

Service Name	Spirometry Delivery Specification and Multi Provider Delivery Model in Primary Care for Staffordshire and Stoke-on-Trent ICB
Service Specification Number	<i>Use this to give this particular specification a unique reference number</i> 01-01102023
Population and/or geography to be served	<p>National context</p> <p>Chronic obstructive pulmonary disease (COPD) remains a constant challenge, with 2 million people diagnosed and up to three times as many people remaining undiagnosed, it has therefore been identified as a clinical priority in the NHS Long Term Plan. In addition, the pressures on the service post the coronavirus pandemic continue with many suffering from long-term symptoms of lung damage, including breathlessness, fatigue and limited ability to exercise.</p> <p>This is placing significant pressures on respiratory services at a time of significant workforce challenges with efforts underway to boost NHS activity and tackle the rising backlog of care (NHS HEE, Respiratory Disease: Understanding the future service and workforce needs).</p> <p>COPD causes around 30,000 deaths in England each year, with one person dying from the condition every 20 minutes. Co-morbidities such as cardiovascular diseases, lung cancer, anxiety, depression, diabetes and osteoporosis are common at all stages of COPD and are often diagnosed late.</p> <p>Patients with COPD and Asthma are also at a much higher risk of premature death from cardiovascular diseases and related morbidities.</p> <p>Around 160,000 people a year in the UK receive an asthma diagnosis, and there are marked differences in asthma incidence across different social and ethnic groups in the UK.</p> <p>Asthma is the most common long-term medical condition in children in the UK, with around 1 in 11 children and young people living with asthma. The UK has one of the highest prevalence, emergency admission for childhood asthma in Europe. Outcomes are worse for children and young people living in the most deprived areas.</p> <p>It is estimated that 30% of patients with a diagnosis have no clear signs of asthma.</p> <p>The UK has among the highest mortality rates in Europe for children and young people with the underlying cause of asthma. Emergency admissions, and deaths, related to asthma are largely preventable with improved management and early intervention. The National Review of Asthma Deaths found that 46% of the children who died from asthma had received an inadequate standard of asthma care.</p> <p>The provision for diagnostic spirometry in primary care was severely disrupted by the COVID-19 pandemic. Whilst there may have been brief intervals when spirometry has been performed, in a limited way, generally there has been little activity in primary care since March 2020.</p> <p>Since the pandemic many medical tests, including spirometry, were put on hold. During this time patients have continued to present with new respiratory symptoms or are yet to present, having stayed away from medical care and tolerated ongoing symptoms.</p>

4 <https://www.asthma.org.uk/about/media/facts-and-statistics/>,

5 <https://www.england.nhs.uk/2019/09/nhs-warning-to-parents-as-asthma-season-hits>

6 Royal College of Paediatrics and Child Health (2020) State of Child Health. London: RCPCH. [Available at: stateofchildhealth.rcpch.ac.uk]

	<p>Whilst the exact number of patients caught in the national backlog for diagnostic spirometry is unknown, it is estimated to be in the region of 200–250 patients per 500,000 population. However, the actual number of patients may be considerably higher, especially in areas with higher underlying levels of respiratory disease due to local, social, industrial and ethnic group factors. We estimate this number to be 2000-2500 across Staffordshire & Stoke on Trent.</p> <p>We are at a stage when we need to restart diagnostic spirometry in primary care but in a way that is safe for patients and for those undertaking the testing.</p> <p>NHS England led an initiative to improve the quality of diagnosis in respiratory care by working with the respiratory community to produce two documents, with Association for Respiratory Technology & Physiology (ARTP) and Primary Care Respiratory Society (PCRS). The purpose of these documents is to aid restoration of spirometry services by mitigating risk to both staff and patients and to raise the standard of performing and interpreting spirometry.</p> <p>Guidance produced by PCRS, ARTP and British Thoracic Society (BTS) offers practical advice on reinstating spirometry, who should carry it out, when and where it should be performed. It looks at the latest evidence on infection control and provides pointers on how to deal with the backlog of patients. See link to update, on spirometry guidance (pcrs-uk.org).</p> <p>Restoration of spirometry is a key step in managing respiratory disease, ensuring the correct diagnosis and therapeutic / referral interventions.</p> <p>The new certification scheme covers:</p> <ul style="list-style-type: none">• All clinical staff to achieve ARTP Certification in Spirometry (ARTP or equivalent standards by recognised training bodies in the performance and interpretation of spirometry)• All clinical staff must be registered on the National Register of Certified Healthcare Professionals in order to perform diagnostic spirometry• Diagnostics used for diagnosis must be quality assured and carried out by trained and assessed staff• ARTP infection control measures must be undertaken to ensure the quality & safety when restarting spirometry procedures due to its aerosol generating nature. <p>Local population</p> <p>The Staffordshire and Stoke-on-Trent Integrated Care System (ICS) serves a population of 1.2 million people.</p> <p>Local context</p> <p>Whilst limited spirometry services are currently available across the region there remains variation in the level of service provided; with some provided via primary care or acute provision.</p> <p>The RightCare programme identified Respiratory as one of the largest areas of opportunity for our local health economy as a consequence of this, there is increased focus on the management and identification of patients.</p> <p>The effects highlighted in the national picture, have as expected, had an impacted on our local population. It is likely that some patients, as a result of the pandemic having increased acuity of undiagnosed conditions, which could have been treated more easily and with better efficacy at early onset. Inherently this will have also led to increased Urgent Emergency Care attendances/admissions and a further pressure placed upon the system.</p>
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The pandemic and the new ARTP guidance calling for additional staff accredited training and spirometry diagnostics and infection control requirements, has resulted in a reduced workforce and capacity to deliver to the required ARTP guidance across the health system.

