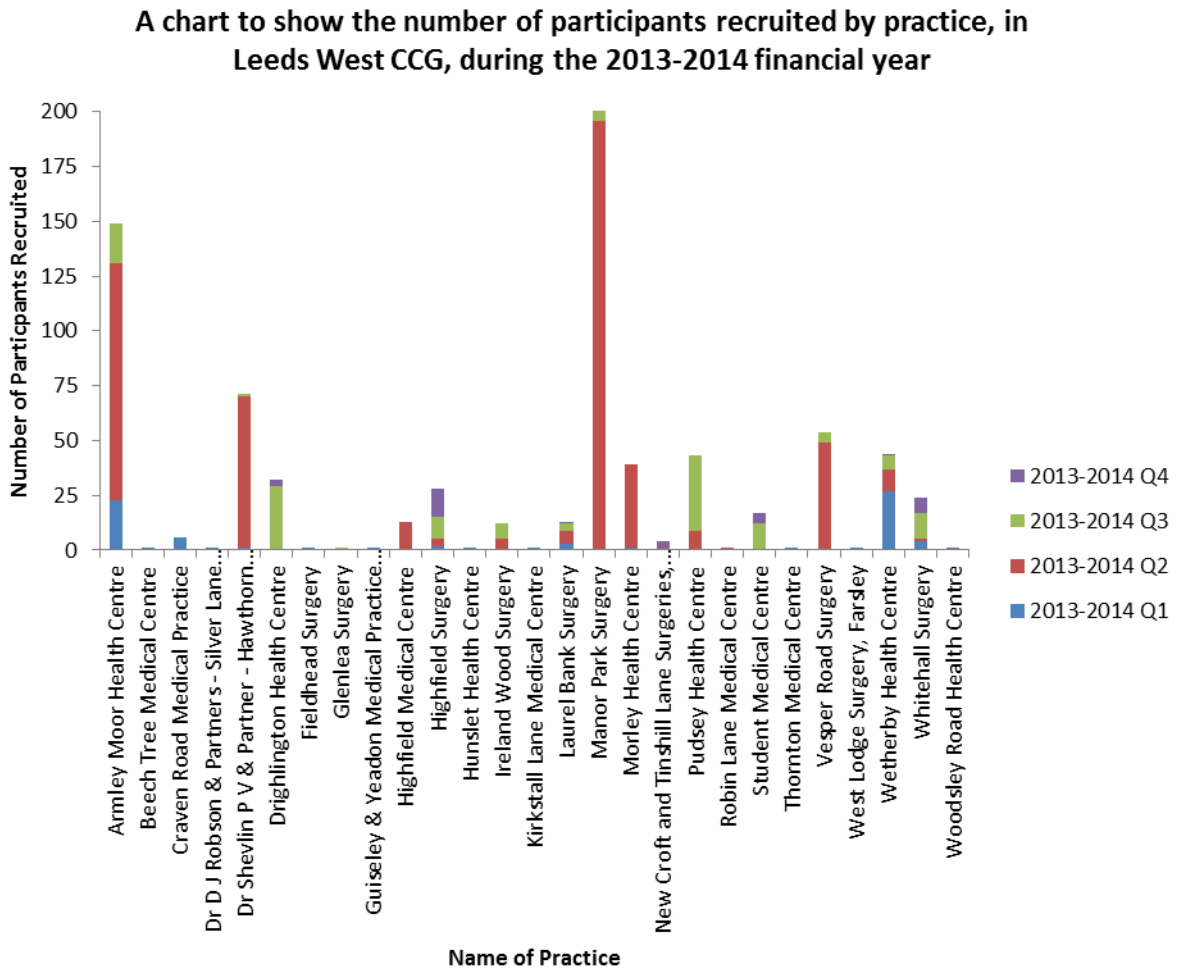
Figure 5: Shows the number of participants recruited by each West Yorkshire CCG in 2013-14



Within NHS Leeds West CCG 71% (n=27) of practices have recruited participants into research. The NIHR Clinical Research Network (CRN) business plan highlights a target of 35%, so NHS Leeds West CCG is fulfilling this network objective.

Across the West Yorkshire CCGs the average number of practices that engage with research recruitment is 46%. The WSYB CSU would like to work with NHS Leeds West CCG to increase the number of practices engaged with research activity, particularly participant recruitment. Figure 6 below shows recruitment into ongoing research studies by practice for 2013-14.

Figure 6: Shows recruitment into ongoing research studies by practice for 2013-14



From the West Yorkshire Comprehensive Local Research Network End of Year 2013-14 report the total recruitment for West Yorkshire CCGs was 2,900 participants. The total primary care recruitment for the whole Yorkshire and Humber region was 10,244 making the West Yorkshire primary care contribution 28.3%.

The total West Yorkshire recruitment across primary, secondary and tertiary care was 27,552 participants making the West Yorkshire primary care contribution 10.5%.

Although twenty seven NHS Leeds West CCG member practices have actively taken part in the recruitment of participants into research, many of the other practices will have also participated

in research through data sharing. The ASPIRE study included in Appendix 2 is an example of this.

The WSYB CSU on behalf of the CCG organises and delivers research network meetings. The meetings are an opportunity for research interested and active primary care practitioners to meet and share best practice and receive information about local research projects which are being developed or delivered. These network meetings are delivered in the Leeds and Bradford CCG's on a quarterly basis and the venue for these are rotated and all research active practices have an opportunity to host a meeting.

Over the last 12 months we have with the kind assistance of the practices across Leeds and Leeds West headquarters hosted events at;

- Thornton Medical Centre on the 30th April 2013
- Craven Road Surgery on the 30th July 2013
- Leafield House on the 15th October 2013
- Gibson Lane Practice on the 29th January 2014

Further details of the activities at each event are detailed in Appendix 4.

Knowledge Transfer

Dissemination of Research Evidence

The Health Research Authority (HRA) was established in December 2011 to promote and protect the interests of patients in health research and to streamline the regulation of research. It was established as a Special Health Authority by Government in response to a review by the Academy of Medical Sciences of research regulation, as announced in the Government's Plan for Growth (2011).

Their aim, with partners, is to make the UK a great place to deliver health research, build confidence and participation in health research, and so improve the nation's health and wealth. One of the strategic priorities of the HRA is to promote openness and transparency of research results within the UK. Transparency encompasses: registration, publication, dissemination, access to data, access to tissue and informing research participants of study results.

The WSYB CSU works on behalf of the CCG to ensure that the underlying objectives of the HRA are enacted. We endeavour to promote research transparency through a number of different methods which include: the 'Applying Research evidence into Commissioning decisions' (ARC) forums (please refer to subsequent section). The WSYB CSU also works with academics and higher education institutions to promote knowledge exchange and integration.

The WSYB CSU research team launched a website (http://www.wsybcsu.nhs.uk/what-we-do/research.htm) which provides information on the four work streams that we deliver on behalf of the West Yorkshire CCGs.

The ARC between Research and Practice

WSYB CSU is pioneering a new way to open up communication between research and practice. The Applying Research evidence in Commissioning decisions (ARC) forums encourage collaboration between key academic researchers and CCGs to promote evidence-based commissioning. WSYB CSU, in collaboration with our West Yorkshire CCGs, is the first to trial the forums, but extensive positive feedback suggests there is great potential for nationwide rollout.

A strong partnership between the NHS and academia benefits both parties; translating research into practice encourages effective use of resources, and insight into what works in practice drives future research. Despite an awareness of the importance of integrating research and practice, both partners often have little insight into the others' agenda. Satbir Saggu, Senior Associate in the WSYB CSU Research team, is the driving force behind the ARC initiative:

"We frequently received requests from CCGs who want to find out more about research relevant to local needs. ARC forums were developed to help bridge the gap between research

and practice, and create an environment for healthcare professionals to have interactive debate with academics. The meetings encourage collaboration of knowledge on current research and practice to promote evidence-based commissioning."

Six further ARC forums are currently scheduled for 2014-15 with topic themes that have been identified based on CCG priorities and the NHS Outcomes Framework. A list of the topics and keynotes speakers for 2014-15 forums has been included below:

Date	Topic Keynote	Speaker
1 May 2014	Patient Safety	Professor Rebecca Lawton
25 June 2014	Mental Health: Adults	Professor Simon Gilbody
17 July 2014	Mental Health: Children & Young People	Professor David Cottrell
24 September 2014	Managing Long Term Conditions	Professor Allan House
16 October 2014	Palliative & End of Life Care	Professor Mike Bennett
12 November 2014	Patient Experience	Dr Jess Drinkwater

The inaugural ARC forum in January 2014 was hosted by Professor Robbie Foy, Head of Primary Care at Leeds University, on the topic of Elderly Care and Dementia. Keynote speakers Professor Murna Downs, Head of Bradford University Dementia Group, and Dr Andrew Clegg, Senior Lecturer in Elderly Care and Rehabilitation at Leeds University, opened the meeting with short presentations about Dementia Care Services. Round table discussion between academics and CCGs followed the presentations as an opportunity to engage with the current research and gather evidence to support commissioning decisions. Dr Paul Bolton, Executive Board member, NHS Airedale, Wharfedale and Craven CCG, commented on his experience of the session:

'The forum was excellent and stimulating. It's great to get commissioners talking to researchers and influencing each other's agendas.'

ARC forums offer a unique opportunity to follow up on the implementation of ideas arising from clinical debate. By transcribing the essence of forum dialogue, WSYB CSU is able to share key discussion points amongst CCGs to support evidence-based commissioning. WSYB CSU is also helping to implement ideas that have potential for improving service delivery and patient outcomes across the districts. Collaboration with commissioners and health care professionals allows WSYB CSU to monitor the influence of ARC forums in practice. Evaluating the impact of ideas adopted from the sessions will demonstrate the value of ARC forums in encouraging evidence-based commissioning.

Though the concept is currently in its infancy, the positive feedback received from forum participants suggests that collaboration is beneficial for both CCGs and academics to consider "*shared decision-making resources to improve practice"* (Dr Paul Bolton). Organised sessions are presently only open to CCGs in West Yorkshire and South Yorkshire, but going forward the framework has potential to be developed and expanded nationally. Interconnecting ARC

networks across the country would be a powerful tool to improve communication between health services and ultimately enhance service delivery and patient outcomes.

Pictures above: (Left) Round table discussion from the Diabetes ARC forum in February 2014 (Right) Round table discussion from the Elderly Care and Dementia ARC forum in January 2014

Further information pertaining to the forums delivered, during the 2013-2014 financial year, can be found in Appendix 5.

Glossary

Academic Health Science Networks (AHSN) see Yorkshire and Humber Academic Health Science Network
http://www.england.nhs.uk/ourwork/part-rel/ahsn/

Academy of Medical Sciences Founded in 1998, the Academy of Medical Sciences is the independent body in the UK that represents the diverse spectrum of medical science – from basic research through clinical application to healthcare delivery. Its mission is to promote medical science and its translation into benefits for society.
http://www.acmedsci.ac.uk/

Bradford Institute for Health Research (BIHR) An organisation set up in 2007 to conduct research activity in the Bradford area, in partnership with universities and embedded within the NHS.
http://www.bradfordresearch.nhs.uk/

Chief Investigator (CI) The lead investigator with overall responsibility for the research. In a multi-site study, the CI has coordinating responsibility for research at all sites. The CI may also be PI (Principal Investigator) at the site in which they work. In the case of a single-site study, the CI and the PI will normally be the same person and are referred to as the PI.

Collaborations for Leadership in Applied Health Research (CLAHRC) Collaborative partnerships between a University and surrounding NHS organisations, which undertake high-quality applied health research focused on the needs of patients and support the translation of research evidence into practice in the NHS.
http://www.nihr.ac.uk/infrastructure/Pages/CLAHRCs.aspx

Comprehensive Local Research Network (CLRN) see NIHR

CSP NIHR Coordinated System for gaining NHS Permission: Standard process for adoption onto NIHR Portfolio of Studies in order to access NIHR CRN Support and funding; streamlines the process for gaining NHS permissions by collating the information for global and local approvals.

Good Clinical Practice (GCP) Defined standards for the terminology, design, conduct, monitoring, recording, analysis and reporting of a study. These standards give assurance that the reported results are accurate and credible and that the rights, integrity and confidentiality of all study participants have been protected throughout the study.

Good practice resource pack A pack which describes the process for handling HR arrangements for researchers and provides a streamlined approach for confirming details of the pre-engagement checks they have undergone with the NHS.
http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

Health and Social Care Act 2012
http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted

Health Research Authority (HRA) The HRA was established in December 2011 to promote and protect the interests of patients in health research and to streamline the regulation of research.
http://www.hra.nhs.uk/

Health Technology Assessment (HTA) The HTA Programme is the largest of the NIHR programmes. It funds independent research about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS. Their studies are funded via a number of routes including commissioned and researcher-led workstreams.
http://www.nets.nihr.ac.uk/programmes/hta

Honorary Research Contracts If you are coming to work at the Trust without a paid contract then we will issue you with an honorary contract. We are bound to issue these contracts to visitors to the Trust. If you are a clinician, researcher, manager or in any other role and you join us for the purposes of education and/or to gain experience we will give you a contract of this type.

In addition, if your clinical interaction, research activity or period of education or observation involves Trust employees or patients; or the use of their organs, tissue or data then we are bound to issue with an honorary contract.

This is to ensure you are bound to take proper account of the NHS 'duty of care'; and that the Trust in turn discharges its own 'duty of care' for the individual.

Letter of Access The research passport system provides a mechanism for Higher Education Institution (HEI) employers to share pre-engagement information about a researcher with relevant NHS organisations in which that researcher will be conducting their research activity.
If you are not an NHS employee, you will need to complete a research passport.
If you are an NHS employee, an NHS to NHS Proforma is completed.

A research passport is:

- a set of checks on a researcher conducting research in the NHS
- a standard form for each researcher to complete
- completed by the researcher and his/her employer, and validated by an NHS organisation
- a streamlined process for obtaining permission for research.

A research passport may be valid for the duration of a project or for a maximum of three years. Once the checks have been completed and a valid research passport has been issued, the checks may be relied upon for the duration of the research passport.
A letter of access or honorary research contract will be issued dependant on type of research activity being undertaken, on receipt of a valid research passport application or valid NHS to NHS Proforma.

National Institute for Health Research (NIHR) Established by the Department of Health for England in 2006 to provide a framework through which the DoH will position, manage and maintain the research, research staff and infrastructure of the NHS in England as a virtual national research facility.
http://www.nihr.ac.uk/Pages/default.aspx

NHS Constitution
http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx

NIHR CRN (formerly known as PCRN and WYCLRN): In 2006, the Department of Health set up the National Institute for Health Research to create a world-class health system within the NHS, and the Clinical Research Network is part of this wider organisation. At the centre of

what we do is the Portfolio – a collection of high-quality clinical studies that benefit from the infrastructure provided by the Clinical Research Network. Many of these studies are Randomized Controlled Trials – considered by many in the medical profession to be the most robust form of clinical trial – although we also support other types of well-designed research.

Western and Yorkshire Cancer Registry The Western and Yorkshire Cancer Teams (Public Health England) monitor patterns of cancer in Yorkshire and the West east of England - via the collection, analysis, interpretation and dissemination of population-based cancer data.
http://www.nycris.nhs.uk/

Plan for Growth
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/31584/2011budget_growth.pdf

Principal investigator (PI) The lead person at a single site designated as taking responsibility within the research team for the conduct of the study.

