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Targeted screening for lung cancer with low radiation dose computed tomography

# Quality assurance standards prepared for the Targeted Lung Health Checks programme

Version 2, 7 November 2022

Prepared with guidance from the Lung Clinical Expert Advisory Group

Changes from version 1 have been highlighted in yellow

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# Introduction

- 1.1. The national Targeted Lung Health Checks 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 has 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</u> <u>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 through the Targeted Lung Health Checks Delivery Group. 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 <u>Targeted Lung Health Checks Standard Protocol</u> – section 2.3.2.

#### 1a. Description

This standard sets out the training and experience requirements for nurses and supporting 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 supporting staff delivering the targeted lung health checks 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.
- Consent training.
- Ionising radiation (medical exposure) regulations [IR(ME)R] for referrers.
- 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.
- 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 recategorised from low to high risk or vice versa following local audit.

#### 1e. Local audit

The clinical director of 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 a proportion of telephone screening assessments conducted per quarter.

#### 1f. National audit

The clinical director of programme will report quarterly against this standard to the Targeted Lung Health Checks 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). Further course information and booking details are available on the <u>Roy Castle Lung Cancer Foundation</u> website.

# Standard 2: Lung cancer screening – radiologists

Cross reference to <u>Targeted Lung Health Checks Standard Protocol</u> – 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 Targeted Lung Health Checks 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
    - 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:

• British Society of Thoracic Imaging (BSTI) Lung Nodule Workshop.

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 Targeted Lung Health Checks 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 programme will report quarterly against this standard to the Targeted Lung Health Checks 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. Further details are available on the <u>Roy Castle Lung</u> <u>Cancer Foundation website</u>.

# Standard 3: Radiology hardware

Cross reference to <u>Targeted Lung Health Checks 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 Targeted Lung Health Checks 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

# Standard 4: Radiology software

Cross reference to <u>Targeted Lung Health Checks Standard Protocol</u> – sections 4.1.6 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 follow-up examinations where possible with emphasis on ensuring that slice thickness, reconstruction increment, reconstruction algorithm is identical.
- 100% of slice thickness are  $\leq 1.25$  mm.<sup>1</sup>

## 4e. Local audit

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

#### 4f. National audit

<sup>&</sup>lt;sup>1</sup> 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 <u>Targeted Lung Health Checks 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 Targeted Lung Health Checks 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.

Minimum standard:

- Software will record the standard clinical dataset data acquired from GP record, the lung health check, CT scanner (including exposure, factors, radiation dose, type of scanner) and radiology reports.
- Software will track participants including recall, and change of participant contact details.
- The software will allow the extraction of the standard clinical dataset for the purposes of audit, evaluation, quality assurance or researches.

Desirable standard:

- Automatic appointment scheduling and recall.
- A single database for all participant data and imaging data.
- Automatic queries for data completeness and quality assurance.
- Web-based entry system with appropriate security.

• Single record linking primary care data and hospital electronic records with data from PACS.

#### 5d. Metric

• Patient administration system and software meets the minimum standard.

#### 5e. Local audit

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

#### 5f. National audit

# Standard 6: Data management

Cross reference to Targeted Lung Health Checks Standard Protocol – 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 sharing agreements are in place to direct how participant data is recorded, handled and used to deliver the Targeted Lung Health Checks programme.
- To ensure the confidentiality of participant data.
- To ensure data is pseudonymised before submission to the evaluator.
- To ensure that processes are accessible to future research requests.

#### 6c. Definition

Projects will ensure local Data Protection Impact Assessments (DPIAs) and Data Sharing Agreements are agreed, detailing how data is collected and used to deliver the project, and shared with the 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

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

#### 6e. Local audit

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

## 6f. National audit

# Standard 7: Lung health checks programme pathway

Cross reference to <u>Targeted Lung Health Checks Standard Protocol</u> – 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 always meets the minimum standard.

#### 7f. National audit

# Standard 8: Participant communications

Cross reference to <u>Targeted Lung Health Checks 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 project 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 letters<sup>2</sup> and the participant booklet is detailed in figure 2 over the page:

<sup>&</sup>lt;sup>2</sup> The standard letters and participant booklet are available on request from england.tlhc@nhs.net.

