NICE National Institute for Health and Care Excellence

NICE guidance

Digital technologies for applying algorithms to spirometry to support asthma and COPD diagnosis in primary care and community diagnostic centres: early-use assessment

HealthTech guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

Can be used during the evidence generation period

1.1 ArtiQ.Spiro can be used in the NHS during the evidence generation period as an option for applying algorithms to spirometry to support asthma and chronic obstructive pulmonary disease (COPD) diagnosis in primary care and community diagnostic centres. It can only be used:

- following clinical assessment and with clinical oversight from a healthcare professional to make the final diagnosis
- if the evidence outlined in the evidence generation plan is being generated
- as long as it has appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

1.2 The company is responsible for ensuring that data collection and analysis takes place. They must confirm that agreements are in place to generate the evidence. NICE will contact the company annually to confirm that evidence is being generated and analysed as planned. NICE may revise or withdraw the guidance if these conditions are not met.

1.3 At the end of the evidence generation period (3 years), the company should submit the evidence to NICE in a format that can be used for decision making. NICE will review the evidence and assess if the technology can be routinely adopted in the NHS.

More research is needed

1.4 More research is needed on the following technologies for applying algorithms to spirometry to support asthma and COPD diagnosis before they can be funded in the NHS:

- EasyOne Connect

- GoSpiro
- LungHealth.

What this means in practice

Can be used with evidence generation

ArtiQ.Spiro can be used as an option in the NHS during the evidence generation period (3 years) and paid for using core NHS funding. During this time, more evidence will be collected to address any uncertainties. Companies are responsible for organising funding for evidence generation activities.

After this, NICE will review this guidance and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.

Potential benefits of use in the NHS during the evidence generation period

- **Access:** Technology that applies algorithms to spirometry could help staff with different levels of experience to perform diagnostic spirometry and interpret results in primary care and community diagnostic centres, rather than wait for a secondary care appointment. This could increase access to spirometry because people would not have to wait for an appointment in secondary care.
- **System and resource benefit:** There is regional variation in accessing diagnostic spirometry. Technology that applies algorithms to spirometry may increase the number of primary care settings and community diagnostic centres that are able to offer diagnostic spirometry as part of their services. This could reduce the referral burden on secondary care settings. Earlier diagnosis of asthma and COPD in primary care and community diagnostic centres could also reduce the number of referrals to secondary care after a person's symptoms get worse.
- **Clinical benefit:** Earlier diagnosis could lead to earlier access to appropriate treatment. This could have long-term benefits for people with asthma or COPD.
- **Equality:** Some populations (for example, people with limited mobility or neurodiverse people) may find it easier to access diagnostic spirometry if the technology allows testing to be done closer to their home.

Managing the risk of use in the NHS during the evidence generation period

- **Resources:** Algorithm outputs from ArtiQ.Spiro may support healthcare professionals to make diagnoses, but do not replace clinical judgement or the

need for a clinical assessment. Implementing ArtiQ.Spiro could lead to staff with different levels of experience doing diagnostic spirometry and interpreting results. It is unknown whether this could affect variation in the quality of spirometry and accuracy of interpretation, and subsequent diagnosis following clinical review.

- **Clinical risk:** The diagnostic accuracy (including the number of false-positive and false-negative results) when the technology is used in primary care and community diagnostic centres is currently unclear. Algorithm-supported diagnosis could influence prescribing decisions, which have potential risks and harms in both overtreating and undertreating asthma and COPD. Algorithm outputs from ArtiQ.Spiro may support healthcare professionals to make diagnoses, but do not replace clinical judgement or the need for a clinical assessment. The impact of ArtiQ.Spiro on long-term patient outcomes is currently unknown.
- **Costs:** Early results from the economic modelling suggest that ArtiQ.Spiro could be cost effective. There is considerable uncertainty in this early cost-effectiveness estimate.
- **Information governance:** Potential risks include confidentiality breaches or issues accessing or retrieving data. All service providers should ensure they have appropriate IT infrastructure and information governance protocols in place.

More research is needed

There is not enough evidence to support funding EasyOne Connect, GoSpiro or LungHealth in the NHS for the purpose of applying algorithms to spirometry to support the diagnosis of asthma and COPD. The technologies in this guidance may have additional functions or use cases that are out of scope for this assessment. This recommendation does not apply to (and thus does not intend to restrict) use of these technologies (or any compatible hardware or software) for any other intended purposes or use cases that are outside of the scope of this NICE assessment. For example, this recommendation does not apply to hardware components used for obtaining spirometry readings, or where a technology can be used to ensure a structured clinical assessment has been done before spirometry.

