



# **Lung Health Check**

## **Operational Pilot for Wales**

Evaluation Report 1  
September 2024



**GIG**  
CYMRU  
**NHS**  
WALES

Gwiriad Iechyd yr Ysgyfaint  
Bwrdd Iechyd Prifysgol  
Cwm Taf Morgannwg  
University Health Board  
Lung Health Check



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Rhwydwaith  
Canser  
Cancer  
Network

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## FOREWORD



Lung cancer is the biggest cause of cancer death in Wales, and whilst we know that patients generally receive very good care and treatment, we also know that survival is below that of our international peers. Most lung cancers are diagnosed at a late stage in Wales and the UK, when treatment options are less likely to lead to long-term survival. It is therefore crucial that we address this to improve outcomes for our patients, and a national screening programme is the ideal approach to achieving this. We also know that lung cancer has differing effects across our population, widening the inequality gap between the most and least deprived in society, further emphasising why this must be a key area of focus to improve the outcomes for our population.

In recognition of this, the Cancer Network has focussed on lung cancer screening as a priority over a number of years, initially by commissioning a scoping report with recommendations for the way forward in Wales, and more recently by introducing a programme team to deliver these. The scoping report highlighted the range of evidence that has been developed, demonstrating the impact that targeted lung cancer screening can have on the identification of lung cancers at an earlier stage and ultimately on patient outcomes. The recommendation to deliver a pilot to test this within the Welsh healthcare system, and to gain advance learning to inform a future national Screening or Health Check Programme, was accepted and the work undertaken since then has been a testament to the opportunities for partnership-working across the NHS as well as with Industry and the Third Sector. We are incredibly grateful for the support of a number of partners as identified throughout this report, without whom this pilot may not have happened.

As this report sets out, targeted lung cancer screening offers significant opportunity to improve lung cancer outcomes across Wales, and we must now embrace this as a nation to implement a national screening service as quickly as possible. We are now in a far better position to engage in the design and roll-out of a screening programme in Wales following the positive recommendation for implementation of lung cancer screening by the UK National Screening Committee in 2022. Whilst there will be many challenges in delivering this, including finance, workforce and capacity, we know that this has the opportunity to transform the lives of people across Wales. Targeted lung cancer screening could have a greater impact on cancer outcomes than any other new intervention that is currently available to us and we must, therefore, work together to ensure that this is delivered. We will work with all our cancer partners and stakeholders in Wales to deliver a high-quality programme that is effective, efficient and providing equitable access to the people of Wales, as soon as safely possible.

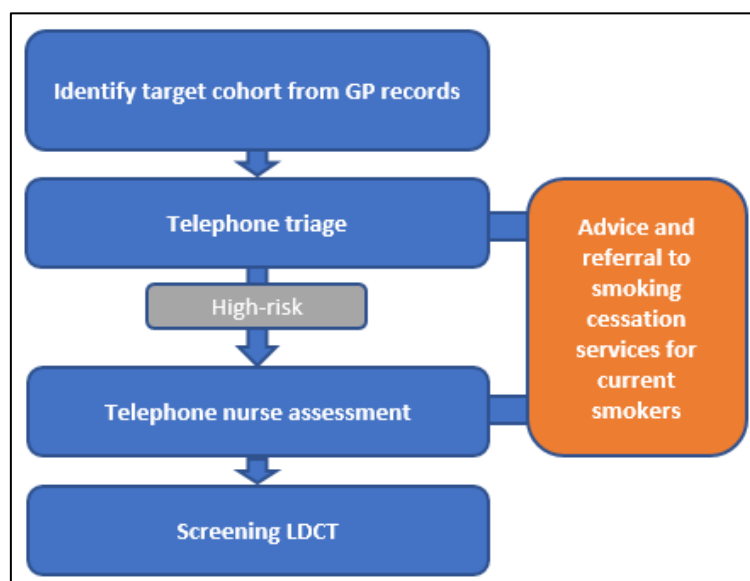


Prof Tom Crosby OBE, National Cancer Clinical Director,  
National Strategic Clinical Network for Cancer, NHS Wales Executive

## EXECUTIVE SUMMARY

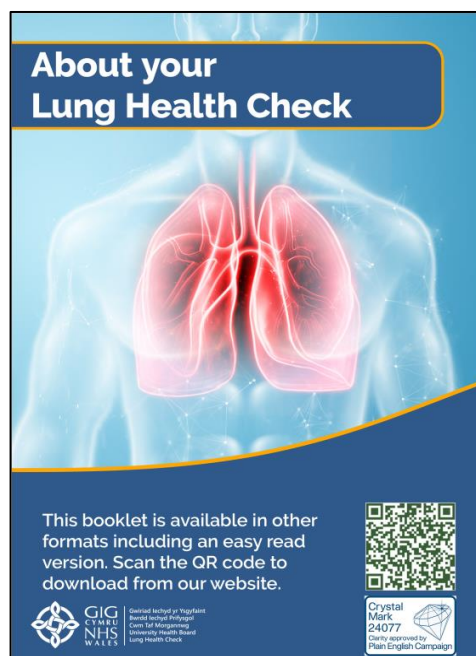
## Background and overview

1. Targeted low-dose CT (LDCT) screening for lung cancer has been recommended for implementation by the UK National Screening Committee. Lung cancer screening reduces lung cancer mortality by around 20% by finding lung cancer at an earlier stage.
2. Plans for the Wales Lung Health Check (LHC) Operational Pilot (OP) developed following scoping work by the National Strategic Clinical Network for Cancer. The aims of the OP are to:
  - a. Provide immediate health benefits to the pilot cohort
  - b. Provide advance learning and modelling to support and de-risk the rollout of a future programme in Wales
  - c. Develop a core team who would gain experience to be used as the nucleus for a future national rollout
3. This report covers the inception, planning, delivery and results of the OP up to the point of completion of baseline and 3-month recall LDCT scans.
4. The OP is being delivered by Cwm Taf Morgannwg University Health Board with support from the National Strategic Clinical Network for Cancer, and funding from Industry and Third sector groups.
5. The OP invited people from selected GP practices in North Rhondda aged 60-74 years, who had ever smoked, for a LHC. The LHC included an opt-out telephone triage appointment to determine the participant's personalised risk of developing lung cancer using standardised multivariable risk assessment tools. Those at high risk were offered a telephone nurse assessment followed by a screening LDCT scan. Current smokers were offered advice and opt-out referral to local smoking cessation services.



## Preparation

6. Extensive planning for the OP was required including development of a business case, securing of funding, establishment of a governance structure, development of a pathway and service model, modelling work to project the expected activity, and gaining of numerous permissions and approvals to proceed. Following a procurement process, aspects of the OP were delivered in partnership with InHealth and Heart&Lung Health.
7. Protocols were established to underpin identification of the target population from GP records, the invitation process, assessment of participants, delivery and reporting of LDCT scans, and management of findings.
8. A comprehensive communications plan was established, including development of evidence-based public-facing materials designed with public and patient involvement.



9. The invitation process, participant pathway and communications plan were designed to optimise uptake of the OP by the at-risk population, aiming to overcome known emotional and practical barriers to participation in lung cancer screening.

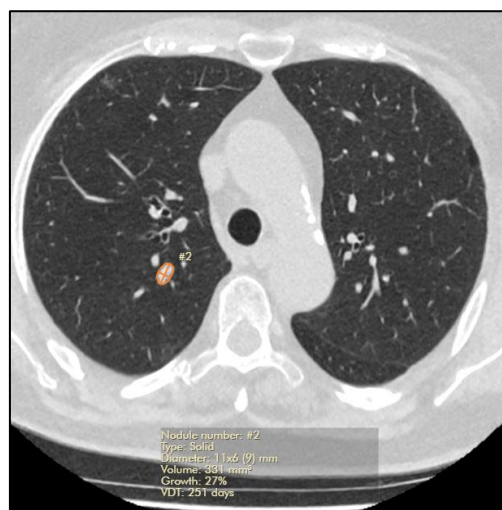
## Delivery

10. Invitations and telephone triage commenced in August 2023, and telephone nurse assessments and baseline LDCT scans were undertaken in September to November 2023. LDCT screening scans were performed using a mobile CT scanner located at Ysbyty Cwm Rhondda.





11. LDCT scans were reported by thoracic radiologists from across Wales using a cloud-based reporting system, supported by Artificial Intelligence computer-aided lung nodule detection software and a standardised reporting protocol.

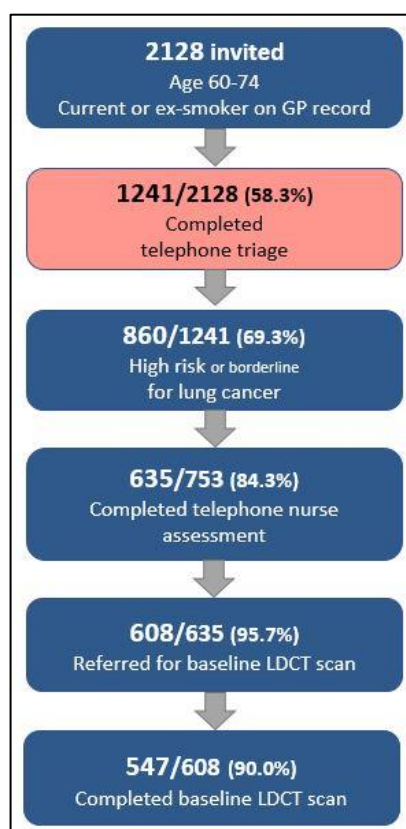


12. Participants with suspected lung cancer underwent further investigation via the Single Cancer Pathway at the Royal Glamorgan Hospital lung cancer service.
13. Participants with small lung nodules requiring surveillance were recalled for a further scan after 3 months. Those with persisting nodules will be recalled for a further scan 12 months after their baseline scan (September to November 2024).
14. All suspected cancers, lung nodules and potentially actionable incidental findings were reviewed at a weekly Screening Review Meeting to determine the most appropriate course of action.
15. Semi-automated standardised results letters were generated and sent to participants, incorporating lifestyle advice for those with common incidental findings such as coronary artery calcification or emphysema.



## Results

16. In total, 2128 people aged 60-74 years who had ever smoked were invited from two GP practice groups. Of those invited, 1241/2128 (58.3%) completed telephone triage and of these, 860/1241 (69.3%) were determined to be at high risk of lung cancer. Following telephone nurse assessments and exclusions due to ineligibility, 608 participants were referred for a baseline LDCT scan, with 547 baseline LDCT scans ultimately performed (547/608, 90.0% of those referred for LDCT). The most common reason for ineligibility to proceed was CT thorax imaging in the previous 12 months.

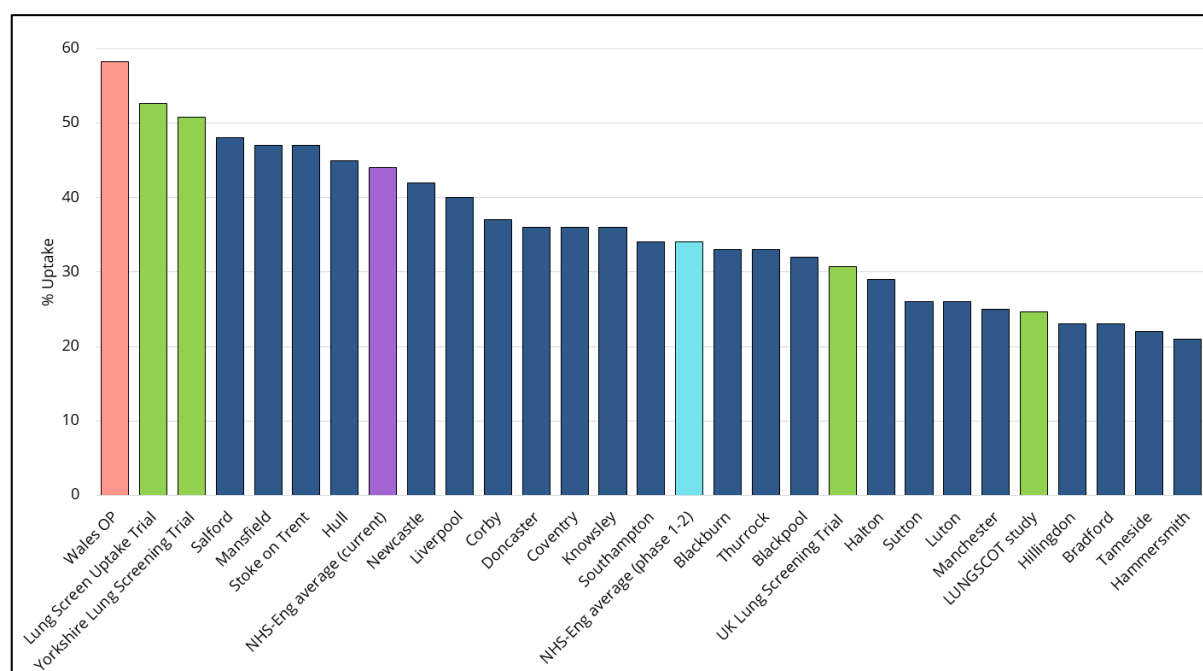


17. Of participants who completed telephone triage, 341/1241 (27.5%) were current smokers. Participants who completed telephone nurse assessment were generally fit, with 90.2% having an ECOG Performance Status of 0-1 and 77.5% having a mMRC Dyspnoea Scale Grade of 0-1.
18. Combined from baseline and 3-month recall scans, thirteen participants underwent further investigations for suspected lung cancer, with 12 ultimately receiving a lung cancer diagnosis (cancer detection rate = 2.2%, number needed to scan per lung cancer diagnosis = 46, false-positive rate = 0.2% of those scanned).
19. Of lung cancers diagnosed through the OP, 66.7% were early stage (stage 1-2), 66.7% underwent surgical resection as the primary treatment modality, and 83.3% received treatment with radical (curative) intent.

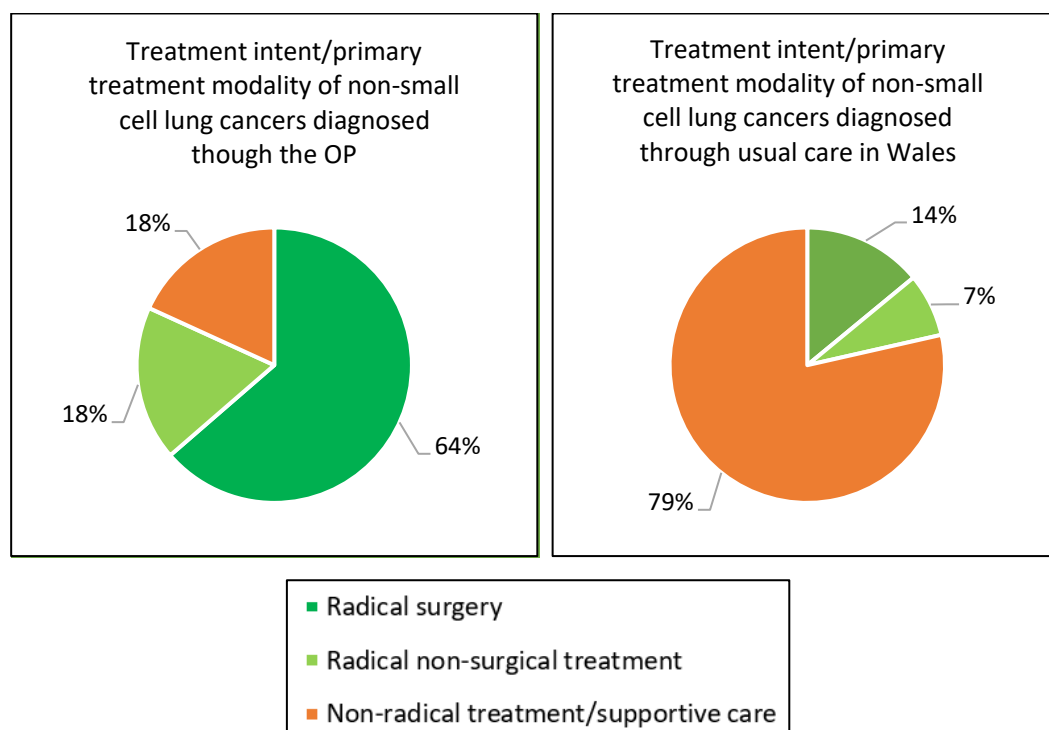
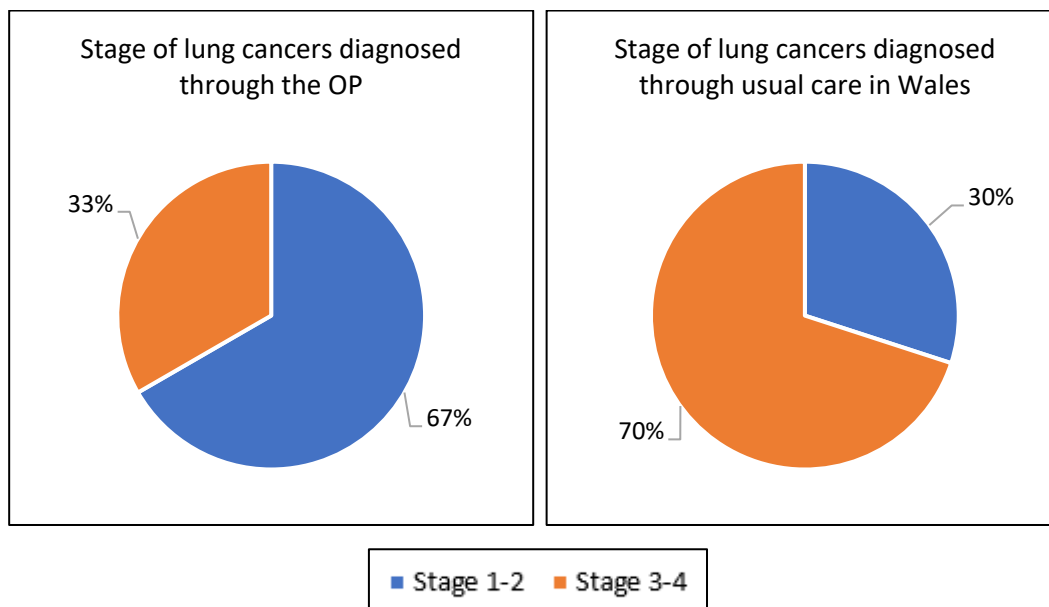
20. Of participants who underwent a baseline LDCT scan, 17.6% had a small lung nodule requiring a recall scan following Screening Review Meeting discussion.
21. There were 7.3 actionable incidental findings per 100 baseline LDCT scans following Screening Review Meeting discussion. The most common actionable incidental finding was moderate/severe aortic valve calcification, which resulted in referral to the local Cardiology service for echocardiography.
22. Through discussion at Screening Review Meetings, almost a quarter of reported small lung nodules (23.6%) and nearly half of potentially actionable incidental findings (42.9%) became non-actionable, most commonly due to findings being present on previous imaging or medical records.
23. Coronary artery calcification and emphysema were common incidental findings, with each finding present on more than half of scans undertaken. Most cases of coronary artery calcification and emphysema were mild, and most with severe findings were already on risk-modifying medication for cardiovascular disease or had a known diagnosis of chronic obstructive pulmonary disease (COPD).
24. No invasive tests or surgical resections for suspected lung cancer were undertaken in participants who were not ultimately diagnosed with lung cancer.

## Discussion

25. Uptake of the OP by the target population compares favourably to most other lung cancer screening/LHC activities elsewhere. This suggests that the strategies employed in the OP to overcome barriers to participation, through communications and pathway design, were successful and can provide a template for a future national programme.



26. Results related to the clinical effectiveness of the OP are aligned with those seen in lung cancer screening activities elsewhere and compare favourably to lung cancers diagnosed through usual care in Wales, particularly in relation to stage of lung cancer at diagnosis and treatment intent.



27. The results of the OP provide assurance that:

- a. Lung cancer screening can be delivered effectively within the Welsh healthcare system
- b. Lung cancer screening is likely to yield benefits similar to those seen in studies, pilots and programmes elsewhere
- c. A lung cancer screening programme would significantly improve lung cancer outcomes compared to current care in Wales

#### Next steps

28. Clinical activity of the OP is due to conclude in late 2024 with completion of 12-month recall scans for small lung nodules. A second report covering 12-month recall scans, smoking cessation pathways and experience of participants and healthcare professionals involved in the OP is planned for March 2025.

29. Welsh Government have commissioned Public Health Wales to undertake a project reviewing how targeted lung cancer screening could be delivered in Wales in the future. This project commenced in April 2024 and will be informed by the delivery and findings of the OP.

## 1. INTRODUCTION

### 1.1 Background

Lung cancer is by far the leading cause of cancer deaths in Wales.[1] Targeted low-dose computed tomography (LDCT) screening reduces lung cancer mortality by around 20% by finding lung cancer at an earlier stage.[2] Around three-quarters of lung cancers detected through screening are early-stage (stage 1-2), in contrast to three-quarters being late-stage (stage 3-4) through other routes of presentation (figure 1a).[1,3–8] Early-stage lung cancer can often be cured by surgery or radiotherapy leading to long-term survival, whereas late-stage lung cancer is rarely curable and confers a poor prognosis.[9]

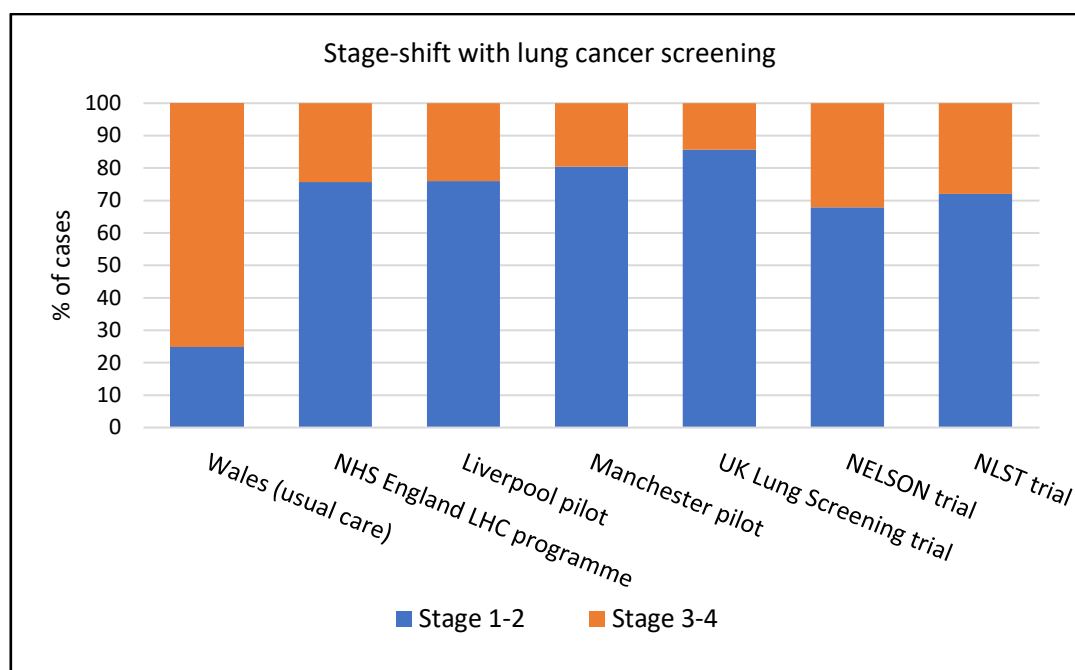


Figure 1a: Stage distribution of lung cancer when detected through usual care in Wales (2014-2019), compared to through screening activity.

LDCT screening also affords an opportunity to engage people who smoke in smoking cessation interventions. The largest randomised controlled trial on lung cancer screening reported a reduction in all-cause mortality,[8] likely due to the combined effects of reduced lung cancer mortality, smoking cessation, and intervention for significant incidental findings. The UK National Screening Committee (NSC) have recommended that targeted LDCT screening for lung cancer should be implemented in the four UK nations, based on evidence of clinical- and cost-effectiveness.[10]

Lung Health Checks (LHCs) are a delivery model for LDCT screening, inviting people in a target age range who smoke or have smoked in the past for assessment.[11] This includes using a multivariable risk assessment tool to calculate an individual's risk of developing lung cancer and offering those at higher risk a screening LDCT, and providing smoking cessation interventions for current smokers.

The Wales Cancer Network (now the National Strategic Clinical Network for Cancer/ "Cancer Network") commissioned a scoping report on LHCs that was completed in 2020.[12] This recommended development of an operational pilot (OP) in Wales as one of the key next steps. This report describes the inception, development, delivery and learning from the LHC OP to date.

## 1.2 Scope of this report

It is planned for the OP to generate two evaluation reports. Clinical activity is ongoing through the OP at the time of writing (mid-2024) and planned to continue until early 2025. However, much has been learnt from the planning and delivery of the OP to date, and as such it was preferable for this information to be made available to support national planning work for lung cancer screening as soon as possible, rather than producing a single evaluation report following conclusion of the OP.

This first evaluation report covers the inception and planning of the OP, together with results from baseline and 3-month recall LDCT screening scans.

A second evaluation report is planned for March 2025 following completion of 12-month recall scans in late 2024. The second report is planned to cover:

- Results from 12-month recall scans and the OP overall
- Smoking cessation pathways
- Experience of participants and healthcare professionals involved in the OP

## 2. INCEPTION OF THE OPERATIONAL PILOT

### 2.1 Scoping

In response to the growing evidence for targeted LDCT screening as an approach to reduce lung cancer mortality, the Cancer Network commissioned a scoping report to review the available evidence. This was led by Dr Sinan Eccles and reported in 2020,[12] identifying evidence in support of LDCT screening and recommending the implementation of an OP within Wales to gain insight into delivering such a service within the Welsh healthcare system. The OP would be designed to provide learning that could inform a future wider roll out, pending an updated evidence review and recommendation from the UK NSC. This was discussed at the NHS Wales Chief Executives Group in November 2021, where the recommendation to undertake an OP was agreed in principle and for this to be delivered within the Cwm Taf Morgannwg University Health Board (CTM UHB) area. This was subsequently confirmed by the NHS Wales Medical Directors Group.

### 2.2 Business case development

Following approval in principle for the OP, it was determined that a business case would be required to initiate the project to set out the scope and resources required to deliver. Discussions were held between the Cancer Network Manager and a key advocate from the third sector, Judi Rhys MBE, Chief Executive Officer of Tenovus Cancer Care, with regards to potential support from Industry to support this. Following these discussions, Tenovus Cancer Care secured grant funding which was provided by Bristol Myers Squibb Pharmaceuticals Limited to support the development of a business case, and Greenwood Roberts Ltd. were commissioned to deliver this. The business case was completed in April 2022 and included an estimate of the resource requirements to deliver 500 or 1,000 initial LDCT scans, so that a range could be considered for implementation.

### 2.3 Funding

Whilst there was agreement in principle to proceed with the OP, no funding was committed to deliver this from the Health Boards or Welsh Government, and so it was on the understanding that a funding source would need to be identified. A stakeholder group was convened by Judi Rhys MBE where discussions were progressed with organisations from the Industry and Third sectors seeking funding commitments to support delivery. Through this approach, funding commitments were made from which discussions could progress with CTM UHB in relation to commencing planning for the OP.

