Title	A framework for achieving earlier diagnosis in symptomatic lung					
	cancer					
Authors	Delegates at the 'Early diagnosis in symptomatic lung cancer'					
	workshop event supported by Roy Castle Lung Cancer Foundation,					
	March 2023					
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Purpose	To provide a clinically agreed framework for processes that drive early					
	diagnosis in symptomatic lung cancer. To promote local innovation and					
	pilot work within cancer alliances (collaborating with other alliances					
	where possible), with associated evidence generation/evaluation to					
	support the development of potential new national strategies in this					
	critical area.					
Priority objectives	To develop improved processes that result in earlier diagnosis					
	in symptomatic lung cancer					
	2. To raise awareness of symptoms in communities and					
	individuals to ensure better access to diagnostic tests and					
	assessment					
	3. To equitably and substantially increase the number of					
	diagnostic tests (chest X-ray and CT) in people with symptoms					
	that may represent lung cancer					

Contents

- 1. Attendees at an 'Early diagnosis in symptomatic lung cancer workshop 8-9th March 2023
- 2. Executive summary
- 3. Introduction
 - 3.1. Why early diagnosis in symptomatic lung cancer is so important
 - 3.2. Harnessing the power of chest x-rays in the diagnosis of symptomatic lung cancer
 - 3.3. Increasing referrals for suspected lung cancer following a normal chest x-ray
 - 3.4 The pathway from symptoms to diagnostic test an unmet need
- 4. Achieving our objectives
 - 4.1. Barriers faced by the public
 - 4.2. Barriers within healthcare professionals and the healthcare system
 - 4.3. Solutions to the barriers faced by the public
 - 4.4. Solutions for healthcare professionals and the healthcare system
- 5. Safety netting and the lower risk
- 6. Key recommendations for research, innovation, pilot projects and evaluation

1. Attendees at an 'Early diagnosis in symptomatic lung cancer workshop 8-9th March 2023

A multidisciplinary group of clinical experts in lung cancer, including general practitioners (GPs), patient representatives, respiratory physicians, radiologists, cancer nurse specialists and experts in lung cancer screening, epidemiology, health behaviour science, and health policy met to consider current evidence on the barriers and solutions to improving early diagnosis in symptomatic lung cancer. The workshop achieved clinical consensus across this broad team of experts on the new mechanisms whereby real progress is possible in this challenging area. The meeting was supported by the Roy Castle Lung Cancer Foundation. The authors would like to express their gratitude to the attendees of this workshop as listed below.

Specialty/Expertise	Name Role & Affiliation		
Roy Castle Lung Cancer	Jesme Fox	Medical Director	
Foundation	Jackie Tebbs	Head of Clinical & Research Projects	
	Rachel Avery	Director of Marketing &	
		Communications	
	Susan Mayor	Medical writer commissioned by Roy	
		Castle Lung Cancer Foundation	
Health policy & charity	Mike Richards	Chair, UK National Screening	
sector		Committee	
	Samantha Harrison	Head of Strategic Evidence &	
		International Cancer Benchmarking	
		Partnership Lead, Cancer Research	
		UK	
	Naser Turabi	Director of Evidence and	
		Implementation, Cancer Research UK	
	Sue Maughn	Head of Cancer NHS England London	
		Director of Transformation, Cancer	
		Team	
		London System (TCST)-TPHC	
General Practice	Amelia Randle	GP Clinical Director, Somerset,	
		Wiltshire, Avon & Gloucester Cancer	
		Alliance	
	Katherine Hickman	Chair of Primary Care Respiratory	
		Society & GP Low Moor Medical	
		Practice	
	Sarah Taylor	GP Cancer early diagnosis lead,	
		Greater Manchester Cancer Alliance	
	Judit Konya	Clinical lecturer in general practice,	
		University of Exeter	
	Samuel Merriel	NIHR academic clinical lecturer,	
		University of Manchester	
	Ben Noble	Cancer Research UK GP lead, East	
		Midlands Cancer Alliance	

Specialty/Expertise	Name	Role & Affiliation
General Practice	Stephen Bradley	NIHR academic clinical lecturer, University of Leeds & clinical lead for cancer Leeds office of West Yorkshire Integrated Care Board
Respiratory Medicine and	William Hamilton David Baldwin	University of Exeter Consultant Respiratory Physician,
Respiratory Medicine and lung cancer services	David Baldwill	Nottingham University Hospitals NHS Trust
	Emma O'Dowd	Consultant respiratory physician, Nottingham University Hospitals NHS Trust
	Karen Clayton	Lead Lung Cancer Nurse East Cheshire NHS Trust and chair of Lung Cancer Nursing UK
	Mat Callister	Consultant respiratory physician, Leeds Teaching Hospitals NHS Trust
	Matthew Evison	Consultant chest physician, Manchester University NHS Foundation Trust & director of Greater Manchester lung pathway board
	Martin Ledson	Clinical lead for respiratory medicine, Liverpool Heart and Chest NHS Trust
	Neal Navani	University College London Hospital
	Sinan Eccles	Consultant respiratory physician and Lung Health Check clinical lead, Royal Glamorgan Hospital / Wales Cancer Network
	Richard Lee	Early Diagnosis and Detection Centre, Royal Marsden NHS Foundation Trust
Behavioural and health services research	Georgia Black	Reader in Applied Health Research, Queen Mary University of London
	Sammy Quaife	Reader in Behavioural Science, Queen Mary University of London
Clinical radiology and radiography	Bobby Bhartia	Consultant radiologist, Leeds Teaching Hospital NHS Trust
	Nick Woznitza	Consultant Radiographer & Clinical Academic, UCLH and Canterbury Christ Church University
	Anand Devaraj	Thoracic radiologist, Royal Brompton & Harefield Hospitals
	Fergus Gleeson	Professor of radiology, University of Oxford

Specialty/Expertise	Name	Role & Affiliation
Patient experts by	Janette Rawlinson	NHS England, Roy Castle Lung Cancer
experience		Foundation, British Thoracic Oncology
		Group, European Lung Foundation,
		European Respiratory Society,
		European Organisation for the
		Research and Treatment of Cancer
		EORTC
	Duncan Edmonstone	Chief Executive, ALK Positive Lung
		Cancer (UK)

2. Executive summary

The existing evidence identifies four key objectives for improving early diagnosis of symptomatic lung cancer:

- To develop improved processes that result in earlier diagnosis of symptomatic lung cancer
- To increase awareness of symptoms and motivation for appropriate help-seeking in the general public
- To ensure better access to diagnostic tests and assessment
- To equitably and sustainably increase the number of diagnostic tests (chest X-ray and CT) in people with symptoms that may represent lung cancer

