Liverpool Healthy Lung Programme – Second year Evaluation Report

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Executive Summary

The Liverpool Healthy Lung Programme (LHLP) is an initiative aimed at improving respiratory health and diagnosing respiratory disease at a more treatable stage, taken by the Liverpool Clinical Commissioning Group (CCG) working with communities across Liverpool.

The programme had 2 sequential phases. The first organised focused public engagement events throughout the city and was independently evaluated by Research Works Ltd.

The second phase (commencing April 2016 and still ongoing) is a programme of individual lung health consultations, risk assessment and referral for CT scans for those at more than 5% risk of lung cancer in the next five years.

Eligible patients are ever-smokers or subjects with chronic obstructive pulmonary disease, aged 58-70 (extended to 58-75 in May 2017). They are invited by their general practice for a lung health check appointment with a respiratory nurse in a community health hub setting where a detailed risk assessment is conducted. Histories and risk factor information are taken, including: emphysema, bronchitis, COPD, tuberculosis, exposure to asbestos, family history of lung cancer, history of malignancy and smoking duration. Height and weight are measured to calculate the body mass index (BMI). In those without a pre-existing diagnosis of COPD, spirometry is used to assess lung function.

Those with abnormal lung function on spirometry are referred for further investigation. Smoking-related and other lifestyle advice is offered, along with referrals to smoking cessation clinics and other services, for example pulmonary rehabilitation for people with COPD.

Five-year risk of lung cancer is estimated using the MyLungRisk calculator. Those with five-year lung cancer risk of 5% or more are offered a referral for a low-dose CT scan. All the patients were asked for their consent to share data for external evaluation.

Data have been supplied to the evaluation team on 3,591 Healthy Lung Programme consultations and associated radiology reports from CT scans from persons consenting to data sharing, up to 10th January 2018. 11,526 people were invited to a healthy lung appointment and 4,566 (40%) had attended. Thus, consent for data use has been given and data processing has been completed for 79% of attenders (3,591/4,566).

Major findings include:

- The median age was 66 years (range 58-76), 1,853 (52%) of the attenders were male, and 2,897 (81%) were in the most deprived Index of multiple deprivation (IMD) quintile.
- The median duration of smoking for the 2,603 individuals reporting this was 40 years (range 0-61).
- Of the 3,591 subjects, 823 (23%) had an existing diagnosis of COPD and 527 (15%) had a previous diagnosis of cancer. 1,173 (33%) subjects had a family history of cancer. The median estimated 5-year risk of lung cancer was 4.4% (range 0.2%-48.9%).
- A high proportion (34.6%) reported exposure to asbestos.
- Of the patients attending the health checks, 745 agreed to receive smoking cessation advice.
- Aggregate data from non-responders and persons attending a lung health check but not consenting to individual data sharing, indicated that age and sex distributions were similar for the responders, non-responders and non-consenters. The IMD distributions did differ

slightly, with 81% in the most deprived quintile among the responders, 83% in the non-responders and 84% in the non-consenters.

- There were significant differences between Neighbourhoods with respect to IMD and five-year lung cancer risk. The most deprived attenders were from Riverside and Croxteth, and the highest lung cancer risks were observed in Riverside and Everton.

- There were 1,557 (43%) patients with 5-year lung cancer risk greater than or equal to 5% and 1,548 (99.3% of those meeting the 5% risk criterion) were recommended for a CT scan. Of these, 1,318 (37% of total, 85% of those recommended) had had a CT scan at the time of close of data collection.

- 119 (9%) patients who had a CT scan required further investigation (follow-up CT scan at 3 or 12 months, or immediate referral to pathway)

- 25 (1.9% of those undergoing CT scan) patients were diagnosed with lung cancer. A further 11 had suspected lung cancer and were undergoing further investigations at the time of data capture.

- Of those attending, 2,255 (63%) underwent spirometry. Spirometry was abnormal in 845 (37% of those tested) subjects. A sub-study of those referred found that 34% would be expected to be diagnosed with COPD, so we anticipate that in this population, 287 (10% of the 2,759 subjects without a pre-existing diagnosis of COPD) subjects will have a new diagnosis of COPD.

- Prior to the age extension 812/2,067 (39%) received a scan and 13 were found to have cancer, a prevalence of 1.6% of those scanned, 6 per thousand consultations. The corresponding figures after the age extension are 507/1,524 (33%) scanned and 12 cancers, 2.4% of those scanned and 8 per thousand consultations. Thus, the age extension has improved both the detection rate and the specificity of referral for a CT scan.

- Data were available on 560 LHLP participants referred to diagnostic spirometry; 119 did not have diagnostic spirometry. Diagnostic data was available for 412 (93%) of the remaining 441 patients. 193 patients (47% of those undergoing diagnostic spirometry with diagnostic outcome recorded, 34% of the 560 referred), were diagnosed with COPD or possible COPD. There were 44 (11%) diagnoses of asthma or possible asthma. 22 (5%) patients were diagnosed with restrictive lung disease.

- In a sub-study on reported SOF from the LHLP CT scan. Patients were identified with a SOF on their CT scan report and risk stratified into major and minor, then questionnaires were distributed, via the CCG, to practices using NHSnet. While a number of benefits of detection of SOF were noted, in-depth evaluation of this will require more effective data capture in the future.

- Of the 25 lung cancers, 16 (64%) were stage 1, 3 (12%) were stage 2, 6 (24%) were stage 3 and none were stage 4. Stage I and II cancers comprised 76% of the lung cancers diagnosed, significantly (p=0.003) greater than the 22% expected from the general lung tumour population.

- The stage distribution of the 25 lung cancers has been combined with national five-year stage specific survival rates to give expected lung cancer deaths in the Programme. We expect 18 deaths from lung cancer in the five years following diagnosis. If the LHLP CT-detected cancers had had the same stage distribution as the national population of lung cancers, we would have expected 23 deaths. Thus, among those consenting, the programme

is expected to have prevented 4-5 deaths from lung cancer, one death prevented per 264-330 CT scans.

- From April 2016 to January 2018, 34 patients were referred from the LHLP to cancer services at Liverpool Heart and Chest Hospital, of whom 27 had consented to having their information shared. The average LLP risk scores for those referred was high at 14.28 (5.61-39.73). The mean age of those referred was 68.5, with similar numbers of males (15) and females (12). 12 of the patients had a diagnosis of lung cancer and 15 were either still under investigation or did not have lung cancer at the time of writing.

- We analysed the pathway for the 15 patients found not to have lung cancer, there were very few harms associated with these patients being referred to cancer services.

- We carried out open-ended interviews of the nurses delivering the LHLP service, focussed on their experience of the programme, the reactions they have received from the public, and the consequent identification of areas for improvement in the programme. Anonymised quotes are provided in the report all very positive, with helpful suggestions. Details of this work is provided in the full report.

There are a number of implications of the above.

- Of the 3,591 subjects, 23% had an existing diagnosis of COPD. Following spirometry of those who did not already have a COPD diagnosis, 845 (24%) had abnormal lung function, and from previous clinical experience it is anticipated that 287 (10% of those without a pre-existing diagnosis) subjects will in due course be diagnosed with and treated for COPD. The sub-study on spirometry and COPD demonstrates that the use of non-diagnostic spirometry does have clinical value and can aid in detecting respiratory disease in patients who are eligible for treatment, which will help to improve their quality of life and prognosis. Especially as many with of those patients with a new COPD diagnosis, were reported as “mild COPD” and are thus much more likely to respond to treatment.

- 1.9% of those scanned were found to have lung cancer. The stage distribution of lung cancer indicated a reduction in mortality compared to that expected from the general population of around 20%, similar to that observed in the US randomised trial. This corresponds to 26% five-year survival in the cancers diagnosed in the programme, compared to the 10% which would be expected without the programme, more than a doubling of the five-year survival rate in cancers detected as a result of CT scans in the programme. This translates to an absolute prevention of 1 lung cancer death per 264-330 CT scans, rather more favourable than observed in the US trial, possibly due to the very high-risk level required for eligibility for a CT scan in LHLP.

- 9% of nodules required further workup in LHLP, considerably lower than observed in the randomised trials, thus requiring less CT scans for the patients and reduced pressure on the radiological services.

- An encouraging proportion of subjects agreed to receive smoking cessation advice, and referral to smoking cessation services.

