2023

Supporting the implementation of lung cancer screening: **a focus on developing a clear protocol for LDCT screening**

Policy brief

LUNG CANCER POLICY NETWORK

This policy brief was written by the Lung Cancer Policy Network Secretariat and co-authored by members of the Lung Cancer Policy Network.

For a full list of Network members, please see: https://www.lungcancerpolicynetwork.com/members/

We would like to thank the following experts for sharing their knowledge with us in interviews:

- Professor Mariusz Adamek, Medical University of Silesia, Medical University of Gdańsk
- Professor David Baldwin, University of Nottingham
- Dr Joanna Bidzińska, Medical University of Gdańsk
- Professor Kate Brain, Cardiff University
- Angela Criswell, GO2 Foundation
- Dr Joelle Fathi, GO2 Foundation
- Professor Sam Janes, Lungs for Living Centre, University College London
- Professor Ella Kazerooni, University of Michigan
- Professor Stephen Lam, University of British Columbia
- Dr Andrea McKee, Lahey Hospital & Medical Center and Tufts University School of Medicine
- Dr Samantha Quaife, Queen Mary University of London
- Professor Witold Rzyman, Medical University of Gdańsk
- Dr Edyta Szurowska, Medical University of Gdańsk
- Professor Emeritus Martin Tammemägi, Brock University
- Dr Carey Thomson, Mount Auburn Hospital/Beth Israel Lahey Health, Harvard Medical School
- Douglas E. Wood, MD, University of Washington

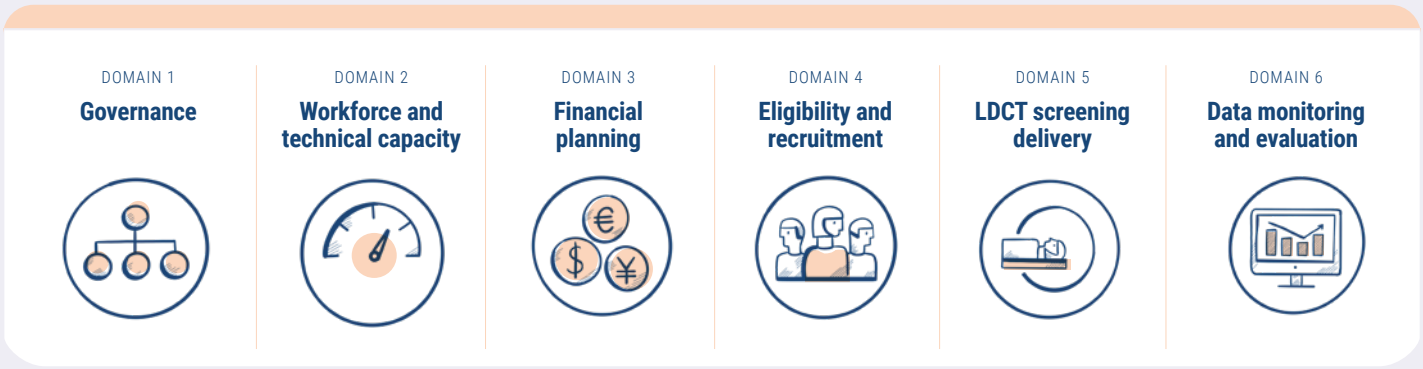
Please cite as: Lung Cancer Policy Network. 2023. *Supporting the implementation of lung cancer screening: a focus on developing a clear protocol for LDCT screening. Policy brief.* London: The Health Policy Partnership.

INTRODUCTION

The momentum for implementing targeted low-dose computed tomography (LDCT) screening programmes for lung cancer has gained pace over recent years, calling for careful consideration of how to optimise these programmes in terms of feasibility and public health impact. Setting up a lung cancer screening programme is complex, but a wealth of implementation research and a growing number of large-scale programmes continue to provide important lessons on how to optimise design and implementation.[1]

The Lung Cancer Policy Network has developed an implementation toolkit, which includes a framework to support those involved in the planning and delivery of lung cancer screening programmes. The framework follows a health systems approach and is organised into six domains, each consisting of a series of metrics. The metrics help users assess whether key requirements for screening are in place and identify gaps that may need addressing (*Figure 1*).

