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NHS England

Targeted screening for lung cancer with low radiation dose computed tomography

Standard protocol prepared for the Lung Cancer Screening Programme

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Prepared with guidance from the Lung Cancer Screening Programme Clinical Expert Advisory Group

Additions from version 2 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 high quality, consistent and equitable approach to the provision and monitoring of targeted screening for lung cancer across England. This protocol covers the pathway from cohorting and invitation to suspected cancer.

1.1.2 This document is designed to outline the minimum and recommended service expected by NHS England to ensure that a high and consistent standard of service is provided.

1.1.3 This document sits alongside the required Quality Assurance Standards and UKNSC Lung Screening Standards by which individual Lung Cancer Screening sites are assessed.

1.1.4 The Lung Cancer Screening Programme (LCSP) is the national lung cancer screening programme for England. It falls within the UK National Screening Committee definitions of targeted and stratified national screening (UK NSC: evidence review process - GOV.UK) The Lung Cancer Screening Programme (now Lung Cancer Screening) was noted to be a feasible and effective starting point for implementation in England (Lung cancer - UK National Screening Committee .All sites participating in the Lung Cancer Screening Programme (LCSP) must adhere to this standard protocol for targeted lung cancer screening.

1.2 Definitions

1.2.1 Although targeted screening for lung cancer and population-based screening follow the same basic principles, they differ because targeted screening uses additional risk factors beyond age and sex to define the eligible population with a higher risk of a specific condition. Lung cancer screening uses smoking history as an additional risk factor. Once invited, participant risk is assessed using multivariable mathematical models.

1.2.2 Stratified screening is a national programme where the frequency or modality of screening may be varied according to risk. In the LCSP,

screening interval is altered according to the presence of pulmonary nodules, which alters the risk of lung cancer developing.

1.2.3 The Lung Cancer Screening Programme selects participants from eligible populations at risk of lung cancer due to smoking history and offers LDCT to higher risk participants.

1.2.4 Until full national rollout is complete, LCSP will be overseen by the NHSE cancer programme including the LCSP Expert Advisory Group.

1.2.5 Programmes may include other health interventions as long as they do not conflict with the Standard Protocol and as long as funding for lung cancer screening is not used to provide them . These may focus on lung cancer prevention, and/or in the diagnosis/management of other conditions. It is important that this does not hinder lung cancer screening and is either evidence based or part of approved research.

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 associated risks
- 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 (e.g. 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, continuing 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 and data protection principles
- facilitate development of new knowledge and learning or processes to improve the programme.

1.4 Capacity and infrastructure

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

- appropriate and suitable facilities for siting of mobile CT scanners, where required
- appropriate and suitable facilities for supporting assessments for eligibility and health checks
- scanning capacity
- appropriately trained radiographers
- appropriately trained radiologists

- clinical service for work up of referred participants including pathology and lab services.
- clinical service for treatment of participants
- smoking cessation support and very brief advice (VBA)
- administrative support for the programme including appointment scheduling, data collection, collation, analysis and submission
- data collection, that should be performed through a data management system to ensure efficient and secure data collection, communication and participant management. Data management systems should be comprehensive with built in failsafes, including invitation, reminders, scheduling, outcomes and follow-up and record data that enable future research and innovation. systems in place to regularly review requirements to adjust capacity and infrastructure as dictated by demand.

1.4.2 Provision of services should take place in the community where this improves participation or participant experience cost-effectively.

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

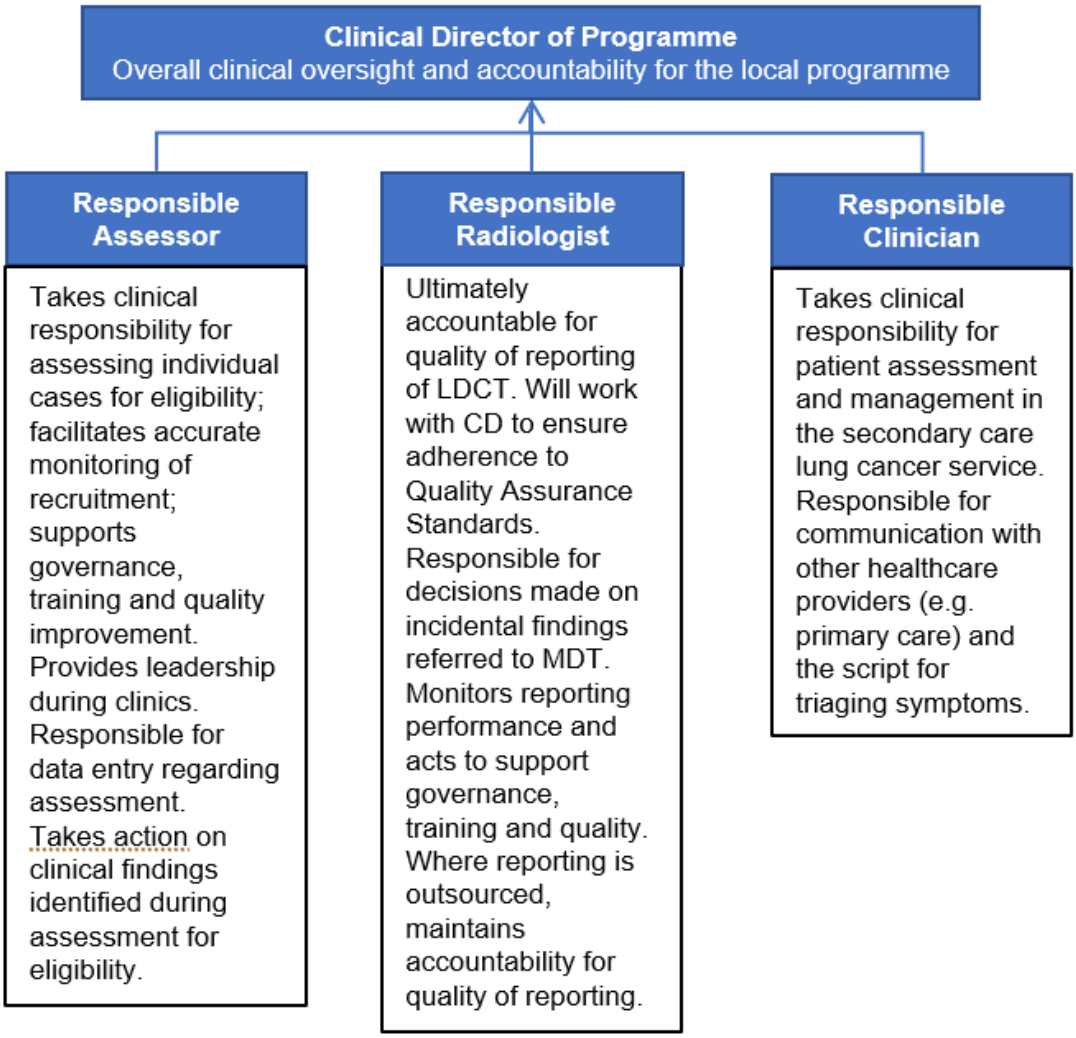
- NHS England regional offices
- cancer alliances
- integrated care boards and integrated care systems
- local NHS trusts
- primary care networks and local medical committees
- imaging networks
- community diagnostic centres
- local authorities
- local patient and public voice groups
- other screening programmes

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 people who are invited to participate. This section outlines the key clinical roles which are mandatory for each LCSP.

