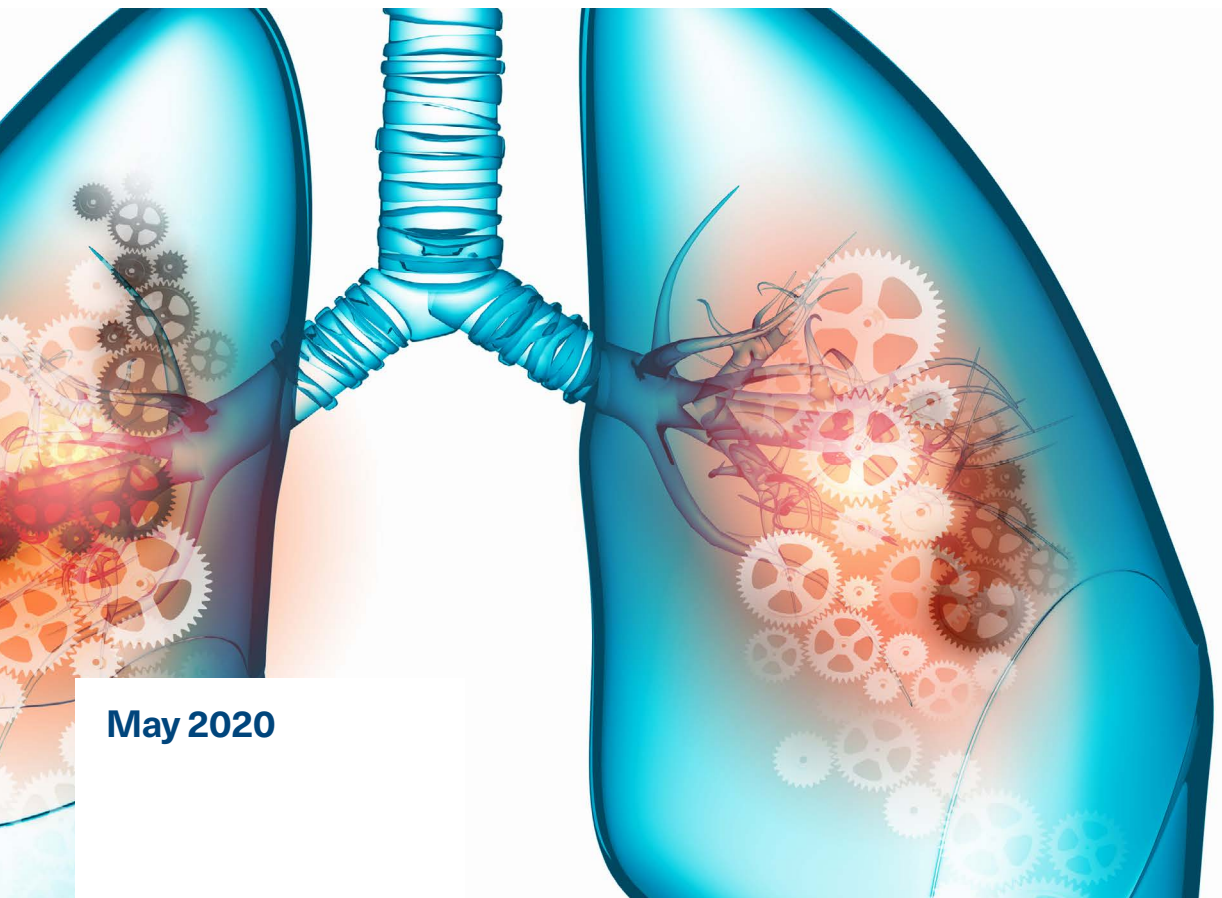# Considerations to ensure optimum roll-out of targeted lung cancer screening over the next five years