Access to the technologies should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.

What evidence generation and research is needed

Evidence generation and more research is needed on:

- diagnostic accuracy of initial diagnosis, including the number of false-positive and false-negative results, when using the technologies in primary care and community diagnostic centres
- the impact of the technologies on the NHS care pathways for asthma and COPD when using them to support diagnosis in primary care and community diagnostic centres
- how using the technologies would affect long-term resource use during and after implementation
- whether benefits from the technologies vary for certain subgroups.

The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

Why the committee made these recommendations

Spirometry is a common test used to help diagnose lung conditions such as asthma and COPD. For COPD, it is the first-line test. But, for asthma it is used as a second-line test (with bronchodilator reversibility) after fractional exhaled nitric oxide and blood eosinophil count. Technologies that apply algorithms to spirometry use a step-by-step set of rules or calculations to check the quality of a spirometry test, interpret results and help guide decisions. This can support healthcare professionals to diagnose asthma and COPD.

The evidence for ArtiQ.Spiro is stronger than that for the other technologies included in this assessment. This evidence includes a UK-based randomised controlled trial using real-world evidence from primary care reviewed by primary care healthcare professionals. Most of the evidence suggests that using ArtiQ.Spiro could lead to better outcomes for people needing diagnostic spirometry and provide benefits to the NHS. But there is limited evidence on diagnostic accuracy when using ArtiQ.Spiro. It is also unclear how it may impact staff resources in primary care and community diagnostic centres. But it has the potential to address high unmet need in the NHS by allowing more people to access diagnostic spirometry. Early economic modelling also suggests that it has the potential to be cost effective. So, ArtiQ.Spiro can be used during the evidence generation period.

There is limited evidence for EasyOne Connect, GoSpiro and LungHealth. So, it is unclear whether using these technologies could lead to better outcomes than current practice. More research is needed on these technologies.

2 Information about the technologies

2.1 The technologies included in this early-use assessment apply algorithms (artificial intelligence [AI]-derived or rules-based algorithms) to spirometry to support the diagnosis of lung conditions (see table 1), alongside other clinical factors. They can be used by healthcare professionals in primary care and community diagnostic centres. The technologies provide algorithmic support for spirometry by:

- quality assessing spirometry performance
- interpreting spirometry results (for example, recognising whether the spirometry trace is obstructive, restrictive, or otherwise)
- suggesting a diagnosis based on spirometry results and other clinical factors.

Technologies included in this guidance may have additional functions or use cases that are outside of the scope of this assessment. The recommendations in this guidance do not apply to the technologies when used to support other aspects of the diagnostic, prognostic or care pathways for asthma and COPD that are out of scope for this assessment.

2.2 All technologies (ArtiQ.Spiro, EasyOne Connect, GoSpiro and LungHealth) are software, but do require spirometry hardware (a spirometer) to obtain spirometry readings. Information on the range of compatible spirometers for each software (at the time of the assessment) is reported in table 2 of the external assessment report. The most up-to-date information on spirometer compatibility may be available on request from manufacturers. Spirometry hardware that is compatible with software for applying algorithms to spirometry is out of scope for this assessment. Additional software that can be integrated with digital technologies for applying algorithms to spirometry to support other aspects of the diagnostic pathway (for example, to enhance data management and workflow) is also out of scope for this assessment. As such, the recommendations in section 1 do not1 apply to the use of spirometer hardware for obtaining spirometry readings, or additional software that can be integrated.

2.3 NuvoAir is no longer available to the NHS, so the committee could not make a

recommendation on this technology.

2.4 Information on MIR Spiro was provided to NICE by the technology manufacturer and UK distributor during consultation on the draft guidance. This information was discussed by committee at the second committee meeting. A decision was made by the Committee Chair (following advice from a specialist committee member) that MIR Spiro is not within the scope of this assessment and should be removed from this guidance.

