NHS
North East Lincolnshire
Clinical Commissioning Group

Research & Development

North East Lincolnshire CCG

Annual Report

2016 -17

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1. **Introduction**

The purpose of this Research and Development (R&D) Annual Report is to present information to the Committee on the full year R&D activity for 2016- 2017. The report provides the evidence that North East Lincolnshire (NEL) CCG is endeavouring to work towards meeting its statutory duty for 'promoting research, innovation and the use of research evidence' (Health and Social Care Act, 2012).

The report presents information on the following:

- Research based activity
- Establishment of the Northern Lincolnshire R and D Working Group
- National R and D Updates
- Excess treatment Costs
- Development work in 2016-17.

2. **Background**

The UK government has stated its firm commitment to promote research throughout the NHS which it sees as essential to continually improve the effectiveness of health services and patient outcomes. Indeed, there is an expectation that the UK will be the first research-led health service in the world.

A number of policy documents have placed a strong emphasis on research activity in the NHS:

- The NHS Constitution
  One of these principles includes a commitment to 'the promotion and conduct of research to improve the current and future health and care of the population'.

- The NHS White Paper, Equity and Excellence: Liberating the NHS
  'The government is committed to the promotion and conduct of research as a core NHS role. Research is vital in providing the new knowledge needed to improve health outcomes and reduce inequalities'.

- The government response to the NHS Future Forum report made the following commitments with respect to CCGs and research
  'CCG's legal duties should reflect their key role in making sure that, at a local level, the need for good research, innovation and a strong evidence for clinical decisions is paramount'.

3. **Research-based Activity – Progress Reports.**

3.1 National Institute for Health Research (NIHR) Portfolio Study Activity (Non-funded by NEL CCG)

The data from the NIHR portfolio study report presents the study activity cut from the data between the periods April 2016 to February 2017.

The report in **Appendix 1** lists the number of practices recruiting and current studies open to more sites.

3.2 North East Lincolnshire Non-portfolio Studies (Non CCG Funded)

There have been currently no non-portfolio studies taking place in the North East Lincolnshire CCG area for the financial year 2016 – 2017 but this opportunity aims to be explored by the Northern Lincolnshire R and D Working group going forward in 2017-18.

4. **Establishment of the Northern Lincolnshire R and D Working Group.**

The Northern Lincolnshire R&D working group has been established which brings together representation from across the North and North East Lincolnshire health/ research community involving Public Health from the local council. As part of the group membership a lay member from NEL has been co-opted onto the group with interest and experience in research.
The group has already established links with the Local Clinical Research Network and the Academic Health Science Network and progression is underway to link in with Hull, York Medical School and other stakeholders in academia. The establishment of the group aims to support and encourage the growth of research and assist in establishing a translation of evidence to underpin commissioning priorities and the Five-year Forward View (2014) for Integration and the Humber, Coast and Vale, Sustainability and Transformation footprint (STP) The inaugural meeting of the Northern Lincolnshire R and D Working Group took place in September 2016. A copy of the final Terms of Reference is in **Appendix 2.**

5. National R&D Updates

5.1 Health Research Authority Changes

In 2015 the Health Research Authority (HRA) instigated the pilot of a new system for managing governance arrangements for research studies undertaken in England to replace local approval systems. Following this pilot, the new HRA process was implemented on 1 April 2016.

HRA approval provides a single authoritative assurance that the study complies with required legislation and guidance and, where applicable for the study type, that a favourable opinion from an independent ethical review is in place.

Sponsors are no longer required to obtain NHS assurance or Research & Development (R&D) approval from NHS Organisations for studies which have HRA approval. Instead the Sponsor must agree and confirm with host organisations in which they which to undertake their research that the host site has the capacity and capability to deliver the study and that the arrangements are in place to do so.

The HRA have defined the different stages that sponsors and NHS organisations must now go through on the way to mutually agreeing that the study can open at that site. These stages are:

- **Assess:** Assessing whether or not the NHS organisation has the capacity and capability to participate in the study
- **Arrange:** Putting any practical arrangements in place to provide the capacity and capability to deliver the study.
- **Confirm:** Confirming that the NHS organisation has the capacity and capability in place to deliver the study and will deliver the study. This confirmation is given through a formal agreement or via a new statement of activities which will be introduced for non-commercial studies.

NHS organisations hosting research can accept assurance of legal compliance from the HRA.