Figure 1. Six domains for assessing health system readiness for the implementation of lung cancer screening



This series of policy briefs explores the six core domains underpinning the implementation framework, with this brief focused on developing a protocol for LDCT screening. This brief provides key insights on establishing a clear protocol for lung cancer screening, presenting case studies from countries where implementation is underway. It also offers recommendations on how stakeholders and policymakers can support successful implementation.

ESTABLISHING A PROTOCOL FOR LDCT LUNG CANCER SCREENING: WHY IS THIS IMPORTANT?

The Wilson and Jungner criteria and the World Health Organization stipulate that, in order to be built into an organised programme, a screening test should be safe, precise, validated and acceptable to the population.[2 3] Therefore, a key component of the planning process for implementing lung cancer screening via low-dose computed tomography (LDCT) is to put a clear protocol in place to ensure that each of these criteria is consistently met across all components of the screening programme. These components include identifying the eligible population, recruiting participants, delivering computed tomography (CT) scans, evaluating results, referring people for diagnosis and treatment when necessary, and managing any other conditions detected incidentally via screening.

A clear protocol can also enable health system leaders to maximise the unique opportunity offered by a lung cancer screening programme to engage a population at high risk of lung cancer in other public health initiatives, such as smoking cessation.

This policy brief highlights some of the key considerations around designing a protocol for LDCT screening programmes to ensure the delivery of effective, safe and high-quality screening.

Health system decision-makers must:

- **develop protocols that are tailored to the target population and can adapt to emerging evidence and innovation** – to maximise effectiveness and ensure participant safety
- **ensure high-quality screening from start to finish** – by monitoring and managing variability in the delivery of screening
- **embed smoking cessation services within screening programmes** – to amplify the success of screening.

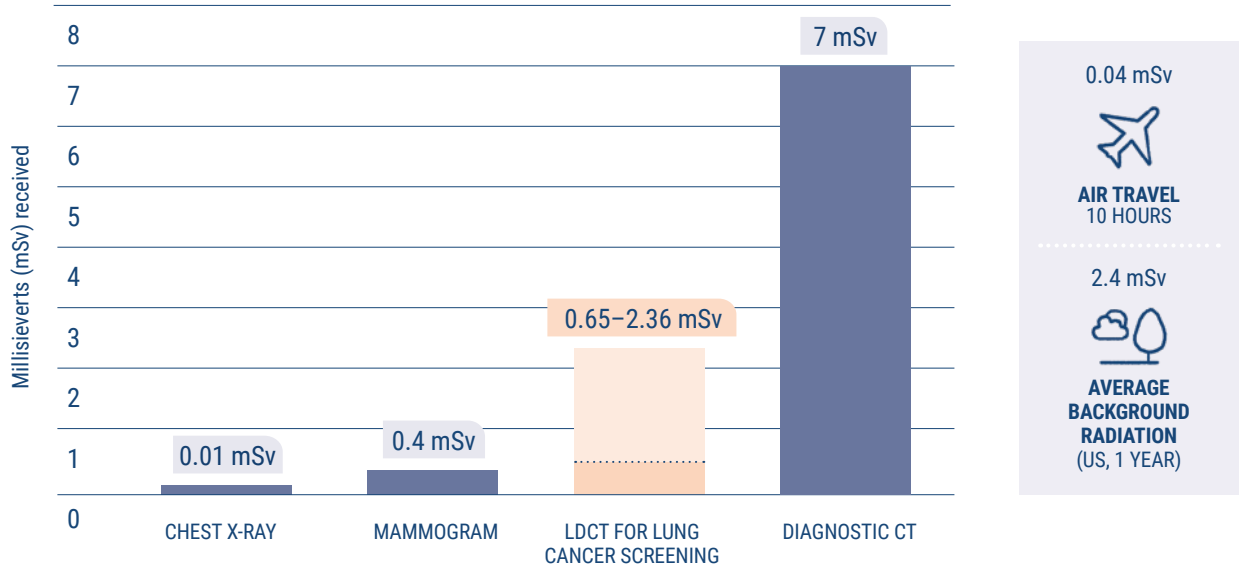
Develop protocols that are tailored to the target population and can adapt to emerging evidence and innovation