- The risk criterion used in the LHLP for a CT scan was 5% risk of lung cancer over five years. From the receiver operating characteristics of the LLP model, 42% of lung cancers would be estimated to arise in this risk group. Relaxing the criterion to 4% would be estimated to capture 50% and a 3% criterion would capture 58%. That is, 42% of lung cancers are estimated to arise in the small group with 5% or higher risk of lung cancer in the next five years. In the slightly larger group with risk 4% or higher, 50% of lung cancers occur. In the group with risk of 3% or more, 58% of lung cancer will arise. Thus, with a 3% or 4% risk

criterion, the majority of lung cancers could ***potentially*** be diagnosed early in the programme. In this population, in addition to the 1557 subjects meeting the 5% criterion, 290 would meet the 4% criterion and a further 337 the 3%. Thus, the increases in scanning activity would lead to similar proportional increases in cancers potentially detected early.

- Based on the information gained from the patient surveys and from interviews with nurses delivering the service, there is considerable patient satisfaction reported from the programme, with enthusiasm that it will continue and a willingness to encourage others to take part.

The results above, therefore, suggest a number of actions in the future.

- Continue with the programme. The LHLP is a prime example of a well-run, integrated lung health programme in the UK.
- It might be worthwhile to return to the Neighbourhoods where only the 58-70 age group was invited, and extend the coverage to ages 71-75 (the decision has been made to implement this from September 2018)
- Reducing the LLP Risk criterion to 3% or 4% for future LHLP recruitment deserves serious consideration.
- Information protocols should be revisited to assess whether information gaps with respect to lung cancer risk factors and the CT scan process can be addressed.
- Ensure that the evaluation team has access to the LHLP data in 2018 after it is held by the Liverpool Heart and Chest Hospital Trust. The recommendation is that the LHLP three-year data set is made available to the Evaluation Team three months after the final patient has had a CT scan and the outcome data is available.
- Augment the data to include a fuller history of smoking and consider how data capture could be improved in all respects.
- Address the issue of re-evaluating risk following a new diagnosis of COPD. The plan will include a comparison of a sub set of individuals LLP risk score with their risk data at the time of the first Primary Care visit and then how much the new COPD diagnoses impacts on the risk score. Thus, a policy decision will depend on further investigation to ascertain the additional information on risk stratification likely to accrue from the COPD diagnoses. Once this is known, a decision can be made.

1. Introduction

It has long been acknowledged that there is considerable room for improvement in survival from lung cancer. Poor survival is partly due to the innate aggression of the disease but also to the fact that it is usually diagnosed at a late stage [1]. With the publication of the US National Lung Screening Trial, it became clear that reduced lung cancer mortality can be achieved with early detection using low dose computed tomography (CT) [2]. Issues of practicability, diagnostic workup, cost and target population remain [3,4].

2. The Liverpool Healthy Lung Programme- Background, design and procedures

The Liverpool Healthy Lung Programme (LHLP) is an initiative aimed at improving respiratory health and diagnosing respiratory disease at a more treatable stage, taken by the Liverpool Clinical Commissioning Group (CCG) working with communities across Liverpool [5]. Liverpool has one of the highest respiratory morbidity rates in England, with double the national lung cancer incidence, particularly in lower socioeconomic groups. The Liverpool Healthy Lung Programme was initiated in response to both the clinical problem and the health inequality.

Liverpool has developed a 'Neighbourhood' model. Groups of General Practices work together around a community, and collaborate with community health, mental health, local authority and voluntary services. A Neighbourhood will commonly serve a population of approximately 30-50,000 population. Liverpool Healthy Lung is a rolling programme working through the Neighbourhoods. The programme started in the Neighbourhoods with higher incidence and mortality from lung cancer.

The programme had 2 sequential phases. The first was a series of co-ordinated focused public engagement events throughout the city, starting in areas with the highest lung cancer incidence. The aims were to promote positive messages around lung health, and address the attitudes of fear and fatalism around lung cancer. These events ran for 1 year from February 2016. These events were independently evaluated by Research Works Ltd [6].

The second phase (still ongoing) was a programme of individual lung health consultations, risk assessment and referral for CT scans for those at more than 5% risk of lung cancer in the next five years.

Neighbourhood by Neighbourhood, General practice (GP) records are used to target ever-smokers and subjects with chronic obstructive pulmonary disease (COPD). In the first instance, the aim was to target those aged 58-70. From 2nd May 2017 the Steering Group agreed to extend the age range to 75 in line with similar projects happening around the country, and also noting that the mean age for diagnosis is 73 years. It should be noted that the consultations frequently take place some time after the initial identification of the patients, so that some patients are above the target age range by the time they are seen.

The GP practices send letters of invitation to a healthy lung check to the eligible patients. The first letter is followed by a second letter if the patient does not respond within a couple of weeks. If the patient does not respond to the second letter, the programme administration team attempt to contact the patient by telephone. Eligible patients are invited for a 30-45-minute lung health check appointment with a respiratory nurse in a community health hub setting. The health checks began in April 2016.

At the appointment, a detailed risk assessment is conducted. Histories and risk factor information are taken, including: emphysema, bronchitis, COPD, tuberculosis, exposure to asbestos, family history of lung cancer, history of malignancy and smoking duration. Height and weight are measured to calculate the body mass index (BMI). In those without a pre-existing diagnosis of COPD,

spirometry is used to assess lung function (FVC and FEV1 are measured and the ratio FEV1/FVC calculated). Those with abnormal lung function on spirometry are referred for further investigation, and potentially a definitive diagnosis of COPD. In addition, smoking advice and referrals to smoking cessation clinics are offered, also lifestyle advice and referrals are offered, such as diet, exercise, and pulmonary rehab for people with COPD.

Five-year risk of lung cancer is estimated using the MyLungRisk calculator, based on the Liverpool Lung Project risk model. Those with five-year lung cancer risk of 5% or more are offered a referral for a low-dose CT scan. Consent is requested from the participating patients to share their data with the CCG for evaluation purposes. All the patients were asked for their consent to share data with the external evaluators.

For those referred and attending for a scan, those with signs of lung cancer or nodules of maximum diameter 10 mm or greater are referred to cancer services. Those with non-calcified nodules of maximum diameter 6.1-9.9 mm are recommended to have a follow-up scan at 3 months. Those with non-calcified nodules of maximum diameter 5-6 mm are recommended to have a follow-up scan at 12 months (however, all sub-solid nodules of diameter greater than 5 mm have a repeat scan at 3 months). No further action is taken for calcified benign nodules and non-calcified nodules of maximum diameter less than 5 mm.

An earlier report is available online [5]. Here we update results following the expansion of LHLP from the first three Neighbourhoods Speke, Picton and Everton to include Norris Green, Anfield, Croxteth and Riverside.

3. Results

3.1 Consultations and diagnostic activity

Data have been supplied to the evaluation team on 3,591 Healthy Lung Programme consultations and associated radiology reports from CT scans from persons consenting to data sharing, up to 10th January 2018. There were a corresponding 11,526 people invited to a healthy lung appointment and 4,566 (40%) had attended. Thus, consent for data use has been given and data processing has been completed for 79% of attenders (3,591/4566).

Table 1 shows the number of attenders by Neighbourhood. Of the 3,591 attenders, 1,264 (35%) attended after the first letter, 1,539 (43%) after the second and 788 (22%) after the telephone call. This indicates that subsequent contact for initial non-attenders was productive.

Table 1. Number of attenders by Neighbourhood

Neighbourhood	Number of attenders
Everton	576
Picton	632
Speke	530
Norris Green	541
Anfield	533
Croxteth	536
Riverside	243

Total	3,591

Table 2 summarises the attributes of those attending the appointments. The median age was 66 years (range 58-76), 1,853 (52%) of the attenders were male, and 2,897 (81%) were in the most deprived IMD quintile. 2,603 (72%) were reported as ever-smokers. It most likely that there is some under-recording of smoking status, as only individuals with a history of smoking or COPD were invited to the LHLP clinics. It is likely that this is due to informatic issues rather than under-reporting by patients or staff. This most likely reflects the way smoking was recorded on the LHLP EMIS database. The median duration of smoking for the 2,603 individuals was 40 years (range 0-61). Of the 3,591 subjects, (23%) had an existing diagnosis of COPD and 527 (15%) had a previous diagnosis of cancer. 1,173 (33%) subjects had a family history of cancer. The median estimated 5-year risk of lung cancer was 4.4% (range 0.2%-48.9%).

Interestingly, a high proportion (34.6%) reported exposure to asbestos. Of the 1,244 subjects reporting exposure, 338 (27%) were female.

