What factors influence GPs' decision to request thoracic imaging?

Version 0.6 08/04/19

Addendum 13/07/2021

This protocol was prepared by the author (Stephen Bradley) to be undertaken as part of a PhD. Prior to obtaining ethical approval the study team decided not to proceed with the project. This protocol is now being shared in case it is useful for other researchers. Please contact Stephen Bradley (medsbra@leeds.ac.uk) if you wish to use this protocol or develop it further.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the research in compliance with the approved protocol and will adhere to

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the research publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the research will be given; and that any discrepancies from the research as planned in this protocol will be explained.

For and on behalf of the research sponsor:

Signature:

.....

Date:

...../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature:

.....

Date:

...../...../.....

Name:

.....

This protocol has regard for the HRA guidance and order of content

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KEY RESEARCH CONTACTS

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Sponsor	
Supervisors	<p>Prof Richard Neal Professor of Primary Care Oncology, Academic Unit of Primary Care, University of Leeds Leeds, LS2 9JT</p> <p>Dr Alice Forster Senior Research Fellow, Institute of Epidemiology & Health, Faculty of Population Health Sciences, University College London</p>
Patient Representative	
Funder(s)	

RESEARCH SUMMARY

Research Title	What factors influence GPs' decision to request imaging for possible lung cancer?
Internal ref. no. (or short title)	Factors that influence GPs' decision to request imaging for lung cancer
Research Design	Qualitative interviews
Participants	General Practitioners (GPs)
Planned Size of Sample (if applicable)	15
Planned Research Period	02/09/19 – 04/01/2021
Research Question/Aim(s)	<p>Aim:</p> <p>To understand the factors which cause GPs to recognise the possibility of lung cancer and how GPs approach investigation for possible lung cancer.</p> <p>Objectives:</p> <ul style="list-style-type: none"> • To understand the symptom related and patient related factors which influence GPs' to consider the possibility of lung cancer • To understand when GPs consider imaging or repeat imaging with chest x-ray or direct access CT • To explore to what factors influence GPs decisions to refer urgently under two week wait pathways in the absence of definitive chest x-ray findings • to understand if and under what circumstances GP consider urgent referral when NICE criteria for two week wait referral are not met • To determine the acceptability of direct access to urgent CT and to explore if acceptability can be improved by through additional measures or support • To understand if GPs believe that their readiness to initiate urgent investigation with CT would be (or is, if

Factors that influence GPs' decisions to request imaging for lung cancer

	direct access is already available) greater than initiating a 'two week wait' referral
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FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
	Travel costs for interviewers to travel for face to face interviews Honorarium to compensate participants for their time in taking part Transcription of interviews

ROLE OF RESEARCH SPONSOR AND FUNDER

Neither the sponsor or the funder has had involvement in the design of the research and will have no involvement in the initiation, management or conduct of the research including data analysis, manuscript writing and interpretation of results.

ROLES AND RESPONSIBILITIES OF RESEARCH MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

The research management group will consist of the chief investigator, the supervisory team and the patient representative. The chief investigator will report progress to this team, principally through his monthly PhD supervision meetings. However additional supervision meetings will be organised with Dr Forster and Prof Neal.

PROTOCOL CONTRIBUTORS

The sponsor and funder have had no involvement in the preparation of this protocol and will have no involvement in research design, research conduct, data analysis and interpretation, manuscript writing and dissemination of results.

KEY WORDS:

Lung cancer, GP, General Practitioner, primary care, chest x-ray, computed tomography

RESEARCH FLOW CHART

Month 0-2

Potential participants contacted through mailing lists of gatekeeping organisations (NIHR Clinical Research Networks, Royal College of General Practitioners and Leeds Institute of Health Sciences) and invited to email chief investigator for participant information leaflet (PIL). If wish to participate to email chief investigator to confirm this once have read PIL.

Month 0-4

GPs express interest in research and consent to further contact from chief investigator

GPs do not respond or decline to be involved in research

Month 0-8

Chief investigator contacts GPs and arranges convenient time and venue for interviews and obtains consent immediately prior to interview taking place, then commences interview.

Month 8-18

Data analysis, manuscript writing and dissemination

RESEARCH PROTOCOL

What factors influence GPs' decision to request imaging for possible lung cancer?

1 BACKGROUND

Achieving early diagnosis of lung cancer is challenging. Previous work has suggested that GPs may overlook the opportunity to request additional relevant information from patients that could help inform the decision to arrange imaging(1). A PhD thesis employed qualitative methods to examine factors which lead GPs to consider investigation for possible lung cancer, highlighting factors such as perceptions of high risk patients(2), awareness of red flag and atypical presentations, individuals' consulting behaviour and personality, experiences of previous cases of lung cancer, clinicians intuition and organisational cultures of education, training and significant event audit. However, this work did not explore in depth the thresholds of risk which GPs felt were required to arrange investigation with chest x-ray or two week wait referral, how empowered GPs felt to deviate from two week wait criteria, how GPs respond to chest x-ray results which are unremarkable or how GPs feel about the possibility of having direct access to investigations such as computed tomography (CT). The interviews in the thesis were conducted in 2012, before the NICE guidance around the circumstances in which to request chest x-ray was updated in 2015 (3). In cases where two week wait is recommended, such as haemoptysis, a significant proportion of GPs still arrange chest x-ray before the referral is made (4).

It has been posited that giving GPs 'direct access' (DA) to tests such as CT chest could reduce diagnostic delay, expediting diagnosis with consequent improved patient survival. Despite the suggested benefits a survey of GPs found that only around a half had DA to CT(5) and even where DA to cancer investigations is available uptake has been shown to be limited(4, 6) (7).

In this research we will explore the circumstances in which GPs suspect that lung cancer could be a possibility and also the factors which contribute to a decision by GPs to arrange imaging. We will also explore GPs attitudes to the possibility of having access to other modalities, such as CT or low dose CT. The research population will be GPs and the research will be conducted through semi structured interviews.

2 RATIONALE

Lung cancer is the single largest cause of cancer death in the UK (8). Stage at diagnosis of lung cancer is strongly associated with survival. Unfortunately a large proportion present in late stage disease. In the most recent lung cancer audit, 73% of patients in England and Wales had stage 3 or 4 disease on diagnosis (9).

