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Developing a pan-European technical standard for a comprehensive high-quality lung cancer computed tomography screening programme: an ERS technical standard

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Shareable abstract (@ERSpublications)
Lung cancer screening with LDCT has been recommended for stepwise implementation in Europe. A high-quality programme is essential for clinical and cost-effectiveness. This ERS technical standard defines the standards needed to achieve this. https://bit.ly/3KT2qOz

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Abstract

Background Screening for lung cancer with low radiation dose computed tomography (LDCT) has a strong evidence base. The European Council adopted a recommendation in November 2022 that lung cancer screening (LCS) be implemented using a stepwise approach. The imperative now is to ensure that implementation follows an evidence-based process that delivers clinical and cost-effectiveness. This European Respiratory Society (ERS) Task Force was formed to provide a technical standard for a high-quality LCS programme.

Method A collaborative group was convened to include members of multiple European societies. Topics were identified during a scoping review and a systematic review of the literature was conducted. Full text was provided to members of the group for each topic. The final document was approved by all members and the ERS Scientific Advisory Committee.

Results Topics were identified representing key components of a screening programme. The actions on findings from the LDCT were not included as they are addressed by separate international guidelines (nodule management and clinical management of lung cancer) and by a linked ERS Task Force (incidental findings). Other than smoking cessation, other interventions that are not part of the core screening process were not included (*e.g.* pulmonary function measurement). 56 statements were produced and areas for further research identified.

Conclusions This European collaborative group has produced a technical standard that is a timely contribution to implementation of LCS. It will serve as a standard that can be used, as recommended by the European Council, to ensure a high-quality and effective programme.

Introduction and scope

A recent independent report commissioned by the European Commission's Group of Chief Scientific Advisors recommended that lung cancer screening (LCS) be added to the other established cancer screening programmes in Europe [1]. The subsequent recommendation adopted by the European Council was that LCS "… can be implemented in a stepwise approach to ensure the gradual and appropriate planning, piloting, and roll-out of the screening programmes within national priorities" [2]. Furthermore, the recommendation stressed the need to follow evidence-based guidelines and standards. Prior to this, two European expert consensus statements recommended preparation for LCS implementation in Europe [3, 4] and more recently the European Respiratory Society (ERS) recommended implementation in an updated statement on LCS [5]. However, to replicate and improve on the results of the trials that have provided the evidence on which these recommendations were made, there needs to be careful adherence to optimal practice, and this requires that screening programmes are well organised with clear guidance, protocols and quality assurance. Although individual national consensus statements exist, none amount to a protocol that can be followed from a pan-European perspective. Rather, there is a risk that a heterogeneous LCS landscape will develop among, and even within, European countries. There is therefore a pressing need to develop a harmonised technical standard bringing together existing protocols and the latest evidence.

A number of screening initiatives have protocols supporting them. In the USA, the International Early Lung Cancer Action Program (I-ELCAP) has produced protocol documents covering nodule work-up and surveillance, management of incidental findings and quality assurance which their screening sites should adhere to [6]. A joint policy statement was published in 2015 by the American Thoracic Society (ATS) and American College of Chest Physicians (ACCP) [7] and more recently, CHEST lung cancer guidelines [8] and an extensive ATS/American Lung Association (ALA) implementation guide including a detailed website [9, 10] have added to the complexity of the available resources in the USA. In the UK, National Health Service England (NHSE) has made significant progress with a phased implementation of a targeted LCS programme called Targeted Lung Health Checks (TLHC). To ensure a standardised approach, a protocol and quality assurance standards were developed [11, 12]. A pan-European technical standard offers the potential to improve the consistency of approach to LCS, but the challenge is to make it sufficiently adaptable to be useful across the spectrum of healthcare systems in Europe.

The clinical management of findings from screening is not part of the scope of this technical standard. Guidelines exist for the management of pulmonary nodules and for the investigation and treatment of lung cancer, so this technical standard will not include details of either of these, although both are essential parts of a screening programme [4, 13–16]. The management of incidental findings by computed tomography (CT) is also a substantial topic and is being addressed by a separate ERS Task Force, which is currently under review and when available will comprise a valuable accompanying document to this technical standard. Health economics was not included in the scope, although adhering to high-quality standards should maximise cost-effectiveness. It is important that each country use existing or new models to determine both cost-effectiveness and total financial impact to determine feasibility and speed of implementation, as indicated in the European Council recommendation [2].

The primary aim of this ERS Task Force was to formulate and agree a pan-European technical standard for a comprehensive high-quality lung cancer CT screening programme. Additional work that the Task Force will undertake includes setting up a pan-European network of experts along with a network of early career members; establishing which components of a screening programme are missing in different countries and which components require a clinical guideline; identifying topics for research; and disseminating the work.

Methods

The assembly of the Task Force was coordinated by the ERS following approval by the ERS Guidelines Working Group and ERS Council in January 2021. The work was conducted by members with expertise in pulmonology, radiology, thoracic surgery and radiation oncology, and thus covered most of the core specialisms involved in LCS. The Task Force received support from ERS methodologists throughout the project. The Task Force was further enhanced by involvement of a patient representative from the European Lung Foundation. Six meetings were held (five virtual and one in person at the ERS Congress 2022). All members of the Task Force signed conflict of interest disclosures at the beginning of the project and updated them at project finalisation or when any new relevant conflict of interest appeared. Conflicts of interest were managed according to ERS policy.

The first exercise was to identify and agree the essential components required for a high-quality LCS programme and list these as topics. Following this, a literature search was performed. The evidence reviewed was restricted to that drawn from CT screening trials and programmes for all topics unless stated

in the relevant section. MEDLINE and Cochrane Library records from 2010 to 2021 were searched. The search terms are shown in supplementary appendix A. Selected references considered to be of particular relevance were included up to June 2021 (although additional references identified by Task Force members were included up to July 2022). In addition, Task Force members were asked to source government and other institutional documents that might be of relevance. All retrieved references were uploaded to Covidence (www.covidence.org). This systematic review software allows for review of abstracts by more than one evaluator. E.L.O'D. and T.G.B. reviewed all abstracts and excluded those of no relevance to the topic. Included articles were classified according to which component of a LCS programme they pertained (they could have multiple classifications). Some articles potentially covered all components and were given a general classification for review by all leads for each topic. Discordant abstracts were arbitrated by a third reviewer (D.R.B.). Full-text review of the remaining articles was conducted by two or more Task Force members, and relevant reference lists were examined for additional citations and these were included up to July 2022. Only studies written in English, or for which an English translation was available, were included. The article screening results are presented in the flow diagram in supplementary appendix B. A total of 1341 abstracts were screened, 680 full-text studies were assessed for eligibility and 260 studies were included. Lead Task Force members for each section drafted a summary of the evidence and statements. This work was then reviewed by all Task Force members, and the evidence summary, statements and research recommendations were finalised.

Results

Topics relating to components of a LCS programme

Supplementary appendix C shows the list of topics identified by Task Force members. The questions relating to each topic are also shown. The clinical management of the findings from low-dose CT (LDCT) was not included in the scope due to existing clinical guidelines (lung cancer management and pulmonary nodules); incidental findings are addressed by the linked Task Force.

Summary of technical standards

Capacity and infrastructure standards

1) Prior to commencement, and at regular intervals during the expansion and full implementation of a LCS programme, there should be a full assessment of the essential components where the capacity and/or infrastructure could jeopardise the safety and effectiveness of the programme. These are shown in table 1 in the Detailed review and results section.

Governance and roles standards

2) LCS programmes should have a clearly defined and documented governance structure.
3) There should be a national oversight committee or a collaborative group to ensure a uniform approach and appropriate equity in coverage and standards; this should involve capacity considerations.
4) There should be regionally and locally based steering committees to oversee and monitor the screening programmes which should report to the national committee.
5) There should be defined roles to which individuals are appointed to take overall responsibility for standards of the assessment and recruitment process, radiology reporting and clinical work-up.
6) There should be documented mechanisms to ensure equity of access to the programme.