British Society of Thoracic Imaging and The Royal College of Radiologists
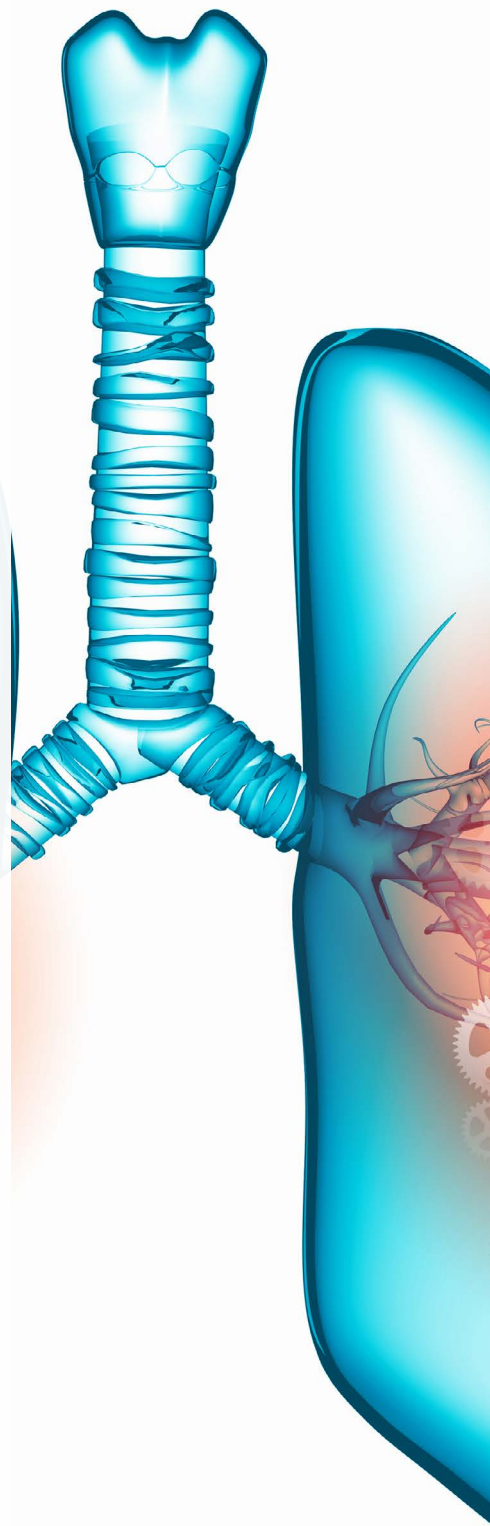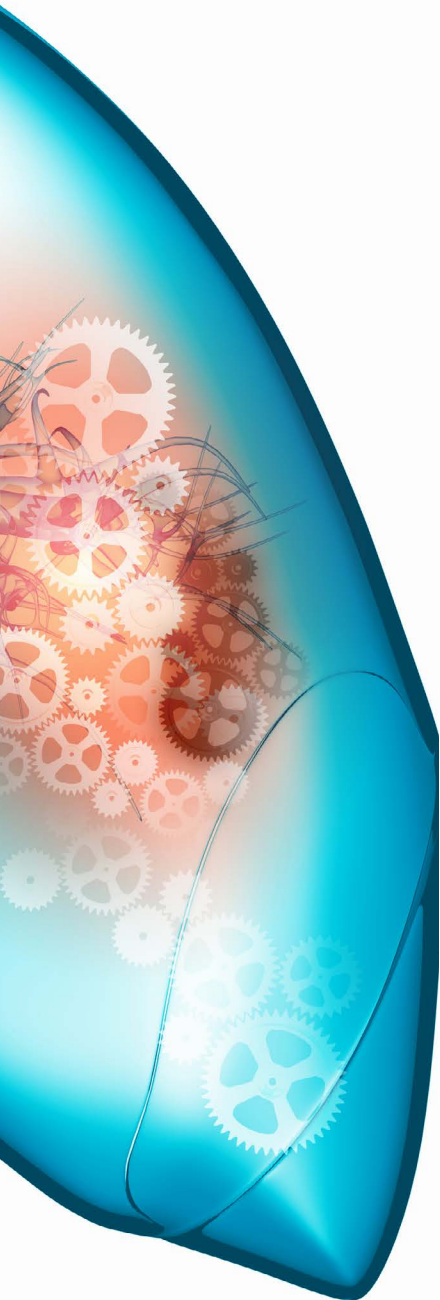
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May 2020

