Cancer Research UK policy statement: Targeted Lung Health Checks and lung screening

Summary

Lung cancer is the third most common cancer in the UK and is the leading cause of cancer death, accounting for 21% of all cancer deaths in 2016. Around 35,600 people die from lung cancer every year in the UK – equating to nearly 100 people every day.

Only 15% of people diagnosed with lung cancer in England will survive their disease for five years or more – and there has been little improvement in long term survival over the past 40 years. A major reason that lung cancer survival is poor is that more than 7 in 10 lung cancer cases are diagnosed at a late stage, when there are less curative treatment options available; only 3% of people diagnosed with stage IV lung cancer in England will survive their disease for 5 years or more compared to 56% of people diagnosed with stage I. It’s therefore essential to reduce the number of people diagnosed with late stage lung cancer as this will give more patients a better chance of successful treatment and survival.

Achieving this will require a wide range of approaches, including improving public and primary care awareness of, and response to, the signs and symptoms of lung cancer. This is essential to increasing the number of patients diagnosed through urgent or routine GP referral, rather than as an emergency presentation. There is also potential to improve the asymptomatic diagnosis of lung cancer. A key area of emerging promise is the use of low-dose CT scans in high risk populations (currently defined as people with a long history of smoking) to detect lung cancer early in people without symptoms. Some people invited for a low-dose CT scans will present with symptoms but did not present to their GP, as they may not identify it as a symptom for lung cancer.

A number of trials have provided evidence for this approach to asymptomatic lung cancer diagnosis. The US National Lung Screening Trial reported a 20% reduction in lung cancer mortality when CT scans were compared to x-rays when scanning individuals at increased risk of lung cancer and this provided a basis for further research. The European NELSON trial started in 2003 and has been investigating the impact of using CT scans in individuals at increased risk of lung cancer, with early results suggesting a significant mortality benefit. Peer-reviewed publication of these results is eagerly anticipated.

In light of emerging evidence from these trials, clinicians in England have started developing local projects offering low-dose CT scans to individuals identified as being at increased risk of lung cancer. As these projects aimed to identify and treat early stage disease in asymptomatic individuals, they can be considered as screening approaches - but are referred to by various terms in practice. Some people offered a low-dose CT scan, through a local project, may have symptoms which they hadn’t presented to their GP with, as they may not identify their symptoms as a potential sign of lung cancer.

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1 In the NLST control arm, high risk individuals received chest x-ray so the comparison was chest x-ray versus CT scan, rather than usual care versus CT scan.
2 Compared to usual care
NHS England is now building on these local projects’ successes by supporting the roll-out of similar activity nationwide via the Cancer Transformation Fund. In February 2019, the 14 sites of the Targeted Lung Health Check programme were announced. Currently, there are no proposals for the roll-out of a similar programme in the devolved nations.

Decisions on national population cancer screening programmes are the responsibility of the UK National Screening Committee (NSC). The NSC decision-making process aims to ensure robust assessment of the balance of benefits, harms and cost-effectiveness associated with screening. A recommendation to Government from the NSC can then help to unlock national funding and high-quality and consistent procedures and quality assurance, which help to ensure equitable access to a safe, sustainable and effective screening programme.

The Targeted Lung Health Check programme is being developed with the advice of PHE screening, in the absence of a recommendation for a national lung screening programme from the NSC. Therefore, while NHS England is financing the first 14 sites, this funding is not guaranteed beyond 2023 nor guaranteed for widespread roll-out. Moreover, the high standards demanded of national screening programmes to ensure equitable access, clinical effectiveness and safety are not guaranteed via piecemeal roll out approaches. It is therefore vital that as these targeted interventions develop, they have safe and standard effective processes with robust, nationally centralised data collection, collation and evaluation. This is vital to ensure minimal patient harm and maximum patient benefit, and to ensure that enough high-quality evidence is available to inform future policy and practice.

