NHS
Bradford Districts
Clinical Commissioning Group


# Annual Report 2015-16

## NHS Leeds West

## Clinical Commissioning Group

# Contents

# 1.0 Foreword

1.1 2015-16 has been a year of transition for West Yorkshire Research and Development as the Yorkshire and Humber Commissioning Support Unit was unsuccessful in its attempt to be accepted onto the Lead Provider Framework. Since the 1st of December 2015, the Research Staff and the service they provide to the 10 Clinical Commissioning Groups (CCGs) is now hosted by NHS Bradford Districts Clinical Commissioning Group. The team continue to work on behalf of NHS Leeds West Clinical Commissioning Group to fulfil its statutory responsibilities in relation to research, as outlined in the 2012 Health and Social Care Act.

1.2 This last year has seen research in the NHS be given more of a focus and its importance reflected in further key policy and guidance updates. In the last year, the NHS constitution has continued to reiterate the requirement for every patient to have equality and equity of access to research participation. Research is now included in the "standard contract" that is provided to NHS organisations for use when commissioning services and the use and uptake of evidence has never been more required. 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 have really helped embed research as a core priority for the NHS.

1.3 The annual report highlights that we are achieving all of the national research governance metrics in relation to research, and in fact they are being exceeded in Leeds West. As part of the National Institute for Health Research (NIHR) Research Support Services (RSS) framework for local health research management we are measured against a local process target of 15 days to grant NHS permission for 80% of all valid applications. Currently the median number of days for NHS Leeds West CCG is 7 days for 100% of all applications to the CCG, well within the process target.

1.4 Following on from the reorganisation of the NIHR Clinical Research Network (CRN) in 2014-15, this year has seen a slow increase in the studies being offered in primary care, but it is still below the levels of several years ago, and this is reflected in the proportion of practices actively offering patients the opportunity to take part in research by recruiting them to studies. In 2014-15 NHS Leeds West CCG had over 51% of practices actively recruiting patients, but this year this decreased slightly to 50%. That said; this still far exceeds the NIHR

Clinical Research Network (CRN) primary care speciality specific target of 5% for the proportion of GP sites within an individual CCG being research capable.

1.5 An NIHR CRN overarching objective is that 25% of general medical practices will recruit to NIHR Portfolio Studies. In 2015-16 Yorkshire and Humber as a region achieved 43% and NHS Leeds West CCG has made an important contribution to this.

1.6 It is also important to note that 57% of NHS Leeds West CCG member practices are participating in the ASPIRE study. So although some practices are not recruiting patients into research they are participating by contributing anonymised data which will actively contribute to improved patient care and outcomes in the future.

1.7 West Yorkshire Research and Development regard making the evidence that research brings more accessible for commissioners. The team is therefore developing a website with key information for researchers, health professional and patients interested in research in West Yorkshire that will include a repository of locally produced research and link to national databases such as that provided by the Collaboration for Leadership and Applied Research in Health Care.

1.8 This annual report reflects the commitment of West Yorkshire Research and Development 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 local patients and the public.

**Paul Carder**
**Head of Service**
**West Yorkshire Research & Development team**

# 2.0 Executive Summary

2.1 In England, the revised NHS constitution has reconfirmed research as a core function of the NHS which maintains 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.

2.2 In April 2015 the NHS entered its third year as realigned in the Health and Social Care Act 2012. NHS England continues to include research in the 2015-16 "standard contract" they provide NHS organisations for use when commissioning services. Research and the usage of research evidence 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 have really helped embed research as a core priority for the NHS.

2.3 This report provides a description of the work that West Yorkshire Research and Development 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 and can demonstrate its willingness to participate and use research evidence in its commissioning activities.

2.4 The key headlines are:

- 29 new studies were granted NHS assurance by the WY R&D team on behalf of NHS Leeds West CCG.
- Currently the median number of days for granting NHS assurance on behalf of NHS Leeds West CCG is 7 days for 100% of all studies; the NIHR CRN local process target is 15 days for 80% of all valid applications to the CCG, so the CCG is well within the process target.
- 57% of NHS Leeds West CCG member practices are participating in research by contributing anonymised patient data as part of the Action to Support Practices Implementing Research Evidence (ASPIRE) study
- Significant national reorganisation of the NIHR Clinical Research Network (CRN) in 2015/16 has seen a slow recovery in research studies being offered, however, 50% of

practices within NHS Leeds West CCG are actively offering patients the opportunity to take part in research by recruiting them to studies well above the CRN performance and operating framework 2015-16 primary care speciality specific target of 5% for the proportion of GP sites within any individual CCG as research capable.

# 3.0 Background

3.1 This report provides a description of the work that the former Yorkshire and Humber Commissioning Support (YHCS) Research Service and as of 1st December the West Yorkshire Research and Development team (WY R&D) 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 for the period 1st April 2015 to 31st March 2016.

CCGs statutory obligations are defined by the following:

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

| | | | |
|---|---|---|---|
| Duty in respect of research | Duty | **Section 14Y NHS Act 2006**<br>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<br>Section 26<br>http://www.legislation.gov.uk/ukpga/2012/7/section/26/enacted |

3.2 The WY R&D team ensures all the research activity which is led or hosted within the West Yorkshire CCGs member practices 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 one for team biographies). This service operates in four core areas:

## Research Governance

3.3 The WY R&D team Head of Service acts as a signatory for permission for research activity and:

- Provides a letter of permission to the researcher outlining that they can now engage with individual General Practices to carry out research activity – pre Health Research Authority (HRA) approval
- Provides acknowledgement of HRA approval and assessment of Capability and Capacity – post HRA approval
- Processes the Research Passport (if required) for the members of the research team
- Issues 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 WY R&D team Head of Service will not provide permissions until authorisation has been given in writing by the CCG.

3.4 Whilst acting on behalf of the General Practices within a CCG the WY R&D team will as part of its core delivery:

- Work with researchers and potential applicants for research governance or HRA approval to support them through the local and site specific elements of the applications processes
- Process applications for research governance permission and assess Capability and Capacity in line with CSP/RDMIS and HRA requirements
- Ensure all necessary documentation is available to facilitate the permission and HRA processes
- Ensure comprehensive risk assessment is undertaken on all applications pre HRA approval, which consider:
    - Science
    - Information
    - Finance
    - Ethics
    - Health and Safety

- Ensure all permission/permission activity pre HRA approval 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 assessment of Capability and Capacity is supported in line with the Research Support Services (RSS) framework as above
- 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 (ETC) funding requests

### Research Management and Development

3.5 The team provides support and involvement in a number of externally funded research grants, acting as the lead NHS organisation and also:

- 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 and stakeholders
- We work closely with the Primary Care Research Network (PCRN)
- We ensure each of the services and 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

3.6 We maintain regular contact with the CCGs and also:

- 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 and HRA approvals
- We provide at least an annual report detailing all NIHR and non NIHR research activity

- We ensure appropriate representation at strategic and operational meetings for each of the functions and services outlined above, for example:
  - YH CRN Board/Executive (as required)
  - YH CRN Study Group
  - 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

3.7 We enable a link between the CCGs, academia, the NIHR CRN and the wider research community and:

- We facilitate dissemination through research network meetings and CCG educational events
- We provide CCGs with six monthly updates on recent research activity
- We enable new evidence to be made available to commissioners
- We provide a platform for research dissemination

# 4.0 Research Governance

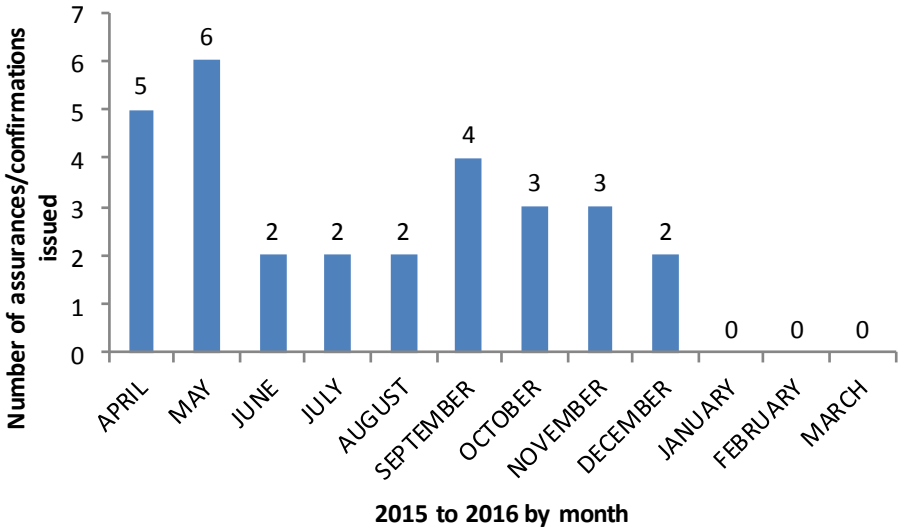
### Research assurance – NHS Permission and HRA Approval confirming capacity and capability

4.1 In total throughout 2015-16 the WY R&D team has provided NHS permission for 28 studies and have confirmed capacity and capability following HRA approval on 1 study on behalf of NHS Leeds West CCG.

Last year we highlighted the seemingly low level of studies received into the region to the NIHR Clinical Research Network (CRN) who have informed us that this current level is a reflection of the lower number of studies coming through nationally. The CRN felt this was inherently linked to the network re-organisation and anticipated this would change. We have seen a significant increase this year from 16 studies in 2014-15 to 29 studies in 2015-16 despite the introduction of HRA approval.

Chart 1 below shows NHS Permissions issued/ HRA Approved studies processed by the WY R&D team on behalf of the CCG, broken down by month, from 1st April 2015 to 31st March 2016.

*Chart 1. NHS assurance (permissions) issued/HRA Approved studies processed*




4.2 Table 1 on the next page lists by month the studies approved. Please see appendix two for further detail of each study.

*Table 1. List of studies*

| **April** |
|---|
| 1. Information and Risk Modification Trial (INFORM) |
| 2. TIME - Treatment In the Morning versus Evening (PIC) |
| 3. UK Aneurysm Growth Study (UKAGS) |
| 4. GPs' views on complementary therapies with palliative patients |
| 5. The AMARANTH study (PIC) |
| **May** |
| 6. Evaluation of VitruCare: Improving Lives Through Self-Care Technology |
| 7. Care Homes Independent Pharmacist Prescribing Service (CHIPPS) |
| 8. The Yorkshire and Humber Community Ageing Research (CARE) Study |
| 9. Exploring how data can cause improvement in hypertension management |
| 10. Consensus intervention strategy development for Rx in RKF |
| 11. Electronic resources in the management of chronic pain |
| **June** |
| 12. The Evaluation of Electronic Palliative Care Coordination System (EPaCCS) |
| 13. Manchester Asthma and Allergy Study (MAAS) |
| **July** |
| 14. Tele-First: telephone triage as an alternative to face to face contact in general practice |
| 15. Investigating GP Information Sharing Behaviour |
| **August** |
| 16. CCG Leadership, Governance and Managerial Behaviours |
| 17. ROSE ACS |
| 18. Patient involvement in diagnosing cancer in primary care (HRA - statement of activities) |
| **September** |
| 19. DS-5565 in pain associated with fibromyalgia |
| 20. The role of the GP in reducing A&E attendance |
| 21. Validation of Medication Nonadherence Model (Leeds) |
| 22. Care Homes Independent Pharmacist Prescribing Service (CHIPPS) WP4 |
| **October** |
| 23. Passive Fluenz Tetra Safety Surveillance Study |
| 24. Steroid Therapy and Adrenal Insufficiency (PIC) |
| 25. The REACT Trial (PIC) |
| **November** |
| 26. Stem cell research in early-onset psychosis |
| 27. ICT and Pain Management |
| **December** |
| 28. PANDA RCT |
| 29. GPs' perceptions of IBS |

4.3 As part of the NIHR Research Support Services (RSS) framework for local health research management we are measured against a local process target of 15 days to grant NHS permission for 80% of all studies. Currently the median number of days for NHS Leeds West CCG is 7 days for 100% of all studies, well within the process target. Now HRA approval is fully rolled out new process targets will be issued, however these are yet to be decided. Where it is possible the WY R&D team will contribute to the development of these targets.

### The Health Research Authority (HRA) Approval

4.4 The HRA was established 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). In accordance with the new Care Act provisions of 2014 the HRA was established as a new, statutory Non Departmental Public Body (NDPB) as of 1st January 2015.

4.5 HRA Approval aligns the Research Ethics Committee (REC) approvals process with NHS R&D approvals, to reduce duplication by creating a single HRA assessment. HRA Approval is an authoritative approval for research studies in the NHS in England. It comprises a review by a Research Ethics Committee (where applicable) and an assessment of regulatory compliance and related matters. HRA Approval provides assurance that a study has fulfilled all regulatory requirements.

4.6 The HRA began the phased roll out of HRA Approval on 11th May 2015 for NHS staff research that did not require review by an NHS Research Ethics Committee. From the 10th August 2015 this continued with all new applications for research activities within independent contractors (GP practice) being processed by the Health Research Authority and be given HRA Approval. This replaces the NHS Permission (assurance) previously provided by the WY R&D team. The WY R&D team still have an active part in the process, this being more focused on local feasibility and delivery and is integral to the streamlining purpose of these national changes. Roll out of further cohorts has seen the HRA achieve their ambition of full roll out by 31st March 2016. The phased approach meant that the WY R&D team were operating two systems of approval during the transition period.

4.7 With HRA Approval, research sponsors and their study services will be required to agree and confirm with CCG member practice sites that they have the capacity and capability to deliver the study and that arrangements are in place to do so. This is not through a formal letter but through completion of a *'statement of activities.'*

4.8 Whilst CCG member practices will continue to have the final decision on whether to undertake a study, the WY R&D team will now also work closely with them and their federations to ensure all local feasibility checks are undertaken in line with the 'statement of activities'. This will mean we will liaise with the appropriate CCG leads on:

- Excess Treatment Costs

- Medicines Optimisation
- Information Governance
- Safeguarding
- When the Principal Investigator is a member of staff within the CCG
- Duty of care for CCG employees for studies involving CCG members of staff

4.9 This will ensure any research proposed observes locally set targets and internal processes for example:

- Formulary and prescribing budgets
- CCG fit, including length of time in study and complexity for participant, potentially leading to local inclusion and exclusion criteria
- Monitoring and in trial issues, such as adverse event reporting
- Post-trial exit plans

These local feasibility criteria will then be included on the '*statement of activities.*'

4.10 In light of the coming HRA changes and in order to establish research sites, sponsors and researchers may contact CCG member practices directly. We would like to recommend that the WY R&D team establishes a mechanism whereby the practice refers the sponsor and researchers to the WY R&D team. We would propose this be a brief email to the WY R&D team to enable us to engage with the sponsor, researchers and the practice in order to facilitate the local feasibility checks as described above. Our new website and the promotion of this going live early summer 2016 will facilitate this process.

4.11 HRA Approval requires a *'statement of activities'* to be signed off by an authorised person(s) for that NHS organisation. This is to confirm that the local research activities outlined in the statement will be undertaken as described and the persons carrying out the activities are qualified to do so. This will continue to be the Head of the WY R&D team or appointed delegate.

The existing caveats where sign off is needed by the CCGs research lead are:

- Where there is an excess treatment cost
- When the Principal Investigator is a member of staff within the CCG
- When the study involves CCG members of staff

Practices will be able to start a study when the HRA Approval letter is granted **AND** local arrangements to set up the study are in place.

### New UK Policy Framework for Health and Social Care Research

4.12 The WY R&D team have actively taken part in the recently closed consultation on the new UK policy framework for health and social care research, which will replace the Research Governance Framework (2005). The team attended the HRA consultation meeting for R&D managers in Birmingham in February 2016 and have also submitted written feedback on the policy document.

