Classification: Official

Publication reference: PRN01867_ii



Targeted screening for lung cancer with low radiation dose computed tomography

Quality assurance standards prepared for the Lung Cancer Screening Programme

Version 3, 3 February 2025

Prepared with guidance from the Lung Clinical Expert Advisory Group

Changes from version 2 have been highlighted in yellow

Contents

Introduction	2
Standard 1: Lung cancer screening – nursing and support staff	3
Standard 2: Lung cancer screening – radiologists	5
Standard 3: Radiology hardware	7
Standard 4: Radiology software	8
Standard 5: Patient administration system software1	0
Standard 6: Data management1	1
Standard 7: Lung health checks programme pathway1	3
Standard 8: Participant communications1	5
Standard 9: General practice communications1	7
Standard 10: Smoking cessation1	8
Standard 12: Low dose CT referral1	9
Standard 13: Low dose CT reporting2	21
Standard 14: Quality assurance of low dose CT scans2	22
Standard 15: External quality assurance of radiologists2	25
Annex 1: Low dose CT reporting proforma2	27
Annex 2: Protocol for the management of incidental findings in lung cancer screening3	34
Table 1: Incidental findings, reporting and management, based on latest evidence*. 3	
Annex 3: National incidental findings pathways for targeted lung cancer screening 4	19

Introduction

- 1.1. The national Lung Cancer Screening Programme offers people aged 55 to 74 who have ever smoked the opportunity to have a lung health check; and for those at risk of lung cancer, a referral to lung cancer screening with a low-dose computed tomography (LDCT) scan of the chest. The programme contributes to the overall Long Term Plan early diagnosis of cancer ambition, stating that by 2028 the proportion of cancers diagnosed at stage one and two will rise to three quarters of cancer patients.
- 1.2. This document sets out 15 quality standards for the programme that together form the quality assurance framework for skills and training, information and communication, and clinical delivery. The quality standards assurance framework sets the standards for staffing, nurse and radiologist qualifications, experience and training, hardware, software, data management, communications, radiology acquisition and reporting, and follow on clinical management in secondary care.
- 1.3. Each standard relates to a specific part of the targeted lung health check pathway and cross references to the published <u>standard protocol</u>. Each standard sets out the objective, definition and metric, and the local and national assurance and audit process to demonstrate that each standard is being met.
- 1.4. The standard protocol outlines the four clinical roles each project must have in place to ensure the effective delivery of care and clinical governance of the programme. The <u>clinical director of programme</u> will work with the <u>responsible assessor</u>, <u>responsible radiologist</u> and <u>responsible clinician</u> to implement and monitor the 15 quality standards.
- 1.5. Each project will establish local processes to ensure the quality standards are continually met. The clinical director of programme will report against these standards on a quarterly basis to NHS England. An annual summary report should be drawn from this quarterly data, incorporating additional metrics better suited to annual review.

Standard 1: Lung cancer screening – nursing and support staff

Cross reference to Lung Cancer Screening Programme Standard Protocol – section 2.3.4.

1a. Description

This standard sets out the training and experience requirements for nurses and support staff who conduct lung health checks and manage the lung cancer screening programme.

1b. Objective

- To ensure that the project has the trained and skilled workforce with the capacity to deliver the programme.
- To ensure nurses and support staff delivering the Lung Cancer Screening Programme are qualified and competent.
- To ensure the service is safe and effective.

1c. Definition

Minimum qualifications for nurses:

- NHS Band 6 qualified.
- Registered with the Nursing and Midwifery Council.
- For those performing spirometry to Association for Respiratory Technology and Physiology (ARTP) guidelines, on the national spirometry register (relevant for all healthcare practitioners performing spirometry).

Minimum training course requirements for nurses:

- Communicating with high-risk individuals about lung cancer screening (offered nationally).
- Consent training (not offered nationally).
- Ionising radiation (medical exposure) regulations [IR(ME)R] for referrers (not offered nationally).
- Locally designed training covering telephone assessment process, call quality expectations and control measures, including identification of red flag symptoms.

Minimum qualifications for support staff:

NHS Band 3 qualified.

Minimum training course requirements for support staff:

- Communicating with high-risk individuals about lung cancer screening.
- Very Brief Advice (smoking cessation) training
- Locally designed training covering telephone assessment process, call quality expectations and control measures, including identification of red flag symptoms.

1d. Metric

- 100% of nurses and support staff conducting lung health checks meet the minimum qualifications and minimum training course requirements.
- 100% of those conducting spirometry are on the national spirometry register.
- A record is maintained to show the % of lung health checks that are re-categorised from low to high risk or vice versa following local audit.

1e. Local audit

The clinical director of the programme will ensure nurses and support staff providing direct care meet the minimum training standard and for practitioners performing spirometry. They will maintain a local minimum training and experience record for nurses and other healthcare practitioners. The quality assurance process should include an audit of the accuracy of 50 or 1% (whichever is smaller) of telephone screening assessments conducted per quarter.

1f. National audit

The clinical director of the programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

Training courses

Training courses are available to demonstrate competence to perform lung health checks, spirometry and to meet the IR(ME)R regulations for referral to computerised tomography (CT).

Standard 2: Lung cancer screening – radiologists

Cross reference to Lung Cancer Screening Programme Standard Protocol – section 4.6.1.

2a. Description

This standard sets out the training and experience requirements for radiologists who report low dose CT lung cancer screening scans for the Lung Cancer Screening Programme.

2b. Objective

- To ensure that the project has the trained and skilled workforce with the capacity to deliver the programme.
- To ensure consultant radiologists reporting low dose CT lung cancer screening are qualified and competent.
- To ensure the service is safe and effective.

2c. Definition

Minimum qualifications for consultant radiologists:

- Registered with the General Medical Council (GMC).
- Fellow of the Royal College of Radiologists (RCR).
 - In the absence of the above qualifications, consultant radiologists who:
 - are on the General Medical Council (GMC) Specialist Register; or
 - have radiology training and qualification accepted for equivalence which has led to the award of a Certificate of Eligibility for Specialist Registration (CESR)
 - can report for the programme subject to approval by the clinical director and responsible radiologist of the project

Minimum training course requirements:

Lung Nodule Identification Workshop (run by NHS England).

Minimum experience:

- Reporting a minimum of 500 thoracic CTs per annum in their routine clinical practice
 - a significant proportion of the CTs are where there is a suspicion of lung cancer.

• Regular participation at a thoracic multidisciplinary training (MDT) meeting (includes virtual attendance) as part of their routine clinical work.

The responsible radiologist must be satisfied that evidence of all the above has been provided before a radiologist is permitted to report for the programme.

2d. Metric

• 100% of consultant radiologists reporting thoracic low dose CT scans for the Lung Cancer Screening Programme meet the minimum requirements.

2e. Local audit

The responsible radiologist will ensure reporting radiologists always meets the minimum standard. They will maintain a local minimum training and experience record for radiologists reporting low dose CT scans for the programme.

2f. National audit

The clinical director of the programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

Training course: Lung nodule workshop

The British Society of Thoracic Imaging (BSTI) provides training events for radiologists to gain specific competency and experience in reading low dose CT lung cancer screening scans.

Standard 3: Radiology hardware

Cross reference to <u>Lung Cancer Screening Programme Standard Protocol</u> – sections 4.1.1 and 4.3.1.

3a. Description

This standard sets out the hardware requirements for CT scanners used to deliver the Lung Cancer Screening Programme.

3b. Objective

- To ensure CT scanning equipment is safe and effective.
- To ensure harm from radiation is minimised by using as low a dose of radiation as possible.
- To ensure image quality will allow radiologists to detect lung cancers.

3c. Definition

Minimum standard:

- 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.
- The calculated radiation dose delivered to each individual is below 2 mSv (based on a median standard 70kg adult).

3d. Metric

- Medical physics expert's (MPE) confirmation that the scanner meets the minimum standard.
- 100% of radiation doses meet the minimum standard.

3e. Local audit

The local MPE will perform regular radiation dose audit. The responsible radiologist will work with the local MPE to ensure the low dose CT scanner always meets the minimum standard.

3f. National audit

The clinical director of programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

Standard 4: Radiology software

Cross reference to <u>Lung Cancer Screening Programme Standard Protocol</u> – sections 4.1 and 4.4.

4a. Description

This standard sets out the software requirements for reporting low dose CT scans.

4b. Objective

- To ensure the reporting radiology environment and process is efficient, using software that assists in producing rapid and accurate reports.
- To ensure auto-population of participant demographic data, scan parameter data, Brock scores and dates of scans into reporting proforma to prevent human error and reduce reporting time.

4c. Definition

Analysis and reporting software, including voice recognition reporting software, is compatible with data acquisition requirements. Volumetric software used for assessment of pulmonary nodules remains constant to allow accurate comparison of volumes.

If software upgrades or changes are made the new software will remeasure the old and follow up nodules unless data is available to demonstrate consistency between models.

