

BUSINESS CASE

Project:	Primary Care Quality Assured Spirometry
Project Number:	
Date:	June 2019
Project Lead:	C Morrissey
Project Sponsor:	
Version No:	0.7

1 Business Case History

Template Revision History

Date of this revision: 01/04/2018

Revision date	Summary of Changes	Changes marked
08/2013	Preliminary Equality Analysis added	1.1
	First issue	
12/2014	Quality Impact Analysis added	1.2
18/06/15	Document Review	1.3
02/03/16	Addition of Task and Finish Section	1.4
17/03/2017	New CCG Logo and document formatting	2.0
01/04/2018	Task and Finish section, DPIA and front sheet	3.0

Task and Finish Group Views

Task and Finish Group Views - please confirm who has been identified as the lead for each of the following areas below, and their initial comments:

Area / Team	Lead Name	Date	Initial comments from the Leads review of the Scoping Report
Clinical	Dr Helen Ward/ Dr John Burrell/ Group leaders	Feb 19	
Public/ Patient			Not required for the purpose of the business case
Finance	S Chhokar/ Lesley Sawrey	Feb 2019	Amendments made to costs, due to 19/20 not being ratified, therefore based upon 18/19 costing template
		Apr 2019	Further amendments made to costs based upon revised (but not signed off) 19/20 costing template
		May 2019	Further amendments made to the timings within the costing template, and emailed through to L Sawrey for sign off
Quality	S Parvez	Feb 2019	QIA signed off
Performance			Not required for the purpose of the business case
PMO			Not required for the purpose of the business case
Contract &			

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Performance			
Medicines Management			Not required for the purpose of the business case
Equality	D King	Apr 2019	Full EQIA
Information Governance	Kelly Huckvale	Apr 2019	Initial DPIA submitted for comment
		May 2019	Approved DPIA received
Legal/ Policy (Corporate Operations Manager)			Not required for the purpose of the business case
Primary Care		Feb 19	Presented at Primary Care Programme board Feb 19, with amended version being presented in May 19
		May 19	Approved in principle at Primary Care Commissioning Committee – with a view that costing template may require further amendments
IMT / IT			Not required for the purpose of the business case
Business Intelligence			Not required for the purpose of the business case
Estates			Not required for the purpose of the business case

All of the sections above must be completed before the report is submitted to the relevant board. If any of these leads are not applicable please indicate why, do not leave blank.

Report Distribution

This document/report has been distributed to:

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3 Purpose

Chronic obstructive pulmonary disease, or COPD, is a group of lung conditions including bronchitis and emphysema. They make it difficult to empty air from the lungs because the airways have been narrowed, this results in a difficulty in taking in oxygen and getting rid of carbon dioxide. Treatment is available for COPD to alleviate symptoms, but the damage done by the condition is irreversible making early diagnosis through spirometry important.

Spirometry measures the total amount of air that an individual can breathe out from their lungs and how fast they can blow it out. It is important that this procedure is carried out correctly to ensure that patients are diagnosed properly.

The Association for Respiratory Technology and Physiology (ARTP) are the guardians of quality-assured diagnostic spirometry in the UK. Training is available to those who are novices to this measurement and a certification system is used to ensure that those who undertake diagnostic spirometry are performing and interpreting the results to internationally acceptable standards.

The All Party Parliamentary Group (APPG) Report on inquiry into Respiratory Deaths (2014) called for a system to assess and certify the competence of all healthcare professionals undertaking and interpreting diagnostic spirometry. This document, which is part of a suite of resources relating to quality assured diagnostic spirometry, sets out a framework for taking forward the APPG recommendations.

Key to this framework is the establishment of a National Register of certified healthcare professionals and operators. This Register will ensure that commissioners, employers, and patients can be assured that healthcare staff performing and/or interpreting diagnostic spirometry hold a valid, current certificate of competence. The Care Quality Commission¹ expects practices to be able to demonstrate:

- How they ensure spirometry equipment is cleaned and maintained according to the manufacturer's guidance (KLOE S3 – reliable systems, processes and practices).
- That all staff who perform spirometry tests or interpret results are competent (KLOE E3 - staff skills, knowledge and experience). They can demonstrate this if the staff are on the National Register.

The ARTP are also responsible for holding the national register of spirometry certified practitioners.

¹ <https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-83-spirometry-general-practice>

4 Reasons

Around 1.2 million people in the UK are living with diagnosed COPD (British Lung Foundation, 2018) and numbers are increasing which indicates un-diagnosed cases are being identified more readily, and that record-keeping is better, as well as a possible increase in incidence. Previous research indicated that around 60% of cases remain undiagnosed, but more research is needed to ascertain if this is still the case. Currently in Wolverhampton there are approximately 5200 individuals with diagnosed COPD. In the last year around 500 new cases were diagnosed in the city which was 10.8% of the current register.

