

London Respiratory Clinical Network

Description of a population level respiratory diagnostic pathway for COPD, asthma and breathlessness with consideration of the endemic phase of COVID-19.

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Version 1.4



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1. Introduction

The NHS Long Term Plan¹ 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.

This clinical consensus document provides the basis of a service description for a quality assured Respiratory Diagnostic Service to meet the needs of a population of approximately 50,000 patients, for example, within a Primary Care Network (PCN) or other framework. It builds upon the Primary Care Respiratory Society document², Respiratory Diagnostic Service Specification (RDSS), the South East London Respiratory Network Spirometry Service Specification³ and the National NHSE/I Spirometry Commissioning Guidance 2020⁴.

Within the context of the COVID-19 pandemic, there is renewed emphasis on optimising the management of patients with COPD and asthma and addressing local health inequalities that contribute to poorer health outcomes, which have been exacerbated by COVID-19.

The British Lung Foundation highlighted in its report on health inequalities⁵ and lung disease that COPD is more common in the most deprived communities due to increased smoking and poor housing. Smoking, which is known to contribute to lung disease, is also more common in people with mental health problems and black Caribbean and Bangladeshi men.

Optimal treatment requires early and accurate diagnosis, and there is much evidence that many patients with airways disease carry an incorrect diagnosis and many patients with COPD in the community are yet to be diagnosed. In addition, patients recovering from COVID-19 may have ongoing respiratory symptoms which require investigation and management, and therefore consistent provision and access to safe quality assured respiratory diagnostics as part of an integrated clinical pathway is urgently required.

When establishing diagnostic services, we encourage collaborative work between commissioners and providers to ensure that access is promoted to reduce health inequities in diagnosis and in turn outcomes.

1.1 National investment

The NHS Long Term Plan commits to improving the quality and reducing variation of spirometry testing. The Long Term Plan Implementation Framework⁶ 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.



1.2 Diagnostic Hub and Spokes

Nationally, there is a plan to develop Diagnostic Hubs based around a population of approximately 350,000⁷. The purpose of these Hubs is to provide diagnostics such as plain film x-ray, CT/MRI scanning, endoscopy services, exercise stress tests, echocardiography and detailed lung function testing in a community setting. The aim is for these Hubs to relieve secondary care of elective diagnostic activity to focus on the emergency pathway and to support equity of access, improved patient experience and better patient outcomes. The plan for lung function testing is for more complex cases that need detailed investigations over and above what can be provided in primary care to be provided in Diagnostic Hubs. It is envisaged that Diagnostic Hubs will integrate with diagnostic services provided by/in primary care. To avoid confusion, the service description proposed in this document is for a Respiratory Diagnostic Spoke Service (RDSS). Thus, several RDSS's will feed into a Diagnostic Hub for more detailed investigations and will focus particularly on the investigation of breathlessness, timely and accurate diagnosis of COPD and asthma at a population level.

The time scale for the commissioning and establishment of Diagnostic Hubs is not clear, but that should not deter the development of RDSS in primary care. More complex cases can be referred to Secondary or Community Respiratory Integrated Care Services that are already established.

1.3 Integration with current services

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In practice, the process through which local systems can develop high quality, equitable and accessible respiratory investigations will vary depending on which services and expertise are already available locally, and the level of integration that exists between them. It is important that local expertise informs both the design and delivery of respiratory diagnostic pathways at a population level. This is particularly important where an Integrated Respiratory Service already exists. A Respiratory Diagnostic Spoke Service based around a PCN population provides an equitable service that makes the best use of resources and workforce available.

The ultimate aim of this service description is to provide partners working in STPs/ICSs, (including accountable officers, acute providers of lung function and primary care leadership) with a clear guide as to best practice, based on clinical consensus, and to support development of pathways to safely investigate breathlessness and diagnose respiratory conditions at population level. Through effective implementation of a Respiratory Diagnostic Spoke Service, systems can resume addressing the respiratory ambitions set out within the NHS Long Term Plan and respond to the needs of patients with ongoing symptoms post COVID-19.

1.4 Challenges to diagnostic services during COVID-19 Pandemic

The London response to COVID-19 has accelerated the Respiratory Integration agenda through the rapid development of primary care hot hubs and, in some areas, secondary care advice lines and triage pathways to meet the needs of suspected and confirmed COVID-19 diagnoses. The need for new models of respiratory diagnostic provision both within and



outside of hospital settings is now urgent. There is currently unprecedented demand for respiratory diagnostic services as a result of both the respiratory follow up care required for those recovering from COVID-19, and the need to address existing diagnostic waiting lists for patients who may be at increased risk. The pandemic has highlighted the impact of inequalities on respiratory health and outcomes, as well as reinforced the need to standardise care with particular focus on hard to reach groups.

Spirometry, peak flow, exhaled FeNO and exhaled CO are classified by the Association of Respiratory Technology and Physiology (ARTP) as potentially Aerosol Generating Procedures (AGP). Moreover, healthcare professionals undertaking these procedures require accredited training and oversight. For both these reasons, it is recommended that these diagnostic tests are no longer performed at individual general practice level. Instead integrated care systems are required to set up services enabling safe quality assured diagnostic testing by staff with appropriate skills, in settings with appropriate infection control processes in place, enabled by pathways with appropriate population level reach.

The advent of rapid testing may change how these diagnostic tests can be conducted. Respiratory diagnostic pathways may need further modification as the COVID-19 pandemic evolves.



2. The Case for Change

The common long-term conditions of asthma and chronic obstructive pulmonary disease (COPD) are the principle focus for the design of this service description. However, the service will also support better diagnosis of other causes of breathlessness as well as uncommon respiratory disease and other non-respiratory conditions.

2.1 Why earlier and accurate diagnosis is important for improving outcomes

COPD

 Currently around a third of people admitted to hospital with exacerbations of COPD have not been previously diagnosed⁸. In the UK 2.1M people are living with undiagnosed, and therefore untreated, COPD – an estimated 70% of the total number of people who have the disease⁹. All London CCGs are in the lowest tertile for detected to estimated prevalence in the country.

Prevalence and detection



Detection of COPD is low compared to the national and lowest 5 similar CCGs averages. Over 37,000 cases could be detected if all London CCGs perform to the average of their lowest 5 similar CCGs. Chronic Obstructive Pulmonary Disease (COPD) (%) Reported to estimated prevalence: Disease Register and Population -2015/16



Patients with COPD are often diagnosed relatively late (in the moderate or severe stages of the disease). There is strong evidence that many people with COPD consult their GP repeatedly with respiratory symptoms before COPD is diagnosed. Jones et al 2014¹⁰ investigated almost 39,000 patients on the GP research database who were diagnosed with COPD. They found that 85% of patients had opportunities for diagnosis missed in up to 20 years before diagnosis, although most were in the preceding year or two. People with COPD have significant healthcare costs in the two years before diagnosis¹¹.



- There is evidence from subgroup analysis in both the TORCH¹² and UPLIFT¹³ trials that the rate of decline in lung function is faster in the earlier stages of COPD. The potential for altering the course of the disease and improving outcomes may therefore be greater in the earlier stages as high value treatments can be convened e.g. treating tobacco dependence. Missing this opportunity means that patients with the condition are being denied appropriate lifestyle and therapeutic interventions which have the potential to improve health status and survival¹⁴.
- Co-morbidities such as heart disease, cancer, osteoporosis and depression are common in all stages of COPD and are often diagnosed late¹⁵. Patients with COPD have also been shown to be at a much higher risk of premature death from heart disease and stroke¹⁶. An integrated model which assesses for known associated comorbidities at COPD diagnosis has been recommended to mitigate these risks¹⁴.

Asthma

- In the UK, 5.4M people are currently receiving treatment for asthma, 1.1M children (1 in 11) and 4.3M adults (1 in 12)¹⁷.
- There is no single diagnostic test for asthma. Diagnosis is based on clinical assessment supported by objective testing. Asthma can be difficult to diagnose as there may be periods of absent symptoms and normal lung function parameters, and thus the diagnosis may only be apparent over a period of observation combined with objective testing.
- Incorrect diagnosis in primary care is common with over diagnosis estimated to be 19% in a UK population where under diagnosis has been reported at between 19 & 73% in research from around the world¹⁸. However, despite urbanisation and poor quality, London has the lowest reported of asthma in the country.