#### 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 four weeks of an appointment or scan.

#### 8e. Local audit

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

#### 8f. National audit

# Standard 9: General practice communications

Cross reference to <u>Targeted Lung Health Checks 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 for a lung health check, the outcome of this and subsequent follow up.
- To ensure the effective management of 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 results from the lung health check appointment (lung health check assessment, risk assessment, add-on investigations such as spirometry and smoking cessation or any other lifestyle advice), low dose CT scan proforma and the plan of care. The issuing of the standard letters<sup>3</sup> 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 four weeks of the participant attending an appointment or scan.

#### 9e. Local audit

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

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

<sup>19 |</sup> QA standards prepared for the Targeted Lung Health Checks Programme by the Lung Clinical Expert Advisory Group

## 9f. National audit

# Standard 10: Smoking cessation

Cross reference to <u>Targeted Lung Health Checks 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 Targeted Lung Health Checks 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

# Standard 11: Participant experience

Cross reference to <u>Targeted Lung Health Checks Standard Protocol</u> – sections 3 to 8.

#### 11a. Description

This standard sets out how the projects will gather insights into participants experiences.

#### 11b. Objective

- To ensure the recording of participant experience and feedback is a catalyst to make improvements and to inform the evaluation of the Targeted Lung Health Checks programme.
- To ensure those invited for a lung health check are asked to provide feedback to amend approaches to maximise uptake in the eligible population.

#### 11c. Definition

The clinical director of programme will ensure that the participant experience survey, designed by Ipsos UK as part of the evaluation of the Targeted Lung Health Checks programme, is distributed to those invited to a lung health check.

#### 11d. Metric

The participant experience survey will measure participants experiences, awareness and understanding of the Targeted Lung Health Checks programme.

#### 11e. Local audit

The clinical director of programme will ensure that the project distributed the participant experience surveys as agreed by the Targeted Lung Health Checks Delivery Group.

#### 11f. National audit

The clinical director of programme will confirm quarterly to the Targeted Lung Health Checks Delivery Group and through the quarterly quality assurance process that the project is on track in its distribution of participant experience surveys.

# Standard 12: Low dose CT referral

Cross reference to <u>Targeted Lung Health Checks Standard Protocol</u> – section 3.3.3.

## 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<sub>m2012</sub>) ≥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 four weeks of their lung health check.

Participants who require a follow up interval low dose CT scan will receive this within a two-week window of their target follow up scan date.

## 12d. Metrics

- 100% of those referred for a low dose CT scans have a risk prediction score of LLPv2 ≥2.5% over five years or PLCO<sub>m2012</sub> ≥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, and a record of reasons for not achieving a same day scan.
- Audit follow up interval scans that are not are completed within the twoweek window of the target interval follow up 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 an interval follow-up scan outside the two-week window and agree an action plan to reduce the number of scans acquired off plan.

#### 12f. National audit

# Standard 13: Low dose CT reporting

Cross reference to Targeted Lung Health Checks 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

# Standard 14: Quality assurance of low dose CT scans

Cross reference to <u>Targeted Lung Health Checks 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 the mean, standard deviation, median, interquartile and range of radiation dose.
- Audit and review reasons for all radiation doses greater than 2 mSv.
- 1. 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).
- 2. 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 Targeted Lung Health Checks 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

Reporting radiologists will undertake an annual external quality assurance programme to read low dose CT scans. This will involve radiologists reviewing a set number of CT scans 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.

## 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 programme.

#### Next steps

NHS England will publish more detail on the external quality assurance programme and the details of the standard as soon as possible.

# 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 input⁴
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

<sup>&</sup>lt;sup>4</sup> 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.

Field description	Variable input options	Type of input <sup>4</sup>
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 <sup>5</sup>	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
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 <sup>6</sup>	Brock score	Autopopulated

<sup>&</sup>lt;sup>5</sup> 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.

<sup>&</sup>lt;sup>6</sup> Brock score is calculated automatically in commercial lung cancer screening reporting software.

Field description	Variable input options	Type of input <sup>4</sup>
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 No	odule 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 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 <sup>6</sup>	Brock score	Autopopulated
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

Field description	Variable input options	Type of input <sup>4</sup>
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 <sup>6</sup>	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	
Nodule3_VDT (days)	Volume doubling time from baseline	
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
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

Field description	Variable input options	Type of input⁴
(multiple selections possible)		
Nodule4_Brock score <sup>6</sup>	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 <sup>6</sup>	None/mild (<25%)/ moderate (25-50%)/ severe (>50%)	Dropdown
Emphysema predominant type <sup>6</sup>	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	
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 <sup>6</sup>	None/ Mild/ Moderate/ Severe	Dropdown
Aortic valve calcification	None/ Moderate/ Severe	Dropdown

Field description	Variable input options	Type of input <sup>4</sup>
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 (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 input⁴
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: Incidental findings management protocol

The principles of managing non-lung cancer incidental findings in lung cancer screening are provided in the NHS England Standard Protocol for lung cancer screening.