Haemoptysis, the symptom which is most easily recognisable for clinicians as well as the most strongly predictive of the disease, is present in only about a fifth of cases (10, 11). The non-specific nature of many presentations of lung cancer is reflected in NICE recommendation to consider chest x-ray in smokers who attend with a variety of presentations including appetite loss, fatigue and thrombocytosis(3).

While the associations between chest x-ray, early diagnosis and survival appear to be complex there is some evidence that those who attend their general practitioner and are not investigated with chest x-ray have the worst outcomes(12). Encouraging GPs to consider chest x-ray has however been promoted as a useful measure to improve the chances of early diagnosis(13), informed by analysis of significant event audits(14). However, patients who are later diagnosed with lung cancer have usually presented to their GP on a number of occasions before referral(15) suggesting there may be an opportunity to shorten the primary care interval.

Despite the advantages of being a widely available, low cost and low risk investigation, chest x-ray has significantly lower sensitivity for lung cancer than CT. Therefore a negative or indeterminate result on chest x-ray connotes only limited reassurance. Access to urgent CT from primary care, and uptake where it is available, is probably low(5). Meanwhile, the stated referral criteria for the 'two week wait' referral pathway for suspected cancer, is limited to either an abnormal chest x-ray or smokers aged over 40 years with haemoptysis.

If direct access CT (DACT) has a role in reducing the diagnostic interval for lung cancer then it will be crucial to overcome barriers to uptake. In non-cancer contexts such as infertility and musculoskeletal investigations GPs have cited concerns about taking on the additional responsibility of organising and acting on the results of DA tests. Other concerns have been raised about overwhelming the capacity of secondary care radiology services while driving over investigation and over diagnosis without any justifiable patient or survival benefits(16). Perhaps direct access also runs contrary to traditional strategy of using the 'test of time' in General Practice consultations (17).

3 THEORETICAL FRAMEWORK

This research addresses two broad subject areas. The first of these is focused around diagnostic decision making and the second is about the acceptability of direct access CT (DACT) to GPs in the diagnosis of lung cancer. Two theoretical frameworks will therefore be used.

In his 'illness representations' framework, Leventhal proposed that the ways in which illness is represented by the individual determine how the illness is appraised and what action is taken in response to the illness. This cognitive process is influenced by factors such as the patient's previous experiences of illness and knowledge and beliefs. Meanwhile, in parallel to this cognitive appraisal, Leventhal proposed that patients process an emotional response (18). In the case of a patient suspecting that their symptoms represent a serious illness such as cancer, the cognitive and emotional aspects may be experienced together, sometimes 'hot cognition'. While the framework is orientated to the patients' perspective we believe this is a useful model to explore clinicians' diagnostic intuition and decisions.

A theoretical framework has been proposed by Sekhon et al for the understanding of the 'acceptability' of healthcare interventions (19). This framework will be used to support the component of this research which explores the acceptability of direct access CT for the investigation of lung cancer. The framework defines acceptability as "a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or

experiential cognitive and emotional responses to the intervention". The framework comprises seven component constructs:

- affective attitude-how an individual feels about the intervention
- burden
- ethicality-the extent to which the intervention has good fit with an individual's value system
- intervention coherence-the extent to which the participant understands the intervention
- opportunity costs
- perceived effectiveness
- self-efficacy –the participant's confidence that they can perform the behaviour(s) required to participate in the intervention.

Figure 1 Theoretical framework of acceptability by Sekhon et al

The theoretical frameworks have been used to inform the writing of the topic guide. This is outlined in appendix 2.

4 AIMS

To understand the factors which cause GPs to recognise the possibility of lung cancer and how GPs approach investigation for possible lung cancer.

4.1 Objectives

- 1) To understand the symptom related and patient related factors which influence GPs' consideration of investigation for lung cancer
- 2) To understand when GPs consider imaging or repeat imaging with chest x-ray or direct access CT
- 3) To explore to what factors influence GPs decisions to refer urgently under two week wait pathways in the absence of definitive chest x-ray findings
- 4) To understand if and under what circumstances GP consider urgent referral when NICE criteria for two week wait referral are not met

- 5) To determine the acceptability of direct access to urgent CT and to explore if acceptability can be improved by through additional measures or support
- 6) To understand if GPs believe that their readiness to initiate urgent investigation with CT would be (or is, if direct access is already available) greater than initiating a 'two week wait' referral

4.2 Outcome

The research will aim to achieve greater understanding of the factors which contribute GPs suspecting lung cancer in their patients and how decisions are subsequently made about investigation. In most parts of the UK chest x-ray is the first line investigation for lung cancer available from primary care, but it has been suggested that giving GPs direct access to CT could be effective in expediting lung cancer diagnoses. Where direct access to CT thorax is available uptake is probably low (5). This second part of this research will explore GPs attitudes to the acceptability of direct access CT including any concerns GPs have which could inhibit uptake of direct access CT.

5 RESEARCH DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

5.1 Research design

This qualitative research, will be based around semi-structured interviews with GPs who have referred patients for investigation for lung cancer.

5.2 Data Collection

Interviews will be conducted by the chief investigator (SB). The interviews will be recorded on an encrypted recording device. Interviews will be arranged at the convenience of the participant. The interviews will be in person or over the phone, depending on the location of the participant and their preference. It is anticipated that most interviews will be conducted over phone to facilitate participation of GPs from widespread locations. Whilst this has some disadvantages in terms of developing rapport between interviewer and participant the importance of representing diverse perspectives outweighs this disadvantage. In addition, telephone interviewing may help ensure that a greater proportion of the communication is intelligibly verbalised, and hence recordable compared to face to face interviews which may result in some attrition of data to non-verbal communication.

The interviews will be semi-structured and allow participants the flexibility to discuss their own perspective and experiences but with sufficient structure that the research objectives are satisfied. The interviews will be informed by a topic guide (see appendix 1) which will be used by the interviewer. The interviewer's use of the topic guides will be at the judgement of the interviewer, so that for example, questions do not need to be asked where the participant has already given a pertinent explanation in response to another question. The topic guides may be adapted during the research following the experience of using them in interviews in order to optimise their effectiveness in eliciting high quality responses. If significant amendments are made to the topic guide then it will be resubmitted to for ethical approval before these changes are instituted.