4.13 The new UK policy framework for health and social care research proposes to set out principles of good practice in the management and conduct of health and social care research that take appropriate account of legal requirements and other standards. The principles proposed aim to protect and promote the interests of patients, services users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

4.14 With due regard to relevant legislation within the UK and European Union, the policy framework will set out principles and responsibilities at a high level. The implementation of these will be supported by operational arrangements and guidance provided by the HRA and the Devolved Administrations, working in collaboration to ensure a consistent approach to co-ordinating and standardising regulatory practice. This will achieve compatibility across the UK for the ethics, conduct and management of health and social care research.

### Research monitoring arrangements

4.15 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 WY R&D team completes a risk assessment for every study and a monitoring plan is put in place accordingly to the level of risk the study poses. To date there are no significant issues to report.

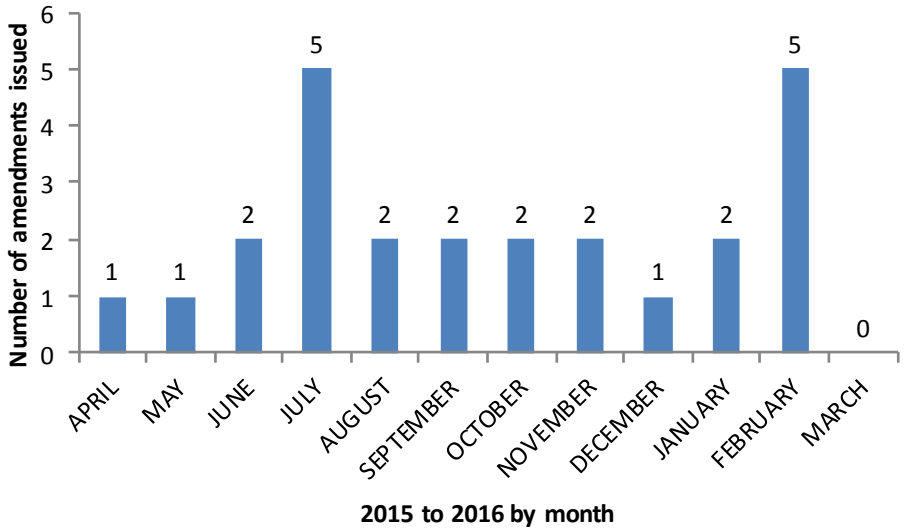
## Research amendments

4.16 The WY R&D team currently processes all amendments according to the agreed protocol with NHS Leeds West CCG and National Guidance on amendment types.

4.17 Going forward the HRA approval process will also include amendments. The WY R&D team Governance Lead sits on the National Steering Group that will define the new mechanism for management of these. Until a National process is agreed amendments to studies will continue to be managed as per the current process.

4.18 25 study amendments have been processed on behalf of the CCG throughout 2015-16. Chart 2 below shows the number of study amendments processed by the WY R&D team on behalf of the CCG, broken down by month, from 1st April 2015 to 31st March 2016.

*Chart 2. Number of amendments processed*




## Letters of access for research and honorary research contracts

4.19 Alongside the assurance/permission process, letters of access and honorary research contracts are needed to engage and allow researchers to commence their research study. 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

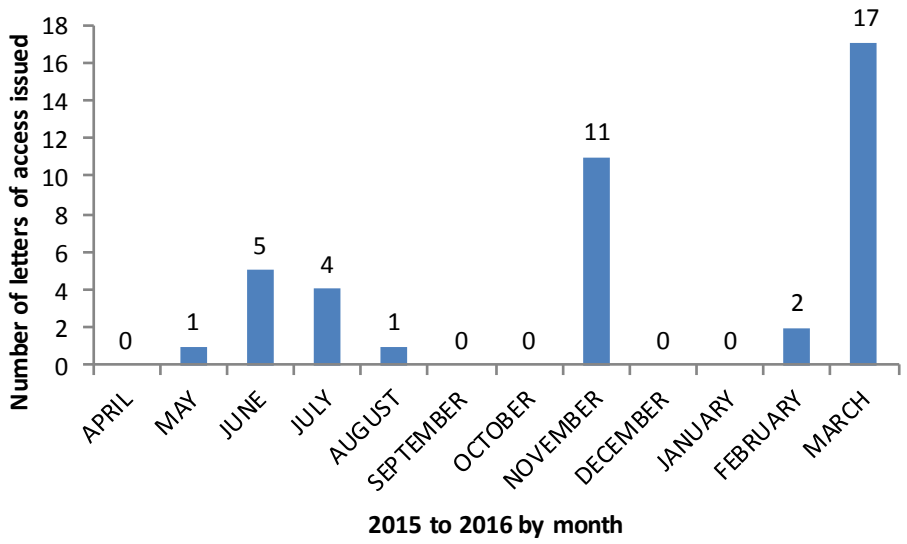
Research Governance Framework requires all parties undertaking research within the NHS to be clear about responsibilities and liabilities.

4.20 The WY R&D team uses the UK Department of Health's HR good practice resource pack to ensure a consistent approach to handling arrangements for those undertaking research in the NHS.

In total 41 letters of access were granted on behalf of NHS Leeds West CCG throughout 2015-16.

4.21 Chart 3 shows the number of letters of access issued by the WY R&D team on behalf of the CCG, broken down by month, from 1st April 2015 to 31st March 2016.

*Chart 3. Number of letters of access issued*



# 5.0 Research Development and Management

## Research Development Portfolio

5.1 The WY R&D team works with a host of academic and NHS organisations, on behalf of the West Yorkshire CCGs, to facilitate the development of research that addresses local and national commissioning priorities.

We have formed close and productive collaborations with the University of Leeds, Leeds Institute of Health Sciences, Academic Unit of Primary Care and Academic Unit of Palliative Care and also with the Leeds Institute of Medical Education.

**University of Leeds – Academic Unit of Primary Care**

5.2 The Academic Unit of Primary Care is led by Professor Robbie Foy. Primary care research at Leeds has rapidly expanded in recent years, bringing in around £12 million of nationally-competitive funding over the past three years as lead or co-investigators. The Unit's research focuses on the implementation of evidence-based practice into routine health care. Clinical research continually produces new evidence that can benefit patients. This evidence does not reliably find its way into everyday patient care. In both policy and research, the selection of implementation strategies tend to be driven by combinations of habit, pragmatism and varied assumptions about how the world works rather than evidence. Robbie and his team aim to inform policy by providing rigorous evidence on the cost-effectiveness of implementation strategies, and how and when they work best.

5.3 The WY R&D team is currently supporting the Action to Support Practices Implementing Research Evidence (ASPIRE) programme. ASPIRE is a five year, £2 million programme funded by the NIHR for General Practice in West Yorkshire which will produce findings of international interest and significance. Over 175 practices are taking part. The aim of ASPIRE is to produce sustainable, feasible, cost-effective interventions that will improve performance and, ultimately, improve patient outcomes.

5.4 Between 2013 and 2015, in a study to understand the prescribing of opioid for chronic non cancer pain in general practice we were able to demonstrate a sustained rise in opioid prescribing, with an accompanying rise in the ratio of strong to weak opioids prescribed which is unlikely to be attributable to greater use in end-of-life care. This finding, will in 2016-2017 working in conjunction with Sally Bower in the medicines optimisation team, mean a sustained programme of work with the Leeds West practices entitled the "Campaign

to Reduce Opioid Prescribing". Practices will receive regular audit and feedback on their prescribing patterns relating to opioids which should improve patient care and may potentially produce savings for the local health economy.

**University of Leeds - Academic Unit of Palliative Care**

5.5 The Academic Unit of Palliative Care is led by Professor Mike Bennett and in the first 5 years has built a National and International reputation for research in palliative care. The Academic Unit of Palliative Care at Leeds Institute of Health Sciences, University of Leeds, was formed in 2011 with St Gemma's Hospice and is the only formal Academic Unit in the UK based within a hospice and a University. This ensures an integrated academic clinical environment: palliative care patients have excellent opportunities to take part in NIHR research while receiving high quality evidence based clinical care. The research addresses current clinical challenges in palliative medicine which can be summarised as improving the management of pain for patients in the community, and evaluating clinical decision making and interventions during end of life care.

5.6 Working with Mike's team, the WY R&D team are named co-investigators on £3.5m of grant funding from NIHR and Yorkshire Cancer Research leading to important publications in the BMJ, JAMA and Lancet Oncology.

5.7 We have supported recruitment of over 1100 patients, carers and staff to develop and test novel interventions to manage cancer pain including electronic pain monitoring system, self-management support programmes, opioids use reviews by pharmacists; currently evaluating these within national NIHR funded RCTs before NHS implementation.

5.8 It is also important to note the Unit have been recognised by NIHR 'Better Endings' in the themed review (2015) of significant research in this field. The Unit has also championed public engagement in research by including patients and carers as co-applicants on grants and developing novel ways to include the public in priority setting, and were runners up in National Co-ordinating Centre for Public Engagement competition (2014) from over 230 entries.

**University of Leeds - Leeds Institute of Medical Education**

5.9 Leeds Institute of Medical Education (LIME) is led by Professor Trudie Roberts and aims to enhance the practice of medical education globally. LIME is involved in conducting and evaluating original enquiry and research; this in the development of innovation and scholarship in the field of medical education. LIME works with a wide range of national and international stakeholders including the academic community, the health professions, the public, regulators, policy makers and other commercial and non-commercial organisations. LIME is committed to helping move forward the discipline of medical education.

5.10 The WY R&D team works with Trudie's team, as well as other partner organisations from across the EU, on the four-year Framework 7 project Learning Layers, with a total value of €9.9 million. Learning Layers focuses on informal workplace learning and supporting this learning through technological tools. The project is currently in its final year and is working on evaluating the tools developed in the project with small pilot groups working in general practice across Bradford and Airedale and nationally. The project has received positive feedback from staff that recognise the value that the tools can have in making discussions more effective, saving time and improving communication. We will look to use the foundations and relationships gained through this project for future collaborations with LIME.

5.11 To take our collaborative work forward the WY R&D team will meet twice a year with Una Macleod, Professor of Primary Care Medicine and Deputy Dean of the Hull York Medical School, John Sandars, Professor of Medical Education and Director of Research at the University of Sheffield and Ian Watt, Professor of Primary and Community Care at the University of York, along with other Yorkshire and Humber Research leads, to discuss local and national research priorities and funding application opportunities.

5.12 With our current collaborative arrangements we have the following research bids submitted pending a funding decision:

- NIHR HS&DR - Evaluating Palliative care Intervention and Opioid New Events (EPIONE)
- NIHR HS&DR - An interrupted time series analysis of a feedback intervention to reduce opioid prescribing in primary care
- NIHR HS&DR - Can social prescribing reduce health care utilisation? An evaluation of social prescribing models in England

- NIHR PGfAR - A multi-stage randomised trial evaluation of clinical decision rules in the management of suspected heart failure in primary care assessing diagnostic accuracy, patient outcomes and experience, and cost effectiveness
- NIHR PGfAR - AntiBiotic Allergy and Microbial ResistAnce (AlaBAMA)
- Horizon 2020 - BReathe EAsy THroghout Europe (BREATHE)

Further work is ongoing towards the following research bids:

- NIHR RfPB submission in January 2017 – An analysis of workforce configuration in General Practice and the health outcomes produced in QoF
- Programme Development Grant for July 2017 submission with Professor Veronica Swallow relating to Online Parent Information and Support (OPIS)
- NIHR PGfAR - for submission 2017-18 with Veronica Swallow
- NIHR RfPB submission in January 2017 – A feasibility study to explore the hypothesis that; Waist height ratio >0.5 and/or increasing ankle blood pressures are a better risk stratification tool for high risk for diabetes in South Asians as compared to BMI >27.5 and or increasing brachial blood pressures.

5.13 A synopsis of each of the proposed projects above is provided in appendix three. Summaries of other ongoing current and recently completed research projects supported by the WY R&D team are in appendix four.

### Research Capability Funding (RCF)

5.14 Further work supported by the WY R&D team includes awards made to researchers in receipt of West Yorkshire generated NIHR Research capability Funding (RCF). The NIHR Research Capability Funding is allocated by the Department of Health to research-active NHS bodies or NHS health care providers in receipt of NIHR income. The West Yorkshire NHS organisations potentially eligible for RCF, qualify to receive funding under two circumstances:

- Either they received sufficient NIHR income in the previous calendar year to reach a threshold to trigger a RCF allocation of at least £20k.
- Or they recruited at least 500 individuals to non-commercial studies, conducted through the NIHR Clinical Research Network (CRN), during the previous NIHR CRN reporting period of October - September.

As the West Yorkshire CCGs both host research and recruit to research studies we receive funding under both trigger points above. Over the last few years this has ranged from £150,000 to £280,000 per annum.

**RCF 2015-16:**

5.15 On Tuesday 1st March 2016 the WY R&D team launched a call to researchers across West Yorkshire for applications for RCF, with the deadline for applications being 12 noon on Thursday 31st March 2016. RCF is a quality driven fund which is supported by the National Institute for Health Research to promote and develop patient and people based research. The purpose of the fund is outlined below:

- To assist research active NHS organisations to sustain research capacity and capability
- To develop, maintain and preserve workforce undertaking or supporting people or patient based research
- To contribute towards the costs of hosting NIHR-funded or adopted research that are not currently fully across other NIHR programmes

5.16 A panel will meet on the 21st April 2016 to consider the funding of the 11 applications received. The review panel includes academics, clinicians and CCG members from across the West Yorkshire locality.

RCF offers a number of benefits to NHS organisations, for example:

- Access to flexible funding
- A means for developing and sustaining research capability, meeting the costs of key research support staff not funded in other ways
- Helping to build critical mass, as increased research capacity attracts additional NIHR research income and so attracts a greater share of Research Capability Funding
- Providing a financial contribution towards the costs incurred through research active NHS organisations hosting NIHR-funded or 'adopted' research
- Funding for developing research management capabilities in those Trusts where R&D departments have been reconfigured within NHS research support services

**RCF 2015-16:**

5.17 A panel was held on 8th May 2015 to allocate the £150,000 Research Capability Funding received from the Department of Health.

From the 14 eligible applications received the 2015-16 funds were allocated to 8 successful applications as follows:

- RCF-2015-001 – Professor Mike Bennet, University of Leeds - The aim of this proposal is to fund a research fellow to develop a strong grant application to RfPB funding programme, to build capacity in community based palliative care research within West Yorkshire while engaging community based researchers and clinicians in Leeds and Bradford
- RCF-2015-002 – Professor Robbie Foy, University of Leeds - This application seeks RCF for bridged funding of an early career academic GP with the intention that they apply for competitive doctoral funding through a fellowship or grant application in 2016 whilst undertaking preparatory work for a PhD
- RCF-2015-004 – Professor Robbie Foy, University of Leeds - This application seeks RCF funding to ensure that Leeds University have a locally grown candidate available for an externally funded NIHR academic clinical lecturer post from 2016. Should the university fail to develop such a candidate, there is a major risk that over £320,000 funding for this post will be lost
- RCF-2015-007 – Professor Alan House, University of Leeds - The aim of this proposal is to provide bridging funding for a senior research fellow (SRF) to develop an application to NIHR to extend the research on which she is currently employed on a fixed-term contract as a SRF and to help her be in a position from which she can apply for an NIHR Career Development Fellowship or similar
- RCF-2015-009 – Professor Robbie Foy, University of Leeds - The aim of this proposal is to provide bridging funding of early career academic GP with the intention that they apply for a competitive NIHR fellowship in 2016, ensuring that they have one day per week of protected academic time to work up a competitive fellowship application (either In-Practice or Doctoral) under the supervision of Professor Foy
- RCF-2015-011, Professor Rebecca Lawton, Bradford Institute for Health Research - RCF will be used to achieve the following objectives: to consolidate existing knowledge on current interventions for patient involvement in diagnosis in primary care and to assist with developing a new intervention, a scoping review of interventions for diagnosis in this context will be undertaken; to undertake semi-structured interviews with patients who have received a cancer diagnosis, GPs and Nurse Practitioners to assess the acceptability, feasibility, cost and burden of patient involvement in cancer diagnosis in primary care (following analysis of these interviews focus group work will be undertaken

with all stakeholders to discuss the types of interventions that would be acceptable and feasible); to undertake analysis of transcripts of semi-structured interviews to assess acceptability, feasibility, cost and burden of patient involvement in cancer diagnosis; and to develop a grant proposal for the development and testing of an intervention for patient involvement in cancer diagnosis in primary care. It is envisaged that this would be submitted for funding to NIHR RfPB or the Health Foundation

- RCF-2015-013 – Dr Helen Elsey, University of Leeds – The aim of this proposal is to retain a senior research fellow between contracts through RCF bridging funding pending outcome from a submission to NIHR PHR on improving mental ill health through the use of care farms. The aim of the funding is to gain funding from NIHR PHR to evaluate the cost-effectiveness of care farms in improving the mental health of patients diagnosed with depression through primary care
- RCF-2015-014 – Professor Mike Lucock – University of Huddersfield - This project is to support a research fellow to build on previous work to refine a self-management intervention to prevent relapse following psychological therapy for depression, develop treatment and training manuals and prepare an NIHR funding application for a randomised controlled trial

Reports and the achievements and milestones along with financials from the above will be reported back to the Department of Health via their standard templates in July 2016. A summary of the RCF activities will be provided to the CCG in the Quarter 2 report.

