Spirometry commissioning guidance

NHS England and NHS Improvement

Contents

1. Context and background

Key messages:

- **Respiratory is a national clinical priority**
- **Primary care networks are shaping how services are delivered in primary care**
- **Under and over diagnosis are issues in respiratory**
- **There is a need to reduce variation in spirometry testing and interpretation**

The NHS Long Term Plan[1] was published in January 2019 and set the plan for the NHS for the next 10 years. Respiratory disease was identified as a national clinical priority alongside, cardiovascular disease, stroke, mental health and cancer.

Respiratory disease affects one in five people in England and is the third biggest cause of death[2]. Hospital admissions for lung disease have risen over the past seven years at three times the rate of all admissions generally[3] and remain a major factor in the winter pressures faced by the NHS. Over the next ten years the NHS will be targeting investment in improved treatment and support for those with respiratory disease, with an ambition to transform our outcomes to equal to, or better than our international counterparts.

Incidence and mortality rates for those with respiratory disease are higher in disadvantaged groups and areas of social deprivation[4], where there is often higher smoking incidence, exposure to higher levels of air pollution, poor housing conditions and exposure to occupational hazards. All these factors drive to increase health inequalities in lung conditions in the most deprived communities[5]. Further variation across respiratory disease in England is shown in the Respiratory Atlas of Variation[6]

Currently around a third of people with a first hospital admission for a chronic obstructive pulmonary disease (COPD) exacerbation have not been previously diagnosed[7]. From 2019 we will build on the existing RightCare programmes to reduce variation in the quality of spirometry testing across the country. Primary care networks will support the diagnosis of respiratory conditions. More staff in primary care will be trained and accredited to provide the specialist input required to interpret results.

The NHS Long Term Plan outlines the new service model for primary care to respond to current challenges in improving care for patients and reducing staffing pressures. The new plans focus on being more joined-up and co-ordinated in care, proactive in delivering services and more differentiated in support offered to individuals. The creation of primary care networks (PCN) means that collaboration between practices and others in the local health systems can provide

[1] https://www.longtermplan.nhs.uk/
[2] Public Health England (2015) Respiratory disease: applying All Our Health. Available from: https://www.gov.uk/government/publications/respiratory-disease-applying-all-our-health/respiratory-disease-applying-all-our-health
[3] British Lung Foundation (2017) Out in the cold – lung disease, the hidden driver of NHS winter pressure. Available from: https://www.blf.org.uk/policy/out-in-the-cold
[4] Strategic Review of Health Inequalities in England Post-2010 (2010) Fair Society, Healthy Lives: The Marmot Review. Available from: https://www.parliament.uk/documents/fair-society-healthy-lives-full-report.pdf
[5] https://www.blf.org.uk/sites/default/files/British%20Lung%20Foundation%20-%20Lung%20disease%20and%20health%20inequalities%20briefing.pdf
[6] https://fingertips.phe.org.uk/static-reports/atlas-of-variation/2ndRespiratoryAtlas_v1.0_20190923.pdf
[7] Bastin, AJ., Starling, L., Ahmed, R., Dinham, A., Hill, N., Stern, M. & Restrick, LJ. (2010) High prevalence of undiagnosed and severe chronic obstructive pulmonary disease at first hospital admission with acute exacerbation. Chronic Respiratory Disease. 7(2) 91–97. Available from: https://doi.org/10.1177/1479972310364587

care that is both personalised and can have an impact through economies of scale[8]. This new way of working will also support PCNs in the most deprived areas, with people experiencing poorest health outcomes to develop effective approaches and interventions to address health inequalities.

It is anticipated that PCNs will work together in delivering and interpreting quality assured diagnostic spirometry for accurate diagnosis of respiratory conditions, in particular COPD.

1.1 The need to improve outcomes

Earlier detection and diagnosis of lung conditions such as COPD and asthma can lead to early interventions for smoking cessation, optimal treatment, better management of the conditions and benefits to the health system. Earlier detection can also lead to a reduction in acute admissions, reduction in non-elective winter admissions, resource utilisation, improvement in quality of life and healthy life expectancy.

Both under and over diagnosis of respiratory conditions leads to delayed treatment and increased chance of acute admission – for example, 10-30% of people with COPD are not diagnosed until they are admitted to hospital with exacerbations[9].

Due to the complexity of respiratory conditions, a suite of objective tests including quality assured spirometry are recommended by the National Institute of Health and Care Excellence (NICE) to ensure accurate diagnosis for asthma[10] and COPD[11]. Other diagnostic tests include: X-ray, computerised tomography (CT) scan and exhaled nitric oxide (FeNO).

Spirometry testing is variable in terms of quality and accurate recording on patient records. There are challenges in having enough trained healthcare professionals who can administer and interpret spirometry tests, both in primary and secondary care[12].

1.2 Purpose of the document

This document is intended as a resource for commissioners, managers and healthcare professionals in the context of delivering objectives of the NHS Long Term Plan. The aim is to ensure a standardised level of competence in the performing and interpreting of spirometry testing and aid accurate diagnosis of COPD (and asthma), in primary care.

The secondary purpose of the document is to support commissioners and PCNs in the development and commissioning of spirometry services.

This guidance should be used in conjunction with the following two documents:

I. A Guide to Performing Quality Assured Diagnostic Spirometry[13]
II. Primary Care Respiratory Society – Network Respiratory Diagnostic Service Specification

[8] https://www.england.nhs.uk/primary-care/primary-care-networks/
[9] http://journals.sagepub.com/doi/pdf/10.1177/1479972310364587
[10] NICE (2017) Asthma: diagnosis, monitoring and chronic asthma management NICE guideline: Published: 29 November 2017
[11] NICE (2018) Chronic obstructive pulmonary disease in over 16s: diagnosis and management Clinical guideline: Published: 23 June 2010
[12] https://www.pcc-cic.org.uk/article/quality-assured-diagnostic-spirometry
[13] https://pcc-cic.org.uk/sites/default/files/articles/attachments/spirometry_e-guide_1-5-13_0.pdf

1.3 National investment

The NHS Long Term Plan commits to improving the quality and reducing variation of spirometry testing. The Long Term Plan Implementation Framework[14] is a national support tool to help local systems in developing their strategic plans. The framework asks local systems to have plans to support local identification of respiratory disease and increase associated referrals to pulmonary rehabilitation services for those who will benefit, particularly for the most socio-economically disadvantaged groups who are disproportionately represented in this patient cohort.

From 2020 – 2024 there will be targeted investment for local systems to train existing staff in quality assured spirometry, supported through primary care network training hubs.

[14] https://www.longtermplan.nhs.uk/implementation-framework/

2. Quality assured spirometry

Key messages:

- **Diagnostic spirometry must be quality assured**
- **Diagnostic spirometry is both a test of inclusion and exclusion**

Spirometry is the most commonly performed lung function test; it provides us with basic information about a patient's airway function and vital capacity. It 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
- as part of diagnosis following full history and appropriate examination
- 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

2.1 Diagnostic spirometry

When spirometry is used for diagnosis of disease, it must be quality assured and be performed to an approved standard – without this assurance the validity of the diagnosis cannot be relied on[15].

The importance of diagnostic spirometry lies in the fact that it is both a test of exclusion and a test of inclusion. It is the recommended objective test performed to identify abnormalities in lung volumes and air flow[16]. The test itself measures exhaled volume and/or flow against time from a maximum intake of breath - how much, and how quickly, patients can breathe in and out. It can detect the presence of airflow obstruction, as well as the degree of reversibility achieved with bronchodilator treatment. It can also detect restrictive defects in lung function.

There are two elements to diagnostic spirometry: the performance of the actual test, and the interpretation of the result. Although it may appear to be a fairly simple test to perform, the ability to produce an accurate picture of volume versus time under forceful effort depends on many factors, both technical and patient-related.

The interpretation of the result relies not only on the test performance and outcome but must be considered in the context of all other clinical information. Evidence[17] suggests that there is significant misdiagnosis and missed diagnoses of respiratory disease and, as a result, less than optimum or appropriate treatment for patients. Spirometry is one part of the diagnostic process.

[15] https://pcc-cic.org.uk/sites/default/files/articles/attachments/spirometry_e-guide_1-5-13_0.pdf
[16] National Institute for Health and Clinical Excellence. Management of chronic obstructive pulmonary disease in adults in primary and secondary care (partial update). 2010. www.nice.org.uk/CG101 NICE has not checked the use of its content in this publication to confirm that it accurately reflects the NICE publication from which it is taken.
[17] Time to take a breath National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme: National primary care audit (Wales) 2014–2015 https://www.rcplondon.ac.uk/projects/outputs/primary-care-time-take-breath

The Guide to Performing Quality Assured Diagnostic Spirometry[18] is aimed at clinicians and explains, step-by-step, the practicalities of quality assuring diagnostic spirometry. It also illustrates common technical errors and offers tips for reporting spirometry results, although it concentrates only on obstructive defects.

2.2 Handheld spirometry

Handheld spirometry can used to detect potential respiratory conditions across a range of settings, which can then lead to full diagnostic tests to confirm or exclude respiratory conditions. Handheld spirometry alone cannot be used as a diagnostic confirmation of respiratory condition.

Standards produced by the American Thoracic Society and the European Respiratory Society have produced a technical statement on spirometry including handheld devices[19].

[18] https://www.pcc-cic.org.uk/article/quality-assured-diagnostic-spirometry

[19] https://www.anzsrs.org.au/media/com_acymailing/upload/standardization_of_spirometry_2019_update.pdf

3. Guidance for commissioners and PCNs

Key messages:

Factors to consider for an accurate diagnosis
Understanding the local health population need to deliver services
Working across a primary care network footprint to deliver diagnostic respiratory services
Benefits to reviewing existing asthma and COPD disease registers

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This section is focused on what to consider when commissioning spirometry and respiratory diagnostic services, in the first instance commissioners and PCNs may want to focus on:

Focus on prevention through smoking cessation and healthy lifestyle strategies and increasing uptake of flu and pneumococcal (where appropriate) vaccines.