Thus, rather than issuing NHS permission for a study to start, NHS organisations confirm to the sponsor that they are ready to start delivering a study either by signing an agreement with the sponsor or working with the sponsor to mutually agree the new 'Statement of Activities' by email.

Site-specific information (SSI) forms are not required for studies with HRA Approval. Sponsors are expected to share the study documents with sites and the new Statement of Activities provides explicit confirmation of the activities expected to be undertaken at site (accessed via http://www.hra.nhs.uk/?s=statement+of+activities)

Studies supported by the NIHR Clinical Research Network (CRN) with HRA approval do not use the NIHR Central System for Permission (CSP) as NHS Permission is no longer required.

The North Yorkshire and Humber Research and Development service hosted by ERY CCG have been involved in working with research teams to offer advice and support during the HRA implementation stage and in 'trouble shooting' any problems quickly and escalating as required to the HRA.

6. **Excess Treatment Costs.**

Treatment Costs are the costs of the patient care which would continue to be incurred if the service in question continued to be provided once the research study has completed.

The responsibility for meeting patient care costs, resulting from research and development was set out within the HSG 9(97)32, it is stated that:

*'In the case of a new or modified service under evaluation, the Treatment Costs are those costs which the **NHS would expect to continue to bear after the research had finished and,** assuming the trial or evaluation was successful, the service had been put in place'*

To calculate Treatment Costs properly it is therefore necessary to assume:

1) All research will be successful **and** 2) the NHS will continue to bear the cost of delivering the intervention after the research has finished.

Examples of Treatment Costs:

- Supplying and administering the treatment/medicine/therapy that is being studied.
- Training clinicians to deliver the treatment.
- Supplying and administering any active comparators – including medicines, devices or therapies, but not placebo or sham treatments.

Excess Treatment Costs (ETCs) can occur when a non-standard of care treatment is being given as part of a study. If the cost of providing the non-standard of care treatment is greater than the cost of the routine Treatment Cost, the total difference between the two costings is the ETC.

To give a practical example:

Routine treatment of 1x paracetamol = £1 per treatment cycle

Study treatment of 1x novel drug = £2 per treatment cycle

The difference between the Treatment Cost of the routine treatment and the costs of providing the study treatment are an additional £1, making the ETCs £1 per treatment cycle.

Funding arrangements for ETCs can be comparatively complex. As per the AcoRD guidance, **ETCs should be funded through normal commissioning arrangements like Treatment Costs.** In practice many institutions have declined to support studied with ETCs because of concerns over funding.

NHS England released additional guidance on ETCs in November 2015 as part of an effort to improve the process for funding ETCs and aims to remove 'a point of friction between providers and commissioners'. The guidance specified the following points:

- Funds to cover ETCs are included within the National Tariff, where applicable. Services outside of the Tariff should be clarified with the relevant commissioners.

- Commissioners will expect to be shown that the costs cannot be covered through the Tariff or by offsetting savings before they will fund ETCs.
- Early engagement from sponsors is helpful when trying to secure funding (but cannot reasonably be expected by the commissioners in each case.)
- A key point raised is that '*Commissioners and their providers cannot refuse to meet Excess Treatment Costs, on the sole basis of affordability and prioritisation, where a legitimate funding request for these costs is submitted…'*

Where ETCs are exceptionally high the Chief investigator can apply to DH Research & Development Directorate for a subvention to cover all or part of the costs.

With the initiation of the Northern Lincolnshire R and D Group the process of how Excess Treatment costs are managed across both NEL CCG and NL CCG is under discussion.

During 2016/ 17 NEL CCG received one ETC application for consideration, the outcome is awaited.

The brief details of the study are listed below:

Study Title	Study Details	ETC Amount requested
BASIL III	The study is based at HEY and is investigating the efficacy of treatments for severe ischaemia of the leg. The principal research objective is to determine which of these methods- plain balloon, drug coated balloon or drug releasing stent keeps the patient alive and with their leg intact the longest. The ETC will cover the use of drug eluting stents/balloons to patients.	£5,025.00

7. **Development work in 2016- 17**

7.1 Gap analysis work.

An R and D gap analysis has been initiated across the NEL and NL CCGs in collaboration with the R and D Lead Manager (Humber). The focus of the work is to identify key areas that require further development. The gap analysis has been underpinned by the National Guidance for commissioners published in April 2016.

Actions have been identified and the work is still on-going.