Invitation methods standards

7) Identification of the potentially eligible population should be *via* electronic records containing data on smoking habits where these exist.
8) National programmes should consider creating a population record of individual smoking habits as part of health surveys.
9) Where there is no such national record, invitation methods should be deployed in a variety of settings that may include high-risk geographic locations, smoking cessation clinics, community centres, occupational health clinics and *via* other screening programmes.
10) Materials providing accurate information about LCS should be distributed to high-risk individuals *via* mail and social media, and should include written material and educational videos.
11) Information and invitations should be tailored to account for potential inequity in access and uptake in minority groups
12) The first approach to potential participants should be *via* primary care, where possible.
13) Invitation methods should include: provision of information in a format sensitively designed for the demographic and designed to reduce fear; pre-invitation letters, texts, reminders and pre-scheduled appointments; and repeat appointments for non-attenders.

14) There should be easy geographical and physical access to screening and appointments with easy rescheduling for participants.
15) Feedback from non-attenders should be sought and used to improve invitation methods.
16) Patient advocacy groups should be part of the engagement with potential participants.

Risk assessment for entry into screening programmes standards

17) Multivariable models that have been externally validated in the local population or one very similar are preferred over age and smoking history alone.
18) Multivariable models or single criteria (*e.g.* presence of pulmonary nodules) may be used to stratify participants into annual or biennial screening intervals.
19) Participants should be reassessed for eligibility by risk threshold; this can be done *in silico* if using multivariable model(s).
20) Participants should be reassessed for fitness at each screening round to ensure they can still benefit from screening.

Smoking cessation standards

21) CT screening programmes should include an integrated smoking cessation intervention for participants who are smokers.
22) The smoking cessation service should be comprehensive, and include smoking cessation practitioners, availability of pharmacotherapy and regular follow-up.
23) Smoking cessation services should be co-located with the screening services and offered at the same time on an opt-out basis.

Non-attendance and exiting the programme standards

24) Methods effective in increasing baseline participation should be employed to reduce non-attendance (see Invitation methods in the Detailed review and results section).
25) In addition, appointments for ongoing screening should be made as soon as possible after the previous screen and reminders provided nearer the time of the scan.
26) Information for participants should emphasise the importance of ongoing screening for the individual.
27) Programmes should have navigators (nurse, patient or both) to support the participants in ongoing screening as well as helping with administration such as reminders, identifying travel needs and facilitating rescheduling.
28) Participants should exit the programme once they no longer meet the eligibility criteria; they should be given clear information why they should no longer be screened and information about what to do if they have symptoms that could be due to lung cancer.

Imaging acquisition and reporting standards

CT and software

29) The minimum specification is a 16-row multi-detector CT calibrated according to the manufacturer's specifications, capable of delivering low radiation dose protocols (see standard 35). There should be regular checks on the equipment according to local protocol.
30) For volumetric software:
    a) It is the preferred method for assessment of solid pulmonary nodules.
    b) The same software should be used to compare volumes.
    c) Where there are software updates these should be recorded and the supplier provide evidence that:
        i) the upgrade provides the same measurements; or
        ii) ensure that the user is prompted to re-measure nodules from preceding scans.
    d) It must be directly or indirectly integrated into picture archiving and communication systems, capable of automated image retrieval of historical imaging.
    e) Additional desirable standards for volumetry are provided in supplementary appendix F.
31) Computer-aided detection should be used as a concurrent or second reader. A false positive rate of <2 per case is desirable for computer-aided detection systems.

CT image acquisition protocol

32) Participants should be comfortably positioned supine, with arms above their head and thorax in the midline of the scanner. Maximal inspiration should be rehearsed prior to the scan and imaging should be performed during suspended maximal inspiration. No intravenous contrast material should be administered.

33) Programmes should use their standard scanogram to localise the start and end positions of the scan. The frontal localiser should be performed in the postero-anterior projection and at the lowest possible setting to minimise breast dose.
34) The lung parenchyma (lung apices to bases) must be scanned in its entirety in a single cranio-caudal acquisition. The field of view should be selected as the smallest diameter as measured from the widest point of outer rib to outer rib large enough to accommodate the entire lung parenchyma. Thin detector collimation ($\leqslant$1.25 mm) will be used.
35) The CT dose index volume ($CTDI_{vol}$) must be kept as low as possible with the effective radiation dose well below 2 mSv. The kVp and mAs settings are adjusted according to the height and weight of participants. Ultra-LDCT should be used where considered to be of equivalent diagnostic sensitivity to LDCT.
36) Image reconstruction should be standardised and used for any follow-up examinations, with particular emphasis on ensuring that slice thickness, reconstruction increment, reconstruction algorithm and field of view are identical. Slice thickness should be $\leqslant$1.25 mm. If iterative reconstruction is used, this should be kept constant at follow-up.

Reporting

37) Image interpretation should be performed on systems which permit scrolling through the dataset with variable thickness and orientation using multiplanar reformations and maximum intensity projection. Volumetric segmentation of nodules should be checked visually.
38) All scan data should be archived and retained; a national repository should be considered to facilitate education and research.
39) Readers must report a substantial number of thoracic CT scans annually as part of their normal clinical practice (over 500), including a significant proportion of lung cancer CT scans.
40) Readers must be familiar with the use and limitations of nodule volumetry software and apply agreed guidelines for nodule management.
41) A structured reporting proforma must be used to promote consistency and assist audit.

Thoracic CT reader quality assurance

42) Each programme should have documented quality assurance mechanisms in place for CT reading. Quality assurance for CT reading may include:
    a) Ensuring a minimum level of training and expertise of readers, including continuous professional development in LCS.
    b) Ensuring initial CT reads of radiologists without experience of LCS are reviewed by more experienced readers (*e.g.* first 50 cases).
    c) Periodic review of CT readers reports by expert panels, including referral recommendations.
    d) Evaluation of all readers' recall rates, false positive rates and false negative rates, with identification of outliers. This includes incidental findings.
    e) Evaluation of readers against validated cases.
43) National or regional consortia of expert radiologists may be the best way to address capacity, education and quality assurance.

Interval and surveillance standards

44) Annual LDCT is the preferred interval if capacity and total economic and health service impact allow.
45) Biennial intervals may be applied for lower risk groups using LDCT findings or multivariable risk prediction models to select participants.
46) Participants should be aware of the reason they have been stratified.
47) Screening intervals should not exceed 2 years.
48) Surveillance scans with a shorter interval than 1 year should follow pulmonary nodule guidelines.

Communication of results standards

49) Communication of results for each finding needs to be systematically designed for local populations, with local patient representative input.
50) The outcome should be communicated within a timeframe not exceeding 4 weeks from the LDCT.
51) Communication of negative and indeterminate findings can be *via* mail with an offer of support *via* telephone or videocall. Communications should include a reminder of the symptoms of lung cancer and the importance of smoking cessation.

52) Communication of positive findings should be face to face, usually within an urgent clinic.
53) Feedback from participants should be collected *via* a formal process and the results used to improve the participant experience.

Data management standards

54) An end-to-end, validated data management system is the optimum system for an organised LCS programme.
55) Data management systems must be supported by an agreed national minimum dataset that allows regular centralised audit and reporting of key outcome metrics (see table 3 in the Detailed review and results section).
56) Data management system have to adhere to information governance and General Data Protection Regulation regulations.

Detailed review and results of technical standards

Capacity and infrastructure requirements

Evidence review

The evidence review for this section was limited to papers which covered capacity and infrastructure requirements. Of 138 full texts reviewed, 30 papers were included, alongside two websites [10, 17]. These ranged from single-site pilot/trial data to national protocol/consensus statements.

A US 10-pillar model has also been produced which summarises the elements that are felt to be required to support a successful LCS programme [18]. The ATS/ALA implementation guide provides detailed guidance on various aspects of capacity and infrastructure, and also gives examples from many sites in the USA [9, 10]. The NHSE TLHC standard protocol has set out requirements for the capacity and infrastructure needed to run LCS [12], and there is a Spanish expert consensus statement on how to implement and evaluate screening in Spain [19]. Smaller trials and single-site pilot projects have also summarised their individual requirements [20–23]. There were key capacity and infrastructure requirements identified as essential to be able to deliver a CT screening programme which are summarised in table 1. The ATS/ALA implementation guide notes that programmes may be “centralised”, where all of the screening process is coordinated from a centre, or “decentralised”, where the programme provides the LDCT but with all other elements left with the referred and hybrid programmes [9, 10].