Early diagnosis through early asthma diagnosis (and monitoring), early COPD diagnosis, stop smoking and behaviour change advice.

Optimise correct treatment by empowering patients and carers with supported self-management plans to keep people in work and children at school.

Reduce non-elective admissions by optimising correct treatment in preventing disease progression, informing and educating patients to self-manage their condition.

Increase healthy life expectancy for those with a respiratory condition.

Spirometry is needed to confirm airways obstruction (which happens in both COPD and asthma, although normal spirometry does not exclude asthma) and to determine accurately the level of severity in COPD. In the context of airway obstruction (reduced FEV1/VC ratio) spirometry services should report severity based on FEV1 (forced expired volume in 1 second) and FEV1 % predicted[20]. Patients who are diagnosed early can benefit the most as they have greater opportunity to reduce the risk factors that contribute to lung damage (e.g. smoking, cardiovascular disease, occupational and environmental hazards).

Factors important in accurate diagnosis include:

- good clinical history and assessment of exposure to risk for COPD *(or other respiratory conditions)*
- quality assured spirometry and interpretation
- access to specialist support where needed

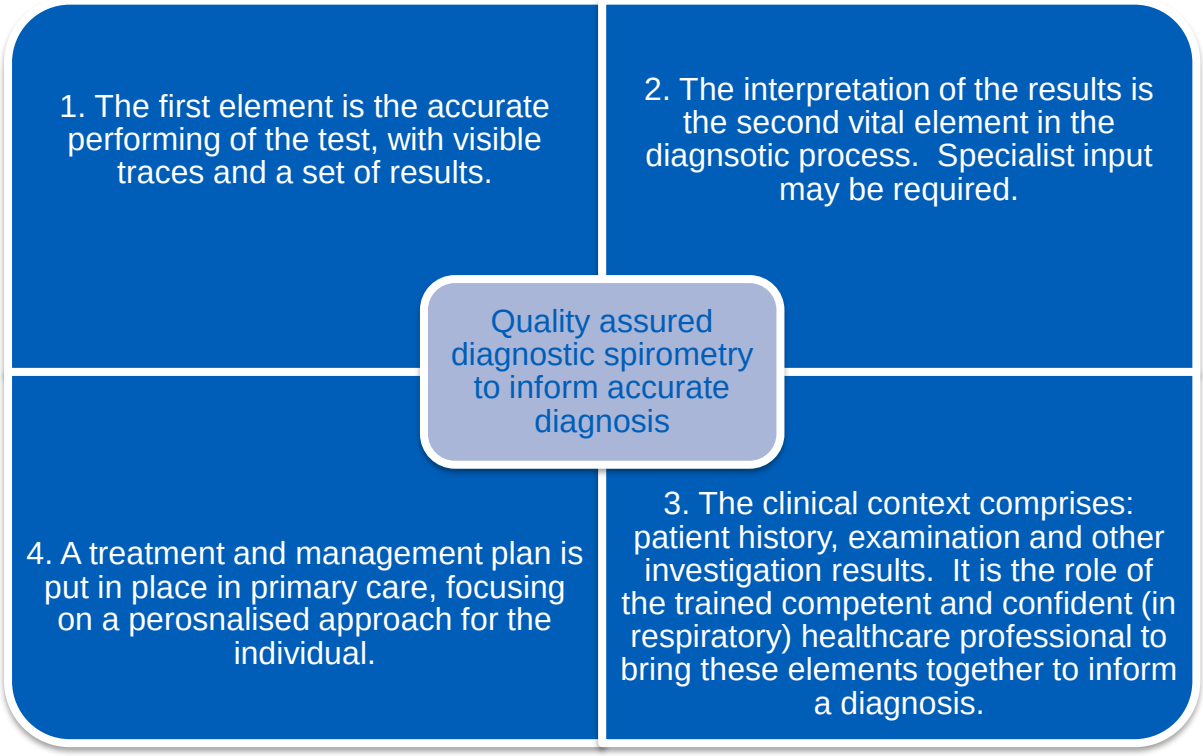
[20] Forced Expiratory Volume in 1 second – the maximum volume of air that the patient is able to exhale in the first second.

Some commissioners and PCNs may face issues around how they can quality assure and drive improvements where necessary, where spirometry is already being provided in their locality. Other commissioners and PCNs may be looking at new ways of working with other partners in their local healthcare system to deliver more effective spirometry services (maybe as part of a diagnostic hub) for their population. This can include partnerships with social care and voluntary sector services, especially in areas where there are increased health inequalities or support is required to engage with marginalised groups and communities.

Questions for commissioners to consider:

- ✓ What is the local COPD / respiratory disease prevalence?
- ✓ What is the baseline data on respiratory disease - (RightCare data packs) for the locality?
- ✓ What are the plans for spirometry / diagnostics for lung function testing within the locality / PCN?
- ✓ How are organisations across the locality working together – what arrangements are in place?

Elements of quality assured diagnostic spirometry to inform an accurate diagnosis:



These elements can be delivered as separate services (i.e. a diagnostic testing service and an interpretation service) or combined as a clinical assessment service (which includes both the test and a clinical assessment and diagnosis).

Spirometry may be provided centrally for a large population or via locality level service hubs, such as PCNs. The following shows three different service models that can be developed across a

locality / PCN footprint. These models can be *place-based* or *team-based*, with flexibility for local systems to implement what is appropriate for the local system and population.

Model 1 Focus in primary care	**Model 2** Diagnostic hubs	**Model 3** Combination
• Diagnostic testing and interpretation done in general practice / PCN	• Patients referred to central diagnostic hub for testing and diagnosis	• Testing done in general practice / PCN • Results sent for interpretation • Results sent back to referrer for diagnosis

3.2 Working across a primary care network

Example of providing spirometry and diagnostic services across a PCN footprint; a service specification has been provided in Annex B.

The option of providing an outcome based diagnostic service for spirometry at a population level has additional benefits:

- Aid in the diagnosis and management of breathlessness
- Support with specialist input
- Support with diagnosis of common respiratory conditions (COPD, asthma, pulmonary hypertension, sleep apnoea)
- Provide quality assurance in line with national guidance
- Identify other health conditions or needs and refer on (such as mental health services)

This model would require healthcare professionals with the necessary, skills, competency and accreditation to deliver the services.

Key features of this model would be the inclusion of diagnostic testing and information back to the GP practice for on-going management of the condition.

Considerations when working across PCNs

- - What model best suits the locality / PCN?

  - How do you link across primary, secondary and tertiary care services?
  - Options to link with social care and the voluntary sector
- - How is access to specialist advice (for children and adults) being provided?
  - Consider a lead GP practice / professional to be the central co-ordination point
  - Any additional costs for commissioned services?
- - What training / education arrangement are required to underpin the model?
  - What mentoring and on-going support (after training) are needed to quality assure the process?
  - How will existing staff with appropriate skills and accreditation be utilised across the model?
  - How will peer supporters, link workers and care navigators be used in the model?

High level service objectives may include:		
Ensure patients have a positive experience	Ensure all diagnostic spirometry is performed and interpreted by a healthcare professional on the National Register	Improve the accuracy of disease registers in primary care against predicted prevalence levels
Empower patients to self-manage their condition	Ensure accuracy of COPD and asthma registers	Increase the number of people accurately diagnosed at an early stage of the disease
Sign-post respiratory patients to appropriate services and resources	Ensure appropriate testing of children under investigation for asthma	

To reduce costs via: fewer inappropriate out-patient attendances, fewer emergency admissions and re-admissions, more efficient respiratory prescribing (e.g. reduced spend on inappropriate inhaled medications)

3.3 Case finding and managing COPD and asthma disease registers

3.3.1 Case finding

Although there are approximately one million people diagnosed with COPD, it is estimated that a further two million remain undiagnosed[21]. Efforts to identify previously undiagnosed COPD (and other respiratory conditions) can be undertaken in general practice / across PCNs.

Active case finding of existing GP practice patients can identify potential COPD and other respiratory diseases. Basic tools that can interrogate GP systems are available to use, such as the GRASP tool. The RightCare respiratory focus packs for CCGs can also support in identifying the 'expected' to reported prevalence of asthma and COPD. A project undertaken by Wessex Academic Health Science Network on case finding for asthma and COPD can be used as an example of conducing such searches on GP systems.

3.3.2 Reviewing COPD and asthma registers

Managing and reviewing existing asthma and COPD registers provide opportunity to identify mis-diagnosed cases. An example from Newcastle Upon Tyne Hospitals trust has shown cost savings when undertaking such a review:

In a cohort of 1,000 patients 500 undiagnosed 500 previously diagnosed, being reviewed	
Cost of delivering the service for one year	**£13,735**
Cost savings (from reduced prescribing and acute admissions)	**£40,162**

The returns continue to increase year on year. A detailed costing for asthma and COPD and prescribing costs has been shown in Annex D.

[21] https://www.nice.org.uk/guidance/ng115

4. Training and certification

Key messages:

The ARTP set the national standards for spirometry
Training can be done by any route
Only ARTP can provide certification on to the national register
Any healthcare professional who is trained and competent can perform/interpret spirometry

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4.1 The role of the ARTP

The Association for Respiratory Technology & Physiology (ARTP)[22], through standards of quality assurance, provides the only national, professionally recognised, qualifications in respiratory function testing and spirometry in the UK. The ARTP oversees the certification process to ensure that individuals are assessed and certified as competent in performing and interpreting spirometry results to nationally acceptable standards.

Quality assured spirometry is only one part of the component in making an accurate diagnosis. Being trained and competent in performing and interpreting spirometry does not necessarily enable an individual to accurately diagnose respiratory conditions. A healthcare professional/clinician who is responsible for making an accurate diagnosis will consider a number of areas, including diagnostic tests, clinical context and patient history.

4.2 The National Register

Competency for the performance of spirometry with or without competence in interpretation is recorded on a single national register (often referred to as "the National Register").

4.3 Routes to certification

Training can be undertaken by any provider or done by local arrangements. Organisations that offer spirometry training and education have been included in section seven.