Contents

The Royal College of Radiologists (RCR) and the British Society of Thoracic Imaging (BSTI) support the incremental roll out of the service set out in the NHS England (NHSE) document *Targeted screening for lung cancer with low radiation dose computed tomography – standard protocol* prepared for the targeted lung health checks programme (henceforth referred to as the 'standard protocol').[1]

Introduction

Lung health checks (LHCs), as set out in the standard protocol, combine risk-stratified lung screening with other health interventions. Participants aged between 55 and 75 who have smoked in their lifetimes are invited for a LHC. During the LHC, the participant has a spirometry test and a discussion to assess their individual lung cancer risk, including questions about smoking habits (and an offer of smoking cessation advice and treatment if appropriate). Any participant assessed as being at 'high risk' of lung cancer will be invited for an immediate low-dose computed tomography scan (LDCT). The programme has the primary aim of reducing mortality from lung cancer and the targeted selection methods involved in LHCs are more efficient than blanket population-based screening.

The implementation of the standard protocol would constitute a major step towards realising the ambitions put forward in the Taskforce for Lung Health's *A national five year plan for lung healt*h and the NHSE *Long term plan*.[i,2,3] For targeted lung cancer screening to be successful, due consideration must be given to questions regarding: capacity; equipment; information technology (IT) infrastructure; sustained funding; quality standards and assurance; and the need for graded, incremental national rollout.

i. One of the recommendations in A National Five Year Plan for Lung Health *is to 'Implement a comprehensive national lung cancer screening programme, targeting those at high risk of developing lung cancer, and offering them low dose CT screening'.*

One of the commitments in the NHSE Long term plan *is that 'The NHS will do more to detect and diagnose respiratory problems earlier'.*

As key stakeholders in the effective and optimum delivery of a targeted national lung cancer screening programme, the RCR and BSTI must be at the forefront of strategic planning. The fundamental role of radiologists and the wider imaging team in the successful implementation of the protocol also needs to be recognised.

This paper highlights the potential strategies and obstacles that must be overcome to ensure effective national lung cancer screening roll-out. It makes recommendations that will be necessary to optimise lung screening over the medium term, with emphasis on aspects within the protocol relevant to radiology.

Protocol overview

The standard protocol and NHSE *Quality assurance standards* document state that the key attributes of an effectively delivered targeted screening programme must include:[4]

- A clear definition of the cohort
- Accurate population identification (to accurately identify the population to whom screening is offered)
- A demonstration that smoking cessation advice is part of the core service
- Robust electronic systems for invitations and recalls
- An underpinning ethos of allowing for informed patient choice
- Having measures in place to maximise uptake
- Transparency about the tests – both in terms of defining what they are and the results criteria used
- Describing the diagnostic and/or treatment pathways that will follow a positive or indeterminate scan
- Facilitating and encouraging research studies into early detection of lung cancer.

Moreover, the standard protocol states that the programme should be led through close collaboration between a clinical lung cancer lead and radiology lung cancer lead. All local multidisciplinary teams (MDTs) should have this clinico-radiological collaboration clearly identified to effectively deliver a targeted screening service. The protocol describes in detail the technical, hardware and software specifications expected for CT screening, as well as information governance and monitoring requirements.