Immediately after interviews are completed they will be transferred onto the secure personal network storage of the chief investigator and summary and reflective notes will be made. Audio recordings will be transcribed verbatim. Participants will be given a numeric identifier and all information which could be used to identify individuals will be removed.

A separate log will hold the participant number, gender, year of qualification as a GP and socio-economic deprivation category (low, medium & high) of place of work of each participant. All data will be retained on password protected personal University server space of the chief investigator.

The chief investigator will introduce himself as a 'GP and health researcher'. If further enquires are made as to the chief investigators professional background there the chief investigator will elaborate that he is 'a GP who is doing a PhD on lung cancer diagnosis. It is likely that interviewees will already know or perceive that the chief investigator has a clinical background and we wish to avoid any perception that the chief investigator is being less than transparent. However we acknowledge that this could promote the use of short hand or condensed explanations, based on an assumed shared understanding of practice between clinicians or that participants may feel that their answers are being judged or scrutinised by a clinical colleague. In order to mitigate this the chief investigator will ask that answers are explicit with reasoning explained 'as it to a lay person'. If necessary the chief investigator will ask to interviewees to clarify points, even if he may be able to assume the meaning or underlying suggestions.

5.3 Data Analysis

A thematic approach will be used for data analysis. This approach has the advantage that biases and values of the team are explicitly acknowledged. Thematic analysis is a highly flexible approach and is particularly well suited to the research of participants' subjectivity and emphasises the role of participants' feelings and experiences. Thematic analysis is also described as not being firmly connected to other theoretical frameworks which makes it suitable to use for data which has been gathered using two theoretical frameworks, as in this research.

Themes will be identified from the data and codes will be generated through analysis of the data. Braun and Clarke have proposed a 'step-by-step' approach to thematic analysis with six stages(20). This six stage approach will be followed in conducting this research. The six stages are as follows:

- 1) Familiarising yourself with the data: Reading & re-reading the data, noting down initial ideas
- 2) Generating initial codes: Coding interesting features in a systematic fashion, collating data relevant to each code.
- 3) Searching for themes: Collating codes into potential themes, gathering all data relevant to each potential theme
- 4) Reviewing themes: Checking if the themes work in relation to the coded extracts and the entire data set, generating a thematic 'map' of the analysis
- 5) Defining and naming themes: Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme
- 6) Producing the report: The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the question and literature, producing a scholarly report of the analysis

The analysis will be conducted primarily by the chief investigator, but will be supported by Professor Richard Neal, who is a supervisor on the research. A comprehensive system of 'double coding' will not be practicable for this research, however Stephen Bradley will outline his coding decisions to Professor Neal and/or Alice Foster, with reference to transcripts of the text in order to ensure that such decisions are reasonable.

5.4 Reflective Practice

In order to facilitate both the development of the chief investigator (SB) as an independent practitioner and to ensure that the quality of interview conduct is optimised, some of the recorded interviews will be listened to by a peer (staff member at University of Leeds) who will offer feedback. Brief notes of

this feedback will be maintained and used to inform the conduct of subsequent interviews. SB will also reflect on the quality of the interviews and will pay particular attention to any evidence of bias or unwarranted 'leading' of participants, and if present whether such limitations need be considered in the data analysis and in SB's thesis write up.

6. RESEARCH SETTING

Interviews will occur over the phone either whilst participants are in their places of work (typically General Practice surgeries or possibly other settings such as the offices of Clinical Commissioning Groups if participants have other non-clinical roles) or in their homes. The chief investigator will conduct the phone calls from an office in the University of Leeds, Worsley Building. The dates and times for these interviews will be dictated mainly by the preference of the participants in recognition of the limited time in which the participants, as busy clinicians are likely to have to participate in the research. No interviews will be conducted in a public space, such as a café or lobby, even if this is stated as the preferred location by the participant. No special requirements or site specific requirements are anticipated as necessary for the research.

The research is based in a single centre (University of Leeds).

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

The research population will be GPs who are currently working in England..

7.1.1 Inclusion criteria

Participants must be working as GPs in England for at least one day per week (two sessions) in order to be eligible for the research.

7.1.2 Exclusion criteria

There are no exclusion criteria, other than those who are not currently employed as GPs or who work outside of England. Trainee GPs will also be excluded.

7.2 Sampling

7.2.1 Size of sample and data saturation

We will aim to recruit approximately 15 participants for this research. We anticipate that this sample size will be sufficient to generate enough data to fulfil the aims of the research. Preliminary analysis of data will be conducted following each interview and if data saturation is found to have occurred before 15 participants have been interviewed the research may be conclude with less than 15 interviews. Similarly, if data saturation is found not to have occurred following 15 interviews we may consider interviewing a small number of further participants.

The model of data saturation used will correspond to that described in a recent review article as 'data saturation', in which saturation is judged to have occurred when new acquisition of new data leads to repetition of themes or codes without any significant new themes or codes emerging(21) . Data saturation will be judged to have occurred by consensus of Stephen Bradley and one of Richard Neal and/or Alice Forster. The team consider that determining when saturation has occurred can not be determined entirely objectively and requires an element of judgement from the study team. We consider that regarding saturation to be a point that has been definitively reached is somewhat artificial, but instead recognise that although it may be possible for new themes or codes to emerge from further data, it will be necessary to make a judgement of when further data collection will deliver ever 'diminishing returns' and is not justified(22).

During assessment for saturation we will use stratification, so that if new data is being generated from particular subgroups (e.g. GPs who work in practices with a greater proportion of patients over age 65) we will attempt to recruit more GPs from such subgroups and stop recruiting others.

7.2.2 Sampling technique

Purposive sampling will be used. We will aim to include at least two participants from practices based in areas where there are low, medium and high levels of socio economic deprivation, as this is likely to reflect incidence of lung cancer. The level of socio-economic deprivation will be determined using the National General Practice Profiles available through Public Health England's website. We will also attempt to represent practice populations with a spread of age groups. The median age in the UK is 40(24), however as lung cancer is much more common in older age groups we will attempt to recruit at least 3 GPs who work in practices in which over 25% of patients are over 65 years old. This data will be obtained from information published online by Public Health England(23). In addition we will aim to recruit at least two participants who work in an area in which there is access to Direct Access CT (which we will define as the capacity of a GP to request a CT for the purposes of excluding lung cancer, which will be performed within 4 weeks and which can be requested by means of regular radiology requesting systems, e.g. without having to discuss the request with a radiologist).