Assessment to gain entry onto the national register can only be conducted by the ARTP.

Diagnostic spirometry tests and interpretation of the results can be separate functions performed by different individuals. There are different competences associated with each function.

The National Register lists individuals' names according to whichever of three categories of certification that person has achieved: *Foundation* (Performing Only), *Full* (Performing and interpretation) or *Interpretation Only*:

[22] http://www.artp.org.uk/en/about-artp/index.cfm

I. **Foundation**: Those who have been assessed as competent to perform safe, accurate and reliable spirometry tests without interpretation.

II. **Full**: Those who have been assessed as competent to perform and interpret spirometry in terms of physiological changes.

III. **Interpretation Only**: Those who have been assessed as competent in interpretation only (i.e. those with no responsibility/requirement to perform spirometry but who do have a requirement to interpret accurately the results of spirometry).

The interpretation of spirometry results is just as important as accurately performing the test. Interpretation has the additional importance to healthcare professionals who also have responsibility to accurately diagnose respiratory conditions and should be considered as part of the whole clinical context.

4.5 Workforce

Diagnostic spirometry can be performed by a wide range of healthcare professionals including, healthcare assistant, nurses, physiologists, pharmacists, physician associates, consults, GPs and physiotherapists. It is not essential for all healthcare professionals to be competent at both performing and interpretation, as these functions may be performed by different individuals. For example, a healthcare assistant may perform spirometry and a nurse may interpret the results. It is important for each individual to be trained and assessed as competent and on the national register for the part of the process that they undertake.

This guidance advocates for any healthcare professional who has undertaken the appropriate training and demonstrated competence (on the national register) can perform and interpret spirometry, regardless of job role. This way of working can ensure greater flexibility for an already limited workforce and ensure there is enough resource across a PCN.

Questions for commissioners to consider:

- ✓ How many people are trained and certified on the ARTP national register, at both performing and interpreting spirometry?
- ✓ What are the requirements for training additional staff?
- ✓ Is there a diagnosis pathway in place to support accurate diagnosis?

- Are there sufficient people, properly trained and certified, to make an accurate diagnosis using the test results with the necessary clinical information readily available (for both children and adults)?

- Is there enough demand to keep the skills of the local workforce who are undertaking tests and/or interpreting the results sufficiently competent (for both children and adults)?

- Consider the workforce across the PCN footprint and working across different multi-disciplinary teams to ensure appropriate expertise.

Issues that commissioners might need to address include:

- Costs for training and backfill
- Time to attend training and undertake any associated course work.
- Staff turnover and future demand of appropriately trained staff.

5. Spirometry in children and young people

The 2014 National Review of Asthma Deaths[23] provided a detailed report of asthma deaths occurring during 2012/13 where information was available. The review found that 14% of deaths occurred in patients aged under 19 years old, and that *"the overall quality of the asthma care received by those that died was judged to reflect good practice for just 16% of people of all ages, but just 4% of children and young people (19 years old and under)."*

Even though deaths from asthma are less common in children, acute attacks of asthma are amongst the most common medical reasons for medical admissions in children in the UK[24]. Both over and under-diagnosis of asthma is an issue and objective tests such as spirometry and reversibility can help alleviate this.

Diagnosing asthma in very young children aged under five can be problematic, due to difficulty in performing the diagnostic tests. Research indicates that with appropriate coaching many children as young as five years are often able to perform acceptable spirometry[25]. Although experienced healthcare professionals can obtain accurate spirometry on children aged five years and upwards, the ability to perform consistently is from age eight onwards.

For older children aged 12-16 years, healthcare professionals competent at testing adults would be deemed competent to perform the tests. Healthcare professionals performing spirometry in younger children (aged 5-12 years) must have appropriate experience and training in paediatric spirometry (including the use of incentive spirometry).

Healthcare professionals interpreting paediatric spirometry should:

- have knowledge of age-specific cut offs using appropriate reference values
- be able to recognise acceptable and un-acceptable spirometry
- be able to interpret spirometry in the context of the child's clinical presentation, manage accordingly, and know when referral to secondary/tertiary care is warranted.

In all children with persistent abnormal lung function despite appropriate treatment, referral to a specialised paediatric service should be considered.

[23] https://www.rcplondon.ac.uk/file/868/download?token=JQzyNWUs
[24] British Thoracic Society. BTS National Paediatric Asthma Audit Summary Report, National Audit Period: 1 November – 30 November 2015
[25] Eigen H, Bieler H, Grant D, et al. Spiro metric pulmonary function in healthy preschool children. Am J Respir Crit Care Med 2001; 163: 619–623

6. Standards

6.1 Care Quality Commission (CQC) requirements

CQC expects practices to be able to demonstrate[26]:

- how they ensure spirometry equipment is cleaned and maintained according to the manufacturer's guidance (Key Lines Of Enquiry (KLOE) S3 – *reliable systems, processes and practices*), and
- 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.

GP practices should ensure that their staff, including practice nurses, have the skills, knowledge and experience to deliver effective care and treatment. This includes ensuring that:

- staff have the right qualifications, skills, knowledge and experience to do their job
- their learning needs are identified
- they receive appropriate training
- they are encouraged and given opportunities to develop

6.2 Quality Outcomes Framework (QOF)

Further improvements have been agreed to the Quality and Outcomes Framework in 2020/21, in line with the findings of the 2018 QOF Review[27]. From 2020/21, a number of improvements will be introduced to the to the asthma and COPD domains.

The agreements on the GP contract have been published in 2020/21 update.

[26] http://www.cqc.org.uk/content/nigels-surgery-83-spirometry-general-practice

[27] NHS England (2018) Report of the Review of the Quality and Outcomes Framework in England. Available from: https://www.england.nhs.uk/wp-content/uploads/2018/07/quality-outcome-framework-report-of-the-review.pdf

7. Useful tools and resources

Standards and documents:

A Guide to Performing Quality Assured Diagnostic Spirometry
ARTP

Professional organisations:

British Thoracic Society
Primary Care Respiratory Society

Third sector organisations:

Asthma UK
British Lung Foundation

Provide training and education for spirometry:

Education for Health
Inspirometry
Quality Clinical Solutions
RespiriCare

Primary Care Training Centre (Bradford)
Email: admin@primarycaretraining.co.uk
https://www.primarycaretraining.co.uk/

Rotherham Respiratory (Rotherham):
Email: enquiries@rotherhamrespiratory.com
https://rotherhamrespiratory.com/

Respiratory Matters (Huddersfield)
Email: info@respiratorymatters.com
http://respiratorymatters.com/

Annex A - Checklist for commissioners to consider

Demand and capacity required	• What is the prevalence of suspected asthma and asthma? • What is the prevalence of COPD? • How many people do we tend to case find for asthma or COPD and confirm diagnosis?	
Disease registers	Consider developing a search query that can be downloaded and run for a given population to check accuracy	
Service models	• What model(s) would best suit our area/localities/geography? • Place level approaches and interventions • What training/education/supervision/mentoring arrangements are needed to underpin the model for quality assurance purposes? • How is access to specialist advice (for both adult and child patients) being provided?	
Misdiagnosis	• What extra resource is required to "de-diagnose" and re-diagnose? • Searching for patients prescribed short acting beta agonists (SABAs) with no diagnosis • Searching for COPD patients prescribed steroids but with FEV1>50% predicted and not exacerbating frequently • Search for patients with diagnosis of COPD with FVC/FEV1 ratio above 0.7 • Number of COPD patients on steroid monotherapy	
Patient experience	• Timeliness - how long do patients have to wait for tests and test results? • Proximity - how far do patients have to travel for tests? Is public transport available? • Co-ordination of care – how joined up is the care we are providing to patients? Are admission and discharge care bundles in place to improve the coordination of care on admission and discharge? • Self-help - what percentage of our asthma/COPD patients have the appropriate health passport? • COPD patients – are patients being signposted to pulmonary rehabilitation? • How are healthcare professionals communicating with individuals who have additional needs, lower levels of health literacy or have learning difficulties? • Have family members and carers been involved when explain a diagnosis of respiratory disease to an individual?	

Workforce	• What is the competence and capacity of our local workforce?
	• How many people are competent (trained and certified, with name on the ARTP Register) at:
	  ○ Performing spirometry
	  ○ Interpreting spirometry
	  ○ Performing and interpreting spirometry
	  ○ Performing and interpreting spirometry – in children
	• Are there are sufficient people, properly trained and certified, to make an accurate diagnosis using the test results with the necessary clinical information readily available?
	• Is there is enough demand to keep the skills of the local workforce who are performing tests and/or interpreting the results sufficiently competent?
	• Are there benefits to practices working in groups / across organisations rather than individually? E.g. sharing scarce skills, developing expertise, opportunities for career progression.
	• Succession planning – is there a plan in place to maintain an active workforce allowing for staff movement/retirement?	

Annex B – Example specification to develop a diagnostic hub

SERVICE SPECIFICATION

Service Specification No.	
Service	**Community Based-Respiratory Diagnostic hub for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Services**
Commissioner Lead	
Provider Lead	SmartCare Federation
Period	
Date of Review	

1. POPULATION NEEDS

1.1 National context and evidence base

Respiratory disease is the third biggest killer in the UK after heart disease and cancer; 1 in 50 adults have Chronic obstructive pulmonary disease (COPD) and 1 in 14 has asthma. Within respiratory disease, the leading causes of death for people under 75 years of age are COPD and pneumonia[28]. Respiratory diseases accounted for 14% of all deaths in the UK in 2011; this rises to 20% when cancers of the respiratory system are taken into account. COPD causes approximately a third of deaths due to respiratory disease.

The National Review of Asthma Deaths (NRAD)[29] estimated that every 10 seconds someone in the UK is having a potentially life-threatening Asthma attack and every day, the lives of three families are devastated by the death of a loved one to an Asthma attack. Tragically two thirds of these deaths are thought to be preventable. Locally, there have been several incidents of Asthma deaths during GP surgery hours.