Multiple barriers exist to achieving these objectives both for patients with the common symptoms of lung cancer and the healthcare system. These relate to awareness of symptoms that may indicate lung cancer, lack of prompt and easy access to healthcare assessment and underuse of imaging in those at risk. Specific issues are:

- Lack of awareness about the common symptoms of lung cancer
- Inconsistent understanding by patients and clinicians that patients in apparently low risk groups such as never smokers (where risk if poorly understood), can get lung cancer and constitute a substantial proportion of cases
- Public and patient fears over being dismissed, judged, or criticised for misuse of the healthcare service
- Patient worry that symptoms are not worthy of investigation
- Lack of easy access by patients and carers to healthcare assessment
- Attribution of common symptoms of lung cancer to common respiratory illnesses,
 such as respiratory tract infection
- Lack of primary care access to timely CXR and report

- Variation in the threshold of primary care clinicians to investigate the common symptoms of lung cancer
- o False reassurance following a normal CXR
- Lack of robust safety netting after a normal CXR
- Lack of clear guidance on which patients require further investigation following a normal CXR

Potential solutions to these challenges include:

- Public education & symptom awareness campaigns
- Engagement with primary care clinicians to support timely investigation
- Alternative routes to CXR and/or CT for people with the common symptoms of lung cancer
 - Self-referral CXR
 - Cancer symptom concern hotline
- Training and support for non-medically qualified clinicians in primary care to request
 CXRs
- Publishing CXR rates by GP practice and administrative units (e.g. Primary Care Networks and Integrated Care Systems)
- Digital clinical decision support tools for general practice
- Proactive safety netting systems following a normal CXR (e.g. telephone call, text message or follow up actions guided by clinical algorithms)
- Specific guidance for which patients to refer on the suspected lung cancer pathway or for CT imaging following a normal CXR
- GP direct access to CT for patients with a suspicion of lung cancer following a normal CXR

3. Introduction

3.1. Why early diagnosis in symptomatic lung cancer is so important

Lung cancer is responsible for nearly 2 million deaths worldwide every year, and is the leading cause of cancer death (20% of all cancer-related deaths)¹. In England, only 45% of patients diagnosed with lung cancer survive for more than 1 year after diagnosis^{2,3}. These poor outcomes are due to numerous factors including late and emergency presentations. Unfortunately, 48% of patients are stage IV at presentation and 35% are diagnosed via an emergency presentation to Hospital. Stage at diagnosis is a key determinant of outcome with 57% of patients diagnosed with stage I lung cancer surviving for five years or more compared to 3% of patients with stage IV lung cancer.

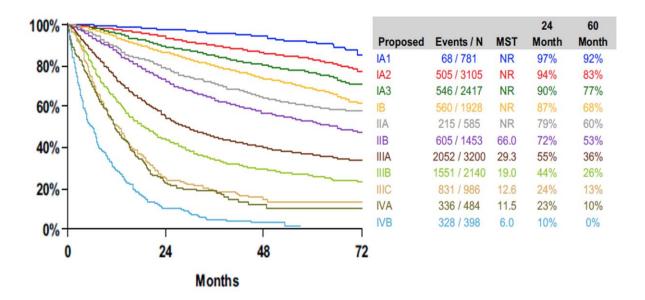
The NHS in England aims to diagnose 75% of cancers at stage 1 or 2 by 2028 (NHS Long Term Plan 2019). Lung cancer is one of our most common cancers with high rates of advanced stage presentation. To support the NHS England objective for early cancer diagnosis, we must make significant improvements in early diagnosis of lung cancer. There are two very different mechanisms by which this is achieved that cover different populations and achieve different outcomes.

- 1. Screening asymptomatic people at higher risk of lung cancer
- 2. Improving the diagnostic pathway for people who have symptoms that could be due to lung cancer

Screening asymptomatic high-risk individuals reduces mortality from lung cancer, the key metric by which screening is measured. There is robust evidence for this from randomised controlled trials, and all-cause mortality is also reduced^{4,5}. It does this by substantially changing the stage at which lung cancer is diagnosed. Around 76% of participants in England's Targeted Lung Health Check programme (a national pilot of targeted screening with low dose computed tomography) were diagnosed at stage I or II compared with only 25% without screening³. We do not know the true impact of a national screening programme on the behaviour of the public and clinicians concerning early diagnosis, but it is likely that screening will result in significant improvements in lung cancer outcomes for the UK as a whole. The more people diagnosed with screen-detected lung cancers, the fewer patients would be expected to present with symptomatic disease in subsequent years. However, screening is unlikely to fully address issues with poor outcomes in lung cancer for two reasons. First, not all people are eligible for targeted screening and not all will choose to participate (Figure 1B)^{6,7}, and second UK and US studies have estimated that as few as one in four people with lung cancer may be diagnosed through a screening programme^{8,9}. This means that the majority of patients with lung cancer will continue to be identified through conventional routes. Improving early diagnosis in symptomatic lung cancer, through substantially increasing radiological investigation of people with the common symptoms of lung cancer, is a pivotal element of the early diagnosis strategy. However, this approach has not received the same strategic focus as screening asymptomatic individuals. Whilst early detection of symptomatic lung cancer is unlikely to yield the same dramatic stage shift seen with participants of a targeted screening programme, the impact on survival that even small changes within staging groups can yield is well described. For example, for a patient diagnosed at stage IIIA rather than IIIB the 5-year survival increases from 26% to 36% (Figure 2)¹⁰. In addition, around 40% of people who have lung cancer are not fit enough for treatment^{3,11}. This is due to both comorbidities and deterioration due to lung cancer, which can be rapid. By

bringing symptomatic diagnosis forward, patients can be diagnosed before they deteriorate and then receive treatment. Dramatically more effective lung cancer treatments have been developed in recent years, so ensuring patients are diagnosed as rapidly as possible in order to benefit from these is crucial¹². Achieving this will maximise the impact of the National Optimal Lung Cancer Pathway. Therefore, any intervention that leads to an earlier diagnosis is likely to yield substantial patient benefits. Early diagnosis in symptomatic lung cancer is widely appreciated in the clinical community as the most important area to focus on to drive improved outcomes. Sustained efforts, including long standing public facing initiatives¹³ and pathway development and evaluation¹⁴, have achieved important progress in diagnosis of symptomatic lung cancer and provide a firm foundation for further improvement. This document provides a framework for how this can be addressed at a local and national level.