7.2 Evidence Informed Commissioning – R and D Baseline Survey.

The ambition set out by NHS England is that by 2020/21 NHS Commissioners will routinely consult the evidence; this includes using research evidence where it exists to identifying evidence gaps and to ensure commissioning decisions are underpinned by the use of good evidence. To support this NHS commissioners need to have the tools, information, support and skills to make best use of information, knowledge and research.
The North Yorkshire and Humber R and D service has produced a baseline survey to establish the following;

- Establish locally what understanding NHS commissioners have of using and applying good evidence and research in the decision making process.
- Recognise any gaps in sourcing and appraising evidence
- Identify any training needs in sourcing and applying good evidence and research.

The survey was distributed to the NEL CCG commissioners

The responses to the survey have been positive and the common themes that have been collated have shown the following:

- **Half** of the respondents have heard of the 'hierarchy of evidence'.
- **Over half** did not have an NHS Open Athens Account to access evidence and research.
- The **majority** had not used any critical appraisal tool(s) or had any training on how to appraise evidence.
- Some of the training gaps that were identified included; sourcing evidence, literature searching techniques and how to appraise evidence.

The next steps from the survey are to set up some workshops for the commissioners in partnership with the library services at the Trust.

7.3 Engaging further practices in research with CRN - Start Up /Practice Nurse Model Funding Opportunities.

The NIHR are currently running a scheme whereby GP practices can receive £6,000 for one year only to identify a practice nurse who would enter into a research nurse development scheme for 4 hours a week. Additionally, a number of expected outcomes would be required during the funding period, such as:

- Identification of a lead GP who would take responsibility for clinical research with the practice and would work with and support the practice research nurse and engage with the CRN team member.

- Work towards RCGP's 'Research Ready' accreditation

- Consider and provide evidence of how research awareness could be promoted within the practice to all staff and patients.

- Increase the number of NIHR portfolio research studies (both commercial and non-commercial) and the number of patients involved in research.

The above scheme provides an ideal opportunity to engage further practices in the North East Lincolnshire area in research. If the CCG could work closely with the NIHR to promote and support this scheme then potentially the opportunity for patients to get involved in research would increase significantly. Increasing the skills and knowledge of practice nurses, GP's and other practice staff would also be a potential outcome of this collaboration.

Recommendations

The Quality Committee are asked to:

1. Consider and discuss the NEL CCG Research & Development Annual Report.

2. Consider and discuss how further work can continue to grow to support the NEL CCG R and D mandate to promote research and the use of research evidence.

3. Consider and discuss how the development work initiated in 2016-17 will be taken forward in 2017-18.

Glossary

NHS	National Health Service
CCG	Clinical Commissioning Group
CRN	Clinical research network
DH	Department of Health
ETC	Excess Treatment Cost
HRA	Health Research Authority
HYMS	Hull York Medical School
NIHR	National Institute for Health Research
STP	Sustainability and Transformation Plan

Appendix 1

NIHR Clinical Research Network Portfolio Study Report
April 2016- February 2017

Recruitment data

The table below gives a summary of portfolio study recruitment data for North East Lincolnshire CCG for the period captured between April 2016 – February 2017. This data only shows the studies recruited during this period.

NHS North East Lincolnshire CCG	
No Practices in CCG	28
No Practices Recruiting	3
% Practices Recruiting	11%
CCG Studies	5
CCG Recruitment	23
CCG Population (2015/16)	159,804
Recruitment per million population	144

Active Studies

The table below illustrates the names of the GP practices/sites that had studies that recruited within NEL CCG for the period April 2016- January 2017. It includes the names of the portfolio studies that are taking place as well as the level of recruitment for each study.

Practice Name	Study Ref	Short Study title	
The Roxton Practice	10470	The United Kingdom Aneurysm Growth Study	1
The Roxton practice	31408	CADPC- 11v1	3
The Roxton Practice	32585	A study of common and rare genetic variants associated with thinness	7
Littlefield Surgery	17252	Understanding the Effects of Acne	6
Littlefield Surgery	2484	A Coordinated programme for improving the outcome of a very early inflammatory arthritis	5
Dr A Sinha	10470	The United Kingdom Aneurysm Growth Study	1

NB: Data is owned by and extracted from the NIHR CRN Business Intelligence Unit.

Appendix 2

Northern Lincolnshire Research and Development (R &D) Working Group
Terms of Reference.