Driven by concerns about diagnostic inaccuracy of asthma in primary care, the Primary Care Respiratory Society (PCRS) UK briefing document and NICE Asthma guidelines (November 2017) recommended the use of fraction exhaled nitric oxide (FeNO)[30] in all people with suspected asthma as a primary investigation, which raises significant additional implementation challenges and could have a number of unintended consequences.

FeNO is largely unavailable in primary care; and its implementation will incur additional investment in training, consumables and ongoing costs. Furthermore, a perceived mandatory requirement for FeNO testing may increase referrals into secondary care, with the knock effect of de-skilling primary care, and potentially overloading secondary care services. PCRS-UK therefore recommends a locality based diagnostic service.

Similarly, NICE guidance[31] suggests that people aged over 35 years who present with a risk factor and one or more symptoms of chronic obstructive pulmonary disease (COPD) have post‑bronchodilator spirometry. However, access to quality spirometry testing and diagnosis is variable and generally lacking across the CCG.

1.2 Local context

Based on a complete respiratory service review (2018/19) it has been recognised that there is a need to increase the identification of patients with chronic respiratory conditions as a priority based on:

- Low COPD prevalence compared to the national average “The Missing Millions”
- High incidence of smoking
- Poor housing and deprivation
- Poor up-take of primary care and specialist interventions

[28] http://www.inhale.nhs.uk/
[29] https://www.hqip.org.uk/former_programmes/national-review-of-asthma-deaths-nrad/#.XGBkaNL7TDc
[30] https://www.nice.org.uk/guidance/ng80/resources/resource-impact-report-pdf-4667652829
[31] https://www.nice.org.uk/guidance/qs10/chapter/quality-statement-1-diagnosis-with-spirometry

- Greater asthma diagnosis than average (compared to the national figures). This is more so in those with late age of onset (> 20 years) and have had smoked for > 20 years (potentially COPD patients mislabeled as asthmatics)
- Huge variation in COPD and asthma prevalence among the practices
- Variable levels of training and expertise in asthma and COPD among primary care staff
- Low level of practice staff with e.g. ARTP training and asthma/COPD diploma /higher qualifications
- Difficulty in recruiting and retaining experience practice staff particularly practice nurses

In addition, levels of smoking in pregnancy based on the latest CCG average (4.5 per cent – 2015/16) are well below the England average of 10.6 per cent (2015/16).
Birmingham males have a life expectancy of 77.2 years (2013-15), compared with 79.6 years (2013-15) for England. Birmingham females have a life expectancy of 82.0 years (2013-15), compared with 83.2 years (2013-15) for the rest of England. The current life expectancy for both males and females across the city has dropped since 2012-14 whereas England's had remained static.
The city's infant mortality rate in 2015 was 7.9 per 1,000 live births against an England figure of 3.9 per 1,000 live births during 2015. Rates are significantly higher in ethnic minority groups.
Solihull has sharp contrasts in wealth and deprivation across different areas, although on average it is more affluent than England as a whole. In the most northerly part of the borough around one in three children live in a household without work or reliant on benefits. There is also a relatively high level of homelessness.

There is therefore an urgent need within the Birmingham/Solihull CCG area for improved patient access to accurate and timely diagnostics and treatment for these common respiratory diseases in primary care. In this proposal we aim to set up a new diagnostic service that can address this, which will ultimately improve clinical outcomes, reduce exacerbations and hospitalisations, and enhance smoking cessation. This will be timely and coincide with the ambitious campaign to lower air pollution as part of Birmingham's Clean Air Zone which is expected to come into operation on 1 January 2020
(https://www.birmingham.gov.uk/info/20076/pollution/1763/a_clean_air_zone_for_birmingham)

Implementation of this diagnostic service specification will align with the wider new model of care that will be delivered by an integrated Community Respiratory Team (CRT) to meet the needs of the adult population (aged 18 years and over) in Birmingham and Solihull.; and therefore, and will provide safe, high quality, clinically effective and cost efficient respiratory services through delivery of:

- Joined-up services at the right time and in the optimal setting, aligned with primary care networks based on neighbouring GP Practices typically covering 30-50,000 people (in line with the NHS Long Term Plan, Jan 2019)

- Patients will experience holistic care, with the service tailored to individual need including:

  - seamless care between primary, secondary, tertiary and community services
  - shared care on an episodic basis, with personalised care planning for those who would benefit; and
  - supporting coordination of care including lifestyle change advice, social care,
  - general practice care and hospital episode co-management

- The service will be outcome based and Provider(s) will be expected to meet all relevant National Institute for Health and Care Excellence (NICE) quality standards including Scottish Intercollegiate Guidelines Network (SIGN) and the British Thoracic Society (BTS) standards. Providers will ensure that care is patient and carer centred and delivered against the models of care set out within the Birmingham and Solihull Clinical Commissioning Group (BSol CCG) Operational Plan.

The Diagnostic service will deliver:
- an improved quality of life experience for patients
- clinical effectiveness and delivery of quality assured diagnostics
- a positive experience of care and improved health outcome
- ongoing educational support to primary care clinical teams

2. OUTCOMES

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	**Yes**
Domain 2	Enhancing quality of life for people with long-term conditions	**Yes**
Domain 3	Helping people to recover from episodes of ill-health or following injury	**Yes**
Domain 4	Ensuring people have a positive experience of care	**Yes**
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	**Yes**

3. SCOPE

3.1 Rationale

Investment in an Integrated Community Based-Respiratory Diagnostic COPD and Asthma Service could potentially support a reduction in acute activity. The service could offer:

- Local accessible quality diagnostic respiratory care
- Earlier diagnosis and early intervention therapies
- Reduced impact of complex unmanaged health
- Cleansing of COPD and Asthma GP registers
- Integrate respiratory services across primary, community, secondary and tertiary care
- Improved primary care respiratory knowledge, clinical expertise and ongoing education
- Reduced impact on primary, community and secondary care capacity
- Reduced escalating secondary care expenditure
- Promote healthier well-being within the community setting
- Support the local RQIP indicators such as:
    - referral for quality assured spirometry
    - LTOT assessment and
    - referral to pulmonary rehabilitation
- Implement latest asthma NICE guidance and FeNO testing

It is recognised that some patients may not be on an appropriate management plan or treatments and as a result are likely to attend hospital services following an exacerbation of their condition. Having local access to diagnostic services will aim to improve earlier accurate diagnosis, intervention, provide education and advice to patients to better manage their health and to prevent future exacerbation or at least know what to look for.

Diagnostics

The service will offer access to a quality respiratory diagnostic service for patients with suspected COPD and Asthma. The provider will carry out the appropriate diagnostic tests to confirm diagnosis and implement the appropriate management plan.

Respiratory Physiology Testing will include Spirometry with reversibility testing, single-breathe Diffusion Capacity for Carbon Monoxide and Fractional Exhaled Nitric Oxide (FeNO) Assessment, and long-term oxygen testing (LTOT) and assessment.

3.2 Aims and objectives of service

The service aims to provide quality respiratory diagnostic services for **adults aged 18 years and over.** The service will be piloted initially across SmartCare Federation GP registered patients with the option to expand across EBHO GP practices during the pilot year. The service will give respiratory clinical specialists an opportunity to work directly within the community at scale, covering a registered population of circa 235,000 patients (SmartCare at circa 80,000 and EBHO at 155,000).

The service will directly link with the wider Community Respiratory Team (CRT) which is a unified and place-based service that is being developed across Birmingham and Solihull locations. Young people who will move from children to adults' respiratory services will meet a practitioner from respiratory adults' services before they transfer (NICE QS140 Dec 2016)[32].

[32] https://www.nice.org.uk/guidance/qs140/chapter/Quality-statements

The provider will deliver a comprehensive holistic assessment, diagnostic, treatment and management service, thus ensuring evidence-based care within the service delivery, at any point of the patient pathway.

The service will:

- Deliver and/or co-ordinate a diagnostic service that will operate locally for those patients registered within the named GP Federation groups and who require a clear diagnosis for COPD or Asthma
- Deliver a quality placed-based service that is local to patients and in line with NICE guidance[33] and the national quality outcomes framework
- Empower patients to self-manage their condition to the best of their ability
- Will be inclusive of appropriate services and resources e.g. smoking cessation and directing patients to advice on housing, green energy grants, breathe easy clubs, psychological support networks etc. (this list is not exhaustive)
- Develop a detailed education plan that will embed a continuous cycle of education with specialist staff working alongside non-specialist staff in virtual clinics as well as dedicated seminars.

3.2 Service description/care pathway

SmartCare Federation will manage the operational functions of the Diagnostic Hub. This will include the engagement of the clinical team. The referral pathway is as follows:

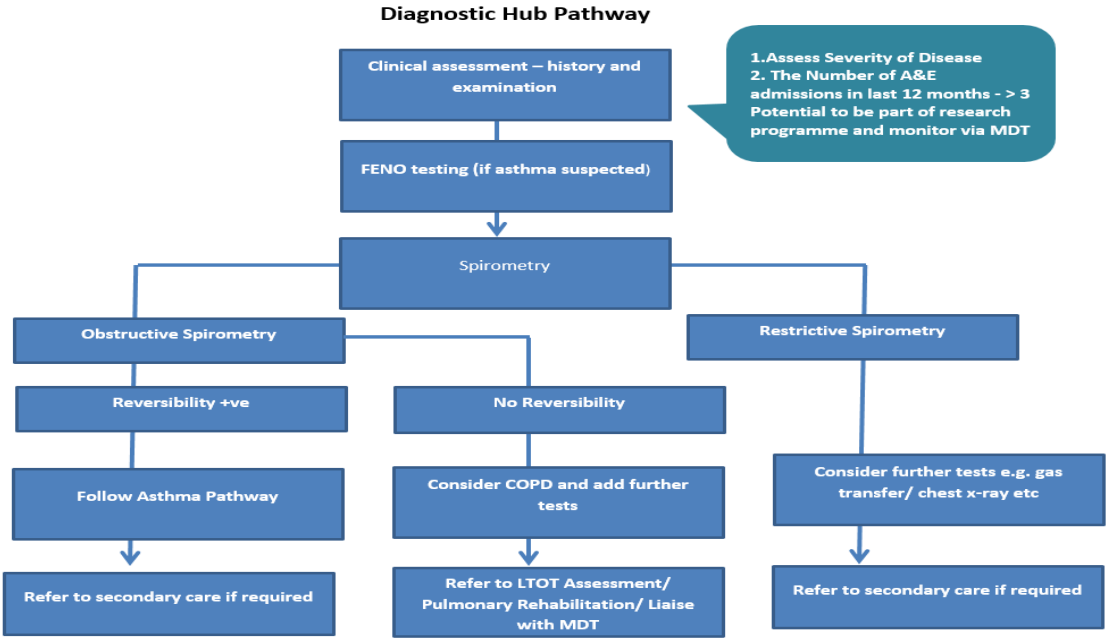

Diagram 1 – Referral Pathway

The service will include current respiratory specialist providers assuring a fully accredited highly motivated, skilled and qualified respiratory multidisciplinary specialist team. This will consist of specialist respiratory clinical teams from both the community and acute Provider Trusts. The service will also aim to improve the clinical knowledge of Primary Care GPs and Practice Nurses through an educational programme.

