Targeted Lung Cancer Screening – Stakeholders Consultation Responses

1-

Name: Vincent Rawcliffe

Email: xxxx xxxx

Organisation: xxxx xxxx

Role: GP Board Member/locum GP

Condition: Lung cancer

Strongly supportive of this program cancers are being identified at earlier stages therefore more likely to receive better treatment outcomes. Other pathologies are also identified which in turn can receive more intensive treatment and therefore improve outcomes.

Unfortunately impact of workload created is inadequately funded and impact of this will be greater in areas where pathologies are higher e.g. higher smoking rates and high deprivation areas. This is made more acute in primary care in regions with diminishing GP workforce a result of poor NHS England and government planning for more than 20 years.

This combination of factors then leads to inequality in provision of service for those communities. You all know this but continue to fail to be capable of changing it or don't have the will or finance to grasp this "nettle".

2-

Name: xxxx xxxx

Organisation: xxxx xxxx

Role: Respiratory Physician

Condition: Lung cancer

I really think that time, effort and money is better directed at smoking cessation. Where are the sustained public message message on buses, TV, posters, radio, price rises on tobacco?

3-

Name: Dr Sinan Eccles

Organisation: Wales Cancer Network

Condition: Lung cancer

The Wales Cancer Network welcomes the clarity brought by these positive recommendations and fully supports them, whilst recognising that additional resources and staffing will be required to implement these successfully.

Name: xxxx xxxx

Organisation: Royal College of General Practitoners

Role: Senior Clinical Policy Officer

Condition: Lung cancer

The Royal College of General Practitioners is supportive of the decision not to

screen for lung cancer in the general population

5-

Name: Coral Higgins

Organisation: NHS Manchester CCG (Manchester Health & Care Commissioning)

Role: Cancer Commissioning Manager

Condition: Lung cancer

Introduction

Manchester Health and Care Commissioning (MHCC) is a partnership between NHS Manchester Clinical Commissioning Group and Manchester City Council.

On behalf of MHCC, I have reviewed the evidence summary and the interim findings of the cost effectiveness evaluation.

MHCC supports the proposals and the further work suggested within the consultation cover note (page 2).

MHCC's consultation response is framed around the lessons learned from Manchester's experience of delivering lung health checks (LHC), risk assessment and targeted lung cancer screening (TLCS).

The response covers:

- Approach to delivery
- Co-production, community engagement and inclusive practice
- The importance of effective data
- Workforce
- Estates
- Wider benefits of the model

Approach to delivery

Manchester was proud to be one of the first areas to test out a proposal for lung

health checks, risk assessment and targeted lung cancer screening as part of a Macmillan Cancer Improvement Partnership (MCIP) funded pilot from 2015 to 2017.

The report from the Macmillan supported Manchester Lung Health Check Pilot can be found here: https://mft.nhs.uk/app/uploads/sites/12/2019/02/lung-health-check-manchester-report_tcm9-309848.pdf

Based on the findings, NHS Manchester Clinical Commissioning Group commissioned one of the first local LHC services for patients in the north of Manchester.

This part of the city was targeted based on lung cancer incidence, smoking rates, and premature mortality from preventable cancers. The service began in April 2019, with a community-based model and one stop assessment and scan service. Smoking cessation and tobacco addiction treatment were also available to participants that were current smokers. Taking the service out into local communities and to patients was crucial to the success of the model and Manchester will continue to champion the community based one stop approach.

The majority of LHC and baseline CT scans were completed by March 2020, and the first round of surveillance scans, for people identified as being at increased risk of lung cancer, were completed in August 2020 to March 2021. Manchester became an onboarded project with national funding from August 2020.

In the first two years of the service Manchester diagnosed approximately 160 lung cancers, 80 per cent of which were at stage 1 and 2. In addition, 270 people were identified with symptomatic undiagnosed Airway Flow Obstruction, and approximately 2,500 people with Cardiovascular Disease. All of these patients were referred appropriately for treatment and ongoing management. Annual / biannual surveillance will continue in line with the national protocol until March 2024.

Further information on the outcomes of the lung health checks can be read in the research papers published on the work delivered in Manchester: https://thorax.bmj.com/content/74/7/700

Manchester has plans to continue the service and the long-standing collaboration with its provider, Manchester University Hospitals NHS Foundation Trust (MFT), and plans to roll out the offer to patients in central and south Manchester from April 2023.

MHCC looks forward to working collaboratively with the cancer alliance in Greater Manchester to support the development of a clinical model and delivery plan, to achieve full coverage of the eligible Greater Manchester population by March 2027.

MHCC's experience in implementing a LHC service is that the time needed to plan and prepare cannot be underestimated. It requires a multi-disciplinary stakeholder approach, with partners focused on a common goal. Furthermore, a consistent approach to the TLCS strategy is necessary, especially regarding patient criteria, round length, threshold for positive scans and follow up protocols. MHCC appreciates that this is still under consideration, with the findings and experience of the national pilot projects and onboarded projects to be considered. The screening programme will grow, develop, and improve over time as learning is taken from its implementation. Regular check-ins and review points would be appropriate, as would the ability to adapt and make changes when necessary.

Co-production, community engagement and inclusive practice
Co-production and community engagement has been crucial to the success of the
LHCs in Manchester. This was achieved not just through communications alone, but
through co-production by and with patients affected by lung cancer and through a
proactive approach to going out to patients and the public and explaining the service.
This enabled partners to listen, understand and address concerns, and to change
the messages based on community need.

In addition, young people were supported to be community LHC champions, a role which involved supporting and influencing their older relatives. Furthermore, voluntary and community sector organisations were commissioned to deliver awareness messages through a range of activities and worked alongside neighbourhood health development co-ordinators.

The Manchester Lung Health Check – Engaging with Communities document can be found here: https://manchesterccg.nhs.uk/wp-content/uploads/MCIP-Engagement-with-communities_NW_V4-2.pdf

Manchester is proud of its cultural diversity and was pleased to welcome patients from over 40 different countries to the service. In this context, interpretation and translation services must be embedded and valued. In addition, "quiet sessions" were provided for patients with a learning disability, autism, and mental health issues

on request. Such approaches are important to the inclusive practice that is essential for equitable access.

The importance of effective data

Effective data is an enabler of the service. For instance, the invitation process must be linked to reliable and accurate primary care data. In Manchester, all people within the relevant age range were invited, with LHC appointments booked based on an assessment of patients who made contact. When comparing the data, it was clear that if invitations had only been sent to patients based on the smoking codes in primary care records, eligible people, and lung cancer diagnoses, would have been missed. Perhaps some incentive to primary care to update records could be considered given that so many national health care policy decisions will be based on 'big data' held in primary care.

MHCC's biggest issue for the service since 2019 has been data collection, which has necessitated using multiple hospital and primary care systems. The workload to be able to collect, validate and then report data back to the national team has been considerable, with very little resource for data management. Provider goodwill and expertise has been essential in reporting back to the national team in a timely way, as has the support of the Commissioning Support Unit.

Given the importance of the service and outcomes information it would be a good investment to have a national system for data collection and data management support within each provider as well as at an alliance level. This system must be able to link with primary care data to identify eligible patients for invitation as well as recording outcomes and transferring information across health care systems.

Patient demographics and equality measures are vital to ensuring that eligible individuals are not being missed or excluded. This is ever more important as the COVID-19 pandemic has disproportionally impacted communities facing racial inequalities and inequity, and it is imperative that any future lung health check programme is inclusive. Such information must be included in records from the start, rather than being treated as an 'add on'. Lessons can be learned from the national breast screening system, which is years behind in this respect.

Timeliness of reporting findings should also be considered so that alliances, via their locality teams, can respond quickly to any issues with uptake and coverage either within Primary Care Networks / neighbourhoods or population groups. Waiting six

months for the latest uptake figures (as is the case for breast and bowel cancer screening) is too long.

Workforce

Having an appropriately skilled and resourced workforce is fundamental for success. Lessons must be learned from the current state of NHS diagnostics and workforce planning should take account of forward planning, talent management, succession plans as staff near retirement, training roles for specialists of the future, extended roles, and career progression. All national cancer screening programmes should be made an attractive employment proposition to health care professionals and managers, including to those who are at an early stage of their career.

It will be important to ensure that the workforce is recruited and developed in line with the phased roll out of the future service across the alliance model. Furthermore, it is necessary to be aware of and plan for the implications of the service model for the wider workforce, for instance for primary and secondary care in relation to diagnoses (cancer or otherwise) requiring intervention or management.

Estates

Manchester believes in a community-based one stop service, where we go to our patients rather than them coming to us. This requires mobile ultra-low dose CT scanners and support units with enough capacity to manage 70+ scans per day (8am-8pm, Monday to Saturday). Suitable locations are not always easy to find that can accommodate the size of the mobile units but also the power and services supply necessary, but they are there. In Manchester, local supermarkets were keen to support the service, and outdoor markets were excellent venues which were familiar to patients.

The TLHC and lung cancer screening programme will result in an increase in the number of patients needing to be referred to the local lung cancer teams for specialist diagnostics and treatments. There must be local / regional consideration in how best to support acute trusts to manage this expected increase. Manchester's partner trust, MFT, in collaboration with xxxx xxxx has developed a case for a joint diagnostic and treatment centre to provide capacity to manage patients with suspected and confirmed lung cancer. This capacity will be available to manage screen detected patients in an efficient and timely manner with expertise available to support patients.

Wider benefits of the model

As set out in section two of this response, Manchester's service has identified a rage of conditions beyond lung cancer, thus enabling timely intervention to support wider

condition management. To this end, clear national guidance on incidental findings would be helpful, covering what is actionable and what should be reported. Manchester's experience has been good regarding over-diagnosis and false positive diagnosis, but it is important to set these expectations to providers and to monitor outcomes.

6 -

Name: xxxx xxxx

Organisation: xxxx xxxx

Role: Respiratory Consultant and Regional TLHC Director

Condition: Lung cancer

Lung cancer screening in high risk individuals has been shown to reduce lung cancer specific and overall mortality. It appears to be cost-effective too. I strongly feel that lung cancer screening should be made available to all eligible people, and for this to happen effectively, efficiently and consistently, it needs to be a national programme with National Screening Committee approval. Without this, I worry that services would develop in a patchwork fashion, creating inconsistency and inequity. Harms may also increase if nationally mandated outcomes, targets and KPIs are not established. Finally, without a national programme, adequate resource to deliver a robust service is unlikely to be forthcoming.

7-

Name: xxxx xxxx

Organisation: Northern Cancer Alliance Role: Lung Cancer Programme Manager

Condition: Lung cancer

Please note, this response has been submitted on behalf of the Newcastle Gateshead TLHC Project Team. It is a collective response from project colleagues and clinical colleagues, working across Commissioning, Primary and Secondary Care.

We are supportive of the rollout of TLHC across the country as a way of detecting lung cancer at an earlier, more treatable stage; however, there are a number of concerns which need to be addressed:

1. There is no national infrastructure in place to support Targeted Lung Health Checks, e.g. no national IT system, no national incident reporting system. There are concerns that this will result in different projects having different processes and rules being applied differently across the country. It also leads to significant work every time a new

project is announced, which is a waste of resources when some centralised shared learning and direction could potentially save time and costs, whilst also increasing equity of provision and sustainability. This is at a time when services are under significant pressure, and the clinicians who need to be involved in planning are also responsible for delivering existing services.

- a. Some sites have developed bespoke IT systems could one of these be adopted nationally?
- Invitation processes are inconsistent across existing projects. There needs to be clear guidance on the approach to be taken to ensure equity of access.
- 3. Some sites have invested significant time into developing pathways for participants who would ordinarily struggle to engage with screening due to additional needs, but these have not been widespread, which this gives rise to inequalities. The NSC should propose minimum standards to be met.
- 4. There is no mention of plans to ensure workforce gaps are addressed. There are significant gaps in terms of:
 - a. Radiographers
 - b. Specialist Thoracic Radiologists
 - c. Generalist Radiologists
 - d. Respiratory Physicians
 - e. Thoracic Surgeons
 - f. Physiologists
 - g. Attendance at Screening Review Meetings

These issues cannot be addressed at a local level and a national workforce strategy is required. Expanding beyond current sites at this point in time is causing immense pressure and there is a risk that the whole system will be destabilised by going too far, too fast.

- 1. Artificial intelligence is still in its infancy and does not address the workforce gap.
- 2. There is only one GP on the Expert Reference Group (xxxx xxxx), yet many of the findings go back to Primary Care for action. Are Primary Care's views adequately represented?
- 3. In other screening programmes, there is little or no additional work for Primary Care, and clear pathways for Secondary Care. There needs to be agreed minimum standards for each incidental finding, i.e.
- a. What abnormalities should be reported, and when?
- b. What action should happen, and who should take the action?
- c. How is the work funded? Is it funded at all?

Until these standards are agreed, each new project will have the same discussions about who does what.

- 1. There are significant financial consequences resulting from incidental findings, both in Primary and Secondary Care. No additional funding has been made available to Commissioners to support this, so every time a project is rolled out, difficult discussions need to take place at a local level and these are becoming more challenging as the Programme expands and the ask on Commissioners grows.
- 2. There are also significant cost and activity implications from a Tertiary Care perspective (i.e. Thoracic Surgery, Cancer Centres). Again, every time a new project is rolled out, Commissioners have to agree funding and no additional funding has been made available to Commissioners to support with this element. Adjacent projects feeding into the same Tertiary Care Centres means that projects are competing for the same finite resources and there are resulting delays to patient care.
- Clear guidance is required on the re-screening of participants who were not previously eligible for LDCT, and tools to support a desktop recalculation in the first instance need to be produced at a national

level, rather than leaving it up to local projects to develop their own tools.

- Further work needs to be completed to understand the benefits of using PLCO and LLP. If the current risk threshold does not change in light of new evidence gathered, there is a risk that services will be overwhelmed.
- 5. The ongoing impact of re-scanning patients with no findings every 2 years needs to be considered.
- 6. COVID-19 has far-reaching effects on the NHS and current indications are that the demand for existing services for symptomatic patients has risen, with resulting challenges to delivering appropriate care.
 - a. Increasing screening projects and throughput risks stretching services to the point where symptomatic patients experience delays and sub-optimal care.
 - b. Is there a comprehensive review planned (or underway), comparing TLHC trajectories alongside national backlogs in diagnostics, treatments, etc.?
- 7. Concerns over national availability/shortages of CT scanners, with extensive lead times for delivery and existing suppliers saturated by the demand. Need to also consider how further rollout is planned alongside the development of CDCs and the impact this will have on lead times, staffing, resources, etc.

8-

Name: Professor Sherwood Burge

Organisation: Occupational Lung Disease Unit, Birmingham

Role: consultant

Condition: Lung cancer

We provide a service for workers with possible occupational lung diseases and patients with interstitial lung diseases.

We have the following comments

The targeted group should include those with a history of asbestos exposure, whose increased risk of lung cancer is substantial, and the less common groups with significant exposure to known lung carcinogens, particularly hexavalent chromium

(and others)

The statement that "There was evidence that there are some people who will be harmed because of lung cancer screening. This includes people whose screen shows they have might have cancer but further tests show that they don't have it or that they have a different condition"

This statement implies that finding other lung diseases is detrimental. On the contrary it often opens the possibility for other life-lengthening treatments. This includes the finding of interstitial fibrosis (including asbestosis), available treatment slows progression so starting antifibrotic treatment earlier is the way forward. Lung fibrosis is in itself a risk factor for lung cancer. The finding of emphysema in our experience increases the chance of smoking cessation in those still smoking and opens the way for inhaled treatment which prolongs life and preserves lung function (as long as it contains an inhaled corticosteroid). Silicosis is also identified from random radiology and affects further work exposure. Although long-term silica exposed workers are supposed to have regular chest X-rays, many that we see are not identified as needing regular radiology, and the CXR is know to be inferior to low dose CT in identifying silicosis. The finding of nodules is perhaps more of a problem, but the algorithms for radiological screening are now much better and lead to few invasive procedures that identify inconsequential lesions. Cost-effective analysis should include the additional benefits of identifying non-lung cancer diseases.

We believe that the UK has been slow to adopt screening for lung cancer. Improving outcome by finding earlier cancer does not need further trials, but implementation of screening. The important questions are who to screen, how frequently, and how to identify disease from the radiology (i.e. the place for machine reporting)

9-

Name:	Stuart Bourne		Email address:	xxxx xxxx
Organisation (if appropriate):		Aneurin Bevan University Health Board (NHS Wales)		
Role:	Consultant in Public Health			

Do you consent to your name being published on the UK NSC website alongside your response?

Yes No

Section and / or page number	Text or issue to which comments relate	Comment Please use a new row for each comment and add extra rows as required.
N/A	Aneurin Bevan University Health Board (ABUHB) overall statement on screening for lung cancer	The UK NSC uses a framework of twenty criteria for appraising the viability, effectiveness and appropriateness of all potential screening programmes. In providing an overall statement on the UK NSC recommendation to introduce a targeted screening programme for lung cancer in people aged 55 – 74 with a history of smoking, ABUHB has assessed and commented on each criteria in turn below. 1. The condition should be an important health problem as judged by its frequency and/or severity. This is the case with lung cancer which is the most common cause of cancer mortality (in Wales).

2. All the cost-effective primary prevention interventions should have been implemented as far as practicable.

Smoking accounts for the majority of lung cancer cases. There is more that could and should be done in relation to reducing tobacco use in the UK, however, it is accepted that the benefits would not be felt among the cohort of current/ex-smokers likely to be eligible for lung cancer screening. As such greater investment in tobacco control would not, in the short term, help with lung cancer incidence.

3. If the carriers of a mutation are identified as a result of screening the natural history of people with this status should be understood, including the psychological implications.

This may not apply in the context of lung cancer screening.

4. There should be a simple, safe, precise and validated screening test.

The risk prediction algorithms that select individuals for screening appear precise, correctly predicting who will develop lung cancer from those who will not over 80% of the time. However, in most of the trials eligibility criteria instead of risk algorithms have been used. The trials also demonstrate differences in eligibility criteria, in the number of screening rounds, the intervals between rounds and the threshold for a positive test. Low dose computed tomography (LDCT) is also shown to have a very wide positive predictive value (3.3%-43.5%), which means that the majority of individuals with a positive result will go onto to have unnecessary investigations.

It is accepted that LDCT is the best test available, it is safe, simple and appropriate communication of the risks and benefits would be part of the screening process. The harms of false positives (and over diagnosis) do also need to be balanced against finding disease at an earlier, more treatable stage.

5. The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.

It is stated on page 69 of the review that across the studies there was a substantial heterogeneity of factors related to outcomes, one of which was the threshold for a positive screen. This suggests that the trials do not provide agreement about a suitable cut off level for a 'positive' result.

6. The test, from sample collection to delivery of results, should be acceptable to the target population.

As noted in the more specific comments below, currently the evidence for the acceptability of the screening test is met but there is a lack of evidence about acceptability of the diagnostic and treatment elements of the pathway. This is acknowledged on p.83 of the review where it is stated that more evidence is required. It will be an option for an individual whether they wish to take up screening or not, and we know that a large proportion will decline this offer. There is also evidence on patients' response from existing lung cancer screening trials.

7. There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.

The review does not cover this in detail, other than noting lung biopsy as the next step. The policy for managing the 5%-20% individuals with significant incidental findings, as well as the timing of repeat screening for high risk individuals with negative results is also unclear. However, as part of any widespread implementation in the UK, it is recognised that protocols and resources would be put in place on how to manage a positive test result, and that guidance does exist currently on the further investigation of CT abnormalities.

- 8. If the test is for a particular mutation or set of genetic variants the method for their selection and the means through which these will be kept under review in the programme should be clearly set out. This criteria will not apply in the case of lung cancer screening.
- 9. There should be an effective intervention for patients identified through screening, with evidence that intervention at a pre-symptomatic phase leads to better outcomes for the screened individual compared with usual care. Evidence relating to wider benefits of screening, for example those relating to family members, should be taken into account where available. However, where there is no prospect of benefit for the individual screened then the screening programme should not be further considered.

The review is clear that screening does have an effect on mortality from lung cancer at the population level, and that it creates a stage shift towards earlier diagnosis and treatment. It is unclear whether overall mortality is reduced however, and the impact of a reduction in lung

cancer mortality due to early detection by screening is likely to be too small compared to other causes of death to make an overall difference in mortality rates.

10. There should be agreed evidence based policies covering which individuals should be offered interventions and the appropriate intervention to be offered.

The consultation materials are limited to matters relating to the screening test. Detail about how individuals with positive results should be treated following screening are not dealt with so this criteria cannot be assessed. Local, patient centred protocols would need to be developed as part of any UK wide implementation.

11. There should be evidence from high quality randomised controlled trials that the screening programme is effective in reducing mortality or morbidity. Where screening is aimed solely at providing information to allow the person being screened to make an "informed choice" (such as Down's syndrome or cystic fibrosis carrier screening), there must be evidence from high quality trials that the test accurately measures risk. The information that is provided about the test and its outcome must be of value and readily understood by the individual being screened.

This is one of the criteria specifically addressed in the review and is judged to have been 'met' on the basis that screening people at high risk of lung cancer with LDCT can reduce lung cancer mortality. A meta-analysis across 7 RCTS reported a significant relative reduction of lung specific mortality in the LDCT group of 17%.

12. There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is clinically, socially and ethically acceptable to health professionals and the public.

In the review this is assessed as met for volume, applicability and quality of evidence, but unmet for consistency. In particular there is a notable lack of evidence about the acceptability of the diagnostic and treatment elements of the pathway. In practice, it will be possible to draw on the real world experience of managing existing patients who have suspicious lesions on CT, but this falls outside the evidence drawn on in the UK NSC review.

It is noted in the more specific comments below that lung cancer has the widest socioeconomic inequality in mortality among different cancers. Given this and the variation in equity of uptake across the trials included in the UK NSC review, it will be important to learn from trials such as in Manchester and Liverpool.

13. The benefit gained by individuals from the screening programme should outweigh any harms, for example from over-diagnosis, overtreatment, false positives, false reassurance, uncertain findings and complications.

This is assessed as 'uncertain' in the review due to the uncertainty about the approach which would be the most clinically effective to reduce mortality and morbidity from lung cancer screening whilst reducing possible harms to a minimum. At an individual level, there will be a differing approach to risks and benefits, which is true for most aspects of personalised healthcare.

14. The opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (value for money). Assessment against this criteria should have regard to evidence from cost benefit and/or cost effectiveness analyses and have regard to the effective use of available resource.

The review assesses this criteria in comments about contextual question 3. In summary, there is such a wide variation in ICERs across strategies in the different studies that the level of cost-effectiveness is uncertain. As noted below in relation to the interim report on cost-effectiveness that accompanies the UK NSC evidence review, ongoing work to address the natural history components of the economic model is necessary to provide greater confidence in the cost-effectiveness of lung cancer screening. The economic review does make it clear that lung cancer screening is not cost-saving due to the effect of over-diagnosis, recognising that over-diagnosis is a common problem in UK healthcare, and that it can be difficult to assess when over-diagnosis outweighs clinical benefit at a population level.

15. Clinical management of the condition and patient outcomes should be optimised in all health care providers prior to participation in a screening programme.

Not examined as part of the review.

16. All other options for managing the condition should have been considered (such as improving treatment or providing other services), to ensure that

no more cost effective intervention could be introduced or current interventions increased within the resources available.

The cost effectiveness of lung cancer screening vs other services to reduce lung cancer mortality is not part of the review. It is recognised that tobacco control will not assist current patients likely to be eligible for screening due to the time lag between smoking and the development of lung cancer.

17. There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.

Not examined as part of the review, but would need to be agreed as part of implementation across the UK.

18. Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme.

This was not assessed as part of the review, although having adequate organisational resources was one the issues cited by professionals when asked about their perceptions and opinions about lung cancer screening. Investment will be required in radiology and expanding diagnostic services to be able to go forward with screening.

19. Evidence-based information, explaining the purpose and potential consequences of screening, investigation and preventative intervention or treatment, should be made available to potential participants to assist them in making an informed choice.

Not examined as part of the review.

20. Public pressure for widening the eligibility criteria for reducing the screening interval, and for increasing the sensitivity of the testing process, should be anticipated. Decisions about these parameters should be scientifically justifiable to the public.

Not examined as part of the review.

In conclusion, while there is evidence of impact on lung cancer mortality for those who take up the offer of lung cancer screening, the evidence of impact on whole population, all-cause mortality is not there. ABUHB is concerned that introducing lung cancer screening would widen inequalities in lung cancer mortality due to the likely inequity in uptake of screening seen with all other screening programmes, and a screening only pathway does not address the widening inequality in smoking prevalence.

There is a single test (LDCT), but important considerations such as eligibility, screening rounds and thresholds for a positive test vary widely in the studies included in the review. This is demonstrated by positive predictive values which range from 3.3%-43.5% in the studies. CT is the standard test for patients with suspected lung cancer and is the reality of the diagnostic situation currently available. Hopefully, this will improve further over time.

About 1 in 2 eligible individuals will attend for screening, but whether this level of uptake is acceptable (as measured by cost-effectiveness) is unclear as the cost-effectiveness review has yet to publish a final analysis. It is clear from comments on page 83 of the UK NSC

external review that evidence about the acceptance of the full screening pathway, including the diagnostic work up and treatment or management of lung cancer is needed.

In terms of harms, there are extremely wide ranges in the rate of over-diagnosis (-13% to 67.2%), and the psychological harm associated with a false positive result is not well understood. The review itself acknowledges that the best approach to balancing harms and benefits is uncertain, although it is recognised by ABUHB that this applies equally to any patient who is currently being investigated with symptoms.

Overall, based on the UK NSC review, the position of ABUHB is that the introduction of lung cancer screening would be supported subject to the following:

- Final conclusions from the Exeter Test Group and Health Economics Group that demonstrate screening is cost-effective;
- Greater evidence about the acceptability of the full pathway, from screening to diagnosis to treatment;
- A delivery model which is shaped by the experience of trials in places like Manchester and which has equity of access as a key principle;
- Greater clarity about how to optimally integrate smoking cessation services into the screening pathway;
- A plan for the workforce and diagnostic capacity necessary to meet demand across the breadth of the screening pathway.

		The evidence for whole population, public health lung cancer screening model does not currently exist and as an integrated Health Board responsible for public health and lung cancer services, we would welcome the opportunity to work with the NSC to pilot a population based approach to lung cancer screening to test approaches designed to prevent lung cancer inequalities widening.
	Aneurin Bevan University Health Board (ABUHB) specific comments on the UK NSC review	
Conclusion (page 67) AND Summary of Findings Relevant to Criterion 11 (met) and criterion13 (uncertain) 1 (page 68)	"It is difficult to assess the balance of harms and benefits of lung cancer screening with LDCT as the outcomes of possible harms are inconsistent across the studies. For example, false positive scan results vary between RCTs from 1.6% to 27.2 %, whilst over diagnosis rates vary from -13% to 67.2%." "The RCTS explored harms associated with lung cancer screening and reported a substantial number of people who received a false positive result leading to unnecessary tests and invasive procedures which may lead to adverse events. Other harms included overdiagnosis, incidental findings and short term anxiety and distress."	One of the UK NSC screening criteria for recommending a screening programme is that the benefit gained by individuals from the screening programme should outweigh any harms, for example, from over-diagnosis, overtreatment, false positives, false reassurance, uncertain findings and complications. This is important because false positive test results and over-diagnosis are both potential sources of harm which may lead to unnecessary interventions with adverse psychological impacts, morbidity and mortality. Given the inconsistency in findings across the trials, ABUHB would support the conclusion on page 69 of the review that further testing of implementation strategies is necessary to identify the most clinically effective screening approach.
Summary of Findings Relevant to Criterion 11 (met) and criterion13	"A meta-analysis across 7 RCTS reported a significant relative reduction of lung specific mortality in the LDCT group of 17% (RR; 0.83 (0.76- 0.91)."	ABUHB notes that trial data indicates LDCT screening reduces lung cancer specific mortality by 17% vs no screening.

(uncertain) 1 (page 68)		
Smoking cessation (page 66-67)	"Overall, Jonas et al (2021)8 identified 5 RCTs comparing smoking outcomes between the screening and control arm (DLCST, ITALUNG, NELSON, NLST, UKLS). Of the 5 studies 3 (NELSON, NLST and UKLS) showed that screening compared to no screening may increase smoking cessation especially in people with a true positive or intermediate screening test result."	Smoking is estimated to cause 72% of lung cancer cases. While evidence from the five RCTs quoted does not indicate the harm of false reassurance following screening, neither is there data demonstrating the best way to align screening with smoking cessation services. If, as stated in the UK NSC consultation covernote, one of the aims is to ensure lung cancer screening is not seen as an alternative to smoking cessation services and that smoking cessation should be an integral part of the screening programme, the review does not provide a clear statement on how to do this to best effect. On a specific point, although the NELSON study is cited as one of three studies demonstrating an increase in smoking cessation due to screening, the accompanying statement about the NELSON trial is: "The NELSON RCT reported that the control group had a somewhat higher abstinence rate than the LDCT group (15.1% vs 19.8%, p=0.04)." This suggests greater abstinence in the control rather than LDCT group?
Lung cancer screening uptake (page 74)	"Older people were less likely to attend than those ≤65 years (OR 0.73, p p<0.001); women were less likely to take part compared to men (OR 0.64, p p<0.001) current smokers were less likely to attend than former smokers (OR 0.70, p p<0.001); and people in highest socioeconomic quintile (5) were more likely to attend than those in the lowest quintile (1) (OR 0.56, p<0.001)."	Among the different types of cancer, lung cancer has the widest socioeconomic disparity in mortality. In Wales, rates of lung cancer mortality in the most deprived segment of the population are two and a half times higher than among the least deprived. When looking at the results of the individual trials included in the UK NSC review, there are wide differences in equity of uptake. The UK Lung Screening Trial did show people in the lowest socioeconomic quintile were significantly less likely to attend for screening, whereas the Manchester

lung health check pilot showed no difference in uptake by deprivation. In implementing screening on a UK wide basis, it will be important to ensure the delivery model reflects the learning in places like Manchester to ensure equity of uptake. One of the UK NSC screening criteria is that a screening "However, a more conclusive statement of the Interim report on programme should provide value for money. the costcost- effectiveness of LDCT in the UK requires Assessment against this criteria should have regard to effectiveness of the ongoing work to address the criticisms of the evidence from cost benefit and/or cost effectiveness natural history component of ENaBL to be low dose analyses and have regard to the effective use of completed and incorporated into the model." computed available resource. tomography The cost-effectiveness report that is part of the (LDCT) screening "Some scenarios, including 2 reported by UK consultation is in an interim state. There are a number of for lung cancer in studies, indicate a lung cancer screening aspects of the natural history model that are being high risk programme would meet the cost effectiveness revised, which are detailed in the report. At this stage, individuals threshold (£10,000-20,000 per QALY) applied to the cost-effectiveness data is insufficient to confirm UK interventions. However, overall there is such whether screening is value for money or not and a final a wide variation in ICERs across strategies that International report is awaited. As such, it is unknown whether evaluations using without a better understanding of the sources of screening is cost effective at this stage. the CISNET variation there could be little confidence that this models (page 70) level of cost effectiveness could be reliably demonstrated in a further study or in practice." AND UK NSC external review - Screening for lung cancer for individuals at increased risk (page 85-86)

10-

Name: Douglas Rigg

Organisation: Scottish Primary Care Cancer Group

Role: Chair

Condition: Lung cancer

Please find attached some categories requiring consideration and bullet points relating to the Lung Cancer Screening Consultation. We acknowledge that this is not a comprehensive response but services to highlight some of the areas and issues we feel need to be addressed. Please contact me at the above e-mail address if any clarification is required:

Patient selection:

- Need to have several data inputs and not GP records alone smoking status recording more variable since QoF removed
- Age option for variation of age depending on local characteristics (deprivation associated with younger patients)

Health inequalities:

- Important to avoid this leading to widening inequalities.
- Location & delivery of service
- Engagement esp with minority groups
- Appropriate patient information and resources

Current service impact:

- Need to minimise impact on primary care services eg avoid requirement for GP to submit information (as current bowel screening) patients being directed to GP for information/advice/discuss results
- Patient info and resources potentially including helpline/online contact
- May need psychological supports also
- Ensure this does not impact 2nd care services for symptomatic patients or those referred on USC pathways

Impact of results:

- Cancer identified impact on clinic, treatment capacity as above
- Prehab where does this fit and how do patients access via screening
- Cancers requiring best supportive care impact on palliative care, district nursing, primary care services.
- Cancers excluded "teachable moment" to engage with health improvement, smoking services, general health.
- Incidental/non-cancer findings ensure appropriate follow up for findings such as coronary artery calcification and lung nodules with minimal impact on primary and secondary care services. I.e. findings and management plan should be fully explained to patients by the screening service before being passed on to primary or secondary care.

11.

Name: Dr John Conibear

Organisation: National Lung Cancer Audit

Role: Oncology Clinical Lead

Condition: Lung cancer

On behalf of the National Lung Cancer Audit (NLCA) team, we fully support and agree with the recommendations set out for lung cancer screening in the UK.

We agree that a quality assured, targeted screening programme for lung cancer in people aged 55 – 74 with a history of smoking should be introduced into the UK as a matter of priority.

In regards data collection, we also believe it is vitally important that patients diagnosed via the new lung cancer screening program are flagged by Trusts in the route to diagnosis field of COSD.

We believe this should be mandated as it will help improve in the analysis of lung cancer patient data at a Trust level which can then be used to refine decisions on how best to advance and improve lung cancer patient care. We hope you will consider and adopt this important recommendation.

Name: Sally Welham

Organisation: British Thoracic Society

Role: Chief Executive Condition: Lung cancer

The British Thoracic Society strongly supports the recommendation of implementing a quality assured targeted screening programme for lung cancer in patients aged 55 to 74 with a history of smoking.

Successful pilot programmes instituted nationwide since 2019 have already ably demonstrated the clinical feasibility of implementing such a programme. From the attached documentation, the UK National Screening Committee (NSC) have thoroughly and comprehensively reviewed the relevant literature and evidence concerning the clinical benefits of a targeted screening programme for lung cancer. When the additional factor of favourable cost effectiveness is added to the discussion, the factors surrounding the screening programme become compellingly favourable.

A centrally managed programme, with clear protocols for management of incidental findings and robust quality assurance/ governance is essential.

The British Thoracic Society is clear that that smoking cessation needs to be an integrated and essential component of any screening programme and is likely to maximise benefit and further improve cost effectiveness.

The need for high quality research to be embedded in the process is essential.

Implementing a targeted screening programme for lung cancer aligns with the government's plan for improving cancer care, outlined in the 2019 NHS Long Term Plan, and so the British Thoracic Society strongly supports the implementation of the proposed targeted screening programme for lung cancer

13-

Name: Dr Rosemary Millar Organisation: NHS Lothian

Role: Consultant in Public Health

Condition: Lung cancer

PRIMARY CARE and IDENTIFICATION OF POPULATION:

Need to ensure programme targets the correct cohort and doesn't involve too much work in Primary Care given work pressures there

Be aware there is limited capacity within primary care to support additional work. Any additional primary care input will need to be adequately funded

Data to identify eligible cohort-

How accurate is primary care data? – is it up to date now that QOF has stopped in Scotland (2015/6)? Pt record accuracy has potential to reduce over time and we won't identify new smokers. Fewer face to face consultation now, to ask these questions also. Status is checked at new patient health check still but how well is this completed and how often updated?

(QOF previously required updating of patient record on smoking status within a 12-24 month period for those current smokers/ pre-existing condition +smoking, respectively)-

Are there other sources that are CHI linked could be used to identify eligible cohort? Will some eligible population be missed – do we need self referral route? Could this be included in smoking cessation services where relevant?

Can Data Loch be used to access primary care information (or alternative?) Process for recruitment-

If done at population level then recruitment process eg lung check questionnaire) would need to be efficient in order to avoid large drop off in numbers.

INEQUALITIES

Need to consider inequalities and ensure these are not increased- note current evidence shows current smokers may be less likely to take up a scan.

Challenges in contacting those in vulnerable groups

Consider linking with other screening services/prevention services to help self identification e.g. raise awareness at AAA screening sites

Ensure good access- possibility for mobile units for scanning

Be aware of potential negative impact on smoking cessation for those with 'all clear' outcomes.

WORKFORCE

Need to ensure adequate workforce across whole pathway

Ensure appropriate screening coordinator and associated staff time available to support this if this is a national programme

Ensure adequate onward capacity in respiratory/ radiology/

pathology/radiotherapy/surgery -

Capacity to follow up incidental findings

Capacity to follow up /surveillance for nodules

note workforce pressures in radiology to read CT scans.

Support services – ensure adequate capacity available in order to manage risk e.g. Consider impact on stop smoking services

Screening intervals

How often should this be done – one off/recurrent invite of schedule (how often?) Should the eligibility search be done annually/other frequency to identify eligible cohort – Need to avoid repeating eligibility questionnaire with same group on recurrent basis especially if no change in circumstance, as this will incur frustration /loss of reputation. Would it be possible to give an estimate of when participants will become eligible to provide personal insight/engagement

Consider impact on services if recurrent screening

All cause mortality – do we need more evidence on the impact on all cause mortality given current unclear situation?

PSYCHOSOCIAL IMPACT

Potential to increase the time patient is aware of diagnosis without opportunity to change outcome – lead time bias

LUNG CANCER PATHWAY -

To ensure adequate services for diagnosis and treatment of earlier stages
To ensure adequate palliative treatment options in place in case of additional late
diagnoses – possibly no impact as patients likely to present with symptoms anyway
regardless of screening programme by that stage

Name: Nick Jones

Organisation: Cancer Research UK

Role: Policy Advisor

Condition: Lung cancer

UK National Screening Committee (UKNSC) consultation on a national targeted lung screening programme, June 2022

Key Points

 Cancer Research UK (CRUK) welcomes and supports the UK National Screening Committee (UKNSC) recommendation in favour of a national targeted lung screening programme, along with the focus on smoking cessation as an integral part of it.

o Lung cancer is the most common cause of cancer death in the UK, accounting for 21% of all cancer deaths. Lung cancer outcomes in the UK are consistently poor, with just around 4 in 10 people diagnosed with lung cancer in England surviving their disease for one year or more, and around 3 in 20 people surviving their cancer for 5 years or more after diagnosis.

o Early diagnosis is vital for improving lung cancer outcomes. More than 55 out of 100 people diagnosed with stage 1 lung cancer will survive their cancer for 5 years or more after diagnosis. In contrast, less than 5 out of 100 people diagnosed with stage 4 lung cancer will survive their cancer for 5 years or more after they are diagnosed.

o A national targeted lung screening programme has the potential to increase the proportion of lung cancers diagnosed at an earlier stage, when treatments are more effective and kinder, and to reduce lung cancer mortality.

 As CRUK supports the UKNSC recommendation for a national targeted lung screening programme, this consultation response focuses on key considerations for governments across the UK in delivering such a programme. There are several considerations for the UKNSC and governments in all four UK nations in recommending and then delivering a targeted lung screening programme.

o Long term investment and planning to tackle shortages in diagnostic capacity will be central to implementing a comprehensive programme. These are principally driven by shortages in key workforce groups in diagnostic services, but must also consider diagnostic equipment. Without an uplift in diagnostic capacity, there is a risk that lung screening programmes may draw capacity from other areas of already strained diagnostic services.

o Maximising the benefits of targeted lung screening will also require an uplift in treatment capacity. Outcomes will only improve if cancer treatment services have sufficient capacity to deliver timely, optimal treatment for more early-stage patients.

o It is essential that invitation to the lung screening programme is based on high quality smoking status data across all UK nations. Smoking cessation should also be an integral part of the targeted lung screening, with opportunities for participants to engage at multiple points in the pathway, and continued cessation support following participation. UK health departments must ensure stop smoking services have enough capacity, resource, and are funded sustainably to cope with additional demand for stop smoking support.

o Upon implementation, consistent and tailored public engagement will be necessary to ensure that those invited consider attending. Targeting this towards those from more deprived populations, where lung cancer is more common, and those who are currently smoking will be particularly important. Moreover, this programme would be the first cancer screening programme to invite participants based on characteristics other than age and gender, meaning engagement to ensure public confidence and mitigate against unintended consequences, such as reinforcing stigma, will also be vital.

o Given the scale of a national lung screening and the potential to do harm as well as good, it is crucial that national lung screening programmes are delivered by expert teams, and that independent quality assurance is in place.

• Additional strategies must also be implemented to effectively tackle lung cancer more broadly, for example by supporting patient presentation and the recognition and referral of symptomatic disease. High quality lung cancer screening has the potential to improve lung cancer outcomes in the UK – however, it will not be a silver bullet. While based on the current evidence it is appropriate that lung screening is targeted, nearly 6,000 people who have never smoked die of lung cancer every year, not all former or current smokers will necessarily be deemed of sufficient risk to undergo a CT scan, and not all deemed of sufficient risk will ultimately undergo their scan.