Programme Grant for Applied Research (PGfAR)NIHR Programme Grants for Applied Research (PGfAR) were established in 2006 to produce independent research findings that will have practical application for the benefit of patients and the NHS in the relatively near future.
http://www.ccf.nihr.ac.uk/PGfAR/Pages/Home.aspx

Research Capability Fund Research Capability Funding is allocated to research-active NHS organisations in proportion to the total amount of other NIHR income received by that organisation, and on the number of NIHR Senior Investigators associated with the organisation. Research Capability Funding (RCF) is also allocated to NIHR Clinical Research Networks for their local research networks, via the NHS organisations that host each local network.
http://www.nihr.ac.uk/infrastructure/Pages/research_capability_funding.aspx

Research Governance Framework DoH guidance for the conduct of research within the NHS in England.

Research Passport A system for HEI employed researchers/postgraduate students who need to undertake their research within NHS organisations, which provides evidence of pre-employment checks undertaken on that person in line with NHS Employment Check Standards (among them CRB and occupational health checks).

Research Support Services (RSS) A set of tools and guidelines to support a consistent and streamlined approach to managing health research studies in the NHS. The RSS framework was developed in collaboration with a wide range of stakeholders, including senior R&D managers and investigators, who identified research processes that could be speeded up or simplified and steered working solutions to help overcome problems.
http://www.nihr.ac.uk/systems/Pages/Research_Support_Services.aspx

Standard Operating Procedures (SOPs) Detailed written instructions designed to achieve uniformity of the performance of a specific function.

YH CRN The Clinical Research Network (CRN) is part of the NIHR. It comprises of 15 Local Clinical Research Networks that cover the length and breadth of England. YH CRN is the network for Yorkshire and Humber. At the centre of what the CRN does is the Portfolio – a collection of high-quality clinical studies that benefit from the infrastructure provided by the CRN.

Yorkshire and Humber AHSN: The Yorkshire and Humber Academic Health Science Network is one of 15 new innovative health networks set up to create and harness a strong, purposeful partnership between patients, health services, industry, and academia to achieve a significant improvement in the health and wealth of the population. The Network was given licence to operate by NHS England in May 2013.

The purpose of the Yorkshire and Humber Academic Health Science Network is to create world-class partnerships to transform healthcare and bring prosperity and wealth to the region. We will do this by working closely with NHS partners, universities, local authorities and industry to bring services and products that have the potential to transform lives to routine clinical practice by working closely with NHS partners, universities, local authorities and industry.

The Yorkshire and Humber Academic Health Science Network will generate significant added value for partner organisations by reducing service variability and improving patient experience. The Yorkshire and Humber Academic Health Science Network will also enable partners to improve efficiency and effectiveness and collectively create an environment that supports inward business investment leading to economic growth. The Yorkshire and Humber Academic Health Science Network will become a partner of choice for local, national and international businesses wishing to innovate in the health sector.

Some definitions taken from Introduction to Good Clinical Practice (GCP) v2.2.

Appendices

Appendix 1: Team Structure and Biographies

The Research Service of the West and South Yorkshire and Bassetlaw Commissioning Support Unit sits within the Transformation, Organisational Development (OD) and Research Business Unit. The Business Unit is led by Claire Seymour, Director of Transformation, OD and Research, supported by Victoria McGregor-Riley, Deputy Director for Transformation and Research.

What our service delivers

- Help in building your portfolio of research studies by working with local universities and NHS trusts to identify local research priorities
- Developing Bids for national grants in partnership with universities, NHS trusts and other NHS health and social care organisations to support research priorities
- Acting as the lead NHS organisation for all grants awarded, providing comprehensive management and governance of research projects to ensure compliance with all statutory obligations
- Building and maintaining strong working relationships with all partners and stakeholders
- Working on behalf of the CCGs to promote and implement research findings into practice

The Research team

- **Erica Warren, Principal Associate for Transformation: Research and Health Economics, Evidence and Evaluation Services**
  Overall strategic and operational lead for the service
- **Paul Carder, Senior Associate for Transformation: Research and Health Economics, Evidence and Evaluation Services**
  Service manager for research
- **Satti Saggu, Senior Associate for Transformation: Research**
  Research engagement lead
- **Rebecca Harper, Senior Associate for Transformation: Research**
  Research governance lead
- **Stella Johnson, Associate for Transformation: Research**
  Research management and engagement support

- **Rosemary Dewey, Project Associate: Research**
  Project coordinator for EU Learning Layers

The Service is provided to all ten CCGs within West Yorkshire.

NHS

West and South Yorkshire and Bassetlaw
Commissioning Support Unit

Erica Warren
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Experience summary

Erica has over 10 years experience as a NHS senior manager within the field of quality and service improvement, with significant experience of leading large scale change programmes within primary and secondary health care settings. She has also spent several years as a Health Services Researcher and Lecturer in Research Methods and Analysis and Psychology

Background

- While studying for her MPhil, Erica was a lecturer in Psychology and Research Methods and began her career in the NHS in 1998 as a health services researcher in the field of the evaluation of evidence based innovation implementation.
- In her role at Bradford Teaching Hospitals NHS Foundation Trust, Erica has worked with the Institute for Health Improvement developing her expertise in improvement methodologies
- Erica is trained in MSP (Managing Successful Programmes)

Skills

- Application of quality and service improvement methodologies to achieve large scale change
- Measurement for Improvement
- Programme management
- Theory informed implementation of innovation within health care services
- Research and evaluation methods and data analysis

Relevant Work Experience

- **Principal Associate for Transformation: Health Economics, Evaluation and Evidence Service (HEEES) – West and South Yorkshire and Bassetlaw Commissioning Support Unit.** Erica is the service lead for HEEES. The service provides expertise, advice, enabling tools, capacity and delivery in the areas of clinical effectiveness and evidence; health economics and evaluation and knowledge transfer.
- **TRiP-LaB Programme Lead – NHS Bradford and Airedale**. Erica led this five year research programme aimed at increasing the adoption, and evaluating the impact of, targeted innovations within health care settings across Leeds and Bradford, applying policy cost effectiveness to determine high cost effectiveness implementation efforts
- **Clinical Quality Lead – Bradford Teaching Hospitals NHS Foundation Trust.** Erica led on the development, implementation and monitoring of the Clinical Governance Strategy. She was also the Trust lead for clinical audit, clinical effectiveness, quality improvement and the IHI Safer Patient Initiative.
- **BRPP Programme Manager – Bradford Teachings Hospitals NHS Foundation Trust.** Erica led on the development and implementation of the BRPP programme which involved the service redesign and quality improvement of ENT, abdominal ultrasound and adult incontinence referral pathways.
- **Lecturer in Research and Evaluation Methods – Manchester Metropolitan University.** Erica developed and delivered the research methods and data analysis module within the Social Sciences department.

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Paul Carder
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Experience summary

Paul has been working in research related roles in both academia and the NHS for over 10 years, contributing to large National Programmes of research and evaluation within both. Recent time has been spent overseeing the research and evaluation activity within primary care across the whole of West Yorkshire, starting with the clustered PCT's and now acting on behalf of all the CCGs and general practices therein

Background

- While studying for his postgraduate degrees at the University of Essex, Paul was also a lecturer to both undergraduate courses linked to the BA honours programme, courses included economic theory, economic policy and quantitative methods and postgraduate courses in the Masters programme, namely quantitative methods and statistics.
- He was also a researcher in a subsidiary of the Economics Department at the University of Essex, known as the Institute for labour studies, contributing to the work on national projects such as the British Household Panel Survey, Evaluations of the Benefits system for the Department of Social Security
- In his role at the PCT he worked closely with the local Universities in West Yorkshire and York to deliver national priority areas of work
- Paul is also an ex professional rugby coach and qualified RFU rugby coach

Skills

- Application of economics in a healthcare setting
- Theory informed implementation of innovation within health care services
- Research and evaluation methods and data analysis

Relevant Work Experience

- **Senior Associate for Transformation: Research, Health Economics, Evaluation and Evidence Service (HEEES) – West and South Yorkshire and Bassetlaw Commissioning Support Unit.** Paul is the service operational lead for both the HEEES service and the Research service. The HEEES service provides expertise, advice, enabling tools, capacity and delivery in the areas of clinical effectiveness and evidence; health economics and evaluation and knowledge transfer. The Research service works with the CCGs and their constituent members to deliver nationally recognised studies that have been adopted onto the NIHR portfolio. In addition he works with academics to bring research funded projects into the local health economy, attracting both National and European Union grants over the last couple of years.

- **Research Lead – NHS Bradford and Airedale.** Paul led on the development and uptake of research within primary care, beginning with the Bradford and Airedale trust and then leading in the clustered PCTs in West Yorkshire prior to the NHS transition ensuring stability and continuation of meeting the NIHR high level objectives for research. He also led a programme of work aimed at increasing the engagement with research activity in national studies. He was also chair of the project management group on several NIHR funded trials, directing work to ensure timely delivery within both time and budget.

  Paul also established and led the Economics working group for the LYBRA CLARHC, chairing sessions at National Conference on this nationally sponsored research work bringing together the academic environment and the NHS.

- **Lecturer in Economics, Quantitative Methods and Statistics – University of Essex.** Paul lectured on both the undergraduate and postgraduate programmes, designing and delivering courses in fields such as economic theory (both macro and micro). He also designed and delivered the foundation quantitative and statistics methods courses for postgraduate students entering the department.

  In addition, working within the Institute for Labour Studies, Paul's work focussed on dynamic bargaining solutions using game theoretic analysis and examining the nature of the frequency and duration of strikes within British Industry (public and private sector).

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Rebecca Harper
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Experience summary

Rebecca is an experienced project and programme manager, trainer and clinician with over a decades experience of working in health, academia and commercial settings. She has a strong track record of service delivery and development work, at local and regional and international level.

Background

- Rebecca began her career in the field of dentistry as a dental nurse in1999, joining the NHS in 2000. After qualifying as a Registered Dental Nurse (RDN) in early 2001, she has since worked in many areas of dental health, including conducting audits of all dental practices within NHS Bradford & Airedale in preparation for the CQC.
- Rebecca has a 2:1 honours degree in Media, working as a counsellor at a children's summer camp in the USA, on TV projects as location manager, assistant director and on an international commercial ,she began her interest in research working commercially as a consultant in eye tracking research. Currently working towards MSc in Health Research.
- She is CMI (Chartered Management Institute) level 5 certificated in leadership and management.

Skills

- Project Management
- Programme Management
- Specialist knowledge in the field of research methods and governance.
- Training development and delivery
- Specialist knowledge in the fields of dental health and research
- Knowledge and experience of media communications

Relevant Work Experience

- **Research Consultant – Training and Project Management.** Rebecca has spent three years delivering services to public and private sector clients including producing tailored eye tracking research reports to commercial and HEI clients. In the public sector providing advice and project management for research projects within the NHS, attending courses provided by WYCLRN including GCP and valid informed consent training and being the PPI lead for research for the NHS.
- Rebecca has also been involved with various projects funded by the NIHR, providing support for researchers from a range of areas including academia, healthcare and industry. Rebecca has completed the MSc Certificate and MSc Diploma at the University of Leeds and is currently completing her dissertation towards qualification as MSc in Health Research.
- **Registered Dental Nurse – Various settings.** Over the course of a 14 year career Rebecca has worked in many areas of dental health including primary care, acute, paediatrics, learning difficulties and domiciliary visits to the elderly, including phobic patients and relative analgesia. She was also manager of COSHH creating a hyperlinked database as a fast response to substance reactions and chosen as dental nurse to work with the Clinical Director. More recently conducting audits and delivering specialist infection control training to audiences of up to eighty dental health practitioners including dentists, dental hygiene/therapists and dental nurses on behalf of the NHS within Bradford & Airedale in preparation for introduction of the CQC.
- **Production Assistant - Project Management.** As Production Assistant for the TV company Studio 163 Rebecca worked on various local and regional projects funded by Bradford Council, the Arts Council and Yorkshire Forward. She was a main point of contact and representative for the company at launch events and pitching proposals. She also taught and acted with children at film workshops at a local school, culminating in a film debuted at the Cubby Broccoli Cinema at the National Museum of Film, Photography and Television in Bradford. She was Location Manager on 'Location, Location, Location' filmed in Bradford and assistant on an infomercial filmed in Los Angeles.

NHS

West and South Yorkshire and Bassetlaw
Commissioning Support Unit

Satbir Saggu
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Experience summary

Satti has extensive experience of research delivery which has been acquired from roles within the public and commercial setting. These roles have been varied encompassing the management of clinical trials within a primary and secondary care setting. Satti's most recent NHS role, as a Research Facilitator for the National Institute for Health Research Primary Care Research Network, entailed increasing the engagement of primary care practitioners in NIHR portfolio studies within West Yorkshire. This role required liaising with a variety of stakeholders which included CCG board members, General Practitioners, Pharmacists, Nurses, Business Managers and Practice Managers to oversee and manage the delivery of research at 26 sites.

Background

- Satti has a 2:1 BSc (Hons) in Pharmaceutical Management from the University of Bradford.
- Satti has a comprehensive knowledge around the practicalities of research delivery in particular the frameworks that regulate the industry. This knowledge has been refined and developed through the delivery of the National Institute for Health Research Good Clinical Practice training course. This is a national course which has been created through the collaborative input of NHS clinicians, universities and the pharmaceutical industry.
- Satti has worked with organisations across the region including universities and other health and social care organisations to increase research engagement.

Skills

- Project Management
- Experience of developing and coordinating research engagement over a number of sites.
- Extensive knowledge and experience of research delivery and the regulatory framework which govern the clinical research industry.
- Excellent communication and presentation skills acquired through the development and delivery of a number of training research courses.
- Excellent negotiation, facilitation and influencing skills.

Relevant Work Experience

- **Research Facilitator - Primary Care Research Network (Northern & Yorkshire), Leeds**

Satti has worked for the National Institute for Health Research Clinical Research Network (NIHR CRN) facilitating research in the primary care sector which included the identification of health care users who are eligible to take part in trials represented on the NIHR CRN portfolio.
Satti has provided support and information to patients and health care users involved in NIHR CRN portfolio studies within the West Yorkshire area. The role involved liaising with NIHR network staff, network managers and programme managers to ensure that research is delivered in a timely manager and to recruitment targets.

Clinical Data Associate Covance Clinical Research Unit, Leeds
Satti worked in the Pharmacometrics department of a Clinical Research Organization performing Data Management duties this entailed performing discrepancy management on data, stored on the Oracle Clinical (OC) database and Case Report Forms
The role involved the Creation and the integration of Data Clarification Forms, accuracy of integration is guaranteed by maintaining a high level of attention to detail.
Undertaking Medical Coding, in accordance to sponsor guidelines, using 'World Health Organisation Drug' and 'MDRA' Dictionaries.
Communicating potential data issues with members of the data management team to ensure specified timelines are met.

Data Manager Airedale General Hospital, Keighley
Satti worked in a Haematology and Oncology research team setting up, maintaining and co-coordinating phase III clinical trials. The role involved locating and assessing the suitability of patients for clinical studies through attending Multi-Disciplinary Team Meetings. The role also the involved Source Document Verification. Designing data collection forms, spreadsheets and databases to capture study related information and provide Source Document. It also entailed the verification,
Initiation and maintenance of clinical trials in line with ICH-GCP guidelines.
Satti was involved in 'spotlight' business improvement projects within the trust as a lean champion.

Scientific Classifier
Medicines and Healthcare Products Regulatory Agency, London
Satti worked in the information-processing unit, which is responsible for the administration of Market Authorisations of medicinal products in the UK.
Proficient in the use of Documentum an Enterprise Content Management platform.
As a scientific Classifier Satti Validated case submissions against the appropriate regulatory requirements.