- Inhaled medications account for up to 90% of the UK spend on asthma¹⁹.
- Asthma is the most common long-term medical condition of childhood.
- There were 77,124 emergency hospital admissions for asthma in the UK in 2016-17 (latest figures available). There were 1,484 asthma deaths¹⁹.
- There are 25-30 asthma deaths in childhood in the UK each year and up to 8 of these are in London.
- An estimated 75% of hospital admissions for asthma and as many as 90% of the deaths from asthma are preventable.
- There is significant morbidity in patients with asthma, many accepting their symptoms and restriction of activity as their normal state. This is exacerbated by poor understanding of the disease with poor levels of adherence with preventative medication and poor inhaler technique.

Recovery from COVID-19

- A proportion of patients continue to have symptoms of exertional breathlessness many months after contracting COVID-19 pneumonia. This can be for a variety of reasons including persistent pneumonitis and fibrosis, pulmonary embolism and dysfunctional breathing.
- Detection of early fibrosis and pulmonary embolism is important as these are treatable conditions with otherwise serious adverse outcomes.
- Cough is another persistent and potentially treatable symptom that may be post viral but may also be related to other causes such as asthma, reflux disease or sinus disease.
- COVID-19 may unmask previously undiagnosed respiratory disease such as asthma or COPD which will require formal assessment and diagnosis as part of a post-COVID-19 pathway.
- Whatever the cause, accurate diagnosis will enable patients to be assigned to the correct treatment pathway thereby improving outcomes and reducing health inequalities.



3. Diagnosing Asthma and COPD during COVID-19 pandemic whilst lung function testing is not available

Respiratory Diagnostic Spoke Services will take time to establish in most STPs/ICSs. However, patients with breathlessness not related to COVID-19 still require a diagnosis. National guidelines currently recommend quality assured spirometry to diagnose both asthma and COPD. At the time of writing, the ARTP consider that forced manoeuvres that may make patients cough during the procedure are potential AGPs and should not be performed routinely, and certainly not without the full PPE protection²⁰. At the current time they recommend that respiratory function tests should only be undertaken when this will definitively inform or change a patient's management. However, they have provided practical information to assist with risk assessing and scaling up services.

This will make the routine diagnosis of asthma and COPD more challenging in primary and community care. Even if spirometry is restricted to a PCN based RDSS, the capacity to test patients will be very restricted, as is currently the case with lung function testing in secondary care. Thus, a pragmatic approach is needed to diagnose asthma and COPD in primary and community care settings, minimising the use of spirometry. Peak Expiratory Flow (PEF) is a common procedure in Primary Care and can be a useful tool to determine airflow obstruction and potentially differentiate between asthma and COPD.

Even if spirometry were available, results may vary significantly and therefore this is rarely diagnostic of asthma unless the patient is symptomatic at the time of testing and exhibits good reversibility. British Thoracic Society / Scottish Intercollegiate Guidelines Network (BTS/SIGN) guideline for the management of asthma (2019)²¹ gives good guidance on how to assess and diagnose asthma based on probability and response to empirical treatment with inhaled steroids. Diagnosis of asthma should therefore be based on good clinical history supported by objective measurements of variability and peak expiratory flow offers a means to accomplish this.

From BTS/SIGN:

Undertake a structured clinical assessment to assess the initial probability of asthma. This should be based on:

- a history of recurrent episodes (attacks) of symptoms, ideally corroborated by variable peak flow when symptomatic and asymptomatic
- symptoms of wheeze, cough, breathlessness and chest tightness that vary over time
- recorded observation of wheeze heard by a healthcare professional
- personal/family history of other atopic conditions (in particular, atopic eczema/dermatitis, allergic rhinitis)
- no symptoms/signs to suggest alternative diagnoses.

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In patients with a high probability of asthma:

- record the patient as likely to have asthma and commence a carefully monitored initiation of treatment (typically six weeks of inhaled corticosteroids)
- assess the patient's status with a validated symptom questionnaire, ideally corroborated by domiciliary serial peak flows to capture times with/without symptoms
- with a good symptomatic and objective response to treatment, confirm the diagnosis of asthma and record the basis on which the diagnosis was made
- if the response is poor or equivocal, check inhaler technique and adherence, arrange further tests and consider alternative diagnoses.

In patients with an intermediate probability of asthma based on clinical assessment:

- patients who have some features of asthma but do not have peak flow variability and are not responding to treatment usually need further assessment including spirometry with reversibility in a diagnostic spoke if available. However, more prolonged domestic peak flow monitoring may be helpful
- if any doubt, refer for whatever specialist advice is available locally, e.g. advice and guidance platforms or the local community respiratory service which should have integrated Respiratory Consultant support

Use of peak expiratory flow rate (PEFR) to investigate possible diagnosis of COPD

The diagnosis of chronic obstructive pulmonary disease (COPD) relies heavily on history of exposure to tobacco smoking and symptoms of breathlessness, cough and sputum production. COPD can only be formally diagnosed if fixed airflow obstruction without reversibility is demonstrated, unless diagnosed as emphysema on a computerised tomographic (CT) scan. However, in the absence of spirometry or rapid testing for COVID-19, peak flow measurement can be used to suggest obstruction:

- PEFR <75% predicted suggests a degree of airflow obstruction^{22, 23}.
- When trying to assess whether this is COPD, a serial measurement over 2 weeks that does not vary but also remains low despite use of salbutamol for symptom relief would suggest fixed airflow obstruction and is suspicious for COPD in the context of supporting clinical history
- Patients who do not have variation in peak flow should have an empirical trial of dual bronchodilator therapy (or ICS/LABA if history of exacerbations and full blood count eosinophils>0.3%)
- In current smokers, offer treatment for tobacco dependency
- Any tentative diagnosis of COPD should be confirmed with spirometry when readily available and a clear record should be made in the patients notes that spirometric confirmation of obstruction without reversibility is required at a later date
- If any doubt, refer for whatever specialist advice is available locally, e.g. advice and guidance platforms or the local community respiratory service which should have integrated Respiratory Consultant support

For patients in whom COPD is suspected and a peak expiratory flow (PEF) test is considered necessary this can be carried out using the patient's own PEF meter and disposable mouthpiece in a room with an open window or outside the building.



If airflow obstruction is not evident on PEFR, symptoms of breathlessness/ cough / sputum production requires further investigation. If a necessary investigation such as spirometry has been deferred this should be clearly flagged in the patient record and the patient informed that this test will be carried out at a later date.

Peak expiratory flow monitoring

Peak expiratory flow should be recorded as the best of three forced expiratory blows from total lung capacity with a maximum pause of two seconds before blowing. The patient can be standing or sitting. Further blows should be done if the largest two PEF are not within 40 L/min.

Peak expiratory flow is best used to provide an estimate of variability of airflow from multiple measurements made over at least two weeks²². Increased variability may be evident from twice-daily readings. More frequent readings will result in a better estimate, but the improved precision is likely to be achieved at the expense of reduced patient compliance. Use of electronic meters and diaries with time and date stamps can overcome problems of compliance and accuracy when recording peak flows in paper diaries.

Peak expiratory flow variability is usually calculated as the difference between the highest and lowest PEF expressed as a percentage of the average PEF, although one study showed that three or more days a week with significant variability was more sensitive and specific than calculating mean differences.

The upper limit of the normal range for variability is around 20% using four or more PEF readings per day but may be lower using twice-daily readings.

NB: Peak flow manoeuvres are also potentially AGP and should not be performed during a face to face consultation and should not be demonstrated to the patient in the same room (training videos for peak flow are available on the internet). The risk may be mitigated by performing peak flow manoeuvres in an outdoor space or a separate room where the patient can be viewed remotely, and room left vacant for the appropriate time period to ventilate⁸ although appropriate infection control measures should be determined locally. Alternating rooms may make this more efficient.



4. Purpose of the Respiratory Diagnostic Spoke Service

The aim of the service is to provide timely, quality assured diagnosis for patients with breathlessness and/or cough and/or other respiratory symptoms by improving access to quality assured diagnostic tests at a population level and usually within a community setting.