Key considerations

Smoking

Availability, quality and transfer of smoking status data

If the UKNSC recommended lung screening pathway involves inviting those who have ever smoked for a risk assessment based on primary care record data, it is essential that there is high quality smoking status data to base selection on. If not, people who are eligible may be missed, and people who are ineligible may be incorrectly invited. GP systems also include several codes to categorise smoking status, so depending on which codes are used as a basis for selection in targeted lung screening, some people who smoke may be unintentionally excluded. To support accurate smoking status records and invitation to targeted lung screening, it will be vital that each national health department maintains commitments for primary care professionals to be trained in and routinely deliver Very Brief Advice (VBA) on smoking in consultations with patients who smoke. These national commitments should also be strengthened: see our Making Conversations Count for All report for further detail.

Health departments must also consider other methods, including quality improvement and development of standards, to optimise both completeness and quality of GP record data. This may include contacting those with absent smoking records to ascertain smoking status. Dr. Sinan Eccles and colleagues at Cardiff University have explored an automated text message system to update data for people with no smoking status recorded, including a follow up prompt to national

smoking cessation support through Help Me Quit. It would be useful to collate and learn from this and other relevant work.

Alternative invitation methods could also be considered to mitigate against the quality of patient data in GP records. For example, the Manchester lung health check pilot sent letters to everyone who was registered with a GP in the target age range, inviting people who have ever-smoked to participate in the risk assessment. While this could create concern from a public understanding perspective given people who never smoked will also receive a letter, it could ensure all people who have ever smoked are invited for risk assessment. It would therefore be useful to consider undertaking cost-effectiveness analyses of different invitation/pathway approaches.

Smoking cessation

The UKNSC's focus on smoking cessation as an integral part of the screening programme is welcomed, alongside their recommendation to provide smoking cessation advice to all participants in the programme.

There are clear opportunities to influence people who smoke through lung screening given the population of people who currently smoke that will invited. There also appears to be an appetite for smoking cessation advice among attendees – in the independent evaluation of NHS England's Targeted Lung Health Check (TLHC) programme, it is reported that 31% of those who smoked cigarettes in the week of completing the survey said they attended the LHC because they thought it would help them to reduce or stop smoking [confidential statistic and reference].

It is therefore vital that, as a minimum, all clinical and non-clinical staff in contact with lung screening invitees and participants receive training on VBA to ensure all staff are educated in smoking cessation. The Hull TLHC programme demonstrates that participants are receptive to smoking cessation interventions when triage staff are trained effectively. Pre-COVID, there were poor levels of engagement with smoking cessation support following nurse triage, but this rose to 70% following a VBA refresh training to triage nurses emphasising the shortness and effectiveness of the intervention, the introduction of specific scripts for triage nurses to support improved referral into the service, and the first promoted follow-up contact being done via telephone. Hull TLHC is now the

second highest source of referral to the Hull stop smoking service since April 2021.

In the Yorkshire Lung Screening Trial, an initial consultation with a trained smoking cessation practitioner following the risk assessment is happening on site on an opt-out basis. Follow-up smoking cessation support is available either face-to-face or by telephone., Where direct follow-up is not possible, or if preferred by the individual, contact details are shared to refer into local stop smoking services. Initial data from this trial indicates positive results from this approach, with 11.9% of eligible people who smoke validated to have successfully quit (7-day point prevalent) at four weeks. When including self-reported quits (some could not be validated due to COVID-19), this figure increased to 15%. A recent qualitive study also suggests immediate on-site approach is also preferred by attendees. Both of these studies suggest that a non-judgemental, positively framed approach taken by staff is key in promoting uptake in smoking cessation support.

Targeted lung screening programmes should also be embedded into national smoking cessation programmes such as Help Me Quit in Wales and Quit Your Way in Scotland. Given public health functions and health and social care provisions, including NHS-delivered services, are linked across devolved – this should be easier to implement.

Continued cessation support is crucial for people who want to stop smoking following participation in targeted lung screening. If UK health departments adopt a positive recommendation by the UKNSC, national programmes will need to ensure that stop smoking services across the UK have enough capacity and are adequately resourced to cope with additional demand for stop smoking support. Collaboration with stop smoking services leads, as well as other stakeholders, early in the planning process for targeted lung screening rollout will be paramount to this.

A barrier that will need to be resolved, particularly in England, is the lack of universal stop smoking services open to everyone to be referred onto. This is causing issues in the North Central London TLHC: there are different smoking cessation offers across boroughs with different referral criteria from programmes such as TLHCs. Similar issues are occurring in Stoke-on-Trent where the stop

smoking service has had to restrict it's referral criteria to support 'Smoking in Pregnancy' or people with moderate to severe mental health problems.

Local stop smoking services, which provide a combination of behavioural support and pharmacotherapy, offer people who smoke the best chance of stopping successfully. However, local authorities in England have experienced a sustained programme of cuts in recent years, which severely compromises their ability to provide vital functions and services that prevent ill health: such as stop smoking services. These funding cuts have also been greatest in more deprived local authorities – which risks exacerbating existing health inequalities. Whilst all areas used to have one, now only 67% of local authorities in England commissioned a specialist service open to all local people who smoke in 2021. Smoking cessation interventions are an extremely cost-effective method of preserving life and reducing ill health. Therefore, effective integration of stop smoking support into the lung screening programme is very likely to also improve its cost effectiveness.

Smoking is also highly profitable to tobacco manufacturers. That's why the UK Government should introduce a fixed annual charge on the tobacco industry, making them pay for the damage their products cause, but without letting them influence how the funds are spent. Funds generated from this charge should be used to help deliver the necessary evidence-based tobacco control measures at a national, regional and local level across the UK, such as stop smoking services.

It is vital that UK-wide tobacco control measures are prioritised across the UK, which is why we also welcome the UKNSC's acknowledgement that implementation of screening for lung cancer should not be seen as an alternative to the delivery of high-quality smoking cessation services across all age groups.

Presentation and public understanding

Maximising presentation among those invited

Recent news reports celebrate the potential of the current TLHC programme in diagnosing lung cancer at an earlier stage, with 600 participants being diagnosed at an early stage so far. However, only around 35% of those invited by the NHS in England attend their lung health check, compared to the anticipated uptake rate of 50%.

Health departments and systems must deliver consistent and tailored engagement with the public to ensure that those invited consider taking part in the initial risk assessment, and in the CT scan should they meet the risk threshold. This includes building opportunities for reminders, text messages and other approaches to raise awareness of, and build engagement with, the screening programme, into the screening pathways, and delivering evidence- and insight-informed public-facing campaigns.

As with other screening programmes, risks, as well as benefits, of taking up screening need to be communicated in a clear, accessible way to all invitees, to allow them to make an informed decision.

Lung cancer is more common in more deprived populations, with smoking a leading driver of health inequalities, accounting for approximately half of the difference in life expectancy between the lowest and highest income groups in England alone. In England, there are over 14,000 excess cases of lung cancer attributable to socio-economic deprivation each year. Deprivation affects uptake across existing screening programmes and in the UKLS trial, participants in more deprived quintiles were more likely to not take up lung screening than those in the least deprived quintile. An initial evaluation of the TLHC programme indicates that uptake may be lower in more deprived groups compared with less deprived. In the 10 original projects launched, there was an uptake of 45% in the most deprived quintile of the invited compared to 66% in the least deprived quintile [confidential statistics and reference]. As people from lower socio-economic groups are more likely to smoke and may be less likely to attend lung screening, there is the strong potential to widen health inequalities in lung cancer outcomes if inequalities in uptake and completion of the screening pathway are not addressed.

Government engagement programmes should be targeted to remove barriers that may prevent people from lower socioeconomic groups from taking part in lung cancer screening and achieve informed uptake, including to the initial risk assessment, CT scan for those who meet the risk threshold, and treatment for those who are found to have lung cancer.

Tackling potential barriers to uptake

CRUK and YouGov polling indicates that people who smoke may face psychological and information barriers to taking up lung screening, such as fatalism. Whilst people who currently smoke are more likely to worry about getting lung cancer compared with people who formerly smoked or never have, they are less likely to agree that lung screening can help to detect cancer early. This notion of fatalism is echoed by research into attitudes towards a potential lung screening programme among people who smoke or used to smoke in socioeconomically deprived communities. Participants were supportive of screening in theory, however many perceived lung cancer as an uncontrollable disease and were doubtful about the ability of screening to improve survival for heavy smokers. In addition, blame and stigma around lung cancer as a selfinflicted disease were also highlighted by participants as social deterrents to attending screening. It is important that the benefits of stopping smoking at any age are highlighted, so participants understand that it is never too late to stop. The language used should not perpetuate the stigma faced by people who smoke. For example, referring to smoking in a person centric manner – "people" who smoke", rather than labelling people as "smokers" which may be considered stigmatising.

Governments must target people who smoke to attend screening in a sensitive manner that does not perpetuate the stigma already faced by many and that counters fatalistic beliefs.

Ensuring public confidence

This programme would be the first UKNSC recommended cancer screening programme to invite participants based on characteristics other than age and gender. This presents unique challenges in building public understanding and confidence and has the potential to be controversial if the public believe they are missing out on a potentially lifesaving health intervention. There may be interest in lung screening among those who are not eligible, with polling from CRUK and YouGov finding 26% of never smokers disagreeing with the statement that they wouldn't mind not being offered lung screening.

Governments across the UK should effectively engage with the public prior to introducing the programme to increase the public's understanding of who is eligible and why, and ensure public confidence in the programme.

Capacity

Diagnostic capacity

Targeted lung cancer screening will require significant diagnostic capacity. Shortages in diagnostic capacity, including imaging, endoscopy and pathology, have led to delays in cancer diagnosis across the UK, for example in England the target to treat 85% of cancer patients within two months of an urgent suspected cancer referral has not been met since 2015.

The UK ranks close to the bottom on average number of CT scanners per million out of 36 OECD countries. We are also overly reliant on ageing, less sophisticated scanners prone to breakdown. In England, the 2021 Spending Review allocated £2.3bn over 3 years to fund the expansion of Community Diagnostic Centres (CDCs) in England, committing to roll out at least 100 CDCs. This was welcome and will increase the availability of the CT scanners needed to deliver this programme. However, it is unclear whether this will be sufficient to meet existing rising demand for cancer services and deliver this programme.

UK Governments should ensure there is sufficient CT scanner capacity to deliver this programme alongside existing planned activity, including reassessing existing plans to expand CT capacity with this programme in mind.

Shortages in the diagnostic workforce would also be a significant concern in the implementation of this programme. The RCR 2020 clinical radiology census found that the radiology workforce across the UK is now short-staffed by 33%, needing almost 2,000 more consultants. Without more training, investment in new models of care and better retention and recruitment they estimate that by 2025 this shortfall will hit 44%. Similarly, there are significant shortages in the diagnostic radiography workforce, with the 2020 diagnostic radiography workforce census published by the College of Radiographers showing an average current UK vacancy rate of 10.5% in diagnostic radiographers. Similarly, evidence of shortages in the pathology workforce are compounded by the fact that around a third of pathologists are 55 or over.

Chronic shortages in the NHS in specialties key to diagnosing lung cancer have hampered progress for several years, with, as of February 2022, 19% of people waiting for a radiology test in England waiting 6 or more weeks. It is vital that

there is sufficient diagnostic capacity to roll out the targeted lung screening programme nationally, without drawing capacity and further exacerbating pressures on other areas of diagnostic services.

UK Governments must set out long-term funding plans to deliver a sustained expansion of the cancer workforce to meet future demand for cancer services – including in the radiography, clinical radiology, reporting radiography and pathology workforce – to deliver a comprehensive and national targeted lung screening programme without drawing capacity out of other services.

To ensure enough staff are trained to meet future demand, robust workforce planning supported by regular, independently verified projections of the future supply and demand of the health workforce is key. Such workforce planning should include the impact that a new national targeted lung screening programme will have on diagnostic demand.

The use of reporting radiographers to report on images is well established across the UK. The proportion of trusts and health boards using radiographer reporting rose from 72% to 82% in the five years to 2020. However, it still varies significantly across trusts and Sir Mike Richards' review of diagnostic services in England recommended that there should be an increase in advanced practitioner radiographer roles. Difficulties accessing training courses and difficulty carving out time for continuous professional development (CPD) act as significant barriers to increasing the use of reporting radiographers. Governments across the UK must ensure that the cancer workforce has both access to and the opportunity to undertake CPD, for example by providing sufficient funding for staff wishing to upskill. However, the most significant barrier to the use of reporting radiographers to support the radiology workforce is radiographer shortages.

Governments should tackle the barriers to the expansion of reporting radiologists, including financial and geographical barriers to training, shortages in radiographers and a lack of time for training, to free up radiologist capacity to support the programme.

Treatment capacity

To be successful, this programme will also require increased treatment capacity, especially in cancer surgery and radiotherapy services which are two of the main

treatment modalities for earlier stage lung cancer. As specified in the consultation document, lung screening can identify people at an earlier stage, compared to people who have no screening and are diagnosed with lung cancer. This stageshift has the potential to improve cancer patients' outcomes as lung cancers detected at earlier stages are more likely to be successfully treated. But outcomes will only improve if cancer treatment services organise and plan for this shift in order to have sufficient capacity to deliver timely, optimal treatment for more early-stage patients.

Performance against the 62-day wait target has been declining over the last decade across the UK. Taking England as an example, the pandemic has impacted performance further. In 2020/21, we saw the 10 worst moths on record for cancer service performance in lung cancer. In February 2022, only 54% of lung cancer patients started treatment within 62 days of urgent suspected referral. During the same time period, performance against the 31-day wait target has been more stable and, even though the pandemic has impacted performance, the 96% target has generally been met in England. While this is positive and may indicate that service capacity to start timely lung cancer treatment following diagnosis is adequate, significant challenges remain.

The UK is lagging behind comparable countries in terms of survival. While this can be ascribed to a range of possible factors, including healthcare system structures, patient choice, and prevalence of comorbid conditions, it may also suggest suboptimal treatment and less willingness or capacity to treat using radical approaches. In 2020, the National Lung Cancer Audit (NLCA) ran its second spotlight audit to understand why patients diagnosed with stage I-II disease were not receiving surgery despite having a good performance status (PS). It found that 35% of patients received no specific anticancer treatment.

In line with the recommendations of the spotlight audit, MDTs should review the case records of patients with early-stage disease and good PS who do not receive treatment with curative intent to help identify and address the underpinning factors driving worse in-stage survival in the UK.

Cancer surgery has been significantly affected by the pandemic. Staff redeployment and restrictions on surgical capacity and intensive care beds meant the number of cancer surgeries fell by an estimated 24% in England between April and November 2020 compared to 2019. The proportion of patients in

England with early-stage non-small cell lung cancer (NSCLC) and PS 0-2 that received surgery fell from 58% in 2019 to 48% in 2020, further demonstrating the impact of the pandemic on lung cancer treatment.

In the coming years, as the NHS seeks to address a significant elective backlog – for cancer as well as a range of other conditions – surgical capacity will continue to be placed under pressure. A national lung screening programme would compound pressures on surgical services and the workforce. Surgical training is a long process which can take up to eight years after graduation. This makes it challenging to address increased demand and reinforces the importance of organising and planning for future changes to demand.

Therefore, health services must implement ongoing reviews of demand, capacity, and workforce requirements to plan and optimise service provision and expand capacity to meet demand where needed.

As with diagnostics, cancer treatment services also suffer from workforce shortages that hamper treatment capacity and may become a barrier to reaping the benefits of diagnosing more lung cancers early as a result of lung screening. According to the RCR's 2020 clinical oncology census, the clinical oncologist consultant workforce has a shortfall of 17% which is set to rise to 28% by 2025. 90% of Heads of Service are reported to be concerned about the continued availability of specialty site-specific expertise and 88% are concerned about treatment delays. 66% reportedly believe that workforce shortages are affecting the quality of patient care, a rise from 51% in 2020.

To manage the changes to demand on treatment services stemming from a national targeted lung screening programme, Governments must set out long-term funding plans to deliver a sustained expansion of the treatment workforce, particularly in the services that treat earlier stage lung cancer.

Operations and rollout

Organisational structure

A national targeted lung screening programme is a public health intervention, aiming to identify cancer amongst people at increased risk of the disease but without symptoms. As such, it interacts with many more people that do not have

cancer than do. With all screening programmes, maintaining a favourable balance of benefits and harms is vital. To ensure that the theoretical balance is achieved in practice, it is essential that the programme falls within the remits of the teams currently responsible for delivering and quality assuring the existing national cancer screening programmes. Not only does this help to ensure that the necessary expertise is brought to this critical public health intervention, it also helps to ensure that targeted lung screening is captured within national transformation agendas, such as IT infrastructure developments, and seizes opportunities to learn, share and improve across screening programmes, including developments and interventions which support the addressing of inequalities.

Frequency of scans, risk stratification and significant results

The recommendation for introducing lung cancer screening doesn't detail the exact approach for implementation to be taken. Trials supporting the recommendation employ different methods of risk stratification, number of screens, screening intervals and definitions of significant results. Employing different methods will result in different outcomes for benefits (reduced lung cancer mortality) and harms (overdiagnosis, false positives, false negatives and radiation exposure) of lung screening. In addition, in two of the largest trials assessing the benefits and harms of targeted lung screening (NELSON and NLST), participants were followed up for several years after their screening ceased, which makes it difficult to interpret the burden of overdiagnosis from these studies and extrapolate these results to a programme with different screening intervals. Further clarity on the chosen protocol and publicly available modelling on its clinical effectiveness is necessary to gauge the exact balance of benefits and harms. Once implemented, this balance should be closely monitored. This will be necessary for positioning public communications and resources to ensure that the public can make an informed choice on attending. Clarity on the protocol to avoid differences in regional outcomes, aiming for consistent, optimal service design across the UK, will be important to mitigate the risk of widening regional inequalities.

Data transparency

Timely and transparent data that reveal how targeted lung screening is performing is crucial. A flag in the relevant datasets will be needed to ensure that

patients who have been through targeted lung screening can be clearly identified, regardless of outcome. We anticipate it will take time to incorporate a lung screening flag into records, therefore we recommend that this be considered early in the process.

A breakdown of the key performance indicators, including screening uptake and coverage (for any lung health check/risk assessment element and the CT scan for eligible individuals) should be provided for participants in targeted lung screening, on a quarterly basis. This must include breakdowns by key demographic groups (ethnicity, age, gender, deprivation, employment status), region and, if programmes continue to be delivered virtually as well as in person, by type of appointment delivered.

We also are aware of reports of data sharing challenges between smoking cessation providers. It will be vital that UK health departments ensure that robust data transfer systems are in place across GP, screening and smoking cessation sites. Any data sharing should be done in a trustworthy and secure way, with proper transparency and communication with the public and patients.

Digital transformation

Information systems for screening are essential for identifying cohorts of people who should be invited for screening at a specific point in time, managing screening programmes for example issuing invitations, and recording outcomes.

However, as was highlighted by the Professor Sir Mike Richards review of Adult Screening Programmes in England, poor digital infrastructure has held other cancer screening programmes back from meeting their potential to improve cancer outcomes – most notably in breast and cervical.

Governments across the UK must ensure that there is sustainable and ongoing capital investment to continually improve digital capabilities across the targeted lung screening programme, horizon scanning for actual or likely innovation requirements into IT development at the earliest reasonable opportunity.

Governments must also ensure that IT systems can identify who has attended the targeted lung screening programme, including a comprehensive demographic breakdown, to ensure that the programme works to tackle health inequalities in

lung cancer outcomes. IT systems should also be able to track patients back to their GP and their smoking outcomes.

Ensuring action for everyone with lung cancer – not just those who are eligible for targeted lung screening or are on a screening pathway

It must be recognised that screening is just one measure necessary to improve lung cancer outcomes in the UK – and is not a silver bullet.

Given that 79% of lung cancers are preventable, all possible action should be taken by the UK Government to reduce the number of cases attributed to preventable risk factors.

Furthermore, there remains a large contingent of people who have never smoked who will develop lung cancer without being eligible for any national lung screening programme targeted on the basis of a current or previous smoking history. Nearly 6,000 people who have never smoked die of lung cancer every year. While lung screening is not suitable for people who haven't smoked, additional strategies must also be implemented to effectively tackle lung cancer more broadly. Efforts to optimise the diagnosis of lung cancer through patient presentation and recognition and referral of symptomatic disease will continue to be key to any comprehensive strategy to improve lung cancer outcomes in the UK.

Appendix 1: Recommendations

Smoking and health

- To ensure smoking status records and invitation to targeted lung screening are as complete as possible, each national health department should continue with commitments for primary care professionals to be trained in and routinely deliver Very Brief Advice (VBA) on smoking in consultations with patients who smoke. These commitments should also be strengthened: see full recommendations in our Making Conversations Count for All report.
- The UKNSC and health departments must consider a range of options including quality improvement methods and specific standards to optimise both completeness and quality of GP record smoking status data.
- All clinical and non-clinical staff within targeted lung screening should receive training on VBA to ensure all staff are educated in smoking cessation.
- UK health departments must ensure there is continued cessation support for people who want to stop smoking following targeted lung screening.

- Alongside ensuring targeted lung screening programmes are embedded into national smoking cessation programmes, UK health departments will need to ensure that stop smoking services across the UK are available to refer patients into.
 Services must have enough capacity and resources to cope with any additional demand for stop smoking support resulting from targeted lung screening.
 Collaboration with stop smoking services leads, as well as wider public health and other stakeholders, early in the planning process for targeted lung screening rollout will be paramount to this.
- Increased investment is needed to support people who want to stop smoking and continue to discourage people from starting. The UK Government should introduce a Smokefree Fund: a fixed annual charge on the tobacco industry that would use their funds, without their interference, to pay for tobacco control measures across the UK such as stop smoking services.

Optimising participation and building public understanding

- Health departments and systems must deliver consistent and tailored engagement with the public to ensure that those invited consider taking part in the initial risk assessment, and in the CT scan should they meet the risk threshold. This includes building opportunities for reminders, text messages and other approaches to raise awareness of, and build engagement with, the screening programme, into the screening pathways, and delivering evidence- and insight-informed public-facing campaigns. o Engagement and communications of people who smoke must be done in a sensitive manner that does not perpetuate the stigma already faced by many, and that counters fatalistic beliefs. It is important that participants understand that it is never too late to stop smoking and that they will experience health benefits from stopping even if they have smoked for many years. The language used should also be sensitive for example referring to smoking in a person centric manner "people who smoke", rather than labelling people as "smokers" which may be considered stigmatising.
- o As with other screening programmes, individual risks of taking up screening need to be communicated in a clear, accessible way to all those that are eligible, to allow them to make an informed decision at each step of the screening pathway.
- To avoid the risk of widening health inequalities in lung cancer outcomes, it is vital that a targeted effort is made to remove barriers and achieve informed uptake for people from lower socioeconomic groups, given this group are more likely to smoke and may be less likely to attend lung screening.
- Health departments and systems, working collaboratively with others such as third sector, should effectively engage with the public prior to introducing the programme to increase the public's understanding of who is eligible and why, and ensure public confidence in the programme.

Diagnostic and treatment capacity

- Governments across the UK should ensure there is sufficient CT scanner capacity to deliver this programme alongside existing planned activity, including reassessing existing plans to expand CT capacity with this programme in mind.
- Governments across the UK must set out long-term funding plans to deliver a sustained expansion of the cancer workforce to meet future demand for cancer services including in the radiography, clinical radiology, reporting radiography, pathology, therapeutic radiography, clinical Oncology, and surgical Oncology.
- To ensure enough staff are trained to meet future demand, robust workforce planning supported by regular, independently verified projections of the future supply and demand of the health workforce is key.
- Governments should tackle the barriers to the expansion of reporting radiographer numbers, including financial and geographical barriers to training, shortages in radiographers and a lack of time for training, to free up radiologists and increase capacity to support the programme.

Operations and rollout:

- It is crucial that national lung screening programmes are delivered by expert teams, and that independent quality assurance is in place, given the programmes scale and the fact that like all screening programmes.
- The UKNSC should provide clarity on the protocol they recommend and the clinical effectiveness modelling, enabling public communications and resources to be positioned to ensure the public can make an informed choice on participation.
- From piloting/the first phase of implementation, any national lung screening programme must provide a timely and transparent breakdown of the key performance indicators, including screening uptake and coverage, with breakdowns by key demographic groups (ethnicity, age, gender, deprivation, smoking status) and by region.
- Robust data transfer systems must be in place across GP, screening and smoking cessation sites to help participant retention across different elements of the lung screening pathway and beyond (such as in the case of ongoing smoking cessation support). Any data sharing should be done in a trustworthy and secure way, with due transparency and communication with the public and patients.
- Governments across the UK must ensure that there is sustainable and ongoing capital investment to continually improve digital capabilities across the targeted lung screening programme, horizon scanning for actual or likely innovation requirements into IT development at the earliest reasonable opportunity.

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15-

Name: Edwin J van Beek Organisation: xxxx xxxx

Role: xxxx xxxx

Condition: Lung cancer

There is now a growing body of evidence that lung cancer screening is both costeffective and can achieve earlier diagnosis, enabling curative treatment and improve patient outcomes and quality of life.

Some of the main issues that will need to be addressed are:

- 1) Workforce to be able to deal with the additional workload required.
- 2) Infrastructure investment to bring CT scanners into the community as appropriate.
- 3) Introduction of properly validated IT tools, such as machine learning tools for detection of lung nodules
- 4) Infrastructure support/administrative support to identify patients at risk, to ensure that those patients are taking up invitations (education), to ensure CT scans are performed and that follow-up scans are properly performed.
- 5) Understand differences between city and rural situations, and how to deal with the points 1-4 above in those different settings.
- 6) Stratify funding streams according to the various settings and requirements of a successful screening program.
- 7) Deal with the incidental findings in a patient centred way. For instance, what to do with findings that have a potentially significant impact on patient outcome, that are NOT lung cancer? (e.g. severe coronary artery calcifications not hitherto known, osteoporosis, emphysema).

Name: xxxx xxxx

Organisation: British Thoracic Oncology Group Role: Senior Executive Officer on behalf of BTOG

Condition: Lung cancer

The British Thoracic Oncology Group (BTOG) enthusiastically welcomes the provisional recommendations of the UK National Screening Committee (UK NSC) published in April 2022. Lung cancer is the leading cause of cancer death in the UK, and one of the major drivers of health inequalities. Low-dose computed tomography (LDCT) screening for lung cancer has been shown to be effective at reducing lung cancer mortality in two large randomised studies, and pilot programmes and research studies in the UK have demonstrated that screening is deliverable within the NHS. Indeed research published from UK screening pilots have demonstrated more advantageous stage distribution and less harms than in the larger randomised studies. The recommendations made by the UK NSC appear entirely consistent with the evidence presented. Although there appear to be ongoing issues with the performance of the ENaBL natural history model, the Incremental Cost Effectiveness Ratio estimates produced to date are such that further refinements to the model performance are unlikely to alter the overall conclusion that this is a highly cost-effective intervention.

BTOG strongly endorses the NSC recommendation that smoking cessation should be an integral part of the screening programme. UK pilots have shown that opt-out smoking cessation services, co-located with screening, are well received with 88% of those attending for screening who continue to smoke taking up the offer of a consultation with a smoking cessation practitioner. Randomised trial data from the UK has now demonstrated significantly reduced quit rates with immediate smoking cessation support compared to very brief advice and signposting to smoking cessation services. We therefore support co-located opt-out smoking cessation services being a mandatory component of a future national UK lung cancer screening programme.

BTOG strongly suggests that a future national lung cancer screening programme be commissioned as an end-to-end service, using the same commissioning arrangements and programme administration as the breast, bowel and cervical programmes. BTOG also endorses establishment of a single national data system

with mandatory reporting by screening programmes, performance metrics, and regular publication against agreed standards to ensure uniform high quality screening nationwide. These metrics should include participation in, and outcomes from smoking cessation services as well as parameters relating to the screening process itself.

We agree with the research priorities highlighted in the UK NSC consultation document regarding eligibility for screening, refinement of the LDCT schedule and addressing inequalities in screening uptake. It is well known that patients who have previously been diagnosed with lung cancer and received curative treatment are at significantly increased future risk of developing new primary lung cancer, and consideration should be given to exploring inclusion of this population in ongoing screening irrespective of their eligibility according to current criteria. Overall, it is essential that a future UK national lung cancer screening programme has research embedded within the programme to facilitate evaluation of strategies to improve the performance of screening. Similarly, it is essential that any future modifications to screening processes, or inclusion of other health interventions, should be based on robust evidence of benefit and deliverability.

In addition, whilst screening is a proven method of detecting earlier stage disease, prompt diagnosis, staging and treatment of screen-detected cancers is required to realise the benefits of these earlier diagnoses. The current challenges to diagnostic and treatment pathways for lung cancer have been well publicised, and BTOG highlights the needs to augment downstream capacity alongside implementation of screening. This is additionally important so that patients with lung cancer detected outside of screening programmes are not adversely affected by capacity issues and resultant delays occurring due to an overall increase in the number of patients being investigated and treated by lung cancer services.

BTOG congratulates the UK NSC and the Exeter Test Group for a robust and comprehensive analysis of the evidence in this area, and sincerely hopes that the committee makes a recommendation to the 4 UK Health Ministers following its meeting on 24th June 2022

Name: xxxx xxxx

Organisation: xxxx xxxx

Role: Lead Pharmacist – xxxx xxxx

Condition: Lung cancer

My comments are based on my experience which is of the current system in Scotland, and not the wider UK.

Some comments regarding the current NHSE Targeted Lung Health Check Strategy and whether this is a possible strategy to continue going forward: identifying and inviting 'ever' smokers aged 55 – 74 from GP records: I know that there is some concern among GPs that this method of identifying participants as a sole source may not be reliable. Has consideration been given to use of pharmacy smoking cessation records, for identification of those who may be eligible? providing smoking cessation advice to all participants in the programme: Will this be linked up with community pharmacy services?

Going forward, is any consideration being given to the potential role/benefits of utilising community pharmacy to assist in identifying eligible patients, and in potentially carrying out the screening assessment in order to help address any issues of inequalities? Community pharmacy staff interact with people from all backgrounds, within their local communities, on a daily basis, many of whom will be in a high-risk category, may be difficult to contact and may be otherwise reluctant to engage with health services and screening programmes.

I am involved currently in a short-term project funded in the North of Scotland to investigate the role of community pharmacists in the earlier diagnosis of cancer. I think that it would be worth exploring the role of pharmacy when considering how to identify patients for the lung screening programme. The role of pharmacy in smoking cessation is already well established and will fit well into this proposal. There are also likely to be other prehabilitation roles (e.g. medication reviews) that can be facilitated by the primary care pharmacy and community pharmacy teams.

Name: Weiqi Liao, Carol Coupland, Judith Burchardt, David Baldwin, Julia Hippisley-Cox

Organisation (if appropriate):

Description: Carol Coupland, Judith Burchardt, David address:

Email xxxx xxxx

Address:

Nothingham

Role: Researchers of the DART initiative (WP6, primary care)

Do you consent to your name being published on the UK NSC website alongside your response?

Yes No

Section and / or page number	Text or issue to which comments relate	Comment Please use a new row for each comment and add extra
		rows as required.
P32-33 The accuracy of risk prediction algorithms	Important risk prediction models for the English population were left out in Table 8.	Developed and validated using electronic health records from the QResearch® database, the QCancer (10-year risk) lung models can be used to select eligible patients for lung cancer screening from the English primary care population. The original paper was published in 2015 (Hippisley-Cox and Coupland, 2015). The risk algorithm is fully published as open source for transparency. A web calculator is available for public use to calculate an individual's risk of various cancer for up to 10 years, at https://www.qcancer.org/10yr/male/ (for men) and https://www.qcancer.org/10yr/female/ (for women). Our original QCancer (10-year risk) models have been included in a systematic review of risk prediction models for lung cancer screening (Toumazis et al., 2020), but not in the external review documents published on the UK

government website (https://view-health-screening-recommendations.service.gov.uk/review/lung-cancer-2022-review/download-documents/external_review/).

Recently, our team has updated the QCancer (10-year risk) lung model as part of the DART initiative (full project name: The Integration and Analysis of Data using Artificial Intelligence to Improve Patient Outcomes with Thoracic Diseases, funded by Innovate UK, grant reference: 40255, project website: https://dartlunghealth.co.uk/). We have published our study findings in a pre-print server (medRxiv) (Liao et al., 2022) https://doi.org/10.1101/2022.06.04.22275868 for this public consultation comments, whilst our paper is under scientific review. We found that both the original model and the updated QCancer2 (10-year risk) lung models have the best model performance using electronic population-based primary care datasets, compared with seven other risk prediction models (LLP_{v2}, LLPv3, LCRAT, PLCOM2012, PLCOM2014, Pittsburgh, and Bach). The Liverpool Lung Project (LLP_{v2}) and the Prostate Lung Colorectal and Ovarian (PLCO_{M2012}) models, currently used in the targeted lung health check programme in England, had only moderate discrimination and were not well-calibrated when externally validated using the Clinical Practice Research Datalink (CPRD) data for the English primary care population by another team (O'Dowd et al., 2021).

Crucially, our QCancer2 (10-year risk) lung model has excellent discrimination (able to distinguish individuals who develop lung cancer from those who do not,

Harrell's C statistics=0.9). It also has excellent calibration, with predicted risks closely matching the observed risks (in twenty risk bands across low and high risk) in the main analysis and two subgroup analyses. Furthermore, it is a flexible algorithm, able to predict an individual patient's risk each year of follow-up, for up to 10 years. The wide range of predictive horizons (e.g. 5, 6, 10 years) gives more flexibility in clinical application. Our prediction model has been developed using a very large representative primary care population (12.99 million patients) and validated in a separate group of 4.14 million patients. Therefore, it can be generalised to the UK population. The algorithm has been using contemporaneous linked electronic health records, which means it can be implemented either in GP clinical systems or by the NHS Digital on its new risk stratification platform in a similar way to the QCovid risk assessment tool, also developed by the authors https://digital.nhs.uk/coronavirus/riskassessment/clinical-tool

It is likely that the model will perform very well in live primary care data, although formal external validation is awaited.

In conclusion, the QCancer2 (10-year risk) lung model has potential utility for sex-specific risk stratification for the UK primary care population and selection of eligible people at high risk for the targeted lung health check programme or lung cancer screening in the UK.

Name:	Rachael	Murray		Email address:	XXXX XXXX	
Organisa appropri			University of Nottingham			
Role:	Professo	or of Population	on Health			
Do you o	consent	to your nam	e being published on the Uh	(NSC website alon	gside your response?	
Section	and /	Text or iss	Text or issue to which comments			
or page number		relate		Please use a new row for each comment and add extra rows as required.		
			The comments below			
	Cons	ultation on t	argeted screening for lung o	cancer in people ag	ed 55-74 with a history of smoking	
Page 2 A quality assured, targeted screening programme for lung cancer in people aged 55-74 with a history of smoking should be recommended in the UK		potential to convey health when combi service. There is ar	cancer with low-dose CT (LDCT) has the significant benefits on cancer survival and public ned with an integrated smoking cessation opportunity to reduce health inequalities, given ed with cancer tend to be from socioeconomically nds.			
				consistent service to is essential. This be the offer of smoking	population health perspective, offering a that is available to all to avoid disparity in quality ecomes particularly pertinent when considering g cessation support, which will be discussed in ocument given the current inconsistencies	

		arising from a lack of directive in the current NHS Targeted Lung Health Check (TLHC) programme.
Page 2	Implementation of screening for lung cancer should not be seen as an alternative to the delivery of high-quality smoking cessation services across all age groups. That smoking cessation should be an integral part of the screening programme	Smoking cessation is the most effective way to reduce lung cancer mortality. Implementing high quality smoking cessation support within a lung cancer screening programme is essential but this should not be to the detriment of a national initiative to support quitting in all age groups, as these people who smoke are the lung cancer screening attendees of the future. Investment should also focussed on national initiatives to reduce smoking uptake amongst youth.
		The above are not outside of current discussion, with the ambition for England to be smokefree by 2030 and the upcoming Tobacco Control Plan likely to include a host of recommendations to achieve this goal. However, the integration of smoking cessation within lung screening provides an unprecedented opportunity to make a real impact on smoking related morbidity and mortality in England and must be considered an essential component of a national screening programme. Sufficient funding and infrastructure must be provided in order for high quality smoking cessation support to be offered to all eligible smokers attending for screening.
		The protocol for the current NHS TLHC states that enhanced smoking cessation interventions are encouraged, including the use of pharmacotherapy, and that there should be sufficient capacity and infrastructure to deliver the programme, including smoking cessation support and advice. There is limited guidance as to how the support should be delivered, or details about how the smoking cessation provision will be funded. the current experience within the

NHS TLHC would suggest that a lack of clear guidance translates to a variable, often sub-optimal (or non-existent) offer of quitting support.

Stop smoking services in England are now funded by the Department for Health and Social Care through the Public Health Grant and have seen cuts to their funding in recent years, to the point that many services are now supporting limited priority groups or in some instances have no community services whatsoever. It is therefore unreasonable to think or expect that existing community services are in a position to absorb this additional demand. In areas where there is no current stop smoking service, there is a huge potential to widen health inequalities if effective stop smoking support is not available to capitalise on the unique opportunity that a national screening programme will offer.

An evaluation progress report of the TLHC programme from December 2021, including interview data from programme stakeholders and participants, and survey data from participants and non-attendees provides information on progress of the TLHC to August 2021. 31% of those attendees who had smoked within the previous week LHC reported attending the appointment because they thought it might help them to reduce or stop smoking. Only around half of current smokers (54%) reported receiving advice on quitting or reducing smoking (usually taking the form of very brief advice, with or without referral to support services), with 82% reporting that they found this advice helpful. Qualitative feedback was mixed, with some respondents reporting feelings of surprise and disappointment and not receiving any advice around smoking cessation. A number of participants who did receive advice reported negative experiences such as lack of eligibility to attend, or lack of follow up following referral to community services and

feelings of disappointment resulting from this lack of support. Others reported feeling encouraged to try and stop smoking as a result of the advice provided at their LHC, though some did not intend to change their behaviour as they did not see the value in doing so.

In recent years there has been a move towards placing responsibility for the identification and treatment of tobacco use back within the NHS. The NHS Long Term Plan has recognised the importance of smoking as a key contributor to health inequality, committing to ensuring that all patients admitted to hospital that smoke being offered tobacco dependency treatment, funded by the NHS, by 2023/24. Future stages of the plan aim to include widening the intervention offer to maternity, mental health and high-risk outpatient settings. Smoking is a strong risk factor for of all five of the clinical priorities in the Core20PLUS5 programme, which forms NHS England & Improvement's core approach to reducing health inequalities and thus incorporating highly effective stop smoking provision into a national lung cancer screening programme would be in keeping with current protocol and ambition.

I am the Principal Investigator on the Yorkshire Enhanced Stop Smoking (YESS) study, funded by Yorkshire Cancer Research, which tested the uptake and effectiveness of a co-located, opt-out smoking cessation delivery model offered to all smokers attending for a lung health check (LHC) as part of Yorkshire Lung Screening Trial (YLST) between December 2018 and December 2020. Stop smoking support was offered in line with National Institute for Health

and Care Excellence (NICE) PH48 guidance comprising one session of behavioural support at the time of the LHC and provision of pharmacotherapy (either as nicotine replacement therapy (NRT) through delegated prescribing at the visit and/or a commercially available e-cigarette and vaping supplies, or arranged a GP prescription for varenicline or bupropion). Follow-up contact was provided either face-to-face or by telephone, typically weekly but more or less frequently according to participant preference for up to 4 weeks from the date of the LHC with replenishment of guit aids on a bi-weekly basis for any individuals engaging with a guit attempt. Recruitment to the study paused for three months during the Covid-19 pandemic, though ongoing support to patients continued via telephone with quit aids sent via post. Following resumption of the study, the baseline visit returned to a face-to-face counselling session, but all subsequent interactions were via telephone and quit aids continued to be dispensed by post. The Covid-19 pandemic necessitated a change in delivery model to telephone only support for all visits after the initial consultation as opposed to face to face. However, both smoking cessation practitioners and participants reported still building a strong rapport through regular phone calls and did not feel this had a negative impact on their experience.