Ultimately the funding for the planning and delivery of the OP was provided through two separate streams:

- 1) Funding for the LHC Programme Team was provided by the Cancer Network, who made a commitment to fund this for the duration of the OP. The budget and costs for this team sat within the Cancer Network and were not managed as part of the OP.
- 2) Funding for the delivery of the OP, based on the cost estimates included in the business case developed by Greenwood Roberts, was provided by a number of Industry and Third sector partners, specifically: a financial grant from Roche Products Ltd, a grant from MSD (Merck Sharp & Dohme (UK) Limited), Sponsorship Agreement from Novartis Pharmaceuticals UK Limited, Partnership Agreement with Moondance Cancer Initiative and funding from Tenovus Cancer Care following a prior donation from Bristol Myers Squibb Pharmaceuticals Limited. It



is important to note that none of these funding arrangements gave any of the partners input into the planning or delivery of the OP, or access to participant data.

## 2.4 Programme support

As described in section 2.1, a Clinical Lead was recruited to undertake the initial scoping work and was supported to deliver this by a Project Manager and Project Support Officer, employed by the Cancer Network. The Clinical Lead and Project Manager remained in place throughout, from the initial discussions to gain approval for the OP through to the subsequent planning and delivery. Once the OP had been approved and the funding was confirmed, the team was expanded, with a Programme Manager and Programme Support Officer recruited to support planning and delivery, coming into post in April and June 2022, respectively.



*Figure 2a: LHC Programme Team.*

### 3. PLANNING FOR THE OPERATIONAL PILOT

#### 3.1 Establishing the project

##### 3.1.1 Outline plan

With agreement to proceed confirmed in principle, funding commitments in place and the Programme Team recruited, detailed planning for delivery of the OP could progress. Further discussions were held with CTM UHB, setting out a plan for delivery of the project and establishing the key objectives for the OP as follows:

- To provide immediate health benefits to the pilot cohort
- To advance learning and provide modelling that would support and de-risk the rollout of a future LHC programme in Wales
- To develop a core team that would gain experience to be used as the nucleus for a future national rollout of LHCs

##### 3.1.2 Governance Structure

Through discussions with CTM UHB, it was agreed that the OP would be delivered under the governance of their Radiology service and reported through the Diagnostics and Specialties Care Group, with the project overseen by the Director of Therapies and Health Science, Lauren Edwards.

An overarching governance structure for the OP was established, ensuring that the responsibilities of CTM UHB and the Cancer Network were clearly defined. This was designed to ensure that accountability and decision-making were retained by the Health Board, whilst providing a separate line of reporting to a Coordination Group to be jointly chaired by representatives from the Cancer Network and Public Health Wales (PHW). This was to allow these bodies to receive feedback and learning from the OP and to ensure that this remained aligned to key objectives of the OP, specifically those related to informing future national planning. An Industry and Third Sector Partnership Group was also developed to provide updates to the organisations that had provided funding for the OP. This group had no input into planning or delivery. Finally, a Clinical Reference Group provided clinical oversight and guidance in relation to the OP. The agreed governance structure is set out in figure 3a.

Clinical Reference Group and Industry and Third Sector Partnership Group meetings began in July 2022, whilst the LHC Operational Group meetings and the LHC Coordination Group meetings began in September 2022.

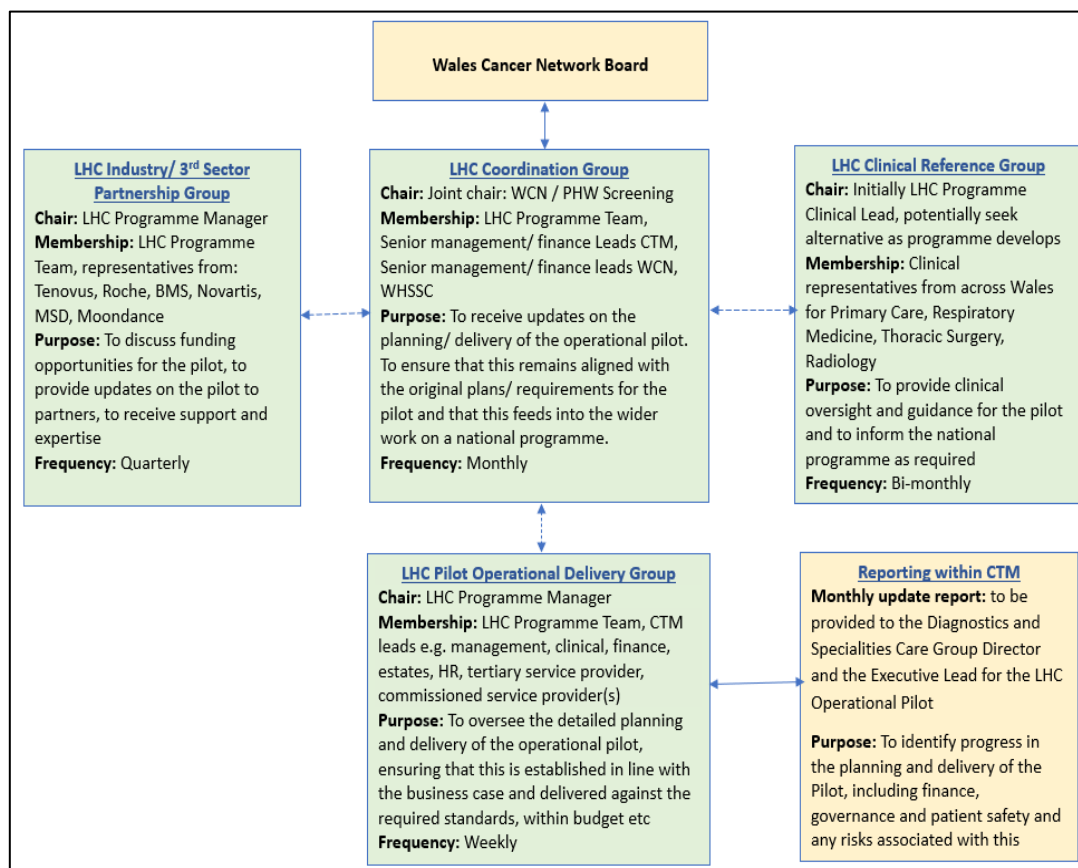


Figure 3a: LHC OP Governance Structure. WCN = Wales Cancer Network; WHSSC = Wales Health Specialised Services Committee; HR = Human resources.

## 3.2 Development of the pathway and service model

### 3.2.1 Pathway overview

In order to ensure that the OP would meet the objective of providing advance learning that would inform any future roll out of LHCs across Wales, it was important that the pathway was designed to provide learning and insight that would be of value to inform this. The pathway was therefore designed using an evidence-based approach, aiming to optimise uptake and efficiency, as set out in figure 3b.

In designing this pathway, it was recognised that participation rates have often been low in lung cancer screening activity elsewhere.[3] Key factors affecting participation have included emotional barriers such as fear and fatalism regarding a lung cancer diagnosis, and practical barriers such as conflicting health or social priorities and difficulty accessing services due to poor literacy, transport or cost.[13–15] Lung cancer risk is greatest in socio-economically deprived populations,[16] where practical barriers are amplified.

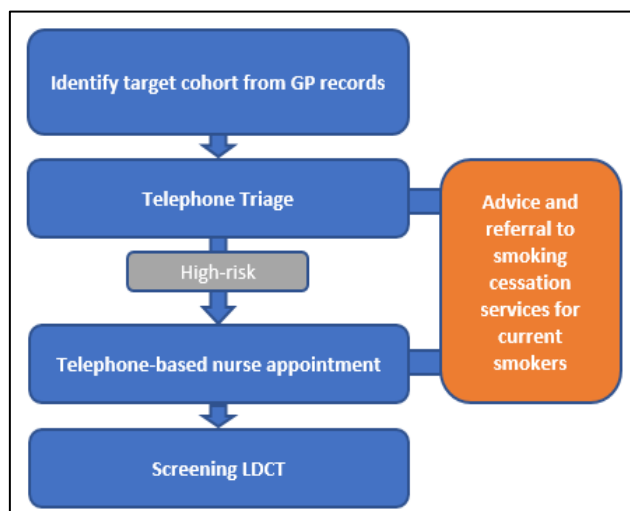


Figure 3b: High-level summary of participant pathway.

The service was designed as an “opt-out” model, with the target cohort actively contacted by the service to undertake the telephone triage stage rather than relying on individuals to make contact with the service. Separate telephone-based triage and nurse appointments were undertaken, rather than a “one-stop” model where participants would attend a site in person to undergo risk assessment +/- LDCT. An initial telephone-based approach has been used successfully in large-scale UK lung screening trials,[17,18] and combined with an opt-out approach was expected to maximise participation. This approach also enables efficient use of appointments and staff time, though carries a greater risk of participation attrition between steps.

Telephone triage was not a feature of early UK LHC activity, and was introduced partly to improve efficiency of nurse and LDCT appointment utilisation, and partly to enable services to continue during the COVID-19 pandemic. Given the inclusion of telephone triage in the pathway for the OP, there was extensive discussion during planning about whether a nurse appointment step was also required, noting that the focus of this could include:

- 1) Confirming the findings of the risk assessment undertaken at telephone triage in order to confirm eligibility for LDCT,
- 2) Assessing for non-cancer-related respiratory diagnoses such as chronic obstructive pulmonary disease (COPD), as part of a wider “Lung Health Check”,
- 3) Discussing the benefits and risks of screening to enable properly informed consent, and
- 4) Enabling an IRMER (Ionising Radiation (Medical Exposure) Regulations)-qualified nurse to request the LDCT scan.

Feedback from other LHC sites at the time reported correlation between risk assessment at telephone triage and at subsequent nurse appointments to be very high, suggesting there may be little added benefit to the risk assessment being confirmed by a qualified nurse (though subsequent findings have disputed this). It was also decided early during planning of the OP that activity would focus on the two elements with clear evidence of clinical and cost-effectiveness, namely targeted lung cancer screening and smoking cessation. Whilst incidental findings would need to be appropriately managed, the OP did not actively seek additional diagnoses such as COPD, and did not include spirometry as part of the assessment process. This therefore negated the first two reasons for the nurse appointment listed above. It is possible that the fourth reason, for an IRMER-qualified nurse to request the LDCT scan, could have been overcome with LDCT scans being requested by an IRMER-qualified individual based on information collected at telephone triage, though this was not fully explored.

Ultimately the nurse appointment was retained as a step in the pathway primarily to allow a more detailed discussion of the benefits and risks of screening. All existing models in England utilise a nurse appointment step, and InHealth staff undertaking the telephone triage stage had not received training on discussing risks and benefits of screening with participants. To streamline a future service, additional focussed training on this topic could be considered to up-skill staff performing telephone triage appointments, with the option of escalation to a nurse or other individual where participants want or need a more detailed discussion.

### 3.2.2 Identification of the target cohort

#### 3.2.2.1 Eligibility criteria

The eligibility criteria for targeted lung cancer screening have varied in activity elsewhere.[12] All have invited people within a defined age range regardless of sex, then used additional criteria to select those at high risk of lung cancer who would proceed to LDCT.

It was determined through scoping and planning work that the initial eligibility criteria for invitation to the OP would be:

- Age 60-74 years
- Current or ex-smoker (“ever-smoker”)

A narrower age range of 60-74 years was selected than is used in the NHS England Targeted Lung Health Check Programme (NHSE TLHCP) and subsequently recommended by the UK National Screening Committee (55-74 years),[10,11] in order to enrich the risk profile of participants and maximise learning in light of the OP’s limited scale.

Once ever-smokers in the target age range have been identified, those at high risk of lung cancer need to be identified to offer LDCT screening. Older trials and screening programmes in some countries (e.g. USA) determine eligibility for LDCT purely based on smoking history, including duration and heaviness of smoking, and duration of abstinence if the person is an ex-smoker.[7,8,19] Most UK lung cancer screening activity, including the UK Lung Screening Trial (UKLS) and the NHSE TLHCP, have used one or more multivariable risk assessment tools that calculate an individual’s risk of developing lung cancer over an approximately 5-year period to determine eligibility.[6,11,20] Evidence suggests that such tools can identify those at higher risk better than smoking history alone, leading to a lower number-needed-to-screen per lung cancer identified and therefore improved cost-effectiveness.[12]

A number of multivariable risk assessment tools exist. Much of the planning for the pilot was based on the planned use of an updated version of the Liverpool Lung Project tool, version 3 (LLPv3).[21] Ultimately, it was not possible for this tool to be accommodated by the software systems used in the OP within a reasonable time-frame. As such, the pilot aligned with the risk tools used in the NHSE TLHCP – a combination of the PLCO<sub>m2012</sub> and LLPv2 tools, with participants who met either criteria proceeding to the offer of LDCT (table 3a).[11]

Table 3a: Multivariable lung cancer risk assessment tools used in the OP.

Tool	LLPv2	PLCO <sub>m2012</sub>
<b>Components</b>	<ul style="list-style-type: none"> <li>• Age</li> <li>• Gender</li> <li>• Smoking duration</li> <li>• History of pneumonia/COPD/emphysema/bronchitis/tuberculosis (TB)</li> <li>• Occupational asbestos exposure</li> <li>• Previous history of malignancy</li> <li>• Previous family history of lung cancer; relative's age at onset (&lt;60 y or &gt;60 years) and whether first degree relative</li> </ul>	<ul style="list-style-type: none"> <li>• Age</li> <li>• Education level</li> <li>• Body mass index</li> <li>• History of COPD/chronic bronchitis/emphysema</li> <li>• Personal history of lung cancer</li> <li>• Family history of lung cancer</li> <li>• Ethnicity</li> <li>• Smoking status</li> <li>• Average number of cigarettes smoked per day</li> <li>• Duration smoked (years)</li> <li>• Years having ceased smoking</li> </ul>
<b>Threshold</b>	≥2.5% risk of lung cancer over 5 years	≥1.51% risk of lung cancer over 6 years

### 3.2.2.2 Identification of ever-smokers

Lung cancer screening trials that used true population-based approaches to invitation (contacting every person in the target age range without any additional initial filter based on smoking history) have typically had low participation rates and found this approach to be highly resource-intensive.[7,14] A more targeted approach, utilising smoking data held on primary care records to identify individuals suitable for further risk stratification, has become the favoured approach in the UK.[22]

An extensive range of “tobacco codes” can be recorded on an individual’s electronic primary care record, indicating smoking status and consumption, and multiple codes can be recorded at different time-points. As such, identifying ever-smokers from primary care records is not as straight-forward as might be assumed. Work had already been undertaken in Wales assessing the completeness of primary care smoking data and examining the effects of using different search strategies for tobacco codes in primary care records,[23–25] and work in England has explored discrepancies between self-reported smoking status and that recorded on primary care records, and the effect of various strategies for identifying eligible participants for lung cancer screening from primary care records.[18,26,27] Briefly, data completeness in a sample of practices in Wales was high, with over 96% of individuals aged 50-74 years having at least one tobacco code ever recorded. Using a broad search strategy for current and ex-smoker tobacco codes recorded at any point is likely to capture almost all current- and ex-smokers. A small number of people only ever coded as “never smoked” may in fact be ever-smokers, but this group are unlikely to have accumulated a sufficient smoking history to be at high enough risk to be eligible for LDCT screening.

Based on the above, it was determined that ever-smoker status, and therefore eligibility for invitation, would be by identification of any individual aged 60-74 years with a current or ex-smoker code ever recorded on their primary care record.

### 3.2.3 Determining the area and specific GP practices to invite

In determining a geographical area in which to target delivery of the OP, and ultimately which General Practice (GP) practices to work with, a number of factors were considered relating to the practicalities of delivery as well as maximisation of benefits. It was felt that delivery would be enhanced by aligning the OP with the lung cancer multi-disciplinary team (MDT) in which the LHC Clinical Lead participates, which is based in the Royal Glamorgan Hospital (RGH) and serves the Rhondda Cynon Taf area. It was also felt that aiming to deliver the OP within one GP Cluster area would support effective planning and communication. Finally, it was felt that targeting an area with high lung cancer mortality and smoking prevalence, both of which are linked to deprivation, would help to maximise the benefits from the OP. Based on consideration of all these factors, the North Rhondda Cluster area was identified as the target area for delivery of the OP.

A delivery plan within the North Rhondda area was developed, focussed on identifying sufficient high-risk participants to generate the required number of LDCT scans, but limiting the risk of generating a volume of scans that exceeded the available funding. Looking at the total population within the age range by GP practice and comparing this to the modelling work that had been undertaken, it was decided to start the OP by inviting participants from GP practices within the Valleys Medical Group, specifically St David's Street Surgery and Llwynypia Surgery; followed by Forest View Health, specifically New Ty Newydd Surgery, Forest View Medical Centre and Treorchy Surgery. A decision regarding any further roll out would be informed by the activity generated from these practices.

All areas within North Rhondda rank in either the most- or second-most deprived quintiles in Wales as measured by the Welsh Index of Multiple Deprivation (WIMD).[28] Table 3b describes the GP practices included in the OP.

*Table 3b: Welsh Index of Multiple Deprivation data at GP practice level.*

Practice	Population	Practice deprivation quintile by WIMD (1= most deprived, 5= least deprived)
Forest View Health	16,058	2
St David's/ Llwynypia	9,168	2

### 3.2.4 Planning the delivery of LDCT scans

Lung cancer screening requires acquisition of a LDCT scan of the thorax without intravenous contrast administration. Acquisition of low-dose CT images is possible using any CT scanner, though more modern scanners allow better image quality to be obtained for equivalent radiation exposure to the participant. It was determined early in planning that scanning activity for the pilot could not be accommodated by existing CT capacity within CTM UHB. It was therefore known that use of a CT scanner would be a required part of a procurement package for the pilot.

Various CT scanner units have been used in LHC activity elsewhere. In some densely populated urban areas such as central London, fixed site hospital-based scanners have been used. In Manchester, a large mobile CT unit is used, which connects three lorries to create an area with a CT scanner, waiting room, consultation rooms and other features. Other programmes have used a simpler set up with a single lorry hosting a mobile CT scanner, without additional on-site features, with other components of the



LHC such as risk assessment taking place separately. For simplicity and to limit costs (and therefore allow a greater number of people to be scanned within the OP's finite budget), it was decided to use a simple mobile scanner unit, without additional on-site facilities. This aligned with plans to streamline the upstream process with telephone-based rather than in-person assessments.

Various locations were considered for where to locate the mobile scanner once North Rhondda had been selected as the target area. Both healthcare settings and community settings have been used in LHC activity elsewhere, with no clear evidence favouring one approach over the other. The RGH site was considered, with advantages of it being a well-recognised location with good transport links and having a mobile unit "pad", allowing direct power provision and data transfer to/from the CT scanner. However, the use of the mobile unit pad was not guaranteed due to its use by other services, and a location closer to North Rhondda was desirable to reduce travel-related barriers to participation. Ysbyty Cwm Rhondda (YCR), a community hospital within CTM UHB, emerged as the preferred location due to its proximity to the target population of North Rhondda, public transport links, availability of free car parking, exiting hospital security arrangements, and the reduced complexity of using a site within Health Board grounds compared to an external location. Some limited scoping of local supermarkets, sports clubs and university facilities was conducted prior to YCR ultimately being confirmed as the scanner location for the OP.

### 3.2.5 Modelling work for scale

#### *3.2.5.1 Modelling the population requirements to meet the target level of activity*

As the initial business case included estimates for the resources required to deliver either 500 or 1,000 initial LDCT scans, work was undertaken to determine the target level of activity for the OP based on the estimated costs and funding available. In parallel, data modelling was undertaken to estimate the total population within the age range that would be required in order to generate the target number of LDCT scans. The modelling work was based on an assumption of a service model aligned to the NHSE TLHCP.[11] Table 3c includes the pathway stages included and the final calculations that were used. Multiple adjustments were made during the planning stages as new evidence became available.

Using these calculations it was possible to model the estimated total population within the age range that would be required in order to generate 500 or 1,000 initial LDCT scans, against different scenarios of uptake and the percentage referred for LDCT, as set out in figure 3c.[3,29,30]

Table 3c: Modelling assumptions to calculate projected delivery of the OP.

Parameter	Considerations	Calculation (from previous parameter)
Total population within age range	'StatsWales' provides population data by GP Practice, broken down by age. Once the estimated population requirements had been projected using the calculations in this table, this data was used to inform a roll-out plan for GP practices.	N/A
% of ever smokers	Based on data from the NHSE TLHCP and Office for National Statistics (ONS) data on smoking rates in Wales.	54%
% of people invited that accept invitation to initial LHC appointment	Evidence from the NHSE TLHCP and other studies demonstrated wide variation in the percentage of people invited for LHC that would respond positively to this invitation (generally referred to as 'uptake', but not consistently defined and measured). It was therefore determined that a range of calculations would be used to reflect the uncertainty regarding expected uptake. It was felt, however, that following the learning from England in relation to engagement and booking strategy, it may be possible to achieve a higher rate of uptake for the OP, so the range of calculations used included a middle calculation that was higher than the average in England, and an upper limit higher than the highest uptake reported in England.	35% / 50% / 65%
% participants attend initial LHC appointment	This calculation was based on the data modelling used by the NHSE TLHCP.	92%
% participants identified as 'high risk' and referred for LDCT	There were a number of considerations when determining this calculation. The first was in relation to the risk tool that would be used. Initially it was planned to use an updated version of the Liverpool Lung Project tool (LLPv3). As no prospective data on the use of this tool was available, a range of estimates was used for modelling. Secondly, the OP planned to invite 60-74 year-olds, a population with a higher risk profile than the broader age range invited to the NHSE TLHCP.  Ultimately it was not possible to use LLPv3 (see section 3.2.2.1), and late in the planning of the OP it was decided to switch to using the same combination of risk tools used in the NHSE TLHCP: LLPv2 and PLCO <sub>m2012</sub> . This was expected to have the effect of increasing this parameter to 50-70% based on figures from the NHSE TLHCP. Given the late stage this change was made, limited further remodelling to account for this was undertaken which is not presented here.	30% / 40% / 50%
% participants attend LDCT	This calculation was based on the data modelling used by the NHSE TLHCP.	85%
% require 3-month + 12-month recall scans	This calculation was based on the data modelling used by the NHSE TLHCP.	14.2%

		Population required: 500 LDCTs			Population required: 1,000 LDCTs		
% accept invitation	65%	9,108	6,072	4,554	18,216	12,144	9,108
	50%	11,840	7,894	5,920	23,681	15,787	11,840
	35%	16,915	11,277	8,457	33,830	22,553	16,915
		30%	40%	50%	30%	40%	50%
		% Referred for LDCT			% Referred for LDCT		

*Figure 3c: Projected range of eligible population required to generate 500 and 1,000 initial LDCT scans. Note that a late change to the risk assessment tools planned for use in the OP increased the predicted % referred for LDCT to over 50%, therefore final invited population sizes were smaller than displayed here.*

As the above demonstrates, the potential variation in some steps of the pathway can have a profound impact. For example, if both uptake and the percentage referred for LDCT were low, then a total population of 16,915 within the age range would be required to generate 500 LDCT scans. In contrast, if these were both at the high end of the modelling the population required would be 4,554.

This insight was important for the planning for the OP for two reasons. Firstly, it gave an indication of the total population within the age range that would be required, so that planning could be focussed on this. Secondly, understanding the potential variation influenced the way that delivery of the OP was planned, highlighting that this would need to incorporate an approach that would mitigate the risk of inviting too large a population for the OP's budget to accommodate. It was therefore planned to start by inviting smaller numbers and expanding as required.

Based on the funding commitments and modelling work undertaken, it was determined that the OP would aim to deliver baseline LDCT scans to 500 participants, plus recall scans for surveillance of small lung nodules detected on baseline scans.

### 3.2.5.2 Modelling the impact on downstream services

Further modelling was undertaken to project expected outcomes and impact on other services. Initially this was based on the calculations used by the NHSE TLHCP (table 3d), from which it was possible to provide assurance to downstream services in relation to projected impact, e.g. for Positron Emission Tomography (PET), thoracic surgery, etc. The projections were based on early data from the Manchester LHC pilot,[5] which have proven to be higher than the lung cancer diagnosis rate seen in the NHSE TLHCP subsequently.[3] As such, these projections were likely to be towards the upper limit of what could be expected in the OP.

*Table 3d: Modelling the downstream impact of the OP. Note that the Manchester LHC pilot, on which the calculations are based, occurred prior to immunotherapy being recommended in the UK as a treatment option for lung cancer.*

Findings	Comment	Projection based on 500 baseline scans
Needs further investigation for suspected lung cancer	5.9% of initial LDCT scans performed	30
Lung cancers found	50.8% of 'Needs further investigation'	15
Surgery (alone)	51.0% of Cancers found	8
Surgery and Adjuvant Chemotherapy	7.7% of Cancers found	1.2
Stereotactic Ablative Radiotherapy (SABR)	12.2% of Cancers found	1.8
Chemo-Radiotherapy	9.1% of Cancers found	1.4
Radiotherapy (alone)	9.1% of Cancers found	1.4
Chemotherapy (alone)	4.6% of Cancers found	0.7
No Treatment / Best Supportive Care	6.1% of Cancers found	0.9

### 3.2.6 Communications and engagement planning

#### 3.2.6.1 Communications Plan

A collaborative approach was taken in the development of a Communications Plan for the OP, led by the Communication Leads from CTM UHB and the Cancer Network. Specific communications needs and objectives were identified as below:

#### Needs

- Optimise uptake of the OP by the eligible population (current or ex-smokers age 60 to 74) in the target catchment areas (selected GP practices in North Rhondda) to allow delivery of approximately 500 baseline LDCT scans.

#### Objectives

- Develop a package of adaptable public-facing communications including a leaflet, poster, booklet and webpage, to promote the OP to the target population.
- Develop a targeted public awareness campaign to promote the OP to the eligible population, signpost to the smoking cessation service and promote awareness with third sector/relevant stakeholders.
- Develop an engagement plan that can be repurposed for potential spread and scale following the completion of the OP.

#### 3.2.6.2 Development of the invitation strategy and public facing communication materials

It is well recognised that individuals who are at the highest risk of lung cancer, including current smokers and those with low socio-economic status, are least likely to respond to a lung cancer screening invitation.[31]

LHC programmes have used different engagement and invitation strategies, leading to wide variation in participation rates.[3,32] Much research has been undertaken to explore reasons for non-participation.[14,15,32,33] These include:

- Lack of awareness
- Lack of engagement
  - Linked to fear of cancer diagnosis, stigma related to lung cancer and smoking, and fatalistic views regarding lung cancer
  - Lack of trust in a new or unknown service
  - Imbalance of perceived benefits and risks of participation
  - Difficulties with language or health literacy
- Practical concerns
  - Difficulty accessing the service (relating to public transport or parking availability; knowledge of location; conflicting priorities such as work; other health problems or family commitments; disability)
  - Cost (including travel; parking)

Many of these barriers to participation disproportionately affect those at highest risk, and so the approach planned for invitation to participate in the OP, and the participant materials produced to support this, was designed to maximise informed and equitable participation. Evidence-based best practice was used to inform the design and content of the public-facing communications materials which included a poster, leaflet and booklet (including Easy Read version), all available in English and Welsh.

User feedback was sought to inform the development of these materials, including input from the Cancer Patient Forum, members of the public recruited from the Tenovus All-Wales Cancer Community and the Health Cancer Research Wales Involving People network organised by Dr Grace McCutchan (Cardiff University Division of Population Medicine/Wales Cancer Research Centre), the Cancer Network Patient Engagement and Experience Team, and the Public Health Wales Screening Engagement Team. The creation of the final materials was undertaken by Dafydd Snelling, Senior Communications and Engagement Officer at CTM UHB, working collaboratively with the Programme Team.

#### 3.2.6.2.1 Invitation process

At a high level, it was planned for the invitation process to incorporate a pre-invitation communication followed by invitation letters with a date and time of the telephone appointment, and an enclosed booklet with detailed information about LHC, to support informed decision-making about participation.