Health system leaders should tailor screening protocols to account for variation among target populations, including who is considered at high risk of lung cancer. Much of the evidence for LDCT screening comes from randomised controlled trials conducted with strict criteria in a select few countries.[4] Applying a protocol that has not been validated on the population to be screened may lead to lower reach or effectiveness of screening; local implementation research can be used to inform how the protocol may be adapted as required.

It is essential to update protocols in line with the latest evidence-based guidelines to ensure that LDCT screening remains a safe tool for early detection. Although the radiation dose from a single CT scan is low (*Figure 2*), the associated risk differs for each individual in a screening programme.[5-7] There is no general definition of a low-dose CT scan, and the concept of 'as low as reasonably acceptable' (ALARA) is widely advocated as best practice.[7-10] While recently published guidelines are a first step towards standardisation,[10-12] the continual monitoring and adjustment of protocols against these guidelines is of utmost importance to ensure the safety of all participants.

Health system leaders should also be ready to adopt new technologies and techniques to optimise the effectiveness, efficiency and quality of LDCT screening. Innovation in medical imaging has not only markedly reduced the minimum radiation dose required per scan but also led to higher-quality CT images.[7 13] Emerging technologies that enhance radiologists' ability to detect the presence of lung cancer on an LDCT scan can reduce the number of false-positive results from screening (*Figure 3*).[14] At the same time, removing the need for a manual evaluation of scans by a second radiologist alleviates the radiology team's workload and streamlines clinical decision-making for diagnostic workup.[14-17] At the planning stage, the protocol should ideally be set up in such a way that the programme is ready to transition to these new techniques as the technology matures and becomes more commonplace.

Figure 2. Understanding the relative radiation dose of LDCT lung cancer screening (US decision aid)



CT, computed tomography; mSv, millisievert, a measure of the amount of radiation absorbed by the body.
Adapted from a decision aid by the US Agency for Healthcare Research and Quality (2016)[18] in line with the latest recommendation statement from the United States Preventive Services Task Force (2021).[19 20]

Figure 3. New techniques that may enhance the detection of lung cancer on LDCT scans[14]

Biomarkers

The presence of certain biomarkers in blood or breath samples may be early indicators that an individual is at risk of lung cancer. Many biomarkers are being assessed for their potential to be used in non-invasive tests for lung cancer, including how they may be combined with other techniques.

Nodule risk calculators

These are models that incorporate an individual's risk factors for lung cancer (e.g. age, smoking history) with features from the LDCT scan (e.g. shape, size and location of the nodule) to estimate the probability that a nodule may be lung cancer.

AI-assisted volumetry*

Volumetric analysis is used to estimate the probability of a nodule being lung cancer based on its growth rate (volume doubling time).[8] AI-assisted volumetry automates this process with software that incorporates machine learning.[21]

Radiomics*

This emerging field of study extracts a large number of features from an LDCT image to model the risk of a nodule being lung cancer. Radiomics also seeks to predict an individual's response to different treatments and their anticipated survival to enable a more personalised approach to cancer management.[21]

*AI-assisted volumetry and radiomics are distinct methods that both use computer-aided detection.