Of the patients attending the health checks, 745 agreed to receive smoking cessation advice. While we did not have data on whether ever-smokers were current or ex-smokers, the post-check patient survey suggested that 29% of ever smokers were current regular or occasional smokers. This would imply that 755 patients were current smokers, so more than 95% of current smokers agreed to receive cessation advice. In addition, 128 (18% of estimated current smokers) agreed to be referred to a smoking cessation clinic.

Table 2. Demographic and respiratory characteristics of those attending healthy lung appointments	
Total number of lung health checks	3,591
Male	1,853 (51.6%)
Female	1,738 (48.4%)
Median age (range)	66 (58-76)
Ever smokers	2,603 (72.4%)
Previous COPD	832 (23.2%)
Previous malignancy	527 (14.7%)
Emphysema	119 (3.3%)
Pneumonia	632 (17.6%)
Bronchitis	1,206 (33.6%)
Tuberculosis	64 (1.8%)
Asbestos exposure	1,244 (34.6%)
Family history lung cancer	1,173 (32.7%)
Median smoking years (range)	40 (0-61)
Median 5-year lung cancer risk (range)	4.4% (0.2%-48.9%)
Most deprived IMD quintile	2,897 (80.7%)

We had access to tabular data on the 8,898 non-responders to repeated invitation and 1,017 persons attending a lung health check but not consenting to individual data sharing for evaluation. Table 3 compares the population of responders to the invitation to lung health checks with the non-responders and with the non-consenters, with respect to age, sex and IMD. Age and sex distributions were similar for the responders, non-responders and non-consenters, although there was a slightly

higher proportion of females among the non-consenters. The IMD distributions did differ slightly, with 81% in the most deprived quintile among the responders, 83% in the non-responders and 84% in the non-consenters. Correspondingly, in the responders, 6% were in the two least deprived quintiles and in the non-responders, 4%. Thus this population of persons attending the health check and consenting to data sharing would appear to be slightly less deprived than, but otherwise similar to, the eligible population as a whole.

Table 3. Age, sex and IMD for the responders giving consent to individual data sharing, the non-responders, and the responders not giving consent to individual data sharing

Factor	Category/quantity	Responders	Non-responders	Non-consenters
Age	Mean (SD)	65.85 (4.30)	65.44 (4.55)	66.22 (4.70)
Sex*	Male	1,853 (52)	4,679 (53)	499 (49)
	Female	1,738 (48)	4,219 (47)	518 (51)
IMD decile*	1	2,396 (67)	6,152 (69)	718 (71)
	2	501 (14)	1,263 (14)	128 (13)
	3	142 (4)	385 (4)	26 (3)
	4	133 (4)	340 (4)	43 (4)
	5	180 (5)	344 (4)	49 (5)
	6	32 (1)	71 (1)	12 (1)
	7	153 (4)	240 (3)	33 (3)
	8	41 (1)	77 (1)	7 (1)
	9	12 (<1)	24 (<1)	1 (<1)
	10	0 (0)	2 (<1)	0 (0)

*Percentages in parentheses. One member of the responder population had missing IMD data.

There were highly significant differences between Neighbourhoods with respect to IMD and five-year lung cancer risk. Table 4 shows the average IMD and five-year lung cancer risk scores by Neighbourhood. The most deprived attenders were from Riverside and Croxteth, and the highest lung cancer risks were observed in Riverside and Everton. It is of note that the IMD scores of the attenders do not necessarily represent the overall deprivation profiles of the Neighbourhoods, although as expected, the most deprived attenders were resident in Everton.

Table 4. Average and SD of IMD and lung cancer risk by Neighbourhood

Neighbourhood	Mean (SD) IMD	Mean (SD) 5-year % lung cancer risk
Everton	1690 (3098)	6.3 (6.1)
Picton	5020 (5861)	6.2 (5.9)
Speke	4354 (6512)	6.0 (5.9)
Norris Green	3382 (4713)	6.2 (5.5)
Anfield	2461 (3622)	6.1 (5.8)
Croxteth	7062 (7161)	5.9 (5.9)
Riverside	6927 (7484)	7.6 (7.0)

Table 5 shows the diagnostic cascade in those attending. There were 1,557 (43%) patients with 5-year lung cancer risk greater than or equal to 5% and 1,548 (99.3% of those meeting the 5% risk criterion) were recommended for a CT scan. Of these, 1,318 (37% of total, 85% of those recommended) had a CT scan at the time of close of data collection. 119 (9%) patients who had a CT scan required further investigation (follow-up CT scan at 3 or 12 months, or immediate referral to pathway) and 25 (1.9% of those undergoing CT scan) patients were diagnosed with lung cancer. A further 11 have suspected lung cancer and are undergoing further investigations.

Table 5. Diagnostic cascade within LHLP		
Outcome	Number	Percentage
Patients attending	3,591	
Spirometry	2,255	63% (of attenders)
CT scan recommended	1,548	43% (of attenders)
CT scan carried out	1,318	37% (of attenders), 85% (of recommended)
Further investigation for nodules	119	9% (of scanned)
Significant other/incidental findings	486	37% (of scanned)
Lung cancer	25	1.9% (of scanned)
Suspicious lesion under investigation	11	0.8% (of scanned)

Of those attending, 2,255 (63%) underwent spirometry. Spirometry was abnormal (defined as FEV1/FVC ratio of less than 70%) in 845 (37% of those tested) subjects. While definitive diagnosis of these is ongoing, results in 3.3 below suggest that 34% would be expected to be diagnosed with COPD, so we anticipate that in this population, 287 (10% of the 2,759 subjects without a pre-existing diagnosis of COPD) subjects will have a diagnosis of COPD, and will have access to treatment earlier than they would otherwise.

3.2 Raising the upper age limit

As noted in Section 2, the upper age limit was extended in May 2017, to include patients up to age 75. Table 6 shows the age ranges at consultation, by Neighbourhood. As noted above, some subjects were aged above the upper limit by the time the consultation took place. This may be explained by the data capture on EMIS, as the system only gives age when the data was extracted not at the time of diagnosis of the patient.

Table 6. Age ranges by Neighbourhood, before and after the age extension in May 2017		
Neighbourhood	Range of ages at consultation	
	Before	After
Everton	59-72	58**-76
Picton	59-72	-
Speke	59-72	-
Norris Green	59-71	62-62*
Anfield	-	58-76
Croxteth	-	58-76
Riverside	63-63*	58-76

*Only one subject

** The reason for the age difference in the Everton group, maybe explained, by some participants deciding to attend later in the recruitment cycle.

Table 7 shows the lung health check consultation and CT scanning activities, and the numbers of lung cancers diagnosed before and after the extension of the upper age limit. Prior to the change 812/2,067 (39%) received a scan and 13 were found to have cancer, a prevalence of 1.6% of those scanned, 6 per thousand consultations. The corresponding figures after the age extension are 507/1,524 (33%) scanned and 12 cancers, 2.4% of those scanned and 8 per thousand consultations. Thus, the age extension has clearly improved both the detection rate and the specificity of referral for a CT scan.

Table 7. Consultation, CT scanning activity and lung cancer diagnosis before and after the extended age range		
	Period	
	Up to 12/04/2017	From 13/04/2017
Number of consultations	2,067	1,524
Number of CT scans	812	507
Number of lung cancers diagnosed	13	12

Table 8 shows the corresponding results when stratified by actual age at consultation. In those aged 70 or under, there were 1,052/3,016 (35%) scanned. There were 20 lung cancers detected, 1.9% of those scanned and 7 per thousand consultations. In those aged 71 or over, 267/575 (46%) received a CT scan, and 5 cancers were detected, 1.9% of those scanned and 9 per thousand consultations.

Table 8. Consultation and CT scanning activity, and lung cancer diagnosis by age		
Quantity	Age at consultation	
	70 or younger	71+
Number of consultations	3,016	575
Number of CT scans	1,052	267
Number of lung cancers diagnosed	20	5

3.3 Diagnostic spirometry and COPD

As noted above, 845 subjects were found to have abnormal lung function on spirometry.

In a separate analytic exercise, data were available on 560 LHLP participants referred to diagnostic spirometry as a result of abnormal spirometry between March 2016 and November 2017. Of these, 119 did not have diagnostic spirometry, in most cases because the patient did not attend the appointment. At the time of analysis, diagnostic data were available for 412 (93%) of the remaining 441 patients. Figure 1 shows the results of diagnostic spirometry in these 412 patients.