Figure 1: Targeted screening for lung cancer clinical governance structure



2.2 Description of key clinical roles

2.2.1 Clinical director of programme (CD)

2.2.2 There should be a single overarching clinical director role who has overall accountability for the QA Standards and safety of participants involved in the programme, including verifying the procedures for selection, scanning, acting on findings, resolving incidents 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.

2.2.3 Responsible assessor (RA)

2.2.4 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 Lung Health Check (LHC) and any prior risk assessment for lung cancer.

2.2.5 The clinician can be a doctor, nurse or other professional with the appropriate clinical knowledge, 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; this may include further management in primary and/or secondary care
- clinical data and information are entered into the appropriate clinical system with a focus on data completeness
- that LHC risk assessment has appropriate QA processes.
- improvements and corrective actions are implemented to support governance, training and improve quality.

2.2.6 Responsible radiologist (RR)

There should be a named radiologist who is ultimately responsible for the justification of exposures and reporting of LDCT for the site. This will normally be a first-read radiologist who oversees all other radiologists reporting. They will work with the CD to ensure adherence to QA standards, and usually lead the radiology component of the Screening Review Meeting (SRM). They will be responsible for decisions made

regarding incidental findings referred to SRM. They will monitor reporting performance, and act on these results to support governance, training and quality. Where radiology reporting is outsourced, the RR retains accountability for overall quality of reporting within the site, in collaboration with the outsourcing partner.

2.2.7 Responsible clinician (RC)

There should be a named secondary care respiratory physician who is responsible for managing the referrals into the secondary care lung cancer service and coordinating the clinical assessment and management of participants in secondary care. They are responsible for approving all communications with other healthcare providers (e.g. primary care) and the participant, they are also responsible for the script for triaging symptoms (see 3.1.11). 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 The clinical director role can be occupied simultaneously with any of the other responsible roles. Any responsible role can be job shared, however good governance requires that individual responsibilities should be clear to ensure accountability is understood and there are no service gaps.

2.3.3 Ideally, key clinical roles will be filled by staff employed by the local Trust but can be employed within the wider ICB. Key clinical roles should not be filled by employees primarily employed by external providers (outside of the NHS) providing services to the LCSP system the clinical role is responsible for. In some instances, for programme inception or resilience, it may be necessary to appoint clinical roles in breach of this, but this should only be on a short-term basis and with the permission of the national team. Clinical roles can be filled by NHSE staff where the majority of the individual's time is spent directly employed by NHSE, but who also work for external providers in addition to their NHSE responsibilities.

2.3.4 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, to maintain their skills and competence. They should meet the requirements of their regulatory body, where applicable, including supporting others in their own development.

2.3.5 Audit: The CD, working in collaboration with the responsible roles, is accountable for ensuring that the assessment process is appropriately carried out (RA); that reporting radiologists adhere to the protocols (RR); and clinical assessment and monitoring of participants is monitored (RC). This should be confirmed by audits of performance, including:

- number of assessments performed (RAs)
- quality of data entry and submission (RAs, RRs)
- quality of risk assessment, including percentage of cases where LDCT eligibility was adjusted following RA audit/review (RAs)
- quality of overall participant experience (RAs, RRs, RCs)
- adherence to details of this protocol (RAs, RRs and RCs).

2.3.6 National audit: The CD 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.

2.3.7 Reporting: The CD reports to NHS England through the national LCSP team.

2.3.8 Steering group: The CD, RAs, RRs and RCs will normally come together through a programme steering group, chaired by the CD. 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 (e.g. in smoking cessation, data collection etc.).

Table 1: Summary of key responsibilities

Responsibilities	CD	RA	RR	RC
Ensure the assessment process is appropriately carried out by all RAs	✓			

Adherence to details of the standard protocol and quality assurance standards		✓	✓	✓
Quality of data entry		✓	✓	✓
Ensure required 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 a Lung Health Check (LHC) are those who:

- are aged between 55 and 74 years, 364 days of age
- are registered with a GP practice in England
- have ever smoked.

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

3.1.2 Participants invited should proceed through the pathway, even if the LHC or baseline scan would take place after the participant turns 75. However, no participant should receive a LHC or baseline scan more than 3 months after turning 75. Invited participants over the age of 75 should exit the programme in line with Section 7.3.

3.1.3 If a participant declines an invitation to a lung health check or does not attend, they should be re-invited according to local processes. Participants should be re-invited in the next screening round unless explicitly stating a wish not to be re-invited. If participants have suggested they no longer wish to be invited, the opportunity should remain for them to opt back in to the programme (See 7.1.5).

3.1.4 Participants who have smoked fewer than 100 cigarettes over their life are certain to not reach the risk threshold for CT and can be considered as low-risk.

3.1.5 GP and/or site records should be re-queried at least every two years from the initial query, to determine who to invite/re-invite (see section 3.3.18). This timescale will reduce in future iterations of the Standard Protocol, as the programme approaches full rollout.

3.1.6 GP re-query should take into account identification of participants previously ineligible by age.

3.1.7 Invitation to attend a Lung Health Check may be by written correspondence, telephone and text.

3.1.8 Initial assessment for suitability for a LHC and the actual LHC appointment must at least be offered via telephone or video-call. The gold standard is that participants should be able to choose whether the LHC is conducted remotely or face-to-face.

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

3.1.10 When initial assessment results in a non-clinical assessor excluding participants from LHC assessment, the lower of 50 or 1% of such cases per quarter should be audited by the RA or a delegated clinician not junior to a Band 6 LHC specialist nurse, for example by review of recorded telephone consultations.

3.1.11 Each participant's risk score, components of medical history used to determine risk scores, and whether the participant was eligible for LDCT or not, must be clearly recorded. Where a participant is eligible for LDCT scan but excluded, the reason(s) for exclusion should also be clearly recorded.