Further fundamental considerations for the LHC programme include quality assurance (QA), nodule management and reporting of incidental findings. The NHSE *Quality assurance standards* guidance for the targeted lung health checks programme sets out the minimum requirements for: practitioners and expected reporting standards; QA metrics; monitoring; training requirements; and expectations for reporting incidental findings (Annex 2 of NHSE quality standards document).[4]

Radiology-specific considerations in the standard protocol

Participant consent

The standard protocol stipulates that 'consent for CT screening should be taken by a suitably trained clinician or non-clinician, familiar with the risks and benefits of the process'. While written consent is considered by some as an ideal, the RCR and BSTI recognise that this is labour and information technology (IT) intensive, in addition to noting that other screening programmes (for example breast screening) primarily use verbal consent supported with detailed patient information (for example participant booklet). As such, detailed verbal consent that includes comprehensive patient information literature should ordinarily suffice. Patients should be provided with the option of a formal, written consenting pre-screening consultation with a clinician should they seek one. Ultimately, informed choice should be

maximised and each local screening unit should devise a consenting process that fits with local needs and resources. As part of the consent process (whether written or verbal), it should clearly be described to participants that CT screening may identify findings that require further testing that do not turn out to be significant, principally benign lung nodules.

As with other screening programmes, results of lung CT screening will typically be conveyed to participants by letter. Prior communication of the potentially serious nature of the results can help to reduce patient anxiety and minimise the need for further consultation. It should also be made clear that the principle aim of the screening CT scan is to identify early-stage lung cancer (because of the benefits of early detection) and not to identify other diseases. Other pathologies, however, may be found and individuals should be informed that these will be managed according to standardised protocols depending on whether the findings are considered actionable. Additionally, individuals should be informed that a negative or 'clear' CT does not exclude a future diagnosis of lung cancer and be made aware of potentially concerning future symptomatology.

As a LDCT scan involves exposure to ionising radiation, consenting information should also include details on radiation exposure. The low-dose nature of a CT lung screening study, designed to minimise cumulative risk should be emphasised. *The Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) 2017* should be adhered to as they provide a framework intended to protect patients from the hazards associated with ionising radiation.[5] The RCR will shortly publish

Implications for clinical practice in diagnostic imaging, interventional radiology and nuclear medicine which focuses specifically on how the regulations translate to radiology services.[6]

Referral for CT

Protocolised requests/request forms can be used to initiate CT screening following locally agreed standard operating procedures, which must include details of practitioners able to request thoracic CT for screening.

Unlike clinically indicated CTs, detailed clinical information is not required beyond that the participant is high risk. While this risk status will ultimately be determined through the initial lung health check, the presence or absence of a family history of lung cancer should also be provided on the request for LDCT (if indicated) to enable the radiologist to calculate a Brock score where appropriate. This avoids the need to refer participants to the MDT purely for this purpose.

CTs requested for nodule follow-up should be clearly indicated as such on the CT request form, along with the required specific time point. For example, when using terms such as '12 month follow-up', it should be made clear whether the follow-up CT is required 12 months from the requested date or from the original/antecedent CT date.

CT acquisition and dose

The standard protocol sets out key attributes for LDCT image acquisition. A screening CT scan should be performed using a low-dose algorithm without intravenous contrast medium. Radiation exposures should be as low as possible while maintaining good image quality.

As per the standard protocol: 'The CT dose index (CTDIvol) must be kept as low as possible with the effective radiation dose well below 2 millisieverts (mSv). The kilovoltage peak (kVp) and milliamperage (mAs) settings will be varied according to participant body habitus. The height and weight of participants will be used to enable accurate selection of exposure factors. Ultra LDCT should be used where available and considered to be of equivalent diagnostic sensitivity to LDCT.'

Sometimes patients may be referred to the MDT for further investigation and, following initial investigations, recommendations may be made for nodule follow-up CTs within the clinical service. Local departments should use the same low-dose CT acquisition protocol for clinical nodule follow-up as is used in the screening programme to ensure consistency of measurements.

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... each local screening unit should devise a consenting process that fits with local needs and resources

CT reporting

Radiologists should use volumetry and computer-aided detection (CAD) software capable of detecting and measuring lung nodules. Factors associated with high-quality, high-efficiency CAD/volumetry software are described in the NHSE document and associated literature. [7,8] CAD should be used as a concurrent reading methodology.[9] Those reading scans should always check segmentation accuracy when relying on volumetric measurements. In addition to detection and measurement, morphological assessment of lung nodules is also a critical component of the reporting process and plays a significant role in minimising false-positive and recall rates.[10,11]

Where practical (and within IT and geographical constraints) previous CT imaging should be made available for comparison at the time of reporting.