This multidisciplinary approach will enable the Provider and GP practices to collaborate on the diagnostic model that best meets the local population need.
The Provider will facilitate on-going educational support through engagement with the clinical experts and continue to cascade this learning through to primary care colleagues.

Other diagnostic services such as lung function, chest X-ray, CT scanning etc. will remain within the secondary care setting.

[33] http://publications.nice.org.uk/chronic-obstructive-pulmonary-disease-quality-standard-qs10
http://www.nice.org.uk/media/541/9D/Draft_Asthma_QS.pdf
http://www.blf.org.uk/Page/IPF

Access
The service will offer both face to face appointments and initially operate from a single base. However, if the opportunity arises we will provide a mobile service that can operate across different locations, which will be local to patients and aim to provide access to a wider patient population. The service will initially be for adults of 18 years and over and who are registered within the SmartCare practice cohort; aiming to expand across the EBHO GP practice group within the pilot phase.

Days of Operation
The service will offer 45 weeks of service which allows for 10 weeks' annual leave. Initially the service will offer 2 half-day sessions per week for 6 months. This will enable the team to understand demand. If there is a need to increase days of service, this can be flexed up to 4 sessions per week if required which will include mobile working.

The service will offer morning and afternoon sessions between the times of: 09.00 – 13.00 and 14.00 to 17.00, which will offer patients more choice in the longer term. In the event of staff sickness, there may be a need to cancel the clinic.
In the event of sickness or emergency leave the clinic may need to be cancelled at short notice.

Appointments
It is expected that there will be a gradual increase before full capacity is achieved. However, the aim is to offer a mix of 30 minute and 60 minute appointments. 30-minute appointment slots will be offered where general assessments are required. Where reversibility and FeNO testing/gas transfer appointments are required this may require a minimum of 60-minute -appointment slots. Possible clinic appointment systems for a 4 week-rota are set out below.

	Team	Time mins	No. Patients at 2 sessions per week	Outcome
Week 1	GPwSI/Nurse/ Physiologist/ Project Manager/Admin	60 mins	8	General assessment
Week 2	GPwSI/Nurse/ Physiologist/ Project Manager/Admin	60 mins	8	Testing and interpretations
Week 3	GPwSI/Nurse/ Physiologist/ Project Manager/Admin	60 mins	8	Testing and interpretations
Week 4	Consultant/GPwSI/ Nurse/ Physiologist/Project Manager/Admin		16	MDT and case management
Total appointments for 2 x 4 hour sessions over 4 weeks			24 (Face to face) 16 virtual MDT	

Where interpreting services are required, the provider will ensure this is made available at the time of the appointment. This will require internal arrangements between providers

Referral Criteria
Referral will be via the EMIS referral template (Appendix 3) via a central triage point.

On receipt of the referral the provider will contact the patient and offer them an appointment within 4 weeks for routine appointments and 2 weeks for urgent appointments.
For advice and guidance only, response will be within 1 working day (24 working hours) via a secure NHS email account.

A discharge summary with a copy of the full management plan will be provided to the referring GP within 10 working days (or sooner).

NOTE: Onward referral to secondary care or other allied health professions e.g. physiotherapy/pulmonary rehabilitation will follow the Standard Operating procedures as required.

Exclusions
Exclusions will include:
- Children and young adults under the age of 18 years

- All contraindications for spirometry.
- Those patients already confirmed with a diagnosis of Asthma or COPD
- Haemoptysis of unknown origin
- Unstable cardiac conditions
- Suspected lung cancer or any other lung disease not specified in the specification e.g. ILD, TB etc

Workforce

Patients referred to the service will have access to a multidisciplinary team consisting of the Respiratory Consultant, a GP with a Specialist Interest (GPwSI) in respiratory medicine; a Respiratory Specialist Nurse; Consultant Clinical Scientist. The Provider will assure that where the patient requires onward referral e.g. Pulmonary Rehabilitation, Home Oxygen etc. this advice is given to the referring GP as part of the management plan.

Skills and Competencies

The Provider will ensure that the Service is delivered by health professionals or other suitably trained and competent individuals. The Provider will ensure staff delivering the service meet the type and level of qualification, training and / or competence set out within the Provider's training policy.

The Provider must ensure that all individuals involved in the delivery of the Service have sufficient and appropriate training and competencies required to deliver the actions and content of the Service and to manage confidential and sensitive personal identifiable data.

- The lead Provider must ensure that all staff:
- if applicable, are registered with and where required have completed their revalidations by the appropriate professional regulatory body;
- have the appropriate qualifications, experience, skills and competencies to perform the duties required of them and are appropriately supervised (including where appropriate through preceptorship, clinical supervision and rotation arrangements), managerially and professionally;
- are covered by the Provider's (and/or by the relevant Sub-Contractor's) Indemnity Arrangements for the provision of the Services;
- carry, and where appropriate display, valid and appropriate identification; and
- are aware of and respect equality and human rights of colleagues, Service Users, Carers and the public.

Delivery of the Service must incorporate training in the delivery of very brief advice for smoking cessation.

The Provider will ensure that all Staff adopt a person-centred, empathy-building approach in delivering the Service. This includes finding ways to help Service Users make gradual changes by understanding their beliefs, needs and preferences and building their confidence over time.

It is envisaged that ongoing training and support to primary care will be provided with an offer of clinical training to the Federation on a bi-annual basis.
For primary care clinicians, GP's and Practice Nurses, there will be the opportunity to work within the clinics and gain clinical expertise.

Whole system Integration and Interdependencies with other services

The respiratory diagnostic service operates within a complex health system. It will be a placed-based service and reach from primary care through to tertiary and secondary care services and continue to work and liaise with:

- Community Respiratory Team (CRT)
- Respiratory Secondary and Tertiary Care Teams
- Primary Medical Services and CCG teams
- District Nursing Teams
- Occupational Therapy
- Psychological Support Therapies
- Other Community Teams E.g. Diabetes, Heart Failure, Frailty etc
- Rapid Response Services E.g. Single Point of Access (SPA)
- Hospice Services
- Nursing Homes
- Laboratory Services

- Medicines Management
- Private Sector and Voluntary Services
- Mental Health, Pharma, Private Health and AQPs
- Ambulance Services
- Out of Hours Services E.g. Walk in Centres, Urgent Care Centres, 111 Services.
- Single Point of Access (SPA)
- Social Care Teams
- Business Intelligence
- Finance
- Contracts
- Neighboring CCG's and communities

Interdependencies
Respiratory and respiratory related services.

Base/Location
The service will initially operate from a SmartCare service base with the potential to rotate across community bases as the service is expanded to serve the EBHO GP practices.

The service will not work in isolation but will work across multi-agencies as part of the STP and BSol CCG wider programme redesign, directly working as a place-based multi-disciplinary team.

Marketing
The Provider must undertake marketing and promotional activity to advertise the existence of the Service, with a view to raising awareness about the availability and benefits of the Service amongst clinical partners in the geographical area covered by the Contract.

The Provider will plan to develop trainees and consider how they will be involved in the service to improve knowledge and career opportunities. The Provider will promote training opportunities within the new integrated roles.

3.3 Population covered
The service will be accessible to all eligible patients **over the age of 18** who are registered within the named GP federation groups moving from circa 80k population to circa 235k population.

3.4 Any acceptance and exclusion criteria and thresholds - Acceptance criteria
The Provider must accept the following referrals into the Service:
- Individuals ≥ 18 years of age with a diagnosis of one of the listed respiratory conditions

The Provider will develop and agree detailed referral protocols with local health economies.
The Provider will follow the Accessible Information Standard, www.england.nhs.uk/ourwork/accessibleinfo in relation to individuals with a learning disability (a reduced intellectual ability and difficulty with everyday activities – for example household tasks, socialising or managing money – which affects someone for their whole life.

Exclusions:
- Patients ≤18 years of age
- Patients who reside outside of these geographical areas will need to be via current services.

3.5 Interdependence with other services/providers
The key relationships will be between the individual patient, their referring clinician and the Provider. A key element for successful service delivery will require the Provider to develop a close working relationship with local geographical neighbourhoods.

3.6 Service Developments
The service will be piloted across the SmartCare Federation GP registered patients with the option to extend across the EBHO group registered patients within the pilot year (dependent on capacity and funding). It is aimed that a fully commissioned service to cover all of BSol CCG registered patients will be implemented as part of the wider respiratory community redesign programme.