Another aspect which was considered in the literature was how to assess the readiness of a centre to implement LDCT screening. One US study proposed that tools could be employed to assess implementation readiness, with the Diabetes Care Coordination Readiness Assessment given as an example [24, 25]. The tool considers five domains: organisational capacity, care coordination, clinical management, quality improvement and infrastructure. A wide range of other readiness assessment tools exist which the authors suggest could be adapted for use to assess readiness to start LDCT screening, with suggested

TABLE 1 Key essential capacity and infrastructure requirements for delivery of a lung cancer screening programme from literature review

1) Risk assessment and recruitment: administrative team, nurse/health advisor, primary care or pulmonology requirement to assess eligibility and coordinate shared decision making required in some programmes
2) Education resource: all members of the delivery team but especially administration, primary care, radiology and pulmonology
3) Information resource for participants
4) Insurance and reimbursement or funding mechanism
5) LDCT scanning capacity and availability, with mobile/community sites available if required
6) Radiology scheduling, reporting and quality assurance
7) Multidisciplinary clinical management teams to work-up and treat referred participants
8) Management teams responsible for screening implementation and quality assurance
9) Programme coordinator and patient navigator
10) Information technology resources to enrol and track patients accurately, ensure follow-up and monitor the programme
11) Integrated smoking cessation support and advice
12) Alignment with local services/support from local leadership

LDCT: low-dose computed tomography.

metrics for implementation readiness being competing priorities, concurrent activities, ongoing or upcoming systems challenges and system readiness [26].

Some small studies have looked at current capacity constraints and what impact LDCT screening may have on these [27, 28]. A 2016 study by Rodin *et al.* [29] highlighted inequities in access to radiotherapy machines, radiation oncologists and medical physicists across Europe. Access to CT scanners also varies widely between countries. Data on the number of CT scanners by country and per million population have been produced by the Organisation for Economic Co-operation and Development (OECD) and show wide geographical variation in availability [17]. A microsimulation model using data from the US National Cancer Database has been published to look at the potential increase in treatment demand that screening may pose [30]. This work suggests that full-scale implementation of LCS would cause a major increase in surgical demand, with a peak within the first 5 years. The authors advise that careful surgical capacity planning is essential for successfully implementing screening. Each country or region will have specific areas which may require focus and investment, considering current infrastructure, the healthcare system and competing priorities. This will also be influenced by screening uptake rates and the proportion of the population who are eligible.

Summary

Although specific capacity requirements and infrastructural considerations will differ between countries, there are common key requirements that are felt to be essential for the delivery of LDCT screening.

Capacity and infrastructure standards

1) Prior to commencement, and at regular intervals during the expansion and full implementation of a LCS programme, there should be a full assessment of the essential components where the capacity and/or infrastructure could jeopardise the safety and effectiveness of the programme. These are shown in table 1.

Clinical governance, roles and responsibilities

Clinical governance has a central position in the overall organisation and running of a screening programme, and is a feature of successful screening programmes [31, 32]. The detail of how clinical governance is organised is likely to be influenced by the way the health services as a whole are organised and funded, the level of funding per capita, and the infrastructural and clinical standards of healthcare, especially for lung cancer [33, 34]. Nevertheless, adhering to established principles is important in all healthcare systems as it will underpin higher quality despite the constraints that may apply. As LCS develops, governance structures will be required and are best defined and implemented before the start.

Evidence review

87 full texts were reviewed. Two systematic reviews on LCS commissioned by two German national agencies [35, 36], a pilot protocol for the National Cancer Screening Programme in South Korea [37], several statement papers by societies and expert groups on the international and national level [3–5, 7, 38, 39] as well as narrative reviews covering aspects of the LCS pathway [18, 19, 21, 40–58] were reviewed. While these described some elements that could be included in a governance structure, none dealt specifically with the topic. Other studies provided experiences and outcome data in LCS pilots as well as implementation initiatives within national programmes [20, 25, 59–63].

The review of society and national management standards was more informative. The American College of Radiology (ACR) has produced accreditation standards for thoracic radiology since 1987 and has described an accreditation process for the radiology for LCS, essentially supporting quality assurance [64]. Similarly, the British Society of Thoracic Imaging (BSTI) and Royal College of Radiologists (RCR) have recommendations on radiology standards [65]. The ATS/ALA implementation guide provides collated information on locally adopted solutions in the USA as examples of how to set up clinical governance and who to involve within LDCT LCS programmes [9, 10]. The NHSE TLHC standard protocol has set out requirements for governance, including descriptions of roles and responsibilities in the running and oversight of the local programme [11, 12]. National LCS standards were also identified from Germany [66] and Poland [67, 68]. We utilised these publications and documents as an available evidence basis to provide a suggested structure and description of the major roles that can be adapted for use in individual national healthcare settings.

The design of the clinical governance structure within a national LCS programme depends on whether the programme is centralised, decentralised or a hybrid. A centralised programme takes full responsibility for enrolling participants, managing them along the entire pathway including follow-up schedules, whereas a decentralised LCS programme is limited to LDCT scanning, reading and reporting to referring providers who are then in charge of organising all subsequent pathway steps.

Figure 1 shows the core roles and their responsibilities that were found in the evidence review, represented is a hierarchical structure. This can be adapted according to the design of the programme (central or local). Supplementary appendix D shows the roles and functions found in the literature review.

Summary

Most, if not all, screening programmes and pilots have some form of governance structure, although this is often not well described. Those that document governance arrangements favour a hierarchical structure and create specific roles within that with defined responsibilities. Effective governance will serve to improve the efficiency, efficacy, monitoring and safety of LCS whether at the decentralised level or when overseen by a national structure.

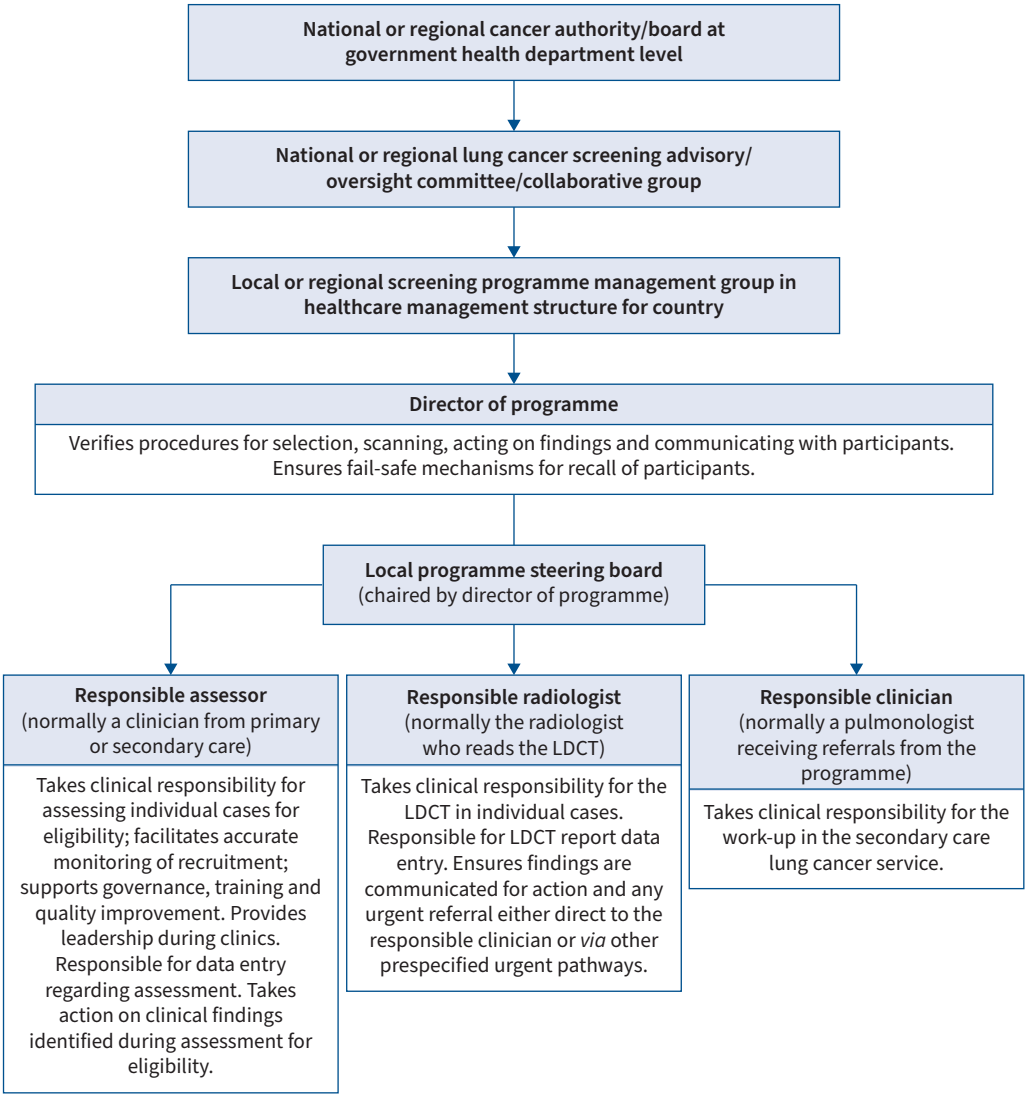

FIGURE 1 A basic centralised structure with hierarchies, roles and responsibilities. LDCT: low-dose computed tomography.