Identification:

General Practices will be identified which serve a variety of areas with differing levels of socio economic deprivation, varying ages of patients and to include some practices where direct access to urgent computed tomography is available to GPs. A list of practices to be contacted will be generated by the study team. This list will be generated with reference to the National General Practice Profiles available through Public Health England (23).

Approach:

West Yorkshire Research and Development will approach the practices on the list on behalf of the study team, by sending the practices an email. This will contain an invitation to email SB to receive a participant information leaflet (PIL) and a request that the email be forwarded on to other people

Recruitment:

The PIL will advise GPs who wish to take part to email SB. We will select participants based on the purposive criteria set out above, in terms of practice location but we will also aim to target GPs with a variety of experience, for example (at least one GP with <10 years, 10-20 years & > 20 years experience as fully qualified GPs).

7.3 Sampling Frame & Recruitment

We will leverage the professional contacts of the research team to identify at least 25 potential participants. However this convenience sampling technique will be informed by purposive sampling in order to preferentially select GPs to provide a sample which includes participants who work in low, medium and high levels of socio-economic deprivation and also to include GPs who have <10 years, 10-20 years and >20 years professional experience following completion of training. We will use socioeconomic deprivation of participants' practices, as documented on Public Health England's website(25) to influence whom we select for the research as we wish to recruit GPs who have a variety of experience in diagnosing lung cancer and socio-economic deprivation is known to influence lung cancer incidence (26).

An honorarium will be paid to participating GPs or to their practices. We estimate that our invitations to General Practices to participate will yield 5 participant for every 100 invitations sent (5%). Therefore in order to recruit 15 GPs we will need to contact 300 practices. If recruitment through this method results in less than 15 participants then we will use the professional networks of the research team in order to invite potential participants directly.

7.3.1 Sample identification

Potential participants will be contacted by email through 'gatekeepers' which will include the National Institute of Health Research's Clinical Research Network, the Royal College of General Practitioners and the Leeds Institute of Health Research's mailing lists. This email will include brief details of the project and an invitation to contact Stephen Bradley by email to receive the participant information leaflet (PIL). Upon reading the PIL, potential participants will be entitled to email Stephen Bradley if they wish to participate to indicate they wish to take part in the study.

7.3.2 Consent

All participants contacted for participation in this research will be sent a PIL which will be attached to the email inviting them to take part in the research. The participant will be asked in the email, if they wish to take part in the research having read the PIL to reply to the chief investigator (SB) to arrange a time in which they can be contacted by phone to obtain informed consent and to conduct the interview.

Consent will be taken at the start of the interview, in accordance with the University of Leeds' 'verbal informed consent protocol'. The justification for obtaining verbal consent is that it is thought that requiring participants to fill in a form and return by email would be a significant barrier to participation.

. The interviewer will assess the participant's ability to consent for participation. It is anticipated that all participants, as practicing clinicians will have the capacity to consent and will readily understand the principles of consent.

The investigator will ask the participant to confirm that they have read the PIL. The consent form (see appendix 4), which contains a summary of the purpose of the research and the interview will be presented to the participant to read and complete, if they wish to proceed. If the consent process and interview is being undertaken over the phone then the investigator will read this out to the participant and ask the participant to indicate if they assent to each statement in the consent form and record these positive responses along with confirmation that the participant has read the information leaflet.

The participant will be asked if they wish to ask any questions before the interview takes place, which the investigator will answer. The participant will also be informed that they will have the right to withdraw their consent, however that once thematic analysis has begun, that it may not be possible to withdraw their individual data from the research. It will not be possible to give an accurate estimate when such a

point will be reached, but they will be advised it is likely to be a number of weeks or months following participation. Therefore if the participant wishes to, they will be able to withdraw their consent within one week of the interview having taken place. After one week they will not be able to withdraw their consent.

Participants will also be informed during the consent process that that should any disclosures be made which necessitate action, for example safeguarding of patients, then this will be raised with research supervisors and further actions may follow.

If the participant is not satisfied to give their consent then the investigator will thank the participant for their time and the interview will not proceed.

8 ETHICAL AND REGULATORY COMPLIANCE

Ethical approval will be sought through the University of Leeds Medical School's Research Ethics Committee (SoMREC).

No significant ethical considerations, which are specific to this topic or methodology are anticipated. Participants will be enrolled only following confirmation of informed consent. The investigators who conduct interviews will do so with respect and will behave in a manner in which upholds the dignity of all participants. This will include accommodating reasonable requests, which are not precluded by the protocol, giving the participants the time to answer questions adequately and ensuring that participants understand the questions they are being asked.

While GPs are required to reflect on their professional practice and are likely to be familiar with recalling and sharing aspects of their practice in which outcomes have been unexpected or

Risks and benefits of participating in the research will be summarised in the participant information leaflet. Benefits include the ability to cite participation as evidence of supporting service improvement in the participants' appraisal portfolios. The main cost perceived from participation is likely to be the time required to conduct the interview.

8.1 Assessment and management of risk

8.1.1 Assessment of risk

No specific risks have been identified with this research, aside from those that might be incurred in routine office environments or in travelling to and from where interviews will take place, in the case of face-to-face interviews. When the chief investigator is leaving his place of work (Rm 10.39 Worsley building) in order to conduct an interview he will inform a colleague that he is going and when he is expected to return. Interviews are expected to be conducted during office hours.

8.1.2 Safeguarding disclosures

This research will ask participants to reflect in general terms on their experience of investigating possible symptoms of lung cancer, it is not anticipated that information will be disclosed regarding specific identifiable patients or information which raises a concern regarding standards of clinical care or of safeguarding or the safety, either of the participant or of their patients or others. However should any disclosures be made which necessitate action, for example a safeguarding concern, then the matter will be raised at the next opportunity (if possible on the same day) with member(s) of the research supervision team who are based at the host institution (University of Leeds). These individuals will be any or all of the following: Professor Richard Neal, ***** & *****. In the case

of such a disclosure being shared with members of the research team, there will be an expectation that a decision is made on what, if any, action should follow and efforts should be made to ensure that the investigator who raised the concern is satisfied that such a decision is appropriate.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

8.2.1 Regulatory review and compliance

Reference to the HRA decision tool, 'do I need NHS REC approval?' has suggested that this project does not require NHR REC approval. This is because the research will not involve any patients and will be conducted with staff only. Ethical approval will be sought from University of Leeds SoMREC.