Minimum standard:

- Computer-aided detection.
- Nodule volumetry software that automatically detects nodules and measures volume.
- Ability to retrieve and compare any previous CT imaging.

Desirable standard:

• Facilitates double reads.

4d. Metric

• 100% of image reconstruction is standardised and used for any subsequent followup examinations where possible with emphasis on ensuring that slice thickness, reconstruction increment, reconstruction algorithm is identical. • 100% of slice thickness are ≤ 1.25mm.¹

4e. Local audit

The responsible radiologist will ensure the reporting software always meets the minimum standard.

4f. National audit

The clinical director of programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

¹ Examples of reconstruction parameters used in low-dose screening CT for moderate spatial frequency/soft tissue are: reconstruction slice thickness 1mm; reconstruction increment 0.7mm; reconstruction FOV of the entire lung parenchyma.

Standard 5: Patient administration system software

Cross reference to Lung Cancer Screening Programme <u>Standard Protocol</u> – section 3.

5a. Description

This standard sets out the software requirements for the patient administration system that projects will use to call and re-call participants invited to the Lung Cancer Screening Programme.

5b. Objective

- To ensure participants invited and all subsequent appointments are managed through an auditable patient administration system.
- To prevent harm to participants caused by failure to recall or to follow up on findings.

5c. Definition

Patient administration software will support participant administration that is reliable and delivers a consistent process which facilitates recall, governance, audit and evaluation. Software should align with the minimum requirements set out in any specification provided by the national team.

5d. Metric

• Patient administration system and software meets the minimum standard.

5e. Local audit

The responsible assessor will ensure the patient administration systems used to deliver the lung health checks programme meet the minimum standard.

5f. National audit

The clinical director of the programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

Standard 6: Data management

Cross reference to Lung Cancer Screening Programme <u>Standard Protocol</u> – section 9.

6a. Description

Standard sets out what data sharing agreements and pseudonymisation processes are in place to control and manage participant data.

6b. Objective

- To ensure data processing agreements and data sharing agreements are in place to direct how participant data is recorded, handled and used to deliver the Lung Cancer Screening Programme.
- To ensure the confidentiality of participant data.
- To ensure relevant data is pseudonymised.
- To ensure that processes are accessible to future research requests.

6c. Definition

Projects will ensure local Data Protection Impact Assessments (DPIAs), Data Processing Agreements (DPAs) and Data Sharing Agreements (DSAs) are agreed, detailing how data is collected and used to deliver the project, and shared with Data Services for Commissioners Regional Offices (DSCRO).

The projects will work with the DSCRO to establish a process to pseudonymise the minimum dataset. DPIA and DSA will be considerate of the need for future accessibility of data that may be required for research purposes.

6d. Metric

- Any necessary Data Processing Agreements agreed.
- Data Sharing Agreements agreed.
- 100% adherence to local and national DPIA processes, including pseudonymisation.

6e. Local audit

The clinical director of the programme will ensure that data management always meets the minimum standard.

6f. National audit

The clinical director of the programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

Standard 7: Lung health checks programme pathway

Cross reference to Lung Cancer Screening Programme Standard Protocol – sections 3 to 8.

7a. Description

This standard sets out what will happen in the lung health checks pathway from the identification of eligible participants, the lung health check, lung cancer risk assessment, smoking cessation and low dose CT scanning through to follow up.

7b. Objective

- To ensure the clinical teams adhere to and ensure accuracy across the lung health checks programme pathway.
- To ensure all participants receive the same level of interventions and care, and opportunities for face to face conversations about lifestyle changes and especially smoking cessation, are maximised.

7c. Definition

The lung health checks programme pathway is shown in figure 1 over the page:

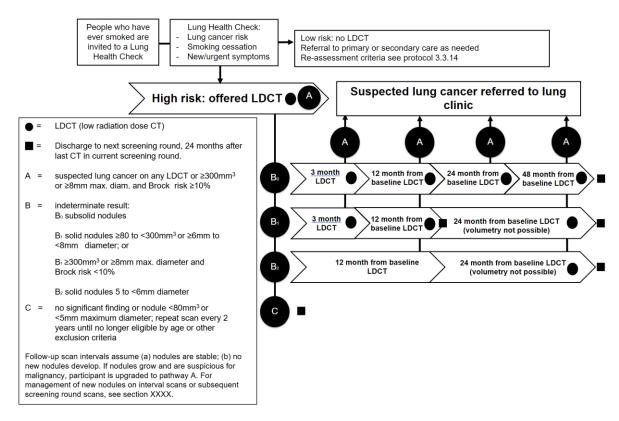


Figure 1: Lung health checks programme pathway

7d. Metric

• 100% of participants follow the lung health checks programme pathway.

7e. Local audit

The responsible assessor will ensure participants follow the lung health checks programme pathway and that the lung health check always meets the minimum standard.

7f. National audit

The clinical director of programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

Standard 8: Participant communications

Cross reference to <u>Lung Cancer Screening Programme Standard Protocol</u> – sections 3.1, 3.4 and 8.

8a. Description

This standard sets out what information participants will receive: from the point of invitation, results and onward referral, up to the point of discharge.

8b. Objective

- To ensure that the site accurately identifies the population eligible for targeted screening.
- To ensure participants are provided with information to allow them to make an informed decision to maximise uptake in the eligible population.
- To ensure communication relating to invitation approach, results, referrals and discharge is consistent across the programme to maximise informed choice at each step of the pathway.

8c. Definition

The issuing of the standard letters² and the participant booklet is detailed in figure 2 over the page:

² The standard letters and participant booklet are available on request from <u>england.TLHC@nhs.net</u>.

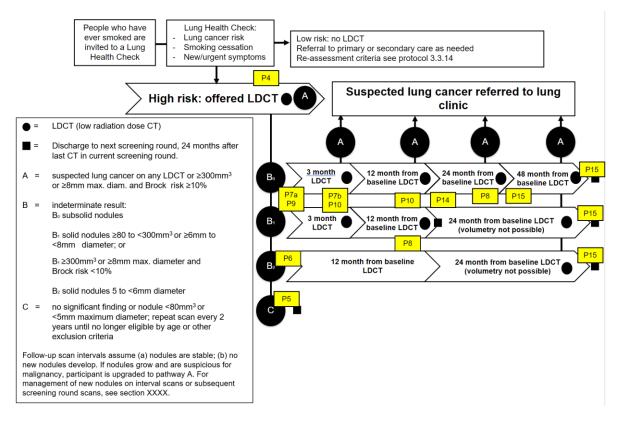


Figure 2: Issuing of standard letters and participant booklet

8d. Metric

- 100% of participants will receive the standard letters and the standard booklet at the correct point in the pathway.
- 100% of participants who attend the lung health check or have a CT scan will receive an outcome letter within 28 days of an appointment
- 100% of participants who receive a technically adequate LDCT will receive an outcome letter within 28 days of LDCT acquisition.

8e. Local audit

The responsible assessor will ensure that communication methods always meet the standard.

8f. National audit

The clinical director of the programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

Standard 9: General practice communications

Cross reference to Lung Cancer Screening Programme <u>Standard Protocol</u> – sections 3.1, 3.4 and 8.

9a. Description

This standard sets out what information a participant's GP will receive.

9b. Objective

- To ensure that GPs have all the information on whether a participant attended a lung health check, the outcome of this and subsequent follow up.
- To ensure the effective management of significant incidental findings that are agreed locally and set out in project clinical pathways.

9c. Definition

Letters to a participant's GP must include details of new results from the lung health check appointment (lung health check assessment, risk assessment, and smoking cessation or any other lifestyle advice), relevant low dose CT scan information and the plan of care. The issuing of the standard letters³ to GPs is detailed in figure 2 above.

9d. Metric

- 100% of GP letters includes the minimum standard information.
- 100% of GP letters are sent within 28 days of the participant attending an appointment or scan.

9e. Local audit

The responsible assessor will ensure that the minimum standard is always met.

9f. National audit

The clinical director of the programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

17 | QA standards prepared for the Lung Cancer Screening Programme by the Lung Clinical Expert Advisory Group

³ The standard template is available on request from <u>england.cancerpolicy@nhs.net</u>.

Standard 10: Smoking cessation

Cross reference to <u>Lung Cancer Screening Programme Standard Protocol</u> – sections 3.2.2 and 3.4.

10a. Description

This standard sets out the expectations for offering smoking cessation interventions as part of the Lung Cancer Screening Programme.

10b. Objective

- To ensure the opportunities for educating, counselling and supporting participants to quit smoking are maximised.
- To ensure lung health check nurses offer opt-out referral to local smoking cessation services to participants that are current smokers.
 - Smoking cessation support should be offered to all participants at their lung health check, including those who are ineligible for LDCT.
 - Where possible this should be provided in the immediate lung health check setting and include offer of pharmacotherapy.

10c. Definition

The uptake of smoking cessation courses and quit rates.

10d. Metric

• 100% of current smokers that attend a lung health check are offered a smoking cessation intervention.