4. APPLICABLE SERVICE STANDARDS

4.1 Applicable national standards (e.g. NICE)

The service will be expected to operate in line with the following National standards:
i. An Outcomes Strategy for COPD and Asthma (2011):
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_131723.pdf
ii. An Outcomes Strategy for COPD & Asthma: NHS Companion Document (2012):
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_134001.pdf
iii. NICE Clinical Guideline for COPD (2018):
https://www.nice.org.uk/guidance/ng115
iv. NICE Quality Standard for COPD (2011):
http://publications.nice.org.uk/chronic-obstructive-pulmonary-disease-quality-standard-qs10
v. Draft NICE Quality Standard for Asthma (2012):
http://www.nice.org.uk/media/541/9D/Draft_Asthma_QS.pdf

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

British Thoracic Society (BTS) guideline for non-CF Bronchiectasis (2010):
http://www.brit-thoracic.org.uk/Portals/0/Guidelines/Bronchiectasis/non-CF-Bronchiectasis-guideline.pdf
British Thoracic Society (BTS) guideline on the management of Asthma
http://www.blf.org.uk/Page/IPF
Idiopathic pulmonary fibrosis (IPF) is one of the British Lung Foundation's key priority areas.
ATS/ERS Standards for Spirometry
https://www.thoracic.org/statements/pulmonary-function.php
ARTP Standards for lung function
http://www.artp.org.uk/en/professional/artp-standards/index.cfm/QADS%20Apr%202013
British Thoracic Society (BTS) Standards for lung function
https://www.brit-thoracic.org.uk/quality-improvement/guidelines/

4.3 Applicable local standards

Quality and Clinical Governance

The Provider will demonstrate robust quality assurance processes which ensure their educators are fully competent to deliver the service. Quality assurance processes must include self-assessment, peer review and external review.
All confidential patient information will be stored and accessed according to NHS national standards on confidentiality.

The Provider will demonstrate user involvement and feedback in the delivery and review of the service.

Any untoward incidents will be recorded on appropriate documentation and details sent to the commissioner as part of the contract reporting mechanisms. The Provider must inform the commissioner immediately if the untoward incident will or has impacted on patient safety. West Midlands Quality Review Service, Care of People with Long Term Conditions
http://www.wmqrs.nhs.uk/review-programmes/view/long-term-conditions#

Clinical Management Guidelines

N/A

Safeguarding

The Provider must comply with the CCG's Safeguarding policy and any required safeguarding audit.

Information Governance

All confidential patient information will be stored and accessed according to NHS national standards on confidentiality.

Data Protection

The Provider will comply with the Data Protection Act 1998 ("the 1998 Act") and the General Data Protection Regulations (GDPR) any other applicable data protection legislation. This will include appointing a Data Protection Officer and keeping commissioners informed as to his/her identity. Where necessary all personal and special category information must be appropriately secured. It is the responsibility of the Provider to put in place appropriate indemnity cover to protect it against increased fines which the Information Commissioners Office may levy for breaches of Data

Protection legalisation. The Provider will report all data breaches which are reportable under Data Protection legislation to the commissioner.
In particular the Provider agrees to comply with the obligations placed on Birmingham and Solihull Strategic Partnership (BSol STP) by the seventh data protection principle ("the Seventh Principle") set out in the 1998 Act, namely: to maintain technical and organisational security measures sufficient to comply at least with the obligations imposed on BSol STP by the Seventh Principle; only to process Personal Data for and on behalf of BSol STP , in accordance with the instructions of BSol STP and for the purpose of performing the Services in accordance with this Agreement and to ensure compliance with the 1998 Act; to allow BSol STP to audit the Provider's compliance with the requirements of this Clause on reasonable notice and/or to provide BSol STP with evidence of its compliance with the obligations set out in this Clause.

Both Parties agree to use all reasonable efforts to assist each other to comply with the 1998 Act. For the avoidance of doubt, this includes the Provider providing BSol STP with reasonable assistance in complying with subject access requests served on BSol STP under Section 7 of the 1998 Act and the Provider consulting with BSol STP prior to the disclosure by the Provider of any personal data in relation to such requests.

Freedom of Information
Each of the parties acknowledges the requirements of the Freedom of Information Act 2000 and each of the parties shall assist and cooperate with the other party (at their own expense) to enable the other party to comply with these information disclosure requests as appropriate.

Where any party receives a request for information in relation to or in connection with this agreement which it is holding on behalf of the other party, it will, where possible and appropriate (and will procure that any subcontractor will), transfer the request for information to the other party as soon as practicable after receipt.

5. QUALITY AND PERFORMANCE INDICATORS

Quality Performance Indicators
There will be four quality indicators (detailed below) and the provider will be responsible for reporting the outcomes of these indicators on a quarterly basis.

Quality Area	Quality Measure	Measurement and Reporting Frequency and Format	Threshold	Consequence of Breach
Patient Experience	100% of patients encouraged to complete patient satisfaction questionnaire (e.g. Friends and Family Test)	monthly report	100% 80%	Remedial action plan to demonstrate quality measures will be resumed
	100% of service users (i.e. clinical referrer) encouraged to complete user satisfaction questionnaire		80%	
Data Capture	National standard for referral to treatment times – 99% of patients seen within 6 weeks of referral	monthly report	99%	
	Referral triaged within 7 working days of receipt of referral			
	DNA rate	monthly report	95%	
	Audit of quality of percent of patients with a confirmed diagnosis.	monthly report	To be no more than current community service DNA rates	

	1 in 20 patients seen in the service to have a review of their CAT or ACQ within 3 months of discharge from the service	End pilot report Quarterly	80% 1 in 20 patients	

Activity Reporting

Activity	Quarter
Number of patients seen	
Number of appropriate referrals received	
Number of inappropriate referrals received	
Number of patients DNA'd	
Number of patients unable to undertake Spirometry test	
Number of patients unable to undertake FeNO test	
Number (split by test type) and reason of inconclusive tests e.g. patient unable to do the test or the test was equivocal	
Number of patients who smoke including, tobacco, e-cigarettes and vaping	
COPD	
Number of patients newly diagnosed with COPD	
Number of patients with suspected COPD with a corrected diagnosis upon assessment (NICE COPD guidelines)	
Baseline CAT score for COPD patients	
Number of patients with advised classification following Spirometry	
Number of patients with suspected COPD advised step-up change to treatment	
Number of patients with suspected COPD advised step-down change to treatment	
Number of patients with non-asthma, non-COPD diagnosis post-assessment (e.g. VCD)	
Number of patients with suspected COPD advised inhaler device(s) change	
Number of patients with Severe COPD require specialist care	
Asthma	
Number of patients newly diagnosed with Asthma	
Number of patients with suspected asthma with a corrected diagnosis upon assessment (NICE Asthma guidelines)	
Baseline ACQ and AQLQ score for asthma patients and end of service score (upon discharge).	
Number of patients with advised classification of: mild to moderate post-assessment (BTS) sever post-assessment (BTS)	
Number of patients with suspected Asthma advised step-up change to treatment	
Number of patients with suspected Asthma advised step-down change to treatment	
Number of patients with suspected Asthma advised inhaler device(s) change	
Number of patients with suspected Asthma that are compliant with treatment	
Number of patients on maintenance OCS	
Number of patients with difficult to treat Asthma referred to specialist care	
Number and percentage of Asthma diagnosis 'converted' to COPD diagnosis or dual diagnosis and number of COPD diagnosis 'converted' to asthma or dual diagnosis	
Percentage of patients referred to the Birmingham Difficult Asthma Service diagnosed with Severe Asthma	
Other	
Number of patients referred with no asthma or no COPD	
Number of patients referred with other confirmed diagnosis (e.g. ILD)	
Number of patients referred with uncertain diagnosis (required on referral)	

Annex C: Improving accuracy of COPD diagnosis, best practice example

Local case study: improving accuracy of diagnosis of COPD

NHS Wakefield and its partners have for many years supported respiratory education for staff across the respiratory pathway, resulting in an informed and engaged workforce committed to working together. Through these collaborative working relationships, standards and measures for respiratory care have been included in successive locally agreed primary care contracts. In 2016, an audit of the quality of spirometry in the primary care contract was introduced.

The audit was on going when the Time to Take a Breath report (TTTAB), part of the National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme, published in 2016, reported that, in the Welsh GP practices taking part, computerised coding of how a COPD diagnosis was made was inconsistent between practices. This included the recording of appropriate diagnostic test code and results for that test. It found that only 14.4% of people on COPD registers had spirometry recorded and in those with evidence that spirometry has been performed, 25% of the values were not consistent with COPD.

In response to this report, an additional audit was carried out centrally and identified 25% (over 2500 people) of those on the GP registers had an FEV1/FVC ratio of equal to or greater than 70% or no record of spirometry.
What we did

The initial action was to work with a small number of practices to look at the results on their systems. It quickly became obvious that in some cases the FEV1/FVC had simply been recorded incorrectly; the system was allowing FEV1/ FVC ratio values greater than 1.0 (100%) to be recorded. In many cases this was an administrative error as FEV1 or FVC results were being entered in the wrong box. The national system developer was contacted and parameters were amended.

The audit findings were discussed with colleagues from primary care and the Clinical Commissioning Group (CCG) and it was decided the best way to raise the profile of this issue and to start to improve practice, was to add a standard requirement to review diagnosis in these patients in the Wakefield Premium Contract. Practices would be required to amend data, review processes and review the patients that were identified.

Standard
All patients on the COPD register will have spirometry consistent with a diagnosis of COPD by 31 March 2020 or an explanation of confirmation of diagnosis.

Actions
- The GP practice review patients on their COPD register to ensure accurate diagnostic coding
- Patients with spirometry showing an FEV1/FVC ratio of less than 0.7 (70%) review as usual
- Diagnosis made on clinical grounds, no record of spirometry; patients identified and diagnosis reviewed including diagnostic spirometry, patients can be excluded from Spirometry if not appropriate e.g. physically unable to undertake the test. Other diagnostics (if appropriate) and specialist advice via e-consultation (if appropriate)
- Those patients with an FEV1/FVC ratio of equal to or greater than 0.7 (70%); records reviewed and a clinical review, including diagnostic spirometry, undertaken. Other diagnostics (if appropriate) and specialist advice via e-consultation (if appropriate) Diagnosis is either confirmed or updated

Outcome
- A ‘work to do list’ was produced for each GP practice, providing a list of names requiring a review. The search was set up by the CCG business intelligence team, with the support of the respiratory lead at the CCG and is updated quarterly.
- By March 2019 patients without spirometry confirming a diagnosis of COPD had reduced to 15% of the primary care register.
- Of those who remain on the list a significant number have received a diagnosis historically from secondary care e.g. based on a chest x-ray, emergency department attendance or admission to a non-respiratory team.