Figure 2: Detailed breakdown of stage categories and survival demonstrating that earlier diagnosis has remarkably consistent association with improved survival and that there important differences in outcomes even within stages

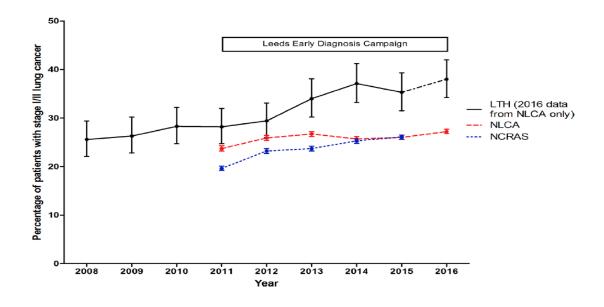


3.2. Chest-rays in the diagnosis of symptomatic lung cancer

Chest x-ray (CXR) is the first imaging test leading to the diagnosis for most people with lung cancer. The sensitivity of the test is approximately 75-80% meaning that up to one in four lung cancers can be missed by CXR¹⁵. However, the prevalence of lung cancer in patients referred for CXR by their primary care team is low (<1%) and the negative predictive value of a normal CXR is very high at 99.7%. This means a normal CXR is reassuring but doesn't entirely exclude lung cancer and risk stratification is required to determine who should have further imaging, commonly a CT.

Pragmatically, CXRs are widely available, low cost to the healthcare service, and can be reported in a tenth of the time taken to report a CT¹⁶. Increasing the number of CXR performed is more achievable within current constraints than a similar increase in CT, which is under extreme pressure for capacity. The diagnostic performance of CXR means approximately 300 CT scans would need to be performed on patients with a normal CXR to detect one missed lung cancer (without risk stratification). The NHS can, therefore, harness the benefits of CXR more effectively by deploying it in more people with common symptoms of lung cancer. This is supported by evidence that suggests that increasing the volume of CXRs performed in patients with the common symptom of lung cancer can lead to a stage shift towards early-stage diagnosis. A symptom awareness campaign in Leeds led to an 81% increase in community CXRs (approximately 15,000 additional CXRs) with a 9% increase in patients diagnosed with stage I/II disease in the period 2008-2015 (approximately 25-50 additional diagnoses of early-stage lung cancer per year)¹⁷. This was associated with a 9% reduction in the absolute number of patients diagnosed with stage III/IV disease. Furthermore, a recent study linked English GP CXR rates (>7000 practices) to cancer registry data for patients diagnosed with lung cancer in 2013-2018 (>160,000 patients)¹⁸. General practices were categorised into quintiles according to adjusted CXR rates (adjusted at practice level for age, smoking rates, ethnicity & deprivation and at patient level for sex, age, ethnicity, Charlson co-morbidity score and deprivation). Results showed that increased CXR rates were associated with earlier detection of lung cancer and improved survival. The odds ratio for diagnosis at stage III/ IV was 0.87 (95% CI 0.83-0.92) for the highest quintile of practices compared to the lowest quintile and the hazard ratio for death within one year was 0.95 (0.90-0.95) and 0.95 (95% confidence intervals 0.91 to 0.99) for five years.

Figure 2: Early-stage lung cancer diagnosis in Leeds during symptom awareness campaign versus national rates



3.3. Increasing referrals for suspected lung cancer following a normal CXR

There is evidence that increasing the number of suspected lung cancer referrals from primary to secondary care is associated with earlier diagnosis and improved survival for lung cancer. A national cohort study of 1.4 million patients demonstrated a reduced risk of death from lung cancer in patients from GP practices with a high referral rate on the suspected cancer pathway (HR 0.95, 95%CI 0.94-0.97)¹⁹. Furthermore, a study from the International Cancer Benchmarking Partnership demonstrated significant variation in primary care physicians' readiness to investigate possible cancer symptoms, including lung cancer, with the lowest investigation rates seen in the UK²⁰. The study also identified an association between a lower threshold for investigation and improved cancer survival (Figure 4).

The National Institute for Health and Care Excellence (NICE) guidelines for the diagnosis and management of lung cancer state that unexplained haemoptysis is the one symptom that is associated with a prevalence of lung cancer high enough to warrant direct referral to secondary care for suspected lung cancer without any initial investigation (therefore implicitly suggesting CT as first test in these individuals)²¹. For all other common symptoms of lung cancer, NICE recommends a CXR which is appropriate given the evidence presented above. Risk stratification has the potential to better select those people who should go directly to CT, have a further CXR or be offered LDCT screening. Safety netting, which may involve CXR or CT is essential for those with unresolving symptoms are referred for further investigation despite a normal CXR.

3.4 The pathway from symptoms to diagnostic test – an unmet need

Whilst national "Be Clear on Cancer" and similar campaigns raise public awareness and lead to increased diagnosis of lung cancer at an early stage, they are intermittent and do not address the need for easy access to healthcare assessment or the need for risk stratification as identified in section 3. Patients commonly experience difficulties arranging an appointment with their GP and this has been more of a problem since Covid 19²²⁻²⁴. Figure 4 shows data from the national cancer rapid registration dataset on routes to diagnosis, with the timing of the recent awareness campaigns. Following the campaigns there was a marked increase in diagnoses through the emergency route but little change in primary care routes. A different system is needed, especially now that primary care is under so much pressure. Aside from addressing the broader workforce and workload pressures experienced by NHS primary care services, a number of specific proposals are discussed here that include self-referral for diagnostic tests, special arrangements for patients to access

primary care, and cancer concern phone lines. The advantage of the latter is they can be directly linked with more personalised awareness campaigns and incorporate risk stratification.

Figure 3: The association between primary care physician willingness to investigate low risk symptoms that could be caused by lung cancer and 1-year lung cancer survival from the International Cancer Benchmarking Partnership Project

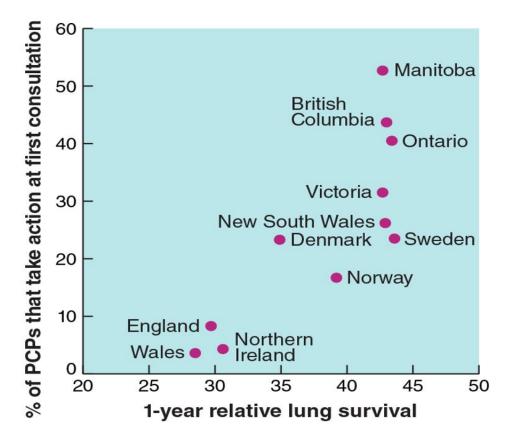
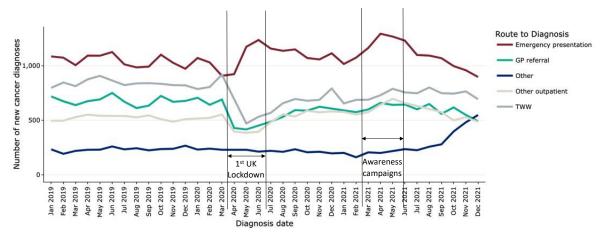


Figure 4: Routes to diagnosis for lung cancer during and after the Covid 19 pandemic. The data show a marked fall in diagnosis during the first national lockdown except for emergency admissions. During the lung cancer awareness campaign the most marked rise in diagnoses was through the emergency route. Data from the Rapid cancer Registration Dataset.