10e. Local audit

The responsible assessor will ensure that smoking cessation interventions are offered to all current smokers who attend a lung health check.

10f. National audit

The clinical director of programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

Standard 12: Low dose CT referral

Cross reference to Lung Cancer Screening Programme Standard Protocol – section 3.3.

12a. Description

This standard sets out how participants with a positive lung cancer risk score are identified and referred for a low dose CT scan.

12b. Objective

- To ensure only participants that are at risk of lung cancer are referred for a low dose CT scan.
- To ensure that the CT scan is acquired at the earliest opportunity following the lung health check appointment.
- To ensure follow up CT scans are acquired as detailed in the participant's clinical record.

12c. Definition

A participant will proceed to lung cancer screening if they meet the minimum threshold of either the Liverpool Lung Project or the Prostate Lung Colorectal and Ovarian risk prediction tool. Each tool assesses risk as follows:

Liverpool Lung Project (LLPv2) ≥2.5% risk of lung cancer over five years

or:

 Prostate Lung Colorectal and Ovarian or (PLCO_{m2012}) ≥1.51% risk of lung cancer over six years.

A participant who scores positive using either risk prediction model and does not meet any of the exclusion criteria will receive a low dose CT scan within 56 days of their lung health check.

Participants who require a follow up surveillance low dose CT scan will receive this within 28 days after the target date for the scan.

Participants invited for a subsequent screening round scan should receive this within 56 days before or after their planned date for the routine screening round.

12d. Metrics

- 100% of those referred for a low dose CT scan have a risk prediction score of LLPv2
 ≥2.5% over five years or PLCO_{m2012} ≥1.51% risk of lung cancer over six years.
- Percentage of participants who have the CT scan on the same day as their lung health check.
- For those who do not have same day CT, the length of time from lung health check to CT scan in days.
- Audit follow up surveillance scans that are not are completed within the 28-day window after target surveillance follow up scan date.

Audit incident screening round scans that are not completed withing 56 days of the target screening round scan date.

12e. Local audit

The responsible radiologist will ensure that the referral for lung cancer screening always meets the minimum standard. The responsible assessor will audit all participants that have a surveillance follow-up scan outside the 28-day window, or incident screening round scans beyond 56 days from the target date, and agree an action plan to reduce the number of scans acquired off plan.

12f. National audit

The clinical director of the programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

Standard 13: Low dose CT reporting

Cross reference to Lung Cancer Screening Programme Standard Protocol – section 4.6.

13a. Description

This standard sets out how low dose CT scans are reported.

13b. Objective

- To ensure reporting of low dose CT scans are consistent and standardised.
- To ensure radiologists clinically report, using the incidental findings guidance for each participant.

13c. Definition

Radiologists will use the low dose CT reporting proforma in Annex 1. Radiologists will report incidental findings using the guidance in Annex 2.

The overall target for referral is <15%. The referral rate is a combination of referrals for suspected lung cancer via fast track clinic, including nodules requiring work-up other than additional LDCT (eg PET-CT), target <7% [Annex 1, nodules 1-3]; and referral for significant incidental findings (<8%) [Annex 1, nodules 1, 4]. Significant incidental findings are defined in Annex 2 along with non-significant incidental findings.

13d. Metric

- 100% of CT reports for the Targeted Lung Health Check programme contain the information detailed in the CT reporting proforma.
- 100% of radiologists use the incidental finding management protocol to inform interpretation of low dose CT scans.
- Overall project referral rates are <15%.

13e. Local audit

The responsible radiologist will ensure that reporting proforma and management of incidental findings process is followed, and that the overall referral rates are <15%.

13f. National audit

The clinical director of programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and through the quarterly quality assurance process.

Standard 14: Quality assurance of low dose CT scans

Cross reference to <u>Lung Cancer Screening Programme Standard Protocol</u> – sections 4.3 and 4.6.2.

14a. Description

This standard sets out the quality assurance of the acquisition and reporting of low dose CT scans.

14b. Objective

- To ensure participants receive low dose CT scans of diagnostic quality with no excessive radiation.
- To ensure radiologists are supported by peers to improve the quality of reporting low dose CT scans.

14c. Definition

- Acquisition of low dose CT scans:
 - Standard 3 defines the acquisition requirements that radiographers must adhere to.
- Double reporting:
 - the first 25 CT scans reported by each radiologist in a lung health check programme are double read. Double reading is performed by radiologists within the same lung health check programme. Where there are discrepancies between reporting decisions, the responsible radiologist should discuss with the clinical director of programme to agree the mechanism for arbitration.
- Quarterly and annual reviews:
 - the responsible radiologist will review reporting performance on a quarterly and annual basis. They will work with the clinical director of programme to support radiologists who are outliers.

14d. Metric

100% of scans are of diagnostic quality

- Audit and review the non-diagnostic CT quality rate.
- Audit and review reasons for all radiation doses greater than 2 mSv.

100% of reporting radiologists have quarterly and annual reviews.

Quarterly review

Audit the mean, standard deviation, median, interquartile and range of the following metrics for each radiologist:

- numbers reported
- recall rates to secondary care for nodules
- recall rates to secondary care for incidental findings
- number of referrals considered inappropriate by the screening or lung cancer MDT (for direct feedback)
- number of additional investigations generated for incidental findings per participant
- number of PET-CTs performed
- benign biopsies
- benign resections
- interval cancer rates
- sensitivity
- specificity.

Annual review

In addition to the quarterly metrics, includes a review of:

- training and experience standards (Standard 2)
- the number of screening scans reported per programmed activity
- incidental finding rate, divided into non-significant incidental findings and significant incidental findings
- lung nodule rate, the number and percentage of:
 - nodules referred for investigation in secondary care
 - indeterminate nodules requiring additional LDCT surveillance at a rate of 11-20%
 [Annex 1, nodules 1-3]
 - nodules requiring no action (false positives).

100% of outliers, as defined from a quarterly or annual review, will have evidence of agreed actions (including a period of double reporting) with the responsible radiologists.

14e. Local audit

The responsible radiologist will ensure that the quality assurance of the acquisition and reporting low dose CT is followed, and quarterly and annual reviews are completed. The responsible radiologist and responsible clinician will compile an annual report on the mean, standard deviation, median, interquartile and range of the aggregate quarterly metrics.

14f. National audit

The clinical director of programme will report quarterly against this standard to the Lung Cancer Screening Programme Delivery Group and submit an annual quality assurance report on the acquisition and reporting of low dose CT scans.

Standard 15: External quality assurance of radiologists

15a. Description

Reporting radiologists will undertake an annual external quality assurance programme (PERFECTS) to read low dose CT scans. This will involve radiologists completing 100 exercises with the results used to benchmark reporting of radiologists with peers. The programme will establish a feedback loop to measure the ongoing quality of radiologists reporting practices.

15a. Objective

To ensure reporting of low dose CT scans is evaluated to flag outliers who have high rates of recalls and high rates of interval cancers being detected. To ensure radiologists that are outliers receive training and ongoing support overseen by the responsible radiologist and clinical director of the programme.

15b. Definition

Any radiologist reporting on the Targeted Lung Health Check programme must complete the PERFECTS assessment at least once a year to be able to continue reporting on the programme.

The assessment involves tasks focused on; detection and interpretation; focused interpretation and baseline nodule management; and nodule management at follow up. It takes between 4 and 6 hours to complete and can be completed in stages.

15c. Metrics

 100% of radiologists reporting complete the PERFECTS assessment at least once per year (newly reporting radiologists starting after the annual deadline should complete PERFECTS within 3 months of starting)

15d. Local audit

The responsible radiologist is responsible for ensuring that all radiologists reporting on the programme have completed PERFECTS training. The responsible radiologist will receive

notification of any radiologists that are outliers and who may need additional support or training.

15e. National audit

The clinical director of the programme will report quarterly against this standard to the Lung Cancer Screening Delivery Group and through the quarterly quality assurance process.

Annex 1: Low dose CT reporting proforma

This reporting template captures all findings in a structured format and provides an example of how this may look. Radiology departments will use this annex to create a structured automated report template in the radiology reporting system currently or hosted as an electronic form.

Commercially available lung cancer screening reporting software will report nodule and other findings in a PDF format and a digital imaging and communications in medicine (DICOM) capture object.

Radiologists will need to report incidental findings not included in the reports from the commercial software once transferred to the picture archiving and communications system (PACS) or exported in an extended markup language (XML) format.

In setting up the programme, the responsible radiologist, the clinical director of programme, local PACS and information technology teams will agree which format is used to capture, store and communicate the report.