3.1.12 Individuals will be assessed 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 3.3.5).

3.1.13 Where participants are referred to secondary care for investigation of potential lung cancer, they should be readmitted to the LCSP once any active secondary care treatment or monitoring has come to an end, with processes and failsafes in place to ensure this happens.

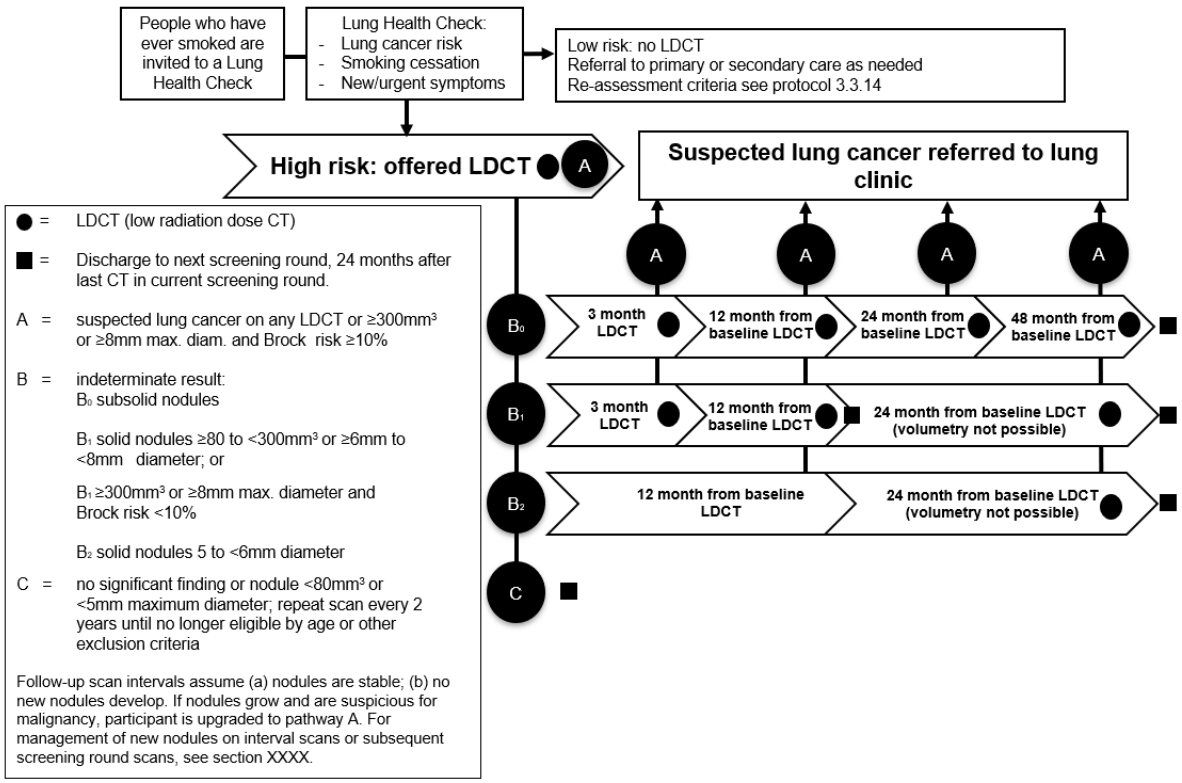
3.1.14 Where necessary, reasonable adaptations should be made to the approach to ensure the service is accessible to all, including those with physical and learning disability and mental illness (e.g. easy read documentation, or engaging a key worker in the invitation [1]).

3.1.15 NHS translation services should be available where required for individuals without adequate English as a first language (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 or initial assessment, participants will have a discussion to assess their individual lung cancer risk. This will include questions about smoking habits. Those at low risk do not require a CT scan.

3.2.3 Current smokers will be offered smoking cessation Very Brief Advice (VBA) and formal smoking cessation service referral on an opt-out basis.

3.2.4 The initial assessment call must also query relevant medical history (in particular relevant exclusion criteria, see 3.3.12) and any new or urgent clinical symptoms that require further assessment (see section 3.6) with escalation as appropriate to clinical colleagues with onward referral to primary or secondary care as needed.

3.2.4.1 Clinical assessment should not be undertaken by non-clinical staff – patients who describe symptoms on the initial assessment should always be referred to clinical staff.

3.2.4.2 Where an initial assessment step is included as part of the risk assessment process, the RA and RC must put in place a robust process to make sure participants with symptoms are assessed by a clinician – urgently where appropriate.

3.2.4.3 An appropriate script approved by the Responsible Clinician for assessing symptoms must be in place, with escalation to a clinician (e.g. 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 Any participant assessed as being at high risk of lung cancer will have their proposed exposure to LDCT justified and authorised in line with IR(ME)R regulations and then be offered a low-dose CT scan within 56 days of the risk assessment, if there are no exclusion criteria. The scan will typically show one of three things:

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

Results	Action
No significant findings or nodules	Return at next screening round in 24 monthly intervals from the last stable or normal scan.
Indeterminate result	Further surveillance 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

3.2.6 Table 4 includes a more detailed nodule management protocol.

3.2.7 Surveillance scans (3months/12months) should be completed a maximum of 28 days after the target date but should not be completed earlier than the target date.

3.2.8 Screening round scans (24 months) can be completed up to 56 days before or after the target date.

3.2.9 Participants returning for surveillance scans or screening round scans should not receive a further Lung Health Check but should be checked for continuing eligibility for LDCT. Participants that did not previously breach the risk threshold, who have been reinvited, should receive a further Lung Health Check.

3.2.10 Participants with non-cancer related symptoms will be referred to their GP or appropriate specialist if required.

3.2.11 Where participants are referred to secondary care for investigation of potential lung cancer, they should be readmitted to the LCSP once any active secondary care treatment or monitoring has come to an end (See 3.1.15).

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. Initial assessment, or pre-population of risk calculator data (see section 3.1.11) 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 refer to LDCT

requires review by an IR(ME)R trained doctor or nurse of Band 6 or greater with experience of conducting lung health checks. A representative sample of 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. Where the assessment is undertaken by an external provider, the provider can support this audit / QA process but the RA (or where this is also contracted to the external provider), a member of the Screening Review Meeting (SRM) must oversee the audit and directly assess the lower of 50 or 1% of cases per quarter (Call recording of pre-assessment steps may be useful in this scenario.

3.3.2 Where initial assessment or LHC has taken place over the phone or virtually the participant's self-reported height and weight can be used, but every effort should be made to ensure that this is accurate.

3.3.3 The LCSP 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 Evidence suggests that a risk threshold of ≥1.51% risk of lung cancer over six years is the minimum threshold for PLCO$_{M2012}$, and ≥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 ≥2.5% is considered the minimum threshold.