Spirometry is required to make a diagnosis in the clinical context of suspected COPD:

- Dyspnoea
- Chronic cough or sputum production
- And/or
- History of exposure to risk factors for the disease

Further information can be found in the most recent [GOLD Report](#) (2018, p. 23)

Spirometry is the most commonly performed lung function test. By performing maximal inspiratory and expiratory manoeuvres through a mouthpiece, it provides health care professionals with basic information about a patient's airways function and lung capacity.

Spirometry may be performed for a variety of reasons, including:

- To detect the presence or absence of lung disease
- To confirm the findings of other investigations
- To quantify the extent of lung impairment
- To investigate the effects of other diseases on lung function
- To monitor the effects of environmental exposures
- To determine the effects of medication interventions

On the 12th September 2016 there was the launch of a competency assessment framework "Quality Assured Spirometry" (2016), and this document sets the minimum competency standards for healthcare practitioners performing spirometry. The ARTP spirometry qualifications are now the recognised competency assessment qualifications for all practitioners performing spirometry. The ARTP are now also responsible for holding the national register of spirometry accredited practitioners at all levels. The framework will be phased in commencing 1st April 2017 with full implementation by 31st March 2021.

COPD register figures produced locally indicate there are c500 newly diagnosis of COPD per year.

Activity within the current direct access for diagnostic spirometry service provided by The Royal Wolverhampton NHS Trust is as follows:

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- Total referrals to March 19 = 1018

Referrals to service per month

	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
RWT	50	84	78	66	63	40	181	94	72	108	103	79

Spirometry will be provided for new diagnoses, and should be considered where a patient's condition has deteriorated to assess any changes in lung function only. Taking into account additional numbers for example those that would need to be screened and found not to have COPD; a total of 2028 appointments would need to be available (four times the number of new diagnoses based on activity from primary care and RWT) across the city this year, and it is expected that this would rise again next year. To be able to meet demand it is important that each practice group is offered the opportunity to provide services to their practice population.

Regarding diagnosis of Asthma; the BTS and NICE are due to release joint guidelines in the summer of 2019. Locally, Wolverhampton, upon clinical advice from Acute and Primary Care respiratory specialists, have adopted BTS guidelines, and will continue to do so until the aforementioned joint guidelines are released.

BTS/SIGN guidelines recommend that Spirometry, with bronchodilator reversibility is the preferred investigating test for patients with **Intermediate** probability of asthma. For the purposes of primary care registers, QOF also requires a prescription within 12 months of diagnosis.

Through primary care data extracts, it is not possible to extract numbers of new diagnosis that were considered to be of intermediate probability, and therefore requiring spirometry with bronchodilator reversibility.

Therefore the below provides an indication at primary care hub level the number of new diagnosis for COPD and Asthma, with a prescription within the previous 12 months

Group	New COPD cases in 2017/18	New Asthma cases with prescriptions in 2017/18	Subtotal of new diagnosis	No of Spirometry appointments required
PCH1	108	119	227	908
PCH2	134	135	269	1076
Unity	149	175	324	1296
VI	116	77	193	772
Total	507	506	1013	4052

5 Options

The below table presents options to consider

Option	Implications
Option 1 – do nothing	<ul style="list-style-type: none"> • CCG has committed to a continuation of commissioning direct access spirometry for newly diagnosed • Additional demand for direct access spirometry at Acute Trust • Will not meet the CCGs commitment within the GP5YFV regarding workforce planning and developing staff to support delivery of services
Option 2 - preferred option	<ul style="list-style-type: none"> • Development of quality assured spirometry skills is in line with both ARTP and CQC guidance • Opportunity for primary care networks to develop and provide services at scale for patients • Support the commitment of developing local workforce within the GP5YFV • Support one of the key clinical priorities for Respiratory conditions as part of the Black Country STP Respiratory Clinical leaders group
Option 3 - other options	<ul style="list-style-type: none"> • Development of quality assured spirometry skills is in line with both ARTP and CQC guidance • Opportunity for individual GP practices to provide services • Support the commitment of developing local workforce within the GP5YFV • Support one of the key clinical priorities for Respiratory conditions as part of the Black Country STP Respiratory Clinical leaders group