Field description	Variable input options	Type of input ⁴
Radiologist	Name	Autopopulated
GMC Number	GMC Number	Autopopulated
Site of LDCT	Autopopulated from DICOM descriptor (StationName, DICOM tag 0008,1010) for the individual CT scanner	Autopopulated
Type of scan	Baseline/ 3 month/ 12 month/ 24 month	Dropdown
Date of Scan	Autopopulated from DICOM descriptor (StudyDate, DICOM tag 0008, 0020)	Autopopulated
Date of Report	Autopopulated from Reporting Solution	Autopopulated
Was computer-aided detection (CAD) available?	Yes/ No - software failed to process study/ No - other (specify)	Dropdown
Scan quality	Adequate/Inadequate due to breathing artefact/Inadequate coverage	Dropdown
Participant Name	Autopopulated from DICOM descriptor (PatientName, DICOM tag 0010,0010)	Autopopulated
Participant unique ID	Autopopulated from DICOM descriptor (PatientID, DICOM tag 0010,0020)- should be NHS number	Autopopulated
Age	Autopopulated from XML from nodule reading software or calculated from DICOM (date of current scan- date of birth)	Autopopulated
Sex	Autopopulated	Autopopulated
History of Extra-Thoracic cancer	No/Yes	Dropdown
Family history of lung cancer ⁵	No/Yes	Dropdown
Nodule1		
Nodule1_sliceNo	Slice from series used for volumetry	Free text
Nodule1_Volumetry reliable?	Yes/No	Dropdown
Nodule1_Nodule size (mm3)	Nodule volume	Free text

⁴ Type of inputs: "dropdown" denotes a field where variables could be inputted as a dropdown menu for the reporting radiologist to choose the correct option, where the reporting tool allows for such a function.
⁵ Include 'History of extrathoracic cancer' and 'Family history of cancer' into the referral for low dose CT, as this information is required by the reporting radiologist. This could be done by, for example, ensuring this information is visible in the electronic or paper request form used to request the CT, or providing access to the lung health check questionnaire answers provided by the participant.

Field description	Variable input options	Type of input ⁴
Nodule1_maximum diameter (mm)	Nodule longest diameter	Free text
Nodule1_Nodule type	pure ground-glass/part-solid/solid/ IPLN/inflammatory consolidation	Dropdown
Nodule1_Lobe	RUL/RML/RLL/LUL/LLL	Dropdown
Nodule1_Position	intraparenchymal/subpleural/endobronchial	Dropdown
Nodule1_Spiculated	No/Yes	Dropdown
Nodule1_suspicious features	none/bubble-like appearance/ air bronchogram/ pleural indentation/ pleural retraction/ cyst with irregular wall	Dropdown
(multiple selections possible)		
Nodule1_Brock score ⁶	Brock score	Autopopulated
Nodule1_change assessment	Growth (Volume change from baseline >25% if volume reliable=Yes, OR diameter change>2mm if volume reliable=No)/ stable/ shrinking/ resolved/ NEW	Dropdown
Nodule1_VDT (days)	Volume doubling time from baseline	Free text
Use same reporting fields	for Nodule 2, 3 and 4 (if applicable)	
Nodule2_sliceNo	Slice from series used for volumetry	Free text
Nodule2_Volumetry reliable?	Yes/No	Dropdown
Nodule2_Nodule size (mm3)	Nodule volume	Free text
Nodule2_Nodule maximum	Nodule longest diameter	Free text

Nodule2_Nodule maximum diameter (mm)	Nodule longest diameter	Free text
Nodule2_Nodule type	pure ground-glass/part-solid/solid/ IPLN/inflammatory	Dropdown
Nodule2_Lobe	RUL/RML/RLL/LUL/LLL	Dropdown
Nodule2_Position	intraparenchymal/subpleural/endobronchial	Dropdown
Nodule2_Spiculated	No/Yes	Dropdown
Nodule2_ suspicious features	none/bubble-like appearance/ air bronchogram/ pleural indentation/ pleural retraction/ cyst with irregular wall	Dropdown
(multiple selections possible)		
Nodule2_Brock score ⁶	Brock score	Autopopulated

⁶ Brock score is calculated automatically in commercial lung cancer screening reporting software.

Field description	Variable input options	Type of input ⁴
Nodule2_change assessment	Growth (Volume change from baseline >25% if volume reliable=Yes, OR diameter change>2mm if volume reliable=No)/stable/ shrinking/ resolved/NEW	Dropdown
Nodule2_VDT (days)	Volume doubling time from baseline	Free text
Nodule3		
Nodule3_sliceNo	Slice from series used for volumetry	Free text
Nodule3_Volumetry reliable?	Yes/No	Dropdown
Nodule3_Nodule size (mm3)	Nodule volume	Free text
Nodule3_Nodule maximum diameter (mm)	Nodule longest diameter	Free text
Nodule3_Nodule type	pure ground-glass/ part-solid/ solid/ IPLN/inflammatory	Dropdown
Nodule3_Lobe	RUL/RML/RLL/LUL/LLL	Dropdown
Nodule3_Position	intraparenchymal/subpleural/endobronchial	Dropdown
Nodule3_Spiculated	No/Yes	Dropdown
Nodule3_ suspicious features	none/bubble-like appearance/ air bronchogram/ pleural indentation/ pleural retraction/ cyst with irregular wall	Dropdown
(multiple selections possible)		
Nodule3_Brock score ⁶	Brock score	Autopopulated
Nodule3_change assessment	Growth (Volume change from baseline >25% if volume reliable=Yes, OR diameter change>2mm if volume reliable=No)/stable/ shrinking/ resolved/NEW	Dropdown
Nodule3_VDT (days)	Volume doubling time from baseline	Free text
Nodule4		
Nodule4_sliceNo	Slice from series used for volumetry	Free text
Nodule4_Volumetry reliable?	Yes/No	Dropdown
Nodule4_Nodule size (mm3)	Nodule volume	Free text
Nodule4_Nodule maximum diameter (mm)	Nodule longest diameter	Free text
Nodule4_Nodule type	pure ground-glass/part-solid/solid/ IPLN/inflammatory	Dropdown

Field description	Variable input options	Type of input ⁴
Nodule4_Lobe	RUL/RML/RLL/LUL/LLL	Dropdown
Nodule4_Position	intraparenchymal/subpleural/endobronchial	Dropdown
Nodule4_Spiculated	No/Yes	Dropdown
Nodule4_ suspicious features	none/ bubble-like appearance/ air bronchogram/ pleural indentation/ pleural retraction/ cyst with irregular wall	Dropdown
(multiple selections possible)		
Nodule4_Brock score ⁶	Brock score	Autopopulated
Nodule4_change assessment	Growth (Volume change from baseline >25% if volume reliable=Yes, OR diameter change>2mm if volume reliable=No)/stable/ shrinking/ resolved/NEW	Dropdown
Nodule4_VDT (days)	Volume doubling time from baseline	Free text
Total number of nodules detected	0/ 1/ 2/ 3/ 4/ other-free text for maximum number	Dropdown
Emphysema extent ^₅	None/mild (<25%)/ moderate (25-50%)/ severe (>50%)	Dropdown
Emphysema predominant type ⁶	None/centrilobular/ paraseptal/ panacinar	Dropdown
Highest Brock score	Highest Brock score from four reported nodules	Autopopulated
Are there incidental pulmonary findings?	No/ Yes	Dropdown
Bronchiectasis	None/ Mild (airways 1.5- 2X size of artery)/ moderate (airways 2-3X size artery/ severe (>3X size of artery AND >1segment)	Dropdown
Respiratory-Bronchiolitis	Absent/Present	Dropdown
Interstitial lung abnormalities (ILA)	None or ILA other than reticulation/ <5% reticulation of total lung volume/ 5-10% reticulation of total lung volume/ >10% of total lung volume	Dropdown
Infective consolidation	No/ Yes	Dropdown
Active Tuberculosis	No/ Yes	Dropdown
Are there incidental intrathoracic findings?	No/ Yes	Dropdown
Mediastinal mass present?	Absent/Present	Dropdown
Mediastinal mass_description	Report position, density and size (use this to describe large lymph nodes that require referral as well)	Free text
Coronary calcification ⁶	None/ Mild/ Moderate/ Severe	Dropdown