The number of patients on the COPD and Asthma register has steadily increased over previous years. There is a significant number of areas across Staffordshire and Stoke-on-Trent which have above average prevalence rates, when compared to the England average as detailed below.

Validated Quality and Outcomes Framework (QOF) 2022/23 Data

	Asthma		Chronic obstructive pulmonary disease	
	Disease Register Size	Prevalence %	Disease Register Size	Prevalence %
England	3,826,470	6.52	1,151,474	1.85
SSoT ICB	77,299	6.95	26,564	2.24
Cannock Chase	8,742	6.80	3,526	2.57
East Staffordshire	9,385	6.64	2,514	1.67
North Staffordshire	15,075	7.27	5,453	2.49
South East Staffordshire & Seisdon Peninsula	14,645	7.05	4,120	1.87
Stafford & Surrounds	10,013	6.89	2,762	1.80
Stoke-on-Trent	19,439	6.88	8,189	2.71

	Above England average
	Below England average

According to the Department of Health deprived populations have the highest prevalence and the highest under-diagnosis of COPD and asthma.

Stoke on Trent is Local Authority Districts with the 12th highest proportion of their neighbourhoods in the most deprived 10% of neighbourhoods nationally on the Index of Multiple Deprivation 2019.

Whilst Staffordshire is a relatively affluent area there are notable pockets of high deprivation in some of its urban areas with nine per cent of its population living in the most deprived fifth of areas nationally.

Local data from the COPD 21-22 QOF register indicates that 2.32% (26,682) of the population with COPD may require ongoing spirometry.

Current backlog figures of unmet patient need for spirometry testing is estimated at 12,000 tests. This figure is taken from modelling previous levels of delivery and extrapolating trends of increasing need from previous financial years (not impacted by the pandemic). The estimated need for spirometry testing in Primary care is assessed as 3,000 tests per year.

Prior to March 2020 most spirometry tests were completed by Primary Care or via a community provision. The backlog has impacted upon secondary care spirometry waiting lists, and therefore there will need to be an element of case-finding at primary care level to ensure the correct patients are followed up according to clinical need. For this reason, the activity mentioned within this specification is indicative only.

In addition, Staffordshire and Stoke-on-Trent ICB is committed to adopting a consistent approach across the ICS. Addressing this inequity in service provision/delivery is a matter of priority for the ICB.