Table 1 Technologies included in the assessment

Technology (company)	CE mark	Population	Type of algorithm	Setting	Component parts
ArtiQ.Spiro (Clario)	IIa	5 to 96 years for quality assessment and pattern recognition, 18 years and over for providing a diagnostic suggestion	AI and rules-based (uses ATS and ERS guidelines)	Clinic	Software that is compatible with specified spirometers.
EasyOne Connect (NDD)	IIa	4 years and over	Rules-based (uses ATS and ERS guidelines)	Clinic	Software that is compatible with specified spirometers.
GoSpiro (Monitored Therapeutics)	IIa	5 years and over	AI and rules-based (uses ATS and ERS guidelines)	Clinic	Software that is compatible with specified spirometers.
LungHealth (LungHealth)	I	18 years and over for COPD, 12 years and over for asthma	AI and rules-based (uses BTS, GOLD, NICE and SIGN guidelines)	Clinic	Software that requires input of spirometry results (done using any spirometry hardware).

Abbreviations: AI, artificial intelligence; ATS, American Thoracic Society; BTS, British Thoracic Society; COPD, chronic obstructive pulmonary disease; ERS, European Respiratory Society; GOLD, Global Initiative for Chronic Obstructive Lung Disease; SIGN, Scottish Intercollegiate Guidelines Network.

Sustainability

2.5 For information, Carbon Reduction Plans for UK carbon emissions for 2 technologies are published here:

- Clairo: Corporate & Social Responsibility
- LungHealth: Carbon Reduction Plan.

NDD and Monitored Therapeutics did not disclose Carbon Reduction Plans.

3 Committee discussion

The diagnostics advisory committee considered evidence on digital technologies for applying algorithms to spirometry from several sources. This included evidence submitted by 4 companies, a review of clinical and cost evidence by the external assessment group (EAG), and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

3.1 Respiratory disease affects 1 in 5 people and is the third biggest cause of death in England. Some lung conditions are classified as obstructive, affecting a person's ability to breathe out all the air in their lungs quickly enough. Asthma and chronic obstructive pulmonary disease (COPD) are the most common obstructive airway conditions. Other lung conditions may be classified as restrictive, in which a reduced lung volume restricts a person's ability to inhale air. Idiopathic pulmonary fibrosis is an example of a restrictive lung condition. Some conditions may be both obstructive and restrictive (for example, COPD–pulmonary fibrosis overlap).

3.2 Asthma is a chronic respiratory condition usually associated with airway inflammation and hyper-responsiveness. In 2023, Asthma + Lung UK reported that asthma is the most common lung condition in the UK, affecting 5.4 million people (1 in every 12 adults and 1 in every 11 children). People with asthma commonly experience exacerbations, which are periods of worsening symptoms.

3.3 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.

Current practice

3.4 People may present to primary care with undifferentiated breathlessness. Breathlessness is commonly caused by cardiac or respiratory issues. People should have a structured clinical assessment by a GP, to consider all possible causes. This assessment should include discussion of a person's symptoms and risk factors. Diagnosis of a suspected lung condition should not be based on clinical assessment of symptoms alone. This is because some symptoms are not specific to only 1 lung condition. Objective tests should be done to confirm a diagnosis after clinical assessment, to help healthcare professionals differentiate between obstructive and restrictive lung conditions.

3.5 Spirometry is the most commonly used objective pulmonary function test for diagnosing lung conditions. NICE's guideline on COPD recommends post-bronchodilator spirometry as the first-line objective test for diagnosing COPD. NICE's guideline on asthma recommends fractional exhaled nitric oxide (FeNO) and blood eosinophil count as first-line tests for asthma diagnosis in adults. Spirometry is recommended as the second-line objective test (with bronchodilator reversibility) for diagnosing asthma in adults. For children 5 to 16 years diagnostic testing is harder because they may find some tests difficult to do and be unwilling to have blood tests. FeNO is recommended first-line for children 5 to 16 years, then bronchodilator reversibility with spirometry if the FeNO level is not raised, or if FeNO testing is not available. Spirometry is not used in the diagnostic pathway for interstitial lung disease but may be used to determine the severity of restrictive lung diseases.

3.6 There are different types of measurements taken during a spirometry test. This includes:

- vital capacity (VC): the maximum amount of air exhaled slowly and steadily after a deep breath
- forced VC (FVC): the amount of air a person can forcefully exhale after taking a deep breath and
- forced expiratory volume in 1 second (FEV_1): the amount of air exhaled in the first second of a forced breath.

The FEV_1 to FVC ratio can be used to determine whether spirometry shows obstruction, restriction, both obstruction and restriction, or a normal pattern. Spirometry may be done in primary or secondary care, or in a community diagnostic centre.