3.3.5 ~~M2012~~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: ≥2.5% risk	$PLCO_{M2012}$: ≥1.51% risk
• Age • Gender • Smoking duration (years) • Previous pneumonia/ COPD/ emphysema/ bronchitis/ TB • Occupational asbestos exposure • Previous history of malignancy • Previous family history of lung cancer – relative's age at onset, ie <60 years or >60 years – whether first degree relative.	• 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. Modifications for UK ethnicity have been made.

3.3.6 For the purposes of the LCSP, participants satisfying either LLPv2 or $PLCO_{M2012}$ are to be considered eligible for a low-dose CT provided they meet the inclusion criteria in 3.3.10 and do not have any of the exclusion criteria listed in 3.3.12.

3.3.7 Inclusion criteria:

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

3.3.8 Exclusion criteria:

- Weight or physical size exceeds restrictions for scanner (e.g. >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. This may include:
  - Participants registered on the palliative care register
  - Participants with severe frailty (electronic frailty index >0.36)

- Participants with metastatic cancer but not metastatic prostate cancer, metastatic breast cancer or metastatic melanoma (unless participants are already receiving annual diagnostic chest CT scans).
- Participants with mesothelioma
- Participants currently under active treatment for lung cancer or under surveillance for lung cancer following treatment

3.3.9 Participants who have had a full thoracic CT scan that meets the image reconstruction parameters of the programme (see section 4.4.) 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

3.3.10 Participants who lack the mental capacity to consent to screening should not be excluded from the programme. 'Consent to cancer screening' guidance on informed consent should be followed, including the use of best interests decisions.

3.3.11 Reasonable steps should be taken to assess whether a full thoracic CT scan has taken place and defer the LDCT appointment if appropriate. 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 LDCT. If a participant receives an out-of-programme (OOP) CT scan covering the thorax between LCSP scans (either screening round or surveillance scans), the date of the participant's planned LCSP scan should not usually be deferred. SRM can defer scans if a clinical role believes SRM should consider deferral. The fact that the participant has had an OOP scan should be flagged on the participant's record on the LCSP database. If there is a new nodule or finding on the planned LCSP scan since the last LCSP LDCT, review the case with the OOP CT scan at the Screening Review Meeting.

3.3.12 Effort should be made to check continuing eligibility for LDCT in advance of surveillance or screening round scans.

3.3.13 Where participants are assessed at below the threshold for LDCT, where possible they should be reinvited at the point where they are likely to

become high risk. Previously ineligible participants must receive a repeat LHC ahead of any LDCT – this LHC could be informed by historical data but this should be carefully verified with the participant.

3.4 Information for participants

3.4.1 Where available, national participant information resources, developed by appropriate patient and public communication experts and co-designed with diverse representatives of the lung screening-eligible population, should be used. Where necessary, for example to improve equity, diversity and inclusion, sites can include minor changes, that should be limited to pre-specified sections of text, with the support of the NHS England team.

3.4.2 All communications should be written in sufficiently lay language to address barriers to participation and support informed decision-making through an understanding of the risks and benefits of lung screening.

3.4.3 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.

- The focus should be on informed choice and supporting participant understanding of risks associated with taking part in lung cancer screening, for example using lay explanations, infographics and easy read versions.
- It should be made clear what the screening programme can find and what it cannot. Specifically, it should be made clear that the LDCT is designed to detect lung cancer, the test is not optimised to find anything apart from lung cancer, but incidental findings are possible.
- 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 physical or learning disabilities or impairments.

- Optimal communications should be co-designed and evaluated with representatives of the intended audience.

3.4.4 As part of an LHC or initial assessment, all current smokers must receive very brief advice on smoking cessation by a trained professional and be referred to smoking cessation services on an opt-out basis.

3.4.4.1 Smoking cessation advice and information about locally available support must 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.

3.4.4.2

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 and radiation exposure. Participants should be informed of the following:

- The primary purpose for undergoing LDCT 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 managed according to the National Optimal Lung Cancer Pathway.
    - The LDCT scan technique is not optimised to detect abnormalities other than lung cancer, but such respiratory and non-respiratory abnormalities can sometimes be detected by LCSP. If potentially significant conditions are identified that require action, the participant will be informed and the LCSP will either make an appropriate referral and/or advise the participant's GP on the appropriate action to be taken. The participant and GP will not be informed of any clinically non-significant findings for which there is no recommended treatment. Action on incidentally detected abnormalities should follow the LCSP Incidental Findings Protocol.
- Indeterminate pulmonary nodules are often benign.
- 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 further investigation and false positives.
- Participants will be asked to consent to 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 LCSP process and quality control. Data will usually be anonymised unless it is considered necessary to link lung health check records to other health records.
    - not providing this level of consent, or declining to participate in a specific research programme, does not stop them in any way from taking part in this programme.

3.5.2 It is recommended that consent to data usage, also includes consent to approach by research teams 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 participant has been informed of the benefits and risks of LCSP LDCT and gives consent to proceed. A separate statement/entry in the medical record should be made that the participant 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 Any new or urgent clinical symptoms that require further assessment should be escalated as appropriate to clinical colleagues with onward referral to primary or secondary care as needed.

3.6.3 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.

3.6.4 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.:

- 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).

3.6.5 If potential participants present with symptoms consistent with exacerbation of COPD or other chronic pulmonary conditions, they should proceed with the LDCT.

3.6.6 Participants who meet eligibility criteria for a LDCT but who have any of the following features or symptoms, as described in NICE referral criteria (NG12), should have their LDCT expedited and prioritised for reporting:

- cough
- fatigue
- dyspnoea
- chest pain
- unexplained weight loss

- appetite loss
- persistent or recurrent chest infection
- finger clubbing
- supraclavicular lymphadenopathy or persistent cervical lymphadenopathy
- chest signs consistent with lung cancer
- thrombocytosis.

3.6.7 Those who are ineligible for LDCT due to a low-risk score 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.

3.6.8 If a participant is not physically well enough to receive a CT scan then this should be deferred.

3.7 Lung health check personnel training

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)
- Employer training for entitlement to refer under LCSP (IR(ME)R compliant CT referral for anyone requesting a scan)
- Very Brief Advice on smoking cessation
- 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, calibrated and appropriately acceptance tested. According to the manufacturer's specifications, capable of delivering low radiation dose protocols. Most modern scanners exceed this specification and will achieve this.

4.1.2 Volumetry should be used for assessment of solid pulmonary nodules as per British Thoracic Society recommendations (REF) (see section 4.7).

4.1.3 Volumetric segmentation of the nodule should be visually assessed for reliability.

4.1.4 The volumetric software should ensure display of all volume metrics, including percentage volume change and volume doubling time (VDT) when more than one LDCT is available.