4.1 Service Objectives

The high-level objectives of the service are:

- to improve the accuracy of diagnosis provided to people with breathlessness and/or cough and/or other respiratory symptoms, leading to improved accuracy of long term condition registers and higher value patient-centred care
- to improve outcomes of patients with COPD and asthma through earlier access to high value treatments
- to reduce health inequalities
- to reduce long term spend on the respiratory pathway through improved diagnosis and earlier management of patients
- to ensure that users of the service have a positive experience of care
- to be an educational resource to primary and community health care professionals through provision of training in diagnosis and management of breathlessness and airways disease delivered by specialist respiratory team and integrated respiratory consultants supporting the RDSS

The high-level expected outcomes of the service are:

- Improvement in the ratio of actual to expected prevalence of COPD following an initial phase where registers may reduce or plateau due to correction of previous diagnostic errors
- Reduction in the number of patients admitted to hospital with COPD without a prior diagnosis or with an incorrect diagnosis
- Reduction in hospital admissions through earlier identification at all stages of COPD allowing optimisation of respiratory disease in primary care or earlier referral to planned specialist care
- Increasing accuracy of COPD and asthma diagnoses
- Allowing earlier appropriate and high value interventions for patients with respiratory disease, yielding more cost-effective prescribing, less waste of medicines and reduced harm
- Increased referrals for and access to treatments for tobacco dependence
- Increased referrals to pulmonary rehabilitation
- Increased uptake of influenza vaccination





4.2 Local Context (Optional)

In order to outline the local context data should be used and compared with similar areas, other areas in the region or the national picture to identify the local drivers. When available, the NHSE High Impact Toolkit will assist with this.

Investigate:

- Percentage of patients on GP lists with diagnosis of COPD (CCG level data available from Respiratory Atlas of Variation)
- Local rates of COPD diagnosis compared with predicted prevalence rates (RightCare data).
- Local emergency COPD admission rates (CCG level data available from Respiratory Atlas of Variation)
- COPD admission length of stay data (CCG level data available from Respiratory Atlas of Variation)
- The percentage of patients with diagnosed COPD confirmed by post bronchodilator spirometry (Respiratory Atlas of Variation data)
- The percentage of patients diagnosed with COPD with an FEV1/FVC ratio >0.7
- The percentage of patients diagnosed with COPD with no spirometry on record due to exception coding
- The number of patients who have inhalers but have no recorded diagnosis (GP record system data)
- Percentage of patients on GP lists with diagnosis of asthma (CCG level data available from Respiratory Atlas of Variation)
- Local emergency asthma admission rates (CCG level data available from Respiratory Atlas of Variation)
- Variation in percentage of asthma on GP registers for those aged 8 and over in whom measures of variability or reversibility are recorded (CCG level data available from Respiratory Atlas of Variation)



5. Model of Service

The expectation is that the provider will establish a population level locality based Respiratory Diagnostic Spoke Service for patients with respiratory symptoms such as breathlessness or cough, or suspected COPD and asthma, or who have ongoing symptoms post COVID-19 pneumonia. This document is based around a population of approximately 50,000 but may be scaled up or down as required. This should contribute to a seamless patient pathway, where diagnosis of COPD and asthma is integrated with on-going management in primary care.

5.1 Essential elements of RDS Service

Note this is the minimum service expected. This should be regarded as a starting point because over time it is expected that services will add all additional steps until they can provide the full RDS service.

Expectations of Respiratory Diagnostic Spoke Service : Quality assured diagnostic assessment and testing (including pre and post bronchodilator spirometry, FeNO, exhaled CO monitoring, pulse oximetry (+/- exercise desaturation testing), MRC dyspnoea score and record of smoking status) is performed by ARTP (or equivalent) accredited staff in both procedure and interpretation. Staff must also be level 1 smoking cessation trained and understand the principles of pulmonary rehabilitation. Patients referred with a clinical suspicion of asthma with normal spirometry may be asked at this appointment to record a peak flow diary and bring it back to the GP. Results must be interpreted and reported in a structured protocolised format agreed with the local integrated / expert team which is in line with local referral pathways and guidelines. Results must be sent electronically to the referring practice. A program of education and support to primary care to support effective use of the pathway should be part of the remit of the service. The service should also work with system leaders to actively support a program of COPD case finding and diagnostic review/virtual clinics in primary care where these exist, to support local implementation of the respiratory components of the NHS Long Term Plan.

Role of Primary Care Team: The GP should receive a report of the results, analysis, suggested diagnosis and actions (see Appendix 1 for an example). Any follow-up appointments required would be provided by the primary care team. This would include communicating the diagnosis to the patient and starting them on a treatment pathway in line with locally agreed management guidelines. Education about their condition should be provided to the patients (possibly by group consultation) by primary care staff. Signposting should be agreed and in place for onward referrals to smoking cessation and PR. Ideally, a Read/SNOMED code should be established to indicate that a quality assured diagnosis has been made/confirmed that will distinguish from those who are already on primary care registers who may not have had a quality assured confirmed diagnosis.

Role of secondary care or Respiratory Diagnostic Hubs: A proportion of patients will require further testing (in secondary care or Respiratory Diagnostic Hubs) before they can be given a diagnosis and started on a treatment pathway. There must be links to a Respiratory



Consultant or Specialist in secondary care for advice and guidance when necessary. Pathways should be established for referral into secondary care or hubs and the protocolised report should signpost clinicians to locally agreed clinical guidance, detail who will require this and how they should be referred.

Ongoing care: Using this service model, the majority of patients would be managed in primary care post diagnostic testing. It is likely that only patients with diagnostic uncertainty, concomitant asthma and COPD, very severe COPD, poorly controlled asthma, possible emphysema with preserved spirometry, resting hypoxia or complex multi-morbidity would be managed by secondary care.

RDSS Staffing: This service model would require a minimum of 2 HCP's for one day a week each. They should be ARTP accredited (or equivalent) for both diagnostic spirometry testing and interpretation and trained to offer 'very brief advice' and signpost to specialist smoking cessation services. There should be provision of administrative support services.

Clinical oversight, support and audit should be commissioned from a respiratory Consultant, ideally with support from an expert respiratory specialist clinician who has access to the consultant through a regular MDT. This respiratory specialist clinician should have significant experience of decision making in this area, e.g. GP, a senior specialist nurse, physiotherapist, pharmacist or physiologist. The extent and organisation of the clinical supervision and governance of the service would need to be agreed but should include regular checks of testing and reporting accuracy and a minimum of 20 reports randomly selected every 6 months.

This service should provide improved accuracy of diagnosis and earlier implementation of appropriate treatment pathways. This level of service may lead to referrals into secondary care and Diagnostic Hubs for further assessment; these will have the advantage of appropriate assessment before such referral.

5.2 Additional steps towards full Quality Assured RDSS

Face-to-face or digital specialist respiratory clinician assessment following or incorporating quality assured diagnosis to enable:

- Discussion of new diagnosis and delivery of disease specific education (leading towards group consultations)
- Follow-up appointments for agreed patient groups e.g. patients who may have asthma attending for peak flow diary review or who have other tests arranged
- Level 2 smoking cessation treatment and advice, with prescription of pharmacotherapy if possible, or onward referral to specialist smoking cessation service
- Referral to pulmonary rehabilitation
- Assessment of inhaler technique and patient centred education and support around inhaled therapy
- Supported self-management and assessment of adherence



Independent prescribers would enable:

• Prescription of expert recommended treatment including tobacco dependence treatment

Allocated Consultant RDS MDT time would enable:

- Optimal clinical governance
- Optimal staff training and ongoing staff development
- Consultant review of difficult diagnoses or cases with multiple related comorbidities (avoiding need for referral to hub or secondary care)

5.3 Level of service overview

	Starting	Full RDSS
	point RDSS	
Integrated Respiratory Consultant support of service	Essential	Essential
Specialist clinician oversight of patient results	Essential	Essential
Specialist clinician oversight of results interpretation	Essential	Essential
Integrated Respiratory Consultant oversight of service audit	Essential	Essential
Specialist clinician oversight of service audit	Essential	Essential
Integrated Respiratory Consultant MDT time	Essential	Essential
Specialist clinician patient facing time	Desirable	Essential
ARTP accredited technical staff	Essential	Essential

Table 1. Consultant and Specialist input

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5.4 Clinical Service Supervision

The structure of the supervision will depend on the level of service to be provided, the expert clinicians involved and the nature of their links e.g. physiology department, pulmonary rehabilitation service or integrated respiratory team.