In conclusion, the existing evidence suggests three key objectives for improving early diagnosis of symptomatic lung cancer:

- To develop improved processes that result in earlier diagnosis in symptomatic lung cancer
- To link awareness of symptoms in communities and individuals to systems for better access to diagnostic tests and assessment
- To equitably and substantially increase the number of diagnostic tests (chest X-ray and
 CT) in people with symptoms that may represent lung cancer

4. Achieving our objectives

4.1. Barriers faced by the public

In preparation for launching a new lung cancer symptom awareness campaign, NHS Cancer Alliances in the North of England commissioned public insight work to gain a deeper understanding of the barriers people perceive and experience with the common symptoms of lung cancer²⁵. A consistent theme raised by the participants as a barrier to seeking a medical review was the need to feel validated to do so. The participants stated they would need to feel justified in their reasons for review and would seek a form of permission to do so. A lack of validation and lack of importance placed on the common symptoms of lung cancer is a complex and multi-layered behaviour (Figure 6). Participants reported previous experiences where they felt these symptoms had been discounted and they feared they would be dismissed if seeking medical review with this again. They also thought there were other explanations for a cough, particularly those that could be used as a negative reflection on them, such as smoking tobacco, and that they might be more likely to interpret their own individual risk of a serious cause for their symptoms as low. These reasons were then used as cumulative reasoning to judge these specific symptoms to be of less importance than the priorities of a busy National Health Service (NHS), a feeling that was magnified by the COVID-19 pandemic and the repeated terminology of the 'risk of overwhelming the NHS'. All these factors combined to make the participants feel that persistent non-specific symptoms such as cough, breathlessness, fatigue, and loss of appetite were not worthy of medical review and may result in a lack of action. Participants also reported a very low threshold for giving up on seeking a medical review if logistical barriers were faced. These included difficulty in contacting a GP practice on the phone and if seeking

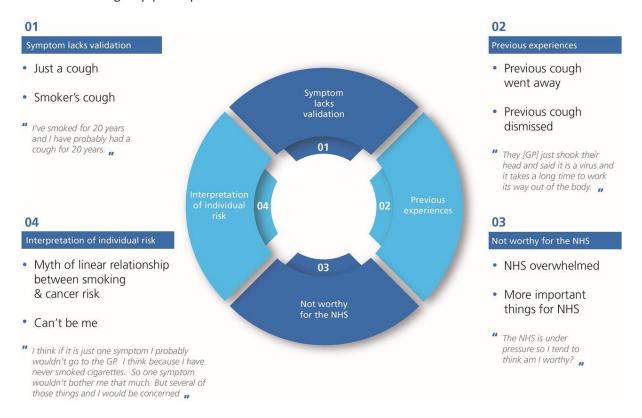
medical review was, in their view, deemed as a time-consuming process when measured against other day-to-day priorities.

The findings from the public insight work described above are supported by numerous other works. Awareness of the common symptoms of lung cancer and the benefits of early detection has generally been low and awareness is lowest in the people most at risk. Recent Cancer Research UK Cancer Awareness Measure (CAM) data show that people can remember on average one symptom, with 38% of people unable to remember any lung cancer symptoms at all ¹⁹. Overall cancer symptom knowledge is lowest among those from lower socioeconomic backgrounds ²⁶. Challenges include the range of symptoms and the vagueness of symptoms/symptoms appearing too trivial to 'bother' the GP, particularly with current pressures on primary care. There is a high level of stigma associated with lung cancer, which hinders help seeking. Lung cancer is not something people want to talk about or are keen to engage with. Those at a higher risk may feel guilt or shame, that there is a powerless 'inevitability' about receiving a diagnosis, or even that it is 'deserved', while those at lower risk do not believe lung cancer is something that will affect them or may not be considered a plausible possibility by clinicians who consult with them..

It has been estimated that up to 10-15% of patients with lung cancer have never smoked²⁷⁻²⁹.

Early detection of lung cancer in patients who have not smoked poses challenges to both GPs and patients in assessing potential risk of lung cancer and making decisions on what investigations to consider. Never smokers experience barriers to investigation compared to those with a smoking history. People who have never smoked are easily reassured by clinicians that their symptoms are not indicative of lung cancer, which lowers their vigilance for persistent or emerging symptoms. A qualitative study of lung cancer patients' experiences found that smoking history was instrumental to how individuals perceived and responded to early symptoms of lung cancer³⁰. Individuals with a smoking history reported seeking help and follow-up urgently, whereas patients who experienced low levels of concern about their risk of lung cancer were more easily reassured by clinicians, resulting in delays. The researchers concluded that interventions such as increasing chest-x-ray utilisation through improved access in symptomatic non-smokers may be effective.

Figure 5: Multi-layered reasoning for the lack of validation placed on common symptoms of lung cancer in focus-group participants



4.2 Barriers within healthcare professionals and the healthcare system

Lung cancer symptoms are exceptionally common in many other conditions. For example, cough is one of the most common reasons for attendances in primary care and the majority will be caused by conditions other than lung cancer. GPs will, therefore, see patients with a cough very commonly but diagnose lung cancer rarely. This challenge in identifying which patients to undertake further investigations in can lead to delayed diagnosis. Approximately 30% of patients with lung cancer complete 3 or more consultations with their GP before they are referred with suspected lung cancer³¹. Whilst it is relatively straightforward for GPs to recognise and take appropriate action for high-risk symptoms (haemoptysis), it is much more difficult for patients with low-risk symptoms, including dyspnoea and persistent cough. Haemoptysis now occurs in less than 5% of lung cancer cases and low-risk and non-specific symptoms are now the most common way the disease presents³². These can lead to variation in the threshold to undertake CXRs in patients with the common symptoms of lung cancer, explaining the variation in the threshold to investigate seen in the ICBP study and the variation in CXR use across GP practices described earlier in this document. In addition, there is a lack of an agreed understanding as to which patients with a normal CXR, but persistent symptoms, require investigation with CT, although NHS England has announced that GPs should have access to the investigation³³ and have issued some guidance to support this³⁴. There is

currently a research call from the National Institute for Health Research investigating using low-dose CT (LDCT) as a first test for people with symptoms that may suggest lung cancer³⁵. Research arising from this call may contribute important information, but could take some years and uncertainties may remain, particularly as the present call is for a feasibility study only. Therefore, it is vital that efforts continue to implement and evaluate methods to symptomatic diagnosis in the meantime.