The table below provides guidance on the management of common incidental findings on low dose CT scans in the context of screening for lung cancer. It should be read in conjunction with the <u>NHS England Standard Protocol</u> and

sections 6, 9, 12 and 13 of the American College of Radiology white paper.

A summary of protocols in use in pilots and research studies in England and a justification for the following recommendations is available on request by emailing england.cancerpolicy@nhs.net.

Finding	Reporting recommendation	Action required	Notes	<mark>Level of</mark> significance
Emphysema	Classify as: Mild (<25%) Moderate (25-50%) Severe (>50%).	Smoking cessation. Consider referral to local community respiratory team for moderate and severe. Enter onto COPD register if diagnosis confirmed.	It should not be used to diagnose COPD.	<ul> <li>Mild: Not significant</li> <li>Moderate/ severe: Significant</li> </ul>

Finding	Reporting recommendation	Action required	Notes	Level of significance
Bronchiectasis	<ul> <li>Classify as:</li> <li>Mild (airways are 1.5-2 times the size of artery)</li> <li>Moderate (2-3 times the size)</li> <li>Severe (greater than three times the size of corresponding artery [7].</li> <li>For bronchiectasis to be categorised as severe, it must also be present in more than one segment of the lung.</li> </ul>	<ul> <li>Mild/borderline bronchiectasis: no action or communication required.</li> <li>Moderate or severe bronchiectasis either:         <ul> <li>refer to chest clinic if chronic cough or recurrent LRTI has been documented at the health check</li> <li>notify participant and GP regarding standard bronchiectasis/ infection prophylaxis management and give the option of referral.</li> </ul> </li> <li>Consider referral to local community respiratory team.</li> </ul>	Information on symptoms should be available from the lung health check. Do not recommend for non- specific clinical correlation. Option, for review at screening review meeting. CT results with moderate and severe disease communicate result to the participant and GP.	<ul> <li>Mild: Not significant</li> <li>Moderate/sever e: Significant</li> </ul>
Bronchial wall thickening	Do not report.	None.		NA
Respiratory bronchiolitis– associated interstitial lung disease (RBILD)	Report.	Smoking cessation.		
Interstitial lung abnormalities (ILAs)	<ul> <li>Report all ILD and recommend:</li> <li>if &gt;10% reticulation based on visual estimation, for respiratory referral</li> <li>if 5-10%, recommend correlation with spirometry.</li> </ul>	<5% ILA does not require action or communication. Consider referral if >10% or >5% with restrictive spirometry for further investigation.	Option should be available for review at the screening review meeting. Only communicate significant CT results to the participant and the GP.	Only significant if >10% reticulation or >5% with restrictive spirometry for further investigation.

Finding	Reporting recommendation	Action required	Notes	<mark>Level of</mark> significance
Consolidation	Categorise as consolidation/likely inflammatory requiring three months repeat CT or consolidation/ possibly malignant requiring MDT referral.	Refer MDT if cancer is possible. Repeat three months CT if looks inflammatory. Assess for clinical infection and prescribe antibiotics as required.	Minor areas of consolidation, unlikely to be of clinical significance should either not be reported or reported as above.	<mark>Significant</mark>
Tuberculosis	Indicate if likely to be TB; indicate differential diagnosis	Refer to tuberculosis service if finding suspicious for tuberculosis.		Significant
Mediastinal mass	Report size of mediastinal mass, position and whether cystic; recommend review by lung cancer MDT or screening review MDT.	See notes for further management.	Options include continued surveillance at next screening round CT or further investigation including PET/CT/MRI, based on size and morphology. Cystic lesions do not require further investigation [9]	<mark>Significant</mark>