### Development of CCGs strategic plans and input into local projects

5.18 CCGs are required to develop Operational Plans that meet the minimum requirements as outlined in NHS England's Planning Guidance "The Forward View into action: planning for 2015-16" for their revalidation. CCGs must submit plans that capture trajectories plus a narrative that describes the CCG approach to delivery of key national and local priorities. The WY R&D team have supported the CCGs and, where requested provided the narrative under the following headings:

- How your plans fulfil your statutory responsibilities to support research?
- How you will use Academic Health Science Networks to promote research?
- How you will adopt innovative approaches using the delivery agenda set out in Innovation Health and Wealth: accelerating adoption and diffusion in the NHS?

5.19 As part of the new CCG Assurance Assessment Framework for 2015-16, to feed into the CCGs Annual Review at Quarter 4, NHS England wanted to assess each CCGs progress under the "Well Led Organisation" domain that required each CCG to complete a self-assessment template. The template asked the CCG to demonstrate compliance with its statutory functions. There were a number of functions which required a particular focus because of the complexity of the issues or the degree of risk involved, one of these was the use of research. The template also asked the CCGs to identify any gaps and the mitigation of those gaps against these key lines of enquiry, but, also offers an opportunity to share any examples of good practice. The WY R&D team have provided detail to support the West Yorkshire CCGs use of research, providing examples of good practice, demonstrating compliance to the NIHR CRNs published national metrics and, where applicable, how the CCGs make available excess treatment costs.

### Ongoing research management

5.20 Members of the WY R&D team sit on various steering and oversight groups to manage local ongoing research projects, to input into regional research strategy and to contribute to the National direction of travel for health and social care research in the UK. The meetings we attend include (not exhaustive):

- ASPIRE Programme Management Team, work package specific Steering Groups and International Scientific Advisory Panel
- SMARTE Steering Group
- OK Diabetes Steering Group
- Time4PallCare Steering Group
- EU Learning Layers work package and weekly flash meetings
- West Yorkshire R&D Managers meeting
- Yorkshire and Humber Primary Care R&D Managers meetings
- Airedale R&I Steering Group
- Yorkshire and Humber CLAHRC Executive Board
- Yorkshire and Humber AHSN Innovation network
- NIHR Yorkshire and Humber CRN Study Group
- NIHR Yorkshire and Humber CRN R&D Operations Group
- HRA Amendments National Steering Group
- UK Policy for Health and Social Care Research consultation meetings
- Annual NHS R&D Forum and NIHR & INVOLVE People in Research meetings

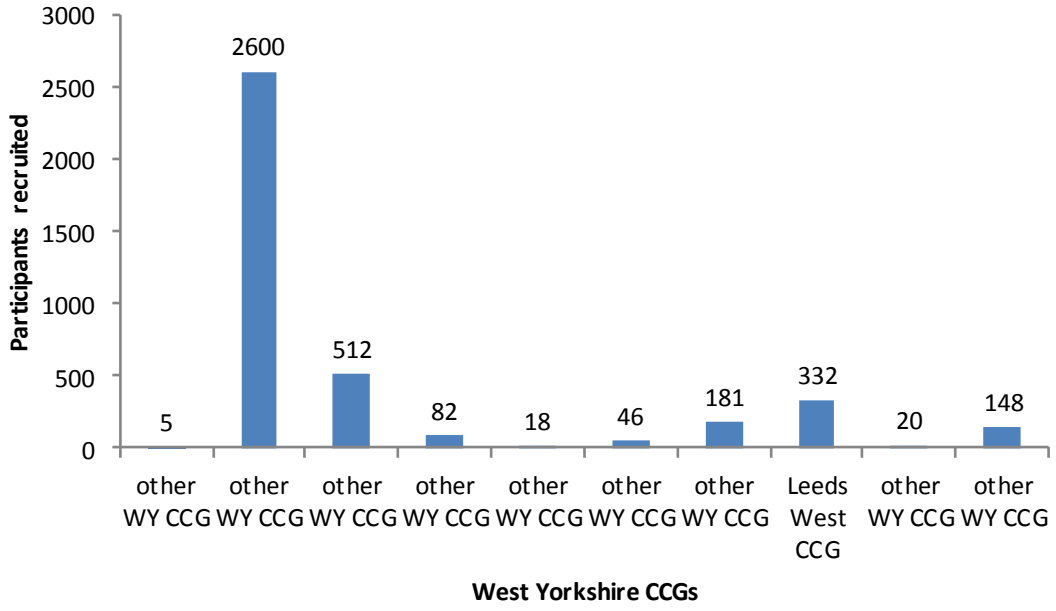
# 6.0 Research Engagement

6.1 The WY R&D team develops research engagement within the CCG, increasing engagement through promotion of local research studies and their delivery requirements to CCG member practices.

### Study Recruitment

6.2 Throughout 2015-16 member practices of NHS Leeds WEST CCG have recruited 332 participants into research studies. Chart 4 shows the CCG's recruitment figures in comparison to the other nine West Yorkshire CCGs throughout 2015-16.

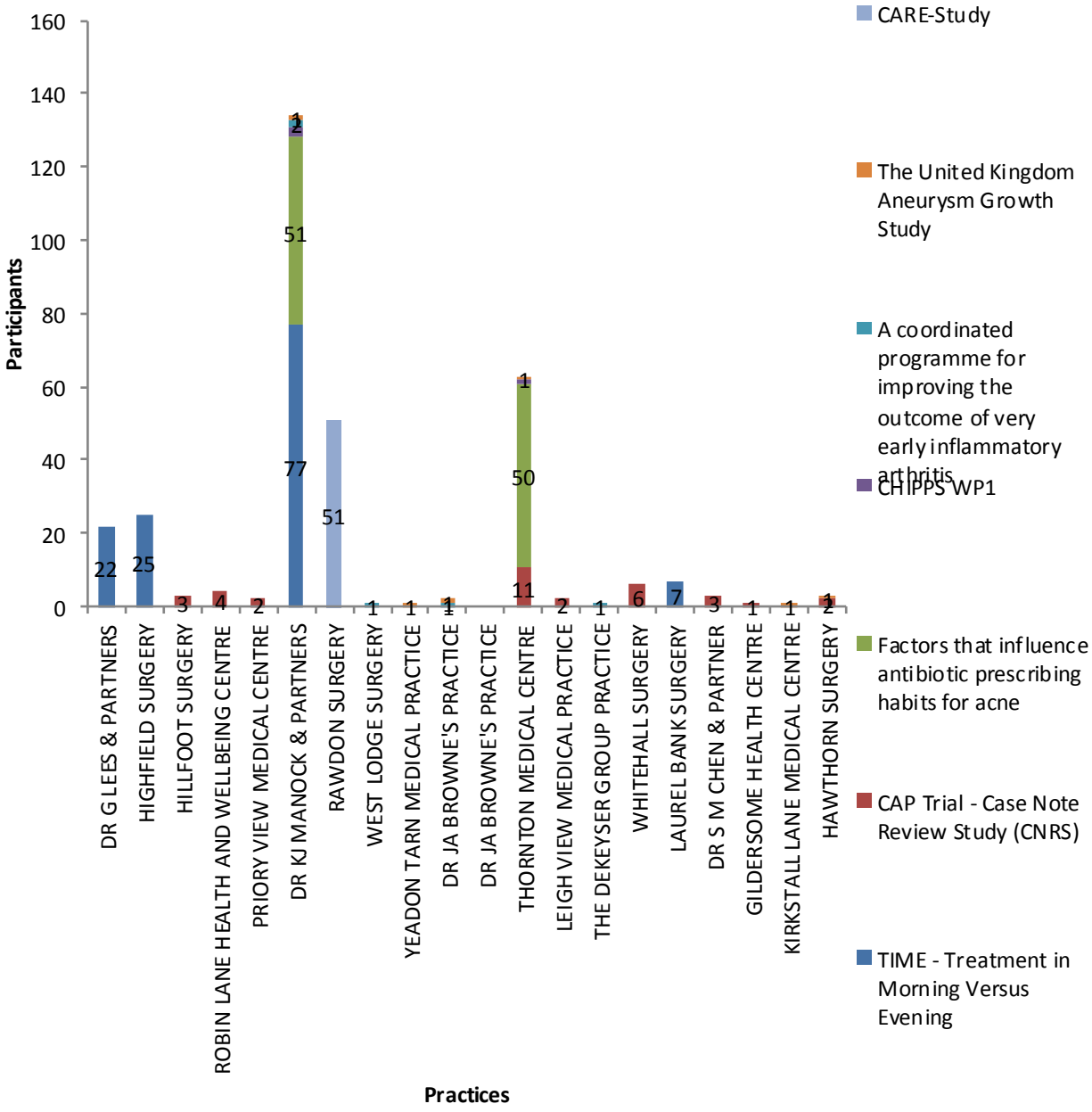
*Chart 4. Study recruitment in West Yorkshire 2015 - 2016*




6.3 Within NHS Leeds WEST CCG 50% (n=19) of practices have recruited participants into research. The NIHR Clinical Research Network (CRN) performance and operating framework 2015-16 highlights a primary care specialty specific target of 5% for the proportion of GP sites within any individual CCG registered as research capable with the NIHR CRN. An NIHR CRN overarching objective is that 25% of General Medical Practices will recruit in to NIHR CRN Portfolio Studies, however when considered as a region Yorkshire and Humber has achieved 43%.

6.4 The WY R&D team are keen to further develop research engagement within the CCG through a collaborative approach. We intend to increase engagement through further promotion of local research studies and their delivery requirements to CCG member practices. We will do this by providing regular input into the CCG newsletter by providing content in our quarterly reports, feeding into Practice Manager Meetings, events and any other opportunities that arise. Chart 5 breaks down recruitment by practice and study.

*Chart 5. NHS Leeds West CCG member practice recruitment*



## Practice Protected Time – TARGET events

6.5 On 30th April 2015, 18th June 2015, 17th September 2015 and 22nd February 2016 the WY R&D team attended the Leeds West CCG TARGET events held at the Mercure Leeds Parkway Hotel. The events were well attended and provided an opportunity for the distribution of material outlining the support available from the WY R&D team, providing an opportunity for attendees to approach the team with any questions they had about taking part in research across West Yorkshire. Following correspondence with Jane Jackson, Associate Consultant at Lumley Associates, it has been agreed that WY R&D will be represented at the next Leeds West CCG TARGET event, to be held in the next financial year, to ensure that there continues to be opportunities for member practices to engage with the team.

## Network Events

6.6 Throughout 2014, on behalf of the CCG, YHCS organised and delivered research network meetings. These meetings were an opportunity for research interested and active primary care practitioners to meet and share best practice and to receive information about local research projects being developed or delivered. The transition of YHCS prevented the network events from taking place in 2015 but these will be resumed in 2016.

## Practice Management

6.7 During 2015-16 the WY R&D team formulated a training package designed to provide an overview of research and its requirements within primary care. This was created for practice managers and administrators and provides a background to research and its practical requirements. The training also includes a checklist for practices outlining what they should be looking for when a study approaches the practice for inclusion to ensure good practice. The WY R&D team Research Governance lead plans to attend a practice managers meeting to present the training.

### NIHR Collaboration for Leadership in Applied Health Research and Care (CLARHC)

6.8 The CLAHRCs were set up to improve patient outcomes across the geographical area covered by the Collaboration through three key interlinked functions:

- Conducting high quality applied health research,
- Implementing the findings from research into clinical practice,
- Increasing the capacity of NHS organisations to engage with and undertake applied health services research.

The CLARHC has set up research themes

- Avoiding Attendance and Admission in Long Term Conditions
- Evidence Based Transformation with the NHS
- Health Economics and Outcome Measurement (HEOM)
- Healthy Children, Healthy Families
- Mental Health and Comorbidity
- Primary care-based management of frailty in older people
- Public Health and Inequalities
- Telehealth and Care Technologies
- Translating Knowledge into Action

6.9 The CLARHC is designed to undertake high quality applied research and evidence-based implementation that is responsive to, and in partnership with, our collaborating organisation, patient, carers and the public.
The WY R&D team currently represent the CCGs at the CLARHC partnership board. For information on the CLARHC please see http://clahrc-yh.nihr.ac.uk/

### Academic Health Science Network (AHSN)

6.10 The aim of the Yorkshire & Humber AHSN is to create significant improvements in the health of the population by reducing service variability and improving patient experience in the health care system. The Yorkshire & Humber AHSN will assist in ensuring new innovative products and services that have the potential to transform lives become part of routine clinical practice. The Yorkshire & Humber AHSN will also assist in providing economic growth for the region, supporting inward investment projects and industry that support the health sector.

6.11 The AHSN's have 4 core aims:

1. Focus on the needs of patients and local populations: support and work in partnership with commissioners and public health bodies to identify and address unmet medical needs, whilst promoting health equality and best practice.
2. Build a culture of partnership and collaboration: promote inclusivity, partnership and collaboration to consider and address local, regional and national priorities.
3. Speed up adoption of innovation into practice to improve clinical outcomes and patient experience – support the identification and more rapid spread of research and innovation at pace and scale to improve patient care and local population health.
4. Create wealth through co-development, testing, evaluation and early adoption and spread of new products and services

The WY R&D team are working with the Improvement Academy, publicising their workshops and helping to access potential funding where appropriate.

# 7.0 Knowledge Transfer

7.1 The translation and integration of evidence synthesized from the delivery of research is a national priority. Effective Knowledge Transfer can improve the service we deliver to patients through the sharing of best practice.

### Knowledge transfer events

7.2 Throughout 2014-15, on behalf of the West Yorkshire CCGs, YHCS organised and delivered the Applying Research evidence in Commissioning decisions (ARC) forums and also held several research network meetings to facilitate knowledge transfer. During 2015-16, the transition of the YHCS and budget constraints relating to the transition has not allowed us to organise similar events.

It is intended that knowledge transfer events will be organised in 2016-17.

### Newsletters

7.3 WY R&D has continued to communicate with Communications and Engagement Manager Carolyn Walker to ensure regular research updates are included in the CCG newsletter. Information disseminated through the newsletter has included material about the HRA approval process, invitations to training and events and the dissemination of research study findings. This platform has also been utilised in an attempt to increase recruitment to portfolio studies, for example following liaison with the National Institute for Health Research's Division 5 WY R&D recirculated information about the Treatment In Morning versus Evening (TIME) Study to general practices in the Leeds West CCG area in December 2015, in an attempt to stimulate interest in and recruitment to the study. NIHR Division 5 colleagues have fed back that there was a notable increase in recruitment to the TIME study following the inclusion of the study flyer in the CCG newsletter.