Field description	Variable input options	Type of input ⁴
Aortic valve calcification	None/ Moderate/ Severe	Dropdown
Thoracic Aortic aneurysm	None/ <4cm/ 4.0cm-5.5cm/ >5.5cm	Dropdown
Pleural effusion/thickening or mass	Absent/ Unilateral right/ Unilateral left/bilateral	Dropdown
Pleural effusion or thickening_description	Describe findings (use this to describe unusual lesions eg schwannoma)	Free text
Are there incidental extrathoracic findings?	No/Yes	Dropdown
Suspicious Breast lesion	Describe size, position and suspicious feature(s)	Free text
Suspicious thyroid lesion	Describe size, position and suspicious feature(s)	Free text
Liver or splenic lesion	benign/indeterminate and potentially malignant (ill- defined margin, heterogeneous density, mural thickening or nodularity, thick septa)	Dropdown
Liver or splenic lesion_description	Describe size, position and suspicious feature(s)	Free text
Renal lesion	benign (too small to characterise or homogeneous)/ benign (homogeneous -10 to 20HU: thin or imperceptible wall, no mural nodule, septa or calcification)/benign (homogeneous >=70HU : thin or imperceptible wall, no mural nodule, septa or calcification)/benign (solitary, contains ROI <-10HU AND no calcification AND <4cm)/indeterminate and potentially malignant (homogeneous 21-69HU : thin or imperceptible wall, no mural nodule, septa or calcification)/ indeterminate and potentially malignant (heterogeneous, thick or irregular wall, mural nodule, septa or calcification); indeterminate and potentially malignant (solitary, contains ROI <-10HU AND calcification); indeterminate and potentially malignant (solitary, contains ROI <-10HU AND calcification); indeterminate and potentially malignant (multiple, contains ROI <-10HU AND calcification); indeterminate and potentially malignant (solitary AND no calcification AND SIZE >=4cm)	Dropdown
Renal lesion_description	Describe size, position and suspicious feature(s)	Free text
Adrenal lesion	Benign (<10HU and <1cm); indeterminate	Dropdown
Adrenal lesion_description	Describe size, position and suspicious feature(s)	Free text
Abdominal aortic aneurysm	None/ 3-5cm/ >5cm	Dropdown
Bones	None/ osteoporotic fracture <=50%/ osteoporotic fracture >50%/ malignant lytic or sclerotic features	Dropdown

Field description	Variable input options	Type of input ⁴
Is there any other urgent finding?	No/Yes	Dropdown
Urgent finding description	Description of urgent finding	Free text
Follow up recommendation_nodules	Urgent referral to lung cancer MDT Refer to Screening Review Meeting-specify reason Interval LDCT at 3 months Interval LDCT at 12 months Interval LDCT at 24 months	Dropdown (multiple selections not allowed) Free text for specifying reason
Follow-up recommendation_other	Urgent referral to other cancer MDT- specify which Urgent referral to other non-cancer team-specify which Refer to Chest Clinic Refer to Tuberculosis service GP action required Specify MDT or GP action for incidental finding requiring action, as per NHS England protocol (see Annex 2)	Dropdown (multiple selections allowed) Free text for specifying reason

Annex 2: Protocol for the management of incidental findings in lung cancer screening

Background

Screening for lung cancer with low-radiation dose computed tomography (LDCT) detects thoracic and extrathoracic radiological findings indicative of conditions other than lung cancer. These are termed incidental findings (IFs). IFs may be clinically significant, but it is important to distinguish them from the purpose of the screening programme which is to detect early-stage lung cancer. The reasons for making this distinction are multiple:

- The screening test (LDCT) is not optimised for the detection of IFs and there is no certainty that they will either be sought or found because of this.
- Where there is a threshold for reporting it may be subjectively judged on the LDCT, so reporting may be variable and precision reduced compared with screening-related findings for which the LDCT is optimised.
- There is often insufficient evidence to allow us to know whether IFs detected in asymptomatic participants in a screening programme cause more good than harm¹.
- Investigation of IFs leads to additional costs, which may impair the cost-effectiveness
 of a screening programme in the absence of associated benefits, although the costs
 are not necessarily borne by the screening programme.

This document sets out to clarify the above points to maximise potential benefit and minimise harm, according to the available evidence and guidelines¹⁻⁴. The authors are primarily clinicians, and are listed on page 11. This document has been approved by the Lung Cancer Screening Expert Advisory Group.

IFs are a common finding on LDCT with the majority being emphysema (~30% of all findings) and coronary artery calcification (~58% of all findings), both to be expected given the link with smoking^{5,6}. IFs may be clinically non-significant and/or not associated with any treatments that lead to beneficial outcomes^{5,7}. Identification of IFs may result in investigations that use healthcare resources with limited or no participant benefit. Therefore, it is imperative that processes are in place that minimise referral of and/or action on clinically non-significant IFs, whilst using the opportunity to identify those IFs for which there is a beneficial intervention that improves patient outcomes. Research evidence has not identified a significant lasting impact on quality of life from the detection of IFs^{8,9} although indeterminate findings are associated with transient distress^{10,11}.

National protocol for management of incidental findings

An NHS England Standard Protocol for the Lung Cancer Screening Programme was published in January 2019 and last updated in 2024, it sets out principles for the management of IFs¹² as follows:

- The finding should be clinically significant.
- Clinically non-significant findings should not be reported to the GP or participant.
- There should be agreement between the local screening programme and primary care as to the nature and benefit of the recommended interventions.
- Recommendations for clinical correlation with symptoms by primary care of CT findings should be specific and only made where there is the potential for benefit.

The protocol recommends that IFs should be categorised as:

- Life threatening (warranting direct hospital admission).
- Urgent (mandating urgent referral, including findings indicative of cancer).
- Non-urgent findings (warranting primary or secondary care referral).
- Clinically non-significant findings (that do not require communication and are usually not included in the radiology report, see Table 1)

The European societies for radiology, respiratory medicine, thoracic surgeons and nuclear medicine jointly published a systematic review and clinical practice statement on IFs in lung cancer screening in 2023¹. This emphasises the importance of establishing which findings have evidence supporting an impact or change to participant management.

Role of Responsible Radiologist

Within each local programme, a Responsible Radiologist (RR) provides ultimate responsibility for the reporting of LDCT scans including the reporting of IFs. The management of the majority of IFs is currently dictated by the LCSP Standard Protocol and Quality Assurance Standards^{12,13}. In cases of uncertainty, or where the management of an IF is not specified, radiologists will refer cases to a local multidisciplinary team (MDT) meeting, which should be a dedicated lung cancer screening review meeting (SRM). The RR should lead and/or have oversight of the radiological aspects of such meetings. In this context, and in conjunction with the responsible clinician (RC), the RR will be accountable for decisions made regarding IFs referred to the MDT/SRM.

The RR will also be responsible for quality assurance aspects of radiology reporting, including monitoring of total number and rate of IF reporting on a per radiologist basis and on an aggregate basis within a local programme.

The RR will be responsible for feedback to local reporting radiologists, particularly where individual radiologists are outliers with respect to the number of IFs reported, and/or the reporting of specific IFs. The RR is responsible for the education and training of reporting radiologists, through local governance meetings, screening quality assurance meetings and national external quality assurance. Where individual radiologists are found to be outliers, there should be feedback, potentially re-training and a re-evaluation against guidelines.

Legal aspects

Concern about being subject to litigation may influence the approach to IFs such that clinically non-significant conditions or those without beneficial interventions are more often flagged. This relates to the management of findings that might, potentially, be a source of litigation even though the chance of that is low. This is not the same as a missed lesion (including cancer) where the "miss" is confirmed and confers harm. The latter should be avoided through training and sound radiology practice. The considerations below relate to the decision to flag a detected IF.

LDCT is designed to detect lung cancer and is suboptimal for the detection of many IFs.

In relation to the decision to flag an IF, the two main legal issues that may be open to complaints and negligence claims are firstly the failure to flag an IF that would be harmful if not treated, and treatment would have been possible; and secondly identification of a finding that is itself harmless, but the consequence of identification is harmful. The consequences of the first issue, in relation to complaints, is that there might be a negligence claim on the grounds that the harm was known, and their failure to disclose/report that information might have delayed the patient's access to treatment.

All staff should be clear about what information the screening test can and cannot find, and the reliability of that finding. The sensitivity of the screening tool will be reviewed periodically such that new potential findings can be considered and a process for reporting can be devised if appropriate. By following this protocol, the chance of a successful negligence claim will be reduced.

The second issue gives rise to complaints that physical and / or psychological harm arose from the disclosure of an IF. Even were this to be the case, and the disclosure of the IF was in breach of a duty of care, the harm that arose – whether physical or psychological – would have to be causally linked to the disclosure of the IF.

IFs identified through asymptomatic screening should be communicated to patients using methods appropriate to the potential significance to health. For common findings this can be by standardised letter. For more serious or urgent findings this should be by direct communication by secondary care to avoid delay, with communication with primary care. For clinically non-significant findings, or those that do not require additional action, no communication is usually appropriate.

Table 1 shows a list of IFs potentially identified through screening, how reliable those findings are, reporting and management recommendations and the consequences for a participant. This is based on the principles outlined in Section 2 and is designed to reflect the best balance of benefit vs. harms that, coupled with IF specific information to patients, will mitigate complaints and make any negligence claim unlikely.

There must be a very clear consent process, where the details are made understandable to participants. Key points are:

- It should be clear exactly what the screening process can find, and what it cannot;
- It should state what results will be communicated to participants and what results are less likely to be communicated;
- It should indicate the level of reliability that can be attributed to the results;
- It must be written in sufficiently lay language, that there is a reasonable expectation that the concept of risk and what the screening process involves (including the possibility of receiving IFs) is understood by the participants so that informed decision making can be supported¹⁴.

If there are incidental findings where the result can be relied on, then the obligation to act on the findings is determined according to whether:

- the finding is harmful;
- there is a recommended change in clinical management that would follow from this finding.

