NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTHTECH PROGRAMME

Algorithms applied to spirometry to support the diagnosis of lung conditions in primary care and community diagnostic centres

Final scope

1. Introduction

NICE early value assessment (EVA) considers technologies which address national unmet need, rapidly assessing products early in the life cycle that need further evidence to support wider adoption. It will review the evidence that is available, assess the potential clinical and cost-effectiveness of the technologies, and identify evidence gaps to help further evidence generation. The technologies included in this assessment use algorithms applied to spirometry to support the diagnosis of lung conditions in primary care and community diagnostic centres.

2. The condition

Respiratory disease affects one in five people and is the third biggest cause of death in England. The NHS 10 Year Plan acknowledges respiratory medicine as a priority in the coming years. Some lung diseases are classified as being restrictive, where there is a small lung volume that restricts a person's ability to inhale air. Conditions and behavioural patterns that can lead to lung restriction include interstitial lung diseases (such as idiopathic pulmonary fibrosis), sarcoidosis, and obesity. Other lung conditions may be classified as being obstructive, affecting a person's ability to breathe out all of the air in their lungs. Asthma and chronic obstructive pulmonary disorder (COPD) are the most common obstructive airway diseases, and other types include bronchiectasis and bronchitis. To differentiate between obstructive and restrictive lung conditions, clinical features should be considered alongside the results of objective pulmonary function tests such as spirometry.

Asthma is a chronic respiratory condition usually associated with airway inflammation and hyper-responsiveness. People living with asthma commonly experience exacerbations, which are periods of worsening of symptoms. Asthma is the most common lung condition in the UK, affecting 5.4 million people (one in every 12 adults and one in every 11 children) (Asthma + Lung UK, 2023a). The Department of Health and Social Care (DHSC) prevalence data estimate that 3,886,879 people in England over the age of 6 years had a diagnosis of asthma in 2023/24, equating to 6.5% of the population (DHSC, 2024). Symptoms of asthma are outlined in NICE’s guidance on asthma.

COPD is a common, treatable (but not curable), and largely preventable lung condition. COPD is an umbrella term that covers a group of respiratory diseases, including chronic bronchitis and emphysema. COPD happens when the lungs become inflamed, damaged and narrowed. The main cause is smoking, although the condition can sometimes affect people who have never smoked (NHS, 2023). In England, there were 1,175,163 people reported as having a diagnosis of COPD in 2023/24 (Department of Health and Social Care, 2025). Symptoms suggestive of COPD are outlined in NICE's guidance on COPD.

Other lung diseases include neuromuscular disease, pulmonary vascular disease, thoracic deformity and pleural disease.

3. Diagnosis

Types of tests

People with suspected lung conditions should have a structured clinical assessment to understand their clinical history, including their symptoms and risk factors (such as smoking history, see NICE's guidance on asthma). A diagnosis should not be made based on clinical history alone, because some symptoms are not specific to just one lung condition. For example, shortness of breath is a common symptom of both obstructive and restrictive lung diseases. Objective tests should be performed to confirm a diagnosis following initial clinical assessment. These tests can highlight a possible site of abnormality (for example, the airways, chest wall, and alveoli) as well as identifying the presence or absence of abnormality (i.e., obstructive, restrictive, or a mixed pattern) (ARTP, 2024). If an abnormality is identified, the test can be used to quantify the extent or severity of the disease (i.e., mild, moderate, severe, or very severe). Table 1 provides a summary of the diagnostic pathways for different lung conditions, according to NICE guidelines.

Blood eosinophil count and fractional exhaled nitric oxide (FeNO) level measurement are recommended as first-line objective tests for adults with a history suggestive of asthma. These tests are usually done in primary care settings or community diagnostic centres (CDC) depending on resource availability, but may otherwise be performed in secondary care. A diagnosis of asthma in adults should be made if the eosinophil count is above the laboratory reference range or the FeNO level is 50 ppb or more (BTS/NICE/SIGN 2024). In children aged 5 to 16, asthma should be diagnosed if the FeNO level is 35 ppb or more.