Once published or made available, the NSC will review the NELSON results, and those of any other relevant trials or studies, to consider whether recommending a national programme is appropriate. However, fundamental questions remain as to whether the NSC considers lung screening to be within its remit, because lung screening focuses on individuals at increased risk rather than the population as a whole. It is therefore not yet clear whether the NSC will itself make a recommendation on a national lung screening programme, nor how to proceed if they do not. This ambiguity should be resolved as a matter of priority.

If a recommendation is made to implement a national lung screening programme, we would like to see all Governments in the UK implement the recommendations as quickly as possible. As the Targeted Lung Health Check programme continues to develop and be implemented in England, it must be governed by clear processes to maintain quality and prevent variation in effectiveness and safety.

Evaluations of the Targeted Lung Health Check programme should be sufficiently rigorous so that the evidence gathered can be used to help support the decision as to whether and how the programme should be expanded and implemented nationally. We recommend that the other UK nations use this evidence, when it emerges, to inform the development of their own programmes. However, we recognise that there is some enthusiasm for this approach now, so we urge any governments intending to pursue the Targeted Lung Health Check approach to carefully consider the recommendations of this paper.

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3 The sites were selected based on: lung cancer incidence and mortality, population size, having no established lung screening/lung health check programme.
This statement sets out Cancer Research UK’s position and makes several recommendations for NHS England, the UK National Screening Committee and others to consider for the Targeted Lung Health Checks and as findings emerge from NELSON and other trials.

**Recommendations**

1. **NHS England must ensure strong national governance for the Targeted Lung Health Check programme.** This should include a clear quality and evaluation framework and plans to centrally gather high-quality data in several key areas, including data on clinical effectiveness, and workforce and equipment requirements.

2. **NHS England should have clear guidance and support in place for CCGs to ensure their programmes have effective patient pathways both for lung cancers diagnosed and for other, non-cancer diagnoses.**

3. **CCGs, supported by NHS England, should ensure that there is sufficient diagnostic capacity and infrastructure, as well as the necessary treatment capacity in surgery and oncology, to meet increased demand from the Targeted Lung Health Check programme.**

4. **NHS England should ensure that Targeted Lung Health Checks integrate comprehensive and fully funded smoking cessation provision.**

5. **NHS England should use the new primary care network specification for the early diagnosis of cancer to ensure that GPs are sufficiently supported and incentivised to gather up-to-date data on patients’ current and past smoking status, so that the initial selection for Targeted Lung Health Check invitees is as effective as possible. Currently this is collected every 24 months through the Quality and Outcomes Framework.**

6. **Careful consideration must be given to whether any new projects should be rolled out at this time, including projects in Scotland, Wales and Northern Ireland. Future projects should benefit from the lessons learned through the implementation and impact of Targeted Lung Health Checks within NHS England. We would advise any new projects to follow the national framework and quality protocol for Targeted Lung Health Checks.**

7. **The Government should consider the forthcoming findings of the Richards’ Review of national screening programmes in England, and subsequently clarify whether the UK National Screening Committee is responsible for making a recommendation on lung screening, and whether population screening includes stratified approaches. If not, the Government should be clear where responsibility for decision-making sits.**

8. **Conditional on recommendation 7, the UK National Screening Committee should review the latest evidence within 9 months of the publication of the NELSON trial in a consultative and transparent manner. If a recommendation *is* made to implement a national lung screening programme we want to see national roll out as quickly as possible to prevent geographically variation.**

9. **NHS England should continue to focus on improving the early diagnosis of lung cancer through other routes, including public awareness campaigns as most people will not qualify for Targeted Lung Health Checks because of age, postcode or the inaccuracy of their recorded smoking status or history, and only a proportion of those receiving the Lung Health Check will meet the risk threshold for a CT scan.**

10. **NHS England must clarify how the Targeted Lung Health Check Programme will be taken forward, if the UK National Screening Committee does not recommend a national lung screening programme.**
Further background

When lung cancer is diagnosed at its earliest stage (Stage I), more than half (56%) of people will survive their disease for five years or more, compared with only 3% of people when diagnosed at the latest stage (Stage IV)\(^4\). Yet currently, in the UK, around 1 in 5 lung cancers are diagnosed at the earliest stage (18-21% are diagnosed at stage I) compared to around 1 in 2 diagnosed at the latest stage (48-50% are diagnosed at stage IV)\(^4\).

