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Crosbie, PA, Balata, H, Evison, M et al. (2019) Implementing lung cancer screening: baseline results from a community-based 'Lung Health Check' pilot in deprived areas of Manchester. *Thorax*, 74 (4). pp. 405-409. ISSN: 0040-6376

<https://doi.org/10.1136/thoraxjnl-2017-211377>

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Implementing lung cancer screening: baseline results
from a community-based ‘Lung Health Check’ pilot
in deprived areas of Manchester.

PAJ Crosbie^{1,2*}, H Balata¹, M Evison¹, M Atack², V Bayliss-Brideaux², D Colligan², R Duerden¹, J Eaglesfield², T Edwards¹, P Elton³, J Foster², M Greaves¹, G Hayler², C Higgins², J Howells⁴, KL Irion⁵, D Karunaratne⁵, J Kelly¹, Z King², S Manson¹, S Mellor⁶, D Miller², A Myerscough², T Newton⁶, M O’Leary², R Pearson², J Pickford², R Sawyer¹, N Screaton⁷, A Sharman¹, M Simons², E Smith¹, B Taylor⁸, S Taylor², A Walsham⁹, A Watts¹, J Whittaker¹⁰, L Yarnell², A Threlfall², PV Barber^{1,2}, J Tonge² and R Booton^{1,2}.

¹Manchester Thoracic Oncology Centre, Manchester University NHS Foundation Trust-Wythenshawe site, Manchester, UK. ²Macmillan Cancer Improvement Partnership, South Manchester Clinical Commissioning Group, Manchester, UK. ³Greater Manchester Health & Social Care Partnership, Manchester, UK. ⁴Dept. Radiology, Royal Preston Hospital, Preston, UK. ⁵Dept Radiology, Manchester Royal Infirmary, Manchester, UK. ⁶Dept. Radiology, Royal Blackburn Hospital, Blackburn, UK. ⁷Dept. Radiology, Papworth Hospital, Cambridge, UK. ⁸Dept. Radiology, The Christie NHS Foundation Trust, Manchester, UK. ⁹Dept. Radiology, Salford Royal NHS Foundation Trust, Salford, UK. ¹⁰Dept. Radiology, Stockport NHS Foundation Trust, Stockport, UK.

***Corresponding author:** Dr PAJ Crosbie, Manchester Thoracic Oncology Centre, North West Lung Centre, Manchester University NHS Foundation Trust, Southmoor Road, Wythenshawe, M23 9LT. Tel +44 (0) 161 291 2116. E-mail: philip.crosbie@manchester.ac.uk

Abstract

We report baseline results of a community-based, targeted, low dose CT (LDCT) lung cancer screening pilot in deprived areas of Manchester. Ever smokers, age 55-74, were invited to 'Lung Health Checks' next to local shopping centres, with immediate access to LDCT for those at high-risk (6-year risk $\geq 1.51\%$, $PLCO_{M2012}$ calculator). 75% of attendees (n=1893/2,541) were ranked in the lowest deprivation quintile; 56% were high-risk and of 1,384 individuals screened 3% (95% CI 2.3-4.1%) had lung cancer (80% early stage) of whom 65% had surgical resection. Taking lung cancer screening into communities, with a 'Lung Health Check' approach, is effective and engages populations in deprived areas.

Introduction

The symptomatic presentation of lung cancer is typically associated with advanced disease and poor survival. Screening asymptomatic at risk subjects with low dose CT reduces lung cancer specific mortality by 20% (1). However, current smoking and low socio-economic status (SES) are associated with reduced participation in lung cancer screening trials (2-4). Reducing barriers to participation in those at greatest risk is a critical challenge to screening implementation (5). To address this and the high burden of lung cancer in our local community, we designed and piloted a community-based, lung cancer screening service. The screening programme was developed around the concept of a one-stop 'Lung Health Check', which incorporated a holistic lung health programme and was located next to local shopping centres. The service was designed to minimise barriers to participation by reducing travel and increasing convenience/service accessibility. We selected screening participants according to individualised risk, using the PLCO_{M2012} model, at a 6-year lung cancer risk threshold of $\geq 1.51\%$ (6). A similar approach was used in the UK Lung Cancer Screening Trial (UKLS), which selected participants based on 5-year risk $\geq 5\%$ (Liverpool Lung Project model), this was cost-effective and resulted in a high prevalence of lung cancer (7).

