

Targeted screening for lung cancer with
low radiation dose computed tomography

Standard protocol prepared for the Targeted Lung Health Checks Programme

Version 2, 7 November 2022

Prepared with guidance from the Lung Clinical Expert Advisory Group

Changes from version 1 have been highlighted in yellow

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1. Background and introduction

1.1 Targeted screening for lung cancer standard protocol

- 1.1.1 The purpose of this standard protocol is to ensure that there is a consistent and equitable approach to the provision and monitoring of targeted screening for lung cancer across England.
- 1.1.2 This document is designed to outline the service and quality indicators expected by NHS England to ensure that a high standard of service is provided. It therefore sets out the specific recommendations and standards that services are expected to meet.
- 1.1.3 The standard protocol is not for a systematic population screening programme. Any proposal to develop and run such a whole population programme would be made by ministers, based on UK National Screening Committee (UKNSC) advice in the normal way.
- Rather, this is an innovative mechanism by which the NHS intends to ensure that the identification, testing and surveillance of participants at high risk of lung cancer is done to very high and consistent standards.
- 1.1.4 Lung health check (LHC) programmes offering low dose computed tomography (LDCT) should adhere to this standard protocol for targeted lung cancer screening.
- 1.1.5 ‘Lung health check’ programmes are titled to maximise participation, recognising that words like ‘cancer’ may put participants off.

1.2 Definitions

- 1.2.1 Although targeted screening for lung cancer and population-based screening follow the same basic principles, they differ in terms of intent and scope.
- 1.2.2 A national population-based screening programme covers the entire population and selects participants from a complete national electronic register, usually based on broad demographic criteria. Participants are invited and those agreeing are offered tests if at high enough risk.

In England, the service specifications, standards and data requirements are written by Public Health England (PHE) and delivered by the NHS via the section 7a agreement. The services are quality assured by PHE. All this in line with English health policy on advice from the UKNSC.

- 1.2.3 A targeted lung cancer screening programme selects participants from a local population at high risk of lung cancer and offers LDCT to eligible subjects. They report to NHS England and funding is through a variety of routes.
- 1.2.4 Programmes may involve other health interventions to increase cost effectiveness and in this context are often referred to as 'lung health checks'.

1.3 Aims

- 1.3.1 The primary aim is to reduce mortality from lung cancer. This must be achieved with minimum physical and psychological harm. To do this, the programmes should be delivered to meet or exceed nationally set standards and pathways that:
 - define who should be invited (the cohort)
 - have robust (electronic) mechanisms to invite the cohort and recall for those who require surveillance or a routine screen after an interval
 - include measures to improve uptake and reduce inequalities (while honouring the principle of informed choice), e.g. ensuring tests are carried out and results are communicated in a format that is most appropriate for the individual participant
 - provide appropriate information for participants to allow them to make an informed choice about participating, including recognition of any risks associated with the test itself and possible outcomes, such as referral for invasive procedures and any risks associated with these
 - describe the tests to be carried out
 - define the results of the tests including positive (abnormality), negative and indeterminate
 - describe (or points at) the follow up diagnostic and treatment pathways according to best practice (eg NICE, British Thoracic Society [BTS])

- guidelines**) for all categories of tests **and their results** (including negative)
- are delivered and supported by clinical and non-clinical staff who are suitably trained **and evidenced to be** competent, and who participate in recognised ongoing continuing medical education, continuous professional development, and external quality assessment schemes
 - describe the level of training required for staff delivering all aspects of the programme
 - specify agreements to submit data as required, to allow for monitoring and operate within a framework of relevant data sharing permissions to enable pooled analyses to inform further design improvement
 - facilitate quality assurance (QA) and audit activities
 - follow QA advice to improve the service
 - use the agreed common data **standards** and definitions
 - describe how smoking cessation is integrated into the programme
 - facilitate research studies into lung cancer early detection and screening, prevention and early detection of lung cancer and other significant pathology (including non-pulmonary morbidity). This may include enabling sharing of data and biological specimens when undertaken in accordance with research governance
 - facilitate development of new knowledge and learning or processes to improve the Targeted Lung Health Checks (TLHC) programme.

1.4 Capacity and infrastructure

1.4.1 There should be sufficient capacity and infrastructure to deliver the programme including:

- community facilities for siting of mobile CT scanners, if required
- primary care facilities for supporting assessments for eligibility and health checks
- scanning capacity
- radiology reporting
- clinical service for work up of referred participants
- clinical service for treatment of participants
- smoking cessation support and advice

- administrative support for the programme including data collection, collation and submission
- data collection, that should be performed through a data management system to ensure efficient and secure data collection, communication and patient management. Preferably, data management systems should be comprehensive, including invitation, reminders, scheduling, outcomes and follow-up
- approaches that build towards standardised, collaborative processes nationally.

1.4.2 The implementation of the programme should be aligned with local services. This will involve working with regional and local healthcare management including:

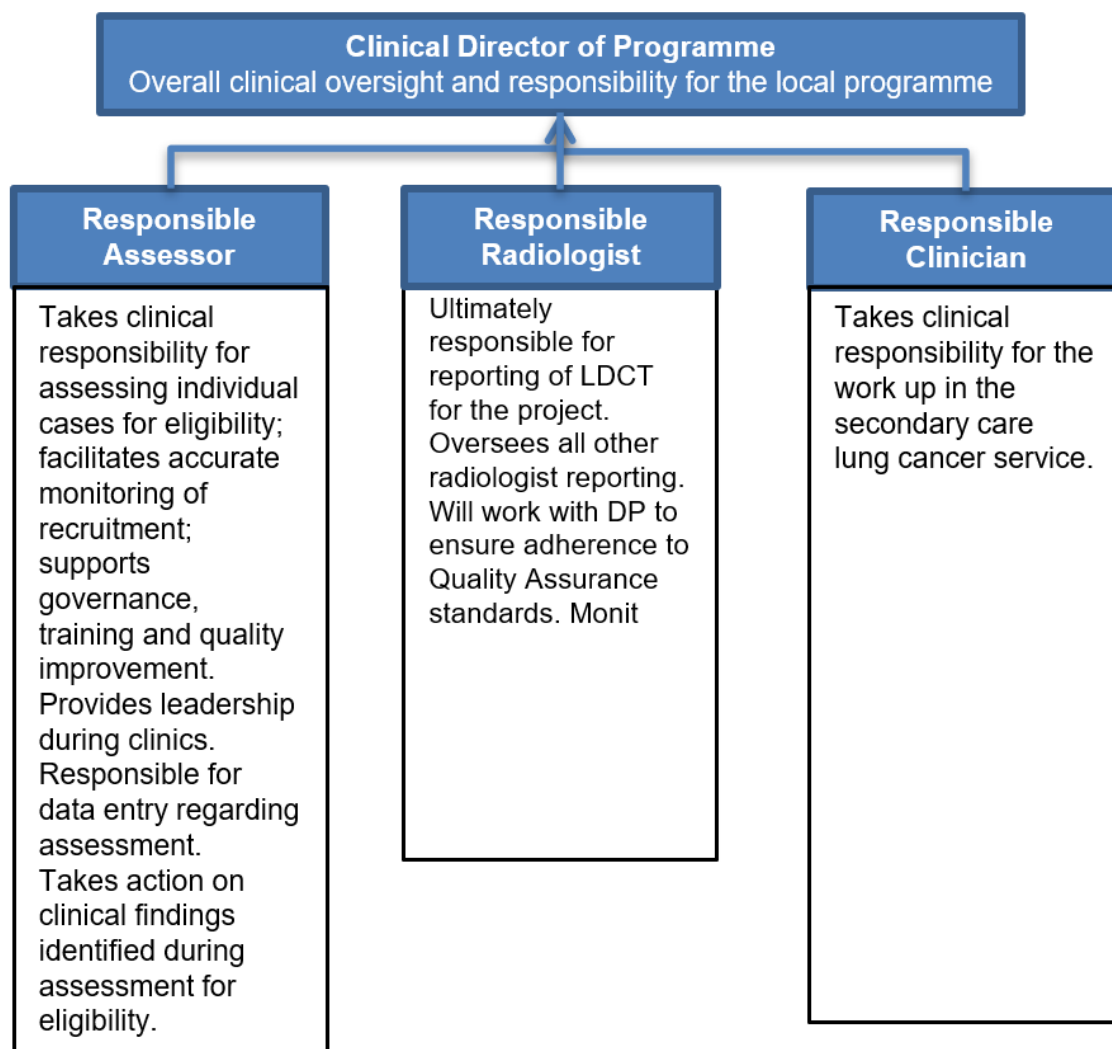
- NHS England regional offices
- cancer alliances
- sustainability and transformation partnerships
- integrated care boards
- local NHS trusts
- local authorities.

