

# **Guidance assessment consultation document for HTE10065 Digital technologies for applying algorithms to spirometry to support asthma and COPD diagnosis in primary care and community diagnostic centres: early-use assessment**

January 2026

## Guidance development process

NICE early-use HealthTech guidance provides recommendations on promising health technologies that have the potential to address national unmet need. NICE has assessed early evidence on these technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated.

Early-use HealthTech guidance recommendations are conditional while more evidence is generated to address uncertainty in their evidence base. NICE has included advice in this guidance on how to minimise any clinical or system risk of early access to treatment.

Further evidence will be generated over the next 3 years to assess if the benefits of these technologies are realised in practice. NICE guidance will be reviewed to include this evidence and make a recommendation on the routine adoption of this technology across the NHS.

Find out more in the [section on early-use HealthTech guidance assessments in NICE's HealthTech programme manual](#).

NICE is producing this guidance on digital technologies for applying algorithms to spirometry to support asthma and COPD diagnosis in primary care and community diagnostic centres in the NHS in England. The

diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

**This document has been prepared for consultation with the stakeholders.** It summarises the evidence and views that have been considered and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the [evidence](#).

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

**Note that this document is not NICE's final guidance on digital technologies for applying algorithms to spirometry to support asthma and COPD diagnosis in primary care and community diagnostic centres. The recommendations in section 1 may change after consultation.**

More details are available in [NICE's HealthTech programme manual](#).

**Key dates:**

Closing date for comments: 21 January 2026

Second committee meeting: 04 February 2026

## 1 Recommendations

### Can be used with evidence generation

- 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:
  - 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 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 digital technologies for applying algorithms to spirometry to support asthma and COPD diagnosis before they can be funded in the NHS:

- EasyOne Connect
- GoSpiro
- LungHealth
- MIR Spiro.

### 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. The company is 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:** This digital technology could help less experienced staff do diagnostic spirometry and interpret results in primary care and community diagnostic centres. 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. This digital technology 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. 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 experiencing severe symptoms or neurodiverse people) may find it easier to access diagnostic spirometry if the digital technology allows testing to be done closer to their home.

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

- **Resources:** 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.
- **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. There are potential harms in both over- and undertreating asthma and COPD. ArtiQ.Spiro supports healthcare professionals to make diagnoses but does not replace clinical judgement. 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.

### **What this means in practice: more research is needed**

There is not enough evidence to support funding the digital technologies in recommendation 1.44 in the NHS.

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, including the number of false-positive and false-negative results, when using the digital technologies in primary care and community diagnostic centres
- the impact of the technologies on NHS care pathways for asthma and COPD when they are used 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

Digital 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 the diagnosis of lung conditions, such as 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 primary-care datasets reviewed by primary-care healthcare professionals. Most of the evidence suggests that using ArtiQ.Spiro could lead to improved outcomes for people needing diagnostic spirometry and the NHS. There is limited evidence on diagnostic accuracy when using ArtiQ.Spiro. It is also unclear how ArtiQ.Spiro may impact staff resource in primary care and community diagnostic centres. But, ArtiQ.Spiro has the potential to address high unmet need within the NHS by allowing more people to access diagnostic spirometry. Early economic modelling also suggests that ArtiQ.Spiro has the potential to be cost effective. So, ArtiQ.Spiro can be used with evidence generation.

There is limited evidence for EasyOne Connect, GoSpiro, LungHealth and MIR Spiro. 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 5 technologies included in this early-use assessment apply artificial intelligence (AI)-derived algorithms or rules-based algorithms to spirometry to support the diagnosis of lung conditions (see Table 1). The technologies provide support 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.

2.2 Four of the included technologies (ArtiQ.Spiro, EasyOne Connect, LungHealth and MIR Spiro) are software only, but do require spirometry hardware to complete testing. One technology (Go Spiro) includes both hardware (such as a spirometer) and software elements. The technologies can be used in primary care and community diagnostic centres alongside a healthcare professional.

2.3 NuvoAir is no longer available to the NHS, so the committee could not make a recommendation on this technology.

**Table 1 Technologies included in the assessment**

Technology (company)	CE mark	Population	Type of algorithm	Setting	Component parts
ArtiQ.Spiro [ArtiQ.PFT] (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
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 (performed using any spirometry hardware)
MIR Spiro (Medical International Research – MIR)	IIa	5 years and over	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 and hardware (such as spirometer) components
NuvoAir (NuvoAir) [Air Next]	IIa	5 years and over	AI (interpretation of spirometry results) and rules-based (ATS 2019)	Home based	Software and hardware (such as spirometer) components provided

Abbreviations: ATS, American Thoracic Society; BTS, British Thoracic Society; ERS, European Respiratory Society; GOLD, Global Initiative for Chronic Obstructive Lung Disease; SIGN, Scottish Intercollegiate Guidelines Network.

## Sustainability

2.4 None of the companies with technologies included in this assessment disclosed their Carbon Reduction Plans for UK carbon emissions.

Draft Guidance – Digital technologies for applying algorithms to spirometry to support asthma and COPD diagnosis in primary care and community diagnostic centres Page 9 of 23

Issue date: December 2025

© NICE 2025. All rights reserved. Subject to [Notice of rights](#).