#### 3.2.6.2.2 Pre-invitation communication

Pre-invitation information was designed with the aim of reducing the likelihood of an initial invitation being ignored, with familiarity at the point of receiving the invitation more likely to lead to engagement.

The pre-invitation communication comprised of a bilingual tri-fold leaflet to introduce the concept of a LHC, together with a letter informing the individual that they would shortly receive an invitation to a LHC telephone appointment. A poster and digital display were also produced to be displayed in participating GP practices and associated pharmacies to align with the initial communications being

sent. A 'happy lungs' image was used consistently through all of the pre-invitation and invitation communications which was inspired and adapted with permission from materials used by the Roy Castle Lung Cancer Foundation. The pre-invitation messaging was designed to gradually introduce the theme of lung cancer to avoid early disengagement due to fear and fatalism. Clear and specific information about who was eligible was included. Social media posts made by CTM UHB also incorporated these key messages and the happy lungs imagery to ensure consistency.

### 3.2.6.2.3 Leaflet and pre-invitation letter

Many aspects of the design and content of the leaflet (figure 3d) were adapted with permission from materials used in LHC programmes in England. Key features of the leaflet include:

- Bright, colourful design to capture attention
- Statements designed to avoid early disengagement due to:
  - Practical barriers – “it’s free”, “convenient telephone appointment”, “if you can’t manage a telephone appointment let us know and we can discuss other options”
  - Lack of trust – local GP endorsement and NHS Wales logo
  - Fear & fatalism - limited mention of lung cancer at this stage of the pathway; positive messaging – “a great way to give your hard-working lungs an MOT”
  - Smoking-related stigma – “no judgements on smoking”
- Enable those with language-barriers or limited health-literacy
  - Welsh version on reverse
  - Clear communication and avoidance of jargon, gaining the “Plain English Campaign” crystal mark accreditation[34]

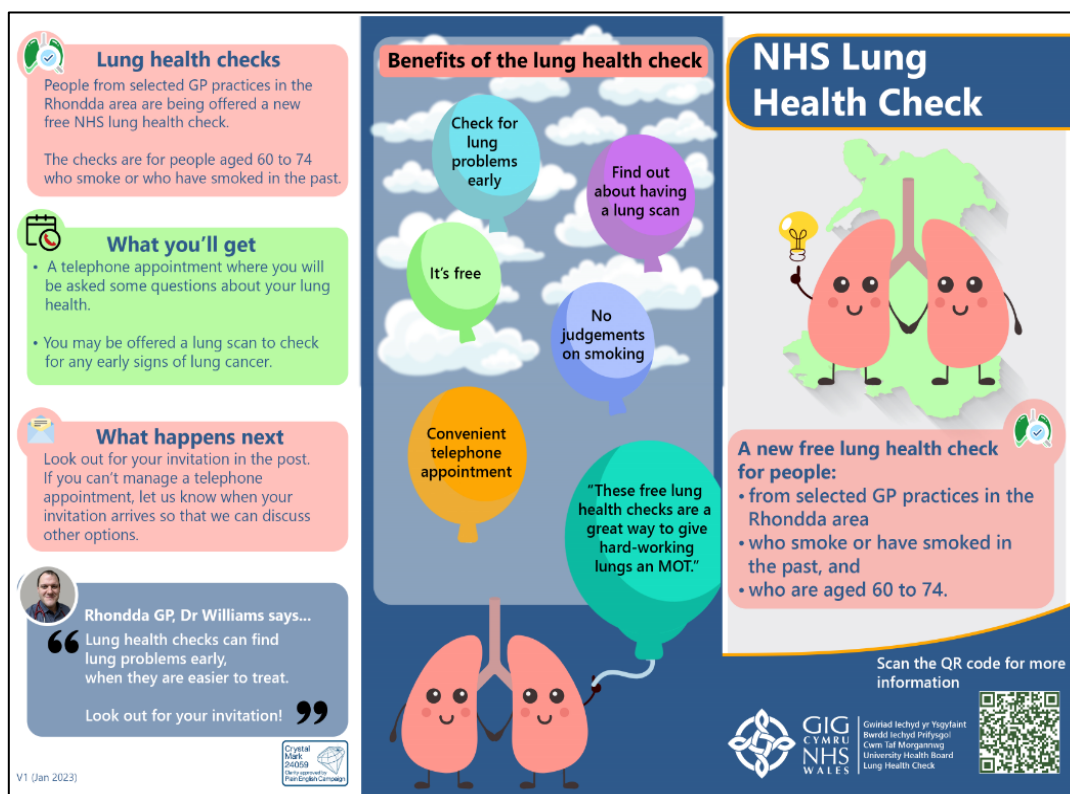


Figure 3d: LHC tri-fold leaflet.



## 3.2.6.2.4 Poster and digital display

To align with the timing of pre-invitation letters being sent, it was planned that posters would be displayed on noticeboards in participating GP practices and associated community pharmacies (figure 3e), as well as a digital version displayed on screens in the waiting areas.

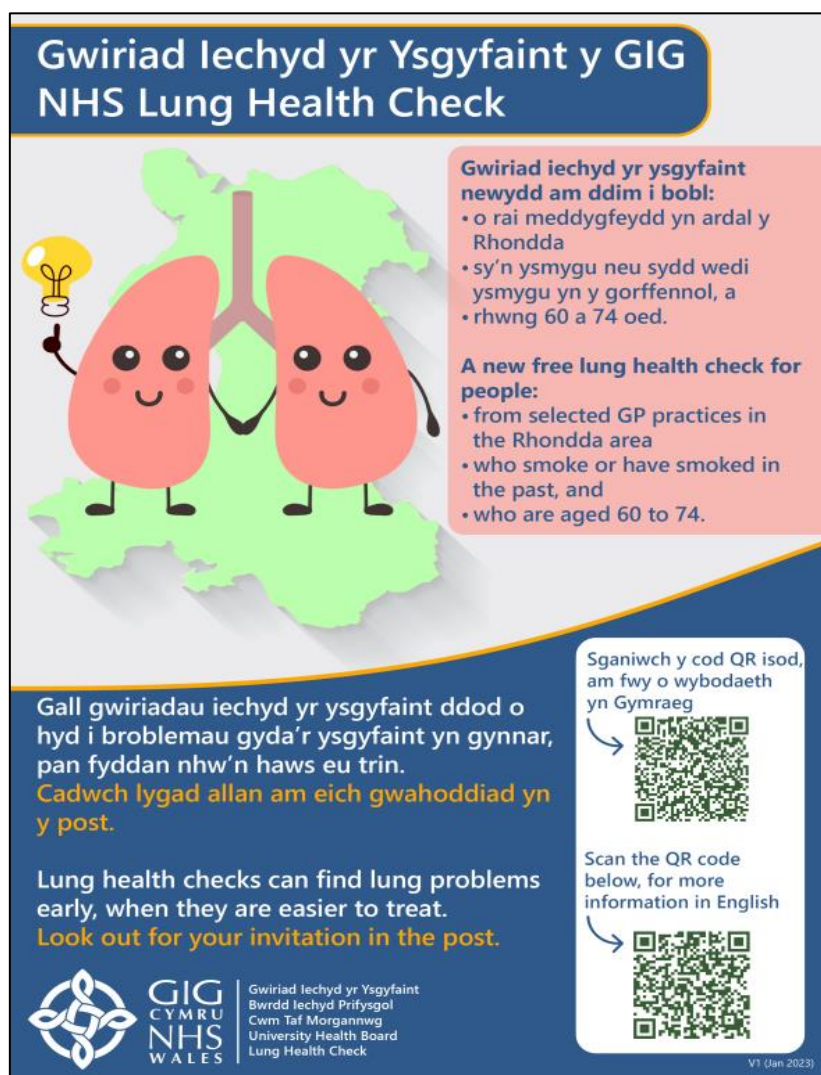


Figure 3e: LHC poster.

## 3.2.6.2.5 Standard Booklet/ Easy Read version and invitation letter

Following the pre-invitation communications, it was planned that an invitation would be sent with a specified date and time that the participant would be called for their LHC appointment, with the option to request an alternative date or time if required. Enclosed with the invitation letter would be a booklet, designed to provide information to participants on the LHC process and the benefits and risks to enable informed consent for screening. Key messages about smoking, healthy living, and “red flag” lung cancer symptoms were also included.



Designing the booklet was a lengthy process, with numerous drafts and rounds of revisions following consultation with multiple stakeholder groups including those consulted during production of the leaflet. Plain English Campaign crystal mark accreditation was gained, and Welsh translation provided on the reverse.

Key features of the booklet included:

- More serious tone and imagery than initial engagement leaflet
  - Use of 'medical' lung image rather than 'happy lungs' cartoon-style image (note – this was a source of conflicting feedback during consultation, with some groups recommending brand consistency and lighter tone, and others suggesting the happy lungs image may not appeal to the target audience in this context)
  - Consistent colour palette with leaflet and NHS Wales/CTM communications to aid brand recognition
- NHS Wales logo
- Simple infographics to indicate likelihood of outcomes at certain stages of the pathway
- Emphasis on ease of participation – “follow simple breathing instructions for 10 seconds”, “the scan is not painful”
- Simplified infographics (e.g. using 100 people as the denominator vs. 250 people in NHS England booklet)
- Example participant experience stories
- “Plain English Campaign” crystal mark accreditation[34]
- Reversible English/Welsh bilingual format

Images 3f-i demonstrate the style of the booklet and how infographics and plain language were used to convey important information.

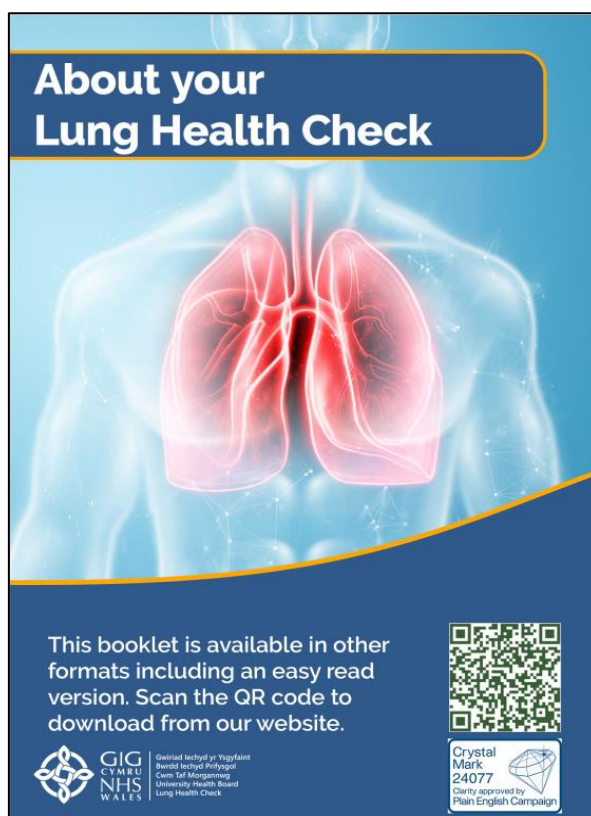


Figure 3f: LHC booklet cover.



Figure 3g: LHC booklet infographic.

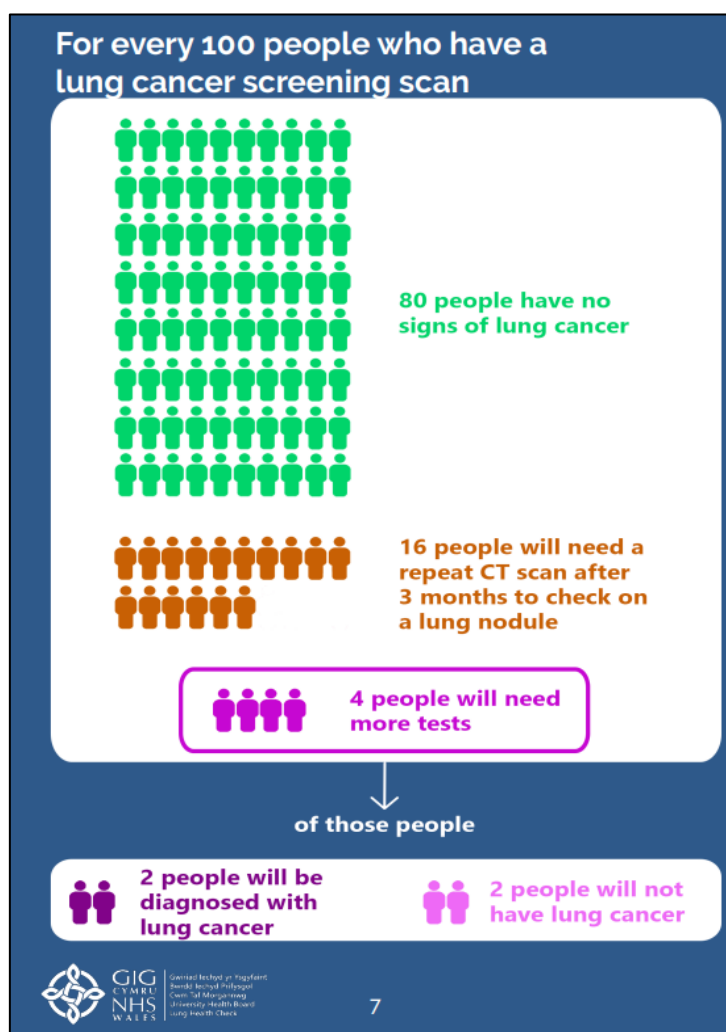


Figure 3h: LHC booklet infographic.



Figure 3i: LHC booklet participant stories.

In addition to the standard version of the booklet, a bilingual 'Easy Read' version was also developed. As is common for Easy Read material, this version is longer, explaining things in simplified language and with additional images. For example, the information on risks of LHCs in the standard and Easy Read booklets are shown in figure 3j.

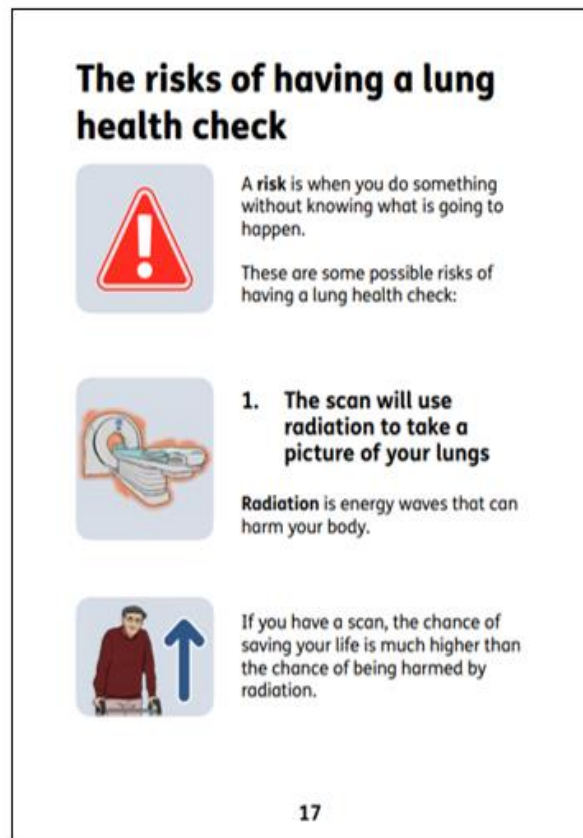


Figure 3j: Information included in the standard booklet (left) and Easy Read booklet (right).

Full versions of the standard and Easy Read booklets are available to download from the OP website:

<http://ctmuhb.nhs.wales/services/lung-health-checks/>

## 4. PROCEEDING FROM PLANNING TO IMPLEMENTATION

### 4.1 Procurement process

It was determined at an early stage that due to the time-limited nature of the OP it would not be viable to establish new services for all of the elements required for delivery, and therefore that a service provider would need to be contracted to deliver elements of the service. Discussions were progressed with the Procurement team at an early stage, through which it was confirmed that LHC services are included in an existing NHS Supply Chain Procurement Framework (the 'Managed Equipment and Clinical Service Solutions' framework). This meant that a contract could be awarded directly to the preferred supplier following a tendering process.

Whilst it was known that separate service providers may have been required to deliver specific elements of the service, it was agreed that the full service would be contracted to one service provider who could sub-contract elements as required. A Service Specification was developed and circulated to potential service providers via the framework, and submissions were assessed and scored against pre-determined criteria. Through this process, InHealth were confirmed as the preferred service provider, with elements of the service sub-contracted to Heart&Lung Health (HLH).

The process took several months due to the initial time taken to confirm the approach, gaining Health Board approval, developing the required documents and agreeing these with the relevant teams, progressing the process through Procurement, arranging review panels, awaiting responses to clarification questions, and finally awarding the contract. As soon as the contract award was confirmed the service provider began working with the Programme Team on the planning for the OP, whilst the actual contract took further time to agree and sign off prior to the service commencing.

### 4.2 Clinical governance

#### 4.2.1 Clinical governance structure

As delivery of the OP included outsourcing several elements of the pathway, it was important that a clinical governance structure was established clearly setting out the responsibilities of each clinical role and ensuring that processes between outsourced and locally delivered elements of the OP would run safely and efficiently. This would also inform the requirements for a clinical team to support delivery of the OP. Figure 4a sets out the clinical governance structure for the OP. The key responsibilities of each role are described in the subsequent sections.

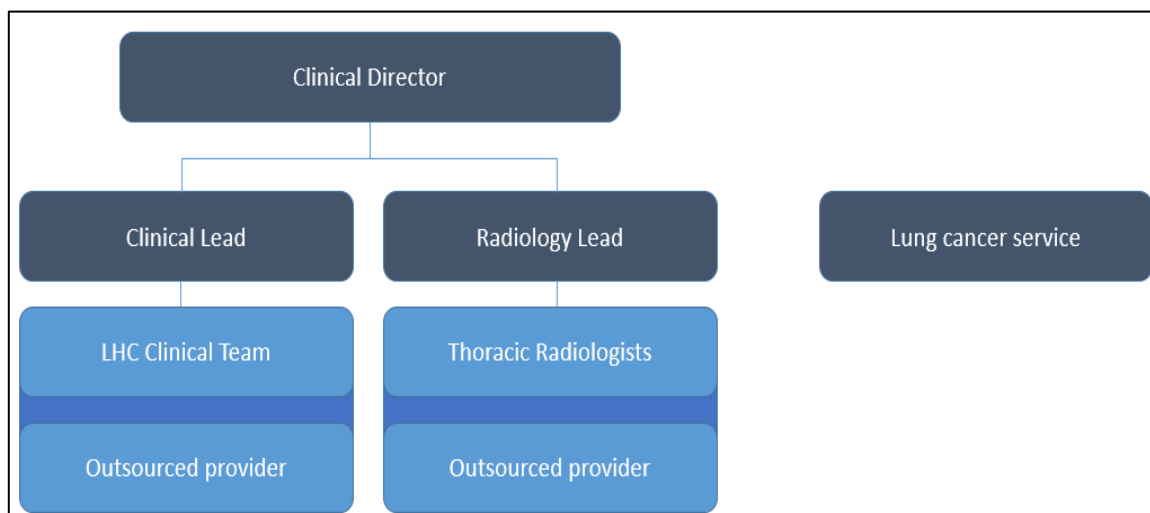


Figure 4a: Clinical governance structure for the OP.

#### 4.2.2 Clinical Director

Overall responsibility for safety of patients involved in the OP, up to the point of discharge from the OP or acceptance of referral to another service (e.g. the Royal Glamorgan Hospital lung cancer service), including:

- Verification of procedures for selection, scanning, acting on findings, communicating with participants, and recall mechanisms.
- Ensuring that delivery of the OP remained aligned to the objectives of the OP as directed by the governance structure in place for the LHC programme, and for reporting broader governance groups.

#### 4.2.3 Clinical Lead

Responsibility for the leadership of the day-to-day processes of the OP, including:

- Selection and assessment for entry to the OP.
- The telephone LHC including risk assessment for lung cancer.
- Referral for LDCT.
- Receiving and acting on results of telephone LHCs and LDCTs, including communication with participants, Primary Care and other services.
- Ensuring clinical data and information related to the above is appropriately recorded.
- Ensure improvements and corrective actions are implemented to support governance, training and improve quality.

#### 4.2.4 Radiologist Lead

Responsibility for leadership and day-to-day processes of the OP relating to:

- LDCT delivery.
- Recruitment and training of thoracic radiologists.
- Quality, timeliness and data completeness of LDCT reporting.
- Mechanisms to ensure LDCT results are communicated to the LHC Clinical Team, including processes for urgent results.

#### 4.2.5 LHC Clinical Team

Responsibility for:

- Receiving, interpreting, acting on, and communicating results from telephone LHCs and LDCTs. Communication will be to participants, Primary Care and referrals to other services as required, and may include letters, telephone calls, and occasionally face-to-face.
- Co-ordination of the LHC Screening Review Meeting, including recording and acting on results of discussions.

#### 4.2.6 Thoracic radiologists

Responsibility for:

- Reporting of LDCT, co-ordinated via an outsourced provider under the leadership of the Radiologist Lead.
- Requirement for appropriate training to be undertaken prior to contributing to reporting for the OP, and reporting to be aligned with processes agreed for the OP including use of Artificial Intelligence (AI) assistance for nodule detection and adhering to the structured reporting template.

#### 4.2.7 Lung cancer service

Responsibility for:

- The Royal Glamorgan Hospital Lung Cancer Service to accept referrals from the OP at the point of suspicion of lung cancer on LDCT. Patients to enter the Single Cancer Pathway from the date of referral from the OP. The date of suspicion to be defined as the date of LDCT report, or the LHC MDT if the initial LDCT report is indeterminate for cancer.
- Responsibility for further investigations on the Single Cancer Pathway, including arranging contrast-enhanced CT, lies with the lung cancer service.

### 4.3 Recruitment of clinical posts

#### 4.3.1 LHC Clinical Team

Based on the clinical governance structure described above and informed by discussion with other LHC Programmes and local insight, it was determined that the resources required for the LHC Clinical Team were:



- Clinical Lead (sessional; also fulfilling the Clinical Director role)
- Radiologist Lead (1-2 sessions)
- Specialty Doctor (full time)
- Specialist Nurse (full time)
- Navigator (full time)

This team would deliver the following key functions:

- To organise and run weekly Screening Review Meetings (SRM), where LDCT images and reports are reviewed and forward pathways agreed for participants.
- Progressing forward plans following the SRM including communication with participants, Primary Care and referrals to other services as required, via letters, telephone calls, or face-to-face.
- Acting as a liaison between the Health Board and the service provider, particularly around clinical issues.
- To support the evaluation of the OP.

As the Clinical Lead role was fulfilled by the existing Programme Clinical Lead, no recruitment was required for this. The remaining posts were recruited by CTM UHB. As the job roles for the OP were new, job descriptions were drafted and job matched within the Health Board against the Agenda for Change Framework, with approvals sought in order to progress with advertising. The timing of the recruitment process was important, as the funding was finite and therefore contracts were time limited, so team members being recruited too soon would mean potentially lost clinical time at the outset and insufficient clinical time at the conclusion of the OP. Recruiting too late, however, would mean the OP potentially being delayed in starting.

The Radiologist Lead commenced in post in March 2023, in order to support the planning for the OP. The Speciality Doctor post had to be advertised twice, with updates made to the job description and advert to ensure that this met the requirements for the post following the initial advert. The Specialist Nurse post was advertised once and both posts were successfully recruited to commence in late August 2023. The Navigator post was advertised three times before a successful appointment was made, with the candidate starting in post in September 2023. Office space had been confirmed in advance of the new team starting, however this had proved challenging to identify and was ultimately agreed at an off-site location (within walking distance of the Royal Glamorgan Hospital where the Clinical and Radiologist Leads were based). Figure 4b shows the Clinical Team.

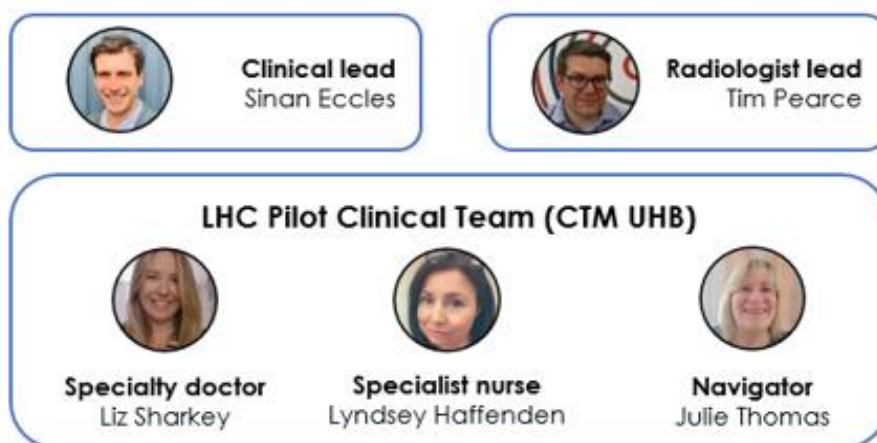


Figure 4b: LHC Clinical Team.

#### 4.3.2 Recruitment of thoracic radiologists from NHS Wales

As one of the objectives of the OP was to develop a core team that would gain experience to be used as the nucleus for a future national rollout of LHCs, it was felt to be important that where possible the reporting of LDCT scans should be undertaken by thoracic radiologists working in NHS Wales. Since the reporting of LDCT scans was subcontracted by InHealth to HLH, who were already providing this service to numerous LHC Programmes across England, software was available to facilitate remote reporting. HLH agreed to support the use of reporting radiologists from Wales where possible, provided that any new team members underwent their usual onboarding and training process.

The minimum qualifications to report for the OP were:

- Consultant radiologist who is on the General Medical Council (GMC) specialist register and is a Fellow of the Royal College of Radiologists, or
- Has radiology training and qualification accepted for equivalence which has led to the award of a Certificate of Eligibility for Specialist Registration

With minimum experience of:

- Reporting at least 500 thoracic CTs per annum in their routine clinical practice, a significant proportion of which are where there is a suspicion of lung cancer
- Regular participation at a thoracic MDT meeting (includes virtual attendance) as part of their routine clinical work

The LHC Clinical Lead and Lead Radiologist therefore approached thoracic radiologists across NHS Wales to promote this opportunity, and shared details with HLH from those that expressed an interest. HLH then liaised directly with the individuals to complete the onboarding process and to arrange the required internal training. HLH provided training on their reporting process including use of nodule detection software, thresholds for reporting findings, use of the structured reporting template, and the colour-coded flagging system for urgency of findings. Radiologists were required to familiarise themselves with HLH's reporting handbook and adhere to its guidance.

In addition, the 'British Society of Thoracic Imaging / NHS England Targeted Lung Health Check Workshop' needed to be completed and this was coordinated by the Lead Radiologist. Finally, once the onboarding and training had been completed, each thoracic radiologist was required to report fifteen training scans, followed by ten new scans that were double-read by an experienced HLH radiologist, before being signed off to report independently. HLH also committed to providing regular quality assurance data.

#### 4.4 Permissions and approvals

A number of permissions and approvals were required to proceed with the planning of the OP and the progression to implementation, some formal and some more informal.

##### 4.4.1 Informal support and permissions

**Clinical services:** In order to be able to proceed with the OP, the support of a number of clinical services was crucial. This included Primary Care, who were key partners in both the planning and delivery. Informal discussions were held with the Cluster leads in the target area early in the planning for the OP and continued throughout, ensuring their support and engagement. There was also Primary Care

representation on the Clinical Reference Group. It was important that downstream services that would be impacted by the OP were also engaged, with discussions held with services such as Cardiology and Radiology within CTM UHB, as well as tertiary services including PET and thoracic surgery. Representatives were again invited to be part of the Clinical Reference Group.