Methods

Ever smokers, aged 55-74, registered at participating GP practices (n=14), were invited to a community-based 'Lung Health Check' (LHC), where respiratory symptoms, spirometry and 6-year lung cancer risk ($PLCO_{M2012}$) were assessed alongside smoking cessation advice (8); anyone with a risk $\geq 1.51\%$ was offered annual screening, over two screening rounds, including an immediate LDCT scan (see supplementary file for more detailed methodology). CT scans were reported by NHS Consultant Radiologists with an interest in thoracic radiology. Pulmonary nodules were managed in accordance with British Thoracic Society (BTS) guidelines adapted for an annual screening programme (9). Scan reports were categorised as negative, indeterminate or positive. Indeterminate results required a 3-month surveillance scan and positives immediate assessment in the rapid access lung cancer clinic. A false positive was any screened individual referred to the cancer clinic who was not diagnosed with lung cancer.

Results

Demand was extremely high and all LHC appointments were booked within a few days; 99.5% consented to the research database (n=2,541). Baseline characteristics are detailed in Table 1. 56.2% (n=1,429) of attendees qualified for screening and 1,384 had a LDCT scan (35 excluded because CT thorax <12 months, 7 declined and 3 unable - claustrophobia); 82.6% of baseline scans were classified negative (n=1,143), 12.7% indeterminate (n=176) and 4.7% positive (n=65) (Figure 1). Negative scans had no nodules (73.8%; n=844), nodules <6mm (24.9%; n=284) or larger stable/benign nodules (1.3%; n=15). Three-month scans were performed for either nodule (87.8%; n=166) or non-nodule surveillance (12.2%; n=23). The dominant nodule at baseline was solid (54.2%; n=90), part solid (12%; n=20) or a pure ground glass opacity (pGGO) (33.7%; n=56).

Of 81 (5.9%) individuals assessed in the cancer clinic, 42 were confirmed to have lung cancer. The false positive rate was 48.1% (n=39/81) as a proportion of cancer clinic referrals, or 2.8% of everyone screened. Patients who ultimately did not have cancer had the following investigations: PET-CT (n=17), bronchoscopy (n=9), endobronchial ultrasound (n=3), staging CT (n=6) and percutaneous biopsy (n=4). No surgical interventions were required for benign disease; one patient had a pneumothorax post CT-guided biopsy.

The prevalence of lung cancer was 3% (95% CI 2.3-4.1%; n=42/1,384); 46 lung cancers were detected as three patients had >1 cancer (Table 1). Cancers were 63% stage I (n=29/46), 17.4% stage II (n=8/46), 8.7% stage III (n=4/46) and 10.9% stage IV (n=5/46). Whilst we recognise the inherent biases associated with historical controls, this represented a significant stage shift (p<0.0001) compared to lung cancers (n=399) diagnosed across the same geographic area the year before the pilot started (31% stage I+II, 48% stage IV). The characteristics of screen detected cancers are detailed in Table 2; pathological types

included adenocarcinoma (n=24), squamous cell (n=13), small cell (n=2), adeno-squamous (n=2) and carcinoid (n=1). Four cases had a clinical diagnosis without pathological confirmation. The surgical resection rate was 65.2% (n=30/46). There was one death within 90 days of surgery. A curative intent treatment was offered for 89.1% (n=41/46) of cancers.

