GP direct access to diagnostic investigations across the North East and Cumbria

PROTOCOL

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Contents

Contents 2

Section 1. Title 3

Section 2. Background/Introduction 3

Section 3. Aims and Objectives 4

Section 4. Project design and methods 4

4.1. Work package 1: quantitative 4

4.2. Work package 2: Qualitative 6

4.3. Data storage and confidentiality 7

4.4. Ethical issues 8

4.5. Dissemination 9

4.6. Monitoring 9

Section 5. Funding 9

Section 6. Study team and contact details 9

Appendices 11

Appendix 1. Interview schedule 11

Appendix 2. HRA Decision tool 13

Appendix 3. Participant Information 14

Appendix 4. Consent 16

References 17

Section 1. Title

GP direct access to diagnostic investigations across the North East and Cumbria.

Section 2. Background/Introduction

The North East and Cumbria covers a population of approximately 3.1 million with areas of high deprivation, relatively high incidence of some cancers such as lung and colorectal, with late stage presentation and is an important factor in one-year survival rates. The region is served by 450 GP practices, 12 CCGs, 9 acute NHS trusts and 2 tertiary centres.

Rapid diagnosis of cancers is important for improving survival rates, and for achieving the national aim of a definitive diagnosis within 28 days of initial presentation for 95% of cancer patients by 2020[1]. National clinical guidelines for suspected cancer were revised in 2015, and GPs are advised to opt for direct referral to diagnostic tests where possible, in order to expedite a diagnosis[2]. The urgent (2 week) referral is the prescribed route to a cancer diagnosis for those with clear symptoms. Direct access to tests can be part of this process, as well as providing GPs with a referral option for patients who do not meet the urgent criteria, but with whom there is still a suspicion of disease.

An initial scoping of the literature reveals important evidence about early diagnosis: a correlation between mortality and time to diagnosis[3], variation in GP use of the urgent referral pathway and mortality and the use of the urgent route[4]. Nicholson et al[5] examine variation in direct access, they suggest variation across the country in accessing most tests and, crucially, in the time taken to obtain test results. Ingeman et al[6] in a Danish retrospective study suggest that Danish GPs are more likely to refer patients directly to test if they have a higher suspicion of cancer, and that this option provides a shorter wait for ultrasound test results. Liverpool Heart and Chest Hospital[7] introduced a 'straight to CT' system, the evaluation of which suggested improved and more rapid lung cancer management, exclusion of patients with no or non-malignant disease from the cancer pathway at an earlier stage and a reduced time to diagnosis.

These studies are helpful in providing background and context; this study is needed to examine local referral data held in hospital radiology departments across the North East and Cumbria in order to assess the extent to which GPs are using direct access to radiology tests, and to explore local contexts and the influences of these on the referral decisions of GPs.

Section 3. Aims and Objectives

The study aims to assess how effectively GPs use direct referrals to radiology tests for investigation of suspected cancers in the North East and Cumbria, and to understand the factors that influence GPs when making referrals. The study will provide a comprehensive picture of GP access and use of direct referral options across the North East and Cumbria. It will inform the planning of services and will explore the potential of digital applications and telemedicine options for improving the referral and diagnostic test parts of the cancer pathway. It will give recommendations for potential reductions in the time to cancer diagnosis.

Study objectives are twofold:

(i) to establish the clinical and cost effectiveness of direct GP access versus the urgent 2 week-wait referral pathway to radiology by GPs for patients in whom cancer is suspected. Clinical process outcomes and costs will be compared along the two pathways.

(ii) to undertake discussions with GPs, radiologists and service managers to explore views of enabling factors and barriers to this diagnostic pathway.

Section 4. Project design and methods

This study will comprise of two interlinked work packages of quantitative and qualitative study.

4.1. Work package 1: quantitative

This part of the study will be delivered by Northumbria University; it aims to estimate the clinical and cost-effectiveness of direct referrals to radiology by general practitioners, which will be combined with the qualitative data gathered in primary and secondary care described in work package 2. Its objectives are to:

- differentiate and quantify direct (open) access referrals for suspected cancer to radiology tests by GPs
- estimate the relevant costs of direct access to radiology tests, any savings or added costs to the NHS and impact on time to diagnosis.
- model the clinical and cost-effectiveness of this diagnostic strategy
- create a digital map of GP referral processes.