**Information Communication Technology (ICT):** As the OP would be generating clinical information via a third-party service provider, agreement was required as to how the ICT systems would link up and the clinical information would be received and stored by the Health Board. It was confirmed that the Health Board would require LDCT images and results to be available on its informatics systems so the teams focussed on how to achieve that. Ultimately it was determined that seeking to fully integrate the systems would be too complex to achieve within the scope of the OP and so a process was agreed whereby the images and results would be manually sent by the service provider and uploaded by the Health Board.

**Support services:** It was crucial that the site managers for Ysbyty Cwm Rhondda (YCR), where the scanner was planned to be sited, were in agreement and would support this, and discussions were progressed early in the planning to confirm. Discussions with Estates and Infection Control informed the development of the service specification to be used for the procurement process, and as this progressed the input of these teams in assessing the submissions from prospective providers and approving the relevant sections was required. The Estates team provided input in relation to the set up for the scanners e.g. provision of power and water, and the Infection Control team provided input in relation to cleaning protocols. Ultimately these teams were required to agree specific elements before the procurement process could be concluded, to avoid the risk of a contract being issued to a service provider that could not meet the requirements of the Health Board.

**Clinical Pathways:** All of the proposed clinical pathways were developed in discussion with the service provider and clinical services anticipated to be affected, as well as input from the LHC Clinical Reference Group. Key areas of focus included management of common incidental findings and referral to smoking cessation services. This also included agreement of a protocol for the management of emergency clinical findings identified out of hours, which was agreed in discussion with the Bed Management team and On Call teams. Final approval for the clinical protocols was sought from the Medical Director, with assurance provided in relation to the consultation process that had been followed.

#### 4.4.2 Formal approvals

**Health Board approval:** The first approval that was required from the Health Board was confirmation of their support to proceed with the OP, following the initial discussions at the Chief Executives Group. A paper was submitted to CTM UHB Executives in April 2021 summarising the position and proposed approach, from which there was agreement to progress, but with a requirement to confirm the governance structure, financial arrangements and proposed location of the scanner. Once this work was complete, a further paper was presented to Executives in August 2022 updating on these areas, from which there was confirmation of the agreement to proceed.

**Equality Impact Assessment (EQIA):** The Health Board required an EQIA to be completed, to ensure that this was incorporated into the planning for the OP. An EQIA was completed by the Programme Team and approved by the Health Board's Equality Team, to be retained and updated as a live document.

**Funding:** Formal approval was required in relation to the contractual arrangements for the funding from Industry and Third Sector partners to be received by the Health Board. This requiring approval by the Executive Director of Finance for a number of 'Grant' and 'Sponsorship' agreements and for the funding request letters to be issued in order for the funding to be received.

**Procurement:** With the funding arrangements confirmed, approvals were required in line with the Scheme of Delegation, up to Executive Director level, in order to proceed with the procurement process to commission of a service provider.

**Recruitment:** In order for the LHC Clinical Team to be recruited by the Health Board, approval to advertise the posts was required through the Health Board's vacancy approval process.

**Ionising Radiation (Medical Exposure) Regulations:** In recognition of the responsibilities of the service provider and CTM UHB in relation to Ionising Radiation (Medical Exposure) Regulations (IRMER), a number of documents had to be agreed and approved, detailing arrangements such as radiation risk assessment, reporting requirements for any radiation incidents and entitlement processes for LDCT referral by non-medical referrers. This required a number of discussions and amendments to original documents, but were ultimately approved by the Health Board's Lead for Radiation.

**Information Governance:** Once a service provider had been confirmed, a number of approvals in relation to Information Governance (IG) were required. These included Data Protection Impact Assessment (DPIA) and Cyber Security approval by the Health Board and Data Disclosure Agreements (DDA) between the provider and the GP Practices. Approval of the DPIA and Cyber Security took some time, predominantly due to capacity constraints within the Health Board's IG team. Ultimately the DPIA was approved with only minor amendments required. Cyber Security proved to be more challenging, with the key issue being in relation to the requirement for remote access by the service provider to run the scripts to extract the participant list from GP Practice systems. Ultimately an alternative approach was approved whereby the GP Practices ran the search scripts locally and securely transferred the data to the service provider. The DDAs were approved by the GP Practices with no amendments required.

**Contract:** Whilst the service provider supported the planning for the OP following the completion of the procurement process, they could not start to deliver this until the contract had been signed. This took time due to the size of the contract and the potential financial penalties in relation to delays once a start date was agreed. The contract required approval to Director level and was ultimately approved in time for the agreed start date.

## 5. DETAILED PLANNING TO COMMENCE THE OPERATIONAL PILOT

Once the procurement process had been completed with InHealth confirmed as the service provider, focussed work commenced to plan for delivery of the service in line with the service model described in previous sections.

### 5.1 Extraction of the target cohort

As described in section 4.4.2, it was not possible for the service provider to log in remotely to GP systems to extract the participant list due to Information Governance constraints. It was therefore determined that the GP practices would provide this information to InHealth via secure transfer. The GP practices were able to exclude people at this stage if invitation was deemed inappropriate, e.g. people listed on the practice's palliative care register with a short life expectancy.

### 5.2 Telephone triage

#### 5.2.1 Telephone triage invitation

It was agreed that as per the invitation strategy, participants would be sent a pre-invitation letter and leaflet explaining their eligibility for a LHC, followed by an invitation letter and booklet. The invitation letter that was agreed with InHealth was designed to optimise uptake, with the following key features:

- Invitation addressed to named person (rather than open invitation)
- GP endorsement
- NHS and happy lungs branding
- Highlighting convenient, short duration initial telephone-based appointment
- "Opt-out/closed invitation" format – potential participants are given a date and time that the service will call them – avoiding the need for participants to undertake an initial action themselves to participate
- Reminder text messages
- Multiple contact options (telephone, email, address) to rearrange, or request additional support or information

#### 5.2.2 Telephone triage process

The main purpose of the telephone triage (TT) was to assess eligibility for LDCT. It was confirmed that TT appointments would be undertaken by InHealth Patient Care Advisers (PCAs), equivalent to Band 3 staff within the NHS. In addition to a generic mandatory training programme, specific training provided by InHealth for this staff group included: training on undertaking telephone triage, soft skills, smoking scenarios, and history-taking conversations.

A handbook and call script were agreed for the pilot to ensure key aspects of the consultation were covered consistently, with responses captured through a structured form on InHealth's SPECTRA software. The appointments would include:

- Introduction and confirmation of participant's identity
- Data protection and training/research statements/consent
- Determining ever-smoker status (defined clinically as lifetime consumption of at least one hundred cigarettes)
- Questions to populate PLCO<sub>m2012</sub> and LLPv2 risk assessments
- Initial check for exclusion criteria (e.g. would you be able to lie flat for a scan?)
- Very Brief Advice<sup>i</sup> [National Centre of Smoking Cessation and Training guidance] and opt-out referral to NHS Wales Help Me Quit smoking cessation service for current smokers

The handbook and script also contained guidance on managing a wide range of possible scenarios, including pathways if contact was not successfully made, if the participant was driving at the time of the call, had hearing difficulties, declined to proceed, or asked a Frequently Asked Question (FAQ).

Participants meeting the criteria for LDCT would be offered a telephone-based nurse assessment, whilst those below the threshold were given standard advice.

### 5.3 Check for recent or planned imaging

#### 5.3.1 Rationale

A recent thoracic CT scan is an exclusion criterion for lung cancer screening. If an individual has undergone recent CT imaging of the chest that did not show a suspicion of lung cancer, it is very unlikely that undergoing a further CT scan in a short time interval will be of benefit. The longer the interval between previous imaging and a screening scan, the more chance there is for a lung cancer to develop during that time and be detected through screening. Whilst there is a small chance that a detectable lung cancer could develop in a short interval, the risks of screening are likely to outweigh the small chance of benefit in this situation.

Various intervals between LDCT screening rounds have been used in lung cancer screening trials.[12] The shortest interval used between rounds in a trial demonstrating mortality benefit was 12 months,[8] therefore a thoracic CT within 12 months was used as an exclusion criterion for the OP. Where it was known that a thoracic CT scan was planned outside of the OP in the next 3 months, this was also used as an exclusion criterion.

Several approaches were planned to be used to check for previous or planned thoracic imaging in the OP, as described below.

#### 5.3.2 Participant-reported previous imaging

Participants would be asked about previous or planned thoracic CT imaging during the telephone triage and nurse appointments. This would not be taken as definitive evidence of meeting exclusion criteria, but to identify individuals where further checks for previous imaging may be required when it had not been identified by the means described below, e.g. where a scan may have been performed by a private provider which would not be visible on NHS systems.

#### 5.3.3 CTM PACS check

It was planned to undertake a check for previous CT imaging on CTM radiology records for participants between the telephone triage and telephone nurse assessment stages of the pathway. The aim was

for this to be set up as an automated algorithm where the list of participants would be used as an input and the previous imaging results reported as an output.

#### 5.3.4 Manual Welsh Clinical Portal check

In addition to the above, it was planned for a manual check for previous imaging to be undertaken through Welsh Clinical Portal for participants either prior to or shortly after their nurse appointment. This was in recognition that Welsh Clinical Portal holds an advantage over a local check since all imaging performed in NHS Wales is recorded, whereas the automated check would only have identified imaging undertaken within CTM UHB.

### 5.4 Telephone nurse assessment

#### 5.4.1 Telephone nurse assessment invitation

Participants eligible to proceed to a telephone-based nurse assessment (TNA) were to be informed of this during their TT and the appointment booked at this time. If the available dates were not convenient, participants would be contacted by telephone to offer dates for the following month. Confirmation letters and text messages would also be sent to remind participants of upcoming appointments.

#### 5.4.2 Telephone nurse assessment process

It was agreed that TNA appointments would be undertaken by InHealth nursing staff at Band 6 equivalent or above. In addition to a generic mandatory training programme, specific training for this staff group included: communicating smoking advice to high-risk individuals; national level 2 practitioner training; IRMER online training and certification (completed every 3 years); and 6 supernumerary shifts with trained colleagues prior to completing a probationary period.

A handbook and call script were agreed for the pilot and responses were to be captured through a structured form on SPECTRA. The TNA appointment would consist of the following components:

- Introduction and confirmation of participant's identity
- Data protection and training/research statements/consent
- Confirmation of smoking status and  $PLCO_{m2012}/LLPv2$  risk assessments
- Enquiry about "red flag" symptoms, e.g. haemoptysis (coughing up blood)
- Brief medical and medication history, focussed on any known respiratory diagnoses, respiratory medications and statin use
- Assessment of Eastern Cooperative Oncology Group (ECOG) Performance Status (a broad measure of fitness) and modified Medical Research Council (mMRC) Dyspnoea Scale Grade (a measure of breathlessness)[35,36]
- Assessment for exclusion criteria for LDCT screening
- Explanation of benefits and risks of LDCT screening, possible outcomes (including common incidental findings), and next steps if proceeding
- Very Brief Advice[37] and opt-out referral to NHS Wales Help Me Quit smoking cessation service[38] for current smokers
- Opportunity for, and answering of, any questions from the participant



The nurse undertaking the appointment would complete a LDCT referral form for participants eligible to proceed. As for the TT stage, the handbook and script contained guidance on managing a wide range of possible scenarios and responses to FAQ.

## 5.5 Screening low-dose CT scans

### 5.5.1 Confirmation of YCR as site for mobile scanner

As described in section 3.2.4, YCR was identified as the preferred location to site the mobile scanner during the planning phase. In order to confirm the suitability of YCR to host a mobile scanner, InHealth undertook an assessment, incorporating the following elements:

- that the mobile CT unit would require multiple parking spaces that would need to be cleared prior to arrival of the unit
- that the scanner would require its own diesel generator and a 4G connection to allow secure data transfer
- that the generator runs continuously and generates significant noise meaning that a preferred location could not be within close proximity to residential properties
- that delivery of the scanner would require suitable access e.g. with a sufficient turning circle for the lorry, avoiding tight bends and bollards
- that a sufficient 4G signal would be required for data transfer
- that the site would comply with radiation exposure requirements
- that there would be access to water for cleaning of the unit

Based on these requirements, a number of locations on the YCR site were considered, with an auxiliary staff car park towards the rear of the hospital selected as the preferred site (figure 5a). A test of the 4G signal demonstrated that this was adequate for data transfer. Locating the scanner within Health Board grounds meant that additional security considerations that may have been required at an external site were not required.



Figure 5a: Mobile CT unit located at Ysbyty Cwm Rhondda.

### 5.5.2 LDCT booking

Participants that were to proceed to LDCT would be identified during the TNA and a LDCT referral form completed by the nurse performing the consultation, who had all undergone IRMER training. This action was to be recorded on SPECTRA, and the process of booking participants into scanning slots would be managed by InHealth's bookings team.

Baseline LDCT scans were planned to be undertaken during three 5-day periods in September, October and November 2023, with the scanner returning to undertake interval scans on single days (due to only a small proportion of participants requiring interval scans) in December 2023, January and February 2024 for 3-month recall scans, and September to November 2024 for 12-month recall scans.

### 5.5.3 LDCT acquisition

Scan images would be acquired by InHealth radiographers at the mobile CT unit, with the lung parenchyma to be scanned in entirety, without administration of intravenous contrast. Radiation dose would be adjusted based on body habitus, with the minimum radiation dose delivered whilst maintaining good image quality. Images would then be transferred by secure 4G connection to a cloud-based system for reporting. All images would later be imported to the local CTM Picture Archiving and Communication System (PACS).

## 5.6 Radiology reporting

### 5.6.1 Reporting radiologists

It was agreed that where possible the reporting of the LDCT scans would be undertaken by thoracic radiologists from Wales (see section 4.3.2 for requirements and recruitment). HLH confirmed that scans would be allocated for reporting to this pool of radiologists in the first instance and to their wider pool of reporters from across the UK only if required.

### 5.6.2 Software

Images would undergo an initial "Artificial Intelligence" (AI) read using Veye Lung Nodule software (figure 5b) and then be reported by a radiologist using the Veye Reporting structured template. Both pieces of software are provided by Aidence, which was integrated into HLH and InHealth's systems. Reporting would be done remotely by radiologists using the CIMAR cloud-based PACS.

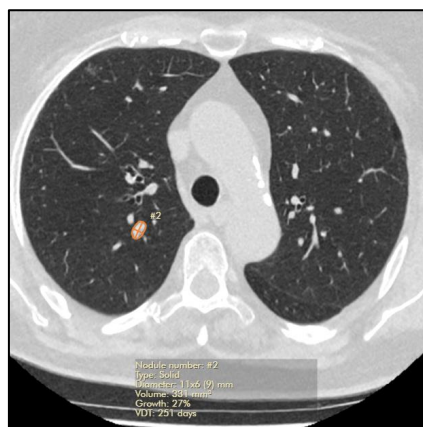


Figure 5b: Lung nodule detected by AI Veye Lung Nodule software.

### 5.6.3 Reporting protocols

Reporting was underpinned by a reporting manual provided by HLH, which aligned with two documents prepared for the OP: Management of Findings, and Incidental Findings. These were broadly aligned with similar documents for the NHSE TLHCP and HLH's reporting guidance, with minor variations accounting for local practices or where additional evidence had emerged.

The reporting protocols were based on the following underlying principles:

*The primary objective of lung cancer screening is to reduce lung cancer mortality. There is uncertainty as to whether acting on findings unrelated to this goal in this setting is beneficial or harmful overall, and therefore such findings should have a high threshold for reporting and action. All reported findings should be clinically significant; clinically insignificant findings should not be reported to the participant or to Primary Care.*

The documents also set out the responsibilities of the radiologist, the LHC clinical team, and others to ensure that the process from scan report to actions was safe and efficient.

#### 5.6.3.1 Categorisation of reports

LDCT reports were to be categorised by reporting radiologists based on the most important finding. A colour-coding system was used to indicate the urgency of action required:

- **Purple:** Emergency finding potentially requiring immediate clinical action (LHC team to be informed by telephone, or relevant on-call team contacted out-of-hours)
  - e.g. pneumothorax, aortic dissection, spinal cord compression
- **Red:** Urgent (not immediate) action required
  - Pulmonary findings: suspected lung cancer, severe active tuberculosis
  - Non pulmonary: e.g. aortic aneurysm >5cms, non-pulmonary malignancy
- **Orange:** Lung nodule requiring a 3- or 12-month recall scan within programme
- **Yellow:** Non-urgent actionable incidental finding
  - e.g. severe bronchiectasis, interstitial lung disease, aortic aneurysm 4-5cms
- **Green:** Normal scan, other than common incidental findings (emphysema or coronary artery calcification)

The colour-code system allowed scan reports to be triaged for action by the LHC clinical team, and to identify scans for review at the Screening Review Meeting (further information at section 5.7).

#### 5.6.3.2 Reporting of LDCT findings

It was agreed that lung masses or mass-like consolidation would be reported as suspected lung cancers and received a Red categorisation. Reporting of lung nodules was aligned with British Thoracic Society guidelines,[39] where nodules are categorised based on calculated volume (or diameter if volume measurement is not possible for technical reasons), nodule characteristics, and the chance of a nodule being malignant based on automated calculation of the Brock risk score.[40] Veye Lung Nodule software was used to aid identification and volume measurement of lung nodules.

Table 5a: Volume measurement of lung nodules and action

Baseline CT nodule size (diameter/volume) and description	Action
No nodules	No further action
Nodules with typical benign features (with diffuse, central, laminated or popcorn pattern of calcification or microscopic fat; or typical perifissural or subpleural nodules suggestive of intrapulmonary lymph nodes)	No further action
<5mm / <80mm <sup>3</sup>	No further action
≥80 to <300mm <sup>3</sup>	3- and 12-month recall scan within LHC programme
≥6mm and <8mm (volumetry not possible)	3- and 12-month recall scan within LHC programme
5-6mm (volumetry not possible)	12-month recall scan within LHC programme
≥8mm or ≥300mm <sup>3</sup> and Brock risk of malignancy <10%	3- and 12-month recall scan within LHC programme
≥8mm or ≥300mm <sup>3</sup> and Brock risk of malignancy ≥10%	Refer to Royal Glamorgan Hospital lung cancer service

Protocols for reporting and management of incidental findings were drafted based on NHSE TLHCP protocols, with adaptations where new evidence was available or to align with local pathways. Extensive consultation was undertaken with relevant specialties that were expected to receive referrals based on findings including local Cardiology, Respiratory, Endocrine and Breast teams, and with Primary Care representatives in the OP Operational Group.

Emphysema and coronary artery calcification were reported based on visual appearance and categorised as none, mild, moderate or severe. The thresholds for reporting other incidental findings were defined and agreed in reporting protocols used by HLH and the OP.

## 5.7 Screening Review Meetings

A weekly SRM was planned to be held during scanning periods with core attendees including the Clinical Lead, Radiologist Lead, and LHC Clinical Team. Thoracic radiologists who reported for the OP were also to be invited to attend via Microsoft Teams.

A low threshold for discussing cases at the SRM would be used for the OP to provide a layer of quality assurance and to maximise data collection for evaluation. As such, all scans with suspected cancers, significant lung nodules, or potentially actionable incidental findings other than emphysema and coronary artery calcification (for which standard advice only was provided on results letters) were to be discussed. The list of cases to be discussed would be developed and distributed by the LHC clinical team based on the colour-coding of LDCT reports. The LHC clinical team would also be responsible for recording outcomes and undertaking actions arising from the meeting.

The purposes of the SRM included:

- Establishing whether reported findings were new or known, by comparison with previous imaging and review of electronic healthcare records
- Verifying whether findings were significant and the recommended actions on the LDCT report appropriate
- Determining the most appropriate course of action for findings, including when this fell outside of written protocols
- Creating a worklist of actions to be undertaken by the LHC clinical team following the meeting

## 5.8 Actioning reports and results letters

Structured LDCT reports would be received by the LHC clinical team electronically and discussed as appropriate through the SRM. Any actions required, including referrals to the lung cancer service, referrals to other specialties, or actions required by the Clinical Team or Primary Care, were to be collated through the SRM into a worklist for the clinical team to action and monitor. Referrals would be made through usual local pathways, e.g. by referral letter to most other specialties.

Results letters were to be generated through SPECTRA, as a semi-automated process with information recorded in the LDCT report triggering standard text to be added to a results letter template. Results letters would then be checked and edited by the clinical team before being finalised. When confirmed as final, results letters would be sent to participants and their GPs by InHealth, with a copy of the results letter sent to the GP uploaded to Welsh Clinical Portal.

## 6. DELIVERY

### 6.1 Timeline

Figure 6a gives a high-level summary of key milestones in the delivery of the OP.

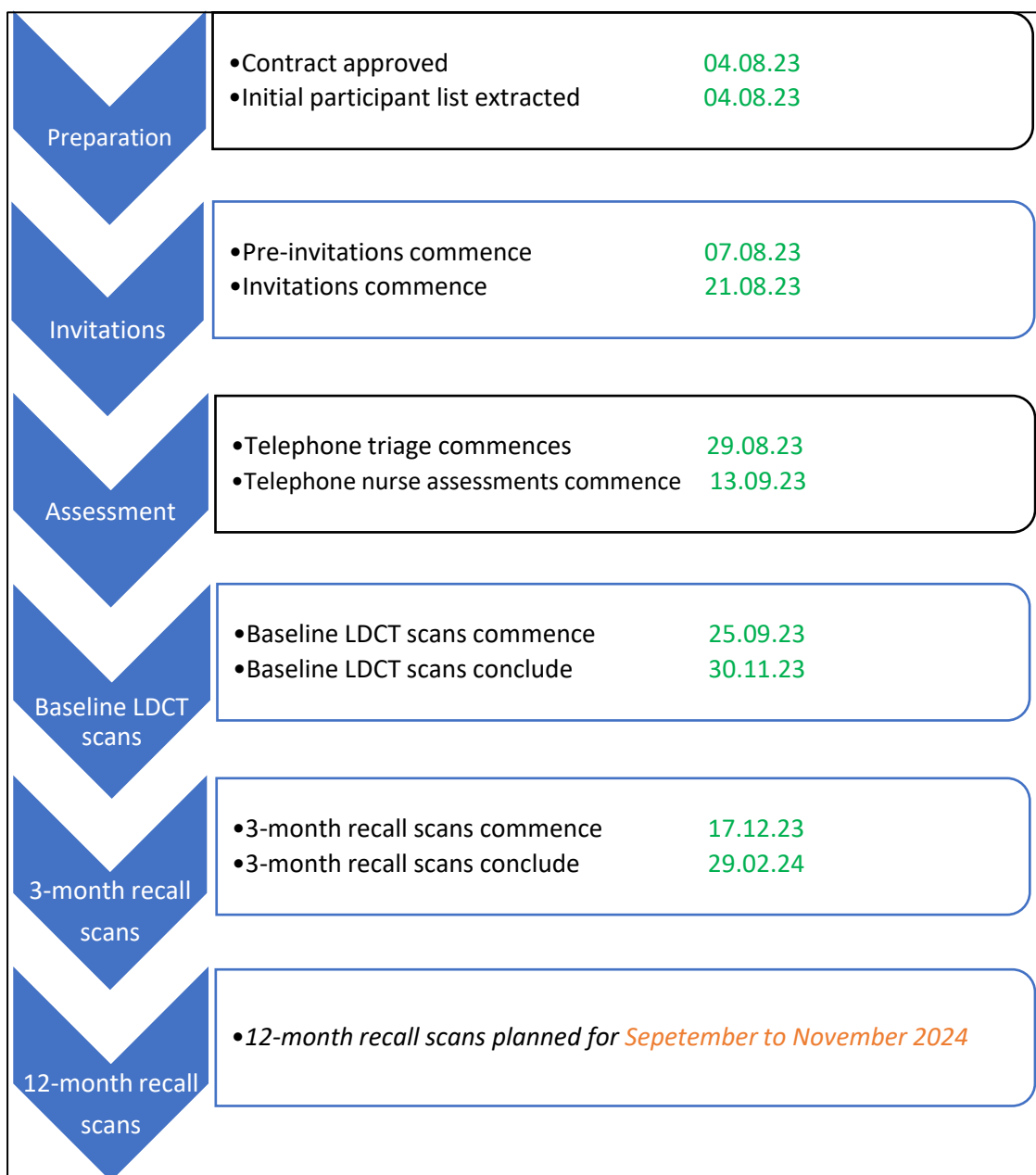


Figure 6a: Key milestones in the OP.

## 6.2 Preparation and invitations

Much preparation for the OP was undertaken in advance of the contract being approved, allowing the participant list to be extracted from the initial GP practices immediately on contract approval in early August 2023 and invitations to be sent shortly after. This was initially for the Valleys Medical Group, with extraction and invitation from the Forest View Practice Group occurring in October 2023. This was to allow an early analysis of uptake and conversion rates from the initial practices, allowing the cohort size to be adjusted to achieve the target of 500 initial screening LDCTs.

## 6.3 Telephone triage & telephone nurse assessment

TT appointments commenced in late August 2023 and continued until two weeks before the final baseline LDCT scans (allowing sufficient time for TNA and booking of baseline LDCTs). TNA appointments commenced 2 weeks after TT appointments, and continued until shortly before the final baseline LDCT scans. Telephone calls for TT and TNA were conducted by InHealth using an auto-dialler system, where an automated outgoing call occurs and the participant is connected to the next available PCA or nurse on answering. Text message reminders of upcoming appointments were also sent to invitees.

## 6.4 Check for prior imaging

The automated check of CTM radiology systems for prior imaging that was planned proved challenging to consistently implement due to short-staffing in the relevant department within the Health Board and the short turnaround time in some cases between the TT and TNA appointments. As such, this step of the process was removed for later participants, with a focus on ensuring that a manual check for previous imaging was undertaken through Welsh Clinical Portal.

## 6.5 Baseline low-dose CT scans

Baseline LDCT scans were undertaken in blocks of activity when the mobile scanner was present at YCR during September, October and November 2023. Participants were sent an invitation letter and a text message reminder for LDCT appointments. When the interval between a TNA appointment and baseline LDCT appointment was short, the LDCT appointment was also confirmed with the participant by telephone.

Baseline LDCT scans were undertaken on:

- 25-30 September 2023
- 21-25 October 2023
- 25-30 November 2023

On scanning days LDCT appointments ran from 0830-1245 and 1345-1930, finishing earlier if days were not booked to full capacity.

Scans were usually reported within 7 days of being performed, with potentially-actionable findings reviewed at the next weekly SRM. Referrals, other actions and results letters were usually generated within 7 days of SRM discussion, or within 14 days of the scan if no potentially actionable findings were present.



## 6.6 Three-month recall scans

The mobile scanner returned to undertake 3-month recall scans for participants with small lung nodules detected on their baseline scan that required surveillance. It was estimated that 15-20% of the cohort would require a 3-month recall scan. A target of +/-14 days from the exact date three months after a baseline scan was permitted, allowing the scanner to return for shorter periods and maximising efficient use of appointments and scanning time. It was initially planned for 3-month recall scans to be undertaken on one day each in December 2023, January and February 2024, however due to technical difficulties on some scanning dates, two additional dates were scheduled for January and February 2024.

Three-month recall scans were undertaken on the following dates:

- 17 December 2023
- 10 & 21 January 2024
- 15 & 29 February 2024

## 6.7 Screening Review Meetings

A SRM was held weekly during the baseline scanning periods. This was attended by the OP's Clinical Lead, Radiologist Lead, Specialty Doctor, Specialist Nurse and Navigator, and occasionally remotely attended via Microsoft Teams by other reporting radiologists for the OP from across Wales. SRMs were also planned for the 3-month interval scanning period, but due to the very small number of cases requiring discussion from this cohort most of these meetings were stood down with individual cases discussed on an *ad-hoc* basis.