### Future Plans

7.4 The West Yorkshire R&D Team will seek to enable appropriate Knowledge Transfer across the 10 West Yorkshire CCGs by:

- Delivering opportunities for the outcomes of research to be disseminated to and shared with healthcare professionals within the CCG through:
    - Research Network meetings;

    - CCG websites;
    - Working with CCG communications teams to deliver expressions of interest for potential research;
    - Enabling dissemination events;
    - A presence at Target educational events.
- Developing a research-based website to provide a point of contact for all four phases of research to be used by local potential researchers but also those working on national programmes who wish to work within West Yorkshire;
- Maintaining a repository of emerging evidence for the benefit of all clinicians and commissioners within West Yorkshire.

# 8.0 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/about/collaborations-for-leadership-in-applied-health-research-and-care.htm

**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 / provides a streamlined approach for confirming details of their pre-engagement checks http://www.nihr.ac.uk/policy-and-standards/research-passports.htm

**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 work streams 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 tothe 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.

**Northern and Yorkshire Cancer Registry** - The Northern and Yorkshire Cancer Teams (Public Health England) monitor patterns of cancer in Yorkshire and the north 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/policy-and-standards/research-capability-funding.htm

**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/policy-and-standards/framework-for-research-support-services.htm

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

**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 license 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.*

# 9.0 Appendices

## Appendix One: Team Structure and Biographies

9.1 Until the end of November 2015 the Research Service sat within the Yorkshire and Humber Commissioning Support Unit (YHCS) Nursing Directorate, led by Director of Nursing, Lynn Poucher. From the 1st of December the research team now sit within the Quality Team of NHS Bradford Districts CCG, led by Director of Quality, Michelle Turner.

9.2 The WY R&D team provides support in various ways, including:

- Help in building CCG portfolios of research studies by working with local universities and NHS trusts to identify local research priorities
- Building and maintaining strong working relationships with all partners and stakeholders
- 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
- Working on behalf of CCGs to promote and implement research findings into practice
- Developing bids for national grants in partnership with universities, NHS trusts and other NHS health and social care organisations to support research priorities
- The WY R&D team supports all ten CCGs within West Yorkshire

**The WY R&D Team**

9.3 The team comprises of:

- Paul Carder, Head of Service
- Stella Johnson, Research Manager
- Rebecca Harper, Research Governance Lead
- Rosemary Dewey, Research Governance Officer
- Gemma Doran, Research Engagement Officer

Team biographies are provided on the forth coming pages

# Paul Carder
# Head of Service


**Experience Summary**

Paul has been working in research related rolesin 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**

2 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.

3 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

4 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

5 Paul is also an ex professional rugby coach and qualified RFU rugby coach

**Skills**

2 Application of economics in a healthcare setting

3 Theory informed implementation of innovation within health care services

4 Research and evaluation methods and data analysis

**Relevant Work Experience**

**Research and HEEES: Yorkshire and Humber 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 Leeds, Bradford and Airedale Primary Care Trust.** 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).

# Stella Johnson
# Research Manager


**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 completing an MSc in Health Research at the University of Leeds
- Stella has extensive experience of development and delivery of training in both manufacturing and health research settings

**Skills**

- PG Dip in Health Research
- NIHR Research Programme Management
- NIHR IS Project Management
- Specialist knowledge in the field of research and evaluation methodology
- Specialist knowledge in return on investment (ROI) evaluation
- NIHR IS training development and delivery
- Trained in GCP, Clinical Risk Management and Project Management for Clinical Research

**Relevant Work Experience**

**Research Manager - Yorkshire & Humber Commissioning Support:** Stella plays a pivotal role in supporting Clinical Commissioning Groups (CCGs) with their statutory requirements and actively contributes to research activity bringing an innovative and business-focused approach to the role. Stella works with our partners and customers and other local and national organisations including, universities, other health and social care providers, NHS England and the Department of Health to secure high quality research funding.

**Research Associate – West & South Yorkshire & Bassetlaw Commissioning Support Unit:** Stella has spent a year at the WSYB CSU working within research governance and management and supporting research engagement activities. Stella has contributed to and led the evaluation of several major projects and is working towards a formal accredited return on investment qualification.

**Senior Programme Officer – National Institute for Health Research:** 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 led the training for roll out in this area. Stella has also been involved with various projects funded by streams of the NIHR, working with and providing support to researchers from a range of areas including academia, healthcare and industry.

# Rebecca Harper
# Research Governance Lead


**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**

1. Project Management
2. Programme Management
3. Specialist knowledge in the field of research methods and governance.
4. Training development and delivery
5. Specialist knowledge in the fields of dental health and research
6. Knowledge and experience of media communications

**Relevant Work Experience**

**Research Consultant/Research Governance Lead – Training and Project Management:** Rebecca has spent six 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 the CRN 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.

# Rosemary Dewey
# Research Governance Officer


**Experience Summary**

Rose is involved in a flagship EU research project and works on the governance of all study applications in primary care. She previously developed extensive project management experience through eight years of working in the academic publishing industry.

**Background**

- Rose has a background in academic publishing, with eight years' experience working for a leading academic journal publisher. Her role involved working with academics as well as other professionals, and gave her a strong grounding in this aspect of the research process.
- She recently completed a postgraduate diploma in Health Research from the University of Leeds.
- Rose has worked closely with the academic community through the EU Learning Layers project, as well as through her time in publishing.
- Over the past year, Rose has gained experience of the research governance process, processing assurances, amendments and letters of access.

**Skills**

- Project management
- Relationship building
- Negotiation
- Research governance

**Relevant Work Experience**

Since October 2013 Rose worked in the Research team, initially getting involved with the research engagement element of the team's remit and for the past year with Rebecca on governance for research studies. Rose supported the team's Research Network meetings, aimed at keeping research-active practices informed about research opportunities and also about the outcomes of research projects which have taken place across the area.

Rose also supported the ARC (Applying Research evidence in Commissioning decisions) forums, which brought together academics and commissioners to enable evidence-based commissioning decisions.

Rose has been heavily involved in 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 and networks in the Bradford& Airedale area and nationally (concluding in October 2016). She works closely with the Leeds Institute of Medical Education (LIME) at the University of Leeds, as well as other academic and commercial partners across Europe.

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

# Gemma Doran
# Research Engagement Officer

West Yorkshire Research and Development

**Experience Summary**
Gemma has a strong academic and administrative background, having supported the NHS in multiple governance roles, as well as robustly developed events management skills.

**Background**

- Gemma gained a strong understanding of the academic community through the completion of her own Master of Arts (MA) degree in English Literature, as well as from her time providing research project support to a published poet and academic working at the University of Glasgow.
- Gemma is gaining experience of the research governance process and of primary care engagement / knowledge transfer and has completed Good Clinical Practice and Research in Health and Social Care training. This training has developed Gemma's knowledge of research methodologies, processes and procedures which she has been able to utilise to promote the importance of adherence to the high quality research governance process.

**Skills**

- Engagement and knowledge transfer
- Event planning and management
- Writing, editing and presenting
- Relationship building
- Governance and administration

**Relevant Work Experience**

From March 2014 Gemma supported the Research team whilst working as Business Support for the Transformation, OD and Research business unit, initially holding a comprehensive co-ordinating role which involved events management and the monitoring of internal systems. As of October 2014 Gemma has acted as Research Engagement Officer for West Yorkshire Research and Development, working to develop the level of primary care engagement with research; she promotes NHS research by engaging with clinicians, academics, and service users to encourage interest and involvement in research activities taking place within Yorkshire and Humber.

Gemma's background is in governance and NHS procedure and she has previously worked in NHS Freedom of Information and Governance and Risk departments. As Business Support to the Governance and Risk team Gemma oversaw the serious incidents process, acting as a link between various stakeholders (including care commissioners and providers) and the local area team, providing critical high level administrative support at all times to ensure the successful management and running of the department. Gemma developed strong administrative skills working for children's charity Barnardo's, acting as a supervisor and administrator.

Gemma developed strong events management skills whilst acting as the Personal Assistant to the Executive Director of the Bronte Society. In this role Gemma organised and supported meetings with various high profile organisations, including The National Portrait Gallery, the BBC and various television/radio broadcasters whilst contributing towards the editing and completion of press releases, news articles and academic presentations.

She develops her communication skills in her voluntary role with the National Trust, maximising visitor experience by educating visitors and supporting the running of events (e.g. theatre productions and art exhibitions); as such Gemma's communication and presentation skills are strong and she is able to adapt information to make it accessible to various groups of people who have different levels of interest.

## Appendix two: Summary of studies which have been granted NHS Assurance/ HRA Approval confirmation of capability and capacity on behalf of NHS Leeds West CCG in 2015-16

**Information and Risk Modification Trial (INFORM)**

Chief Investigator: Professor Simon Griffin, Professor of General Practice, University of Cambridge

Risk: Low – intervention consisting of advice/information

Start/End date: 01/11/14 – 31/12/15

CCG costs/income: N/A

Sponsor: University of Cambridge

Brief overview of the study: This is a randomised controlled trial of different types of information and lifestyle advice to try to encourage behaviour change in CVD, for example diet, exercise and smoking, in patients between 40 and 84 years old. The groups will be provided with different types of information; either phenotypic risk score (current practice) or genetic risk score (scores calculated in a different way), or no risk information. They will also receive online lifestyle advice. A control group will receive no advice or risk score. The study will consist of:

- A baseline and follow-up questionnaire will be completed by the patient online
- The advice will be delivered online at 3 points over 8 weeks
- Physical activity data will be measured using a device worn on the wrist over 7 days (once at the start and once at the end of the study)
- A blood sample will be taken at the patient's GP practice
- Around 50 participants will also be invited to take part in interviews/focus groups

The genetic risk score will be obtained via DNA testing of blood samples provided in the previous INTERVAL study (from which participants are recruited). The phenotypic risk score will be calculated from blood samples and information provided in the INTERVAL study. Patients will be in the study for approx. 5 months and follow-up is 12 weeks. The only part of the study involving GP practices will be the blood sample. The kit will be provided by the study and a pre-paid "safebox" for posting the sample back to the lab. Practices can invoice the study £10 for each sample taken.

After the study all patients will receive the information/advice that they did not receive during the trial, i.e. the information/advice given to the other study arms. Estimated sample size across England is 932 with estimated 746 requiring the blood test. Number of participants in this area is not known until patients sign up. Participants will be recruited from an existing study – INTERVAL (a study about donating blood). Participants in INTERVAL have previously consented to being contacted about other studies. Participants will receive an email with information and an invitation to take part

in the study. They will then complete an online eligibility questionnaire and complete an online consent form if eligible. Recruitment runs to June 2015.

The study is funded as part of the EPIC-CVD programme which is an EU Framework 7 programme.

There was a Substantial Amendment to the study prior to approval which updated the protocol to cover calculating the participants' 10 year risk of coronary heart disease instead of CVD as all of the variables for calculating CVD were not available in the data.

**TIME - Treatment In the Morning versus Evening (PIC)**

Chief investigator: Professor Thomas MacDonald, University of Dundee / NHS Tayside

Risk: low

Start/end date: 04/07/2011 - 04/07/2016

Sponsor: University of Dundee

Brief overview of the study: A trial comparing evening dosing of usual antihypertensive therapy with conventional morning dosing. Subjects already taking antihypertensive medication in usual care will be identified from collaborating practices and within secondary care clinics. Subjects will be invited to participate in the study by registering on a study website. Registered subjects who meet the inclusion criteria will be randomised to continue taking medication at their usual time (most often in the morning) or to switch to taking medication in the evening (or morning if evening is their usual time). Subjects will receive regular emails with simple links to record responses at regular intervals to track progress. Participants, surrogates or GPs can record adverse events or endpoints at any time online.

The principle objective is to determine if antihypertensive therapy taken in the evening has improved cardiovascular outcomes compared with more conventional morning dosing. Night-time blood pressure (BP) has consistently been a better predictor of cardiovascular outcome than daytime BP. As the night:day BP ratio increases, cardiovascular risk appears to decrease. There is also evidence to suggest that antihypertensive drugs taken in the evening rather than in the morning reduce nocturnal blood pressure to a greater extent and might have more benefit. The present study seeks to discover if night-time dosing of antihypertensive medication reduces cardiovascular events compared with conventional morning dosing.

**UKAGS –UK Aneurysm Growth Study**

Chief investigator: Mr Matthew Bown, Lecturer in Surgery, University of Leicester

Risk: medium-low

Start/end date: 01/06/2012 – 31/07/2020

CCG costs/income: N/A

Status: already running study in various PCTs/trusts including Wakefield and North Kirklees, which is requesting assurance in Bradford (all), Leeds (all) and Calderdale.

Sponsor: University of Leicester (Graham Hewitt)

Brief overview of the study: This research aims to determine genetic and biochemical factors associated with the growth of abdominal aortic aneurysms. The research will also determine the psychological impact of screening and surveillance on patients with abdominal aortic aneurysms (AAA).

This research will consist of a 10-year cohort study of patients with screening-detected small aneurysms. Participants with small AAA will be requested to provide blood and urine samples on a yearly basis whilst they remain in the AAA surveillance programme (which on average is 4.8 years). There will be an option for participants to provide samples on only one occasion. In addition to the biological samples, the participants will be requested to complete questionnaires designed to assess the effect of participating in screening and surveillance programmes on their psychological health.

When a patient attends for their standard AAA screening they will be invited to participate in the study. They will be given a reply-paid card on which the patient can indicate their wish to receive further information about the study.

Once completed consent forms have been received these will be copied and sent to the patient and their GP together with a study sampling pack. This sampling pack will contain the necessary blood and urine sample containers and a psychological questionnaire. The participants will be requested to take the sample containers to their GP surgery to have blood drawn and give a urine sample. These will be returned to the coordinating centre for laboratory studies in specially designed sample transport packages. All samples and questionnaires will only be labelled with a barcode and study identification number and not patient details.

The cost of taking the sample can be reclaimed from PCRN (NB this was before Division 5).

On a yearly basis, those participants who consent to continued participation in the study will be sent a further sampling pack. This will continue until the patient reaches the threshold for surgery or leaves the surveillance programme.

Blood samples will be processed and stored as DNA, RNA, plasma and serum. Urine will be stored without any pre-processing other than centrifugation. DNA samples will be used for genotyping of common genetic variants. RNA and plasma/serum/urine will be used to determine biological markers of aneurysm size.

A large number of amendments have already been submitted and processed for this study. These consisted of:

- Changes to patient documents
- Addition of NHS number to documents (requesting GPs to provide NHS numbers where the patients have not provided them)
- Improvement to the electronic storage of data at University of Leicester
- Introduced that some CLRNs will approach patients directly at screening clinics to recruit
- Addition of sites
- Patients have the option to only provide 1 sample and still remain in the study, as it was sometimes putting patients off when they had to provide a second sample
- They will obtain data not only from HSCIC but also from HES and GP records

A later amendment changed the sampling procedure so there will be no urine samples taken (they couldn't find a suitable way of transporting these), and some patients can provide a saliva sample rather than a blood sample.

**GPs' views on complementary therapies with palliative patients**

Chief investigator/Academic Supervisor/Principal Investigator: Dr Julia Hackett, Research Fellow, Leeds Institute of Health Sciences, University of Leeds

Student: Miss Isabel Turner, 4th Year Medical Student, Leeds Institute of Health Sciences, University of Leeds

Risk: low

Start/end date: 12/01/2015 – 14/06/2015

CCG costs/income: n/a

Sponsor: University of Leeds

Brief overview of the study: This study is being undertaken as part of a BSc in Applied Health (Primary Care). The research aims to investigate the attitudes of General Practitioners towards the use of complementary therapies in patients with terminal illness (palliative patients). GPs will be interviewed within their practice about the views and beliefs they hold about the use of complementary therapies in palliative care. It will investigate how GPs view their role regarding the referral or signposting of palliative patients to complementary therapies, and what they think the benefits or advantages of these therapies are in this type of patient. Participants will be identified via an email to GP surgeries in Leeds requesting GP volunteers take part in the study. The email will contain a brief overview of the study, consent form and participant information sheet.