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Stella Johnson
Associate for Transformation: Research Service
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Experience summary

Stella is an experienced project and programme manager, with knowledge of quality control and management principles. She has a strong track record of health research coordination and management working for the National Institute for Health Research (NIHR) Trainees Coordinating Centre in several posts since 2005

Background

- Stella began her career in manufacturing quality control and management, travelling extensively across the Far and Middle East
- Stella already holds postgraduate qualifications in Health Research and Epidemiology and is currently working towards an MSc in Health Research from the University of Leeds
- Extensive experience of development and delivery of training in both manufacturing and health research settings

Skills

- NIHR Research Programme Management
- NIHR IS Project Management
- Specialist knowledge in the field of research methods and governance.
- NIHR IS training development and delivery
- Specialist knowledge in return on investment evaluation
- Trained in GCP, Clinical Risk Management and Project Management for Clinical Research
- Large scale event management

Relevant Work Experience

- **Research Associate.** Stella has spent year at the WSYB CSU working within research governance on supporting research engagement activities. Stella has also been involved with the evaluation of several major projects and is working towards a formal accredited return on investment qualification.

Stella has also been involved with various projects funded by various streams of the NIHR, working with and providing support to researchers from a range of areas including academia, healthcare and industry.

- **Senior Programme Officer** Stella was involved with programme development and management of the NIHR Research Professorships scheme, one of the key initiatives delivered by the NIHR that was highlighted in the Strategy for UK Life Sciences: One Year on. The initiative was aimed to develop research leaders capable of making a real difference in the translation of research into everyday practice. Her role also involved management of the Integrated Academic Training pathway for Doctors and Dentists, the In-Practice Fellowships for GPs and GDPs and the Clinician Scientist Schemes. Working with England's Lead Dean for Medicine and the National Workforce Manager, Stella supported the national management of all supernumerary posts.

Stella also spent time working on the Personal Awards Team managing the Doctoral, Post-Doctoral and Career Development Fellowships at the NIHR TCC. Working across all programmes she contributed to the programme guidance notes and application forms having input into the NIHR Strategy and Advisory boards on scheme development.

Stella was also the NIHR TCC lead for implementation of the new IS system for award and programme management and also lead the training for roll out in this area.

Whilst at the NIHR TCC Stella also managed and administrated the annual conference for NIHR Clinical Lecturers and was part of the team organising the NIHR Faculty Trainees Annual Conference

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Rose Dewey
Project Associate : Research
Mobile: 07432 721839
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Experience summary

Rose developed extensive project management experience through eight years of working in the academic publishing industry.

Background

- Rose started her career working for an academic publishing company, developing an extensive knowledge of all aspects of the publishing industry and academic research.
- Rose is currently studying for a postgraduate certificate in Health Research from the University of Leeds
- Gained a strong understanding of the academic community through working with editors and authors in her time in publishing.

Skills

- Project management
- Relationship building
- Negotiation

Relevant Work Experience

- **Project Associate: Research.** Rose has been heavily involved in WSYB CSU's input into Learning Layers, a four-year EU project which is part of the EU's FP 7 programme.

Learning Layers is investigating informal workplace learning and ways of supporting this through technology. The project focuses on workplace learning in two sectors – construction and healthcare. Rose is working on facilitating the roll-out plan and programme in the healthcare cluster, engaging with GP practices initially in the Bradford area but aiming to widen this out over the coming years.

- Rose also gained experience of working with clinical and administrative staff at GP practices through other project work for WSYB CSU, working directly with the CCGs and with practice staff.

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Robbie Foy
Professor of Primary Care: Leeds Institute of Health Sciences

Telephone: 0113 343 4879
Email: R.Foy@leeds.ac.uk

Experience summary

Robbie Foy is Professor of Primary Care at the Leeds Institute of Health Sciences and a general practitioner in inner-city Leeds. His research focuses on the development and evaluation of approaches to improve the quality of health care. Robbie is an Academic Director for the Research Service within West and South Yorkshire and Bassetlaw Commissioning Support Unit

Background

- Robbie joined the Leeds Institute of Health Sciences in September 2008.
- He held previous posts at Newcastle University (Clinical Senior Lecturer in Primary Care, 2002–8) and the University of Edinburgh (MRC/Scottish Executive Health Department Training Fellow in Health Services Research, 1998–2002).
- Prior to this, he completed training in general practice and in public health medicine. He was a 2006–7 Harkness/Health Foundation Fellow in Health Care Policy, based jointly between the Veteran's Administration Centre for the Study of Healthcare Provider Behavior and RAND in Los Angeles.
- His research focuses on understanding and closing the gap between best evidence and routine practice.
- Robbie also works one day per week as a General Practitioner at Craven Road Medical Practice in Leeds.

Qualifications

- PhD – Edinburgh, 2004
- MFPHM – Royal College of Physicians (Faculty of Public Health Medicine), 1997
- MSc in Public Health & Epidemiology – Manchester, 1995
- MRCGP – Royal College of General Practitioners, 1992
- DCH – Royal College of Physicians (London), 1991
- MB ChB – Edinburgh, 1988

Current research

- **Development and evaluation of strategies to provide longer-term health and social care for stroke survivors and their carers.** Forster A, Young J, Hewison J, House A, Hulme C, Hawkins R, Dickerson J, Richardson G, Bhakta B, Hartley S, Speed M, McKevitt C, Farrin A, Fay M, McEachan R, Foy R. NIHR Programme Grants for Applied Research. £1,673,049. Co-investigator.

- **The development and evaluation of enhanced audit and feedback interventions to increase the uptake of evidence-based transfusion practice.** Stanworth S, Glidewell L, Prior M, Hartley S, Foy R, Farrin A, Michie S, Grant-Casey J, Goddard F, Campbell H, Rowley M, Murphy M, Francis J. NIHR Programme Grant. £1,962,219. Co-investigator.

- **Is involvement with education associated with higher quality clinical care in general practice?** Pearson D, Farragher T, Foy R, Riley D. NIHR Flexibility and Sustainability Funding; NHS Airedale, Bradford and Leeds. £40,010; 2012-3. Co-investigator.

- **Targeted and sustainable implementation of high impact clinical practice recommendations in general practice.** Foy R, Lawton R, Glidewell L, Ward V, West R, McEachan R, Farrin A, Rathfelder M, Clamp S, McCabe C, Seymour C, Richardson J, Stokes T, Taylor-Whilde E, Watt I, Hartley S. NIHR Programme Grant. £1,995,432; 2012-17 for 60 months. Principal investigator.

- **Understanding prescribing of opioids for chronic, non-cancer pain in general practice.** Foy R, Montana C, Bennett MI, Closs J, House A, Glidewell L, Petty D. NIHR Research for Patient Benefit. £248252; 2012-13 for 21 months. Principal Investigator.

- **Improving the Management of Pain from advanced Cancer in the Community (IMPACCT).** Bennett MI, Allmark C, Bewick B, Blenkinsopp A, Brown J, Closs J, Flemming K, Foy R, Godfrey M, Hall G, Hulme C, Jones R, Pavitt S, Rainey P, Ziegler L, Fox D. NIHR Programme Grant. £1,994,907; 2012-2017 for 60 months. Co-investigator.

- **Evaluation of screening for depression in patients with chronic physical disease in primary care.** Foy, R, Alderson S, McLintock K, West R, Potrata B, House A, Johnson K. NIHR Research for Patient Benefit. £242141; 2011-13 for 18 months. Principal Investigator

- **Incentives, inequalities and influences: an evaluation of a local pay-for-performance scheme for primary care.** Foy R, Glidewell L, West R, Hand W, Doran T, Newton M. NIHR Research for Patient Benefit £203,339; 2011-13 for 18 months. Principal Investigator.

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Mahendra Patel
Professor of Primary Care: Leeds Institute of Health Sciences

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Experience summary

Mahendra Patel is a Senior Lecturer and Pharmacist in the Division of Pharmacy University of Huddersfield, Fellow of the National Institute for Health and Clinical Excellence and Honorary Research Fellow at Bradford University. Since graduating and gaining his PhD in Pharmacy Practice, his career has spanned community practice, health promotion, academia, research, guideline development and voluntary work. Pharmaceutical Society

Background

- Mahendra is Adjunct Professor of Pharmacy Wilkes University, Pennsylvania USA
- Honorary Senior Lecturer of the Academic Unit, Primary Care Medical School, University of Sheffield
- Board member of the Royal Pharmaceutical Society
- Ambassador for NHS Evidence, helping health and social care professionals access high quality evidence based information

Current research

- My area of research and knowledge, specifically focussing around South Asian health, has now been recognised nationally through the Department of Health's NICE Guideline Development Group for Clinical Concordance published in 2009. This guidance could help influence health recommendations to Primary Care Trusts and GPs at a national level in order to improve medicines concordance and ultimately health outcome. I am also developing this work through my recognition as a Fellow of NICE with a particular focus around cultural, religious and language barriers.

- As Coronary Heart Disease is a major cause of premature death and illness resulting in serious social and economic problems. The benefits of Lipid Lowering Drugs (LLDs) and aspirin for the prevention of Coronary Heart Disease (CHD) are well documented and effective management of CHD is a national priority. I am currently exploring the relationship between practice demographics and prescribing rates of key drugs used for the prevention of CHD for 2006 – 2007 and determine whether there is any change since that reported using data for 1996 – 1997 in Bradford, when the prescribing of LLDs and certain practice demographics (indices of deprivation and workload, percentage of SE Asian patients, number of GPs and gender of both patient and prescriber) demonstrated that prescribing rates were the lowest among patients in practices with the greatest proportion South East Asian population (Patel et al BMJ 2002).

Recent publications

- Tucker, R., Patel, M., Layton, A. and Walton, S. (2013) 'An examination of the comparative ability of primary care health professionals in the recognition and treatment of a range of dermatological conditions ' International Journal of Pharmacy Practice . ISSN 2042-7174

- Culshaw, M. and Patel, M. (2012) 'Tackling health inequalities by means of an evidence-based health promotion programme' International Journal of Pharmacy Practice , 20 (S1), pp. 20-21. ISSN 0961-7671

- Taskila, T., Macaskill, S., Coleman, T., Etter, J., Patel, M., Clarke, S., Bridson, R. and Aveyard, P. (2012) 'A Randomised trial of nicotine assisted reduction to stop in pharmacies - The RedPharm Study' BMC Public Health , 12 (1), p. 182. ISSN 1471-2458

- Patel, M. and Culshaw, M. (2011) 'Examples of good practice for management of CVD in South Asians'. In: 12th Annual Conference of the South Asian Health Foundation (SAHF), 7th-8th October 2011, Birmingham, UK

- Patel, M (2011) 'Working together with opportunities presented by Portfolio research'. In: Royal Pharmaceutical Society GB Doncaster & South Humber Local Practice Forum Pharmacy Practice Meeting, September 2011, Doncaster, UK

- Patel, M (2011) 'Diabetes, adherence to medicines - NHS evidence'. In: RPS Royal Pharmaceutical Society Conference 2011, 11-12 September 2011, London, UK

- Patel, M (2011) 'Health and diversity in the UK'. In: Grand Rounds Pennsylvania Medical Society Dept of Medicine St Luke's Hospital and Health Network CME program, May 2011, Pennsylvania, USA

- Patel, M (2011) 'Inter disciplinary and transcultural medicine'. In: Interprofessional Education Coalition Interprofessional Care Summit , 30th March 2011, Pennsylvania, USA

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Carl Thompson
Professor of Primary Care: Leeds Institute of Health Sciences

Telephone: 01904 321350
Email: carl.thompson@york.ac.uk

Experience summary

Carl Thompson is a Professor in the Department of Health Sciences, University of York. His research focuses on the diffusion of innovations; clinical judgement and decision making; knowledge transfer and behaviour change; and evidence based policy and practice. Carl is an Academic Director for the Research Service within West and South Yorkshire and Bassetlaw Commissioning Support Unit

Background

- Carl trained as a nurse before working in a variety of NHS and private sector jobs in the UK and overseas. After a PhD in Social Policy, he worked in a joint NHS-University post, promoting research and the uptake of research findings in the NHS. This job sparked a long-standing interest in how healthcare professionals and managers use research evidence in their clinical decision and policy making. More recently, Carl has led the NIHR CLAHRC for Leeds York, and Bradford's TRiP-LaB (Translating Research into Practice in Leeds and Bradford) theme. This is a £4 million initiative to increase the uptake of innovation and research evidence in the NHS in West Yorkshire.
- Carl is a Non-Executive Director of Leeds & York Partnership NHS Foundation Trust

Qualifications

- PhD Social Policy, University of York, 1997
- BSc Hons Social Policy, 1st class with distinction, University of York, 1993
- RN, York College of Nursing, 1989

Recent publications

- An agenda for clinical decision making and judgement in nursing research and education. Thompson, C., Aitken, L., Doran, D. & Dowding, D. Dec 2013. Article in International Journal of Nursing Studies
- Immediate versus sustained effects: interrupted time series analysis of a tailored intervention, Hanbury, A., Farley, K., Thompson, C., Wilson, P. M., Chambers, D. & Holmes, H. Nov 2013. Article in Implementation science
- Decision Curve Analysis for Assessing the Usefulness of Tests for Making Decisions to Treat: An Application to Tests for Prodromal Psychosis. Pulleyblank, R., Chuma, J., Gilbody, S. M. & Thompson, C. Sep 2013. Article in Psychological assessment
- Exploring the feasibility of Conjoint Analysis as a tool for prioritizing innovations for implementation. Farley, K., Thompson, C., Hanbury, A. & Chambers, D. May 2013. Article in Implementation science
- The effect of improving task representativeness on capturing nurses' risk assessment judgements: a comparison of written case simulations and physical simulations. Yang, H., Thompson, C., Hamm, R. M., Bland, M. & Foster, A. May 2013. Article in BMC medical informatics and decision making
- Effect of improving the realism of simulated clinical judgement tasks on nurses' overconfidence and underconfidence: Evidence from a comparative confidence calibration analysis. Yang, H., Thompson, C. & Bland, M. Dec 2012. Article in International Journal of Nursing Studies
- Clinical simulation fidelity and nurses' identification of critical event risk: a signal detection analysis. Thompson, C., Yang, H. & Crouch, S. Nov 2012. Article in Journal of Advanced Nursing
- The effect of clinical experience, judgment task difficulty and time pressure on nurses' confidence calibratio in a high fidelity clinical simulation. Yang, H., Thompson, C. & Bland, M. Oct 2012. Article in BMC medical informatics and decision making
- Initiating artificial nutrition support: a clinical judgement analysis. Baker, S. M. & Thompson, C. A. Oct 2012. Article in Journal of human nutrition and dietetics
- Social network analysis in healthcare settings: a systematic scoping review. Chambers, D., Wilson, P., Thompson, C. & Harden, M. Aug 2012. Article in PLOS ONE
- Challenges in identifying barriers to adoption in a theory-based implementation study: lessons for future implementation studies. Hanbury, A., Farley, K. L., Thompson, C. A., Wilson, P. & Chambers, D. 2012. Article in BMC Health Services Research
- Public Preferences for Health Service Innovations: The Evidence from a Conjoint Analysis: A Report for the UK's National Health Service Foundation Trust. Erdem, S. & Thompson, C. A. 2012 Public Preferences for Health Service Innovations: The Evidence from a Conjoint Analysis: A Report for the UK's National Health Service Foundation Trust. Research output: Chapter in Book/Report/Conference proceeding › Chapter

Appendix 2: Future plans for Action to Support Practices Implementing Research Evidence (ASPIRE)

The WSYB CSU is working closely with academic colleagues at the University of Leeds to deliver the ASPIRE study. The ASPIRE study team have asked us to put forward the below request for support to all ten West Yorkshire CCGs for the next phase of their work.

What is ASPIRE?

ASPIRE is a five-year, £2 million research programme for primary care in West Yorkshire funded by the National Institute of Health Research. We are a multi-disciplinary group including senior researchers (from Leeds, Bradford and York) and representation from general practitioners, managers, and patients. Our aim is to develop and evaluate cost-effective, sustainable ways to help general practices implement evidence-based care. All CCGs in West Yorkshire have expressed their support for ASPIRE, which has helped us to win funding and encourage practices to participate.