2. Clinical governance

2.1 Clinical governance structure

2.1.1 Each programme will need to have robust clinical governance **in place** to ensure the effective delivery of care to patients who are invited to participate. This section outlines the key clinical roles which each programme will **require**.

Figure 1: Targeted screening for lung cancer clinical governance structure



2.2 Description of key clinical roles

2.2.1 Clinical director of programme (DP)

There should be a single clinical director who takes overall responsibility for the safety of patients involved in the programme, including verifying the procedures for selection, scanning, acting on findings and communicating with participants. These procedures should include failsafe mechanisms to ensure that decisions to recall participants for assessment are actioned, including reminders for individuals who fail to attend.

2.2.2 Responsible assessor (RA)

There should be a named clinician who is responsible for the leadership of the process to select and assess the individual cases for entry into the programme, the LHC and the risk assessment for lung cancer.

The clinician can be a doctor, nurse or other professional with the appropriate clinical authority and accountability, from either the local primary or secondary care team. They will continually oversee and monitor the clinical programme, the management of participants and provide day to day leadership of the clinical service. They will ensure:

- appropriate action is taken when clinical findings are identified as part of the assessment for eligibility and during any add-on investigations, such as spirometry and assessing cardiovascular risk; this may include further management in primary and/or secondary care
- clinical data and information is entered into the appropriate clinical system with a focus on data completeness
- improvements and corrective actions are implemented to support governance, training and improve quality.

2.2.3 Responsible radiologist (RR)

There should be a named radiologist who is ultimately responsible for the reporting of LDCT for the project. This will normally be a first-read radiologist who oversees all other radiologists reporting. They will work with the DP to ensure adherence to QA standards, and usually lead the radiology component of the LDCT review multidisciplinary team (MDT). They will monitor reporting performance, and act on these results to support governance, training and quality.

2.2.4 Responsible clinician (RC)

There should be a named secondary care respiratory physician who is responsible for managing the referrals into the rapid access lung clinic and coordinating the clinical work up of participants in secondary care. This will normally be the respiratory physician who works in the lung cancer service and who receives referrals from the programme.

2.3 Responsibilities

2.3.1 The expected responsibilities of all roles should be followed as a minimum, ensuring governance is effective with a consistent approach across sites.

2.3.2 Skills

Professionals involved in screening assessment are expected to fulfil the requirements for individual professional training and for their continuing professional development. They should carry out assessments and procedures regularly, so they can maintain their skills and competence.

2.3.3 Audit

The DP, **working in collaboration with the RR**, is responsible for ensuring that the assessment process is appropriately carried out by all RAs; that RRs adhere to the protocols; and clinical work-up by RCs is monitored. This should be confirmed by audits of individual RA assessment performance, including:

- number of assessments performed (RAs)
- quality of data entry (RAs, RRs)
- adherence to details of this protocol (RAs, RRs and RCs).

2.3.4 National audit

The DP is responsible for ensuring that all data is available for inclusion in a national audit with the purpose of comparing the programmes and measuring the overall success and impact. Data submission will be according to a national minimum dataset and submission is mandatory.

2.3.5 Reporting

The DP reports to NHS England through the **national TLHC team**.

2.3.6 Steering group

The DP, RAs, RRs and RCs will normally come together through a programme steering group, chaired by the DP. Membership of the programme steering group should include representatives drawn from primary care, public health and patient advocates. There should be access to expertise relevant to the LHC, eg in smoking cessation, data collection, etc.

Table 1: Summary of key responsibilities

Responsibilities	DP	RA	RR	RC
Ensure the assessment process is appropriately carried out by all RAs	✓			
Adherence to details of the standard protocol		✓	✓	✓
Quality of data entry		✓	✓	
Ensure the data is available for inclusion in a national audit	✓			
Report to NHS England through the Cancer Alliance Board	✓			

3. Assessment process

3.1 Initial invitation

3.1.1 Participants invited for an LHC are those who:

- are, at the date of the first low dose CT scan, aged between 55 and 74 years, 364 days of age
- are registered with a GP practice
- have ever smoked.

Those who attend will be assessed to calculate their individual risk of developing lung cancer.

3.1.2 GP and/or project site records should be re-queried at least every two years from the initial query, to determine who to invite/re-invite (see also section 3.3.13).

3.1.3 GP re-query should take into account identification of participants previously ineligible by:

- i) age
- ii) lung cancer risk score (eg LLP/PLCO) – this might consider existing baseline risk score data which may evolve with time
- iii) future protocol modifications (eg modifications to selection criteria).

3.1.4 Invitation to attend for an assessment for suitability for LDCT may be by correspondence or telephone via primary or secondary care, or by offering assessment in a mobile setting in high-risk areas, as part of an LHC.

3.1.5 Assessment for suitability for an LHC and the actual LHC appointment can be conducted by telephone, video-call or face-to-face conversation, prior to inviting the patient to attend for a LDCT scan.

3.1.6 Initial assessment, or triage, can be conducted by a Band 3 member of staff, but a Band 4 is recommended, ahead of a Band 6 (or greater) nurse conducting the LHC. Triage, or pre-population of risk calculator data is distinct from the lung health check clinical assessment (see section 3.3).