A recently published study, which found an increase in prescribing of respiratory medications in patients with established COPD five months prior to a diagnosis of lung cancer, indicates that a diagnostic window of appreciable length does exist within primary care during which earlier diagnosis might be achievable³⁶. Presentations of patients who have known respiratory disease with symptoms that overlap those of possible lung cancer represents an opportunity to organise imaging tests to exclude lung cancer instead of, or as well as arranging treatment for presumed benign causes such as an exacerbation of COPD.

4.3 Solutions to the barriers faced by patients

Solutions to the barriers faced by the public to accessing healthcare assessment include:

- ✓ Education to increase the awareness of the common symptoms of lung cancer (including specific campaigns directed towards those that have not smoked)
- ✓ Providing new ways to access diagnostic testing that do not require consultation within primary care including:
 - o Self-referral CXR service
 - Lung symptom concern hotline
 - Community pharmacy CXR requesting

Public awareness campaigns. In planning campaigns to encourage the public/patients to seek help early for possible symptoms of lung cancer, the Model of Pathways to Treatment conceptualises two key intervals to target³⁷:

- ✓ Appraisal interval: the time period where a person detects a bodily change and perceives a reason to discuss with an HCP but hasn't yet made the decision to seek help.
- ✓ Help-seeking interval: the time between making a decision to consult an HCP and arranging an appointment.

In order to promote a change behaviour towards a decision to consult, three primary factors need to be addressed: motivation, capability, and opportunity³⁸. These are influenced by a multitude of factors affecting individuals during both of the above intervals. Symptom awareness is a necessary

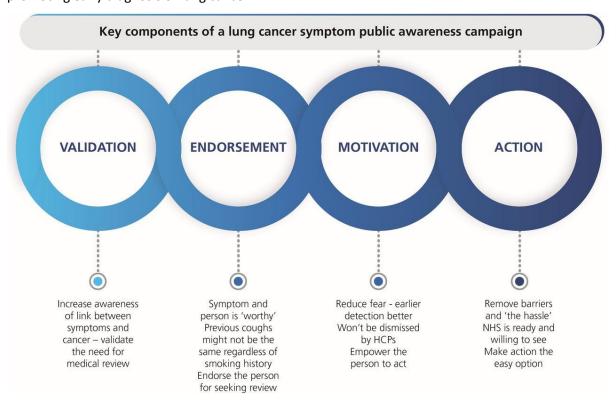
but not sufficient condition for supporting symptom presentation as the individual also needs to be motivated (i.e. having recognised such a symptom within themselves, believing that presenting to a healthcare professional is worthwhile/received positively). Therefore, when raising awareness of lung cancer and its symptoms, campaigns need to be encouraging and innovative, presenting the information and content in an engaging way that is most suitable to its intended audience. Relevant patient stories connect effectively with different target audiences and can be helpful to communicate the different types of symptoms that can occur in lung cancer. Positivity is also important, show-casing stories of early detection, hope, and people living well with late-stage disease and those who have had treatment with curative intent.

National campaigns promoting timely presentation for symptoms of lung cancer have run since 2012, initially under the 'Be Clear on Cancer' brand and more recently under the 'Help Us Help You' (HUHY) umbrella. These campaigns aim to raise awareness of cancer symptoms, tackle barriers to help-seeking and encourage people to get checked. A key aim is to reach people aged 50 years and over and from more deprived communities, in whom cancer incidence is higher, as well as those more likely to experience health inequalities including minority ethnic populations and our most deprived communities. Results for the HUHY 'persistent cough' campaigns that ran in 2021 and August-October 2022 suggested it was raising public awareness of persistent cough as a potential sign of cancer and increasing intention to act. A tracking survey of the target audience showed a 7% increase in awareness of cough as a cancer symptom in November versus May 2022, and a 15% increase in intention to contact the GP over the same period. Evaluation of the ABACus programme showed that targeted cancer awareness interventions are viable and potentially more effective for communities with higher lung cancer incidence³⁹.

Following on from the public insight work across cancer alliances in the North of England, a framework for developing public awareness campaigns was proposed: the 'Validation-endorsement-motivation-action' model (Figure 7)²⁵. This framework recommends that any public awareness content should support people to feel validated to seek medical review with symptoms such as cough, breathlessness, fatigue and loss of appetite⁴⁰. 'Be clear on cancer' has conveyed this validation by prominently featuring GPs along with clear messaging about symptoms that require attention. Linking these symptoms to lung cancer and increasing the importance placed on them by the medical community will help to validate the reason for seeking medical review.'

The public must also feel an endorsement from the NHS to seek review in the presence of these symptoms through educational messaging. Presence of the highly recognisable NHS logo in communications is important in conveying this sense of official endorsement and to assure patients the health service wishes them to seek help for symptoms. This messaging should include not dismissing the cause of the symptom based on previous experiences and that anybody can develop lung cancer regardless of smoking history. As it is challenging to convey all of the information we would wish the public, it is vital that communication strategy is pragmatic in prioritising simple impactful messages, whilst also utilising hierarchies of messaging across different media, which can offer additional detail and secondary, or 'follow on' messaging which can build on earlier iterations in a campaign. The motivation to seek review is centred on dispelling the nihilism in lung cancer and focusing on early diagnosis that improves the chances of curative treatment. Facts describing the difference in outcomes between early-stage lung cancer and late-stage lung cancer may help illustrate this but ensuring the messaging remains upbeat with references to 'surviving lung cancer' with good quality of life is critical. Finally, empowering the public to request medical help by removing perceived or real logistical barriers to seeking review would increase the probability of taking action. This might include a very specific, clear and focused instruction to request a CXR if symptoms persist beyond 3 weeks or alternative routes to a CXR that do not require a consultation in primary care (e.g. self-referral). Participants in the focus groups strongly supported these messages being delivered by healthcare professionals and patients who have received successful treatment for lung cancer, including those who have had curative treatment without significant impact on their quality of life and those who have had treatment to control their cancer and continue to lead fulfilling lives allowing them to experience crucial life events such as children's weddings or graduations.