Discussion

In this paper, we report baseline results from the UK's first community-based, LDCT lung cancer screening service, utilising mobile CT scanners. Our approach was to target high-risk individuals in deprived areas of Manchester, with an invitation to convenient community-based 'Lung Health Checks' with immediate access to CT. We selected the screened population according to individual risk scores ($PLCO_{M2012}$). The prevalence of lung cancer was 3% and most screen detected lung cancers were early stage (80.4%). The surgical resection rate was 65%, four-fold higher than the UK average. Median deprivation rank was within the lowest decile for England (2,873), markedly lower than UKLS (17,374) (7) and in contrast to screening trials where participation favours more affluent and better educated individuals (2); suggesting our approach engaged individuals of lower SES from deprived areas, a key demographic of the 'hard-to-reach'.

To minimise overdiagnosis only persistent pGGOs ≥ 5 mm were surveyed and sub-solid lesions with a solid component ≥ 8 mm investigated; intervention was generally reserved for lesions with avidity on PET scan above the mediastinal blood pool or a volume doubling time < 400 days. All surgically resected adenocarcinomas had $\geq 10\%$ non-lepidic and invasive histology, suggesting this approach was appropriate. No surgery was performed for benign disease. One death occurred within 90 days of surgery (in a patient with 2 confirmed lung cancers). This mortality is below the national average, but underlines the importance of appropriate patient selection and minimising unnecessary invasive procedures.

In conclusion, our results have demonstrated that an appropriately designed service, using a 'Lung Health Check' approach, can engage participants at high risk of lung cancer from deprived areas. This resulted in high rates of early stage lung cancer detection with minimisation of harms. It was not a clinical trial but an evidence based pragmatic evaluation

of an NHS commissioned and implemented service within a regional lung cancer service. Further evaluation of the Manchester 'Lung Health Check' model will be undertaken in a roll out of the service across the whole of North Manchester and at a number of additional sites as recently announced by NHS England (10).

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Role of funding sources

The pilot was supported by funding from Macmillan Cancer Support. The Macmillan Cancer Improvement Partnership facilitated the design and development of the pilot. The service was delivered by the lung cancer team at Wythenshawe Hospital, Manchester University NHS Foundation Trust, in partnership with Alliance Medical. LDCT reporting was performed by a consortium of NHS consultant radiologists with sub-speciality interest in thoracic medicine. The pilot service was commissioned by South Manchester Clinical Commissioning Group on behalf of the three Manchester Clinical Commissioning Groups. Community engagement was delivered by multiple members of the team and was led by MCIP and the Manchester CCGs in conjunction with Manchester City Council, Macmillian Cancer Support and BHA for Equality.

Table 1. Characteristics of individuals who attended the LHC, stratified by lung cancer risk.