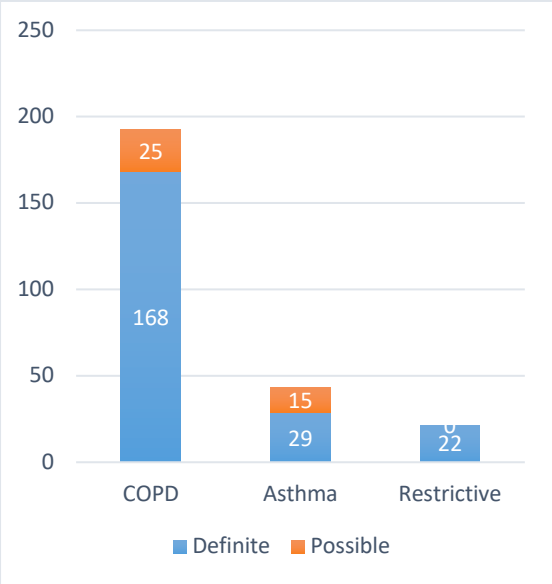

Figure 1. Numbers of participants given a diagnosis of respiratory disease after diagnostic spirometry. 25 patients were given a diagnosis of 'Possible COPD' and 15 patients were given the diagnosis 'Possible Asthma.'

193 patients (47% of those undergoing diagnostic spirometry and with diagnostic outcome recorded, 34% of the 560 referred) were diagnosed with COPD or possible COPD. The 'possible Diagnoses' were due to the absence of reversibility testing. Due to a lack of clinical history in conjunction with reversible obstructive spirometry, some patients were given a diagnosis of 'Possible Asthma.' There were 44 (11%) diagnoses of asthma or possible asthma. The patient groups given 'possible' diagnoses were reviewed by a respiratory physician and considered highly likely to have COPD/asthma. There were 22 (5%) patients diagnosed with restrictive lung disease.

Figure 2 shows the severity of COPD in those diagnosed. The majority, 126 (65%) were diagnosed with mild disease. Presence of COPD was strongly associated with smoking duration, with averages of 39 years in those diagnosed with COPD vs 32 years in those without disease. It was also associated with male gender (67% in those with COPD vs 52% in those without disease and with lower body mass index (23% overweight in COPD vs 40% in no disease). This data is potentially useful to the patients GP when monitoring their respiratory history. The diagnosis of COPD at an early, mild stage enables early intervention and is likely to be associated with better outcomes [7].

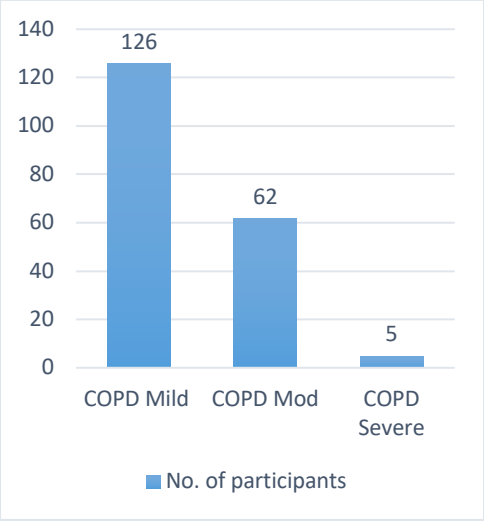

Figure 2. Severity of COPD cases diagnosed

3.4 Significant Other Findings (SOF)

We performed a sub-study to explore the value of reported SOF from the LHLP CT scan directly to the patient and to the general practitioner responsible for their care. In addition, gaining an understanding of the common type of SOF reported, investigating the attitudes of individuals working within the LHLP. Patients were identified with a SOF on their CT scan report. These patients were risk stratified into major and minor, then questionnaires were distributed, via the CCG, to practices using NHSnet.

In a 13-month period (from April 2016 to end of May 2017), 278 scans reported SOF.

From the 278 CT scans, 188 reports were considered by the lead physician to be of no pathological significance (68%), 63 showed minor findings (23%) and 27 had major findings (9%). The 90 patients with major/minor SOF were represented by 19 practices. All 19 practices were contacted using the methods stated above; resulting in 53 patient questionnaires being distributed (23 for major SOF and 30 for minor SOF – a sample size of 59%).

Several reminders were required to obtain the 29 returned questionnaires (overall response rate of 55%) and in certain instance the detail was very limited. Respondents comprised 15 major SOF (65% response rate) and 14 minor SOF (47% response rate). Extra data around age, gender, smoking years and risk score was only available for the 22 subjects who had consented for the full data set to be shared.

As there was only data on a small number of individuals with SoFs, very limited statistical analysis was performed on the dataset. Individuals aged from 60 to 71 years old; with 55% being male and 45% female. Smoking length ranged from 25 to 57 years. Risk scores ran from 5.61 up to 42.34; there is no suggestion of a higher risk score being associated with more serious SOF.

There were a number of key benefits associated with the reporting of SOFs, when focusing on individual cases. Reported SOF resulted in 2 cardiac diagnoses; abdominal aortic aneurysm (AAA) and mild myocardial ischaemia, however these would have been identified by the reporting radiologist.

There were 10 reported SOFs which were respiratory in nature; including asthma, COPD, interstitial lung disease, malignant and inflammatory lung nodules. 3 cases of COPD were identified and treatment initiated with appropriate inhalers. One of the SOF patients (with a lung cancer risk score of 15% and smoking history of 50 years) was found also to have malignant lung nodules; with a lung risk score of 15 and a smoking history of 50 years.

A Further patient was found to have liver metastases, from an unknown primary. This patient subsequently received a referral to secondary care and underwent chemotherapy. A further patient had osteoporosis.

The real value of SOF in the LHLP will require a much more in-depth analysis of the data. The evaluation team had access the CRIS radiology reports, however these included unstructured free text within an Excel document and thus were extremely difficult to interpret.

Furthermore, the evaluation team did not have access to outcome data for the SOF patients; ie what long term benefit did the patient derive from these further investigations.

If the SOF data are to be analysed at the end of the three year LHLP, it will require specialised software to extract specific words and phrases from the CRIS reports, or provision to the evaluation team of structured radiology reports. In addition, the Evaluation team will require more information from the GP Practices on the details timing and outcomes of the SOF referrals.

There is an accepted pathway for GPs to handle SOFs; it is appreciated that the follow-up of SOFs may create a degree of extra work within Primary Care. Traditionally, the clinician requesting the investigation is responsible for following up any abnormality, however, in the LHLP it is not the GP who requests the CT scan. A clear protocol is in place describing where responsibility for actioning results, and communication with patients. However, it is possible that some GP practices believed that the MDT in secondary care should take the responsibility for SOFs, as well as, lung cancer. This is an important issue to address in further roll-out of LHLP and when planning for possible national lung cancer control activities of this nature.

3.5 Cancers diagnosed, management of suspected cancers and projected effect on lung cancer mortality

Of the 25 cancers, 16 (64%) were stage 1, 3 (12%) were stage 2, 6 (24%) were stage 3 and none were stage 4.

Table 9 shows the stage distribution of the 25 lung cancers, with the expected numbers of deaths within five years based on national stage specific survival [8]. The table also shows the expected stage distribution from the general population of lung cancers in the UK, and the expected 5-year deaths if these 25 cancers had had the same stage distribution as the general population. Thus, we can compare the projected deaths from our observed data with those expected if these cancers had been allowed to progress to symptomatic diagnosis.

Stage I and II cancers comprised 76% of the lung cancers diagnosed, significantly (p=0.003) greater than the 22% expected from the general lung tumour population. On the basis of the stage of cancers diagnosed, and rounding to the nearest integer, we expect 18 deaths from lung cancer in the five years following diagnosis. If the LHLP CT-detected cancers had had the same stage distribution as the national population of lung cancers, we would have expected 23 deaths. The number of deaths prevented will be larger than this, since there are cancer data pending from those still under investigation. However, among those consenting, the programme is expected to have prevented 4-5 deaths from lung cancer, one death prevented per 264-330 CT scans.

Patients referred to lung cancer services following their LHLP scan were managed by Aintree Hospital or Liverpool Heart and Chest Hospital (LHCH). To investigate the MDT follow up of these patients, we focussed on those under the care of LHCH. The Evaluation Team had detailed information from the LHCH regarding the assessment pathways, treatment and outcomes.