The study found that 88% of 2151 eligible smokers attending for lung cancer screening agreed to a consultation with the smoking cessation practitioner at the time of the screening appointment. Of these, 75% agreed to ongoing cessation support, with around half provided with an e-cigarette, either alone or in combination with NRT. 20% of those accepting ongoing cessation support were successfully quit at 4 weeks (15% of all eligible smokers) (unpublished data). The YESS study is also testing the efficacy of adding a personalized intervention comprising the use of heart and

lung images captured during the LDCT scan, highlighting areas of coronary artery calcification and emphysema, as part of the smoking cessation intervention in a randomized controlled trial, with results due summer 2022.

Given the success of the YESS study, the model is continuing into the second round of lung cancer screening as part of YLST and is offering stop smoking support to individuals who were unsuccessful in their quit attempt, who declined to accept stop smoking support or did not attend for the baseline screening round. Whilst still ongoing, the sustained offer of stop smoking support is again being well received, with the majority of smokers who declined a consultation in the baseline round now agreeing to see a smoking cessation practitioner (SCP). Many smokers declining support or making an unsuccessful quit attempt report that it was just 'not the right time for them', despite being motivated to try and stop smoking and these findings reinforce the need for effective stop smoking support at all stages of lung cancer screening, not simply a one-off offer at the initial screening appointment.

An embedded process evaluation undertaken as part of the YESS trial has shown that individuals attending for a LHC expected to discuss smoking and it did not surprise them; some even indicated that they had attended the appointment in the hope of receiving support to stop smoking. They found the offer of stop smoking support acceptable, largely due to the lack of stigma, the non-judgemental style of discussion and positive support they received from smoking cessation practitioners at the time of the LHC. Those that did not want to take up smoking cessation support at the time of the LHC did so because it was not the right time for them, not

because they felt it was unacceptable to offer smoking cessation in a LHC context.

Reflections from the team running the YESS study revealed several considerations that may be useful to inform future decisions regarding the implementation of smoking cessation provision with SCS, alongside quantitative data on efficacy and effectiveness. Having a team of smoking cessation practitioners who are experienced in engaging with the high-risk group that are eligible for LCS was viewed as valuable. This population are often highly dependent with long and complex smoking histories and require specialist support, in much the same way that specialist advisors support pregnant women that smoke. Second, placing the smoking cessation as part of the LHC, both in terms of the staffing team and physical location was viewed as being important for maximising uptake of support offered as attendees considered the smoking cessation support as an integrated part of the LHC.

The co-location of the service was also convenient, since people accepting smoking cessation support did not need to make an additional trip to another location at another time, and the provision was made even more convenient by the direct supply of NRT/e-cigarettes at the time of the LHC and repeated provision of quitting aids for engaged individuals via post. The provision of e-cigarettes was valued; many of those trying to quit had preciously tried using NRT but not an e-cigarette and thus having something new to offer helped smoking cessation practitioners to engage with more reticent participants. Finally, whilst the results of the randomised controlled trial using personalised heart and lung images has not yet reported, feedback from study participants is that the intervention has been positively received and has been a motivator in quit attempts, either

supporting quitting or preventing relapse in individuals who had quit before receiving the intervention (unpublished data).

Similar reflections have been presented by the Manchester LHC site. The team reported that having specialist nurses on site to offer support and provide NRT/e-cigarettes on an opt-out basis was a strength of their service model and was a key factor in the high uptake rates. A continuity in the supply of e-cigarettes and liquids on the mobile LHC unit and in the community smoking cessation service was also viewed as a strength, providing a seamless transition between services. It was felt that the onward referral to the local smoking cessation service was a hindering factor (despite the community service being highly effective) and being able to offer follow up either on the mobile LHC unit or a virtual follow up service with delivery of NRT/e-cigarettes would increase engagement in follow up after the LHC.

Further information can be accessed in the paper: Yorkshire
Enhanced Stop Smoking (YESS) study: a protocol for a randomised
controlled trial to evaluate the effect of adding a personalised
smoking cessation intervention to a lung cancer screening
programme | BMJ Open

The effects of smoking cessation extend beyond lung cancer. People who smoke are also at risk of premature death due to chronic obstructive pulmonary disease (COPD), heart disease and stroke. Subjects eligible for lung cancer screening have a 3 times greater relative risk death due to heart disease than a non-smoker. 62% of participants in the Lung Screening Uptake Trial had coronary artery calcification present on the scan. Further, nearly

one quarter of participants undergoing LDCT screening in the International Early Lung Cancer Action Programme (I-ELCAP) were found to have emphysema. There is thus a potential opportunity to provide better management and reduce the clinical impact of these conditions through effective smoking cessation intervention, building on the teachable moment in those attending for LCS. Based on the evidence above and experience of researching in the

area. I would advise that quidelines for smoking cessation as an integrated component of lung screening, not a bolt-on service, are developed and published as part of the final recommendation. Consideration must be given to how smoking cessation provision will be funded and organised, drawing on available evidence, to ensure availability to and equity of provision of high quality intervention.

The comments below all relate to the document: Screening for lung cancer in individuals at increased risk

Exteri	nal review against programme appraisal crit	teria for the UK National Screening Committee, Version 3.2
Page 66	Sub-section: Smoking cessation	Smoking cessation is a vital component of a lung screening programme, and should not be viewed as an 'optional extra' or an undertaking to tick a box. As provided earlier in this written response in relation to Page 2, Point I for the associated document 'Consultation on targeted screening for lung cancer in people aged 55-74 with a history of smoking' I recommend that smoking cessation should be an integrated and co-located service, delivered as an opt-out service as standard and offered prior to LDCT, and be delivered by a dedicated team of smoking cessation practitioners, rather than relying on referrals to existing services.

Name:	e: Rebecca Thorley on behalf of the Yorkshire Enhanced Stop Smoking (YESS) study team)		Email address:	rebecca.thorley@nottingham.ac.uk	
Organis appropr	sation (if riate):		University of Nottingham	1	
Role:	Trial Ma	anager – Yo	rkshire Enhanced Stop S	moking Study	
Do you Yes	consent	to your na	me being published on	the UK NSC wel	osite alongside your response?
Section and / or page number Comment Comment Comment Please use a new row for each comment and add extra rows as required.		row for each comment and add extra rows as required.			
					relate to the document:
		Consultat	ion on targeted screening	ng for lung canc	er in people aged 55-74 with a history of smoking
Page 2		lung cance as an alter of high-qua cessation s groups. Th should be	r should not be seen native to the delivery ality smoking services across all age at smoking cessation an integral part of the programme	Enhanced Stop Smoking (YESS) study, funded by Yorkshire Cancer Research, test the uptake and effectiveness of a co-located, opt-out smoking cessation delivery moffered to all smokers attending for a lung health check (LHC) as part of Yorkshire Screening Trial (YLST) between December 2018 and December 2020. Stop smoking support was offered in line with National Institute for Health and Care	

Our team of SCP's have real life, on the ground experience of providing a stop smoking service within a lung cancer-screening programme. All absolutely support the notion of providing stop smoking intervention as they experience first-hand the impact that such provision is having on the lives of many people who smoke that attend for lung screening. They have briefly provided their thoughts and experience below:

Sue O'Shea

"Providing smoking cessation at the time of screening is important as smokers often require some sort of 'event' to happen in their life to give them the opportunity to consider giving a quit attempt a go. Having SCP's on the screening van makes quitting so much more accessible. Seeing the SCP there and then and choosing their treatment to take away presents an opportunity for patients, rather than them having to access services themselves."

Sue Tyrell

"As recently as today and not unusually, a patient has said to me that even though stopping smoking had been on his mind for many years, he would still be smoking now if he hadn't come to speak to me. Talking it through with me and the added benefit of continued support gave him the 'kick' he needed to make a quit attempt."

Gail Barden

"One of my patients told me that as well as quitting themselves through the YESS service they had also managed to encourage their son and sister to quit smoking, and also colleagues at work. They were so impressed that XX [the person attending for screening] had managed to quit after all of these years of smoking that they went to their local stop smoking service for support to quit themselves."

Having a team of smoking cessation practitioners who are experienced in engaging with the high-risk group that are eligible for lung cancer screening is extremely important and valuable. This population are often highly dependent with long and complex smoking histories and require specialist support, in much the same way that specialist advisors support pregnant women that smoke. Second, placing the smoking cessation as part of the LHC, both in terms of the staffing team and physical location is important for

		maximising uptake of support offered as attendees considered the smoking cessation support as an integrated part of the LHC. Further information on the YESS study can be accessed in the paper: Yorkshire Enhanced Stop Smoking (YESS) study: a protocol for a randomised controlled trial to evaluate the effect of adding a personalised smoking cessation intervention to a lung cancer screening programme BMJ Open Based on the evidence above and experience of researching in the area, we would advise that high quality smoking cessation provision should be an integrated and co-located component of lung screening, available to every person that smokes who attends for lung cancer screening
		omments below all relate to the document: for lung cancer in individuals at increased risk
	_	e appraisal criteria for the UK National Screening Committee, Version 3.2
Page 66	Sub-section: Smoking cessation	Smoking cessation is a vital component of a lung screening programme, and should not be viewed as an 'optional extra' or an undertaking to tick a box. We recommend that smoking cessation should be an integrated and co-located service, delivered as an optout service as standard and offered prior to LDCT, and be delivered by a dedicated team of smoking cessation practitioners, rather than relying on referrals to existing services.

Name:	Oliver Clark	Email address:	xxxx xxxx	
Organisation (if appropriate)	•	The Royal College of Radiologists (RCR)		
Role:		Senior Policy Advisor – Compiling views from members and officers of the RCR		
Do you consent to your nam	e being published on the UK N	NSC website alongside your	response?	
Yes √ No				
Section and / or page number	r Text or issue to wherelate	Please	e use a new row for each ent and add extra rows as	
General position	General position	establi a natic cancer	ance, the RCR is supportive of shing low dose lung CT as part of nal screening programme for lung . Like all cancers, the earlier it is ed the more	

Name:	Leah Holtam		Email address:	XXXX XXXX	
Organis approp	sation (if riate):		Yorkshire Cancer Research		
Role:	Head of	Cancer Insigl	ht		
Do you Yes	consent	to your nam	e being published on the UK I	NSC website along	gside your response?
or page	Section and / Text or issue to work or page relate number		F	Comment Please use a new row for each comment and add extra rows as required.	
			The comments below		
	Cons	ultation on t	argeted screening for lung ca	ncer in people age	ed 55-74 with a history of smoking
Page 2		programme aged 55-74	for lung cancer in people with a history of smoking ecommended in the UK	unders of the Yorks (XXX XXXX) and the a Smoking (YESS) S (creening for lung c (DCT) has the pote	esearch welcomes this recommendation. As shire Lung Screening Trial (YLST) (led by associated Yorkshire Enhanced Stop tudy (led by xxxx xxxx), we firmly believe that ancer with low-dose CT (hereafter referred to as ntial to convey significant benefits on cancer health when combined with an integrated service.
					ess we believe that a consistent service must ngland (and the devolved nations), with the

Page 2	Implementation of screening for lung cancer should not be seen as an alternative to the delivery of high-quality smoking cessation services across all age groups. That smoking cessation	We agree that screening for lung cancer should not be seen as an alternative to the delivery of high-quality smoking cessation services across all age groups and that smoking cessation should be an integral part of the lung screening programme. We wholly support the delivery of smoking cessation services, however, also believe
		service commissioned once at a national level as an end-to-end service (as for the breast, bowel and cervical screening programmes). We have experienced through conversations with Cancer Alliance colleagues relating to the NHS Targeted Lung Health Check (TLHC) programme, that where commissioning is done at a local level there is room for variation in services and the offer available to patients (particularly in relation to smoking cessation). This approach has the potential risk of introducing inequality into a service that is targeted at people who are likely to already be facing numerous health inequalities and inequities. Given the emerging evidence in this space and the acknowledgement that there is more to learn, Yorkshire Cancer Research also suggest it is vital that any future lung screening programme is set up to support future research activity (whether this is through clinical trials or service evaluation). There should also be a clear evaluation framework for the screening programme developed to not only ensure consistency across different geographical areas, but also so that adaptations can be made to the programme as new evidence emerges. This should be able to happen in a timely manner following the required reviews to ensure maximum impact for patients. Key performance indicators should be set with data collection covering uptake as a minimum, and with regular publication against agreed standards as for the other screening programmes. Data should also be collected on smoking cessation services including engagement and outcome data.

should be an integral part of the screening programme

further reduce smoking rates and stop people from taking up smoking. Yorkshire Cancer Research agree with the ambition for England to be smokefree by 2030 and expect clear guidance on how this should be achieved to be outlined in the long-awaited Tobacco Control Plan and addressed through the government's independent review into the 2030 target. We believe there is no single solution to driving down smoking rates and a whole system approach to smoking cessation should be adopted with support to stop fully embedded throughout all touchpoints within the NHS and beyond. This would support the move to stopping smoking becoming the norm, with smoking treated as an addiction rather than a lifestyle choice. Integrating smoking cessation within lung screening provides a unique opportunity to bolster the community offer of smoking cessation, not replace it.

Considering this position, it is noted there is a lack of further information in relation to the importance of including smoking cessation within a future lung screening programme. The charity's experience funding smoking cessation alongside lung screening (and lung health check - LHC) programmes has shown that different models seem to have more success than others and it will be important to continue to gather evidence as new findings are published to ensure the smoking cessation offer is highly effective.

The YESS study, funded by Yorkshire Cancer Research, is leading the way nationally in terms of gathering evidence for the integration of smoking cessation alongside lung cancer screening. It is testing the uptake and effectiveness of a co-located, opt-out smoking cessation delivery model offered to all smokers attending for a LHC as part of YLST (also funded by Yorkshire Cancer Research) between December 2018 and December 2020. Stop smoking support was offered in line with National Institute for Health and

Care Excellence (NICE) PH48 guidance comprising one session of behavioural support at the time of the LHC and provision of pharmacotherapy (either as nicotine replacement therapy (NRT) through delegated prescribing at the visit and/or a commercially available e-cigarette and vaping supplies, or arranged a GP prescription for varenicline or bupropion). Follow-up contact was provided either face-to-face or by telephone, typically weekly but more or less frequently according to participant preference for up to 4 weeks from the date of the LHC with replenishment of guit aids on a bi-weekly basis for any individuals engaging with a guit attempt. At 4 weeks the offer of continued support was provided with the option to participate in the YESS study (randomised to intervention or control). Those who chose not to participate were still eligible for a further 8 weeks of behavioural support. Recruitment to the study paused for three months during the Covid-19 pandemic, though ongoing support to patients continued via telephone with guit aids sent via post. Following resumption of the study, the baseline visit returned to a face-to-face counselling session, but all subsequent interactions were via telephone and guit aids continued to be dispensed by post. The Covid-19 pandemic necessitated a change in delivery model to telephone only support for all visits after the initial consultation as opposed to face-to-face. However, both smoking cessation practitioners and participants reported still building a strong rapport through regular phone calls and did not feel this had a negative impact on their experience.

The study found that of 2151 eligible smokers attending for lung cancer screening, 88% of smokers agreed to a consultation with the smoking cessation practitioner at the time of the screening appointment. Of these, 75% agreed to ongoing cessation support, with around half provided with an e-cigarette, either alone or in combination with NRT. 20% of those accepting ongoing cessation

support were successfully quit at 4 weeks (15% of all eligible smokers) (unpublished data). Considering the participants' significant smoking history these rates of engagement are much higher than expected. However, the quit rate should not be compared against local stop smoking service data given the difference in population and the fact that these people are very unlikely to present to their local service.

The YESS model is continuing into the second round of lung cancer screening as part of YLST and is offering stop smoking support to individuals who were unsuccessful in their quit attempt, who declined to accept stop smoking support or did not attend for the baseline screening round. Whilst still ongoing, the sustained offer of stop smoking support is again being well received, with the majority of smokers who declined a consultation in the baseline round now agreeing to see a smoking cessation practitioner (SCP). Many smokers declining support or making an unsuccessful quit attempt report that it was just 'not the right time for them', despite being motivated to try and stop smoking and these findings reinforce the need for effective stop smoking support at all stages of lung cancer screening, not simply a one-off offer at the initial screening appointment.

An embedded process evaluation undertaken as part of the YESS study has shown that individuals attending for a LHC expected to discuss smoking and it did not surprise them; some even indicated that they had attended the appointment in the hope of receiving support to stop smoking. They found the offer of stop smoking support acceptable, largely due to the lack of stigma, the non-judgemental style of discussion and positive support they received from SCPs at the time of the LHC. The co-location of the smoking cessation service alongside the LHC reduced burden on the

participants as they were provided with behavioural and pharmacological support straight away, not referred on to someone else or another service where there may be a delay in receiving support. Those that did not want to take up smoking cessation support at the time of the LHC did so because it was not the right time for them, not because they felt it was unacceptable to offer smoking cessation in a LHC context.

Further information can be accessed in the paper: Yorkshire
Enhanced Stop Smoking (YESS) study: a protocol for a randomised
controlled trial to evaluate the effect of adding a personalised
smoking cessation intervention to a lung cancer screening
programme | BMJ Open

Based on the evidence above and further learnings, Yorkshire Cancer Research requests that smoking cessation is a mandatory feature of a lung screening programme, and that guidelines for smoking cessation alongside lung screening are published (the charity would be willing to work closely with those developing these). Although the protocol for the current NHS TLHC states that enhanced smoking cessation interventions are encouraged there is limited guidance as to how the support should be delivered or funded and the current experience within the NHS TLHC programme would suggest that this lack of guidance and clarity is leading to significant variations in the smoking cessation offer.

Yorkshire Cancer Research has published a <u>'Position Statement on Smoking Cessation Models for Lung Health Check with LDCT Scan Programmes</u>' where you can read about the charity's learnings in detail. This will be updated with new evidence from our funded

awards as it is available. A summary of the main recommendations are included below:

- 1. The lung screening and smoking cessation interventions must be regarded by all staff and patients as an integrated service. Essential to this integration are three key factors: co-location of the services (they must be physically in the same space and appear as a single service), smoking cessation should be an opt-out default and offered before the CT scan (we found this increases the number of people open to seeing a SCP) and a consistent nurse and SCP team should deliver the service (dedicated resource and highly trained and experienced staff are essential to successful delivery).
- A comprehensive smoking cessation package should be offered, building on the recommendations outlined within NHS, National Centre for Smoking Cessation and Training and NICE standards. Including:
 - The immediate provision of stop smoking aids, including vaping products. By virtue of being a smoker at the time of attending lung screening, people are likely to be habitual and committed smokers, having smoked for many years and either have not engaged with smoking cessation support, and/or have a history of multiple failed quit attempts. Therefore, we recommend removing as many barriers to smoking cessation as possible. As they are the most popular stop smoking aid in England, vaping products should be offered, either to take away from the service (preferred given removal of barriers), posted out to a home address, or accessed through a voucher scheme.
 - Ongoing face-to-face or virtual behavioural support for 12 weeks. This should be accessible to people at a time and location convenient to them. Our experience has shown that delivering this as a standalone and specialised service

(integrated within the lung screening pathway) may have greater success than doing an initial consultation and then referring people into existing services – where they may have had unsuccessful quit attempts in the past. The lung screening smoking cessation service could be set up as a separate arm of the local offer of smoking cessation but should be subject to minimum requirements specific to the lung screening setting, both in terms of the service provided but also the data collected so it aligns with local and national requirements and contributes to locally recorded quit data, with appropriate data sharing agreements in place. The service must also be appropriately funded. It will not be sufficient to expect local areas to fund this service from their existing public health budgets – particularly as some local areas offer services only to specific targeted populations and in some cases, there is no local offer of smoking cessation.

- 3. Telephone risk assessment should be included as part of the LHC model, which evidence shows reduces time and travel costs to patients, enriches the cohort of LHC patients with smokers (thereby ensuring the smoking cessation provision is utilised) and is likely to increase the cost effectiveness of the service, while also reducing the time needed by nursing staff to see patients, (this is being evaluated in YLST). This is also aligned with the addendum to the NHS TLHC participant pathway specification that was in place during the COVID-19 pandemic.
- 4. The LHC, LDCT scans and smoking cessation services should be located in convenient community locations, which are disassociated from healthcare environments such as GP surgeries and hospitals.

	participants were able to cut down or cease smoking on their own, there was a theme of disappointment in local services failing to provide support that had been promised. In one case, a participant who did hear from the stop smoking service was "stunned" to be told, after a short conversation about her smoking habits, that she was not eligible for help because she did not exhibit any mental health issues" [Page 64]. These findings are clear indicators that an integrated stop smoking service is vital to the success of a smoking cessation offer within the lung screening setting and not offering this could fail patients, acting as a missed opportunity to engage them in quitting smoking, whilst also risking increasing health inequalities in a population who
and inviting 'ever' smokers 4 from GP records	commonly experience health disparities. We agree that in some instances using GP records of smoking status is an appropriate method for inviting people to lung screening, however it heavily relies on smoking status being

not accurate enough to use this method for inviting people into the service.

For example, in the Manchester Lung Health Check pilot (funded by Macmillan Cancer Support) the team conducted an audit to review smoking status data held within GP records ahead of the programme roll out. With around 40 different codes available to record smoking status in EMIS it was found that GP patient records were often not completed, not up to date, or inconsistently recorded. To avoid missing people who were eligible, an invitation was sent to everyone within the eligible age range (as age was accurately recorded within GP patient records) asking people who were current or former smokers only to book an appointment.

In YLST, funded by Yorkshire Cancer Research, similar problems have also been encountered. The team originally planned to include 62,890 people from across Leeds across the screening and control arms, however subsequently found this level of invitation was not sufficient to obtain the required number of trial participants. The team had to increase invitations by 26,937 to a total of 89,917 (note a Zelen's design is used in this trial so the control group do not receive an invitation to participate and are blind to their involvement in the clinical trial). This was driven from the recorded smoking status within GP records not being accurate enough to get the number of people eligible for LDCT. Anecdotally, GP patient records had smoking status inaccurately recorded for between 10-25 % of people. Unpublished data from YLST shows that 15.1% (n=3,437) of people contact based on their GP records were ineligible because they self-reported never smoking (despite the having a smoking-related code in their GP record).

		 We suggest that: Work is urgently undertaken to increase the accuracy of smoking status on GP records for example through text campaigns asking people to provide up to date details or asking for this information in routine patient appointments. This is something that could be actioned ahead of roll out of the lung screening programme. Guidance is published on how best to invite people to lung cancer screening where areas may not be able to rely on GP record smoking status. This guidance should include how to capture and engage with those people missed through the GP records.
Page 2	ii. assessing eligibility for low dose CT (LDCT) using a multivariable risk assessment tool	We agree that using a multivariate risk assessment tool is an appropriate way to distinguish those most at risk of lung cancer and therefore eligible for a LDCT scan. However, we believe that the use of telephone-based risk assessment should be a permanent feature of the guidance and has the benefits of reducing travel time and costs to patients, enriches the cohort of patients with smokers (which ensures the SCP's are busy), and could increase the cost effectiveness of the service.
		YLST, funded by Yorkshire Cancer Research, is using PLCO _{m2012} and LLPv2 to assess eligibility for a LDCT scan and using a telephone-based risk assessment method. Unpublished data from YLST shows that this method (where the initial risk assessment is conducted via telephone and only those meeting the inclusion criteria are invited for a LHC with LDCT scan) has been successful in getting people into the programme with a 51% response to invitation rate. Of those responding around 34% were eligible for LDCT screening and offered an appointment (lower than the anticipated 48% due to poor smoking status records). Around 87%

		of patients attended their appointment and almost 100% of those attending the appointment had a baseline LDCT scan (indicating very high accuracy of the risk assessment protocol – unpublished data). Further information on the Charity's recommendations for LHC guidelines can be found here: position-statement-on-lung-health-check-quidelines-may-2022.pdf (yorkshirecancerresearch.org.uk). Although it is not proposed here that spirometry is used as a risk assessment tool, Yorkshire Cancer Research would like to take the opportunity to highlight that a number of the studies included in the evidence review, along with the current NHS TLHC do include spirometry as part of the LHC. However, we would like to see evidence of the benefit of spirometry in terms of outcomes for patients before this is included within any lung cancer screening pathway guidance. This is not to question the benefit of using spirometry for identifying undiagnosed COPD within this target population, but we question the relevance of this for a programme aimed at diagnosing lung cancer at an early stage. No impact on patients (beyond reduced appointment time) was seen when spirometry was removed from YLST as a result of the COVID-19 pandemic trial adaptations.
Page 2	iii. offering a LDCT schedule based on the baseline CT	The charity requests that further clarification is provided on this point in future guidance. It is not clear whether this is offered on an individual basis or according to broad grouped outcomes of baseline LDCT.
Page 2	vi. providing smoking cessation advice to all participants in the programme	As written above the charity has provided important points of consideration when including a smoking cessation element to lung screening. We believe it is important that this is a full and integrated

		service, rather than just providing very brief advice to screening participants.
Page 2	i. whether re-screening people with a history of smoking who are not eligible for LDCT should be part of the overall screening strategy	Yorkshire Cancer Research believes it will be important to consider how the system will account for people who may not be eligible at first invitation but who later hit the inclusion criteria to ensure they receive an invitation in the future. For example, they may not have a high enough pack year history at 55 (if this is used as an inclusion criteria) but hit this threshold at age 60 or 65. Appropriate records and recall systems, with a suitable safety-netting function need to be in place to ensure these people are not overlooked at future screening rounds. Modelling based on learnings and evidence from existing programmes should be conducted to estimate how many patients might be included within this group to estimate the scale of the issue. Also for consideration are the learnings from YLST, funded by Yorkshire Cancer Research, which will specifically look at lung cancer screening in the older 75-80 cohort.
		w all relate to the document:
F.4		er in individuals at increased risk
		reria for the UK National Screening Committee, Version 3.2
Page 4	In 2017 there were about 48,000 people who were diagnosed with lung cancer and about 35,000 people who died from the disease in the UK.	We query the use of incidence and mortality data from 2017. We appreciate this may be related to national registries but data for England is readily available for 2019. Note this data is also referenced on pages 6 and 13 without the year included, we suggest a consistent approach to referring to data in text is adopted to ensure it cannot be misinterpreted.
Page 6	It has one of the lowest survival rates of all cancers with 16.2% of people living beyond 5 years and 9.5% living beyond 10 years.	Note that this data applies to England only but sits alongside incidence and mortality data for the UK. We recommend that this difference for the survival data is made clear.

Page 13	Lung cancer has one of the lowest survival rate of all cancers with 16.2% of people living beyond 5 years and 9.5% living beyond 10 years (Office for National Statistics 2019) ⁶	Amend 'survival rate' to plural: '[] one of the lowest survival rates of all cancers []'. Note that this data applies to England only but sits alongside incidence and mortality data for the UK. We recommend that this difference for the survival data is make clear.
Page 13	Symptoms of lung cancer vary from person to person and include a persistent cough, breathlessness, fatigue and weight loss which may not concern patients until they become severe ⁷	It is worth noting from this same reference that symptoms not concerning patients until they are severe leads to a high proportion of emergency presentations, which often leads to poorer survival outcomes. Evidence suggests these symptoms may also be attributed to existing comorbidities, such as COPD, a 'smokers cough' etc. which may in itself delay help-seeking. Birt et al (2014) (bmj.com)
Page 17	Within Table 2: Screening programmes using low dose computed tomography (LDCT) (any type of LDCT) for the prevention of lung cancer in individuals at increased risk.	We would like to query the use of 'prevention'. Should this be 'detection'?
Page 18	Within Table 2: Screening programmes for the prevention of lung cancer using LDCT.	We query the use of 'prevention'. Should this be 'detection'?
Page 20	It is the leading cause of death due to cancer with 35,137 deaths in 2016-18.	Without prior knowledge it is unclear that rolling data gives an average over the time-period specified (in this case 3 years). Earlier in the document a single year of 2017 has been referred to for cancer deaths (35,000). We suggest making it clear that this is not the total number of deaths from 2016 to 2018 inclusive.
		Please also consider the prior comment related to using the most recent data if available for nations other than England.

Page 20	Data for 2013-2017 in England show 16.2% of people diagnosed with lung cancer survived for 5 years or more dropping to 9.5% surviving over 10 years.	More recent data is available for 5-year lung cancer survival in England. Data for patients diagnosed in 2015 and followed to 2020 shows 18.7% of patients survived 5 years and 9.4% of patients survived 10 years. Although these are not huge differences when compared with the survival rates included within the report, we suggest it would be appropriate to include the most recent data available. https://www.cancerdata.nhs.uk/survival/cancersurvivalengland
Page 20	An overview of the evidence by CRUK ⁵	A number of references have been included linking directly to CRUK. We recommend that the original source is referenced where possible. The fraction of cancer attributable to modifiable risk factors in England, Wales, Scotland, Northern Ireland, and the United Kingdom in 2015 British Journal of Cancer (nature.com)
Page 21	Lung cancer accounts for 13% of new cancer cases of cancer among both males and females, with 48% (23,087 cases) in females and 52% (24,881 cases) in males in 2017 in the UK. The incidence of lung cancer rises steadily with age in both females and males (Figures 1 and 2). In the UK the highest incidence rates for females are those aged 80 to 84 years and for males, those aged 85 to 89 years. In 2017 lung cancer incidence was 22% higher in males than females (89.1 vs 69.6 cases	Amend the first sentence to read 'Lung cancer accounts of 13% of new cancer cases of cancer []'. We query the use of data from 2017 here. Whilst we appreciate the use of less up to date data for the UK may be due to national registries, data is available from 2019 for England (CancerData). Further, the reference used for the UK data has been updated to include 2016-2018 (Lung cancer statistics Cancer Research UK) indicating more recent data may be available. It should also be noted that the age breakdowns 80-84 and 85-89 are referenced in the text though in figure 1 the age breakdown of

	per 100,000). Overall, lung cancer incidence rates decreased by 8% in the UK between 1993-95 and 2015-17, but there were marked differences between males and females.	80+ is used. We recommend that either the text is updated to be reflective of the content of Figure 1, or Figure 1 is updated to reflect the age breakdowns used in the text.
Pages 21-23	Figures 1-4	Incidence data here covers 2015-2017 whilst the mortality data covers 2016-2018. We would like to query why data from different years is used here. From the source referenced (<u>Lung cancer statistics Cancer Research UK</u>) there is data available up to 2018 for both. Also note that data for England for 2019, or 2017-2019 is available (<u>CancerData</u>).
Page 23	In 2017 the age-standardised incidence for females was lower in England and Wales than the UK average, and higher in Scotland than the UK average. For males, the rate was higher in both Scotland and Northern Ireland than the UK average (Table 3)5. The picture for mortality rates is similar with Scotland and Northern Ireland having the highest rates compared to the UK average for both males and females.	We request that you acknowledge the significant variation in lung cancer incidence and mortality within each of the devolved nations where data is available. We suggest that as a minimum the highest and lowest agestandardised incidence and mortality rates are reported at the geographical breakdown split by Cancer Alliance, alongside variation in survival rates (also split by Cancer Aliance). Lung cancer is a particular issue in some areas of the country and is a priority area for Yorkshire Cancer Research - when compared to all regions in England, Yorkshire has the 3 rd highest incidence and mortality rate from lung cancer (2017-2019). Furthermore, parts of Yorkshire have some of the highest rates of lung cancer incidence and mortality in the country. Hull has the 4 th highest incidence rate and the 2 nd highest mortality rate (2017-2019). Yorkshire makes up 9% of the England population, however 11% of lung cancer cases and deaths occur in Yorkshire.

Page 23	Table 3	We query why data from 2017 is used for incidence while mortality data is from 2018?
		Note that more recent data is available from <u>Lung cancer incidence</u> <u>statistics Cancer Research UK</u> .
Page 24	Table 4	We request clarification on why 2013-17 data is used for incidence while 2007-2011 data is used for mortality. We appreciate that this may be the most up to date data with breakdown by deprivation, however if this is the case it should be made clear and acknowledged as a weakness in the data.
		For consistency it would be appropriate to include the average number of deaths per year alongside the mortality rates, as shown for incidence.
Page 25	Table 5	This data is almost 20 years old, and therefore we query its relevance.
		Updated data (2013-2017) can be found here: <u>Differences in cancer incidence by broad ethnic group in England, 2013–2017 British Journal of Cancer (nature.com)</u> . In the supplementary information of this report there is a downloadable dataset. Lung cancer rates are much higher in this most recent dataset, for example, 53.45 in Asian males compared to 23.1-37.2 in the report.
Page 25	The Office for National Statistics (2021) ¹⁵ reported the trend analysis from the Annual Population Survey from 1974 to 2020.	Further clarification on what trend analysis is referred to here is needed. It should be made clear if this is referring to adult smoking rates or another measure.

Page 25	There is estimated to be an approximately thirty-year lag time between smoking prevalence and lung cancer rates, the current epidemiology of lung cancer is largely dictated by historical patterns of cigarette smoking	Given the lag time between smoking prevalence and lung cancer rates, and declining smoking prevalence over recent years, what modelling has been done to predict resource requirements for a lung screening programme with smoking cessation provision built in? Yorkshire Cancer Research believe it is vitally important this programme is fully resourced and funded and modelling may help to predict the number of people in local populations eligible for LDCT, allowing a comprehensive roll out and supporting those most in need.
		Although not an issue for the short/medium term, it is also worth noting that given declining smoking rates, over time the lung screening programme may be targeting a smaller section of the population. However, this is in the context of a growing body of evidence and research into how to also screen/test for other cancers using the same/similar eligible population, how best to define the eligible population, what risk algorithms should be used etc. We would like to see evidence of how this will be accounted for in the recommendations (for example built in review points to reassess modelling and latest evidence).
Page 26	Table 6 shows that the proportion of smokers in the UK who were 16 and over halved from 30% in 1990 to 14.5% in 2020	This wording is misleading and suggests that 30% of smokers were aged 16 and over (and therefore 70% were under 16). In fact, 30% of those over 16 years old were smokers (and 70% of people over 16 were non-smokers). We suggest amending the wording to 'Table 6 shows that the proportion of people aged 16 and over in the UK who were smokers
Page 26	Table 6	halved from 30% in 1990 to 14.5% in 2020.' The source of this data is unclear. The reference included states
		smoking rates for age 18+ whereas the table references 16+. Further, the reference is for 2019 data whereas the table indicates

		that the data is from 2020. It should be made clear what year this data is from, and the reference updated accordingly. Note: If 2020 data is being used, it should be considered that there may have been changes to the way data were collected due to the pandemic (switching from an in-person questionnaire to over the telephone) and therefore this may affect the data quality.
Page 30	although in the UK primary care practices also collect smoking status of patients.	Whilst we agree that smoking status of patients is recorded by primary care practices, we would like to highlight the potential inaccuracy of this data which may cause an issue when used to determine the eligibility and invitation schedule for lung screening. Please see further comments in relation to Page 2, Point I for the associated document 'Consultation on targeted screening for lung cancer in people aged 55-74 with a history of smoking' as given earlier in this written response.
Page 30	Lung cancer screening studies have used a staged approach to recruiting people; by inviting a broader population group to express an interest in screening followed by individual assessment of eligibility for the screening test of those who respond	Based on learnings from our funded programmes and other evidence, Yorkshire Cancer Research recommends the use of telephone-based risk assessment meaning only those eligible for LDCT attend an appointment in-person, which may have numerous benefits including saving time, being more cost effective and reducing travel time and costs for patients. YLST, funded by Yorkshire Cancer Research, uses GP records to identify people of the correct age and smoking status and sends them an invitation to a telephone-based risk assessment to assess eligibility for screening. A subset of these patients who meet the risk assessment thresholds are then invited to book an appointment for screening. Other models have been used where people need to attend in person for their risk assessment, with varying drop-out rates between LHC and LDCT. For example, the Liverpool Healthy Lungs programme used a model where patients had their LHC at their GP

		surgery and then made a separate appointment for a LDCT scan. This model had a 15% drop out rate between LHC and LDCT scan appointments. Similarly, a programme funded by the West Yorkshire and Harrogate Cancer Alliance in Bradford following a very similar model had a 12% drop out rate between LHC and LDCT (unpublished data). Conversely, only 3% of eligible patients in the Manchester pilot, funded by Macmillan, opted out of a LDCT scan where mobile units were used and LHC and LDCT took part on the same day. YLST has around an 13% drop out rate between eligibility for LDCT telephone assessment and attending the appointment, but for those that attend the appointment almost 100% (99.7%) have a baseline LDCT scan (unpublished data).
Page 32	Sub-section: The accuracy of risk prediction algorithms	YLST, funded by Yorkshire Cancer Research uses both the PLCO _{m2012} risk (≥1.51% over 6 years) and LLPv2 score (5-year risk of ≥2.5%) algorithms to assess eligibility for LDCT, alongside smoking history (30 pack year history of smoking and current smoker or quit within the last 15 years). We hope that future publications from YLST will add to the growing body of evidence on the most appropriate risk algorithms to use. We expect data from the SUMMIT Study, funded by GRAIL, Inc. will also contribute to the knowledge base on this topic.
Page 36	Sub-section: Summary	We support further evidence gathering to further knowledge on the most appropriate and accurate risk prediction algorithms, eligibility criteria, number of screening rounds and screening round intervals as well as the threshold for a positive test result. We hope that results from YLST, funded by Yorkshire Cancer Research will add to this growing body of evidence.
Page 43	Sub-section: Summary	We are pleased to see that irrespective of the screening strategy, LDCT is reported to be more effective than no screening, despite being more costly.