Spirometry is another objective test, measuring lung function to indicate whether obstruction or restriction is present. Spirometry is the most commonly performed lung function measurement test for the diagnosis of lung conditions (NHS England and NHS Improvement, 2020). Spirometry is recommended:

- as the first-line test for suspected COPD in adults,

- if asthma is suspected in people aged 16 and over or in children aged 5 to 16, but has not been confirmed by eosinophil count or FeNO level, and
- as one of the first-line tests for suspected idiopathic pulmonary fibrosis in adults. However, further investigations (e.g gas transfer, chest X-ray and CT of the thorax) are very commonly necessary to confirm a diagnosis of restrictive lung diseases following identification of a restrictive spirometry pattern.

Spirometry may be performed in different clinical settings, such as:

- directly in the primary care practice or as part of a primary care network (PCN), by a nurse/healthcare assistant with a general practitioner (GP) interpreting the results
- in a CDC following referral by a GP. Spirometry results may also be interpreted in the CDC, or be sent back to the GP for interpretation and diagnosis
- in secondary care settings if there is limited or no access to the required resource in primary care/CDCs, or there is diagnostic uncertainty that requires specialist input.

There are 2 types of measurement taken during a spirometry test, forced vital capacity (the amount of air a person can forcefully exhale after taking a deep breath, FVC) and forced expiratory volume in 1 second (the amount of air exhaled in the first second of a forced breath, FEV1). FEV1/FVC ratio can be used to determine whether spirometry shows obstruction, restriction or a normal pattern. For conditions such as asthma in which exacerbations can occur, normal spirometry results at a single time point do not rule out asthma (NHS England and NHS Improvement, 2020). NICE guidelines recommend using an FEV1/FVC ratio of less than 0.7 (70%) to indicate an obstructive airflow pattern.

Bronchodilator reversibility (BDR) testing is recommended to distinguish between a diagnosis of COPD or asthma. For BDR, spirometry will be done before and after bronchodilator medication is given, to observe any improvements from the medication. ATS/ERS guidance says to diagnose asthma if the FEV1 increase is 12% or more and 200 ml or more from the pre-bronchodilator measurement (or if the FEV1 increase is 10% or more of the predicted normal FEV1). If COPD is suspected following BDR, FEV1 can be used to grade severity of disease. FVC can be used to indicate whether restriction is present, prompting referral for lung volume measurement to confirm a diagnosis.

Table 1: Summary of the diagnostic pathways for common lung conditions, according to NICE guidelines.

	Asthma		COPD	Idiopathic pulmonary fibrosis
Age group	Adults and young people (aged over 16 years)	Children aged 5 to 16	Aged 16 and older	Aged 18 and older
NICE guideline	Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN)		Chronic obstructive pulmonary disease in over 16s: diagnosis and management	Idiopathic pulmonary fibrosis in adults: diagnosis and management
Initial investigations	Clinical history	Clinical history	Clinical history	• Clinical history • Blood tests
First line objective tests	Blood eosinophil count or fractional exhaled nitric oxide (FeNO) level	FeNO	Bronchodilator reversibility testing with spirometry	• Spirometry • Gas transfer
Second line objective tests	Bronchodilator reversibility testing with spirometry	Bronchodilator reversibility testing with spirometry	-	-
Other investigations	• Peak expiratory flow • Bronchial challenge test.	• Peak expiratory flow • Skin prick test or Total IgE and blood eosinophils • Bronchial challenge test	• Chest radiograph to exclude other pathologies • Full blood count to identify anaemia or polycythaemia • Body mass index (BMI) calculated	• Chest X-ray • CT of thorax

4. Unmet need

4.1 Delayed, missed and incorrect diagnosis

The NHS 10 Year Plan emphasises the importance of preventing illness. Early detection of lung conditions can lead to early interventions to reduce risk factors (such as smoking cessation), optimal treatment, better management of conditions, slower disease progression and improved quality and length of life. Early detection can also benefit the health system by reducing acute admissions and non-elective winter admissions (which are estimated to increase by 80% in winter months).