Variable	All	Lung Cancer Risk		p value	
		High (PLCO ≥1.51%)	Low (PLCO <1.51%)		
Number of attendees (%)	2,541	1,429 (56.2)	1,112 (43.8)	-	
Mean age (years ±SD)	64.1 (5.5)	64.7 (5.4)	63.4 (5.5)	*	
Sex M/F (F%)	1245/1296 (51.0)	706/723 (50.6)	539/573 (51.5)	0.64	
Median IMD rank (interquartile range)	2873	2866 (3994)	3109 (8345)	*	
BMI (%)	<18.5	42 (1.7)	33 (2.3)	9 (0.8)	*
	18.5-24.9	531 (20.9)	353 (24.7)	178 (16.0)	
	25-29.9	982 (38.7)	541 (37.9)	441 (39.7)	
	30-39.9	875 (34.4)	460 (32.2)	415 (37.3)	
	≥40	111 (4.4)	42 (2.9)	69 (6.2)	
Education (%)	Less than 'O' level	1567 (61.7)	998 (69.8)	569 (51.2)	*
	'O' level	511 (20.1)	255 (17.9)	256 (23.0)	
	'A' level	106 (4.2)	49 (3.4)	57 (5.1)	
	University/college	213 (8.4)	84 (5.9)	129 (11.6)	
	University degree	91 (3.6)	31 (2.2)	60 (5.4)	
Postgrad/professional	53 (2.1)	12 (0.8)	41 (3.7)		
Smoking status (%)	Current	891 (35.1)	754 (52.8)	137 (12.3)	*
	Former	1650 (64.9)	675 (47.2)	975 (87.7)	
Smoking exposure (mean ±SD)	Duration (years)	34.6 (14.7)	43.8 (8.2)	22.8 (12.6)	*
	Cigs / days	20.4 (13.0)	24.0 (12.9)	15.8 (11.5)	*
	Packyears	36.7 (27.8)	51.6 (26.8)	17.7 (14.2)	*
Spirometry (mean ±SD)	FEV ₁	2.3 (0.8)	2.1 (0.7)	2.6 (0.8)	*
	% predicted FEV ₁	90.1 (25.0)	84.0 (24.3)	98.0 (23.6)	*
	FVC	3.3 (1.0)	3.1 (1.0)	3.4 (1.0)	*
	% predicted FVC	102.6 (24.9)	99.4 (24.5)	106.6 (24.7)	*
	FEV ₁ /FVC ratio	70.8 (10.6)	67.8 (11.0)	74.7 (8.7)	*
Airflow Obstruction	Yes (%)	944 (37.2)	716 (50.1)	228 (20.5)	*
COPD/emphysema	Yes (%)	566 (22.3)	471 (33.0)	95 (8.5)	*
FH Lung cancer	Yes (%)	553 (21.8)	392 (27.4)	161 (14.5)	*
MRC Dyspnoea Score (%)	1	1791 (70.5)	920 (64.4)	871 (78.3)	*
	2	494 (19.4)	310 (21.7)	184 (16.6)	
	3	163 (6.4)	123 (8.6)	40 (3.6)	
	4	91 (3.6)	74 (5.2)	17 (1.5)	
	5	2 (0.1)	2 (0.1)	0 (0)	
Performance Status (%)	0	1552 (61.1)	768 (53.7)	784 (70.5)	*
	1	763 (30.0)	481 (33.7)	282 (25.4)	
	2	187 (7.4)	152 (10.6)	35 (3.1)	
	3	38 (1.5)	28 (2.0)	10 (1.0)	
	4	1 (0.0)	0 (0)	1 (0.0)	

(FH = Family History; IMD = Index of Multiple Deprivation; BMI = Body Mass Index)

*p value < 0.0001

Table 2. Clinical details of screen detected lung cancers.