		We hope that future publications from YLST, funded by Yorkshire Cancer Research will provide further information on cost effectiveness of lung screening. We expect data from the SUMMIT Study, funded by GRAIL, Inc. will also contribute to the knowledge base on this topic.
Page 51	Sub-section: Discussion of findings	Yorkshire Cancer Research are pleased to see evidence included that shows a reduction in lung-cancer specific mortality following lung screening. As shown in the sub-group analysis sub-section it will be important to understand whether differences occur between different demographic sub-groups and we support the data collection and analysis in future studies and services that allow for services to be tailored in the future. Yorkshire Cancer Research would encourage any future trials to be adequately powered to assess lung-cancer specific mortality and contribute to this body of evidence.
Page 54	The NLST RCT compared all-cause mortality outcomes for white participants (n=47,902, 89%), black participants (n=2361, 4%) and a third group combining other (n=2969, 5%) and missing (n=220, 0.4%) ethnicity []	Yorkshire Cancer Research believe it will be vitally important for any future service to collect ethnicity data in relation to the programme. This will help to identify groups that may need more targeted work to ensure adequate participation in the programme and indicate where adaptations may be required. This will help to ensure a UK service is fit for purpose and tailored to needs based on ethnicity and local populations where appropriate.
Page 55	The difference in incidence between the LDCT and control arms was not always statistically significant. The NLST RCT at 11.3 years follow up showed no statistical difference in incidence between the LDCT and chest x-ray (RR 1.01; 95% CI 0.95-1.08) and similarly for	Despite a higher cumulative incidence, it is encouraging to see that there was no statistical difference in lung cancer incidence between the LDCT and chest x-ray arms for the NLST and LDCT and no screening for NELSON at the point of follow up. This indicates that rates of overdiagnosis are low and lung screening is not finding significant numbers of additional cancers but is instead finding them

	NELSON at 10 years follow up comparing LDCT with no screening (RR 1.14,95% CI 0.97-1.33).	earlier (as covered on page 56) and therefore at a time when more treatment options are available.
Page 56	All RCTs reported more stage I cancers in LDCT groups than control groups	It is encouraging to see more early-stage cancers being diagnosed in LDCT groups compared to control groups. Given that one of the important factors for introducing a screening programme is ensuring there is adequate treatment options available, seeing a significant stage shift to early-stage lung cancers could save thousands of lives.
		The following data highlights some of the specific statistics to highlight the problem of late stage diagnosis: In Yorkshire 4,270 people are diagnosed with lung cancer each year with rates as high as 127.6 per 100,000 in Hull compared to 74.9 in England (CancerData)
		 In Yorkshire and England, 70% of lung cancers are diagnosed at a late stage (<u>CancerData</u>) In England, 1 year survival for stage 1 lung cancers is 89.7% while survival of stage 4 lung cancer is just 21% (<u>NHS Digital</u>) In England, the 1 year survival rate for lung cancer is 44.4% and 5 year survival rate is 19.7% (<u>NHS Digital</u>)
Page 57	Sub-section: Lung cancer screening intervals	Yorkshire Cancer Research would like to see some clear guidance on screening intervals in future guidance documents. YLST, funded by Yorkshire Cancer Research, is screening people at baseline (T0) and then at 2-yearly intervals to a total of three screens (T0, T2 and T4) – note this does not include any monitoring screens for those referred to a treatment pathway.
Page 58	Sub-section: Harms and adverse events resulting from screening	As with other screening programmes, it is important to ensure that the benefits of lung screening outweigh any potential harms. Yorkshire Cancer Research therefore support the adaptation of the

		screening programme in the future based on the latest findings for aspects such as what defines a positive screen, improvements to the diagnostic tests over time etc. Where possible data should be captured on non-screened individuals in terms of AEs from further tests etc.
Page 61	Jonas et al (2021) reported that for the NLST RCT with a follow up of 6.5 years there were 4 cases of overdiagnosis and 3 lung cancer deaths prevented per 1000 people screened in the same period. A further study of NLST RCT data estimated a rate of 1.38 cases of cancers were over diagnosed for every 320 patients needed to screen to prevent 1 death from lung cancer.	It will be important to clearly communicate the potential risks of screening to those choosing to take part so they can make an informed choice. However, this may need to incorporate specific interventions given the demographics of those likely to be eligible for lung screening (i.e. long-term smoker, potentially from a more deprived area, lower levels of education and health literacy etc.) As with other factors relating to lung cancer screening it will be important to continue to study the risk of overdiagnosis in future trials and services, especially given a long follow-up period is required to accurately assess overdiagnosis. Given that overdiagnosis is always a potential harm with screening programmes (for example estimates for breast screening state that
		for every breast cancer death prevented, approximately three women are over diagnosed and treated (The benefits and harms of breast cancer screening: an independent review (nih.gov)) it will be important to understand this in the context of lung cancer screening in the future and ensure the risks (and the benefits) are communicated clearly to both health professionals and the public. It must be made clear that in lieu of having more knowledge on those cancers that we need to treat and those that would be unlikely to cause harm and therefore could be left untreated/put under active surveillance then the default is to offer treatment.
Page 64	Sub-section: Anxiety, depression and distress	We appreciate that both true and false positives result at lung screening are likely to increase anxiety, depression and distress when compared to control (no screening). However, these findings

		do not compare the anxiety, depression and distress experienced after a positive result at lung screening to the anxiety, depression and distress of those who are diagnosed with lung screening through another route. Lung screening aims to diagnose lung cancers at an earlier stage when survival is greatest, therefore in the long-term, we believe lung screening will reduce anxiety, depression and distress for those diagnosed with lung cancer. In the paper, there is no evidence of increased anxiety, depression and distress in those with a negative result but who later go on to be diagnosed with lung cancer.
Page 65	Sub-section: Incidental findings	It will be of significant importance to ensure incidental findings are appropriately referred, diagnosed and treated. Pathways must be established to manage these where required and modelling should be performed to understand the potential impact at a local level. Unpublished data from YLST, funded by Yorkshire Cancer Research shows more than 50 people have a confirmed other (nonlung cancer), approximately 0.5% of screened participants. Yorkshire Cancer Research supports further research in this area, and believes it will be important to communicate to patients the risk of other incidental findings that may occur as a result of screening. Please note, further to the level of incidental findings in YLST we have started to investigate the possibility of combining lung and kidney screening through an initial exploratory trial (further details found here: https://clinicaltrials.gov/ct2/show/NCT05005195).
) Page 66	Sub-section: Smoking cessation	Yorkshire Cancer Research strongly believes that smoking cessation is an essential element of a lung screening programme. As provided earlier in this written response in relation to Page 2, Point I for the associated document 'Consultation on targeted screening for lung cancer in people aged 55-74 with a history of smoking' our recommendations are that smoking cessation should be an integrated and co-located service, delivered as an opt-out

		service as standard and offered prior to LDCT, and be delivered by a dedicated team of smoking cessation practitioners, rather than relying on referrals to existing services.
Page 67	It is difficult to assess the balance of harms and benefits of lung cancer screening with LDCT as the outcomes of possible harms are inconsistent across the studies.	It will important that publications from high quality clinical trials and service evaluations are able to contribute to learning in this space in the future.
Page 69	Therefore, evidence addressing criterion 13 (ratio of benefits to harms) is met for volume, applicability and quality of evidence but unmet for consistency of findings. Further testing of implementation strategies is therefore necessary to evaluate the most clinically effective screening approach.	We hope that the findings from YLST, funded by Yorkshire Cancer Research will contribute to the national and international evidence based for the most clinically effective screening approach for lung cancer.
Page 70	Sub-section: Description of the evidence	Please correct the typo at the start of the sentence 'Ocontains a full PRISMA flow diagram'. A qualitative study into views of people at high risk of lung cancer about targeted lung cancer screening in Manchester has been missed off the list. This is Tonge JE, Atack M, Crosbie PA, Barber PV, Booton R, Colligan D. "To know or not to know?" Push and pull in ever smokers lung screening uptake decision-making intentions. Health Expect. 2019 Apr;22(2):162-172. doi: 10.1111/hex.12838. Epub 2018 Oct 5. PMID: 30289583; PMCID: PMC6433322. Available from; "To know or not to know?" Push and pull in ever smokers lung screening uptake decision-making intentions - Tonge - 2019 - Health Expectations - Wiley Online Library

Page 71	The RCTs and cohort studies reported screening uptake	For clarity please further define what is meant by screening uptake. Should this be interpreted as measuring screening participation, rather than using the current definition of uptake used as a metric for assessing breast and bowel cancer screening.	
Page 72	There were few concerns about the study methodology which aimed to explore views from a representative sample of the older general population, although this group would not necessarily reflect the characteristics of the cohort who would be invited for lung cancer screening	We would like to reiterate the importance of ensuring participants of future studies reflect the target screening population/capture the opinion of those from culturally diverse communities, cover a range of ethnicities, people of relevant smoking status, different educational backgrounds etc.	
Page 73	 inviting a large group of people to express an interest in screening using a set of criteria assess who is eligible and book them for a lung health check (LHC), prior or during the LHC ask detailed questions to evaluate their eligibility for LDCT 	Based on learnings from our funded programmes and other evidence, Yorkshire Cancer Research recommends the use of telephone-based risk assessment meaning only those eligible for LDCT attend an appointment in-person, which may have numerous benefits including saving time, being more cost effective and reducing travel time and costs for patients. This approach is discussed earlier in this written response in more detail in relation to comments on page 30 of the report. The recommendations currently state that people should be invited for a lung screening risk assessment if they are aged 55-74 and 'ever' smokers (based on GP records). Insight from the Manchester trial found that a short audit of GP records (during the trial design phase) highlighted that GP smoking data was of insufficient quality (inconsistent use and incomplete and out of date records) to base invitation on and would have meant that some eligible smokers were not invited. Therefore, only age data was used to inform invitations, and invitees who were interested in lung screening were asked to book a lung health check with a nurse if they were a	

		smoker or ex-smoker. Issues with GP records must be considered in the implementation of a national lung screening programme - there should be an approach for tackling these data issues and ensure those smokers not identified through GP data are invited for screening. In some areas with particularly low GP smoking data quality, it may not be appropriate to base invitations off this data. This is also discussed in relation to Point I, Page 2 on the associated document "Consultation on targeted screening for lung cancer in people aged 55-74 with a history of smoking".
Page 73	Uptake of lung cancer screening in the UK was reported in 4 articles from 2 RCTs and 1 cohort study and they reported that between 46.5% and 92.4% who were eligible for a LHC attended their appointment and of those who were evaluated as eligible for LDCT >90% attended.	As with other screening programmes, Yorkshire Cancer Research believe that it will be necessary to tailor invitations and deliver specific interventions to increase engagement and participation in lung screening. Given the target population for lung screening it is not unreasonable to expect lower engagement than with other national screening programmes and therefore any communications to the public must be done with care to encourage participation and delivered across multiple platforms and at both local and national levels. We also recommend producing invitation materials in multiple languages according to the local population. It may also be necessary to ensure adequate resource within translation services both for telephone calls and/or appointments.
Page 74	4061 (46.5%) took attended the appointment and were eligible for screening	Possible typo – please amend.
Page 76	The following year those people who had tested negative	Is the use of the phrase "tested negative" in this context appropriate? For the other screening programmes this is sometimes referred to as a 'normal result' – would this wording be more appropriate?
Page 76	Both positive and negative view points were voiced with the overall balance	Yorkshire Cancer Research are encouraged to read that people are supportive of lung cancer screening. We would be interested in

	being that people supported lung cancer screening.	more recent data following the roll out of the NHS TLHC as well as greater prominence of the current UK clinical trials as we assume more people will have now heard of the concept of lung health checks/lung screening. It will be extremely important that lung screening is well-received by the public and healthcare professionals when rolled out and that the appropriate communications budget and resources are developed by experts.
Page 78	Sub-section: Public perceptions and opinions about lung cancer	Move sub-heading so it is on the same page as the following content. Findings from Tonge et al (2019)., "To know or not to know?" Push and pull in ever smokers lung screening uptake decision- making intentions. Health Expect. could be included here. The study involved exploring the views of 33 current and ex-smokers in three focus groups held in Manchester in 2016. Lung screening was found to be widely acceptable to study participants. Benefit perceptions included reassurance about lung health and early detection and treatment opportunity. Participant's desire to know about their lung health via screening described as 'push and pull' of views about perceived benefits, emotions (worry about a positive diagnosis and undergoing screening); practicalities such as accessibility; and smoking-related issues including perceptions of individual risk and smoking stigma. The findings were used in the design of the Manchester Lung Health Check pilot.
Page 80	Public perceptions and opinions about lung cancer	It will be crucial before, during and after the introduction of lung cancer screening (and any future screening programme) that there is extensive marketing and communications work (for example public health campaigns) to tackle the barriers to lung cancer screening, as well as misconceptions and stigma. Communications should aim to reduce inequalities in screening uptake, for example

		between more and less deprived populations, to ensure that screening does not exacerbate any existing inequalities.
Page 80	A total of 1354 (91.7%) thought lung cancer screening was a good idea and of those who were current or former smokers (n=642), 91.6% (n=588) indicated they would participate in screening if they received an NHS invitation, 95.8% (n=615) if they received a GP invitation and 91.9% (n=590) if a pre-scheduled appointment was made for the following month71.	Although this information is encouraging and gives an insight that receiving an invitation from their GP may yield slightly higher interest in a screening programme, it is important to note the difference between intention to screen and actual screening behaviour. Recent headlines in the media have indicated that the NHS TLHC sites have had low engagement highlighting the disparity between intentions and actual behaviour:

Page 84	Sub-section: Clinical effectiveness of lung cancer screening	Yorkshire Cancer Research are pleased to see there is sufficient evidence on the effectiveness of lung cancer screening to reduce mortality and morbidity for criterion 11 to be met, particularly as this does not include the results of two large UK based clinical trials (YLST, funded by Yorkshire Cancer Research, and the SUMMIT study, funded by GRAIL Inc). We expect that the evidence on the effectiveness of lung cancer screening should continue to be reviewed as new evidence emerges.
Page 85	Sub-section: Clinical effectiveness of lung cancer screening	Regarding criterion 13, Yorkshire Cancer Research agree there is a need for a UK model incorporating the latest evidence on cost-effectiveness as well as considering the latest evidence on benefits and harms. We hope that with this further evidence criterion 13 will be met.
Page 85	Sub-section: Acceptability of lung cancer screening	Yorkshire Cancer Research are pleased to see that aspects of criterion 12 are met. We suggest that evidence gathering following the more recent roll out of two further UK studies, as well as the NHS TLHC sites will provide further evidence on the acceptability of the full screening pathway, including diagnostic work up and treatment of lung cancer, given this has been implemented across many health systems in England.
Page 85	Sub-sections: Contextual questions	Yorkshire Cancer Research are supportive of summary comments in this section. We agree that lung cancer is well understood, and that lung cancer screening represents a good test for identifying people with early stage disease. We also agree that more research is needed to clarify the best risk algorithm and cost effectiveness – both of which may be addressed through findings of YLST, funded by Yorkshire Cancer Research when published.
Page 86	To address the uncertainty about the best approach to achieve maximum clinical effectiveness in reducing mortality and morbidity from lung cancer	We suggest rewording this sentence to focus on reducing mortality and morbidity from lung cancer, rather than lung cancer screening.

	screening whilst reducing possible harms to a minimum.	For example, 'To address the uncertainly about the best approach for lung cancer screening to achieve maximum clinical effectiveness in reducing mortality and morbidity from lung cancer whilst reducing possible harms to a minimum.
Page 86	Sub-section: Limitations	Yorkshire Cancer Research understand the fast-moving nature of this subject and that new articles will be published on a relatively frequent basis. We would like to see agreed time points for further literature searches to ensure the latest evidence is considered within the lung screening programme.
Throughout	53Error! Bookmark not defined.	This error occurs on the following pages: 64, 66, 67, 74, 75 (x3), 76 (x5), 77, 78 (x3), 79 (x7), 80 (x4), 81 (x4), 82 (x2), 144, 146, 149, 155,
Throughout	Formatting of text needs amending so words are not split over pages.	This error occurs on the following pages of the main report: 74, 75, 76, 78, 79, 80, 81, 82.

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Name:	Leah Holtam		Email address:	xxxx xxxx
Organi:	sation (if riate):	Yorkshire Cancer Research		
Role:	Head of Cancer Insig	ht		
Do you Yes	Do you consent to your name being published on the UK NSC website alongside your response?			

Section and / or page number	Text or issue to which comments relate	Comment Please use a new row for each comment and add extra rows as required.
_		ow all relate to the document:
Con	sultation on targeted screening for lung	cancer in people aged 55-74 with a history of smoking
Page 2	A quality assured, targeted screening programme for lung cancer in people aged 55-74 with a history of smoking should be recommended in the UK	Yorkshire Cancer Research welcomes this recommendation. As funders of the Yorkshire Lung Screening Trial (YLST) (led by Professor xxxx xxxx) and the associated Yorkshire Enhanced Stop Smoking (YESS) Study (led by Professor xxxx xxxx), we firmly believe that screening for lung cancer with low-dose CT (hereafter referred to as LDCT) has the potential to convey significant benefits on cancer survival and public health when combined with an integrated smoking cessation service. Essential to its success we believe that a consistent service must be offered across England (and the devolved nations), with the service commissioned once at a national level as an end-to-end service (as for the breast, bowel and cervical screening programmes). We have experienced through conversations with Cancer Alliance colleagues relating to the NHS Targeted Lung Health Check (TLHC) programme, that where commissioning is done at a local level there is room for variation in services and the offer available to patients (particularly in relation to smoking cessation). This approach has the potential risk of introducing inequality into a service that is targeted at people who are likely to already be facing numerous health inequalities and inequities. Given the emerging evidence in this space and the acknowledgement that there is more to learn, Yorkshire Cancer Research also suggest it is vital that any future lung screening

		programme is set up to support future research activity (whether this is through clinical trials or service evaluation). There should also be a clear evaluation framework for the screening programme developed to not only ensure consistency across different geographical areas, but also so that adaptations can be made to the programme as new evidence emerges. This should be able to happen in a timely manner following the required reviews to ensure maximum impact for patients. Key performance indicators should be set with data collection covering uptake as a minimum, and with regular publication against agreed standards as for the other screening programmes. Data should also be collected on smoking cessation services including engagement and outcome data.
Page 2	Implementation of screening for lung cancer should not be seen as an alternative to the delivery of high-quality smoking cessation services across all age groups. That smoking cessation should be an integral part of the screening programme	We agree that screening for lung cancer should not be seen as an alternative to the delivery of high-quality smoking cessation services across all age groups and that smoking cessation should be an integral part of the lung screening programme. We wholly support the delivery of smoking cessation services, however, also believe that innovative approaches to smoking cessation are required to further reduce smoking rates and stop people from taking up smoking. Yorkshire Cancer Research agree with the ambition for England to be smokefree by 2030 and expect clear guidance on how this should be achieved to be outlined in the long-awaited Tobacco Control Plan and addressed through the government's independent review into the 2030 target. We believe there is no single solution to driving down smoking rates and a whole system approach to smoking cessation should be adopted with support to stop fully embedded throughout all touchpoints within the NHS and beyond. This would support the move to stopping smoking becoming the norm, with smoking treated as an addiction rather than a lifestyle choice. Integrating smoking cessation within lung screening provides a unique opportunity to bolster the community offer of smoking cessation, not replace it.

Considering this position, it is noted there is a lack of further information in relation to the importance of including smoking cessation within a future lung screening programme. The charity's experience funding smoking cessation alongside lung screening (and lung health check - LHC) programmes has shown that different models seem to have more success than others and it will be important to continue to gather evidence as new findings are published to ensure the smoking cessation offer is highly effective.

The YESS study, funded by Yorkshire Cancer Research, is leading the way nationally in terms of gathering evidence for the integration of smoking cessation alongside lung cancer screening. It is testing the uptake and effectiveness of a co-located, opt-out smoking cessation delivery model offered to all smokers attending for a LHC as part of YLST (also funded by Yorkshire Cancer Research) between December 2018 and December 2020. Stop smoking support was offered in line with National Institute for Health and Care Excellence (NICE) PH48 guidance comprising one session of behavioural support at the time of the LHC and provision of pharmacotherapy (either as nicotine replacement therapy (NRT) through delegated prescribing at the visit and/or a commercially available e-cigarette and vaping supplies, or arranged a GP prescription for varenicline or bupropion). Follow-up contact was provided either face-to-face or by telephone, typically weekly but more or less frequently according to participant preference for up to 4 weeks from the date of the LHC with replenishment of guit aids on a bi-weekly basis for any individuals engaging with a guit attempt. At 4 weeks the offer of continued support was provided with the option to participate in the YESS study (randomised to intervention or control). Those who chose not to participate were still eligible for a further 8 weeks of behavioural support. Recruitment to the study

paused for three months during the Covid-19 pandemic, though ongoing support to patients continued via telephone with quit aids sent via post. Following resumption of the study, the baseline visit returned to a face-to-face counselling session, but all subsequent interactions were via telephone and quit aids continued to be dispensed by post. The Covid-19 pandemic necessitated a change in delivery model to telephone only support for all visits after the initial consultation as opposed to face-to-face. However, both smoking cessation practitioners and participants reported still building a strong rapport through regular phone calls and did not feel this had a negative impact on their experience.

The study found that of 2151 eligible smokers attending for lung cancer screening, 88% of smokers agreed to a consultation with the smoking cessation practitioner at the time of the screening appointment. Of these, 75% agreed to ongoing cessation support, with around half provided with an e-cigarette, either alone or in combination with NRT. 20% of those accepting ongoing cessation support were successfully quit at 4 weeks (15% of all eligible smokers) (unpublished data). Considering the participants' significant smoking history these rates of engagement are much higher than expected. However, the quit rate should not be compared against local stop smoking service data given the difference in population and the fact that these people are very unlikely to present to their local service.

The YESS model is continuing into the second round of lung cancer screening as part of YLST and is offering stop smoking support to individuals who were unsuccessful in their quit attempt, who declined to accept stop smoking support or did not attend for the baseline screening round. Whilst still ongoing, the sustained offer of stop smoking support is again being well received, with the majority

of smokers who declined a consultation in the baseline round now agreeing to see a smoking cessation practitioner (SCP). Many smokers declining support or making an unsuccessful quit attempt report that it was just 'not the right time for them', despite being motivated to try and stop smoking and these findings reinforce the need for effective stop smoking support at all stages of lung cancer screening, not simply a one-off offer at the initial screening appointment.

An embedded process evaluation undertaken as part of the YESS study has shown that individuals attending for a LHC expected to discuss smoking and it did not surprise them; some even indicated that they had attended the appointment in the hope of receiving support to stop smoking. They found the offer of stop smoking support acceptable, largely due to the lack of stigma, the nonjudgemental style of discussion and positive support they received from SCPs at the time of the LHC. The co-location of the smoking cessation service alongside the LHC reduced burden on the participants as they were provided with behavioural and pharmacological support straight away, not referred on to someone else or another service where there may be a delay in receiving support. Those that did not want to take up smoking cessation support at the time of the LHC did so because it was not the right time for them, not because they felt it was unacceptable to offer smoking cessation in a LHC context.

Further information can be accessed in the paper: Yorkshire
Enhanced Stop Smoking (YESS) study: a protocol for a randomised
controlled trial to evaluate the effect of adding a personalised
smoking cessation intervention to a lung cancer screening
programme | BMJ Open

Based on the evidence above and further learnings, Yorkshire Cancer Research requests that smoking cessation is a mandatory feature of a lung screening programme, and that guidelines for smoking cessation alongside lung screening are published (the charity would be willing to work closely with those developing these). Although the protocol for the current NHS TLHC states that enhanced smoking cessation interventions are encouraged there is limited guidance as to how the support should be delivered or funded and the current experience within the NHS TLHC programme would suggest that this lack of guidance and clarity is leading to significant variations in the smoking cessation offer.

Yorkshire Cancer Research has published a <u>'Position Statement on Smoking Cessation Models for Lung Health Check with LDCT Scan Programmes</u>' where you can read about the charity's learnings in detail. This will be updated with new evidence from our funded awards as it is available. A summary of the main recommendations are included below:

- 5. The lung screening and smoking cessation interventions must be regarded by all staff and patients as an integrated service. Essential to this integration are three key factors: co-location of the services (they must be physically in the same space and appear as a single service), smoking cessation should be an opt-out default and offered before the CT scan (we found this increases the number of people open to seeing a SCP) and a consistent nurse and SCP team should deliver the service (dedicated resource and highly trained and experienced staff are essential to successful delivery).
- A comprehensive smoking cessation package should be offered, building on the recommendations outlined within NHS,

National Centre for Smoking Cessation and Training and NICE standards. Including:

- The immediate provision of stop smoking aids, including vaping products. By virtue of being a smoker at the time of attending lung screening, people are likely to be habitual and committed smokers, having smoked for many years and either have not engaged with smoking cessation support, and/or have a history of multiple failed quit attempts. Therefore, we recommend removing as many barriers to smoking cessation as possible. As they are the most popular stop smoking aid in England, vaping products should be offered, either to take away from the service (preferred given removal of barriers), posted out to a home address, or accessed through a voucher scheme.
- Ongoing face-to-face or virtual behavioural support for 12 weeks. This should be accessible to people at a time and location convenient to them. Our experience has shown that delivering this as a standalone and specialised service (integrated within the lung screening pathway) may have greater success than doing an initial consultation and then referring people into existing services – where they may have had unsuccessful quit attempts in the past. The lung screening smoking cessation service could be set up as a separate arm of the local offer of smoking cessation but should be subject to minimum requirements specific to the lung screening setting, both in terms of the service provided but also the data collected so it aligns with local and national requirements and contributes to locally recorded guit data, with appropriate data sharing agreements in place. The service must also be appropriately funded. It will not be sufficient to expect local areas to fund this service from their existing public health budgets – particularly as some local

- areas offer services only to specific targeted populations and in some cases, there is no local offer of smoking cessation.
- 7. Telephone risk assessment should be included as part of the LHC model, which evidence shows reduces time and travel costs to patients, enriches the cohort of LHC patients with smokers (thereby ensuring the smoking cessation provision is utilised) and is likely to increase the cost effectiveness of the service, while also reducing the time needed by nursing staff to see patients, (this is being evaluated in YLST). This is also aligned with the addendum to the NHS TLHC participant pathway specification that was in place during the COVID-19 pandemic.
- 8. The LHC, LDCT scans and smoking cessation services should be located in convenient community locations, which are disassociated from healthcare environments such as GP surgeries and hospitals.

In addition to the above the importance of providing a specialised stop smoking service integrated within the lung screening pathway is highlighted in the December 2021 Evaluation Progress Report of the NHS TLHC programme. Within this report data shows that only 54% of smokers received advice at their LHC about quitting or reducing smoking and again highlights that people who smoke expect to be asked about smoking at these appointments "I've been smoking since I was 17. They didn't even ask if I'd considered giving up smoking." [Page 64]. It also supports the theory that referrals to an external stop smoking service may not be adequate "[...] there were **reports that nothing had come of their referral**—that having been told the local service would contact them to follow up after the LHC, they didn't hear anything further. Although some participants were able to cut down or cease smoking on their own,

		there was a theme of disappointment in local services failing to provide support that had been promised. In one case, a participant who did hear from the stop smoking service was "stunned" to be told, after a short conversation about her smoking habits, that she was not eligible for help because she did not exhibit any mental health issues" [Page 64]. These findings are clear indicators that an integrated stop smoking service is vital to the success of a smoking cessation offer within the lung screening setting and not offering this could fail patients, acting as a missed opportunity to engage them in quitting smoking, whilst also risking increasing health inequalities in a population who commonly experience health disparities.
Page 2	i. identifying and inviting 'ever' smokers aged 55 - 74 from GP records	We agree that in some instances using GP records of smoking status is an appropriate method for inviting people to lung screening, however it heavily relies on smoking status being accurately recorded and therefore may not be appropriate for all areas. We have evidence that for some localities, GP records are not accurate enough to use this method for inviting people into the service.
		For example, in the Manchester Lung Health Check pilot (funded by Macmillan Cancer Support) the team conducted an audit to review smoking status data held within GP records ahead of the programme roll out. With around 40 different codes available to record smoking status in EMIS it was found that GP patient records were often not completed, not up to date, or inconsistently recorded. To avoid missing people who were eligible, an invitation was sent to everyone within the eligible age range (as age was accurately recorded within GP patient records) asking people who were current or former smokers only to book an appointment.

In YLST, funded by Yorkshire Cancer Research, similar problems have also been encountered. The team originally planned to include 62,890 people from across Leeds across the screening and control arms, however subsequently found this level of invitation was not sufficient to obtain the required number of trial participants. The team had to increase invitations by 26,937 to a total of 89,917 (note a Zelen's design is used in this trial so the control group do not receive an invitation to participate and are blind to their involvement in the clinical trial). This was driven from the recorded smoking status within GP records not being accurate enough to get the number of people eligible for LDCT. Anecdotally, GP patient records had smoking status inaccurately recorded for between 10-25 % of people. Unpublished data from YLST shows that 15.1% (n=3,437) of people contact based on their GP records were ineligible because they self-reported never smoking (despite the having a smoking-related code in their GP record).

We suggest that:

- 3) Work is urgently undertaken to increase the accuracy of smoking status on GP records for example through text campaigns asking people to provide up to date details or asking for this information in routine patient appointments. This is something that could be actioned ahead of roll out of the lung screening programme.
- 4) Guidance is published on how best to invite people to lung cancer screening where areas may not be able to rely on GP record smoking status. This guidance should include how to capture and engage with those people missed through the GP records.

Page 2	ii. assessing eligibility for low dose CT	We agree that using a multivariate risk assessment tool is an
	(LDCT) using a multivariable risk assessment tool	appropriate way to distinguish those most at risk of lung cancer and therefore eligible for a LDCT scan. However, we believe that the use of telephone-based risk assessment should be a permanent feature of the guidance and has the benefits of reducing travel time and costs to patients, enriches the cohort of patients with smokers (which ensures the SCP's are busy), and could increase the cost effectiveness of the service.
		YLST, funded by Yorkshire Cancer Research, is using PLCO _{m2012} and LLPv2 to assess eligibility for a LDCT scan and using a telephone-based risk assessment method. Unpublished data from YLST shows that this method (where the initial risk assessment is conducted via telephone and only those meeting the inclusion criteria are invited for a LHC with LDCT scan) has been successful in getting people into the programme with a 51% response to invitation rate. Of those responding around 34% were eligible for LDCT screening and offered an appointment (lower than the anticipated 48% due to poor smoking status records). Around 87% of patients attended their appointment and almost 100% of those attending the appointment had a baseline LDCT scan (indicating very high accuracy of the risk assessment protocol – unpublished data).
		Further information on the Charity's recommendations for LHC guidelines can be found here: position-statement-on-lung-health-check-guidelines-may-2022.pdf (yorkshirecancerresearch.org.uk).
		Although it is not proposed here that spirometry is used as a risk assessment tool, Yorkshire Cancer Research would like to take the opportunity to highlight that a number of the studies included in the

		evidence review, along with the current NHS TLHC do include spirometry as part of the LHC. However, we would like to see evidence of the benefit of spirometry in terms of outcomes for patients before this is included within any lung cancer screening pathway guidance. This is not to question the benefit of using spirometry for identifying undiagnosed COPD within this target population, but we question the relevance of this for a programme aimed at diagnosing lung cancer at an early stage. No impact on patients (beyond reduced appointment time) was seen when spirometry was removed from YLST as a result of the COVID-19 pandemic trial adaptations.
Page 2	iii. offering a LDCT schedule based on the baseline CT	The charity requests that further clarification is provided on this point in future guidance. It is not clear whether this is offered on an individual basis or according to broad grouped outcomes of baseline LDCT.
Page 2	vi. providing smoking cessation advice to all participants in the programme	As written above the charity has provided important points of consideration when including a smoking cessation element to lung screening. We believe it is important that this is a full and integrated service, rather than just providing very brief advice to screening participants.
Page 2	i. whether re-screening people with a history of smoking who are not eligible for LDCT should be part of the overall screening strategy	Yorkshire Cancer Research believes it will be important to consider how the system will account for people who may not be eligible at first invitation but who later hit the inclusion criteria to ensure they receive an invitation in the future. For example, they may not have a high enough pack year history at 55 (if this is used as an inclusion criteria) but hit this threshold at age 60 or 65. Appropriate records and recall systems, with a suitable safety-netting function need to be in place to ensure these people are not overlooked at future screening rounds. Modelling based on learnings and evidence from existing programmes should be conducted to estimate how many patients might be included within this group to estimate the scale of

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		the issue. Also for consideration are the learnings from YLST,
		funded by Yorkshire Cancer Research, which will specifically look at
		lung cancer screening in the older 75-80 cohort.
	The comments belo	w all relate to the document:
	Screening for lung cance	er in individuals at increased risk
Exte	rnal review against programme appraisal crit	eria for the UK National Screening Committee, Version 3.2
Page 4	In 2017 there were about 48,000 people who were diagnosed with lung cancer and about 35,000 people who died from the disease in the UK.	We query the use of incidence and mortality data from 2017. We appreciate this may be related to national registries but data for England is readily available for 2019. Note this data is also referenced on pages 6 and 13 without the year included, we suggest a consistent approach to referring to data in text is adopted to ensure it cannot be misinterpreted.
Page 6	It has one of the lowest survival rates of all cancers with 16.2% of people living beyond 5 years and 9.5% living beyond 10 years.	Note that this data applies to England only but sits alongside incidence and mortality data for the UK. We recommend that this difference for the survival data is made clear.
Page 13	Lung cancer has one of the lowest survival rate of all cancers with 16.2% of people living beyond 5 years and 9.5% living beyond 10 years (Office for National Statistics 2019) ⁶	Amend 'survival rate' to plural: '[] one of the lowest survival rates of all cancers []'. Note that this data applies to England only but sits alongside incidence and mortality data for the UK. We recommend that this difference for the survival data is make clear.
Page 13	Symptoms of lung cancer vary from person to person and include a persistent cough, breathlessness, fatigue and weight loss which may not concern patients until they become severe ⁷	It is worth noting from this same reference that symptoms not concerning patients until they are severe leads to a high proportion of emergency presentations, which often leads to poorer survival outcomes.

		Evidence suggests these symptoms may also be attributed to existing comorbidities, such as COPD, a 'smokers cough' etc. which may in itself delay help-seeking. Birt et al (2014) (bmj.com)
Page 17	Within Table 2: Screening programmes using low dose computed tomography (LDCT) (any type of LDCT) for the prevention of lung cancer in individuals at increased risk.	We would like to query the use of 'prevention'. Should this be 'detection'?
Page 18	Within Table 2: Screening programmes for the prevention of lung cancer using LDCT.	We query the use of 'prevention'. Should this be 'detection'?
Page 20	It is the leading cause of death due to cancer with 35,137 deaths in 2016-18.	Without prior knowledge it is unclear that rolling data gives an average over the time-period specified (in this case 3 years). Earlier in the document a single year of 2017 has been referred to for cancer deaths (35,000). We suggest making it clear that this is not the total number of deaths from 2016 to 2018 inclusive. Please also consider the prior comment related to using the most recent data if available for nations other than England.
Page 20	Data for 2013-2017 in England show 16.2% of people diagnosed with lung cancer survived for 5 years or more dropping to 9.5% surviving over 10 years.	More recent data is available for 5-year lung cancer survival in England. Data for patients diagnosed in 2015 and followed to 2020 shows 18.7% of patients survived 5 years and 9.4% of patients survived 10 years. Although these are not huge differences when compared with the survival rates included within the report, we suggest it would be appropriate to include the most recent data available. https://www.cancerdata.nhs.uk/survival/cancersurvivalengland

Page 20	An overview of the evidence by CRUK ⁵	A number of references have been included linking directly to CRUK. We recommend that the original source is referenced where possible. The fraction of cancer attributable to modifiable risk factors in England, Wales, Scotland, Northern Ireland, and the United Kingdom in 2015 British Journal of Cancer (nature.com)
Page 21	Lung cancer accounts for 13% of new cancer cases of cancer among both males and females, with 48% (23,087 cases) in females and 52% (24,881 cases) in males in 2017 in the UK. The incidence of lung cancer rises steadily with age in both females and males (Figures 1 and 2). In the UK the highest incidence rates for females are those aged 80 to 84 years and for males, those aged 85 to 89 years. In 2017 lung cancer incidence was 22% higher in males than females (89.1 vs 69.6 cases per 100,000). Overall, lung cancer incidence rates decreased by 8% in the UK between 1993-95 and 2015-17, but there were marked differences between males and females.	Amend the first sentence to read 'Lung cancer accounts of 13% of new cancer cases of cancer []'. We query the use of data from 2017 here. Whilst we appreciate the use of less up to date data for the UK may be due to national registries, data is available from 2019 for England (CancerData). Further, the reference used for the UK data has been updated to include 2016-2018 (Lung cancer statistics Cancer Research UK) indicating more recent data may be available. It should also be noted that the age breakdowns 80-84 and 85-89 are referenced in the text though in figure 1 the age breakdown of 80+ is used. We recommend that either the text is updated to be reflective of the content of Figure 1, or Figure 1 is updated to reflect the age breakdowns used in the text.
Pages 21-23	Figures 1-4	Incidence data here covers 2015-2017 whilst the mortality data covers 2016-2018. We would like to query why data from different years is used here. From the source referenced (<u>Lung cancer statistics Cancer Research UK</u>) there is data available up to 2018

		for both. Also note that data for England for 2019, or 2017-2019 is available (CancerData).
Page 23	In 2017 the age-standardised incidence for females was lower in England and Wales than the UK average, and higher in Scotland than the UK average. For	We request that you acknowledge the significant variation in lung cancer incidence and mortality within each of the devolved nations where data is available.
males, the rate w Scotland and No UK average (Tab mortality rates is	males, the rate was higher in both Scotland and Northern Ireland than the UK average (Table 3)5. The picture for mortality rates is similar with Scotland and Northern Ireland having the highest	We suggest that as a minimum the highest and lowest age- standardised incidence and mortality rates are reported at the geographical breakdown split by Cancer Alliance, alongside variation in survival rates (also split by Cancer Aliance).
	rates compared to the UK average for both males and females.	Lung cancer is a particular issue in some areas of the country and is a priority area for Yorkshire Cancer Research - when compared to all regions in England, Yorkshire has the 3 rd highest incidence and mortality rate from lung cancer (2017-2019). Furthermore, parts of Yorkshire have some of the highest rates of lung cancer incidence and mortality in the country. Hull has the 4 th highest incidence rate and the 2 nd highest mortality rate (2017-2019).
		Yorkshire makes up 9% of the England population, however 11% of lung cancer cases and deaths occur in Yorkshire.
Page 23	Table 3	We query why data from 2017 is used for incidence while mortality data is from 2018?
		Note that more recent data is available from <u>Lung cancer incidence</u> <u>statistics Cancer Research UK</u> .
Page 24	Table 4	We request clarification on why 2013-17 data is used for incidence while 2007-2011 data is used for mortality. We appreciate that this

		may be the most up to date data with breakdown by deprivation, however if this is the case it should be made clear and acknowledged as a weakness in the data. For consistency it would be appropriate to include the average number of deaths per year alongside the mortality rates, as shown for incidence.
Page 25	Table 5	This data is almost 20 years old, and therefore we query its relevance. Updated data (2013-2017) can be found here: Differences in cancer incidence by broad ethnic group in England, 2013–2017 British Journal of Cancer (nature.com). In the supplementary information of this report there is a downloadable dataset. Lung cancer rates are much higher in this most recent dataset, for example, 53.45 in Asian males compared to 23.1-37.2 in the report.
Page 25	The Office for National Statistics (2021) ¹⁵ reported the trend analysis from the Annual Population Survey from 1974 to 2020.	Further clarification on what trend analysis is referred to here is needed. It should be made clear if this is referring to adult smoking rates or another measure.
Page 25	There is estimated to be an approximately thirty-year lag time between smoking prevalence and lung cancer rates, the current epidemiology of lung cancer is largely dictated by historical patterns of cigarette smoking	Given the lag time between smoking prevalence and lung cancer rates, and declining smoking prevalence over recent years, what modelling has been done to predict resource requirements for a lung screening programme with smoking cessation provision built in? Yorkshire Cancer Research believe it is vitally important this programme is fully resourced and funded and modelling may help to predict the number of people in local populations eligible for LDCT, allowing a comprehensive roll out and supporting those most in need.

Table 6 shows that the proportion of smokers in the UK who were 16 and over halved from 30% in 1990 to 14.5% in 2020	This wording is misleading and suggests that 30% of smokers were aged 16 and over (and therefore 70% were under 16). In fact, 30% of those over 16 years old were smokers (and 70% of people over 16 were non-smokers). We suggest amending the wording to 'Table 6 shows that the proportion of people aged 16 and over in the UK who were smokers halved from 30% in 1990 to 14.5% in 2020.'
Table 6	The source of this data is unclear. The reference included states smoking rates for age 18+ whereas the table references 16+. Further, the reference is for 2019 data whereas the table indicates that the data is from 2020. It should be made clear what year this data is from, and the reference updated accordingly. Note: If 2020 data is being used, it should be considered that there may have been changes to the way data were collected due to the pandemic (switching from an in-person questionnaire to over the telephone) and therefore this may affect the data quality.

Page 30	although in the UK primary care practices also collect smoking status of patients.	Whilst we agree that smoking status of patients is recorded by primary care practices, we would like to highlight the potential inaccuracy of this data which may cause an issue when used to determine the eligibility and invitation schedule for lung screening. Please see further comments in relation to Page 2, Point I for the associated document 'Consultation on targeted screening for lung cancer in people aged 55-74 with a history of smoking' as given earlier in this written response.
Page 30	Lung cancer screening studies have used a staged approach to recruiting people; by inviting a broader population group to express an interest in screening followed by individual assessment of eligibility for the screening test of those who respond	Based on learnings from our funded programmes and other evidence, Yorkshire Cancer Research recommends the use of telephone-based risk assessment meaning only those eligible for LDCT attend an appointment in-person, which may have numerous benefits including saving time, being more cost effective and reducing travel time and costs for patients. YLST, funded by Yorkshire Cancer Research, uses GP records to identify people of the correct age and smoking status and sends them an invitation to a telephone-based risk assessment to assess eligibility for screening. A subset of these patients who meet the risk assessment thresholds are then invited to book an appointment for screening. Other models have been used where people need to attend in person for their risk assessment, with varying drop-out rates between LHC and LDCT. For example, the Liverpool Healthy Lungs programme used a model where patients had their LHC at their GP surgery and then made a separate appointment for a LDCT scan. This model had a 15% drop out rate between LHC and LDCT scan appointments. Similarly, a programme funded by the West Yorkshire and Harrogate Cancer Alliance in Bradford following a very similar model had a 12% drop out rate between LHC and LDCT (unpublished data). Conversely, only 3% of eligible patients in the Manchester pilot, funded by Macmillan, opted out of a LDCT

		scan where mobile units were used and LHC and LDCT took part on the same day. YLST has around an 13% drop out rate between eligibility for LDCT telephone assessment and attending the appointment, but for those that attend the appointment almost 100% (99.7%) have a baseline LDCT scan (unpublished data).
Page 32	Sub-section: The accuracy of risk prediction algorithms	YLST, funded by Yorkshire Cancer Research uses both the PLCO _{m2012} risk (≥1.51% over 6 years) and LLPv2 score (5-year risk of ≥2.5%) algorithms to assess eligibility for LDCT, alongside smoking history (30 pack year history of smoking and current smoker or quit within the last 15 years).
		We hope that future publications from YLST will add to the growing body of evidence on the most appropriate risk algorithms to use. We expect data from the SUMMIT Study, funded by GRAIL, Inc. will also contribute to the knowledge base on this topic.
Page 36	Sub-section: Summary	We support further evidence gathering to further knowledge on the most appropriate and accurate risk prediction algorithms, eligibility criteria, number of screening rounds and screening round intervals as well as the threshold for a positive test result. We hope that results from YLST, funded by Yorkshire Cancer Research will add to this growing body of evidence.
Page 43	Sub-section: Summary	We are pleased to see that irrespective of the screening strategy, LDCT is reported to be more effective than no screening, despite being more costly.
		We hope that future publications from YLST, funded by Yorkshire Cancer Research will provide further information on cost effectiveness of lung screening.