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	<p>The above aligns to the NHS Long Term Plan which commits to improving quality & reducing variation of spirometry testing and calls for local systems to have plans in place “to support local identification of respiratory disease”.</p>																				
Service aims and desired outcomes	NHS Outcomes Framework <p>The Spirometry service will align to the NHS Outcomes Framework</p> <table><tr><td>Domain 1</td><td></td><td>Preventing people from dying prematurely</td><td>√</td></tr><tr><td>Domain 2</td><td></td><td>Enhancing quality of life for people with long-term conditions</td><td>√</td></tr><tr><td>Domain 3</td><td></td><td>Helping people to recover from episodes of ill-health or following injury</td><td></td></tr><tr><td>Domain 4</td><td></td><td>Ensuring people have a positive experience of care</td><td>√</td></tr><tr><td>Domain 5</td><td></td><td>Treating and caring for people in safe environment and protecting them from avoidable harm</td><td>√</td></tr></table>	Domain 1		Preventing people from dying prematurely	√	Domain 2		Enhancing quality of life for people with long-term conditions	√	Domain 3		Helping people to recover from episodes of ill-health or following injury		Domain 4		Ensuring people have a positive experience of care	√	Domain 5		Treating and caring for people in safe environment and protecting them from avoidable harm	√
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	Local defined outcomes <p>The service aims to achieve the following outcomes:</p> <ul style="list-style-type: none">Increases the number of people accurately diagnosed at an early stageImproved quality of life – patient feels supported to self-manage and stabilise their condition & can get back to living their livesImproved prescribing and optimised pharmacotherapyDrive up standards – follow/complying with ARPT guidanceEnsure accuracy of diagnosis and severity assessment.Increase in the percentage of people who feel supported to manage their conditionTo ensure effective communication between relevant health professionalsAdmission and re-admission rates are reducedFewer unnecessary and inappropriate appointments taking place in the hospital and in general practice meaning fewer journeys for patients.																				
Service description and location(s) from which it will be delivered	Service description <p>The Staffordshire and Stoke-on-Trent ICB are commissioning spirometry service delivery across primary care and the ICS footprint, for patients in locations closer to home.</p> <p>The overall aim is to achieve a place-based Spirometry service which drives up clinical outcomes and quality of life for patients and their carers.</p> <p>The service shall meet the needs of patients who are deemed to be at risk and display the symptoms suggestive of COPD or Asthma, but who have not already received a diagnosis confirmed by quality-assured diagnostic spirometry. (Spirometry should not be used in isolation when making diagnoses and clinical decisions and should always be used alongside other investigations and clinical judgement.)</p> <p>The premises utilised by the provider to deliver spirometry testing must adhere to all relevant Infection Prevention Control (IPC) and Aerosol Generating Procedure (AGP) guidelines</p>																				

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The provider shall:

- Deliver the service in line with new guidance produced post covid and ensure all infection control standards are met including ventilation, social distancing, PPE etc., conforming with updated spirometry guidance (pcrs-uk.org) Resuming Spirometry - ARTP Aerosols and Lung Function Testing Update Version 1.1 December 2022.
- Manage all referrals into the Service including assessment against eligibility criteria.
- Ensure that all patient data is transferred securely and in-line with GDPR and information governance requirements.
- Contact patients to arrange appointments for their test within five working days of receipt of referral.
- Provide the patient who are eligible, with confirmation of their appointment and for their appointment to take place within three weeks of making initial contact with the patient.
- Patients currently receiving antibiotic and or oral steroids, a minimum 6 week wait post infective exacerbation will apply before testing, but it may take up to 3 months for the infection to fully resolve and lung function to return to as good as it can be.
- Provide the patient with a patient information leaflet in advance of their appointment date detailing clear instructions on inhaler and clinical advice, what the tests involve and length of time the tests are likely to take.
- Check that any pre-visit requirements have been adhered to by the patient before performing the test.
- Providers should ensure that all diagnostic procedures are performed using a single patient use mouthpiece, bacterial/viral filter and clean nose clip. For reversibility providers should also ensure there is access to bronchodilator medication.
- Perform spirometry, reversibility testing and interpretation in accordance with the ARTP Standard Operating Procedure
- Performance of Spirometry 2023 SOP - Spirometry (artp.org.uk)
- Electronically forward all test results and interpretation back to the referring GP to enable follow up and ongoing management within two working days.
- Where the need arises, ensure mechanisms are in place for test results and interpretation of these to be forwarded to primary care, community services, pulmonary rehab, and secondary care.
- Ensure all healthcare professionals either performing and/or interpreting diagnostic spirometry are on the National Register of certified healthcare professionals.

Standard Operating Procedures (SOP):

It is expected that all providers will adhere at all times to the ARTP SOP when delivering spirometry, calibration of equipment etc. [Spirometry \(artp.org.uk\)](https://artp.org.uk)

Storing and communicating results

The Data Protection Act 2018 is the UK's implementation of the General Data Protection Regulation (GDPR). Everyone responsible for using personal data must follow strict rules called 'data protection principles.' They must make sure the information is: used fairly, lawfully and transparently.

