Targeted Screening for Lung Cancer with Low Radiation Dose Computed Tomography

Standard Protocol prepared for the Targeted Lung Health Checks Programme

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Targeted Screening for Lung Cancer with Low Radiation Dose Computed Tomography

Standard Protocol prepared for the NHS England Targeted Lung Health Checks Programme

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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 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 may be 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 protocol, 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 (preferably electronic) mechanisms to invite the cohort and recall for those that require surveillance or a routine screen after an interval;
- describe measures to improve uptake and reduce inequalities (while honouring the principle of informed choice);
- provides 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 that;
- describes the tests to be carried out;
- define the results of the tests including positive (abnormality), negative and indeterminate;
- describes (or points at) the follow up diagnostic and treatment pathways (e.g. NICE, British Thoracic Society) for all the categories of tests (including negative);
- are delivered and supported by suitably trained, competent, clinical and non-clinical staff who, participate in recognised on-going Continuing Medical Education, Continuous Professional Development, and External Quality Assessment (EQA) schemes;
- describes 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 QA and audit activities;
- follow QA advice to improve the service;
- use the agreed common data records and definitions;
- describe how smoking cessation is integrated into the programme; and
- facilitate research studies into lung cancer early detection and screening.

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; and
- administrative support for the programme including data collection, collation and submission.

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:
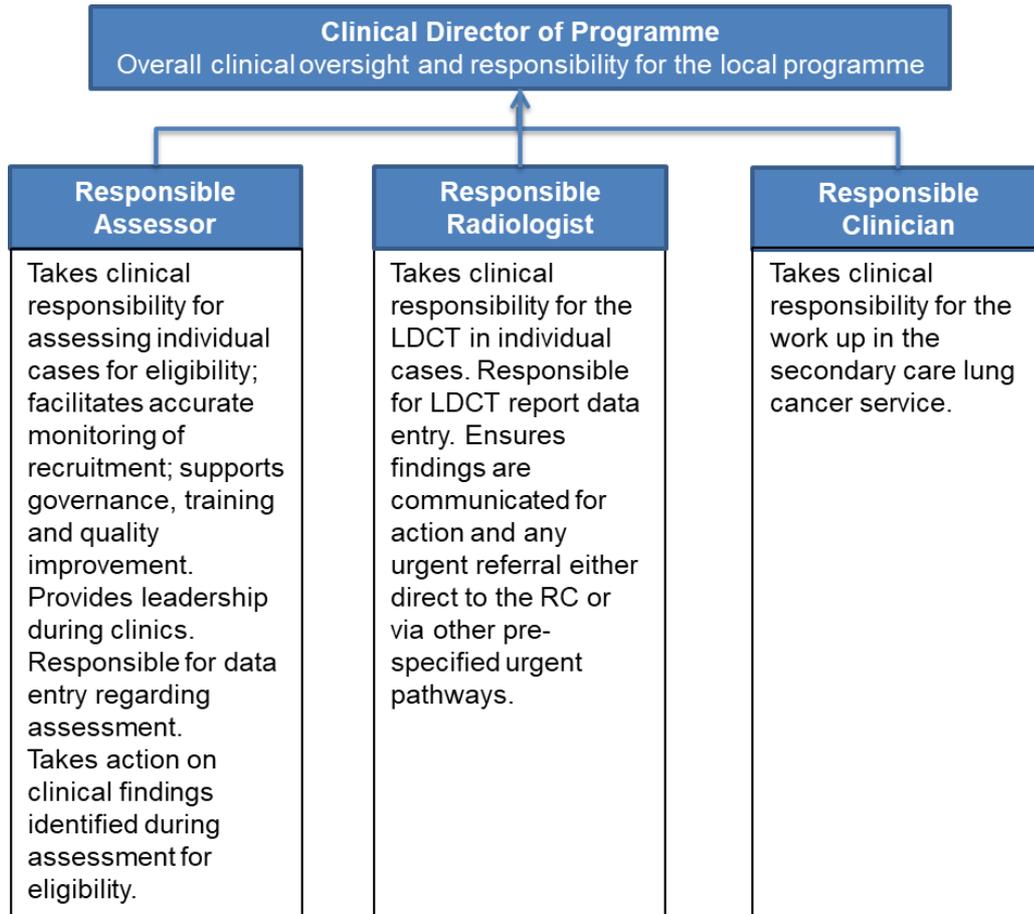- Regional Office, NHS England;
- Cancer Alliances;
- STPs;
- CCGs;
- Local NHS Trusts; and
- Local Authorities.