		We expect data from the SUMMIT Study, funded by GRAIL, Inc. will also contribute to the knowledge base on this topic.
Page 51	Sub-section: Discussion of findings	Yorkshire Cancer Research are pleased to see evidence included that shows a reduction in lung-cancer specific mortality following lung screening. As shown in the sub-group analysis sub-section it will be important to understand whether differences occur between different demographic sub-groups and we support the data collection and analysis in future studies and services that allow for services to be tailored in the future. Yorkshire Cancer Research would encourage any future trials to be adequately powered to assess lung-cancer specific mortality and contribute to this body of evidence.
Page 54	The NLST RCT compared all-cause mortality outcomes for white participants (n=47,902, 89%), black participants (n=2361, 4%) and a third group combining other (n=2969, 5%) and missing (n=220, 0.4%) ethnicity []	Yorkshire Cancer Research believe it will be vitally important for any future service to collect ethnicity data in relation to the programme. This will help to identify groups that may need more targeted work to ensure adequate participation in the programme and indicate where adaptations may be required. This will help to ensure a UK service is fit for purpose and tailored to needs based on ethnicity and local populations where appropriate.
Page 55	The difference in incidence between the LDCT and control arms was not always statistically significant. The NLST RCT at 11.3 years follow up showed no statistical difference in incidence between the LDCT and chest x-ray (RR 1.01; 95% CI 0.95-1.08) and similarly for NELSON at 10 years follow up comparing LDCT with no screening (RR 1.14,95% CI 0.97-1.33).	Despite a higher cumulative incidence, it is encouraging to see that there was no statistical difference in lung cancer incidence between the LDCT and chest x-ray arms for the NLST and LDCT and no screening for NELSON at the point of follow up. This indicates that rates of overdiagnosis are low and lung screening is not finding significant numbers of additional cancers but is instead finding them earlier (as covered on page 56) and therefore at a time when more treatment options are available.
Page 56	All RCTs reported more stage I cancers in LDCT groups than control groups	It is encouraging to see more early-stage cancers being diagnosed in LDCT groups compared to control groups. Given that one of the

		important factors for introducing a screening programme is ensuring there is adequate treatment options available, seeing a significant stage shift to early-stage lung cancers could save thousands of lives. The following data highlights some of the specific statistics to highlight the problem of late stage diagnosis: In Yorkshire 4,270 people are diagnosed with lung cancer each year with rates as high as 127.6 per 100,000 in Hull compared to 74.9 in England (CancerData) In Yorkshire and England, 70% of lung cancers are diagnosed at a late stage (CancerData) In England, 1 year survival for stage 1 lung cancers is 89.7% while survival of stage 4 lung cancer is just 21% (NHS Digital) In England, the 1 year survival rate for lung cancer is 44.4% and 5 year survival rate is 19.7% (NHS Digital)
Page 57	Sub-section: Lung cancer screening intervals	Yorkshire Cancer Research would like to see some clear guidance on screening intervals in future guidance documents. YLST, funded by Yorkshire Cancer Research, is screening people at baseline (T0) and then at 2-yearly intervals to a total of three screens (T0, T2 and T4) – note this does not include any monitoring screens for those referred to a treatment pathway.
Page 58	Sub-section: Harms and adverse events resulting from screening	As with other screening programmes, it is important to ensure that the benefits of lung screening outweigh any potential harms. Yorkshire Cancer Research therefore support the adaptation of the screening programme in the future based on the latest findings for aspects such as what defines a positive screen, improvements to the diagnostic tests over time etc. Where possible data should be captured on non-screened individuals in terms of AEs from further tests etc.

Page 61	Jonas et al (2021) reported that for the NLST RCT with a follow up of 6.5 years there were 4 cases of overdiagnosis and 3 lung cancer deaths prevented per 1000 people screened in the same period. A further study of NLST RCT data estimated a rate of 1.38 cases of cancers were over diagnosed for every 320 patients needed to screen to prevent 1 death from lung cancer.	It will be important to clearly communicate the potential risks of screening to those choosing to take part so they can make an informed choice. However, this may need to incorporate specific interventions given the demographics of those likely to be eligible for lung screening (i.e. long-term smoker, potentially from a more deprived area, lower levels of education and health literacy etc.) As with other factors relating to lung cancer screening it will be important to continue to study the risk of overdiagnosis in future trials and services, especially given a long follow-up period is required to accurately assess overdiagnosis.
		Given that overdiagnosis is always a potential harm with screening programmes (for example estimates for breast screening state that for every breast cancer death prevented, approximately three women are over diagnosed and treated (The benefits and harms of breast cancer screening: an independent review (nih.gov)) it will be important to understand this in the context of lung cancer screening in the future and ensure the risks (and the benefits) are communicated clearly to both health professionals and the public. It must be made clear that in lieu of having more knowledge on those cancers that we need to treat and those that would be unlikely to cause harm and therefore could be left untreated/put under active surveillance then the default is to offer treatment.
Page 64	Sub-section: Anxiety, depression and distress	We appreciate that both true and false positives result at lung screening are likely to increase anxiety, depression and distress when compared to control (no screening). However, these findings do not compare the anxiety, depression and distress experienced after a positive result at lung screening to the anxiety, depression and distress of those who are diagnosed with lung screening through another route. Lung screening aims to diagnose lung cancers at an earlier stage when survival is greatest, therefore in

		the long-term, we believe lung screening will reduce anxiety, depression and distress for those diagnosed with lung cancer. In the paper, there is no evidence of increased anxiety, depression and distress in those with a negative result but who later go on to be diagnosed with lung cancer.
Page 65	Sub-section: Incidental findings	It will be of significant importance to ensure incidental findings are appropriately referred, diagnosed and treated. Pathways must be established to manage these where required and modelling should be performed to understand the potential impact at a local level. Unpublished data from YLST, funded by Yorkshire Cancer Research shows more than 50 people have a confirmed other (nonlung cancer), approximately 0.5% of screened participants. Yorkshire Cancer Research supports further research in this area, and believes it will be important to communicate to patients the risk of other incidental findings that may occur as a result of screening. Please note, further to the level of incidental findings in YLST we have started to investigate the possibility of combining lung and kidney screening through an initial exploratory trial (further details found here: https://clinicaltrials.gov/ct2/show/NCT05005195).
) Page 66	Sub-section: Smoking cessation	Yorkshire Cancer Research strongly believes that smoking cessation is an essential element of a lung screening programme. As provided earlier in this written response in relation to Page 2, Point I for the associated document 'Consultation on targeted screening for lung cancer in people aged 55-74 with a history of smoking' our recommendations are that smoking cessation should be an integrated and co-located service, delivered as an opt-out service as standard and offered prior to LDCT, and be delivered by a dedicated team of smoking cessation practitioners, rather than relying on referrals to existing services.

Page 67	It is difficult to assess the balance of harms and benefits of lung cancer screening with LDCT as the outcomes of possible harms are inconsistent across the studies.	It will important that publications from high quality clinical trials and service evaluations are able to contribute to learning in this space in the future.
Page 69	Therefore, evidence addressing criterion 13 (ratio of benefits to harms) is met for volume, applicability and quality of evidence but unmet for consistency of findings. Further testing of implementation strategies is therefore necessary to evaluate the most clinically effective screening approach.	We hope that the findings from YLST, funded by Yorkshire Cancer Research will contribute to the national and international evidence based for the most clinically effective screening approach for lung cancer.
Page 70	Sub-section: Description of the evidence	Please correct the typo at the start of the sentence 'Ocontains a full PRISMA flow diagram'. A qualitative study into views of people at high risk of lung cancer about targeted lung cancer screening in Manchester has been missed off the list. This is Tonge JE, Atack M, Crosbie PA, Barber PV, Booton R, Colligan D. "To know or not to know?" Push and pull in ever smokers lung screening uptake decision-making intentions. Health Expect. 2019 Apr;22(2):162-172. doi: 10.1111/hex.12838. Epub 2018 Oct 5. PMID: 30289583; PMCID: PMC6433322. Available from; "To know or not to know?" Push and pull in ever smokers lung screening uptake decision-making intentions - Tonge - 2019 - Health Expectations - Wiley Online Library
Page 71	The RCTs and cohort studies reported screening uptake	For clarity please further define what is meant by screening uptake. Should this be interpreted as measuring screening participation, rather than using the current definition of uptake used as a metric for assessing breast and bowel cancer screening.

Page 72	There were few concerns about the study methodology which aimed to explore views from a representative sample of the older general population, although this group would not necessarily reflect the characteristics of the cohort who would be invited for lung cancer screening	We would like to reiterate the importance of ensuring participants of future studies reflect the target screening population/capture the opinion of those from culturally diverse communities, cover a range of ethnicities, people of relevant smoking status, different educational backgrounds etc.
Page 73	 inviting a large group of people to express an interest in screening using a set of criteria assess who is eligible and book them for a lung health check (LHC), prior or during the LHC ask detailed questions to evaluate their eligibility for LDCT 	Based on learnings from our funded programmes and other evidence, Yorkshire Cancer Research recommends the use of telephone-based risk assessment meaning only those eligible for LDCT attend an appointment in-person, which may have numerous benefits including saving time, being more cost effective and reducing travel time and costs for patients. This approach is discussed earlier in this written response in more detail in relation to comments on page 30 of the report. The recommendations currently state that people should be invited for a lung screening risk assessment if they are aged 55-74 and 'ever' smokers (based on GP records). Insight from the Manchester trial found that a short audit of GP records (during the trial design phase) highlighted that GP smoking data was of insufficient quality (inconsistent use and incomplete and out of date records) to base invitation on and would have meant that some eligible smokers were not invited. Therefore, only age data was used to inform invitations, and invitees who were interested in lung screening were asked to book a lung health check with a nurse if they were a smoker or ex-smoker. Issues with GP records must be considered in the implementation of a national lung screening programme - there should be an approach for tackling these data issues and ensure those smokers not identified through GP data are invited for

		screening. In some areas with particularly low GP smoking data quality, it may not be appropriate to base invitations off this data. This is also discussed in relation to Point I, Page 2 on the associated document "Consultation on targeted screening for lung cancer in people aged 55-74 with a history of smoking".
Page 73	Uptake of lung cancer screening in the UK was reported in 4 articles from 2 RCTs and 1 cohort study and they reported that between 46.5% and 92.4% who were eligible for a LHC attended their appointment and of those who were evaluated as eligible for LDCT >90% attended.	As with other screening programmes, Yorkshire Cancer Research believe that it will be necessary to tailor invitations and deliver specific interventions to increase engagement and participation in lung screening. Given the target population for lung screening it is not unreasonable to expect lower engagement than with other national screening programmes and therefore any communications to the public must be done with care to encourage participation and delivered across multiple platforms and at both local and national levels. We also recommend producing invitation materials in multiple languages according to the local population. It may also be necessary to ensure adequate resource within translation services both for telephone calls and/or appointments.
Page 74	4061 (46.5%) took attended the appointment and were eligible for screening	Possible typo – please amend.
Page 76	The following year those people who had tested negative	Is the use of the phrase "tested negative" in this context appropriate? For the other screening programmes this is sometimes referred to as a 'normal result' – would this wording be more appropriate?
Page 76	Both positive and negative view points were voiced with the overall balance being that people supported lung cancer screening.	Yorkshire Cancer Research are encouraged to read that people are supportive of lung cancer screening. We would be interested in more recent data following the roll out of the NHS TLHC as well as greater prominence of the current UK clinical trials as we assume more people will have now heard of the concept of lung health checks/lung screening. It will be extremely important that lung

Do so 70	Sub-section: Public perceptions and	screening is well-received by the public and healthcare professionals when rolled out and that the appropriate communications budget and resources are developed by experts.
Page 78	opinions about lung cancer	Move sub-heading so it is on the same page as the following content.
		Findings from Tonge et al (2019)., "To know or not to know?" Push and pull in ever smokers lung screening uptake decision-making intentions. Health Expect. could be included here. The study involved exploring the views of 33 current and ex-smokers in three focus groups held in Manchester in 2016. Lung screening was found to be widely acceptable to study participants. Benefit perceptions included reassurance about lung health and early detection and treatment opportunity. Participant's desire to know about their lung health via screening described as 'push and pull' of views about perceived benefits, emotions (worry about a positive diagnosis and undergoing screening); practicalities such as accessibility; and smoking-related issues including perceptions of individual risk and smoking stigma. The findings were used in the design of the Manchester Lung Health Check pilot.
Page 80	Public perceptions and opinions about lung cancer	It will be crucial before, during and after the introduction of lung cancer screening (and any future screening programme) that there is extensive marketing and communications work (for example public health campaigns) to tackle the barriers to lung cancer screening, as well as misconceptions and stigma. Communications should aim to reduce inequalities in screening uptake, for example between more and less deprived populations, to ensure that screening does not exacerbate any existing inequalities.

Page 80	A total of 1354 (91.7%) thought lung cancer screening was a good idea and of those who were current or former smokers (n=642), 91.6% (n=588) indicated they would participate in screening if they received an NHS invitation, 95.8% (n=615) if they received a GP invitation and 91.9% (n=590) if a pre-scheduled appointment was made for the following month71.	Although this information is encouraging and gives an insight that receiving an invitation from their GP may yield slightly higher interest in a screening programme, it is important to note the difference between intention to screen and actual screening behaviour. Recent headlines in the media have indicated that the NHS TLHC sites have had low engagement highlighting the disparity between intentions and actual behaviour:
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		mortality and morbidity for criterion 11 to be met, particularly as this does not include the results of two large UK based clinical trials (YLST, funded by Yorkshire Cancer Research, and the SUMMIT study, funded by GRAIL Inc). We expect that the evidence on the effectiveness of lung cancer screening should continue to be reviewed as new evidence emerges.
Page 85	Sub-section: Clinical effectiveness of lung cancer screening	Regarding criterion 13, Yorkshire Cancer Research agree there is a need for a UK model incorporating the latest evidence on cost-effectiveness as well as considering the latest evidence on benefits and harms. We hope that with this further evidence criterion 13 will be met.
Page 85	Sub-section: Acceptability of lung cancer screening	Yorkshire Cancer Research are pleased to see that aspects of criterion 12 are met. We suggest that evidence gathering following the more recent roll out of two further UK studies, as well as the NHS TLHC sites will provide further evidence on the acceptability of the full screening pathway, including diagnostic work up and treatment of lung cancer, given this has been implemented across many health systems in England.
Page 85	Sub-sections: Contextual questions	Yorkshire Cancer Research are supportive of summary comments in this section. We agree that lung cancer is well understood, and that lung cancer screening represents a good test for identifying people with early stage disease. We also agree that more research is needed to clarify the best risk algorithm and cost effectiveness – both of which may be addressed through findings of YLST, funded by Yorkshire Cancer Research when published.
Page 86	To address the uncertainty about the best approach to achieve maximum clinical effectiveness in reducing mortality and morbidity from lung cancer screening whilst reducing possible harms to a minimum.	We suggest rewording this sentence to focus on reducing mortality and morbidity from lung cancer, rather than lung cancer screening. For example, 'To address the uncertainly about the best approach for lung cancer screening to achieve maximum clinical effectiveness

		in reducing mortality and morbidity from lung cancer whilst reducing possible harms to a minimum.
Page 86	Sub-section: Limitations	Yorkshire Cancer Research understand the fast-moving nature of this subject and that new articles will be published on a relatively frequent basis. We would like to see agreed time points for further literature searches to ensure the latest evidence is considered within the lung screening programme.
Throughout	53Error! Bookmark not defined.	This error occurs on the following pages: 64, 66, 67, 74, 75 (x3), 76 (x5), 77, 78 (x3), 79 (x7), 80 (x4), 81 (x4), 82 (x2), 144, 146, 149, 155,
Throughout	Formatting of text needs amending so words are not split over pages.	This error occurs on the following pages of the main report: 74, 75, 76, 78, 79, 80, 81, 82.

23-

Name:	Hazel Cheese	eman	Email address:	xxxx xxxx
_	Organisation (if Action on Smoking and Health (ASH) appropriate):			
Role:	Deputy Chief	Executive		
Do you	Do you consent to your name being published on the UK NSC website alongside your response? Yes No			ongside your response?
	on and / or e number	Text or issue to which comments relate	Please use a new row fo	Comment or each comment and add extra rows as required.

Consultation	Consultation recommendations	ASH welcomes the consultation recommendations to:
covernote, page 2		 Recommend a quality assured, targeted screening programme for lung cancer in people aged 55-74 with a history of smoking in the UK Not view the implementation of screening for lung cancer as an alternative to the delivery of high-quality smoking cessation services accessible to all age groups For smoking cessation to be an integral part of the screening programme For using the lung cancer screening strategy piloted by the NHSE Targeted Lung Health Check (TLHC) as a model for implementation
		As outlined in the consultation documents and alongside the recommendations, screening for lung cancer is effective, likely to be cost-effective and is acceptable to both the public and healthcare professionals. Large scale randomised controlled trials have provided conclusive evidence that lung cancer screening programmes detect cancer more frequently, at an earlier stage, and reduce mortality.
		Smoking is a key consideration and smoking cessation is rightfully recognised as an integral part of a successful lung cancer screening programme. An estimated 79% of cancer cases in the UK are preventable. Smoking significantly outstrips other causes of lung cancer, accounting for an estimated 72% of cases and 86% of lung cancer deaths with a further 1% of cases resulting from secondhand smoke.
Consultation covernote, page 2	Third bullet point/recommendation RE using the TLHC as a model for implementation	While the TLHC appears to have been successful and provides a feasible, practical, and effective approach for implementation of a lung cancer screening programme in the UK, there is room for improvement in relation to how smoking is addressed. The evaluation findings indicate that smoking cessation was not integrated into the programme sufficiently

resulting in inequitable access to support and a missed opportunity to support smokers who can otherwise face many barriers to quitting.

An evaluation progress report undertaken by Ipsos Mori on behalf of NHSEI of the TLHC programme from December 2021, found that 31% in those who had smoked within the previous week attended because they thought it would help them to reduce or stop smoking. Despite this, only around half of current smokers (54%) reported receiving advice on quitting or reducing smoking (usually taking the form of very brief advice, with or without referral to support services), with 82% reporting that they found this advice helpful. However, in qualitative feedback the experience of accessing support varied with many reports of referrals breaking down. Some respondents reported feelings of surprise and disappointment and not receiving any advice around smoking cessation.

The concerns identified in the evaluation as to whether GP records are accurately recording smoking status is also of concern. Having an accurate picture of the local smoking population and the extent to which they are adequately being reached through screening will be important for the success of the programme and the impact on health inequalities.

Given the association between smoking and lung cancer and the opportunity to reduce cancer risk and outcomes with smoking cessation, this is missed opportunity. Dedicated funding, a clear protocol and metrics are needed within the programme to ensure all current smokers attending lung health checks are provided with meaningful cessation advice and support.

Metrics should cover a number of things including:

- Rate of smokers attending: In order to ensure health inequalities are reduced rather than exacerbated, metrics need to include the proportion of smokers in the target population that should be engaged to attend screening. There is a steep social gradient in both smoking rates and levels of addiction with the heaviest smokers likely to be the poorest. If screening programmes do not ensure that an appropriate proportion of smokers attend screening (and are provided with advice and support to quit) then programmes risk widening existing inequalities in lung cancer rates between rich and poor.
- Levels of advice provided: all smokers should receive VBA and an offer or support. This is like to be best done on an opt-out basis. All staff can be trained to deliver VBA and free training is already available online.
- Support uptake: Programmes should be judged on whether initial advice translate to engagement with support. Effective delivery of VBA and good referral routes will support this.
- Treatment outcome: Evidence-based smoking cessation support
 has predictable outcomes if delivered well. Services should be
 judged on their performance. However, it may be necessary to flex
 some metrics for areas with very high levels of deprivation where
 barriers to quitting are highest.

Service protocols should include training requirements, equal and sufficient access to pharmacotherapies for smoking cessation, timeliness of access to support and duration of support.

ASH is working with the University of Nottingham to look at optimal delivery models within lung cancer screening context and what an appropriate level of funding would be to secure best practice across the

		whole scheme. This report will be ready for publication in coming months and can be shared with the committee if it suits their timeframes.
External review	Contextual question 1	This section does not appear to adequately recognise the extent to which smoking cessation can improve cancer outcomes and infers all benefits are longer term. This is not supported by the evidence.
		While smoking is the leading cause of lung cancer, smoking cessation does reduce risk of cancer and improves treatment outcomes. Even when diagnosed with lung cancer, quitting smoking can nearly double life expectancy For those who smoke but haven't been diagnosed with lung cancer, quitting can also mitigate and reduce some of the accumulated risk, and unless a person quits their risk of lung cancer continues to grow.
External review	Contextual question 1, risk algorithms	ASH has no comment on whether the risk algorithms used in the review are more or less likely to identify the target population.
		However, we do have concerns about whether the quality of data exists in primary care, or anywhere else, to be able to use a more sophisticated approach. While screening questionnaires could be used, any process needs to mindful of participants that will lost at each stage. This may have a particular impact on inequalities as those with less time, lower literacy, or other barriers to engaging with services may be more likely to be lost from the whole programme.
External review	Contextual question 3	Embedding smoking cessation programmes effectively into lung screening programmes has been shown to halve costs and improve cost effectiveness. This is exemplified by one review in Canada, which found the cost per quality adjusted life year (QALY) for a low-dose computed tomographic screening programme was \$52,000 without a smoking cessation programme and \$24,000 with one. This is prior to accounting for the benefit for other conditions beyond lung cancer.

External review	Review question 4	Effectiveness of the programme should also include the extent to which the programme can also contribute to the avoidance of lung cancer through prompting behaviour change. This will increase the benefit of screening to the healthcare system but also to individuals. Smokers who are screened and do not have lung cancer can still benefit from receiving an intervention which reduces their chances of developing lung cancer in the future (and many other conditions).
External review	Review question 5	There is good evidence that embedding smoking cessation into a lung health check programme is not only acceptable, but expected. For example, some smokers attending the YESS trial reported that seeking smoking cessation advice had been one of their motivators and, as cited above, 31% of smokers attending the TLHC. For a population with entrenched smoking behaviour, quit attempts may be more infrequent and less likely to succeed. Therefore, maximising the opportunity to prompt quit attempts is important.
		Patient feedback in the review (page 77) shows that smoking is intrinsically linked to the lung check for most participants – many older smokers carry anxiety about the impact of their smoking on their health. The feedback in this section demonstrates clearly that the lung health check is a 'teachable moment' for smoking cessation which can accelerate progress towards quitting.
		Conversely not addressing smoking within the lung health check is likely to reinforce pre-existing beliefs among current smokers that their smoking is their fault and something they have to deal with alone. Given unaided quit attempts are the least effective and have the lowest chances of success, reinforcing this idea could have a negative impact on future quitting.
External review	Review question 5	The finding in the external review (pages 74 and 75) that smokers are less likely to attend lung screening than ex-smokers is relevant to addressing

		both clinical risk factors and health inequalities. As smokers they are at greater clinical risk and as people who have not yet managed to quit they are more likely to be experiencing disadvantage – smoking and smoking dependency are linked to socioeconomic status, mental health conditions, educational attainment and other indicators of disadvantage. To ensure that the clinical value of lung checks are maximized and that they make a positive contribution to addressing health inequalities, emphasis must be placed on ensuring that smokers access lung health checks in proportion to their prevalence in the population. Lessons can likely to be drawn from the COVID-19 vaccine uptake work. Specific requirements to ensure access by target populations experiencing higher smoking rates as part of the screening programme would likely be appropriate.
External review	Review question 5	The evidence set out on pages 79 and 80 regarding older people's views of lung cancer demonstrates the need for more insights work among communities likely to be targeted by and benefit from lung health checks.
		People's views of lung cancer are likely informed by experience. Older more disadvantaged smokers will be more likely to have grown up in communities where smoking, and therefore lung cancer, is common. Understanding how best to communicate the benefits of detecting cancer early and the benefits of stop smoking will be valuable in overcoming some of the misperceptions that may prevent uptake of a lung health check. Some of this work can and should be done nationally. However, engaging with communities in a meaningful way will also require more local engagement and the skills of local government public health teams.
		While not necessarily a matter for the screening committee, ASH sees a clear role for both local government public health teams and the NHS in maximising the uptake and quality of lung health checks. Both partners have deep and unique connections into their local communities, and the

value they could potentially add to lung health checks deserves further consideration.		value they could potentially add to lung health checks deserves further consideration.
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Name: Jonathan Rodrigues

Organisation: British Society of Thoracic Imaging Role: Guidelines LeadCondition: Lung cancer

BSTI full endorses a national lung cancer screening programme. As a society of thoracic radiology imaging specialists, we would like to highlight the joint Royal College of Radiologist and BSTI document

(https://www.rcr.ac.uk/sites/default/files/final_pdf_considerations_to_ensure_optimu m_roll-out_of_targeted_lung_cancer_screening.pdf) that sets standards for imaging and reporting. Cost effective analysis of a lung cancer screening programme will rely on expert thoracic radiology reporting.

25-

Name: Elspeth Spencer Organisation: xxxx xxxx

Role: Consultant Respiratory Physician

Condition: Lung cancer

I fully support the introduction of a national screening programme for lung cancer that is targeted at risk people and performed alongside a lung health check that includes advice and help to treat tobacco addiction. This is the only way to diagnose lung cancer at an early stage in a higher proportion of people, to enable treatment with curative intent and significantly improve survival. The pilots have developed appropriate ways to deal with incidental findings and minimise harm

Name:	3		Email address:			
Organisation (if Hull University Hospitals Teaching Ni appropriate):			ng NHS Tru	st and	NHS Hull CCG	
Role:	ole: Programme Lead, LHC Hull					
Do you	consent to	your nam	e being published on the UK Na	SC website	alonç	gside your response?
Section	Section and / or		Text or issue to which comments relate		Comment	
page number				_		se a new row for each comment and add extra required.
Cover note page 2			er re-screening people who have a f smoking who are not eligible for	an LD cor	CT at	mmend re-screening smokers not eligible for their initial lung health check. Include as part of ion\expansion every 2 years if triggered risk to f the programme.
						consider people who smoke but recorded as ker on GP registers
				Sm nor Brid ces end nur refi	noking n-clinice of Adv ssation gagem se tria resh tr	cessation service: it was vital all clinical and cal staff within TLHC receive training on Very ice to ensure all staff are educated in smoking a. Pre-COVID, there were poor levels of the with smoking cessation support following age, but this rose to 70% following post covid aining on VBA emphasising the shortness and these of the intervention, the introduction of

		specific scripts for triage nurses to use to support improved referral into the service, and the first promoted follow-up contact and assessment being done via telephone. Hull TLHC is now the second highest source of referral to Hull stop smoking service April 2021. This demonstrates that participants are receptive to smoking cessation interventions when triage staff are trained effectively.
Cover note, page 2	ii. which multivariable risk assessment tool or combination of tools should be used to maximise efficiency within the screening programme	Prefer to carry on with both current risk scores.
Cover note, page 2	iii. further refinement of LDCT schedule for those with negative scans	Participants discharged with nodules at 12 months should be recalled in 2 years together with participants discharged at 24 months.
		Need to balance the likelihood of developing cancer with the likelihood of doing harm (including raising anxiety in patients who will never develop lung cancer, but we don't know who they are)
Cover note, page 2	iv. how the cost effectiveness of incidental findings from screening might be evaluated in the cost effectiveness model	Need to compare with cost effectiveness of not finding things ie if don't diagnose coronary artery calcification, lung cancer and not doing spirometry for COPD.
		There is a need to balance screening with consequential findings and to distinguish what is generated that is business as usual and add cost associated with this across the whole spectrum.

There is a need to assess the impact across the whole healthcare system, for example, additional theatre capacity, thoracic surgeons, radiology reviews, additional biopsies and scans, histopathology, lung function, PET-CT etc. Outsourcing scanning and reporting is expensive. The radiology workforce is a risk as resources are defined and specialist at the risk of other specialities. Respiratory nurses also a risk as recruiting from one pool. Lower grade not thought to be appropriate. There is a need to maintain nursing teams and grow a flexible and extendable team of expert nursing staff. Suggest local centralised, trained workforce to manage the service. Also thisgnificant increased workload to primary care in management of incidental findings causing work pressures, risk exacerbated by diminishing clinical workforce in primary care settings
An impact assessment is suggested. Resources could be diverted and workforce planned out. Suggest local centralised, trained workforce to manage the service.
Costing primary care clinicians to tackle inequalities such as coronary artery calcification etc. which might cost in the short term reducing the number of individuals who develop CVD will reduce the longer term costs of treatment (although will increase the social care costs because people are living longer). Is the intent for this to be a pure lung cancer screening
treatment (although will increase the so- because people are living longer).

		participants and we would wish to revert to the original protocol and continue spirometry. Also potential to add in Q-risk and serum lipids for this cohort of participants.
Cover note, page 2	v. issues of inequalities	Due to local geography, flexibility of mobiles allowing local flow of the service will mitigate inequalities re access The process fundamentally looks to close some of the inequalities gap as smoking is more prevalent in deprived communities, late presentation of cancer is higher in deprived communities, so basing the LHC on this feels like it will help with some of the inequalities work However, funding is not always proportionate to deprivation from a primary care perspective From a programme perspective not all LHC planners/commissioners will have access to a PH consultant who can spend time supporting the programme so how do those areas try to target resources What about non-smokers in areas with poor air quality – likely to be more deprived areas, but individuals may not smoke but are at similar risks.

Name: Rosie Mughal

Organisation: AstraZeneca UK Role: Associate Director UK Policy

Condition: Lung cancer

AstraZeneca welcomes the draft recommendation from the UK National Screening Committee (NSC) to introduce a targeted screening programme for lung cancer in people aged 55-74 with a history of smoking.

Lung cancer is the leading global cause of cancer deaths. In the UK only 16% of patients survive five years or more after diagnosis.(1) This poor prognosis is a direct consequence of the typically late stage of diagnosis, when treatment options are significantly decreased. However, we can change this. Evidence shows that lung cancer screening shifts the detection of cancer to earlier stages, significantly improving outcomes. (2)

Given this evidence, the NSC's recognition in its draft recommendation of the urgency of unmet need in lung cancer and importance of pursuing a timely recommendation is strongly supported by AstraZeneca.

This consultation response sets out our support for the NSC's interim findings on cost-effectiveness and provides an overview of our own modelling which mirrors the NSC findings, highlighting the value and cost-effectiveness of a national lung cancer screening programme.

Given the strength of the NSC's interim economic findings and anticipation that the final modelling will support the case for lung cancer screening, we have used this response to set out key issues which we believe should be included in the NSC's final recommendation to Government to support timely and impactful implementation of a successful programme.

We acknowledge that managing implementation is not the responsibility of the NSC but hope that these recommendations may be valuable for the Department of Health and Social Care, devolved administrations and the NHS to take forward with appropriate resourcing.

We look forward to the NSC's final recommendation and stand as a supportive partner in bringing about this change which will represent a significant step forward in turning the tide on this disease.

The economic model:

AstraZeneca welcomes the findings in the interim report on the cost-effectiveness of low dose computed tomography (LDCT) screening for lung cancer in high-risk individuals. We are supportive of the findings indicating that 'LDCT screening strategies would likely be cost-effective compared to no screening at a willingness to pay of £20,000 per quality adjusted life-year (QALY) gained' and that 'all LDCT screening strategies were estimated to be more effective than no screening, suggesting a QALY gain of 0.0006 to 0.00029 per person, depending on the strategy.' (3)

AstraZeneca has undertaken its own modelling based on long-term insights provided by the NELSON Study into the cost-effectiveness of volume-computed tomography in lung cancer screening. The study evaluated the cost-effectiveness of lung cancer screening with volume-based LDCT versus no screening for asymptomatic high-risk populations across the UK.

The analysis was conducted using a decision tree and a state-transition Markov model, to simulate the identification, diagnosis, and treatments for a lung cancer high-risk population, from a UK NHS perspective. The modelling predicted the number of screen-detected lung cancers, costs, QALYs, and the incremental cost-effectiveness ratio (ICER).

The study concluded that annual volume CT screening resulted in 129,150 more lung cancers detected in early stage, and 80,652 fewer cases in late stage, averting 68,300 premature lung cancer deaths and 996,371 additional QALYs in comparison to no screening. The ICER was £3,686 per QALY. (4)

The findings from this study mirror the positive findings of the NSC model, also showing that annual LCS with volume based LDCT for high-risk asymptomatic populations is cost-effective in the UK, at a threshold of £20,000 per QALY, and therefore an efficient use of NHS resource. The conclusions bolster the findings of the NSC economic model, demonstrating the improved outcomes for lung cancer

patients and making the case that national lung cancer screening should be implemented in the UK.

The NSC interim report highlights that further work is needed on the model. It's encouraging that the NSC anticipates the case for lung cancer screening being strengthened by the additional analysis to address uncertainties, which aligns with our own cost-effectiveness modelling. We therefore look forward to reviewing the final results.

Supporting rapid implementation of a lung cancer screening programme:

Given the strength of these economic findings and the interim positive recommendation, it's important that those responsible for roll-out are already planning implementation to enable equitable and high uptake of screening that drives the impact of the programme and supports its cost effectiveness.

AstraZeneca supports the interim recommendation that the Targeted Lung Health Checks (TLHCs) are an effective model for the expansion of a national lung cancer screening programme. It is also worth considering the current drive in expanding Community Diagnostic Centres as an additional route for delivering screening within existing infrastructure.

We believe a thorough review of the impact of TLHCs across infrastructure, workforce, pathways, and screening uptake should be undertaken to enable the Government to better understand resourcing for a national lung cancer screening programme, and ensure best use of efficiencies within the system as well as targeted investment where there are notable gaps.

As set out above, this section includes recommendations based upon a literature review undertaken by AstraZeneca on implementing lung cancer screening programmes around the world and on findings from lung screening trials. The recommendations have been divided across the topics of infrastructure, workforce, patient pathways and patient activation, identifying tangible solutions to help deliver a successful programme.

Infrastructure

It is estimated that there are around 500-700 CT scanners in England.(5) The UK has less CT scanner capacity than other developed countries, ranking it fourth lowest in the OECD. (6) These shortages will need to be addressed when implementing a national lung cancer screening programme. The implementation of such a programme will also require improvements in the IT system that currently makes the collation of images and data difficult.

The following recommendations should be shared with Government:

- Invest in scanners to increase capacity and ensure equitable distribution across the country
- Optimise the current IT system to ensure full connectivity across all relevant primary and secondary care sites allowing for a national screening data set with image sharing, reporting network, training and quality assurance capabilities
- Consider how Artificial Intelligence-led technologies can alleviate workload and streamline opportunistic case-finding, facilitated through centralised imaging databases such as the Greater Manchester PACS project

Workforce:

A recent review of diagnostic services recommended that an additional 2,000 radiologists and 4,000 radiographers were needed to meet current demand, as well as an expansion of 2,500 assistant practitioners and 2,670 support staff. (7) To overcome challenges in the current workforce shortage, the following recommendations should be shared with Government:

- Increase recruitment and encourage former radiographers, radiologists, and clinicians to return to work
- Introduce training programmes to meet changing demands in skillset as the lung cancer landscape evolves over the medium-to-long term

Patient pathways:

The introduction of a national lung cancer screening programme will result in an increase in diagnoses, referrals and incidental findings. This shift will result in increased demand for biopsies and CT-guided lung ablation, for pathology and genetic tests to identify increased cancer sub-types, and for surgery, putting pressure on the workforce and on clinical infrastructure.

To prepare for these changes and ensure patients progress smoothly from screening into the correct care pathway, the following recommendations should be made to Government:

- Integrate a national cancer lung screening programme into the existing National Optimal Lung Cancer Pathway
- Amplify the impact of lung cancer screening by implementing it into other public health initiatives including smoking cessation programmes

There is also growing recognition of the need to address the burden of COPD, including within the NHS Long Term Plan, Core20Plus5 and the Life Sciences Vision. Pre-pandemic, it was the second most common cause of hospital admissions (8) and had a cost to the NHS of £1.9 billion a year. (9) COPD is the fifth most common cause of death in the UK, causing nearly 30,000 deaths every year in England alone. It is also a significant risk factor for future incidence of lung cancer. (10)

There is an opportunity to maximise screening efficacy by incorporating COPD case-finding into the programme's core remit (in addition to early diagnosis of lung cancer). An important step towards doing this is also including spirometry in the mandate, as included in the TLHC protocol. (11) Not only will this provide a longer-term benefit of prevention by detecting and managing a cohort more at risk of lung cancer in the future, it will provide additional value for money. A study from Lambe et al. demonstrates that there is cost effectiveness in early detection of COPD: 'Model-based evaluation of the long-term cost-effectiveness of systematic case-finding for COPD in primary care' (2018).(12)

Looking at the TLHC Standard Protocol, rather than being treated as an incidental finding, we would recommend that if any form of COPD is detected (via Spirometry or CT) then the mandate should require that the responsible radiologist should have

a clear patient pathway to follow. A named individual should be responsible for ensuring the patient is followed up within primary or secondary care as appropriate. Additionally, a detailed summary of the findings from screening should be sent to a patient's GP. This will mean that even patients who already have a previous COPD diagnosis will have the opportunity for treatment review if their disease has progressed.

Patient activation:

Research shows that uptake of screening checks is lowest amongst those from socio-economically deprived backgrounds who are more at risk of lung cancer.(13) The latest TLHC data shows that only 35% of patients attend their lung health checks. (14) These figures indicate that work will be needed to ensure consistent engagement with a future national lung cancer screening programme delivered through this model.

With regard to user acceptability, research into the TLHCs has shown that their framing as a 'lung health check' avoids some of the stigmatisation of lung cancer, and the communication of information and benefits to the participant at every step of the process has enabled shared decision making and increased participation.(15) Further research highlights the importance of service design in helping secure attendance from people in lower socio-economic positions. For example using mobile screening units can help address the physical, logistical and financial barriers to attendance by reducing transport costs and the need for absence from work. (16) These lessons should be shared with the Government as they plan the national expansion of screening. The following recommendations should also be shared to support uptake of screening:

- Roll out a patient activation campaign, targeting key audiences, from lower socio-economic backgrounds. This campaign must address stigma around lung cancer and highlight the importance of early diagnosis
- Ensure patient data, including GP smoking records, are up to date to enable correct identification of target audiences for campaigns and screening invitations

Conclusion:

The draft positive recommendation from the NSC on the implementation of a national lung screening programme is hugely welcomed and moves us closer to improving lung cancer outcomes, saving lives, and addressing health inequalities. With the Government looking to meet the NHS Long Term Plan's ambition to increase cancers diagnosed at stages I and II to 75% by 2028 in England, a final positive recommendation will also provide an important mechanism to support this ambition in a cancer with significant unmet need across the UK.

AstraZeneca is fully aligned with the findings in the interim cost-effectiveness model. They mirror our own data and clearly demonstrate support for a final conclusion of a positive recommendation. Given the strength of this evidence, once a final recommendation is over the line, the Government and NHS must push forward with implementation at pace across the UK. Momentum must be sustained through supportive implementation plans in each of the devolved nations and adequate funding to ensure rapid roll out.

We hope the inclusion of recommendations for the Government in this response might be a useful addition in your final paper to expedite implementation and we look forward to working with the community in this roll-out.

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Name: xxxx xxxx

Organisation: Novartis
Role: Access xxxx xxxx

Condition: Lung cancer

Novartis response to the lung cancer screening consultation

Overview

Novartis welcomes the consultation on targeted screening for lung cancer and supports the National Screening Committee's (NSC) recommendation to approve screening for those aged 55 – 74, with a history of smoking. Novartis believes that a national lung cancer screening programme is critical given the high prevalence of the condition and low 10-year survival rate of 10%. However, Novartis acknowledges reservations expressed by the NSC regarding false positives and the adverse impact this can have on patients. Novartis believes that as the screening programme is rolled out there are opportunities for partnership and collaborative working between the health service, third sector, academia, and industry to improve on techniques and ameliorate these concerns. The NHS breast screening programme demonstrates the potential of screening programmes and the impact they can have in identifying cancers at an early stage. The programme has found cancers at a 'generally early stage' and led to a 1,300 annual reduction in deaths.

Innovating to support the rollout of screening and produce new evidence

Novartis believes that any new screening programme should be supported by utilising new diagnostics, innovative technologies, and genomics to increase the accuracy of tests and support patients to receive a faster and more accurate diagnosis. In particular, Novartis recommends that in the second phase of research, screening alongside genomic testing should undergo an investigation to help identify genetic factors which may increase the likelihood of developing lung cancer. This would also help to create an evidence base for the development of a more cohesive and efficient diagnostic pathway through better integration and linkage between different diagnostic services. This can be used to determine the genetic risk of cancer as well as other health issues, as highlighted in the NSC's 'Generation Genome'. In the long term, this can also help to support the spread of personalised medicine across the system. One fundamental barrier to achieving this is ensuring that data is both accessible and interoperable, as such Novartis recommends the NSC should engage with NHS Trusts and ICSs to ensure that data collection and storage is consistent across care settings.