Ensure high-quality screening from start to finish

Quality assurance processes are essential to ensure that all CT scans performed within a screening programme are of consistently high quality. The conditions under which LDCT screening is delivered can vary between sites depending on individual technique and the selected equipment manufacturer.[13 22] A clearly defined workflow can support the core members of the team involved in delivering scans (e.g. medical physicists, radiographers, radiologists, respiratory medicine specialists) to establish a process to reduce this variability and address any deviation from the protocol. The availability of medical devices, such as phantoms, can also support continual monitoring of how each CT scan is delivered for quality control (*Case study 1*).[23]

Accreditation and ongoing training are effective approaches to embedding quality standards within programmes and enhancing public trust in LDCT screening. All personnel involved in screening should receive training focused on embedding quality standards across the entire programme, including recruitment, equipment and examination performance, image interpretation, diagnostic workup and reporting. In addition, external accreditation, which involves conducting regular audits of sites that offer screening to ensure that they meet all regulatory requirements,[3] can help enhance public trust in LDCT screening programmes. Even if an established accreditation provider is not available locally, standards published in other countries can serve as a helpful reference and benchmark for all participating sites (*Case study 2*).[24-26]

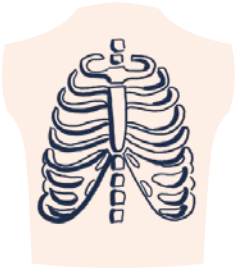
Case study 1

The use of phantoms for quality control of LDCT screening

Poland

Phantoms are medical devices that simulate a body and are used to calibrate and test the accuracy of CT equipment.[23] Each time CT equipment is adjusted (e.g. a lamp is replaced) or after a prolonged period of use, a phantom may be used to test whether CT scanner specifications remain unchanged and safe for human use.

The Medical University of Gdańsk (Poland) conducted a series of phantom studies to ensure participant safety when developing a protocol for LDCT screening. The study findings informed the development of a quality management system (QMS), which has been implemented by the National Lung Cancer Screening Pilot Program in Poland (WWRP).[27]



During scans, the radiation dose for every participant is closely monitored by a medical physicist, and any deviation from the CT acquisition protocol is logged in the QMS for monthly evaluation by the Multidisciplinary Tumor Board. Should a significant error be detected, the participant is immediately referred by the programme coordinator for a precautionary medical examination.

Case study 2

Example criteria for accreditation to ensure the quality and safety of screening programmes

South Korea

USA

	South Korea	USA
Example provider	The Korean Institute for Accreditation of Medical Imaging offers accreditation to sites participating in the Korean National Lung Cancer Screening Program (KNLCS).[17 28]	Accreditation from the American College of Radiology (ACR) allows screening providers to become Designated Lung Cancer Screening Centers in the national screening programme.[29]
Example criteria for accreditation	• Only hospitals with CT scanners that meet a minimum specification can participate. • Hospitals must also be staffed by at least one radiologist who has undergone certified training in LDCT screening for lung cancer.[28] • CT scanners and the protocol for screening must be externally audited every three years for quality control.[17] • The use of the ACR's Lung-RADS system modified for a South Korean population is recommended to standardise reporting of screening results to a quality control unit at the National Cancer Center.[28]	• Centres must have at least one CT unit that meets the minimum requirements for acceptable performance for lung cancer screening.[29] • Radiologists at each centre must be certified by the American Board of Radiology. • A quality control programme must be established and implemented under the supervision of a qualified medical physicist.[25] • Each centre must also submit data to the ACR Lung Cancer Screening Registry.[29]

Embed smoking cessation services within screening programmes

The success of lung cancer screening can be amplified by combining it with smoking cessation. Screening offers an opportunity to engage a high-risk population who might otherwise not seek smoking cessation services. Smoking cessation results in better clinical outcomes for people who participate in screening, increasing both the impact and the cost-effectiveness of screening programmes.[30 31] This relationship is also bidirectional; people who participate in lung cancer screening programmes are more likely to quit smoking than the general population.[32]

Offering a package of different smoking cessation services could maximise the benefits of these services within an LDCT screening programme. Currently, there is no 'one size fits all' approach to the delivery of smoking cessation.[33] However, numerous studies suggest that services that incorporate multiple strategies to support participants to stop smoking yield better outcomes than usual care.[33-35] For example, a combination of counselling and pharmacotherapy (e.g. nicotine replacement) may be more effective than either intervention alone.[35]