Governance and roles standards

2) LCS programmes should have a clearly defined and documented governance structure.
3) There should be a national oversight committee or a collaborative group to ensure a unform approach and appropriate equity in coverage and standards; this should involve capacity considerations.
4) There should be regionally and locally based steering committees to oversee and monitor the screening programmes which should report to the national committee.
5) There should be defined roles to which individuals are appointed to take overall responsibility for standards of the assessment and recruitment process, radiology reporting and clinical work-up.
6) There should be documented mechanisms to ensure equity of access to the programme.

Participant pathway

The participant pathway is important to define for each programme as it will be a clear summary of the process and may be important in ensuring cost-effectiveness. There are numerous such pathways in implementation guides but little in the way of evidence to inform an evidence-based pathway (other than that reviewed in this paper for individual steps, *e.g.* invitation method). A sample pathway developed for the UK National Screening Committee health economics evaluation that led to the recent recommendation for a UK targeted LCS programme is shown in supplementary appendix E [69].

Invitation methods

Despite the established efficacy of LDCT LCS, participation in programmes has been mostly low, although variation is seen within and between countries. In the USA, where LDCT screening has been funded since 2015, participation rates were 3.3% of the eligible population in 2015 and more recently estimated to be 14–19% in 2018, although only 4–7% in the uninsured [70–73].

Barriers to participation include emotional and practical barriers that reduce engagement and uptake and limit the effectiveness of interventions. Practical barriers include travel, employment and other commitments, costs of screening (especially where there is limited medical insurance) [74], and comorbidity [75]. Among the emotional issues, we include fatalism about risk and survival, low perceived efficacy of treatment, fear of diagnosis, stigma, guilt, and misunderstanding [75–80]. There are also practical barriers from the provider perspective, such as difficulties in identifying eligible individuals due to the lack of reliable data on smoking history in the population registries and electronic medical records [77]. Most studies show that older people, females, current smokers and those in lower socioeconomic status groups are less likely to participate [75, 81–83]. Physical distance and access are also known to be practical barriers [84], leading to the provision of mobile CT in some programmes [12, 85–89], with one study showing a preference for this among participants [90] and another showing no difference in attendance rates [91].

Evidence review

Of 124 full texts reviewed, 58 were included as providing some details of invitation methods into pilots and programmes. Invitation methods described fell broadly into two approaches: a systematic approach, where there is an attempt to offer the whole eligible population screening, and an unsystematic approach, where the strategies did not attempt to provide uniform access.

Systematic approaches

The UK Lung Screen (UKLS) [92] and NELSON [93] studies employed a population approach where all people of eligible age were sent an initial letter (NELSON recruited mainly men). This was clearly shown to have very low uptake from the total people contacted (1.6% UKLS and 2.6% NELSON). Similarly, a study in Milan, Italy, tested the feasibility of recruiting participants *via* telephone contact. The call recipient was asked if there were any family members who were over the age of 50 years and had a greater than 30 pack-year smoking history. Those meeting these criteria were contacted and asked to participate in the programme. Only 1.9% of a total of 2300 persons were eligible for screening and only 27% of these (0.5% overall) agreed to participate [94]. This contrasts with the targeted systematic approach used in several UK studies [85, 86, 91, 95, 96] and the TLHC [12, 97] where participation rates are generally over 30% and in some of the TLHC centres, over 60% (unpublished data from NHSE National Cancer Programme Team). These studies and pilot programmes all used the NHS primary care record to identify ever-smokers in the eligible age range and then either telephone or clinic assessment of eligibility. The invitation method was modelled on both research from other cancer screening programmes and from LCS. The Lung Screen Uptake Trial (LSUT) was primarily designed to test the impact on informed screening uptake of low-burden tailored information in a population with high levels of social deprivation [98]. Although the intervention had little impact, the participation was 52–53%. This may have been because of

the efficacy of the invitation method which combined an approach from primary care, the use of pre-invitation letters (information about the programme before invitation), reminder letters for non-responders, pre-scheduled appointments and a framing of the invite akin to a "Lung Health Check" in an opt-out fashion. The reminder letter with a second appointment explained 10% uptake. The NHSE TLHC protocol recommends ensuring easy access to the LDCT, including obtaining appointments and changing these where desired. It recommends a formal process for contacting non-attenders and feedback from non-attenders to evaluate their reasons [12]. There is little evidence about how to encourage repeated non-attenders to participate.

Unsystematic approaches

Unsystematic invitation methods are the most used of all methods in trials and are also used in some programmes. They are necessary because of the absence of a central database of people that contains details of lung cancer risk factors, primarily smoking [99]. In a study from Canada, a primary care administered questionnaire was developed to collect these data, but the uptake was low, and a recommendation made for this to be incorporated into appointments [100]. Recommendations to establish a better primary care record have been made in parts of the USA [101, 102]. Invitation methods employ advertisements [103], media campaigns, social media [104], telephone contacts [105] and other methods [106, 107]. Information about potentially eligible people has been obtained from questionnaires in different settings. For example, one study administered questionnaires to new consults in a Department of Radiation Oncology and Otolaryngology and found that of 546 new consults, 528 people completed questionnaires and 104 (20%) met criteria for LCS [108]. A further study incorporated information about CT screening into an information video on smoking cessation, and showed that this increased the usage of both CT and LDCT among those shown the video [109].

Equality

Disparities have been described in several minority groups, including racial [110–114] and sexual orientation [115, 116]. A study used what is said to be the first mobile CT to screen uninsured people in the USA, aged 55–64 years from underprivileged backgrounds. This study found a baseline cancer detection rate of 2.2% (12 out of 550); this was despite excluding people aged over 64 years with Medicare cover [117].

Summary

Invitation methods for LCS need to take into account the barriers that prevail in the eligible population. The invitation methods associated with the highest participation rates identify and approach the potentially eligible population *via* primary care electronic records. They use primary care as the first approach, providing information in a format which has been designed for the demographic and designed to reduce fear (*e.g.* the "Lung Health Check"). They employ pre-invitation letters, texts, reminders, pre-scheduled appointments and repeat appointments for non-attenders. New programmes should have high visibility and person-facing materials need to present balanced information on benefits and harms, tailored to the demographic. The lack of a population-based electronic record containing details of smoking habits means that other approaches need to be taken which are less effective but can include a variety of methods to engage with potential participants. Patient advocacy groups may play an important part in supporting informed decisions about participation.

Invitation methods standards

7) Identification of the potentially eligible population should be *via* electronic records containing data on smoking habits where these exist.
8) National programmes should consider creating a population record of individual smoking habits as part of health surveys.
9) Where there is no such national record, invitation methods should be deployed in a variety of settings that may include high-risk geographic locations, smoking cessation clinics, community centres, occupational health clinics and *via* other screening programmes.
10) Materials providing accurate information about LCS should be distributed to high-risk individuals *via* mail and social media, and should include written material and educational videos.
11) Information and invitations should be tailored to account for potential inequity in access and uptake in minority groups
12) The first approach to potential participants should be *via* primary care, where possible.
13) Invitation methods should include: provision of information in a format sensitively designed for the demographic and designed to reduce fear; pre-invitation letters, texts, reminders and pre-scheduled appointments; and repeat appointments for non-attenders.