When such triage leads to participants being excluded from LHC assessment by a non-clinical assessor, such cases should be audited by

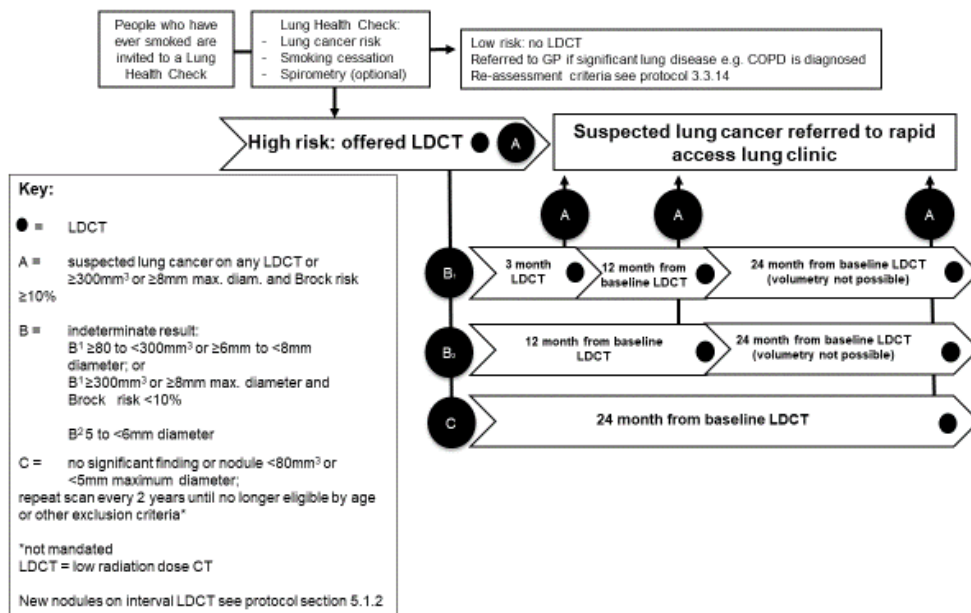
the RA or a delegated clinician not junior to a Band 6 LHC nurse, for example by review of recorded telephone consultations.

- 3.1.7 Clear records should be maintained that describe why a patient was included or excluded from LHC or LDCT scan.
- 3.1.8 Individuals will be assessed for eligibility criteria by confirming medical, social and employment history and risk factors for lung cancer. Validated lung cancer risk assessment tools will be used to quantify risk (see section 3.3).
- 3.1.9 Where necessary, reasonable changes should be made to the approach to ensure the service is accessible to all, including those with physical and learning disability and mental illness eg easy read documentation, or engaging a key worker in the invitation [1].
- 3.1.10 NHS translation services should be available where required for individuals without adequate English language skills (see 3.4).
- 3.1.11 Participants who have difficulty understanding the purpose of the programme should be able to access the programme (see 3.4).

3.2 Participant journey

- 3.2.1 Figure 2 illustrates the participant journey for both those assessed at the LHC as low risk of developing lung cancer and those at high risk. Appendix A provides a more detailed clinical pathway.

Figure 2: High-level participant journey



3.2.2 At the LHC, participants will have a discussion to assess the participant’s individual lung cancer risk. This will include questions about smoking habits. Current smokers will be offered smoking cessation advice, formal smoking cessation service referral on an opt-out basis, and treatment, eg nicotine replacement therapy. Those at low risk do not require a CT scan.

3.2.3 Assessment of any new or urgent symptoms should be undertaken at the time of assessment with escalation as appropriate to primary or secondary care colleagues.

3.2.4 Where an admin triage step is included as part of the risk assessment process, the RA should put in place a robust process by which relevant data can be established to make sure patients with symptoms are assessed by a clinician – urgently where appropriate.

An appropriate clinically-approved script for triaging symptoms should be in place, with escalation to an LHC nurse if any urgent symptoms are identified. It may be appropriate to do so by telephone in advance of the LDCT scan and a clinician should be available for this purpose.

3.2.5 It is recommended that participants assessed as being at high risk of lung cancer should have add-on investigations including spirometry and blood pressure measurement.

3.2.6 Any participant assessed as being at high risk of lung cancer will be invited to a prompt low-dose CT scan. The scan will typically show one of three things:

- i) No significant findings or nodules <80mm³ or 5mm maximum diameter.
- ii) Indeterminate results.
- iii) Something that requires further investigation.

Results	Action
No significant findings or nodules <80mm ³ or 5mm maximum diameter	Return at next screening round in 24 monthly intervals from baseline.
Indeterminate result	Further scans at three and/or 12 months from baseline, and where appropriate further scan at 24 months from their baseline scan (see Figure 2); then return to next screening round assuming all findings stable or no significant change*.
Requires further investigation	Referred to local specialist lung clinic

*no significant growth or altered morphology/consistency

3.2.7 Participants with non-cancer related symptoms, or an abnormal spirometry result, will be referred to their GP or appropriate specialist if required.

3.3 Risk assessment

3.3.1 Assessment of risk of lung cancer is essential to maximise the cost effectiveness of the intervention. There are a number of methods, and

further research may lead to newer models in the future. This will form part of the evaluation of the THLC programme.

3.3.2 Triage, or pre-population of risk calculator data (see section 3.1.3) can be performed by appropriately trained admin staff. It is recommended these staff are at least Band 4, but at a minimum must be Band 3. The decision to proceed to LDCT requires review by a doctor or nurse of Band 6 or greater with experience of conducting lung health checks.

Cases excluded from LHC assessment by a non-clinician should be audited by the responsible assessor, or a delegated clinician not junior to a Band 6 lung health check nurse. (Cases excluded do not necessarily all need individual case review where audit processes are satisfied. Call recording of pre-assessment steps may be useful in this scenario.)

3.3.3 The THLC programme will use the prostate lung colorectal and ovarian (PLCO)_{M2012} risk prediction model and the Liverpool lung project (LLP) version 2 [2, 3] to select participants to be offered an LDCT. The American PLCO_{M2012} model has been adapted for use in the UK to reflect UK ethnic groups.

3.3.4 The latest evidence suggests that a risk threshold of $\geq 1.51\%$ risk of lung cancer over six years is the minimum threshold for PLCO_{M2012}, and $\geq 2.00\%$ risk of lung cancer over five years for LLPv2 [4, 5]. However, the latter has only been shown in modelling studies and may lead to substantially more LDCTs. Thus, a risk threshold for LLP of $\geq 2.5\%$ is proposed.

3.3.5 This standard protocol uses two thresholds to identify participants: a risk threshold of $\geq 1.51\%$ risk of lung cancer over six years as the minimum threshold for PLCO_{M2012}; and $\geq 2.5\%$ risk of lung cancer over five years for LLPv2.