Patients are more likely to be diagnosed at an early stage when referred through a managed route such as an urgent or routine GP referral\(^i\). Patients diagnosed following emergency presentation are much more likely to be diagnosed at a late stage – yet this is currently the most common route to diagnosing patients with lung cancer. 32% of patients with lung cancers are currently diagnosed as an emergency\(^ix\).

Several trials and pilots are currently exploring the potential for using low-dose CT scanning in high risk populations to detect lung cancers earlier. The European NELSON trial tested this approach to determine whether it is effective at a population level. Following initial evidence of mortality benefit from NELSON, NHS England’s Targeted Lung Health Check Programme will generate further evidence on the effectiveness of low-dose CT scanning, as well as a greater understanding of how this approach could work within the NHS.

Reducing late stage diagnosis is multifaceted, so efforts must be made to encourage the public to seek help earlier and to encourage GPs to use appropriate referral guidelines, so patients can have early access to the right diagnostic tests and receive their results in a timely way. This approach will support the diagnosis of more lung cancers at an early stage for patients with symptoms as well as those diagnosed through Lung Health Checks.

Targeted Lung Health Checks

NHS England is developing the Targeted Lung Health Check programme. 14 CCGs across 10 Cancer Alliances have been identified to take part in the next phase of the programme to 2023, targeting areas with the highest rates of incidence and mortality of lung cancer in the relevant patient population. These areas will be responsible for delivering Targeted Lung Health Checks according to a standard protocol, offering low-dose CT to individuals at high risk of lung cancer and gathering data for the evaluation of the programme.

Cancer Research UK supports the development of the Targeted Lung Health Check programme as it provides an opportunity to generate evidence on the feasibility, quality and impact of this type of activity within the NHS. It will also help to assess whether and how a national lung screening programme could be embedded within the NHS and understand how targeted high-risk case finding will impact the early diagnosis of lung cancer in England.

The NHS England programme builds on evidence from large-scale trials and is informed by other local projects such as those within the Accelerate, Coordinate, Evaluate (ACE) Programme\(^x\).

approach involves inviting patients considered at an increased risk of developing lung cancer to have a lung health check. This is likely to be based on their smoking status and history in their GP record.

A lung health check includes a further assessment of lung cancer risk based on a range of factors and may also include other ‘add on’ health interventions such as a spirometry test. This also provides opportunities to refer people who currently smoke to smoking cessation services – or to provide these services directly – to help people quit and lower their lifetime risk of developing lung cancer as well as other diseases. Any patient assessed as being at high risk of lung cancer is immediately invited to a low-dose CT scan, with three potential outcomes:

- No significant finding – follow-up scan 24 months later
- Indeterminate results – second scan 3 months later, with a further follow-up at 12 months later, depending on the nodule
- Results require further investigation – referral to a local specialist lung clinic

Where the results are inconclusive, or all clear, appropriate monitoring and follow-up procedures are put in place. We think it’s important that people have time to properly consider whether a low-dose CT scan is right for them. Participants should have the option to have a low-dose CT later if they choose not to have one right there and then.

Because lung health checks are aimed at apparently healthy people, and because tests for suspected lung cancer, such as lung biopsy or bronchoscopy, can be invasive - these local projects need to be supported by evidence and have effective governance and oversight in place to ensure that they are safe, effective and generating positive outcomes for patients. They must:

- be steered by evidence-led guidelines;
- have national oversight;
- collect data that can inform detailed evaluation and learning;
- be quality assured; and
- provide high quality information to patients on the benefits and harms, to ensure participation in lung health checks is an informed choice.