All correspondence from SoMREC will be maintained.

Before enrolling any participants the chief investigator will ensure that all appropriate approvals which are required in order for participants to be enrolled, are in place. This may require the primary care research and development body in each area to be informed.

8.2.2 Amendments

Any amendments to the research will be made following the approval of the sponsor and resubmission to University of Leeds SoMREC. University of Leeds SoMREC has a specific form for submitting amendments and this will be used if any amendments are made following an initial favourable opinion. If amendments are requested after the research has begun, no subsequent participants will be enrolled until the outcome of the amendment submission has been determined.

8.3 Peer review

8.4 Patient & Public Involvement

The chief investigator's PhD supervisory team, who are overseeing the conduct of this research, includes a patient and public representative *****.

*****s participation in the research is on the basis of the terms (including remuneration) outlined by INVOLVE (www.invo.org.uk).

8.5 Protocol compliance

The research will be overseen by the chief investigator's (SB) PhD supervision team. SB has monthly supervision meetings where he will present the progress of the research. Any known significant deviation, accidental or otherwise, from the research protocol will be presented at that meeting. The deviation will be documented in the meeting minutes along with any actions arising. Should actions arising include notification of the sponsor and/or ethics committee this will be undertaken by the chief investigator. If a

deviation arises which the chief investigator feels requires redress immediately then he will have recourse to consult with his supervisors based at the University of Leeds, including any or all of Prof Richard Neal, ***** and *****. If a significant deviation occurs that may reasonably be thought to undermine the analysis or interpretation then this will be acknowledged in any written outputs.

8.6 Data protection and patient confidentiality

8.6.1 Data protection

All data will be collected, stored and processed in accordance with the Data Protection Act and General Data Protection Regulation 2018. Informed consent will be obtained from all participants for all aspects of the research. Personally identifiable data (i.e. name and place of work) will be retained on a secure computer system (personal login of staff member, University of Leeds). After transcription of interview data, the name of the interviewee will not be associated with data but will be replaced with a numeric identifier. A separate log will hold the participant number, year of qualification as a GP and socio-economic deprivation category (low, medium & high) of place of work of each category. No other personal data will be retained.

Participants will be free to withdraw consent up to one week after the interview taking place. Where consent is withdrawn, all participant identifiable information held by the research team will be destroyed, and the participant will not receive any further contact regarding the research.

7.2 Data anonymisation

Interviewees will be given a numeric so that they remain non-identifiable in the reporting of the qualitative data. A separate log will hold the participant number, gender, year of qualification as a GP and socio-economic deprivation category (low, medium & high) of place of work of each category. No other personal data will be retained. If any third parties are named in the transcripts these will be redacted. If any personal details of the individual are mentioned, for example naming their place of work, these will be redacted or will not be included in any published extracts of the transcripts.

7.3 Data Storage

Encrypted voice recorders will be used for the interviews. Audio data will be downloaded and kept on secure servers at the University of Leeds until transcription is completed and any peer review of interviews for reflective practice. Thereafter the transcripts will be anonymised with identification through a numeric identifier. Any audio files sent to professional third parties for transcription will be anonymously labelled with their participant code, and encrypted for transfer. Following transcription the audio files will be deleted. All physical data such as consent forms, interview notes, and transcripts of interviews will be scanned and saved on the secure server space (M: drive) of the chief investigator at the University of Leeds, with the originals destroyed.

All personal data (names and places of work of participants) will be securely destroyed within 12 months after the end of the research, following corrections to any publications.

Following completion of the research, the anonymised transcripts will be deposited to the University of Leeds data repository. Data will be retained for 3 years following the completion of the research in the repository, after 3 years the data will be destroyed. Only the chief investigator (SB) will have access to the transcripts on the data repository, although SB may consider requests to share the data with other researchers who request access to the data.

The data custodian will be the chief investigator (SB).

8.7 Insurance

Confirmation will be made prior to starting the research that arrangements are in place for insurance and/or indemnity by the University of Leeds to meet the potential legal liability of the sponsor for harm to participants arising from the management, design or conduct of the research.

NHS indemnity scheme will apply for insurance and/or indemnity to meet the potential legal liability of the investigator arising from harm to participants in the conduct of the research at NHS sites.

There are no arrangements in place for payment of compensation in the event of harm to the research participants where no legal liability arises.

8.8 Access to the final research dataset

Access to the research dataset will be restricted to the chief investigator (SB) and the supervisory team.

9 DISSEMINATION POLICY

9.1 Dissemination policy

The chief investigator and the supervisory team will seek to publish a manuscript based on the findings of the research. The findings will also inform a chapter of Dr Bradley's PhD thesis. In addition the findings may be submitted to conferences.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Criteria for authorship of any manuscripts will be based on the International Committee of Medical Journal Editors authorship criteria.

11. APPENDICIES

11.1 Appendix 1- Topic Guide

Factors that influence GPs' decisions to request imaging for lung cancer: Topic Guide

Aims and objectives

This research will address explore the factors which cause GPs to recognise the possibility of lung cancer and how GPs then approach investigation for possible lung cancer.

Objectives:

- To understand the symptom and patient related factors which influence GPs' to consider the possibility of serious lung pathology
- To understand when GPs consider imaging or repeat imaging with chest x-ray or direct access CT
- To explore to what factors influence GPs decisions to refer urgently under two week wait pathways in the absence of definitive chest x-ray findings
- to understand if and under what circumstances GP consider urgent referral when NICE criteria for two week wait referral are not met
- To determine the acceptability of direct access to urgent CT and to explore if acceptability can be improved by through additional measures or support

1. Introduction (3 minutes)

Introduce the research and set the context for the proceeding discussion

- Introduce self ('GP and health researcher')
- Introduce the research: who is it for, who is it funded by and what is it about
- Talk through key points:
 - o Purpose and length of interview
 - o Voluntary nature of participation and right to withdraw
 - o No right or wrong answer – interview will be like a conversation, but mainly interviewee speaking
 - o Audio-recording
 - o Although interviewer is a GP, please speak as if talking to 'lay colleague' without any shared understanding of primary care and explain explicitly, so that someone without experience as a GP could easily understand
- Confidentiality, data security, how findings will be reported, disclosure.
- Any questions

2. Background and experience (3 minutes)

Establish details of professional experience and context of practice.