Evidence suggests that there are a significant number of people living with a respiratory disease who have not received a formal diagnosis or investigation. There is a large backlog of people awaiting diagnostic testing, estimated to be 200–250 patients per 500,000 (Spirometry Task and Finish Group, 2021). For lung conditions, the avoidable mortality rate has improved by 14% on average across England over the past 20 years. This is much less than advances made for cardiovascular disease, where the equivalent improvement was 58% (Asthma + Lung UK, 2023a). The estimates of underdiagnosis of asthma vary widely from 19% to 73% (Kavanagh et al., 2019), and it is estimated that around 2 million people in the UK are affected by COPD but do not have a formal diagnosis (Scottish Government, 2017; PHE, 2018). These people may be missing out on receiving life-changing treatment, and may not go on to receive a diagnosis until they are admitted to hospital with exacerbation (NHS England and NHS Improvement, 2020).

As many as 750,000 people in England are misdiagnosed as having asthma and receive treatment that they do not need, costing an estimated £132 million every year (Asthma + Lung UK, 2023b). For those with a label of COPD, the diagnosis is estimated to be incorrect in 27% (The Welsh National COPD Audit, 2019). A 2023 meta-analysis incorporating UK data suggested a COPD overdiagnosis rate of between 25 and 50%, representing potentially costly inappropriate treatment for a large portion of patients (Perret et al., 2022).

4.2 Availability of spirometry testing in primary care

Asthma + Lung UK reports that many cases are misdiagnosed because they are made without performance of objective testing. In many areas in the country, basic lung function equipment (including spirometry), has been unavailable for years. The provision for diagnostic spirometry in primary care was severely disrupted by the COVID-19 pandemic. This means the recommended diagnostic pathway is often not implemented in practice, contributing to the number of missed diagnoses and misclassification of lung condition diagnoses, as many diagnoses are made based on clinical context alone. In the COPD survey 2022, only 50.6% of respondents diagnosed with COPD in the previous 2 years recalled having spirometry test done as part of their diagnosis. It is estimated that an uptake in spirometry testing in primary care to just 40% of eligible patients would result in just over £60 million in direct NHS cost savings in reduced COPD exacerbations (Asthma + Lung UK, 2023a). The NHS 10 Year Plan aims to enhance community-based care. AI technologies may increase the capability of primary care and community settings to perform lung function measurement testing and enable people to receive a diagnosis and appropriate treatment for their condition.

4.3 Quality of spirometry performance and interpretation

Globally, most clinicians do not have timely access to quality spirometry (Global Initiative for Asthma, 2024). The ability to produce quality spirometry results depends on many factors, both technical and patient related. Some spirometry devices used in current practice will automatically give feedback on the quality of the test. However, this may be based on quantifiable objective measures only, such as time to peak expiratory flow, forced expiratory time and acceptable number of manoeuvres. It is essential to also consider subjective measures when quality assuring spirometry, such as identifying technical errors during the test (e.g an extra breath taken, sub-maximal effort, coughing, slow start and early stop). Missing such factors could lead to spirometry results that are not reliable, and subsequently an incorrect diagnosis being made. It is therefore essential to have competently trained staff who perform tests to a high quality, and report results clearly. The NHS

Long Term Plan commits to improving the quality and reducing variation of spirometry testing.

The interpretation of spirometry results is just as important as the quality of the test performance for accurately diagnosing respiratory conditions. The numeric outputs of lung function tests are not always easily perceptible, and patterns are not always appropriately recognised. Objective test results should be considered in the context of the patient's whole clinical history (NHS England and NHS Improvement, 2020).

A "normal" lung function is dependent on factors including a person's age, sex, race, ethnicity and height. An FEV1/FVC ratio of <0.7 can be normal in elderly people, so a diagnosis based on spirometry using a fixed cut off could lead to over-diagnosis of obstructive lung diseases in this patient population. In contrast, younger people may have an FEV1/FVC ratio that is significantly higher than 0.7, as such there may under-diagnosis in this patient population This has led to the adoption of a definition of normality using the Lower Limit of Normal (LLN) and/or z-score/Standardised Residuals (SR) instead of a fixed percentage FEV1/FVC ratio, notably by the European Respiratory Society and American Thoracic Society.