4.1.5 VDT must be calculated from the first appearance of a nodule [e.g. for a nodule detected at the first (baseline) LDCT, VDT should be calculated from that baseline LDCT.

4.1.6 Software and technique should remain consistent to allow accurate comparison of volumes. When the supplier of volumetric software performs software updates/upgrades, the dates of such upgrades should be recorded and a log of version control kept. 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 alters measurements.

4.1.7 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.

4.1.8 Other desirable features are high automated segmentation accuracy rates (>85%), and automated structured reporting.

4.1.9 Computer aided detection (CAD) systems should be used in a concurrent or second reader format. A false positive rate of <2 per case is required 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 isocentre 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 scout view (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.

4.2.4 Participant height and weight should be recorded alongside other participant data entered as part of the CT scan.

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.

4.3.2 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.

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

4.3.4 Medical physics input should be obtained in advance of setting up LDCT scanning protocols.

4.3.5 The cause of poor diagnostic quality images should be documented where possible.

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 must be ≤ 1.25mm. 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 consistent at follow up.

Table 3: Example of 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 3.3.15 to 3.3.17).

4.6 Thoracic CT reader

4.6.1 Lung cancer screening CT reading requires unique skills beyond the skillset needed for 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, the majority of which should be CTs performed for the evaluation of lung cancer (this should include a mix of LCSP LDCTs, pulmonary nodule follow-up and symptomatic lung cancer).

- Radiologists should participate in a thoracic MDT meeting as part of their routine clinical work. This excludes Screening Review Meeting (SRM) attendance, as those are problem-solving meetings for lung cancer screening and not for lung cancer diagnosis and management.
- 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.
- Radiologists will participate in regular personalised performance review via a centrally curated educational self-assessment and training scheme for LHC CT reading (PERFECTS), as described in the Quality Assurance Standards
- The RR is responsible for ensuring all the above criteria are met, and for all relevant aspects of clinical governance.

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 once the reasons are understood.

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.
- 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 home reporting situations.

4.6.4 The lung nodule size threshold for characterisation is ≥ 5mm or 80mm^3. Where multiple nodules are detected, at least two nodules, including the largest nodule, and where possible all nodules >200mm^3, should be recorded. Smaller nodules may be characterised for research purposes. All new nodules on interval LDCT ≥30mm^3 or ≥4mm 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 Programmes should follow national guidelines and have protocols in place for reporting and management of incidental findings (see section 6.4). Narrative/descriptive reports should be avoided. Clinically non-significant 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 ≥25% has occurred (as a <25% difference in volume may be within the limits of expected inter-scan variation). 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.

4.7.2.1 Where more than one prior scan is available, VDT should be calculated relative to the earliest (preferably baseline) LCSP LDCT with technically acceptable segmentation.

4.7.3 Images showing the boundaries of solid nodule volume segmentation, including size and VDT calculation where appropriate, should be available to radiologists to allow visual assessment of segmentation reliability. This assists with the reading process at follow up and ensures that the information is efficiently conveyed to the lung cancer MDT or Screening Review Meeting for relevant cases.

5. Surveillance of indeterminate nodules (pathway B)

5.1 Scan intervals

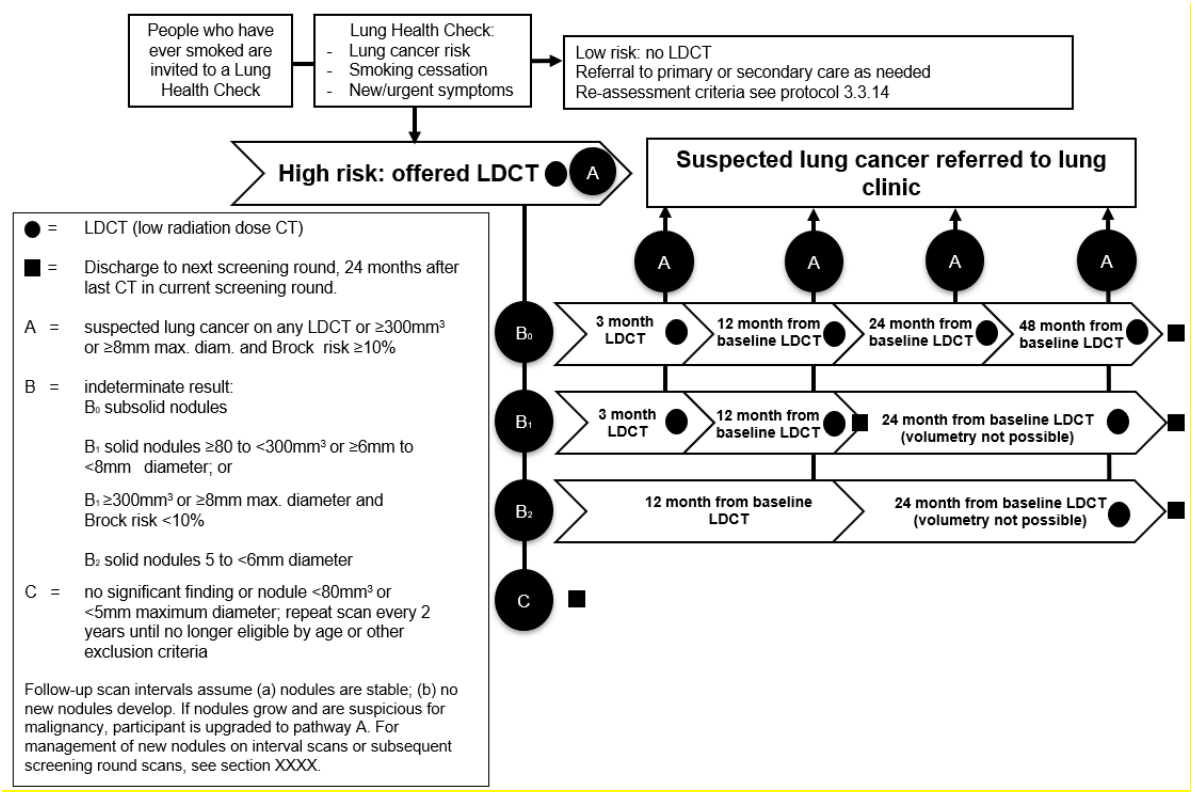
5.1.1 Nodule management should be protocolised and based upon the BTS 2015 pulmonary nodule guidelines [6] and NICE guidelines for the management of lung cancer [7].

5.1.2 Local or regional modification of nodule management guidelines is not encouraged. Where such modification is deemed necessary, clinical justification should be provided and permission for modification sought.