Unmet need and innovative aspects

3.7 There is a substantial number of people living with a lung condition who have not had a formal diagnosis or investigation. There is an estimated backlog of 200 to 250 people awaiting diagnostic testing per 500,000 people (Spirometry Task and Finish Group, 2021). Technologies that apply algorithms to spirometry may give faster access to high-quality diagnostic spirometry (where it is commissioned locally; see section 3.21) by supporting delivery within appropriately governed diagnostic pathways. Staff with different levels of experience may be able to use the technologies in primary care and community diagnostic centres to do high-quality spirometry and interpret results accurately. This means people may be able to access high-quality and accurate diagnostic spirometry closer to their home, without needing to wait for an appointment in secondary care. This could reserve more capacity in secondary care for people with complex diagnoses that need specialist input and expert review.

3.8 There is a considerable number of people who are diagnosed with a lung condition that they do not actually have (a false-positive diagnosis). These people may go on to have unnecessary (and potentially harmful) treatment. Conversely, some people are not diagnosed with a condition that they do actually have (a false-negative or missed diagnosis) and may miss out on treatment for that condition. This may be because the results of the spirometry test were poor quality (for example, technical errors in test performance were not identified), and therefore unreliable for supporting diagnosis. In many services, spirometry may be done and interpreted by staff who have less experience, because of resource and capacity constraints. Algorithmic support may improve the quality of spirometry and accuracy of the subsequent diagnosis made alongside other clinical factors. This could potentially reduce the number of people referred to secondary care because of doubts in diagnosis, or because of an exacerbation after misdiagnosis, unnecessary treatment or a lack of treatment.

Clinical effectiveness

Available evidence

3.9 The EAG identified 11 studies on ArtiQ.Spiro, 9 studies on LungHealth and 1 study on GoSpiro. No relevant evidence was identified by the EAG (or submitted by the company) for EasyOne Connect. NuvoAir was removed from the assessment because it is no longer available to the NHS. MIR Spiro was removed from the guidance following the second committee meeting because it was not considered to be relevant to the scope of the assessment.

3.10 No studies were identified that reported long-term outcomes for any of the included technologies. These outcomes include:

- mortality
- morbidity
- time to diagnosis
- staff time and resource use
- number of secondary care referrals for diagnosis, and
- hospital admissions.

Diagnostic accuracy of initial diagnosis

3.11 Diagnostic accuracy evidence was available for ArtiQ.Spiro and LungHealth. Comparative diagnostic accuracy evidence (for example, compared with a reference standard) was lacking for LungHealth.

3.12 Diagnostic accuracy evidence was most comprehensive for ArtiQ.Spiro. This included SPIRO-AID, a UK randomised controlled trial. It included 133 primary care healthcare professionals (who refer for, perform, or interpret spirometry) who were randomised to review 50 retrospective spirometry records with or without ArtiQ.Spiro. The EAG calculated sensitivity and specificity of ArtiQ.Spiro

using SPIRO-AID data, which was provided as academic-in-confidence by the study authors. The committee acknowledged that sensitivity was higher when using ArtiQ.Spiro to support asthma and COPD diagnosis, but that specificity was similar in both trial arms. The committee discussed that the sample of 50 records reviewed in the SPIRO-AID study was small, but also had a low proportion of people without disease (only 20% had a 'normal' spirometry pattern). The committee noted the importance of evidence showing a pre-test probability of disease that is in line with the populations in which ArtiQ.Spiro would be used in primary care and community diagnostic centres. The committee agreed that the UK diagnostic accuracy validation study of ArtiQ.Spiro (Sunjaya et al. 2025) also had a low proportion of people with a 'normal' spirometry pattern (30 out of 1,113 people). Sensitivity of ArtiQ.Spiro was low for identifying 'normal' cases (reported as 33.3%), with 66.7% of the 30 true 'normal' cases misclassified mainly to be interstitial lung disease or asthma. This could lead to a high number of people having treatment for, or a life-long label of, a condition that they do not actually have.