Table 9. Stage distribution of LHLP CT detected lung cancers and of the UK lung cancer population, with expected numbers of deaths in five years predicted from national stage-specific survival rates (one thymoma is included with the stage II cancers)

Stage	Expected population frequency (%)	5-year % fatality	Predicted deaths (population)	LHLP frequency (%)	Predicted deaths LHLP
NK	2 (10)	94	1.9	0 (0)	0
I	4 (15)	65	2.6	16 (64)	10.4
II	2 (7)	79	1.6	3 (12)	2.4
III	5 (19)	94	4.7	6 (24)	5.6
IV	12 (49)	100	12	0 (0)	0
Total	25 (100)	90	22.8	25 (100)	18.4

Working closely with the Respiratory Physician at LHCH, an NHS list was devised for those LHLP patients who had consented to information sharing. Data was collected from the LHCH computers using the Somerset cancer registration database and CRIS (computerised radiology information system). The aim was to gather information which would identify the pathway each patient had undertaken since their referral. The date of their first LHLP scan, their interaction with the LHCH and the extent to which they had undergone investigation was captured. We analysed the follow-up management, treatment and outcome as well as the investigations undertaken to exclude cancer. In addition, we utilised information regarding the patients' smoking history and LLP risk score from their EMIS records.

From April 2016 to January 2018, 34 patients were referred from the LHLP to cancer services at LHCH, of whom 27 had consented to having their information shared. The average LLP risk scores for those referred was high at 14.28 (5.61-39.73). The mean age of those referred was 68.5, with nearly an equal number of males (15) to females (12).

12 of the patients were given a diagnosis of lung cancer and 15 were either still under investigation or did not have lung cancer.

We focus here on the 15 patients found not to have lung cancer; one is still under investigation (CT biopsy showing benign neoplasia); one was treated for a type AB thymoma; one required no further follow up (PET scan showed low grade tracer uptake and suggested a round atelectasis or pleural plaques); eleven were undergoing CT follow up and one patient has since died following pneumonia and heart failure. The interval of CT follow-up was dependent on clinical recommendation, but patients are overseen for 2 years by the hospital. Of the 11 patients that are undergoing CT surveillance none have yet been found to have developed lung cancer to date. Three patients had CT scans not correctly reported in accordance with the LHLP protocol and were incorrectly coded for lung cancer referral. These patients have been followed up through the LHCH.

We also analysed the pathway for these 15 LHLP patients, to either diagnose or exclude lung cancer. Of the 15 patients not so far diagnosed with lung cancer, only 4 underwent an invasive diagnostic procedure: 3 had CT guided biopsies, one was performed on a patient that has an unconfirmed diagnosis and is still under investigation for lung cancer and one was for histological confirmation of a thymoma. The other patient underwent an endobronchial ultrasound (EBUS) biopsy as the PET scan suggested disease stage T1bN0/N1M0, but was found to have a benign neoplasm. Six of the 12 confirmed cancer patients underwent invasive diagnostic tests. Three were treated with radiotherapy. One patient had a bronchoscopy showing benign cytology after an EBUS biopsy had shown the same. This patient had severe lung function impairment was given a clinical diagnosis of malignancy.

Updated information for which detailed data are not yet available to the evaluation team indicate that of the cancers diagnosed at LHCH in referrals from the programme, 74% were resected.

On examining the management pathway, only two patients were seen at MDT that were not diagnosed with cancer. Furthermore, the LHCH also offers a service whereby patients can choose to have assessments, results and consent for investigations dealt with over the phone by a nurse or can choose to come into the hospital. It was found that the non-cancer patients were seen in hospital an average of 1.8 times during investigation and the cancer patients 2.4 times up to diagnosis (this included appointments for investigative tests).

Among the LHLP patients who were found not to have lung cancer, there were very few harms associated with being referred to cancer services. A very small number had invasive diagnostic tests and none were operated on for benign disease. The amount and type of contact with the hospital was, to a certain extent, also dependent on patient preference. As the number of patients going through the LHLP increases, the management by lung cancer services and outcomes will become

clearer but for the present time the results seen are very encouraging. This piece of work is naturally ongoing and will be reconsidered in the final 3rd year report.

3.6 Nurse interviews

We carried out open-ended interviews of the nurses delivering the LHLP service, focussed on their experience of the programme, the reactions they have received from the public, and the consequent identification of areas for improvement in the programme.

Three semi-structured interviews were done with the nurses involved in the risk assessment clinics. The interviews lasted 42.25 min, 29:18 min and 25:09 min and were led by Dr Sam Smith. A copy of the interview schedule can be found in Appendix 1. The interviews were transcribed verbatim and analysed using thematic analysis. Anonymised quotes are provided.

Public enthusiasm and expectations

There was consensus among the nurses that the public were enthusiastic and positive about the LLP. The nurses reported that the majority of people responding to invitations were pleased to have been invited and felt strongly that the LLP should continue:

'In all areas people have been very positive coming in, saying this should have started 40 years ago'

'…A lot of the patients are really positive, [patients say] "This is brilliant that we're doing this." I always explain that it is just a programme at the moment, hopefully…in the future it could be rolled out. They say, "It's brilliant. It's not fair that it's just for us. If everybody could have it that would be really beneficial."

There was the occasional attendee who reported less enthusiasm for the LHLP, but the nurses felt that their attitudes were influenced by factors other than the LHLP:

'I think it's just a very small…number of patients whose general attitude towards the NHS, not necessarily towards the programme, because when you speak to them it's like they've had bad dealings…in the past and things like that. So it's not necessarily about the programme.'

While most attendees understood the broad purpose of the consultation, and indeed some attendees had been told what to expect by family members or friends who had attended a risk assessment, the nurses felt that a proportion of individuals were unclear as to why they had been invited:

'A lot of people think they've been referred because of something that happened with the doctor, example of a lady today who had some sort of allergic reaction…and she was convinced that's why she's been referred. I always ask them to sit down. "Hiya, I'm [name], do you know why you're here today?" A hell of a lot of people don't know why they're here.'

The nurses reported being very comfortable in communicating the aims of the programme to those that had attended, and felt that all attendees were appropriately informed of the LHLP objectives within the risk assessment clinic. However, there were concerns that individuals who were unsure why they had been invited may not be attending the clinic. One suggestion was to improve the educational materials provided with the initial invitation. This is now being taken forward with the introduction of the UCL's information leaflets, for which they had a 54% uptake. However we need to be aware that we may not get the same impact in Liverpool.

Public attitudes towards CT scans

The nurses reported that most people who were not referred for a CT scan accepted the decision. However, some individuals were disappointed and had expected to be referred:

'We have all had odd patients who have been quite insistent that they want to go for the scan and when you explain it it can take a bit of explaining to go through. But other people turn it round, they say, "Oh that's great". They've had a normal lung function, their risks are low, they are aware what to look for'

A particular concern about the scan was the use of contrast dye. One nurse described having patients querying this with her, and she now addresses it when discussing the referral for a scan:

'We have had a couple of patients that have cancelled or have phoned up the service because they've been a bit confused about the letter that has been sent from the CT department, because it explains about contrast dye. So they get a little bit wary of that.'

Implementation problems and recommendations

The nurses reported some difficulties at the system level when running the risk assessment clinics. Information Technology issues such as remote working and accessing hospital records made implementing the risk assessment clinics more challenging:

'It's a struggle sometimes to get onto certain systems because we are employed by the hospital, so some of the systems, the hospital-based systems are difficult to access because we're not on site and we're remote workers, so it means it's difficult for us to do mandatory training and to keep up to date sometimes with things.'

'We don't have full access to EMIS still and that's another sort of concern as well is trying to get information from people.'

In terms of introducing a national lung programme, the nurses raised some issues that should be considered. They were asked about the use of more junior nursing staff within such a programme, and what challenges that might bring. One nurse felt that although junior nursing staff may be able to run the risk assessment clinics, they may not have sufficient expertise and experience to discuss the complex health complaints that patients presented with:

When anybody comes in they don't come in…for their health assessment, they come in with all [their] other problems, so it's being able to have the competence and the knowledge to be an autonomous practitioner…There's been patients who have been vulnerable and had other issues and then obviously there's the reporting back of the results as well, what would a more junior nurse need to do when she had to report the CTs or something? That's what sort of worries [me].

The nurses felt that the reporting of the scan results could be improved by providing a clear 'bottom line' for the observations:

'…so you look at them and you think well what's the conclusion, what's the bottom line here? A little bit more clarity would be really, really useful for us and obviously patients can get the results quicker.'