This is an academic study sponsored by the University of Leeds

**The AMARANTH study (PIC)**

Chief investigator: Lefkos Middleton, Imperial College, London

Risk: low (PIC)

Start/end date: 05/02/15 – 04/02/17

CCG costs/income: N/A

Sponsor: AstraZeneca

Brief overview of the study: A 24-month, multi-centre, randomised, double-blind, placebo-controlled, parallel-group, efficacy, safety, tolerability, biomarker, and pharmacokinetic study of AZD3293 in Early Alzheimer's Disease. AZD3293 is an experimental drug for the treatment of Alzheimer's disease (AD) which is not yet approved. The drug is an inhibitor of BACE1 (an enzyme involved in forming amyloid plaques in AD) and has been shown to reduce peptide fragments in mice, rats, guinea pigs, dogs, and humans. 6 phase 1 trials have been carried out on the drug in humans. No significant safety/tolerability concerns have been identified.

This is a multi-centre randomised, double-blind study which will take place across 15 countries and approximately 1551 patients will be recruited worldwide from up to 175 centres. One third of patients will receive the study drug at a dose of 20mg, one third the dose at 50mg and the other third will receive a placebo. They will receive the treatment for 110 weeks. There are 2 biomarker sub-studies – all patients in the study will take part in one. These are different ways of measuring levels of amyloid in the brain or spinal fluid.

The primary objective is to evaluate the effectiveness of the drug as measured by the Clinical Dementia Rating – Sum of Boxes (CDR-SB) score. There are many secondary objectives, in short:

- To calculate the effectiveness of the drug measured by different scales
- To calculate the effect of the drug on the biomarkers
- To evaluate the safety and tolerability of the drug
- To assess the breakdown of the drug in the body
- To investigate the effect of the drug in the breakdown of donepexil

There are also many exploratory objectives.

We are acting as a PIC for the study. This means GP practices will identify patients from routine clinical practice – by reviewing patient notes during visits to assess if they are eligible. Practices will then give some brief information to potential participants and refer them to the main site. A printed advertisement will be used in local media – if patients see this and want to take part they will contact the research site directly.

**Evaluation of VitruCare: Improving Lives Through Self-Care Technology**

Chief investigator: Professor Paula Ormandy, Professor Long-Term Conditions Research, University of Salford

Risk: low

Start/end date: 09/03/2015 – 09/03/2016

CCG costs/income: N/A

Sponsor: University of Salford

Brief overview of the study: This research evaluates the impact of an innovative internet based service (VitruCare) that presents patients' medical information in an actionable way. This service supports patients to manage their LTC or EoL pathway using a holistic, motivational approach with goal setting, action planning and the use of patient selected trackers to enable patients to achieve their outcomes, while remaining connected to their clinician.

The research follows two cohorts of patients, those managing a long term condition (LTC) and others at the end of life (EoL) and related health professionals to explore their perspectives of using the internet based program. The focus of the study is the impact of the program on: patient health outcomes, symptoms and quality of life; the relationship between the patient and their clinician; staff satisfaction; contextual success factors for implementation and uptake across different primary

care settings; and the exploration of potential cost benefit audit measures. The study uses a mixed methods approach including focus groups and health outcome measures, to examine impact and provide a deeper understanding of the use of telehealth to influence self-management, healthy behaviour and care preferences. VitruCare includes a diary, teleconsultant, personal information and preferences on care services.

Patients will be identified by their GP and/or primary care specialist nurse/Palliative Care Consultant from the patient records and will be invited to take part. No one outside of the clinical team will have access to patient records prior to consent being given by participant. Participants can choose to be sign up to using VitruCare and decline being involved in the evaluation if they wish.

This study is funded by the Technology Strategy Board – Knowledge Transfer Partnership (£100,526 over 18 months).

**Care Homes Independent Pharmacist Prescribing Service: CHIPPS**

Chief investigator: Professor David Wright, Professor of Pharmacy Practice, Norwich Research Park, University of East Anglia

Principal Investigator: Dr David Alldred, Associate Professor of Pharmacy Practice, School of Healthcare, University of Leeds (formerly Senior Lecturer in Pharmacy at University of Bradford)

Risk: low

Start/end date: 01/05/2015 – 01/05/2016

CCG costs/income: n/a

Status: new

Sponsor: South Norfolk Clinical Commissioning Group

Brief overview of the study: The main objectives of this research study are to update evidence regarding the optimisation of medicines use within care homes, to obtain stakeholder views (GPs, pharmacists working in care homes, care home managers and other staff (care home residents and relatives – being undertaken in other locations not this one) to inform the development of the service specification for a pharmacist independent prescriber (PIP) who assumes responsibility for the management of prescribing within care homes; and to prepare and refine a service model and initial service specification for pharmacist independent prescribing within care homes.

Six small linked work projects will be undertaken; this is the first part of the funded programme – WP1. WP1 consists of an update in knowledge of the research on how best to prescribe and use

medicines in care homes, gathering of expertise from those working in care homes to find out how best to introduce and use pharmacist prescribers so that they become an effective member of the team, also to find the best ways to measure the effect of these pharmacists on (residents – not at this location), staff and the home by looking at how other researchers have measured the effect of changes in prescribing and rank those methods for suitability. The WP1 work will provide information on how best to introduce, run and test this new service and inform the next part of the programme (WPs 2-6).

Focus groups (1 ½ hours) will be facilitated by the study co-ordinator and a research assistant, these will be conducted at a place and time convenient for the participants at each research site. One interview (30 mins), participants will be asked to attend a focus group or an interview – interviews will be conducted by a research assistant, either face-to-face (at a place and time convenient for the participants at each research site) or by phone. 15 of the focus group participants will be asked if they are interested in also attending a Stakeholder Intervention Development Meeting. The meeting is for one day and will be led by a PI and organised by research assistant at a time and place convenient to the participants within care homes.

This study is funded by the NIHR CCF (£1,986,159.00 over full research programme, this is WP1 of six work packages).

**The Yorkshire and Humber Community Ageing Research (CARE) Study**

Chief Investigator: Dr Andrew Clegg, Clinical Senior & Honorary Consultant Geriatrician, Academic Unit of Elderly Care & Rehabilitation, BIHR

Other Key Investigators: Professor John Young, Head of Academic Unit of Elderly Care and Rehabilitation, BRI . Anne Heaven, Research Project Manager, Primary Care Based Management of Frail Older People, BRI. Lesley Brown, Senior Research Fellow and Theme Manager for Primary Care Based Management of Frailty in Older People, BRI

Risk: Low

Start/End Date: 01/10/14 to 31/12/20

Brief overview of study: The aims of the study are:

- To demonstrate the feasibility of recruitment to the CARE study and the feasibility of recruitment to future trials of interventions to improve health and wellbeing outcomes (interventions could include exercise, occupational therapy, nutrition and medication)

- To study longitudinal frailty transitions (following frail older people over four years), and health and social care resource use
- To investigate the clinical utility of the electronic frailty index (eFI)
- To identify older people with frailty for the planned series of studies in the CLAHRC2 programme (to refine an existing home-based exercise programme, a qualitative investigation of resourcefulness and enhancing communication skills of practitioners)
- To establish a biobank (blood samples) for future frailty and ageing research

The study team aim to recruit approximately 200. Participants will be recruited by working with research ready GPs to identify participants within primary care. Potential participants will be posted a study invitation pack containing a letter of invitation, participant information leaflet, photographs of the research staff involved in the home visits, an a letter of support from the GP. This will be followed up by a phone call from the researcher after two weeks to discuss the study in further detail. Following an expression of interest an appointment will be made for a home visit with the researcher.

**Exploring how data can cause improvement in hypertension management**

Chief investigator/ Academic Supervisor: Dr Thomas Willis, Research Fellow, Academic Unit of Primary Care, Leeds Institute of Health Sciences, Leeds University

Student researcher: Anton Minty, Intercalating BSc Medical Student, Leeds University

Risk: low

Start/end date: 01/03/2015 – 08/06/2015

CCG costs/income: n/a

Status: new

Sponsor: University of Leeds

Brief overview of the study: This study is being undertaken as part of a BSc. The main aim of the study is to investigate the impact of different methods of presenting clinical audit data upon general practice staff; how might data be presented to make behaviour change more likely. In this study, General Practice staff will be presented with clinical data representing practice performance on an indicator of hypertension management. The same data will be presented in different formats and participants will be asked to provide their thoughts on each format. Short 'think-aloud' interviews (lasting approximately 15 minutes) will be conducted with 7-15 practice staff (including GPs, nurses, practice managers). Interviews will be recorded and transcribed. Transcripts will then be analysed to examine whether any components of the presented data were considered to be more important

than others. Qualitative thematic analysis will be used to try to establish links and differences between peoples' opinions of the graphs.

The data used has been collected by an existing research study in the Leeds Institute of Health Sciences. However, prior to use in this study it will be anonymised so that no individual practices are identifiable.

Practices will be approached initially via email, then participant information sheet and consent form will be sent to interested participants.

**Consensus intervention strategy development for Rx in RKF**

Chief investigator: Mrs Susan Wood, PhD student, University of Leeds

Academic Supervisors: Professor Theo Raynor, School of Healthcare, Baines Wing, University of Leeds; Dr Duncan Petty, Pharmacy Department, University of Bradford; Dr Liz Glidewell, Charles Thackrah Building, University of Leeds

Risk: low

Start/end date: 01/02/2015 – 31/10/2015 – please note that start dates are estimated by the researcher on initial application

CCG costs/income: n/a

Status: new

Sponsor: University of Leeds

Brief overview of the study: This study is being undertaken by a student as part of their PhD at the University of Leeds. The aim of the study is to develop an intervention strategy to produce behaviour change to improve prescribing for older people with reduced kidney function through a consensus group.

The formal group consensus process the 'RAND Appropriateness Method' will be used to systematically combine research evidence and expert opinion to generate a consensus. Statements will be initially rated individually by experts and stakeholders in related fields and completed online via the Bristol Online Survey (BOS). There will then be a group discussion held at the University of Leeds (or more than one, if needed to allow participants to be able to attend) in the form of a structured group style consultation exercise lasting for approximately 1 – 1.5 hours, at the end of which, the group will come to a consensus agreement on the statements and priorities for intervention strategy and future research.

Potential participants will initially be approached by an invitation letter from the Principal Investigator along with a consent form, information sheet and SAE. Non-responders will be mailed or emailed one reminder two weeks after the initial mailing. Individuals who reply stating that they are interested will be telephoned by the Principal Investigator. After the potential participant has had the opportunity to discuss the project, they will be asked if they wish to take part. Those who agree to participate will be asked to complete a consent form by the Principal Investigator.

Project data will be securely stored and password protected; participant identifiable documents such as consent forms will be stored in a locked filing cabinet at the University of Leeds and only accessible by the student and academic supervisors for the purposes of the research. Data will be stored to comply with the Data Protection legislation and the University of Leeds guidelines. Group discussion transcripts will be anonymised before analysis is undertaken, any strong identifiers will be checked for and removed.

**Electronic resources in the management of chronic pain**

Academic supervisor: Dr Matthew Allsop, University of Leeds

Student: Miss Iesha Mistry, Leeds Medical School, University of Leeds

Risk: low

Start/end date: 25/05/2015 – 08/06/2015

CCG costs/income: n/a

Status: new

Sponsor: University of Leeds

Brief overview of the study: This study is being undertaken by an intercalating student (BSc Applied Health and Primary Care) at the University of Leeds. The aim of the study is to determine GPs' views on electronic resources for managing chronic pain patients in primary care.

The student has obtained a list of Leeds GP contact details from Division 5. GPs will be emailed an introduction and a link to a survey about their usage of and views about electronic resources – these are apps rather than systems like SystmOne or EMIS. GPs will be invited, if they are interested in taking part in interviews to explore further, to give their details at the end of the survey.

7-10 GPs will be selected to take part in these interviews which will have 2 parts – one looking at their opinions and usage of pain management electronic resources and the other giving 2 case

studies of patients with chronic pain and asking about how they might see electronic resources fitting in.

**The Evaluation of Electronic Palliative Care Coordination System (EPaCCS)**

Chief investigator: Professor Michael Bennett, St Gemma's Professor of Palliative Medicine, Leeds Institute of Health Sciences, University of Leeds

Principal Investigator: Dr Matthew Allsop, Research Fellow, Leeds Institute of Health Sciences, University of Leeds

Risk: low

Start/end date: 06/04/2015 – 01/10/2015

Status: new

Sponsor: University of Leeds

Brief overview of the study: This study will evaluate the implementation of an electronic system designed for use by health professionals working with palliative care patients. Electronic Palliative Care Coordination Systems (EPaCCS) are a way of health professional documenting end of life care preferences for patients. This project will assess changes in documentation of end of life care preferences by comparing data from before and after EPaCCS implementation.

This project will explore the extent of EPaCCS implementation across Leeds in the last four quarters, examine the level of documentation currently occurring, and explore patient and health professional perspectives of the EPaCCS approach. The project will adopt a mixed methods approach, using routinely collected data extracted from existing EPaCCS systems alongside qualitative enquiry through focus groups with health professionals and face-to-face interviews with patients. The qualitative component of the research will serve to identify ways to improve quality of care for patients, and to create a more efficient and effective system for patients receiving palliative care.

**Manchester Asthma and Allergy Study (MAAS)**

Chief investigator: Professor Adnan Custovic, Professor of Allergy and Honorary Consultant Allergist, University of Manchester

Risk: low

Start/end date: 04/05/2015 - 04/05/2016

Sponsor: University Hospital of South Manchester

Brief overview of the study: Asthma and other allergic disorders are the most common chronic childhood diseases in the UK. Improved understanding of individuals at risk would facilitate better targeting of intervention, treatment and resources in primary and secondary care. The Manchester Asthma and Allergy Study (MAAS) is a prospective cohort, of 1000 children born between February 1996 and April 1998, in which environmental exposures, immune responses, behaviour/family functioning, genetic epidemiology and clinical outcomes have been investigated since birth. IFWIN (Inhaled Fluticasone in Wheezy Infants) is an early intervention study involving 200 children born between February 1996 and April 2000. As well as monitoring response to treatment IFWIN children have undertaken the same clinical review process as MAAS children at age 3, 5, 8, and 10-12 years. The intervention aspect of IFWIN has been completed and the two studies continue "observational" follow up as the Manchester Asthma and Allergy Study (MAAS).

**Tele-First: telephone triage as an alternative to face to face contact in general practice**

Chief investigator: Professor Martin Roland, Professor of Health Services Research, The Primary Care Unit, University of Cambridge

Risk: low

Start/end date: 01/07/2015 – 28/02/2017

CCG costs/income: n/a

Sponsor: NHS Cambridgeshire and Peterborough CCG

Brief overview of the study: The main aim of this study is to explore how a GP telephone triage affects patient experience and use of NHS primary and secondary care services. The secondary aims are to establish what impact GP telephone triage has on the nature of consultations for patients and staff, and how appropriate this approach is for hard-to-reach groups; and to find out what the cost consequences are of a telephone triage approach in general practice.

To address these research questions a mix of qualitative and quantitative approaches and a cost-consequences analysis will be used. The study will evaluate the impact of the scheme on practices enrolled within two companies providing management support to practices using a GP telephone triage approach.

There will be a screening survey to establish intervention and control practices. There will then be a survey to be completed by patients and carers, and a survey to be completed by practice managers on their experiences of the system. There will be interviews carried out with patients and carers about the convenience of using the triage system and interviews with GPs and practice staff about

the systems convenience, workload, practice environment, impacts on the doctor-patient relationship and quality of care. A structured telephone survey will be conducted with practice managers to establish the costs attributed to the triage system.

The purpose of the study is to provide an evidence base for the use of triage systems within primary/secondary care and hopes to show how the triage approach could be rolled out more widely, what the potential barriers would be, and how they might be overcome.

**Investigating General Practitioners' (GP) Information Sharing Behaviour**

Chief investigator/Principal Investigator/Academic Supervisor: Professor Peter Bath, Professor of Health Informatics, Information School, University of Sheffield

Student researcher: Adrian Adewunmi, MSc student in Health Informatics, Information School, University of Sheffield

Risk: low

Start/end date: 15/09/2014 – 31/08/2015

CCG costs/income: n/a

Status: new

Sponsor: University of Sheffield

Brief overview of the study: This study is being undertaken as part of an MSc in Health Informatics. The aim of the study is to understand the factors which influence the willingness of GPs to participate in shared EPR (Electronic Patient Record) for use in managing elderly patients with multiple chronic diseases.