Lung screening can act as a tool to support the identification and recruitment of patients that are eligible for clinical trials. Novartis is the leading sponsor of clinical trials in the UK and recognises the UK's many potential strengths in R&D including data, scientific expertise and a health system that can act as a test bed for innovation. However, the UK is becoming a less attractive market to conduct clinical research, compounded by the relatively slow recovery from COVID-19 in terms of restarting trials and commending new trials, compared to similar countries. In the context of growing global competition to attract commercial studies, the UK needs to ensure industry can set up trials quickly and efficiently and recruit more patients into studies.3 A national programme for lung cancer screening helps to achieve this by spreading clinical research outside of large academic centres and in the community. However, this will require greater collaboration with the health and social care system, third sector and industry.

Reducing health inequalities

Through our health inequalities pledge, Novartis has committed to collaborating with policymakers and healthcare systems to build solutions for faster diagnosis and earlier intervention for those population groups who are at the greatest risk of ill-health and poor health outcomes and would welcome the opportunity to partner with the NSC team. Novartis is supportive of early diagnosis and screening programmes as an effective means of encouraging awareness of symptoms and supporting the NHS in achieving the Long Term Plan target of diagnosing 75% of cancers at stage 1 or 2. However, it is important to recognise that there are socioeconomic inequalities which may impact the uptake of the lung cancer screening programme. Data suggests that smokers may be less prevention-minded than average target groups for other cancer types leaving them at an already biased inequality. The NHS and PHE will need to run National campaigns to encourage participation in screening programmes with the implementation of such programmes delivered closer to communities. The model highlighted in the Bringing Lung Cancer Screening into Communities pilot is one successful example of this.

It should be acknowledged that patient advocacy groups (PAGs) play an important role in raising awareness of cancer signs and symptoms and continued to do so during the COVID-19 pandemic. Novartis notes a recent collaboration with Prostate Cancer UK and NHS England which sought to encourage men to check their symptoms using an online screening tool. This should act as an exemplar for a co-produced campaign by NHS England (NHSE) and the third sector. Recognising the success of the COVID-19 vaccine rollout, there are also further opportunities for partnership between industry, the NHS and PAGs to raise awareness of the signs and symptoms of cancer. Novartis believes there is an opportunity to leverage the success of the ZOE study app, which was used during the COVID-19 pandemic to identify new symptoms of COVID-19. The app also featured a symptoms tracker that can alert patients to seek medical advice based on their symptoms.

With the collection of greater population level data on lung cancer incidence and outcomes via a national screening programme, Novartis believes there are further opportunities to analyse datasets utilising technologies such as artificial intelligence. This can be coupled with behavioural analysis to assess the various barriers to patients engaging with the health system and coming forward for screening programmes. This is vital to support the health system in moving towards a population health approach and will help

ICSs to create tailored campaigns for at-risk populations and those who suffer from the greatest health inequalities. This could support the NSC and the Office for Health Improvement and Disparities to deliver on key government commitments to level up outcomes across the country and reduce health disparities.

Tackling the backlog

Research suggests the COVID-19 pandemic is expected to cause an increase in late-stage presentations of lung cancer. This research has highlighted the need for a multifaceted strategy including public awareness campaigns to promote healthcare engagement for patients with persistent chest symptoms. This analysis highlighted the lack of importance that is currently placed on the symptoms of lung cancer, particularly in areas of higher socioeconomic deprivation. To alleviate some of the current pressures on primary care, Novartis recommends virtual appointments for those who are referred to screening programmes. This can be supported by digital applications that can support the collection of patient-reported outcome measures (PROMs) which help to keep patients out of secondary care settings. This has proved effective in alleviating capacity issues in previous Novartis Joint Working Projects. Novartis is also funding a pilot for the Vinehealth digital platform which utilises behavioural science and AI to deliver highly personalised patient support to optimise cancer care. The platform utilises a mobile app that incentivises patient tracking of symptoms, toxicity, and adherence data and pairs this with lifestyle data from smartphones and wearable devices. Vinehealth is able to provide personalised patient support and track patient reported outcome measures (PROMS) and patient reported experience measures (PREMS) data in real-time. Furthermore, Novartis welcomes the rollout of Community Diagnostic Hubs and believes they will help to combat capacity pressures on primary and secondary care. The Hubs should be utilised to conduct screening programmes, given their location in the community and ability to conduct multiple tests in a single, off-site care setting. However, there must be a whole system approach to ensure screening programmes, such as in lung cancer, work to encourage engagement with the health system.

Name:	1 - 3		ail dress:	xxxx xxxx
Organisation (if Cancer Research Wales appropriate):		Cancer Research Wales		
Role:	Role: Policy and Public Affairs Manager			
Do you	consent to	your name being published on the UK NSC w	vebsite along	gside your response?
Section	on and / or	Text or issue to which comments relate		Comment
page	number		Please u	se a new row for each comment and add extra required.

In response to the consultation covernote and associated External review against programme appraisal criteria for the UK National Screening Committee.

Cancer Research Wales supports the UK UK NSC proposal for a quality assured, targeted screening programme for lung cancer in people aged 55 – 74 with a history of smoking (covernote bullet point 1).

It is our view that on balance a targeted screening programme of this design, implemented across Wales will identify people ordinarily at risk with asymptomatic lung cancer, contributing to more positive patient outcomes than at present.

A growing body of evidence from UK-based pilots and trials – documented within the External Review, points to the effectiveness of targeted lung checks amongst the atrisk population. The UKLS trial demonstrated "it was possible to detect lung cancer at an early stage and delivering potentially curative treatment in over 80% of cases". Such an intervention, conducted at scale across the UK should be a cost-effective exercise – we hope the UK NSC cost-effectiveness report confirms this is the case.

This body of beneficial evidence outweighs the potential harms commonly associated with screening, such as false-positives, over-diagnosis, incidental findings, distress, and emotional trauma. Additional research, that's able to draw upon data from a far larger screened population, will assist with better striking the balance, and refining the selection criteria to assist with reducing harms.

No screening programme of this nature is currently provided or being piloted in Wales, though a pilot project is planned irrespective of the UK NSC's decision.

A targeted screening programme for lung cancer has the potential to impact when and where lung cancer is diagnosed. The contextual factors unique to Wales leads us to support additional action to diagnose more lung cancers earlier when they are more treatable, and more survivable.

ICBP Module 4, based on 2012 - 2015 data found that lung cancer in Wales has been associated with incidental diagnosis (1 in 3 diagnosis, however a more recent study, published in 2022 and based on 2019 – 2020 cancer registry data found lung cancer is more recently associated with diagnosis in an emergency setting (1 in 3 diagnosis). Lung cancer is also becoming one of the common cancers diagnosed across Wales via the Rapid Diagnostic Centre vague symptom pathway. In these settings, lung cancer is diagnosed at a late stage, with few, if any curative treatment options.

The number of people being diagnosed with lung cancer via the urgent GP route has fallen by an alarming rate over the last decade. Over the period constituting the ICBP4 study, 2012 – 2015 just over half (52%) of people were diagnosed via the urgent GP route, that has fallen to around a third in 2020.

Page 86 Recommendations and research implications	Lung screening programmes also provide excellent platforms for medical imaging and biomarker research. The non-intrusive incorporation of research into lung cancer screening platforms will certainly improve and refine targeted lung cancer screening as it did during the NELSON 10-year study. Also, research offers the future possibly to extend screening beyond the current targeted population in a
	cost-effective way without the risk of over-diagnosis and subsequent harm of repeated low dose radiation scans. One in four lung cancers in UK are now in non-smokers. While these are outside the scope of the current targeted cohort, we hope that future studies will drawn up, discussed and planned with these stakeholders in mind.
Covernote to the consultation.	We also welcome the additional UK NSC recommendation concerning the further work proposed by the UK NSC concerning the potential widening of scope and ongoing optimisation of targeted lung cancer screening programmes across the UK nations (covernote bullet point 4).

Name:	Jon Foster	Email address	xxxx xxxx
Organisation (if appropriate):		Asthma + Lung U	<
Role:	Role: Senior Policy Officer		
_	onsent to your nar e your response?	me being publishe	ed on the UK NSC website

Asthma + Lung UK is extremely supportive of the TLHC programme with the offering of quality assured, targeted screening programme for lung cancer in people aged 55–74 years of age with a history of smoking intended to identify it at a stage where effective treatment can be delivered. We believe this also has the potential to make a significant difference to the diagnosis and management of a wide range of other lung conditions as well, as well as driving the delivery of enhanced smoking cessation in this high-risk population. We are keen to ensure that the potential of the programme is fully realised ensuring (i) timely diagnosis of lung cancer (ii) accurate identification and action on other lung conditions identified (iii) integration of high-quality evidence based smoking cessation (iv) integration of TLHC into breathlessness pathways including spirometry and symptom screening tools (v) positive steps to ensure uptake of TLHC targets the highest risk populations for smoking related disease - considering deprived groups, people in social housing, the homeless, people with mental health conditions and the LGBT communities.

We strongly support the stated intention that smoking cessation should be an integral part of the screening programme, and would encourage an integrated screening and smoking cessation service that includes interventions and treatment on site before a referral into existing smoking cessation services. There is growing evidence that attendance at the TLHC is a "teachable moment" and that immediate provision of smoking cessation support is effective, being associated with a substantial increase in quit rates at 3 months. In addition, there are significant opportunities to further respiratory research expanding our understanding of early disease, and for ensuring that people with lung disease are able to access programmes such as pulmonary rehabilitation, appropriate pharmacotherapy and smoking cessation support, which are known to be both effective and cost effective, before their condition has progressed.

The opportunities for improved diagnosis, better patient outcomes, accelerated respiratory research and reduced future demand on the NHS are significant.

1. The case for maximising the diagnosis of COPD and other lung conditions

The cohort invited to attend TLHCs is very likely to include those who have or are at risk of developing a range of other medical problems, especially respiratory conditions. In order to maximise both the effectiveness and cost effectiveness of TLHCs, efforts should be made to identify and diagnose these systematically. The Interim Cost Effectiveness Report, at page 9, states that:

The model does not consider the costs or health impacts of incidental findings from LDCT screening. Thus, any additional benefits unrelated to lung cancer that may arise from LDCT screening have not been incorporated.

At page 76 the Interim Cost Effectiveness report suggests further development of ENaBL, including 'the impacts of smoking cessation and incidental fundings' and we fully support this. We would like to see a more holistic consideration of the impact a screening programme would have on the highrisk target population, where the identification of other respiratory conditions such as COPD and pulmonary fibrosis is likely. This is likely to further increase the cost effectiveness of TLHCs.

It is extremely likely that more cases of suspected incidental respiratory conditions are identified than of suspected lung cancer:

- Data from the NELSON trial and Manchester Lung Health Check pilot, as referenced in the external review published alongside this consultation, suggests only 1-2% of attendees are diagnosed with early lung cancer, but many more reported obstructive spirometry results.
- Recent research in Spain and the Netherlandsⁱⁱⁱ indicates that the prevalence
 of bronchiectasis in individuals participating in an international multicentre
 lung cancer screening consortium that included LDCT (I-ELCAP), was 11.6%.

There are also suggestions that diagnosis of other respiratory conditions may aid cancer outcomes; recent research in Canada has found that earlier diagnosis of COPD is likely to prevent delays in lung cancer detection, and that 55% of all lung cancer patients in Ontario had coexisting COPD.^{iv}

Patients identified with these conditions, who would have otherwise remained undiagnosed, can then be given treatment and advice to manage their conditions – something that will improve their health outcomes and reduce future NHS demand. Looking specifically at COPD, there are thought to be around 1.3 million people in the UK, around half of the entire case load, who have this condition but remain undiagnosed. Vi

TLHCs are of course not the main vehicle for solving this problem, but their potential to make an impact on the diagnosis and subsequent treatment for wider respiratory conditions should not be underestimated.

2. Mandated use of spirometry

Spirometry was included as a mandatory test in the original TLHC protocol. Existing Lung Health Check sites have not had to deliver spirometry since March 2020, due

to the COVID-19 outbreak which prompted a change in practice. Despite the publication of spirometry guidance making clear that spirometry is not an aerosol generating procedure, we are deeply concerned by reports that spirometry is no longer a mandated part of the Lung Health Check and that some existing sites will not be restarting spirometry. This is out of line with the original Lung Health Check protocol and will significantly limit the ability of TLHCs to diagnosis conditions such as COPD.

This needs to be combined with systematic assessment of screening symptoms (cough, sputum, breathlessness), ideally making use of a validated self-completion symptom score such as the CAT questionnaire.

Everyone who attends for a low-dose CT scan will be at high risk of both lung cancer and COPD, so there will be no need to stratify those who need spirometry and those who do not. Mandatory spirometry testing is essential for the diagnosis of COPD and pulmonary fibrosis, as per <u>NICE guideline [NG115]</u>, and we would like to see this clearly incorporated within the TLHC protocol. With 51% decline in COPD diagnosis rates in 2020^{vii} (expected to be similar reduction in 2021) TLHCs have a role to play in picking up individuals living with undiagnosed COPD and helping tackle the pandemic backlog.

It is important that spirometry testing is done by someone with the necessary qualifications, being accredited on the ARTP Spirometry National Register, and this is also necessary for those HCPs interpreting spirometry results. While this will require a sufficiently trained workforce on site for assured spirometry to be performed, we believe that the benefits clearly justify this. The programme could also provide a vehicle through which new spirometric devices can be tested and/or validated.

We believe that the available evidence suggests that the addition of spirometry is likely to be a costeffective measure. When looking at the long term effectiveness of COPD case finding Lambe et al (2019) found that 'the incremental cost-effectiveness ratio of systematic case-finding versus current care was £16 596 per additional QALY gained, with a 78% probability of cost-effectiveness at a £20 000 per QALY willingness to-pay threshold.' This study was conservative in its approach and did not for example include smoking cessation within the cost effectiveness calculation, something known to be extremely cost effective. In particular, there is evidence that the identification of lung function abnormalities and sharing this with smokers, is itself a prompt that enhances quit rates. VIII

In addition, Whittaker et al 2022 found that even a single moderate COPD exacerbation increased the risk of both the number and severity of future events and, subsequently, the risk of COPDrelated, and cardiovascular-related mortality. This strengthens the case for early intervention, diagnosis and treatment, from both a patient outcomes and NHS systems cost effectiveness perspective.^{ix}

The effective diagnosis of conditions such as COPD and bronchiectasis, for which spirometry is essential, offers additional benefits which are extremely likely to further increase the effectiveness and cost effectiveness of TLHC. For example, Pulmonary Rehabilitation (PR) is known to be costeffective and to lead to cost savings. The NHS COPD Commissioning Toolkit which states that PR is "substantially below the NICE threshold for cost effectiveness, at only £2,000- £8,000/QALY" and that "It has also been shown to be cost-saving. One recent study showed an overall cost saving of £152 per patient per pulmonary rehabilitation programme."x

As with smoking cessation, Lambe et al did not take PR into account within their cost effectiveness calculations. The use of spirometry within TLHCs, with patients who have limiting breathlessness passported into a relevant PR programme, will clearly result in additional benefits.

While we believe that the evidence for mandatory spirometry is strong, we are aware that it is not as well developed as the case for LDCT scans within this population. Should the NSC not go ahead with mandatory spirometry despite the high level of incidental findings within the target population, we would encourage the NCS to consider working with partners to develop a research component within TLCH in order to strengthen the evidence in this area. Evidence for the potential benefits of spirometry within this population is clear.

We are also aware of concerns around the evidence that early diagnosis for conditions such as COPD does not necessarily result in better patient outcomes; as pointed out by the National COPD Policy Action Plan^{xi}, significant clinical inertia is common within the treatment of COPD and there is a real need to improve standards of care and supported self management. We do not however believe that poor standards of care should disqualify early and accurate diagnosis but rather that both are areas in need of improvement. This issue is especially important from a patient perspective where diagnosis enables someone to take action and better manage their condition, and with good evidence that the earlier this happens the better for both patients and the NHS.^{xii}

3. Unintended consequences

Concerns have been raised with us about the pathway of care for patients with lung symptoms not considered at high risk for lung cancer. Such patients may not have CT scanning immediately available to them. A CT-first pathway for older people with lung symptoms alongside a national screening programme for high-risk individuals may be appropriate to address this issue. See:

https://cdn.shopify.com/s/files/1/0221/4446/files/final_Taskforce_position_paper_on_ CTfirst_approaches_- May_2021.pdf?v=1623918146

4. The case for detecting worsening conditions within those who already have a diagnosis of COPD or other lung diseases

Under-treatment of those with a COPD diagnosis is known to be a problem, leading to a greater risk of disease progression. 38% of those admitted to hospital with a COPD exacerbation remain under treated post hospital discharge, xiii,xivxv for example, while our survey of over 8000 people with a diagnosis of COPD found that 75.5% did not receive the five fundamentals of COPD care as set out in NICE clinical guidelines.xvi Unsurprisingly, those who did receive the five fundamentals of COPD care reported better outcomes and a better ability to self-manage their condition. We believe that for those with an existing diagnosis of COPD who undergo a TLHC, providing their GP with a spirometry reading and a LDCT scan offers a fantastic opportunity to review their situation, to detect any potential deterioration, and to take appropriate action.

As pointed out by the National COPD Policy Action Plan^{xvii}, significant clinical inertia is common within the treatment of COPD, and the use of TLHCs in this manner could be extremely beneficial above and beyond the programme's core aims.

Multimorbidity is the norm rather than the exception in people with COPD, so holistic approaches are desirable.

5. Data quality

TLHCs must be offered to the widest possible eligible population. We have been told that some pilot areas have suggested that patient smoking information is not recorded correctly in GP records. We would like to see recommendations for PCNs, both to improve accuracy of this data, and to generate new, accurate data. This might be achieved through the greater use of Very Brief Advice (VBA) for smoking cessation by GPs (see the smoking section below), especially within the 45 – 74 age group, in order to screen for eligibility for TLHCs.

Our own research into the use of VBA by GPs in the UK found that over half have never had any training in VBA. Just 2% said that the training they had done was comprehensive, and only 8% of GPs use VBA on a daily basis. VIII Clearly there is huge room for improvement on this issue, with the benefits accruing to TLHCs and the wider NHS.

We would be interested to know more about alternative sources of data that have been used within the pilots, such as data from local stop smoking services.

6. Frequency of TLHC invitations

The protocol does not currently specify the frequency in which eligible people should be invited to attend a scan. The original Lung Health Check protocol stated that everyone who had a check through this programme would be invited back two years later for a second scan, with this continuing until they are over the upper age limit (75), and we support this approach.

7. Potential for false reassurance from a negative screen and deferral of seeking evaluation of emergence respiratory symptoms

We have some concern regarding the false reassurance a negative screen may afford in a broader context of lung health. It will be important to ensure that patients understand screening as a 'point in time' evaluation and that they receive clear advice that they should seek healthcare support for any emergent, or ongoing, lung symptoms regardless of screening results.

Breathlessness as a symptom is frequently either downplayed or overlooked as part of the ageing process. If TLHCs could play a role in changing this perception, especially within high-risk groups, it would be extremely welcome.

8. Impact on capacity for routine CT scanning services and workforce

It is a little unclear as to whether the screening programme will be delivered through existing services or whether CT scanning capacity will be expanded to accommodate the screening programme. This will be important to understand any potential impact on availability and wait times for CT scanning services and on reporting times.

Workforce planning and capacity is an area in need of attention, both in terms of radiologists and radiographers to deliver and interpret results, secondary care oncology services to accommodate additional referrals and primary care services to accommodate referral/reporting of incidental lung issues. The gradual introduction of Community Diagnostic Centres is likely to also put additional demand on this workforce, as well as the expected influx in demand from the changes to the eligibility criteria expected for antifibrotic drugs for the treatment of pulmonary fibrosis this year, and the influx in asthma cases that could be experienced from the implementation of the Accelerated Access Collaborative's pathway. A unified national approach to these challenges is needed.

9. Quality of the lifetime risk and survival data

Some of the lifetime risk and survival rates are 5–7 years old and future projections are based on these, likely outdated, risk estimates. We would encourage a more up to date and more granular approach to future risk projection that acknowledges changes in smoking habits such as increases among young women, that will likely impact future lung health at a societal level.

10. Health inequalities

With smoking rates historically higher amongst more deprived communities, the TLHC programme will by design target these communities in way that seems likely to help address health inequalities. The External Review document notes the fact that those from more deprived communities are overrepresented within the cohort invited to undertake TLHCs, and that:

'Incidence and mortality rates for both males and females are almost 3 times higher in the most deprived quintile of England compared with the least deprived quintile, with the largest increase between the fourth and fifth quintiles. This translates to an estimated 6,571 excess cases of lung cancer in females and 7,760 excess cases in males per year in deprivation quintiles 2 to 5 compared with those in the least deprived quintile, which had an average number of 2,510 cases in females and 2,941 in males.

Broadening out from lung cancer to overall respiratory mortality, it is known that those from the most deprived communities are seven times more likely to die of respiratory conditions than the least deprived communities.^{xix}

With this in mind we strongly recommend that everything reasonable be done to diagnose and treat as wide a range of respiratory conditions as possible, in the knowledge that these conditions have a disproportionately large impact upon the high-risk group invited to TLHCs. Should this be achieved, which is entirely possible, the positive impact of TLHCs on addressing health inequalities could be considerable.

However, evidence suggests that these communities are systematically less likely to engage with healthcare and screening programmes, and so there is a need for the TLHC programme to be proactive in reaching out and encouraging patients to come

forward for screening. Specific groups less likely to attend but also more at risk of smoking-related morbidity and mortality, are those with low income, residents of social housing and the homeless, as well as people with mental health problems and certain ethnic groups.

For communities TLHCs could consider an outreach based service that feels more comfortable to access than more formal health settings. With the NHS's Core20PLUS5 programme also targeting these same communities, and requirements for each ICS to carry out work within this programme, we would like to see coordination with Core20PLUS5.

11. Ensuring follow up and good care post diagnosis

Follow up for smokers is dealt with below, but we would like to stress the need for effective follow up for all those diagnosed with a lung condition, and with a stress on those with a non-lung cancer diagnosis. The TLHC programme will need to effectively passport those with a diagnosis of COPD or other lung conditions to their GP, including all the available information about their diagnosis, for this to be done in a timely manner, and for the patient to be kept informed of this process so that they know what to expect.

At present it remains up to local areas to plan out pathways for 'incidental findings' but we believe that it would be extremely beneficial for the NSC to help identify best practice in this area and make firm recommendations on this issue, to ensure maximum effectiveness and cost effectiveness and a good patient experience. This should include the integration of spirometry alongside lung CT screening, clear reporting and follow-up pathways of results to primary care/secondary care. Consideration should also be given to enable direct referral to breathlessness diagnosis hubs/services where appropriate.

12. Maximising the use of TLHC for research and development

In 2021 Office for Life Sciences published the Life Sciences Vision Respiratory Mission: 'Reducing the mortality and morbidity of respiratory disease, in the UK and globally' which has an ambition to: 'Reduce the pressure on the NHS and improve clinical outcomes, through driving improvements in the underpinning understanding of respiratory disease, as well as its treatment and diagnosis'.

Leveraging the TLHC could provide an invaluable recruitment route to kickstart our understanding of the progression of respiratory diseases. This would enable the NHS to contribute to the delivery of the Life Sciences Vision and help to make the UK the best place in the world to undertake respiratory research and innovation, attracting inward investment from industry.

Screening involves annual or bi-annual low dose CT scans and spirometry which, while predominantly screening for lung cancer, have the potential to identify patients with other nonmalignant respiratory disease such as COPD, bronchiectasis, pulmonary fibrosis (IPF).

Many respiratory patients have no current access to clinical trials (commercial or academic) and are hard-to-reach unless they are known to local investigators and are therefore at a disadvantage for access to new treatment options and clinical

research. The TLHC programme could facilitate the recruitment of people with early stage lung disease into clinical trials which would significantly improve and speed up the development of new treatments and which could attract significant funding from the pharmaceutical industry. The screening programme also presents an opportunity to recruit for in-depth -omics studies and other research activities, with the potential to drive inwards investment for a Life Sciences Sector Deal with industry partners.

The UKRI/CRUK-funded DART programme provides a useful insight into the opportunities to drive large-scale trials that utilise data from TLHCs. Designing comparable programmes that take advantage of this data to advance our understanding of respiratory disease would maximise the value from integration of spirometry.

A dataset of this complexity and magnitude could also be used to test and validate new diagnostic tests which could transform our ability to accurately diagnose and differentiate between respiratory diseases which again could be very attractive to commercial partners in the diagnostic innovation space. The dataset could also be used to train a machine-learning programme to identify normal CT scans which would save significant amounts of NHS money through reducing radiologists time in reviewing individual scans if they are negative. There may be opportunities to link this programme to UKRI funding schemes to enable and facilitate researcher access to data and funding.

In summary, the data generated through the TLHC programme could, if organised with research and the potential for large public-private collaborations in mind, be used to transform respiratory diagnosis and treatment as well as improving access to existing interventions including smoking cessation.

13. Ensuring smoking cessation is effectively incorporated within the programme a. Identifying smokers

As already mentioned, the effective inclusion of smoking cessation within TLHCs will improve both effectiveness and cost effectiveness and is not currently included within cost effectiveness calculations. There is a huge opportunity to provide advice and treatment to active smokers within TLHCs, ensuring that even if their CT-scan comes back clear they can access support to address their tobacco dependency. As referenced in the NSC external review, Jones et al (2021) found that 'screening compared to no screening may increase smoking cessation especially in people with a true positive or intermediate screening test result.'

A significant proportion of those attending TLHCs are current smokers, and for this group stopping smoking is likely to be the single best thing they can do for their health. Having continued to smoke until the age at which they are eligible for a TLHC they are by definition likely to find it hard to quit. Supporting this group to quit smoking is also likely to be one of the most cost-effective interventions that the NHS could provide. It is known that the systematic treatment of smokers is highly costeffective in almost all settings, this is likely to be even more effective within the cohort seen by TLHCs. For example, it was found that among those with COPD, stopping smoking is associated with a 43% decreased risk of hospitalisation.**

British Thoracic Society found that, within a population of 411 COPD patients, spending just £500 helped two patients quit smoking and saved four hospital admissions costing a total of £9,408.^{xxii}

A minimum that should be done on smoking throughout the NHS is to train staff in Very Brief Advice (VBA) for smoking cessation. VBA is a cost-effective method of triggering a quit attempt in smokers, approved by NICE for use across primary care, xxiii and included within the NHS Health Check best practice guidance.xxii

VBA is not enough however, and once identified smokers should be supported onsite by a tobacco dependency specialist in order to start the quit journey as swiftly as possible during this "teachable moment". Pharmacological support should be offered, as well as behavioural support, with coordination as appropriate with local stop smoking services. Evidence from the QuLIT-1 trial found that in smokers attending form TLHC, immediate face to face provision of smoking cessation support was associated with a 12-week quit rate of 29.2% compared to 11% with usual care of signposting to stop smoking services. In QuLIT-2, an immediate telephone-based approach produced a 21.1% 12week quit rate compared to 8.9% with usual care. XXVI

We strongly support the provision of funding for a comprehensive, stop smoking support integrated within the TLHC programme, ensuring that a tobacco dependency specialist is available onsite to deliver support and treatment.

b. Supporting smokers to quit – integration with local services

Given that the majority of local authorities have dedicated stop smoking services it may make sense to integrate smoking cessation referrals from TLHCs with these as effectively as possible once the initial on-site consultation and offer of support is complete. Evidence from the pilots suggest that a number of approaches to this have been taken, and it would be advantageous if best practice was identified and centrally written into protocols.

Research into attitudes from patients undergoing TLHCs on this issue concluded that:

The integration of smoking cessation into lung cancer screening was viewed positively by those eligible to attend. Screening appointments providing personalized lung health information may increase cessation motivation. Services should proactively support participants with possible fatalistic views regarding risk and decreased cessation motivation upon receiving a good screening result. To increase engagement in cessation, services need to be person-centred.

We support these suggestions.

c. Supporting smokers to quit - funding

Once smokers are identified it is essential that they are supported to quit effectively. Smokers aiming to quit with professional support are three times more likely to be successful, xxviii and it is estimated that for every £1 invested in Stop Smoking Services, £2.37 will be saved on treating smoking-related diseases and reduced productivity.xxviii

Unfortunately stop smoking services across the country have seen significant cuts in recent years, and in 2021 only 76% of councils were able to provide a dedicated specialist stop smoking service. **XiX** Capacity within those services is also variable, and we are aware of areas involved in the TLHC pilots where referrals from the screening programme overwhelmed local stop smoking services. We are also concerned about areas without specialist stop smoking services, such as Stoke. How will smokers offered treatment in these areas as part of TLHC's be offered continuing support to quit?

The age and profile of those attending lung health checks makes them a crucial population to engage in quitting and having a negative experience of this could impair their chances of making another quit attempt for some time. We would like to see contingency funds from the TLHC budget available where necessary so that all current smokers starting a quit attempt through their TLHC are offered continuing support, with the cost effectiveness figures mentioned above as the rationale for this. We also encourage the National Screening Committee to urge the Government to implement a

'smokefree 2030' levy on tobacco industry profits (estimated to be able to raise around

£700million/year), with the proceeds being used to fund stop smoking services nationally.** Funding for smoking cessation within TLHC could also come from this source.

d. Smokers with a negative screening outcome

Consideration should be given to the potential impact of a negative screen on patient's desire and impetus to stop smoking. It will be important to ensure that there is understanding that a negative screen does not indicate no future risk of smoking-related lung cancer and that smoking cessation remains the single most important action individuals can take to reduce their future risk of malignancy and other lung disease.

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Maximising the opportunities presented by Targeted Lung Health Checks

parliamentary-group-on-smoking-and-health-recommendations-for-a-polluter-pays-levy-on-tobacco-

As a leading group of lung health experts, we believe the Targeted Lung Health Check (TLHC) programme has the potential to deliver considerable benefits beyond the diagnosis of lung cancer – from accelerating progress and expanding participation in respiratory research; to significantly reducing smoking rates in a high-risk population; and eventually to improving the diagnosis and management of a wider range of lung conditions.

We are keen to ensure that the potential of the programme is fully realised, including through:

(i) timely diagnosis of lung cancer;

manufacturers/

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- (ii) integration of high-quality evidence-based smoking cessation;
- iii (iii) positive steps to ensure uptake of TLHC targets the highest risk populations for smoking related disease;
- iv (iv) facilitating respiratory research and helping develop the evidence-base on the diagnosis of lung conditions;
- v (v) accurate diagnosis of other lung conditions, in addition to lung cancer;
- vi (vi) and eventually, integration of TLHC into breathlessness pathways including spirometry and symptom screening tools.

If the potential of TLHCs is fully realised then the opportunities for improved diagnosis, better patient outcomes, accelerated respiratory research and reduced future demand on the NHS are substantial.

Maximising opportunities for scaling up respiratory research and accelerating diagnosis beyond lung cancer

To maximise both the effectiveness and cost effectiveness of TLHCs efforts should be made to identify and diagnose as many lung conditions as possible. Evidence suggests that incidental findings such as COPD, pulmonary fibrosis and bronchiectasisi are likely to be more frequent than lung cancer diagnoses ii within the target population.

Spirometry testing is essential for the diagnosis of COPD and pulmonary fibrosis.iii Spirometry was included as a mandatory test in the original TLHC protocol, but because of a change in practice due to the COVID-19 outbreak, existing Lung Health Check sites have not had to deliver spirometry since March 2020. Given it is now considered safe to conduct spirometry, we are disappointed that there are no plans to restore it as a mandated part of TLHCs. However, we understand the difficulties with mandating spirometry testing given resource constraints, and the need to develop further evidence to demonstrate that the inclusion of spirometry would provide more good than harm at a reasonable cost.

We would like to see an ambition for lung health checks to eventually include diagnostic tests for lung conditions beyond lung cancer, as we believe this could improve health outcomes, reduce future NHS demand, and present significant benefits from a patient perspective. However, we appreciate it is necessary to produce a more robust cost-benefit analysis before spirometry testing can be restored as a mandated part of TLHCs. We want to ensure opportunities to maximise the effectiveness of TLHCs are fully explored, including opportunities to facilitate respiratory research and help develop data and evidence on the diagnosis of other lung conditions beyond lung cancer. We encourage the NSC to consider this within TLHC programme if possible.

Leveraging the TLHC could provide an invaluable recruitment route to kickstart our understanding of the progression of respiratory diseases. This would enable the NHS to contribute to the delivery of

the Life Sciences Vision and help to make the UK the best place in the world to undertake respiratory research and innovation, attracting inward investment from industry.

Opportunities to maximise smoking cessation in local areas

A considerable proportion of current smokers – as many as a third of those who smoke in England – are eligible for participation in TLHCs, presenting a huge opportunity to reduce smoking rates and begin to address health inequalities in some of the hardest to reach groups.

We strongly support the provision of a comprehensive stop smoking support integrated within the TLHC programme, ensuring that a tobacco dependency specialist is available onsite to deliver support and treatment, something that will improve both the effectivenessiv and cost effectiveness of TLHCs.v A considerable proportion of those attending TLHCs are current smokers. Having continued to smoke until the age at which they are eligible for a TLHC they are likely to find it hard to quit. Supporting this group to quit smoking is also likely to be one of

the most cost-effective interventions that the NHS could provide, and for this group stopping smoking is likely to be the single best thing they can do for their health. Given that the majority of local authorities have dedicated stop smoking services it makes sense to integrate smoking cessation referrals from TLHCs with these, once the initial on-site consultation and offer of support is complete. Unfortunately stop smoking services across the country have seen significant cuts in recent years, and in 2021 only 76% of councils were able to provide a dedicated specialist stop smoking service.vi Capacity within those services is also variable, and we are aware of areas involved in the TLHC pilots where referrals from the screening programme overwhelmed local stop smoking services. We are also concerned about areas without specialist stop smoking services, such as Stoke.

To address this, we would like to see funds from the TLHC budget available where necessary so that all current smokers starting a quit attempt through their TLHC are offered continuing support. We also encourage the National Screening Committee to urge the Government to implement a 'smokefree 2030' levy on tobacco industry profits (estimated to be able to raise around £700million/year), with the proceeds being used to fund stop smoking services nationally.vii Funding for smoking cessation within TLHC could also come from this source.

Signatories:

Sarah Woolnough, Chief Executive, Asthma + Lung UK

Charles Swanton, Principal Group Leader, The Francis Crick Institute

Professor John Hurst, Professor of Respiratory Medicine, University College London

Professor Sanjay Agrawal, Chair, Royal College of Physicians Tobacco Advisory Group

Professor Jørgen Vestbo, Professor of Respiratory Medicine, University of Manchester

Dr Tom Fardon, Consultant Chest Physcian, University of Dundee

Carol Stonham, Executive Chair, PCRS

Anne Powell, Project Manager for The Integration and Analysis of Data using Artificial Intelligence to Improve Patient Outcomes with Thoracic Diseases, DART.

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Name:	Tracey Lonero	gan	Email address:	XXXX XXXX
Organisation (if appropriate): Primary Care Respirato		spiratory Society and	Taskforce for Lung Health (joint response)	
Role:	Role: Policy Coordinator, Primary Care Respiratory Society			

Do you consent to your name being published on the UK NSC website alongside your response?

Yes No

Section and / or page number	Text or issue to which comments relate	Comment Please use a new row for each comment and add extra rows as required.
	General comments	PCRS and the Taskforce for Lung Health welcome the proposal from the UK NSC to recommend a quality assured, targeted screening programme for lung cancer in people aged 55–74 years of age with a history of smoking. The stated intention that screening for lung cancer should not be seen as an alternative to the delivery of high-quality smoking cessation services is particularly encouraging. PCRS and the Taskforce for Lung Health would encourage an integrated screening and smoking cessation service that includes interventions and treatment rather than referral to existing smoking cessation services.
Interim cost effectiveness report Limitations p.9	The model does not consider the costs or health impacts of incidental findings from	The impact a screening programme may have on people identified with other respiratory conditions such as COPD and pulmonary fibrosis should be considered.

	LDCT screening. Thus, any additional benefits unrelated to lung cancer that may arise from LDCT screening have not been incorporated.	COPD is a common incidental finding from lung screening programmes. There will be many more people picked up with suspected COPD than there will be people identified with lung cancer - data from the NELSON trial and Manchester Lung Health Check pilot suggests only 1-2% of attendees are diagnosed with early lung cancer, but many more reported obstructive spirometry results. For this reason, screening affords an opportunity to achieve earlier diagnosis. This is especially relevant given the 51% decline in people diagnosed with COPD in 2020 (expected to be similar reduction in 2021). Thus a national LDCT screening programme has a role to play in picking up individuals
		living with undiagnosed COPD. More people being picked up with COPD, and indeed other chronic lung conditions, who would have otherwise remained undiagnosed until a more advanced stage, will enable interventions to manage and control their symptoms. The impact on healthcare resource consumption for early diagnosis and long-term management vs late diagnosis and related healthcare requirements needs to be understood.
		Integration of spirometry alongside lung CT screening and clear reporting and follow-up pathways of results to primary care/secondary care would be appropriate. Consideration should also be given to enabling direct referral to breathlessness diagnosis hubs/services where appropriate.
		Rollout of a national LDCT programme will therefore have significant impact on diagnosis, treatment and care pathways for conditions such as COPD, and the extent of this impact needs to be understood.
Inclusion and exclusion criteria Table 2, Page 17	No clear definition of an 'Ever smoker' is provided	The inclusion of 'ever smokers' as a criterion for screening may be less than optimal as currently defined. A more robust criterion may be individuals with at least 2 recorded instances of declared current smoking in the medical record. Exposure to second hand smoke (e.g. in an occupational environment) may also be an important risk criteria especially for the current older generation.
	Previous evidence of asbestos exposure	Asbestos exposure, occupational history and history of asbestos-related disease as important risk factors for the development of mesothelioma.

Impact of opportunity to offer smoking cessation services	 Lung screening affords an opportunity to deliver VBA for smoking cessation and direct patients to appropriate stop smoking services should they wish to utilise them. We would encourage this as an integral part of the screening process for all current smokers. We would encourage an integrated approach to LDCT screening and tobacco dependency services, ideally delivered onsite alongside screening. This is especially important as anecdotal evidence suggest local stop smoking services have been overwhelmed with referrals from pilot Lung Health Check sites. Any national LDCT screening programme should seek to increase capacity rather than rely on local stop smoking services. Consideration should be given to the potential impact of a negative screen on patients desire and impetus to stop smoking. It will be important to ensure that there is understanding that a negative screen does not indicate no future risk of smoking-related lung cancer and that smoking cessation remains the single most important action individuals can take to reduce their future risk of malignancy and other lung disease.
Frequency of screening	There is no clarity in the protocol of the national programme on appropriate screening intervals. The original Lung Health Check protocol was that everyone who had a check through this programme which was clear, would be invited back 2 years later for a second scan. Would a national screening programme seek to replicate this?
Quality of the lifetime risk and survival data	It was noted that some of the lifetime risk and survival rates were 5–7 years old and future projections were based on these, likely outdated, risk estimates. We would encourage a more up to date and more granular approach to future risk projection that acknowledges changes in smoking habits such as increases among young women, that will likely impact future lung health at a societal level.
Selection of the population for screening	Concerns were raised regarding the limited evidence base upon which conclusions about selection of the population for screening were based, specifically with regard to how often to screen, interpretation of findings and anticipated cost effectiveness of the programme overall.