The focus of the study will be on 4 cancers: brain, lung, pancreas, sarcoma and on 4 radiology tests: non-obstetric ultrasound, brain MRI, CT, and chest x-ray. Clinical process measures will include median time to radiology test results, to onward referral and time to diagnosis. Cost measures include comparing tariff

elements of diagnostic pathways and cost impacts on changes in GP referral and patient attendance patterns.

Routinely collected datasets managed by NHS Digital and Public Health England (PHE) will be used as a basis for the analysis. Data sets will be requested through the Office for Data Release (ODR) and/or the NHS Digital Access Request Service (DARS). The Diagnostic Imaging Dataset (DID)[8] will be used to identify cohorts of referrals from GPs to radiology of patients with suspected cancer. The data extracted will be limited to the North East and Cumbria and we anticipate covering a 12-month time period 2015-2016. The DID dataset will provide data on the method of referral, date of referral request, date of request received, date of test request, date of test request received, date of test, date of report, and suspicions of early cancer diagnosis. The DID dataset will be linked to the cancer registry dataset held by PHE[9] to identify those patients with an eventual diagnosis of cancer, time of diagnosis, and stage of cancer at the time of diagnosis. This will be further linked to both the Routes to Diagnosis for cancer national dataset held by PHE[10] to identify the route to diagnosis (GP direct referral or GP two-week-wait referral) and the Hospital Episode Statistics (HES) Outpatient dataset held by NHS Digital[11] to identify outpatient resource use between referral and diagnosis. All data requested will be pseudonymised post linkage.

Using the retrospective routinely collected data we will estimate and compare the effectiveness of diagnostic pathways with and without the option of direct access to radiology tests, using established good practice modelling guidelines[12]. The primary outcome will be the time to diagnosis from referral. The secondary outcomes will be positive and negative predictive values (PPV and NPV) of each referral strategy. The PPV and the NPV will inform the cost-effectiveness analysis, the perspective of which will be that of primary care and secondary care. Within secondary care the scope will be limited to radiology. The cost-effectiveness analysis will report the cost per day to diagnosis and will conform to current best practice[13, 14].

Using appropriate regression techniques, and controlling for case-mix, we will estimate the association between referral pathway and time to final diagnosis amongst those referred. The data will also be used to estimate the PPV and NPV of each referral pathway. The PPV and NPV are the proportions of true positives amongst predictive positives and true negatives respectively amongst the referred population. Together the PPV and NPV of each pathway will describe the resource implications of each test as well as its performance in terms of the populations referred under each pathway. For example, the PPV will inform estimates of the resources needed to image not just those with cancer but those referred who do not have cancer.

Resource use will be measured in terms of the resources used to provide imaging and outpatient activity. Resources will be estimated in terms of staff time and the equipment used. Resource use will be valued using the Department of Health NHS reference costs and we will also conduct activity based costing within the partner NHS trusts where possible. The cost-effectiveness will be presented as incremental cost-effectiveness ratios. Variations in resources and costs will be used along with data from the Personal Social Services Research Unit (PSSRU) to conduct sensitivity analysis of our estimates[15]. Similarly, to estimate uncertainty around our estimates of PPV and NPV, we will use a boot-strapping process to inform probabilistic sensitivity analysis (PSA) on our model[16], and the results presented as cost-effectiveness acceptability curves (CEACs)[17].

4.2. Work package 2: Qualitative

Work package 2 will be delivered by University of Cumbria and aims to provide an in-depth understanding of: enablers and barriers to GP direct access; the contexts in which GP practices and radiology departments operate; the impact that these have on referral decisions. Its objectives are to explore:

- barriers and enablers for GPs referring patients direct to radiology tests
- the potential of digital applications and telemedicine to improve GP communications with secondary care (e.g. accessing test results)
- implications for commissioners and radiology services of referral options.