Diagnostic testing oversight

The accuracy of testing procedures must be reviewed regularly. This will involve both checking that cleaning and calibration procedures have been followed and that tests are reaching appropriate standards e.g. percentage of variance. Cleaning and calibration procedures should be noted in a log book/ spreadsheet to enable review. The frequency of checks and the personnel involved in this procedure should be documented. This should normally be performed by the tester's line manager or service manager.

Checking testing standards will require clinical cases to be reviewed by the clinical service lead. The number of test results reviewed and the time period for review should be documented. The cases should be pulled randomly from the caseload over that time period.

Interpretation of test results oversight

How results should be presented and interpreted will require agreed protocols to be developed with specialist respiratory consultant and local GP lead. Where results are interpreted, the interpretation should also be reviewed periodically. This supervision may vary over time as the interpreter becomes more skilled e.g. initially all cases may be discussed with the Integrated Respiratory Consultant when a staff member is new in post and as experience and accuracy increases this may become a regular MDT discussion about difficult to interpret cases. Again, the frequency of these reviews and the minimum number of cases to be reviewed in the specified time period should be documented (recommended minimum 20 cases reviewed every 6 months).

Clinical pathway management

The recommended treatment post interpretation of results should also be reviewed regularly. This may be done as part of the MDT difficult case review above or separately but may follow a similar format.

5.5 Pathways

The patient pathway should be agreed before initiation. The order of diagnostic testing procedures is vital to ensure results are not affected by previous tests.







Figure 2. Additional pathway for optimal RDS services



5.6 Essential considerations

Case finding

Practice lists may be screened to target patients who would benefit most from the service. This may include:

- Patients with a diagnosis of COPD but FEV1/FVC > 0.7
- Patients with a diagnosis of COPD but no post bronchodilator spirometry recorded
- Patients who are on inhalers with no COPD / asthma diagnosis
- Patients with a code for breathlessness but no diagnosis recorded
- Patients with poorly controlled disease/ frequent rescue pack use with lack of quality assured diagnosis
- Smokers > age 40 with respiratory symptoms
- Groups with highest needs e.g. substance misuse or mental ill health
- Difficult to reach groups like non English speakers should also be considered
- Patients living in areas with greatest deprivation may be targeted first

Pathway

As part of the referral pathway, testing required before assessment should be specified e.g. BNP, CXR, FBC and ECHO etc. Also, GPs should indicate on the referral that administration of bronchodilator medication may safely be administered by the service team and include an instruction to do so.

Triage

All services will require triage of referrals. It is important to plan who will take on this task and to ensure they have the necessary access to provide this as well as designated time for this task.

Staff

Where possible, the RDSS should be commissioned and delivered as part of an integrated population level respiratory pathway. It should have operational and clinical governance from specialist COPD & asthma healthcare professionals including physiology staff from the local lung function department, the local Integrated Respiratory Team if this exists, local Pulmonary Rehabilitation service and local respiratory virtual clinic programme leads. This will ensure the staff are experienced in this area and improve integration of services.

Training

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The service must be delivered with staff who have appropriate training, experience and expertise in respiratory care. Completion of a respiratory assessment module would likely be beneficial. Staff providing testing should all be trained to ARTP accreditation standards, to provide both quality assured spirometry and interpretation of the results of spirometry tests. Staff should be trained in level 1 tobacco dependence support and be able to signpost or refer to local specialist smoking cessation services where they exist. They should be able to assess MRC dyspnoea score, CAT and ACT as required, understand and be able to explain



the principles of pulmonary rehabilitation and signpost referring GPs to refer patients to their local PR service where appropriate.

Access & Data

Access to primary care clinical notes systems is desirable to staff performing diagnostic spirometry and essential for higher levels of service to enable a full history to be obtained and information regarding medications and adherence.

Interoperability is required between primary care and secondary care computer systems to enable oversight of service data.

Children and young people

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. 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.

If it is not possible to provide this, a pathway for paediatric diagnostic services should also be considered by commissioners, either from an adjoining PCN who have paediatric trained staff, or referral to a specialized paediatric service.

5.7 Safe delivery of respiratory function tests (RFTs) during COVID-19 endemic phase

The ARTP have produced a document that provides essential advice and guidance for recommencing physiological testing during the endemic phase of COVID-19. This document presents a risk mitigation approach to reinstating and maintaining services using a 3P's (patient, procedure, plant) methodology. This approach will allow local flexibility in the delivery of respiratory services without compromising the safety of patients and healthcare staff. Pre-screening of patients should always be undertaken to reduce risk and it is recommended that RFTs should only be undertaken when it will definitively inform or change a patient's management.



It acknowledges that service delivery must be responsive to local and national lockdowns due to spikes in COVID-19 prevalence and provides a risk stratified approach to infection control for respiratory function testing that can be stepped up or down.

Key considerations:

1) The ARTP guidelines are the cornerstone of mitigating risk and reducing cross infection between staff and patients undergoing RFTs. This includes the need for rigorous enforcement of infection control and cleaning policies and the use of specialist viral and bacterial filters during exhalatory measurements. These steps continue to be important to reduce infection risk from not only potential COVID-19 infection but also from other airborne pathogens (e.g. Influenza).

2) The heightened risk associated with potential exposure to COVID-19 mandates increased scrutiny over infection control issues for RFTs and it is vital that infection prevention and control (IPC) teams are empowered to oversee local procedures and ensure best practice is followed.

3) At the current time it is recommended that RFTs should only be undertaken when this will definitively inform or change a patient's management (i.e. they are 'need to know' and not 'nice to know'). This reduces any unnecessary risk exposure for patients and acknowledges and is cognisant of the current very limited capacity for testing and challenges currently faced by physiology services in the UK.

4) Pre-screening considerations should always be undertaken to reduce risk. These will vary based on local policies but should align with national guidance and include the use of preattendance questionnaires (i.e. to rule out patients arriving for testing with COVID-19 symptoms) ± temperature checking. The approach should be in-line with local infection control procedures with the addition of rapid point of care testing for COVID-19 (when it becomes available) prior to testing.

5) The risk of infection from a given RFT procedure is unlikely to be uniform. There is currently a paucity of definitive research in this area. However, individuals who have a productive cough after a deep or forced airway expiratory manoeuvres, are likely to expose any individual in close proximity (i.e. the clinician performing the test) to a greater degree of risk. Likewise, RFTs conducted in facilities with poor air circulation are likely to be associated with a heightened risk for staff and any subsequent patients using that facility.

6) It is proposed that when RFTs are being considered in a clinical facility, the following three P's components of this activity are assessed and discussed with local infection control policy makers (Table 1)

Patient:

- Is there a history of cough-inducing lung disease? If so, the procedure should be considered akin to an 'induced sputum procedure', and thus must be approached with a higher degree of caution.
- Whilst it is accepted that it can often be difficult to predict who may or may not cough during a procedure, individuals with a history of regular sputum production (e.g. individuals with bronchiectasis) should be classified in this category.



• Patients with distinct immune vulnerability (e.g. individuals post-transplant or are immunosuppressed) should also be considered at increased risk and may be best tested in a specialist secondary care setting as they are likely to need more detailed tests.

Procedure:

- In line with statements above, local infection protection and control SOPs should be followed for standard spirometry in the RDSS and during the COVID-19 pandemic. This must include the provision of PPE.
- Low effort procedures that are not likely to cause coughing with deep expectoration (e.g. rate control exhalation during FeNO and CO monitoring), should not be considered to be in a high-risk group.

Plant:

- The air circulation performance in a testing facility (i.e. how quickly air changes) is an important component of infection risk reduction. This should be measured for every room used for testing in any given facility and all reasonable efforts made to create an air change rate of at least 6 per hour to mitigate aerosol persistence in the environment.
- The use of fans should be discouraged since they probably disperse virus more than clear it from the room. Room air circulation is complex and appropriate engineers should be consulted regarding changing any airflows. The use of HEPA filter air purifiers may also help reduce risk from viral aerosols within the room.
- The use of appropriately placed Perspex screens can reduce the infection transmission between the patient and the operator during testing.
- Cleaning of any RFT facility should align with local IPC policy but, importantly, ensure that there is an increased provision of cleaning support for these facilities.
- The risk for an individual clinician undertaking RFT should be assessed by the local service leads and all efforts made to assess and reduce exposure risk. Nationwide policy indicates that individuals deemed to be at heightened risk of developing severe COVID-19 infection should not be undertaking or exposed to high risk procedures.