Work is now underway with the secondary care respiratory team to review those diagnoses and introduce processes in primary and secondary care that will prevent coding of COPD in this way in the future.

Annex D: Financial efficiency through accuracy of COPD and asthma diagnosis

Newcastle Hospitals Trust

1. **Case finding**
   (Identification of the population to be screened, appropriately targeted screening)
2. **Diagnostic Quality Spirometry** (performance and interpretation)
3. **Management**

1. **Case finding**

Several search tools are available to interrogate GP patient data bases to identify sub populations enriched for (undiagnosed) COPD / asthma e.g. RAIDAR and GRASP.

The specific criteria applied can be varied starting with specific and progressing to more sensitive.

Reviewing the already Diagnosed?
It is strongly recommended that any patient who has not had diagnostic quality spirometry be put through the same diagnostic process given the evidence on existing diagnostic inaccuracy.

Diagnostic quality spirometry – quality standards:
Ease of referral for clinicians
Use of an agreed referral proforma
Easily accessible – i.e. close to home for patients
The test is performed by an individual with certified competency (ARTP)
The result is interpreted by an individual with at least ARTP certified competency (see later)
Report used to inform a structured review of the patient and plan further management.

Accredited workforce – ARTP training and assessment

Equipment
- **Spirometer** with flow-volume and volume-time traces + numerical values for: FEV1, FVC predicted values and Z scores.
- **Stadiometer** + **weighing scales**
- **FeNO** equipment
  Use based on BTS recommendations
- **Salbutamol inhalers**
- **Volumatic spacer devices**

Clinic structure
- 8 spirometry appointments per hour – only fill the first 5 slots
- Not all will demonstrate obstruction so not all will need reversibility testing
- The exact number in each clinic will be unknown until the testing is done, though from experience leaving 2-3 free slots at the end tends to work out about right on average
- Interpretation of results is critical
- Management - if greater expertise is utilised, clearer guidance can be offered.

Costs (based on 1,000 patient cohort):
500 undiagnosed – screening
500 previously diagnosed – review

Set-up and running costs for 1 year - £13,735

Impact of treatment on exacerbations and admissions	
Reduction in exacerbation (per patient per year) in newly diagnosed patients at risk of exacerbation – following commencement of triple therapy	0.44
Reduction in hospitalisations (per patient per year) in newly diagnosed patients at risk of exacerbation – following commencement on triple therapy	0.05
Proportion of newly diagnosed patients who also have asthma	10%
Reduction in exacerbations (per patient per year) in newly diagnosed patients who also have asthma	1
Reduction in hospitalisation (per patient per year) in newly diagnosed patients who also have asthma	0.1
Cost savings from reduced exacerbations and admissions (COPD)	
Cost saving from a reduction in exacerbations	£3,250.45
Cost saving from a reduction in hospitalisations	£7,837.20
Total cost saving from reduction in exacerbations and hospitalisations for newly diagnosed patients at risk of exacerbation – following commencement of triple therapy	**£11,087.65**
Cost savings from reduced exacerbations and admissions (asthma)	
Number of newly diagnosed patients who also have asthma	15
Cost saving from a reduction in exacerbations	£2,638.35
Cost saving from a reduction in hospitalisations	£5,598.00
Total cost saving from reduction in exacerbations and hospitalisations for newly diagnosed patients who also have asthma	£8,236.35
Total cost saving from reduction in exacerbations and hospitalisations for all newly diagnosed patients	**£19,324.00**

Cost of new prescriptions – newly diagnosed patients	
Proportion of patients not previously diagnosed found to have COPD	30%
Proportion of patients newly diagnosed with COPD *not* at risk of exacerbations	62%
Proportion of patients newly diagnosed with COPD *at* risk of exacerbations	28%
Proportion of patients newly diagnosed with COPD who also have asthma	10%
% of patients newly diagnosed and *not at risk* of exacerbations on the following therapies:	
LAMA	73%
LABA	19%
LAMA/LABA	8%
% of patients newly diagnosed *at risk* of exacerbations on the following therapies:	
Closed triple therapy	100%
% of patients newly diagnosed with COPD who also have a diagnosis of asthma on following therapies:	
ICS/LABA	100%

Screening cohort not currently diagnosed with COPD	500
Number of patients not previously diagnosed found to have COPD	150
Number of patients *not at risk* of exacerbations	93
Number of patients *at risk* of exacerbations	42
Number of patients newly diagnosed with COPD who also have a diagnosis of asthma	15
Annual cost of prescribing for newly diagnosed patients *not at risk* of exacerbation	£35,062.61
Annual cost of prescribing for newly diagnosed patients *at risk* of exacerbation	£22,284.94
Annual cost of prescribing for newly diagnosed patients who also have a diagnosis of asthma	£5,321.29
Total annual cost of prescribing for newly diagnosed patients	**£62,668.85**

Mis-diagnosed patients	
Mis-diagnosis rate	**40%**
Proportion of current COPD patients on the following therapies:	
LAMA	46%
LABA	12%
LAMA/LABA	5%
ICS/LABA	21%
Open triple therapy	10%
Closed triple therapy	6%

Cost savings from stopping medication	
Screening cohort already diagnosed with COPD	500
Number of patients mis-diagnosed in cohort	200
Annual prescribing cost from stopping medication in mis-diagnosed patients	**£83,507.44**
Overall costs and savings:	
Cost of implementation and running for one year	**£13, 735.47**
Total annual cost of prescribing for newly diagnosed patients	£62,668.85
Total cost savings from reductions in exacerbations and hospitalisations for newly diagnosed patients	£19,324.00
Annual prescribing cost saving from stopping medications in mis-diagnosed patients	**£83,507.44**

Costs of delivering the service for one year	**£13,735.47**
Overall cost savings (reduced prescribing and admissions)	**£40,162.59**

The returns continue to accumulate year on year.

Annex E: Example CCG diagnostic spirometry service

Introduction
This protocol is designed to describe all the procedures for the new Ealing Diagnostic Spirometry Service (EDSS). All spirometry within EDSS will be Quality Assured and will therefore only be carried out by clinicians familiar with its content and trained to ARTP standard. Patients will be seen at a suitable time and day of the week and will be offered an appointment at a venue close to their home; supporting Ealing CCG's strive for Care Closer to Home. Ealing is divided into seven health networks and it is envisaged that patients will be seen at a venue within the network that their registered General Practice is based.

Patients will have a full assessment, complete spirometry and provided with information and advice. Referrers will be provided with a summary of the assessment and the spirometry results. Patients will be signposted to other services where necessary, for example Ealing Pulmonary Rehabilitation Service, Smoking Cessation Services, Breath Easy groups, etc. Patients will be given the opportunity to have a follow-up appointment within the service if the GP diagnoses COPD. At this appointment, inhaler technique, medication and rescue packs will be discussed as necessary. It is envisaged that the service will improve the accuracy of diagnosis, specifically of patients with COPD and will increase the prevalence of patients with a COPD diagnosis and hence improve the management of patients at an earlier stage of the disease.

The following protocol will describe the patient journey through the service from a procedural perspective starting from referral through to discharge. It is based on the most up-to-date evidence and incorporates recommendations from NICE, DoH, BTS and other sources.

Aim
To undertake quality assured diagnostic spirometry for suitable patients within Ealing CCG and provide patients and the referrer with information to enable a more accurate diagnosis and better inform their future management.

Objectives
- To ensure the accuracy of diagnosis and severity assessment in patients with COPD
- To increase the number of people accurately diagnosed at an early stage of the disease
- To increase the proportion of people with COPD who are diagnosed comparing recorded prevalence with predicted prevalence
- To ensure that users of the service have a positive experience of care

Patient Entry into Service
Referral Criteria
Patients can be referred from both secondary and primary care but must be registered with a General Practice in Ealing.
ESSENTIAL CRITERIA:
- Aged over 35
- Has a smoking history of 15 pack years or more AND/OR has been exposed to environmental and/or significant domestic pollutants
- Has had a chest x-ray in the last 3 months to exclude any pathology

PTS MUST THEN HAVE ONE OF THE FOLLOWING:
- Unexplained shortness of Breath / Wheeze
- Unexplained cough of unknown origin
- Frequent chest infections in the last 12 months
- Asthma

Patients will be referred to the service using a service-specific referral form (see Appendix 1). Patients must satisfy the criteria above to be given an appointment.

Processing Referrals and Booking Appointments
The EDSS will have its own dedicated email address. All referrals will be received into this email box which will be checked daily. As soon as a patient is referred in to the service they will be allocated a number which will be sequential starting from 001. This number will be inserted on to all forms used for the patient. The administrator will review all referral forms. If a patient fulfils all of the criteria, they will be contacted by phone and asked when and

where they would like to be seen. This will depend on availability of appointments and where the patient lives. Priority will be given to patients who live within the defined network for the venue and if a patient works they will be given priority for the late evening and Saturday appointments. Patients will be asked about any recent chest infections and/or hospital admissions for respiratory problems. If they have had one of these their appointment will be delayed until 6 weeks have elapsed since this episode. Otherwise they will be offered the next available, convenient appointment.

When a patient is referred and there is doubt about the suitability, the administrator will send the form to one of the service clinicians who will review the form, possibly contact the referrer and make a judgement about whether the patient is suitable to be seen.

If a patient is referred and the form has not been completed satisfactorily, the administrator will send the form back to the referrer requesting the required information.