1. Purpose

1.1 North Lincolnshire (NL) and North East Lincolnshire (NEL) CCG's have agreed to establish a **Northern Lincolnshire Research and Development (R&D) working group** which will aim to promote:

- Opportunities for high quality and relevant research and making links to local health and care need or clinical practice.
- Good research that leads to innovation and provides a strong evidence base for clinical decision making.
- The promotion and conduct of research embedded in the CCG.
- A developing and evolving knowledge base is established to improve health outcomes and reduce inequalities.

1.2 Links and Interdependencies

- The Northern Lincolnshire R&D working group will link into the following forums:-
- Quality Committee(s)
- Council of members (NEL) and Engine Room (NL)
- Clinical governance groups
- Data and performance teams (NL/NEL/Public Health)

2. Accountability

The Research and Development working Group will provide regular updates to and obtain final approval for projects from the NL & NEL Quality Committee(s).

3. Reporting Arrangements

3.1 Documentation
All meetings will be formally recorded/noted and there will be a formal written 6 monthly update provided to the NL & NEL Quality Committee(s). Proposals for approval will be submitted as required to the next available Committee.

3.2 Disclosure/Freedom of information Act (FOI)
The Chair will be responsible for ensuring that FOI requirements in relation to the meeting records are met. All records from the group are classed as public documents. Should the chair or working group member identify a subject or issue that is not in the public domain, the Chair will make appropriate arrangements with the support of the Information Governance and Corporate Governance leads of the CCG(s).

4. Membership

Core Membership of the Research and Development Working Group will comprise of the following members:

- Director of Quality and Governance/Executive Nurse / or CCG (s)representative (NL/NEL)
- R&D Lead (or representative), North Yorkshire and Humber R&D Service (Chair)
- Senior Commissioning Manager (CCG or representative)
- Senior Clinician CCG(s)
- Representative from Academia
- Quality Manager, CCG (s)
- Lay representative (NL /NEL)
- Research Practice member, GP or Nurse (NL/NEL)
- Public Health Representative
- Primary care education lead, GP or Nurse (NL/NEL)
- Data analysts (to be co-opted as required)

Additional attendance from other experts or stakeholders will be sought at the discretion of the Chair. Attendance will be monitored throughout the year and any concerns to be raised with the chair and relevant member.

5. Appointment of Chairs

The group will agree the Chair and Vice Chair in its first quorate meeting.

6. Curacy

The quorum for meetings shall be four members which should include the following

- Director of Quality and Governance / Executive Nurse or CCG(s) representative(NL/NEL)
- R&D lead, North Yorkshire and Humber R&D service.
- Senior Commissioning Manager CCG's (NL/NEL)
- Senior Clinician CCG(s) (NL/NEL)

If a Quorum has not been reached, then the meeting may proceed if those attending agree, but any record of the meeting should be clearly indicated as no decisions may be taken by the non-quorate meeting of the group.

7. Attendance

Expert advice and/or stakeholder attendance will be arranged as required for specific items on the agenda.

8. Meetings

Meetings of the R&D working group shall be held quarterly and then be reviewed. The CCG(s) will ensure the group has administrative support, and will oversee the following:

- Agreement of agenda with the chair and attendees and the Collation/ circulation of papers.
- Taking of formal notes/records from meetings and issues to be carried forward.

An annual schedule of Meetings shall be agreed at or before, the last meeting each year in order to circulate the schedule the following year.

9. Confidentiality

All members are expected to maintain confidentiality where required.

10. Remit

10.1 Strategic Development

- To develop and implement a joined up NL/NEL strategy to R&D which provides a framework for the promotion and conduct of the research agenda. This will align to the commissioning priorities and values. It will give a focus to the 'forward view' planning work.

10.2 Process development and implementation

- To ensure sound processes for promoting identifying and supporting locally driven projects that will help and inform the Strategic priorities and future research ideas.
- To ensure that there are robust processes/ systems in place for R&D which are in line with statutory requirements, national policy and guidance?
- Monitor and review provider research activity to ensure the NL/NEL population is able to participate in studies.
- Develop and implement an excess treatment costs process.

10.3 Research Activity

- To help facilitate and further develop portfolio research studies being conducted in primary care with collaborators across the network, for example the Local Clinical Research Network (CRN).
- To help create research leadership amongst GP Practices across North Lincolnshire and North East Lincolnshire.
- To help facilitate with research recruitment across a range of practices and link into the CRN portfolio adopted community cluster funding arrangements.
- To facilitate and promote 'locally' grown research and grow innovative ideas.

- To support the further growth of development relevant research from commercial and non-commercial studies.

11. Review of the terms of Reference

The terms of Reference will be reviewed annually or as and when required.