Figure 7: The validation-endorsement-motivation-action framework for public awareness campaigns promoting early diagnosis of lung cancer



Self-referral CXR (SRCXR) Service. A number of such services have been established over the last decade many areas across the UK^{40,41}. An example of a recent project is in Greater Manchester (GM). The GM Cancer Alliance has implemented self-referral to chest x ray within two localities. Symptomatic patients can attend one of three hospital sites without any prior consultation or referral from primary care and complete a CXR if they fulfil criteria based on NICE guidelines for patients who have symptoms which require imaging.

The outcomes of the CXR are managed by secondary care with automatically generated letters to GPs and the patient following a normal CXR, advice or secondary care appointment for abnormal non-cancer findings and direct to CT for suspected cancer findings. The project went live in July 2022. Approximately 1500 self-referral CXRs have been performed over a 9-month period across two localities in Greater Manchester with the following outcomes & insights:

- 97% of attendees were eligible for a SRCXR and 100% completed a CXR on time of attendance
- 45% of participants fall into the three lowest deciles for socio-economic deprivation

- The SRCXR breaks down multiple barriers to accessing CXRs in patients with the common symptoms of lung cancer
 - One in ten patients had tried unsuccessfully to contact primary care about their symptoms
 - Over half had already contacted primary care about these symptoms but had not been deemed eligible for a CXR despite having the common symptoms of lung cancer
 - One third of patients had not made any contact with primary care about these symptoms
 - One quarter of patients believed they were unlikely to ever contact primary care about these symptoms
- 95% of CXRs are normal, 3% have significant non-cancerous pathology and 2% were suspicious of lung cancer.

The GM SRCXR pilot shows it is a feasible, acceptable, and innovative route for patients in the community with the common symptoms of lung cancer to access a NICE recommended first line diagnostic test (CXR). This self-referral service breaks down numerous barriers that patients with the common symptoms of lung cancer face and may help to address health inequalities. At scale, this service has the potential to drive early diagnosis of symptomatic lung cancer and improve outcomes in the leading cause of cancer death.

Lung symptom concern hotline. Telephone services for people to call with the common symptoms of lung cancer, linked to awareness activities and manned by non-medical working to strict protocols, are being trialled in some areas of the country as an alternative option to seeking a primary care consultation. This could help overcome some of the logistical barriers and fears of being dismissed that some patients face. A national lung cancer concern hotline for people that are worried about the common symptoms of lung cancer was recommended in the UK Lung Cancer Coalition (UKLCC) report 'The route back to 25 by 25' as a key action to reinvigorate efforts to achieve a 25% 5-year survival by 2025 in the recovery from the covid-19 pandemic⁴³. The Nottingham City Lung Cancer Hotline is integrated with local cancer awareness campaigns to streamline access and provide rapid action for patients. A potential advantage of this approach is the ability to use risk stratification algorithms to determine who should have a CXR or CT, the latter providing the opportunity for even earlier diagnosis. It is also able to provide a safety netting process for the lower risk group. Early outcomes from this important pilot work are awaited.

Community Pharmacy. Pharmacies are regarded positively by many patients as a source of support and health advice. They are accessible with many remaining open during evenings and weekends and many patients often have a relationship already with their local pharmacy which are generally well trusted⁴⁴. The easy access afforded by community pharmacies may be particularly helpful where patients find it difficult to access general practice, which the 2020 General Practice Patient Survey suggested was more of a problem in deprived areas⁴⁵. Qualitative studies have shown that patients are relatively open to discussing possible cancer symptoms with pharmacy staff and see pharmacies as a place of expertise. There are, however, challenges in direct referral to radiology through this route. Protocols would need to be in place to ensure good practice and adherence to regulations — for example, that pharmacies have space for confidential consultations, radiation regulations are followed and that appropriate follow up of test results is undertaken. NHS England is currently piloting direct referrals from community pharmacists in a number of Cancer Alliances. There have been several small studies of direct access for community pharmacies to CXR referrals though the numbers involved are small and difficult to draw conclusions at this stage (Table 1).

Table 1: Summary of studies evaluating community pharmacies to identify patients with common symptoms of lung cancer requiring further investigation

Study/Evaluation	Number of pharmacies	Referral type (chest x-ray or clinic)	Number investigated	Duration of programme	Number investigated per pharmacy per month
Holland-Hart 2021	17	Chest x-ray	12	12 months	0.06
Punwani 2014	43	Hospital clinic	47	3 months	0.4
Robinson 2017	9	Chest x-ray	10	8 months	0.1

4.4. Solutions for healthcare professional and the healthcare system

Solutions to the barriers within healthcare professionals and the healthcare system include:

- ✓ Primary care education
- ✓ More allied healthcare professionals trained to request CXRs
- ✓ Direct access to CT from primary care
- ✓ Supporting primary care clinicians in appraising symptoms
- ✓ Publish CXR rates by GP practice, Primary Care Network (PCN) & Integrated Care System (ICS)

Primary care education. Education programmes for the diverse range of primary care workforce are required that focus on key messages including on increasing the volume of CXRs in patients with the common symptoms of lung cancer and the evidence that supports this approach.

Training of non-medically qualified clinicians to request CXRs The primary care workforce is becoming increasingly diverse beyond GPs and integrates pharmacists, physician associates, nurses & physiotherapists into routine frontline community healthcare. The diverse and common nature of lung cancer symptoms means all of this workforce will encounter patients with symptoms that could be caused by lung cancer and, therefore, represents an opportunity to increase the volume of CXRs performed. With the appropriate training, these professionals can safely request CXRs which could in turn support access to this important diagnostic tool early in the symptomatic journey. Such training has been instituted in some areas and an evaluation of such a scheme is currently underway in Leeds.

GP Direct access to CT.

A cluster randomised trial randomised 119 general practices (with 266 GPs) in Denmark to an intervention including direct access to low-dose CT chest for patients with signs and symptoms of lung cancer supported by a continuing medical education programme or usual care with CXR as the initial investigation. Results showed no significant differences in primary care interval, diagnostic interval, or lung cancer stage at diagnosis. However, associated studies showed the diagnostic interval was significantly shorter in practices that complied with the intervention and patient and clinician satisfaction was high⁴⁶⁻⁴⁸. A systematic review evaluating direct access to cancer testing in primary care found similar rates of appropriateness of investigation, in terms of diagnosis, comparing GP- to specialist-requested testing⁴⁹. There were no significant differences in patterns of requests, suggesting that GPs were requesting tests appropriately. Where reported, the time to test was shorter and the patient and clinician satisfaction was high, which suggested GPs might be open to this approach. Pilot evaluations of direct access to CT imaging for GPs in the UK suggest the pathways led to shorter time to CT and increased patient and clinician satisfaction with the pathways⁵⁰⁻⁵².