2 Clinical governance

2.1 Clinical governance structure

2.1.1 Each programme will need to have in place robust clinical governance 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 need to have in place.

Figure 1: Targeted Screening for Lung Cancer Clinical Governance Structure

Clinical Director of Programme Overall clinical oversight and responsibility for the local programme		
Responsible Assessor	**Responsible Radiologist**	**Responsible Clinician**
Takes clinical responsibility for assessing individual cases for eligibility; facilitates accurate monitoring of recruitment; supports governance, training and quality improvement. Provides leadership during clinics. Responsible for data entry regarding assessment. Takes action on clinical findings identified during assessment for eligibility.	Takes clinical responsibility for the LDCT in individual cases. Responsible for LDCT report data entry. Ensures findings are communicated for action and any urgent referral either direct to the RC or via other pre-specified urgent pathways.	Takes clinical responsibility for the work up in the secondary care lung cancer service.

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 lung health check 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 responsible for the LDCT in individual cases and will normally be the first-read radiologist. The radiologist should urgently refer either direct to the rapid access lung clinic/ named consultant or via other urgent pathways in secondary care. The radiologist will accurately monitor reporting performance, and act on these results to support governance, training and improve quality. They will be responsible for data entry relating to the LDCT report and ensure findings are communicated for action.

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 is responsible for ensuring that the assessment process is appropriately carried out by all RAs, 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); and
- adherence to details of this protocol (RAs, RRs and RCs).

2.3.4 **National audit:** The DP is responsible for ensuring that all data are 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 Cancer Alliance Board.

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 Lung Health Check e.g. 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 aged between 55 and 74 and 364 days of age at the date of the first low dose CT scan, registered with a GP practice who have ever smoked will be invited for a Lung Health Check. Those who attend will be assessed to calculate their individual risk of developing lung cancer.

3.1.2   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 a Lung Health Check.

3.1.3   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 may be used to better quantify risk.

3.1.4   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 e.g. easy read documentation, engaging key worker in invitation [1].

3.1.5   NHS translation services should be available where required for individuals without adequate English language skills (see 3.9).

3.1.6   Participants who have difficulty understanding the purpose of the programme should be able to access the programme (see 3.9).