Finding	Reporting recommendation	Action required	Notes	Level of significance
Coronary calcification	Report as mild / moderate / severe based on visual estimation of most affected artery [10].	Cardiovascular risk assessment to be completed and primary prevention recommended where not already in place.	Projects will agree locally whether to add in cardiovascular risk assessment as an additional clinical intervention into the lung health check appointment. Cardiovascular risk assessment may have been performed in primary care for participants meeting LHC eligibility criteria, so CT-detected coronary artery calcification may not add to this.	Not significant
Aortic valve disease	Report if moderate or severe calcification involving 2 or 3 cusps. Isolated specks of calcification do not require reporting.	Primary care to refer for echocardiogram if moderate or severe non-localised aortic valve calcification, and not known to have aortic valve disease [11].		Significant if moderate or severe
Aortic aneurysms	<ul> <li>Thoracic:</li> <li>&lt;4cm, no action</li> <li>4.0cm-5.5cm, for GP to refer</li> <li>&gt;5.5cm, for urgent referral.</li> <li>Abdominal:</li> <li>3-5cm, to refer</li> <li>&gt;5cm, for urgent referral.</li> </ul>	<ul> <li>Thoracic:</li> <li>&lt;4cm, no action</li> <li>4.0cm-5.5cm, referral</li> <li>&gt;5.5cm, urgent referral.</li> <li>Abdominal:</li> <li>3-5cm, referral</li> <li>&gt;5cm, urgent referral.</li> </ul>	This does not require discussion at the screening review meeting.	Thoracic: • <4cm, not significant • ≥4cm, significant Abdominal: • any is significant

Finding	Reporting recommendation	Action required	Notes	Level of significance
Breast nodules	Specify site and size.	Breast MDT referral if not previously know or no information.		Significant
Liver lesions	Further guidance on evaluation of liver lesions on unenhanced CT is provided in ACR white paper [12]. Classification options have been built into the reporting template (Annex 1). Lesions are classified into malignant, indeterminate and benign or incompletely imaged/ unable to evaluate.	<ul> <li>See notes and reporting recommendations.</li> <li>Clinical teams to agree local pathways: <ul> <li>malignant lesions refer to the appropriate cancer pathway</li> <li>indeterminate lesions refer to the screening review meeting</li> <li>all other lesions require no action.</li> </ul> </li> </ul>	Images and information available will inform the radiological assessment. Incompletely imaged lesions or lesions too small to characterize should not by itself prompt further investigation.	Only lesions referred to a cancer pathway MDT (following screening review meeting discussion where appropriate) are considered significant
Renal lesions	Further guidance on evaluation of renal lesion density is provided in ACR white paper [13]. Classification options have been built into the reporting template (Annex 1). Lesions are classified into malignant, indeterminate and benign or incompletely imaged/ unable to evaluate.	<ul> <li>See notes and reporting recommendations. Clinical teams to agree local pathways:</li> <li>malignant lesions refer to the appropriate cancer pathway</li> <li>indeterminate lesions refer to the screening review meeting</li> <li>all other lesions require no action.</li> </ul>	Assessment should be made on images and information available. Incompletely imaged kidneys or lesions too small to characterize should not prompt further investigation by itself.	Only lesions referred to a cancer pathway MDT (following screening review meeting discussion where appropriate) are considered significant.

Finding	Reporting recommendation	Action required	Notes	<mark>Level of</mark> significance
Bone abnormalities	GP to refer for bone density evaluation for >50% osteoporotic fractures.	Recommended to participant and GP bone risk assessment and protection.		<mark>Significant</mark>
Thyroid abnormalities	Report only if any local lymphadenopathy and/or punctate calcification.	Refer to thyroid MDT.		<mark>Significant</mark>
Adrenal lesions	<ul> <li>Report size and attenuation.</li> <li>if &lt;1cm, do not recommend referral</li> <li>for other lesions, recommend review at screening review meeting.</li> </ul>	<1cm or <10HU, <sup>7</sup> no action. 1-4cm and >10HU, <sup>7</sup> no action but participant to return for 12 months scan. >4cm for endocrine referral.		>4cm only considered significant
Pleural effusions/ thickening	Report size and laterally if malignant features seen, refer to lung cancer service. This includes schwannomas.	Discuss at screening review meeting or for lung cancer referral.		Significant

<sup>&</sup>lt;sup>7</sup> Radiologists to measure adrenal lesions as they would in clinical practice - that is, using the mean HU from the ROI measured on average multiplanar reconstructions of 3-5mm thickness (radiologist to manipulate the thickness in current software packages).

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