3.3.6 The factors used in these models that would need to be collected are shown in table 2 below:

Table 2: Factors included in two multivariable risk prediction models

LLPv2: $\geq 2.5\%$ risk	PLCO _{M2012} : $\geq 1.51\%$ risk
<ul style="list-style-type: none"> • Age • Gender • Smoking duration (years) • Previous pneumonia/ COPD/ emphysema/ bronchitis/ TB • Occupational asbestos exposure • Previous history of malignancy • Previous family history of lung cancer <ul style="list-style-type: none"> – relative’s age at onset, ie <60 years or >60 years – whether first degree relative. 	<ul style="list-style-type: none"> • Age (years) • Education level • Body mass index • COPD/ chronic bronchitis/ emphysema • Personal history of lung cancer • Family history of lung cancer • Ethnicity* • Smoking status • Average number of cigarettes smoked per day • Duration smoked (years) • Years having ceased smoking.

* referred to as ‘race’ in the original PLCO_{M2012} risk model.

3.3.7 For the purposes of the TLHC programme, participants satisfying either LLPv2 or PLCO_{M2012} are to be considered eligible for a low-dose CT provided they meet the inclusion criteria in 3.3.8 and do not have any of the exclusion criteria listed in 3.3.9.

3.3.8 Inclusion criteria:

- Age is from 55 years, to 74 years and 364 days.
- Willing and able to undergo LDCT.
- PLCO_{M2012} risk of $\geq 1.51\%$ over six years or LLPver2 five-year risk of $\geq 2.5\%$.

For the TLHC programme, due to its duration, at point of referral participants must be at least 55 years of age, and no older than 74 years and 364 days.

3.3.9 Exclusion criteria:

- Participant does not have capacity to give consent (standard criteria for assessing capacity apply).
- Weight exceeds restrictions for scanner (>200kg).
- Participant unable to lie flat.

- Poor physical fitness such that treatment with curative intent would be contra-indicated. This may require a second opinion or advice from the local lung cancer MDT.

3.3.10 Participants who have had a full thoracic CT scan in the last 12 months are not excluded from the programme, but would have their LDCT appointment deferred until 12 months have elapsed since that last scan, provided they:

- still meet all inclusion criteria
- have no exclusion criteria

3.3.11 If a participant mentions they may have had a prior full thoracic CT scan, reasonable steps should be taken to assess whether a full thoracic CT scan has taken place, and defer the LDCT appointment if appropriate.

3.3.12 However, in the absence of any conclusive evidence of a prior full thoracic CT scan, the participant should be given benefit of doubt and booked for an immediate LDCT.

3.3.13 Where participants are assessed at below the threshold for LDCT, but with a risk score that is close to the threshold, they should be invited for re-assessment.

3.4 Information for participants

3.4.1 Written and/or video information should be provided at all stages, with specific information on what is involved. For those eligible for LDCT, this should include the risks and benefits of the test. This should be followed by a discussion between the individual and the clinician to facilitate informed decision-making and subsequent acceptance/decline of the test.

- Participant information leaflets should clearly state the risks and benefits of screening. Such information should have participant contributors as part of any team compiling it – not just healthcare professionals.
- The focus should be on informed choice.
- Information should be available at all relevant points throughout the pathway.
- A trained interpreter should be available during appointments where the functional language is not English.

- Participants with learning disabilities should be provided with appropriate support to enable them to understand all processes and results.
 - All information will be provided in accessible font sizes and in plain English.
 - Flexible appointments and all reasonable adjustments will be made for screening participants with learning disabilities.
- 3.4.2 As part of an LHC, all **current smokers** should be advised on smoking cessation **by a trained professional**. Some of these participants may then go on to a lung cancer screening LDCT scan.
- 3.4.3 Smoking cessation advice **and information about locally available support** should be incorporated into written correspondence and should be face-to-face where **possible**. Enhanced smoking cessation interventions are also encouraged including the use of pharmacotherapy.
- 3.4.4 Current smokers should be offered **on-site advice** smoking cessation **advice and** support and **an opt-out referral to further smoking cessation support**.
- 3.4.5 **National participant information resources, developed by patient and public communication experts should be used. Where necessary, for example to improve equity, diversity and inclusion, project sites can include minor changes, that should be limited to pre-specified sections of text, with the support of the NHS England team.**

3.5 Consent process

- 3.5.1 Consent for CT screening should be taken by a suitably trained clinician or non- clinician, familiar with the risks and benefits of the process. Participants should be informed of the following:
- The primary purpose for undergoing CT is to identify lung cancer at a stage when there may be options for curative treatment. **Information about the estimated chance of finding a lung cancer should be stated in accessible language.**

- If lung cancer is identified, the participant will be directly referred to an appropriate lung cancer service and be managed according to the National Optimal Lung Cancer Pathway.
- The primary purpose is to identify lung cancer. It is important that the patient is aware of this, but also that a number of other respiratory diseases can be detected by TLHC. If other significant conditions are identified that require action, then either an appropriate referral will be made and/or the GP and participant will be informed. Action on incidentally detected conditions will follow NICE guidance.
- Indeterminate pulmonary nodules requiring repeat CT or further investigation are often benign, appropriate estimated individual probability of malignancy should be determined.
- LDCT uses low radiation with information about the associated risks.
- A negative CT scan does not exclude the possibility of having lung cancer in the future. Participants should be informed about the need to report future symptoms of lung cancer if they develop.
- Cancer may be identified that would not have led to harm (over diagnosis).
- There are some risks of harm relating to the further investigation and treatment of findings on the CT.
- Protocols will be followed that minimise harms from over diagnosis, further investigation and false positives.
- They will be asked to consent the retention of clinical data and radiological images for evaluation and future research purposes, under the correct NHS and Human Research Authority (HRA) governance procedures. It should be made clear to the participant that such data enables improvements to the TLHC process and quality control. Data will usually be anonymised unless it is considered necessary to link lung health check records to other health records.
- Participants not wishing to provide this level of consent, or who are offered to participate in a specific research program but decline, would not be stopped from participating in this programme. This must be clearly stated to the patient.

3.5.2 Projects should refer to separate guidance documents on consent and research standards. It is recommended that consent to data usage, also includes consent to approach by a research team in future.

3.5.3 Either verbal or written consent are acceptable.

3.5.4 As a minimum the clinical record must indicate that the patient has been informed of the benefits and risks of TLHC and gives consent to proceed. A separate statement/entry in the medical record should be made that the patient consents to research data use ± contact by the research team.

3.5.5 Details of what consent was given and how this was elicited should also be recorded in the clinical record.

3.6 Pathways for new symptoms

3.6.1 Participants at high risk of lung cancer often have comorbidities that cause symptoms. These may be unrelated to cancer and – in the circumstances described below in section 3.6.5 – permit continuing with the LDCT screen.

3.6.2 Those presenting with respiratory infection should be booked in for a deferred appointment in six weeks' time, to avoid false positive results. Evidence of respiratory infection will be assessed at time of appointment, including cough, new or changed sputum colour or volume, breathlessness, wheeze, chest pain, fever, sore throat and coryza.