14) There should be easy geographical and physical access to screening and appointments with easy rescheduling for participants.
15) Feedback from non-attenders should be sought and used to improve invitation methods.
16) Patient advocacy groups should be part of the engagement with potential participants.

Risk assessment for entry into screening programmes

Screening for lung cancer differs from other established cancer screening programmes in that it is targeted to a population at higher risk of developing lung cancer because the benefit is greater [118]. In addition, it may also be a stratified programme where an element of the programme (for LCS, this is the screen interval) is varied according to level of risk. Definitions of targeted and stratified screening have been published by the UK National Screening Committee [119]. In most randomised controlled trials of LCS, eligibility has been determined by age and tobacco smoking criteria [120, 121]. A number of multivariable risk prediction models have been developed that are more sensitive and specific, but are still heavily dependent on smoking and age [122, 123]. Some have been used successfully in trials and pilot programmes and have yielded higher detection rates, although they may also select people with more comorbidities [8, 92, 124, 125].

Evidence review

Of 137 full texts reviewed, 58 contained information about entry criteria according to risk. Both NELSON and the National Lung Screening Trial (NLST) used age and smoking criteria [93, 120], and some later trials used multivariable models [85, 96, 125–128].

Age and smoking criteria

NLST entry criteria were a minimum of 30 pack-years and a quit time within 15 years of entry in people aged 55–74 years [120]. These were later modified to a recommendation to screen people in the wider age range of 55–80 years. Most recently, the US Preventive Services Task Force (USPSTF) has widened the criteria considerably to include people aged 50–80 years who have smoked at least 20 pack-years and quit within 15 years [129]. However, it has been shown that multivariable models provide a more efficient method to select participants, although they may select some individuals who have greater comorbidity [130–133].

Multivariable models

In a recent systematic review, 27 studies were identified describing 30 different models that predicted either lung cancer incidence or mortality [134]. 14 out of 27 studies described external validation. Studies have shown that criteria used in studies based on age and smoking select fewer people who develop lung cancer and a fitter population, mainly by virtue of including younger people [127, 135–137]. Models vary in their complexity and most earlier comparative studies show similar performance, with the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial $PLCO_{m2012}$ model often achieving the highest discrimination [122, 123, 138]. However, these comparative studies did not test the latest models [139, 140], and performance of any model may be influenced by the population to which it is applied and the quality of the input data [141]. Another suggested approach is to apply a simple “pre-screening” approach where basic criteria are applied to electronic data records to “enrich” the population before more complex models are employed [141, 142]. Although most models predict risk, an alternative approach is to predict benefit in terms of life years gained [143].

Risk prediction in selected populations

People with a previous history of cancer have been shown to be at increased risk of lung cancer and this has led some to suggest these should be included in LCS, *e.g.* survivors of lymphoma [144], breast, head and neck, and lung cancer [145].

Age and smoking criteria have been shown to be less effective in some East Asian populations because of their reliance on smoking history [146]. Here, bespoke multivariable models have been developed, *e.g.* in Taiwan where screening is offered to never-smokers [146–148]. Newer models have been proposed using blood biomarkers and/or genetic information in both Western and Eastern populations [149–155].

Occupational exposures are included in the National Comprehensive Cancer Network (NCCN) selection criteria. One study showed that when NCCN guidelines were applied in a group of workers exposed to carcinogens the cancer detection rate was 1.6% despite only 45% meeting NLST criteria [156]. Similarly, working for 5 years or more in US construction was found to be equivalent to having a positive family history, a previous history of cancer or a diagnosis of COPD [157]. Several screening programmes for

workers exposed to asbestos have been described [158–162]. Mortality from lung cancer and all-cause mortality was reduced by 59% and 39%, respectively, in one retrospective study that compared participants in a screening programme with a non-participant control group [158]. While a systematic review of seven cohort studies concluded that workers exposed to asbestos had a similar lung cancer incidence to heavy smokers [161], another study suggested that asbestos exposure alone was not sufficient to make workers eligible for screening and instead other risk factors were required [160]. The Liverpool Lung Project risk models include asbestos exposure as a variable [163, 164].

There is little evidence to support simple age and smoking criteria as the preferred method to assess eligibility other than as a way to identify a population that is potentially eligible. Furthermore, risk thresholds can be more precisely defined. Never-smokers are unlikely to be eligible for screening unless/until biomarkers become available that can be applied [165]. Combining clinical data with genetic variants has been shown to improve risk prediction in smokers [149], but how this can be cost-effective in screening programmes is not clear. Novel approaches include using artificial intelligence applied to chest radiographs in the prediction of lung cancer [166].

Stratification

Analyses of both NELSON and the NLST showed that the presence of nodules on baseline or subsequent screens increases the risk of lung cancer [167, 168], and a lower risk in NLST participants with a negative baseline screen prompted the suggestion of a longer screening interval in this population [169]. More recently, multivariable models have been developed to better define subsequent risk and may offer a risk-stratified approach to screening [139, 170–173].

Fitness assessment

Participants should have a reasonable chance of benefiting from early detection of lung cancer. This essentially means that there is a high chance of cure.

It is noted that even early detection of lung cancer that is at a later stage can benefit lung cancer patients because their fitness is better and they may therefore benefit more from systemic anticancer therapy. However, this is not considered further here. A check should be made for any of the exclusion criteria for fitness enough to prevent curative intent treatment. Using this approach, most screening trial and pilots show high treatment rates [85, 92, 120, 121].

Reassessment method

Reassessment may apply to people who exit the programme if risk falls below the baseline criteria, *e.g.* having quit smoking for more than 15 years or developed a new health problem in USPSTF criteria [129]. Where multivariable models have been used, there can be a repeat risk assessment that could be first completed *in silico* using existing data but with the age changed and assuming there has been no change in smoking status and other model parameters. This can be followed up using confirmed data. The interval between risk assessments may need to vary depending on proximity to risk threshold.

Summary

Selecting a population at high risk of lung cancer is a key factor in ensuring efficiency. Multivariable models are evolving and show superior cancer detection rates compared with simple age and smoking criteria. They can also facilitate variable thresholds according to cost-effectiveness and willingness-to-pay threshold. Newer models and those incorporating biomarkers, genetic factors, artificial intelligence and applied in specific populations may further improve accuracy.

Risk assessment for entry into screening programmes standards

17) Multivariable models that have been externally validated in the local population or one very similar are preferred over age and smoking history alone.
18) Multivariable models or single criteria (*e.g.* presence of pulmonary nodules) may be used to stratify participants into annual or biennial screening intervals.
19) Participants should be reassessed for eligibility by risk threshold; this can be done *in silico* if using multivariable model(s).
20) Participants should be reassessed for fitness at each screening round to ensure they can still benefit from screening.

Research recommendations

- Multivariable models should be validated in the population in which they will be used.

- Evaluation of novel approaches using additional risk factors and in specific populations should ensure that the impact on prognosis and hence efficacy of screening is included.
- Research into the best multivariable model for individual programmes should investigate accuracy, ease of application and potential to increase inequities.
- Evaluation of the best way, and at what interval, risk should be recalculated in individuals previously found to be below the risk threshold.

Smoking cessation

In most populations, LCS is offered to people who have ever smoked tobacco. In most screening trials and pilots, a substantial proportion of those screened were current smokers, typically 35–55% [85, 92, 120, 121]. Smoking cessation is a well-established cost-effective intervention that reduces mortality from many conditions, including COPD and ischaemic heart disease, and has been shown to double the impact of LCS on mortality reduction from lung cancer in the NLST [174–176].