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	<p>Providers procedures for data storage should ensure:</p> <ul style="list-style-type: none"> Secure digital backup of the tests; results and traces should be stored electronically in such a way that the data cannot be easily lost/corrupted or altered Good quality clearly presented reports with the minimum amount of patient data, to comply with GDPR Ease of access to facilitate the sharing of results between primary care, community services, pulmonary rehab and secondary care. <p>Training / Workforce / Staffing</p> <p>The Provider shall ensure that all staff either performing and/or interpreting spirometry tests are competent and hold a certificate with the Association for Respiratory Technology and Physiology (ARTP).</p> <p>It is expected that providers will have adequately and suitably accredited workforce in place to enable provision for both adults and paediatrics.</p> <p>Key to quality assured diagnostic spirometry is the establishment of a national register of certified healthcare professionals and operators. Staff must be listed on the national register according to the category of certification they have achieved. and will be expected to keep their skills up to date.</p> <p>Certification</p> <p>All individuals who hold an ARTP Spirometry certificate, must ensure they keep their certificate up to date by renewing it annually. For those who certified prior to 2021 and were previously required to renew their certificate every 3 years, if their certificate expired prior to 2021 and it has not been renewed, this is no longer possible.</p> <p>Acceptance criteria</p> <ul style="list-style-type: none"> Patients must be registered with Staffordshire or Stoke GP Patients who are assumed to be asthmatic need to have completed regular peak flow readings over a period of 2 to 4 weeks before performing a spirometry Aged 6yrs+ for diagnosis where airflow obstruction is suspected Children - It is expected that a peak-flow (positive test) is required before COPD FeNo can be done. Spirometry is performed to confirm and challenge purposes only Patients must have 1 or more of the following symptoms: <ul style="list-style-type: none"> Breathlessness usually exertional in nature Cough which may be intermittent particularly nocturnal. It may be productive or dry Recurrent wheezing episodes (particularly in children with a history of atopy) Recurrent respiratory infections Environmental exposure to e.g., smokes or dusts Diurnal variation of symptoms Suspected COPD on imaging. <p>Post-Covid19 backlog</p> <ul style="list-style-type: none"> Patients who have been identified as being part of the post-Covid backlog and who have already had a long wait and their condition may have deteriorated. In these cases, an assessment of current condition and clinical need must be factored in when prioritising the delivery of this service.
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Exclusion criteria

- Not seen by an appropriate member of the primary care team.
- Aortic aneurysm, pregnancy
- Existing or suspected respiratory infection
- Haemoptysis of unknown origin
- Pneumothorax
- Long covid
- Unstable cardiovascular status; recent (within 1 month) myocardial infarction, uncontrolled hypertension, pulmonary embolism, or chest pain.
- Uncontrolled hypertension or history of haemorrhagic cerebrovascular event
- Annual reviews as this is a diagnostic service only
- On behalf of non-primary care providers.

Interdependence with other services/providers

- General Practitioners
- Midlands Partnership Foundation Trust Respiratory Team
- University Hospital of North Midlands
- University Hospitals of Derby and Burton NHS Foundation Trust
- Royal Wolverhampton Trust
- Heart of England Foundation Trust
- Home Oxygen Services
- Walsall NHS Trust
- Spirt Health
- Concept Health.

Prioritisation for backlog patients

Where the capacity to deliver spirometry requires prioritisation for delivery of the service, it is expected that patients identified as being part of the backlog should take priority over new patients presenting with a need to spirometry.

Patient (Pt) data	COPD (EMIS) 01.03.23	Asthma (EMIS) 01.03.23	COPD (EMIS + pro-rata TTP practices) 01.03.23	Asthma (EMIS + pro-rata TTP practices) 01.03.23
Patients (Pts) unresolved	24,445	66,351	26,645	72,322
Pts Diagnosed After	4,858		5,295	
Pts on the register without a spirometry	4,371	66,351	4,764	72,322
Pts without a PCA	3,353		3,654	
Pts with a PCA	1,018		1010	
Minimum Pts Backlog need testing	3,353	00	3,654	00
Potential Pts Backlog	4,371	00	4,764	00

(PCA, Personal Care Adjustment)