Guideline-based practice for diagnosing lung conditions can be time consuming, and adherence to this practice is not consistent across the NHS. It has been reported that there are low levels of agreement on the interpretation of spirometry between primary care and specialist respiratory physicians (Doe et al., 2023). The NHS 10 Year Plan prioritises embracing digital technologies. Artificial intelligence has the potential to speed up interpretation of lung function tests and subsequent diagnosis or referral for further testing, whilst maintaining accuracy.

It is nationally recommended that all staff performing and/or interpreting spirometry in the UK should be certificated and registered on the Association for Respiratory Technology & Physiology (ARTP) Spirometry Register. There are recognised challenges in having enough trained healthcare professionals who are ARTP accredited to perform and/or interpret spirometry tests, in both primary and secondary care (NHS England and NHS Improvement, 2020). ARTP accreditation comes with a non-reimbursable monetary cost, and staff may be unable to find time to complete the portfolio required for accreditation around their usual work duties. These challenges mean that spirometry performance and interpretation may be done by staff who have not received appropriate training. The NHS Long Term Plan stated that more staff in primary care would be trained and accredited to provide the specialist input required to interpret results (NHS Long Term Plan v1.2, 2019).

5. The technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions. The technologies included in this evaluation apply algorithms to spirometry to support the diagnosis of lung conditions in primary care and community diagnostic centres. Sections 5.1 to 5.6 and Table 2 describe the included technologies. All the included technologies were understood to be available to the NHS at the time of writing this scope. The technologies will only be assessed within their intended use in terms of target condition and population.

The scope focusses on technologies that support clinicians to make a diagnosis of lung conditions in primary care and community diagnostic centres. These technologies:

- Use algorithms (artificial intelligence or rules-based) to support healthcare professionals to diagnose lung conditions. This can be by:
    - quality assessing spirometry performance by providing real-time identification of technical errors and coaching for improved technique, and
    - spirometry pattern recognition (e.g. using fixed cut off values and lower limit of normal/z-scores, see section 3) and/or

    - decision support (e.g. combining clinical history with spirometry results to calculate disease probabilities or indicate grade of disease severity).
- Are available or working towards being available to the NHS
- Have appropriate regulatory approval or are actively working towards regulatory approval, for example CE mark / UKCA mark and DTAC compliance

5.1 Artiq.Spiro (ArtiQ, a Clario company)

ArtiQ.Spiro is a class IIa decision support software. It is currently integrated with 2 spirometer providers, i.e. Vitalograph (Spirotrac6 software) and MedChip (SpiroConnect software). It can support staff in performing quality assessed spirometry with abnormality detection, based on international ATS/ERS guidelines. This real-time support provides detailed and actionable user feedback if the quality of the trial is suboptimal, so the user can coach the patient better for a next trial and interpreting results. After spirometry, ArtiQ.Spiro automatically generates a report which provides a description of the lung function pattern observed (e.g. obstructive, restrictive), according to ATS/ERS guidelines. The report also uses spirometry measurements and patient characteristics (such as age, sex, BMI, and smoking history) of the patient to calculate disease probabilities for Asthma, Chronic Obstructive Pulmonary Disease (COPD), Normal lung function, Interstitial Lung Disease (ILD, including idiopathic pulmonary fibrosis, nonspecific interstitial pneumonitis, sarcoidosis) or Unidentified (including neuromuscular disease, pulmonary vascular disease, thoracic deformity, pleural disease). The quality control element can be used for people aged 5-96 years, but disease probabilities are only calculated (and can only be used for) adults who have not had a lung transplant or been diagnosed with COVID-19 in the past 2 weeks. A user manual is provided which is reported to take 15 minutes to read, install and start using the software.