To make the appointment, the administrator will contact the patient, agree a date and time and then send the patient a letter. This will contain the details of when and where the appointment is with an attached map. It will also provide instructions to the patient about what to do and what not to do before their appointment (see Appendix 2 for a sample letter with instructions). The service will also be asking the referrer to provide a prescription for each patient. This will be for a salbutamol inhaler and a spacer. This will enable 2 things to happen: patients will use their own salbutamol for the purposes of reversibility and it will allow the clinicians to show the patients how to use their inhaler. Lastly, the patient will be sent, with their letter and map, a Generalised Anxiety Disorder (GAD) questionnaire which they will be asked to complete and bring with them to their appointment (see Appendix 3).

Procedures at Appointment

Patient Assessment
At their appointment patients will be assessed for their suitability for spirometry and they will have a full medical and social history taken. This will cover all aspects of being able to perform spirometry safely and will ascertain a clinical picture to enable an accurate diagnosis to be made. Blood pressure, height and weight will be measured. Please see Appendix 4 for a sample of the Assessment Form and Appendix 5 for the Spirometry Checklist.
If a patient has any history suggesting infection may be present, he/she will be asked to be seen at the end of the clinic to reduce the risk of infection to other patients. If a patient has any comorbidity suggestive of a reduced or compromised immune system, they will be seen at the beginning of the clinic.

Undertaking Spirometry
Before each spirometry assessment, ensure that the patient is suitable, that the machine has been calibrated, that infection control procedures have been followed and that the machine has been cleaned according to the manufacturer's instructions. Then follow these instructions:

- Ensure the patient is relaxed and seated in a chair with arms, sitting for at least 5 minutes. Dentures can be left in unless they are loose.
- Record age, blood pressure, height (shoes off, feet together; if the patient has a chest deformity, the arm span from fingertip to fingertip can be used to estimate height) and weight.
- Record race using ethnic correction factors:-

Adjusting Caucasian reference values to other ethnic groups. To apply these, multiply the FEV1 and FVC by the factors below		
Population	**FEV1**	**FVC**
Hong Kong Chinese	1.0	1.0
Japanese American	0.89	-
Polynesian	0.9	0.9
N Indian and Pakistani	0.9	0.9
S Indian, African	0.87	0.87

- Use single use disposable one way filter mouth piece for most patients. If you suspect the presence of any infection consider using an antibacterial filter.
- Give patients clear instructions and demonstrate the procedures.
- Use disposable nose clips during Expiratory Relaxed Vital Capacity test.

- Instruct the patient to take the deepest breath in as possible and to place their teeth and lips around the mouthpiece
- Encourage the patient to keep blowing out for as long as possible.
- Carry out three relaxed Vital Capacity (VC) measurements by asking the patient to take a full inspiration and then to perform a full expiration in a steady manoeuvre.
    - 2 tests should be within 5% (Note if patient leans forward place hand on shoulder to discourage as this will compromise the result).
- Carry out three Forced Vital Capacity (FVC) measurements without nose clips by asking the patient to take full inspiration and to exhale fully using a forced manoeuvre
    - 2 blows should be within 5% of each other and the FEV_1 and FVC should be within 100mls.
- Allow the patient to rest in between blows. A maximum of 8 attempts is believed to be acceptable in any one session. If the patient is unable to perform the test, arrange a further appointment
- All diagnostic assessments of lung function will be made on the basis of a post-bronchodilator reading. Patients will therefore be given 400mcg of salbutamol via a spacer. They will use the inhaler and spacer they have brought with them. A PGD will provide guidance for the use of salbutamol at this higher dose (see Appendix 6). They will then need to wait 15 minutes for this to take effect. They will be asked to repeat another 3 FVC measurements.
- Print out numerical and graphical spirometry results, including pre and post bronchodilator results.
- Document spirometry results (Post-bronchodilator FEV1, VC or FVC and FEV1/VC or FEV1/FVC ratio) and record them on the clinic letter to be sent to the referrer.
- Ensure the file is saved on the hard drive and also emailed to the administrator. This should then be later saved on the server at CLHC.

Procedures with the Patient after Spirometry testing

Interpretation of Results

All results will be reviewed immediately after the test and must be accurate and reproducible:

- 3 technically acceptable VCs – the best two tests within 5% or 100mls (whichever is greatest) of each other.
- A minimum of 3 forced manoeuvres with the best two readings being within 5% or 100mls of each other
- Recording continued long enough for a plateau to be reached on a volume/time curve for 2 seconds at least.
- A rapid rise at the start of the flow/ volume trace until a peak is reached. The trace should rise almost vertically.
- Maximum effort maintained throughout the procedure with no sudden cessation of flow.
- Trace is smooth and free from any irregularities

Advice to Patients

Clinicians will use the spirometry results and the patients' history and symptoms and will discuss these with the patient. The patient will be asked to make a follow-up appointment with their GP/Clinician to discuss the results further. If the patient is subsequently diagnosed with COPD, the GP may refer the patient back to the service for a follow-up appointment. This will involve their inhaler technique being checked, medication use discussed and signposting to other services as necessary.

All patients who currently smoke will be offered the opportunity to be referred to the smoking cessation service and advice will be given about what treatments and counselling are available in Ealing.

Patient Satisfaction Survey

All patients will be asked to complete a short questionnaire relating to their experience of the service. Please see Appendix 7 for a sample questionnaire. The data from these questionnaires will be collated and form part of the service evaluation.

Administrative Procedures after seeing the Patient

The Clinicians Responsibilities

Each clinician will be responsible for uploading the results from the assessment and the spirometry onto a template clinic letter (see Appendix 8). This will include details about both the assessment and the spirometry and will provide the referrer with a summary of the interpreted results and the implications of this.

Once completed, the clinician will send the clinic letter with relevant attachments (spirometry report) via email to the administrator. The email will be identified in the same format as per registration to allow for a logical paper trail to be identified for audit purposes.

The Administrators Responsibilities
Once the administrator receives the clinic letter he/she will send this to the original referrer via email. Also attached to the email will be a questionnaire that we hope the referrer will complete and send back to us asking about their level of satisfaction with the service (see Appendix 9).
The administrator will file the clinic letter with the original referral form in the patients' file on the server. The patient journey within the service is now complete.

Quality Assurance
Quality Control
Only appropriately trained personnel can undertake the spirometry ensuring that it is quality-assured each time. This means that they must be ARTP registered and must be undertaking the required number of spirometry assessments each month to maintain the required level of skills.

All spirometers will be calibrated at the start of each session using a 3 litre calibration syringe (or after 10 patients) and the result will be documented in the machines log book. Each machine may also be checked using a person with no known chest disease and where their known average range is documented – the Physiological Control. This will only be needed if there is a problem with the syringe calibration and the result will also be recorded in the log book for each machine. Please see Appendix 10 for full instructions on how to register and record the physiological control.

Errors in Spirometry Testing
To ensure the diagnostic spirometry assessment is accurate and represents the patients' best effort with his/her optimum lung function, errors need to be identified and if present as seen on the graphs after the patient has left, spirometry will need to be repeated. Such errors include:

- Poor seal around mouthpiece
- Hesitation or false start
- Early termination on exhalation
- Poor intake of breath
- Poor forced expiratory effort
- Cough during procedure
- Incorrect data into the spirometer prior to testing

Equipment
Types of equipment
Pneumotachographs will be used in all spirometry assessments. There are currently 3 that have been purchased specifically for the service. Each spirometer will have its own record of cleaning, daily calibration with the 3 litre syringe and weekly quality control. Each machine will be serviced annually.
Peak Flow meters will also be used. These will be maintained and cleaned as per manufacturer's instructions.
Automatic sphygmomanometers will be used to measure blood pressure and will be serviced and maintained as per manufacturer's instructions.
Measurements of height and weight will be done using locally available equipment in each venue.
Individual clinicians will have laptop computers on to which will have the spirometry software uploaded. Each clinician is responsible for ensuring the security and safety of the laptops at all times. Laptops will be secured according to NHS IG guidelines and fully encrypted.

Infection Prevention and Control
Recorded cases of infection transmission from spirometry equipment, between patients, and between patients and staff, are rare. Cross contamination through mucosal contact with spirometry equipment and aerosolisation of infective particles during forced expiratory manoeuvres are the main potential sources of infection. Measures to reduce the risk to both staff and patients are summarised below. Cross infection is more likely when inspiratory manoeuvres are undertaken. This is not routinely undertaken in primary care settings, but it can be difficult to prevent accidental inhalation through the equipment. Therefore disposable, one-way valved mouthpieces should be used. If inspiratory manoeuvres are undertaken, disposable antibacterial and viral filters must be used.

Infection Control Measures
The Following Table shows the potential sources of infection, the transmission route and the risk reduction measures to be taken:

Infection Transmission	**Likely sources of contamination**	**Risk Reduction measures**

Direct contact – URTI, enteric infections, blood borne infection (from bleeding gums or mouth ulcers/sores)	• Nose clips
	• Tubing, flow heads
		• Do not test patients with known infection, if possible
		  ○ If tests are necessary, test potentially infectious patients at the end of a session and dismantle and sterilise equipment after use
		• Test vulnerable patients (e.g. immunocompromised) at the start of a session on newly sterilised equipment
		  ○ For infection control in these patients, use disposable nose clips and valved mouthpieces with an antibacterial filter
		• Wash hands before and after handling equipment and in between patients
		• Use disposable plastic gloves for handling used mouth pieces and potentially contaminated surfaces
		• Wash surfaces in contact with mucous membranes in hot soapy water prior to decontamination and disinfection.

Indirect contact (aerosol droplet) – TB, viral infections, opportunistic infections, nosocomial pneumonia	• Mouthpieces • Tubing	

Each spirometer will be cleaned according to manufacturer's instructions at the end of each spirometry clinic. The date and time of cleaning will be documented on a sheet attached to the spirometer.

Maintenance
All equipment will be serviced annually and will be documented on a service documentation sheet attached to each piece of equipment.

Governance
The service will have a consultant clinical lead who will act as the expert from whom the clinicians seek advice. The consultant will audit a given number of patients per month. This may be done via email, telephone or face to face.

The service will also have a risk register that identifies the areas of clinical risk, staff safety and information governance risks and will be updated regularly to ensure the service does not have any significant risks during its operation. See Appendix 12 for a copy of the risk register.