Learnings from other countries	It was noted that there was no consideration of experience from other countries, notably the USA, with regard to issues such as uptake of screening offers, performance of population selection criteria and algorithms for the interpretation of findings such as nodules. Such insights would be valuable in guiding interpretation of results and next steps when findings indicate conditions other than malignancy.
Impact on capacity for routine CT scanning services	It was unclear whether the screening programme will be delivered through existing services or whether CT scanning capacity will be expanded to accommodate the screening programme. This will be important to understand any potential impact on availability and wait times for CT scanning services and on reporting times. Critical workforce pinch points will likely include radiologists and radiographers (delivery of screening and interpretation of results), secondary care oncology services to accommodate additional referrals and primary care services to accommodate referral/reporting of incidental lung issues.
Potential to miss more rapidly growing and aggressive tumours such as small cell lung cancer	Concerns were raised that the more aggressive small cell lung cancers are likely to be missed by screening because of their often rapid development. This may mean that screening will preferentially identify the slower growing cancers (including those that would never have become clinically significant).
Potential for false reassurance from a negative screen and deferral of seeking evaluation of emergence respiratory symptoms	A concern was raised regarding the false reassurance a negative screen may afford in a broader context of lung health. It will be important to ensure understanding that screening is a 'point in time' evaluation and individuals should seek healthcare support for any emergent lung symptoms regardless of screening results.
Ensuring maximum uptake	Are plans (and funding) in place to promote the screening programme?
Unintended consequences	A concern was raised about the pathway of care for patients with lung symptoms not considered at high risk for lung cancer. Such patients may not have CT scanning immediately available to them. A CT-first pathway for patients with lung symptoms alongside a national screening programme for high risk individuals

	may be appropriate to address this issue. See: https://www.blf.org.uk/taskforce/about/our-diagnosis-working-group/lung-disease-diagnosis-pathway
Any additional benefits unrelated to lung cancer that may arise from LDCT screening have not been incorporated	There may be an opportunity to identify patients with early signs of asbestos-related disease (pleural plaques and pleural thickening) as well as an opportunity to provide health education on asbestos risk and exposure with regard to lung health.

Somerset County Council Public Health Department

Formal Response to Public Consultation on Lung Cancer Screening

Firstly, I very much welcome this public consultation and the fact that the National Screening Committee is able to revisit its longstanding stance on lung cancer screening.

I understand that the NHS has rolled out numerous pilot "lung cancer health checks" (LCHC) over the last several years over wide geographical areas. As with all pilots, these require review against nationally accepted screening criteria, to ensure effective use of public funds. I would like to point out that during the same time period, the national public health grant, which funds stop smoking services and wider tobacco control work, has been cut in real terms by 25%. As a result of those cuts these services have been reduced in many areas, and in some places cut entirely. Very effective regional tobacco control programmes have also been lost, including in the South West. It is without doubt the case that population level tobacco control programmes are more cost effective than lung cancer screening. So I would hope that if the NSC does make a recommendation favouring lung cancer screening, based on the results of the pilots and the current evidence base, it does so making it explicit where lung cancer screening sits in terms of effectiveness and cost-effectiveness versus population level tobacco control programmes and stop smoking services, so that Ministers and Commissioners are clear on the tradeoffs and relative impacts of the options for committing expenditure.

I now turn to some specific issues arising from the consultation papers and our local experience to help inform your decision making.

- Somerset, in common with many rural areas, struggles to secure clinical specialities, as we do not have a teaching hospital, and radiology has been a problem for some years. I understand the LCHC pilots have been outsourced to private providers, so there is no direct impact on existing services from the scanning programme itself, but if a national screening programme is approved, where will the resources come from to deliver a full programme and all the follow up, especially radiographers?
- 2. Furthermore, increased demand for stop smoking services, in itself a good thing, is not resourced through the LCHC, with the expectation that the local authority will provide the service, ideally one to one at the screening location. While the latter is ideal in terms of engagement with persons being screened, it can and does result in a lot of dead time for advisors, a scarce resource funded from the public health grant. The cost of such a model should be factored into any evidence-based recommendation issued by NSC, based on economic analysis real world cost effectiveness not just efficacy.

3. Most of the studies in the full cost-effectiveness modelling used stage shift as the outcome, not reduced mortality for stage 1 and 2 cancers, which gives rise to the risk of lead time bias. The NHS pilots may not yet have sufficient mortality outcome data to help with this uncertainty. It is accepted that earlier detection of lung cancer in particular should reduce 5-year mortality from lung cancer, but the all-cause mortality position however suggests no significant difference. I was particularly struck by this sentence:

"The impact of a reduction in lung cancer deaths due to early detection by screening is therefore too small compared to other causes of death to make an overall difference in mortality rates."

This does beg the question whether investment in lung cancer screening offers value for money versus other smoking-related programmes which have suffered disinvestment in recent years.

- 4. The issue of BAC tumours appears to be rather important, perhaps analogous to DCIS in breast cancer screening, or slow-growing prostate cancers. The LUSI RCT showed that 90% of these findings would not have become clinically apparent (not sure on what timeframe). Should BAC tumours be effectively disregarded in the analyses and if so, what impact does that have on effectiveness and costeffectiveness findings? I don't know how BAC tumours are dealt with in the pilot programme, but would have concerns about the psychological impact on persons being screened becoming persons or patients with cancer if in reality 90% of them would never have known in their lifetime. The founding principle of screening programmes overseen by the NSC is to do no harm. This would be brought into question by these findings.
- 5. There is a relatively high probability of false positive results (as well as BAC +ve). The NLST trial included participants receiving extensive counselling about that happening, and that trial reported lower anxiety etc for those receiving false positive results than some other trials. As we know real world support is typically much less than in the artificial world of RCTs. Is there adequate information and counselling to potential participants to enable fully informed consent in the NHS schemes and has this been factored into a costed model?
- 6. It is not clear if lung cancer screening is cost-effective taking into account all the studies, but it does appear clear that the more narrowly defined the high-risk group of smokers is, then the greater the likelihood that screening will be cost-effective. Do we know how the detected incidence of lung cancer through these pilots or trials is distributed between current and former smokers, and for the latter, years since last smoked, as well as total pack years? Might there be further work required to better target a screening programme, if that is the direction of travel? I also note that people with COPD and more than 35 pack years of smoking were at 2-5 times higher risk of death. Does COPD form part of the risk algorithms?

I noted also that only the NELSON and NLST RCTs were adequately powered, both of which are multi-round programmes. Only the UKLS had a single round. So, worth noting that in the GM pilot, of 19 with subsequently diagnosed lung cancer found at a 3 month follow up scan, 13 of them had <5mm nodule at first scan. Has the cost-effectiveness paper incorporated costs of follow up scans? And on the more general point about single versus multi-round screening, as the NELSON trial is the basis of this consultation, is there sufficient evidence of effectiveness for single round screening?

- 7. NSC routinely set review dates for all screening programmes and we would support a review at both 5- and 10-year points, by which time it should be evident whether or not the programme has been effective and cost-effective. The incidence rate for lung cancer should have fallen substantially from current rates by the early 2030s anyway and if a "smokefree" England by 2030 is achievable, then future demand will also be falling. There must come a point at which a screening programme will become uneconomic, but it is very difficult to stop screening programmes once they have started (hence my concern about the NHS LCHC pilots). If NSC is minded to endorse lung cancer screening should there at least be an indication of by when or at what prevalence of smoking the committee considers it likely that screening will no longer make economic sense?
- 8. Evaluation must include an assessment of the impact on health inequalities. A few points of concern arise from the papers:
 - a. The odds ratio of current smokers attending versus former smokers was 0.7
 - b. The odds ratio for least versus most deprived was 1.93
 - c. Current smokers were more likely to believe that a negative screening result gave them "permission" to continue smoking.

All of which might suggest a risk of widening health inequalities given current and recent smoking rates are much higher in most deprived groups.

Finally, and as committee members are very well aware, screening is much misunderstood by many clinicians and politicians, the media and the public, typically seen as an unmitigated good, without an adequate understanding that there are also harms and costs, including opportunity costs, that must be taken fully into account through the application of the full set of screening programme criteria. It is not a new problem that "case finding" and "screening" proposals, and indeed actual programmes, come forward at locality level through the best of intentions, but without proper consideration of all the criteria. It is vital that the evidence is reviewed robustly against the NSC criteria to inform the best use of public funds and achieve better health outcomes from lung cancer, for all of our patients, the best outcome being that people do not contract the disease in the first place through robust stop smoking and population-level tobacco control programmes.

Name: Jackie Tebbs Email: xxxx xxxx

Organisation: UK Clinical Expert Group for Lung Cancer and Mesothelioma

Role: CEG secretariat Condition: Lung cancer

UK Clinical Expert Group for Lung Cancer and Mesothelioma

Consultation comments on the National Screening Committee's recommendation for targeted screening for lung cancer in people aged 55-74 with a history of smoking

https://view-health-screening-recommendations.service.gov.uk/lung-cancer/

- 1. 1 The Clinical Expert Group (CEG) strongly supports the recommendation of targeted screening for lung cancer in people aged 55-74 with a history of smoking.
- 1. 2 The CEG strongly supports the recommendation that high-quality smoking cessation is an integral part of the programme.
- 3 Lung cancer is the largest cause of cancer death in the UK. The Clinical Expert Group believes that implementation of lung cancer screening across the UK in individuals at high risk of lung cancer is the most important single measure that can reduce deaths from lung cancer through both early detection of lung cancer and enhanced smoking cessation rates in current smokers.
- 4 The CEG strongly supports the recommendation that implementation should be supported by further work on optimisation and repeated modelling to determine the process needed to maximise the overall impact of the programme.
- 5 The clinical community is supportive of lung cancer screening but has significant concerns about workforce, diagnostics and other

resources needed to deliver a programme. Workforce planning and interim mitigation steps required for delivery, will need to be addressed. Furthermore, there is a need to ensure end to end service, with increased capacity in downstream services, such as respiratory, PET, thoracic surgery and SABR. This should be acknowledged.

- 6 This important recommendation, in the context of the NHS's
 excellent coverage and reach, is an opportunity for the UK to be an
 international leader in lung cancer screening and provide the
 evidence and a road map for other countries to implement the first
 large, targeted cancer screening programme.
- 1. 7 A risk-based targeted screening programme for lung cancer is contingent upon high quality demographic data in primary care and improvement in data quality (e.g. smoking status) should be supported. For ongoing quality assurance of the programme robust data collection (including utilisation of the screening option in the route to diagnosis field in the cancer registry) should be mandated

2. Consultation cover note

- 1. 1 This is clearly written and the CEG strongly supports the recommendations.
- 2 In the background it would be worth stating that a systematic evaluation of all available evidence (9 RCTs) has been used to generate this recommendation to avoid any suggestions of overreliance on the NELSON mortality results.
- 3 The rationale for utilising the interim cost-effectiveness report is clear. It would be useful to understand why there is uncertainty on the timescale for the completion of the cost-effectiveness model. We assume that this is not due to lack of consensus of the committee.

- 1. 4 The pathway is stated to include "offering a LDCT schedule based on the baseline CT". This statement requires clarification as it seems to imply a personalised scheduled of follow-up. We assume follow-up is based upon the presence / absence of a nodule on the baseline scan and that follow-up would otherwise be annual.
- 5 If no nodule is present, then it should be clarified whether annual screening should continue to be recommended until criteria are no longer met.
- 6 It should be clarified whether a participant entering the recommended screening programme at the age of 55 will be offered annual LDCT screening until up to the age of 75 (that is, age 74 and 364 days).
- 1. 7 The recommendation for eligibility does not indicate whether patients with life-limiting co-morbidities should be included for example, those who are housebound due to physical health and/or unable to lie flat for 30 minutes. Also, the recommendation should consider the exclusion of those who have had a CT thorax, within the previous 12 months.
- 8 Further work could include strategies to maximise life years gained in patients with competing causes of mortality.
- 1. 9 In the "Current evaluation" paragraph it is stated: "But the economists are confident that this will not change the conclusion that there are cost effective screening strategies for cancer in people with a history of smoking." This should be modified to ensure that the statement applies to lung cancer only.
- 2. Comments on external review v3.2

- 1. 1 This is a comprehensive document organised around 3 contextual questions and 2 key review questions
- 1. 2 It is stated on page 6 that contextual question 2 is "What is the accuracy of risk assessment algorithms and/or low dose computed tomography (LDCT) to predict/detect lung cancer? (UK NSC criterion 4)". When discussing the findings of this question on page 8 sensitivity and specificity are quoted for LDCT. To some clinicians these figures may appear much lower than in clinical practice. It would be important to clarify whether this refers to diagnosing stage 1 disease and what the cut off for a positive test is? The predictive values are highly dependent upon lung cancer prevalence in the population screened and the NPV should be quoted with a pooled prevalence.
- 1. 3 On page 9, there is an important paragraph about harms. This is a key area that will be scrutinised and requires more detail for the reader to understand the extent of the problem. Currently, the paragraph contains no results for the reader to assess the magnitude or range of harms. It also would be important to acknowledge that the literature to date has overestimated the harms from diagnostic work-up and the use of the BTS guideline has significantly reduced harms in this respect.
- 1. 4 On page 10 it is stated that "the balance of these harms compared to benefits is uncertain due to the heterogeneity of screening strategies employed by RCTs". This statement seems to suggest that criterion 13 is not met and to be at odds with the conclusions and recommendation in the cover note.
- 5 On page 11 the limitations should include that data on harms from UK studies are not included. The study by Balata et al. (Lung Cancer 2021) of 5 UK screening programmes showed that the false positive CT scan was 2% (n = 219/10,898) and of those with a positive result,

one in two had lung cancer diagnosed (53.3%). An invasive test was only required in 0.6% (n = 61/10,898) of screening attendees without lung cancer and in these patients there were no associated major complications or deaths. The benign surgical resection rate was 4.6% (n = 8/173), equating to 0.07% of the screened population.

- 6 On page 54 important data is shown on racial inequalities in outcomes for people with lung cancer. The data from screening trials show a higher reduction in all-cause mortality in black individuals. Lung cancer screening should therefore be highlighted as an important driver of reducing inequalities. It has also been shown (e.g. NLST, NELSON, LUSI trials) that women may benefit more than men from lung cancer screening but information on this has not been included.
- 7 The conclusion on page 67 from the 3 systematic reviews and meta-analyses states that these are well conducted with a low risk of bias. However, the conclusion should also clearly state that the available data show that screening high-risk persons with LDCT can reduce lung cancer mortality.
- 1. 8 On page 69, it is stated that there is uncertainty around harms from published international trials. However, real world UK data on harms from screening (Balata et al) has not been included and in the view of this committee would meet criterion 13.
- 2. Comments on interim report on cost-effectiveness (ENaBL) v1.3
- 1. 1 A major criticism of the previous report was that the natural history model underestimated the observed stage shift seen in clinical trials and pilot programmes. The fact that it has not been updated undermines confidence in the results. Is there a timescale for when the new model might be available?

- 2 Minor point page 13 Table 1 D Stage IIIB (typo) to remain as they were. Stage IIIC is missing but should be included with Stages IIIB and IV
- 1. 3 It has been assumed that only patients with relatively good performance status would accept screening. Have the survival curves (page 24) and inputted NLCA data been adjusted to reflect this? Given 1 year survival data only was provided by Prof Baldwin from the NLCA, why does the graph for stage IIA and IIB remain the same beyond 1 year? We would predict that they have different 5 year outcomes.
- 1. 4 Use of brigatinib in 33% of patients with stage III disease would appear to be an error / typo, with potentially important financial consequences (it should be 1%).
- 5 We appreciate that both survival figures from the NLCA and the usage data from 2018 were provided but note that things may change as newer therapies are approved, for example the availability of adjuvant immunotherapy and adjuvant osimertinib.
- 6 Cost of biomarker testing for patients with T≥2b and N≥1 does not appear to be included. This will add to costs of patients diagnosed at higher stages.
- 1. 7 It is stated (page 67) that the S-55-75-4% is the most cost-effective strategy. This option does not appear to be labelled in figure 11 (titled All screening programmes). We note that, at a threshold to pay of £20000 per QALY gained, the A-55-80-3% strategy is most likely to be the most cost-effective programme.
- 1. 8 The results of the ENaBL interim report are very encouraging for the cost-effectiveness of lung cancer screening. However ongoing

problems with the model acknowledged throughout the report appear to detract from the importance of the findings.

Overall, the Clinical Expert Group for Lung Cancer strongly supports the recommendation for targeted screening for lung cancer. The documents provide important evidence to support this recommendation. The implementation of lung cancer screening in the UK would significantly reduce the number of deaths from lung cancer, which currently remains the biggest cancer killer.

34-

Name: xxxx xxxx
Email: xxxx xxxx
Organisation: Merck

Role: xxxx xxxx

Condition: Lung cancer

MSD Response to: Consultation on Targeted Screening for Lung Cancer in People Aged 55-74 with a History of Smoking

MSD welcomes the targeted screening recommendation for lung cancer in people aged 55-74 with a history of smoking as a positive step forward but sees a national rollout as necessary to truly meet the needs of all lung cancer patients. Consequently, we believe a population screening approach to be more beneficial than a targeted approach per Ania Bobrowska et al.'s definition in Targeted screening in the UK: A narrow concept with broad application (1). As is, the recommendation does not benefit lung cancer patients over 74 (~44% of lung cancer patients) (2), or non-smoking lung cancer patients (~20% of lung cancers are not caused by smoking) (3).

Implementing a comprehensive national lung screening approach would not only enable later-stage patients to benefit from life-extending therapy but would also increase the number of patients diagnosed at earlier stages of cancer, a widely acknowledged challenge in the UK (4). This national approach would make the UK a leader in lung screening and help reduce the disparity between the UK and other

European countries in cancer outcomes. Matching the best cancer outcomes in Europe is a key goal of England's 10 year cancer plan (5) and a bold intervention in a major cancer is required to make a significant impact.

Further, the proposed targeted approach may risk increasing health inequalities and exacerbating the 'post-code lottery' by limiting the opportunity to be screened to certain individuals. If a national screening rollout were to be implemented, the necessitated greater investment in a sustainable approach and comprehensive infrastructure would better address the existing unequal access to screening across the nation.

Lastly, in implementing a national lung screening programme, there may be opportunity to move towards a more general or combined cancer screening approach. Not only does this present the opportunity to detect other cancers at an earlier stage, it would also be more cost effective than multiple screening programmes for different cancers. Interest in these approaches is growing as demonstrated by the Yorkshire Kidney Screening Trial (YKST) which is trialing a combined lung and renal cell cancer screening approach (6). These more sophisticated approaches would also be aligned with the movement toward rapid diagnostic centres which are based on the idea of streamlining and centralizing diagnostic procedures (7).

National availability of screening for lung cancer is necessary but not enough to catch all lung cancer cases as early as possible. Within a national screening approach, programs at the local level to ensure uptake and increase sensitivity are required for long term and sustainable success.

Industry stands ready to partner to increase the accuracy and efficiency of the lung screening approach, including through helping to develop and implement innovative technologies. For example, within a national rollout there are opportunities to use case-finding approaches to ensure high-risk patients receive the extra attention they require. MSD is keen to support the use of AI to enable more effective case finding of patients eligible for a targeted lung health check. These innovations allow for the health system to 'meet patients where they are' and reduce health inequalities by mitigating barriers to access.

A second key component for success of the national screening program is improvements in primary care data records and data sharing across primary and

secondary care. The richness and interoperability of these datasets will determine the impact that innovative technologies, such as AI, can make in this space. Specifically, efforts to decrease inconsistencies across GP systems, standardize best practice guidelines for users and increase data integration across the health system must be focused on. With these improvements and enhanced case-finding techniques, the uptake and sensitivity of a national lung screening program will be improved.

Finally, it will be important to consider the downstream effects of increased screening in the health system. The health system must be prepared for a greater number of cancer diagnoses as well as those diagnosed earlier. Unless preparations to update pathways and increase capacity across the system are made now, patients will not be able to realize the benefits of their cancer being caught earlier.

Job Code: GB-NON-06039

Date of Production: June 2022

References:

- (1) Bobrowska, A. et al., 2022. Targeted screening in the UK: A narrow concept with broad application. The Lancet Regional Health Europe, 16, p.100353.
- (2) Royal College of Physicians, 2022, NLCA annual report
 2022, https://www.rcplondon.ac.uk/file/34341/download (Accessed May 2022)
 (3) Hofmarcher, T. Et al., 2022. Diagnosed but not treated: How to improve Patient Access to Advanced NSCLC Treatment in Europe, IHE Report (Accessed May 2022)
- (4) Department of Health and Social Care, March 2022, 10-Year Cancer Plan: Call for Evidence GOV.UK (www.gov.uk) (Accessed May 2022)
- (5) Department of Health and Social Care, March 2022, 10-Year Cancer Plan: Call for Evidence GOV.UK (www.gov.uk) (Accessed May 2022)
- (6) University of Leeds, 2021, Yorkshire Kidney Screening
 Trial, https://clinicaltrials.gov/ct2/show/NCT05005195 (Accessed May 2022)
 (7) NHS England and NHS Improvement, Rapid Diagnostic Centres Vision and 2019/20 Implementation Specification, 2019, NHS England » Rapid Diagnostic Centres Vision and 2019/20 Implementation Specification (Accessed May 2022)

Name: Andrew Hince

Email: xxxx xxxx

Organisation: Scottish Radiation Protection Advisers Group (SRPA)

Role: SRPA Chair

Condition: Lung cancer

The Scottish Radiation Protection Advisers group representing the NHS radiation protection and diagnostic radiology physics community in Scotland discussed this consultation at it's meeting on 29th March 2022.

We noted the evidence for such a programme appears stronger however a number of questions were immediately apparent which do not appear to be covered in the early doors document. We would like to flag them now as they have implications for resourcing and governance of such a screening programme.

In terms of risks and benefits from the additional radiation from CT screening which would be incurred only a very brief statement appeared to be in the consultation:

"Acceptance by professionals is predicated on reassurance about the evidence for the harms and benefits of lung cancer screening in tandem with the right resources and guidance."

At present there is no discussion of QA/Medical Physics programme. Consider what has been put in place for the mammography screening programme to note that this is a considerable undertaking.

No discussion of where the imaging equipment will be (will additional dedicated screening CT scanners be provided or sessions on existing symptomatic scanners?).

There is no evidence of radiation risk being considered. Patients need to be assured of the risks/benefits.

The requirements of the Ionising Radiation (Medical Exposure)Regulations 2017 require consideration with respect to screening with X-ray equipment.

Resourcing will be required for additional NHS Medical Physics Experts to ensure dose and image optimisation, equipment QA etc are in place.

It is noted that IPEM are now one of the stakeholders and it is likely they will echo these points and possibly expand on.

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Name: Richard Booton

Email: xxxx xxxx

Organisation: Manchester University NHS Trust

Role: Programme Director & Clinical Director, Lung Cancer & Thoracic Surgery

Condition: Lung cancer

Lung Cancer Screening Consultation

Screening for Lung Cancer in Individuals at Increased Risk

External Review against programme appraisal criteria for the UK National

Screening Committee

Version 3.2

February 2022

Response from: Professor Richard Booton, Programme Director for Manchester & Tameside Targeted Lung Health Check (TLHC) Programme, & Clinical Director, Lung Cancer & Thoracic Surgery Directorate, Wythenshawe Hospital, Manchester University Foundation NHS Trust (MFT)

On behalf of:

- 1. Manchester & Tameside TLHC Steering Group
- 2. North West Lung Centre, Wythenshawe Hospital
- North West Thoracic Surgery Centre, Wythenshawe Hospital Consent to Name Being Published: Yes Official Response on Behalf of Organisation: Yes

On behalf of MFT, and as a provider of lung screening (since 2016), lung cancer diagnostics and surgical treatment, we have reviewed the evidence summary and support the conclusions therein, namely that

 Contextual question 1: Lung Cancer is an important health problem, and that the epidemiology, incidence and natural history is well understood, with an opportunity to intervene and detect early stage disease (UK NSC criterion 1)

In Greater Manchester, Lung Cancer is a major driver of health inequality and we expect the implementation of lung screening across the Cancer Alliance to be crucial to address this. We also have an advanced GM system-wide offer for embedding management of tobacco dependency that will address UK NSC criterion 2.

2. Contextual question 2: Low-dose CT and ultra-low dose CT is an accurate screening modality with good performance metrics. Whilst risk-assessment algorithms have had limited testing in the largest RCTs, the UK RCT demonstrated their value in reducing false positives, unnecessary investigations and associated harm. Indeed, in our NHS commissioned service from 2017, we embedded the PLCOm2012 risk assessment, leading to significantly lower false positives, a higher cancer yield and extremely low rates of surgery for benign disease, compared with the large RCT's.

We understand that the NHSE TLHC programme is considering removing spirometry from the screening programme. As the service has evolved, this is not used to identify early COPD, but is an opportunity to identify undiagnosed COPD patients with high symptom burden, exacerbations and hospitalisation who would benefit from treatment according to GOLD criteria and where there is clear excess mortality, helping to reduce any potential overdiagnosis from competing causes of mortality.

One of the reasons this was included in the original Manchester programme at its start was its ability to predict all cause and lung cancer mortality. Whilst we would accept there is no prospective randomised evidence of its utility in this regard as part of a TLHC programme, systematic collection within screening may help to evaluate and improve performance of current risk prediction calculators, and potentially contribute to the resolution of population health inequality.

(Wasswa-Kintu S, Gan WQ, Man SF, Pare PD, Sin DD. Relationship between reduced forced expiratory volume in one second and the risk of lung cancer: a systematic review and meta-analysis. Thorax. 2005

- Jul;60(7):570-5. doi: 10.1136/thx.2004.037135. Erratum in: Thorax. 2005 Nov;60(11):975. PMID: 15994265; PMCID: PMC1747470.)
- 3. Contextual question 3: Lung cancer screening is more effective but more costly than no screening. Whilst you cite that 'there is such a wide variation in incremental cost effectiveness ratio's across strategies that without a better understanding of the sources of variation there could be little confidence that this level of cost effectiveness could be reliably demonstrated in studies or in practice, we believe it is important to highlight our experience of performing an NHS commissioned pilot that the TLHC programme is now based upon. We performed a health economic analysis of the original LHC service (short term and more expensive than current programmes, without including smoking cessation) using the same methodology as the UKLS RCT in collaboration with the Centre for Health Economics at University of York, demonstrating an ICER of £10,069/QALY. Assuming a realistic stage shift, this was expected to reduce further to an ICER of £5,579/QALY. The robust operational framework and business planning requirements of NHS care delivery support that this programme can be delivered reliably in routine NHS practice (Hinde S, Crilly T, Balata H, Bartlett R, Crilly J, Barber P, Threlfall A, Tonge J, Booton R, Crosbie PA. The cost-effectiveness of the Manchester 'lung health checks', a community-based lung cancer low-dose CT screening pilot. Lung Cancer. 2018 Dec;126:119-124. doi: 10.1016/j.lungcan.2018.10.029. Epub 2018 Nov 2. PMID: 30527175.) and the consultations estimated cost per QALY is entirely reasonable assuming maturity of programmes, embedding of smoking cessation and economies of scale.
- 4. Clinical Effectiveness of Lung Cancer Screening (UK NSC criterion 11/13)
 - We strongly agree with the conclusion, based on RCT evidence, that criterion 11 is met. We note the uncertainty in relation to criterion 13 (harms and benefits of lung cancer screening) from the RCT evidence caused by the heterogeneity of screening strategies. However, we would point out the NHSE TLHC service specification and quality standards aimed at minimising variation with safe, effective

implementation. There is a significant difference between research trials and clinical practice, where service delivery is subject to robust clinical governance, training, and education. Indeed, in the leading UK implementation centres, only 4.2% of screening CTs were considered positive, with a false positive rate of 2%. Of those with a positive scan, over 53% were diagnosed with lung cancer. Of those positives without lung cancer, only 0.6% required an invasive test and there were no associated major complications or deaths. The surgical resection rate was 66%, the benign surgical resection rate was 4.6% and 90-day mortality low at 1.2%. (Lung Cancer 2021 Nov;161:136-140. doi: 10.1016/j.lungcan.2021.09.012. Epub 2021 Sep 20). Furthermore, the post RCT introduction of new standards in TNM staging and adenocarcinoma classification in conjunction with the introduction of an 'indeterminate' CT outcome category, contributes to the management of overdiagnosis by robustly recognising indolent disease and minimising intervention in this cohort. We would recommend some consideration is given to the role of designated centres for lung CT screening where appropriate skilled manpower, estate and facilities can ensure the minimisation of harm.

5. Acceptability of Lung Cancer Screening (UK NSC criterion 12) We note the uncertainty surrounding the evidence for criterion 12 but would suggest this is confounded by the desire to participate in research as much as lung cancer screening. Real world evidence can offer some crucial insight noting that there is no positive recommendation from the NSC, no national campaign to encourage awareness or adoption of screening for those that receive an invitation. Against this backdrop, the NHSE TLHC programme has demonstrated 30-60% uptake from a simple invitation strategy with variable initiatives for community engagement. This is in stark contrast to a postal invitation to participate in the UKLS research study that resulted in only 1.6% participating in the trial. This suggests that the concept of lung screening is welcome to a UK population of ever-smokers, with adherence to screening also remaining high (80-90%). Extremely low rates of refusal to participate in the diagnosis or treatment work up are also seen in real practice suggesting on both counts that the

uncertainty is less of a concern. Endorsement by NSC for lung screening ensures all opportunities for coordinated information giving and public awareness are delivered and can only improve these preliminary positive experiences.

As a provider of lung screening, in which we also mean the provision of downstream diagnostics and surgical treatment for positive screens and subsequent lung cancer diagnoses, we wish to highlight the urgent need, should NSC recommend lung screening, to provide clarity to funding of the downstream consequences so that providers can construct and approve robust business cases to ensure 'adequate staffing and facilities for testing, diagnosis, treatment and programme management' prior to the commencement of the NHSE TLHC roll out. This is an essential tenet of the NSC implementation criteria. A positive recommendation for lung screening is a hugely positive step forward for the NHS Long Term Plan; if we are to realise the benefits we have to have clarity of funding and clear plans for investment to sustain the large burden of lung resections and patient benefit that will follow.

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UK Lung Cancer Consultation

Johnson & Johnson Family of Companies (J&J) welcomes the National Screening Committee (NSC) proposal to update the 2007 recommendation on lung cancer screening. We are hopeful that this will be a positive step towards earlier diagnosis, aligning with the Life Sciences Vision aim that by 2028, 75% of people with cancer will be diagnosed at an early stage (stage one or two).¹

Currently in the UK, only 39.1% of lung cancer patients are diagnosed at early stage, with 42.4% of people diagnosed with Stage Four lung cancer, and 18.5% with Stage Three.² In this population we therefore see a large gap between current status quo and stated Government aims for diagnosis rates, and while we are hopeful that this screening recommendation will help the NHS achieve this aim, we wanted to further raise three key considerations:

• **Smoking cessation:** The risk that lung cancer screening may be regarded as a surrogate to smoking cessation to reduce mortality, has been recognized and confirmed by many authors³ It is therefore critical that all smoking cessation work continues, and that the two approaches are complementary.

¹ Life Sciences Vision. H M Government 2021. Available <u>here</u>.

² Cancer Research UK. Early Diagnosis. Available <u>here</u>.

³ Zeliadt SB, Heffner JL, Sayre G, et al. Attitudes and Perceptions About Smoking Cessation in the Context of Lung Cancer Screening. JAMA Intern Med 2015;175:1530-7. [Crossref] [PubMed]

- Consideration of other at-risk groups: With a number of patients with lung cancer who would fall outside the proposed screening criteria⁴, we are keen to see the 'further work' recommended by NSC include other groups of people at risk from lung cancer including those from socioeconomically disadvantaged backgrounds, people with certain genetic predispositions and comorbidities, those with occupational exposure, and people from certain ethnic backgrounds
- Communications to at risk groups: Given the proposed restricted target population to be screened, we wanted to highlight the importance of continuing with Public Health campaigns around smoking cessation, lung cancer symptoms and risk factors, and lung checks for those not in target population. In addition, with rising rates of lung cancer in females by around a third since the early 1990s⁵, and 14,300 cases of lung cancer each year in England linked with deprivation,⁶ we would urge this be reflected in any communications around screening, or parallel Public Health Campaigns to guard against potential health inequalities.

As this ambition for earlier diagnosis is achieved, we would also note the importance of investing in infrastructure, care and access to treatments at earlier stages of the pathway. The total number of patients awaiting NHS treatment in England now stands at 6 million, of which 1.7m are waiting more than the target of 18 weeks. Should this screening programme achieve it's purpose and drive more people through referral for treatment, it will be important that additional resource is invested in ensuring the current backlog does not create a bottleneck for patients seeking treatment.

Smoking cessation

Patient Groups have highlighted that many people may not openly self-identify to their health care professional as a smoker, so would therefore not be eligible for screening. In addition, for those who do identify it will be imperative to ensure smoking cessation programmes are imbedded as part of the screening pathway.

Smoking is the largest preventable cause of cancer in the UK and is known to cause at least 15 different types of cancer and 3 in 20 cancer cases.⁷

To mitigate the risk of unhealthy lifestyle behaviours, J&J support the Government's focus on promoting healthy diets and reducing smoking as set out in its 'Advancing our health: prevention in the 2020s' Green Paper.⁸

Although the Government's ambition for England is to be smokefree by 2030, and while smoking rates have significantly decreased in Great Britain over the past decade – from 20.3% in 2010 to 14.5% in 2020 – progress towards the Government's target

⁷ Cancer Research UK. Smoking and cancer. Available <u>here</u>.

⁴ Bhopal A, Peake M, Gilligan D, Lung Cancer in never-smokers: a hidden disease. Journal of the Royal Society of Medicine: 2019, Vol 112(7) 269-271.

⁵ Cancer Research UK, Lung Cancer Statistics. Available <u>here</u>.

⁶ Ihid

⁸ Department of Health and Social Care. Advancing our health: prevention in the 2020s. July 2019. Available here.

of reducing smoking rates in England has been impacted by the Covid-19 pandemic.⁹ In 2019, there were 74,600 deaths attributable to smoking in England and 25% of deaths for cancer were estimated to be attributable to smoking.¹⁰

In addition to screening smokers, we urge Government to ensure that adult smoking rates continue to decline to meet the Government's "smoke free" England ambition, by giving specific consideration to the role of health warnings on tobacco and nicotine containing products:

- J&J believe that all tobacco products whether combustible or smokeless should have combined health warnings on their packaging. Text warnings should also include clear direction and signposting to stop-smoking support services, quit-lines or further resource materials. Combined health warnings should be complemented with plain packaging for all tobacco products on the UK market.
- J&J appreciate the unprecedented financial burden the Covid-19 pandemic has caused the economy. However, the benefits to the health of the nation (and to the economy itself) of increased investment into smoking cessation – particularly appropriately funded Stop Smoking Services - remain clear. We believe a dedicated, long-term funding allocation towards evidence-based smoking cessation services must be made if delivery is to match ambition.
- J&J urges the Government ensure the forthcoming Tobacco Control Plan for England, as well as focusing on measures to achieve the Smokefree England 2030 objectives, also considers ways smoking cessation support and guidance can be built into national cancer screening programmes.

LDCT Screening

Multiple studies have shown that low dose computed tomography (LDCT) screening significantly reduces lung cancer mortality. The largest being the US National Lung Screening Trial (NLST)¹¹ and the Dutch-Belgian NELSON study¹², both demonstrating over 20% reduction in mortality.

A recent meta-analysis of nine randomised, controlled trials revealed a 16% relative reduction in mortality when the LDCT screening arm is compared with the non-LDCT control arm, providing "unequivocal support for lung cancer screening in identified risk groups¹³."

Given the strength of the evidence, we welcome the recommendation of the NSC that a targeted screening programme for lung cancer in people aged 55 – 74 with a history of smoking should be recommended in the UK. Several countries (Croatia,

⁹ Office for National Statistics. Adult smoking habits in the UK: 2019. Available <u>here</u>

¹⁰ NHS Digital. Statistics on Smoking, England 2020. Available <u>here</u>.

¹¹ National Lung Screening Trial Research Team, Aberle DR, Adams AM, Berg CD, Black WC, Clapp JD, Fagerstrom RM, Gareen IF, Gatsonis C, Marcus PM, Sicks JD. *Reduced lung-cancer mortality with low-dose computed tomographic screening*. New England Journal of Medicine, 365 (2011), pp. 395-409

de Koning HJ, van der Aalst CM, de Jong PA, Scholten ET, Nackaerts K, Heuvelmans MA, et al. Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial. New England Journal of Medicine, 382 (2020), pp. 503-5013.
 JK Field, D Vulkan, MPA Davies, et al. Lung cancer mortality reduction by LDCT screening: UKLS randomised trial results and international meta-analysis. Lancet Regional Health – Europe, 10 (2021), Article 100179.

Poland) have already implemented national LC screening programmes and several more are considering their implementation (Germany, France).

Consideration of other at-risk groups

Most screening trials have generally excluded never-smokers. Thus, the feasibility and effectiveness of lung cancer screening of individuals who never smoked are uncertain.

However, several known and suspected risk factors for lung cancers in neversmokers such as exposure to second-hand smoke, occupational carcinogens, radon, air pollution, and pulmonary diseases, such as chronic obstructive pulmonary disease and interstitial lung diseases, and intrinsic factors, such as age, are well noted.¹⁴

Therefore, given the prevalence of these risk factors within the UK, J&J call for any 'further work' recommended by NSC to consider extending targeted screening to include other groups of people at risk from lung cancer including those from socioeconomically disadvantaged backgrounds, people with certain genetic predispositions and comorbidities, those with occupational exposure, and people from certain ethnic backgrounds.

Communications to at risk groups (including females and those from socioeconomic deprivation)

The efficacy of public awareness campaigns in cancer in the UK is measurable. In lung cancer, we see evidence around increased public recognition of the messages to increases in attendance at GP practices, increases in urgent GP referrals for suspected cancer to secondary care, some evidence of an increased number of cases and more use of diagnostic tests, a shift to earlier stage disease with better performance status at the time of diagnosis and increased numbers of patients undergoing surgery.¹⁵

Lung cancer incidence rates in England in females are 174% higher in the most deprived quintile compared with the least, and in males are 168% higher in the most deprived quintile compared with the least¹⁶ (2013-2017).

Around 14,300 cases of lung cancer each year in England are linked with deprivation¹⁷ (around 6,600 in females and around 7,800 in males).

We would therefore call for:

 ¹⁴ Kerpel-Fronius A, Tammemagi M, Cavic M. Screening for Lung Cancer in Individuals who never snoked: An international Association for the Study of Lung Cancer early detection and screening committee report. J Thorac Oncol. 2022; 17 (1); 56-66
 ¹⁵ Public Health England, national Cancer Registration and Analysis Service. Be Clear on Cancer: Regional and national lunch cancer awareness campaigns 2011 to 2014. Available here.

 ¹⁶ Cancer Research UK Incidence Statistics. Found here
 17 Cancer Research UK Incidence Statistics. Found here

- an equality impact assessment of this screening programme as part of any implementation strategy, with a focus on women and those from a lower socioeconomic background
- any additional work or evaluation to look at the cause behind increasing rates in these groups
- tailored invitations, and screening messages to target groups to be considered to help reach the most at-risk groups on a broad scale.

Name: xxxx xxxx Email: xxxx xxxx

Organisation: Illumina

Role: xxxx xxxx

Condition: Lung cancer

71% of total cancer deaths occur in cancers for which there is currently no established screening paradigm (source: estimate from Grail). For this reason, it is critical that that cancer screening programmes should not be limited to targeting breast, cervical and colorectal cancers: the latest genomics-based technologies that are now becoming available offer the possibility of screening for multiple types of cancer at the same time through a simple blood test.

One such test, which originated in Illumina's own labs, is being trialed in the UK by the NHS (as well as in the U.S.). This is a new multi-cancer early detection test that can diagnose 50 cancers at once in asymptomatic patients, and, uniquely, can identify the tissue in which a cancer has developed, all through a simple blood test. Research in the US suggests that these tests could prevent over a quarter of five-year cancer deaths in those aged over 50.

39-

Name: xxxx xxxx Email: xxxx xxxx

Organisation: Intuitive Surgical

Role: xxxx xxxx

Condition: Lung cancer

Our organization supports the Adult screening programme for lung cancer as screening should be offered to individuals at high risk for lung cancer, which is largely defined based on tobacco use history. This change will increase early identification of lung cancer and allow for earlier intervention resulting in improved survival.

A patient has a better prognosis if lung cancer is detected, diagnosed and aggressively treated early versus in late stages. Advancements in CT technology, dosing protocols and reporting in the past 10 years have increased accuracy and lessened patient exposure to radiation. As compared to other screening protocols, LDCT scans require no patient self-prep, are non-invasive and require minimal time investment by the patient.

The profile of main cancers world-wide, shows lung cancer is now at the same level as breast cancer. However there are now 2.8 times more deaths from lung cancer than breast cancer. One third of all cancer deaths are due to 5 leading behavioural and dietary risks: High BMI, lack of vegetable intake, lack of exercise, tobacco use and alcohol use. Lung cancer is the fourth most diagnosed invasive cancer in the UK and it causes more deaths than any other cancer in both males and females. Its high mortality rate results from both a high incidence rate and a low survival, with only 13% of those diagnosed with lung cancer surviving 5 years after diagnosis https://www.who.int/news-room/fact-sheets/detail/cancer

Screening for lung cancer in individuals at increased risk will play an important role in addressing this problem.