The RCR and BSTI wish to emphasise that it is paramount that LDCT scan reporting in lung cancer screening is structured and focused on the identification of lung cancer. This intention should be stated in the report. As with other large-volume screening programmes, direct patient/screening physician interaction is usually absent/limited for the majority of individuals. Therefore, unlike in the setting of patients referred for specific clinical reasons, CT screening reports cannot be routinely integrated with clinical or patient factors.

CT screening reports should stipulate the management outcome for each participant. These outcomes should be communicated to general practitioners (GPs) and participants using clear and

appropriate terminology and language. This should be done using bespoke templated letters (such as suggested in the standard protocol). These should ideally be generated automatically from the screening CT reports .

Lung-nodule management

Nodule management should be based on the British Thoracic Society (BTS) guidelines, which may need to be customised for CT screening using the latest evidence or expert opinion where necessary.[12]

Incidental findings

The RCR and BSTI agree with the standard protocol that 'minor incidental findings are common on LDCT and have the potential to cause increased unnecessary investigations and anxiety to participants'.

The standard protocol (page 23) broadly categorises incidental findings as:

- **Critical results that may be life threatening** – these should prompt direct referral for admission to hospital by the LDCT targeted lung cancer screening programme.

- **Findings indicative of extrapulmonary cancer which should prompt urgent referral** via the secondary care cancer pathway upgrade process. Efficient pathways should be in place to, where possible, limit the further investigational impact of actionable incidental findings on primary care where the outcome requires a secondary care referral.

- **Non-urgent but actionable non-cancer findings** requiring referral to secondary care (for example, significant fibrotic interstitial lung disease).

- **Findings that are usually not directly associated with a beneficial intervention** and that do not require separate, dedicated communication (for example, incidental benign appearing thyroid nodules, bronchial wall thickening, mild bronchiectasis, atelectasis, hiatus hernia).

❝ ... radiologists have a responsibility to ensure that the benefits of reporting incidental findings outweigh any potential for harm and increased cost

Every effort should be made during CT acquisition to limit the field of view to the lungs. Nevertheless, thoracic CT in lung cancer screening will encompass extrapulmonary soft tissues, bone, heart and

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upper abdomen slices. It has the potential to identify innumerable incidental findings.[13]

This means that radiologists have a responsibility to ensure that the benefits of reporting incidental findings outweigh any potential for harm and increased cost. This requires a pragmatic radiological approach to the management of incidental findings that emphasises the need to minimise unnecessary investigation, patient harm and anxiety while ensuring that findings other than lung cancer are flagged where appropriate. Indeed, such an approach has also been advocated for incidental extracolonic findings on CT colonography, as such findings can potentially lead to a cascade of further expensive tests and procedures with negligible clinical benefit to the patient.[14,15] In this regard, the RCR and BSTI support the broad principles behind the NHSE *Lung CT screening incidental findings management protocol* (Annex 2 of NHSE quality standards document) which asserts:[4]

- The management of incidental findings will be protocol based so as to limit ambiguous follow-up pathways, thereby alleviating some of the added work created for primary and secondary care – a clear protocolised algorithm should be in place for incidental finding management

- The emphasis will be on actionable findings that will directly impact management

- The identification and reporting of findings should be based on there being a beneficial intervention.

Radiology reader requirements

The RCR and BSTI support the requirement for lung screening readers to be involved in the reporting of lung cancer CTs in routine clinical practice and the requirement to participate in lung multidisciplinary team meetings (MDTMs). As with many MDTMs, lung MDTMs provide an invaluable, dedicated forum to review lung nodule or lung cancer cases, with the ability to receive continuous feedback on cases. This serves as an informal medium for continuing professional development (CPD) and attendance should be a requirement for screening CT readers.