Any finding that results in a Duty of Candour issue should be approached via a defined process, as in other screening programmes. This may include IFs. Guidance on duty of candour in NHS screening programme can be found here: https://www.gov.uk/government/publications/nhs-screening-programmes-duty-ofcandour

Any IF reported by a radiologist may be added to the patient's record, regardless of whether the radiologist or MDT/SRM determine it to be clinically significant or clinically nonsignificant, and whether the IF is communicated to the patient. All individuals have the legal right to access information held about them by health and care organisations, usually through a Subject Access Request. Thus, participants may become aware of clinically nonsignificant diagnoses that were not previously disclosed to them. It is important that participants receive information about this possibility and the reasons that they may not be informed as part of the consent process.

It is recommended that this protocol is referenced in any clinically non-significant additions to the patient record by the lung cancer screening programme that are not communicated to patients.

Role of NHSE/national team

NHS England (NHSE) is responsible for performance metrics for the programme. This includes the management information that must be submitted by local and regional systems so the NHSE national team can monitor programme performance. Included in these performance metrics are incidental findings referrals. In addition, the programme clinical dataset suggests a larger number of data metrics that individual areas are recommended to collect but does not need to be submitted to the national team. These metrics are periodically updated. Currently, the NHSE Quality Assurance Standards stipulate overall rates of clinically significant incidental findings should be <8%.

Approach to outliers

Once outliers are identified, feedback can be provided to responsible and individual radiologists and SRMs for education and calibration.

Table 1: Incidental findings, reporting and management, based on latest evidence*.

This list is not exhaustive and other, less common findings, may be reported according to normal radiological practice. The evidence for this table was based on a recent systematic review of IF in LDCT screening¹,

FINDING	Reliability of detection and characterisation by LDCT (Low Dose Computed Tomography)	recommendations		Potential consequences for participant (benefit / <u>harm)</u>
PULMONARY Emphysema	Good	Classify as: mild (<25%) moderate (25-50%) severe >50%.	moderate to severe radiological emphysema about the findings and recommend they seek	Early diagnosis and treatment of symptomatic COPD. Increased incentive to quit smoking.
			advice from primary care if they have symptoms. Do not refer participants with known diagnosis of COPD or if LHC establishes the participant is not impacted by dyspnoea and or cough.	No benefit and extra worry where no symptoms or no response to treatment.

Interstitial lung abnormalities (ILA)	Good	Report all ILA as an estimated percentage of whole lungs	Smoking cessation referral for all current smokers. Further emphasis on smoking cessation in results letter in those with moderate or severe emphysema. Further scanning within the lung cancer screening programme may flag progression for all ILA not referred. ILA involving more than 10% of either the whole lungs should be referred for specialist review / reviewed at the Screening Review Meeting (SRM).	No benefit and extra worry.
Bronchiectasis	Good	Report bronchiectasis when moderate or severe (more than 2X the diameter of the artery and involving more than one segment).	moderate or severe.	Identification and treatment of symptoms including prompting early treatment of future infections. Identification of an underlying cause. <i>No benefit if asymptomatic</i> <i>and not underlying cause.</i> <i>Unnecessary treatment.</i>

Respiratory bronchiolitis (RB)	Good	Do not report.	Smoking cessation will be offered to all current smokers irrespective of the presence of RB-ILD.	
Consolidation	Good	Classify as: Possibly inflammatory possibly malignant	If cancer more likely than inflammation refer to SRM. 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). Do not report minor areas of consolidation or tree in bud that are clearly inflammatory.	gnancy / ry, further ıp and -limiting
Pleural effusion/ thickening	Moderate	Report size and laterality and whether malignant features present.	Refer directly via SRM for clinical assessment and work-up if suspicious appearances including a new effusion, pleural thickening suspicious for malignancy or mass lesion. This includes schwannomas.	gnancy / rry, further

Pleural plaques	Good	Do not report, or do so only as a note. Reporting is only recommended in context of screening where compensation is available (i.e. Scotland and Northern Ireland	No clinical activity should be generated for benign appearances.	In some UK countries, compensation is available to people exposed to asbestos who have pleural plaques.
Tuberculosis (TB)	Good	Report if active TB likely and differential diagnoses.	Referral into local TB service.	Opportunity for treatment and contact tracing.
Bronchial wall thickening	Good	Do not report.	No action required.	
Coronary calcification (CAC) Note: all participants should have had a Q-risk or similar assessment.	Good	Report CAC, classify (using simple visual scoring) as: Mild Moderate Severe	Cardiovascular (CV) risk assessment reminder if moderate or severe CAC present, unless already on lipid lowering therapy or known to have ischaemic heart disease. Note: it is not established that mild CAC confers extra risk over Q-risk or similar assessment.	prevention regardless of coronary calcification.
Aortic valve disease	Good	Report aortic valve calcification (AVC) if moderate or severe. Classify using simple visual scoring. Isolated specks of calcification do not require reporting.	Refer those with moderate or severe AVC for evaluation with echocardiography via SRM.	Earlier assessment of aortic valve disease <i>No benefit and extra worry,</i> <i>unnecessary further</i> <i>investigations</i> .

Thoracic aortic calcification/ dilatation	Good	Do not report thoracic aortic calcification. Report thoracic aorta diameter if ≥45mm.	Referral for further assessment for those with thoracic aorta > 45mm diameter according to local guidelines/ pathways; if >50mm urgent referral.	Earlier option for medical treatment / monitoring / surgical intervention <i>No benefit in outcome, extra</i> worry / harm from work-up
Mediastinal mass	Moderate	Report size, morphology, position, and density / texture, including whether cystic.	lesions to SRM.	Early identification of malignant or harmful lesion. <i>Extra worry and work up for</i> <i>benign disease.</i>
Mediastinal lymph nodes	Moderate	Report mediastinal and hilar lymphadenopathy ≥ 15mm short axis.	Refer to SRM for further assessment.	Early diagnosis of significant disease. <i>Worry and work up for</i> harmless findings.
Thyroid abnormalities	Poor	Report nodules with suspicious features such as local lymphadenopathy, punctate microcalcification.	Refer to thyroid MDT via SRM for nodules with suspicious features that are ≥ 20mm.	Early diagnosis of thyroid cancer. <i>Work up of benign or</i> indolent disease.
Cardiac decompensation / pericardial effusion	Moderate	Report moderate or large pericardial effusion. Report features of significant decompensation.	Referral for echocardiography and clinical assessment via SRM or primary care; urgent referral may be indicated for concerning features.	Early diagnosis and treatment of pericardial disease / cardiac failure <i>Unnecessary activity if</i> already known

Oesophageal lesions		Report diffuse wall thickening, or focal lesions.	Referral for further assessment via SRM.	Early diagnosis of oesophageal disease. Unnecessary work up and worry for no significant disease or normal findings.
Abdominal aortic aneurysm (AAA)	Moderate	Report all AAA.	Referral for further assessment / surveillance according to guidelines; 3-5cm, referral >5cm, urgent referral.	Early identification of AAA.
Breast nodules	Moderate	Report size, site, calcification, density, and interval change.	Refer any breast lesion (via SRM) that is NOT clearly benign, (i.e., stable, well-defined margins or multiple) to the breast service unless already known.	Early diagnosis of breast cancer Overdiagnosis; worry and harm from benign disease.
Liver lesions	Poor (Including partial imaging)	Report size and attenuation Benign features: sharp margin and homogenous low attenuation (≤ 20 Hounsfield Unit (HU)), (focal) fatty sparing or deposition do not require further investigation or reporting Incompletely imaged lesions or lesions too small to characterize should not by itself	Lesions < 1cm: no further investigation Lesions ≥ 1cm and no benign features: referral via SRM: refer malignant lesions to the appropriate cancer pathway indeterminate lesions consider further investigation with CE CT/ ultrasound/ MRI.	Diagnosis of primary or secondary cancer. <i>Unnecessary worry, and work up for non-significant</i> <i>disease</i> .

		prompt further		
		investigation.		
Renal lesions	Poor	Report size, site,	Homogenous hypodense	Diagnosis of primary or
	(Including partial imaging	attenuation, calcification	cysts do not require	secondary cancer.
		Classify as malignant,	further investigation. Soft	Unnecessary worry, and
		indeterminate, and benign	tissue, hyperdense or	work up for non-significant
		or incompletely imaged/	mixed density renal mass	disease.
		unable to evaluate.	>1cm – or masses >3cm	
		Incompletely imaged	that show growth in	
		lesions or lesions too	comparison with prior	
		small to characterize	imaging if available refer	
		should not by itself	to SRM.	
		prompt further		
		investigation.		
Bone abnormalities	Moderate	Report >50% loss of	Refer via SRM to primary	Prevention of fracture.
		vertebral height in at least	care or osteoporosis	Worry and inconvenience.
		one vertebra.	service for >50% loss of	
			vertebral height	
		Report any lesions	Refer to SRM.	
		suspicious for		
		malignancy.		
Adrenal lesions	Moderate	Report size and	Refer to SRM lesions	Early identification of
		attenuation	which are >10-40mm	adrenal disease
		Lesions < 10mm or	diameter with attenuation	Worry and work up of non-
		<10HU in density and 10-		significant lesion.
		40mm diameter do not	these characteristics	
		require reporting.	growing on serial scans.	
			Refer lesions >40mm	