ID	Sex	Age	PS	MRC	TNM	Final Stage	Pathological type	Histology sub-type (Resected Adenocarcinomas)	Treatment
1	M	57	1	1	cT1a N0 M0	IA	Adenocarcinoma	-	Radiotherapy ^(R)
2	F	61	2	3	pT1a N0	IA	Adenocarcinoma	Undetermined	Surgery
3	F	69	0	1	pT1a N0	IA	Squamous	-	Surgery
4	F	65	0	1	pT1a N0	IA	Adenocarcinoma	Acinar	Surgery
5	F	74	1	1	pT1a N0	IA	Adenocarcinoma	Acinar	Surgery
6	F	70	0	1	pT1b N0	IA	Adenocarcinoma	Lepidic 40%; Papillary 35%, Acinar 20%, Solid 5%	Surgery
7 ^A	F	60	3	4	pT1a Nx	IA	Adenocarcinoma	Acinar	Surgery
8 ^A					pT1a Nx	IA	Adenocarcinoma	Papillary	
9 ^A					pT1a Nx	IA	Adenocarcinoma	Acinar	
10	F	74	2	4	cT1b N0 M0	IA	Clinical	-	Surgery - Declined
11	M	69	0	1	pT1a N0	IA	Adenocarcinoma	Papillary	Surgery
12	M	66	0	1	pT1a N0	IA	Squamous	-	Surgery
13	F	65	1	1	pT1a N0	IA	Adenocarcinoma	Lepidic 90%; Acinar 10%*	Surgery
14 ^B	F	74	1	1	pT1a N0	IA	Adeno-squamous	Acinar	Surgery
15 ^B					pT1a N0	IA	Squamous	-	
16	F	72	2	1	pT1b N0	IA	Typical Carcinoid	-	Surgery
17	M	73	0	1	pT1a N0	IA	Adenocarcinoma	Acinar	Surgery
18	M	64	1	1	cT1a N0 M0	IA	Clinical	-	SABR
19	F	65	1	2	pT1a N0	IA	Adenocarcinoma	Acinar 80%, Lepidic 20%	Surgery
20	F	73	0	1	cT1a N0 M0	IA	Clinical	-	Surgery - Declined
21	F	72	0	2	pT1a N0	IA	Squamous	-	Surgery
22 ^C	F	73	1	1	pT1aN0	IA	Adenocarcinoma	Acinar 70%, Lepidic 30%	Surgery
23 ^C					pT2aN0	IB	Squamous	-	
24	M	70	0	1	pT2a N0	IB	Adenocarcinoma	Mixed Acinar (>10%), Lepidic, Papillary	Surgery
25	F	71	0	1	pT2a N0	IB	Squamous	-	Surgery
26	M	67	1	3	pT2a N0	IB	Adenocarcinoma	Lepidic 55%, Papillary 40%, Acinar 5%	Surgery
27	F	64	1	4	pT2a N0	IB	Adenocarcinoma	Solid 90%, Acinar 10%	Surgery
28	F	67	1	3	pT2a N0	IB	Adenocarcinoma	Acinar 95%, Lepidic 5%	Surgery
29	F	62	3	4	cT2 N0 M0	IB	Squamous	-	SABR
30	F	60	0	1	cT1a N1 M0	IIA	Small	-	Chemo-Radiotherapy ^(C)
31	M	68	1	2	pT1a N1	IIA	Adeno-squamous	Solid	Surgery/Chemotherapy ^(A)
32	M	63	0	1	cT1 N1 M0	IIA	Squamous	-	Radiotherapy ^(R)
33	M	72	1	2	pT2b N0	IIA	Adenocarcinoma	Acinar	Surgery
34	M	69	3	5	cT1a N1 M0	IIA	Small	-	Chemotherapy
35	F	70	1	2	pT3 N0	IIB	Adenocarcinoma	Acinar 50%, Lepidic 40%, Papillary 10%	Surgery
36	M	73	0	1	cT3 N0 M0	IIB	Squamous	-	Radiotherapy ^(R)
37	M	57	3	5	cT3 N0 M0	IIB	Clinical	-	Radiotherapy ^(R)
38	F	61	0	1	pT2a N2	IIIA	Squamous	-	Surgery/Chemotherapy ^(A)
39	M	65	0	2	pT2a N2	IIIA	Adenocarcinoma	Acinar 60%, Lepidic 30%, Solid 5%, Papillary 5%	Surgery/Chemotherapy ^(A)
40	M	74	0	1	cT4 N2 M0	IIIA	Squamous	-	Chemo-Radiotherapy ^(S)
41	M	73	0	1	pT4 N2	IIB	Squamous	-	Surgery/Chemotherapy ^(A)
42	F	65	2	3	cT4 N0 M1a	IV	Adenocarcinoma	-	Chemotherapy
43	F	66	1	1	cT4 N2 M1b	IV	Adenocarcinoma	-	Radiotherapy ^(P)
44	M	63	0	1	cT4 N2 M1b	IV	Squamous	-	Chemotherapy - Declined
45	F	71	0	1	cT2 N2 M1b	IV	Adenocarcinoma	-	Chemo-Radiotherapy ^(S)
46	M	71	2	4	cT4 N1 M1b	IV	Adenocarcinoma	-	Chemotherapy

^(R) Radical treatment, ^(C) Concurrent treatment, ^(S) Sequential treatment, ^(P) Palliative treatment, ^(A) Adjuvant chemotherapy. ^{A,B,C} = cancers in the same patient

*Case with a rapid development of a solid component over 3-months

TNM staging using version 7

Figure Legend

Figure 1. Diagram showing flow of participants through the screening service.

(LHC = lung health check; LDCT = low dose CT scan;
* = based on GP recorded smoking status for 15,072 invitees).