3.2 Participant journey

3.2.1   Figure 2 illustrates the participant journey for both those assessed at the Lung Health Check 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 pathway
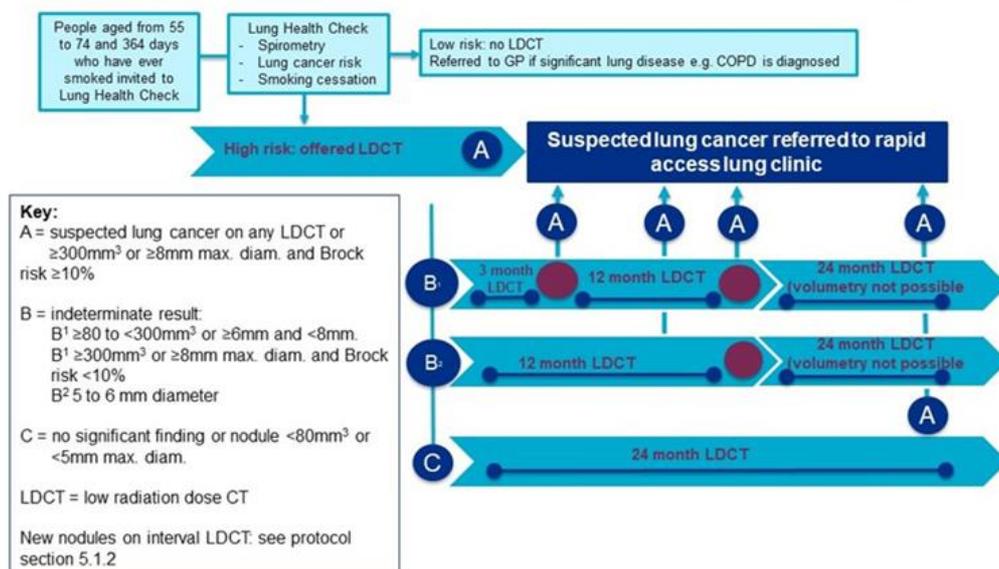
3.2.2 At the Lung Health Check, the participant will have a spirometry test and a discussion to assess the participant's individual lung cancer risk. This will include questions about smoking habits and they will also be offered smoking cessation advice and treatment. Those at low risk do not require a CT scan.

3.2.3 Any participant assessed as being at high risk of lung cancer will be invited to an immediate low-dose CT scan. The scan will show one of three things:

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

Results	Action
No significant findings or nodules <80mm³ or 5mm max diameter	Second scan 24 months later
Indeterminate result	Second scan 3 months later, with follow up scan 12 months later
Requires further investigation	Referred to local specialist lung clinic

3.2.4 Participants with an abnormal spirometry result or other non-cancer related symptoms will be referred to their GP.

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 identify which is the best. This will form part of the evaluation of the Targeted Lung Health Check Programme.

3.3.2 The Targeted Lung Health Check 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 a LDCT. The American PLCO$_{M2012}$ model has been adapted for use in the UK to reflect UK ethnic groups.

3.3.3 The latest evidence suggests that a risk threshold of ≥1.51% risk of lung cancer over 6 years is the minimum threshold for PLCO$_{M2012}$ and ≥2.00% risk of lung cancer over 5 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 proposed.

3.3.4 This standard protocol uses two thresholds to identify participants: a risk threshold of ≥1.51% risk of lung cancer over 6 years as the minimum threshold for PLCO$_{M2012}$; and ≥2.5% risk of lung cancer over 5 years for LLPv2.

3.3.5 The factors used in these models that would need to be collected are shown in the table below.

Table 2: Factors included in two multivariable risk prediction models

LLPv2: ≥2.5% risk	PLCO$_{M2012}$: ≥1.51% risk
Age	Age (years)
Gender	Education level
Smoking duration (years)	Body mass index
Previous pneumonia/ COPD/ emphysema/ bronchitis/ TB	COPD/ chronic bronchitis/ emphysema
Occupational asbestos exposure	Personal history of lung cancer
Previous history of malignancy	Family history of lung cancer
Previous family history of lung cancer; and relative's age at onset i.e. <60 y or >60 years; whether first degree relative	Ethnicity[1]
	Smoking status
	Average number of cigarettes smoked per day
	Duration smoked (years)
	Years having ceased smoking

3.3.6 For the purposes of the Targeted Lung Health Checks 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 3.3.7 and do not have any of the exclusion criteria listed in 3.3.8.

3.3.7 **Inclusion criteria:**
- Aged range from 55 to 74 and 364 days;
- Willing and able to undergo LDCT; and
- PLCO$_{m2012}$ risk of ≥1.51% over 6 years or LLP$_{ver2}$ 5-year risk of ≥2.5%.

For the Targeted Lung Health Checks 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.

3.3.8 **Exclusion criteria:**
- Participant does not have capacity to give consent (standard criteria for assessing capacity apply);
- Full thoracic CT scan within the last 12 months or planned, for clinical reasons, in the next 3 months (Note, may still be included if CT essentially equates to a baseline scan and there are no other exclusion criteria);
- Weight exceeds restrictions for scanner (>200kg);
- Participant unable to lie flat; or
- 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.