NHS England’s Lung Cancer Clinical Expert Group has developed a national quality protocol. This is a welcome step to ensuring that there is a clinically agreed model for the expanded programme and it will be important to ensure that local projects are meeting this protocol, and that they are effectively quality assured against the protocol.

NHS England has established a Delivery Group for the programme which reports to the National Cancer Programme, and an Expert Advisory Group has been established to provide clinical oversight to the programme. It is important that the programme is run transparently and has strong oversight, so these steps are welcome. NHS England must use these structures effectively to ensure that the programme is informed by expert insight throughout and that they are able to provide effective governance.

Crucially, it is essential to ensure that these projects operate within a robust evaluation framework, and that data produced by the sites is used both to generate learnings about best practice and for quality assurance. The development of the programme beyond the next phase will rely on there being strong data demonstrating clinical effectiveness and safety, as well as data on infrastructure requirements such as workforce and diagnostic equipment.
Future projects should benefit and learn from this data so careful consideration must be given to whether any new projects should be rolled out at this time, including projects in the devolved nations. We would advise any new projects to follow the national framework and quality protocol for Targeted Lung Health Checks. This is particularly important for projects happening outside of the 14 initial CCGs in England, where the national framework must be followed to ensure that variation is not introduced.

As well as ensuring strong standards and oversight for the expanded programme, there are several priorities which we feel NHS England and participating CCGs must consider when establishing services, and which other projects outside the NHS in England should also consider carefully.

**Integrating Targeted Lung Health Checks with existing services**

It is important that local areas provide clarity about the way that the Targeted Lung Health Check pathway operates, according to national standards set out by NHS England. The involvement of general practice is important to define: for example, whether GP records will be used to invite participants on behalf of their general practice, or whether GPs will be involved in vetting data drawn from the GP record – and if so, how they will be resourced to do this.

CCGs must ensure that local programmes have effective diagnostic referral pathways in place so that the results of the initial low-dose CT scans can be reported in a timely manner and are read by an appropriately trained reporter. If there are concerning findings resulting from the initial low-dose CT, it will also be important to ensure that patients can be seen quickly by specialist diagnostic services, without adversely impacting on the ability of diagnostic services to plan their capacity or to the detriment of patients referred via other routes who are suspected to have lung cancer.

Finally, the programme must be effectively integrated with existing services to facilitate the management of findings other than cancer. The diagnosis of other respiratory diseases such as COPD was a key component of several Lung Health Check pilots conducted as part of the ACE programme. Results from the Liverpool pilot suggested that 386 people (out of 612 people with abnormal spirometry) would receive a new diagnosis of COPD. It is essential that patients who receive a new, non-cancer diagnosis through a lung health check can access the care that they need.

**Increasing capacity in diagnostic services**

Pressures in diagnostic services are well-documented. It will therefore be essential for local areas, supported by NHS England, to ensure that there is sufficient capacity in services to meet additional demand from the introduction of Targeted Lung Health Checks.

Over a thousand low-dose CT scans were performed as part of the Manchester trial. Scaling up the programme will require significant additional numbers of CT scans to be performed. However, figures suggest that significant funding is required to replace ageing CT scanners, and the OECD has demonstrated that the UK has a very low number of CT scanners per million population. As the 14 areas develop Targeted Lung Health Check programmes they must plan carefully to ensure that they have sufficient equipment to be able to deliver increased numbers of low-dose CT scans – and NHS England must ensure that local areas are supported to be able to provide this equipment capacity.

Delivering and reporting these CT scans, as well as carrying out the initial lung health check and any resulting investigations, will also rely on there being sufficient numbers of appropriately trained staff. A recent report by Cancer Research UK identified the potential roll-out of lung health checks as
a key driver of increased demand on the workforce, particularly the nurses and support staff involved in delivering the lung health check and the radiographers and radiologists responsible for delivering and reporting CT scans.