What have we done so far?

With your help, we've made excellent progress since 2012. We have identified a set of evidence-based quality indicators – which closely match existing priorities (e.g. diabetes, prescribing safety) and explored variations in practice. At least 100 practices have engaged with ASPIRE in some way – largely through data sharing, interviews or guiding the development of quality improvement interventions.

What are we doing next?

We are now planning a randomised trial to test the effects of the quality improvement interventions on the delivery of care amongst practices in West Yorkshire. This will involve randomly allocating at least 60 practices to different interventions and measuring effects on patient care and value for money. The trial will be designed so that every participating practice receives one of two intervention packages, e.g. support to improve diabetes care, or support to reduce risky prescribing.

What would participation in the trial mean for practices and patients?

Practices will receive or be offered a range of quality improvement interventions, including brief in-practice educational meetings, feedback of audit data, and computerised decision support. The impact of these activities will be measured using remotely extracted *anonymised* patient data. *Therefore, practices will not be obliged to do any extra work*. Practices can decline the
interventions at any time but we would still be keen to collect the patient data to reduce bias.

What would opt-in participation entail?

Conventionally, for this type of 'cluster' randomised trial, we would ask practices to give 'opt-in' consent. (Consent is unnecessary for patients since we are collecting anonymised patient data.) However, we know how busy general practices are and we have found from earlier work that 'opt-in' approaches can result in less typical practices participating in research. We want our research to replicate 'real life' conditions as much as possible.

What would opt-out participation entail?

We would notify all practices in advance via existing communication channels within CCGs, as well as other routes (e.g. University newsletters) of our intentions. We would then randomly select at least 60 practices from West Yorkshire. We would write twice to these practices, using recorded delivery, explaining the trial and what it entails. We would also email each practice twice. Practices which decline to participate would readily be able to do so by email or by telephone. In this way, by maximising publicity and making it as easy as possible to decline, we hope we could avoid the sort of difficulties encountered elsewhere (e.g. care.data). We would also hope to reduce hassle to practices and end up with a good representative sample of typical general practices.

What are the ASPIRE team and collaborators recommending?

We have already canvassed a wide range of opinion on this opt-in/out question, and suggest an opt-out approach. Feedback from discussions with GPs, patient representatives and our International Scientific Advisory Panel favours an opt-out approach because it will help ensure our research resembles real-life conditions as far as possible. We will need to seek research ethics and governance approvals to use an opt-out approach; this is more likely to happen if we can demonstrate evidence of acceptability.

What are we seeking from our collaborating CCGs?

We are seeking endorsement for an opt-out approach from each CCG that we can include in our advance communication to practices.

For further information contact:

Robbie Foy, Professor of Primary Care & ASPIRE Lead Investigator: 0113 343 4879; r.foy@leeds.ac.uk Paul Carder, Research Manager, WSYBCSU: 01274 237406; Paul.Carder@wsybcsu.nhs.uk

Appendix 3: Summary Information on the studies which the WSYB CSU has issued NHS Permissions for on behalf of the CCG.

Research Project into Triage Study

Chief Investigator: Dr Sarah Alderson, University of Leeds
Local Investigator (Student): Miss Lucy Owen (BSc in Primary Care)
Risk: Low
Start/End Date: 23/03/2013 – 13/06/2013
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

A literature review carried out by the researcher identified triage, defined as assessing the urgency of a patient's complaint and then giving them advice or signposting them to the appropriate resource, as one way of managing the increasing demand for same-day appointments in general practice. The proposed methodology for this research is similar to a study by Charles-Jones et al. 2003; however this study compares triage systems with standard management of same-day appointment requests, most commonly fitting urgent cases on to the end of surgeries. This research project aims to compare the views of different staff members in general practice on what they believe to be the consequences of GP-led triage compared to Nurse-led triage on workload, satisfaction and patient safety. Where possible this will be compared to any previous systems of managing requests for same-day appointments that the GP practice has used, through semi-structured interviews. Furthermore there is limited up to date research with many studies being carried out over 10 years ago and there has been no such research in the West Yorkshire area.

Participants will include GPs, nurses and receptionists, as the preceding literature review found that receptionists' views are under-represented in existing research. Single interviews of 30 to 60 minutes duration will be carried out with 6-9 participants across 2-3 GP surgeries that have been identified as suitable participants from practice websites and then recruited via email.

The study is an academic study carried out as part of a BSc sponsored by the University of Leeds.

The Mechanisms and Reversibility of Heart Failure associated with Diabetes Study

Chief Investigator (Student): Dr Peter Swoboda, University of Leeds
Academic Supervisor 1: Professor Sven Plein
Academic Supervisor 2: Dr John Greenwood
Risk: Low

Start/End Date: 01/04/2013 – 01/04/2016

CCG Costs/Income: N/A
Status: New study

Brief overview of study:

Patients with diabetes have a higher incidence of heart failure and worse outcomes than non-diabetic subjects. In this study we will investigate the relationship between diabetes and heart failure by exploring the correlation between microvascular dysfunction (in this study defined as the onset of microalbuminuria, in lay terms protein leak from the kidneys) and cardiac magnetic resonance (CMR) markers of left ventricular (LV) hypertrophy, cardiac dysfunction and fibrosis.
Patients with new onset microalbuminuria would routinely be treated with an ACE inhibitor and it is hypothesised that with this treatment some of these observed changes in cardiac structure and function will be reversible. This could have important clinical ramifications in type 2 diabetes by increasing the indications for treatment with RAAS inhibition or making a case for lower blood pressure targets.

Patients with diabetes will be recruited for the study from primary care practices nearby the Leeds General Infirmary and will include both patients with recently diagnosed microalbuminuria and stable patients without microalbuminuria.GPs and primary care nurses with an interest in diabetes will be advised of the recruitment criteria for this study and will identify patients at their annual diabetes clinics. If the patient advises their own doctor or nurse that they would wish to be enrolled in the study their details will be passed on to the CI or research nurse involved in the study. Suitable patients will be sent a study information leaflet by post and asked to contact the research team if they would be interested in learning more about the study. A telephone conversation will then be arranged between the patient and the CI or study nurse to explore their eligibility for the study and to address any questions that the patient may have. Written informed consent will be obtained by the CMR research fellow or research nurse when the patient attends the cardiac MRI department at the Leeds General Infirmary.

It is planned to study patients who have diabetes and measure their blood pressure over 24 hours with a self-inflating cuff, hormone levels and structure and function of their hearts by cardiac MRI scan (CMR). These tests will be carried out before and after the patient has been treated with an ACE inhibitor for 9 months. After the second scan the patients involvement in the study will end.

The study is an academic study sponsored by the University of Leeds and funded by the British Heart Foundation Clinical PhD Studentship.

The Reviewing Provision of Medical Abortion Services Study

Chief Investigator (Academic Supervisor): Dr Gail Nicholls, University of Leeds
Local Investigator (Student): Miss Ruth Watson, Intercalated BSc student in Applied Health (Primary Care)
Risk: Low
Start/End Date: 15/04/2013 – 07/06/2013
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

A pilot study supported by the Department of Health (Ingham, R. and Lee, E. 2008) investigated the provision of medical abortions from non-traditional community based settings. This concluded that the opinions of medical professionals towards potential changes in the way medical abortions are provided should be investigated in order to inform further developments in the area. Despite this recommendation, a search of the current literature has found no published research seeking to investigate these opinions since the publication of the pilot study results. Since any large scale changes in the way medical abortion services are provided would be likely to require changes in legislation, it is important to know if there is professional backing behind the proposals.

The aim of this study is to explore the views of key stakeholder groups involved in the provision medical abortion services towards potential changes in the way these services are provided. These potential changes are:
-providing services from non-traditional community based settings
-home use of misoprostol

The objectives are:
-To explore perceived benefits and barriers to the potential changes in the way services are provided
-To identify any clear differences in the views of key stakeholder groups
-To consider the reasons for any differences in the views between stakeholder group
-To consider the implications of the potential changes in the way services are provided for future practice.

The project will use semi-structured interviews, with 6-8 participants identified from key stakeholder groups involved in the provision of medical abortion services in the Leeds/Bradford area using a purposive sampling method. The project will aim to interview six participants. Participants will be asked to take part in one interview each, which will be 45 minutes in length. Each interview will be based around an appropriate topic guide developed by the researcher and will be audio recorded. The audio recordings will then be transcribed in full, and the transcription data interpreted by thematic analysis

Potential participants will be asked by post to take part in the project. A purposive sampling method will be used in order to select information-rich individuals regarding the topic area. For all stakeholder groups identified individuals will be targeted who are directly involved with either the referral to medical abortion services or provision of such services.

The study is an academic study sponsored by the University of Leeds.

The Patient Perspective of QOF related to opportunistic Health Promotion Study

Chief Investigator: Dr Michael Scales, University of Leeds
Local Investigator (Student): Miss Cristina Hearnshaw (BSc in Primary Care)
Risk: Low
Start/End Date: 28/02/2013 – 28/06/2013
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

This study is being carried out as part of a BSc, the aim of the study is to explore primary care patients' attitudes towards the Quality and Outcomes Framework (QOF). The QOF was implemented in the UK's primary care system in April 2004. It is a pay-for-performance scheme where financial rewards are given for carrying out and achieving certain tasks. The QOF was designed to improve the quality of care that patients receive. This research question is being addressed due to the lack of knowledge in this subject area. This research is important for the public and patients because patients' views are key when assessing and managing a scheme designed to improve healthcare quality. Exploring patient attitudes is further warranted by the negative feedback that doctors have voiced about the QOF. Patients' attitudes will be explored within a recorded one-on-one semi-structured interview format, lasting 20 minutes.

Participants will be identified at GP practice level as NHS patients from within Glenlea Medical Practice, GP's will be asked to recruit patients for interview with student (Cristina Hearnshaw) and informed consent will be taken by Dr Cathyrne Hearnshaw (GP and partner based at Glenlea Medical Practice). All patients will be eligible to take part unless GP's decide that the individuals' health may be adversely affected by the inclusion/exclusion criteria.

Participants will be asked questions about consultations with the doctor. This will reveal if the concerns the doctors have about QOF are mirrored or opposed by patients. Knowing patients attitudes towards the QOF is beneficial. It may help doctors think more positively about the QOF or it may help the Department of Health/doctors to alter the QOF/change the way it is implemented in order to improve patient satisfaction.

The study is an academic study sponsored by the University of Leeds.

The Routine Assessment and Monitoring of Pain in Advanced Cancer Study

Chief Investigator: Professor Mike Bennett, University of Leeds
Principle Investigator: Dr Matthew Allsop, University of Leeds
Local Investigator: Sally Taylor, University of Leeds
Risk: Low
Start/End Date: 01/01/2012 – 01/01/2016
CCG Costs/Income: N/A
Status: Study linked to main study IMPACCT

Brief overview of study:

This piece of research relates to one work stream of a larger overarching NIHR programme grant. The IMPACCT programme grant comprises a coherent and integrated programme of work that will address four principal objectives and that will focus on enabling patients and carers to experience improved cancer pain management within routine care. The work streams focus on:

- WS 1. People: An integrated system of support
- WS 2. Data: Routine assessment and monitoring of pain
- WS 3. Medicines: Good management of analgesic drugs
- WS 4. Evaluation: Cost effectiveness and feasibility

The details outlined in this request for NHS permissions relate to the research activities within work stream 2. Separate permissions have been/will be sought for the other work streams.

This research aims to enable patients to communicate pain data to professionals routinely and more easily, and allow this data to be shared between professionals. A functioning system will be developed that allows patients at home to report data on pain which is then presented to clinicians to act on as appropriate and who may provide feedback. The project involves the intended users of the system in the design: patients with advanced cancer and community-based specialist nurses based in hospices, hospice doctors, and district nurses from palliative care. A range of methods (pain diaries, online survey, qualitative interviews and system usability testing) will be used with both groups to obtain their preferences for the design and function of the system and for evaluating prototypes during development.

The study will be conducted with 2 participant groups (group 1 patients; group 2 health professionals) and will have two stages (stage 1 pain diaries/online survey and interviews; stage 2 ‘think aloud’ interviews and home pilot).

The patient cohort (n=20) will participate in all stages of the research (paper diary completion, face-to-face interview, think-aloud interviews, home pilot of a new system, and follow-up interview.

Community based health professionals in the region will be recruited via groups that the study team has already established relationships with (n=140) The initial survey sample size will allow the team to then interview 15 of the respondents for face-to-face interviews and think-aloud interviews. A sampling matrix with be developed to ensure the perspectives of a diverse mix of community healthcare professionals managing advanced cancer patients are captured.

The research activity taking place in NHS Bradford City CCG, NHS Bradford District CCG and NHS Airedale, Wharfedale and Craven CCG will only involve group 2, health professionals. The Leeds North, West and West CCGs will be used to recruit participants to group 1.

This is an academic study, sponsored by the University of Leeds and is funded by the National Institute for Health Research Programme Grant for Applied Research.

National Guidance for Measuring Assistive Technology

Chief Investigator: Dr Georgia Spiliotopoulou, Brunel University
Investigator: Ioannis Paraskevopoulos
Risk: Low
Start/End Date: 15/07/13 to 30/10/15
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

The aim of the study is to develop national guidance on measuring the home environment for provision of minor assistive devices and make it available on-line for service users and providers (http://www.dlf.org.uk/content/asksara).

In the process of assistive technology (AT) provision, poor fit or inaccurate measurements of the service users and their home environment can be a reason for equipment abandonment. Equipment abandonment is associated with a number of factors including knowledge about the device, involvement in the process of selecting it, attitude towards the technology and lack of fit of the AT between service users and their environment. The purpose of this research is to develop, validate and determine the usability and reliability of national guidance on measuring the home environment for provision of minor assistive devices. The study will involve five stages using both quantitative and qualitative methods, such as nominal and focus groups. Experts in provision of AT, occupational therapists and service users will be involved in all stages of the guidance development. The guidance will be made available on AskSARA (http://www.dlf.org.uk/content/asksara), which is an online Self-assessment guide for AT provision used by service providers and service users. Having access to the right information will empower service users to choose and control their service provision, which is an important aspect of the personalisation agenda. The personalisation agenda is proposing to change the way in which health and social care services operate by

promoting a person centered approach, re-ablement and prevention, supporting carers, access to services and resources and self-directed support. This study will be an important part of enhancing service delivery and quality of care for service users.

For this low-risk observational study the study team will be recruiting staff only via the NHS, not service users. The only direct contact with the NHS will be in Stage 1 of the study (5 stages in total).

The study team will identify all Occupational Therapy (OT) services in England and contact team managers/clinical leads/heads of these services. They will then ask them to circulate the research call to OTs involved in provision of Assistive Technology for adults, asking them to provide existing guidance and comment on the quality of this guidance.
Participating OTs will be invited to access an on-line website and upload any guidance or email/telephone the researchers to request stamped envelopes so that they can post the hard copy. They will also be asked to complete a brief on-line questionnaire, which will include open questions on the quality of the guidance.

They will be made aware that this is Stage 1 of a larger study aiming to develop guidance on taking measurements and will be provided with recruitment information and a brief outline of the whole of the study. The OTs will be asked to nominate up to 2 OTs (if known) that they consider experts in minor assistive devices/adaptations. They will also be asked to tick a box and provide their names if they wish to participate in further parts of the study, which will involve attending focus groups to be held at the Disabled Living Foundation.

All non-online research activity will take place at the Disabled Living Foundation and Brunel University and not on NHS premises. A thank you gift voucher of £15 will be given and travel expenses will be reimbursed by the study team via the awarded grant.

This study is sponsored by Brunel University and funded by the UK Occupational Therapy Research Foundation, Research priority Grant (£79,185 over 3 years).