		RISK	
	LOW	MODERATE	HIGH
Procedure	Low exhalatory flow on filter system (e.g. FeNO), gas transfer measurement	Spirometry (acute and community Trusts). Full respiratory function testing (mouth pressures, lung volumes, etc.)	Procedures with raised potential to induce coughing (e.g. broncho- provocation testing), and those causing increased levels of patient ventilation (e.g. CPET)
Patient	Isolated ± COVID protected admission pathway	Pre-screened and COVID-19 point of care negative on the day prior to the procedure	Frequent sputum production, immunosuppressed. Do not test if COVID-19 suspected or swab test positive.
Plant	Negative pressure testing rooms. High rate of air changes in testing room(s). Use of HEPA air filtration Outside testing	Air changes per hour >6 but <12 in testing rooms still need regular cleaning and "fallow" periods.	Air changes per hour < 6 in testing rooms Mixed clinical traffic

Table 2: Approach to assessing risk of undertaking RFTs

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	Low Risk Stratification	High Risk Stratification	Local/National Lockdown
	Proceed - Caution	Proceed - Greater	Proceed - Extreme
		Caution	Caution
PPE Mask Level*	Low (Type IIR) minimum	High (FFP3/Hood)	High (FFP3/Hood)
Patient	Expanding	Stable & selective	Urgent only
throughput			
Air changes	Wherever	Always	Always
>6/hr, etc.	reasonably		
	practicable		
Equipment	Routine	Routine	Before Each Patient
cleaning			
Floor cleaning	Once daily	Between patients if	Between Patients
		any coughing occurs	
Innovative	Expand with	Continue with	Suspended
working	caution	heightened caution	

* Assumes appropriate clothing (e.g. scrubs) and use of gloves ± face protection in line with local policies.

Table 3. Escalation of Infection Control for Respiratory Function testing.

Car spirometry services

When it is not possible to test indoor due to unsuitable plant (i.e. lack of rooms with adequate ventilation), an option has been to perform spirometry in the patient's car. This has been published (Moore, Inspire, 2020)

Methods and Testing

Spirometry can be performed with the car window up to contain any aerosol, but some practical precautions may be necessary:

- On warm days the testing should take place in a shaded area if possible.
- The window should be down for the initial pre-test questions, contraindications and instructions.
- The window should be up when performing the test.
- Communication needs to be kept to a minimum to avoid things being misheard.
- Staff ask patients to call a designated phone number to take instruction/sort problems.
- In certain circumstances, it may be desirable to perform in-car spirometry with the window down but with testers in full PPE. This will enable staff to rapidly assist the patient in the case of an adverse event.
- It is recommended that the car-door remains unlocked to enable staff to access the patients should there be an adverse event.



PPE

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It is recommended that the performing the spirometry should engage in regular hand hygiene as per NHS England guidelines and wear:

- standard issue hospital gloves and plastic apron
- a standard (Type IIR) surgical mask or FFP3 if required by at risk staff.
- Visor /eye cover is to be worn.



6. Service Description

The RDSS service will be available to all patients registered with GP practices within the specified locality and will offer:

- Diagnostic quality assured spirometry in breathless / patients with COPD / asthma (and ideally include children age 6 and above)
- Diagnostic quality assured spirometry in patients whose previous diagnosis of COPD has been made without post-bronchodilator spirometry or where the patient has a diagnosis of COPD with a FEV1/FVC ratio of greater than 0.70
- Diagnostic spirometry to clarify diagnosis in patients with dual COPD and asthma diagnosis in primary care
- Diagnostic reports to general practice with actions / suggestions for action
- Patient centred care
- Opportunity to make every contact count

The service should ensure non-English speaking patients are included by using interpreters.

6.1 Referral Criteria

The RDSS service is designed to meet the needs of patients who report respiratory symptoms or are deemed to be at risk of and display symptoms suggestive of COPD or asthma, but who have not received quality assured spirometry. In addition, patients who have had confirmed or suspected COVID-19 pneumonia and continue to experience breathlessness who need assessment.

Patients aged 6 or above requiring diagnostic spirometry in the categories below should be referred to the diagnostic spirometry service:

- Patients who present to a clinician with clinical features that suggest the possibility of COPD or asthma: Such features might include exertional breathlessness, chronic cough, regular sputum production, frequent winter "bronchitis" and wheeze)
- Patients with respiratory symptoms who are over 35 years and who are smokers with > 10 pack years of smoking
- Patients with a diagnosis of COPD whose previous diagnosis of COPD has been made without post-bronchodilator spirometry or where the patient has a diagnosis of COPD with a FEV1/FVC ratio of greater than 0.70
- Patients who have had confirmed or suspected COVID-19 pneumonia and continue to experience breathlessness

6.2 Exclusion Criteria

Primary care settings may not be the most appropriate setting for diagnostic testing and others may not be appropriate for diagnostic testing in any setting. Contraindications should



be reviewed prior to undertaking spirometry. The following patients are therefore not appropriate for these services:

- Patients requiring specialist review in the chest clinic
- TB or patients with suspected cancer (2 week wait referrals) or any other respiratory "red flags"
- Routine follow up spirometry as part of annual review
- Patients under the age of 6 years-old
- Bed-bound patients or patients who are unable to sit upright
- Patients with cognitive impairment or dementia to a degree that they will not be able to follow instructions
- Patients who have contraindications for forced expiratory manoeuvres (e.g post cataract surgery, presence of aortic aneurysm etc).

6.3 Referral sources

Referrals should be via a secure electronic system (such as EMIS/SystmOne) from (GPs and nurse practitioners in-line with referral protocols. The provider is responsible for setting up a secure electronic system and should promote and support referrals via this means. An nhs.net account should also be created for practices as a back-up referral route and for referrers to send general enquiries about the service.

Referrals should be submitted and accepted on a designated referral form to ensure completeness of information required to appropriately review and assess the referral. The referral form should indicate if referring for breathlessness if initial investigations such as BNP, CXR or screening spirometry have been performed. The service is responsible for developing a referral form in collaboration with commissioners.

It is critical to the success of the service that general practices identify and refer patients to the service.

The service must be able to receive and view referrals in order to meet the timeframes specified in managing the referral.

6.4 Location(s) of Service Delivery

Services will be provided in conveniently located and accessible healthcare settings to ensure equitable access for all residents. The location must be accessible for wheelchairs. This may be at fixed locations or on a peripatetic basis moving from practice to practice.

During COVID-19, consideration must be made to allow for possible patient testing before any procedures are performed (ideally on the day of testing with rapid point of care testing). Rooms should have appropriate ventilation and known air changes (as outlined above)¹⁴. Staff will need access to the appropriate PPE.



The service must be contactable Monday to Friday during normal working hours. A response should be received within 72 hours via email.

6.5 Interdependencies with other services

The service should be supported by an Integrated Respiratory Consultant.

The service will need to develop strong relationships with and be closely aligned to locality GP practices (GPs/Practice Nurses/Practice Managers) in their role as primary care providers to ensure diagnostic spirometry is not distinct from primary care case-finding and on-going management. The service will need to engage with locality GP practices in order to encourage referrals into the service and effectively communicate results back to primary care.

The service will play a role in a whole systems approach to proactive respiratory care and should develop in collaboration with the Integrated Respiratory Care Team.

Key interdependencies with other services are:

- Locality GP Practices in their role as primary care providers
- Integrated Respiratory Team
- Pulmonary Rehabilitation services
- Smoking Cessation Services
- Hospital based respiratory services
- Cardiology / Heart failure services
- Care of the elderly / frailty team



7. Suggested Service Delivery

The suggested detailed requirements for each stage of the pathway for the Diagnostic Spirometry Service are set out below.

7.1 Manage referral and arrange assessment

The Provider is responsible for encouraging as many referrals as possible to the Diagnostic Spirometry Service. The Provider shall ensure that all appropriately referred patients are offered quality assured diagnostic spirometry.