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. (i.e. 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 Table 4 below shows how the nodule size affects follow-up interval and referral:

Table 4: Nodule size and follow-up interval and referral (*must be interpreted in conjunction with notes below*)

Notes and definitions:

- **"Stable"**: as per current guidelines
    - Solid nodules with reliable volumetric segmentation: percentage volume change (relative to the nodule's first occurrence) of <25%
    - Solid nodules with unreliable segmentation: difference in maximum diameter of <2mm
    - Sub-solid nodules: difference in maximum diameter of <2mm of the entire nodule or the solid component if present
- Baseline screening round: the first screening round that the individual undergoes, which includes their baseline (first) scan in the programme and all follow-up CT scans performed during that screening round. This timepoint is often referred to as T0. The screening round concludes when the minimum follow-up period for any indeterminate findings concludes and there are no new findings, or when the participant is referred to a lung cancer service, whichever is sooner.
- Incident screening round: screening rounds that occur after the baseline round. These timepoints are often referred to as T1, T2, and so on.
- Next screening round: 24 months after the last stable or negative scan. E.g. if a solid nodule with volume ≥80 to <300mm^3 at baseline CT is stable after 12 months of follow-up, the next screening round is 24 months from that point, i.e. 36 months from baseline.
- Size thresholds change where nodules were not seen on a previous CT. Follow-up is based on the same minimum time-periods as for nodules seen at baseline: at least 12 months for a reliably volumetrically segmented nodule, and at least 24 months for a non-volumetrically segmented nodule.
- This table provides recommendations for surveillance scans **relative to the current scan**. For example, 'follow-up in another 9 months0 on a 3 month scan is the same as '12 months from baseline'
- In the event a participant has a delayed follow-up scan, radiologic judgement should be applied to decide when the subsequent follow-up scan (if still needed)

should be performed, with the principle at all times being to bring the participant back in line with the original timeline for their follow-up, while at the same time allowing sufficient time to pass to enable reliable estimation of stability or growth. For example, following a baseline scan, if a 3-month scan to follow up a volumetrically segmentable indeterminate solid nodule only occurs at 7 months from the baseline scan, if the nodule is stable there is no point in performing another scan 3 months from then (i.e. 10 months from the first scan); it would be sensible to choose the next best option (e.g. 6 months from the current scan which would be a total of 13 months from baseline- and still within 1 month of the original intended 12-month follow-up from baseline). Where there is any doubt, discussion at the SRM is encouraged to ensure consistency.

- Radiologists should use their clinical discretion to dismiss overtly inflammatory nodules, especially ground-glass nodules, even if these are flagged by the computer-aided detection system. These systems are only meant to be aids to reading and the radiologist decides the final disposition of any nodule. NB: Please note the Incidental Findings guidance on consolidation- if Inflammation more likely than cancer refer to SRM consider repeat CT Repeat CT at 6 weeks or 3 months depending on concern (within or outside screening programme).

- The timepoint of the scan being reported should be explicitly made clear to the radiologist at the time of reporting.

- For new nodules, we emphasise only discrete nodules considered non-inflammatory should be designated for follow-up.

CT Nodule type and size (measure)	Follow-up interval from current scan
BASELINE ROUND CT	
No nodules	None- discharge to next screening round
Solid nodules	
<80mm^3 or <5mm max. diam.	None- discharge to next screening round (NB: if a prior adequate non-screening thoracic CT is available, and the nodule is proven to be new in comparison, the lower threshold for new solid nodules apply – see below)
≥80 to <300mm^3	3 months, if stable in another 9 months, then discharge to next screening round if stable
≥6mm and <8mm max. diam. (volumetry not possible)	3 months, if stable in another 9 months, then 12 months, then discharge to next screening round if stable
5 to 6mm max. diam. (volumetry not possible)	12 months, if stable in another 12 months, then discharge to next screening round if stable
≥300mm^3 max. diam. And Brock risk <10%	3 months, if stable in another 9 months, then discharge to next screening round if stable
≥8mm max. diam. And Brock risk <10% (volumetry not possible)	3 months, if stable in another 9 months, then 12 months, then discharge to next screening round if stable
≥300mm^3 or ≥8mm max. diam. And Brock risk ≥10%	Refer
Sub-solid nodules	
<5mm max. diam (including PSNs with solid component <5mm max. diam)	None- discharge to next screening round
Ground-glass nodule ≥5mm max. diam.	3 months- if persists assess malignancy risk (size, morphology, density, Brock score)- if low risk in another 9 months, then 12 months, then

	24, then 48 months. If stable, discharge to the next screening round
Part-solid nodule, solid component ≥5mm max. diam	3 months- if persists assess malignancy risk (size and growth of solid component, morphology, density, Brock score)- in another 9 months, then 12 months, then 24, then 48 months. If stable, discharge to the next screening round
Pericystic lesions*	In the absence of formal guidance on these types of lesions in the current BTS guidelines, follow-up based on the presence and characteristics of any associated ground-glass or solid component, as appropriate
INCIDENT ROUND CT	
Solid nodules	
Present on most recent prior CT	
Stable since the most recent prior CT	Discharge to next screening round if minimum surveillance period for nodule has been completed
Growing since the most recent prior CT	Consider referral for further investigation or CT surveillance depending on VDT and size of nodule (see section 6)
NEW discrete nodules since the most recent prior CT	
<30mm^3 or <4mm max. diam	None- discharge to next screening round
≥30mm^3, <300mm^3	3 months, if: Resolves- discharge to next screening round Persists but stable- in another 9 months, if stable discharge to next screening round
≥4mm, <8mm max. diam (volumetry not possible)	3 months, then if: Resolves- discharge to next screening round

	Persists but stable- in another 9 months, then 12 months, if stable discharge to next screening round
≥300mm^3/≥8mm	Refer
Subsolid nodules	
Stable since the most recent prior CT	Discharge to next screening round if minimum surveillance period for nodule has been completed
Growing in size (in the case of part solid-nodules, size of solid component) or density, or altered morphology	Consider referral or closer CT surveillance depending on level of concern
NEW discrete nodules since the most recent prior CT	As per baseline round CT
New discrete non-inflammatory nodules on any interval CT	
At any timepoint: Solid <30mm^3 or <4mm max. diam. OR sub-solid <5mm max. diam.	None- continue with any planned screening or surveillance CT
Solid	
Appears at 3 month follow-up CT	3 months, if: Resolves- discharge to next screening round Persists but stable- in another 9 months, then 12 months, if all nodules stable discharge to next screening round
Appears at CTs performed after 9 or 12 months	
≥30mm^3, <300mm^3	3 months, if: Resolves- discharge to next screening round Persists but stable- in another 9 months, if all nodules stable discharge to next screening round

≥4mm, <8mm max. diam. (volumetry not possible)	3 months, if: Resolves- discharge to next screening round Persists but stable- in another 9 months, then 12 months, if all nodules stable discharge to next screening round
Sub-solid	As per baseline round CT

**Guidance on new pericystic lesions on incident round or follow-up CT is not given as a genuinely new pericystic lesion would be unlikely.*

5.2 Reducing measurement variability

5.2.1 Each CT scanner vendor has its own reconstruction algorithms. To reduce the impact of these, as much as possible the scanner make and model should be kept the same as the baseline.