Cumbria University has developed expertise in digital health and has developed the Stakeholder Empowered Adoption Model (Steam)[18]. The model recognises that conventional evaluation techniques can be ineffective for innovations that are complex, involve multiple stakeholder groups across different professions and do not take account of change management and workforce impact. The result is that evaluations tend to generate inappropriate evidence that does not support effective decision making (hence can be wasteful of resource and even be counter-productive). The StEAM method is grounded in related theory, particularly Normalization Process Theory and the Technology Acceptance Model, but develops theory into a practical tool, in which stakeholders are engaged in a negotiated evaluation process. The StEAM model has been validated through several case studies[19, 20]. The key stakeholder groups in this study are cancer lead GPs, generalist GPs in GP practices, secondary care radiology staff and commissioners within specific areas of the region.

i. Initial Scoping Exercise – stakeholder meetings

We have found that it is important to engage with stakeholders before starting the study and then using their input to inform and develop the study design. In this instance, we have held scoping meetings with representatives of the key

stakeholder groups based in North and West of Cumbria; the aim was to gather insight on the current context; opinion on the evidence needed, and input on how data collection might proceed. Participants included Macmillan GPs, cancer leads in secondary care and radiologists. Their responses have informed the initial design of the data collection tools (see appendix one).

ii. Study participants

The key stakeholder groups in this study are cancer lead GPs, generalist GPs in GP practices, secondary care radiology staff and commissioners within specific areas of the region; the sampling frame will be GP practices, NHS Trusts and CCG commissioners in the North East and Cumbria.

iii. Patient involvement

To ensure that all important areas are covered and that information on barriers and enabling factors can be elicited, the data collection tools will be further developed in collaboration with patient representatives who will be accessed with the assistance of the Macmillan Engagement and Co Design Project Manager at the Northern Cancer Alliance.

iv. Methods

In-depth qualitative interviews will be undertaken with representatives of the key stakeholder groups in three locations across the Northern Cancer Alliance footprint: County Durham and Darlington, North Cumbria and Teesside. In each area interviews will be undertaken with: 1-2 radiology staff; 1-2 commissioners, 1-2 GP cancer leads and 4 generalist GPs (i.e. 8 interviews per area).

v. Data analysis

All interviews will be recorded with the consent of participants, and transcribed into word documents. Transcripts will be subjected to traditional thematic analysis to reveal dominant themes. This approach will be used to elicit an initial understanding of the data by themes and by participant, after which a broader thematic approach will be used to ensure that all data has been considered in the analysis.

4.3. Data storage and confidentiality

i. Work package 1: quantitative

All data will be handled confidentially. No patient identifiable data will be requested or available to the project study team. Pseudonymised patient level data will be stored on the University of Northumbria password protected network. Where necessary, the data will be shared on a Northumbria University faculty shared drive with restricted access to the project study team only. Dr Peter

McMeekin (PI) will be the data controller of this shared drive. Storage arrangements of all data will be in accordance with the Data Protection Act 1998 and adhere to all university guidelines around information and data protection. Northumbria University employees are all fully data protection trained and IT security trained as this is part of their mandatory training on an annual basis.

ii. Work package 2: qualitative

The qualitative study will be subject to all currently recommended safeguards to ensure participants' fully informed consent and to protect participants' confidentiality.

All audio-recordings and computer records from the qualitative interviews will be stored on a password protected computer on the University of Cumbria's password protected network in an encrypted folder; only members of the project study team will have access to this information. All records which contain participant identifiable information will be stored in a locked filing cabinet in a secure office.

In accordance with current data protection legislation, audio-recordings will be stored until data transcription is complete and then they will be destroyed. As required, anonymised copies of transcripts will be stored securely for 15 years by the University of Cumbria.

4.4. Ethical issues

i. Work package 1: quantitative

Work package 1 will use routinely collected secondary and pseudonymised data for which no ethical approval is required.

ii. Work package 2: qualitative

Work package 2 will not involve researchers in randomising participants into different groups, changing the treatment of patients or producing generalizable findings and will not require NHS REC approvals, in line with the Health Research Authority, (appendix two)[21]. Stakeholder groups involved in the study will be informed of the study and the extent of the involvement.