The approach to embedding smoking cessation within an LDCT screening programme should be based on local-level evidence. In some countries, such as the UK and Canada, an opt-out approach to smoking cessation during screening is being considered.[36 37] A different approach has been taken in South Korea, where the national screening programme has made smoking cessation counselling mandatory for all participants who currently smoke.[28] Personalising smoking cessation to the needs of each participant in a screening programme is another approach being investigated in the UK.[32] Regardless of the services offered, the choice of which model to adopt for integrating smoking cessation into screening should be based on local evidence of its impact in practice (*Case study 3*), including consideration of potential barriers to uptake.[36 38]

Case study 3

Examples of different approaches to integrating smoking cessation services into LDCT screening

Country	Types of services offered	Implementation research evidence for approach
 **UK** Targeted Lung Health Check (TLHC) pilot programme	In England, services include behavioural support sessions with specialists who can also dispense pharmacotherapy aids to help with stopping smoking.[36] The Yorkshire Enhanced Stop Smoking (YESS) trial assessed the outcomes of taking a personalised approach to smoking cessation on an opt-out basis.[32]	Various TLHC pilot sites have offered different solutions to integrating smoking cessation services into screening.[36] Among the people with lung cancer detected during screening in the YESS trial who then participated in a personalised smoking cessation programme, the abstinence rate was more than 30%.[32]
 **South Korea** Korean National Lung Cancer Screening Program (KNLCS)	Following the model adopted in the national pilot (K-LUCAS), participants in the national programme who currently smoke are offered mandatory smoking counselling after their LDCT scan, as well as pharmacotherapy for free or at subsidised cost.[28 39] People attending smoking cessation clinics are also invited to attend screening.	In the national pilot, willingness to participate in smoking cessation programmes increased by 9%.[39] Additionally, 25% of people who smoked reported that they had stopped smoking six months after LDCT screening.
 **Canada** Ontario Lung Screening Program (OLSP)	In 2017, a pilot for the ongoing OLSP investigated how to embed smoking cessation into screening on an opt-out basis. Participants were offered a minimum of 10 minutes' behavioural counselling, a recommendation for prescribed pharmacotherapy and arrangements for proactive follow-up by a specialist in smoking cessation.[37]	Acceptance of the opt-out model among participants in the pilot OLSP was very high; 88% of people offered an LDCT scan attended a hospital-based counselling session for smoking cessation, and surveys reported a 93% satisfaction rate.[37]

KEY CONSIDERATIONS
when developing a protocol for LDCT lung cancer screening implementation

Develop protocols that are tailored to the target population and can adapt to emerging evidence and innovation

- Anticipate the need for implementation research to refine protocols and account for variability in target populations
- Regularly review guidelines to ensure protocols are up to date with the latest evidence
- Consider the adoption of emerging techniques to improve the ability of screening programmes to detect lung cancer.

Ensure high-quality screening from start to finish

- Strive for a comprehensive approach to quality assurance across the entire screening programme for lung cancer
- Support the development of processes to enhance the quality of screening, such as benchmarking and accreditation
- Enable continuing professional development of healthcare professionals in standards for quality assurance

Embed smoking cessation services within screening programmes

- Promote the delivery of multiple types of smoking cessation interventions into screening programmes to maximise their effectiveness
- Consider the optimal approach to engaging the target population for screening in smoking cessation services

REFERENCES

1. Lung Cancer Policy Network. 2022. *Lung cancer screening: learning from implementation.* London: The Health Policy Partnership

2. Wilson J, Jungner G. 1968. *Public Health Papers 34: Principles and practice of screening for disease.* Geneva: World Health Organization

3. World Health Organization. 2022. *A short guide to cancer screening: Increase effectiveness, maximize benefits and minimize harms.* Copenhagen: WHO Regional Office for Europe

4. Hunger T, Wanka-Pail E, Brix G, *et al.* 2021. Lung cancer screening with low-dose CT in smokers: A systematic review and meta-analysis. *Diagnostics* 11(6): 1040