We are pleased to see the interim report and recommendations that screening for lung cancer with LDCT would likely be considered a cost-effective intervention. The insights showing the average number of lung cancer deaths per 100,000 joiners of those screening strategies on the cost-effectiveness frontier was 18,686, compared to an average of 15,702 in the equivalent no screening populations has material impact. These strategies that offer a benefit of approximately 3,000 fewer deaths due to lung cancer per 100,000 programme joiners further supports targeted screening for lung cancer.

40-

Name: Bev Bower

Organisation: xxxx xxxx

Role: RGN

Condition: Lung cancer

Early diagnosis =increases positive outcomes

Name: Dr Alasdair Taylor Organisation: xxxx xxxx Role: Consultant Radiologist Condition: Lung cancer

Experience from other cancer screening programmes (cervical, breast, bowel) suggests that the benefits achieved in practice fall some way short of the projections made when such programmes are proposed. While machine learning and artificial intelligence will doubtless contribute to more efficient scan interpretation, in the immediate future a screening programme dependent on substantial radiologist input will divert scarce resources from other areas of critical importance to the success of the NHS cancer plan.

Bearing down heavily on the use of tobacco as a primary goal of public health policy will ultimately lead to a substantial reduction in the incidence of lung cancer (and a range of other cancers). The advent of vaping in recent years suggests that rapid progress towards the elimination of tobacco smoke as a carcinogen could be made within the next decade.

On a more speculative note, in clinical practice we are now seeing the impact of a revolution in medical oncology based on genomic medicine. In my view this will have an exponential impact on the control of cancer in the next 20 years, transforming the potential natural history of the disease and the most effective treatment strategies, with less reliance on surgery and greater acceptance that living with cancer, controlled by targeted systemic anti-cancer medicines, may result in longer survival with an acceptable quality of life.

In summary, imaging-based screening is, in my opinion, a 20th century approach to cancer control and is likely to perpetuate the UK's perceived poor performance in cancer diagnosis and survival relative to comparable OECD nations. The achievements of the "cancer 2-week-wait" programme of the past decade have been nugatory in relation to the enormous resource invested. Had similar resource been invested in areas where the UK leads rather than lags the World (for example, our university laboratories' excellence in molecular biology) we might be in a substantially stronger position today.

42-

Name: xxxx xxxx

Organisation: xxxx xxxx

Role: xxxx xxxx

Condition: Lung cancer

Whilst it would be excellent to pick up lung cancer early, I have concerns about screening as CT can be very non-specific for nodules, with lots of incidental nodules occurring. This can lead to a lot of patient stress as they are followed up for years to determine if a nodule is growing, and quite a proportion will turn out to be benign.

Also I didn't see much mention of the breast radiation doses and risks.

Lastly I am concerned about the resources – whilst the screening program is likely to be funded, the knock on effect on the NHS with all the incidental findings and follow up, needs to be considered in a perpetually short staffed health system, especially outside of London.

To go ahead I would expect it to be fully funded and staffed including the after effects on the NHS

43-

Name: xxxx xxxx

Organisation: xxxx xxxx

Role: xxxx xxxx

Condition: Lung cancer

Lung cancer screening is essential for early detection of disease and enhances rates of cure. Lung cancer screening is a cornerstone of the long term plan for cancer-diagnose 25% of cancers at early stage. I would strongly support that lung cancer screening is made routine for at risk individuals

44-

Name: Sean Walsh Organisation: xxxx xxxx Role: Salaried GP Condition: Lung cancer

I think this screening programme shows a lot of promise. However it does clearly need to be evidence based. One particular concern of mine would be of overdiagnosis and none of the studies to date seem to address this, nor does it seem to be on the mind of the key researchers. There is no point finding hundreds of lung cancers that would never have harmed people. I hope the committee take into account the evidence base/ lack thereof when making a decision with regards to screening.

45-

Name: xxxx xxxx

Organisation: xxxx xxxx

Role: xxxx xxxx

Condition: Lung cancer

Please include women equally to men as lung cancer incidence is equal. Consider including non-smokers as much adenocarcinoma is being diagnosed in non-smokers. 46-

Name: Cgm leire

Organisation: xxxx xxxx

Role: Gp

Condition: Lung cancer

My wife died recently of lung cancer

She was à smoker

I have suspicion only 3-4 months before the diagnosis.

She was diagnosticed stage 4 and it is a death sentence.

I do not think k it wil have make any différence to be start 3 months hourlier

Only systématiquement screening wil have save her

She survive only 3 months

Please start low radiation ct scan sceening programme as soon as possible. France

is starting now.

Dr cgm leire

47-

Name: xxxx xxxx

Organisation: xxxx xxxx
Role: Respiratory consultant
Condition: Lung cancer

We are being asked to roll out screening regionally without sufficient funding or resource. Clearly lung cancer screening increases the number of early stage lung cancers that are diagnosed but also reduces respiratory morbidity through smoking cessation and early diagnosis and intervention for other respiratory illnesses (copd, ILD, bronchiectasis). We can't implement this without the national screening programme running and funding it, primary abd secondary care clinicians are too stretched as it is. The TLHCs are all very well but cancer networks should not each be reinventing the wheel in designing programmes and running it themselves. Economies of scale and uniform management are required. Please approve a national screening programme for lung cancer.

48-

Name: John Pilling
Organisation: xxxx xxxx

Role: Consultant Thoracic Surgeon

Condition: Lung cancer

The evidence that lung cancer screening works and saves lives is overwhelming, in fact it is far stronger than for some conditions that are currently screened for. I would fully support a national screening programme for lung cancer, a disease which for

too long has been under resourced due to the socio-economic group it mostly affects.

49-

Name: xxxx xxxx

Organisation: xxxx xxxx

Role: GP lead for cancer Condition: Lung cancer

I welcome this move towards targeted screening and hopefully earlier diagnosis. However primary care is not resourced to contribute to this and I am concerned about any additional burden on GPs. GPs nationally I think would be grateful for your consideration on this matter.

50-

Name: xxxx xxxx

Organisation: xxxx xxxx Role: Medical Director Condition: Lung cancer

Are Spec Comm aware of the need to resource the added requirements for thoracic surgery including clinical teams, theatre availability, robotics and beds
There is inadequate resource for managing the 'incidentalomas' and patients requiring follow up CT's

Where are the radiologists coming from? – plans with HEE?

Fully support the programme but the planning for the outcomes appears woeful....

TARGETED SCREENING FOR LUNG CANCER IN PEOPLE AGED 55 – 74 WITH A HISTORY OF SMOKING (Evidence Summary)

Consultation comments pro-forma

Name:	Anne McCurrach		Email address:	XXXX XXXX		
Organisation (if appropriate):		NHS National Services Scotland				
Role: Medical Physics Expert						
Do you consent to your name being published on the UK NSC website alongside your response? Response from NSS medical physics team. Yes						

Please return to the Evidence Team at screening.evidence@nhs.net by 08 June 2022

Lung screening response to consultation

Radiation Risk

The report doesn't quantify harms by a new programme due to additional exposure to radiation (though there is a reference on page 29 to equivalent background dose). The breast screening programme regularly provide updates comparing cancer detection with cancer induction to demonstrate the risk benefit.

Quality Control

For a quality-controlled programme using ionising radiation, a similar set up to that currently used by the breast screening programme is recommended to ensure compliance with the Ionising Radiations Regulations 2017 and the Ionising Radiation (Medical Exposures) Regulations 2017 (IRMER). This will require significant resource from medical physicists in their roles as Radiation Protection Advisers and Medical Physics Experts. Would a similar model be adopted for the lung screening programme, how will this be funded and what would be governance be? As an example in breast screening, Clinical Professional Groups form a key part of this model.

Equipment

What CT scanners will be used for the programme? Are mobile CT scanners being considered? Will the programme use existing equipment or purchase additional equipment? For the latter, this will require a procurement process (including pathways for future equipment replacement), assessments of shielding requirements, critical exams, radiation risk assessments, local rules and staff dose monitoring? IRMER requires that a robust QA programme is in place, starting with commissioning and acceptance testing of the CT equipment.

Optimisation

IRMER requires that particular attention be paid to medical exposures as part of a health screening programme in respect to optimisation. This aims to ensure that adequate image quality is achieved, whilst ensuring patient effective doses satisfy diagnostic reference levels once these are established. Will CT supplier and model specific standard exposure protocols be set in place to ensure that low dose CT scans are consistent? Will there be an overarching physics service reviewing this or a centre of expertise such as the National Centre for the Coordination of the Physics of Mammography (NCCPM)?

Staff Resources

Currently there is a shortage of MPEs in the UK

(https://www.ipem.ac.uk/resources/workforce-intelligence/workforce-intelligence-resources/diagnostic-radiology-and-radiation-protection-workforce-report-2021/). Will there be additional funding for MPEs and clinical technologists within the lung screening programme?

Optimisation requires the setup of an interdisciplinary team including MPEs, radiographers, and radiologists input to ensure that CT exams are optimal. Initial work would need to focus on setting up low dose protocols for chest imaging, followed by collection of patient dose data and establishing of national and local DRLs.

QA resources

Test equipment such as image quality phantoms, anthropomorphic phantoms, and dosimeters, are required to carry out the commissioning, acceptance testing, critical exam, optimisation and routine quality control work associated with the QA programme.

A patient dose management system, which is set up to access the PACS system used for reviewing the CT screening images, will help meet the QA requirement to carry out dose audits.

Name: xxxx xxxx

Organisation: xxxx xxxx Role: GP/Cancer Lead Condition: Lung cancer

Age criteria: presumably risk of lung cancer changes with different personal characteristics (eg socioeconomic deprivation) – would there be consideration of lowering age range for highly deprived areas to try to avoid screening increasing health inequalities?

Health inequalities: What measures will be in place to ensure that this doesn't widen the equalities gap?

Data extraction/reliability – need to have back up options for history of smoking data as recording in GP practices, particularly for new patients, may not be 100% accurate. This data is not required or routinely captured since new GP contract.

Needs to be clear that this runs as a screening service and be separate from primary or secondary care. Similar to breast or bowel screening services in Scotland rather than cervical screening which is run in primary care practices.

53-

Name: Jackie Fenemore, Current Acting Chair Lung Cancer Nurses U.K. (LCNUK.org)

Email: xxxx xxxx

Organisation: LCNUK.org

Role: Lung Cancer Nurse Clinician

Condition: Lung cancer

On behalf of Lung Cancer Nursing U.K. I would like our organisation to be included in the interested organisations alongside UKLCC, RCLCF etc.

Our LCNUK response to this Lung Cancer Screening consultation is as follows;

LCNUK would recommend the following actions;

- 1. Identifying and inviting 'ever' smokers aged 55 74 from GP records
- 2. Assessing eligibility for low dose CT (LDCT) using a multivariable risk assessment tool
- 3. Offering a LDCT schedule based on the baseline CT
- 4. Assessing CT results using the nodule management guidance by the British Thoracic Society

- Include patients in the screening programme with existing co-morbidities which may mask their earlier diagnosis of a lung cancer. Include existing co-morbities such as C.O.P.D. and asthma
 - 1. Follow NICE guidance in relation to diagnosis and treatment of detected cancers
- 2. Provide smoking cessation advice to all participants in the programme

Thank you for looking into this need. LCNUK would recommend by introducing lung cancer screening lives will be saved and lead to earlier identification of lung cancer at at earlier timepoint. This will improve outcomes and save lives and be cost effective.

Thank you
On behalf of the LCNUK committee
LCNUK.org
Email; xxxx xxxx

54-

Name: Daniel Lange Email: xxxx xxxx

Organisation: City of Wolverhampton Council

Role: Public Health Registrar

Condition: Lung cancer

Following discussion at the senior leadership team, Wolverhampton City Council Public Health Department considers the implementation of a national targeted lung cancer screening programme as, overall, a favourable intervention. The evidence presented by the NSC on clinical effectiveness and cost effectiveness look promising and this programme has the potential to benefit many people. However, concerns around the delivery of the programme were raised namely:

- Reliance on GP records: We feel the accuracy of "ever smoker" coding likely to be fairly high (unlike "current smoker" coding). However, relying on GP level data will lead to increased local workload demands which must be factored into the programme planning.
- Incidental findings: One of the members at our meeting had previous experience of being involved in a lung cancer screening pilot programme and pointed out the high level of incidental findings generated by it. Serious consideration of the negative impacts of this (both in terms of anxiety caused to

- patients and workload generated for healthcare services) needs to be carried out.
- Effect on inequalities: Location of screening sites and travel demands was raised as a potential driver for widening already existing inequalities.
 Possibilities of mobile screening sites were suggested as a potential way to mitigate this.
- Link with smoking cessation services: Wolverhampton does not currently commission universal smoking cessation services. Will additional funding/services be provided in areas where the public health grant is already committed to other priorities?

55-

Response

Oncology care requires integrated approaches across patient pathways. From design of the screening programme, management of the programme, diagnosis and staging, to treatment decision, therapy planning and follow-up. Philips is a leading HealthTech company which addresses the challenges in oncology by providing solutions across the entire care delivery pathway (as shown in Figure 1 and 2) - including lung cancer diagnosis and data management programs for lung cancer screening programmes.

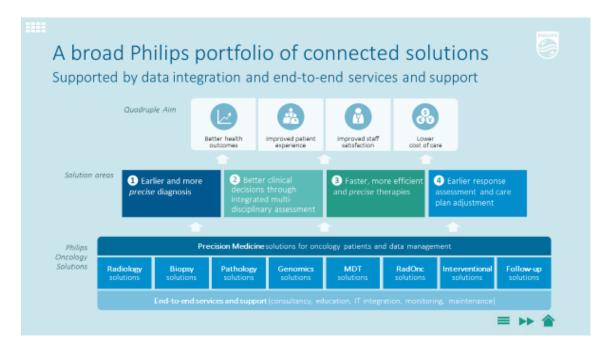


Figure 1. A broad Philips portfolio of connected solutions

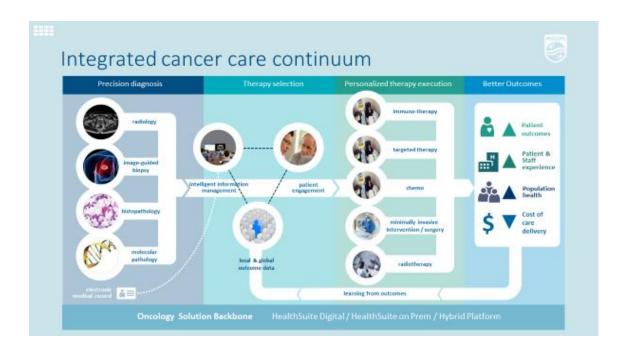


Figure 2. Integrated cancer care continuum

At Philips we are delighted to have the opportunity to provide our views to the National Screening Committee's consultation on lung cancer screening, in support of a national screening programme for lung cancer.

The National Screening Committee's previous consultation on lung cancer screening did not recommend a national screening programme on the basis that three important conditions had not been met. Those being: (1) lack of evidence showing the screening programme being clinically and economically effective; (2) absence of clinical trials in lung cancer screening; and (3) unsuitable testing for lung cancer screening programme. Since then, we believe that the situation has changed and that those three requirements can now be met. National and international studies have found that screening high-risk individuals using low dose computed tomography scans offers a safe and effective way to diagnose lung cancer at an earlier stage¹.

Lung cancer is the second most common form of cancer in the UK². Diagnosing lung cancer at an early stage improves survival as a surgical cure is still possible³. Unfortunately, most lung cancer cases are found at an advanced stage when survival rates are low. According to data by Public Health England, over 70% of people are diagnosed in stage 3 or 4 of the disease. This is devastating given that the 1-year lung cancer survival rates for those diagnosed in stage 4 is only 20%, compared to 88% for those diagnosed at stage one⁴. The pandemic has made matters worse, with greater

numbers of people being diagnosed in the later stages because of delayed access to diagnosis and care¹. To address this issue, earlier detection needs to be prioritised by health leaders. At Philips we believe that should be done through a national screening programme which targets high-risk individuals, alongside smoking cessation programmes¹.

In addition to offering our support for a national lung cancer screening programme in England, Philips would also like to highlight the benefit that the screening programme would have on improving the entire lung cancer pathway, leading to a whole host of complementary approaches being adopted concurrently. These include clinical benefits such as incidental pulmonary nodule identification, detection of non-communicable diseases or cardiac abnormalities (such as abdominal aortic aneurysm (AAA) and calcification screening). Moreover, gaining workflow efficiencies like enhanced management protocols and rapid referral pathways from primary to secondary care to multidisciplinary care teams that encompasses specialist diagnosis and personalized treatments. In this way, implementing a national lung cancer screening programme can deliver benefits beyond finding lung cancer¹.

Philips offers a wide range of diagnostic and informatic systems, which offer excellent image quality and low dose needed for lung cancer screening (as shown in Figure 3). In addition, the Philips IntelliSpace Portal software offers a comprehensive toolset to track pulmonary disease from detection to follow-up. These solutions improve patient throughput as they just require one reading, saving time, money and increasing the number of patients being screened⁵.

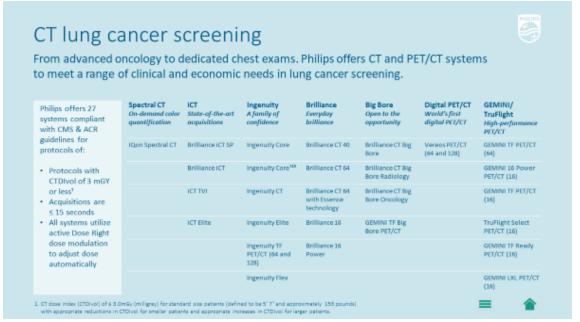


Figure 3. Philips CT Lung Cancer Screening

Philips has partnered with many organisations to deliver large-scale lung screening programmes around the world. A notable example is Philips' partnership with RadNet (the largest owner of outpatient imaging centres in the United States) where both companies are working together to offer lung cancer screening for more than 15 million Americans - many of whom are in densely populated, ethnically diverse communities with at-risk populations. This is in response to meeting government cancer targets (known as the Cancer Moonshot goal), where President Biden has called for more national action on cancer screening⁵.

Philips has found that successful lung cancer screening requires a comprehensive solution to address the challenges inherent in large-scale programs⁶. This goes beyond the need for good image quality and analysis required for any scan. For instance, a patient management tool is needed to keep track of the many screening patients, each perhaps, with several scans to collate over the years. Intelligent software underpinned by artificial intelligence and data insights can help effectively detect, characterize, and diagnose nodules. Furthermore, automated tools that enable workflow improvements ensure that eligibility can be met without undue burdens on clinical staff⁶. Philips provides solutions across the entire lung cancer care delivery pathway as shown in Figure 4.



Figure 4. Philips Portfolio of Lung Cancer Solutions

Philips Lung Cancer Orchestrator is a comprehensive solution to arm clinical teams with the tools they need to successfully implement an effective lung cancer screening program. By enabling effective patient screening and follow-up as well as efficient collaboration, early intervention can be

prioritized – saving both cost and time. Determining who is eligible, notifying, and scheduling follow-ups, and reporting program status can be labour intensive – and potentially risky, as patients may be lost if details are overlooked. Philips Lung Cancer Orchestrator is just one solution from the Philips Oncology portfolio which helps identify and speed patients through the pathway by streamlining workflow through a single interface which seamlessly links diagnostics, informatics and patient scheduling. This enables a complete dataset to follow the patient through the pathway.



Figure 5. Oncology care pathways orchestration

A further challenge for large-scale screening programmes is making them accessible for individuals regardless of their background or where they live. This can be overcome through diagnostic testing in the community through mobile trailer units and Community Diagnostic Centres (CDCs). Philips has extensive experience offering diagnostics in the community through both mobile trailer units and CDCs. A recent report from Imperial College London, working independently via Imperial Consultants, with Philips UK and Ireland, revealed that CDCs should be positioned in locations of greatest socioeconomic deprivation and with the highest waiting times, to help improve patient outcomes and diagnosis. Moreover, Imperial found that CDCs are best placed to serve patients in underserved communities when they are based near where people reside, away from congested secondary care settings⁷.

Philips recognises the challenge that screening programmes bring in terms of an increase in the volume of lung cancer patients needing therapy. Philips offers tools to deliver therapy efficiently and

effectively, reducing tumour recurrence while minimizing side effects to improve the staff and patient experience.

With the results from many clinical trials and the advancements in precision diagnostics and personalized treatments - we believe there is strong evidence that the committee should recommend a national lung cancer screening programme in England. Philips remains committed to improving lung cancer care in England by providing meaningful solutions across the entire lung cancer delivery pathway.

We look forward to hearing the results of the consultation.

Richard Small

Business Development Manager, Oncology Informatics, UK&I

Precision Diagnosis, UK&I

Philips UK

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Name:	XXXX XXXX		Email address:	хххх хххх			
Organis	sation (if appropriate):	MSD UK					
Role:	Policy and Commun	and Communications					
Do you consent to your name being published on the UK NSC website alongside your response? Yes No **xxx xxxx***************************							
	Section and / or page number Text or issue to which comments relate			Comment Please use a new row for each comment and add extra rows as required.			
		Please see below f	or	-			

Consultation on Targeted Screening for Lung Cancer in People Aged 55-74 with a History of Smoking

MSD welcomes the targeted screening recommendation for lung cancer in people aged 55-74 with a history of smoking as a positive step forward but sees a national rollout as necessary to truly meet the needs of all lung cancer patients. Consequently, we believe a population screening approach to be more beneficial than a targeted approach per Ania Bobrowska et al.'s definition in *Targeted screening in the UK: A narrow concept with broad application.* ¹ As is, the recommendation does not benefit lung cancer patients over 74 (~44% of lung cancer patients)², or non-smoking lung cancer patients (~20% of lung cancers are not caused by smoking³).

Implementing a comprehensive national lung screening approach would not only enable later-stage patients to benefit from life-extending therapy but would also increase the number of patients diagnosed at earlier stages of cancer, a widely acknowledged challenge in the UK.⁴ This national approach would make the UK a leader in lung screening and help reduce the disparity between the UK and other European countries in cancer outcomes. Matching the best cancer outcomes in Europe is a key goal of England's 10 year cancer plan⁵ and a bold intervention in a major cancer is required to make a significant impact.

Further, the proposed targeted approach may risk increasing health inequalities and exacerbating the 'post-code lottery' by limiting the opportunity to be screened to certain individuals. If a national screening rollout were to be implemented, the necessitated greater investment in a sustainable approach and comprehensive infrastructure would better address the existing unequal access to screening across the nation.

Lastly, in implementing a national lung screening programme, there may be opportunity to move towards a more general or combined cancer screening approach. Not only does this present the opportunity to detect other cancers at an earlier stage, it would also be more cost effective than multiple screening programmes for different cancers. Interest in these approaches is growing as demonstrated by the Yorkshire Kidney Screening Trial (YKST) which is trialing a combined lung and

renal cell cancer screening approach.⁶ These more sophisticated approaches would also be aligned with the

movement toward rapid diagnostic centres which are based on the idea of streamlining and centralizing diagnostic procedures.⁷.

National availability of screening for lung cancer is necessary but not enough to catch all lung cancer cases as early as possible. Within a national screening approach, programs at the local level to ensure uptake and increase sensitivity are required for long term and sustainable success.

Industry stands ready to partner to increase the accuracy and efficiency of the lung screening approach, including through helping to develop and implement innovative technologies. For example, within a national rollout there are opportunities to use case-finding approaches to ensure high-risk patients receive the extra attention they require. MSD is keen to support the use of AI to enable more effective case finding of patients eligible for a targeted lung health check. These innovations allow for the health system to 'meet patients where they are' and reduce health inequalities by mitigating barriers to access.

A second key component for success of the national screening program is improvements in primary care data records and data sharing across primary and secondary care. The richness and interoperability of these datasets will determine the impact that innovative technologies, such as AI, can make in this space. Specifically, efforts to decrease inconsistencies across GP systems, standardize best practice guidelines for users and increase data integration across the health system must be focused on. With these improvements and enhanced case-finding techniques, the uptake and sensitivity of a national lung screening program will be improved.

Finally, it will be important to consider the downstream effects of increased screening in the health system. The health system must be prepared for a greater number of cancer diagnoses as well as those diagnosed earlier. Unless preparations to update pathways and increase capacity across the system are made now, patients will not be able to realize the benefits of their cancer being caught earlier.

¹ Bobrowska, A. et al., 2022. Targeted screening in the UK: A narrow concept with broad application. The Lancet Regional Health - Europe, 16, p.100353.

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https://www.rcplondon.ac.uk/file/34341/download (Accessed May 2022)

³ Hofmarcher, T. Et al., 2022. <u>Diagnosed but not treated: How to improve Patient Access to Advanced NSCLC Treatment in Europe</u>, IHE Report (Accessed May 2022)

⁴ Department of Health and Social Care, March 2022, <u>10-Year Cancer Plan: Call for Evidence - GOV.UK (www.gov.uk)</u> (Accessed May 2022)

⁵ Department of Health and Social Care, March 2022, <u>10-Year Cancer Plan: Call for Evidence - GOV.UK (www.gov.uk)</u> (Accessed May 2022)

⁶ University of Leeds, 2021, Yorkshire Kidney Screening Trial, https://clinicaltrials.gov/ct2/show/NCT05005195 (Accessed May 2022)

⁷ NHS England and NHS Improvement, Rapid Diagnostic Centres Vision and 2019/20 Implementation Specification, 2019, NHS England » Rapid Diagnostic Centres Vision and 2019/20 Implementation Specification (Accessed May 2022)

Royal College of General Practitioners response to targeted screening for Lung Cancer

The RCGP is supportive of population screening when it has been proven to be of benefit and follows evidence-based practice, however, at the current time, without further information, the RCGP is unable to support the use of targeted screening in lung cancer (hence supportive of the committee's decision) unless the follow concerns are addressed.

Health and care bill requirements

The forthcoming health and care bill 2022, contains the legal duty for NHS bodies (ICBs, FTs, England etc.) to consider three aims in making their decisions, which includes consideration of:

- 1. Improving the health and wellbeing of people
- 2. Access to high quality healthcare services
- 3. Efficient and sustainable use of resources

The NELSON trial does not show an improvement in all-cause mortality from using targeted lung screening and so we cannot be certain that this programme will meet criteria 1, improving health and wellbeing. If the trial is under powered then, we would request further research be undertaken before rolling out a national screening programme to ensure the perceived benefits are realised.

Workload/ resourcing

At a time of unprecedented workforce pressures following the pandemic, it is essential that any new programme considers the impact on and required funding for workforce. We cannot be reassured at the current time, given the lack of data on all-cause mortality, that the targeted screening programme will meet criteria 3, efficient and sustainable use of resources. Smoking cessation advice has been proven to be if significant benefit, yet public health prevention funding for these services has been significantly cut. It is essential that we consider the whole patient journey and holistic funding, rather than focus on one area such as targeted screening.

When considering targeted lung cancer screening the impact on all services must be considered, including:

- <u>Primary care</u>. Additional workload may include case finding, review of notes, formal searches, patient appointments to explain the process and risk/benefit of targeted screening, patient appointments to support during the screening programme journey as is seen with all other screening programmes, filing of reports and explaining outcomes to patients, chasing results that are not returned as seen with many other screening programmes. The risk is that a funded targeted screening programme may become an unfunded addition to GP workload
- Additional workload due to incidental findings on scans. It is essential that the screening programme is set up to deal with not only the lung nodules / cancer it aims

to find, but also anything else found on scan incidentally such as breast lumps, aortic aneurysms, bone changes etc. Clinical provision should be sourced as part of the screening programme to reassure patients who may have increased anxiety/ concern because of incidental findings and undertake the follow up tests, referrals and investigations required, rather than assuming primary care will undertake this work, unless funded/ resourced adequately. This additional clinical work must be funded through the targeted screening programme and taken into account if it progresses to a national programme.

• <u>Pathology and radiology</u>. With all specialities in the middle of a workforce crisis it is essential that the workload impact is taken into consideration to prevent increasing delays on sample/ scan results if the programme is taken forward.

Patient information

- We understand that in one area, the "Targeted Lung Health" team produced a patient pamphlet which suggests this screening programme will ultimately "save more lives"; this is, at least, misleading our patients. In the 'Reduced lung-cancer mortality with volume CT screening in a randomized trial' in the NEJM in 2020 reported a reduction in lung cancer deaths but no overall difference in death from any cause. It is essential that the screening programme information accurately reflects the evidence. It may reduce death from lung cancer, but not overall death rate from all causes.
- Patient information on incidental findings, including lung nodules must be clear with support offered as part of the screening programme, rather than relying on primary care to pick up this additional workload.
- Smoke cessation should be considered as part of the targeted lung cancer screening programme for all.

Health inequality

The fingertip data shows that it is highly likely that the most deprived area will have the greatest need due to highest levels of tobacco consumption and it is essential that health inequalities impacts are considered to ensure those that need the screening most are able to access it.

 $\frac{\text{https://fingertips.phe.org.uk/profile/tobacco-control/data\#page/7/gid/1938132888/pat/159/par/K02000001/ati/15/are/E92000001/iid/93753/age/202/sex/4/cat/-1/ctp/-1/yrr/1/cid/4/tbm/1/page-options/ine-yo-1:2019:-1:-1_ine-ct-113_ine-pt-0}$

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FPH ADPH meeting on Lung Cancer Screen GF note

- 1 My thoughts on outstanding issues (accepting I am not up to date with the latest evidence on clinical benefit). These are for the NSC to judge
 - Tidying up and making sure there is good QA of what is there. QA > "the scan", but the whole pathway.

- 2. The **politics of trying to go back** would prob fatally kill NSC (which would defo do more harm than good in net terms). Not sure how open to be on this
- 3. **the financial, workload and clinical consequences of incidental findings**. What's the knock on consequence opportunity cost of what radiologists and others wont be doing in all the follow up. How is it all factored into the economic analysis.
- 4. Cost effective? Scope of CE analysis

Whether the CE analysis actually factored in ALL the costs inc all the lifelong follow up and all the radiology impact that would be needed for this I would say is highly debateable. That said, is it a fair ask – same bar as per any other economic analysis It is actually hard to do, and most economists in my experience like it when it is neat and defined and quite focused. I would hope (but don't know) that the econ analysis did thoroughgoing economic analysis in an NHS context, including costs and harms to those false-positive diagnosed and overtreatment of indolent cases. All the real life stuff that is in the mix in real world but often not on econ analysis. Certainly that was my experience in NICE

CE not cost save etc. More health but more cost at a valuation society willing to bear etc Experience = it is usually the easy targets that bear that (like primary care..... or community nursing Or physio), not less investment in sexy shiny things and drugs that end in mab ... often are barely cost effective so net loss of efficiency and health overall Its never as overt and explicit as this but there is a reasonable evidential case this has been happening for decades

- 5. CE doesn't mean makes resource available. No further resource for smoking cessation simply puts pressure on PH Grant. No further resource for radiology puts pressure there. So someone else, somewhere else bears the opp cost by rote of crappier service or disinvestment to pay for this one My experience and intuition then says there simply wont be investment in all the diagnostics (esp staff) needed for all the pathway that follows screen Thus exacerbating the points that James Crick makes in experience from the Hull pilot.
- 6. Rolling it forward, will the economics and clinical benefit still work at lower and lower smoking prevalence rates. Taiwan study where smoking prevalence is 5% (I suspect will get close to that in some parts of England soon). Yes contextual difference to UK but some interesting insights into net benefit and net harm and how this balances at lower smoking prevalence.
 Once you start, however, it is almost impossible to stop
 Would be worth doing a bit of work to put in context the maximum impact of a successful scheme alongside necessary shift in prevalence etc. I suspect the potential population scale of impact will be tiny in comparison to what is needed and to what can be delivered through broader public health measures.
- 7. hard to separate out lead time bias. Have we REALLY got that bit sorted
- 8. how well proven is the assumption that people with a clear scan will regard it as spur to a quit attempt? Obv could be a teachable moment. Important caveat re WHETHER negative scan could be green light "I am OK" thus carry on. Mostly heavy and persistent smokers and we know that some of them, at least, will see a clear scan as a green light to continue smoking. Perversely, at an extreme, clear scans could discourage rather than encourage net cessation. This needs proper evaluation.

Paying millions for scans but not budgeting for the SSS elements (if effective) is perverse (see my points below on stop smoking).

We all want a scenario whereby routine referral to stop smoking services is a critical component of the lung cancer screening pathway (opt out referral?)

2 Views I have heard from DsPH (mostly on behalf of their teams)

I honestly think there are relatively few DsPH who have really taken the time on this

Id guess there are few DPH per se who are sighted on this (Im a bit of a nerd) but plenty of PH staff who still are oriented around NHS

for almost all of the screening stuff there currently is it rarely comes across my desk or team desk in terms of active involvement. Maybe the initial pilots were a bit "special" in terms of doing all this working out stuff

Cancer screening is one thing within screening, which is one thing within "health care" which is one thing within the totality of public health

Most of us have barely enough capacity to cover the "health care" bit of the role adequately. What requires additional capacity to do necessary stitching together / skilled PH work we don't have General sense this is going to get implemented regardless of the concerns expressed. Too late to roll back now NHSE have set up and started the ball rolling. One you start you cant stop.

3 Views I have heard on the experience of pilots

Overall

Don't underestimate the challenges in getting this set up (from an NHS perspective) – hearts and minds work with Practices to get the necessary searches done (may be a moot point if it is centrally coordinated)

Needs all the usual planning etc that a breast screening van needs if van based model. Community comms, lots of opportunities to not miss. Don't just plonk a van in a car park. Who (if anyone) does that wider community comms to not miss opportunistic work done to support smoking cessation.

Cohort identification

Robustness of smoking coding – thus accuracy of the list. still needed to be a clinical validation process and this added work (substantial amounts in some cases) to an already stretched GP workforce

There are people for whom this is not appropriate (frail older adults for example) – using "ever smoked" as a search criteria picks up a lot of people who may have smoked in their teens in the post-war years so a clinical review of ALL search results was required

Numbers

Liverpool/Halton/Knowsley triangle.

Total Eligible Patients 42653 Invites sent (% of total) 38373 90% responded (% of sent) 27728 72% accepted (% of responded) 13174 48%

12733 attended - ...lung cancer identified 34 ...of which stage 1 20 ...of which stage 2 3 ...of which stage 3 3 ...of which stage 4 5 Receiving surgery? 10 ...non lung cancer identified 5 Numbers can also give a sense of possible stop smoking service referrals

Donny

Roughly 53,000 people referred – over 24,000 'off boarded' and where there are patient reasons only for 10% of those the reasons were doesn't meet eligibility (65%), or unable to contact patients or patient doesn't feel they will benefit (30%)

13,000 checks by April 2022

5,700 low dose scans, 1074 follow up scans

Range of CT findings including 146 suspected lung cancers, thoracic and aortic aneurysms By march 79 cancers – 62 lung cancers (78% stage 1 or2) with 47 receiving 'curative surgery 670 patients refereed for stop smoking with 240 setting a quit date

I've not seen any demographic data or outcome data yet for attenders or non attenders.

Lung health checks and the wider programme it sits in

Targeted lung health checks are only part of the programme – it is unethical to identify people with a potentially urgent need for a treatment in the knowledge that there is no capacity in the cardiothoracic service to accommodate these patients. Capacity in the surgical workforce (recognising that the aim is to get more cases identified at a time where surgical resection is possible and therefore cardiothoracic surgeon, theatre, and ICU capacity is needed).

Incidental cancers - The Hull programme has picked up cancers... lung, one or two oesophageal, and I think a few breast – so that's good, and the lung cancers have been amenable to resection in the main.

the tumour might be amenable to resection, but the morbidity of the patient may mean that they (as a human being) may not be amenable to surgery.

Identification of other issues and implications

Nodules – protocol in place but not clear how the follow up is coordinated and what the impact is on diagnostics (as diagnostics is often cited as reasons for other pathway delays (Hull) – are we just moving the bottle neck from one specialty to another?).

Primary care

Reasonable number of GPs are exercised by the high number of dubious findings on scan that they will need to handle the uncertainty of with patients, feels hard given very poor access to primary care that we are already struggling with.

One example - of 1385 attendance from that's GPs PCN area 874 had scans and 506 resulted in primary care referral- over about 2 months (130k pop, 14 practices). Take great care landing this with primary care. Will anyone resource the workload.

Coronary artery calcification – probably puts individuals at higher risk of CVD but unclear how that feeds through existing NHS prevention approaches as these individuals probably require a risk stratification score (QRISK – not currently done but next iteration of the SOP looks like it might be included) and a clinical conversation about risk reduction approaches (probably high intensity statins in addition to the usual lifestyle modifications). Impact on NHS Health Checks and on primary care capacity

4 Role of PH team (from pilots – accepting this will change)

Healthcare public health/PH Intelligence

Coordinating the data and turning it into actionable intelligence

Estimating the likely need for the service

Describing the potential need and linking it to some of the social determinants of health to support conversations about prioritisation

Advocating for particular locations based on need

Advocating for locations based on travel/socioeconomic status/etc. (so GIS – I used SHAPE) Keeping the wider pathway conversation on the agenda (i.e. we diagnose more, but have no more treatment capacity – where do they go then? What is the impact on other parts of the system? Etc.). Keep nudging around those populations who did not smoke but may be at greater risk – AQ around the A63 is not great – trunk road from the docks to the M62 with people living close by in some areas

Evaluation – being the critical friend in any evaluation process

Currently still quite process orientated due to the delays in the last 18months, but I would see my role as being involved in the evaluation to understand if it did do good (in terms of early diagnosis, but also in terms of other opportunities to impact on population health – e.g. tobacco), identify what harms it might have had an impact on, and whether it narrowed or widened the inequalities gap.

Health Improvement

Linking the local programme with tobacco programme lead/provider. (bitter) experience says the workload implications for this from our tobacco leads is enormous, that is before we get to funding for SSS.

4 Tie to stop smoking

Making this smooth and slick is key. The implementation of the Ottowa / CURE model hasn't been simple or easy.

Don't under estimate the enormous effort that has been put in by our tobacco leads on tying up pathways between hospital model (Ottawa) and LA commissioned SSS. It has been a royal trauma and maybe more trouble than worth. SSS is one part of tobacco control programme and our tobacco leads thus only have a small part of a job on SSS.

Funding for SSS

Local Authorities cant soak up financial risk of lots of extra community SSS activity as a result of SSS referrals coming out of Lung Cancer Screen. We WANT to (it is a good thing), but where there is no "slack capacity" in SSS we need to invest more for more activity.

We don't have the budget – or we do but at opportunity cost of other bits of PH Grant.

Want a money follows quitter principle – the actual budget will probably vary. Sheff pays £210 per referral (currently get 3,00 a yr) and £550 for 12 week quit attempt

Funding medicines is critical. NHS cost for us. Negotiating that difficult.

No getting away from the fact that some possibly lots of authorities have significantly cut or wholly decommissioned funding for smoking cessation services

NHS will obv want to be assured that any additional NHS resource being used in the right way across the country so need to think carefully about what sanctions and ring fencing could be applied to ensure investment goes where it is needed and does not just plug the gap for a lack of service provision overall.

TDLR - if we want a win win

- 1. the NHS needs to be flexible and work with systems already established and not either impose a system (that wont work with local) or set up some completely parallel systems.
- a principle of funding for a quality assured stop smoking service comes as part of the package (delivered to evidence based model recommended by NICE and NCSCT, OHID, Not just NHSE that develops new guidance that is out of synch). Somebody needs to be responsible for assuring the model of stop smoking services is delivering to the right standard, OHID? (resourcing to do)
- 3. Funding for stop smoking. The current Ottowa / Cure model is short term NRT and not long enough psych support. What happens on discharge? ...referral to community SSS. I WANT more referrals to community SSS, but I have no budget to pay for it.... thus if I have to I will just sack some sexual health doctors or some health visitors etc. funding for NRT also been thorny.
- 4. QUIT as it is currently incepted is a community SSS referral service where the money doesn't follow the person
- 5. local authorities have to be responsible for commissioning this (the patient and health professionals will get confused otherwise it will be too hard and we will create more barriers than enablers). Clinicians get confused, patients get confused and we end up with an inefficient mess. Which we then need to tidy up. We are trying to avoid patient/smokers having to navigate a confusing system and leaves the onus on the system to support effectively and efficiently. It has taken 3-4 years to sort this re Ottawa (admittedly a pandemic got in way).

- 6. focus on the end outcome certified 4 and 12 week quit is as good a proxy as we can hope for.
- 7. That said flexibility in delivery is key here to ensure we can meet needs of local populations. Local pathway might need to look different place by place (nature and look and feel of services differs clue is in the title *Local* Govt)

Mansfield data on SSS referrals

Data for the period 1st April 2021 and 30th April 2022 shows: 263 referrals, 141 (54% take up) setting a quit date, 65 quits

GF 20/5/22