The RCR and BSTI advocate that a BSTI-endorsed screening-reading induction and training course should form part of initial reader training. Such courses must include hands-on volumetry training as well as providing guidance on the limitations and benefits of volumetry, BTS nodule guidance (including limitations relating to screening), the importance of morphological assessment and reporting of incidental findings.

Responsible radiologist

The RCR and BSTI endorse the standard protocol requirement for a named responsible radiologist for each local screening unit. This screening lead radiologist should accurately monitor reporting performance of other local screening readers, and act on these results to support governance and training and to improve quality. The responsible radiologist will ensure reporting radiologists always meet the minimum standard (as outlined below). They will maintain a local minimum training and experience record for each radiologist.

The responsible radiologist should liaise closely with the clinical screening lead to ensure that robust systems are in place for both data entry relating to the LDCT report and ensuring findings are communicated for action.

Radiology quality assurance

Lung cancer screening (LCS) programmes should have a documented QA mechanism in place for CT reading. As stated in the NHSE quality standards document, QA for CT reading may include:[4]

- Stipulating and ensuring a minimum level of training and expertise of readers

- Ensuring initial CT reads of radiologists without experience of LDCT screening are reviewed by more experienced readers (for example the first 50 cases)

- Review of all initial MDT referrals of readers without previous experience of LDCT screening by more experienced readers

- Evaluation of all readers' recall rates, false-positive rates and false-negative rates, with identification of outliers.

As per the NHSE *QA standard guidance*, the overall target referral rate for each local unit is <15%.[4] The referral rate is expected to comprise a combination of referrals for suspected lung cancer via fast track clinic, including nodules requiring work-up other than additional LDCT (for example, positron emission tomography- computed tomography [PET-CT]), target <7%; and referral for significant incidental findings (<8%). The RCR and BSTI

acknowledge this guidance and urge close monitoring and adherence. To help achieve these targets, readers are expected to attend a BSTI-endorsed CT screening course prior to live reading, as outlined below.

In the medium term, the RCR and BSTI would like to highlight the requirement for a national lung cancer screening database to collate findings, including metrics of radiology performance. To enable this, local systems that collate this data are required. Such systems also enable quality metrics to be provided in real-time (dashboard). As per the NHSE Quality standards document, 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 local responsible radiologist.[4]

In addition, an annual reader assessment akin to the online breast cancer screening radiologist self-assessment and training resource PERFORMS is recommended to ensure a high level of accuracy for LDCT interpretation.

Radiology reporting workload

There is significant differentiation between low-dose lung screening reporting and the reporting of clinically indicated thoracic CTs in patients with specific symptoms or underlying conditions. The primary consideration in targeted lung screening is to identify lung cancer. Screening CT reports should therefore be focused, non-narrative and structured. High-quality/high-efficiency CAD/volumetry software and a concurrent reading methodology, as well as high-quality IT infrastructure and workflows, allow for more rapid CT reading than in clinical practice. However, it should be noted that the task of lung screening

CT reading is detrimentally repetitive and should be performed in short batches and in uninterrupted conditions wherever possible.[16]

Lung screening MDTMs

A networked 'screening' MDTM is strongly advised. Most cases will not need to go to the MDTM if the protocol is used correctly. Indeterminate nodule management should also be protocol based and would not typically need formal MDTM referral.

In many instances, the first investigation of choice for the MDT will be PET-CT. On this basis, some previous screening trials have incorporated PET-CT within the nodule management algorithm, to be undertaken prior to MDTM discussion. Such an approach potentially allows for more rapid work-up and diagnosis.[17,18] Recommendations for PET-CT or CT biopsy should be communicated to patients as agreed at a local level.

Some screening pilots have developed a stand-alone screening MDTM, led by the responsible radiologists and respiratory physician. This has the advantage of not only being able to deal with management decisions relating to cases suspicious for lung cancer arising from lung screening, but can also act as a form of quality assurance, ensuring protocol adherence. A stand-alone screening MDTM can also act as a platform for providing second opinion reviews for challenging cases, for reviewing previously unavailable historical imaging or for reviewing reports of less experienced readers.