Symptoms Awareness Study (SASS)

Chief Investigator: Professor Una Macleod
Investigator: Dr Julie Walabyeki
Risk: Low
Start/End Date: 01/09/12 to 31/08/14
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

Recognition by patients of symptoms that are potentially serious and so presenting them to their doctor is a key part of the early cancer diagnosis pathway. In order to improve overall

cancer outcomes we need to understand individual responses to symptoms prior to presentation in order to direct interventions at this part of the pathway appropriately.

Smokers are at higher than average risk of several cancers and therefore a group whose understanding of potential cancer symptoms and intentions in relation to help seeking behaviour it is particularly important to investigate.

The aim of this study is to investigate the impact of smoking status on responses to potential cancer symptoms. We will focus on symptoms of lung cancer and head and neck cancers as examples of cancers of which smokers are at higher risk than non-smokers.

The main research question is: What are the barriers and facilitators for smokers in presenting with cancer related symptoms to primary care when there is a new or perceived change in respiratory or head and neck symptoms?

The study has two parts:
(1) Questionnaire study: will identify smokers and non-smokers over the age of 50 years from GP lists in Hull and Leeds and send them a specially developed postal questionnaire, which includes questions about symptoms, response to symptoms, triggers to consultation, and use of health services.

(2) The second part is an in depth interview study with smokers and social contacts: The team will purposively sample a subset of respondents of smokers from the questionnaire study. These interviews will cover smoking behaviour and attempts to give up; perceptions of health and illness, experience of symptoms, health seeking behaviour including contact with health care, the influence of others in presenting symptoms; experience and perceptions of smoking cessation awareness both in general and in healthcare interactions.

This study is funded by the Cancer research UK, National Awareness and Early Diagnosis Initiative.

CANDID - CANcer DIagnosis Decision rules

Chief and Principle Investigator: Professor Paul Little, University of Southampton
Risk: Low
Start/End Date: 01/03/12 to 01/01/20
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

There have been very few studies to develop prospectively and then adequately validate clinical prediction rules (CPRs) for cancer in primary care, and yet concern about delaying a

diagnosis of major pathology but avoiding over investigation remains a major concern for both patients and doctors at first presentation of symptoms in primary care.

This study seeks to work out which of the symptoms and examination findings are the most effective in predicting lung or colon cancer.

To decide the best clinical information to collect the study team will use information from a separate study (Delphi study) that will interview patients and get consensus from a group of experts, approval for this study will be under separate application. Within this CANDID study, the team will recruit 20,000 patients who consult their GP, half with lung symptoms and the other half with low bowel symptoms. Clinical information will be collected using standardised internet based forms. Willing patients will complete lifestyle questionnaires and be asked to provide blood or saliva samples (including for genetic analysis). The National Cancer Registry will then be monitored and GP notes reviewed to see which patients develop cancer, and statistical analysis will determine the most important clinical variables that predict cancer. The clinical prediction 'rules' or decision aids developed from these studies will then be tested with a further 2000 patients for each condition for validity.

This study is a large multi partner project sponsored by the University of Southampton and funded by the National School of Primary Care Research (NSPCR), £2,085,431 over the duration of the study. It is hoped that the study will also lead to the funding of several related studies – both new cohorts and studies of impact analysis.

Service support costs are provided by the Primary Care Research Network for participation in this study. Other identified costs such as sample transport and storage are covered within the NSPCR funds.

Txt4Flu -Text Messaging Reminders for Influenza Vaccine in Primary Care (v1)

Chief and Principle Investigator: Professor Liam Smeeth, London School of Hygiene and Tropical Medicine
Risk: Low
Start/End Date: 10/09/13 to 31/05/14
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

Influenza causes a substantial burden to the NHS and the UK as a whole. Influenza vaccine is safe and effective but is required annually. In 2012, the UK government recommended that at least 75% of elderly people (aged 65+) and 75% people under 65 with certain chronic conditions (e.g. chronic heart disease, diabetes, asthma, etc) should be vaccinated. While primary care practices are achieving targets for the elderly, they are under-performing in

patients with chronic conditions, missing a third of eligible patients in 2011/12. Therefore strategies to increase flu vaccine uptake in these patients are required. Text messaging is already being used in some practices for flu vaccine reminders but there has been no trial assessing its effectiveness.

This is a feasibility study for a cluster randomised trial of text messaging reminders for influenza vaccine in patients under 65 in clinical risk groups in English primary care.

The study will recruit general practices (n=60, with approx 750 eligible patients per practice) from three settings: (1) among practices contributing data to the Clinical Practice Research Datalink (CPRD), (2) among practices using ResearchOne (SystmOne), (3) among practices in London using iPlato. Practices that use other text messaging software will be excluded. Practices that used text messaging for influenza vaccination reminders in the 2012/13 season will also be excluded as their planned seasonal campaign is likely to include a text message to the target group.

The recruited practices will then be block randomised, by setting to either standard care (seasonal flu campaign as planned), or to receive additional resources allowing them to send a targeted text messaging campaign to eligible patients aged under 65 and with a chronic condition.

Practices in the intervention arm will be asked to deliver a text message intervention to patients. Practices will receive additional support for this, comprising guidance notes regarding delivery of the message (content, timing, eligible patients) and payment for the time of a practice administrator to deliver the intervention (£200).

Evaluation of the study objectives will consist of a descriptive analysis of cost, recruitment rate and ability to ascertain data on exposure and outcome. Evaluation of vaccine uptake by clinical risk group will be a comparison of uptake between the intervention and control arms.

A small sub-study will also be conducted in two of the participating intervention practices. Each of these practices will send a short anonymous questionnaire to patients that were targeted in the seasonal influenza campaign; again these practices will receive additional support for this (£1,200).

These payments per practice, £200 for participation and £1,200 for participation in the sub-study are provided by the funder. In our area the text message is delivered free via the SystmOne SMS system.

If this feasibility study is successful, then a full scale trial will be carried out to establish the effectiveness of text messaging for vaccination reminders.

This is an academic study sponsored by the London School of Hygiene and Tropical Medicine and is part of a Senior Research Fellowship funded by The Wellcome Trust (£1.9 million over 5 years).

BAFTA - Birmingham Atrial Fibrillation Treatment of the Aged Follow up Study

Chief Investigator: Dr Kate Fletcher University of Birmingham
Key Investigators: Professor Jonathan Mant University of Cambridge, Professor Richard Hobbs University of Oxford, Professor Richard McManus, University of Oxford, Professor David Fitzmaurice, University of Birmingham
Risk: Low
Start/End Date: 01/03/2013 – 31/07/2013
CCG Costs/Income:
Status: Follow up of original BAFTA study

Brief overview of study:

Atrial fibrillation is an important risk factor for stroke. Randomised Controlled Trials (RCTs) have shown that this risk can be reduced substantially by treatment with warfarin, or more modestly by treatment with aspirin. The Birmingham Atrial Fibrillation Treatment of the Aged (BAFTA) Study was an RCT of warfarin versus aspirin for stroke prevention in atrial fibrillation in people aged 75 and over recruited from a primary care setting. BAFTA found there were fewer strokes in the group taking warfarin, and no evidence that warfarin was more hazardous than aspirin. 973 patients were recruited and followed up for a mean of 2.7 years. A further 467 patients who were eligible but did not want to be enrolled into the main trial gave consent for researchers to have access to their medical records (total 1440 patients).

This study (BAFTA 2) is a long term follow up of the original BAFTA study. The aim is to extend the follow up of study patients to approximately 9 years to determine the longer term effects of anticoagulation (as compared to antiplatelet or no therapy) on overall mortality, and risk of stroke and cardiovascular events. The study will also give information on the longer term adherence to anticoagulation therapy in this age group, the incidence of haemorrhage in people taking anticoagulants as compared to antipatelet agents or no therapy, and the survival of people who did and did not take part in BAFTA.
Searches of the electronic medical records of the original BAFTA patients will be carried out and data collected about major vascular events, haemorrhages and use of warfarin or antiplatelet agents. Statistical analysis will compare all-cause mortality; stroke and vascular event rates; and haemorrhage rates.
The data search requires the running of a MIQUEST programme which will be supplied by the research team on the practice clinical computer system. The report can be run by anyone in the practice with access to the clinical system. The data is then returned to the research team via secure email.

It is estimated that the report will take approximately 30 minutes to complete. In return for this, the practice will receive a one off payment of £50 via service support costs managed by the PCRN. This is an academic study sponsored by the University of Birmingham and is funded by the National Institute for Health Research, National School for Primary Care Research.

IMPACCT - Improving Management of Pain from advanced Cancer in the CommuniTy

Chief Investigator: Professor Michael Bennett, University of Leeds
Principle Investigator: Ms Mary Godfrey, Reader, University of Leeds
Local Investigator: Dr Julia Hackett, Research Fellow, University of Leeds
Risk: Low
Start/End Date: 01/11/12 to 01/11/16
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

This piece of research relates to one work stream of a larger overarching NIHR programme grant. The IMPACCT programme grant comprises a coherent and integrated programme of work that will address four principal objectives and that will focus on enabling patients and carers to experience improved cancer pain management within routine care. The work streams focus on:
WS 1. People: An integrated system of support
WS 2. Data: Routine assessment and monitoring of pain
WS 3. Medicines: Good management of analgesic drugs
WS 4. Evaluation: Cost effectiveness and feasibility

The details outlined in this request for NHS permissions relate to the research activities for Work stream 1. Separate permissions will be sought for the other work streams.

This study is aimed at reducing pain, related distress and pain related hospital admissions among patients with advanced cancer in the community.

Many patients with advanced cancer experience unrelieved pain significantly impacting on health and life quality. Although there exists a method for cancer pain relief developed over two decades ago that has been shown to be effective for a majority of patients, evidence suggests that poor implementation, including in the NHS, is preventing effective pain management. Barriers exist at every level. Patients are reluctant to complain about pain, have unfounded fears about addiction to strong pain relief resulting in poor compliance with medication; Care givers lack knowledge about effective pain management; Healthcare professionals experience difficulties in assessing, and responding effectively to pain; and

systems for communicating information about pain and coordinating a response between professionals are poor.

This study will model a cancer pain care pathway for patients with advanced disease, enable professionals to identify more easily patients in primary and secondary care that are in need of support, and develop an intervention and delivery system which provides tailored advice and support for cancer pain management at home.

This will be delivered via 2 work packages;

Package 1.
Patients that are living at home in the community with advanced cancer and experiencing pain representing four main cancer sites (breast, lung, colorectal and prostate) will be sent or given a recruitment letter by the oncologist or clinic/hospice day centre nurse asking if they are willing to be approached by a researcher. Once recruited (n=20) in depth qualitative interviews will be conducted with the patient and their caregiver to explore how they develop and apply strategies to manage pain complexity, the ongoing negotiations involved to achieve 'balance' between pain, effects of medication and sustaining what is valued in terms of life quality. The study team will examine how patients and caregivers identify new sources and types of pain, how and with which professionals they communicate this to, how information is sought from, and conveyed by professionals, its meaning and significance for patients (and families) and sense of control over their illness.

The team will also run two focus groups (n=15-16, one group will be conducted within St James's Institute for Oncology and one at either St Gemma's or Wheatfield's hospice) to identify the key attributes of good pain management and preferences for care covering aspects such as location of care, type of healthcare professional involved, speed and ease of access to pain and side effect assessment and treatments.

Package 2.
The team will build on previous work and conduct one more focus group with oncologists in Bradford and Leeds (n= 6-8) to examine beliefs and attitudes around what is 'advanced' cancer, perception of pain needs among such patients and behaviours/practices in assessing and managing pain. They will draw on existing literature, their PDG work and patient accounts in package 1 to develop vignettes of cases. These will consist of patients at different transition points in the illness trajectory, with different types and intensity of pain to ground the discussion in the particularities of actual practice.

The study team will survey practice managers by questionnaire to examine variation in engagement with the Gold Standards Framework and to identify different approaches to cancer care coordination, specifically in advanced cancer. From the questionnaire findings, they will purposively select 3/4 practices reflecting differing patterns of coordination with specialist cancer services. Through observation of Gold Standard Framework meetings they will examine how care of patients with advanced cancer is routinely organised, how

decisions are made about assessment of pain, how this is communicated between professionals, how strategies for management are devised and which professionals are seen as key in delivering support and care. The team will also invite for interview from each of the 3/4 practices a GP that is taking a lead role in cancer care to explore the same issues as in the focus group with oncologists.

This is an academic study sponsored by the University of Leeds and is funded by the National Institute for Health Research Programme Grant for Applied Research.

The PMR Study

Chief Investigator: Professor Christian Mallen, Keele University
Local Investigator: Dr Sara Muller, Keele University
Risk: Low
Start/End Date: 01/03/12 – 29/02/16
CCG Costs/Income: N/A
Status: New study with minor amendments 1 to 4

Overview of amendments:

1) Changes have been made to the follow up invitation and reminders at the request of the ethics committee to make these personally addressed rather than being “Dear patient”. An additional line of thanks has alos been added.
2) Due to internal email system changes documents have been amended to reflect a change in contact email address.
3) A new study coordinator was appointed.
4) The amendment relates to a new way that the Arthritis Research UK Primary Care Centre can receive a new patient referral. This is an addition of a nhs.net secure email address so the fax form can also be completed electronically and emailed.

Brief overview of study:

Polymyalgia Rheumatica (PMR) is the most common inflammatory condition in people aged 50 years and over. It is usually diagnosed and treated in primary care, but the majority of research so far has been conducted in secondary care settings.
This is an observational epidemiological study which will form a cohort of patients with newly diagnosed PMR and follow them up using self-completion questionnaires over a period of two years accompanied by medical record review and linkage to national follow up data (with participant consent).

The questionnaires will ask about pain, stiffness, activities of daily living, common mental health problems (anxiety and depression), sleep and fatigue, socio-demographics and PMR treatments. These data will be used to look at how PMR is currently managed in primary

care and what happens to patients during the follow up time. The aim is to provide evidence to improve the way GPs diagnose and manage PMR.

Eligible patients will be identified via one of two methods: Method A and Method B. The different methods will be applied in different practices, according to practice preference and the computing system used locally. In both methods, when a patient consults with a new case of PMR and the GP enters an appropriate PMR Read code, a popup window will appear reminding the GP of the study. This window will request that the GP orders blood tests recommended for the diagnosis of PMR and that they give the patient a postcard containing details of the study.

In Method A, in addition to the blood test and reminder to give out the postcard, the pop-up window will ask the GP to complete a fax form and return it to the Research Centre with the patient's name, address, practice identifier and confirmation that he/she has a new diagnosis of PMR. Where possible, this form will be generated by the clinical computer system.

The pop-up can be installed in practices which operate any version of EMIS. Where a practice does not use EMIS then they are still able to take part in the study however will just use the paper based reminder posters (also provided by the study team) to remind themselves of the eligibility criteria for referring a patient into the study

Information from the fax form will be stored at the Research Centre on a secure database. Hard copies of the fax forms received by the Research Centre will be stored in securely and separately from research data provided by participants.
In Method B, practice staff and staff from the Primary Care Research Network (PCRN) will conduct fortnightly electronic searches of the primary care records in participating practices in order to identify patients with a new diagnosis of PMR. Eligible patients' names and addresses will be downloaded to a secure database by the PCRN staff, to be used for mailing.

The patient identification process will not interfere with routine primary care management except in that all participating general practices will be provided with access to the British Society for Rheumatology guidelines for the management of PMR.

The study is sponsored by the Arthritis Research UK Primary Care Centre, Keele University and is funded by an Arthritis Research UK Clinician Scientist Fellowship (£411,389).