This study will be conducted using a quantitative method of questionnaires which will be applied to ascertain the information sharing behaviour of GPs as regards a shared EPR. Primarily GPs will be asked to complete an online questionnaire. The information gathered from the online survey will then be subjected to statistical analysis to demonstrate whether or not the positive impacts of a shared EPR on elderly chronic disease care is linked to better adherence of government policies and professional guidelines by GPs.

This study is an academic study sponsored by the University of Sheffield.

**CCG Leadership, Governance and Managerial Behaviours**

Chief investigator: Prof Beverly Alimo-Metcalfe, University of Bradford

Risk: low

Start/end date: 01/08/2015 - 31/12/2015

Sponsor: Bradford University - School of Management

The rationale behind the radical changes to the NHS and the creation of Clinical Commissioning Groups is that CCGs "will put healthcare professionals in the driving seat so that they have the freedom and responsibility to design services on behalf of their patients – delivering better-quality and integrated care". Led by GPs, they will work with patients and healthcare professionals in partnership with local authority Health & Wellbeing Boards, and the wider community; as a result they will be more responsive to patient needs, and improve equity of access. Research aims and objectives: What are the leadership, governance and managerial behaviours undertaken by the governing bodies of CCGs that create a culture of innovation for the benefit of the services they provide to their community, and the most effective according to the criteria their key stakeholders believe are the most important outcome measures of their work?

More specifically, the objectives are to gain an understanding of:

- What are the leadership, management and governance behaviours that enable the effective functioning of the CCG Governing Body as a team
- What are the ways in which such behaviours can contribute to supporting and encouraging practices and a culture of innovation within a CCG
- How, in combination, effective leadership, management and governance of CCGs, and support for innovative practice, can bring about improvements in the quality of healthcare provided
- Exploring how CCGs work in partnership and collaboration with other agencies to support innovative practice

The methodology is a multi-method approach which, in summary, will consist of:

- Interviews with CCG Governing Body members at 2 CCGs, and their partners, that focus on understanding and illustrating the leadership, management and governance behaviours that promote a culture of innovation within CCGs.
- Findings from the above interviews and relevant literature to be used to inform the creation of a CCG multi-rater review instrument (the CCG 360) which will be administered to 4 CCG Governing Bodies and their stakeholders. This tool assesses the Governing Body as a collective, rather than individual members.

- The CCG Governing Body will receive confidential feedback on the results of the multi -rater review during a group feedback session.
- The production of a Leadership, Management and Governance for Innovation Framework that can be adopted widely by CCGs.

**ROSE ACS - An Observational Post-authorisation Safety Specialist Cohort Event Monitoring Study to Monitor the Safety and Utilisation of Rivaroxaban (XARELTOA®) Initiated in Secondary Care for the Prevention of Atherothrombotic Events in Patients who have had Acute Coronary Syndrome in England and Wales**

Chief Investigator: Professor Saad Shakir

Risk: Low

Start/End Date: 01/09/15 to 01/06/19

CCG Costs/Income: N/A Payments for participation will be made directly from funder to participating GP practices

Status: New study

Brief overview of study: Rivaroxaban is a medicine which reduces the formation of blood clots. Acute coronary syndrome (ACS) comprises a range of disorders, including heart attack and unstable angina, caused by a sudden reduction in blood flow to part of the heart muscle. This study aims to collect information on the use of rivaroxaban and its safety when used by patients for the prevention of artherthrombotic (plaque rupture leading to blood clot) events following ACS, during the first three months after starting. This study was requested by the European regulatory body (EMA). It will last approximately three years and is a national study coving the whole of England and Wales.

The study aims to recruit 1193 patients who have been prescribed rivaroxaban and antiplatelet therapy and 1193 patients who have been prescribed alternative dual antiplatelet therapy for the secondary prevention of artherothrombotic events following ACS. Each patient will be monitored for the first 13 weeks after hospital admission for ACS.

Patients who choose to take part will complete a consent form. The patient's care team will be asked to complete a baseline questionnaire about the patient at the time the medicine is given and a further questionnaire up to 16 weeks later, specifically asking about the patient's experiences whilst on the medication. If anything unusual is reported during the observation period, the care team may be asked to fill out a follow-up questionnaire. With the patient's consent, the study team will also inform the patient's GP of their participation in the study and will ask the GP to complete an

abridged questionnaire from the patient's medical records. The study team will analyse and aggregate the data, protecting patient confidentiality, to classify events of interest, in particular bleeding events.

The only research activity that will take place in Primary Care is the abridged questionnaire to be completed by the patient's GP, all other research activities (including consent) will be taken within Secondary Care.

This study is sponsored by the Drug Safety Research Unit (DSRU) and is funded by Bayer Pharma AG – an independent statistician has been sub-contracted from Select Statistical Services Ltd to conduct a statistical review of the study protocol.

**Patient involvement in diagnosing cancer in primary care (HRA - statement of activities)**

Chief investigator: Professor Rebecca Lawton, Professor in Health Psychology, Bradford Institute for Health Research, BRI

Risk: low

Start/end date: 14/09/15 – 31/01/16

CCG costs/income: n/a

Sponsor: Bradford Teaching Hospitals NHS Foundation Trust

Brief overview of the study: This study asks whether acceptable and feasible intervention that assists the timely follow-up and review of patients after an initial presentation to primary care with potential cancer symptoms can be identified by stakeholders in primary care. The objectives of this study are:

- To consolidate existing knowledge on current interventions for patient involvement in diagnosis in primary care and to assist with developing a new intervention.
- To assess the acceptability, feasibility, cost and burden of patient involvement in an intervention that assists the timely follow-up and review of patients after an initial presentation to primary care with potential cancer symptoms.
- To assess and identify the types of interventions that assist the timely follow-up and review of patients after an initial presentation to primary care with potential cancer symptoms and that have the potential to become a sustainable component of standard care and improve diagnostic outcomes for cancer in a primary care setting.

- To develop a grant proposal for the development and testing of an intervention that assists the timely follow-up and review of patients after an initial presentation to primary care with potential cancer symptoms in primary care.

The following local capabilities/capacities required are:

- The participant group is 10 patients and 10 healthcare professionals (6 GPs and 4 Nurse Practitioners). The 10 healthcare professionals will be recruited from practices within West Yorkshire CCGs to take part in one 60 minute face-to-face interview and one 60 minute focus group.
- To conduct the 60 minute interview in a private room at the GP practice if this is more convenient for the GP or Nurse Practitioner. Interviews will be audio-recorded and transcribed.
- To recruit up to 3 practice managers and 3 CCG leads (1 practice manager and 1 CCG lead at each focus group) to attend one 60 minute focus group.
- Dr Mark Purvis, Director of Postgraduate GP Education has agreed to act as local collaborator. Dr Purvis' time will collate contact details for CCG leads, GPs and Nurse Practitioners and coordinate sending the study recruitment email and reminder email via West Yorkshire Schemes of Advanced Training Practice Network and through Training Programme Directors.

For the recruitment of patients, the research team will contact local cancer support groups within West Yorkshire to request permission to attend a group meeting. Patients who are interested in taking part will be given a study pack and can choose to take part in both the interview and focus group or just take part in an interview. Participants will be reimbursed £10 to cover travel costs, this will come from the Bradford Institute for Health Research (BIHR), Quality and Safety Research Team budget for travel. £10 shopping vouchers will be provided to participants to thank them for their time/participation, the cost of these vouchers will be covered by Professor Rebecca Lawton's personal research expenses account.

**DS-5565 in pain associated with fibromyalgia**

Chief investigator: Professor Anthony Jones, Salford Royal NHS Foundation Trust

Risk: low (PIC)

Start/end date: 02/03/15 – 28/02/17

CCG costs/income: n/a

Status: PIC

Sponsor: Daiichi Sankyo Development Ltd

Brief overview of the study: The study aims to collect information about a new drug called DS-5565 which may help treat pain associated with Fibromyalgia. It is looking at the safety and effectiveness of the drug compared to placebo. The new drug has not yet been approved for use in fibromyalgia. There is an initial washout period to allow any current medication to leave the system, then the drug will be given over a 13 week period followed by 1 week tapering and 4 weeks follow up. There is an optional separate extension study. There are 4 arms of equal size:

- DS-5565 15mg per day
- DS-5565 30mg per day
- Placebo
- Pregabalin 300mg per day

The study will take place in 300 sites worldwide with 1200 patients. In the UK they are seeking to recruit 97 patients from 23 sites. The primary objective is to compare change in pain measured by Average Daily Pain Score (ADPS) over the course of 13 weeks. As a secondary objective, the study team is also measuring other scores e.g. fatigue, depression and anxiety, general health, quality of life, sleep. Patients will return to the clinic every 2 weeks. At treatment visits, staff will ask about patients' health and pain. Patients will have their weight, temperature, heart rate and blood pressure measured. Staff will review participants' medication use. Blood samples will be taken for pharmacokinetic assessment. Pregnancy tests will be given to participants capable of becoming pregnant. An ECG (x2) and fundoscopy eye examination (x3) will be carried out. The follow up after the study will be by telephone.

The study team will delegate certain activities to other organisations:

- Covance will carry out clinical chemistry, clinical haematology
- Celerion will carry out clinical chemistry, clinical haematology
- PHT will carry out primary/surrogate end-point text, patient questionnaires and provide devices
- Transperfect Translation International Inc will carry out translation of study documents
- Perceptive e-clinical Limited will carry out treatment randomisation
- INC research will carry out monitoring, regulatory, investigator recruitment, Data management, eData capture, SUSAR reporting
- MMS Holdings Inc will carry out Data and Safety Monitoring Board and Hepatic Adjudication Committee Support

The study team will have access to patients' full medical records, with patients' consent. Reasonable travel expenses will be paid to patients. Patients will be recruited via referral to the Investigator, via computerised searching of GP records (this will only be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisations).

Patients will also be recruited via research user groups and fibromyalgia support groups and by approaching patients using the Patient Invitation Letter. Meds management raised a concern about the study as Pregabalin, the other active drug in the trial, has been the subject of controversy and many GPs are moving away from prescribing this. The meds management leads for the Leeds CCGs have requested exclusion criteria so that patients who have not been prescribed Pregabalin in the past 12 months are not included, and also that participants are informed that neither Pregabalin nor the study drug will be available after the study.

**The role of the GP in reducing A&E attendance**

Chief Investigator – Colin Bicknell, Imperial College London

Risk: low

Start/end date: 14/08/15 – 30/09/15

CCG costs/income: n/a

Status: new

Sponsor: Imperial College London

Brief overview of the study: This qualitative interview study aims to establish whether GPs in England see themselves as having a role in reducing use of A&E departments and what their views are on inappropriate use of A&E. The researcher will conduct semi-structured interviews with 10-15 GPs, via Skype or in the practice.

The researcher will recruit GPs by sending invitation letters.

**Validation of Medication Nonadherence Model**

Chief investigator: Dr Nicholas Thomas, Principal General Practitioner, Windrush Medical Centre, Oxfordshire

Risk: low

Start/end date: 01/07/15 – 01/07/16

CCG costs/income: n/a

Sponsor: Philips

Brief overview of the study: The study is looking at the barriers for medication adherence in patients with chronic conditions. Patients are asked to complete a questionnaire to enter into the study. Questionnaires can be completed on paper or electronically at home. In addition, data about their chronic condition, their medications (prescriptions filled) and any adverse events, will be collected by the research nurse, pseudonymised and sent to Philips to be analysed alongside their questionnaire scores. A secure data transfer will be used. Only the nurse based at the GP centre will approach patients. This will be done either in writing or when the patient visits the GP clinic. The nurse will identify suitable participants by carrying out a database search at the practice. A £10 gift card will be given to patients from Philips on completing the questionnaire to compensate them for their time. Philips is aiming to use the data to inform the creation of a tool to support medication adherence. The study aims to consider the relationships between adherence determinants and adherence behaviour. They also want to gain insight into how their tool/service could be integrated into GP practices in the UK.

**Care Homes Independent Pharmacist Prescribing Service (CHIPPS) WP4**

Chief investigator: Professor David Wright, Professor of Pharmacy Practice, Norwich Research Park, University of East Anglia

Principal Investigator: Dr David Alldred, Associate Professor of Pharmacy Practice, School of Healthcare, University of Leeds (formerly Senior Lecturer in Pharmacy at University of Bradford)

Risk: low

Start/end date: 01/05/2015 – 20/01/2020

CCG costs/income: n/a

Status: new

Sponsor: South Norfolk Clinical Commissioning Group

Brief overview of the study: The main objectives of this research study are to update evidence regarding the optimisation of medicines use within care homes, to obtain stakeholder views (GPs, pharmacists working in care homes, care home managers and other staff (care home residents and relatives – being undertaken in other locations not this one)) to inform the development of the service specification for a pharmacist independent prescriber (PIP) who assumes responsibility for the management of prescribing within care homes; and to prepare and refine a service model and initial service specification for pharmacist independent prescribing within care homes.

Six small linked work projects will be undertaken; this application is for WP4 which focuses on how best to prepare pharmacists for this role, looking at the training needs of pharmacists. After a rapid literature review, the study team will draft a competency framework for pharmacists performing a meds management function in care homes. Focus groups and interviews will be carried out with different professional groups in different areas to develop and validate the framework. In Leeds they will look at primary care pharmacists. An appropriate healthcare professional with experience in care home meds management will be identified (one for each area) and interviewed by telephone to identify local training courses and local needs. The aim is to reach a consensus on how best to amend and enhance the framework and support pharmacists to achieve competency. Attendance time for the focus groups will be paid at standard NHS rates, plus travel expenses.

**Passive Enhanced Safety Surveillance (ESS) of the Quadrivalent Live Attenuated Influenza Vaccine (QLAIV) Fluenz Tetra in Children and Adolescents during the early 2015/2016 Influenza Season in England**

Chief investigator: Professor Saad Shakir, Director, Drug Safety Research Unit Education and Research Ltd (DSRU), Southampton

Risk: Low

Start/end date: 01/10/2015 – 31/03/2016

CCG costs/income: n/a

Status: new

Sponsor: Drug Safety Research Unit (DSRU)/AstraZeneca

Brief overview of the study: This is a passive enhanced safety surveillance (ESS) study on the live - attenuated nasal influenza vaccine, Fluenz Tetra®. The aim of the surveillance is to rapidly detect changes in the frequency or severity of reactions to the vaccination in children during the 2015/2016 influenza season. The surveillance is being conducted to satisfy the European Medicines Agency's (EMA) requirement for enhanced safety surveillance for seasonal influenza vaccines in the EU. Children will be provided with a safety report card with an integral consent form following vaccination (by the practice nurse, school nurse, local immunisation team or other HCP who gives the vaccination in either the GP practice or school) for completion by their parents in the event that any suspect side effects are experienced. Any data received will be collated and analysed and a report for the EMA will be written 6 weeks after the first vaccination.

This study is co-sponsored by the Drug Safety Research Unit (DSRU) and AstraZeneca and is funded by AstraZeneca (£277,226 over 7 months).

**Steroid Therapy and Adrenal Insufficiency in Patients with RA (PIC)**

Chief Investigator – Dr Will Dixon, University of Manchester

Risk: low (PIC)

Start/end date: 01/06/2014 – 31/05/2016

CCG costs/income: n/a

Status: new

Sponsor: University of Manchester

Brief overview of the study: This observational study is looking at adrenal insufficiency (AI) caused by steroid therapy, measuring steroid use and adrenal output in patients currently or recently taking steroid therapy. The aim is to find out the relationship between taking steroids and developing AI – and in particular look at what the predictors are. Patients are required to give 2 saliva samples (for cortisol levels and a genetic test) and complete a diary about their steroid use. They do this themselves at home (chewable swab) and send the samples in the post. Further information will be gathered from medical records. Patients can opt out of the genetic test if they prefer. If the test shows up a high level of cortisol which could be indicative of AI, they will be informed and their GP (with permission).