The committee noted that there are risks associated with both underdiagnosis and overdiagnosis of lung conditions. If people have a false-positive diagnosis, they may be offered unnecessary and potentially harmful treatment. For example, bronchodilators may be associated with increased cardiovascular risk. If people have a false-negative diagnosis, they could miss out on treatments to help manage their condition and symptoms. Algorithmic support for diagnostic spirometry could influence prescribing decisions following diagnosis. Therefore, diagnostic accuracy of the technologies is important to reduce incorrect prescribing decisions. So, more evidence is needed on the diagnostic accuracy of ArtiQ.Spiro when used as part of care pathways in primary care and community diagnostic centres.

3.13 The in-scope diagnostic accuracy evidence for LungHealth was non-comparative. This means it could not be used to determine accuracy compared with a reference standard. No evidence was available on diagnostic accuracy for EasyOne Connect or GoSpiro. The committee concluded that more research is needed on the diagnostic accuracy of these technologies before they can be used in the NHS.

3.14 There was limited evidence available to conclude whether diagnostic accuracy of the technologies was affected by inter-reader variability of different grades of

staff doing and interpreting spirometry. One of the value propositions of the clinic-based intervention technologies is an increase in access to spirometry. This is because more types of staff would be able to perform and interpret spirometry. The committee concluded that diagnostic accuracy evidence should capture staff who would use the technologies in primary care and community diagnostic centres, including people with different levels of experience and specialist knowledge. This would show whether diagnostic accuracy differs depending on who is using the technology.

3.15 The committee noted that even if the technologies, when used by different grades of staff, have equivalent (non-inferior) diagnostic accuracy to that of current practice, there may still be benefits such as improved access to spirometry. This could reduce the burden on secondary care services if fewer referrals from primary care are needed to make a diagnosis. The committee agreed that more evidence was needed on this.

3.16 NICE's guideline on asthma notes that people should be offered treatment immediately if they are acutely unwell or highly symptomatic at presentation. It also notes that objective tests that may help support a diagnosis of asthma should be performed if the equipment is available (for example, eosinophil count, FeNO, spirometry or peak expiratory flow before and after bronchodilator). A specialist committee member noted that spirometry results can be influenced by the presentation of a person's symptoms at the time of testing. If spirometry is done while a person is not experiencing an asthma exacerbation (or after they have taken medication), then their spirometry pattern may appear to be 'normal'. If testing is done when the condition is unstable, this may result in overdiagnosis and unnecessary treatment. The committee discussed that asthma diagnosis may be more accurate if repeat spirometry measurements are taken over a period of time. It agreed that technologies bringing diagnostic spirometry closer to a person's home may increase the number of asthma diagnoses that can be based on a series of spirometry measurements. Evidence of diagnostic accuracy based on a series of diagnostic spirometry tests was not available.

3.17 Paediatric spirometry has higher technical failure rates and greater interpretative uncertainty. More caution is therefore necessary when using technologies in populations of children and young adults (where indicated for use in these populations). The committee agreed that more research on diagnostic accuracy

of the technologies in populations of children and young people is needed.

3.18 The committee discussed that, in practice, technologies that apply algorithms to spirometry could also be used to support a corrective diagnosis of asthma or COPD, if it is suspected that the initial diagnosis was incorrect.

Comparative evidence

3.19 Comparative evidence for the other outcomes defined in the scope was available for ArtiQ.Spiro, and was limited for the other technologies included in this assessment. The studies used real-world primary care datasets and included primary care healthcare professionals who perform and interpret spirometry. The evidence showed examples of changes in practice through using the technology in primary care settings. Findings included a non-significant difference in accuracy of spirometry interpretation (for example, recognising an obstructive or restrictive spirometry pattern) using ArtiQ.Spiro (Doe et al. 2025). An increase in the quality of spirometry (Doe et al. 2025) was also reported, along with reductions in the time to perform and interpret spirometry (Hayes et al. 2025 [PDF only] and Adams et al. 2024 [PDF only]). Regional variation in resource and capacity in primary care settings and community diagnostic centres may mean that there is regional variation in the magnitude of change seen through the use of ArtiQ.Spiro. Further evidence generation could show the benefits that are seen in practice.

Access to spirometry and the number of tests performed

3.20 Evidence from 1 abstract suggested that using ArtiQ.Spiro led to an increase in testing capacity (75 more tests per month) and improvement in wait times (before and after not reported). It also projected full-test-backlog resolution within 8 months. The committee acknowledged the potential of the technologies to address unmet system need by increasing access to diagnostic spirometry. The committee noted that this evidence comes from a single abstract, that is not peer-reviewed, on 1 of the technologies. It concluded that further evidence of the impact of all technologies on access to diagnostic spirometry in care pathways is needed.