Local areas should work with NHS England and Health Education England to ensure that there is sufficient workforce capacity to effectively staff the Targeted Lung Health Check programmes including nurses - to perform the initial assessment and the spirometry - and smoking cessation support staff. Ensuring that the programmes are established effectively and well-integrated with other parts of the system will also require there to be dedicated programme management support, which cannot be neglected. Efforts should be made in parallel to explore technology solutions which could be used to increase diagnostic capacity such as networked radiology services to enable reporting from any site to be completed from anywhere.

Moreover, if the programme were to achieve a significant shift to diagnosing patients at an early stage, the staff capacity required to deliver increased levels of curative treatment must also be considered in workforce plans for surgery and clinical oncology. This should be done at the national and local level to understand the impact of stage shift and ensure there is sufficient capacity in the current workforce and inform future training requirements.

As part of data gathered through the expanded programme, it should be a priority to understand the impact of Targeted Lung Health Checks on diagnostic and treatment capacity, so that if the programme is further expanded, for instance into a screening programme, then the impact on workforce and capacity can be clearly modelled and planned for.

**Integrating smoking cessation services in the Targeted Lung Health Check programme**

Lung cancer is highly preventable, with around 7 out of 10 lung cancers caused by smoking. Therefore, efforts at the national and local level to reduce adult smoking rates and support people to quit are as vital as efforts to reduce late stage diagnosis of lung cancer. Smoking is estimated to cost the NHS £2.5bn every year, while quitting smoking is also beneficial for wider health and can have a positive effect on the progression of some illnesses that may also be diagnosed through a lung health check, such as COPD.

Therefore, using the Targeted Lung Health Check programme as an opportunity to deliver smoking cessation support is an important way of reducing tobacco use, especially among at-risk populations. It is particularly important to provide smoking cessation advice as an integrated part of the Lung Health Check, to ensure funding and access at a time when local services are being cut significantly. Smoking cessation advice will help counter the risk that patients who receive a normal result from their low-dose CT scan continue to smoke. It is crucial this risk is considered carefully and the effect on cessation in patients evaluated effectively.

It is welcome that integrated smoking cessation support is reflected in the protocol for new Targeted Lung Health Check programmes, and it is essential that this is delivered in practice. Local areas, supported by NHS England, should ensure that they have sufficient numbers of staff trained in delivering smoking cessation support to ensure that all current smokers who take part in the Targeted Lung Health Check programme are given stop smoking support on an opt-out basis.

**Lung screening**
Screening involves testing people who don’t have any symptoms of the disease in question. This means that the harms and benefits must be weighed up carefully. In the UK, screening policy changes are recommended by the National Screening Committee (NSC). The committee is responsible for considering the balance of evidence about introducing new approaches in the NHS as part of a national screening programme.

As approaches to risk stratification become more sophisticated, so too will the ability of cancer screening programmes to adopt these approaches, potentially becoming more targeted, more effective and safer. It will therefore be essential to ensure that clear decision-making processes are in place to consider new cancer screening programmes based on risk stratification, as well as the introduction of greater risk stratification in existing programmes. It is vital that this question is resolved so that when evidence is available to support a potential screening programme, it is reviewed as efficiently as possible and a clear recommendation made.

This is important in the case of lung cancer screening, which would be based on enhanced risk stratification. It is currently unclear whether a decision to recommend a lung screening programme would be made by the National Screening Committee because of this enhanced risk stratification approach.

Risk stratified patient management programmes do currently exist within the NHS. For example, the National Institute for Health and Care Excellence (NICE) currently provides guidance on screening people at high and moderate risk of developing breast cancer. Particularly pertinent in the case of lung cancer screening, the Targeted Lung Health Check programme is being developed according to a protocol developed by experts advising NHS England. Questions have been raised as to whether Targeted Lung Health Checks could be considered a risk stratified, clinical management approach that could fall within the remit of NICE, rather than a screening programme. It is important to resolve this ambiguity in anticipation of any future expansion of the Targeted Lung Health Checks programme.