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	<p>Multi provider delivery model</p> <p>On-going demand</p> <p>On average there are 1,600 new patients diagnosed with COPD a year and 2,300 new patients diagnosed with asthma a year. Therefore, there will be a minimum demand of 3,900 spirometry tests needed to be commission ever year in primary/community care.</p> <p>Whilst we are aware of the number of patients diagnosed with COPD and/or Asthma a year, there is no record for patients that have had a spirometry test in the community for negative results.</p> <p>The serviced specification for delivery of spirometry across SSOT ICB has been created to enable a multi-provider delivery approach across Primary Care. The delivery model will also support equity of access across the ICB giving all practices the opportunity to deliver spirometry.</p> <p>The providers in this service model are deemed as: GP practices, Primary Care Networks (PCNs) with the PCNs lead practice responsible for delivery for the PCN as the provider, or by a Federation (Fed) single organisation entity as the provider.</p> <p>The service delivery for spirometry can be delivered in two parts with a fixed tariff for each element based which of the element(s) the service the provider has provided.</p> <p>Contract</p> <p>The contract for this service will be for a two-year period (plus 1 year). The tariff payment for delivering this service is effective from 1st October 2023 and will cease on the 30th of September 2025.</p> <p>The delivery of spirometry will be reviewed in two years (2025) to align services with the national community framework for Community Diagnostic Centres (CSCs), before the end date of this contract.</p> <p>The delivery model and tariff rates</p> <p>The multi-provider delivery model provides the opportunity for all providers in this model to deliver spirometry and analytics across the ICB.</p> <p>All providers regardless of the model of delivery, will be on the same proposed tariff rate of £70.00, which is 81% of National tariff rate (£86.00).</p> <p>The proposed tariff covers a service delivery model that has two payment delivery elements.</p> <p>A provider can deliver one of the elements on its own, or both and receive payment dependent upon what has been delivered and contractually agreed.</p> <p>This model gives the provider the opportunity to outsource either part of the pathway through provider subcontracting arrangements.</p> <p>Practices will be expected to utilise a provider from the multi-provider model for subcontracting arrangements and for keeping the ICB informed of delivery arrangements.</p> <p>Provider fixed tariffs</p> <ul style="list-style-type: none">• 1 – £50.00 tariff for diagnostic (delivery of spirometry test, incl. reversibility)• 2 – £20.00 tariff for reporting on the results (interpretation of results)
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This place-based delivery model has the expectation that all parts of the multi-provider service offer will work collaboratively, establish connections with each other to ensure a seamless and effective service for their patients.

What is included in the tariff cost:

- Band 6 – 45 minutes plus oncosts
- Band 3 – admin – 15 minutes
- GP – Reporting time – 10 minutes
- Consumables for routine test and pro-rata reversible FeNO test
- ARTP accreditation and license
- On-going training (£5 per spirometry test)
- Spirometry test, including reversibility and analytics.

Delivery reporting for tariff payment allocation and KPIs

The provider will report to the ICB on:

- Number of patients receiving spirometry that are from their backlog (already identified)
- Backlog – of the patients that are on the register:
- Number of patients tested, any that had a Personal Care Adjustments
- Number of patients that have had:
 - their diagnosis changed
 - or stopped
 - or changed medication
- Number of patients delivered spirometry that were not identified in the backlog and currently not on the register:
- Spirometry Positivity rate:
 - COPD
 - Asthma
- Which element(s) of spirometry have been delivered to each patient
- Patients that have had a spirometry test and had a negative result.
- Any impact on Admission rates
- Collection of Health Inequality information

Tariff payments and reporting arrangements

Tariff payments will be dependent on consistent reporting KPI to the ICB.

All providers must ensure that this service specification along with the SOP, [SOP - Spirometry \(artp.org.uk\)](#), are adhered to when delivering spirometry that complies with the British Thoracic Society (BTS) guidance.

Applicable national standards (e.g., NICE)

- NICE [CG101] Chronic Obstructive Pulmonary Disease Diagnosis & Management, 2010
- NICE [NG115] Chronic obstructive pulmonary disease in over 16s: diagnosis and management, 2018
- NICE [NG80] Asthma: diagnosis, monitoring and chronic asthma management, 2017
- NICE [QS25] Asthma, 2013
- NICE [QS10] Chronic obstructive pulmonary disease in adults, 2011

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

- An Outcomes Strategy for COPD and Asthma: NHS Companion Document, 2012 (gov.uk)
- Spirometry Assessment – ARTP Spirometry Standards, 2023 (artp.org.uk)
- A Guide to Performing Quality Assured Diagnostic Spirometry (https://www.brit-thoracic.org.uk/media/70454/spirometry_e-

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	<p>guide_2013.pdf)</p> <ul style="list-style-type: none"> NICE guidance for Asthma: diagnosis, monitoring and management https://www.nice.org.uk/guidance/ng80/chapter/Recommendations#initial-clinical-assessment <p>Applicable local standards The service will adhere to all relevant local policies, procedures, and guidelines, including use of Staffordshire and Stoke-on-Trent pathways.</p> <p>National and local guidance will be continuously reviewed and updated.</p> <p>Applicable Quality Requirements (See Schedule 4 Parts [A-D]) The service will adhere to the NICE Patient experience in adult NHS services standards, outlined here</p> <p>Applicable CQUIN goals (See Schedule 4 Part [E]) The Provider's Premises are located at: The Provider shall ensure that the Services are provided taking into account patient need and choice mapped to the CCG Localities. Providers are to ensure that venues are easily accessible to patients, including availability of public transport and car parking.</p>
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