3.21 The committee discussed that a key factor in access to spirometry is local commissioning decisions. Without local commissioning, services are unable to provide spirometry due to the lack of funding. There is regional variation in spirometry commissioning in primary care settings, with commissioning more common in community diagnostic centres. So, implementation of the technologies included in this guidance is unlikely to improve access to diagnostic spirometry in areas where spirometry is not commissioned.

Long-term outcomes

3.22 There was a lack of longitudinal outcomes across all included technologies. This includes mortality, morbidity, time to diagnosis, staff time and resource use, number of secondary care referrals for diagnosis and hospital admissions. The EAG reported that the conceptual economic model was not sensitive to small differences in these outcomes (see section 3.32), but there was uncertainty in some the model inputs because of the lack of available clinical evidence. The committee concluded that evidence generation on long-term outcomes (along with other outcomes related to diagnostic accuracy and resource use) could help to address uncertainties.

Patient preferences

3.23 Lay specialist committee members emphasised the importance of early and accurate diagnosis of lung conditions. This could lead to earlier access to effective treatment options, and enhanced quality of life for people with asthma or COPD and their family or carers.

3.24 The committee heard that while many people would feel comfortable trusting a diagnosis made by a staff member with less experience (with algorithmic support), some people may prefer to have their diagnosis made by a staff member with more experience.

3.25 Technologies that enable spirometry to be done closer to a person's home could benefit them. For people living with an undiagnosed lung condition, their symptoms may mean they find it difficult to attend an in-person appointment in

secondary care. For example, if their journey would require them to walk for a period of time. Neurodivergent people may also be more comfortable doing spirometry in a setting that is more familiar to them. There may also be cost barriers for some people when attending an in-person hospital appointment. People living in areas of deprivation may have an increased risk of lung conditions, and may not be able to travel to an in-person hospital appointment because of their financial situation. Technologies that would bring spirometry into primary care and community diagnostic centres could allow easier access to diagnostic testing for these people.

Healthcare professional perspective

3.26 Evidence related to healthcare professional acceptability, ease of use, experience and satisfaction was available from surveys on ArtiQ.Spiro and LungHealth. This evidence generally indicated positive healthcare professional experience with using the technologies, highlighting potential benefits in terms of workflow efficiency. One study (Hayes et al. 2025 [PDF only]) highlighted that users felt that additional training and support was needed for interpreting artificial intelligence reports from ArtiQ.Spiro. The committee noted that support may be needed to ensure seamless integration of the technologies in current workflows and care pathways, to maximise the benefits seen in practice.

3.27 Evidence was available for ArtiQ.Spiro on healthcare professional confidence in interpreting spirometry results and making a diagnosis. Studies by Doe et al. (2025) and Adams et al. (2024 [PDF only]) did not report significant differences in healthcare professional confidence when using ArtiQ.Spiro. Willaert et al. (2023) reported that GPs using ArtiQ.Spiro recognised the need for more objective findings before making a diagnosis or altering treatments. Concerns about unfamiliarity with the spirometry procedure and limited time and resources were considered barriers to implementation. The committee recommended evidence generation on how the technologies would be implemented in care pathways in primary care and community diagnostic centres. This includes demonstrating efficiencies and resource impact.

Cost effectiveness

Conceptual model

3.28 The EAG developed a conceptual economic model in which the general structure could apply to all asthma, COPD and restrictive lung disease populations included in the scope. The structure incorporated a decision tree to model the diagnostic phase, which is embedded within a 'testing state' of a Markov model to model the wider care pathway of diagnosis and management. The model has a 10-year time horizon with monthly cycles (with alternative time horizons considered in sensitivity analysis). Further details of the economic modelling are in section 6 of the external assessment report. Many of the model inputs were derived from assumptions and clinical opinion, given the limited evidence available. The committee agreed that the model structure and input parameters were appropriate for this early-use assessment.

3.29 Two base-case scenarios were modelled, based on the 2 value propositions of the included technologies: increased diagnostic accuracy, and faster access to objective testing. Assumptions were made to model these value propositions. For improved diagnostic accuracy, a 10% increase in sensitivity was assumed in the intervention arm. For access to spirometry, the intervention arm assumed 70% of people had testing within 6 months, compared with 63.2% for the comparator arm. The committee noted that these assumptions were suitable given the limited evidence available for diagnostic accuracy (see sections 3.11 to 3.15) and access to testing (see section 3.20). It concluded that more evidence was needed on diagnostic accuracy and efficiencies when the technologies are used in care pathways.