- Open question e.g. 'can you tell me a little about yourself as a GP?'
- How many years experience do you have as a qualified GP?
- Would you describe your practice location as urban, suburban or rural?
- What would you consider the level of smoking rates and socio-economic deprivation in your practice to be (e.g. low, medium or high)?

3. Factors that influence consideration of imaging (5 minutes)

What factors might make you consider serious lung pathology during a consultation other than the symptoms for which NICE recommends a two week wait referral?

- Are there other symptoms that you would consider as reason to suspect lung cancer?
- Are there co-morbidities and/or other risk factors that would make you think of lung cancer?
- Is there anything about the type of patient (e.g. socio-economic status) that might make you consider lung cancer?
- Are there co-morbidities that would incline you to attribute the symptoms to already diagnosed illness rather than a new diagnosis of lung cancer?
- If there hadn't been a recent 'normal' chest x-ray result, would that make you think about cancer as a possibility? If so, how recent is recent enough?

4. Facilitators for requesting chest x-ray (5 minutes)

What factors would make you more likely to organise a chest x-ray, other than the symptoms for which NICE recommends a two week wait referral?

- When would you image for suspected pneumonia?
- Other symptoms?
- co-morbidities & risk factors?
- type of patient (e.g. socio-economic status)?
- absence of recent 'normal' chest x-ray result? How recent?
- might you organise a chest x-ray partly as a way to communicate risk to the patient and help motivate them to stop smoking?

5. Barriers for requesting chest x-ray (5 minutes)

What factors would make you less likely to organise a chest x-ray?

- Worry about radiation?
- Concern about resource implications? (e.g. cost and access for radiology?)
- Concern about provoking patient anxiety?
- Are there co-morbidities which might dissuade you from requesting a chest x-ray?
- sense of fatalism and futility of early diagnosis in patient or GP
- uncertainty that particular patients would attend?
- insufficient risk (if so, then below what % threshold is risk too low to investigate with chest x-ray?)
- Influences of culture/community/background/upbringing/values
- recent unremarkable chest x-ray (how recent?)

6. 2 week wait criteria (5 minutes)

- Do you know are there any symptoms that meet the criteria for referral for 2ww even without having had a chest x-ray?
- Do you refer for a two week appointment without first arranging for a chest x-ray? Can you explain what strategy you tend to use (for example see patient with results of chest x-ray first or arrange 2ww at same time as requesting the chest x-ray etc).
- If the patient does meet the criteria for 2ww and you have said that you would request a chest x-ray before 2ww referral can you explain why you do this?

Factors that influence GPs' decisions to request imaging for lung cancer

- Are there circumstances under which you would refer under two week wait, even in cases in which it wouldn't meet the criteria? Please explain (e.g. gut feeling, risk factors, length of symptoms etc)
- Have you heard of the multidisciplinary diagnostic centres? Do you have access to an MDC? Would you use it under these circumstances?

7. Unremarkable chest x-ray (5 minutes)

What do you do when you have organised a chest x-ray because you were worried about the possibility of lung cancer in someone who doesn't meet NICE criteria and the result is unremarkable?

- How reassured are you?
- Would you repeat the chest x-ray? If so, then at what interval? If not, why not? How many times would you repeat the chest x-ray?
- Would you organise a CT? if not, why not?
- Would you give your patient safety netting advice? Can you explain how you do this? Would you make any formal plan to follow them up?

8. Direct Access CT (5 minutes)

Can you easily request a CT scan that will occur within two weeks because of suspicion of lung cancer (direct access CT)?

If no then answer hypothetically

- Have you (would you) use(d) this? If not, then why not?
- How do you (would you) feel about having access to DACT?
- Do you use (would you) direct access CT for patients whom you would not refer under two week wait because they do not criteria for referral?
- Do you think it would be an effective way to diagnose lung cancer? Would it be 'better' than chest x-ray?
- Should GPs have access to DACT? If so, why? If not, why not?

9. Direct Access CT barriers & enablers (8 minutes)

Are there any factors that would make you reluctant to use direct access CT to investigate possible lung cancer?

- Are you concerned about over-diagnosis?
- Would you feel confident in handling the results?
- Would you worry about taking responsibility for test results?
- Would the radiation exposure to your patients discourage you from requesting DACT? If so, would the prospect of 'low dose CT' (equivalent to about 12 chest x-rays) make this more acceptable?
- if yes are there measures that would help overcome reluctance (education/email or phone support/ low radiation dose CT)

10. Next steps (3 minutes)

Thank you and any questions or anything else you would like to say?

11.2 Appendix 2- Theoretic basis of topic guide

Theoretical basis of Topic Guide

This research examines aspects of diagnostic decision making and considers how acceptable direct access CT (DACT) would be to GPs in the diagnosis of lung cancer.

This appendix will outline the ways in the theoretical frameworks of Leventhal et al. and Sekhon et al. have informed the design of the topic guide and the aspects of this research which required omissions or deviations from those theoretical frameworks. In particular, both frameworks are orientated towards patients, whereas this research examines the role of the GP.

Diagnostic decision making (Leventhal)

Sections 3-6 of the topic guide examine GPs approach to diagnosis of lung cancer. Leventhal's 'illness representations' frame work has been used to inform these sections of the topic guide. Leventhal described how illness representations can be shaped by both conceptual knowledge and experience.

The questions in sections 3-6 have been written to draw out both GPs conceptual knowledge and how this influences their clinician practice. For example, section 3 asks GPs about the factors that might make them consider the possibility of lung cancer. This includes prompts which are predominantly related to GPs' knowledge, however some prompts such as the 'type of patient' might draw in elements of GPs experience.

The research team were also interested in practical aspects around arranging chest x-ray, such as when GPs would consider arranging repeated imaging (section 6), which were included in the topic guide despite not being pertinent to the theoretical framework.

Acceptability of direct access CT (Sekhon)

Sections 7 & 8 of the topic guide are concerned with the acceptability of direct access CT (DACT) to GPs for the investigation of lung cancer. Sekhon's framework of acceptability of healthcare interventions was used to inform these sections. Most of the participants are likely to not have experience of DACT, however even where they do not have direct experience of requesting the test it is expected that they will have a good understanding of what it entails and will be able to comment on all seven components of the framework (affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self efficacy) prospectively, concurrently and retrospectively. As it is not the GPs themselves who undergo the test it was deemed appropriate to omit discussions of concurrent acceptability so this has been omitted from the topic guide.