## 6.8 Communications plan

During delivery of the OP, each of the deliverables that had been identified as 'high priority' within the communications plan were delivered, plus radio interviews with BBC Radio Wales and GTFM (a local Rhondda radio station). A record of all participant materials that were developed was kept, together with the associated wider communications including media coverage and social media releases, to ensure a comprehensive record that can be referred back to as required in the future.

### 6.8.1 Social media

CTM UHB released a number of social media posts throughout the delivery of the OP, aiming to raise awareness and provide consistent messaging (figure 6b). This initially aligned with the first invitations being sent and continued throughout.

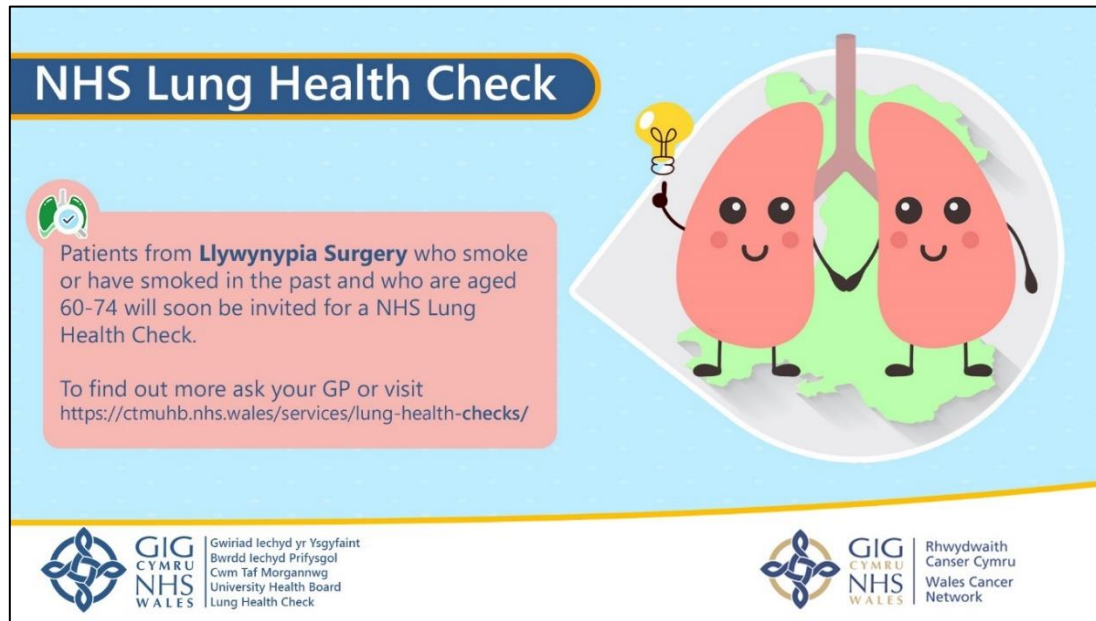


Figure 6b: Social media post through CTM UHB's Facebook and Twitter accounts.

#### 6.8.2 Wider engagement and awareness of the LHC pilot

As well as a focus on communications as a means of raising awareness and increasing participation in the OP, the OP offered an opportunity to engage more broadly, highlighting the positive work being undertaken by the Health Board and Network, and to promote LHCs as a potential future national screening programme in Wales. Examples include:

- Press release prior to the start of the OP and associated media coverage[41]
- News stories on the CTM UHB website
- Updates in the Cancer Network newsletter
- BBC Wales News article[42] and associated media coverage, incorporating interviews with the LHC Clinical Lead, on BBC Wales today and BBC Radio Wales (figure 6c)
- Radio interview with the LHC Clinical Lead on a North Rhondda radio station, GTFM
- Visit to the scanner by Eluned Morgan, Minister for Health and Social Services in Wales, and associated social media (figure 6d)
- Visit to the scanner by Buffy Williams, MS for Rhondda, and associated social media
- Supporting third sector partner communications



Figure 6c: BBC News online article.

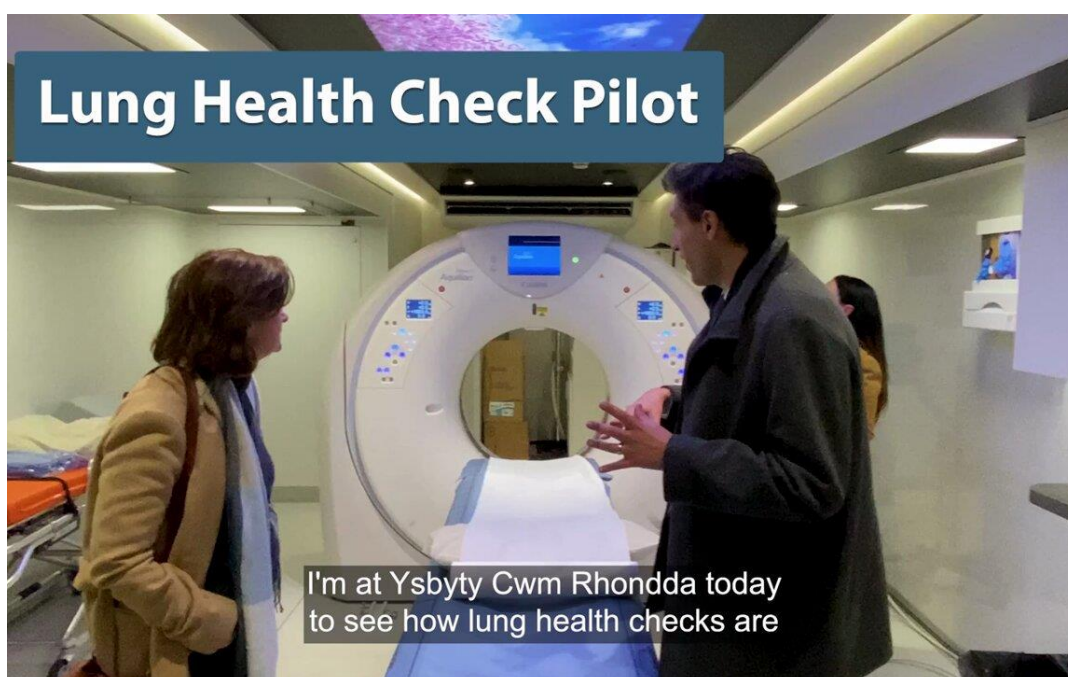


Figure 6d: Screen shot from social media post from Welsh Government on the visit of Eluned Morgan, Minister for Health and Social Services in Wales, to the LHC OP.

## 7. RESULTS

### 7.1 Summary of participation

Figure 7a summarises the flow of participants through the OP pathway from extraction of the target population list from GP records through to completion of baseline LDCT scans. Further detail regarding results from each of these stages is provided in subsequent sections.

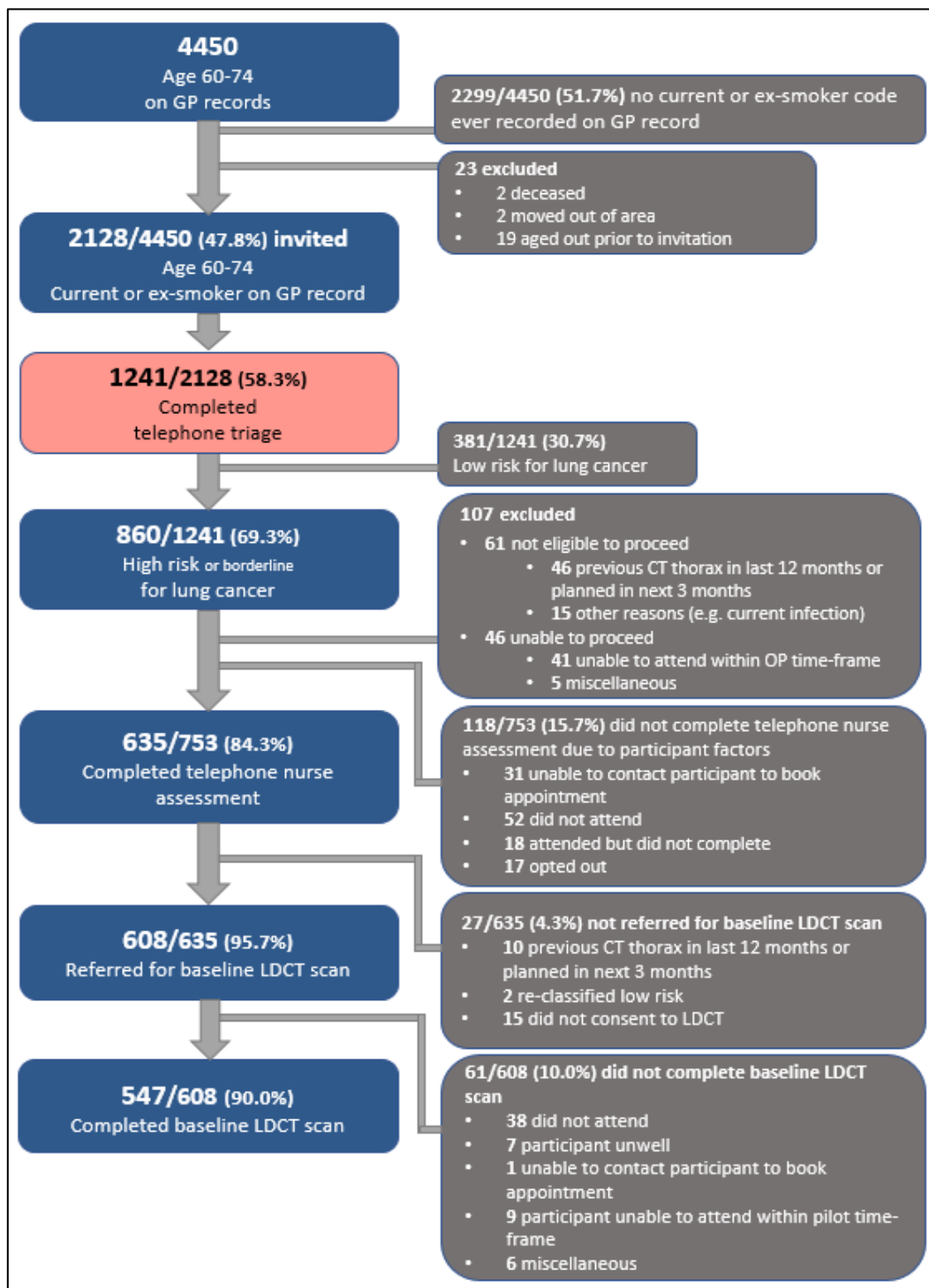


Figure 7a: Summary of activity at each pathway stage.

## 7.2 Invitation

The total population (all ages and smoking statuses) registered to the practices participating in the OP as of August 2023 was 25,226. Of these, 4450 (17.6%) were aged 60-74 years on the date of data extraction from the practices, and of these 2151/4450 (48.3%) were identified as ever-smokers based on the presence of at least one “current smoker” or “ex-smoker” tobacco code recorded on their GP record at any time-point. Of these, 752/2151 were recorded as current smokers on their GP record (35.0% of ever-smokers aged 60-74 years, 16.9% of all aged 60-74 years), and 1399/2151 recorded as ex-smokers (65.0% of ever-smokers aged 60-74 years, 31.4% of all aged 60-74 years).

Twenty-three individuals were excluded at this stage (n=2 deceased; n=2 moved out of area; n=19 aged out of the target age range prior to invitations being sent). This resulted in 2128/4450 (47.8%) of individuals aged 60-74 years being invited to participate in the OP.

## 7.3 Telephone triage

### 7.3.1 Characteristics of invitees & uptake of telephone triage

Of those invited, 1241/2128 (58.3%) completed a TT appointment. Table 7a summarises the characteristics of people who were invited, completed, and did not complete a TT appointment.

*Table 7a: Characteristics of invitees to telephone triage.*

		Invited (total)	Completed TT	Did not complete TT
Number of people		2128	1241/2128 (58.3%)	887/2128 (41.7%)
Age (median)		66 years 8 months	66 years 6 months	67 years 0 months
Sex	Male	1103/2128 (51.8%)	655/1103 (59.4% of males)	448/1103 (40.6% of males)
	Female	1025/2128 (48.2%)	586/1025 (57.2% of females)	439/1025 (42.8% of females)
Smoking status on GP record	Current smoker	745/2128 (35.0%)	374/745 (50.2% of current smoker)	371/745 (49.8% of current smoker)
	Ex-smoker	1383/2128 (65.0%)	867/1383 (62.7% of ex-smoker)	516/1383 (37.3% of ex-smoker)

No strong signal for participation based on age or sex of those invited was seen. A greater proportion of those invited who were recorded as ex-smokers on their GP record completed a TT appointment (62.7%) than those recorded as current smokers (50.2%), consistent with findings from other lung cancer screening activities.

As targeted lung cancer screening is a multi-step process, there has been inconsistency in how uptake has been reported. In activity that includes a triage stage, only a proportion of those who undergo triage proceed to a subsequent nurse appointment or baseline LDCT, meaning that using all those invited as the denominator for uptake calculations for these stages of the process leads to a falsely low reported uptake. The UK NSC draft effectiveness standards for lung cancer screening[unpublished]

suggest using the proportion of the eligible population who complete a lung cancer risk assessment as a measure of uptake, regardless of whether this occurs during a triage stage or with a nurse, or whether the assessment is performed remotely (e.g. by telephone) or face-to-face. The risk assessment performed during TT in the OP fits this definition, giving an uptake of 58.3% by this definition.

### 7.3.2 Characteristics of those who completed telephone triage

Self-reported smoking status and smoking history were ascertained during TT appointments, these are summarised in table 7b.

*Table 7b: Smoking history and status as declared by participants at TT appointments.*

<b>Smoking status at TT</b>	Current smoker	341/1241 (27.5%)
	Ex-smoker	900/1241 (72.5%)
<b>Smoking exposure</b>	Duration (mean)	32.1 years
	Cigarettes per day whilst smoking (mean)	25.2 cigarettes
	Smoking history in pack-years (mean, 20 cigarettes/day for 1 year = 1 pack-year)	26.3 pack-years

Smoking status reported at TT compared to that recorded in GP records is summarised in table 7c. There was good agreement (>90%) between GP records and TT when both smoking statuses were recorded as “ex-smoker”. Over one-fifth (20.1%) of participants recorded as current smokers as the most recent smoking status on their GP recorded reported to be ex-smokers at TT. This may partly reflect the falling smoking prevalence over time,[43] with a lag in updating of primary care tobacco codes.

*Table 7c: Comparison of smoking status as declared by participants at TT and recorded on GP record.*

			<b>Smoking status on GP record*</b>	
			<b>Current smoker</b>	<b>Ex-smoker</b>
			373/1241 (30.1%)	867/1241 (69.9%)
<b>Smoking status at TT</b>	<b>Current smoker</b>	341/1241 (27.5%)	298 (24.0% of total, 79.9% of current smokers on GP records, 87.4% of current smokers at TT)	43 (3.5% of total, 5.0% of ex-smokers on GP records, 12.6% of current smokers at TT)
	<b>Ex-smoker</b>	900/1241 (72.5%)	75 (6.0% of total, 20.1% of current smokers on GP records, 8.3% of ex-smokers at TT)	824 (66.4% of total, 95.0% of ex-smokers on GP records, 91.6% of ex-smokers at TT)

*\*One ex-smoker participant was recorded as a never-smoker on GP record and completed TT after contacting the service.*



Using an auto-dialler system for TT calls, 1397/1467 (95.2%) of calls where the invitee picked up were connected to a PCA. Further calls were made to invitees if a first call was not connected. The average call duration for the 1241 completed TT appointments was 13 minutes 9 seconds. Calls had an average wrap time (typing up notes or taking actions following the call) of 1 minute 37 seconds, giving an average total appointment time of 14 minutes 46 seconds per TT completed call.

### 7.3.3 Characteristics of those who did not complete telephone triage

Of those who were invited for TT, 887/2128 (41.7%) did not complete a TT appointment. Of these, 371/887 (41.8%) were recorded as “current smoker” by the most recent tobacco code on their GP record, and 516/887 (58.2%) as “ex-smoker”. Table 7d summarises the reasons for non-completion of TT.

*Table 7d: Reasons for non-completion of TT.*

Reason for non-completion	Number (% of non-completers)
Did not answer	577 (65.1%)
Did not consent for LHC	76 (8.6%)
Claimed to have never smoked	44 (5.0%)
Answered but did not complete	172 (19.4%)
Deceased	2 (0.2%)
Invalid contact number	16 (1.8%)
<b>Total</b>	<b>887</b>

Common reasons for answering but not completing a TT appointment included active surveillance for another cancer or recent imaging. Reasons for not consenting to a LHC were varied, with the most commonly documented reason being participants “not seeing the need (for a LHC)”.

### 7.3.4 Outcomes of telephone triage

Figure 7c summarises the outcomes of completed TT appointments. Of those who completed TT, 860/1241 (69.3%) were classified as being at high risk of developing lung cancer as defined by the risk assessment tool thresholds; this included two individuals on borderline between high-risk and low-risk who proceeded to telephone nurse assessment. Of those who were high risk, 333/860 (38.7%) were current smokers and 527/860 (61.3%) were ex-smokers. Of note, 9/1241 (0.7%) of those who completed TT were current smokers at the time of TT but found to be at low risk of developing lung cancer by the risk assessment tools due to lack of other risk factors and limited smoking exposure.



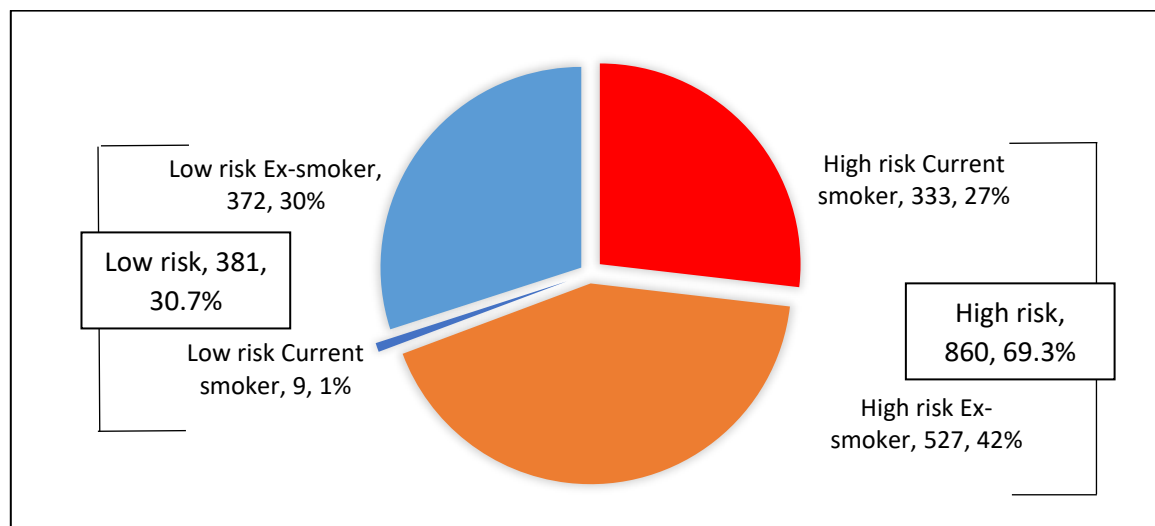


Figure 7c: Outcomes of telephone triage.

## 7.4 Telephone nurse assessment

### 7.4.1 Eligibility for and completion of telephone nurse assessment

Of those classified as high risk at TT, 753/860 (87.6%) were eligible to proceed to TNA. Reasons for exclusion of 107/860 (12.4%) participants at this stage are summarised in table 7e.

Table 7e: Reasons for exclusion from proceeding to TNA.

Reason for exclusion		Number
Not eligible to proceed	Previous CT thorax in last 12 months or planned in next 3 months	46
	Other reasons (e.g. current infection)	15
Unable to proceed due to participant factors	Unable to attend within OP time-frame	41
	Miscellaneous	5
Total		107

Of those who were eligible for TNA, 653/753 (84.3%) completed a TNA. Reasons for non-completion by 118/753 (15.7%) participants are summarised in Table 7f.

Table 7f: Reasons for non-completion of TNA.

Reason for non-completion	Number
Unable to contact to book appointment	31
Did not attend	52
Attended but did not complete	18
Opted out	17
Total	118

The nurses who undertook TNAs estimate that the average call duration was 10 minutes though this could vary widely. The total time for a TNA including administration, documentation and LDCT referral was estimated to be 25-30 minutes.

#### 7.4.2 Outcomes of telephone nurse assessment

Of those who completed TNA, 608/635 (95.7%) were referred for a baseline LDCT scan. The reasons for non-referral for a baseline LDCT scan for the remaining 27/635 (4.3%) are summarised in table 7g.

Table 7g: Reasons for non-referral for baseline LDCT.

Reason for non-referral	Number
Previous CT thorax in last 12 months or planned in next 3 months	10
Reclassified as low risk following nurse assessment	2
Did not consent to LDCT	15
<b>Total</b>	<b>27</b>

Due to the short turnaround time between TT and TNA stages during some periods of the OP, it was not always possible to complete a check for prior imaging as per the OP's exclusion criteria between these steps. As such, some participants were excluded at this stage for this reason, whilst others were excluded earlier in the pathway.

Most participants who completed a TNA had an ECOG Performance Status (a measure of functional status, where a lower number indicates better functional status) of 0-1 (573/635, 90.2%), and a mMRC Dyspnoea Scale Grade (a measure of functional disability due to breathlessness, where a lower score indicates less impairment) of 0-1 (492/635, 77.5%). These results are summarised in figure 7d.

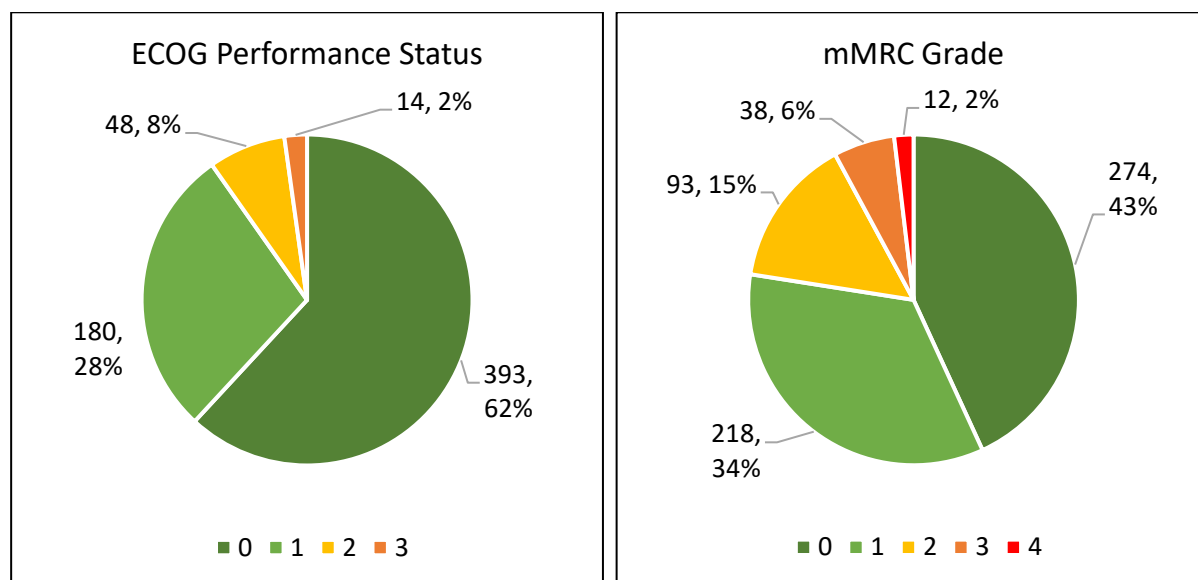


Figure 7d: ECOG Performance Status and mMRC Dyspnoea Scale Grade of participants who completed TNA.

## 7.5 Baseline low-dose CT scans

### 7.5.1 Booking and completion of baseline LDCT scans

Of those referred for a baseline LDCT scan, 547/608 (90.0%) underwent a baseline LDCT scan. Reasons for non-completion of baseline LDCT scans for the remaining 61/608 (10.0%) are summarised in table 7h.

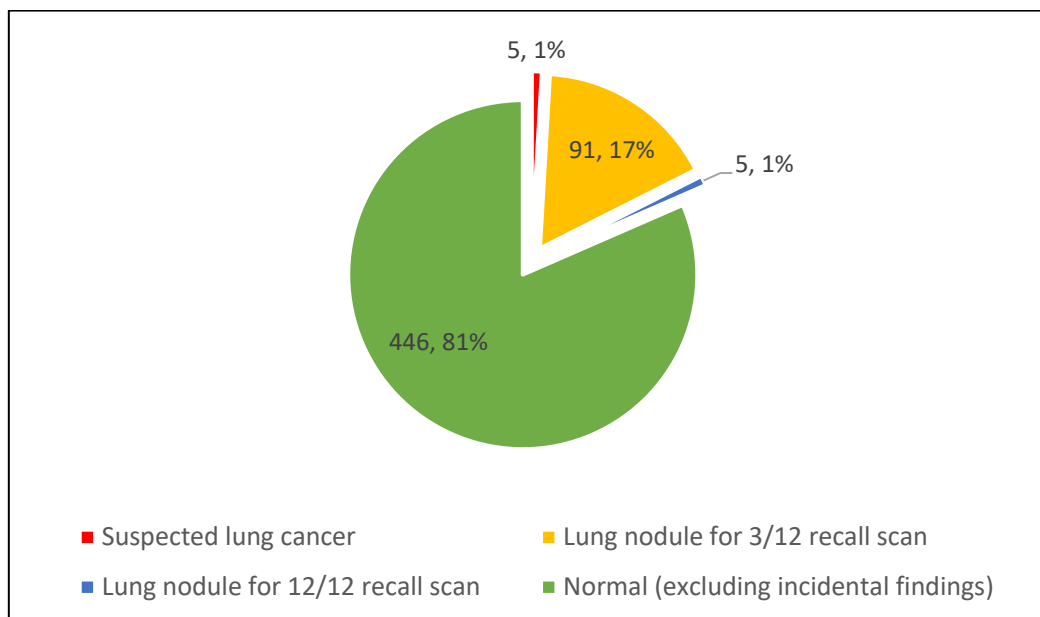
*Table 7h: Reasons for non-completion of baseline LDCT scans.*

Reason for non-completion	Number
Unable to contact to book appointment	1
Unable to attend within OP time-frame	9
Did not attend	38
Unable to proceed due to illness	7
Miscellaneous	6
<b>Total</b>	<b>61</b>

Over 17 baseline scanning days, a total of 639 appointment slots were booked (average 37.6 slots/day, range 15-47) and 546 baseline scans were performed (average 32.1 scans/day, range 15-43). One additional participant underwent a baseline scan at a later date when the scanner returned to perform 3-month recall scans. If participants did not or were unable to attend a booked appointment then they were offered an additional opportunity where this was possible, leading to the total number of appointments exceeding the number of people referred for a baseline LDCT. The completion rate of booked appointments was 85.4% (546/639). A lower number of scans were booked on certain dates: to accommodate a “soft launch” on the first day of scanning (to avoid cancelling a large number of appointments if technical difficulties were encountered), and on the final day of each scanning period where some excess capacity was allowed.