This table assumes no clinical information is available. *Review recommended for new evidence January 2026

Authors:

LCSP Expert Advisory Group David R Baldwin Arjun Nair Richard Lee Matthew Callister Ruth Stirton Tim Windle Anne Mackie Liz Rochelle Alan Bagnall Anand Devaraj Emily Bartlett Emma O'Dowd

Protocol for the management of incidental findings in lung cancer screening - references

1.	O'Dowd EL, Tietzova I, Bartlett E, et al.
	ERS/ESTS/ESTRO/ESR/ESTI/EFOMP statement on management of
	incidental findings from low dose CT screening for lung cancer. Eur Respir
	<mark>J 2023. DOI: 10.1183/13993003.00533-2023.</mark>
2.	Williams MC, Abbas A, Tirr E, et al. Reporting incidental coronary, aortic
	valve and cardiac calcification on non-gated thoracic computed
	tomography, a consensus statement from the BSCI/BSCCT and BSTI. Br J
	Radiol 2021;94(1117):20200894. DOI: 10.1259/bjr.20200894.
3.	Munden RF, Carter BW, Chiles C, et al. Managing Incidental Findings on
	Thoracic CT: Mediastinal and Cardiovascular Findings. A White Paper of
	the ACR Incidental Findings Committee. J Am Coll Radiol
	2018;15(8):1087-1096. DOI: 10.1016/j.jacr.2018.04.029.
4.	Radiology ACo. ACR Lung Cancer Screening CT Incidental Findings
	Quick reference Guide. (https://www.acr.org/-/media/ACR/Files/Lung-
	Cancer-Screening-Resources/LCS-Incidental-Findings-Quick-Guide.pdf).
5.	Bartlett EC, Belsey J, Derbyshire J, et al. Implications of incidental findings
	from lung screening for primary care: data from a UK pilot. NPJ Prim Care
	Respir Med 2021;31(1):36. DOI: 10.1038/s41533-021-00246-8.
6.	Bradley P, Bola BM, Balata H, Sharman A, Booton R, Crosbie PAJ.
	Incidental findings in low dose CT lung cancer screening of high-risk
	smokers: Results from the Manchester lung Health Check pilot. Lung
	Cancer 2022;173:1-4. DOI: 10.1016/j.lungcan.2022.08.017.
7.	Gareen IF, Gutman R, Sicks J, et al. Significant Incidental Findings in the
	National Lung Screening Trial. JAMA Intern Med 2023;183(7):677-684.
	DOI: 10.1001/jamainternmed.2023.1116.
8.	Clark SD, Reuland DS, Brenner AT, Jonas DE. Effect of Incidental
	Findings Information on Lung Cancer Screening Intent: a Randomized
	Controlled Trial. J Gen Intern Med 2022;37(14):3676-3683. DOI:
	10.1007/s11606-022-07409-4.
9.	Gareen IF, Duan F, Greco EM, et al. Impact of lung cancer screening
	results on participant health-related quality of life and state anxiety in the
	National Lung Screening Trial. Cancer 2014;120(21):3401-9. DOI:
	10.1002/cncr.28833.
10.	Brain K, Lifford KJ, Carter B, et al. Long-term psychosocial outcomes of
	low-dose CT screening: results of the UK Lung Cancer Screening
	randomised controlled trial. Thorax 2016;71(11):996-1005. DOI:
	10.1136/thoraxjnl-2016-208283.
<mark>11.</mark>	Kummer S, Waller J, Ruparel M, Duffy SW, Janes SM, Quaife SL.
	Psychological outcomes of low-dose CT lung cancer screening in a
	multisite demonstration screening pilot: the Lung Screen Uptake Trial
	(LSUT). Thorax 2020;75(12):1065-1073. DOI: 10.1136/thoraxjnl-2020-
	<mark>215054.</mark>
12.	National Health Service England, - National, Cancer, Programme.
	Targeted Screening for Lung Cancer with Low Radiation Dose Computed
	Tomography. Standard Protocol prepared for the Lung Cancer Screening
	Programme. (https://www.england.nhs.uk/publication/targeted-screening-
	<u>for-lung-cancer/).</u>

- National Health Service. England. Targeted Screening for Lung Cancer with Low Radiation Dose Computed Tomography. Quality Assurance Standards prepared for the Lung Cancer Screening Programme. (<u>https://www.england.nhs.uk/wp-content/uploads/2019/02/B1647-quality-assurance-standards-targeted-lung-health-checks-programme-v2.pdf</u>).
- 14. Hotson v East Berkshire AHA. House of Lords; 1987.
- 15. Mamudu HM, Paul TK, Veeranki SP, Budoff M. The effects of coronary artery calcium screening on behavioral modification, risk perception, and medication adherence among asymptomatic adults: a systematic review. Atherosclerosis 2014;236(2):338-50. DOI: 10.1016/j.atherosclerosis.2014.07.022.

Annex 3: National incidental findings pathways for targeted lung cancer screening

Locally agreed pathways for the management of incidental findings are important to maximise efficiency whilst bringing any benefits to participants that may result from detection. All incidental findings flagged by LDCT readers should be discussed at the Screening Review Meeting (SRM) where previous imaging and clinical factors can be included in the assessment. If the SRM is unsure of the significance of a finding outside it specialism then advice should be sought from the relevant speciality prior to any action. The SRM should request tests that are required to determine if a referral needs to be made, according to local agreements (e.g. echocardiogram for aortic valve calcification).

All participants should have received at the time of consent, and have ongoing access to, detailed information about incidental findings. This is important for the participant to understand why the findings have or have not been communicated to them and why action is or is not recommended.

Most findings and actions can be communicated by letters in a standardised format to the participant with copies to primary care. Bespoke letters may be needed to communicate outcomes of additional investigations or where a standard letter is not available. Standard letters and return to screen outcomes can be managed by the screening admin team.

The requesting of investigations and certain referrals may need to be done by medical staff deputising for the Responsible Clinician. In general, sites should avoid asking primary care to action incidental findings although this can vary according to local agreements. Alternative pathways are given in the table where primary care may be involved; "No alternative pathway" indicates the finding should be managed by secondary care or within the programme. Where alternative pathways include extra investigations and interventions, there should be in-service evaluation.

Where participants will exit screening (e.g. for age reasons), consideration can be given to act upon more significant incidental findings which otherwise would have been reasonable to survey at incident rounds. When participants are known to have new or existing comorbidities that mean they may not benefit in continuing screening, this should be discussed with the participant and a shared decision about continuation in the programme reached.

Programmes are encouraged to work closely with primary and secondary care teams to avoid uncertainty in onward referral.

FINDING	Pathway Recommendations <u>Review at Screening Review Meeting or Triage</u> (Referral may not be required if finding is already known; all participants returned to screening via the screening coordinator)		Communications and responsibilitie SC = Screening Coordinator RC = Responsible Clinician or deput	
	Preferred	Alternative	Format and Content SL = standard letter; BL = bespoke letter.	<mark>Responsibl</mark> e
Emphysema (action required for moderate or severe only)	Communication only.	Locally agreed and funded services may offer assessment in either primary or secondary care. This may include assessment of symptoms and integration of spirometry.	SL Inform participants about the findings. Recommend they seek advice from primary care if they have symptoms. Encourage smoking cessation.	SC
Interstitial lung abnormalities (ILA)	 Referral by the screening service direct to the local ILD service for ILA >10% or for that which has progressed. For <10% return to screen or discharge, with standard letter. If concern and exiting the programme, referral to ILD service for potential ongoing surveillance 	Referral to primary care for onward referral to ILD service. (Same thresholds as for preferred pathway.)	SL Explain the referral and the finding. Discharge letter if no further screening	SC RC

Bronchiectasis	Direct referral to local respiratory / bronchiectasis service for moderate or severe disease.	Referral to primary care for clinical assessment and onward referral.	SL to participants communicating the referral and the finding.	SC RC
Consolidation	 SRM discussion regarding likelihood of malignant vs. benign aetiology then 1. Urgent cancer pathway referral for findings suspicious of cancer. 2. Interval CT if findings more suggestive of infection, either within programme or in secondary care. 3. Primary care clinical review only if a decision about antibiotics is needed. 	SRM discussion regarding likelihood of malignant vs. benign aetiology then Referral to primary care for clinical assessment and onward referral if malignancy unlikely.	SL to participants communicating the referral and the finding. BL follow-up letter with outcome	SC RC
<mark>(Pleural</mark> plaques)	(In Scotland and Northern Ireland participant needs to be informed. A flag for SRM discussion is only needed in these countries.)		(SL Emphasise that plaques are benign. Compensation may be available as they result from asbestos exposure.)	(SC)
Tuberculosis (TB)	Direct referral to local TB service for active TB	Referral into local TB service via primary care	SL to participant	SC RC
Coronary artery calcification (CAC)	No referral. Letter to participant with moderate or severe CAC to encourage primary prevention and lifestyle change including seeking medical advice if symptoms.	Where local service funded there may be a trigger for primary care review and active intervention.	SL to participant about the finding, eligibility for lipid lowering therapy, and need to seek medical advice for symptoms.	SC