6 Benefits Expected

- Improved offer of diagnostic quality assured spirometry within primary care, care closer to home
- Improved early diagnosis
- Improved reported prevalence
- Greater number of people living with respiratory conditions feeling supported and empowered to manage their own condition
- Reduction in acute based activity (ED presentations, unplanned admissions, avoidable outpatient appointments)
- Reduction in bed days
- Reduction in GP attendances

7 Risks

ID	Description of Risk	Likelihood	Impact	Action/Contingency	Owner	Status
1	May not be approved of appropriate programme board	2	2	Seek approval from primary care commissioning committee	Primary care Programme delivery board.	Open
2	Low uptake within primary care	3	3	Work collaboratively with locality managers to improve engagement with primary care networks	Primary Care programme delivery board	Open
3	Maintenance of competencies	3	3	Work collaboratively with primary care to ensure maintenance of competencies to deliver a quality assured service	Primary care programme board	open

8 Cost

Funding for the project has been identified through Primary Care budget.

The costs of the project are dependent upon the chosen option

Option 1 – There will be no change from the on-going situation. The CCG has previously commissioned Direct Access for diagnostic spirometry with the local Acute Trust at a cost of £48,000 for 1000 tests, and have committed to extending this arrangement for 19/20² with the Trust whilst primary care undertake training to provide at scale within the respective networks.

Costs for Option 1 - £48,000

Option 2 (**preferred option**) – approve the development of primary care quality assured spirometry within primary care networks. The breakdown of costs for this option uses the recent costing template and the following methodology:

- Each spirometry appointment would be 55 mins
- It is anticipated that a practice nurse (top band 6) or appropriately trained health care professional will undertake the test

² Cost for Direct Access Diagnostic Spirometry is £48,000 for 1000 tests

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- Some administration time has been incorporated into the costs for letters regarding the outcome of the appointment are sent to the referring GP practice

Unit cost has been calculated as:

- Practice Nurse (top-point) band 6 = £21.84 per 55 mins
- Additional indirect costs = £9.39 per appointment
- Total appointment cost = £31.22

Group	No of Spirometry appointments required	Appointment Cost	FYE
PCH1	908	£31.22	£28,347.76
PCH2	1076	£31.22	£33,592.72
Unity	1296	£31.22	£40,461.12
VI	772	£31.22	£24,101.84 ³
Total	4052		£126,503.44

It is anticipated that the service within primary care would not commence until Q3 (practices to undertake training and submission of required portfolio) therefore for 19/20 it is estimated that costs for primary care would be **c£62,440** and c£126,503.44 thereafter.

If the total amount of projected activity were to be commissioned directly through RWT, it is anticipated this would cost **£194,496**

Costs for Option 2 (part year effect – costs included for Primary Care and RWT)

	Q1	Q2	Q3	Q4
Direct Access (RWT)	350 (£16,800)	300 (£14,400)	200 (£9,600)	150 (£7,200)
Primary Care	0	0	750 (£23,415)	1250 (£39,025)
Total	£16,800	£14,400	£33,015	£46,225
Grand Total				£110,440

There is currently a gap of c1000 tests in projected activity levels. However further work is scheduled through the Black Country STP Respiratory clinical leaders group, and as part of NHSE Right Care Respiratory National Priorities Initiatives for 19/20, to develop further schemes regarding enhanced case finding to increase the prevalent population to reduce the gap from observed to estimated prevalence. During 20/21 there will need to be additional provision for an increase in activity.

Therefore this scheme is needed to ensure primary care are upskilled and competent to undertake increased diagnostic testing.

It is expected that secondary care activity will reduce as primary care are upskilled and start performing diagnostic testing. However it should be noted that a level of activity into

³ It is important to note there is potential that VI practices will utilise Direct Access Spirometry through the Trust

secondary care will continue, with some practices opting to not undertake quality assured spirometry within primary care.

Regarding Diagnostic and follow up costs, if someone has a confirmed diagnosis made, then the patient will be added to the appropriate QOF disease register and will be managed/ followed up through the GMS contract and QOF+ framework.

Option 3 – approve the development of primary care quality assured spirometry within individual GP practices. The cost for this will be the same as option 2.

9 Timescales

Milestone	Deadline
Finalise business case	Apr 2019
Primary Care programme board submission	July 2019
Approval of business case	July 2019
Primary Care to undertake training	Sept – Dec 2019
Mobilisation/ implementation	Jan 2020
Monitoring	Jan – Feb 2020
Evaluation of service provision and performance monitoring	March 2020

10 Equality – Appraisal



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11 Quality Impact Analysis (QIA)



QIA QA Spirometry
Feb 19 v0.2.xlsx

12 Data Privacy Impact Assessment (DPIA)



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