The service will offer the following response times. Times are measured from the date a referral is received from the GP (and may be delayed if the referral form is incomplete) unless stated otherwise.

Function	Process	Timescales
Manage referral	Check all referrals and confirm that all patients are eligible.	
	Accept or reject the referral based on the information contained in the referral.	
	Send acknowledgment of the receipt of the referral back to the referrer and confirm if patient is eligible for the service. If the referral is rejected the provider shall state the reason (if the referral information is not complete, the provider may reject the referral).	Within 5 working
Arrange assessment	Initial contact to eligible patients/carers by pre- agreed letter to introduce the service and inform patient of offered appointment date. Directions, contact details and confirmation of appointment time/date are communicated to the patient, along with details of how to cancel or re-arrange the appointment.	days
Assessment	Patient seen in clinic for diagnostic spirometry.	Within 90 working days

The Provider shall advise the patient how to prepare for the appointment in advance of the appointment.

The Provider shall ask the patient to avoid, if possible:



- smoking for at least 24 hours before the test
- eating a large meal before the test
- vigorous exercise before the tests
- wearing tight clothing
- bronchodilators prior to the test (see below)
- The patient should have been tested for COVID-19 and received a negative result within 24 hours of the appointment

The Provider shall ask the patient to bring all prescribed inhalers to the appointment (in the event that the patient has been prescribed inhalers but has not undergone quality- assured diagnostic spirometry).

Patients should be asked to avoid inhaled medications or the necessary interval prior to testing. The Provider must be aware of latest recommendations and ensure that this is communicated clearly to patients in patient information letters / leaflets.

The Provider shall send confirmation of the date, time and all relevant information to the patient and/or carer regarding the appointment.

7.2 Clinical Assessment

A diagnosis shall only be provided after a comprehensive assessment, which should include a clinical assessment and physiological investigation of airflow obstruction. The Provider will provide an assessment of airflow obstruction and report back to general practice whether the assessment results are normal, could be consistent with possible COPD or possible asthma, or whether the results are inconclusive and what further steps would be recommended.

7.3 History and Examination

- The Provider shall ensure that the patient has adhered to pre-visit requirements and confirm that there are no contraindications.
- The Provider shall undertake an assessment of the patient in an appropriate setting; the assessment should ideally include history and clinical examination if appropriate. Questionnaires may be used to assist with history taking (see Appendix 2 for example).
- The Provider shall ensure that an up-to-date smoking history is established, and any medications are recorded. The history shall include an assessment of pack years smoked (number of cigarettes smoked per day, divided by 20, multiplied by the number of years smoked) and any history of inhaled recreational drug use (with the consent of the patient).
- MRC score (3 plus air flow obstruction shall trigger a recommendation, in the report to the GP, to refer to pulmonary rehabilitation)



7.4 Assessment of Airflow Obstruction

- The Provider shall undertake a quality-assured diagnostic spirometry test which shall be performed on the same day and in the same location as the clinical assessment.
- The Provider shall undertake FENO testing and exhaled CO testing and pulse oximetry
- The Provider shall ensure that the testing is undertaken in an appropriate setting.
- The Provider shall, depending on the extent that any of the pre-test advice has been followed by the patient, use their discretion to decide whether or not to proceed with the test on that day and rebook if required.
- The provider shall follow recommendations specified in the Primary Care Commissioning guidance on Quality-Assured Diagnostic Spirometry²⁴.
- The Provider shall assess the patient for contraindications to spirometry and perform baseline oxygen saturation prior to the spirometry test. Anybody at or below 92% (room air) should will need a referral made for a specialist oxygen assessment.
- The Provider shall explain and demonstrate to the patient what will happen during the tests and ensure that the patient understands what is required of them, and why it is important to perform each manoeuvre as best they can. The Provider shall explain to the patient the nature of the test, the type of blow required, and that a minimum of three acceptable and a maximum of 8 test results are needed.
- The Provider shall make sure that there is no more than 0.1L (100ml) variation ideally (and certainly no more than 150 mls in the occasional highly variable patient) between each blow.
- If the referral and/or history suggest that reversibility testing would be indicated, this should be performed as per the guide to performing quality assured diagnostic spirometry document²⁴.
- The provider shall perform post-bronchodilator spirometry. The usual bronchodilator dose is 400micrograms salbutamol via spacer. The GP should give permission for this in the referral but a PGD may enable administration if this is missed.
- The Provider shall record the post-bronchodilator results using the largest postbronchodilator FEV1 and the largest FVC to determine the FEV1/(F)VC ratio, the flow/volume and time/volume graphs, any technical comments on the spirometry as detailed in the Guide.
- The Provider shall grade severity of airflow obstruction in accordance with the NICE guidance
- If the patient has been referred for breathlessness following confirmed or presumed COVID-19 pneumonia, an exercise desaturation test can be performed after spirometry testing (1-minute sit to stand or 40 step walk test).



7.5 Diagnosis

The provider shall suggest a possible diagnosis of COPD or asthma or normal spirometry based on the findings of the clinical assessment and physiological tests in accordance with recommendations set out in NICE Clinical Guidance on COPD and BTS/SIGN asthma guidelines. The provider must ensure the diagnosis is quality assured. The ARTP interpretation module will assist with this but initially, this may require significant Consultant oversight to safety net.

Where the provider has been unable to arrive at a diagnosis, the provider shall advise the GP whether additional investigations or a referral to a specialist is recommended.

Ideally, a Read/SNOMED code should be established to indicate that a quality assured diagnosis has been made/confirmed that will distinguish from those who are already on primary care registers who may not have had a quality assured confirmed diagnosis.

7.6 Communicating the Diagnosis

Primary Care

The provider shall communicate the likely diagnosis to the patient's GP within 7 days of the appointment (this also applies where the provider has been unable to arrive at a diagnosis) via a secure electronic system. The management responsibility of the patient remains with the referring GP.

The report to general practice should conclude whether the patient has COPD/asthma, does not have COPD/asthma or whether the results are inconclusive and further diagnostic investigation is required.

The report should include suggestions for action and advice on whether any additional investigations or a referral to a specialist is necessary.

The following should be reported to the GP:

- FEV1, whether the readings are pre- or post-bronchodilator
- FEV1 % predicted and severity categorisation according to NICE 2010 guidelines
- FVC
- FEV1/FVC ratio
- Exhaled CO and implications of this as to tobacco dependence
- FENO
- MRC dyspnoea score
- Flow volume loop interpretation
- Resting oxygen saturations
- Exercise desaturation if performed



The report should also document whether onward referral is recommended in line with locally agreed pathways or if further diagnostic tests are required in line with local guidelines, providing rationale for the recommendation e.g. CXR, ECG, BNP, echocardiogram, peak flow diary

- Symptoms that contributed to the diagnosis of COPD (cough, sputum and breathlessness)
- Functional impairment (e.g. MRC dyspnoea scale)
- Exacerbation frequency
- BMI
- Smoking history and status (what methods, if any, of smoking cessation are being provided)
- Oxygen saturations

Patient/Carer

For starting point services, the Provider should advise the patient to make an appointment with their GP to discuss the results of the diagnostic spirometry.



8. Monitoring and Evaluation

The service should gather activity data to a level which enables:

- Evaluation of the impact of the service in addressing the accurate diagnosis of people with COPD and asthma, and its impact on health inequalities. This should focus on the uptake and outcomes where there are known inequalities, particularly in people from the most socioeconomically deprived areas, those from a black and minority ethnic background and those with a mental health condition
- Internal and external clinical audit to take place effectively
- Identification of local demand and educational needs, which can then be fed into the development of the service
- Evidence to be submitted in a timely fashion for prompt payment of itemised invoices
- Performance management of the service against agreed objectives

Specifically, a standard, searchable management information system should be in place, which collects key performance indicator (KPI) and case mix data. The Commissioners and Provider should work together to develop this. A quarterly report, based on data collected via this system, should be provided to the Commissioner by the 14th of the month following the end of the quarter.

The service should be audited annually by an external partner.

In addition, the service will conduct an annual GP and patient evaluation and demonstrate that they have considered and, where appropriate, acted on feedback.