The NSC is responsible for deciding on whether to recommend a screening programme according to several criteria, including that the target population should be sufficiently large to enable safe, clinically and cost-effective screening and that the target population would not necessarily regard themselves as having symptoms or to be at risk of the disease in question.

Cancer Research UK values the quality assurance that the NSC provides to screening programmes through the objective assessment of the balance of risks and harms, and clinical and cost-effectiveness. When the NSC recommends adopting a screening programme, national funding can be provided to ensure a consistently safe and high-quality programme with equity of access throughout the country. This is not necessarily the case for guidance issued by NICE or NHS England. It is therefore important to resolve wider questions about decision making for new approaches to screening programmes. The forthcoming review of national screening programmes in England should seriously consider this question, and the Government should use its findings to clarify where these decision-making responsibilities lie.

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Regardless, the UK NSC should review the latest evidence for lung screening within 9 months of publication of the findings from the NELSON trial. This should be reviewed carefully and transparently, in consultation with relevant experts, to inform the ongoing development of projects and so that the NSC is able to make a recommendation if it is decided that they are the appropriate decision-making body. This review should be robust but flexible, and sensitive to the nuances of a potential risk stratified programme, such as the size of the population and the method of its selection. It is important both to ensure the safety and quality of a potential lung cancer screening programme and to ensure that a potential opportunity is not missed to improve the early diagnosis of lung cancer.

Symptomatic diagnosis of lung cancer

In the three cancer types with national screening programmes in the UK (breast, bowel and cervical), routine and urgent GP referrals continue to be the most common route for these cancers to be diagnosed. It is welcome that NHS England are trying to improve lung cancer outcomes, but it is important to remember that Targeted Lung Health Checks or a screening programme are only part of the solution. Improving early diagnosis of symptomatic lung cancer is multifaceted and is important as most people will not qualify for a lung health check, and fewer still for the low-dose CT scan.

While smoking is a leading cause of lung cancers, it remains the case that around 3 out of 10 lung cancers are not attributable to smoking. These cancers would not currently be detected by a risk stratified Lung Health Check or screening programme for which the initial approach is based only on age and smoking history, so it is important to ensure that other routes to diagnosis are also continually improved to support the earlier diagnosis of all lung cancers.

Efforts must be made to encourage the public to seek help earlier and for GPs to use appropriate referral guidelines so patients can have the right diagnostic tests and results in a timely way. NHS England and NHS Wales should continue to focus on ensuring that NG12 guidelines are implemented nationwide so that GPs are making appropriate urgent referrals for suspected lung cancer at a lower threshold of risk, and these referrals are being accepted in diagnostic services. The Northern Ireland Department of Health should aim to adopt these guidelines, while in Scotland the update Scottish Referral Guidelines for suspected lung cancer should be implemented effectively.

Similarly, encouraging patients to present early to general practice with potential symptoms of lung cancer is important to support a reduction in emergency presentations and late stage lung cancer diagnoses. Increasing symptom awareness among the public is important to this as well as improving access to general practice. Public awareness campaigns such as Be Clear on Cancer are an important means of encouraging the public to seek help earlier with any signs or symptoms that could be cancer— it is important to ensure that these campaigns find ways to reach those most in need.

Efforts must be made to dispel the myth that only past or current smokers develop lung cancer.

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viii CRUK, Why is early diagnosis important? https://www.cancerresearchuk.org/about-cancer/cancer-symptoms/why-is-early-diagnosis-important


xiii Capacity to Diagnose? CRUK 2018 https://www.cancerresearchuk.org/sites/default/files/mar18_capacity_to_diagnose.pdf

xiv Ibid.


xvi Ibid.


xxii https://www.cancerresearchuk.org/health-professional/awareness-and-prevention/be-clear-on-cancer/lung-cancer-campaign