Pathways that provide direct access for GPs to request CT chest scans, for patients with suspected lung cancer, ensure they receive the optimal imaging test promptly. Direct access to CT Chest requested by a GP for a patient with a high index of suspicion for lung cancer but a normal CXR may be a valuable use of these pathways. There has been a recent announcement from NHS England, of a national roll out for direct access to CT for GPs⁵³. The roll out of community diagnostic hubs may support these pathways in the future. Guidance has been issued as to which patients should be considered for the investigation, including those with prolonged cough, but it remains challenging

for GPs to understand how to implement the announced roll out of direct access to CT in an equitable and effective manner⁵⁴. Further development of such guidance, should be considered a priority⁵⁵ (see *Specific guidance for 'high-risk' & 'persistent symptoms' following a normal CXR.*).

Whilst using CT instead of CXR as a first test for more patients with symptoms of possible lung cancer is likely to improve sensitivity, there is currently a lack of evidence indicating the optimal way to assess risk, and appropriate risk thresholds to use in this context. In addition, the number of additional CT scans which might result from a such a change in policy is potentially very large. Over 1.8 million CXRs were requested from Primary Care in 2021/22, and although there are no published estimates of the proportion of these that might fulfil NG12 criteria, it is possible that hundreds of thousands of additional CT scans might be required annually across the UK were all CXR requests that meet NICE NG12 criteria for suspected lung cancer were to be converted to CT. Given current shortages in radiologists, radiographers and CT scanners in the UK, coupled with the planned roll-out of LDCT screening for lung cancer over the remainder of the decade, this is likely to cause significant capacity issues. Outputs from a future research study resulting from the recent NIHR funding call on this topic is likely to be critical to informing practice in this area.

Supporting primary care clinicians in appraising symptoms. Around 90% of healthcare contacts in the UK are with primary care and most patients with lung cancer first present with symptoms to their GP. It is relatively straightforward for GPs to recognise and take appropriate action for high-risk symptoms, like coughing blood (haemoptysis) but much more difficult for patients with low-risk symptoms, including dyspnoea and persistent cough. Clinical decision support tools might help identify more patients with common symptoms of lung cancer who should be referred for a CXR. Some of the available clinical decision support tools quantify risk of undiagnosed cancer in symptomatic patients. These include electronic risk assessment tools (eRATs) and QCancer®56. These can interrogate GP records and alert the GP when a patient has a symptom or other feature that suggests a risk of cancer. A prompt appears as a pop-up on a GP's computer screen when a patient has at least a 2% risk of one or more of the cancers for which eRATs currently exist (lung, oesophagogastric, kidney, bladder, ovary, colorectal, pancreas). GPs can then explore the possibility of cancer further with the patient using a symptom checker included in the tool; this can allow the GP to add further symptoms and the risk of cancer is automatically recalculated. In England Cancer Alliances have been allocated funding in 2022 -2023 to establish universal coverage of clinical decision support tools for cancer⁵⁷. The Electronic Risk Assessment for Cancer (ERICA) trial is assessing the

clinical and cost-effectiveness of six eRATs, including that for lung cancer; the primary outcome is the proportion of cancers diagnosed at stage I/II versus stage III/ IV⁵⁸.

Publish CXR rates by GP practice, Primary Care Network (PCN) and Integrated Care System (ICS). If variation in CXR rates across GP practices is driven by differing clinician thresholds for investigation (see above), using the Diagnostic Imaging Dataset (DID) as an opportunity to publish CXR rates by GP practice, PCN and ICS would provide valuable audit, peer review, quality assurance and the opportunity to identify outlying areas where targeted interventions could be completed to reduce this variation.

Prioritising lung cancer within existing policy on health inequalities (Core 20 Plus 5)

Cancer registration data shows that lung cancer has the most significant difference in age-standardised incidence rates between those living in the most and least deprived areas ⁵⁹. The difference in 1-year survival between persons living in the least deprived areas compared to the most deprived areas is 7.4 percentage points for lung cancer ⁵⁹. Early diagnosis of lung cancer has been identified as one of NHS England's national approach to health inequalities, Core20plus5. It is essential that in addition to a focus on early diagnosis in general, there is a specific focus on the most deprived communities where the incidence of and survival from lung cancer is the poorest to achieve a meaningful reduction in the equality gap. ICSs are encouraged to identify these populations locally, which should include particular groups such as people experiencing homelessness, drug and alcohol dependence and people in contact with the justice system. We hope the approaches detailed in this report can be used particularly for the benefit of underserved populations to meaningfully mitigate health inequalities.

5. Safety netting and patients at lower risk

5.1. High and intermediate risk patients with a normal CXR

'Safety-netting' is no longer considered solely as a doctor-patient interaction but as a responsibility of the "system," which should provide robust safety-netting protocols within the electronic health record (EHR). As patients move through the multiple clinical contacts that lead up to a diagnosis, improvements in the safety-netting process could reduce the number of errors in the diagnostic process. The lack of robust safety-netting process is likely to be a barrier to early diagnosis in symptomatic lung cancer.

Since CXRs detect 75-80% of lung cancer, 20-25% will be missed by CXR. It is therefore a critical component of early diagnosis of symptomatic lung cancer to not take false reassurance from a normal CXR in high-risk patients or those with persistent unexplained symptoms. Although a normal CXR reduces the likelihood of lung cancer as a cause for the symptoms⁶⁰, it does not exclude this

diagnosis, and so clinicians should be vigilant to the possibility of lung cancers, and patients should be advised to represent if symptoms persist or deteriorate.

A normal CXR could increase the fears of being dismissed or judged by their symptoms and work against the framework of validation-endorsement-motivation-action. The threshold to stop seeking medical review when faced with logistical barriers might be lowered with the knowledge of a normal CXR. This may be an issue for self-referral CXR services unless there is sufficient scrutiny of the risk of patients. If patients are still judged to be at high risk, even after a normal CXR, it is likely that some will merit a CT scan, although the precise criteria for triggering such review are currently not known. Another element of safety netting is in those patients that are not at high risk enough risk to justify a CT but still have some elevated risk. Here there needs to be a follow-up plan that includes seeking an alternative diagnosis, monitoring for persistent or new symptoms, and having a further CXR or CT.

For primary care, current guidelines recommend that GPs give patients clear, specific advice on symptoms to monitor, with a clear timeframe and action for the patient to follow rather than a generically worded "come back and see me if you are worried". However, research suggests that in practice, GPs often adopt this passive safety netting practice and that patients perceived this as suggesting that they should not come back³⁰. Lack of health literacy precautions (delivering simple messages and checking comprehension) in delivering safety netting advice is an additional factor with particular relevance to inequalities in lung cancer outcomes in areas of greater deprivation⁶¹. A lack of robust and specific safety netting processes might be contributing to delayed diagnosis of lung cancer following a normal CXR. Safety netting for the high and intermediate risk needs to be built in as part of cancer concern hotlines and self-referral CXR.