8.1 Evaluation of Impact

The following broad measures will be used by Commissioners to evaluate the overall impact of the Service within the health economy:

- Ratio of actual v expected prevalence of COPD delineated by deprivation quintile, ethnicity and mental health status (improvement expected following an initial phase in year 1 and 2 where registers may reduce or plateau due to correction of previous diagnostic errors).
- Diagnostic accuracy of primary care COPD and asthma registers
- Impact on number of patients admitted to hospital with COPD without a prior diagnosis per year.
- Impact on number of COPD and asthma hospital admissions per year.
- Impact on prescribing of COPD and asthma inhalers.
- Number of people diagnosed at an early stage of the disease (MRC score of 1 and 2)



8.2 Suggested Key Performance Indicators

Performance management of the service will be reported quarterly and will focus on the following KPIs. KPIs will be reviewed at the end year 1. Failure to achieve the KPIs would not result in financial penalty but will form part of a contractual review process.

These KPI's should be informed by local modelling including expected versus reported prevalence etc.

Outcome	Indicator	Indicator	Measurement	Consequence of
		Threshold		Breach
Effective management of referrals and arrangement of assessment.	The percentage of referrals accepted/reject ed within 5 working days and communication sent to eligible patients and GP	95%	 (x) The number of referrals actioned within 5 working days (y) The number of referrals received [x/y] x 100 = percentage of referrals actioned within timeframe 	Provider to undertake internal review into reasons for breach and report back to commissioners on plan to ensure target is met in next quarter.
	Average wait time per month from referral received date to assessment date	Should not exceed 30 working days	 (x) The number of patients offered an appointment within 20 working days of referral received (y) The number of patients offered an appointment [x/y] x 100 = percentage of patients offered an appointment within set timeframe 	Provider to undertake internal review into reasons for breach and report back to commissioners on plan to ensure target is met in next quarter.
Effective management of assessment.	Monthly DNA rate	Should not exceed 15% (av)	 (x) The number of patients who do not attend an appointment (y) The total number of patients booked for an appointment [x/y] x 100 = percentage of patients who DNA 	Provider to undertake internal review into reasons for breach and report back to commissioners on plan to ensure target is met in next quarter.



Effective	The percentage	95%	(x) The number of	Provider to
Communication	of patients who		patients with a diagnostic	undertake
of Results to	have diagnostic		report and suggestions	internal review
patient's GP	report and		for action sent back with	into reasons for
	suggestions for		7 days of appointment	breach and
	action sent		(y) The total number	report back to
	back to GP		of patients attended	commissioners
	within 7 days of		for an appointment	on plan to
	appointment		$(x) [x/y] \times 100 =$	ensure target is
			percentage of	met
			patients with a	in next quarter.
			diagnostic	•
			report sent back	
			to GP within set	
			timescales	
More people	The percentage	90% of	(y) The number	Provider to
using the	of people and	patients	of surveys	undertake
service and	carers surveyed	surveved	received with a	internal review
their carers are	who are	report	satisfactory	into reasons for
satisfied with	satisfied with	satisfaction	score	breach and
the service	the service	with the	(z) The number of	report back to
		services they	people and carers	commissioners
		receive	surveyed $[x/y] \times 100$	on plan to
		100% of	= percentage of	ensure target is
		natients are	people and carers	met in next
		offered an	surveyed who are	quarter
		opportunity to	satisfied with the	quarter.
		complete a	service	
		natient	Service	
	/	satisfaction		
	/	SURVOV		
CPc within the	Tho	Survey.	(x) The number	Providor to
	norecentere	90% OF GFS		Hovider to
	of CD	suiveyeu	or surveys	
the service	UI GF	report		internal review
the service	satisfaction in	satisfaction	salislaciory	Into reasons for
provided	respect of	with the	score	breach and
	reterral	services they	(y) The number of GPs	герогт раск то
	process,	receive.	surveyed	commissioners
	waiting times,	100% of GPs	$[x/y] \times 100 =$	on plan to
	care given to	are offered an	percentage of GPs	ensure target is
	patients,	opportunity to	surveyed who are	met in next
	quality of	complete a	satisfied with the	quarter.
	Information	patient	service	
	received from	satistaction		
	the Service.	survey.		

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Where	The	90% of	(x) The number	Provider to
clinically	percentage of	patients	of patients	undertake
appropriate, all	patients seen	assessed in	receiving post-	internal review
newly	in the service	the service	bronchodilator	into reasons for
diagnosed	who have	are assessed	spirometry	breach and
patients on	post-	with post-	(y) The patients who	report back to
COPD register	bronchodilator	bronchodilator	have attended	commissioners
have diagnosis	spirometry.	spirometry or	assessment [x/y] x 100	on plan to
confirmed by		a clear reason	= percentage of	ensure target is
post-	It is estimated	given why	patients assessed with	met in next
bronchodilator	that a maximum	post-	post-bronchodilator	quarter.
spirometry	of 10% of	bronchodilator	spirometry	
	patients may	spirometry		
	not be able to	was not	Exception report where	
	perform	performed	patient has not been able to	
	spirometry to	e.g. poor	perform post-bronchodilator	
	allows for	technique or	spirometry with clear reason	
	patients unwell	exacerbation	given as to why it was not	
	in exacerbation		performed.	
	and patients			
	unable to			
	perform 3 blows			
	etc.			

NHS England and NHS Improvement



8.3 Data Requirements from the Service

The following data should be compiled on a monthly basis in order to measure KPI's and support further service evaluation:

Referrals:

- Number of referrals received from each practice (with practice code, including date referral received)
- Number and % of referrals that are returned to GP for further information (broken down by practice)
- Number and % of referrals accepted/rejected within 5 working days
- Number and % of referrals accepted/rejected outside of 5 working days (broken down by days)
- Number and % of referrals where acknowledgement and outcome of referral has been sent to GP within 5 working days
- Number and % of referrals where acknowledgement and outcome of referral has been sent to GP outside 5 working days (broken down by days)
- Number and % of referrals where initial contact is attempted with eligible patients within 5 working days
- Number and % of referrals where initial contact is attempted within eligible patients outside 5 working days (broken down by days)

Appointments:

- Number and % of patients seen in the clinic within 20 working days of the referral being received
- Number and % of patients not seen in the clinic within 20 working days of the referral being seen (broken down by days)
- Number and % of patients who DNA appointment
- Number of, date of, and location of attended appointment

Diagnosis:

- Number and % of patients assessed with post bronchodilator spirometry (report on reason for any exceptions)
- Number and % of patients who have diagnostic report and suggestions for action sent to GP within set timeframe
- Number and % of patients who have diagnostic report and suggestions for action sent to GP outside set timeframe (broken down by days)
- Number of and % patients who have results consistent with a diagnosis of COPD or asthma;
- Number of and % of patients already on COPD or asthma registers who have results not consistent with previous diagnosis
- Number in each MRC category and the % distribution of MRC scores



 Number of patients in each NICE 2010 severity category and the % distribution of severity scores

Satisfaction with Service:

- Number and % of GPs who are satisfied with the service they received
- Number and % of patients who are satisfied with the service

8.4 Accreditation and Equipment

To be of clinical value, diagnostic spirometry has to be performed to a high standard. If it is not, there is significant risk that the diagnosis will be incorrect and that as a result patients will receive inappropriate and potentially harmful treatment. The provider needs to ensure that every spirometry test meets the necessary standards set out in the Primary Care Commissioning Guide on Quality Assured Diagnostic Spirometry <u>https://www.brit-thoracic.org.uk/media/70454/spirometry_e-guide_2013.pdf</u>

Accreditation

- The Provider is responsible for ensuring all clinical staff have the necessary licence to practice and qualifications and continuing professional development required to maintain their qualification. As a minimum this should include:
- Staff performing and interpreting spirometry to be trained and assessed to ARTP or equivalent standards by recognised training bodies in the performance and interpretation of spirometry, and that they receive regular updating (e.g. every three years)
- Minimum of 5 diagnostic spirometry tests performed per week (Healthcare Professional responsible for keeping a record of number of tests performed).
- Staff performing and interpreting spirometry to have adequate regular formal supervision and an agreed number of tests/interpretations reviewed per annum.

Equipment

- The provider is responsible for providing all equipment.
- Equipment used by the service should meet the standards set out in the Primary Care Commissioning Guide on Quality Assured Spirometry 2013.
- The provider is responsible for ensuring that all equipment is appropriately calibrated.
- The maintenance, including replacement of consumables, of any equipment is the responsibility of the provider.
- Conduct quality control checks at least weekly to ensure reliability and reproducibility of results.