### 7.5.2 Primary outcomes of baseline LDCT scans

The primary outcomes of the 547 baseline LDCT scans are summarised in figure 7e. Further details regarding these outcomes, including the effect of the SRM on outcomes, are discussed in subsequent sections.



*Figure 7e: Primary outcomes of baseline LDCT scans (following SRM discussion).*

## 7.6 Three-month recall scans

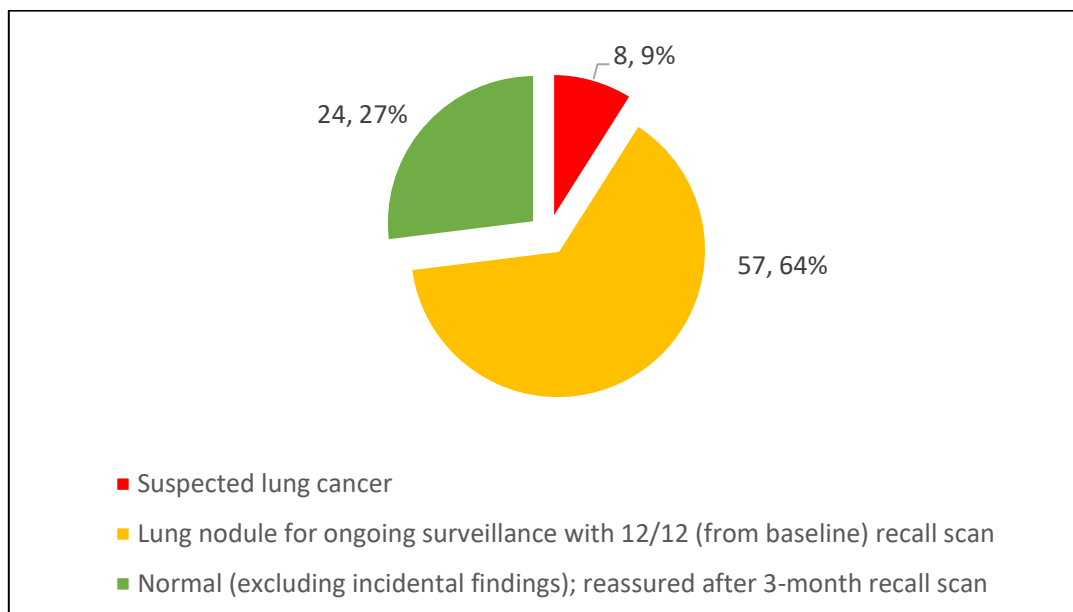
### 7.6.1 Booking and completion of 3-month recall scans

Of those referred for a 3-month recall scan, 89/91 (97.8%) underwent a 3-month recall LDCT scan. The two participants who did not undergo a 3-month recall scan were contacted and did not wish to proceed due to deteriorating health or competing health priorities.

Over five 3-month recall scanning days, a total of 140 appointment slots were booked (average 28/day, range 18-38) and 87 three-month recall scans were performed (average 17.4/day, range 5-29). Due to an operational error relating to sending out of appointment letters, only 5 participants were scanned on the first 3-month recall scanning date. On the remaining 4 dates, 109 appointment slots were booked (average 27.3) and 82 three-month recall scans were performed (average 20.5/day), giving a completion rate of booked appointments of 75.2% for these days. As for the baseline LDCT scanning days, participants were offered an additional opportunity to attend if they did not or were unable to attend a booked appointment. The scanning days for 3-month interval scans did not utilise the full appointment capacity due to the limited size of the OP. Two participants were unable to attend for a 3-month recall scan on the planned scanning days and underwent recall scans at RGH.

### 7.6.2 Primary outcomes of 3-month recall scans

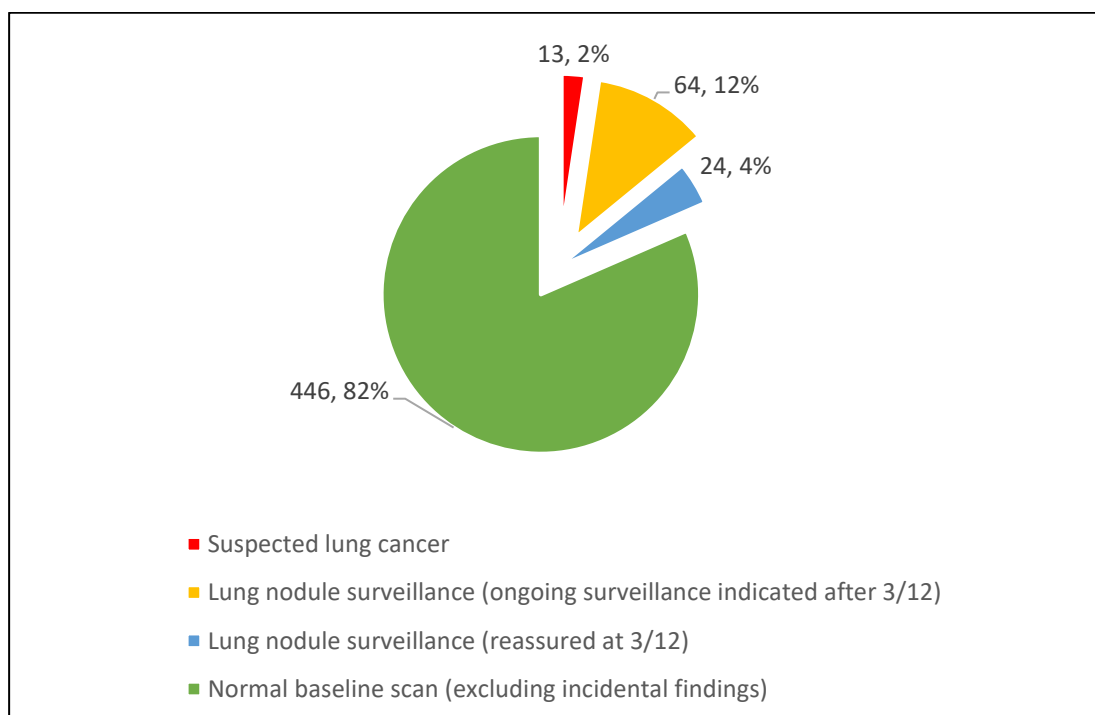
The primary outcomes of the 89 three-month recall scans are summarised in figure 7f. Further details regarding these outcomes are given in subsequent sections.



*Figure 7f: Primary outcomes of 3-month recall scans (following SRM discussion).*

### 7.7 Combined primary outcomes of baseline and 3-month recall scans

The overall outcome after baseline and 3-month recall scans for the 547 participants who underwent a baseline LDCT is summarised in figure 7g. In total 13/547 (2.4%) of participants had suspected lung cancer and were referred to the RGH lung cancer service for further investigation, outcomes from which are discussed in section 7.10.



*Figure 7g: Combined primary outcomes of baseline and 3-month recall scans.*

## 7.8 Radiology reporting

All baseline and 3-month recall scans bar one were reported by thoracic radiologists from across Wales. Reporting radiologists estimated a reporting speed of 5-10 baseline scans per hour and 5-8 three-month recall scans per hour. They estimated that straight-forward scans were reported in approximately 5 minutes, and more complex scans in 10-15 minutes. Recall scans took longer than baseline scans to report due to the need to compare to the baseline scan.

As part of HLH's quality assurance processes, a proportion of baseline LDCT scans undergo a second read by a HLH radiologist (figure 7h). The second read was in full agreement for 34/35 (97.1%) of OP scans that underwent this process. No moderate or major issues were identified on second reads.

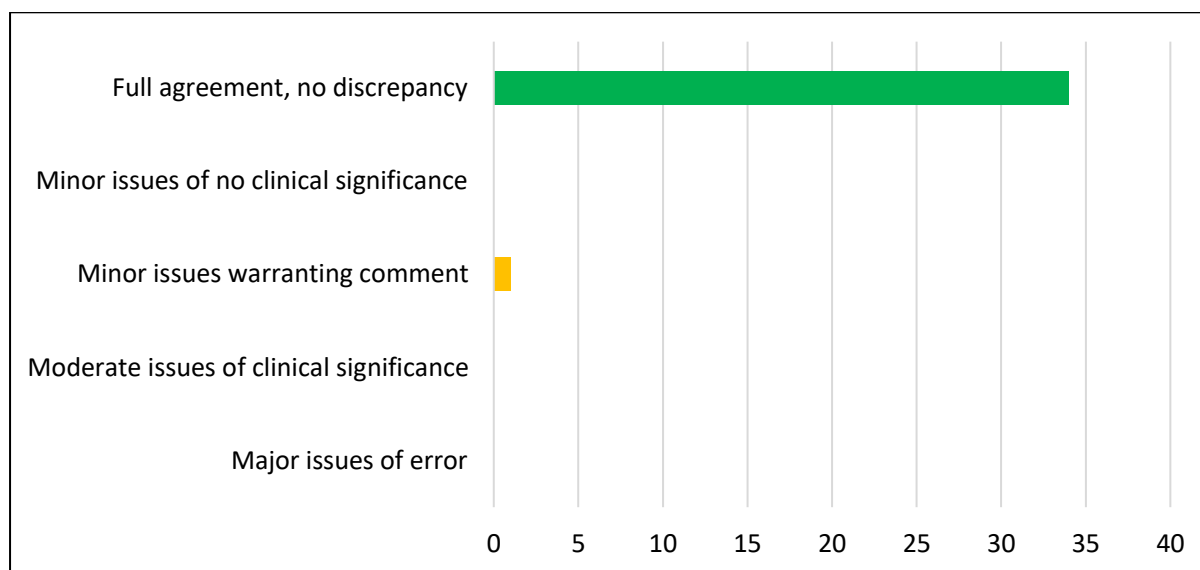


Figure 7h: Outcome of second reads of baseline scans.

## 7.9 Screening Review Meetings

In total, 201 findings on 177 baseline scans were reviewed at SRM (177/547, 32.4% of baseline scans reviewed). Most cases were discussed during seven meetings held between October and December 2023, where an average of 24.6 scans were discussed per 90-minute meeting (range 12-35). The average discussion time per scan, including accessing images and recording decisions, was 3.7 minutes. The purpose of the SRM was a focussed review of potentially actionable findings rather than a full re-reporting of the scan, hence the relatively short discussion time per case. A low threshold for discussion at SRM was employed for the OP to allow robust data collection on findings and for quality assurance purposes; all baseline scans with suspected malignancy, reportable lung nodules and potentially actionable incidental findings (excluding emphysema and coronary artery calcification) were listed for discussion.

In addition to these meetings an additional focussed SRM was held to review Cardiology-related findings which was attended by a local consultant Cardiologist. This was arranged to discuss some subjectivity in the reporting of aortic valve-related findings and refine the thresholds for referral.

Only 3/89 (3.4%) three-month recall scans required further discussion after reporting. Different thresholds for discussion were used for recall scans; suspected cancers were referred directly to the

RGH lung cancer service, and stable lung nodules requiring further surveillance were not discussed; only new or evolving incidental findings were discussed. This was done on an *ad hoc* basis due to the low number of cases requiring discussion.

In addition to in-meeting discussion time, preparation time for SRM meetings was required. This involved checking for relevant previous imaging, correspondence and GP records via Welsh Clinical Portal. Relevant findings were collated on a list prior to each meeting by the LHC Clinical Team in order to facilitate efficient discussion during the meetings. The team estimate that this preparation took 6-9 minutes per participant discussed. Actions such as onward referrals or communication with participants through results letters or other means were performed following rather than during meetings.

## 7.10 Suspected and confirmed lung cancers

### 7.10.1 Investigations through the Single Cancer Pathway

Thirteen suspected lung cancers were identified; five from baseline LDCT scans and eight from 3-month recall scans. These were investigated further by the lung cancer service at RGH via the Single Cancer Pathway. Table 7i summarises the further investigations undertaken.

*Table 7i: Further investigations for suspected lung cancers.*

Investigation	Number
PET scan	12
Lung function tests	12
CT-guided lung biopsy	6
Endobronchial ultrasound (EBUS)	3
Magnetic Resonance Imaging (MRI) - brain	3
CT - brain	1
CT-guided biopsy of metastasis	1
Echocardiogram	1
Cardiopulmonary exercise test	1

### 7.10.2 Confirmed lung cancers

Of the thirteen suspected lung cancers identified, 12/13 (92.3%) were subsequently histologically-confirmed as lung cancers. The one remaining case is discussed in section 7.14.2. Of participants who underwent a baseline LDCT scan, the lung cancer diagnosis rate was 2.2% (12/547). This equates to a number of *participants* needed to scan per lung cancer diagnosed of 46, and a number of *scans* (including baseline and 3-month recall scans) per lung cancer diagnosed of 53.

#### 7.10.2.1 Characteristics of participants diagnosed with lung cancer

The median age of participants diagnosed with lung cancer through the OP was 68 years (range 63-74 years). Six cancers occurred in male participants (50%) and six in female participants (50%).



Five participants were current smokers at the time of diagnosis (41.6%). Of the seven participants (58.3%) diagnosed with lung cancer who were ex-smokers at the time of diagnosis, 3/7 (42.9%) had quit smoking during their participation in the OP.

The ECOG Performance Status and participant-reported exercise tolerance of participants diagnosed with lung cancer are shown in figure 7i. These were generally slightly less favourable than for the participating population as a whole (e.g. 67% ECOG Performance Status 0-1 in those diagnosed with lung cancer vs. 90% for whole participating population), likely reflecting the risk profile, particularly related to age and smoking exposure, of those diagnosed with lung cancer.

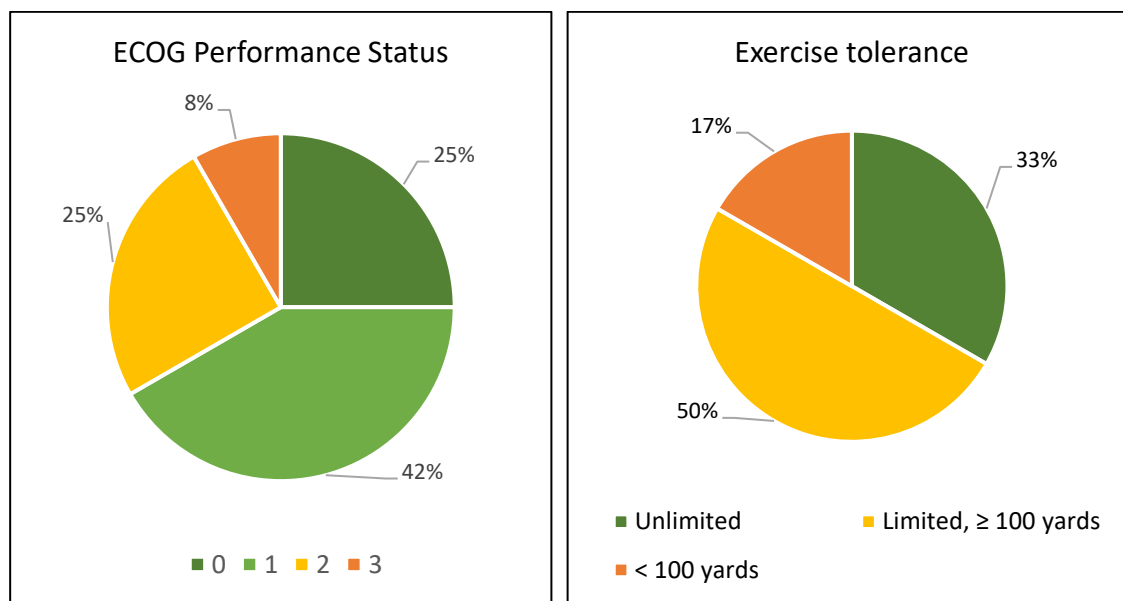


Figure 7i: ECOG Performance Status and exercise tolerance of participants diagnosed with lung cancer.

#### 7.10.2.2 Characteristics of lung cancers diagnosed

The stage distribution of lung cancers diagnosed is shown in figure 7j. Eight lung cancers (8/12, 66.7%) were diagnosed at stage 1-2, of which 6 were at stage 1 (6/12, 50% of lung cancers diagnosed).

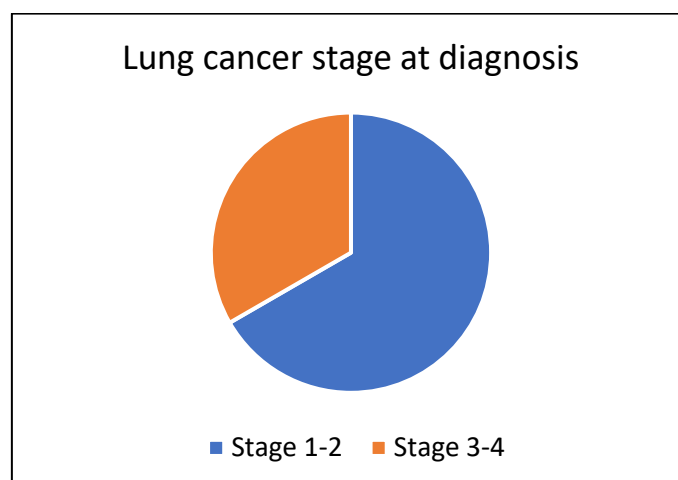
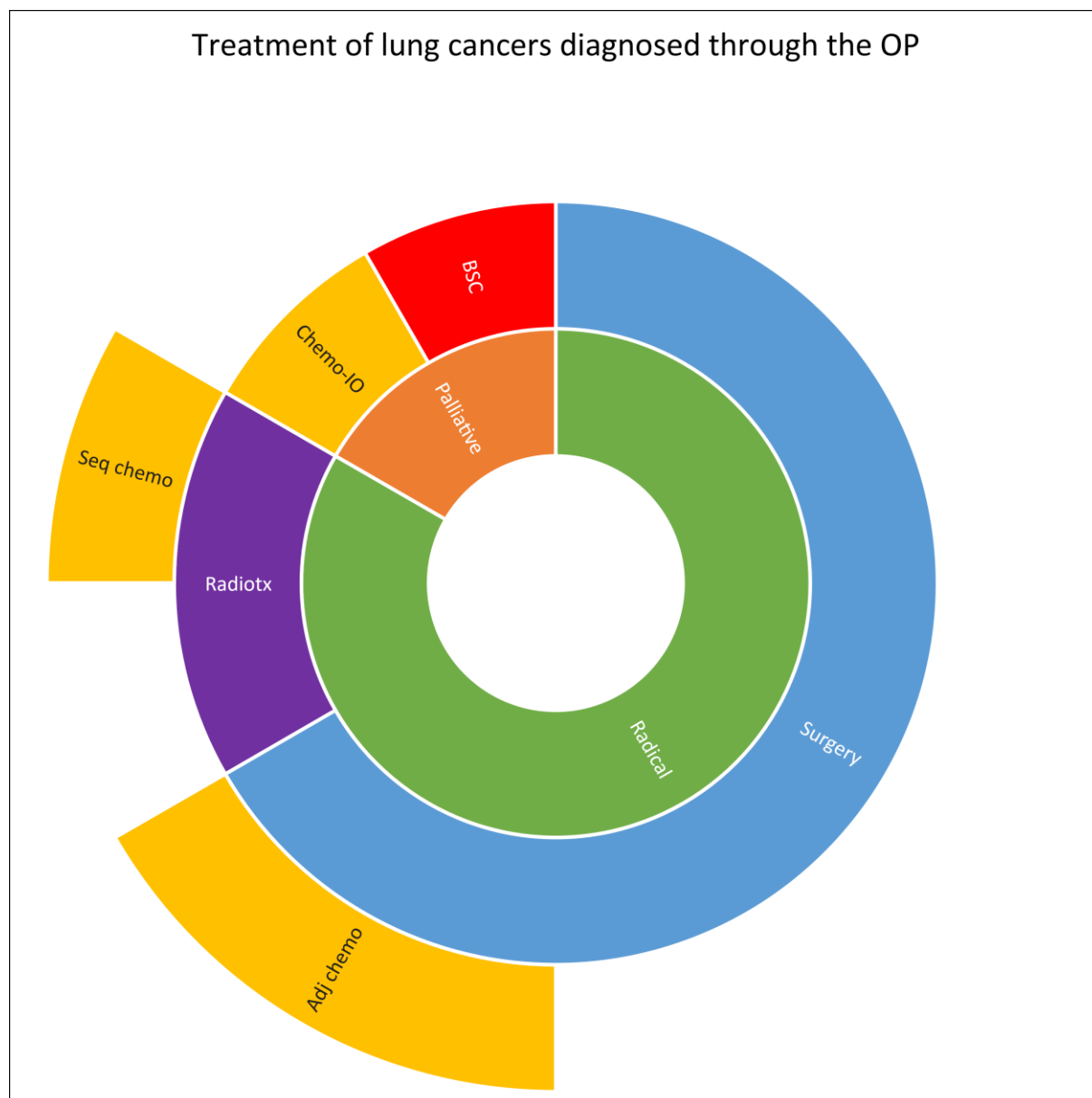


Figure 7j: Stage distribution of lung cancers diagnosed through the OP.

Eight lung cancers were histologically classified as adenocarcinoma (8/12, 66.7%), three as squamous cell carcinoma (25.0%) and one as mixed small cell carcinoma/adenocarcinoma (8.3%).

The treatment of lung cancers diagnosed through the OP is summarised in figure 7k. Radical treatment (treatment with curative intent) was given in 10/12 cases (83.3%), and 11/12 (91.7%) received some form of active anti-cancer treatment. Eight lung cancers (8/12, 66.7%) underwent surgical resection as the initial or only treatment modality.



*Figure 7k: Treatment intent and modality for lung cancers diagnosed through the OP. Inner ring = treatment intent; middle ring = primary treatment modality; outer ring = additional treatment modality. Adj chemo = adjuvant chemotherapy, Seq chemo = sequential (non-concurrent) chemotherapy, Radiotx = radiotherapy, Chemo-IO = combined chemotherapy and immuno-oncology therapy, BSC = best supportive care.*

## 7.11 Lung nodules

### 7.11.1 Nodules detected on baseline LDCT scans

Figure 7I summarises the detection, discussion at SRM, and follow-up of lung nodules reported on baseline LDCT scans. Potentially actionable lung nodules were reported on 123/547 (22.5%) baseline scans. Of these, 29/123 (23.6%) were dismissed at SRM, with the majority dismissed due to the nodule being visible on previous imaging. In total, 91/547 (16.6%) of participants required a 3-month recall scan. This included two participants whose scan report suggested referral to the lung cancer service but was down-graded to a 3-month recall scan following discussion at SRM.

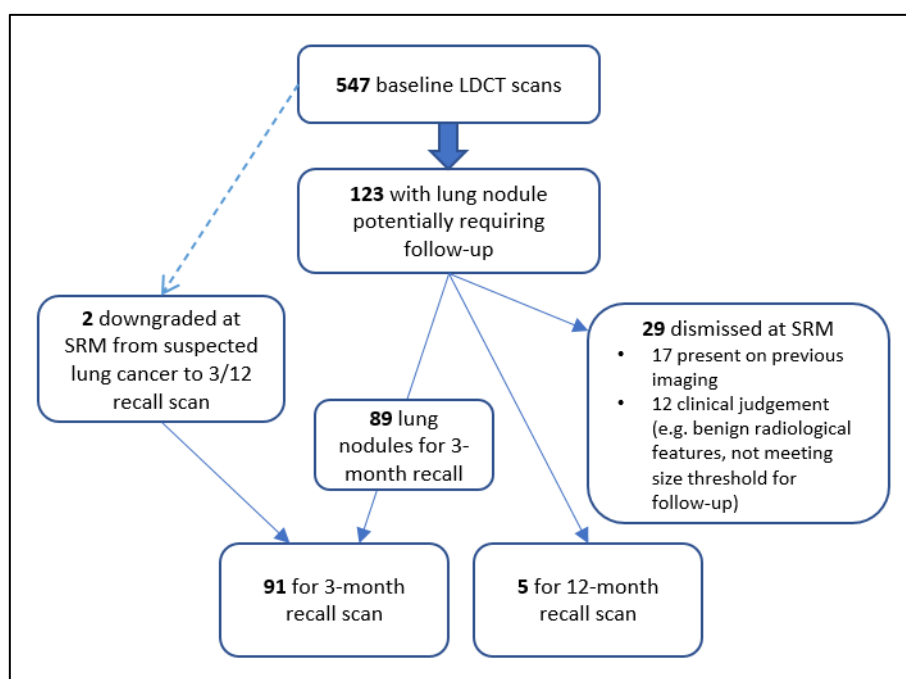


Figure 7I: Nodules detected on baseline LDCT scans.

Of those with a lung nodule potentially requiring follow-up on a baseline LDCT scan, 15/123 (12.2%) had at least one other potentially actionable incidental finding that was also discussed at SRM.

### 7.11.2 Nodules on 3-month recall scans

Lung nodules on 3-month recall scans were not routinely discussed at SRM; nodules reported as stable were referred for a 12-month recall scan, nodules reported as having resolved or shrunk had no further follow-up within the OP, and nodules that were growing or had concerning features were referred to the RGH lung cancer service for further investigation.

Following 547 baseline scans, a total of 160 recall scans were indicated at 3 months or 12 months (91 at three months, 5 at twelve months direct from baseline scans, and 64 at twelve months following three-month scans). Overall, 29 interval scans were required for every 100 baseline scans undertaken. It should be noted that this number is higher following the first (prevalent) round of screening which the OP equates to, and would be expected to be lower for subsequent (incident) rounds of screening, as most lung nodules would be “known” from incident rounds and not require recall scans unless they were new or progressing.

## 7.12 Common incidental findings

### 7.12.1 Emphysema

Emphysema was classified as none, mild, moderate or severe on baseline scans. Figure 7m summarises these findings. In total, 72/547 (13.1%) of participants had moderate or severe emphysema on their baseline scan.

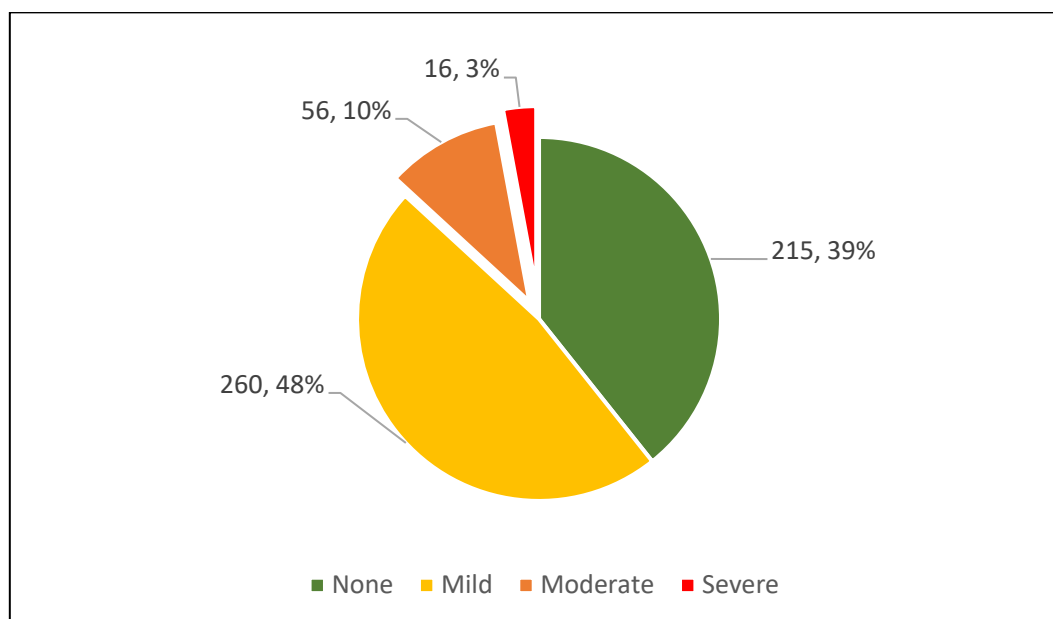


Figure 7m: Extent of emphysema on baseline LDCT scans.