			Include smoking cessation and other lifestyle advice.	
Aortic valve calcification (with no previous echocardiogra m)	Echocardiogram requested in secondary care for moderate and severe calcification and only referred to cardiology if significant aortic valve disease – may simply be added to the local valve register.	Refer to primary care for moderate and severe calcification to request echocardiogram and onward management.	SL Reason for echocardiogram BL or SL Outcome.	SC RC
Thoracic aortic dilatation	Aorta >45-50mm return to screen and check BP in primary care >50mm urgent referral to cardiology	No alternative pathway	 SL 1. Aorta >45-50mm: About finding and need to check blood pressure. 2. For >50mm, standard letter about finding and referral 	SC RC
Mediastinal mass (non-cystic)	Options for management include surveillance as part of the screening programme or work-up depending on clinical assessment.	No alternative pathway	SL Explain finding. Explain plan. BL for outcome of further imaging	SC RC
Suspected Cancer (includes Thyroid, oesophageal, pleural, renal,	 Clear evidence of cancer on LDCT: direct referral to cancer service either via site specific MDT or cancer upgrade. Possible evidence of cancer on LDCT but further investigation needed to 	No alternative pathway	SL Inform about urgent referral BL	SC RC

liver, breast, adrenal, bone)	 clarify whether referral is needed: direct referral for further imaging and review. 3. See incidental findings protocol for thresholds 		Inform and explain further imaging and outcome	
<mark>Mediastinal</mark> lymph nodes	If referral required (for nodes ³ 15mm short axis), manage within respiratory service.	No alternative pathway	SL Inform about referral.	SC
Cardiac decompensati on / pericardial effusion	 Discussion at SRM 1. Significant pericardial effusion – manage in secondary care (echocardiogram). 2. For cardiac decompensation clinical assessment in primary care. 	Manage both scenarios in secondary care	SL Inform about echocardiogram BL Findings, and outcome	SC RC
Abdominal aortic aneurysm (AAA)	Refer to vascular team as follows: 3-5cm, referral >5cm, urgent referral.	Referral for primary care to action with clear recommendation (unless >5cm).	<mark>SL</mark> Findings and need for referral	SC RC
Osteoporosis (fracture > 50% of vertebral height)	Refer direct to osteoporosis service.	Refer to primary care for management.	SL	SC RC

QA Standards Authors

Prof David	Consultant Respiratory Physician, Nottingham University
<mark>Baldwin</mark>	Hospital
Dr Claire	Chief Operating Officer for Medical Imaging, University of Oxford
Bloomfield	
Dr Matthew	Consultant Respiratory Physician, Leeds Teaching Hospitals
Callister	NHS Trust
Dr Yan Chen	Associate Professor of Cancer Screening, School of Medicine at
	University of Nottingham
<mark>Dr Philip</mark>	Senior Lecturer of Respiratory, Manchester University
<mark>Crosbie</mark>	
Prof Anand	Consultant Thoracic Radiologist, Royal Brompton Hospital
<mark>Devaraj</mark>	
Dr Jesme Fox	Medical Director, Roy Castle Lung Cancer Foundation
Prof Fergus	Professor of Radiology, Oxford University
<mark>Gleeson</mark>	
Dr Samanjit	Consultant Radiologist, Barnet General Hospital
Hare .	
Nicola Keat	Head of Clinical Research Groups, National Cancer Research
	Institute
Prof Sam Janes	Consultant Respiratory Physician, University College London
	Hospitals NHS Foundation Trust
Dr Jodie Moffat	Head of Early Diagnosis, Cancer Research UK
Dr Arjun Nair	Consultant Thoracic Radiologist, University College London
	Hospitals NHS Foundation Trust
Dr Nicholas	Consultant Radiologist, Royal Papworth NHS Foundation Trust
Screaton	
Dr Anna	Consultant Thoracic Radiologist, Manchester University NHS
<mark>Sharman</mark>	Foundation Trust
Dr Nicola	Consultant Radiologist, Imperial College Healthcare NHS Trust
Strickland	
Dr Alexis Webb	Cancer Research UK
Dr Richard Lee	Consultant Respiratory Physician, The Royal Marsden NHS
	Foundation Trust

Reviewed by CT Screening Advisory Sub-Group of the Lung Cancer Clinical Expert Group.

References

- Berlin, L., *The incidentaloma: a medicolegal dilemma.* Radiol Clin North Am, 2011. 49(2): p. 245-55.
- van de Wiel, J.C., et al., Neglectable benefit of searching for incidental findings in the Dutch-Belgian lung cancer screening trial (NELSON) using low dose multidetector CT. Eur Radiol, 2007. 17(6): p. 1474-82.
- 3. Booth, T.C., Incidental findings on imaging. BMJ, 2018. 361: p. k2611.
- RCR, Management of Incidental Findings Detected During Research Imaging. RCR publications, 2011.
- Ding, A., J.D. Eisenberg, and P.V. Pandharipande, *The economic burden* of incidentally detected findings. Radiol Clin North Am, 2011. 49(2): p. 257-65.
- Berland, L.L., et al., Managing incidental findings on abdominal CT: white paper of the ACR incidental findings committee. J Am Coll Radiol, 2010.
 7(10): p. 754-73.
- Roberts, H.R., et al., Airflow obstruction in bronchiectasis: correlation between computed tomography features and pulmonary function tests. Thorax, 2000. 55(3): p. 198-204.
- Doyle, T.J., et al., Interstitial lung abnormalities and reduced exercise capacity. Am J Respir Crit Care Med, 2012. 185(7): p. 756-62.
- Munden, R.F., et al., Managing Incidental Findings on Thoracic CT: Mediastinal and Cardiovascular Findings. A White Paper of the ACR Incidental Findings Committee. J Am Coll Radiol, 2018. 15(8): p. 1087-1096.
- 10. Chiles, C., et al., Association of Coronary Artery Calcification and Mortality in the National Lung Screening Trial: A Comparison of Three Scoring Methods. Radiology, 2015. 276(1): p. 82-90.
- 11. Raju, P., et al., Aortic valve calcification a commonly observed but frequently ignored finding during CT scanning of the chest. Int J Clin Pract, 2012. 66(6): p. 552-5.

- 12. Gore, R.M., et al., Management of Incidental Liver Lesions on CT: A White Paper of the ACR Incidental Findings Committee. J Am Coll Radiol, 2017. 14(11): p. 1429-1437.
- 13. Herts, B.R., et al., Management of the Incidental Renal Mass on CT: A
 White Paper of the ACR Incidental Findings Committee. J Am Coll Radiol,
 2018. 15(2): p. 264-273.
- 14. Lee, J. H., S.Y. Jeong, and Y.H. Kim, *Clinical significance of incidental* thyroid nodules identified on low-dose CT for lung cancer screening.
- 15. Multidiscip Respir Med, 2013. 8(1): p. 56.
- 16. Field JK, Duffy SW, Baldwin DR, Brain KE, Devaraj A, Eisen T, Green BA, Holemans JA, Kavanagh T, Kerr KM, et al: *The UK Lung Cancer Screening Trial: a pilot randomised controlled trial of low-dose computed tomography screening for the early detection of lung cancer*. Health Technol Assess 2016, 20:177.
- 17. Liverpool Healthy Lung Programme Second year Evaluation Report. Available at: <u>https://www.liverpoolccg.nhs.uk/media/3245/final-lhlp-2nd-</u> year-report-10-july-2018-with- logos.pdf
- 18. Crosbie PA, Balata H, Evison M, Atack M, Bayliss-Brideaux V, Colligan D, Duerden R, Eaglesfield J, Edwards T, Elton P, et al: *Implementing lung cancer screening: baseline results from a community-based 'Lung Health Check' pilot in deprived areas of Manchester*. Thorax 2018.
- Van de Wiel JC, Wang Y, Xu DM, Van der Zaag-Loonen HJ, Van der Jagt EJ, Van Klaveren RJ, Oudkerk M, group Ns: Neglectable benefit of searching for incidental findings in the Dutch-Belgian lung cancer screening trial using low-dose multidetector CT. Eur Radiol 2007, 17:1474-1482.

NHS England Wellington House 133-155 Waterloo Road London SE1 8UG

Contact: enquiries@england.nhs.uk

This publication can be made available in a number of alternative formats on request.

© NHS England 2022 | PR1647