5.2 LungHealth Diagnostic Spirometry module (LungHealth Ltd)

LungHealth's Diagnostic Spirometry module is a class I clinical decision support software that can be used for supporting clinicians in diagnosing cases of asthma and COPD. LungHealth's Guided Consultation can be used by healthcare staff of different levels in primary care, including consultants, GPs, nurses and healthcare assistants (with virtual oversight from specialists). The software first guides healthcare professionals through taking a structured clinical history and physical examination according to the latest NICE/BTS/GOLD/SIGN guidelines. Spirometry is performed using existing equipment at the site of diagnosis, and then results are entered into the LungHealth software and interpreted to indicate whether the pattern observed is restrictive or obstructive. The software will also indicate whether any additional investigations should be done. LungHealth then combines the person's clinical history with interpretation of spirometry to generate a final diagnosis of asthma or COPD (including GOLD classification). LungHealth COPD reviews are only for patients over the age of 18 years. LungHealth Asthma reviews are currently only for patients over the age of 12 years (additional consent required for people aged 12 to 16 years old).

5.3 MIR Spiro software

MIR Spiro is a class IIa spirometry software that is compatible with all professional MIR devices, for use in people aged 5 and over. MIR Spiro is compliant with the latest international ATS/ERS guidelines and standards for spirometry and other tests. The software can advise healthcare professionals when tests do not meet the criteria set out in the guidelines, prompting the user as to what is required in order to achieve optimum spirometry. There are paediatric incentives to support the performance of spirometry by children. MIR Spiro shows the relationship between the interpretation of the spirometry (obstruction/restriction) and the shape of the flow/volume curve, providing support for diagnosis (MIR Spiro brochure, accessed August 2025).

5.4 EasyOne Connect (NDD)

EasyOne Connect software is a class IIa integrated spirometry software platform, compatible with a number of NDD devices (Easy on-PC, EasyOne Air and EasyOne Sky). It gives real-time coaching and feedback to the healthcare professional and patients (including paediatric incentives for children) based on ATS/ERS 2005. The software can provide spirometry quality grading and result interpretation based on 2019 ATS/ERS standards to indicate the pattern observed (e.g. obstructive, restrictive). The software can be used in people aged 4 years and older.

5.5 GoSpiro (Monitored Therapeutics)

GoSpiro is a class IIa spirometry device that can be used by adults and children over 5 years old in physician's offices, clinics and home settings. It comes with built-in quality control and avatar-based coaching to guide the patient through the spirometry test and prompt for corrections on the next measurement. The platform can also collect relevant respiratory histories and provide a clinical impression for the professionals based on the ATS/ERS interpretation guidelines, including recommendations for specialist or further testing follow up.

5.6 NuvoAir (NuvoAir)

NuvoAir Home is a class IIa technology, combining hand-held spirometry, a patient-facing app to track trends and a web-based portal for clinicians to view results and reports. NuvoAir offer home-based diagnostic spirometry for people with suspected lung conditions. Primary care clinicians (e.g. nurses, GPs) can refer a patient for a home-based NuvoAir assessment for a number of reasons. For example, the patient has been on a waiting list for spirometry at their GP, or they require spirometry testing over multiple days/weeks (rather than a single point in time) for a diagnosis to be made. Patients with a NuvoAir referral will receive a kit to their front door, with instructions of when and how the kit should be used. For diagnosing suspected lung conditions, the Air Next spirometer is intended to be used by adults that have been trained by a healthcare professional to perform spirometry. An accompanying adult can assist a child who is age 5 or older to perform the spirometry test. The technology offers quality control and real-time feedback to optimise the patient’s spirometry technique and encourage learning. The algorithm will determine the pattern of results (e.g. normal, obstructive and restrictive) using both fixed cut-off values and by comparing the data to a 'normal' data set to provide percentage of predicted results and z scores. A report is then generated and shared with a primary care clinician for review, and to form the basis of a referral to secondary care if deemed appropriate. Otherwise, along with the clinical history, it can support diagnosis and treatment decisions to be made in primary care with a means to also assess response to treatment.

Table 2: Summary of the technologies to be included in the assessment.