Evidence review

Of 76 full texts reviewed, 26 contained some details of smoking cessation used in the development of the statements. The majority of LCS trials provided brief advice and referral for smoking cessation. Trials that measured smoking cessation all concluded that the smoking cessation rates were above that observed in the general population [177–181]. The optimal strategy for integrating smoking cessation has been the focus of much research [15, 174, 179, 182–194]. There are limited data around provision of other services, such as psychological support, within the screening programme. There is no consistent evidence of a "licence to smoke" effect, whereby a normal scan discourages quitting. Indeed, there is some research to suggest that LCS represents a "teachable moment" where participants maybe particularly receptive to smoking cessation interventions [189, 195–197]. Research published in abstract form from the UK has shown that quit rates of over 30% at 1 year can be achieved using opt-out, co-located, comprehensive cessation services with follow-up [183, 198]. Of all current smokers attending for screening, 86% took up the initial consultation, with 85% of these agreeing to a 4-week period of smoking cessation support [198]. Another randomised trial in the UK showed that immediate telephone-based smoking cessation, including pharmacotherapy, resulted in a 21% self-reported quit rate at 3 months compared with 9% in controls [199].

Smoking cessation is known to be cost-effective, so in assessing cost-effectiveness of screening programmes the quit rate needs to be included. From the literature, quit rates vary, so a variety of quit rates should be modelled to allow an assessment of how achieving these might influence the overall cost-effectiveness of the screening programme.

In the context of the light-touch intervention in the UKLS trial, the smoking cessation rate in the intention-to-treat population at 2 years was 15% [177]. This should be regarded as the worst-case scenario (15% 2-year quit rate) and increments above this should be modelled up to 30%.

Summary

Evidence shows that LCS is an opportunity to markedly increase smoking cessation rates. The most effective method is to use comprehensive smoking cessation services that are located at the site, and provided at the time, of the LDCT.

Smoking cessation standards

21) CT screening programmes should include an integrated smoking cessation intervention for participants who are smokers.
22) The smoking cessation service should be comprehensive, and include smoking cessation practitioners, availability of pharmacotherapy and regular follow-up.
23) Smoking cessation services should be co-located with the screening services and offered at the same time on an opt-out basis.

Research recommendations

- Research should directly compare co-located services with those at a separate site.
- Research should determine the optimal strategy to deliver smoking cessation in individual programmes.

Non-attendance and exiting the programme

Non-attendance may be an issue at the start of the screening process where participants elect not to take up an appointment where this is offered. The factors that influence this, and their mitigations, are reviewed in the Invitation methods section. Attendance at subsequent screening rounds, essential if the full potential of the process is to be realised for participants, is usually termed "adherence". It is variously defined in studies as attendance within a timeframe, *e.g.* adherence was defined as attendance for the annual screen within 18 months of the baseline scan in a US study from Colorado by Hirsch *et al.* [200]. In other studies, adherence included attendance for additional imaging and work-up.

Evidence review

Of 82 full texts reviewed, 16 had useful information about this topic, including three systematic reviews [81, 201, 202] and four additional papers identified from reference lists. As the evidence review found that some studies measured adherence to the next screen, while others included adherence to any recommendation, both are included particularly because the findings were very similar.

Participant and programme features important in non-attendance

The features of individuals that are less likely to attend are similar to those that characterise people that choose not to participate in screening at baseline [81]. These are people in underprivileged groups [203–205], current smokers [201], the non-White population in the USA [112, 202], participants with a lower risk perception [201, 204, 205] and negative baseline CT [201, 206]. Unlike baseline participation, there was no clear relationship with sex and people aged under 60 years were least adherent while those aged 60–75 years were most adherent [201]. Programme-related factors associated with adherence are shown in table 2.

In the meta-analysis by Lam *et al.* [201], the overall second round non-attendance rate from 12 studies was 28% (95% CI 20–37%), with a wide range of 5–63%. Much of the evidence for both non-attendance and methods employed to improve adherence comes from the USA, which has the longest Western implementation period for a national programme. Navigators have been identified as an important way to improve adherence [205, 207, 208]. It is established that either nurse navigators or lay patient navigators improve baseline participation. In one primary network-based randomised controlled trial in the USA, patient navigators assessed eligibility, undertook shared decision making, and addressed concerns and barriers [209]. Participation among eligible people was 94% and of all people approached, 31% in the navigator arm and 17% in the control arm had a CT. The Hirsch *et al.* [200] study in Colorado showed that a nurse navigator-administered reminder achieved reattendance in 63% of participants. Both the ATS/ALA implementation guide and the NHSE TLHC protocol recommend the same methods that are applied at the baseline invitation to be applied for ongoing screens [10, 12]. In addition, some examples given in the ATS/ALA implementation guide are to schedule a repeat appointment as soon as possible and to provide reminders 30, 60 and 90 days after the screening due date to participants and their physicians. The evidence for the efficacy of this is mainly found in other cancer screening programmes [82].

Exiting the programme

Most programmes have defined eligibility criteria and hence participants are assumed to exit the programme when they no longer meet these due to exceeding the age threshold or other exclusion criteria developing, such as another life-limiting condition. The NHSE TLHC protocol states that participants

TABLE 2 Programme-related factors associated with attendance/adherence in lung cancer screening programmes [201]

Factor	Impact on attendance/adherence
Primary care recommendation	Increased
Programme navigator	Increased
Mobile LDCT [203, 259]	Increased in some settings where access to fixed site limited
Increased distance to service [205]	Decreased
Reminders	Increased
Centre type (academic *versus* community)	No impact
Urban *versus* rural setting [72]	Unclear
Uninsured [260]	Decreased

LDCT: low-dose computed tomography.

should exit the programme when they reach the upper age limit, but should also be assessed for comorbidity and fitness to confirm eligibility and should exit if they are no longer eligible [12]. There is also a recommendation to hand over any ongoing follow-up need, specifically nodules under follow-up or new nodules on the final screening CT. The ATS/ALA implementation guide notes that the ALA do not force people to exit the programme if they reach the 15-year smoking quit duration [10].

Summary

Non-attendance is a substantial issue in LCS, with high rates seen in trials, pilots and programmes. Similar factors are associated with reduced adherence and baseline participation, so the same methods used to maximise participation seem appropriate, adapted to ongoing screening and follow-up of findings. Exiting the programme has little evidence but it is defined in at least one programme protocol; participants should understand why they are exiting.

Non-attendance and exiting the programme standards

24) Methods effective in increasing baseline participation should be employed to reduce non-attendance (see Invitation methods section).
25) In addition, appointments for ongoing screening should be made as soon as possible after the previous screen and reminders provided nearer the time of the scan.
26) Information for participants should emphasise the importance of ongoing screening for the individual.
27) Programmes should have navigators (nurse, patient or both) to support the participants in ongoing screening as well as helping with administration such as reminders, identifying travel needs and facilitating rescheduling.
28) Participants should exit the programme once they no longer meet the eligibility criteria; they should be given clear information why they should no longer be screened and information about what to do if they have symptoms that could be due to lung cancer.

Research recommendation

- Future research into the ongoing psychological outcomes of screening and how this might influence adherence is needed [210, 211].

LDCT acquisition, reading and reporting

Evidence review

The evidence was taken from trials and protocols for pilot programmes as well as the NHSE protocol and quality assurance standards [11, 12], the ACR/Society of Thoracic Radiology (STR) technical statement [212], and the European Society of Thoracic Imaging (ESTI) standard [213]. A total of 54 full-text references were reviewed.

Acquisition

Minimising radiation dose is important to maximise the benefit/risk ratio (cancer deaths prevented/cancers caused by radiation) [214]. In a recent evaluation, assuming NLST mortality benefit of 20%, the ratio was 10 for women and 25 for men [215]. However, this is likely an underestimate as modelling was from age 50 years for eligible lifetime annual screening and with an underestimate of deaths prevented (higher in NELSON). It is also noted that the benefits of screening occur earlier than the risks of cancer caused by screening [215].

Improvement in technology has resulted in a reduction in effective radiation dose [216]. For example, in the NLST 4–16-detector-row scanners delivered 2.19–2.4 mSv [217] compared with NELSON where 16-row scanners were used, to achieve a lower dose for participants <80 kg [218]. The ESTI advise the use of at least a 32-row CT scanner, 100–120 kVp for standard-sized participants, 140 kVp for larger participants, a slice thickness of maximum 1.0 mm (preferred ⩽0.75 mm), and a CT dose index volume ($CTDI_{vol}$) of 0.4, 0.8 and 1.6 mGy for participants <50, 50–80 and >80 kg, respectively [213]. The NHSE protocol and quality assurance standards provide the same recommendations as the ESTI standard [11, 12]. The ACR/STR statement is less restrictive on number of detectors and slice thickness [212].