Participants with emphysema, and their GPs, were informed of the finding, and smoking cessation advice was reinforced to current smokers. No specific recommendation for further investigation or assessment was made to participants or primary care based on this finding.

Of the participants with severe emphysema on their baseline LDCT scan, 10/16 (62.5%) had a known diagnosis of COPD prior to the OP. Of those with moderate emphysema, 24/56 (42.9%) had a prior diagnosis of COPD.

### 7.12.2 Coronary artery calcification

Coronary artery calcification (CAC) was classified as none, “previous intervention” (e.g. evidence on LDCT of stenting of coronary arteries) mild, moderate or severe on baseline scans. Figure 7n summarises these findings. In total, 190/547 (34.7%) of participants had moderate or severe CAC on their baseline LDCT.

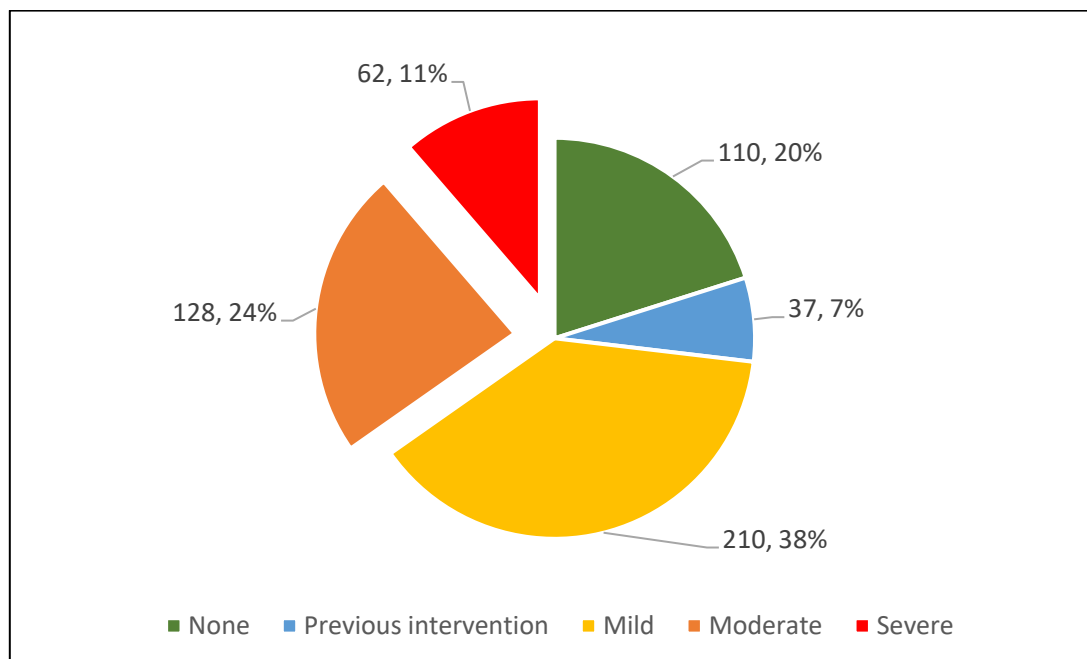


Figure 7n: Coronary artery calcification on baseline scans.

Of those with moderate or severe CAC, 130/190 (68.4%) were already prescribed a statin medication prior to their LHC. Overall, 60/547 (11.0%) of participants who underwent a baseline scan had moderate or severe CAC and were not already prescribed a statin (figure 7o).

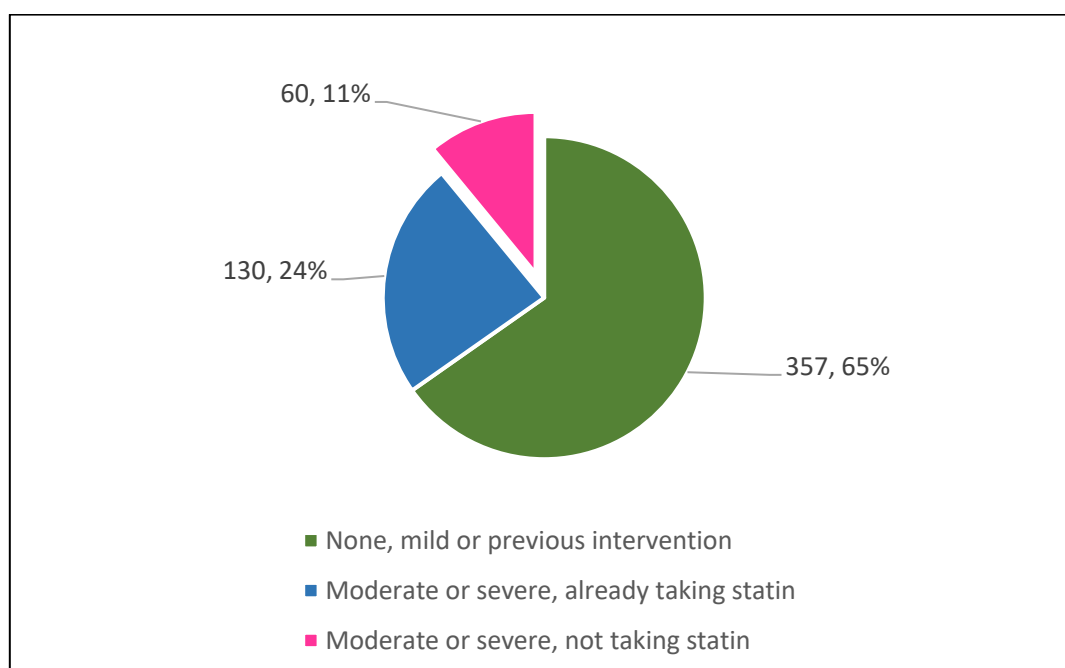


Figure 7o: Statin prescription for moderate and severe coronary artery calcification on baseline scans.

Participants with CAC (of all severities), and their GPs, were informed of the finding. Smoking cessation advice was reinforced to current smokers. Standard advice was included on results letters, including a recommendation to participants who were not already prescribed a statin to consider making a routine appointment with their GP to discuss possible statin treatment.

## 7.13 Other incidental findings

### 7.13.1 Summary of other incidental findings

Seventy potentially actionable incidental findings (excluding emphysema and CAC) were identified on the scans of 68 participants (68/547, 12.4% of participants; 12.8 potentially actionable incidental findings per 100 baseline scans). Following SRM discussion, 30/70 (42.9%) findings were downgraded to non-actionable, leaving 40 actionable incidental findings (7.3 actionable incidental findings per 100 baseline scans). Figure 7p and Table 7i summarise the incidental findings on baseline scans.

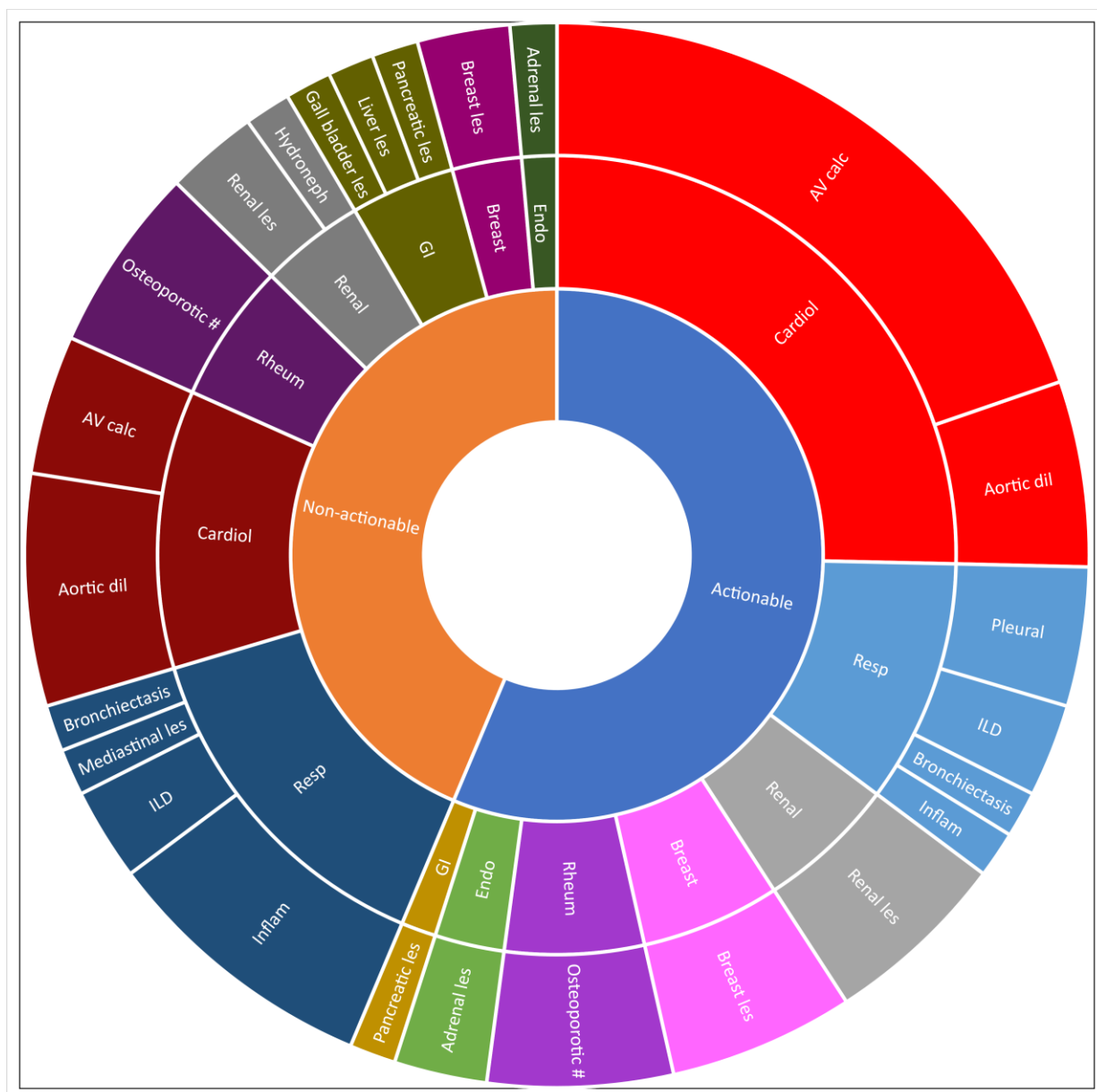


Figure 7p: Summary of incidental findings on baseline scans. Inner ring = status of finding following SRM discussion; middle ring = specialty; outer ring = finding. Abbreviations expanded in Table 7i.

Table 7j: Summary of incidental findings and actions from SRM discussions.

System	Finding	Total	Actionable	Non-actionable following SRM discussion
Cardiology	Aortic valve calcification	17	14: Referred to Cardiology	3: Known finding
	Aortic dilatation	9	3: Referred to Cardiology 1: Referred to Vascular	5: Updated guidance
Respiratory	Interstitial lung disease (ILD)	4	2: Referred to Respiratory	2: Known finding
	Inflammatory changes	6	1: Clinical review	3: Clinical judgement 2: Known finding
	Pleural	3	3: Referred to Respiratory	0
	Bronchiectasis	2	1: Referred to Respiratory	1: Known finding
	Mediastinal lesion	1	0	1: Clinical judgement
Rheumatology	Osteoporotic fracture	8	4: Referred to Rheumatology	3: Known finding 1: Clinical judgement
Breast	Breast lesion	6	4: Referred to Breast team	2: Known finding
Gastro-intestinal (GI)	Pancreatic lesion	2	1: Referred to GI team	1: Clinical judgement
	Liver lesion	1	0	1: Clinical judgement
	Gall bladder lesion	1	0	1: Known finding
Endocrine	Adrenal lesion	3	2: Referred to Endocrine	1: Known finding
Renal	Renal lesion	6	3: Referred to Urology 1: Further imaging	2: Known finding
	Hydronephrosis	1	0	1: Clinical judgement

### 7.13.2 Workload from incidental findings

Incidental findings from baseline scans resulted in 38 referrals to secondary care services (6.9 referrals per 100 baseline scans). Almost half of these were to Cardiology for moderate or severe aortic valve calcification or aortic dilatation. During the OP, updated external guidance was issued recommending a higher threshold for referral for aortic dilatation detected during lung cancer screening. If this guidance had been in place from the beginning of the OP, two fewer referrals would have been made, resulting in 2.7 Cardiology referrals per 100 baseline scans.

A Cardiology-focussed SRM meeting was held as a one-off during the OP to review appropriateness of referrals given the high initial referral rate. Other than adopting the higher threshold for aortic dilatation referral, it was agreed to keep other referral thresholds unchanged for the duration of the OP. All Cardiology referrals were handled in a “test-first” manner, with an echocardiogram requested by the Cardiology team as the first step, with a view to some individuals then being seen in outpatient clinics, some having ongoing echocardiogram surveillance, and some being discharged. The majority of these pathways are ongoing; further analysis of the outcomes of these referrals is planned in due course.



The LHC Clinical team made 15 outbound telephone calls relating to incidental findings (2.7 outbound calls per 100 baseline scans), and 8 unscheduled inbound telephone calls were received from participants to discuss incidental findings or lung nodules (1.5 inbound calls per 100 baseline scans).

#### 7.13.3 Incidental malignancies

To date, three individuals have been diagnosed with histologically-confirmed non-lung malignancies that were detected on OP scans, and a further two individuals have highly suspicious lesions which have not yet been histologically confirmed (table 7k). All individuals with confirmed malignancy are receiving active treatment.

*Table 7k: Incidental malignancies*

Malignancy type	Status	Treatment
Breast cancer	1 confirmed	1 surgery & systemic therapy
Mesothelioma	1 confirmed	1 immunotherapy
Renal cell carcinoma	1 confirmed	1 surgery & immunotherapy
	2 highly suspected	1 surgery planned
		1 offered surgery, opted for surveillance

#### 7.14 Potential harms

##### 7.14.1 Radiation exposure

The Dose Length Product (DLP) was recorded for all LDCT scans performed. The effective (radiation) dose of the scan can be estimated by multiplying the DLP by a constant “k” factor.[44] The quality standards for the NHSE TLHCP state that the LDCT effective dose delivered to an individual undergoing a screening scan should be below 2mSv (based on a median standard 70kg adult).[45]

The DLP was audited and estimated effective dose calculated for a random selection of 62 baseline LDCT scans performed across the baseline scanning period. The median estimated effective dose was 0.979mSv (range 0.371 – 1.828 mSv).

##### 7.14.2 False-positives

One participant with suspected lung cancer underwent a PET scan that suggested a low probability of cancer and is now undergoing surveillance with interval CT scans. Whilst the possibility of lung cancer has not been completely dismissed, this is considered a false-positive case in the context of the OP. The false-positive rate in the OP was 0.2% of all participants (1/547), or 7.7% (1/13) of participants with suspected lung cancer on screening LDCT.

No participants in the OP who were not ultimately diagnosed with lung cancer underwent invasive tests (CT-guided biopsy, bronchoscopy, etc.) or thoracic surgery.

## 8. DISCUSSION

### 8.1 Optimising uptake

#### 8.1.1 Participation in lung cancer screening

Participation rates in lung cancer screening activity elsewhere has often been low, particularly by those at greatest risk.[17,18,31] Phase 1 & 2 NHSE TLHCP sites had an average uptake of 34%, defining this as the percentage of people who attended a LHC appointment out of those invited.[46] This varied widely between the twenty areas in England that were delivering the programme, from 48% in Salford to 21% in Hammersmith & Fulham. Whilst the NHSE TLHCP uses a standard protocol to align practice across its sites, it does allow some variation in delivery.[11] For example, some sites utilise telephone-based assessments, whilst others are entirely in-person; some sites deliver the service as a “one-stop” appointment whilst others use multiple steps; and some sites use mobile community-based CT scanners whilst others use hospital-based scanners. As learning gained from this variation in delivery has been gathered and shared, and the programme has become more established and awareness of it has increased amongst the target population, average uptake of the NHSE TLHCP has steadily increased to 44% as of late 2023.[unpublished]

Various UK-based lung cancer screening trials have also reported low rates of participation amongst those invited, with uptake of 30.7% in the UK Lung Screening trial,[31] 41% in SUMMIT,[18] 24.7% in LUNGSCOT[47] and 50.8% in the Yorkshire Lung Screening Trial.[17] The Lung Screen Uptake Trial (LSUT) compared different approaches to delivering information on lung cancer screening to invitees and found no significant difference between its two arms, but did have an overall uptake of 52.6%,[32] leading to many of the approaches included in the trial to be considered good practice.

Relatively few countries are currently delivering lung cancer screening at scale, making international comparisons of uptake difficult. Lung cancer screening is available nationally in USA and Croatia, but this is primarily accessed through health insurance rather than as a comprehensive public health intervention like national screening programmes in the UK. Estimates suggest that <10% of people eligible for lung cancer screening in USA have undergone a screening scan.[48]

Uptake of lung cancer screening activity in England has generally been lower than that seen in other national screening programmes.[49] Uptake of breast cancer and abdominal aortic aneurysm screening in Wales has generally been around 70% or greater over the last decade, with some variation during the COVID-19 pandemic. Uptake of bowel screening has been somewhat lower, usually between 50-60%, which may be partly due to the perceived acceptability of the test by the target population.

#### 8.1.2 Strategies to optimise uptake

There is an active research community examining the reasons for low participation in lung cancer screening and exploring potential strategies to address these. Cardiff University’s Division of Population Medicine are particularly active in this field, and the team delivering the OP made links with this group to inform the plans for the OP.

Well-recognised barriers to participation in lung cancer screening include:[14,15,32,33]

- Lack of awareness
- Lack of engagement
  - Linked to fear of cancer diagnosis, stigma related to lung cancer and smoking, and fatalistic views regarding lung cancer
  - Lack of trust in a new or unknown service
  - Imbalance of perceived benefits and risks of participation
  - Difficulties with language or health literacy
- Practical concerns
  - Difficulty accessing the service (public transport or parking availability, knowledge of location, disability, and conflicting priorities such as work, other health problems or family commitments)
  - Cost (including travel and parking)

Many of these issues are amplified in people who are at highest risk of lung cancer due to risk correlating strongly with socio-economic deprivation. For example, socio-economic deprivation correlates with lower literacy levels, meaning providing written information about a service may not lead to better awareness or willingness to participate. Similarly, socio-economically deprived groups may be less likely to have their own transport and be more reliant on public transport, or may find the cost of parking prohibitive.

The OP aimed to overcome these barriers to participation through two main strategies: (1) by designing evidence-based public-facing materials and communications to engage and inform the OP's target population, and (2) by constructing a participant pathway, incorporating ideas and systems that had worked well elsewhere, that would encourage participation in and retention through the OP's pathway.

### 8.1.3 Public-facing materials and communications

The process to develop the public-facing materials and communications used in the OP is discussed in section 3.2.6. Briefly, existing LHC materials used elsewhere were reviewed and permission was gained to adapt these for use in the OP. Evidence from the NHSE TLHCP,[3,46] Lung Screen Uptake Trial[32,50] and other sources was reviewed, and advice was sought from Public Health Wales's Screening Engagement Team and the Wales Cancer Network's Patient Engagement and Experience Team.

Materials including a tri-fold leaflet and information booklet were drafted, then further co-developed with extensive Patient and Public Involvement (PPI) via the Tenovus All-Wales Cancer Community, Health Cancer Research Wales's Involving People Network, and the Wales Cancer Network patient forum.

The leaflet, which was sent to invitees alongside a pre-invitation letter, was designed to reduce early disengagement due to:

- Practical barriers – “it's free”, “convenient telephone appointment”,
- Lack of trust – local GP endorsement and NHS Wales logo,
- Fear and fatalism – stepped approach to discussion of lung cancer and positive messaging – “it's a great way to give your hard-working lungs an MOT”, and
- Smoking-related stigma – “no judgments on smoking”.

A more detailed booklet accompanied the invitation letter. This incorporated example participant stories, and infographics that had been simplified compared to existing materials (figure 8a).

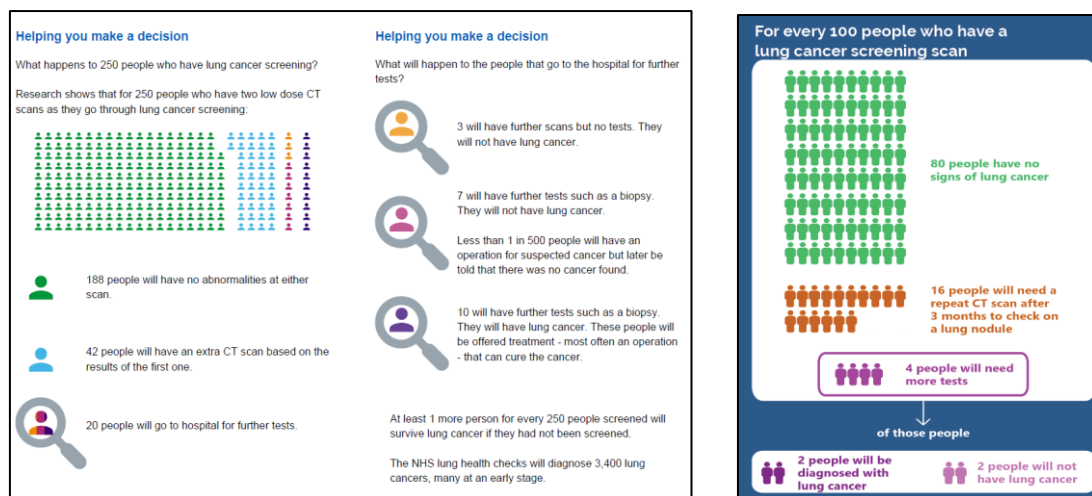


Figure 8a: Infographic used in the NHSE TLHCP (left), and simplified version developed for the OP following extensive consultation with engagement teams and PPI groups (right).

The materials were edited following advice from the Plain English campaign,[34] simplifying language and avoiding jargon, gaining their crystal-mark accreditation. Easy Read versions were developed to benefit invitees with lower literacy, and all materials were made bilingual. Further communications were developed including a poster and digital displays to be used in local pharmacies and GP practice waiting rooms, and social media posts that were posted through CTM's account.

The OP did not spend any funds on public advertising. A small proportion of the budget was utilised to align with the Plain English campaign's standards and to develop the Easy Read booklet, and to print posters for display. Otherwise, the communications plan was largely delivered utilising existing resources: displaying posters and digital displays in local healthcare settings, and posting through CTM UHB's existing Facebook account without paying for additional visibility. Sites in the NHSE TLHCP have varied in the extent to which they have marketed their service to their target populations, with limited success; an Evaluation Progress report found that almost three-quarters of LHC participants had not heard of the service prior to their invitation letter.[46] Given the limited budget of the OP and the limited evidence that advertising could make a difference to uptake, it was decided to focus on optimising uptake through evidence-based pathway design and materials rather than through advertising.

Finally, a website providing additional information to invitees to the OP was developed. A significant amount of additional information was included on this about the benefits and risks of lung cancer screening. This was in response to the diverse opinions expressed through PPI groups about the amount of information desired to help them make an informed decision about participation. Some individuals wanted only very basic information, whilst others wanted detailed statistics to help them decide. Whilst discussions during TNA appointments can be tailored to the level of information desired, this is more difficult in standard written information, and providing excessive information to those who did not want it could lead to disengagement. Providing detailed information on a website, with instructions for how to access this in the standard materials, was considered a reasonable compromise.

#### 8.1.4 Pathway design

As for the development of public-facing materials, the design of pathways for the OP was informed by a growing body of evidence made available from UK-based lung cancer screening activity including various trials, pilots, and the NHSE TLHCP.[11,17,18,20,22,32]

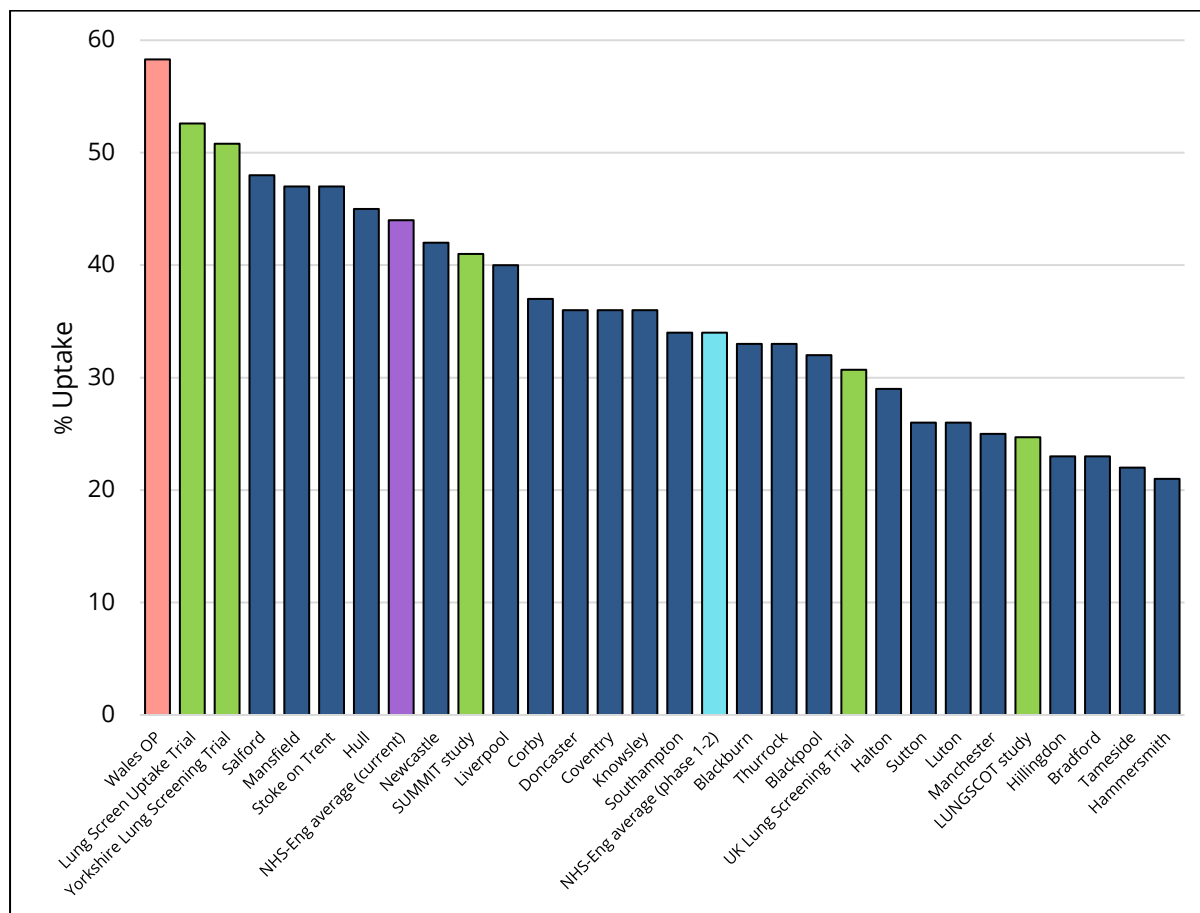
Some leeway for variation in delivery of the NHSE TLHCP by site was included by design, allowing additional insights to be gained where participation varied between sites with different pathways. Much of this is captured in TLHCP Evaluation Progress reports.[3,46] In addition, many changes were made to how sites deliver their programmes during and following the COVID-19 pandemic, when face-to-face services were more difficult to deliver and more remote assessments were trialled. Some key features that were incorporated into the OP based on observations from other activities included:

- Sending pre-invitation information to the target population prior to their invitation to engender recognition of the service
- Specifying a date and time for appointments, rather than offering an “open” invitation
- The service contacting the invitee by telephone rather than the invitee having to initiate the contact (opt-out, rather than opt-in model)
- Inclusion of a TT stage, to optimise efficient use of higher banded staff’s time further down the pathway
- Conducting the TNA appointment by telephone to improve efficiency and avoid the need for travel at this stage of the pathway, with this approach appearing acceptable to participants when incorporated elsewhere
- Locating the mobile CT scanner at a local community hospital – a location the target population were familiar with, with good public transport links and ample free parking
- Use of reminder letters and text message reminders shortly prior to appointments

#### 8.1.5 Impact of strategies used to optimise uptake in the OP

There has been inconsistency in how the uptake of lung cancer screening activity has been reported previously. This is partly due to the variation in pathways between different activities, meaning that activities where a face-to-face nurse appointment is the first step may use this to define uptake, others with earlier triage or remote steps may use other measures as only a proportion of those who engage initially will then be eligible for a subsequent nurse appointment step. The UK NSC draft effectiveness standards for lung cancer screening[unpublished] have been designed to improve consistency in measuring various outcomes, including uptake. These recommend using the proportion of the eligible population who complete a lung cancer risk assessment as a measure of uptake, regardless of whether this occurs during a triage stage or with a nurse, and whether the assessment is performed remotely or face-to-face. In the OP this risk assessment was performed during the TT step, giving an uptake of 58.3% by this definition.