Technology	Age group	CE mark	Algorithm inputs	Technology output
ArtiQ	5-96 years	IIa	• Patient characteristics (age, sex, BMI, and smoking history) • Spirometry performance • Spirometry results	• Quality assurance of spirometry test (based on international ATS/ERS guidelines) • Description of the lung function pattern (based on international ATS/ERS guidelines) • Calculation of disease probabilities for asthma, COPD, Interstitial Lung Disease normal lung function and unidentified • Recommendation of further tests to confirm diagnosis
EasyOne*	4 years+ **	IIa	• Spirometry performance • Spirometry results	• Coaches on test quality • interpretation of spirometry results
GoSpiro	5 years+	IIa	• Spirometry performance • Spirometry results • Respiratory histories	• Quality control of spirometry • Interpretation of spirometry results • Diagnostic impression
LungHealth	18 years + for COPD, 12 years + for asthma	I	• Findings from a structured clinical assessment • Spirometry results	• Interpretation of spirometry results • GOLD classification of COPD, identification of patients with asthma. Identification of key comorbidities (e.g., heart failure) • Recommendations for ongoing treatment and management
MIR Spiro*	5 years +	IIa	• Spirometry performance	• Advises when tests do not meet the criteria set out in the guidelines • Provides interpretation of spirometry based on ATS/ERS guidelines

			• Spirometry results	
NuvoAir	5 years +	IIa	• Spirometry performance • Spirometry results	• Error identification and prompts for improved spirometry technique • Description of the lung function pattern

*Technology summaries based on publicly available information only

**Spirometry is currently recommended by NICE for diagnosing asthma in children aged 5 and over

5.7 The place of technologies in the care pathway

This assessment will look at technologies that apply algorithms to spirometry to support healthcare professionals in making an initial diagnosis for patients with suspected lung conditions. This includes technologies that:

- quality assess spirometry performance by providing real-time identification of technical errors and coaching for improved technique, and/or
- give spirometry pattern recognition (e.g. using fixed cut off values and lower limit of normal/z-scores, see section 3) and
- give decision support (e.g. combining clinical history with spirometry results to calculate disease probabilities or indicate grade of disease severity).

5.8 Innovative aspects

These technologies may:

- enable more types of healthcare staff to perform and interpret spirometry,
- improve the number and quality of diagnostic spirometry performed in primary care/community diagnostic centres or patients' homes,
- reduce the time for interpretation of spirometry results in primary care/community diagnostic centres whilst maintaining or improving accuracy,
- improve confidence and accuracy of diagnoses in primary care/community diagnostic centres,
- reduce the number of patients referred to secondary care because of doubt in diagnosis,
- reduce hospital admissions due to exacerbations because of incorrect diagnosis and treatment
- reduce over-diagnosis of lung conditions and subsequent over-treatment
- increase the capacity of secondary care teams to work with patients for whom diagnosis is complex and requires specialist input.

6. Comparator

The comparator in this assessment is recommended usual care, whereby

- quality assurance of spirometry is done by an accredited clinician, without algorithm support
- interpretation of spirometry is done by an accredited clinician, without algorithm support
- a diagnosis is made by an accredited clinician, considering the results of objective tests in the context of a person's characteristics, without algorithm support.

Recommended usual care is not widely implemented in current practice due to a number of issues (see section 4).

7. Patient issues and preferences

For some people, the breathing technique required to successfully perform lung function measurement tests such as spirometry is difficult to achieve. Experts have suggested that around 5% of people undergoing spirometry testing are unable to perform the test for this reason. Diagnostic spirometry is recommended for children aged 5 and over who have suspected asthma, but it is not always possible to have a successful spirometry test performed by children, who may find it difficult to understand and follow the instructions given to them during the test. Spirometry may be contraindicated in some people. The test increases the pressure inside a person's head, chest, stomach and eyes as they breathe out, so it may need to be delayed or avoided if a condition is present that could be made worse by this. For example, spirometry may not be safe in people who have, or have recently had, unstable angina, a heart attack, uncontrolled high blood pressure, or an operation to their head, chest, stomach or eyes (NHS, 2025). For these people, diagnosis of lung conditions is thought to be even more complex.