### 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. 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 small lung volume restricts a person's ability to inhale air. Idiopathic pulmonary fibrosis is an example of a restrictive lung condition.
- 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 of 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 a 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 spirometry as the first-line objective test for diagnosing COPD, and the [BTS, NICE and SIGN guideline on asthma](#) recommends spirometry as the second-line objective test (with bronchodilator reversibility) for diagnosing asthma in people aged 5 years and over. The BTS, NICE and SIGN guideline on asthma notes that diagnostic testing is harder in children and young people (aged 5 to 16 years) because they may find some tests difficult to do and be unwilling to have blood tests. 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 2 types of measurements taken during a spirometry test: forced vital capacity (FVC, the amount of air a person can forcefully exhale after taking a deep breath) and forced expiratory volume in 1 second (FEV1, the amount of air exhaled in the first second of a forced breath). The FEV1 to FVC ratio can be used to determine whether spirometry shows obstruction, restriction or a normal

pattern. Spirometry may be done in primary care, in a community diagnostic centre or in secondary care settings.

## 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 patients per 500,000 people awaiting diagnostic testing. Technologies that apply algorithms to spirometry may give faster access to diagnostic spirometry. Less experienced staff may be able to use the technologies in primary care and community diagnostic centres to do and interpret spirometry. This means people may be able to access 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.

3.8 There is a considerable number of people who have an incorrect diagnosis and who may go on to have unnecessary (and potentially harmful) treatment, or have no treatment if the diagnosis is missed. This may be because the results of the spirometry test were of poor quality (for example, technical errors in test performance were not identified), and therefore unreliable for making a diagnosis. In many services, spirometry may be done and interpreted by staff who are less experienced, because of resource and capacity constraints. Algorithm support may improve the quality of spirometry performance, interpretation and accuracy of the subsequent diagnosis. 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 evidence for 4 of the 5 technologies included in this assessment. This included 11 studies on ArtiQ.Spiro, 1 study on GoSpiro, 9 studies on LungHealth and 3 studies on MIR Spiro. 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.

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.

### Accuracy of initial diagnosis

3.11 Diagnostic accuracy evidence was available for all the technologies except EasyOne Connect and GoSpiro. 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 a UK randomised controlled trial (RCT; SPIRO-AID), in which 133 primary-care healthcare professionals (who refer for, perform or interpret spirometry) 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 provided as academic-in-confidence by 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 pretest 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 by Sunjaya et al. (2025) also had a low proportion of people with a ‘normal’ spirometry pattern (30 out of 1,113 people). For those with a true ‘normal’ spirometry pattern, sensitivity of ArtiQ.Spiro was low, reported as 33.3%. This can be interpreted as meaning that there were a high number of people for whom ArtiQ.Spiro should have given a classification of ‘normal’, but instead their spirometry pattern was classified as not ‘normal’ (for example, that the pattern was suggestive of asthma). This could lead to a high number of people having treatment for, or a lifelong label of, a condition that they do not actually have.

The committee noted that there are risks associated with both under- and overdiagnosis of lung conditions. If people are diagnosed with a lung condition that they do not actually have (a false-positive diagnosis), they may be offered treatment that is potentially harmful to them. For example, bronchodilators may be associated with increased cardiovascular risk. If people are not diagnosed with a condition that they do actually have (a false-negative diagnosis), they could miss out on being offered treatment options to help manage their condition and symptoms. 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 Evidence from 1 Italian RCT (Lusuardi et al. 2006) reported diagnostic concordance by GPs with and without the MIR Spirobank Office spirometer. The EAG notes that this is likely an older model of the version of MIR Spiro included in this

assessment. The committee noted that generalisability of this study to the current version of the technology is unknown. Diagnostic accuracy evidence in scope for LungHealth was non-comparative, meaning 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 [The BTS, NICE and SIGN 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. 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 when 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 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**

3.18 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. 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; Adams et al., 2024). Regional variation in resource and capacity in primary care and community diagnostic centres may mean that there is regional variation in the magnitude of change observed through the use of ArtiQ.Spiro. Further evidence generation could demonstrate the benefits that are observed in practice.

### **Access to spirometry and the number of tests performed**

3.19 Evidence from 1 abstract suggested that using ArtiQ.Spiro led to an increase in testing capacity (75 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, non-peer-reviewed abstract on 1 of the technologies. It concluded that further evidence of the impact of all the technologies on access to diagnostic spirometry in care pathways is needed.

### **Long-term outcomes**

3.20 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 3.30](#)), but there was uncertainty in some of 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

3.21 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 any people who have a role in caring for them.

3.22 The committee heard that while many people would feel comfortable trusting a diagnosis made by a less experienced staff member (with algorithm support), some people may prefer diagnosis by a more experienced staff member.

3.23 Technologies that enable spirometry to be done closer to a person's home could benefit them. People living with an undiagnosed lung condition may find it difficult to attend an in-person appointment in secondary care because of their symptoms. 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

3.24 Evidence related to healthcare professional acceptability, ease of use, experience and satisfaction was available from surveys on ArtiQ.Spiro, LungHealth and MIR Spiro. 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) 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 observed in practice.

3.25 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) 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.

## Cost effectiveness

### Conceptual model

3.26 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 EAG’s 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.

3.27 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 3.19](#)). It concluded that more evidence was needed on diagnostic accuracy and efficiencies when the technologies are used in care pathways.

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

3.29 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 (ICERs) 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 3.26](#)). 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

3.30 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.

3.31 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 3.29, these results are to be treated as illustrative only. No technology costs were available for EasyOne Connect or MIR Spiro, so cost-effectiveness estimates were not reported for these technologies.

3.32 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 EAG's 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**

3.33 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**

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

3.35 People who live in areas of deprivation 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.

## 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 technologies 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, diagnostics 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

ISBN: [to be added at publication]