All participants will be provided with an information sheet explaining the study and given the opportunity to ask questions (appendix 3). All participants will be asked to give their consent to the interview; in face to face interviews they will be ask to sign a consent form, in the case of telephone interviews consent will be gained verbally and digitally recorded (appendix 4). All participants will be assured that they are entitled to refuse or to withdraw their consent, at any time.

During qualitative data collection disclosures or observations which compromise the professional integrity of the project study team and/or participants, or the safety of patients, will be dealt with at the time and the collection will cease if necessary. Assurances of confidentiality will not apply in situations where professional accountability or patient safety is at risk.

4.5. Dissemination

Findings will be written into a summary report for Cancer Research UK and the Northern Cancer Alliance. Findings will also be written into one or more papers for conference presentations or publication in academic journals. The data might also be used for any grant application support.

4.6. Monitoring

Project delivery will be monitored by Kath Jones, Cancer Alliance Delivery Manager at the Northern Cancer Alliance.

Section 5. Funding

This project is funded by the Cancer Research UK Early Diagnosis Advisory Group (EDAG).

Section 6. Study team and contact details

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Appendices

Appendix 1. Interview schedule

A systematic, comprehensive picture of the extent and nature of GP direct access to diagnostic investigations across the North East and Cumbria.

Introduction

Our aim is to assess how effectively GPs are using direct access to diagnostic testing and to understand the factors influencing whether GPs use it or not; what are the enablers and barriers to direct access.

There are also questions around the workability of direct access; the implications of it to individual clinicians, to GP surgeries and radiology departments, as well as about how direct access might be improved, facilitated.

The focus of our study is on 4 cancers: brain, lung, pancreas, sarcoma, and on 4 radiology tests: non-obstetric ultrasound, brain MRI, CT, and chest x-ray

Q1 Can you tell me about what's in place locally with regards to direct access to radiology diagnostic testing?

- Who has direct access?
    - Practice nurses? Locums? Out of hours' services?
- How is direct access facilitated?
    - Are there systems in place?
    - Are these electronic/paperless?
    - Are these the same for different modalities?
- Is direct access being used?
    - How you imagined it would be used?
    - As frequently as it could be?

Q2 What is your experience of using direct access to radiology diagnostic testing?

- What are the circumstances in which you would choose direct access to imaging?
- Do you find referring straightforward?
    - What are the processes involved?
    - Are they easy to use?
    - Do they work?
    - How might referring be improved?
- What about reporting, is this straightforward?
    - How quickly do reports come back?
    - What happens when something is found?
    - Is this satisfactory?
    - What should happen?
- What is the quality of communication between primary and secondary care?
    - How easy is it to communicate?
    - How could communications be improved?

Q3 When a patient is referred to radiology for tests what information are they given?

- Who informs them?
- Are they made aware of the importance of attending?
- Do they know that tests may show cancer?
- Do patients 'take on' information when confronted with such news?
- Is there written information for patients to take away and read later?
- Are 'Do Not Attends' common here?
    - What are the reasons?
    - What can be done to counter this?

Q4 What are the benefits of direct access to radiology diagnostic testing?

- Does direct access facilitate appropriate referrals?
- … help in picking up cancers that may have been missed?
- … speed up diagnoses? Produce earlier diagnoses?
- … free up capacity within the specialist 2WW pathways?
- Is it better for patients? In what ways?

Q5 Are there any negative impacts?

- Are there issues around accountability? Trust?
- Does direct access impact on your workload? In what ways?
- Does direct access impact on capacity elsewhere? Has it the potential to decrease workload elsewhere?

Q6 Do the characteristics of GP practices influence the use of direct access?

- What about appointment systems used? e.g. are routine appointments available or are 'on the day demand systems' in place? Are telephone consultations undertaken?
- Do GP appointment systems impact upon continuity of care?
- Are consultation times sufficient? To check notes? To gather patient histories?
- Does the size and quality of GP practice impact upon referral and diagnoses rates?

Q6a Do economic factors influence usage of direct access?

- Do restricted finances lead GPs to ration testing?

Q6b Are there other factors that might influence the use of direct access?

- For example: geographical factors?
- Capacity in secondary care?
- Level of GP training in oncology?
- What about patient characteristics? Are demanding patients more likely to be referred? Can they request referrals?