The nurses also recommended ensuring that when inviting people, they should be offered the opportunity to be seen at their local GP practice whenever possible. They felt this would be important for a national programme to consider:

'Definitely invite people to the area where possible, to the GP, because when people come and it's not their GP practice they want to know why they haven't gone to their [GP practice]… "Why have I come all the way here?" Because at the moment I'm in a doctor's [and] people are not very happy…they want to know why they're not in their own GP.'

A further issue which was raised was the fact that the decision to recommend or not recommend a CT scan is made before diagnostic spirometry. See section 3 below.

Smoking cessation

The nurses reported confidence in their ability to discuss the issue of smoking cessation with patients. Two of the nurses felt that the new 'opt out' system for smoking cessation referrals was not working, and had not affected the proportion of patients they were referring to the service:

'Yes, it's not changed my amount of referrals, I would say in honesty. I don't think my amount of referrals to Smokefree have changed yet, it's only slowly, we're only a few weeks into it but I don't think it's changed.'

One nurse reported that the opt-out approach may not be particularly helpful for some people who had no interest of smoking cessation:

'I feel like I'm quite soft about it and I'll say so, "These are when the clinics are," and you can see on people's faces, the shutters come down in the eyes, you know with your background and you know you're not going to get anywhere, so I don't think, for me, it's that great.'

Nurse satisfaction

Overall, the nurses reported being supported in the LLP once it was up and running. They were enthusiastic about the LLP and the role they played in delivering the project. All were hopeful that the LLP would continue in the future and that patients were meaningfully benefiting from the project:

'I would say I've been doing [the risk assessment]…and I'm really happy with it. It's nice to meet patients that are healthy, and to be identifying lung cancers early, to be able to identify lung disease, to give patients education.'

3.7 Patient surveys and further qualitative work

We also carried out surveys of subjects after the health check and for those who had a CT scan, after the scan, to obtain patient perspectives and identify information gaps. We reported on the first 71 post-check subjects and the first 60 post scan subject surveyed [5]. Here we update these to 95 and 64 subjects respectively.

To date, 95 patients have returned post-lung health check questionnaires. Levels of satisfaction with the lung health check consultations were generally high. Table 10 shows responses to questions in relation to the experience of the consultation. There was a high level of satisfaction, with 20% reporting being satisfied and 73% very satisfied, with the overall experience of the lung health check. Two patients clearly had problems with the interaction with the consulting nurse, but all subjects reported that the appointment was helpful, and 97% reported that if a friend asked them if they should attend, they would encourage or strongly encourage the friend to do so.

One area which merits further investigation is that some participants may be experiencing noticeable stress, and the consultation needs to be sensitive to this. Those with pre-existing COPD may be stressed from the physical effort, whereas those without disease may be intimidated by a consultation which might in turn lead to diagnosis of a life-threatening illness.

Table 11 shows the survey results with respect to how informed the participants perceived themselves to be following the consultation. Generally, a strong majority felt quite informed or well informed, although there was an information deficit with respect to the process, benefits and risks associated with a CT scan. This may reflect the fact that those not referred for a scan did not need detailed information on the subject.

Table 10. Survey responses in relation to the experience of the lung health check consultation				
Question	Response %			
	Strongly disagree	Disagree	Agree	Strongly agree
The nurse considered any stress I was facing	2	21	37	40
The nurse helped me to identify what I needed to know to make decisions about my lung health	0	0	34	66
I feel better about my lung health after meeting the nurse	0	2	28	64
The appointment was about the right length of time	0	0	32	68
The nurse was concerned about my wellbeing	1	2	27	70
The appointment was helpful to me	0	0	29	71
Question	Response %			
	Very	Moderately	A little	Not at all
Did the nurse in your appointment seem well informed?	99	0	0	1
Did the nurse in your appointment seem caring?	98	1	0	1
Did the nurse in your appointment seem rushed?	2	1	2	95
Did the nurse in your appointment seem overworked?	2	5	4	88
Question- satisfaction with	Response %			
	Very dissatisfied	Dissatisfied	Satisfied	Very satisfied
Information you received before your appointment?	0	1	49	50
Booking your appointment?	0	0	34	66
Waiting room facilities?	0	0	34	66
Clinic room?	0	0	32	68
Nurse at your appointment?	0	0	10	90
Conversation you had about stopping smoking?	2	2	22	73
Conversation you had about your lung health?	0	0	20	80
The way your risk of lung cancer was explained?	0	0	19	81
The decision whether to refer you for a CT scan?	0	0	22	78
Overall experience of the lung health check?	0	0	11	89

Interestingly, levels of worry about lung cancer did not increase as a result of the invitation to the lung health check. Prior to receiving their invitation, 65% of subjects reported being at least slightly worried about their chances of developing lung cancer. Only 56% reported being worried since the invitation to the health check.

Among smokers, 75% reported wanting to stop smoking. 4% reported intending to stop in the next month and 8% in the next three months. A further 20% reported an aspiration to stop soon.

To date, 64 completed post-CT scan questionnaires have been returned. Of the 64 participants, 70% were ex-smokers, 23% current smokers and 6% occasional smokers. 78% reported having a normal result. Of those with an abnormal result, 56% were referred on for further investigation and 44% referred back to their GP.

Table 12 shows levels of satisfaction with aspects of the CT scan referral and process.

Table 11. Survey responses in relation to how informed the participants felt following the consultation				
Question. How informed do you feel about	Response %			
	Not informed	Quite uninformed	Quite informed	Well informed
What I can do to improve my lung health?	2	1	18	78
What I can do to increase my chances of stopping smoking?	4	6	10	80
The stop smoking services available to me?	2	2	7	89
My risk of lung cancer?	2	2	18	77
My risk of lung diseases, such as emphysema, bronchitis or COPD?	1	2	15	81
The process of having a lung CT scan?	5	4	36	55
The benefits of having a lung CT scan?	4	4	25	66
The risks of having a lung CT scan?	5	4	32	59

Overall, levels of satisfaction were high, but the results suggest an information deficit with respect to CT scans. There were 16% who reported dissatisfaction with the information provided with the CT scan results and 18% with the way the results were explained to them. Whereas only 2% reported unanswered questions at the time of the scan, 13% reported unanswered questions after receiving the results of the scan. When subjects were asked what would be helpful if they were to have the scan again, 30% would want more written information, 49% would want simpler information and 38% would want to spend longer talking to the nurse.

Table 12. Survey responses in relation to the experience of the CT scan				
Question- satisfaction with	Response %			
	Very dissatisfied	Dissatisfied	Satisfied	Very satisfied
The information given before you had a CT scan?	8	2	26	65
The time of your CT scan appointment?	8	2	30	60
The location of your CT scan appointment?	8	0	27	66
The way your lung CT scan was performed?	8	2	19	72
The time it took to receive your CT scan results?	9	3	22	66
The information provided with your CT scan results?	8	8	26	58
The way your scan results were explained to you?	8	10	25	57

There was also a level of dissatisfaction with time taken to receive the results (9% very dissatisfied). The questionnaire allowed a space for free text comments, and these were consistent with this. Comments included:

- *I was called less than 24 hours after my CT scan, I missed the phone call just before 17:30. Tried to call back (Department closed for the night). Thinking the worst, my wife and I had a restless night. Called next [day] and found out everything OK.*
- *The results of the CT scan took more than two weeks to arrive at my GP's. I was then unable to get an appointment before going on holiday but was able to talk to my doctor by phone and was told everything was normal. I am not sure how it could be improved, possibly the delay was at GP's.*

When asked if they would recommend a friend to have a CT scan, 97% reported that they would encourage it. 98% reported that they were glad they had had the scan.

Table 13 shows results with respect to worry in relation to the CT scan. 61% of subjects reported at least being slightly worried on being referred for the scan. Since the scan, 47% were at least slightly worried about the results, and 69% at least slightly worried about the chances of lung cancer. While a degree of worry is inevitable, 16% reported being quite a bit or extremely worried about the results.

Table 13. Worry in relation to the CT scan

Question	Response %				
	Not at all	Slightly	Moderately	Quite a bit	Extremely
After you were referred, how worried were you about having a CT scan?	39	28	17	14	2
Since your CT scan, how worried have you been about the results?	53	22	9	13	3
Since your CT scan, how worried have you been about your future chances of developing lung cancer?	31	41	17	9	2

Table 14 shows the lung cancer signs and symptoms from the cancer awareness measure and the proportion of subjects surveyed identifying these as possible signs of lung cancer. The average number of signs identified by the subjects was 9.7 (SD 3.5) out of 14, 69%. The least frequently recognised signs were finger and fingernail changes (19%) and shoulder pain (46%).