The Stool Sampling in Primary Care: A Feasibility Study

Chief Investigator: Professor Mark Hull, University of Leeds
Local Collaborator: Dr Andrew Bolton, The Newcroft Surgery, Horsforth
Local Investigator: Dr David Gracie, University of Leeds/ John Hodgson Primary Care Research Network (PCRN)
Risk: Low

Start/End Date: 01/06/2013 – 31/01/2014
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

Obesity is associated with inflammation throughout the body including the large bowel. Calprotectin is a protein that is released from white blood cells in response to inflammation. It is readily measured in the stools of individuals who have inflammatory bowel conditions such as Crohn's disease and ulcerative colitis. An increased incidence of bowel cancer in both inflammatory bowel disease and obesity is well described and, one hypothesis is that inflammation affecting the large bowel in obesity contributes to the increased risk of bowel cancer. Hence, the use of a non-invasive biomarker of obesity related bowel inflammation like faecal calprotectin (FCP) may be useful when determining future bowel cancer risk in obese individuals.

It is proposed for a pilot study to be conducted to assess the feasibility of a large primary care study designed to investigate the utility of FCP as a marker of bowel wall inflammation in obesity. The aim is to collect information that will inform the design of this study by way of a review of pilot recruitment rates, as well as assessing the acceptability of repeated faecal sampling in an obese primary care cohort of individuals.

In conjunction with the West Yorkshire Primary Care Research Network, suitable individuals will be identified using GP databases. Postal invitations containing a patient information leaflet, consent form and questionnaire will be sent out to eligible individuals. Those who respond will be invited to provide a stool specimen and attend for weight, height, waist and hip circumference measurements at their local GP. This process will repeated at 3 and 6 months.

Individuals who complete the faecal sampling phase of the study will be invited to attend a focus group discussion about the acceptability of undertaking blood testing and a camera test of their lower bowel, which could form part of the definitive study.

The study is an academic study sponsored by the University of Leeds.

EVRA - Early Venous Reflux Ablasion Ulcer Trail v1.0

Chief and Principle Investigator: Professor Alun Davies, Professor of Vascular Surgery and Honorary Consultant Surgeon, Imperial College London
Risk: Low
Start/End Date: 01/06/13 to 31/05/17
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

A large number of patients (around 1% of the adult population) suffer from an ulcer (break in the skin surface) near the ankle. In most people, such an injury should heal up within a week or two. However, when there is an underlying problem with the skin, ulcers do not heal and may result in longstanding (chronic), painful, smelly and embarrassing wounds. The ulcers are often due to "varicose veins" in the legs, which can cause skin breakdown and ulcer formation. To get the ulcer to heal, the current best treatment is to wear a tight compression bandage with multiple layers, with which about 60% of these ulcers will heal within 24 weeks. There is evidence that treatment of the varicose veins by surgery will
prevent the ulcer from returning after it has healed. Recent studies have suggested that newer techniques of treating varicose veins, such as injecting a medicine into the varicose vein (sclerotherapy) or treating the vein with heat ablation to seal it (using laser or radio frequency), in an outpatient setting may help the ulcers to heal more quickly and (like surgery) reduce the chance of the ulcer coming back. These techniques can be carried out in the outpatient setting and are much better tolerated by patients in comparison to surgery.

To see if early treatment of the varicose veins using sclerotherapy or heat ablation helps with healing, the study team would like to carry out a trial in which patients with a leg ulcer and varicose veins are treated either by compression bandaging with treatment of varicose veins after the ulcer has healed (the current best treatment) or by compression bandaging and early treatment of the veins.

Patients will be referred from the community (by primary care and ulcer clinics) to secondary care for evaluation of the management of their leg ulcer as part of the standard pathway of care. At the initial leg ulcer clinic visit the patient will be evaluated by clinical assessment and colour duplex examination which is part of the normal investigation of a patient with leg ulceration. Dependant on the results of these tests, the patient will be asked if they would consider taking part in the trial and approached for consent.

500 patients will be recruited nationally and be randomly allocated to each group.
1. Compression bandaging alone.
2. Compression bandaging PLUS early treatment of superficial venous reflux with endovascular (keyhole) techniques.

Participants will be asked to complete quality of life questionnaires and the Aberdeen varicose vein questionnaire at the baseline visit and at 6 weeks (at Clinic), 6 months and 12 months (at home by post). The patients will receive routine follow-up appointments as per normal standard care. The only additional hospital visit will be at 6 weeks for assessment (contract in place to cover costs). Travel costs up to £30 will be reimbursed by the study team for this additional visit. The study team will contact participants by telephone every month to check progress. The trail research nurse may contact the community nurse or GP surgeries by phone (or in rare cases in person) to confirm patient follow up data only. No other research will be carried out in the primary care setting.

The trial will look at the number of ulcers healed in both patient groups and the speed at which the ulcers healed. Costs of the two treatment groups will be investigated. The information gained from the study will be helpful in guiding primary and secondary care healthcare professionals as to the best approach to treating venous ulcers in the future and if early treatment of varicose veins of these patients improves healing rates in patients with leg ulcers, there will be significant cost savings for the NHS as well as great benefit for this patient group.

This study is sponsored by Imperial College London and funded by the NIHR Health Technology Assessment Programme (£1,479,324 over 4 years)

MALT Study - Phase 2

Chief Investigator: Professor Mark Hawley, Professor of Health Services Research, University of Sheffield
Investigator: Dr Elizabeth Coates, University of Sheffield
Risk: Low
Start/End Date: 01/04/13 to 30/11/14
CCG Costs/Income: N/A
Status: New study

Brief overview of study:
The future large scale deployment of Assisted Living Technologies crucially depends on establishing cost effectiveness and patient benefit at scale. This entails overcoming barriers to uptake, and devising viable service and business models. This project is exploring these issues with a focus on the delivery of tele-health in four specific sites in the Yorkshire & Humber region. Work has been underway since June 2011 and the project has three interrelated phases.

This study is Phase 2: Implement, evaluate and refine (April 2013 – April 2014)

The research objective for phase 2 is to evaluate the implementation and delivery of new or revised tele-health services within the research sites through cycles of action research. This encompasses the following sub-objectives:
• To understand how sites have already overcome identified barriers to delivery and uptake of tele-health services and build on early good practice;
• To explore the issues for implementation of tele-health from the perspectives of key stakeholder groups – senior management, organisational management, frontline staff, patient and carers;
• To understand how experiences are impacted by the scale of the tele-health service;
• To estimate the cost effectiveness of service changes using the bespoke financial models and evaluate those models with respect to validity, functionality and user acceptability.

Through phase 1 of the study, key areas for change in the tele-health service have been identified through collaboration between the research team and key local stakeholders.
The plan is to work with each site to implement agreed changes to the delivery of tele-health and evaluate the implementation and delivery of these new or revised services through cycles of action research. The participants will participate in 2 ways, by means of Action Inquiry Group meetings, for Patients, Careers and Staff and on an individual basis (as appropriate). The research team will act as facilitators and advisers of the evaluation of part of this methodology.

This non-commercial study is funded by the Technology Strategy Board, Assisted Living Innovation Platform (£1,844,265 all phases) and is sponsored by the University of Sheffield.

Staff time for participation in the study will be reimbursed via the University of Sheffield from the funding source.

OA treatments- patient adherence, QoL and healthcare resource use

Chief Investigator: Dr Gordon Crawford, Director, Patients Direct
Risk: Low
Start/End Date: 30/11/12 to 31/12/14
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

The OA Treatments study is an observational study using self-completed questionnaires by patients suffering from osteoarthritis and who are currently being treated with BuTrans, Tramadol or Co-codamol. Questionnaires will be completed at defined time points – baseline then monthly for three months. Participants will complete the questionnaire directly via the website or for those without internet access by a freephone telephone number with a trained, experienced research nurse. No interference to treatment or extra visits to any healthcare professional are required.

The principle research question asks feedback from sufferers of knee and hip osteoarthritis on their overall satisfaction with their pain control medicines with a focus on buprenorphine, tramadol and co-codamol. The outcome measures are medication adherence, impairment on Quality of Life, resource utilitsation, concomitant medicines used, frequency of continuation/discontinuation of treatment and reason, and safety.

This study will only identify participants from our area(s), therefore we are only acting as a PIC (Participant Identification Centre) and no research activity will take place.

The study application mentions payment of monies (£500) to GPs and incentives for participants, we have had confirmation that all of these costs will be picked up by the study funder NAPP Pharmaceuticals.

This study is a commercial study sponsored and funded by NAPP Pharmaceuticals.

Promoting Self-Management of Pain from Advanced Cancer (IMPACCT work package 1.3)

Chief Investigator: Professor Michael Bennett, Professor of Palliative Care, University of Leeds
Principle Investigator: Dr Nicholas Hughes, Senior Research Fellow, University of Leeds
Risk: Low
Start/End Date: 01/06/13 to 30/06/14
CCG Costs/Income: N/A
Status: New Study linking in to previous work

Brief overview of study:

This is a low risk academic study that will model a cancer pain care pathway for patients with advanced disease, enable professionals to identify more easily patients in primary and secondary care that are in need of support, and develop an intervention and delivery system which provides tailored advice and support for cancer pain management at home.
This work package links into work already done and will consist of qualitative methods seeking to understand what might be the optimal content and timing for a patient-based educational intervention to facilitate self-management of cancer pain. The research team have conducted a review of systematic reviews on patient education for self-management and now want to complement the knowledge gained from this literature review with insights from a series of 'expert panels' with people who have experience of cancer pain, their caregivers and health professionals involved in treating and caring for people with cancer.

Health or social care professionals (clinical nurse specialist, district nurse, GP, palliative care physician, oncologist, social worker, pharmacist) who provide care for people with cancer in the community have already or will be identified through previous links and networks.

Practices that have been involved previously are Foundry Lane Surgery, Gibson Lane Practice, Hyde Park Surgery and Laurel Bank Surgery and will be approached for this part of the project as their views and experiences regarding patient education for self-management of cancer pain will continue to be a valuable contribution to the overall project. Other practices in the three Leeds CCG areas may also be approached.

If the staff choose to be included this means taking part in one or two focus group meetings of 6-8 health and social care professionals. One focus group will consider ideas for the

content of an educational intervention for self-management of cancer pain. A similar focus group will be held with a group of people who have experience of cancer pain and with a group of caregivers. Following analysis of the data generated by these focus group meetings, the study team will build a pilot educational intervention. They will then hold a further focus group with health and social care professionals to consider practicalities of delivering the intervention. Health professionals may be asked to join one or both of these groups.

Each focus group meeting will last approximately 1 ½ hours. It is expected that the focus groups to be conducted in working hours, with staff members who would already be on the premises. Service support costs are in place for the whole IMPACCT programme.

This is an academic study sponsored by the University of Leeds and funded a NIHR Programme Grant for Applied Research (£1.9 million over 5 years).

Pain Reduction with Oral Methotrexate in knee Osteoarthritis, a pragmatic phase III trial of Treatment Effectiveness (PROMOTE)

Chief Investigator: Dr Philip Conaghan, Rheumatology Department, Chapel Allerton Hospital
Risk: Low
Start/End Date: 01/10/13 – 01/10/17
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

This study will look at painful knee osteoarthritis (OA). Methotrexate is commonly used to treat inflammatory arthritis, such as rheumatoid arthritis, recent studies have also suggested that inflammation is important in causing pain in OA. This study will examine the cost effectiveness and success in the use of Methotrexate for the treatment of inflammation and reduction of pain in people with knee OA. The study is a 12 month randomised double-blind, placebo controlled study. Potential participants will be screened for eligibility including vital signs, blood test, urine test and x-ray of the knee and chest (if not previously done in the last 6 months – if they have these will be used rather than re-taking). Throughout the study patients will complete questionnaires about their health and wellbeing including EQ-5D and HADS. Participants will be asked to take a folic acid supplement 6 days/week as well as either the placebo or Methotrexate once a week for 12 months. Those participants involved in the MRI sub-study will have an MRI scan of their knee conducted at the start and at 6 months to assess for synovitis in the knee joint.

Those participants in the Biological sub-study will have additional blood/urine samples taken at baseline and 6 months to analyse bio markers important to inflammation in OA and response to treatment.

Leeds will only be a PIC (Participant Identification Centre) site for the study, with possible participants being sent a letter about the study via their GP and posters advertising the study within practices. Approximately 160 participants will be recruited across 17 centres within the UK.

This study is an academic study co-sponsored by the University of Leeds and York Trials Unit and funded by Arthritis Research UK.

Vitamin D and Longevity (VIDAL) Trial

Chief Investigator: Dr Adrian Martineau
Risk: Low
Start/End Date: 01/01/12 to 01/01/15
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

This study is a feasibility trial for a larger trial. The main trial will ask whether Vitamin D supplementation reduces morbidity and increases lifespan in men and women aged 65-84.

The study compares a placebo-controlled trial in 10 GP practices against an open randomised trial in 10 practices; randomising 800 people aged 65-84 double-blind to monthly placebo versus monthly vitamin D for 2 years, and 800 to no treatment versus 2 years of monthly vitamin D.

Participant acceptability, costs, treatment compliance and recruitment rates will be tested using the two approaches to decide whether the main trial should have a placebo control group, as well as studying the effect of treatment on vitamin D blood levels.

Participants will be asked to visit their GP twice (at entry and at 2 years) to answer a few lifestyle questions and provide a blood sample; and reply to a brief communication every 3 months during the 2 year study period. Those allocated to vitamin D or placebo will take oral study medication once a month for 2 years.

The research nurse or GP at the practice will screen their notes and contact eligible patients for possible recruitment into the study.

This study is an academic study sponsored by the London School of Hygiene and Tropical Medicine and funded by a NIHR Health Technology Assessment programme.

The RESTART Study - REstart or STop Antithrombotics Randomised Trial

Chief Investigator: Professor Rustam Al-Shahi Salman, Division of Clinical Neurosciences, Western General Hospital, Edinburgh
Risk: Low
Start/End Date: 03/01/13 to 03/01/18
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

More than one third of the adults with a stroke due to bleeding into the brain (known as brain haemorrhage) are taking drugs to prevent clotting when they have a brain haemorrhage.

These patients had previously suffered illnesses like angina, heart attack, or stroke due to blood vessel blockage, which is why they are treated with drugs to prevent further clots occurring. These drugs are usually stopped when the brain haemorrhage occurs.

When patients recover from brain haemorrhage, they and their doctors are often uncertain about whether to restart these drugs to prevent further clots occurring, or whether to avoid them in case they increase the risk of brain haemorrhage happening again.

In this preliminary study of 720 such people who survive a brain haemorrhage, the study team will look into the potentially beneficial effects of antiplatelet drugs such as aspirin on the risks of heart attack, stroke and other clotting problems as well as their effect on the risk of a brain haemorrhage happening again.

This will inform the study team to decide whether antiplatelet drugs are a promising treatment. If they are, a much larger number of patients will be recruited to determine whether the beneficial effects of antiplatelet drugs on the risk of clotting outweigh any risks of a repeat brain haemorrhage for such people.

The primary objective of the pilot phase is to estimate, when all participants have completed at least two years of follow-up, the relative and absolute effects of antiplatelet drugs on the risk of brain haemorrhage happening again associated with a policy of starting antiplatelet drugs after the acute phase of brain haemorrhage. The study team want to determine whether antiplatelet drugs are beneficial for patients after brain haemorrhage because the gains from prevention of clotting problems outweigh the risks of bleeding at any site. This pilot phase of the trial may roll seamlessly into the larger main phase if the Data Monitoring Committee approves this following the pilot phase.
The secondary objective is to determine whether patients with tiny deposits of blood in the brain called ‘micro bleeds’ on brain magnetic resonance imaging (MRI) have an increased

risk of having a recurrent brain haemorrhage if prescribed antiplatelet drugs following a brain haemorrhage.

This study is an academic study sponsored by ACCORD (Academic and Clinical Central Office for Research and Development) and funded by the British Heart Foundation (£1,342,826 over 5 years).