3.6.3 If the individual presents with clinical features of lung cancer or any of the following symptoms they should proceed directly to an urgent CT of the neck, thorax and abdomen with administration of intravenous contrast. This may be in a mobile scanning unit or urgently through the secondary care service:

- persistent haemoptysis
- signs of superior vena cava obstruction (SVCO) (face and/or neck and/or arm swelling, raised and non-pulsatile JVP)
- stridor
- signs of malignant cord compression (new onset back/shoulder pain, sensory and/or motor deficit, urinary and/or faecal incontinence, gait abnormalities).

- 3.6.4 If potential participants present with symptoms consistent with exacerbation of COPD or other chronic pulmonary conditions, they should proceed with the LDCT.
- 3.6.5 Participants who meet eligibility criteria for a LDCT but who have the following features or symptoms, as described in NICE referral criteria, should proceed with LDCT to avoid delay:
- cough
 - fatigue
 - dyspnea
 - chest pain
 - weight loss
 - appetite loss
 - persistent or recurrent chest infection
 - finger clubbing
 - supraclavicular lymphadenopathy or persistent cervical lymphadenopathy
 - chest signs consistent with lung cancer
 - thrombocytosis.
- 3.6.6 Those who are ineligible should be managed according to the NICE NG12 cancer recognition and referral guidelines. Local arrangements for requesting urgent chest X-rays and direct referral for CT may reduce delays.

3.7 Lung health check personnel

- 3.7.1 LHC personnel should be trained in all necessary procedures, for example:
- Informed consent (national consent training)
 - Lung cancer risk assessment (including LLP and PLCO scores)
 - IR(ME)R compliant CT requesting
 - Process for onward referral.

4. Low dose computed tomography acquisition and reading

4.1 CT equipment and volumetry software requirements

- 4.1.1 The minimum specification is for a 16-channel multi-detector CT, fixed site or mobile, and calibrated according to the manufacturer's specifications, capable of delivering low radiation dose protocols (see below). Most modern scanners exceed this specification and will achieve this.
- 4.1.2 Volumetric software should be used for assessment of pulmonary nodules and should remain constant to allow accurate comparison of volumes.
- 4.1.3 **When the supplier of volumetric software performs software updates/upgrades, the dates of such upgrades should be recorded.** The supplier should provide evidence that the upgrade provides the same measurements or ensure that the user is prompted to re-measure nodules from preceding scans if the software upgrade provides altered (and likely improved) measurement capability.
- 4.1.4 Volumetric software must be directly or indirectly integrated into **picture archiving and communications systems (PACS)**, capable of automated image retrieval of, **and comparison with**, historical imaging **where appropriate**.
- 4.1.5 Other desirable features are high automated segmentation accuracy rates (>85%), and automated structured reporting.
- 4.1.6 Computer aided detection (CAD) systems are **to be** used, they should be used in a concurrent or second reader format. A false positive rate of <2 per case is desirable for CAD systems.

4.2 CT image acquisition protocol

4.2.1 Subject position:

Participants should lie supine on the CT table with arms above their head and thorax in the midline of the scanner. Subject comfort should be optimised, and maximal inspiration rehearsed prior to the scan to minimise

motion during the CT. Imaging should be performed during suspended maximal inspiration. No intravenous contrast material will be administered.

4.2.2 Localiser:

Sites should use their standard scanogram to localise the start and end positions of the scan. The frontal localiser should be performed in the PA projection and at the lowest possible setting to minimise breast dose.

4.2.3 Volumetric CT scan:

The lung parenchyma (lung apices to bases) must be scanned in its entirety in a single cranio-caudal acquisition. The field of view selected as the smallest diameter as measured from widest point of outer rib to outer rib large enough to accommodate the entire lung parenchyma. Thin detector collimation ($\leq 1.25\text{mm}$) will be used.

4.3 Exposure factors

4.3.1 Radiation exposures will be as low as possible while maintaining good image quality. The acquisition parameters will be set to ensure that the calculated radiation dose delivered to each individual is below 2 mSv (based on the median standard 70kg adult). This will be done by ensuring that the kVp and mAs settings are varied according to participant body habitus.

The height and weight of participants will be used to enable accurate selection of exposure factors. Ultra LDCT should be used where available and considered to be of equivalent diagnostic sensitivity to LDCT.

4.3.2 Appropriate standardisation of image quality to ensure reproducible high image quality should be performed.

4.3.3 Medical physics input should be obtained when setting up LDCT scanning protocols.

4.4 Image reconstruction

4.4.1 Image reconstruction should be standardised and used for any subsequent follow-up examinations where possible, with particular emphasis on ensuring that slice thickness, reconstruction increment, and reconstruction algorithm are identical.

- 4.4.2 Slice thickness should be $\leq 1.25\text{mm}$. An example of reconstruction parameters used in low-dose screening CT are outlined in table 3 below.
- 4.4.3 If iterative reconstruction is used, this should be kept constant at follow up.

Table 3: Reconstruction parameters for LDCT

Reconstruction algorithm	Reconstruction thickness	Reconstruction increment	Reconstruction FOV
Moderate spatial frequency/soft tissue	1mm	0.7mm	Entire lung parenchyma

4.5 Image interpretation

- 4.5.1 Image interpretation should be performed on systems which permit scrolling through the data set with variable thickness and orientation using multi-planar reformations (MPR) and maximum intensity projection. Where volumetry is used, radiologists should **visually** check for appropriate segmentation of nodules.
- 4.5.2 All reconstructed scan data (according to minimum requirement for volumetric analysis) acquired from the participants should be archived and retained at a local or central site.
- 4.5.3 There should be a mechanism for obtaining the previous thoracic CT imaging for the participant, as far as is practically possible (see also 3.3.10 to 3.3.12).

4.6 Thoracic CT reader

- 4.6.1 Lung cancer screening CT reading requires both unique skills as well as those that overlap with clinical thoracic CT reading. **Lung cancer screening requirements include the following:**
 - Radiologists should report a minimum of 500 thoracic CTs per annum in their routine clinical practice, a significant proportion of which should be CTs performed for the evaluation of lung cancer.

- Radiologists should participate in and ideally lead a thoracic MDT meeting (which may include virtual attendance) as part of their routine clinical work.
- Readers must be familiar with the use and limitations of nodule volumetry software and apply the BTS guidelines for nodule management in their usual practice.
- Radiologists should complete a Royal College of Radiologists-British Society of Thoracic Imaging (RCR/BSTI) training course approved by NHS England on CT screening.
- The RR is responsible for ensuring all the above criteria are met, and for all relevant aspects of clinical governance.
- NB: It is envisaged that all radiologists will eventually need to be inducted at entry into programme, and accredit and demonstrate personalised performance review via a centrally curated educational self-assessment and training scheme for LHC CT reading

4.6.2 The quality of the scan should be documented as diagnostic or non-diagnostic in the CT report. If non-diagnostic, the reasons should be given. Protocols should be in place for efficient recall of these participants

4.6.3 Reading workload and environment

- Radiologists should aim to report 12-20 scans per PA of clinical time, with a view to achieving 20 or more scans per PA as screening reporting experience and familiarity with automated reporting increases.
- Radiologists should not regularly do more than three PAs DCC of CT screening activity per week, as part of a full-time job plan.
- The reporting environment must meet minimum standards for ergonomics including screen and chair position, room lighting and display requirements set-out in the RCR recommendations; this should also apply in the home reporting room.