Lung cancer screening radiologists – minimum requirements

The RCR and BSTI recommend that minimum requirements for screening readers include:

- Reporting a minimum of 500 thoracic CTs per annum in their routine clinical practice, where a significant proportion of the CTs will have a suspicion of lung cancer

- Regular attendance at a thoracic MDTM (includes virtual attendance) as part of their routine clinical work

- Attendance at a BSTI-endorsed CT screening workshop, prior to live LDCT reading, with subsequent attendance at lung cancer educational meetings as part of regular CPD

- Participating in local QA against national standards as outlined in the NHSE quality standards document.[4]

What is needed to deliver this programme effectively?

The RCR and BSTI reiterate the statement in the standard protocol that targeted lung cancer screening is likely to be the single most important implementation to improve outcomes in patients with lung cancer. However, there are functional, logistical and resource issues that need consideration to facilitate effective adoption of the programme over the next five years. The LHC programme should take into account the overarching recommendations of Professor Sir Mike Richards' *Screening review* and the United Kingdom Lung Cancer Coalition's *Pathways matter* report.[19,20]

The RCR and BSTI advocate that the lessons and findings from several ongoing LHC pilots and LCS trials should be continually evaluated and used to refine the nuances of the standard protocol.

Capacity issues are paramount. Clinical imaging is integral to almost all patient pathways, with timely scanning and reporting essential. Demand for imaging is increasing annually as a result of several factors, including a growing and aging population. Imaging techniques themselves are becoming more complex. Adequate staffing is vital if these demands are to be met; however, at present, there are still concerning shortages across the imaging workforce.

The RCR's *Clinical radiology UK workforce census 2019 report* found that more than two-thirds of clinical directors of UK radiology departments feel there are insufficient clinical radiologists to deliver a safe and effective level of patient care, with increasing numbers of unreported imaging studies waiting over a month. Furthermore, the census shows a particular dearth of thoracic radiologists, with fewer joining the specialty than are expected to leave over the next five years. This is also in the context of approximately one-in-five trusts and health boards already having at least one vacant chest/lung radiologist consultant post.[21]

Radiographer capacity also needs to be addressed. The Society and College of Radiographers' (SCoR) 2018 workforce census shows high radiographer vacancy rates across the UK – particularly in England where trusts reported a vacancy rate of 10%.[22]

Access to **diagnostic equipment infrastructure** is also a concern. In the NHS *Long term plan*, published in January 2019, it was noted that capacity in diagnostic services has not kept pace with the growth in demand.[3] The plan acknowledged that the UK has fewer magnetic resonance imaging (MRI) and CT scanners per capita than most countries in the Organisation for Economic Co-operation and Development (OECD), yet the number of patients referred for diagnostic imaging tests has risen by more than 25% over the last five years. Delivering an effective, high-quality service will require investment in new equipment and staffing, with robust strategies to maximise output from existing resources. This should be underpinned by a new model of diagnostic provision which includes a collaboration between NHSE/Improvement, BSTI and the RCR.

Workforce planning for the next five years

The capacity implications of LHCs and a national lung cancer screening programme go beyond purely the scanning and reporting demands. A further key capacity consideration is delivery of the necessary additional mentored training to provide the requisite expertise for reporting LDCTs and performing percutaneous lung biopsies. There are additional knock on effects to the system at a broader level which will need careful attention. These include:

- **PET-CT-reporting nuclear medicine physicians and radiologists:** there will be greater demand for fluorodeoxyglucose (FDG)-PET scans to characterise nodules detected on LDCT screening studies

- **Interventional radiologists:** there will be a greater demand for percutaneous lung biopsy (and potentially CT-guided lung ablation treatments)

- **Pathologists:** pathologists will be required to interpret an increased number of biopsies undertaken as a result of the screening programme. The introduction of the NHS 28 day faster diagnosis standard for cancer by 2020, as outlined in the *Long term plan*, will be challenging to deliver, particularly in light of the time required to undertake molecular pathology.[3] Earlier stage nodule detection could result in smaller, more complex biopsies that are more difficult to interpret. More definitive histology could be needed as greater numbers of patients may be amenable to surgical resection if down-staged.