5. Nekolla EA, Brix G, Griebel J. 2022. Lung cancer screening with low dose CT: Radiation risk and benefit-risk assessment for different screening scenarios. *Diagnostics* 12(2)

6. Cohen SL, Wang JJ, Chan N, *et al.* 2019. Lung cancer screening CT: Sex-specific conversion factors to estimate effective radiation dose from dose-length product. *Chest* 156(6): 1214-22

7. Pozzessere C, von Garnier C, Beigelman-Aubry C. 2023. Radiation exposure to low-dose computed tomography for lung cancer screening: should we be concerned? *Tomography* 9(1): 166-77

8. International Early Lung Cancer Action Program. I-ELCAP Protocols. Available from: http://www.ielcap.org/protocols [Accessed 25/03/23]

9. Rzyman W, Didkowska J, Dziedzic R, *et al.* 2018. Consensus statement on a screening programme for the detection of early lung cancer in Poland. *Advances in Respiratory Medicine* 86(1): 53-74

10. Kazerooni EA, Austin JHM, Black WC, *et al.* 2014. ACR–STR practice parameter for the performance and reporting of lung cancer screening thoracic computed tomography (CT) (Resolution 4). *J Thorac Imaging* 29(5): 310-6

11. European Society for Thoracic Imaging. 2019. Lung Cancer Screening Certification Project: Technical standards. [Updated 14/06/19]. Available from: https://www.myesti.org/lungcancerscreeningcertificationproject/ [Accessed 21/05/23]

12. The American Association of Physicists in Medicine. 2019. *Lung cancer screening CT protocols version 5.1.* Alexandria, VA: AAPM

13. Vonder M, Dorrius MD, Vliegenthart R. 2021. Latest CT technologies in lung cancer screening: protocols and radiation dose reduction. *Transl Lung Cancer Res* 10(2): 1154-64

14. Voigt W, Prosch H, Silva M. 2023. Clinical scores, biomarkers and IT tools in lung cancer screening: can an integrated approach overcome current challenges? *Cancers* (*Basel*) 15(4): 1218

15. Bidzińska J, Szurowska E. 2023. See lung cancer with an AI. *Cancers* (*Basel*): 10.3390/cancers15041321

16. Lancaster H, Heuvelmans M, Yu D, *et al.* 2023. AI negative predictive performance exceeds that of radiologists in volumetric-based risk stratification of lung nodules detected at baseline in a lung cancer screening population. *J Thorac Oncol* 18(4): 106P

17. Kim S, Jeong WK, Choi JH, *et al.* 2022. Development of deep learning-assisted overscan decision algorithm in low-dose chest CT: Application to lung cancer screening in Korean National CT accreditation program. *PLoS One* 17(9): e0275531

18. Agency for Healthcare Research and Quality. 2016. *Is lung cancer screening right for me? A decision aid for people considering lung cancer screening with low-dose computed tomography.* Rockville, MD: AHRQ

19. US Preventive Services Task Force. 2021. Screening for lung cancer: US Preventive Services Task Force recommendation statement. *JAMA* 325(10): 962-70

20. Jonas DE, Reuland DS, Reddy SM, *et al.* 2021. Screening for Lung Cancer With Low-Dose Computed Tomography: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA* 325(10): 971-87

21. Binczyk F, Prazuch W, Bozek P, *et al.* 2021. Radiomics and artificial intelligence in lung cancer screening. *Transl Lung Cancer Res* 10(2): 1186-99

22. Rydzak CE, Armato SG, Avila RS, *et al.* 2018. Quality assurance and quantitative imaging biomarkers in low-dose CT lung cancer screening. *Br J Radiol* 91(1090): 20170401

23. Iball GR, Darby M, Gabe R, *et al.* 2021. Establishing scanning protocols for a CT lung cancer screening trial in the UK. *Br J Radiol* 94(1128): 20201343

24. NHS England. 2019. *Targeted screening for lung cancer with low radiation dose computed tomography: Quality assurance standards prepared for the Targeted Lung Health Checks Programme.* London: NHS England