4.6.4 The lung nodule size threshold for characterization is $\geq 5\text{mm}$ or 80mm^3 . Where multiple nodules are detected, at least two nodules, including the largest nodule, and where possible all nodules $>200\text{mm}^3$, should be recorded. Smaller nodules may be characterised for research purposes. All new nodules on interval LDCT $\geq 30\text{mm}^3$ or $\geq 4\text{mm}$ max diameter, and that

are not thought to be due to infection/inflammation, should be reported as this determines scan interval in these nodules (see Table 4).

4.6.5 Other findings

Programmes should have protocols in place for reporting and management of incidental findings (see section 7.4). Narrative/descriptive reports should be avoided. Clinically insignificant findings should either not be reported or clearly identified as such. An emphasis should be placed on reporting of findings where there are proven interventions for participant benefit.

4.7 Volumetric analysis

- 4.7.1 **Solid** nodules should be measured using semi-automated volumetry. Where volumetry segmentation is not possible or judged to be inaccurate, maximal axial manual diameter measurements should be recorded on lung window settings, excluding any spiculation. Manual adjustment of volumetric analysis should be avoided as this may introduce unquantified variability.
- 4.7.2 Subsequent scans should measure volume in the same **solid** nodules and a volume doubling time (VDT) calculated for each where an increase $\geq 25\%$ has occurred. A less than 25% increase may be within the margin of error. Where volumetry is not possible, the growth rate should be based on visual assessment or diameter measurements, accepting that this can be less accurate.
- 4.7.3 3D reformats showing reliable **solid** nodule volume segmentation, including size and VDT calculation where appropriate, should be sent to PACS. This assists with the reading process at follow up and ensures that the information is efficiently conveyed to the lung cancer or nodule MDT for relevant cases.

5. Repeat low dose computed tomography

5.1 Scan intervals

- 5.1.1 Nodule management should be protocolised and based upon the BTS 2015 pulmonary nodule guidelines [6] and NICE guidelines for the management of lung cancer [7]. Where local or regional programmes choose to modify nodule management guidelines, this should be clinically justifiable.
- 5.1.2 Local or regional modification of nodule management guidelines is not encouraged. Where such modification is deemed necessary, permission for deviation from the protocol should be sought. See protocol deviation notification form.
- 5.1.3 Participants with CT scans showing nodules are managed according to nodule composition and size. Volumetry is the preferred method for solid nodules.
- 5.1.4 Maximum axial diameter is used in the case of:
- solid nodules with unreliable segmentation
 - subsolid. (ie part-solid [PSN] and ground glass [GGN] nodules: Management is dependent on the overall maximum diameter of the nodule, and of the solid component in case of PSNs.)
- 5.1.5 Note – size thresholds change where nodules were not previously seen on a previous CT. Table 4 below shows how the nodule size affects follow-up interval and referral:

Table 4: Nodule size and follow-up interval and referral

Baseline CT Nodule size (measure)	Interval CT(s) before next screening round*	Next screening round CT*
No nodules	None	24 months
<80mm ³ or <5mm max. diam.	None	24 months
≥80 to <300mm ³	3 months then 12 months	36 months
≥6mm and <8mm max. diam. (volumetry not possible/permissible**)	3 months then 12 months	24 months
5 to 6mm max. diam. (volumetry not possible/permissible**)	12 months	24 months
≥300mm ³ max. diam. and Brock risk <10%	3 months then 12 months	36 months
≥8mm max. diam. and Brock risk <10% (volumetry not possible/permissible**)	3 months then 12 months	24 months
≥300mm ³ or ≥8mm max. diam. and Brock risk ≥10%	Refer	
New nodules found on interval CT	Interval CT(s) before next screening round	
At any timepoint: <30mm ³ or <4mm max. diam.	No change to subsequent CT interval	
Discovered on 3-month CT:		
<ul style="list-style-type: none"> • ≥30mm³, <300mm³ 	6 months, 12 months, then 24 months	36 months
<ul style="list-style-type: none"> • or – ≥4mm, <8mm (volumetry not possible/permissible**) 	6 months, then 12 months	24 months

<p>Discovered on 12-month CT:</p> <ul style="list-style-type: none"> • $\geq 30\text{mm}^3$, $< 300\text{mm}^3$ • or – $\geq 4\text{mm}$, $< 8\text{mm}$ (volumetry not possible/ permissible**) 	<p>15 months, then 24 months</p> <p>15 months</p>	<p>36 months</p> <p>24 months</p>
<p>At any timepoint: $\geq 300\text{mm}^3/\geq 8\text{mm}$</p>	<p>Refer</p>	

6. Non-attendance and exiting the programme

6.1 Non-attendance

- 6.1.1 First-time attendance should be facilitated by offering LDCT that is easily accessible for the participant, eg mobile scanners in community settings, easy transport links.
- 6.1.2 The process of changing appointments should be straightforward for those who request this.
- 6.1.3 There should be a formal process for contacting non-attenders.
- 6.1.4 Feedback from non-attenders should be sought to evaluate the reasons and improve access.

6.2 Exiting the programme

- 6.2.1 Participants exit the programme at 75 or 76 years of age (depending on whether the timing of the final LDCT is 12 or 24 months from the baseline).
- 6.2.2 Participants should have assessment of co-morbidity and fitness to confirm continued eligibility. This may be at the screening visit or via confirmation of eligibility through the subjects GP. They should exit the programme if no longer eligible.

7. Management of findings

7.1 Lung nodule management and follow-up/further diagnostics

7.1.1 The protocol for management of participants with significant findings should follow the BTS 2015 pulmonary nodule guidelines and NICE guidelines for the management of lung cancer.

7.2 Multidisciplinary team meetings

7.2.1 There are two multidisciplinary meetings that are relevant. All programmes should have access to these MDTs:

- The LDCT review MDT (or 'screening MDT'), which may also include the pulmonary nodule MDT. Here the management of all findings, other than those previously identified as requiring urgent referral by the RR, are discussed and management plans are devised and communication with the participant and any healthcare professionals co-ordinated. Pulmonary nodules may also be managed or referred to a separate pulmonary nodule MDT (see 7.3).
- The lung cancer MDT, where the outcome of investigation of higher risk nodules and suspected lung cancer is discussed, and treatment planned.