Q6 Is there anything really important that we should be doing in the study?

- Anything we should measure? Anything we should ask?

Thank you for your time.

Appendix 2. HRA Decision tool

Go straight to content.

NHS
Health Research Authority

MRC Medical Research Council

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

A systematic comprehensive picture of the extent and nature of GP [illegible] access to diagnostic investigations across the North East and Cumbria

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision (s) that you need further advice on to the HRA Queries Line at HRA.Queries@nhs.net.

For more information please visit the Defining Research table.

Follow this link to start again.

Print This Page

Appendix 3. Participant Information

GP DIRECT ACCESS TO DIAGNOSTIC INVESTIGATIONS ACROSS THE NORTH EAST AND CUMBRIA STUDY

The North East and Cumbria covers a population of approximately 3.1 million with areas of high deprivation, relatively high incidence of some cancers such as lung, with late stage presentation.

Rapid diagnosis of cancer is important to improve survival rates and for achieving the national aim of a definitive diagnosis within 28 days of initial presentation for 95% of cancer patients by 2020. GP's are advised to opt for direct referral for diagnostic test where possible in order to accelerate a diagnosis.

This study is funded by Cancer Research UK Early Diagnosis Advisory Group [EDAG] and supported by the Northern Cancer Alliance. The aim is to assess how effectively GP's use direct referrals to radiology tests for the investigation of suspected cancers and determine what factors influence GP's when referring patients.

The study will:

Inform commissioning and provider decisions and provide a basis for addressing regional variation in patient outcomes

Explore the potential of digital applications and telemedicine options to improve referral processes, data-sharing and access to test results

Explore the potential of digital applications and telemedicine options to improve referral processes, data-sharing and access to test results

There will be two elements to this study – quantitative and qualitative some of which will require groups of people to contribute into the study. Our key stakeholder groups are cancer lead GP's, generalist GP's, hospital radiology staff and commissioners; they will be invited to participate in semi-structured interviews.

We have developed and piloted interview schedules with the assistance of volunteer participants including patient representatives; this is to ensure that all important areas are covered and that we are able to elicit the barriers and enabling factors.

Work package 1: quantitative

This package aims to estimate the clinical and cost-effectiveness of direct referrals to radiology by general practitioners. Its objectives are to:

- Differentiate and quantify direct [open] access referrals for suspected cancer to radiology tests by GP's
- Estimate the relevant costs of direct access to radiology tests, any savings or added costs to diagnosis
- the NHS and where use of direct access tests may reduce time to diagnosis
- Model the clinical and cost-effectiveness of this diagnostic strategy
- Create a digital map of GP referral processes

Work package 2: qualitative

This aims to offer an in-depth understanding of the contexts in which GP practices and radiology departments operate and the impact that these have on referral decisions.

Its objectives are to explore:

- Barriers and enabling factors for GP's referring patients direct to radiology tests
- The potential of digital applications and telemedicine to improve GP communications with secondary care i.e. accessing test results
- Implications for commissioners and radiologist services of referral options

The focus of the study will be on 4 cancers**: brain, lung, pancreas, sarcoma** and on 4 radiology tests: **non-obstetric ultrasound, brain MRI, CT, and chest x-ray**

Appendix 4. Consent

This project will be subject to all currently recommended safeguards to ensure participants' fully informed consent and to protect participants' confidentiality.

- All audio-recordings and computer records will be stored on a password protected computer on the University of Cumbria's password protected network in an encrypted folder.
- All records which contain participant identifiable information will be stored in a locked filing cabinet in a secure office.
- In accordance with current data protection legislation, audio-recordings will be stored until data transcription is complete and then they will be destroyed.
- As required, anonymised copies of transcripts will be stored securely for 15 years by the University of Cumbria.

Disclosures or observations which compromise the professional integrity of the project study team and/or participants or the safety of patients will be dealt with at the time, the evaluation will cease if necessary. Assurances of confidentiality will not apply in situations where professional accountability or patient safety is at risk.
Your participation is voluntary. We will ask you for your signed consent. Please be assured that you are entitled to refuse to participate or to withdraw your consent, at any time.

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