Table 14. Percent of survey participants identifying signs of lung cancer from the Cancer Awareness Measure

Sign	Yes	No	Unsure
Weight loss	81	5	14
Persistent (3 weeks or more) chest infection	81	5	14
A cough that does not go away for two or three weeks	85	3	12
Persistent shortness of breath	84	4	12
Persistent tiredness or lack of energy	77	8	15
Persistent chest pain	67	14	19
Persistent shoulder pain	46	22	32
Coughing up blood	91	1	8
Ache or pain when breathing	80	9	11
Loss of appetite	69	12	19
Painful cough	70	6	23
Changes in the shape of your fingers or nails	19	17	64
Developing un unexplained loud, high pitched sound when breathing	53	9	38
Worsening or change in an existing cough	82	1	17

Table 15 shows the responses of the survey participants with respect to recognition of risk factors for lung cancer. For all except radon exposure, the majority of the participants agreed or strongly

agreed that these were risk factors, and for the smoking-relative factors, more than 90% agreed or strongly agreed.

We investigated whether survey results varied significantly by age, sex or lung cancer risk level. Results were negative with a number of exceptions. There were two such exceptions in relation to the consultation. The first was that males were more likely than females to agree strongly with the statement, 'The nurse helped me to identify what I needed to know to make decisions about my lung health' (74% vs 54%). The second was that those at higher lung cancer risk were less likely to report feeling informed about their risk of lung cancer after the consultation. For those with 5-year risk below 5%, 98% reported feeling quite informed or well informed. For those with risk 5% or above, the proportion was 91%.

Interestingly, there were three significant differences by sex in recognition of risk factors. Males were significantly more likely than females to strongly agree that personal history of smoking increased risk of lung cancer (80% vs 53%). Males were also more likely to identify air pollution (84% vs 61%) and previous respiratory diseases (91% vs 71%) as risk factors.

Table 15. Risk factors for lung cancer and proportions of survey participants in agreement or disagreement that these can increase risk of the disease

Factor	Strongly Disagree	Disagree	Not sure	Agree	Strongly agree
Radon exposure	1	2	56	19	22
Passive smoking	1	1	6	38	54
Treatment for previous cancer	10	8	18	30	34
Close relative with lung cancer	6	6	20	37	31
Exposure to chemicals (eg asbestos)	1	0	3	31	65
Previous head and neck cancer	3	4	27	27	39
Air pollution	1	0	24	30	45
Active smoking	1	0	1	28	70
Previous lung disease (eg COPD)	0	0	17	24	59

We also carried out qualitative, open-ended interviews of subjects participating in LHLP, and reported the findings (generally very positive) from these in the previous report [5]. Since then, further qualitative work has taken place, with a focus group comprising twelve members of the lay members of the LHLP Programme steering group. The latter provided a number of recommendations to amend the programme, but did emphasise enthusiasm for the objectives and a strong consensus that the programme should continue.

Recommendations included:

- Start with less deprived areas, as there were teething problems, and this affected recruitment. It would have been better to start with somewhere with fewer challenges and lung health problems, so that fewer cancers/COPD would have been missed.
- Leave some nurses in areas so that the area is not left without people attending.
- More training for nurses would be helpful, especially spirometry and information giving.
- Less travelling between clinics would be helpful, since this takes up a lot of time and is difficult logistically. (Note this is being trialled from September 2018)
- There is a need for ways for increasing recruitment – possibly more advertising.
- The age range should be extended.
- Team of admin workers should be assigned to the programme.
- Better coding of EMIS data for patient selection is needed.

- The patients scanned would appreciate more clarity on the nodule pathway, including contact numbers for queries from patients.

Quotations from the Steering committee members:

"96% are glad that they got involved and would recommend it to a friend."

"I'm incredibly proud of what we have achieved because we have had huge collaboration between primary and secondary care, great patients and volunteers involved and a brilliant project manager."

"Honestly, I think it's amazing to be involved with and would not change anything."

From the interviews it was obvious how, every single person working within the LHLP, was extremely proud of what had been achieved and how they had adapted and changed techniques to run the project to the best of their abilities. This is reflected in that 96% of people are glad that they got involved with the LHLP and would recommend it to a friend (97% in most up to date results).

The clinicians who responded to questionnaires were very pleased with the reporting of SOF and the majority of patients were provided with a diagnosis; thereby enabling further monitoring or active treatment. Therefore, this study shows the value, for both patient and clinician, of reporting SOF in programmes of early diagnosis of lung cancer.

4. **Implications and discussion**

Phase 2 of the LHLP has now been running since April 2016, and has conducted 4,566 lung health checks to January 2018 (40% of the invited population). From data available on 3,591 of these, we found that 72% were ever smokers. It is likely that smoking status is under-reported, due mainly to the data capture conventions. Of note, more than 80% of the subjects are in the most deprived socioeconomic quintile, indicating that we are reaching deprived populations. The programme may not be reaching black and minority ethnic populations and those with English as additional language in representative numbers, however. An overview of the issues in this respect is given by Dr Katy Gardner in Appendix 2.

Of the 3,591 subjects, 23% had an existing diagnosis of COPD. Following spirometry of those who did not already have a COPD diagnosis, 845 (24%) had abnormal lung function, and from previous clinical experience it is anticipated that 287 (10% of those without a pre-existing diagnosis) subjects will in due course be diagnosed with and treated for COPD.

43% of attenders had five-year lung cancer risk of 5% or more and 85% of those offered a CT scan underwent the scan. This figure is likely to increase as the scan data for those recommended for a scan after a consultation in January was not yet processed at the time of analysis. Around 2% of those scanned were found to have lung cancer. The stage distribution of lung cancer indicated a reduction in mortality compared to that expected from the general population of around 20% (18 deaths vs 23 expected from the general population), similar to that observed in the US randomised trial [2]. This corresponds to 26% five-year survival in the cancers diagnosed in the programme, compared to the 10% which would be expected without the programme, more than a doubling of the five-year survival rate in cancers detected as a result of CT scans in the programme. This translates to an absolute prevention of 1 lung cancer death per 264-330 CT scans, rather more favourable than observed in the US trial, possibly due to the very high risk level required for eligibility for a CT scan in LHLP.

The sub-study on spirometry and COPD demonstrates that the use of non-diagnostic spirometry does have clear clinical value and can aid in detecting respiratory disease in patients with mild disease who are likely to respond to treatment, which will help to improve their quality of life and prognosis.

A health economic evaluation undertaken as part of the ACE Proactive Lung Cluster report suggested that the programme was on the borderline of cost-effectiveness [9], at around £13,000 per quality adjusted life-year (QALY). This, however, excludes any QALY benefits from smoking cessation or early diagnosis of COPD. Our results suggest that there may also be non-negligible health benefits from early diagnosis and treatment of COPD, on the basis of the number of abnormal spirometries identified in LHLP.

We observed a rate of around 9% of nodules requiring further workup. This is a considerably lower rate than was observed in the randomised trials [2,10]. It is at least partly due to the fact that in these projects, nodules smaller than 5 mm in maximum diameter were not acted on. There is a need for further follow-up of all subjects undergoing health checks to assess the extent to which the risk eligibility criteria and the diagnostic algorithm might be causing cancers to be missed. Both the low rate of further investigations following CT and the promising results with respect to stage of disease are consistent with results from a similar project in Manchester [11].

This project found encouraging proportions of subjects agreeing to receive smoking cessation advice, and to referral to smoking cessation services. Numbers referred to smoking cessation services will increase in future, as in March 2018 the Steering Group agreed that patients would be referred to smoking cessation on an opt out basis from now on, in line with similar projects.

The risk criterion for a CT scan was 5% risk of lung cancer over five years. While this is a very high risk group, it is also a small minority of the general population. Consideration of the receiver operating characteristics of the LLP model, 42% of lung cancers would be estimated to arise in this risk group [12]. Relaxing the criterion to 4% would be estimated to capture 50% and a 3% criterion wold capture 58%. In this population addition to the 1557 subjects meeting the 5% criterion, 290 would meet the 4% criterion and a further 337 the 3%. Thus a 20% increase in scanning activity would lead to a similar proportional increase in cancers potentially detected early, and a 40% increase in scanning activity would lead to an approximate 40% increase in cancers potentially diagnosed early.