3.3.9 Participants previously assessed at below the threshold for LDCT, but who may meet eligibility criteria as they become older and/or accumulate pack years of smoking, should be reassessed at 2-year intervals.

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

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[1] referred to as 'Race' in the original PLCO$_{M2012}$ risk model

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 a Lung Health Check, both eligible and ineligible participants should be offered spirometry and advised on smoking cessation. Some of these participants may then go on to a lung cancer screening CT scan.

3.4.3   Smoking cessation advice should be incorporated into written correspondence and should be face-to-face where participants attend. Enhanced smoking cessation interventions are also encouraged including the use of pharmacotherapy.

3.4.4   Current smokers not meeting the inclusion criteria for LDCT, should be offered smoking cessation support.

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 that:
- The primary purpose for undergoing CT is to identify lung cancer at a stage when there may be options for curative treatment. An estimated chance of finding a lung cancer should also be provided;
- 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 purpose of the scan is not to identify diseases other than lung cancer. However, 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 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;
- That cancer may be identified that would not have led to harm (over diagnosis);
- That there are some risks of harm relating to the further investigation and treatment of findings on the CT;

- That protocols will be followed that minimise harms from over diagnosis, further investigation and false positives; and
- That they will be asked to consent the retention of clinical data and radiological images for evaluation and future research purposes, under the correct governance procedures. (However, participants not wishing to provide this level of consent would not be stopped from participating in this programme.)

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 3.65 permit continuing with the LDCT screen.

3.6.2 Those presenting with respiratory infection should be booked in for a deferred appointment in 6 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 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; or
- 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; or
- thrombocytosis.

3.6.6 Those 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.

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 sixteen 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. Software updates should be recorded.

4.1.3   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 PACS systems, capable of automated image retrieval of historical imaging.

4.1.5   Other desirable features are high automated segmentation accuracy rates (>85%), automated volume doubling time calculation, and automated structured reporting.

4.1.6   If computer aided detection (CAD) systems are used, they should only 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 minimize 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 (≤1.25mm) will be used.

4.3 Exposure factors

4.3.1   Radiation exposures will be as low as possible whilst maintaining good image quality. The CT dose index (CTDIvol) must be kept as low as possible with the effective radiation dose well below 2 mSv. The kVp and mAs settings will be 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.

4.4 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 ≤ 1.25mm. An example of reconstruction parameters used in low-dose screening CT are outlined in table 2.

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 slice 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 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.

4.6 Thoracic CT reader

4.6.1   **Requirements**

Lung cancer screening CT reading requires both unique skills as well as those that overlap with clinical thoracic CT reading.
- Radiologist readers must regularly attend and lead at their local lung cancer MDT.
- Readers who do not lead the lung cancer MDT must report a substantial number of thoracic CTs annually as part of their normal clinical practice (>500), including a significant proportion of lung cancer CTs.
- 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.

- CT readers should attend education programmes on nodule management and LDCT screening as part of continuous professional development and training.

4.6.2 Quality Assurance

Each programme should have a documented quality assurance mechanism in place for CT reading. QA for CT reading may include:
- Stipulating and ensuring a minimum level of training and expertise of readers;
- Ensuring initial CT reads of radiologists without experience of LDCT screening are reviewed by more experienced readers (e.g. first 50 cases);
- Periodic review of CT readers reports by expert panels;
- Review of all initial MDT referrals of readers without experience of LDCT screening by more experienced readers; or
- Evaluation of all readers' recall rates, false positive rates and false negative rates, with identification of outliers.

4.6.3 Lung Nodule Characterisation

The nodule size threshold for characterization 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 should be reported as this determines scan interval in these nodules (see 4.6.3.1). At the last screen, all nodules including any new nodules should be reported as a further follow up LDCT may be indicated.