The population is patients with rheumatoid arthritis who have used steroids in the past 2 years. The primary outcome measure is the morning salivary cortisol level which gives an indicator of baseline adrenal function. Secondary outcome measures include symptoms of AI.

The study is funded by the NIHR under the Manchester Musculoskeletal Biomedical Unit research programme. The study team is aiming to recruit 400 participants in the UK. Participants will be found using pseudonymised medical records provided by the CPRD (Clinical Practice Research Datalink). CPRD will then contact GP practices which have eligible patients to ask if the practice wishes to take part. The practice will then review the list of eligible patients to assess the patients' suitability to take part, then will contact the patients with details to invite them to take part. The cost of the time to do this will be covered by the study funding.

Patient identifiable data will be used to post information and sample packs to patients, but will be kept securely and separately from the study data.

**An online randomised controlled trial to evaluate the clinical and cost effectiveness of a peer supported self-management intervention for relatives of people with psychosis or bipolar disorder: Relatives Education And Coping Toolkit (REACT)**

Chief investigator: Dr Fiona Lobban, Lancaster University

Risk: Low (PIC)

Start/end date: 01/10/2015 – 30/09/2018

CCG costs/income: n/a

Status: new

Sponsor: Lancaster University

Brief overview of the study: This study is testing an online toolkit for families and friends of people with psychosis and bipolar disorder. The study is looking at the clinical and cost-effectiveness of the toolkit. There are 2 arms; one arm gets access to the toolkit and the other gets access to an online resource directory with information about other currently available services. The participants will then complete questionnaires about their distress and wellbeing.

Participants will be recruited via social media, mental health organisations, news media and via NHS Trusts and CCGs. The CRN will support the study to conduct database searches in GP practices.

There will be an online consent process. The toolkit is on a private, closed website and participants will be advised to avoid referring to their friend or relative using real names or contact details. Participants will receive a £10 Amazon voucher for completing the questionnaires.

**Stem cell research in early-onset psychosis**

Chief investigator: Dr Anthony James, Oxford Health NHS Foundation Trust/Oxford University

Risk: low

Start/end date: 17/03/2014 – 16/03/2019

CCG costs/income: n/a

Sponsor: University of Oxford

Brief overview of the study: The study is a focused on early-onset psychosis and will be collecting genetic information about adolescents and their parents. They will be conducting psychiatric interviews, blood tests and nasal/skin swabs. The study is based in Oxford and is only coming to other areas in the event that an adolescent who lives in Oxford has a parent living in another area. In our area they will therefore only be doing the part of the research which pertains to parents, which involves a blood test only. Blood samples will then be delivered by post to the research site in

Oxford. Genome sequence analysis will be performed. The aim is to identify possible de novo mutations which are thought to be potential causes of schizophrenia. The study is looking to recruit 20 patients with psychosis and 20 controls, along with their parents, so a potential group of 120 participants.

**How do health professionals respond to electronic pain reports from advanced cancer patients in the UK?**

Academic supervisor: Dr Matthew Allsop / Dr Sally Taylor, University of Leeds

Students: David Maud and Geetu Jethwani, year 5 medical students, University of Leeds

Risk: low

Start/end date: 09/11/2015 – 01/02/2016

CCG costs/income: n/a

Sponsor: University of Leeds

Brief overview of the study: The study aims to explore health care professionals' perceptions of pain management in palliative care, to determine any specific information, presented by an ICT system, that would trigger a change in patient pain management in the UK and to describe the HCPs' decision making process, based on the ICT system response. The study has a qualitative design. The study team will interview GPs and District Nurses, with a series of open-ended questions as well as scenarios. The aim is to identify factors or triggers which warrant a change in pain management by the HCPs. The study is being conducted in association with the IMPACCT study. The study outcomes will be provided to the IMPACCT team to help to inform their study.

**PANDA RCT – a phase IV, double blind randomised placebo-controlled, parallel group multi-site trial of sertraline compared to placebo in patients presenting with depressive symptoms in primary care where treatment with SSRIs is uncertain. What are the indications for Prescribing ANtiDepressants that will lead to a clinical benefit? (PIC)**

Chief investigator: Professor Glyn Lewis, University College London

Local researcher: Professor Simon Gilbody, Hull York Medical School

Risk: low (PIC)

Start/end date: 19/01/2015 – 31/08/2017 (country-wide)

CCG costs/income: n/a

Sponsor: University College London

Brief overview of the study: NICE recommends Selective Serotonin Reuptake Inhibitors (SSRIs) as a first line antidepressant, but there is uncertainty around the severity and duration of depression that are needed for someone to benefit from antidepressants. This study aims to compare an SSRI with a placebo in patients where the participant and GP are uncertain about the likely response to antidepressants and are willing to be randomised. There are no entry criteria around severity or duration of symptoms, but clinical judgement of the recruiting doctor will be used to determine study entry, and then the team will investigate its hypothesis in the analysis phase. The reason for the broad criteria is to reflect current practice.

An initial baseline interview will be carried out. There will be questionnaires to assess psychiatric symptoms and emotional processing tasks which may be a marker of treatment response. Follow up will be carried out at 2, 6 and 12 weeks to include measures of depressive symptoms, QOL and adverse effects of antidepressants. Resource use data will also be collected to determine the actual cost of treatment. The primary research question is to investigate the severity and duration of depressive symptoms which lead to a clinically important response to sertraline as compared to placebo. The outcome measure is PHQ 9 questionnaire as a continuous score. The aim is to produce a practical guide in the longer term for the prescription of antidepressants.

To recruit patients, GPs will be asked to approach patients during a consultation and give them the PIS. If the patient is interested they will be asked to complete a release of personal details form and then it will be sent on to the study team. GPs will also be asked to complete a database search and mail out a letter to eligible patients asking for permission for the research team to contact them. Associated costs would be refunded to the practice.

**GPs' perceptions of irritable bowel syndrome**

Chief Investigator – Dr Sarah Alderson. Robbie Foy second academic supervisor

Student – Dr Stephen Bradley, MSc Health Research

Risk: low

Start/end date: 02/11/2015 – 25/03/2016

CCG costs/income: n/a

Status: new

Sponsor: University of Leeds

Brief overview of the study: This study aims to explore GPs' perceptions towards IBS. The study uses a Q-sort methodology. The study aims to ultimately establish where clinicians' interactions with patients with IBS could be enhanced and improve the prospect of successfully managing the disorder. Around 60 statements will be constructed to express different perceptions of IBS. GPs will be recruited to take part (will approach 100 to achieve a population of 30-40). Participants will take part in an online survey to indicate their agreement or disagreement with each statement. Basic demographic information will be collected. This will help to derive a few broad strands of opinion within the group, from which the team can characterise particular perceptions of the disease.

A small number of 1-1 interviews will also be conducted, to add qualitative detail to the statistical conclusions of the study. The study team will contact 100 practices with an information sheet and will invite them to participate by following a web address. An online consent form will be used. The survey is expected to take no more than 30 minutes and the interview, for those who wish to, 10-15 mins.

## Appendix three: Development work

With our current collaborative arrangements we have the following research bids submitted pending a funding decision:

**NIHR HS&DR - Evaluating Palliative care Intervention and Opioid New Events (EPIONE)**

EPIONE was the Greek goddess of soothing pain; this captures our primary aim which is to generate evidence that allows NHS organisations to optimise referral practices and optimise access to opioid analgesia for patients with advanced cancer. This will be achieved by studying the relationships between the configuration of services, referral practices and opioid prescribing. We will identify English patients that died from cancer in 2014 and 2015 from national cancer registry data and link these to data on their healthcare use and prescribing in the last year of life using hospital and community records. From this dataset we will analyse how and when patients used healthcare services (clusters of trajectories) and determine the relationship between palliative care service use, access to strong opioids and quality of end of life care.

We will summarise these different trajectories as vignettes, determine the costs and cost - effectiveness of these vignettes, and discuss them with service users and service providers using a Nominal Group Technique. This will help us to understand how patients access services and strong opioids, and why patients receive different combinations of services and analgesia. We will summarise our findings in order to identify opportunities for intervention and to develop guidance for commissioners and providers. We are an experienced team that has worked together on similar NIHR projects; we will generate important outputs from this research that will have national and international impact, and will disseminate these well.

**NIHR HS&DR - An interrupted time series analysis of a feedback intervention to reduce opioid prescribing in primary care (CROP)**

Opioid medicines, such as the 'weak' opioid, codeine, and the strong opioid, morphine, are useful for short lived pain (e.g. following injury) and in treating cancer pain. However, their value in chronic (lasting more than three months) non-cancer pain is less certain. Opioids can cause problems of addiction, side effects such as constipation, withdrawal symptoms and lead to more hospital admissions and death. There is concern that patients with chronic pain are being put onto more and stronger opioids without first exploring other less harmful pain relieving options, such as talking therapies, mindfulness, and pain clinic referrals.

The Campaign for Reducing Opioid Prescribing involves 10 clinical commissioning groups and researchers. Practices receive regular feedback reports on their opioid prescribing every two months over April 2016 to March 2017. These show how many prescriptions of both strong and weak opioids they prescribe compared to the other practices within their area and the number of prescriptions given to patients at higher risk of long-term use or escalating to stronger opioids. The feedback also includes helpful hints and ideas to reduce opioid prescriptions.

We plan to gather anonymised patient data and use statistical techniques to examine whether the feedback reports make a difference to underlying trends in opioid prescribing. We will also look at whether prescriptions to particular groups of high risk patients change and whether any other events or factors could be responsible for any changes found. Our economic evaluation will assess whether the feedback reports represent value for money. We also know that many well-intentioned approaches to change practice don't work as predicted or hoped. We will therefore interview staff from practices which do and don't change their prescribing to examine how the feedback reportsare received and acted upon.

**NIHR HS&DR - Can social prescribing reduce health care utilisation? An evaluation of social prescribing models in England**

The overall aim of this study is to assess the cost effectiveness of social prescribing in reducing health service use and improving patients' quality of life and mental well-being. Many different models of social prescribing are being established by Clinical Commissioning Groups (CCGs) across England. This is despite limited evidence of the effectiveness of the approach in improving patient outcomes or reducing health service use.

Across primary, secondary and emergency care there are a small group of frequent users of services who account for a disproportionately large amount of health care utilisation. These patients are often of low socioeconomic status have multiple medical, psychiatric and social disorder and have a high mortality. Social prescribing (SP) has been defined as a mechanism for linking patients in primary care with sources of support within the community. Support often includes access to interventions such as arts and crafts, self-help groups, computerised CBT, adult learning, nature-based interventions, debt advisory services and physical activities.

There is limited evidence on the impacts of social prescribing on patient outcomes or health service delivery. Yet reportedly 19% of GPs are using SP. This study aims to evaluate the costs and

effectiveness of different SP models in England in reducing health care utilisation compared to GP care with no social prescribing.

Our aim is to fill this gap by providing evidence of the impact of social prescribing on patients and health systems, including any costs incurred or saved.

The study will draw on routinely collected data from GP practices, hospitals, Mental Health Trusts, third sector and social services to compare impacts on patients receiving SP compared to those with similar characteristics (age, sex, deprivation (IMD) and number of GP appointments over the past year) not in receipt of SP. These characteristics will be used to adjust for differences in the SP and non-SP patients so that direct comparisons between the two groups can be made.

**NIHR PGfAR - A multi-stage randomised trial evaluation of clinical decision rules in the management of suspected heart failure in primary care assessing diagnostic accuracy, patient outcomes and experience, and cost effectiveness**

Patients with HF have worse quality of life, more hospital admissions and die earlier. When HF is due to heart muscle weakness, prompt treatment from a specialist clinic can improve outcomes. However, diagnosing HF in GP clinics is difficult: symptoms and signs (such as breathlessness, fatigue and ankle swelling) may be caused by other conditions.

NICE guidance says that if a GP suspects HF a blood test for natriuretic peptide (NP) levels should be taken and people with raised NP levels should be referred to a hospital HF clinic; people with a normal level do not need to be referred.

We looked at 4305 patients undergoing the blood test in Leeds and found that half of those with raised NP level were referred. Of those people who were referred the test was inaccurate in a large proportion and this varied between age groups and for different levels of NP. Also approximately one in 10 people with a 'low' result have HF, and are reassured incorrectly. Our patient involvement group have described that waiting for the hospital appointment to get the all clear is distressing for patients and their carers.

Our project will provide important information to determine the best patient management pathway so that;

- Fewer patients will be incorrectly told that they might have HF and referred unnecessarily, and

- Fewer patients will be reassured incorrectly.

By targeting services at those most likely to benefit we will improve the patient experience and the cost effectiveness of the pathway as a whole.
The overall aim of this study is to improve the way that heart failure (HF) is detected and managed

**NIHR PGfAR - AntiBiotic Allergy and Microbial ResistAnce (AlaBAMA)**

Antibiotics (also called antimicrobials) are important medicines used to control infections caused by bacteria. Antibiotics have been used widely and this has caused a worrying rise in antibiotic resistance– this is when bacteria change so the antibiotics no longer work and then doctors struggle to control infections. Antibiotic resistance causes people to be sick for longer and can increase health risk including death.

The spread of resistant bacteria can be slowed by using antibiotics more carefully. Penicillins are an important group of antibiotics that are often the first-choice treatment for many common infections. However about 1 in 10 people report a penicillin-allergy; their "allergy label" in their electronic health records (eHR) alerts doctors to avoid penicillin and restrict antibiotic prescriptions to alternatives-often not as good as penicillin, with worse side-effects and greater cost. These alternative antibiotics act against a much broader range of bacteria, thereby potentially destroying more of the body's normal "healthy" bacteria this in turn increases the risk of infection with resistant bacteria.

Recent research suggests that patients with a penicillin-allergy label have a higher risk of infection with resistant bacteria and poorer health outcomes compared to people without a penicillin-allergy-label. Importantly, it is suspected that as many as 9 out of 10 people who think they are penicillin allergic don't have a real allergy and may be avoiding penicillin unnecessarily and receive antibiotic treatments that work less well and are potentially more risky, impact on their health and contribute to the spread of antibiotic resistance.

The aim of this study will be to improve antibiotic prescribing, patient health and reduce antibiotic resistance by testing patients with penicillin-allergy and identify those with a false penicillin-allergy label to enable doctors to prescribe penicillin safely to treat infections.

**BReathe EAsy THroghout Europe - BREATHE**

Our project aims at optimizing the therapeutic strategy (both pharmacological and not) of patients diagnosed with Chronic Obstructive Pulmonary Disease (COPD) according to GOLD guidelines throughout an innovative and effective approach of Chronic Care Model (CCM), improving the therapeutic outcome of COPD with significant impact on the individual patient and the healthcare system. This approach is focused on the improvement of the interactions between each member of the multi-professional team as well as the patient through an ecosystem based on web and m-health technologies.

This study is aimed to compare the ability in preventing exacerbations that may lead to utilisaiton of secondary care. Patients will be randomised to receive either the current usual Chronic Care Model (CCM) or an "enhanced" CCM where the enhancement is the incorporation of a technological solution. This solution being an "app" able to permit the interaction between pulmonologist, general practitioner (GP) and patient, in two populations of COPD patients, comparable in terms of baseline characteristics (age, gender, comorbidity, COPD duration).

BREATHE is the first trial addressing the ability of a computer based model (an app) of a patient's care in the risk reduction of COPD exacerbations

Further work is ongoing towards the following research bids:

**NIHR RfPB submission in January 2017 – An analysis of workforce configuration in General Practice and the health outcomes produced in QoF**

This project is a collaboration between HEYH, Leeds University and West Yorkshire Research and development.

In the recent 5 Year Forward View delivered by Simon Stevens at NHS England states, "We expect providers and commissioners to work with Local Education and Training Boards (LETBs) to ensure that they can secure the right staff to meet future service needs and their workforce plans are affordable and reflect local strategies for transformation (5YFV, p5, Dec 2014). In lieu of the 5YFV HEYH have started collecting workforce data from General Practices.