Section 7 of the topic guide is designed to obtain insight into the participant's 'affective attitude', 'perceived effectiveness' and 'ethicality' towards the intervention by facilitating general comments, with prompts such as 'how would you feel about having access to DACT' and 'should GPs have access to DACT?'. Section 8 references the 'burden', 'opportunity costs' and 'self-efficacy' of DACT with

prompts around factors which might discourage them from using the intervention such as over-diagnosis, exposure to radiation and confidence in handling the results.

Though no questions are contained in the topic guide to assess 'intervention coherence', it is believed that participants will understand broadly how the intervention works and also that elements of this domain are likely to be referenced in participants responses to the general questions in section 7.

If GPs already do have access to DACT they will be able to draw on their experience to comment on aspects pertinent to retrospective acceptability (which includes opportunity costs, perceived effectiveness and self-efficacy) in section 8.

The GP is not the individual who 'participates' in the intervention, therefore the concurrent acceptability is not relevant and this will not be included.

11.3 Appendix 3- Email to potential participants

Dear GP,

Researchers in Leeds are investigating the factors that influence GPs' decisions to request imaging such as chest x-ray, for suspected lung cancer.

If you are a post CCT GP based in England, who works at least two sessions per week and could spare up to 50 minutes to be interviewed on the phone then email the project's chief investigator, Stephen Bradley medsbra@leeds.ac.uk to find out more about the project.

If you know of other GPs who may be interested in taking part in this study, please forward on this email.

11.4 Appendix 4- Participant Information sheet

What factors influence GPs' decision to request thoracic imaging? Participant Information Sheet

We are writing to invite you to take part in research. Please read the following information to decide whether you would like to take part.

Who is doing the research?

The chief investigator is Stephen Bradley, a GP and Clinical Research Fellow at the University of Leeds. This research is being undertaken as part of Dr Bradley's PhD thesis, 'the role of imaging in the diagnosis of lung cancer in primary care'. Dr Bradley is being supervised for the this research by Prof Richard Neal, Dr Alice Forster (University College London) and ***** (patient and public representative). The study is funded through *****.

What is the research about?

This research is trying to explore how GPs make decisions about how and when to investigate for suspected lung cancer.

Aim: To understand the factors which cause GPs to recognise the possibility of lung cancer and how GPs approach investigation for possible lung cancer.

Objectives:

- 1) To understand the symptom related and patient related factors which influence GPs' consideration of investigation for lung cancer
- 2) To understand when GPs consider imaging or repeat imaging with chest x-ray or direct access CT
- 3) To explore to what factors influence GPs decisions to refer urgently under two week wait pathways in the absence of definitive chest x-ray findings

- 4) To understand if and under what circumstances GP consider urgent referral in the when NICE criteria for two week wait referral are not met

What does the research involve for me?

Participants in this research will be asked to take part in an interview with Stephen Bradley or another investigator which will last approximately 50 minutes. The interview will take place at a time when both you and the interviewer are free. Interviews will take place over the phone or in person. If you are willing to take part in the research please email the Stephen Bradley (medsbra@leeds.ac.uk) expressing your interest. If you are chosen to be a participant this will be confirmed to you via email and you will be contacted to arrange a time for in which to be contacted or met for your consent to be obtained and the interview to take place.

What will happen to the data?

Each interview will be audio recorded. Immediately after the focus group has finished we will upload the recording to the University of Leeds secure drive, which will only be accessible via the personal log-in details of the investigator. The audio recording will then be deleted from the Dictaphone. We will transcribe the data which will be fully anonymised - participants will not be able to be identified. The anonymised transcribed data will be analysed through the qualitative method thematic analysis. In this process the chief investigator and one or more other investigators will 'code' and arrange parts of the transcripts thematically. Extracts from the transcripts, including anonymised quotations, will be used in Dr Bradley's PhD thesis and in any other outputs such as publications or conference submissions.

How will confidentiality be ensured?

Following the interview the audio recording will be transcribed. The transcript will be associated with a single or double digit number.

Under what circumstances might confidentiality be broken?

We will be asking participants to discuss their practice in general terms and do not anticipate any circumstances under which confidentiality will need to be broken. However if a disclosure is made that raises a safeguarding concern, regarding either the participant or another or other individual(s) then the participant may be obliged to break confidentiality. If such an instance were to arise the investigator would take advice from members of the supervisory team.

Why have you been chosen and do you have to take part?

You have been chosen as you eligible to take part in this research as a practising GP. Participation is entirely voluntary. If you consent to take part but later wish to withdraw your consent, it may not be possible to withdraw your data after one weeks after the interview has taken place.

What are the benefits of taking part?

We hope that this research will contribute to a greater understanding of how GPs make decisions about investigating possible lung cancer. Ultimately we hope that such understanding will facilitate improvement of diagnostic strategies and addressing barriers to appropriate investigation, should they be identified. Participants will be able to reference their participation in the research as evidence of their support for research in their annual appraisal portfolio of evidence. A letter can be supplied to participants as evidence if requested.

What are the disadvantages of taking part?

Taking part in an interview will take approximately 50 minutes

Contacts for further information

If you would like further information or have any questions or problems please contact either Stephen Bradley, medsbra@leeds.ac.uk or Prof Richard Neal R.D.Neal@leeds.ac.uk

Thank you for reading this information sheet, and considering whether to take part in this research. If you are interested please contact the research team via the email address above.