5.2.2 If it is not practical to use the same make and model of scanner then efforts should be made to ensure the same vendor and reconstruction algorithm are used and the image quality and metrics remain comparable.

5.2.3 If it is not practical to use the same vendor then the same or similar reconstruction algorithm must be used. The Medical Physics Expert must be satisfied that the algorithms from different manufacturers have similar technical parameters.

5.2.4 Slice thickness and slice increment must be the same regardless of scanner make, model, vendor or reconstruction algorithm.

6. Pathway A: Findings requiring further investigation

6.1 Lung nodule management and follow-up/further diagnostics

6.1.1 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. In brief:

- 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 (e.g. PET-CT, percutaneous biopsy, lung resection, according to participant preference).
- For PSN, any change in morphology or growth of solid component (≥2mm) 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.

6.1.2 Nodules with a Herder risk score >10% following FDG-PET/CT may be referred and managed within the respiratory clinic or within the screening programme. Nodules with a higher score should be managed within the respiratory service. The Herder tool is validated risk calculator that incorporates findings from FDG-PET scans (available in BTS pulmonary nodule app).

6.2 Multidisciplinary team meetings

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

- The Screening Review Meeting (SRM), where the management of findings (either nodules or incidental findings) requiring urgent investigation, especially those with relevant prior imaging, are discussed and management plans are devised so that communication with the participant and any healthcare professionals can be co-ordinated.
- The lung cancer MDT, where the outcome of investigation of higher risk nodules and suspected lung cancer is discussed, and treatment planned.
- It is permissible for the SRM and lung cancer MDT to be run simultaneously as a 'hybrid'.

6.2.2 All pulmonary nodules that are indeterminate should be discussed at the LDCT review or Screening Review Meeting. These include:

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

6.2.3 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, or prior imaging is available).

6.3 Management by lung cancer service

6.3.1 Referral: LDCT suspicious for lung cancer will receive a screening referral into the suspected lung cancer rapid assessment and diagnosis pathway [8].

6.3.2 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 non-significant findings should not be communicated to the GP or participant.

- Findings that the GP and participant are already aware of, including findings identified on previous LCSP scans, should not be communicated to the GP or participant as actionable findings.
- There should be agreement between the LDCT 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.

6.3.3 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 Lung Cancer Screening Programme.
- Findings mandating urgent referral (e.g. 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 (e.g. significant fibrotic interstitial lung disease).
- Non-cancer findings that may require management in primary care.
- Other findings that may prompt NICE recommended assessment to be done, where they have not been included in the assessment performed by the RA (e.g. significant coronary calcification on CT may prompt recommendation for cardiovascular Q-Risk assessment).
- Other findings that are usually not directly associated with a beneficial intervention, would not usually be reported by radiologists, or can be deemed clinically non-significant and that do not require communication (e.g. bronchial wall thickening).

6.3.4 Incidental findings will be reviewed by the Screening Review Meeting (SRM) and clear recommendations will be made to the relevant clinicians and to the participant.

6.3.5 The Responsible Radiologist will be accountable for decisions made regarding incidental findings referred to SRM.

6.3.6 There should be a policy agreed between the targeted lung cancer screening site and primary care about management of LDCT findings, including the referral process for incidental findings.

6.3.7 The NHS England LCSP Incidental Findings Management Protocol provides guidance on the management of the most common findings.

7. Non-attendance, moving out of area and exiting the programme

7.1 Non-attendance

7.1.1 First-time attendance should be facilitated by offering LDCT that is easily accessible for the participant (e.g. mobile scanners in community settings, easy transport links, evening and weekend appointments).

7.1.2 The process of changing appointments should be straightforward for those who request this.

7.1.3 There should be a formal process for contacting non-attenders.

7.1.4 Where possible and in line with data protection law, feedback from attenders and non-attenders should be sought to evaluate and improve access.

7.1.5 Participants who do not attend scheduled appointments should be re-invited according to local processes. Participants should be re-invited in the next screening round unless explicitly stating a wish not to be re-invited. If participants have suggested they no longer wish to be invited, the opportunity should remain for them to opt back in to the programme (See 3.1.3).

7.2 Moving out of area

7.2.1 Where possible, sites should identify that a participant has moved address and no longer lives within the LCSP area before any appointment is due, in order to prevent delays.

7.2.2 The site with which a participant sits remains responsible for that participant until the potential receiving site agrees to accept the transfer of that participant to their site, or the participant actively opts-out of the LCSP. If a provider is managing the transfer of a participant, the Cancer Alliance is responsible for ensuring the transfer is completed in a timely manner.

7.2.3 Every effort should be made to ensure that participants requiring future surveillance (3 month / 12 month) or screening round (24 month) scans receive those scans if they move out of the area covered by the individual LCSP site. This should include, where appropriate, offering the participant the opportunity to return to the original LCSP site for scans.

7.2.4 Where a project is made aware of a participant moving to an area already covered by a Lung Cancer Screening site, the original site should get in touch with the participant's new site to ensure they are added to that programme.

7.2.5 Where a site is made aware of a participant requiring surveillance scans (e.g. for a lung nodule), moving to an area where Lung Cancer Screening is not currently available, they must contact the local hospital Trust to suggest the participant receives surveillance scans in line with this Standard Protocol ahead of Lung Cancer Screening becoming available in the new area. The patient must be informed of the need for further follow up in their new site. Screening round scans should wait until the programme moves to the area and the participant is invited to that programme.

7.2.6 For the avoidance of doubt, any case where a participant has their scan delayed because of moving out of area must be formally raised as an incident with the national LCSP team.

7.3 Exiting the programme

7.3.1 All participants should receive at least two LDCT screening round scans (baseline or 24 month scan) before exiting the programme. Once a participant turns 75, as long as the participant has received at least two LDCT screening round scans, they should not be booked for any further screening round scan and should exit the programme.

7.3.2 For participants receiving a baseline scan shortly before turning 75, if the scan finds no indeterminate nodules, then the participant will receive one further screening round scan 24 months after their baseline scan. This screening round scan can take place after the participant turns 75.