Having access to their own data may make patients feel more confident in the diagnosis that has been given to them.

8. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics and others.

8.1 Potential equality issues relating to lung conditions

- Incidence and mortality rates of respiratory disease are higher in people with lower socioeconomic backgrounds or who live in areas of social deprivation, where there is often higher smoking incidence, exposure to higher levels of air pollution, poor housing conditions and exposure to occupational hazards. These factors drive to increase health inequalities in lung conditions in the most deprived communities. People in the poorest areas are five times more likely to die from COPD and three times more likely to die from asthma than the richest areas. There is a stronger link between respiratory deaths and deprivation than for any other major disease area (Asthma + Lung UK, 2023a).
- In many areas in the country, objective testing (including spirometry), is not available. For people in these areas, a diagnosis may be based on clinical assessment alone. This means that many people living with lung conditions are either not diagnosed, or receive an incorrect diagnosis (Asthma + Lung UK, 2023a).
- There are concerns over not only regional inequity in spirometry, but also the inequity of all services for respiratory patients when compared with those with other diseases (such as cardiovascular diseases) (Doe et al., 2023).
- NICE's guideline on asthma recommends spirometry for diagnosis in children aged 5 and over (Overview | Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN) | Guidance | NICE). No evidence was available for diagnostic tests in children under 5 when this guideline was developed. The age at which a child can co-operate with tests will vary, but it is usually necessary to manage these children pragmatically based on symptoms and signs only.

- It is recommended in NICE's guidance on COPD that European Respiratory Journal GLI 2012 and GLI 2022 reference values are used for spirometry, but it is recognised that these values are not applicable for all ethnic groups.

8.2 Potential equality issues relating to the technology

Some people may particularly benefit from the technologies in this assessment, for example:

- People who live in geographical areas where there is less access to diagnostic tests and larger waiting lists. These people may have received no diagnosis at all, or may go on to receive an incorrect diagnosis that is based on clinical history alone.
- People who are unable to leave their home to undergo diagnostic spirometry. Technologies that enable spirometry to be performed at home have the potential to make spirometry more accessible for these people.
- Children for whom diagnostic spirometry is recommended but find it difficult to perform spirometry in current practice. Technologies that have paediatric spirometry coaching and incentives may help children to correctly perform spirometry.

There are some considerations to ensure the technologies do not add to health inequalities, for example:

- The patient population used in the training and validation set for AI technologies may be biased, and may not be inclusive of people from all ethnic backgrounds, ages or sex.
- For some patient groups, spirometry testing may be difficult to perform in certain settings, or at all. For example, some people with cognitive impairment or neurodiversity.
- Patient views and acceptability of artificial intelligence (AI)

9. Decision problem

The key decision questions for this assessment are:

- Does the use of technologies that apply algorithms to spirometry for supporting the diagnosis of lung conditions have the potential to be clinically and cost-effective to the NHS?
- What are the key gaps in the evidence base?

Table 3: Decision problem

Populations	People who have suspected lung conditions and will undergo spirometry to support initial diagnosis. Where data permits, the following subgroups may be considered: • People who have suspected COPD and will undergo spirometry to support initial diagnosis • Adults who have suspected asthma and will undergo spirometry to support initial diagnosis • Children who have suspected asthma and will undergo spirometry to support initial diagnosis • Adults who have suspected restrictive lung disease and will undergo spirometry to support initial diagnosis • Children who have suspected restrictive lung disease and will undergo spirometry to support initial diagnosis
Interventions	Technologies that use algorithms (artificial intelligence or rules-based) to support diagnosis of lung conditions in primary care and community diagnostic centres (see section 5): • ArtiQ.Spiro (ArtiQ, a Clario company) • LungHealth Diagnostic Spirometry module (LungHealth Ltd) • MIR Spiro (MIR) • EasyOne Connect (NDD) • GoSpiro (Monitored Therapeutics) • NuvoAir (NuvoAir)
Comparator	Recommended usual care, whereby: • Quality assurance of spirometry is done by an accredited clinician, without algorithm support • Interpretation of spirometry is done by an accredited clinician, without algorithm support • A diagnosis is made by an accredited clinician, considering the results of objective tests in the context of a person's characteristics, without algorithm support.
Setting	Spirometry performed in the following settings to support a diagnosis made in primary care or community diagnostic centres:

	• primary care • community diagnostic centres • the patient's home
Outcomes (may include but are not limited to)	Intermediate outcomes: • Access to spirometry and the number of spirometry tests performed • Quality of spirometry performance • Accuracy of interpretation of spirometry • Time to perform and interpret spirometry • Time-to-diagnosis • Diagnostic accuracy of initial diagnosis • Number of referrals to secondary care for a diagnosis to be made Clinical outcomes: • Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment • Mortality • Morbidity Clinician-reported outcomes: • Clinician confidence in performing quality-controlled diagnostic spirometry, interpreting results and making a diagnosis in primary care/CDCs • Clinician acceptability, perceived ease of use, experience and satisfaction Patient-reported outcomes: • Health-related quality of life (EQ-5D-3L) • Patient and carer acceptability, views, experience and satisfaction Costs and resource use: • Cost of technology (including hardware cost for software-only technologies) • Cost of treatment and management • Cost of training and/or accreditation • Staff time and cost at different specialisms and levels of pay • Health service resource use at different settings
Economic analysis	• A health economic model will be developed where possible, using a cost-comparison or cost utility analysis • Costs will be considered from an NHS and Personal Social Services perspective

	• Sensitivity and scenario analysis should be done, where possible, to address the relative effect of parameter or structural uncertainty on model results
Time horizon	The time horizon for estimating potential for clinical and cost effectiveness should be sufficiently long to reflect potential for differences in costs or outcomes between the technologies being compared
Evidence gap analysis	Evidence gaps in clinical evidence and cost modelling should be identified to help direct further evidence generation

10. Other issues for consideration

10.1 Health economic modelling

This assessment covers multiple conditions with different diagnostic and care pathways. Scenario analysis may be done to model the effects of the included technologies in different patient populations and in different settings.

10.2 Implementation considerations

- In many areas in the country, spirometry, a key basic lung function test, has been unavailable for years. This means that many people with lung conditions are either not diagnosed, or are misdiagnosed (Asthma + Lung UK, 2023a). Services with more existing resources may be more likely to adopt the technologies in this assessment.
- The technologies in this assessment may be used to confirm an already given diagnosis of lung conditions as well as supporting an initial diagnosis. This could reduce the number of people living with an incorrect diagnosis of (and receiving treatment for) a lung condition that they do not actually have.
- Uptake of these technologies may depend on how easy they are to use in practice. It may be preferable to implement technologies that are easily integrated into current pathways in such a way that does not create further complication for healthcare providers.
- Internet connection may be required to share spirometry results from some technologies to primary care systems.
- Technologies that are intended to be used to support clinicians when performing and interpreting lung function measurement tests could

increase workforce capacity by enabling staff working on lower bands to complete these tasks, without compromising quality of service.

- Possible over-reliance on AI should be considered, as this may result in reduced clinical judgement or deskilling of clinical staff (Doe et al., 2023). Even with AI reporting, there is still a need to ensure that practitioners are skilled and spirometry equipment is maintained, calibrated, and cleaned appropriately.
- For technologies that may be used in both primary and secondary care, the training and validation sets used for any AI components should be considered to ensure they are reflective of the patient populations and level of experience of the staff members who will be operating the technologies in practice. For example, the lung function skillset of a practitioner is likely to be higher in hospital lung function laboratories than is seen in primary care settings. The training set should also be reflective of different patient populations.

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Appendix A Related NICE guidance

- Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN)
- Chronic obstructive pulmonary disease in over 16s: diagnosis and management
- Idiopathic pulmonary fibrosis in adults: diagnosis and management