11.4 Appendix 4- Consent Form

Factors that influence GPs' decisions to request imaging for lung cancer

Interviewer name:

Date:

If you are happy to participate please complete and sign the consent form below (in case of phone interviews, interviewer to initial agreement on behalf of participant if verbally communicated)

	Add your initials next to the statement if you agree
I confirm that I have read and understand the information sheet version * dated **/**/19 explaining the above research and I have had the opportunity to ask questions about the research.	
I understand that my participation is voluntary and that I am free to withdraw up to 1 week after the interview without giving any reason and without there being any negative consequences. Any data already collected will be deleted. After 1 week it will not be possible to delete the data collected.	
I agree that the interview can be audio-recorded.	
I agree transcriptions of my interviews and this consent form can be stored securely on University of Leeds computers for 3 years after the research has ended.	
I understand that relevant sections of the data collected during the research may be looked at by individuals from regulatory authorities at the University of Leeds.	
I understand that my responses will be kept strictly confidential. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research.	
I agree to the use of anonymous quotes in research reports.	
I give permission for members of the supervisory team to have access to my anonymised transcripts.	
I agree for the data collected from me to be stored and shared for use in relevant future researches in an anonymised form.	
In the case of safeguarding disclosures confidentiality may be broken	
I agree to take part in the above research	

Name of participant

Date

Signature

Name of person taking consent

Date

Signature

11.5 Appendix 5 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	0.2	04/02/18	SB	Clarification of status of project (research) & correction of incorrect recording of sponsor details
2	0.3	07/02/18	SB	Changes made suggested by ***** peer review, stage 1 (***** & *****)
3	0.4	21/02/19	SB	Change made to how CI introduces self (page 5) and amendments to interview schedule based on PhD supervision meeting
4	0.5	05/03/19	SB	Changes in response to comments from *****. Clarification of data saturation and who will contribute to data analysis.
5	0.6	08/04/19	SB	Changes following discussion with ethics committee senior administrator on 21/3/19 and RN/AF on 8/4/19

References

1. Sheringham J, Sequeira R, Myles J, Hamilton W, McDonnell J, Offman J, et al. Variations in GPs' decisions to investigate suspected lung cancer: a factorial experiment using multimedia vignettes. *BMJ Quality & Safety*. 2017;26(6):449-59.
2. Robinson S. What are the factors influencing GPs in the recognition and referral of suspected lung cancer? : Hull York Medical School; 2016.
3. Nice guideline NG12 2015. Available from: <https://www.nice.org.uk/guidance/ng12>.
4. Rubin GP, Saunders CL, Abel GA, McPhail S, Lyratzopoulos G, Neal RD. Impact of investigations in general practice on timeliness of referral for patients subsequently diagnosed with cancer: analysis of national primary care audit data. *Br J Cancer*. 2015;112(4):676-87.
5. Nicholson BD, Oke JL, Rose PW, Mant D. Variation in Direct Access to Tests to Investigate Cancer: A Survey of English General Practitioners. *PLoS One*. 2016;11(7):e0159725.
6. Guldbrandt LM, Fenger-Grøn M, Folkersen BH, Rasmussen TR, Vedsted P. Reduced specialist time with direct computed tomography for suspected lung cancer in primary care. *Dan Med J*. 2013;60(12):A4738.
7. Guldbrandt LM, Rasmussen RR, Ramussen F, Vedsted P. Implementing direct access to low-dose computed tomography in general practice-method, adaption and outcome. *PLoS One*. 2014;9(11):1-9.
8. Cancer mortality for common cancers: Cancer Research UK; [5th December 2018]. Available from: <https://www.cancerresearchuk.org/health-professional/cancer-statistics/mortality/common-cancers-compared#heading=Zero>.
9. National Lung Cancer Audit Annual report 2017 (for the audit period 2016). London: Royal College of Physicians, January 2018. Report No.
10. Hamilton W, J Peters T, Round A, Sharp D. What are the clinical features of lung cancer before the diagnosis is made? A population based case-control study 2005. 1059-65 p.
11. Walter FM, Rubin G, Bankhead C, Morris HC, Hall N, Mills K, et al. Symptoms and other factors associated with time to diagnosis and stage of lung cancer: a prospective cohort study. *Br J Cancer*. 2015;112:S6.
12. O'Dowd EL, McKeever TM, Baldwin DR, Anwar S, Powell HA, Gibson JE, et al. What characteristics of primary care and patients are associated with early death in patients with lung cancer in the UK? *Thorax*. 2014.
13. Lung cancer campaign: Information for GPs: Cancer Research UK; 2014 [25th September 2018]. Available from: https://www.cancerresearchuk.org/health-professional/early-diagnosis-activities/be-clear-on-cancer/lung-cancer-campaign/information-for-gps#collapseBCOC_lung_info for GPs9.
14. Mitchell E, Macleod U, Rubin G. Cancer in primary care: An analysis of significant event audits (SEA) for cancer diagnosis 2008-2009. National awareness and early diagnosis initiative 2009 July 2009. Report No.
15. Swann R, McPhail S, Witt J, Shand B, Abel GA, Hiom S, et al. Diagnosing cancer in primary care: results from the National Cancer Diagnosis Audit. *Br J Gen Pract*. 2018;68(666):e63-e72.
16. Birchall D. Primary care access to diagnostics: a paradigm shift. *The British Journal of Radiology*. 2010;83(986):101-3.
17. Heneghan C, Glasziou P, Thompson M, Rose P, Balla J, Lasserson D, et al. Diagnostic strategies used in primary care. *BMJ*. 2009;338.
18. Diefenbach MA. Illness Representations: National Cancer Institute; [updated 28th April 2008 6th December 2018]. Available from: https://cancercontrol.cancer.gov/brp/research/constructs/illness_representations.html.
19. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res*. 2017;17(1):88.
20. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*. 2006;3(2):77-101.
21. Saunders B, Sim J, Kingstone T, Baker S, Waterfield J, Bartlam B, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. *Quality & Quantity*. 2018;52(4):1893-907.

22. Mason M. Sample Size and Saturation in PhD Studies Using Qualitative Interviews. *Forum: Qualitative Social Research*. 2010;11(3).
23. National General Practice Profiles Public Health England; [cited 2019 29th January 2019]. Available from: <https://fingertips.phe.org.uk/profile/general-practice/>.
24. Overview of the UK population: February 2016: Office for National Statistics 2016 [updated 26 February 2016; 05 Mar 2019]. Available from: <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/articles/overviewoftheukpopulation/february2016>.
25. National General Practice Profiles: Public Health England; [05 Mar 2019]. Available from: <https://fingertips.phe.org.uk>.
26. Riaz SP, Horton M, Kang J, Mak V, Lüchtenborg M, Møller H. Lung Cancer Incidence and Survival in England: An Analysis by Socioeconomic Deprivation and Urbanization. *J Thorac Oncol*. 2011;6(12):2005-10.