It is worth noting that both directly from patients in posted surveys and interviews, and from the interviews with nurses delivering the service that here is considerable patient satisfaction from the programme, with enthusiasm that it continue and a willingness to encourage others to take part. There may be ways of building on this last observation. On the other hand, there are information gaps, in terms of the purpose of both the health check appointments and the CT scans. It would be prudent to revisit information materials and procedures. Further, the nurses were sometimes not certain how best to interpret the CT scan reports for the patients.

Another information deficit identified by the survey was in awareness of risk factors in female participants, notably with respect to air pollution, personal smoking history and history of non-malignant respiratory disease. With respect to the latter two, it would be worthwhile to consider strengthening the printed information or oral information given at consultation.

As noted in section 2.5, there is a policy issue in relation to COPD. There is no doubt that COPD is associated with increased risk of lung cancer, but it is only explicitly included in the risk calculation if there is a previous diagnosis [12]. It is worth considering whether, if a patient is referred from the programme to diagnostic spirometry and is then diagnosed with COPD a few weeks after the LHLP consultation, can this be fed back into their risk assessment and the decision with respect to a CT scan revisited?

The results above, therefore, suggest a number of actions in the future.

- Continue with the programme. The LHLP is a prime example of a well-run, integrated lung health programme in the UK.
- It might be worthwhile to return to the Neighbourhoods where only the 58-70 age group was invited, and extend the coverage to ages 71-75 (the decision has been made to implement this from September 2018)
- Reducing the LLP Risk criterion to 3% or 4% for future LHLP recruitment deserves serious consideration.
- Revisit the information protocols to assess whether information gaps with respect to lung cancer risk factors and the CT scan process can be addressed.
- Ensure that the evaluation team has access to the LHLP data in 2018 after it is held by the Liverpool Heart and Chest Hospital Trust. The recommendation is that the LHLP three year data set is made available to the Evaluation Team three months after the final patient has had a CT scan and the outcome data is available.
- Augment the data to include a fuller history of smoking.
- Address the issue of re-evaluating risk following a new diagnosis of COPD. The plan will include a comparison of a sub set of individuals LLP risk score with their risk data at the time of the first Primary Care visit and then how much the new COPD diagnoses impacts on the risk score. Once this is known, will provide a recommendation as to whether this is implemented.

In conclusion, the results suggest that it is feasible to achieve similar clinical outcome benefits to those observed in the US trial of low dose CT screening for lung cancer, with lesser harms in terms of unnecessary diagnostic activity [2]. However, this needs confirmation with extended follow-up, larger numbers of lung cancers diagnosed, and the addition of mortality data. Additional randomised trial results would also add to the precision of estimation of benefits and harms, in particular mortality results from the large European trial, NELSON [13]. In the meantime, the results of LHLP suggest that it is succeeding in early detection of both COPD and lung cancer. The evaluation team would be happy to provide a further overview in 2019 if the programme continues.

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APPENDIX 1. INTERVIEW SCHEDULE FOR QUALITATIVE STUDY OF NURSE PERCEPTIONS AND EXPERIENCE

Thank you for agreeing to take part. If at any point you would like to stop, or if you do not want to answer a question, please say so. Anything you say to me today will be kept confidential, and if you are quoted in any of our reports, your name will not be mentioned and you will be given a pseudonym. If you would like further information about anything that we discuss today, you can contact me and I'll do my best to help. Before we begin, I wanted to make you aware that the interview will be recorded with your permission. Are you happy for us to continue?

GENERAL EXPERIENCE OF LIVERPOOL HEALTHY LUNG

To begin, can you please tell me about your overall impression of running the clinics for the Liverpool Healthy Lung Programme?

INVITATION PROCESS

From what patients have told you, what can you tell me about the invitation process?

Prompts

- Were there any problems regarding the invitation process reported by patients?
- Is there anything that could be done to improve the appointment booking process?
- If Liverpool Healthy Lung were to continue, what changes would you recommend for the invitation process?
- Are there any aspects of the process that worked well, which you would recommend keeping the same?

AT THE NURSE CLINIC

Based on your experience, can you tell me more about the clinics that you ran?

Prompts

- What level of understanding did patients have about why they have been invited to the nurse clinic?
- What level of understanding did patients have about what could happen next?
- Were there particular questions that patients commonly raised about the Lung Health Check or CT scan process/results?
- Were there any problematic issues when referring patients for a CT scan?
- Were there any problematic issues when not referring patients for a CT scan?

- How did patients react once you referred them for a scan (or not)?
- Did you have any difficulties discussing specific topics with patients? If so, what could be done to support you better?
    - Were there any risks or benefits of the CT scan that you found difficult to explain to patients or found patients were not receptive to?
    - How did you find discussing lung cancer risk with patients?
- The nurse clinics may be an opportunity to discuss other topics with patients (e.g. smoking cessation). How do you feel about that? What support/information would you need?
- If Liverpool Healthy Lung were to continue, other healthcare professionals could support aspects of the programme. In your opinion, could parts of the clinic be run by healthcare support workers?
- If Liverpool Healthy Lung were to continue, what changes would you recommend for the nurse clinics?
- Are there any aspects of the clinics that worked well, which you would recommend keeping the same?
- What are the challenges you think nurses might face with delivering these clinics in the future? How would you suggest these could be overcome?
- If Liverpool Healthy Lung were to be extended nationwide, what challenges to do see in scaling the programme up?

APPENDIX 2. REACHING BLACK AND MINORITY ETHNIC (BAME) COMMUNITIES AND THOSE WITH ENGLISH AS ADDITIONAL LANGUAGE (EAL) IN LIVERPOOL HEALTHY LUNG

Dr Katy Gardner, LHLP GP

In the interim evaluation of LHL only 5 patients required an interpreter out 2171 attending lung health checks. The three initial neighbourhoods evaluated included Picton GP Neighbourhood with an estimated population of 38.6% Not White British or Irish, and 10% "other Ethnic group" including Arab (2011 Census). 18.2% have English as an additional language, though we do not know the age profile of this population. We therefore suspect we have had a problem in attracting people from BAME/ EAL and that these patients are underrepresented in take up of this project.

The importance of Engaging BAME patients and patients with EAL was recognised form the start. When project had initial approval, a Patient and Public Engagement Group (PPEG) was set up, at which the Liverpool Social Inclusion Team was represented as well as public health managers and people from BAME groups involved locally in research.

In the first year of the project, community events were organised to "warm up" communities before the patients were invited for a Lung Health check. These were overall very well attended and evaluation was positive . The events tended to attract a younger population than our target group of 58-70. Unfortunately, it did not appear to result in more awareness of the LHL clinics.

A decision was made not to collect data on ethnicity from patients attending the clinics. There were several reasons for this: a) GP systems (EMIS) though holding some data on ethnicity, had already been found to have little useful information due to coding issues and inconsistency of recording, b) the lung nurses had limited time, and c) the project had limited resources to collect this data properly and accurately. Language spoken is not routinely coded in primary care. Ideally in any future project /programme this data should be collected, ideally through the accurate recording of ethnicity and language in primary care.

Instead, the Public and Patient Engagement Group(PPEG) felt that the key to reaching BAME/ EAL patients was by presenting very clear and concise and simple information, (in addition to the warm up sessions above). The patient letters were personalised and sent out by GP practice and were scrutinised by the PPEG for language and understanding. All information given out /sent out by the lung nurses was similarly scrutinised. Patients/relatives ringing to book an appointment were offered an interpreter if required.

Following the interim evaluation (as mentioned above) the PPEG revisited the issue and instituted two new actions. First following the initial invite letter, a second reminder letter included a quote from a health Lung volunteer and emphasised prominently the opportunity to request an interpreter. It is known from national screening programmes that reminder letters do increase uptake. Ideally in BAME communities, a follow up phone call would further improve uptake, particularly if members of the Social Inclusion team were on hand to provide information in the invitee's first language. However, even this (used recently in a project helping to increase bowel screening uptake) is not without difficulties and is also more resource intensive than the budget allowed for. Secondly participating practices were visited and encouraged to use their knowledge of local communities to assist in enabling/attracting patients. Local Patient Participation Groups were also alerted and engaged.

Finally, the initial evaluation noted that while Picton GP Neighbourhood was one of the most deprived with the highest mortality from lung cancer, it also had the highest population of BAME in Liverpool. Therefore, starting with this Neighbourhood, although it could have yielded a higher number of lung cancers at an early stage than other neighbourhoods, was not ideal in that teething problems had to be ironed out along the way including difficulty making appointments, which might have deterred some people from attending the clinic.

Further tactics for engaging BAME and EAL groups should be considered as the project continues.