The ROSE Study - Rivaroxaban Observational Safety Evaluation

Chief Investigator: Professor Saad Shakir, Bayer Pharma AG
Risk: Low
Start/End Date: 18/02/13 to 18/02/17
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

Prior to raising an SSI for our area the study has undergone 3 minor amendments and 1 substantial amendment.

The substantial amendment changes the proportions of payments to GPs for completion of the questionnaires. It was thought that the amount initially suggested was disproportionate to the amount of information requested. One of the minor amendments is to the GP letter detailing these amounts. Another minor amendment was made to rectify some grammatical errors in the study documents and another minor amendment was made rearranging question order within some of the study documents and the protocol has been updated. The protocol changes do not affect trial conduct or patient safety.

Rivaroxaban is an antithrombotic medication which reduces the formation of blood clots. It has previously been used in patients having hip or knee replacement surgery but will also now be used for patients with irregular heart rhythm (specifically nonvalvular atrial fibrillation) to prevent blood clots in the brain (causing stroke) and other blood vessels in the body. Rivaroxaban will also be used to treat blood clots in the veins of patients' legs (deep vein thrombosis) and lungs (pulmonary embolism) and to prevent blood clots from reoccurring in the veins of a patient's leg or lungs.
This study aims to evaluate use of rivaroxaban and its short term safety when used for these new indications. This study was requested by the European Medicines Agency as part of a Post Authorisation Commitment.

The study will recruit patients starting rivaroxaban treatment and asking their care team to answer some simple questions about them at the time they start and again in 12 weeks' time. The study will also recruit patients starting alternative anticoagulant therapy and their

care team will also be asked the same questions. These patients will be used to compare the differences between users of rivaroxaban and users of alternative anticoagulant therapy. If a participant has an adverse event (side effect) during the 12 week period, we may ask the patient's care team to fill out a further follow up questionnaire. Participant consent will be obtained to access the patient's medical records. Any adult patient started by their care team on rivaroxaban or alternative anticoagulant therapy for the specified indications during the study period will be eligible to take part. It is a national study covering the whole of England. The study will last for approximately 3 years of data collection although each patient will only be involved for a 12 week period of observation.

This study is a commercial study sponsored and funded by Bayer Pharma AG (£4.8 million over 4 years)

An Exploration into Prescribing Behaviour for Older People with Reduced Kidney Function

Chief Investigator: Mrs Su Wood (PhD student)
Academic Supervisors: Professor Theo Raynor, University of Leeds; Dr. Duncan Petty, University of Leeds; Professor Robbie Foy, University of Leeds; Dr Liz Glidewell, University of Leeds

Risk: Low
Start/End Date: 01/09/13 – 31/08/14
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

The aims of the study are to understand the experience of General Practitioners when prescribing for the older patient with reduced kidney disease function; to understand why recommendations for drug use in reduced kidney function are not applied when prescribing for the older patient in primary care, and to consider whether psychological theory can further our understanding of prescribing by General Practitioners. The total sample size will be 15.

GPs working within general practices in the Bradford and Leeds CCGs will be identified as potential participants from the CCG publically accessible websites. They will be sent an invitation letter, consent form, participant information sheet and SAE.

Individual semi-structured interviews will be conducted with consenting GPs to understand their experience of prescribing for older patients with reduced kidney function, the interviews are expected to take between 30-40 minutes. Open questions will be used to elicit the personal experience. Theory based prompts will be used to explore barriers and enablers.

Data will be gathered and thematic analysis will explore attitudes and beliefs about prescribing different drugs to older people with RKF.

This study is an academic study being undertaken as part of an educational project (PhD). sponsored by the University of Leeds.

A randomised, multi-centre, open-label, active-comparator, pragmatic clinical trial of low-dose colchicines versus naproxen in patients with acute gout (CONTACT)

Chief Investigator: Dr. Edward Roddy, Arthritis Research UK Primary Care Centre, Keele University

Risk: Low
Start/End Date: 25/11/13 to 24/08/15
CCG Costs/Income: N/A (Funded by NIHR School for Primary Care Research)
Status: New study

Brief overview of study:

This study will compare the use of newly recommended low-dose colchicines with naproxen (both drugs are currently licensed for use in the treatment of gout). Naproxen is currently a common use for the treatment of gout and will act as the comparator for the study. Colchicines are currently recommended for treatment of gout in low-doses but GPs seem to be infrequent in prescribing this, previously colchicines were used for the treatment of gout at a higher dosage but this commonly caused severe diarrhoea which may explain GPs seeming preference for other treatments.

This trial will be the first direct comparison of the effectiveness, pain-reduction and side-effects of a NSAID (naproxen) and low-dose colchicines to treat acute gout in Primary Care.

Participants will be randomised at the trial site using web access to a secure remote allocation system, the participant will be asked to complete a baseline questionnaire, a 7 day pain diary and 4 week follow up questionnaire and take either a four day course of the trial drug colchicine (0.5mg every eight hours as per BNF guidelines) or a 7 day course of the comparator drug naproxen (single initial dose of 750mg followed by 250mg every eight hours as per BNF guidelines). The funder will cover the costs of participant's prescriptions whilst participating in the research study.

Patients consulting their GP with an acute attack of gout in up to 100 general practices will be invited to participate. Treatment success will be assessed by comparing pain reduction between the two drugs. The trial will also monitor side-effects, quality of life, and cost-effectiveness.

This study is an academic study sponsored by Keele University and funded by the NIHR School for Primary Care Research (£769,553 over 2 years).

Developing Alternative Methods to Detect Influenza Antibodies

Chief Investigator: Professor Richard Pebody, Consultant Epidemiologist and Flu Section Head, Centre for Infectious Disease Surveillance and Control (CIDSC), Public Health England
Risk: Low
Start/End Date: 01/06/13 to 31/03/15
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

The main aim of the study is to assess the feasibility of using oral fluid and dried blood spot samples, collected by self-sampling, for diagnosis of influenza infection. The secondary aim is to provide oral fluid and dried blood samples that can be used for the development of diagnostics for acute influenza infection.

Oral fluid (OF) and dried blood spot (DBS) samples will be provided by participants who have already been recruited to an on-going seroepidemiological surveillance study 'Establishing a population-based system for the serological surveillance of influenza in England'.

Participants will be identified from those who are participating in the main study and indicated that they would also be willing to participate in a separate work being carried out by the Health Protection Agency/Public Health England, they were informed that this would involve providing biological samples. Ipsos MORI used random digital dialling methods and quota sampling when the original contact was made. The contact details of these participants were then securely sent to the HPA/PHE using encryption methods. Members of the study team will contact the participants GP and an OF and DBS self-sampling kit will be sent out to the participant along with a participant information leaflet and consent form. A blood test will be taken by the participants GP (GPs will be reimbursed £10 per participant for this; costs will be covered by the PHE project funding for this fiscal year).

The primary outcome is evaluation of the performance of the alternative specimen/assay approach for detecting antibody to influenza viruses and participants experience of self-sampling for oral fluid and dried blood spot samples. The secondary outcomes are total IgG concentration in all samples, specific (by influenza strain) IgG concentration in all samples and to determine whether it is possible to distinguish between vaccinated and unvaccinated individuals.

This study is a non-commercial study sponsored by Public Health England.

TIRCON - A randomised, double-blind, placebo-controlled trial of deferiprone in patients with pantothenate kinase-associated neurodegeneration (PKAN)

Chief Investigator: Professor Patrick Chinnery, Institute for Genetic Medicine, Newcastle University
Risk: Low/Medium
Start/End Date: 01/07/13 – 01/07/15
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

Neurodegeneration with Brain Iron Accumulation (NBIA) are a group of 7 diseases which cause increased levels of iron to become stored within the brain. The most common of these diseases is Pantothenate Kinase Associated Neurodegeneration or PKAN. The excess iron in PKAN interferes with the normal functioning of parts of the brain, in particular affecting learning, communication and movement of the arms and legs. PKAN is very progressive, and many patients die in early childhood or early adulthood. At present there is no proven treatment.
Recently, the drug 'deferiprone' has been developed and is used to treat other conditions such as the blood disorder thalassaemia – this drug is an iron binding agent much better at getting to the brain, and recently a small number of patients with PKAN showed some improvement in a small study of the drug.

The aim of this study is to determine whether deferiprone, over an 18 month period, is able to improve the symptoms in patients with PKAN and also reduce the levels of iron in the brain seen with MRI scans.

The primary objectives are:

1. To evaluate the changes in severity of dystonia (BAD scale) in patients with PKAN treated with deferiprone for 18 months compared to placebo.
2. To evaluate the patients global impression of conditions improvement treated with deferiprone for 18 months compared to placebo (PGI-I)

The study will be considered positive if both co-primary end points reach statistical significance.

The secondary objectives are; To evaluate the deferiprone compared to placebo:

1. in the change in globus pallidus iron levels (MRI) (subset of patients)
2. on the change in motor symptoms (UPDRS)

3. on a measure of functional independence (WeeFIM or FIM)
4. on quality of life (PedsQL)
5. on the patients quality of sleep (PSQI)
6. To evaluate the pharmacogenetics of deferiprone and its 3-0-glucuronide metabolite (subset of patients)
7. To evaluate the safety and tolerability of deferiprone in patients with PKAN.

Other procedures include checks of medical history, vital signs, physical exam, Likert scale, ECG, PK sample, genetic sample, serology and haematology, including pregnancy testing for those women of childbearing age.

This is a multicentre study including the EEC, with a sample size of 8 for the UK (90 in total). Patients will be initially identified either by being known to the clinical team in Newcastle or referred from consultant colleagues at Patient Identification Centre sites within the UK to be considered for entry to the study.

A member of the medicines management team has taken a look at the protocol for this study and agreed that there are no concerns about the study from a medicines management perspective.

This study is a commercial study sponsored by ApoPharma Inc and funded by the European Commission. ApoPharma have confirmed that they will cover the cost of the study drug during and after the study has ended.

The influence of 'significant others' on sickness absence due to back pain

Chief Investigator: Dr Serena McCluskey, University of Huddersfield
Risk: Low
Start/End Date: 01/07/13 to 31/12/14
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

There is little understanding of the individual and social influences involved in the everyday life experiences of those with LBP which may act as obstacles to recovery, and ultimately, work participation. The study team are proposing to design and validate a method which will allow a more in-depth examination of the illness perceptions of individuals with LPB, and the influence of their 'significant others' (spouses/close family members) on these illness perceptions and work participation. The findings from this study will provide a useful insight into the beliefs, perceptions and social circumstances that influence LBP, and could meaningfully inform future treatment plans and intervention programmes aimed at restoring work participation. Whilst the importance of individual illness perceptions is widely

acknowledged in health research, there is less understanding of the influence of the illness representations of close family members, or 'significant others'.
The proposed study will form part of a wider exploration around the influence of significant others on illness perceptions and work participation in relation to LBP. Two previous exploratory studies have been completed by the research team, exploring these issues with samples of chronic back pain patients and their significant others (funded by BackCare and the BUPA foundation). The proposed study adds to these findings, collecting data from those experiencing work difficulties in the early stages of LBP, and will help to further understand important psychosocial mechanisms associated with recovery and work participation. Our aim is to use these findings to design a larger scale intervention study.

This research will be comprise a series of twenty in-depth dyadic interviews with a convenience sample of individuals with LBP (and their 'significant others') who have taken recent spell of sickness absence. Individuals with non-specific LBP of up to 4 weeks duration, who have taken a recent spell of sickness absence, will be eligible for inclusion. Supporting GP practices in this area will identify and approach eligible participants for the study.

This is an academic study sponsored and supported by the University of Huddersfield

Making the Case for Exceptionality

Chief Investigator: Professor Mike Baynham, Professor of TESOL, School of Education, University of Leeds
Local Investigator: Dr. John Callaghan, Researcher, School of Education, University of Leeds
Risk: Low
Start/End Date: 01/01/14 – 30/07/14 (start/end dates are estimated at the time of application)
Status: This study is linked to a previous study 'Cultural dynamics of decision making in care commissioning (funders ref no. RCF/03/12).

Brief overview of study:

This study aims to explore what factors impede GPs in making effective applications to the Individual Funding Request Panel (IFRP), also whether there is any evidence that quality of applications is linked to geographical areas of social and economic disadvantage. The secondary aims are to find out the characteristics of effective applications to the IFRP and whether there are interventions that could improve the quality of IFR applications, by supporting GPs in the process.

There are four phases to the study as follows:

Analysis of a sample of 20 (max) redacted/anonymised IFR applications and interviews with key IFRP members with a view to identifying the characteristics of an effective application.
In-depth interviews with a sample of six to ten GPs from areas with contrasting indexes of socio-economic disadvantage, to probe further issues concerning the application process.
Online survey to be carried out by GPs to identify the issues and problems they encounter in making applications to the IFRP
Recommendations for interventions (possibly including an on-line resource) to support doctors in making applications to the IFR

Potential participants will be identified in the following ways:

IFR panel members will be identified with the help of the WSYB CSU Research & Development Team and existing connections with IFRP members made during a previous research project.
GPs will be recruited with help from WSYBCSU, largely through forums and research report meetings with the various CCG groups (Airedale, Wharfedale and Craven, Bradford City, Bradford Districts and the three Leeds CCGs).

This is an academic study sponsored by the University of Leeds

A Longitudinal study of cognition in people over 50

Chief Investigator: Professor Clive Ballard, Professor of Age-Related Diseases, Wolfson Centre for Age-Related Diseases, King's College London
Risk: Low
Start/End Date: 01/11/13 – 01/11/23 (start/end dates are estimated at the time of application)

Brief overview of study:

This study is a PIC (Participant Identification Centre) study and therefore no research activity will be undertaken within our area.

This study will measure cognition in 5000 adults over 50 over eight years via an online study. Participants will complete a series of cognitive tests each year, including questions about lifestyle and medical status; this will be compared with their genes to see how they affect their cognition. This information will be retained for use in future research into cognition.

Genetic material for DNA extraction will be collected by the participant (at home and returned by post) using a self-administered saliva kit. All other tests and consent are completed online by the participant.

The study is an academic study co-sponsored by King's College London and South London and Maudsley NHS Foundation Trust; and is funded by the NIHR Central Commissioning Facility Biomedical Research Unit for Dementia (£100,000 over 5 years)

Patterns of Engagement with Health Care among Homeless Persons

Chief Investigator & Academic Supervisor: Dr Chris Burton, Senior Lecturer, University of Aberdeen
Local Investigator: Emma Mills, BMedSci Intercalated Degree, University of Aberdeen
Risk: Low
Start/End Date: 31/01/14 to 06/05/14
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

How patients engage with healthcare (whether they keep regular appointments, take prescribed medication, and use services in a mutually beneficial way) appears to be an important predictor of treatment outcome in hard to reach groups of patients.
While engagement has been explored from the patient perspective, little is known about how healthcare professionals conceptualise, assess and promote engagement with healthcare.
The aim of this study is to use qualitative interviews with healthcare professionals working with homeless and hard to reach patients to examine their views about patients' engagement with healthcare, how these views influence practice, and whether understanding of these views can be used to propose a measure of patient engagement for future development.