25. American College of Radiology. Quality control: CT. [Updated 19/12/22]. Available from: https://accreditationsupport.acr.org/support/solutions/articles/11000056188-quality-control-ct [Accessed 09/05/23]

26. Canadian Association of Radiologists. 2016. *Canadian Association of Radiologists: Guide on CT screening for lung cancer*. Ottawa: CAR

27. Ministry of Health of the Republic of Poland. 2019. *National Lung Cancer Screening Pilot Program (WWRP) using Low Dose Computed Tomography (LDCT) - a combination of secondary and primary prevention to improve awareness of lung cancer among the public and healthcare personnel.* Warsaw: Ministry of Health

28. Kim HY. 2019. National lung cancer screening in Korea: Introduction and imaging quality control. *Journal of the Korean Society of Radiology* 80(5): 826-36

29. American College of Radiology. Lung Cancer Screening Center Designation. [Updated 09/03/23]. Available from: https://accreditationsupport.acr.org/support/solutions/articles/11000061040-lung-cancer-screening-center-designation-revised-11-9-2022- [Accessed 05/06/23]

30. Cadham CJ, Cao P, Jayasekera J, *et al.* 2021. Cost-effectiveness of smoking cessation interventions in the lung cancer screening setting: A simulation study. *J Natl Cancer Inst* 113(8): 1065-73

31. Goffin JR, Flanagan WM, Miller AB, *et al.* 2016. Biennial lung cancer screening in Canada with smoking cessation – outcomes and cost-effectiveness. *Lung Cancer* 101: 98-103

32. International Association for the Study of Lung Cancer. United Kingdom-based smoking cessation program reports that 30 percent of support in a lung cancer screening program: The Yorkshire Enhanced Stop Smoking Study (YESS). [Updated 07/08/22]. Available from: https://www.iaslc.org/iaslc-news/press-release/united-kingdom-based-smoking-cessation-program-reports-30-percent-support [Accessed 01/05/23]

33. Cadham CJ, Jayasekera JC, Advani SM, *et al.* 2019. Smoking cessation interventions for potential use in the lung cancer screening setting: a systematic review and meta-analysis. *Lung Cancer* 135: 205-16

34. Moldovanu D, de Koning HJ, van der Aalst CM. 2021. Lung cancer screening and smoking cessation efforts. *Transl Lung Cancer Res* 10(2): 1099-109

35. Stead LF, Koilpillai P, Fanshawe TR, *et al.* 2016. Combined pharmacotherapy and behavioural interventions for smoking cessation. *Cochrane Database Syst Rev*: 10.1002/14651858.CD008286.pub3 (3)

36. Murray R, Davises N, Cheeseman H. 2022. *The role of smoking cessation services within the Targeted Lung Health Checks programme.* Nottingham: Action on Smoking and Health and University of Nottingham

37. Kale D, Gilbert H, Sutton S. 2019. An exploration of the barriers to attendance at the English Stop Smoking Services. *Addict Behav Rep* 9: 100141

38. Evans W, Darling G, Miller B, *et al.* 2018. Acceptance of smoking cessation services in Cancer Care Ontario's Lung Cancer Screening Pilot for People at High Risk. *J Thorac Oncol* 13(10): S341

39. Lee J, Kim Y, Kim HY, *et al.* 2021. Feasibility of implementing a national lung cancer screening program: Interim results from the Korean Lung Cancer Screening Project (K-LUCAS). *Transl Lung Cancer Res* 10(2): 723-36

LUNG CANCER POLICY NETWORK

The Lung Cancer Policy Network is a global multi-stakeholder initiative set up by the Lung Ambition Alliance. The Network is funded by AstraZeneca, Guardant Health, Johnson & Johnson, MSD and Siemens Healthineers. Secretariat is provided by The Health Policy Partnership, an independent health research and policy consultancy. All Network outputs are non-promotional, evidence based and shaped by the members, who provide their time for free.