Thin slices (0.9–1.25 mm) are necessary for accurate volumetric assessment of pulmonary nodules [126, 218–221]. Changing slice thickness or reconstruction algorithms between screening rounds should be avoided in case volume measurement of lung nodules is affected [222].

With the development of newer radiation dose reduction techniques such as iterative and model-based reconstruction, photon-counting technology, CT with tin filtration, and denoising algorithms, dose can be

further reduced [223–228]. Thus, scanning protocols with a radiation dose similar to that of a chest radiograph, so-called "submillisievert" or ultra-LDCT, are possible.

Reading and reporting

There are no well-defined standards for human and automated reading of imaging, or for documentation of findings. Although double-reading was employed in several trials, this was not replicated in programme protocols except for initial training [7, 11, 12, 64, 218, 229]. Expertise is variously defined by national thoracic radiology societies and in protocols [11, 18]. These give minimum requirements for number of CT scans reported, attendance at training courses and multidisciplinary meetings. Most LCS programmes provide further education tools for those recent to field. The ESTI, for example, has a certification course (LCS diploma) [230]. For semi-automated and automated reading, commercially available software should be "CE" approved in the European Union. Several structured reporting proforma [11] have been used and can be linked to management guidelines such as the ACR Lung-RADS [13].

Decision making within the LCS programme

The management of actionable findings from the screen are not within the scope of this technical standard as they are the subject of established guidelines. However, it is important to ensure the aforementioned infrastructural elements are in place so that guideline-driven management is implemented efficiently. This often involves multidisciplinary teams (MDTs) dedicated to the review and management of findings, although other alert mechanisms are employed. There is evidence to show that MDT management of findings reduces the number of actionable findings [231] compared with no such approach [232].

Imaging acquisition and reporting standards

CT and software

29) The minimum specification is a 16-row multi-detector CT calibrated according to the manufacturer's specifications, capable of delivering low radiation dose protocols (see standard 35). There should be regular checks on the equipment according to local protocol.
30) For volumetric software:
    a) It is the preferred method for assessment of solid pulmonary nodules.
    b) The same software should be used to compare volumes.
    c) Where there are software updates these should be recorded and the supplier provide evidence that:
        i) the upgrade provides the same measurements; or
        ii) ensure that the user is prompted to re-measure nodules from preceding scans.
    d) It must be directly or indirectly integrated into picture archiving and communication systems, capable of automated image retrieval of historical imaging.
    e) Additional desirable standards for volumetry are provided in supplementary appendix F.
31) Computer-aided detection should be used as a concurrent or second reader. A false positive rate of <2 per case is desirable for computer-aided detection systems.

CT image acquisition protocol

32) Participants should be comfortably positioned supine, with arms above their head and thorax in the midline of the scanner. Maximal inspiration should be rehearsed prior to the scan and imaging should be performed during suspended maximal inspiration. No intravenous contrast material should be administered.
33) Programmes should use their standard scanogram to localise the start and end positions of the scan. The frontal localiser should be performed in the postero-anterior projection and at the lowest possible setting to minimise breast dose.
34) The lung parenchyma (lung apices to bases) must be scanned in its entirety in a single cranio-caudal acquisition. The field of view should be selected as the smallest diameter as measured from the widest point of outer rib to outer rib large enough to accommodate the entire lung parenchyma. Thin detector collimation ($\leqslant$1.25 mm) will be used.
35) The CT dose index volume ($CTDI_{vol}$) must be kept as low as possible with the effective radiation dose well below 2 mSv. The kVp and mAs settings are adjusted according to the height and weight of participants. Ultra-LDCT should be used where considered to be of equivalent diagnostic sensitivity to LDCT.
36) Image reconstruction should be standardised and used for any follow-up examinations, with particular emphasis on ensuring that slice thickness, reconstruction increment, reconstruction algorithm and field of view are identical. Slice thickness should be $\leqslant$1.25 mm. If iterative reconstruction is used, this should be kept constant at follow-up.

Reporting

37) Image interpretation should be performed on systems which permit scrolling through the dataset with variable thickness and orientation using multiplanar reformations and maximum intensity projection. Volumetric segmentation of nodules should be checked visually.
38) All scan data should be archived and retained; a national repository should be considered to facilitate education and research.
39) Readers must report a substantial number of thoracic CT scans annually as part of their normal clinical practice (over 500), including a significant proportion of lung cancer CT scans.
40) Readers must be familiar with the use and limitations of nodule volumetry software and apply agreed guidelines for nodule management.
41) A structured reporting proforma must be used to promote consistency and assist audit.

Thoracic CT reader quality assurance

42) Each programme should have documented quality assurance mechanisms in place for CT reading. Quality assurance for CT reading may include:
    a) Ensuring a minimum level of training and expertise of readers, including continuous professional development in LCS.
    b) Ensuring initial CT reads of radiologists without experience of LCS are reviewed by more experienced readers (*e.g.* first 50 cases).
    c) Periodic review of CT readers reports by expert panels, including referral recommendations.
    d) Evaluation of all readers' recall rates, false positive rates and false negative rates, with identification of outliers. This includes incidental findings.
    e) Evaluation of readers against validated cases.
43) National or regional consortia of expert radiologists may be the best way to address capacity, education and quality assurance.

Research recommendation

- Further research into the impact of lower radiation dose techniques on the quality of images is needed.

CT interval and surveillance

Varying the interval between LDCT is important to ensure that indeterminate findings are properly monitored and in stratifying the screening programme according to risk. Surveillance of pulmonary nodules is not within the remit of this technical standard because there are well-established and effective guidelines in existence. These recommend shorter intervals than the next annual screen from the index CT depending on the size of the nodule as measured either by manual diameter or semi-automated volumetry [4, 13, 14]. However, varying the interval between scheduled screens may also depend on the presence of nodules.

Evidence review

Of 43 full texts reviewed, useful evidence on this topic was obtained from nine. Some trials of CT screening have described different screen intervals but the majority used annual screens. The Multicentric Italian Lung Detection (MILD) trial randomised 4099 participants to no screening, annual screening or biennial screening and found after a 5-year follow-up that 36% more cancers were detected in the annual group compared with the biennial group; the trial was underpowered for mortality outcomes [220]. In an analysis of the NLST, the finding of any non-calcified nodule (⩾4 mm) was associated with a 2-fold increased risk of lung cancer between 2–5 years and 5–7 years after the screen [233]. The NELSON trial showed that previously indeterminate findings conferred a greater subsequent risk of lung cancer [167]. Participants with a negative screen (no nodules, or nodule <50 mm^3 or nodule with a volume change of <25% if on follow-up) had a 0.6% chance of lung cancer in the next 2.5 years compared with 3.7% of participants who had at least one indeterminate screen (nodule 50–500 mm^3 or volume doubling time 400–600 days on follow-up). However, another study [171] found that the risk of developing cancer was also related to the risk as estimated by a multivariable model in people with negative scans. This has led others to develop risk prediction models that use the CT findings and other risk factors to predict risk more accurately, which may then be used to define the best screening interval [234]. This study found that compared with the TLHC protocol, where scans with nodules <5 mm in diameter prompt a biennial CT, the use of a multivariable model delayed diagnosis in 30% of lung cancers compared with 40% in the simple TLHC approach but referred a similar proportion for biennial CT. The evidence for extending screening beyond 2 years is limited; in the NELSON trial the final screening round was at an interval of

2.5 years and the proportion of interval cancers was higher and with more late-stage cancers than the 2-year interval between rounds 2 and 3, leading to the conclusion that this was too long an interval [235].

Simulation health economic models have been used to estimate relative cost-effectiveness of annual, biennial and risk-stratified screening. Goffin *et al*. [236], based on the Canadian healthcare system, concluded that over 20 years, biennial screening was associated with the same number of quality-adjusted life years and was more cost-effective than annual screening. However, in another analysis for the Canadian Government, Ten Haaf *et al*. [237] concluded that annual screening was more cost-effective. The analysis for the USPSTF showed that all annual scenarios modelled were more cost-effective than biennial [238], while a modelling study for the UK was less clear [239]. A further modelling study showed that stratified screening reduced harms while maintaining mortality benefit [240]. National protocols and statements recommend annual screening with the exception of the NHSE TLHC where a stratified approach is taken.