Due to the previous lack of an agreed definition of uptake the metrics used to report uptake have differed in LHC activity elsewhere. Nevertheless, uptake of the OP appears to compare favourably to reported uptake of other UK LHC activity (figure 8b).[17,18,31,32,46,47]



*Figure 8b: Uptake of the OP (pink) compared to UK-based lung cancer screening studies (green), phase 1-2 NHS England TLHC programme sites (dark blue; average light blue), and current NHSE TLHC programme uptake (purple, as of November 2023).*

Much of the pathway design was aimed at making initial participation as easy as possible for the participant. Whilst this approach is likely to maximise initial participation, it does carry a risk of participation attrition through the pathway, particularly due to the number of steps involved. Reassuringly, there was good retention of participants who were eligible to continue proceeding through the pathway once they had engaged initially. Almost 85% of participants who were high risk at TT went on to complete a TNA, and 90% of participants who were referred for a baseline LDCT scan went on to complete this.

These results suggest that the strategies employed in the OP to overcome barriers to participation by the target population, through public-facing materials and communications, and pathway design, were successful and can be used as a template for a future national programme.

## 8.2 Clinical effectiveness

### 8.2.1 Clinical effectiveness of lung cancer screening

The clinical effectiveness of LDCT screening for lung cancer is already proven. A prerequisite for a positive recommendation from the UK NSC for a screening programme to be implemented is sufficient evidence that screening is effective. The body of evidence from randomised controlled trials over the last two decades has demonstrated that LDCT screening for lung cancer reduces lung cancer mortality.[2,7,8] The UK NSC also consider whether the benefits of screening outweigh the risks overall, as well as cost-effectiveness, feasibility, and acceptability to the target population. In addition to evidence from randomised controlled trials and small pilots, the NHSE TLHCP has provided evidence that such a programme can be delivered at scale within the UK healthcare setting. A high bar is set for a positive recommendation to be made by the UK NSC, to ensure that the publicly-funded UK healthcare system does not waste its finite resources on programmes that are ineffective or poorly cost-effective.[51] The UK NSC were satisfied that LDCT screening for lung cancer fulfilled their criteria for a positive recommendation to be made to the UK governments that lung cancer screening should be implemented.[10]

Given that the effectiveness of LDCT screening for lung cancer has been demonstrated by large-scale randomised controlled trials and has been accepted by the UK NSC, the primary aims of the OP did not include providing evidence that LDCT screening for lung cancer is effective. Nevertheless, the OP delivering results similar to other lung cancer screening activities would provide assurance that such a programme would provide similar benefits to those seen elsewhere.

### 8.2.2 Clinical effectiveness of the OP

#### *8.2.2.1 Comparison with lung cancer screening activities elsewhere*

Reassuringly, results from the OP have largely been in line with expectations. Table 8a summarises key clinical outcomes of the OP alongside those in lung cancer screening activities elsewhere.[3,5,7,8,20,46] Results related to the benefits of lung cancer screening (lung cancer detection, stage at diagnosis, radical treatment and surgical resection rates) were all closely aligned to activities elsewhere, including the large-scale randomised controlled trials demonstrating lung cancer mortality reduction. The extremely low number of harm-related outcomes in the OP is likely to reflect these events being relatively infrequent and the size of the OP being relatively small compared to activities elsewhere. Nevertheless, this does provide some reassurance that the protocols used in the OP are likely to be effective at minimising harms in a larger-scale programme, accepting that when delivering at scale some false-positive cases, invasive tests and surgical resections for benign disease will be inevitable.



*Table 8a: Key clinical outcomes in the OP compared to lung cancer screening activities elsewhere. Results elsewhere are listed in order of sample size, from largest to smallest. Note that the eligibility criteria, number of screening rounds and screening intervals varied in activities elsewhere.*

<b>Metric</b>	<b>Result in OP</b>	<b>Results elsewhere</b>
% of participants scanned <b>diagnosed with lung cancer</b>	<b>2.2%</b>	1.3% - NHSE TLHCP 1.7% - NLST 0.9% - NELSON 2.2% - 5 combined UK studies
% of lung cancers detected at an <b>early stage</b> (stage 1-2)	<b>66.7%</b>	75.0% - NHSE TLHCP 70.2% - NLST 67.9% - NELSON 81.2% - 5 combined UK studies
% of lung cancers undergoing <b>radical (curative) treatment</b>	<b>83.3%</b>	89.1% - Manchester pilot
<b>Surgical resection rate</b> of lung cancers	<b>66.7%</b>	66% - 5 combined UK studies
<b>False-positive rate</b> (% of people scanned who had further investigations for suspected lung cancer who were not subsequently diagnosed with lung cancer)	<b>0.2%</b>	1.2% - NELSON 2% - 5 combined UK studies
% of people scanned who underwent an <b>invasive test</b> who were <b>not</b> <b>ultimately diagnosed with lung</b> <b>cancer</b>	<b>0%</b>	0.6% - 5 combined UK studies
<b>Benign surgical resection rate</b> (% of people who underwent surgical resection who did not ultimately have lung cancer)	<b>0%</b>	21% - NLST 23% - NELSON 4.6% - 5 combined UK studies
% of people completing a baseline LDCT screening scan who required a <b>recall scan for small lung nodules</b>	<b>17.6%</b>	19.7% - NELSON 11.1% - 5 combined UK studies

#### 8.2.2.2 Comparison with lung cancers detected through usual care in Wales

The stage of diagnosis and treatment intent of lung cancers diagnosed through the OP compare favourably to those diagnosed through usual care in Wales (figures 8c-d).[52] This was expected given the known lung cancer mortality reduction associated with lung cancer screening, which is due to stage-shift and increased radical treatment rates.

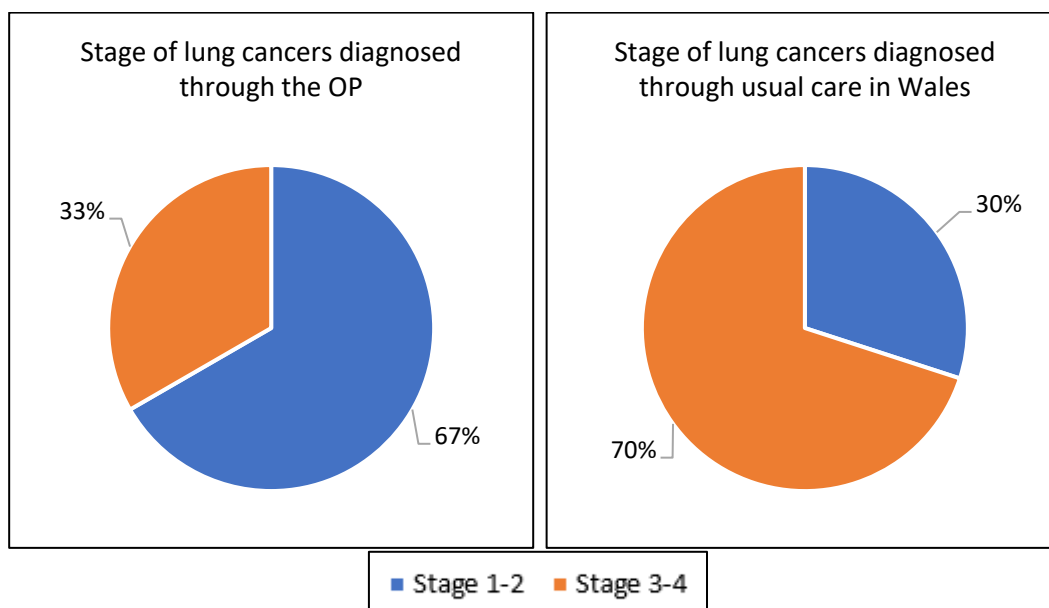


Figure 8c: Stage of lung cancers diagnosed through the OP (left), and through usual care in Wales (right; National Lung Cancer Audit, 2022 cohort).

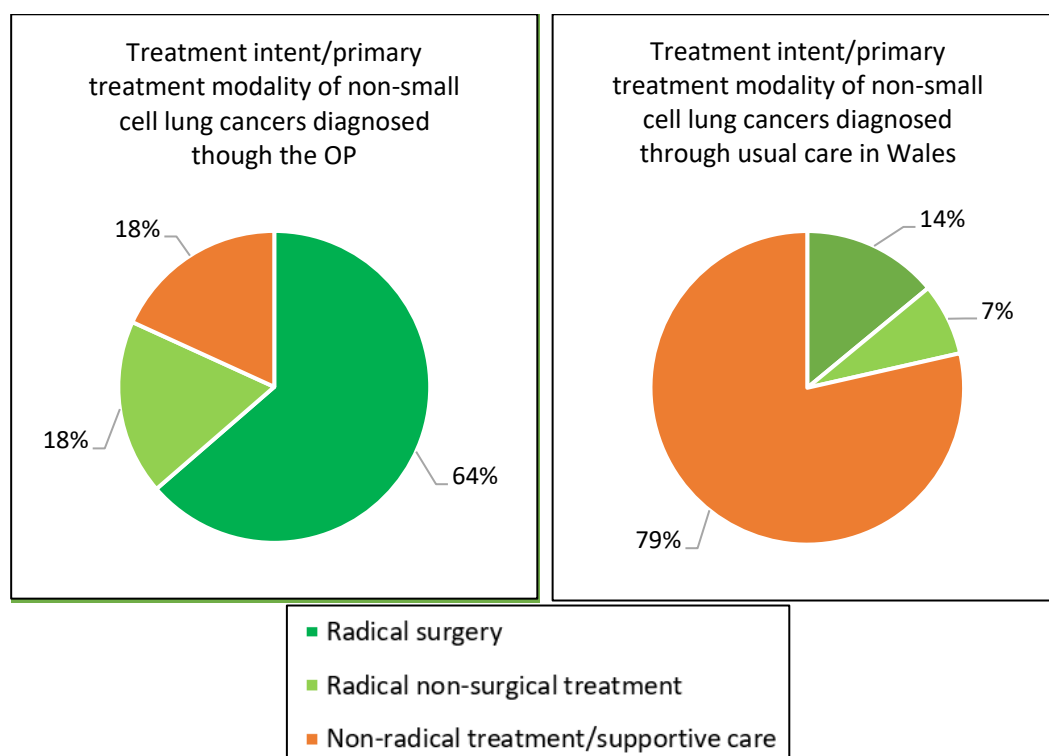


Figure 8d: Treatment intent and primary treatment modality for non-small cell lung cancers diagnosed through the OP (left) and detected through usual care in Wales (right; National Lung Cancer Audit, 2022 cohort). Non-small cell lung cancer accounted for 90.6% of lung cancers diagnosed in Wales in 2022. Data on radical treatment rates for small cell lung cancer is not available from the National Lung Cancer Audit, therefore treatment intent for non-small cell lung cancers only is displayed here.

Overall, these findings provide assurance (1) that lung cancer screening can be delivered effectively within the Welsh healthcare system, (2) that lung cancer screening is likely to yield benefits similar to those seen in studies, pilots and programmes elsewhere, and (3) that a lung cancer screening programme would significantly improve lung cancer outcomes compared to current care in Wales.

### 8.3 Incidental findings

#### 8.3.1 Incidental findings in lung cancer screening

LDCT screening has far greater potential to detect incidental findings than tests used in other screening programmes, both in terms of frequency and variety. The approach to managing incidental findings has differed across different programmes.[53] Detection and management of incidental findings has the potential to cause harm through anxiety, unnecessary healthcare and waste of resources if the finding is not clinically significant or is overdiagnosed. The approach in the UK has therefore been to limit reporting and actioning of incidental findings to those that are likely to be clinically significant and with an evidence base to support action.[22,45]

Small lung nodules are an expected, indeterminate finding rather than an incidental finding. Surveillance of small lung nodules that could represent very early lung cancers through recall scans is a core component of lung cancer screening. This is emphasised by the results of this OP, where more lung cancers were diagnosed following 3-month recall scans than following baseline scans. There is a strong evidence base underpinning national guidance on surveillance of small lung nodules, much of which draws on evidence from lung cancer screening trials.[39]

#### 8.3.2 Common incidental findings

CAC and emphysema are common and share risk factors with lung cancer, primarily age and smoking. Both are readily detectable on LDCT, and as such are extremely common incidental findings in lung cancer screening.[53] Both findings can be graded by severity on rapid visual assessment during LDCT reporting. Increasing severity of CAC correlates strongly with risk of major cardiovascular events, and risk factor modification (through smoking cessation and statin medication) can reduce adverse outcomes.[54–57] The evidence-base for early action for emphysema, by investigation for COPD through spirometry, is less clear with smoking cessation being the only intervention with convincing evidence of benefit.[58] Smoking cessation already forms a core part of the LHC offer.

For CAC in particular, reporting of this finding and advising action, either to the participant or primary care, offers an opportunity of clear health benefits to a high-risk population through initiation of statin medication. Results from the OP show that whilst CAC severity already correlated with statin prescription[unpublished data], suggesting risk assessment and modification was already occurring, there remained a proportion of participants with moderate or severe CAC who were not receiving statin medication.

The OP took the approach of informing participants of the finding of CAC and offering standard advice in their results letter, including suggesting making a routine appointment with their GP to discuss taking a statin medication if they were not already taking one. Primary care were informed of the finding, but the onus was on the participant to act. This approach may reduce the workload for primary care compared to a more comprehensive strategy of primary care actively contacting participants who may benefit from statin medication, but is likely to lead to missed opportunities for benefit and means

that the workload for primary care is more uncontrolled. Further exploration of primary care's experience of the OP is planned for a subsequent evaluation report in 2025.

Informal feedback from participants has highlighted that the finding of CAC on results letters did lead to some anxiety. Whilst contact details including a telephone number and email address to discuss results with the LHC team were included on results letters, some participants contacted their GP directly to discuss results. Whilst the possibility of incidental findings was mentioned in information provided to participants prior to LDCT, given the very high incidence of CAC and emphysema on screening LDCTs it may be prudent to provide more information about these findings to participants prior to LDCT.

### 8.3.3 Other incidental findings

The OP has demonstrated the wide breadth of incidental findings that can occur in lung cancer screening. These findings were managed through agreed pathways that largely aligned with those used in the NHSE TLHCP with some local adaptations incorporated. Two key pieces of learning emerged from the OP relating to this:

**1) The SRM is an important part of the screening pathway and can markedly reduce the clinical activity generated due to incidental findings.**

Previous imaging was not routinely available to radiologists at the time of reporting screening LDCTs. The SRM allowed previous imaging and existing healthcare records to be reviewed in relation to incidental findings detected on LDCT.

An alternative approach could be to make previous imaging available to radiologists and mandate comparison to any previous imaging at the time of reporting. Overall this would be less efficient than doing so through a SRM, adding a step of comparison to previous imaging for all screening scans rather than a focused review of a proportion of scans at SRM. In addition, SRMs allowed clinic letters and GP records to be reviewed through Welsh Clinical Portal which was often insightful in allowing incidental findings to be dismissed, particularly where the finding was not on recent or local imaging.

Overall, SRMs allowed almost half of reported incidental findings and almost a quarter of lung nodules to become non-actionable mostly due to them being known findings. SRMs would need to be adequately resourced, including preparation time, meeting time and resources (including a meeting room with video-conferencing facilities), and post-meeting administration time. This would be needed for a mixture of healthcare professionals which would include a radiologist, respiratory physician, and clinical and administrative support. Nevertheless, this would almost certainly be resource- and cost-saving overall given the reduced number of onward referrals and recall scans for nodules that SRMs would result in.

**2) The most common incidental findings (other than CAC and emphysema) were Cardiology-related.**

Perhaps surprisingly, more incidental findings occurred in the OP related to aortic valve calcification and thoracic aortic dilatation than respiratory incidental findings. This correlates with recent data from the NHSE TLHCP showing similar results.[unpublished]

Aortic valve calcification severity can be graded on rapid visual assessment during LDCT reporting. Through review at SRM some subjectivity in reporting was noted, and strengthened guidance may aid

a future programme. A one-off Cardiology-specific SRM was held during the OP which was supported by Dr Claire Williams, Consultant Cardiologist in CTM UHB, to review cases given the unexpectedly high frequency of cardiology-related findings. The local agreement during the OP was that these cases would be referred to the local Cardiology service for an echocardiogram +/- further assessment. Further evaluation of the results of these referrals will be undertaken in due course.

An evidence review was also undertaken at this time which confirmed that severity of aortic valve calcification correlates with likelihood of aortic valve disease, and can be predictive of need for future intervention such as aortic valve replacement.[59–61] Late presentation of aortic valve disease confers a poor prognosis, and as such it was agreed to continue to refer cases to Cardiology at the previously agreed threshold (moderate or severe calcification).

During the early stages of the OP, guidance in the NHSE TLHCP was updated to alter the threshold for referral for thoracic aortic dilatation from 4cms to 4.5cms. This change was implemented in the OP following several participants already being referred. Adopting this newer threshold for a national programme would substantially reduce the number of Cardiology referrals.

In a long-term programme with a regular recall interval (likely to be every 2 years until age 75), many incidental findings such as mild thoracic aortic dilatation could be monitored on LDCT within the programme, with only those with progressive changes requiring referral to other specialties.

Finally, it should be noted that the frequency of incidental findings such as these will be much greater in the first (prevalent) round of LDCT screening. In subsequent (incident) rounds, most findings will already be known having been detected during previous rounds, and only incidental findings that are progressing, newly developed, or occur in new participants will require action. A phased roll-out of a national programme would help to reduce large spikes in referrals for such incidental findings.

## 8.4 Service providers

### 8.4.1 Working with external service providers

For the reasons described in section 4.1, elements of the OP were delivered by external service providers, under one contract. This approach brought numerous benefits which are listed in table 8b.

*Table 8b: Benefits of working with external providers to deliver the OP.*

<b>Benefit</b>	<b>Description</b>
<b>Speed of implementation</b>	<p>By working with external service providers that had established service models and existing infrastructure to support delivery, once the procurement process was complete it was possible to progress planning and implementation far quicker than would have been possible if establishing this as an entirely new service within the NHS.</p> <p>This included key areas such as:</p> <ul style="list-style-type: none"> <li>• Staffing: for the elements of the OP that were delivered by external providers, the need to develop new roles and to recruit and train these staff was avoided, meaning that the Programme Team could focus on developing the LHC Clinical Team roles e.g. Clinical Lead, Radiologist Lead, Speciality Doctor, Specialist Nurse, Navigator and reporting radiologists.</li> <li>• Clinical protocols: existing protocols could be adapted for use in the OP, avoiding the need for these to be created in full but ensuring that bespoke versions for NHS Wales were developed.</li> <li>• IT systems: existing IT systems could be used, avoiding the need to establish new IT systems or adapt existing systems used within the NHS.</li> <li>• CT scanner capacity: mobile CT scanners could be provided, supporting the proposed model of providing scans as close as possible to the target population and avoiding the need to develop this provision within NHS facilities.</li> </ul>
<b>Cost</b>	The cost of establishing a new service within the NHS would have been significant, including planning time and infrastructure costs. These costs were avoided by working with external providers that had existing service models and infrastructure.
<b>Impact on core NHS services</b>	The OP was delivered within the service provider's existing staffing and infrastructure, meaning that this had minimal impact on core NHS capacity for these services.
<b>Resilience</b>	By working with providers that support LHC services on a wider scale, there was added resilience in case of unforeseen circumstances. This provided assurance overall in terms of the ability to maintain delivery, but as a specific example, a Radiographer absence due to sickness was covered at short notice by calling on the wide pool of staff available, meaning that cancelled scans were minimised. Further, an additional scanning date could be arranged at short notice to accommodate the cancelled scans by calling on the infrastructure available to the provider.

Working with external service providers did, however bring certain challenges, which are listed in table 8c.

*Table 8c: Challenges of working with external providers to deliver the OP.*

Challenge	Description
<b>Procurement and contracting</b>	Whilst establishing a service within the NHS would certainly have taken longer, the procurement process to contract with a service provider was protracted and time-intensive. The contracting approach did also provide some challenge for instance in relation to potential financial risk in case of delays (which were avoided) and the finite nature of the contract meaning that any proposed extension would require a contract amendment and be limited to a fixed proportion of the original contract, therefore limiting flexibility.
<b>Aligning policies and protocols</b>	Since the service provider had existing policies and protocols, some negotiation and amendment was required to ensure that these aligned with requirements in Wales and specific to the Health Board. This included very specific points such as cleaning products that could be used on the mobile scanner and wider points such as the reporting requirements to Health Inspectorate Wales, as opposed to the Care Quality Commission. Ultimately these were all resolved, but this was dependent on support from specific individuals within the Health Board which may not always be available and added complexity to the planning stage.
<b>Oversight and control</b>	Whilst protocols were agreed in advance between the LHC Programme Team and service providers, since the service provider was responsible for implementation the Programme Team did not have direct oversight or control in terms of delivery of certain aspects of the pilot. Although there was close and collaborative working between the teams throughout, an NHS delivered service would provide the programme with a greater level of control.

#### 8.4.2 Use of mobile CT scanner

One specific feature of the contracted service was mobile CT scanner provision, delivered and installed at the YCR site on pre-determined dates. The mobile scanner did not have any services provided, using a generator for power and 4G IT connection. Again, this approach had a number of benefits and challenges as outlined in table 8d.



*Table 8d: Benefits and challenges of using a mobile CT scanner in the OP.*

Use of mobile CT scanner	
Benefits	Challenges
Scans could be offered close to the target population, making it easier for participants to attend and ultimately aiming to increase engagement.	There were numerous practical considerations before a site for the mobile scanner could be confirmed. This included internet connection, distance from houses and people (due to noise/radiation), turning circle requirements for the delivery and suitable space for installation.
Due to the relatively small scale of the OP, scanning dates were spread out and the mobile scanner could be moved to other sites in between, minimising down time.	Each time the scanner was delivered, the car park that it was situated in had to be clear and access to the site was required. Whilst no issues were encountered, it is feasible that this could not always be guaranteed.
The mobile scanner was not part of the core radiology service meaning that core service capacity was not impacted and also ensuring ring fencing of the capacity for LHC scans.	Scanning time was lost on two occasions due to IT issues on the scanner, the risk of this may be reduced in a fixed facility.
	Scanning time was lost on two occasions due to staff absence. In a fixed facility there may be greater staff numbers to add resilience to reduce this risk.
	Scanning dates were arranged to incorporate other sites where the scanner was required, adding some complexity to the scheduling, although not impacting on the delivery of the OP.

## 9. NEXT STEPS

### 9.1 Ongoing OP activity

This report has been delivered prior to the conclusion of all clinical activity in the OP to allow the learning from the OP to inform planning work for a national lung cancer screening programme in Wales. Further recall scans, twelve months after baseline scans, are planned for participants with small lung nodules in September-November 2024.

A second evaluation report on the OP is planned to be delivered in March 2025. The scope of the second report will include:

- Outcomes of 12-month recall scans
- Smoking cessation pathways
- Qualitative feedback on experience of the OP from:
  - Participants
  - Invitees who did not participate
  - Healthcare professionals involved in the OP, including radiologists, the LHC Clinical team and primary care

### 9.2 National planning

In July 2023, a written statement by Eluned Morgan MS, Minister for Health and Social Services in the Welsh Government, was published in relation to lung cancer screening in Wales.[62] This statement recognised the positive recommendation from the UK NSC and the learning being gained from the OP, stating that “the Welsh Government has accepted the UK National Screening Committee’s recommendation for targeted lung screening in principle and is considering how this could be delivered in Wales”. Public Health Wales have subsequently been commissioned by Welsh Government to undertake a project reviewing how targeted lung cancer screening could be delivered in Wales in the future, setting out a proposed pathway, estimated costs and possible phasing strategies, with a final recommendation to be made by September 2025. This project commenced in April 2024 with a small team recruited to deliver this work, incorporating several members of the programme team that led the delivery of the OP, ensuring that the learning from this will directly inform the planning for a national service, as intended.

## 10. ACKNOWLEDGEMENTS

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- Paul Johnston, Superintendent Radiographer, Royal Glamorgan Hospital
- Andrew Jones, Assistant Director of Finance
- Philip Jones, PACS Manager
- Paul Mears, Chief Executive
- Lucy Morgan, Hospital cessation smoking advisor, Smoking Cessation
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- Carl Verrecchia, Care Group Service Director
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## 12. LIST OF ABBREVIATIONS

Acronym/ abbreviation	Meaning
AI	Artificial intelligence
BSTI	British Society of Thoracic Imaging
COVID	Coronavirus disease caused by SARS-CoV-2 virus
CTM UHB	Cwm Taf Morgannwg University Health Board
DDA	Data Disclosure Agreement
DPIA	Data Protection Impact Assessment
EBUS	Endobronchial ultrasound
ECOG	Eastern Cooperative Oncology Group
EQIA	Equality Impact Assessment
FAQ	Frequently Asked Question
GMC	General Medical Council
GP	General Practice <i>or</i> General Practitioner
HLH	Heart&Lung Health
IG	Information Governance
IRMER	Ionising Radiation (Medical Exposure) Regulations
LDCT	Low-dose computed tomography
LHC	Lung Health Check
LLP	Liverpool Lung Project
MDT	Multi-disciplinary team
mMRC	Modified Medical Research Council
MRI	Magnetic Resonance Imaging
NHS	National Health Service
NHSE TLHCP	NHS England Targeted Lung Health Check Programme
NSC	National Screening Committee
ONS	Office for National Statistics
OP	Operational pilot
PCA	Patient Care Advisor
PACS	Picture Archiving and Communication System
PET	Positron Emission Tomography
PHW	Public Health Wales
PLCO	Prostate, Lung, Colorectal and Ovarian (cancer screening trial)
RGH	Royal Glamorgan Hospital
SRM	Screening review meeting
TB	Tuberculosis
TNA	Telephone Nurse Assessment
TT	Telephone triage
UHB	University Health Board
UK	United Kingdom
WIMD	Welsh Index of Multiple Deprivation
YCR	Ysbyty Cwm Rhondda