7.2.2 All pulmonary nodules that are suspicious should be discussed at the LDCT review or pulmonary module MDT. These include:

- nodules that are $\geq 300\text{mm}^3$ or $\geq 8\text{mm}$ diameter with a $\geq 10\%$ chance of malignancy by Brock score; these usually require a PET-CT for further evaluation
- nodules that show significant growth after interval LDCT.

Note that nodules that only require repeat CT as a further test should be managed by radiologists within the programme, and do not require discussion at MDTs (unless a second opinion is being sought).

7.3 Low dose computed tomography review MDT or pulmonary nodule MDT

- 7.3.1 Nodules requiring a PET-CT or that show growth will be managed within the clinical service. Management, in brief, will follow BTS guidelines:
- Nodules with confirmed VDT>600 days can be referred back for annual LDCT.
 - Nodules with VDT 400-600days, surveillance or biopsy / resection can be offered depending on participant preference.
 - Nodules with VDT<400 days should be further investigated, **but only if they have reached a size suitable for meaningful intervention** (eg PET-CT, percutaneous biopsy, lung resection, according to participant preference).
 - For PSN, any change in morphology or growth of solid component ($\geq 2\text{mm}$) as well as a Brock risk of malignancy of >10% should prompt consideration of a histological diagnosis and definitive management. Such lesions have a better prognosis, so further observation may be indicated to avoid over diagnosis.
 - For **pure** GGN, any change in morphology or **appearance** of solid component as well as a Brock risk of malignancy of >10% should prompt consideration of further imaging follow-up or histological diagnosis and definitive management, noting the very good prognosis of these lesions and potential for over diagnosis.
- 7.3.2 Nodules with a Herder risk score <10% will be referred for annual screening. The Herder tool is validated risk calculator that incorporates findings from FDG-PET scans (available in BTS pulmonary nodule app).

7.4 Management by lung cancer service

7.4.1 Referral

LDCT suspicious for lung cancer will receive a consultant upgrade into the suspected lung cancer rapid assessment and diagnosis pathway [8]. This will be done immediately by the RR who will ensure this information is passed to the responsible clinician and copied to the GP.

7.4.2 Incidental findings

Minor incidental findings are common on LDCT and have the potential to cause increased unnecessary investigations and anxiety to participants. Incidental finding reporting, and management should be based on the following principles:

- The finding should be clinically significant.
- Clinically insignificant findings should not be reported to the GP or participant.
- There should be agreement between the LDCT targeted lung cancer screening programme and primary care as to the nature and benefit of the recommended interventions.
- Recommendations for clinical correlation by primary care of CT findings should be avoided, and if made, should be specific.

7.4.2.1 Incidental findings can be broadly categorised as follows:

- Major findings that may be life threatening and should prompt direct referral for admission to hospital by the LDCT targeted lung cancer screening programme.
- Findings mandating urgent referral (eg significantly dilated aortic aneurysm).
- Findings indicative of cancer at another site which should prompt urgent referral via the cancer pathway upgrade process.
- Other non-cancer findings requiring referral to secondary care (eg significant fibrotic interstitial lung disease).
- Non-cancer findings that may require management in primary care (eg minor bronchiectasis).
- Other findings that may prompt NICE recommended assessment to be done, where they have not been included in the assessment performed by the RA (eg significant coronary calcification on CT may prompt recommendation for cardiovascular Q-Risk assessment).
- Findings that are usually not directly associated with a beneficial intervention and that do not require communication (eg bronchial wall thickening).

- 7.4.2.2 Incidental findings will be reviewed by the LDCT review MDT and clear recommendations will be made to the relevant clinicians and to the participant.
- 7.4.2.3 There should be a policy agreed between the targeted lung cancer screening service and primary care about management of LDCT findings, including the referral process for incidental findings.
- 7.4.2.4 The NHS England TLHC Incidental Findings Management Protocol provides guidance on the management of the most common findings.

8. Communication of results

8.1 Process

- 8.1.1 Participants will be sent communication about the results of the LDCT and spirometry as shown in Appendix A.

8.2 Serious findings

- 8.2.1 Potentially serious findings will be acted on immediately and more indeterminate findings followed up as required.

8.3 Letters

- 8.3.1 Standard letters have been prepared, adapted from the UKLS and lung screen uptake randomised controlled trials.
- 8.3.2 The outcome of the LDCT should be communicated by standard letter to the GP (preferably electronic to facilitate audit) with a copy of the CT report, with the action taken, if any, included.
- 8.3.3 These outcomes should be communicated to the participants by standard letter, except in the unusual circumstance where direct admission is arranged. Letters will not include details of serious findings; this will be explained at clinic visits. In some circumstances, it may be appropriate for

a participant to receive generic or customised written information at the end of their LHC rather than by post.

- 8.3.4 It is expected that template letters provided by the national team should be used in the majority of circumstances to ensure consistency across the programme.

8.4 Telephone

- 8.4.1 There should be a support line for optional contact with an experienced nurse or administrator, based locally in primary or secondary care.
- 8.4.2 Telephone communication may also be offered as well as communication by letter.
- 8.4.3 There should be an advice line for participants to phone for further information and clarification when they receive their results.

8.5 Timeframe

- 8.5.1 The outcome should be communicated within a maximum of four weeks from the LDCT. Safety net processes should be in place to ensure that findings requiring urgent referral are flagged and communicated appropriately.

8.6 General

- 8.6.1 Generic, non-personalised, information about programmes should be available on the public NHS website.
- 8.6.2 For participants who are being given a 'normal' result, the possible effect of over-reassurance will be mitigated by including information about continued risk of lung cancer (which may be provided as a percentage based on a multivariable model), the importance of not ignoring red flag symptoms and the importance of not smoking.

8.7 Participant feedback

- 8.7.1 Following the communication of results, consideration should be given to offering participants a basic questionnaire about their experience including:

- the lung health check
- booking experience
- consent process
- scanning
- information provided to them
- understanding of the checks process and results process
- willingness to continue in the programme
- the impact of smoking cessation advice on willingness to quit and on participation.

9. Low dose computed tomography data management

9.1 Collection

- 9.1.1 Data should be collected by the local team in a format that will allow submission to the National Cancer Registration and Analysis Service.

9.2 Handling

- 9.2.1 All data will be handled in adherence to the Data Protection Act 1998 and information governance legislation. Audit trails will be in place to fully trace data entry and edit.

9.3 Inputting

- 9.3.1 Inputting of data will comply with information governance legislation.

9.4 Dataset

- 9.4.1 A minimum mandatory dataset has been agreed.