4.6.3.1 Nodules should be characterised in detail as follows (where multiple nodules are detected, at least two, including the largest should be characterised):
- Site (lobe, juxta-pleural, perifissural), volume, density and presence or absence of spiculation or a benign pattern of calcification.
- Nodule type should be classified as solid (SN), part-solid nodules (PSN) or pure ground glass nodules (pGGN).
- SN with benign features (such as popcorn calcification, intrapulmonary lymph nodes etc.) should be disregarded and may be mentioned in the report at the discretion of the reporter.
- The total number of nodules and other findings should be recorded.
- At follow up, nodules should be classified as old or new. New nodules should be differentiated from nodules present on prior CT, but previously ignored. There are different thresholds for nodule follow up for new nodules (section 5.1.2).
- Baseline scans that show nodule(s) that are <80mm^3 or 5mm max diameter should be classified as negative.

4.6.3.2 Readers should flag all cases where CTs are non-diagnostic or suboptimal (e.g.: due to motion artefact or inadequate coverage). Protocols should be in place for efficient recall of these participants.

4.6.4 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 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 nodules and a volume doubling time (VDT) calculated for each where an increase ≥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 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 Participants with a CT scans showing nodules are managed according to nodule size. Volumetry is the preferred method except where not possible, when the maximum axial diameter is used. Note size thresholds change where nodules were not previously seen on a previous CT. Box 1 shows how the nodule size affects follow-up interval and referral.

Box 1:

Baseline CT Nodule size (measure)	Interval CT(s)	Final CT
No nodules		24 months
<80mm^3 or <5mm max. diam.		24 months
≥80 to <300mm^3	3 months	12 months
≥6mm and <8mm max. diam. (volumetry not possible)	3 and 12 months	24 months
5 to 6 mm max. diam. (volumetry not possible)	12 months	24 months
≥300mm^3 or ≥8mm max. diam. and Brock risk <10%	3 months / 12 diam. only	12 months / 24 diam. only
≥300mm^3 or ≥8mm max. diam. and Brock risk ≥10%	Refer	
New nodules found on any interval CT		
<30mm^3 or <4mm max. diam.	No change to FU	
≥30mm^3 <300mm^3	3 months	12 months
≥4mm <8mm (volumetry not possible)	3 and 12 months	24 months
≥300mm^3/≥8mm	Refer	

5.1.3 Interval surveillance scans for stable PSN and pGGN should occur at 1, 2 and 5 years (the latter if annual or biennial screen not planned due to exit from the programme). For programmes that do not plan to scan beyond 1 or 2 years, appropriate handover and recommendations should be made to the local respiratory service for continued management of these nodules. Similar processes should be in place for continued management of new nodules identified at the end of the programme.

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 subject e.g. 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   Subjects 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 baseline).

6.2.2   Subjects 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, which may also include the pulmonary nodule MDT. Here the management of all findings other that 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 coordinated. 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 Nodule MDT; 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; and
- 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 (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 pGGN, any change in morphology or growth of solid component (≥2mm) 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 responsible radiologist 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 should prompt direct referral for admission to hospital by the LDCT targeted 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 (e.g. 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 (e.g. 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 (e.g. 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.

8 Communication of results

8.1 Process

8.1.1 Subjects 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 The outcome 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.

8.4 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 2 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.

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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 (IG) legislation. Audit trails will be in place in order to fully trace data entry and edit.

9.3 Inputting

9.3.1   Inputting of data will comply with information governance legislation.

9.4 Consent

9.4.1   Written consent will be obtained from participants.

9.4.2   At the time of consent participants will be informed of the purpose of data collection and intentions for its use.

9.5 Dataset

9.5.1   A minimum mandatory dataset has been agreed.

10 Evolution of the Standard Protocol for the Targeted Lung Health Checks 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 Targeted Lung Health Checks 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 Targeted Lung Health Checks 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 findings from 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.

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Appendix A

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

Acknowledgements