8.5 Clinical Governance

- The Provider is responsible for all aspects of clinical governance through an effective system of quality and risk management in line with the requirements Care Quality Commission standards.
- The Provider shall nominate a senior manager or clinician who shall have responsibility for ensuring the effective operation of clinical governance including training and risk management. This applies to both the referral management and clinical services.
- The Provider must provide an up-to-date document outlining clinical governance arrangements to the ICS prior to service commencement. This will include relevant policies e.g. incident management policy, service continuity policy, complaints handling policy, etc., details of formal supervision arrangements and quality control, along with any sub- contract arrangements associated with the Service. All clinical governance documents must outline how the Provider will meet the Standards for Better Health and the Provider's CQC registration status.
- The Provider will provide the ICS with evidence that all practitioners providing the service meet the accreditation requirements appropriate to their role.



9. Activity

The numbers in the table below are an estimate of the average annual referrals to the service.

Financial Year	Estimated annual referrals per annum	Estimated annual referrals by locality per annum

Good practice indicates that clinicians need to complete a minimum of 5 spirometry tests and interpretation per week to maintain quality expertise. Activity will be reviewed in Quarter 2 to determine if the service is performing to expectations. If the service is not performing as expected, mitigating actions will be agreed between provider and commissioners and implemented within agreed timescales.



10. Financial considerations and funding of service

Routine monitoring spirometry for COPD is no longer a QOF requirement. There are no direct QOF payments for spirometry, but there is a requirement for the diagnosis of COPD to be confirmed by quality assured spirometry and for the diagnosis of asthma, spirometry with reversibility may be used as an option.

Currently, diagnostic spirometry is either a commissioned service by the CCG from a service provider such as a Community Trust or Respiratory Integrated Care Team on a service level agreement or agreed tariff. More costly alternatives are direct access spirometry from secondary care (£65/test) or, most costly, referral to secondary care for an outpatient appointment (£250 for specialist referral + £155 for full lung function). More commonly, spirometry is performed in individual practices which are paid per case from a Local Enhanced Service (LES) arrangement.

10.1 Costings for diagnostic spirometry services

The current estimated costs of spirometry services provided by LES per CCG are approximately ± 1 /head of population²⁵. Thus, for the population level proposed, the estimated maximum cost per PCN if spirometry is provided by a LES is $\pm 50,000$.

The average reimbursement per test (which is spirometry with reversibility testing – not just post bronchodilator spirometry) is approximately £40-50. The maximum number tests projected per year will be 1,000 per PCN which seems rather excessive for a population of 50,000. It is more likely that 500 tests will be required for a population of 50,000 per year. This equates to approximately 10 tests per week (5 per half day session).

If reimbursed at £40 per test on a LES, 500 tests provides an income of £20,000

The cost of a diagnostic spoke service:

Set up (many spirometers, calibration syringes (not always required) and CO monitors, stadiometers are already available in most practices):

FENO machine x 2: These can be leased on a per test basis at around £3 per test = £1,500/year

Band 4 HCP – one day a week: £6,000 (mid-point)

Band 7 specialist - half day a week: £4,800

Admin support - half day a week: £2,000

Basic Consultant Supervision (0.5PA): £4,500

Total cost for 1 year to PCN: £18,800



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12. Appendix 1. Example report from an RDSS

Gender	Male			1	Height		¹ 171 c	m	~ .		
					Weight		97 k	g	BMI 3	3.2	
Smoker	FORME	R; 10 Cig	arette(s)	per Day;	Years Sr	moking 3	30; (15 Pac	ck Years)			
FVL Tidal							Yo	ur FE\	/1 / P	redicte	d: 60%
Test Date: 02/05/201	18 10:14:47	Prec	licted: Q	uanjer (G	LI), 2012					,	
			Pre			Post				14-	
Parameter	Pred	LLN	Best	%Pred	Z	Best	%Pred	Z	%Chq		
FEV1 [L]	2.82	2.01	1.68*	60	-2.29	1.93*	68	-1.79	15*	12	
FVC [L]	3.74	2.74	3.12	83	-1.02	3.55	95	-0.30	14*		
VCmax [L]	3.74	2.74	3.84	103	0.17	3.84	103	0.17	0	10	·····
FEV1/VCmax	0.759	0.618	0.438*	58	-3.73	0.504*	66	-2.97	15	0	
FEV1/FVC	0.759	0.618	0.539*	71	-2.55	0.544*	72	-2.50	1	8	
FEF25-75 [L/s]	2.13	0.89	0.62*	29	-2.00	0.61*	29	-2.01	-1	6	
PEF [L/min]	-	-	327	-	-	332	-	-	2	0	
* Indicates value outs	side norma	al range	or signifi	cant post	change.					4	
Session Quality		Pre	B (F	EV1 Var	=0.03L (2.0%); F	VC Var=0	.13L (4.1	1%))		
		Post	B (F	EV1 Var	=0.06L (3.3%); F	VC Var=0	.13L (3.7	7%))	2	
Overall Syst. Interpre	et.	Significa	ant pre -	post char	nge					Usj	
										≥ 0-	
0										Ê Î	
0.					1111					~~ ~~	
[4		****					-4	





SVC

Test Date: 02/05/2018 10:10:20	Predie	cted: Quan	jer (GLI), 2	2012	
Parameter	Pred	LLN	Best	%Pred	Z
VCex [L]	3.74	2.74	3.84	103	0.17
VCin [L]	3.74	2.74	3.82	102	0.13
VCmax [L]	3.74	2.74	3.84	103	0.17
Session Quality	Pre	A (VC V	ar=0.02L ((0.6%))	

Comment

tc 02/05/2018 cw 10/05/2018

Reason for referral: ?COPD

Ex-smoker with a 15 pack year history exCO = 2ppmCO 0.95 CO level consistent with non-smoker

MRC score = 2

Patient takes Salbutamol, Incruse Ellipta and budesonide inhalers.

Inhalers withheld on day of test.

Pre bronchodilator spirometry shows mild airflow obstruction (in accordance with z (SR) values and LLN for FEV1/VC ratio). Bronchodilator response tested using 400mcg Salbutamol via MDI and spacer. Post bronchodilator spirometry shows a change in FEV1 of 250mls (15%) FeNO = 155ppb (normal <40ppb).

Results suggest airflow obstruction with a significant response to bronchodilator. An elevated FeNO test suggests eosinophilic inflammation and provides supportive evidence for an asthma diagnosis.

Airflow obstruction remains post bronchodilator and patient is an ex-smoker. Results could be consistent with asthma/COPD overlap. CW(TF) (IP)





13. Appendix 2. Example respiratory assessment questionnaire

<u>Respiratory</u> Name	Assessment Unit Patient	t Questionnaire	Date
Have you e v Yes	ver smoked? No		
What age di How many o	d you start? Wh cigarettes did you smoke	nat age did you stop? daily?	
Would you Yes	l ike help stopping smokir No	ng?	
Do you cou Yes	gh? No		
Do you hav Yes	e phlegm? No	If so, what colour is your phleo Colour	jm?
Have you e v Yes	v er coughed up blood? No		
Do you whe Yes	eze? No		
Is your whe	eze worse at any time?		
Do you hav Yes	e chest tightness? No		
Do you hav Yes	e chest pain? No		
Do you hav Yes	e swelling in your ankles ' No	?	
Are your sy	mptoms constant or do t	hey vary between daytime and n	ight time?

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Do you get breathless? Yes No

Does the breathlessness limit your activity?YesNo

How far can you walk without stopping?

Please circle any of	f the following t	riggers that mak	e your breat	hing worse:
----------------------	-------------------	------------------	--------------	-------------

Cold Air	Perfume	Smoke	Work	Animals
Emotions	Laughter	Dust	Smells	Seasons
Exercise				

Have you experienced?Weight LossYesNoNight SweatsYesNo

Relevant past respiratory history as adult or childhood respiratory illness's Yes No

Family History of Asthma; any early respiratory deaths (Anti-trypsin A deficiency)YesNo

H/o atopy; (eczema, hay fever) & allergies to food or medication. Yes No

Occupational or environmental exposure

No

Yes

400