- **MDTM time will increase**

- **Increased assessment/lung cancer clinics** and a co-ordinated approach to ensure appropriate clinic capacity at short notice

- **Surgeons:** there will be a greater requirement for pre-operative discussions with radiologists to aid lesion finding at surgery. Down staging of lung cancer at diagnosis will result in an increase in workload with concomitant requirements for theatre capacity, anaesthetists, recovery ward, and intensive care beds

- **Lung clinical nurse specialists:** for assessment clinics and those diagnosed with lung cancer

- **Respiratory nurse specialists:** for those diagnosed with other respiratory conditions

- **Clinical oncologists:** due to earlier diagnosis, there may be a greater requirement to provide curative radiotherapy with potential reduction in intense chemo-radiotherapy regimens and palliation

- **Implications of incidental findings:** additional imaging/clinical requirements for investigation, diagnosis and treatment.

The RCR and BSTI recommend discussions with members of the wider MDT throughout the process of setting up the lung cancer screening programme. To maximise the use of expensive equipment and staff (as recommended in the NHS standard protocol), the RCR guide to seven-day working should be followed. The setting up of imaging networks, as suggested by NHSE/I may have a role in overcoming some of these challenges.[23,24]

IT considerations

Data logging and sharing, image sharing and retrieval, and interoperability with picture archiving and communication systems (PACS) are essential components of the service. It is crucial that efficient IT systems are in place to facilitate these functions. The underpinning IT infrastructure needs to be robust, have full connectivity across all relevant sites in primary and secondary care and have the flexibility to implement algorithmic software tools (such as CAD systems and proforma reporting). The IT architecture should also allow:

- Case tracking
- Appointment and scheduling systems
- Automated or semi-automated letter generation systems
- Significant finding alert system
- Onward referral to rapid access lung cancer/assessment clinic
- Onward referral for non-lung cancer suspicious findings
- Recording of patient outcomes including individuals not eligible for the lung health check or for CT screening.

The RCR and BSTI recommend the use of a curated national cloud screening repository. This would integrate all sites under a single framework. Using NHS number as a unique identifier, all centres would publish to the repository. This would allow for a national screening data set, image sharing, reporting networks, training and a quality-assurance portal. It also allows access from multiple sites, including primary care, and integration with third party software including artificial intelligence and new CAD tools.

CAD and machine learning/artificial intelligence (AI) software are expected to become more prevalent over the next five years. While following the stipulations of the standard protocol, if adopting one of the 'augmented clinician' new technologies, the clinical director of the programme must consider:

- Is the product consistent, validated, regulated and quality assured?
- Will it be for the whole screening programme or different products used at different centres?
- Does it enable nodule detection, volumetric analysis and tracking?
- How does the software interact with the nodule management protocols?
- Will clients be notified of its use?
- Where does liability lie?

Summary

The Royal College of Radiologists (RCR) and the British Society of Thoracic Imaging (BSTI) support the incremental roll-out of targeted lung cancer screening as set out in the NHS England (NHSE) document.[1] There are specific radiology aspects of the protocol that warrant special attention from practitioners which have been outlined throughout this paper.

A lung cancer screening programme will reduce mortality from lung cancer through early diagnosis. It is paramount, however, that such a programme is based around strict adherence to protocols that: maximise early detection; minimise recall and false-positive rates; and minimise additional investigations for clinically insignificant incidental findings. Quality assurance, capacity and workforce planning, as well as IT infrastructure, require special and dedicated focus. The RCR and BSTI should be at the forefront of a collaborative planning process to ensure optimum and sustainable implementation of the lung health check programme.[1]

With thanks to the authors of this document:

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