3.30 The base-case scenarios assumed technology costs for LungHealth, with available costs for other technologies applied in the sensitivity analysis (see section 3.32).

3.31 Results of the economic model were presented for each base-case scenario, for populations of adults with asthma, children with asthma, and people with COPD. The committee discussed that, in the base-case scenarios (which used technology costs for LungHealth), there were small differences in total costs between the intervention and comparator arms. It was also noted that over the

10-year time horizon, incremental quality-adjusted life years (QALYs) appeared to be small. Base-case incremental cost-effectiveness ratios appeared below a threshold of £20,000 per QALY gained in each of the base-case scenarios, for each of the modelled populations. But, there is uncertainty in many of the model inputs because of the limited available evidence (see section 3.28). The committee concluded that cost-effectiveness estimates are therefore only to be treated as illustrative, and cannot be used to determine whether the interventions are cost effective.

Sensitivity analysis

3.32 The committee noted that the purpose of this conceptual modelling work was to highlight key evidence gaps and key drivers of differences in costs and utilities of the intervention technologies when compared with standard care. Key drivers of cost effectiveness in the model were identified as being diagnostic accuracy of the interventions and technology costs per patient. Other parameters to which the model was sensitive to include initial prevalence of disease, time horizon and costs of further testing. The EAG reported that small differences in long-term outcomes may not significantly impact the overall cost effectiveness of the technologies, but there was a lack of evidence to inform model parameters on long-term outcomes for all technologies.

3.33 Technology costs for ArtiQ.Spiro were applied, along with diagnostic accuracy (sensitivity and specificity) calculated from the SPIRO-AID trial. In this scenario, the intervention arm would be considered dominant for each of the populations modelled. Scenarios were also tested in which technology costs for GoSpiro were applied, with all other parameters applied as they were in the base case, because of the lack of evidence on this technology to inform model parameters. The intervention arm was again dominant for each of the populations modelled. As in section 3.31, these results are to be treated as illustrative only. No technology costs were available for EasyOne Connect, so cost-effectiveness estimates were not reported for these technologies.

3.34 The EAG tested a scenario in which the technology costs were assumed to include spirometry performance and interpretation by a GP, instead of a band 5 practice nurse as in the base case (see section 6.3.2.3 of the external

assessment report). The EAG concluded that the model is sensitive to technology costs, and this is influenced by the grade and time of staff using the technologies. The committee discussed that, in practice, other grades of staff may use the technologies, so more evidence is needed on who in the care pathway may use the technologies.

Interstitial lung disease

3.35 The EAG noted that restrictive lung disease was not included in its economic analysis, because of a lack of evidence available for this population. The committee discussed that spirometry is not typically used as a first-line diagnostic test for suspected restrictive lung disease. Spirometry may be used to exclude obstructive disease, and as a prognostic tool for staging the severity of disease once restrictive disease has been diagnosed. So, the committee concluded that it was acceptable for the illustrative model results to be in populations with suspected obstructive diseases only (asthma and COPD).

Equality considerations

3.36 The committee discussed digital exclusion, which would be of particular consideration for technologies that have patient-facing aspects. It was noted that while necessary equipment and instructions will be provided, some people may not feel comfortable using components of the hardware and software.

3.37 People who live in deprived areas may have less access to diagnostic spirometry than others. This may be because of limited availability of testing in primary care or community diagnostic centres local to them. For these people, technologies that apply algorithms to spirometry may increase access to diagnostic spirometry by providing options closer to their home.

3.38 The committee discussed that for technologies using AI algorithms, it is important to consider the validity of the training data set, ensuring that this is reflective of the populations in which the technology will be used. Where technologies are indicated for use in children and young people, data collection in these populations is important to demonstrate the impact of the technologies.

4 Committee members and NICE project team

This topic was considered by specialist committee members appointed for this topic and NICE's diagnostics advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Thomas Clutton-Brock
Chair, diagnostic advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, project manager and an associate director.

Sophie Harrison
Technical lead

Kimberley Carter
Technical adviser

Catherine Pank
Project manager

Rebecca Albrow
Associate director

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