7.3.3 If indeterminate nodules are found on any screening round scan then surveillance scans (e.g. 3 month or 12 month) should take place, even if these take place after a participant turns 75.

7.3.4 Once a participant over the age of 75 has received two screening round scans and any surveillance scans resulting from those screening round scans, the participant should exit the programme.

7.3.5 Where a participant requires longer follow-up at the final planned surveillance scan e.g. a new nodule or sub-solid nodule, the participant should be referred to the local respiratory service for further follow-up.

7.3.6 If a participant who has not yet received two LDCT screening round scans does not attend a screening round scan and a subsequently booked scan would take place after the participant turns 75, the participant should be given one further opportunity to attend.

7.3.7 If a participant has a CT scan out of programme that necessitates delaying the lung cancer screening LDCT then this can be accommodated, even if that delay extends the LDCTs beyond the point the participant turns 75.

7.3.8 Under no circumstances should a participant be invited for a screening round scan after turning 78.

7.3.9 The letter informing participants of the outcome of their final LDCT scan should also inform participants that they are being released from the programme.

8. Communication of results

8.1 Process

8.1.1 Participants will be sent communication about the results of the LDCT 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 any action taken or recommended to be taken, included.

8.3.3 SNOMED codes should be used to record the participant journey and outcomes on the participant's GP patient record. National guidelines on SNOMED codes to use for the LCSP should be referred to.

8.3.4 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.

8.3.5 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 Telephone communication of results by an appropriately trained clinician should be offered as well as communication by letter when clinically appropriate, e.g. serious findings such as malignancy.

8.4.2 There should be a telephone number 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 to the participant, 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.

9.1.2 Where possible and present on CT scanners, a patient dose management system should be used to record data on scans. This should be collected locally in a format that will allow submission to the UK Health Security Agency.

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. All sites must report data against the minimum dataset to NHS England on a routine basis.

10. Nonadherence with Standard Protocol and governance documents

10.1.1 In some rare instances, it may be necessary to deviate from the Standard Protocol, for example to carry out research. To do this, the Standard Protocol Deviation Form should be completed, any deviation will need to be signed off by the national team SRO and national clinical experts.

10.1.2 If an inadvertent breach of the Standard Protocol is discovered, then this should be considered an incident. The national team should be notified immediately and the LCSP Incident Assessment Form should be completed.

11. Evolution of the standard protocol for the LCSP

11.1 Updating the standard protocol

11.1.1 It is recognised that this targeted screening for lung cancer with low radiation dose computed tomography and standard protocol prepared for the LCSP will evolve over time.

11.1.2 This will be influenced by the LCSP Expert Advisory Group, 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.

11.1.3 Furthermore, this document will need to adapt as further research findings from screening studies emerge.

11.1.4 Advice and consultation with the UKNSC will be ongoing and could influence future iterations of this document.

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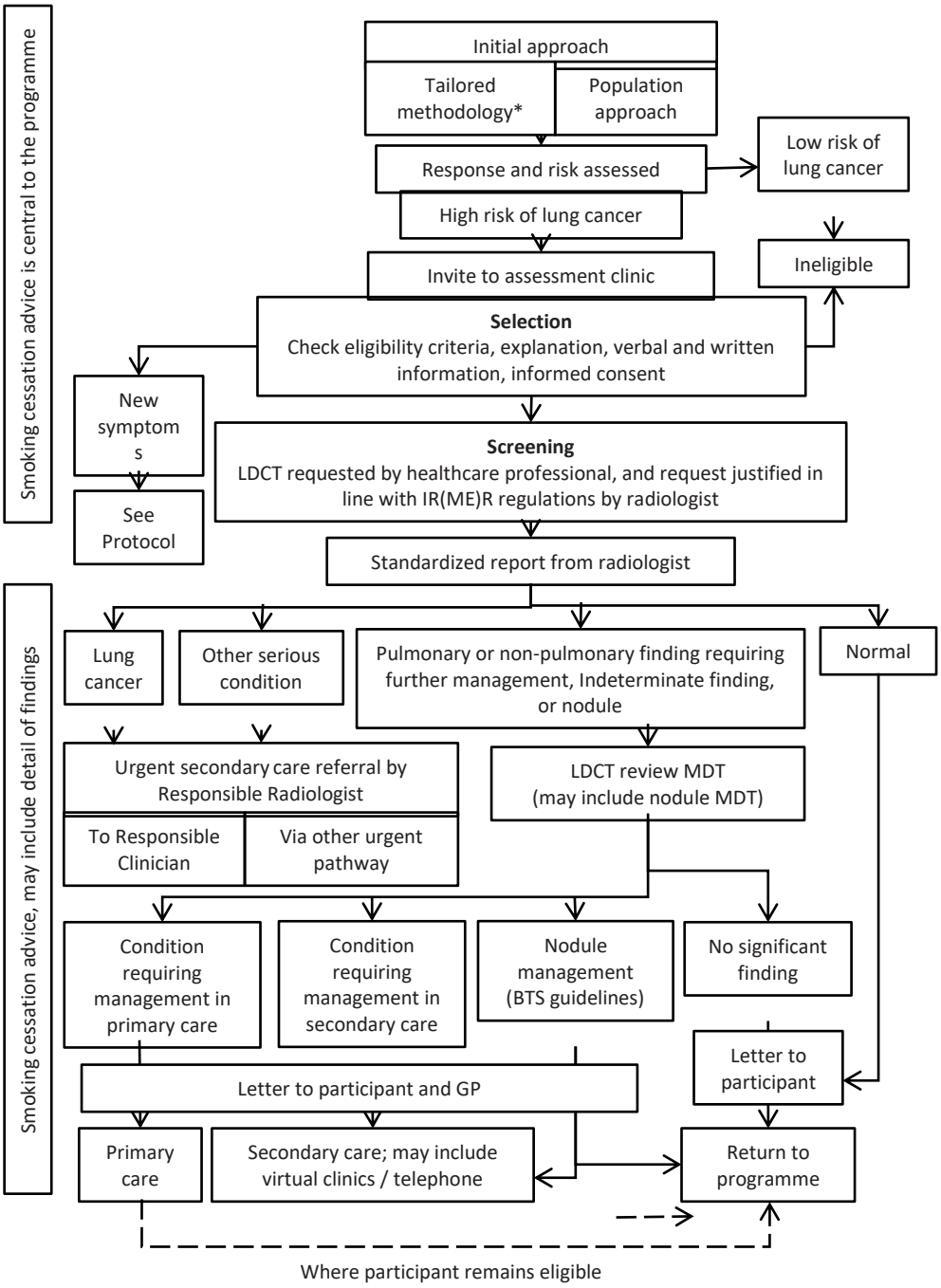
Appendix A

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



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