10. Evolution of the standard protocol for the TLHC programme

10.1 Updating the standard protocol

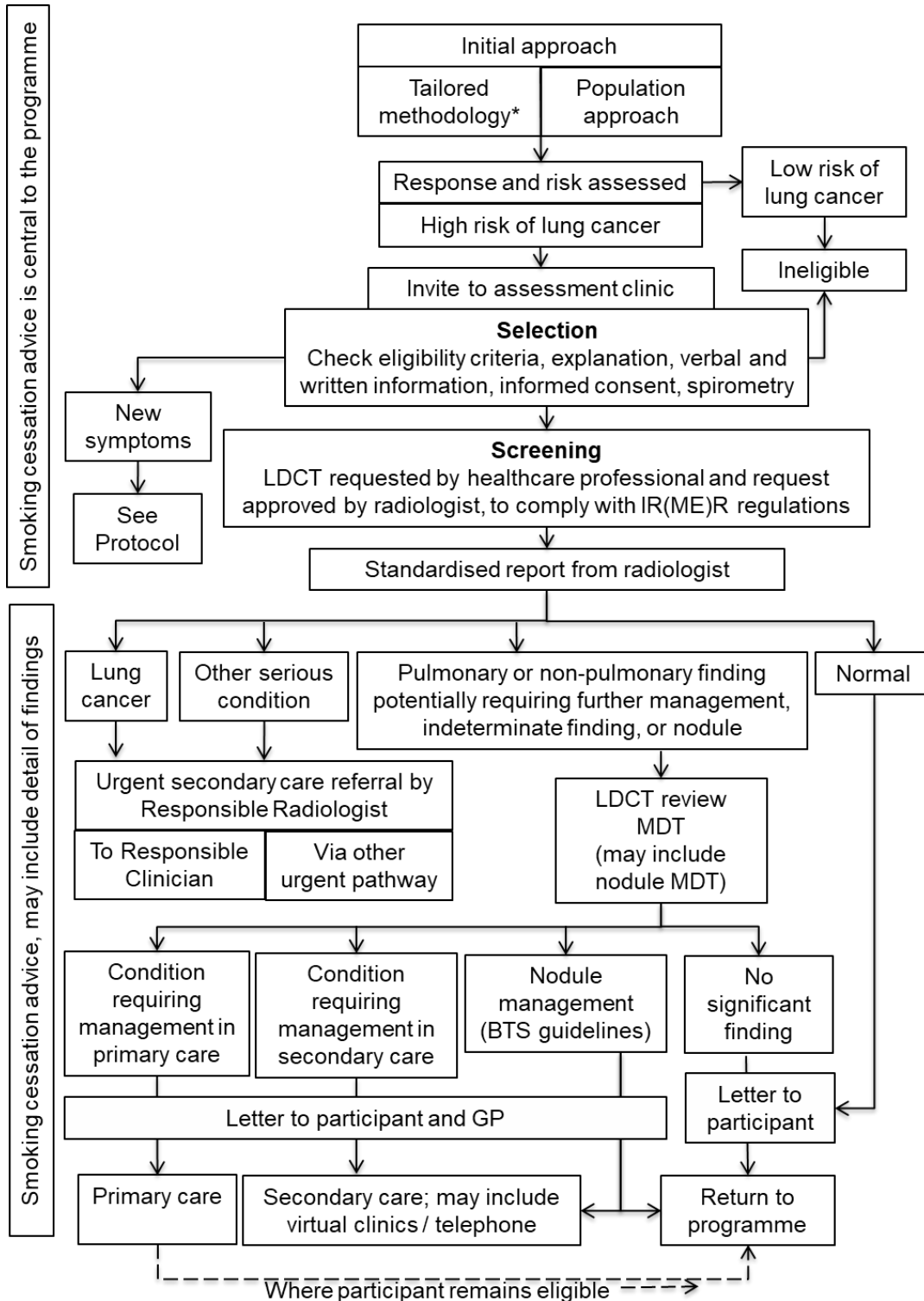
- 10.1.1 It is recognised that this targeted screening for lung cancer with low radiation dose computed tomography and standard protocol prepared for the TLHC programme will evolve over time.
- 10.1.2 This will be influenced by the Cancer CEG Lung Sub-Group in its role as an expert advisory group for the TLHC programme tasked with providing expert advice, support and guidance to the evaluation of the programme, implementation of the standard protocol, and bringing knowledge and expertise on innovation and developments which would impact on lung cancer outcomes.
- 10.1.3 Furthermore, as **long-term** findings from studies such as the Dutch-Belgian NELSON randomised controlled trial emerge [9], and further work is done on interpreting these data and findings, this document will also adapt in line with this thinking.
- 10.1.4 It should also be noted that advice and consultation with the UKNSC will be ongoing and will also influence future iterations of this documentation.

11. References

1. Marriott, A. and Turner, S. (2015). Making Reasonable Adjustments to Cancer Screening. [online] London: Public Health England. Available at: https://www.ndti.org.uk/uploads/files/Updated_reasonable_adjustments_in_cancer_screening_report.pdf
2. Kovalchik SA, Tammemagi MC, Berg CD, Caporaso NE, Riley TL, Korch M, Silvestri GA, Chaturvedi AK, Katki HA: Targeting of Low-Dose CT Screening According to the Risk of Lung-Cancer Death. *New England Journal of Medicine* 2013, 369:250
3. Raji OY, Duffy SW, Agbaje OF, Baker SG, Christiani DC, Cassidy A, Field JK: Predictive accuracy of the Liverpool Lung Project risk model for stratifying patients for computed tomography screening for lung cancer: a case-control and cohort validation study. *Annals of Internal Medicine* 2012, 157:242-250.
4. Tammemagi MC, Katki HA, Hocking WG, Church TR, Caporaso N, Kvale PA, Chaturvedi AK, Silvestri GA, Riley TL, Commins J, Berg CD: Selection criteria for lung-cancer screening. *New England Journal of Medicine* 2013, 368:728-736.
5. Ten Haaf K, Jeon J, Tammemagi MC, Han SS, Kong CY, Plevritis SK, Feuer EJ, de Koning HJ, Steyerberg EW, Meza R: Risk prediction models for selection of lung cancer screening candidates: A retrospective validation study. *PLoS Med* 2017, 14: e1002277.
6. Callister, M. Baldwin, D. Akram, A. Barnard, S. Cane, P. Draffan, J. Franks, K. Gleeson,
7. F. Graham, R. Malhotra, P. Prokop, M. Rodger, K. Subesinghe, M. Waller, D. Woolhouse, I. (2015). [online] London: BTS Guidelines for the Investigation and Management of Pulmonary Nodules. Available at: <https://www.brit-thoracic.org.uk/document-library/clinical-information/pulmonary-nodules/bts-guidelines-for-pulmonary-nodules/>
8. NICE (2011). [online] London: Lung Cancer: diagnosis and management clinical guideline (CG121). Available at: <https://www.nice.org.uk/guidance/CG121>
9. NHS England (2018). [online] London: Implementing a timed lung cancer diagnostic pathway. Available at: www.england.nhs.uk/wp-content/uploads/2018/04/implementing-timed-lung-cancer-diagnostic-pathway.pdf
10. Wclc2018.iaslc.org. (2018). NELSON Study Shows CT Screening for Nodule Volume Management Reduces Lung Cancer Mortality by 26 Percent in Men. [online] Toronto: The International Association for the Study of Lung Cancer

Appendix A

Patient pathway from invitation, through LDCT, and follow up:



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