The current literature suggests that there is lack of evidence about the 'best way' of determining staff skill-mix in Primary Care. Most of the UK workforce studies are focused on finding the difference in quality of care provided by various types of practitioners rather than multidisciplinary arrangements and effective team working.

In this project we will look at the routinely available data sets, linking workforce configuration and health outcomes to try to understand:

- The impact of the current General Practice workforce on health outcomes as described by (QOF);
- The impact of General Practice workforce on A&E attendance;
- The impact of General Practice workforce on Non-elective admission;

Once these impacts have been estimated, the project will then carry out a simulation exercise to identify the 'mini-max' configuration of workforce for each practice which maximises clinical QOF achievements.

The overall aim of this project is to get a better understanding of what the skill mix in general practice produces in terms of patient outcomes.

**Programme Development Grant for July 2017 submission with Veronica Swallow**

In previous work to develop Online Parent Information and Support (OPIS) funded by the NIHR, a resource was co- produced by Families and Health Professionals to support home-based management of CKD from child- to young adult-hood. This initial study conducted age-appropriate, qualitative, semi-structured interviews with 26 five to nineteen year olds. Interviews were informed by topic guides developed respectively for 5-8, 9-12 and 13-19 year olds. Data were collected and analysed iteratively using the Framework Technique.

Three themes were identified in the initial study:

- INTERACTIVE TEACHING: e.g. age-appropriate interactive games and activities that would help patients to learn about the condition and its management
- VIDEO LEARNING: videos of clinical procedure they need to perform at home to help patients learn to manage procedures themselves and reduce the need to 'call on' staff and/or parents as they mature,
- SOCIAL NETWORKING: to communicate with others of the same age with similar conditions through responsibly managed sites

The results demonstrates that the intervention helps improve parents' management ability and feeling of competence

However some questions form this work remain unanswered and so further research evidence needs to be generated, initially focussing on the following 4 questions;

1. What are the Digital development, IPR and Commercialisation relevant issues associated with the longer term implementation of OPIS across the NHS and charity sector?
2. What are parents' current OPIS usage practices (e.g. how often and which of its components do they prefer) in RMCH
3. What are the perspectives of parents and health professionals on the refined version of OPIS and does it meet their needs?
4. What novel approaches are available (e.g. games) for use in a future version of OPIS

This development work would then inform a subsequent grant application in 2017 with Dr Swallow

**NIHR PGfAR - for submission 2017-18 with Veronica Swallow**

The likely questions to be considered in this follow on application include:

- What is the feasibility of adapting and empirically optimising an existing software application for managing childhood CKD that can serve as a model for diabetes and other conditions and what are the components and processes needed to deliver optimum information and support to parents and children managing these conditions at home?
- Will a refined information and support software application to supplement standard support confer sustained benefits on family management, individuals' self-efficacy, illness-related knowledge and behaviours, quality of life and cost effectiveness in two common long term conditions?
- Is general implementation of evidence-based, user-led software applications in the wider NHS feasible?

**NIHR RfPB submission in January 2017 – NIHR RfPB submission in January 2017 – A feasibility study to explore the hypothesis that; Waist height ratio >0.5 and/or increasing ankle blood pressures are a better risk stratification tool for high risk for diabetes in South Asians as compared to BMI >27.5 and or increasing brachial blood pressures.**

The National Diabetes Prevention Program is currently being implemented in UK. The first step of this program is the identification of high risk patients defined as;

- BMI of 30 or over, or 27.5 or over in individuals from the Indian, Pakistani, Bangladeshi, Other Asian and Chinese ethnicity categories
- Blood pressure at or above 140/90mmHg, or where the systolic blood pressure or diastolic blood pressure exceeds 140mmHg or 90mmHg respectively.

Individuals meeting these criteria are considered to be at high risk of developing diabetes and are advised to have HbA1c or a fasting blood glucose test. If HbA1c ≥ 6.5% / 48mmol/mol or fasting blood glucose ≥ 7mmol/l then they are referred for healthy eating and lifestyle education, help to lose weight, and bespoke physical exercise programme.

However at this time there is no firm evidence that current predictive factors apply in the same way in the South Asian community as they do in the European community. This project would like to explore this with the hypothesis that;

*Waist height ratio >0.5 and/or increasing ankle blood pressures are a better risk stratification tool for high risk for diabetes in South Asians as compared to BMI >27.5 and or increasing brachial blood pressures.*

We propose a an application for a feasibility trial to collect the information to support the hypothesis, the reasons for this proposed approach are;

- Obesity assessed by BMI is a measure of generalised obesity and is less appropriate for South Asians, who are more likely to have visceral or metabolic obesity - even in the presence of a normal BMI. Waist to height ratio is a more appropriate marker of metabolic obesity and a ratio of >0.5 is considered abnormal across all populations and either sex. Moreover, increase in ankle blood pressures and cardiovascular diseases is significantly greater with increased metabolic obesity in South Asians than Europeans.
- There is evidence that hypertension may not be a sufficiently sensitive marker for type 2 diabetes in the South Asian population. A study of patients with diabetes showed that, compared with European patients, mean HbA1c concentration was greater among South Asian patients, but mean systolic blood pressures were lower. However there is increasing evidence to suggest that increasing ankle blood pressure may have utility as a biomarker for type 2 diabetes. Greater increases in ankle blood pressure and cardiovascular disease have been reported in South Asian patients than in Europeans with a history of type 2 diabetes.

Hence in order to detect South Asians at high risk of diabetes we propose that a better risk stratification tool is waist height ratio >0.5 and/or increasing ankle blood pressures.

## Appendix Four - Summary of current and recently completed research projects supported by the WY R&D team

**Current**

**ASPIRE - Action to Support Practices Implement Research Evidence**

The ASPIRE trial involves approx. 200 practices across West Yorkshire. ASPIRE (Action to Support Practices Implement Research Evidence) is a programme of research based at the University of Leeds that focuses on supporting practices implement evidence-based practice. We wish to thank all those that have supported ASPIRE and their contribution to the programme so far. Practices randomised to receive the ASPIRE intervention should have been sent their fourth report via email recently; postal copies will be sent shortly. Practices receiving support around diabetes management, blood pressure control or anticoagulation in atrial fibrillation may be interested in the section of the report that outlines how the ASPIRE indicators are aligned with QOF.

The trial ended on the 31st March 2016 but there is still time remaining to make use of the support tools available: an outreach visit (and follow-up for those that have had their initial visit), up to 2 days of additional pharmacist support, and SystmOne searches to identify patients that may need to be reviewed. If you have any queries about ASPIRE, please contact aspire@leeds.a c.uk

**ISCOMAT - Improving the Safety & Continuity Of Medicines management At Transitions of care**

The WYR&D team is working with Professors Alison Blenkinsopp and Gerry Armitage, University of Bradford to promote the Improving the Safety & Continuity Of Medicines management At Transitions of care (ISCOMAT) study. This is a study of medicines management for patients with heart failure across a range of health economies in England, including Leeds and Calderdale. Over £2 million of funding has been provided by the National Institute for Health Research, Programme Grants for Applied Health Research to complete this study. First, the study team will look at how patients' medicines are managed at discharge and then after discharge. They will do this by watching what happens to patients and also by interviewing patients and staff in hospitals, doctors' surgeries and local pharmacies. They will also look at the key documents used by patients and staff. From this they will identify examples of good practice. The team will then bring together groups of patients and staff in each area to hear about the findings and those from previous research and to come up with ideas about what might work best in the future. All this information will be used to produce a 'toolkit' which contains the things staff and patients need to make good practice happen. Following this development work the 'toolkit' will be tested in a cluster randomised controlled trial across 42 healthcare districts. The team will measure the impact of the intervention by checking whether patients have had any serious health problems and whether three important medicines for heart

failure are still being prescribed 12 months after leaving hospital. They will also look at how much the toolkit costs to put into action and how well it fits into local practice. This means that if it is shown to work, they will know how to spread its use across the country. The study commences February 2016 for 30 months in the first instance and if approved, a further 38 months. More information will be shared once the work is underway.

**IMPACCT - Improving the Management of Pain in patients with Advanced Cancer in the CommuniTy**

IMPACCT is another 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.

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.

**SMARTE - Self-Management of Analgesia and Related Treatments at the End of life**

The WY R&D team are also working with Professor Mike Bennett on another project, the Self-Management of Analgesia and Related Treatments at the End of life (SMARTE) funded by the NIHR Health Technology Assessment programme. We are interested in adults (aged over 18 years) approaching the end of life, suffering from significant pain and being cared for in their own home. The main aim of this study is to develop a support tool that enables these patients and their carers to more confidently manage medications for pain as well as constipation, nausea and drowsiness at home.

The objectives are divided into three distinct phases, in-line with the MRC framework on developing and evaluating complex interventions, and with normalisation process.

- Development objectives:
    - Establish the content of a SMST that enables patients to better manage their medications for pain relief, nausea, constipation and drowsiness (the intervention).

- Establish the content of a manualisation strategy that includes a protocol to standardise (i) the training of HPCs and (ii) the delivery of the intervention.
- Understand and define usual care of management for pain relief, nausea, constipation and drowsiness in this patient group.

- **Modelling objectives:**
  - Use experience based co-design with a sample of patients, informal carers and HCPs to optimise the intervention regarding content and manualisation strategy, and the acceptability of the planned consent and randomisation procedures.
- **Feasibility testing objectives:**
  - Gather data on the proposed trial processes from 4 palliative care services, in both West Yorkshire and in Hampshire. This will involve evaluating the eligibility screening process, participant consent, recruitment, retention, attrition.
  - Assess the feasibility of obtaining clinical and health economic outcome data for a definitive RCT including: change in medication use, improved symptom relief, improved self-management efficacy/confidence, quality of life , acceptability of the intervention, frequency of healthcare resource use, and place of death.
  - Conduct qualitative follow-up interviews with patients (where possible), carers and HCPs to assess the acceptability, uptake and fidelity of the intervention.

All the described will be complete by the end of 2017 and the expected outputs are:

- A developed and refined self-management support tool and manualisation strategy.
- A developed and refined protocol to train Clinical Nurse Specialists to deliver the manualised intervention.
- Conclude whether the feasibility trial meets the success and progression criteria for undertaking a definitive RCT.

**TIME4PALLCARE**

The WY R&D team are currently working with Dr Lucy Ziegler who is a Senior Research Fellow in the Academic Unit of Palliative Care, Leeds Institute of Health Sciences. We are aiming to determine when and how to involve palliative care services in the care of cancer patients and to identify groups of patients who are not currently referred. Dr Pablo Martin, the Leeds West CCG lead for Palliative Care is also a co- applicant in this work. Currently 30% of cancer patients die without receiving specialist palliative care. For those who are referred, it is often in the last weeks or days of life. Research evidence shows involvement of palliative care alongside routine cancer care improves

symptoms, reduces hospital admissions, improves quality of life and enables patients to make choices about their end of life care. Despite the growing evidence about potential benefits of integrating palliative care alongside cancer care, there is no evidence available about the most appropriate time to refer patients or which patients to prioritise. Without this information oncologists cannot translate this research evidence in practice.

We have successfully submitted a funding application to the Yorkshire Cancer Research fund to address this gap in knowledge by using data from the electronic medical records of 7,000 patients who died from cancer between 2008 and 2012. The data is located within 3 systems; i) The Yorkshire Cancer Registry ii) the electronic patient record system used by the Leeds Cancer Centre and iii) the electronic patient record system used by GPs and community palliative care teams. A process to access and link data from these three systems has already been established and successfully executed by the research team as part of the IMPACCT NIHR programme grant. In this project we will exploit this existing linkage. The team will track the timing and nature of palliative care involvement and the extent to which quality markers for end of life care are met for each of the 7,000 patients.

**EU Learning Layers**

Learning Layers, a flagship four-year project as part of the EU's Framework 7 funding stream, is focused on informal learning in the workplace and supporting this through the development of technology tools. The project works across 7 countries with 17 partners and in the UK the pilot is focused on GP practices as examples of SMEs where informal learning could benefit from support. The project has received positive feedback, especially in December 2015 when the penultimate year of the project was evaluated by external reviewers.

The past 12 months of the Learning Layers project have been focused on getting the technology tools into a useable form to be piloted in real-world contexts by wider groups than the initial 3 practices. The project has used a co-design approach to capture real users' requirements from a tool. Users have then voted and prioritised the features which have been fed into the final design. Rose Dewey from the research team has been accepted to present at a conference in Sheffield on co-production which will happen in May 2016.

The evaluation pilots have now started in two federation groups in Bradford and Airedale and also nationally in a working group of Health Education England and a working group of the Academic Health Science Network. This began at the end of the 2015/16 financial year and will proceed for approximately 3 months into 2016/17. This pilot is being qualitatively and quantitatively evaluated and will be one of the major outputs of the project.

Members of the CCG research team recently met with a representative of the NHS European Office, who said that he had only been aware of one other CCG in England involved in an EU-funded project – most of the EU-funded research in the NHS is taking place in hospitals.

**Recently Completed**

**OK Diabetes**

Phase 2 of the OK Diabetes study is now complete. Throughout the trial the study team recruited participants from 60% of general practices in West Yorkshire, interviewing 171 adults with type 2 diabetes and a mild to moderate learning disability about their diabetes, as well as interviewing their main supporter. In total 82 participants were recruited into a trial of supported self-management. Following the completion of phase 2 the study team has created a newsletter detailing highlights from the OK Diabetes study (please see appendix 2).

The team's easy read guide to managing type 2 diabetes remains available for download: http://www.nhs.uk/Conditions/Diabetes/Documents/Type%202%20Diabetes%20Easy%20Read%20Guide.pdf

The study team intends to attend education events across the West Yorkshire locality throughout 2016 to disseminate results and learning from the OK Diabetes study. Any opportunities that the CCG can offer for this would be appreciated.

**An Investigation of the Leadership, Governance and Managerial Behaviours of CCGs that Increase Innovation and Quality of Healthcare as Defined by Key Stakeholders**

The research was carried out by Professor Beverly Alimo-Metcalfe, Professor of Leadership Studies at The University of Bradford School of Management in partnership with researchers from Real World Group Ltd. The main rationale for the research is that the future of the NHS requires more innovation and change in order to deliver new models of care and to improve care quality, so understanding how innovation can be enhanced is crucial.

The aims of the project were to identify and explore:

- The leadership, management and governance behaviours that enable the effective functioning of the CCG Governing Body as a team;
- The ways in which such behaviours can contribute to supporting and encouraging innovative practices and a culture of innovation within a CCG;
- How, in combination, effective leadership, management and governance of CCGs, and support for innovative practice, can bring about improvements in the quality of healthcare provided;

- How CCGs work in partnership and collaboration with other agencies to support innovative practice.

Three CCGs participated in the Project and the methodology was as follows:

- Identification of the leadership, management and governance behaviours of CCG governing bodies that increase innovation and quality of healthcare through:
    - A review of the relevant literature
    - 25 semi-structured interviews with members of the CCG governing bodies (sometimes referred to as governing boards) and their stakeholders
    - Statistical analysis of data gathered from the piloting in 3 CCGs of the revised CCG Leadership and Innovation 360™ to identify strong correlations between the leadership, management and governance behaviours assessed on the instrument with:
        - engagement and wellbeing of governing body members and CCG staff; and
        - ratings of stakeholders' confidence in the CCG's effectiveness in delivering the highest quality of service to the community, which are proxy measures of CCG effectiveness
- Revision and validation of an existing CCG 360 model and feedback instrument (CCG360™, Real World Group, 2012) based on the interview findings
- Piloting the revised tool (renamed the CCG Leadership & Innovation 360) in the participating CCGs (198 responses in total), including feedback reports and feedback sessions to the governing bodies
- Evaluation of the content of the CCG Leadership & Innovation 360, and the implementation and impact of the intervention through interviews, focus groups and analysis of the quantitative data, and a comparison of the CCG Leadership & Innovation 360 with two other tools currently used by CCGs.

A dissemination event is currently being planned to share the key findings of the research.