The following are proposed to conduct the study;

- Conduct a literature review of engagement with healthcare in relation to homeless and hard to reach patients.
- Carry out approximately 15 semi-structured interviews with doctors and nurses working with homeless and hard to reach patients in primary and secondary care regarding their views on patient's engagement with healthcare
- Analyse these interviews using qualitative thematic analysis to examine
    - How the professionals conceptualise patient engagement with healthcare
    - How they use explicit or implicit judgements based of patient engagement in managing treatment of patients, both in general and with specific reference to two exemplar conditions: Chronic Obstructive Pulmonary Disease and Chronic Hepatitis C
    - What strategies practitioners use to promote patient engagement with healthcare
- Analysis of the transcript data will be by thematic analysis using a constant comparative method. Preliminary coding will be used to identify emergent themes

and this will be followed by more in depth coding and analysis with appropriate discussion between the researchers.
- Use the results of the analysis to propose elements of a possible tool to measure engagement with healthcare

This is an academic study sponsored by the University of Aberdeen

ADDRESS-PMR: The Diagnostic Accuracy of Ultrasound in Suspected PMR

Chief Investigator: Dr. Sarah Mackie, Academic Clinical Lecturer, Academic Unit of Muculoskeletal Disease, Chapel Allerton Hospital, Leeds
Risk: Low
Start/End Date: 02/09/13 – 02/09/25
CCG Costs/Income: N/A
Status: New study

Brief overview of study:

This study is a PIC (Participant Identification Centre) study and therefore no research activity will be undertaken within our area.

This study aims to find out whether ultrasound is useful for diagnosing polymyalgia rheumatic (PMR), compared to current best standard of diagnosis (clinical diagnosis by an expert, confirmed on year later). The study team will also explore the following:

- whether ultrasound is likely to be a cost-effective intervention if made directly available to primary care doctors
- how useful patient-reported outcomes and novel new blood tests may be in diagnosis of PMR
- how well proposed measures of disease activity actually perform in predicting who is likely to flare in PMR
- how GPs conceptualise PMR, and;
- how existing or new tests might fit in with this

Patients with suspected PMR will be recruited by the doctor within their healthcare team.

Soluble biomarker analyses, gene expression and DNA will be undertaken from blood samples, consent will be sought to use these samples beyond the duration of the study as and when new techniques/research questions arise. The patient will also undergo thoracic spine x-rays, ultrasound, applanation tonometry (application of intraocular pressure), height, BP and hip/waist measurement. Patients will also be asked to complete symptom/use of NHS services diaries and questionnaire booklet. There will be telephone contact at 3 months to check all is well and follow-up via medical records for a further 8 years – if a participant loses capacity during the study then no further tests will be undertaken, but the study team will continue to collect relevant data from medical records.

The primary endpoint of the study will be the reference standard diagnosis (clinical diagnosis by an expert, confirmed on year later).

This study is an academic study sponsored by the University of Leeds and is funded by an NIHR Clinician Scientist Fellowship (£1.3 million over 5 years).

Appendix 4: Summary Information for presentations given at each Leeds Research Network meeting.

30th April 2013, Thornton Medical Centre

HERO and PROMOTE

Sarah Kingsbury presented her current research, conducting two large multi-centre clinical trials to examine the effectiveness of anti-synovial agents as treatments for osteoarthritis (OA); the HERO trial, a 12 month, 252 patient trial of hydroxycholoroquine (200-400mg bd) versus placebo in patients with moderate to severe symptomatic, radiographic hand OA; and PROMOTE which is a 12 month, 160 patient trial of methotrexate (maximum dose 25 mg per week) versus placebo in patients with moderate to severe symptomatic, radiographic knee OA.

IMPACCT

Lucy Ziegler, senior research fellow at the University of Leeds and Kath Black a research nurse at the Academic Unit of Palliative Care based at St Gemma's Hospice presented their current work on the IMPACCT research programme. IMPACCT is a 5 year research programme funded by the National Institute for Health Research and led by Professor Mike Bennett. The overarching aim is to improve pain management for patients with advanced cancer living at home.

30th July 2013, Craven Road Surgery

OK Diabetes

OK-Diabetes is a NIHR Health Technology Assessment funded three year project based at the University of Leeds, Institute of Health Sciences led by Professor Allan House. Dr Amy Russell from the study team presented the OK-Diabetes project detailing its two phases; the aim of the first phase of the project is to identify adults who have mild or moderate learning disability, and type 2 diabetes, and who are not taking insulin. The study team at the University of Leeds wants to talk to these individuals and maybe a supporter, to find out how they are managing their diabetes. Amy invited all Leeds practices to help identify participants for the study.

RESPONDS

RESPONDS is a research study funded by the Department of Health and led by Professor Gene Feder at Bristol University. Dr Jess Drinkwater presented the study which aims to develop new training and resources to support primary health care response to domestic violence combined with child safeguarding. This is a quick and easy study for practice members to be involved in – it simply requires being interviewed for 20-30minutes. Participating in this study will potentially shape the sort of resources that become available in this field. Other GPs, Practice Managers and Nurses have said that participating in the study has been a valuable opportunity to reflect on their work in this area.

15th October 2013, Leafield House

Evaluation of the Department of Health's Health and Social Care Volunteering Fund

Jane South is Professor of Healthy Communities in the Institute for Health and Wellbeing at Leeds Metropolitan University. Jane talked about her work in evaluating the Department of Health's Health and Social Care Volunteering Fund. This innovative fund was set up in 2009 with the aim of enabling voluntary sector organisations to play a more effective role in health and social care, alongside and in partnership with statutory services in their localities. Jane spoke about the idea behind the fund and presented some of the evidence from the evaluation to show how volunteer projects were able to address health and social care needs. There was an opportunity to discuss some the challenges of doing community health research and what the findings mean for health services and local commissioning bodies.

Mechanisms and Reversibility of Heart Failure associated with Diabetes (MRHD)

Peter Swoboda is a British Heart Foundation (BHF) research fellow at the University of Leeds and cardiology registrar in Leeds General Infirmary. His research, supervised by Professor Plein, entitled "Mechanisms and Reversibility of Heart Failure associated with Diabetes (MRHD)" uses cardiac MRI to look for early signs of heart failure in patients with type 2 diabetes. He plans to recruit 70 patients from primary care with diabetes and microalbuminuria to assess their cardiac structure and function before and after treatment with an ACE inhibitor and 55 control patients with stable diabetes.

29th January 2014, Gibson Lane Practice

CASPER

Shaista Meer and Jakki Birtwistle presented the CASPER Study **C**oll**A**borative Care in **S**creen-**P**ositive **E**lde**R**s. They are both researchers from Leeds Institute of Health Sciences, at The University of Leeds, working in collaboration with the University of York. This is a multi-site randomised controlled trial which aims to investigate the effectiveness and cost-effectiveness of collaborative care in older adults. There are four geographical regions acting as recruitment sites, of which one is Leeds. The Collaborative Care approach has been adapted to address depression in older people. Collaborative Care includes a case manager who provides information (on low mood/depression and antidepressants) and helps the participant to work through an activity focused intervention. In the CASPER trial, case managers support participants with an activity based intervention called Behavioural Activation. They also work with the participant to identify ways to keep well in the future. Recruitment to the study has been on-going since 2011 and the team were wanting to invite more practices to get involved.

Living Care Research

Living Care Research is a division of the Living Care Group, an organisation with an excellent track record in setting up and running a variety of services in the primary care setting. These services include endoscopies, various community outpatient clinics, and outreach minor surgery. Living Care recently incorporated the Leodis Healthcare group, along with its research division that continues to strive to provide the infra-structure to carry out high quality primary care research in conjunction with both academic units and pharmaceutical companies. Gareth O'Hare Clinical Research Director, Living Care presented details about how to become involved with Living Care Research.

COBRA

COBRA is a research study testing two types of psychological therapy for depression (Behavioural Activation (BA) and Cognitive Behaviour Therapy (CBT). The trial will compare the *cost* and the *outcome* of the therapies in order to find out which will be most useful for the treatment of depression. The study is being co-ordinated by researchers at The University of York but is running in Leeds in collaboration with Leeds Primary Care Mental Health Service. The study team were recruiting GP practices in the area to take part.

Appendix 5: Applying Research evidence into Commissioning decisions forums

Frailty in Elderly and Dementia – 29th January 2014

The inaugural meeting was hosted by Professor Robbie Foy at the Holiday Inn Brighouse and attended by a diverse range of academics, CCG leads, managers and local healthcare professionals. We had representation from six of the West Yorkshire CCG's at the event.

This and subsequent forums will consist of keynote speeches proceeded by round table discussions between both commissioners and academics on the current research evidence base within each of the themed topics. The keynote speeches for the opening forum were delivered by Professor Murna Downs who is a Professor in Dementia Studies and Head of the Bradford Dementia Group at the University of Bradford and Dr Andrew Clegg Senior Lecturer in the Academic Unit of Elderly Care & Rehabilitation, University of Leeds and Honorary Consultant Geriatrician at Bradford Teaching Hospitals NHS Foundation Trust.

'Dementia Care and Services – Research Implications for Commissioning' was a central topic during Professor Downs's presentation. Her talk put a particular emphasis on improving diagnosis and post diagnostic support.

Dr Andrew Clegg spoke on 'Frailty in Older People: A Clinical and Research Perspective' which outlining the mechanisms for Frailty and how care for Older people with Frailty could be improved.

The forum generated lively debate and discussion between the commissioners and academics about current research evidence to support commissioning decisions

Some of the main points raised during the meeting have been summarised below.

'There is good evidence that incorporating a 'discharge to assess' model for older people in hospital can significantly reduce length of hospital stay, readmissions and mortality (Silvester et al Age Ageing 2013)

Dr Andrew Clegg - Honorary consultant geriatrician at Bradford Teaching Hospitals NHS Foundation Trust

'*Joint working between primary and secondary care is important to reduce first line use of antipsychotics to try and reduce behavioural distress or psychiatric symptoms in people with dementia'*

Dr Subha Thiyagesh - Consultant Old Age Psychiatrist

'For older people with frailty,international consensus guidelines recommend exercise programmes, nutritional interventions, targeted medication reviews using e.g. STOPP/START criteria and vitamin D prescription for those who are deficient (Morley et al, JAMDA 2013).'

Dr Andrew Clegg - Honorary consultant geriatrician at Bradford Teaching Hospitals NHS Foundation Trust

'Until we have figured out how to give effective post diagnostic support we will not improve rates of diagnosis or, perhaps more importantly, we will not improve the experience of people with dementia and their families at the time of diagnosis'

Professor Murna Downs – Professor of Dementia Studies and Head of the Bradford Dementia Group at the University of Bradford

'There is good evidence that integrated models of care can improve outcomes (e.g. hospital bed days, long-term care admission) at lower overall cost (e.g. Torbay experience, Kings Fund 2011). Commissioners should consider how services will be aligned with current integrated care systems during the decision making process.'

Dr Andrew Clegg - Honorary consultant geriatrician at Bradford Teaching Hospitals NHS Foundation Trust

'We now need to test various approaches to improving rates of diagnosis, ensuring that we measure their effectiveness from the perspective of people with dementia and their families, and not just by number counts alone.'

Professor Murna Downs – Professor of Dementia Studies and Head of the Bradford Dementia Group at the University of Bradford

'Individualised care plans for co-existing conditions, integrated by case conference of key consultants or professionals, and overseen by GP, could be one step towards a more efficient care pathway'

Dr Subha Thiyagesh - Consultant Old Age Psychiatrist

'There is good evidence that integrated models of care can improve outcomes (e.g. hospital bed days, long-term care admission) at lower overall cost (e.g. Torbay experience, Kings Fund 2011). Commissioners should consider how services will be aligned with current integrated care systems during the decision making process.'

Dr Andrew Clegg - Honorary consultant geriatrician at Bradford Teaching Hospitals NHS Foundation Trust

'There needs to be specialists working closely in the community/different locations – linking specialist to generalist (through multidisciplinary discussions) – enabling a clear line of communication and a more linear joint plan for patients with dementia.'

Dr Subha Thiyagesh - Consultant Old Age Psychiatrist

'We need to de-commission things that don't work or only reduce a minor amount of admissions, also need to decommission diagnosis only services – need diagnosis and support available in the same place.'

Detailed below is some feedback from the delegates who attended the forum:

'The forum provided evidence to support business case, commissioning decisions, development of CQUINS, quality indicators.'

'Increased value placed in Multi Disciplinary Team meetings on individualised care planning.'

'Looking at shared decision making resources to improve practice'

'The forum was excellent and stimulating. It's great to get commissioners talking to researchers and influencing each other's agendas.'

Dr Paul Bolton - Executive Board member Airedale, Wharfedale and Craven CCG

Diabetes – 27th February 2014

The keynote speech for the second forum was delivered by Dr Ramzi Ajjan who is an Associate Professor and Consultant in Diabetes and Endocrinology at the Leeds Institute of Genetics, Health and Therapeutics.

'Individualise therapy according the need of each patient: diabetes is not a single condition' was a central topic of Dr Ajjan's presentation. His talk put a particular emphasis on improving the integration between primary and secondary care to improve patient outcomes and glycaemic control.

The forum generated lively debate and discussion between the delegates about current research evidence to support commissioning decisions and the development of localised approaches.

Some of the main points raised during the meeting have been summarised below;

'Impaired glucose tolerance tends to lead to diabetes and if people with impaired glucose tolerance could be targeted earlier then this could possibly lead to less people developing diabetes.'

Dr Ramzi Ajjan - Associate Professor and Consultant in Diabetes and Endocrinology at the Leeds Institute of Genetics, Health and Therapeutics

'It is not just about the up-skilling our workforce but is about delivering and high quality care is expensive. However this shouldn't be seen as specialist care, it should be core.'

Dr Judith Parker – Deputy Clinical Lead Greater Huddersfield Clinical Commissioning Group

'Public Health policy promotes intensive lifestyle clinical interventions with individuals or groups'

Greg Fell - Consultant in Public Health at Bradford Council

'Level Three Diabetes practices have a multidisciplinary meeting each month in protected time involving consultants, GPwSI's, podiatrist, dietician's, GP's, Diabetes Specialist Nurse's, practice nurse's to discuss complex cases'

Sarah Crossley - Service Improvement Manager Airedale, Wharfedale and Craven CCG

'The year of care works well for us (across several practices). All our practices use it as it enables you to see everything. The goal setting part is unrealistic as patients don't really understand – different ways needed to tackle that maybe.'

'Glycaemia is more complex and requires considerable input to: Individualise HbA1c target and adequate support'

Professor Allan House - Professor of Liaison Psychiatry in the Academic Unit of Psychiatry and Behavioral Sciences

'Individualise therapy according to the need of each patient: diabetes is not a single condition'

Dr Ramzi Ajjan - Associate Professor and Consultant in Diabetes and Endocrinology at the Leeds Institute of Genetics, Health and Therapeutics

'Single holistic reviews in Leeds for patients with CHD/diabetes instead of a separate review for each condition – people have not been referred as much since the introduction of this arrangement'

'Consultant clinics in Primary Care have been shown not to work. A better model is for the consultant to mentor the GP's and nurses to up-skill'

Dr Judith Parker – Deputy Clinical Lead Greater Huddersfield Clinical Commissioning Group

'We should focus on areas of the pathway where there is either high cost and or limited value'

Greg Fell - Consultant in Public Health at Bradford Council

'Kirklees Council have begun to use community access points to provide information about healthy lifestyles and diabetes; they are now looking at the possibility of doing health promotion work on industrial estates, to try and tap into the working populations'

'Tight versus less tight glyceamic control – The cost comparison of getting patient to target is six fold variation in Bradford'

Greg Fell - Consultant in Public Health at Bradford Council

Detailed below is some feedback from the delegates who attended the forum:

'As a result of the forum I will tailor diabetic care for each patient'

'Review/audit cholesterol and blood pressure target in my practice'

'Discuss with diabetes lead the importance of patient engagement during service re-design'

'Very useful listening to experiences and ideas from other CCGs'

'The forum provided meaningful dialogue with different health professionals involved in patient care. Sharing of good practice and models of care that deliver tangible benefits is really important in determining ' the direction of travel' when commissioning diabetes services/ care provision'

Dr Judith Parker – Deputy Clinical Lead Greater Huddersfield Clinical Commissioning Group

'I will think about what is important for commissioning services – patient involvement and better integration of primary and secondary care'

NHS

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