Summary

The difference in cost-effectiveness between annual and biennial screening is small, although annual screening may prevent more deaths. Based on baseline CT findings and other risk factors, participants may undergo stratified screening to reduce harms while maintaining mortality benefit.

Interval and surveillance standards

44) Annual LDCT is the preferred interval if capacity and total economic and health service impact allow.
45) Biennial intervals may be applied for lower risk groups using LDCT findings or multivariable risk prediction models to select participants.
46) Participants should be aware of the reason they have been stratified.
47) Screening intervals should not exceed 2 years.
48) Surveillance scans with a shorter interval than 1 year should follow pulmonary nodule guidelines.

Research recommendations

- Do multivariable models incorporating imaging findings improve the clinical and cost-effectiveness of LDCT screening through stratifying screening intervals?

Communication of results

Timely and accurate communication of the outcome of the screen is essential to mitigate any anxiety and to ensure prompt management of any actionable findings.

Evidence review

Of 52 full texts reviewed, detail of communication methods was limited, but informative in 21. Communication may involve patient navigators [20], primary care physicians, pneumologists or others. If letters are used, details on serious findings were not included, but were addressed in face-to-face conversations [12, 241]. Support lines were described for patients for contact with an experienced healthcare worker or administrator [12, 229].

Focus on patients

At the time of results disclosure, patients want to be treated with empathy, have their concerns recognised and addressed, and understand the care plan [78, 241–243]. Communicating concrete information on the next steps can improve adherence [244].

Timeframe

Half of patients in the NELSON trial reported “dread” while awaiting LCS results [245]. Early communication of results can help alleviate distress [246]. It is important that serious findings are acted on immediately and indeterminate findings followed up as required [247].

Communication of normal results should be accompanied by information about continued risk of lung cancer (which may be provided as a percentage based on a multivariable model) in order to mitigate possible over-reassurance of patients. Patients who were allocated to follow-up scans or referrals to MDT boards were more likely to experience psychological distress [248]. The importance of not ignoring red flag symptoms and the importance of not smoking should be emphasised. A number of commercially available software tools are available to help generate result notification letters, among other functions [18].

Form of communication

Letters are a commonly used form of informing patients. In the UK SUMMIT study involving 1900 participants, 82.8% were satisfied with receiving their results by letter. 86.3% stated it was their preferred communication method. Patients from less deprived socioeconomic quintiles were more likely to report that the letter contained insufficient information; elderly individuals (over 70 years old) were less likely to do so [249]. A qualitative investigation among patients and healthcare providers involved in LCS programmes revealed that even among patients with normal findings, patients would have preferred a conversation over a letter, while physicians thought the letter to be sufficient [241]. There is tension between clinicians' preference for efficiency and patients' strong preference for a conversation. In the setting of incidental nodules, patient-centred communication is associated with lower distress and greater adherence to evaluation [250, 251]. Information may also be integrated with smoking cessation advice [109, 252].

Summary

Communication of results is a key point in the participant pathway and provides an opportunity for support, education and encouragement to continue with the screening process. Although time- and resource-efficient methods are often preferred, these may not be appropriate when communicating indeterminate or unclear results. There appears to be some disparity in the views of participants and healthcare professionals on the method and type of information needed, which is the subject of ongoing and future research [78].

Communication of results standards

49) Communication of results for each finding needs to be systematically designed for local populations, with local patient representative input.
50) The outcome should be communicated within a timeframe not exceeding 4 weeks from the LDCT.
51) Communication of negative and indeterminate findings can be *via* mail with an offer of support *via* telephone or videocall. Communications should include a reminder of the symptoms of lung cancer and the importance of smoking cessation.
52) Communication of positive findings should be face to face, usually within an urgent clinic.
53) Feedback from participants should be collected *via* a formal process and the results used to improve the participant experience.

Data management

Evidence review

The evidence reviewed was limited to data management systems which have been used in LCS trials or programmes. Six full texts were reviewed, of which three were included as they mentioned data management approaches [12, 18, 253]. They comprised one protocol document, one expert summary and one implementation pilot. Two websites about specific data management systems currently available for LCS were also accessed as part of this process, alongside one Bill (H.R.107 – Lung Cancer Screening Registry and Quality Improvement Act of 2021) which is currently undergoing review in the US Congress, and the website for the Centers for Medicare & Medicaid Services (CMS) [254–257].

Systems that allow administration, registration of data and monitoring of participants in a screening programme in an integrated solution are optimal. A good data management system provides structured and automated data collection which enables participants to be identified and tracked throughout the screening programme. Integration with imaging platforms, ideally with an all-in-one, end-to-end software solution is ideal. Data management systems that collect data in a format that facilitates submission, ideally in real-time, to national datasets for analysis, allow continuous monitoring and mitigation of clinical risks. The data management system must also adhere to information governance and General Data Protection Regulation requirements.

Data management systems are required to have a minimum mandatory dataset, which is agreed in advance and may be updated. Two publications have suggested data items to be included in a minimum dataset, which are summarised in supplementary appendix G [12, 255]. However, the CMS have subsequently removed the requirement for imaging facilities to participate in a CMS-approved screening registry, along with the minimum required data elements, pending the outcome of US Congress Bill H.R.107.

Commercial bespoke data management programmes are currently available and many more are in development [256, 257]. US Congress Bill H.R.107 seeks to establish grant programmes and requirements for registries that collect data from LCS under Medicare. It aims to provide funding to help establish free

TABLE 3 Key performance indicators

Invitation and attendance: proportion and total number	Proportion of eligible age range identified as ever-smokers from registry or questionnaire
	Proportion of ever-smokers who undergo lung cancer risk assessment
	Proportion of ever-smokers who are eligible for LDCT and invited
	Proportion attending for CT scan if high risk and invited for screening
Smoking cessation	Proportion of people attending for LDCT and are current smokers who are offered smoking cessation advice
	Proportion of current smokers meeting smoking cessation practitioner
	Proportion of current smokers attending screening who report quitting at 12 months
Screening outcome (all screened)	Proportion of participants screened who receive screening results within 4 weeks
	Proportion of participants screened with indeterminate findings
	Proportion of participants screened with referral for incidental findings
	Proportion of participants screened recalled for interim surveillance CT (prevalence/incidence)
	Proportion of participants undergoing further investigation other than surveillance CT
	Proportion of participants screened attending an urgent cancer clinic or similar
	Proportion of participants with screen-detected lung cancer stage I/II
	Proportion of participants who have surgery for adenocarcinoma *in situ* and atypical adenomatous hyperplasia
	Proportion of participants who develop interval lung cancers
	Proportion of participants with lung cancer undergoing treatment with curative intent
	Proportion of participants with suspected lung cancer undergoing invasive test(s) for benign disease
	Proportion of participants who have surgery for suspected lung cancer that have lung resections for benign disease
	Proportion of participants referred for surgery who undergo surgery within 4 weeks from referral
	Proportion of cancers diagnosed after surveillance at stage IB and higher
Ongoing screening	Proportion of participants remaining eligible who attend for next screen within 6 months of intended interval

(LD)CT: (low-dose) computed tomography.

registries, with the requirement that these registries are interoperable. The Bill also provides grants to support the development of related quality measures for LCS [254].

Quality metrics

The data management system must collect data required to provide the performance metrics for the programme. A detailed report on quality metrics for US LCS was published in 2021 [258]. From 30 suggested metrics, seven items achieved consensus for inclusion, but performance targets were not agreed for any. A suggested collection of performance metrics is provided in table 3.

Data management standards

54) An end-to-end, validated data management system is the optimum system for an organised LCS programme.
55) Data management systems must be supported by an agreed national minimum dataset that allows regular centralised audit and reporting of key outcome metrics (table 3).
56) Data management systems have to adhere to information governance and General Data Protection Regulation regulations.

Conclusions

The extensive literature review completed for this collaborative ERS Task Force provided the basis for a technical standard that will be an important reference for LCS programmes at all stages of development. It will help those tasked with implementation to negotiate with policymakers, stakeholders and funders for the best financial and structural environment to achieve a high-quality programme. Furthermore, the standard will foster common best practice across Europe and facilitate international comparisons on programme performance, with optimisation a likely outcome.

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