A substantial proportion of lung cancers diagnosed after CXRare not identified on initial imaging but following repeated imaging to ensure an abnormality has resolved⁶², for example evidence of an apparent chest infection, or following further clinical assessment for a non-specific abnormality. As these abnormalities, which do not immediately lead to further investigation with CT, are an important route to diagnosis, it is vital there are robust follow up processes in place to avoid unnecessary delays to diagnosis and that clinicians are empowered to arrange further investigation with CT if required.

5.2. Low risk patients and people who have never smoked

Low risk patients present more of a challenge to diagnosis, illustrated by the higher proportion of late-stage disease in these patients. It is not yet clear what the best approach is, but a similar

approach to the intermediate risk group may be appropriate, in particular ensuring a diagnosis is made, advising patients on the expected course of symptoms if that a diagnosis of benign disease is correct (for example resolution or improvement of symptoms within a stated timeframe) and consideration of imaging to exclude lung cancer, even where this is felt to be unlikely. Although there is some evidence clinical intuition can help doctors recognise when cancer should be excluded, GPs need clearer guidance on which patients, aside from those with 'red flag' symptoms like haemoptysis, require additional imaging such as CT, when initial CXR is unremarkable. Such guidance should be informed by evidence-based risk stratification where possible, but where uncertainties remain consensus recommendations are necessary to support GPs to rationalise which patients should receive additional investigation, beyond reliance on clinical intuition alone.

5.3. Safety netting and the public – healthcare interface

Public awareness campaigns, whilst focusing on the key message of the importance of CXRs early in the symptomatic journey, can also support those with persistent symptoms not to be fully reassured by a normal CXR. This could validate and endorse them to take action and continue to seek further healthcare review.

Proactive safety netting. Pro-active safety-netting that reaches out to the patient, such as telephone calls or text reminders, might overcome some barriers that currently result in patients not reconsulting or having further investigations if their symptoms do not resolve. This might, in turn, help reduce diagnostic errors and delays. This could be a key area of further research and evaluation.

Specific guidance for 'high-risk' & 'persistent symptoms' following a normal CXR. Whilst a key message for primary care clinicians is not to be fully reassured by a normal CXR and to consider referral on the suspected lung cancer pathway for patients at high risk of lung cancer or with persistent symptoms/concerns, no specific definition of 'high risk' or 'persistent symptoms' exists. Providing specific guidance on which patients should be refer on the suspected lung cancer pathway or for further investigation with CT scan could reduce undue variation in investigative practice that results from reliance on clinical intuition of individual GPs alone A key barrier to producing such specific guidance is the uncertainty about patients' risk, beyond a small number of symptoms and smoking status⁶³.

Recent research has demonstrated that a basic risk estimate can be generated for patients in primary care who are referred for CXR based on age and smoking status⁶⁴. For example, people who currently smoke aged over 60 who are referred for CXR have a risk of lung cancer that exceeds 3%, the threshold used by NICE to justify urgent referral under suspected cancer pathways. Accordingly, guidelines or referral protocols could support GPs to refer such patients directly to CT, although consideration of the likely volume of CT investigations that would result and the health service's capacity to cope with these would need to be made. Robust evidence is lacking for the emphasis that should be placed on other aspects of presentation, such as duration of symptoms. In view of these uncertainties and the practical implications, such as additional CT tests that could result, a multi-disciplinary group should be convened to consider available evidence along with expert opinion where evidence is not available, to formulate consensus recommendations for GPs. Box 1 presents an example of criteria that might be considered as a starting point for discussion in formulating such recommendations. It should be recognised that that even following development of recommendations, not all patients with lung cancer will fit 'text book' presentations, so GPs' clinical intuition and/or patient concern will remain important in guiding selection for CT or urgent referral, even where specific criteria are not met.

Box 1: Example of criteria that could be proposed for discussion as part of consensus recommendations for identifying patients who should be investigated with CT following normal CXR.

Clinical indictors to consider referring patients on the suspected lung cancer pathway or for urgent CT imaging following a normal CXR:

- Symptoms persist for 4 weeks or more following the CXR
- Blood test abnormalities: thrombocytosis, anaemia
- 2 or more courses of antibiotics for respiratory infection in the previous 12 months
- Age >60 and a current smoker
- Age >70 and an ex-smoker

6. Key recommendations for research, innovation, pilot projects and evaluation

- What are the most effective symptom awareness campaigns and interventions to increase the number of CXRs performed in people with the common symptoms of lung cancer?
- What are the most effective primary care education strategies to increase CXRs in patients with the common symptoms of lung cancer?

- What community-based interventions and relational approaches are most effective for supporting earlier diagnosis of lung cancer, particularly among those from lower socioeconomic backgrounds?
- What support is required for people who face barriers to getting help for possible lung cancer symptoms, for example with travel, taking time from work etc?
- Evaluate new ways for symptomatic patients to access CXR (SRCXR, symptom hot-line), including:
 - Patient uptake
 - Acceptability
 - Patient experience
 - Clinical effectiveness
 - Health economic evaluation
- What are the most effective strategies to increase referrals on the suspected lung cancer pathway or for CT imaging in high-risk patients and/or persistent symptoms following a normal CXR?
- Evaluate the effectiveness of various safety-netting systems and processes for patients with a normal CXR in reducing diagnostic delay
- Evaluate CT as a first test for patients with symptoms of possible lung cancer in the context of well- designed research studies including risk stratification where appropriate.

Conclusion

Much progress has been made in lung cancer care over the last two decades. Most recently, the recommendation by the UK National Screening Committee that LDCT screening should be offered to people at increased risk of lung cancer is a major step forward and the success of the NHS England Targeted Lung Health Check programme illustrates what can be expected in terms of detection of early stage. Treatment for early and later stage lung cancer has advanced considerably and demands that people with lung cancer are diagnosed as soon as possible, before physical fitness deteriorates, to maximise the benefit. An area where little progress has been made despite considerable research, is in early diagnosis in people with symptoms. This is an area where improvements might have the most benefit overall, especially considering the advances in treatment. Given the lack of progress, this workshop set out to identify new ways to tackle the issues and recommend the most

promising strategies. Key themes emerged that are a considerable departure from current practice. These link awareness of symptoms with better access to healthcare assessment. It is strongly recommended that these methods are taken forward in research studies and pilots in the NHS and if evaluated favourably are adopted as policy.

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